

## § 900.23

## 21 CFR Ch. I (4–1–03 Edition)

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

**Food and Drug Administration, HHS**

**§ 900.25**

certified or seeking certification by it of its probationary status within a time period and in a manner approved by FDA.

(2) Probationary status shall remain in effect until such time as the certification agency can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and that the corrective actions have substantially eliminated all identified problems, or

(3) If FDA determines that a certification agency that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, FDA may withdraw approval of the certification agency. The certification agency shall notify all facilities certified or seeking certification by it, as well as the appropriate accreditation bodies with jurisdiction in the State, of its loss of FDA approval, within a

timeframe and in a manner approved by FDA.

(c) *Transfer of records.* A certification agency that has its approval withdrawn shall transfer facility records and other related information as required by FDA to a location and according to a schedule approved by FDA.

**§ 900.25 Hearings and appeals.**

(a) Opportunities to challenge final adverse actions taken by FDA regarding approval of certification agencies or withdrawal of approval of certification agencies shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

(b) A facility that has been denied certification is entitled to an appeals process from the certification agency. The appeals process shall be specified in writing by the certification agency and shall have been approved by FDA in accordance with §§900.21 and 900.22.