

containing components that radiographically model aspects of breast disease and cancer.

(l) *Phantom image* means a radiographic image of a phantom.

(m) *Provisional certificate* means the provisional certificate described in 42 U.S.C. 263b(c)(2).

(n) *Radiographic equipment* means x-ray equipment used for the production of static x-ray images.

(o) *Radiological technologist* means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements in § 900.12(a)(2).

(p) *Qualified practicing physician* means a physician meeting the requirements of an interpreting physician as specified under § 900.12(a)(1).

(q) *Survey* means an on-site physics consultation and evaluation of a facility performed by a medical physicist.

(r) *Diagnostic mammography* means mammography performed on a patient with: clinical signs, symptoms, physical findings suggestive of breast cancer; an abnormal or questionable screening mammogram; a history of breast cancer with breast conservation surgery regardless of absence of clinical breast signs, symptoms, or physical findings; or, augmented breasts regardless of absence of clinical breast signs, symptoms, or physical findings. Diagnostic mammography is also called problem-solving mammography or consultative mammography. This definition excludes mammography performed during invasive interventions for localization or biopsy procedures. The definition further excludes mammography performed as part of a scientific study to evaluate an experimental mammography device conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

(s) *Screening mammography* means mammography performed on an asymptomatic patient to detect the presence of breast cancer at an early stage. This definition excludes mammography performed as part of a scientific study to evaluate an experimental mammography device conducted in accordance with FDA's investigational device ex-

emption regulations in part 812 of this chapter.

[58 FR 67562, Dec. 21, 1993; 59 FR 6899, Feb. 14, 1994, as amended at 59 FR 49812, Sept. 30, 1994]

### § 900.3 Application for approval as an accrediting body.

(a) *Eligibility.* Private nonprofit organizations or State agencies capable of meeting the requirements of this subpart A may apply for approval as accrediting bodies.

(b) *Application.* One copy of an application for approval as an accrediting body shall be submitted to the Center for Devices and Radiological Health (HFZ-200), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and should be marked ATTENTION: Mammography Program. Applications for approval as an accrediting body should include the following information:

(1) Name, address, and phone number of body and evidence of nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the body is not a State agency;

(2) Standards the body agrees to impose on facilities pursuant to 42 U.S.C. 263b(e)(3);

(3) Methods for performing clinical image review as required in 42 U.S.C. 263b(e)(1)(B)(i)(I);

(4) Methods for monitoring and evaluation of annual surveys of facilities by medical physicists as required in 42 U.S.C. 263b(e)(1)(B)(v);

(5) Methods for performing on-site inspections of facilities as required in 42 U.S.C. 263b(e)(4);

(6) Fee schedules, with supporting cost data; and

(7) Satisfactory assurances that the body will comply with the requirements of § 900.4.

(c) *Ruling on application.* FDA will approve an accrediting body if FDA determines upon review of the application that the body substantially meets (or will substantially meet when it begins to evaluate facilities) the requirements of this subpart, and the body's standards are substantially the same as the quality standards published

under subpart B of this part in accordance with 42 U.S.C. 263b(f). If the applicant fails to substantially meet the requirements set forth in this subpart A, or if the applicant's standards are determined not to be substantially the same as the quality standards published under subpart B of this part, or if FDA determines that the applicant has not provided satisfactory assurances that it is capable of meeting the requirements established in this subpart A, FDA will notify the applicant of any problems it has identified with the application and request that the applicant resolve such problems within 90 days of receipt of notice. If the problems are substantially resolved to the satisfaction of FDA within the 90-day time period, the body will be approved as an accrediting body. If the problems are not substantially resolved to the satisfaction of FDA within the 90-day time period, the application for approval as an accrediting body will be rejected and the applicant so notified. A rejected application that has been modified so as to render it satisfactory is subject to resubmission at any time.

#### §900.4 Responsibilities of accrediting bodies.

(a) *Facility standards.* The accrediting body shall require that each facility it accredits meet standards for the performance of quality mammography that are substantially the same as those promulgated in subpart B of this part under 42 U.S.C. 263b(f). The requirements set forth by the body for accreditation of a facility shall address, at a minimum, the following aspects of performing quality mammography:

- (1) Physician training, experience, certification, and continuing education;
- (2) Technologist training, experience, certification, and continuing education;
- (3) Medical physicist training, experience, certification, and continuing education;
- (4) X-ray equipment characteristics, including a requirement that the x-ray equipment be specifically designed for mammography;
- (5) Quality assurance and quality control programs for ensuring that

quality mammography is practiced by the facility;

(6) Phantom image quality testing and objective criteria to be used for passing the image quality test;

(7) Maximum radiation dose for a single view for specific imaging systems;

(8) Information update provisions that require accredited facilities to update at least annually the information listed in this section that they have provided the accrediting body; and

(9) Medical recordkeeping and patient notification requirements.

(b) *Clinical image review.* The accrediting body shall review clinical images from each facility accredited by the body at least once every 3 years and shall also review a random sample of clinical images from each facility accredited by the body in each 3-year period beginning October 1, 1994. These clinical image reviews shall be conducted by a qualified practicing physician not associated with the facility. The clinical image reviews shall ensure that quality clinical images are produced in the facility on a routine basis, as measured by proper breast positioning and compression and overall image quality. Any qualified practicing physicians who conduct clinical image quality reviews shall not have a financial interest in the facilities they review for the accrediting body, nor shall such physicians have any other interest that would constitute an apparent or real conflict of interest, other than receiving a service fee from the accrediting body itself related solely to the work performed in conducting the clinical review.

(c) *Fees.* Fees charged to facilities for accreditation shall be reasonable. FDA will usually find fees to be reasonable if they are limited to recovering costs to the accrediting body, including overhead incurred proportionately in accrediting a given facility. Accrediting bodies may adjust fees annually for inflation in accordance with the Consumer Price Index (CPI).

(d) *Reports of physics survey.* (1) The accrediting body shall require every facility applying for accreditation to submit to the accrediting body, with its accreditation application, a report of a survey by a medical physicist to assess the facility's compliance with