

### § 900.3

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

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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

additional mammography review in accordance with § 900.12(j);

(B) Procedures for performing phantom image review;

(C) Procedures for assessing mammography equipment evaluations and surveys;

(D) Procedures for initiating and performing onsite visits to facilities;

(E) Procedures for assessing facility personnel qualifications;

(F) Copies of the accreditation application forms, guidelines, instructions, and other materials the applicant will send to facilities during the accreditation process, including an accreditation history form that requires each facility to provide a complete history of prior accreditation activities and a statement that all information and data submitted in the application is true and accurate, and that no material fact has been omitted;

(G) Policies and procedures for notifying facilities of deficiencies;

(H) Procedures for monitoring corrections of deficiencies by facilities;

(I) Policies and procedures for suspending or revoking a facility's accreditation;

(J) Policies and procedures that will ensure processing of accreditation applications and renewals within a timeframe approved by FDA and assurances that the body will adhere to such policies and procedures; and

(K) A description of the applicant's appeals process for facilities contesting adverse accreditation status decisions.

(iv) Education, experience, and training requirements for the applicant's professional staff, including reviewers of clinical or phantom images;

(v) Description of the applicant's electronic data management and analysis system with respect to accreditation review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems;

(vi) Resource analysis that demonstrates that the applicant's staffing, funding, and other resources are adequate to perform the required accreditation activities;

(vii) Fee schedules with supporting cost data;

(viii) Statement of policies and procedures established to avoid conflicts

of interest or the appearance of conflicts of interest by the applicant's board members, commissioners, professional personnel (including reviewers of clinical and phantom images), consultants, administrative personnel, and other representatives of the applicant;

(ix) Statement of policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body;

(x) Disclosure of any specific brand of imaging system or component, measuring device, software package, or other commercial product used in mammography that the applicant develops, sells, or distributes;

(xi) Description of the applicant's consumer complaint mechanism;

(xii) Satisfactory assurances that the applicant shall comply with the requirements of § 900.4; and

(xiii) Any other information as may be required by FDA.

(c) *Application for renewal of approval.* An approved accreditation body that intends to continue to serve as an accreditation body beyond its current term shall apply to FDA for renewal or notify FDA of its plans not to apply for renewal in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of a body's approval, the body shall inform FDA, at the address given in § 900.3(b)(1), of its intent to seek renewal.

(2) FDA will notify the applicant of the relevant information, materials, and supporting documentation required under § 900.3(b)(3) that the applicant shall submit as part of the renewal procedure.

(3) At least 6 months before the date of expiration of a body's approval, the applicant shall furnish to FDA, at the address in § 900.3(b)(1), three copies of a renewal application containing the information, materials, and supporting documentation requested by FDA in accordance with § 900.3(c)(2).

(4) No later than July 28, 1998, any accreditation body approved under the interim regulations published in the FEDERAL REGISTER of December 21, 1993 (58 FR 67558), that desires to continue to serve as an accreditation body under

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the final regulations shall apply for renewal of approval in accordance with the procedures set forth in paragraphs (c)(1) through (c)(3) of this section.

(5) Any accreditation body that does not plan to renew its approval shall so notify FDA at the address given in paragraph (b)(1) of this section at least 9 months before the expiration of the body's term of approval.

(d) *Rulings on applications for initial and renewed approval.* (1) FDA will conduct a review and evaluation to determine whether the applicant substantially meets the applicable requirements of this subpart and whether the accreditation standards the applicant will require facilities to meet are substantially the same as the quality standards published under subpart B of this part.

(2) FDA will notify the applicant of any deficiencies in the application and request that those deficiencies be rectified within a specified time period. If the deficiencies are not rectified to FDA's satisfaction within the specified time period, the application for approval as an accreditation body may be rejected.

(3) FDA shall notify the applicant whether the application has been approved or denied. That notification shall list any conditions associated with approval or state the bases for any denial.

(4) The review of any application may include a meeting between FDA and representatives of the applicant at a time and location mutually acceptable to FDA and the applicant.

(5) FDA will advise the applicant of the circumstances under which a denied application may be resubmitted.

(6) If FDA does not reach a final decision on a renewal application in accordance with this paragraph before the expiration of an accreditation body's current term of approval, the approval will be deemed extended until the agency reaches a final decision on the application, unless an accreditation body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of authority.* An accreditation body that decides to relinquish its accreditation authority be-

fore expiration of the body's term of approval shall submit a letter of such intent to FDA, at the address in § 900.3(b)(1), at least 9 months before relinquishing such authority.

(f) *Transfer of records.* An accreditation body that does not apply for renewal of accreditation body approval, is denied such approval by FDA, or relinquishes its accreditation authority and duties before expiration of its term of approval, shall:

(1) Transfer facility records and other related information as required by FDA to a location and according to a schedule approved by FDA.

(2) Notify, in a manner and time period approved by FDA, all facilities accredited or seeking accreditation by the body that the body will no longer have accreditation authority.

(g) *Scope of authority.* An accreditation body's term of approval is for a period not to exceed 7 years. FDA may limit the scope of accreditation authority.

[62 FR 55976, Oct. 28, 1997; 62 FR 60614, Nov. 10, 1997]

### § 900.4 Standards for accreditation bodies.

(a) *Code of conduct and general responsibilities.* The accreditation body shall accept the following responsibilities in order to ensure safe and accurate mammography at the facilities it accredits and shall perform these responsibilities in a manner that ensures the integrity and impartiality of accreditation body actions.

(1)(i) When an accreditation body receives or discovers information that suggests inadequate image quality, or upon request by FDA, the accreditation body shall review a facility's clinical images or other aspects of a facility's practice to assist FDA in determining whether or not the facility's practice poses a serious risk to human health. Such reviews are in addition to the evaluation an accreditation body performs as part of the initial accreditation or renewal process for facilities.

(ii) If review by the accreditation body demonstrates that a problem does exist with respect to image quality or other aspects of a facility's compliance with quality standards, or upon request by FDA, the accreditation body shall