SUBCHAPTER I—MAMMOGRAPHY QUALITY STANDARDS ACT

PART 900—MAMMOGRAPHY

Subpart A—Accreditation

Subpart B—Quality Standards and Certification

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

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 follows the text of this part.

Subpart A—Accreditation

SOURCE: 58 FR 67562, Dec. 21, 1993, unless otherwise noted.

§900.1 Scope.

The regulations set forth in this part implement 42 U.S.C. 263b(b) through (f). The intent of subpart A of this part is to establish application procedures for accrediting bodies and to establish requirements and standards for such bodies to ensure that all mammography facilities in the United States are adequately and consistently evaluated for compliance with quality standards for mammography. The intent of subpart B of this part is to establish procedures for facility certification and to establish quality standards for mammography facilities to assure safe, reliable, and accurate mammography on a nationwide level.

§900.2 Definitions.

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

(a) *Accrediting body* or *body* means an entity that has been approved by FDA under 42 U.S.C. 263b(e)(1)(A) to accredit mammography facilities.

(b) *Certificate* means the certificate described in 42 U.S.C. 263b(b)(1).

(c) *Certification* means the state of approval of a facility by FDA to provide screening and diagnostic mammography services.

(d) *Clinical image* means a mammogram.

(e) *Facility* means a hospital, outpatient department, clinic, radiology practice, or mobile unit, office of a physician, or other facility that conducts breast cancer screening mammography activities or conducts diagnostic mammography activities, including the following: The operation of equipment to produce a mammogram, processing of film, 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.

(f) *Interpreting physician* means a physician who interprets mammograms made during screening or diagnostic mammography procedures and who meets the requirements of §900.12(a)(1).

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

(h) *Mammography* means radiography of the breast.

(i) *Medical physicist* means a person meeting the qualifications for a medical physicist set forth in §900.12(a)(3).

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

(k) *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.

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

(m) *Provisional certificate* means the provisional certificate described in 42 U.S.C. 263b(c)(2).

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

(o) *Radiological 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 in § 900.12(a)(2).

(p) *Qualified practicing physician* means a physician meeting the requirements of an interpreting physician as specified under § 900.12(a)(1).

(q) *Survey* means an on-site physics consultation and evaluation of a facility performed by a medical physicist.

(r) *Diagnostic mammography* means mammography performed on a patient with: clinical signs, symptoms, physical findings suggestive of breast cancer; an abnormal or questionable screening mammogram; a history of breast cancer with breast conservation surgery regardless of absence of clinical breast signs, symptoms, or physical findings; or, augmented breasts regardless of absence of clinical breast signs, symptoms, or physical findings. Diagnostic mammography is also called problem-solving mammography or consultative mammography. This definition excludes mammography performed during invasive interventions for localization or biopsy procedures. The definition further excludes mammography performed as part of a scientific study to evaluate an experimental mammography device conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

(s) *Screening mammography* means mammography performed on an asymptomatic patient to detect the presence of breast cancer at an early stage. This definition excludes mammography performed as part of a scientific study to evaluate an experimental mammography device conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

[58 FR 67562, Dec. 21, 1993; 59 FR 6899, Feb. 14, 1994, as amended at 59 FR 49812, Sept. 30, 1994]

§ 900.3 Application for approval as an accrediting body.

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

(b) *Application*. One copy of an application for approval as an accrediting body shall be submitted to the Center for Devices and Radiological Health (HFZ–200), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and should be marked ATTENTION: Mammography Program. Applications for approval as an accrediting body should include the following information:

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

(2) Standards the body agrees to impose on facilities pursuant to 42 U.S.C. 263b(e)(3);

(3) Methods for performing clinical image review as required in 42 U.S.C. 263b(e)(1)(B)(i)(I);

(4) Methods for monitoring and evaluation of annual surveys of facilities by medical physicists as required in 42 U.S.C. 263b(e)(1)(B)(v);

(5) Methods for performing on-site inspections of facilities as required in 42 U.S.C. 263b(e)(4);

(6) Fee schedules, with supporting cost data; and

(7) Satisfactory assurances that the body will comply with the requirements of § 900.4.

(c) *Ruling on application*. FDA will approve an accrediting body if FDA determines upon review of the application that the body substantially meets (or will substantially meet when it begins to evaluate facilities) the requirements of this subpart, and the body's standards are substantially the same as the quality standards published

under subpart B of this part in accordance with 42 U.S.C. 263b(f). If the applicant fails to substantially meet the requirements set forth in this subpart A, or if the applicant's standards are determined not to be substantially the same as the quality standards published under subpart B of this part, or if FDA determines that the applicant has not provided satisfactory assurances that it is capable of meeting the requirements established in this subpart A, FDA will notify the applicant of any problems it has identified with the application and request that the applicant resolve such problems within 90 days of receipt of notice. If the problems are substantially resolved to the satisfaction of FDA within the 90-day time period, the body will be approved as an accrediting body. If the problems are not substantially resolved to the satisfaction of FDA within the 90-day time period, the application for approval as an accrediting body will be rejected and the applicant so notified. A rejected application that has been modified so as to render it satisfactory is subject to resubmission at any time.

§ 900.4 Responsibilities of accrediting bodies.

(a) *Facility standards.* The accrediting body shall require that each facility it accredits meet standards for the performance of quality mammography that are substantially the same as those promulgated in subpart B of this part under 42 U.S.C. 263b(f). The requirements set forth by the body for accreditation of a facility shall address, at a minimum, the following aspects of performing quality mammography:

(1) Physician training, experience, certification, and continuing education;

(2) Technologist training, experience, certification, and continuing education;

(3) Medical physicist training, experience, certification, and continuing education;

(4) X-ray equipment characteristics, including a requirement that the x-ray equipment be specifically designed for mammography;

(5) Quality assurance and quality control programs for ensuring that quality mammography is practiced by the facility;

(6) Phantom image quality testing and objective criteria to be used for passing the image quality test;

(7) Maximum radiation dose for a single view for specific imaging systems;

(8) Information update provisions that require accredited facilities to update at least annually the information listed in this section that they have provided the accrediting body; and

(9) Medical recordkeeping and patient notification requirements.

(b) *Clinical image review.* The accrediting body shall review clinical images from each facility accredited by the body at least once every 3 years and shall also review a random sample of clinical images from each facility accredited by the body in each 3-year period beginning October 1, 1994. These clinical image reviews shall be conducted by a qualified practicing physician not associated with the facility. The clinical image reviews shall ensure that quality clinical images are produced in the facility on a routine basis, as measured by proper breast positioning and compression and overall image quality. Any qualified practicing physicians who conduct clinical image quality reviews shall not have a financial interest in the facilities they review for the accrediting body, nor shall such physicians have any other interest that would constitute an apparent or real conflict of interest, other than receiving a service fee from the accrediting body itself related solely to the work performed in conducting the clinical review.

(c) *Fees.* Fees charged to facilities for accreditation shall be reasonable. FDA will usually find fees to be reasonable if they are limited to recovering costs to the accrediting body, including overhead incurred proportionately in accrediting a given facility. Accrediting bodies may adjust fees annually for inflation in accordance with the Consumer Price Index (CPI).

(d) *Reports of physics survey.* (1) The accrediting body shall require every facility applying for accreditation to submit to the accrediting body, with its accreditation application, a report of a survey by a medical physicist to assess the facility's compliance with

the accrediting body's standards established under paragraph (a) of this section. The accrediting body shall require that every facility it accredits undergo an annual survey by a medical physicist to assure continued facility compliance with applicable standards and to provide continued oversight of the facility's quality assurance program. The accrediting body shall require that the results of this survey be transmitted to the accrediting body, together with quality control records and any other information the body may require, as a part of the annual report about the facility.

(2) The accrediting body shall review the report of the annual physicist's survey, the quality control records of the facility, and other information that may come to its attention to determine if all the accrediting body's standards are being met by the facility. If the results of the survey or other information create doubt as to the quality of clinical images produced by the facility, then the accrediting body shall investigate by examination of recent clinical images from that facility to verify that the images meet the evaluation criteria of the accrediting body. If the accrediting body determines that the images are not of sufficient quality, the body shall determine necessary corrective measures to be taken by the facility, establish a schedule for implementation of such measures, and notify the facility that it must implement these measures within the specified schedule in order to retain accreditation. The accrediting body shall verify that the appropriate and necessary steps are taken by the facility within the schedule specified and that all accrediting body standards are being substantially met or will be substantially met. However, the responsibility for compliance remains with the facility.

(e) *On-site inspections.* On an annual basis, in accordance with methods specified in the accrediting body's application for approval, the accrediting body shall make on-site visits to a sufficient number of facilities accredited by the body to assess overall compliance with the accrediting body standards and the quality of performance of mammography. The accrediting body shall prepare and submit one copy of a report of the findings of each of these visits to FDA at the address specified in § 900.3(b). The facility may be given advance notice at the discretion of the accrediting body.

(f) *Complaints.* The accrediting body shall require all facilities it accredits to publish an address where complaints can be filed with the accrediting body, shall investigate such complaints within 90 days of receipt, and shall maintain records of all of such complaints for a period of 3 years from the time of completion of the investigation. Complaint records shall include a summary of the complaint and of the results of the accrediting body's investigation.

(g) *Reporting and recordkeeping.* All reporting requirements listed in this section shall be fulfilled by the accrediting body by sending reports to FDA at the address specified in § 900.3(b). Reports required within 48 hours may be made by phone initially but must be followed by a written notification within 5 days. The accrediting body shall:

(1) Comply with any reporting and recordkeeping requirements specified in paragraphs (a) through (f) of this section;

(2) submit to FDA the names of any facilities for which the accrediting body denies, suspends, or revokes accreditation, and the basis for the action, within 48 hours of the action;

(3) obtain FDA authorization for any change the accrediting body proposes to make in the standards of the body under § 900.3(c);

(4) collect the information required by 42 U.S.C. 263b(d) for each facility accredited by the body and submit it to FDA within 5 days of the date of accreditation;

(5) accept applications containing the information required in 42 U.S.C. 263b(c)(2) for provisional certificates and in § 900.11(b)(2) for extensions of provisional certificates, on behalf of FDA and notify FDA within 5 working days of the successful completion of the initial application; and

(6) provide to FDA any information requested by FDA about any particular facility accredited by the body within 5 days of receipt of the request.

§ 900.5 Evaluation.

FDA will evaluate annually the performance of each approved accrediting body by:

(a) Inspecting a sample of the facilities accredited by the body and evaluating the reports of inspections to ascertain whether the facilities accredited by the accrediting body are in compliance with the standards promulgated by the agency in subpart B of this part, and

(b) Evaluating a sample of the body's clinical image and phantom image reviews, evaluating the body's speed and efficiency in accrediting facilities, evaluating the body's ability to file reports within deadlines, and reviewing the body's records and recordkeeping processes.

§ 900.6 Withdrawal of approval.

If FDA determines, through the evaluation activities of § 900.5 or through other information that comes to the attention of the agency, that an accrediting body is not in substantial compliance with this subpart, FDA shall initiate enforcement actions as follows:

(a) *Major deficiencies.* If FDA determines that the accrediting body has major deficiencies in performance, such as commission of fraud, or material false statements, or failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart A, FDA will withdraw its approval of that accrediting body and notify such body of the grounds on which the approval was withdrawn.

(b) *Minor deficiencies.* If FDA determines that the accrediting body has minor deficiencies in the performance of an accreditation function, including minor failure to comply with this subpart A, FDA will notify the body that it has 90 days to submit to FDA a plan of corrective action addressing the problems specified by FDA. This plan must include a summary of planned corrective actions and a schedule for their implementation.

(1) If the corrective action plan is received within the 90-day time period specified and is satisfactory to FDA, FDA will notify the body that it is on probationary approval status until further notice. This probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems. When such determination of restoration of satisfactory performance is made, FDA will restore the body to full approval status.

(2) If the body does not submit a satisfactory corrective action plan within the designated 90-day time period or does not implement an FDA-approved corrective action plan within the time interval specified in the corrective action plan (as amended, with FDA approval, if necessary) FDA will withdraw approval of the body as an accrediting body. In cases of withdrawal of approval of accrediting bodies, if FDA finds that there are satisfactory assurances that the unacceptable performance of the accrediting body has been substantially resolved, on application by the accrediting body, FDA may reinstate the approval of the accrediting body, unless there have been fraud or material false statements.

§ 900.7 Hearings.

Opportunities to challenge final adverse actions taken by FDA regarding approval of accrediting bodies, withdrawal of approval of accrediting bodies, or rejection of a proposed fee shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

Subpart B—Quality Standards and Certification

SOURCE: 58 FR 67570, Dec. 21, 1993, unless otherwise noted.

§ 900.10 Applicability.

The provisions of this subpart are applicable to all facilities under the regulatory jurisdiction of the United States that provide screening and/or diagnostic mammography services, with the exception of facilities of the Department of Veterans Affairs.

§ 900.11 Requirements for certification.

(a) *General.* After October 1, 1994, a certificate issued by FDA will be required for lawful operation of all facilities. In order to obtain a certificate from FDA, facilities are required to meet the quality standards in § 900.12 and to be accredited by an accrediting body approved by FDA. On request from a facility, FDA will provide such facility with a current list of approved accrediting bodies. Any request for such list shall include the name and address of the facility and must be sent to the address provided in § 900.3(b).

(b) *Application*—(1) *Certificates.* When applying for accreditation to an approved accrediting body, a facility shall submit to such accrediting body the information required in 42 U.S.C. 263b(d)(1). If and when the facility becomes accredited, information required for certification of the facility shall be forwarded to FDA by the accrediting body, in accordance with § 900.4(g)(4).

(2) *Provisional certificates.* Facilities that have not obtained a certificate by October 1, 1994, but have applied for accreditation to an approved accrediting body by then are eligible to receive a provisional certificate. To receive a provisional certificate, a facility shall submit the information required in 42 U.S.C. 263b(c)(2) to an approved accrediting body. New facilities may also submit such information directly to FDA. If and when the accrediting body determines that such application is sufficiently complete for review purposes, this fact shall be communicated to FDA by the accrediting body in accordance with § 900.4(g)(5). To apply for a 90-day extension to a provisional certificate, a facility shall submit to the accrediting body a statement of what the facility is doing to obtain certification and evidence that a significant adverse impact on the regional availability of mammography would result if such facility did not obtain an extension. Such information shall be forwarded to FDA by the accrediting body in accordance with § 900.4(g)(5).

(c) *Issuance and renewal of certificates*—(1) *Certificates.* FDA will issue a certificate to a facility within 30 days of receipt of notification from an approved accrediting body of the accreditation of such facility. The initial certificate for a facility shall remain in effect until 30 days after the date of expiration of the facility's existing accreditation unless certification and/or accreditation of the facility is revoked prior to such deadline. FDA will issue a renewed certificate to a previously certified facility within 30 days of receipt of notification from an approved accrediting body of renewal of the accreditation of such facility. A renewed certificate shall be effective for a period of 3 years from the date of issuance, unless certification and/or accreditation of the facility is revoked prior to such deadline.

(2) *Provisional certificates.* FDA will issue a provisional certificate to a facility within 10 days of receipt of notification from an approved accrediting body of satisfaction of the requirements of paragraph (b)(2) of this section. A provisional certificate shall be effective for 6 months from the date of issuance. FDA will issue a 90-day extension for a provisional certificate within 10 days of receipt from the accrediting body of the information required in paragraph (b)(2) of this section, provided that FDA determines that the statutory prerequisites for the extension as set forth in section 354(c)(2) of the Public Health Service Act have been met. No renewal of a provisional certificate beyond the 90-day extension can occur.

§ 900.12 Quality standards.

The following requirements establish the minimum quality standards that must be met by a facility to be eligible for certification to provide screening and/or diagnostic mammography services:

(a) *Personnel.* The following requirements apply to personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities. Lists of personnel certifying bodies approved by FDA and referenced in this section may be obtained by submitting to FDA at the address specified in § 900.3(b) a request containing the information needed and the name and address of the facility.

(1) *Interpreting physician*. Interpreting physicians shall meet the following requirements:

(i) Be licensed to practice medicine in the State or facility in which they are practicing; and

(ii) Have the following training:

(A) Be certified by one of the bodies approved by FDA to certify interpreting physicians; or

(B) Have had at least 2 months of documented full-time training in the interpretation of mammograms, including instruction in radiation physics, radiation effects, and radiation protection; and

(C) Have 40 hours of documented continuing medical education in mammography. Time spent in residency specifically devoted to mammography will be accepted, if documented in writing by the radiologist; and

(iii) Have the following initial experience:

(A) Have read and interpreted the mammograms from the examinations of at least 240 patients in the 6 months preceding application; or

(B) Read and interpret mammograms as specified in paragraph (a)(1)(iii)(A) of this section under the direct supervision of a fully qualified interpreting physician; and

(iv) Have the following continuing experience:

(A) Continue to read and interpret mammograms from the examination of an average of at least 40 patients per month over 24 months; and

(B) Continue to participate in education programs, either by teaching or completing an average of at least five continuing medical education credits in mammography per year.

(2) *Radiological technologist*. Radiological technologists shall meet the following requirements:

(i) Have a license to perform radiographic procedures in the State or facility where they are practicing; or

(ii) Have certification by one of the bodies approved by FDA to certify radiologic technologists; and

(iii) For those radiological technologists associated with facilities applying for accreditation before October 1, 1996:

(A) Have undergone training specific to mammography, either through a training curriculum or special mammography course, and accumulate at least an average of five continuing education units per year related to mammography; or

(B) Have 1 year of experience in the performance of mammography and by October 1, 1996, meet the training requirements of paragraph (a)(2)(iii)(A) of this section; and

(iv) For those radiological technologists associated with facilities applying for accreditation on and after October 1, 1996, meet the requirements of paragraph (a)(2)(i) or (a)(2)(ii) of this section and undergo specific training in mammography through documented curriculum and on-the-job training under the direct supervision of experienced mammographers; and

(v) Participate in formal continuing education programs and accumulate an average of at least five continuing education units in mammography per year.

(3) *Medical physicist*. Medical physicists shall meet the following requirements:

(i) Have a license or approval by a State to conduct evaluations of mammography equipment and procedures as required under the Public Health Service Act; or

(ii) Have certification in an accepted specialty area by one of the bodies approved by FDA to certify medical physicists; or

(iii) For those medical physicists associated with facilities applying for accreditation before October 27, 1997, meet the following criteria:

(A) Have a masters, or higher, degree in physics, radiological physics, applied physics, biophysics, health physics, medical physics, engineering, radiation science, or in public health with a bachelor's degree in the physical sciences; and

(B) Have 1 year of training in medical physics specific to diagnostic radiological physics; and

(C) Have 2 years of experience in conducting performance evaluation of mammography equipment; and

(iv) Participate in continuing education programs related to mammography, either by teaching or completing an average of at least five continuing education units per year.

(b) *Equipment*—(1) Radiographic equipment designed for conventional radiographic procedures that have been modified or equipped with special attachments for mammography shall not be used for mammography.

(2) Radiographic equipment used for mammography shall:

(i) Be certified pursuant to § 1010.2 of this chapter as meeting the applicable requirements of §§ 1020.30 and 1020.31 of this chapter in effect at the date of manufacture;

(ii) Be specifically designed for mammography;

(iii) Incorporate a breast compression device; and

(iv) Have the provision for operating with a removable grid, except for xeromammography systems.

(c) *Dose.* The average glandular dose delivered during a single cranio-caudal view of an accepted phantom simulating a 4.5 centimeter thick, compressed breast consisting of 50 percent glandular and 50 percent adipose tissue, shall not exceed 3.0 milliGray (0.3 rad) per exposure for screen-film mammography procedures and 4.0 milliGray (0.4 rad) per exposure for xeromammography procedures. The dose shall be determined at least annually under the technique factors and conditions that are used to produce the phantom images submitted for accreditation.

(d) *Quality assurance*—(1) *Equipment.* Each facility shall establish and maintain a quality assurance program to assure the adequate performance of the radiographic equipment and other equipment and materials used in conjunction with such equipment sufficient to assure the reliability and clarity of its mammograms. The program shall also require periodic monitoring of the dose delivered by the facility's examination procedures to ensure that it does not exceed the limit specified in paragraph (c) of this section and is appropriate for the image receptor used. Such quality assurance program shall:

(i) For film-screen systems, be substantially the same as that described in the 1992 or 1994 edition of ''Mammography Quality Control: Radiologist's Manual, Radiologic Technologist's Manual, and Medical Physicist's Manual,'' prepared by the American College of Radiology, Committee on Quality Assurance in Mammography, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American College of Radiology, Mammography Accreditation Program, 1891 Preston White Dr., Reston, VA 22091–5431; and may be inspected at the Center for Devices and Radiological Health, Division of Mammography and Radiation Programs (HFZ–200), 5600 Fishers Lane, Rockville, MD 20857; or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(ii) For systems with alternate image receptor modalities, be substantially the same as the quality assurance program recommended by the image receptor manufacturer, which, if followed, will allow a facility to maintain high image quality; and

(iii) For all image receptors, provide for the maintenance of log books documenting compliance with the applicable requirements in paragraph (d)(1) of this section and recording corrective actions taken.

(2) *Phantom images.* Each facility shall establish and maintain a program to assess the performance of the mammography system through the evaluation of radiographic images obtained with a phantom. The phantom must be of a type approved or accepted by the American College of Radiology or of an equivalent type accepted by FDA. The phantom images must score at least the minimum required by the accrediting body.

(3) *Clinical images.* Each facility shall establish and maintain a clinical image quality control program, including:

(i) Monitoring of mammograms repeated due to poor image quality; and

(ii) Maintenance of records, analysis of results, and a description of any remedial action taken on the basis of such monitoring.

(4) *Clinical image interpretation.* Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports.

(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

Subpart A—Accreditation

Subpart B—Quality Standards and Certification

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.