

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.