

(5) *Surveys.* As a part of its overall quality assurance program, each facility shall have a medical physicist establish, monitor, and direct the procedures required by paragraphs (d)(1), (d)(2), and (d)(3) of this section and perform a survey of the facility to assure that it meets the quality control and equipment standards as specified in paragraph (b)(2) of this section. Such surveys shall be performed at least annually, and reports of such surveys shall be prepared and transmitted to the accrediting body in accordance with §900.4(d)(1). Each such report shall be retained by the facility until such time as the next annual survey is satisfactorily completed.

(e) *Medical records.* (1) Each facility shall maintain mammograms and associated records in a permanent medical record of the patient as follows:

(i) For a period of not less than 5 years, or not less than 10 years, if no additional mammograms of the patient are performed at the facility, or longer if mandated by State or local law; or

(ii) Until requested by the patient to permanently transfer the records to a medical institution, or to a physician of the patient, or to the patient herself, and the records are so transferred.

(2) Each facility shall prepare a written report of the results of any mammography examination. Such report shall be completed as soon as reasonably possible and shall:

(i) Be signed by the interpreting physician; and

(ii) Be provided to the patient's physicians (if any); or

(A) If the patient's physician is not available or if the patient does not have a physician, the report shall be sent directly to the patient; and

(B) If such report is sent to the patient, it shall include a summary written in language easily understood by a lay person; and

(iii) Be maintained in the patient's record in accordance with paragraph (e)(1) of this section.

[58 FR 67570, Dec. 21, 1993; 59 FR 6899, Feb. 14, 1994, as amended at 59 FR 49812, Sept. 30, 1994]

§900.13 Revocation of accreditation and accrediting body approval.

(a) *Accreditation.* If a facility's accreditation is revoked by an accrediting body, the facility's certificate shall remain in effect until such time as determined by the agency on a case-by-case basis after an investigation into the reasons for the revocation. If FDA determines that the revocation was justified by violations of applicable quality standards, FDA will revoke or suspend the facility's certificate and/or require the submission and implementation of a corrective action plan, whichever action will protect the public health in the least burdensome way.

(b) *Accrediting body approval.* If the approval of an accrediting body is revoked by FDA, the certificates of the facilities accredited by such body shall remain in effect for a period of 1 year after the date of such revocation subject to FDA's determination that the facility continues to perform quality mammography. By the end of a year following revocation of approval of a facility's accrediting body, the facility must obtain accreditation by another accrediting body.

§900.14 Hearings regarding certification decisions.

Opportunities to challenge final adverse actions taken by FDA regarding denials of certification or suspension or revocations of certification of facilities will be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

§900.18 Alternative requirements for MQSA quality standards.

(a) *Criteria for approval of alternative standards.* Upon application by a qualified party as defined under paragraph (b) of this section, the Director, Division of Mammography Quality and Radiation Programs (the Director), may approve an alternative to a quality standard under §900.12, when the Director 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 amending the standard, or

(ii) Offers an expected benefit to public health which is so great that the time required for the processing of an amendment to the standard would present an unjustifiable risk to public health, and

(3) The granting of the alternative is in keeping with the purposes of the Mammography Quality Standards Act of 1992.

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

(2) State governments that are not accrediting 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), (c), and (d).

(c) *Application 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, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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 it is believed necessary to propose 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 assure 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) The Director 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 will 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 will also include the effective date and the termination date of the approval, 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 will be assigned an identifying number.

(2) Notice of an approved request for an alternative standard or any amendment or extension thereof will be placed in the public docket file in the office of the Dockets Management Branch and may also be in the form of a notice published in the FEDERAL REGISTER. The notice will 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 approval of the alternative standard.

(3) Summaries of approved alternative standards, including information on their nature and number, will 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 will 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 assure equal or greater quality of production, processing, or interpretation of mammograms than the original standard.

(f) *Applicability of the alternative standards.* 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, except that when an alternative standard is approved for a manufacturer of equipment, any facility using that equipment will also be covered by the alternative standard. Other entities interested in similar or identical approvals must file their own application by following the provisions of §900.18(c).

(g) *Withdrawal of approval of alternative standards.* The Director shall amend or withdraw approval of an alternative standard whenever the Director determines that this action is necessary to protect the public 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 the Director determines that such action is necessary to prevent an imminent health hazard.

[59 FR 49812, Sept. 30, 1994]

EFFECTIVE DATE NOTE: At 62 FR 55976, Oct. 28, 1997, part 900 was revised; and at 62 FR 60614, Nov. 10, 1997, it was republished and corrected, effective Apr. 28, 1999, with excepted provisions effective Oct. 28, 2002. For the convenience of the user, revised and corrected part 900 is set forth as follows:

PART 900—MAMMOGRAPHY

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- 900.2 Definitions.
- 900.3 Application for approval as an accreditation body.
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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.

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 and B 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.