

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.

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