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standard whenever the agency determines that this action is necessary to protect the human health or otherwise is justified by § 900.12. Such action will become effective on the date specified in the written notice of the action sent to the applicant, except that it will become effective immediately upon notification of the applicant when FDA determines that such action is necessary to prevent an imminent health hazard.

[62 FR 55976, Oct. 28, 1997; 62 FR 60614, Nov. 10, 1997, as amended at 75 FR 20916, Apr. 22, 2010]

Subpart C—States as Certifiers

SOURCE: 67 FR 5467, Feb. 6, 2002, unless otherwise noted.

§ 900.20 Scope.

The regulations set forth in this part implement the Mammography Quality Standards Act (MQSA) (42 U.S.C. 263b). Subpart C of this part establishes procedures whereby a State can apply to become a FDA-approved certification agency to certify facilities within the State to perform mammography services. Subpart C of this part further establishes requirements and standards for State certification agencies to ensure that all mammography facilities under their jurisdiction are adequately and consistently evaluated for compliance with quality standards at least as stringent as the national quality standards established by FDA.

§ 900.21 Application for approval as a certification agency.

(a) *Eligibility*. State agencies may apply for approval as a certification agency if they have standards at least as stringent as those of § 900.12, qualified personnel, adequate resources to carry out the States as Certifiers' responsibilities, and the authority to enter into a legal agreement with FDA to accept these responsibilities.

(b) *Application for approval*. (1) An applicant seeking FDA approval as a certification agency shall inform the Food and Drug Administration, Center for Devices and Radiological Health, Director, Division of Mammography Quality and Radiation Programs, Attn: States as Certifiers Coordinator, 10903 New Hampshire Ave., Bldg. 66, rm. 4521, Silver Spring, MD 20993–0002, in writing, of its desire to be approved as a certification agency.

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

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

(i) Name, address, and phone number of the applicant;

(ii) Detailed description of the mammography quality standards the applicant will require facilities to meet and, for those standards different from FDA's quality standards, information substantiating that they are at least as stringent as FDA standards under § 900.12;

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

(A) Policies and procedures for notifying facilities of certificate denials and expirations;

(B) Procedures for monitoring and enforcement of the correction of deficiencies by facilities;

(C) Policies and procedures for suspending or revoking a facility's certification;

(D) Policies and procedures that will ensure processing certificates within a timeframe approved by FDA;

(E) A description of the appeals process for facilities contesting adverse certification status decisions;

(F) Education, experience, and training requirements of the applicant's professional and supervisory staff;

(G) Description of the applicant's electronic data management and analysis system;

(H) Fee schedules;

(I) Statement of policies and procedures established to avoid conflict of interest;

(J) Description of the applicant's mechanism for handling facility inquiries and complaints;

(K) Description of a plan to ensure that certified mammography facilities will be inspected according to MQSA (42 U.S.C. 263b) and procedures and

policies for notifying facilities of inspection deficiencies;

(L) Policies and procedures for monitoring and enforcing the correction of facility deficiencies discovered during inspections or by other means;

(M) Policies and procedures for additional mammography review and for requesting such reviews from accreditation bodies;

(N) Policies and procedures for patient notification;

(O) If a State has regulations that are more stringent than those of § 900.12, an explanation of how adverse actions taken against a facility under the more stringent regulations will be distinguished from those taken under the requirements of § 900.12; and

(P) Any other information that FDA identifies as necessary to make a determination on the approval of the State as a certification agency.

(c) *Rulings on applications for 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 certification standards the applicant will require facilities to meet are the quality standards published under subpart B of this part or at least as stringent as those of subpart B.

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

(3) FDA shall notify the applicant whether the application has been approved or denied. The 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.

(d) *Scope of authority.* FDA may limit the scope of certification authority delegated to the State in accordance with MQSA.

[62 FR 55976, Oct. 28, 1997; 62 FR 60614, Nov. 10, 1997, as amended at 75 FR 20916, Apr. 22, 2010]

§ 900.22 Standards for certification agencies.

The certification agency shall accept the following responsibilities in order to ensure quality mammography at the facilities it certifies and shall perform these responsibilities in a manner that ensures the integrity and impartiality of the certification agency's actions:

(a) *Conflict of interest.* The certification agency shall establish and implement measures that FDA has approved in accordance with § 900.21(b) to reduce the possibility of conflict of interest or facility bias on the part of individuals acting on the certification agency's behalf.

(b) *Certification and inspection responsibilities.* Mammography facilities shall be certified and inspected in accordance with statutory and regulatory requirements that are at least as stringent as those of MQSA and this part.

(c) *Compliance with quality standards.* The scope, timeliness, disposition, and technical accuracy of completed inspections and related enforcement activities shall ensure compliance with facility quality standards required under § 900.12.

(d) *Enforcement actions.* (1) There shall be appropriate criteria and processes for the suspension and revocation of certificates.

(2) There shall be prompt investigation of and appropriate enforcement action for facilities performing mammography without certificates.

(e) *Appeals.* There shall be processes for facilities to appeal inspection findings, enforcement actions, and adverse certification decision or adverse accreditation decisions after exhausting appeals to the accreditation body.

(f) *Additional mammography review.* There shall be a process for the certification agency to request additional mammography review from accreditation bodies for issues related to mammography image quality and clinical practice. The certification agency should request additional mammography review only when it believes that