

§ 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 accredi-

tion 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.

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§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