

## SUBCHAPTER I—MAMMOGRAPHY QUALITY STANDARDS ACT

### PART 900—MAMMOGRAPHY

#### Subpart A—Accreditation

- Sec.  
900.1 Scope.  
900.2 Definitions.  
900.3 Application for approval as an accreditation body.  
900.4 Standards for accreditation bodies.  
900.5 Evaluation.  
900.6 Withdrawal of approval.  
900.7 Hearings.  
900.8-900.9 [Reserved]

#### Subpart B—Quality Standards and Certification

- 900.10 Applicability.  
900.11 Requirements for certification.  
900.12 Quality standards.  
900.13 Revocation of accreditation and revocation of accreditation body approval.  
900.14 Suspension or revocation of certificates.  
900.15 Appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification.  
900.16 Appeals of denials of certification.  
900.17 [Reserved]  
900.18 Alternative requirements for § 900.12 quality standards.

#### Subpart C—States as Certifiers

- 900.20 Scope.  
900.21 Application for approval as a certification agency.  
900.22 Standards for certification agencies.  
900.23 Evaluation.  
900.24 Withdrawal of approval.  
900.25 Hearings and appeals.

AUTHORITY: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

SOURCE: 62 FR 55976, Oct. 28, 1997, unless otherwise noted. Republished and corrected at 62 FR 60614, Nov. 10, 1997.

#### Subpart A—Accreditation

##### § 900.1 Scope.

The regulations set forth in this part implement the Mammography Quality Standards Act (MQSA) (42 U.S.C. 263b). Subpart A of this part establishes procedures whereby an entity can apply to become a Food and Drug Administration (FDA)-approved accreditation body to accredit facilities to be eligible

to perform screening or diagnostic mammography services. Subpart A further establishes requirements and standards for accreditation bodies to ensure that all mammography facilities under the jurisdiction of the United States are adequately and consistently evaluated for compliance with national quality standards for mammography. Subpart B of this part establishes minimum national quality standards for mammography facilities to ensure safe, reliable, and accurate mammography. The regulations set forth in this part do not apply to facilities of the Department of Veterans Affairs.

##### § 900.2 Definitions.

The following definitions apply to subparts A, B, and C of this part:

(a) *Accreditation body* or *body* means an entity that has been approved by FDA under § 900.3(d) to accredit mammography facilities.

(b) *Action limits* or *action levels* means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

(c) *Adverse event* means an undesirable experience associated with mammography activities within the scope of 42 U.S.C. 263b. Adverse events include but are not limited to:

- (1) Poor image quality;
- (2) Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and
- (3) Use of personnel that do not meet the applicable requirements of § 900.12(a).

(d) *Air kerma* means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less

## § 900.2

## 21 CFR Ch. I (4–1–03 Edition)

than 300 kiloelectron volts (keV), 1 Gy = 100 rad. In air, 1 Gy of absorbed dose is delivered by 114 roentgens (R) of exposure.

(e) *Breast implant* means a prosthetic device implanted in the breast.

(f) *Calendar quarter* means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

(g) *Category I* means medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

(h) *Certificate* means the certificate described in § 900.11(a).

(i) *Certification* means the process of approval of a facility by FDA or a certification agency to provide mammography services.

(j) *Clinical image* means a mammogram.

(k) *Consumer* means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

(l) *Continuing education unit* or *continuing education credit* means one contact hour of training.

(m) *Contact hour* means an hour of training received through direct instruction.

(n) *Direct instruction* means:

(1) Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

(2) The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

(o) *Direct supervision* means that:

(1) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or

(2) During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

(p) *Established operating level* means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

(q) *Facility* means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: Operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

(r) *First allowable time* means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the certifying body.

(s) *FDA* means the Food and Drug Administration.

(t) *Interim regulations* means the regulations entitled "Requirements for Accrediting Bodies of Mammography Facilities" (58 FR 67558–67565) and "Quality Standards and Certification Requirements for Mammography Facilities" (58 FR 67565–67572), published by FDA on December 21, 1993, and amended on September 30, 1994 (59 FR 49808–49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994, and April 28, 1999.

(u) *Interpreting physician* means a licensed physician who interprets mammograms and who meets the requirements set forth in § 900.12(a)(1).

(v) *Kerma* means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

(w) *Laterality* means the designation of either the right or left breast.

(x) *Lead interpreting physician* means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of § 900.12(d) through (f). The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

(y) *Mammogram* means a radiographic image produced through mammography.

(z) *Mammographic modality* means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography and xeromammography.

(aa) *Mammography* means radiography of the breast, but, for the purposes of this part, does not include:

(1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

(2) Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

(bb) *Mammography equipment evaluation* means an onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in § 900.12(b) and (e).

(cc) *Mammography medical outcomes audit* means a systematic collection of mammography results and the comparison of those results with outcomes data.

(dd) *Mammography unit* or *units* means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum: An X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

(ee) *Mean optical density* means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

(ff) *Medical physicist* means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in § 900.12(a)(3).

(gg) *MQSA* means the Mammography Quality Standards Act.

(hh) *Multi-reading* means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram.

(ii) *Patient* means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

(jj) *Phantom* means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

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

(ll) *Physical science* means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

(mm) *Positive mammogram* means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

(nn) *Provisional certificate* means the provisional certificate described in § 900.11(b)(2).

(oo) *Qualified instructor* means an individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of § 900.12(a) would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.

(pp) *Quality control technologist* means an individual meeting the requirements of § 900.12(a)(2) who is responsible

### § 900.3

### 21 CFR Ch. I (4-1-03 Edition)

for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

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

(rr) *Radiologic 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 set forth in § 900.12(a)(2).

(ss) *Serious adverse event* means an adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

(tt) *Serious complaint* means a report of a serious adverse event.

(uu) *Standard breast* means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

(vv) *Survey* means an onsite physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

(ww) *Time cycle* means the film development time.

(xx) *Traceable to a national standard* means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within  $\pm 3$  percent of the national standard in the mammography energy range.

(yy) *Review physician* means a physician who, by meeting the requirements set out in § 900.4(c)(5), is qualified to review clinical images on behalf of the accreditation body.

(zz) *Certification agency* means a State that has been approved by FDA under § 900.21 to certify mammography facilities.

(aaa) *Performance indicators* mean the measures used to evaluate the certification agency's ability to conduct certification, inspection, and compliance activities.

(bbb) *Authorization* means obtaining approval from FDA to utilize new or

changed State regulations or procedures during the issuance, maintenance, and withdrawal of certificates by the certification agency.

[62 FR 55976, Oct. 28, 1997; 62 FR 60614, Nov. 10, 1997, as amended at 63 FR 56558, Oct. 22, 1998; 64 FR 32407, June 17, 1999; 67 FR 5467, Feb. 6, 2002]

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

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

(b) *Application for initial approval.* (1) An applicant seeking initial FDA approval as an accreditation body shall inform the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiology Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, marked Attn: Mammography Standards Branch, of its desire to be approved as an accreditation body and of its requested scope of authority.

(2) Following receipt of the request, FDA will provide the applicant with additional information to aid in submission of an application for approval as an accreditation body.

(3) The applicant shall furnish to FDA, at the address in § 900.3(b)(1), three copies of an application containing the following information, materials, and supporting documentation:

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

(ii) Detailed description of the accreditation standards the applicant will require facilities to meet and a discussion substantiating their equivalence to FDA standards required under § 900.12;

(iii) Detailed description of the applicant's accreditation review and decisionmaking process, including:

(A) Procedures for performing accreditation and reaccreditation clinical image review in accordance with § 900.4(c), random clinical image reviews in accordance with § 900.4(f), and