

§ 900.22

21 CFR Ch. I (4-1-08 Edition)

(L) Policies and procedures for monitoring and enforcing the correction of facility deficiencies discovered during inspections or by other means;

(M) Policies and procedures for additional mammography review and for requesting such reviews from accreditation bodies;

(N) Policies and procedures for patient notification;

(O) If a State has regulations that are more stringent than those of § 900.12, an explanation of how adverse actions taken against a facility under the more stringent regulations will be distinguished from those taken under the requirements of § 900.12; and

(P) Any other information that FDA identifies as necessary to make a determination on the approval of the State as a certification agency.

(c) *Rulings on applications for approval.* (1) FDA will conduct a review and evaluation to determine whether the applicant substantially meets the applicable requirements of this subpart and whether the certification standards the applicant will require facilities to meet are the quality standards published under subpart B of this part or at least as stringent as those of subpart B.

(2) FDA will notify the applicant of any deficiencies in the application and request that those deficiencies be corrected within a specified time period. If the deficiencies are not corrected to FDA's satisfaction within the specified time period, FDA may deny the application for approval as a certification agency.

(3) FDA shall notify the applicant whether the application has been approved or denied. The notification shall list any conditions associated with approval or state the bases for any denial.

(4) The review of any application may include a meeting between FDA and representatives of the applicant at a time and location mutually acceptable to FDA and the applicant.

(5) FDA will advise the applicant of the circumstances under which a denied application may be resubmitted.

(d) *Scope of authority.* FDA may limit the scope of certification authority delegated to the State in accordance with MQSA.

§ 900.22 Standards for certification agencies.

The certification agency shall accept the following responsibilities in order to ensure quality mammography at the facilities it certifies and shall perform these responsibilities in a manner that ensures the integrity and impartiality of the certification agency's actions:

(a) *Conflict of interest.* The certification agency shall establish and implement measures that FDA has approved in accordance with § 900.21(b) to reduce the possibility of conflict of interest or facility bias on the part of individuals acting on the certification agency's behalf.

(b) *Certification and inspection responsibilities.* Mammography facilities shall be certified and inspected in accordance with statutory and regulatory requirements that are at least as stringent as those of MQSA and this part.

(c) *Compliance with quality standards.* The scope, timeliness, disposition, and technical accuracy of completed inspections and related enforcement activities shall ensure compliance with facility quality standards required under § 900.12.

(d) *Enforcement actions.* (1) There shall be appropriate criteria and processes for the suspension and revocation of certificates.

(2) There shall be prompt investigation of and appropriate enforcement action for facilities performing mammography without certificates.

(e) *Appeals.* There shall be processes for facilities to appeal inspection findings, enforcement actions, and adverse certification decision or adverse accreditation decisions after exhausting appeals to the accreditation body.

(f) *Additional mammography review.* There shall be a process for the certification agency to request additional mammography review from accreditation bodies for issues related to mammography image quality and clinical practice. The certification agency should request additional mammography review only when it believes that mammography quality at a facility has been compromised and may present a serious risk to human health.

(g) *Patient notification.* There shall be processes for the certification agency to conduct, or cause to be conducted,

patient notifications should the certification agency determine that mammography quality has been compromised to such an extent that it may present a serious risk to human health.

(h) *Electronic data transmission.* There shall be processes to ensure the timeliness and accuracy of electronic transmission of inspection data and facility certification status information in a format and timeframe determined by FDA.

(i) *Changes to standards.* A certification agency shall obtain FDA authorization for any changes it proposes to make in any standard that FDA has previously accepted under §900.21 before requiring facilities to comply with the changes as a condition of obtaining or maintaining certification.

§ 900.23 Evaluation.

FDA shall evaluate annually the performance of each certification agency. The evaluation shall include the use of performance indicators that address the adequacy of program performance in certification, inspection, and enforcement activities. FDA will also consider any additional information deemed relevant by FDA that has been provided by the certification body or other sources or has been required by FDA as part of its oversight mandate. The evaluation also shall include a review of any changes in the standards or procedures in the areas listed in §§900.21(b) and 900.22 that have taken place since the original application or the last evaluation, whichever is most recent. The evaluation shall include a determination of whether there are major deficiencies in the certification agency's regulations or performance that, if not corrected, would warrant withdrawal of the approval of the certification agency under the provisions of §900.24, or minor deficiencies that would require corrective action.

§ 900.24 Withdrawal of approval.

If FDA determines, through the evaluation activities of §900.23, or through other means, that a certification agency is not in substantial compliance with this subpart, FDA may initiate the following actions:

(a) *Major deficiencies.* If, after providing notice and opportunity for cor-

rective action, FDA determines that a certification agency has demonstrated willful disregard for public health, has committed fraud, has failed to provide adequate resources for the program, has submitted material false statements to the agency, has failed to achieve the MQSA goals of quality mammography and access, or has performed or failed to perform a delegated function in a manner that may cause serious risk to human health, FDA may withdraw its approval of that certification agency. The certification agency shall notify, within a time period and in a manner approved by FDA, all facilities certified or seeking certification by it that it has been required to correct major deficiencies.

(1) FDA shall notify the certification agency of FDA's action and the grounds on which the approval was withdrawn.

(2) A certification agency that has lost its approval shall notify facilities certified or seeking certification by it, as well as the appropriate accreditation bodies with jurisdiction in the State, that its approval has been withdrawn. Such notification shall be made within a timeframe and in a manner approved by FDA.

(b) *Minor deficiencies.* If FDA determines that a certification agency has demonstrated deficiencies in performing certification functions and responsibilities that are less serious or more limited than the deficiencies in paragraph (a) of this section, including failure to follow the certification agency's own procedures and policies as approved by FDA, FDA shall notify the certification agency that it has a specified period of time to take particular corrective measures as directed by FDA or to submit to FDA for approval the certification agency's own plan of corrective action addressing the minor deficiencies. If the approved corrective actions are not being implemented satisfactorily or within the established schedule, FDA may place the agency on probationary status for a period of time determined by FDA, or may withdraw approval of the certification agency.

(1) If FDA places a certification agency on probationary status, the certification agency shall notify all facilities