

§ 900.13

21 CFR Ch. I (4-1-01 Edition)

FDA may require. Such notification shall occur within a timeframe and in a manner specified by FDA.

[62 FR 55976, Oct. 28, 1997; 62 FR 60614, Nov. 10, 1997, as amended at 63 FR 56558, Oct. 22, 1998; 64 FR 18333, Apr. 14, 1999; 64 FR 32408, June 17, 1999; 65 FR 43690, July 14, 2000]

EFFECTIVE DATE NOTES: 1. At 62 FR 60614, Nov. 10, 1997, § 900.12 was corrected in paragraphs (b)(8)(i), (e)(4)(iii)(B), and (e)(5)(i)(B) by correcting "October 28, 1999" to read "October 28, 2002", effective Oct. 28, 2002.

2. At 63 FR 56558, Oct. 22, 1998, § 900.12 was amended by revising paragraph (e)(4)(iii)(B), effective Oct. 28, 2002. For the convenience of the user, the revised text is set forth as follows:

§ 900.12 Quality standards.

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(e) * * *

(4) * * *

(iii) * * *

(B) Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

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§ 900.13 Revocation of accreditation and revocation of accreditation body approval.

(a) FDA action following revocation of accreditation. If a facility's accreditation is revoked by an accreditation body, the agency may conduct an investigation into the reasons for the revocation. Following such investigation, the agency may determine that the facility's certificate shall no longer be in effect or the agency may take whatever other action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan of action that will permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is no longer in effect because it has lost its accreditation may not practice mammography.

(b) Withdrawal of FDA approval of an accreditation body. (1) If FDA withdraws approval of an accreditation body under § 900.6, the certificates of facilities previously accredited by such body shall remain in effect for up to 1 year from the date of the withdrawal of ap-

proval, unless FDA determines, in order to protect human health or because the accreditation body fraudulently accredited facilities, that the certificates of some or all of the facilities should be revoked or suspended or that a shorter time period should be established for the certificates to remain in effect.

(2) After 1 year from the date of withdrawal of approval of an accreditation body, or within any shorter period of time established by the agency, the affected facilities must obtain accreditation from another accreditation body, or from another entity designated by FDA.

§ 900.14 Suspension or revocation of certificates.

(a) Except as provided in paragraph (b) of this section, FDA may suspend or revoke a certificate if FDA finds, after providing the owner or operator of the facility with notice and opportunity for an informal hearing in accordance with part 16 of this chapter, that the owner, operator, or any employee of the facility:

(1) Has been guilty of misrepresentation in obtaining the certificate;

(2) Has failed to comply with the standards of § 900.12;

(3) Has failed to comply with reasonable requests of the agency or the accreditation body for records, information, reports, or materials that FDA believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of § 900.12;

(4) Has refused a reasonable request of a duly designated FDA inspector, State inspector, or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

(5) Has violated or aided and abetted in the violation of any provision of or regulation promulgated pursuant to 42 U.S.C. 263b; or

(6) Has failed to comply with prior sanctions imposed by the agency under 42 U.S.C. 263b(h).

(b) FDA may suspend the certificate of a facility before holding a hearing if FDA makes a finding described in paragraph (a) of this section and also determines that;