(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