

§ 900.16

(B) All information the facility submitted to the accreditation body as part of the appeals process;

(C) A copy of the accreditation body's adverse appeals decision; and

(D) A statement of the basis for the facility's disagreement with the accreditation body's decision.

(iii) DMQRP will conduct its reconsideration in accordance with the procedures set forth in subpart B of 42 CFR part 498.

(4) A facility that is dissatisfied with DMQRP's decision following reconsideration is entitled to a formal hearing in accordance with procedures set forth in subpart D of 42 CFR part 498.

(5) Either the facility or FDA may request review of the hearing officer's decision. Such review will be conducted by the Departmental Appeals Board in accordance with subpart E of 42 CFR part 498.

(6) A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

§ 900.16 Appeals of denials of certification.

(a) The appeals procedures described in this section are available only to facilities that are denied certification by FDA after they have been accredited by an approved accreditation body. Appeals for facilities that have failed to become accredited are governed by the procedures set forth in § 900.15.

(b) FDA may deny the application if the agency has reason to believe that:

(1) The facility will not be operated in accordance with standards established under § 900.12;

(2) The facility will not permit inspections or provide access to records or information in a timely fashion; or

(3) The facility has been guilty of misrepresentation in obtaining the accreditation.

(c)(1) If FDA denies an application for certification by a facility that has received accreditation from an approved accreditation body, FDA shall provide the facility with a statement of the grounds on which the denial is based.

(2) A facility that has been denied accreditation may request reconsideration and appeal of FDA's determination in accordance with the applicable provisions of § 900.15(d).

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

§ 900.17 [Reserved]

§ 900.18 Alternative requirements for § 900.12 quality standards.

(a) *Criteria for approval of alternative standards.* Upon application by a qualified party as defined in paragraph (b) of this section, FDA may approve an alternative to a quality standard under § 900.12, when the agency determines that:

(1) The proposed alternative standard will be at least as effective in assuring quality mammography as the standard it proposes to replace, and

(2) The proposed alternative:

(i) Is too limited in its applicability to justify an amendment to the standard; or

(ii) Offers an expected benefit to human health that is so great that the time required for amending the standard would present an unjustifiable risk to the human health; and

(3) The granting of the alternative is in keeping with the purposes of 42 U.S.C. 263b.

(b) *Applicants for alternatives.* (1) Mammography facilities and accreditation bodies may apply for alternatives to the quality standards of § 900.12.

(2) Federal agencies and State governments that are not accreditation bodies may apply for alternatives to the standards of § 900.12(a).

(3) Manufacturers and assemblers of equipment used for mammography may apply for alternatives to the standards of § 900.12(b) and (e).

(c) *Applications for approval of an alternative standard.* An application for approval of an alternative standard or for an amendment or extension of the alternative standard shall be submitted in an original and two copies to the Director, Division of Mammography Quality and Radiation Programs (HFZ-240), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. The application for approval of an alternative standard shall include the following information:

(1) Identification of the original standard for which the alternative standard is being proposed and an explanation of why the applicant is proposing the alternative;

(2) A description of the manner in which the alternative is proposed to deviate from the original standard;

(3) A description, supported by data, of the advantages to be derived from such deviation;

(4) An explanation, supported by data, of how such a deviation would ensure equal or greater quality of production, processing, or interpretation of mammograms than the original standard;

(5) The suggested period of time that the proposed alternative standard would be in effect; and

(6) Such other information required by the Director to evaluate and act on the application.

(d) *Ruling on applications.* (1) FDA may approve or deny, in whole or in part, a request for approval of an alternative standard or any amendment or extension thereof, and shall inform the applicant in writing of this action. The written notice shall state the manner in which the requested alternative standard differs from the agency standard and a summary of the reasons for approval or denial of the request. If the request is approved, the written notice shall also include the effective date and the termination date of the approval and a summary of the limitations and conditions attached to the approval and any other information that may be relevant to the approved request. Each approved alternative standard shall be assigned an identifying number.

(2) Notice of an approved request for an alternative standard or any amendment or extension thereof shall be placed in the public docket file in the Dockets Management Branch and may also be in the form of a notice published in the FEDERAL REGISTER. The notice shall state the name of the applicant, a description of the published agency standard, and a description of the approved alternative standard, including limitations and conditions attached to the approval of the alternative standard.

(3) Summaries of the approval of alternative standards, including information on their nature and number, shall be provided to the National Mammography Quality Assurance Advisory Committee.

(4) All applications for approval of alternative standards and for amendments and extensions thereof and all correspondence (including written notices of approval) on these applications shall be available for public disclosure in the Dockets Management Branch, excluding patient identifiers and confidential commercial information.

(e) *Amendment or extension of an alternative standard.* An application for amending or extending approval of an alternative standard shall include the following information:

(1) The approval number and the expiration date of the alternative standard;

(2) The amendment or extension requested and the basis for the amendment or extension; and

(3) An explanation, supported by data, of how such an amendment or extension would ensure equal or greater quality of production, processing, or interpretation of mammograms than the original standard.

(f) *Applicability of the alternative standards.* (1) Except as provided in paragraphs (f)(2) and (f)(3) of this section, any approval of an alternative standard, amendment, or extension may be implemented only by the entity to which it was granted and under the terms under which it was granted. Other entities interested in similar or identical approvals must file their own application following the procedures of paragraph (c) of this section.

(2) When an alternative standard is approved for a manufacturer of equipment, any facility using that equipment will also be covered by the alternative standard.

(3) The agency may extend the alternative standard to other entities when FDA determines that expansion of the approval of the alternative standard would be an effective means of promoting the acceptance of measures to improve the quality of mammography. All such determinations will be publicized by appropriate means.

(g) *Withdrawal of approval of alternative requirements.* FDA shall amend or withdraw approval of an alternative 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]

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 Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, Rockville, MD 20850, marked Attn: SAC¹ Coordinator, in writing, of its desire to be approved as a certification agency.

¹SAC means States as Certifiers.

(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;