

**641—41.7(136C) X-ray machines used for stereotactically guided breast biopsy.**

**41.7(1) Definitions.** In addition to the definitions provided in rules 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions are applicable to this rule.

“*Collaborative setting*” means a setting in which a qualified radiologist and surgeon (under 41.7(3) “a” or 41.7(3) “c”) are working together in consultation and in performing stereotactically guided breast biopsies with a common goal of the patient’s benefit.

“*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 41.7(3) to perform stereotactically guided breast biopsies and who has performed at least 24 procedures.

“*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 which 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.

**41.7(2) Registration and application standards and requirements.**

*a.* Each radiation machine used to perform stereotactically guided breast biopsies shall be registered according to 641—subrule 39.3(2).

*b.* Each facility wishing to perform stereotactically guided breast biopsies shall apply to the agency for authorization by providing or verifying the following information for each machine:

(1) The stereotactically guided breast biopsy equipment and facility meet the general requirements of these rules for radiation machines.

(2) The radiation machine is specifically designed to perform stereotactically guided breast biopsies.

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

(4) The radiation machine is operated by individuals meeting the requirements of this rule.

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

(6) The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

*c.* Suspension, revocation, or denial of authorization.

(1) Authorization may be suspended or revoked with cause if any machine does not meet one or more of the standards of these rules.

(2) The facility shall have an opportunity for a hearing in connection with a denial, suspension, or revocation of authorization.

(3) An emergency order suspending or revoking authorization may be issued if the agency finds the radiation machine or facility violates rules that seriously affect the health, safety and welfare of the public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

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

*d.* Reinstatement of authorization.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application. If the reinstatement is after a revocation, appropriate corrective action shall be submitted with the application.

(3) A full reinstatement shall be issued only after the agency has inspected the radiation machine and facility and determined that they meet the requirements of these rules.

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

**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) Initial training and qualifications.

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

2. 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 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

4. Shall be responsible for mammographic interpretation, be experienced as noted in 41.7(3) "a"(1)"2" above and be experienced in the specific recommendations for each biopsy and lesion identification at time of each biopsy performed by that physician.

5. Shall be responsible for the supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. 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 three procedures under direct supervision of a qualified training physician or an agency-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 agency in stereotactic-guided breast biopsy 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. 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) Initial training and qualifications.

1. Must be licensed to practice medicine in Iowa.

2. Must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy which includes instruction on triangulation for lesion location.

3. Must 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 biopsy procedures according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

4. Shall be responsible for post-biopsy management of the patient.
5. Shall be responsible for supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. 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 three procedures under direct supervision of a qualified training physician or an agency-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 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. 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) Initial training and requirements.

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

2. Initially, must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

3. Initially, must obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

4. Must 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 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

5. Must be responsible for mammographic interpretation.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.

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

(2) Maintenance of proficiency and CME requirements.

1. 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 three procedures under direct supervision of a qualified training physician or an agency-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 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. 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) Initial training and requirements.

1. Must be licensed to practice medicine in Iowa.
2. Must have evaluated at least 480 mammograms in the prior 24 months in consultation with a physician who is qualified according to 41.6(3)“a.”
3. Initially, must have at least 15 hours of Category 1 CME or 15 hours of training approved by the agency in stereotactically guided breast imaging and biopsy or three years' experience having performed at least 36 stereotactically guided breast biopsies.
4. Must have four hours of Category 1 CME in medical radiation physics.

5. Must 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 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.

8. Must be responsible for post-biopsy management of the patient.

(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. 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 three procedures under direct supervision of a qualified training physician or an agency-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 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. A current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

**41.7(4) Medical physicist.**

a. Must be qualified according to 41.6(3)“c.”

b. Must 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 medical physicist qualified through 41.7(4)“a” and 41.7(4)“b.”

c. Maintenance of proficiency and continuing education requirements.

(1) 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; and

(2) 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 3 CME credits in the prior 36 months.

**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 in stereotactically guided breast biopsy.

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

(1) 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:

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 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, 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 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.

**41.7(6)** *Obtaining and preserving records.*

a. The facility must make, for each procedure, a record of the service provided including:

- (1) The date of the procedure.
- (2) The name of the patient and one additional patient identifier.
- (3) The name of the radiologic technologists and physicians performing the procedure.
- (4) A description of the service provided.
- (5) The name of the referring physician, if any.

b. Records retained by the medical facility must be retained for at least ten years.

**41.7(7)** *Quality assurance program.*

a. The facility shall have an equipment quality assurance program specific to stereotactically guided breast biopsy systems and covering all components of the system to ensure high-quality images with minimum patient exposure.

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

c. The facility shall name a supervising stereotactic biopsy physician who shall be responsible for:

- (1) Quality assurance activities including the medical audit,
- (2) Oversight of the quality control program, and
- (3) Supervision of the radiologic technologist(s) and the medical physicist.

d. Under the direction of the supervising physician, the medical physicist shall have the responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(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.

- X-ray field must not extend beyond the image receptor by more than 5 mm on any side.

- Any failures must be corrected within 30 days of the survey.

3. Evaluation of focal spot. 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.

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 4.2 centimeter breast. Failures must be corrected before further procedures are performed.

8. Image quality evaluation.
    - 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.
    - 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.
    - (2) Analyzing the monitoring results to determine if there are any problems requiring correction.
    - (3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventative maintenance.
  - e. 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:
    - (1) Localization accuracy (daily before use and before using the localization unit after it is adjusted). Each coordinate must be within manufacturer specifications for the intended target value. Failures must be corrected before further procedures are performed.
    - (2) Visual checklist (monthly). Any failed items must be corrected within 30 days.
    - (3) Phantom image (weekly). 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. Failures must be corrected before further procedures are performed.
    - (4) Compression (semiannually). The maximum auto drive compression force shall not exceed 45 pounds. Failures must be corrected within 30 days.
    - (5) Any additional quality control testing indicated by the stereotactic breast biopsy unit manufacturer must be completed as outlined in the quality control manual applicable to the unit.
  - f. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include an imaging-pathology correlation for each biopsy performed, an ongoing analysis of biopsy results and periodic review of the utilization of the procedure. The program must include the number of biopsies performed, the number of cancers found, the number of benign lesions found, and the number of biopsies repeated.
  - g. 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. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.7(7). All problems shall be corrected before the new or changed equipment is put into service for examinations. The stereotactic equipment evaluation shall be performed by a medical physicist qualified under 41.7(4) or by an individual under the direct supervision of a medical physicist qualified under 41.7(4).
- 41.7(8) Equipment standards.**
- a. Be specifically designed for stereotactically guided breast biopsy.
  - b. Meet the Food and Drug Administration (FDA) standards found in 21 CFR.
- 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. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

- c.* Equipment shall be shockproof and grounded to protect against electrical hazards.
- d.* Records of all inspection reports and medical physicist surveys shall be maintained for at least seven years.

This rule is intended to implement Iowa Code chapter 136C.

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