

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - MAMMOGRAPHY FACILITIES

AUTHORITY TO ENSURE THAT MAMMOGRAPHY FACILITIES MEET QUALITY STANDARDS

Effective Date: July 05, 2013

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

- A. The following officials are authorized to ensure mammography facilities obtain certificates under Section 354(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 263b(b)):
1. Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), Office of Medical Products and Tobacco (OMPT).
 2. Director and Deputy Directors, Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH, OMPT.
 3. Director and Deputy Directors, Division of Mammography Quality Standards (DMQS), OIR, CDRH, OMPT.
- B. The following officials are authorized to issue, renew and extend certificates to mammography facilities under Section 354(c) of the PHS Act (42 U.S.C. 263b(c)):
1. Director and Deputy Directors, CDRH, OMPT.
 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.
- C. The following officials are authorized to accept an application for a certificate under Section 354(d)(1) of the PHS Act (42 U.S.C. 263b(d)(1)):
1. Director and Deputy Directors, CDRH, OMPT.
 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.

D. The following officials are authorized to approve accreditation bodies to accredit mammography facilities under Section 354(e)(1)(A) of the PHS Act (42 U.S.C. 263b(e)(1)(A)):

1. Director and Deputy Directors, CDRH, OMPT.
2. Director and Deputy Directors, OIR, CDRH, OMPT.
3. Director and Deputy Directors, DMQS, OIR, CDRH, OMPT.

E. The following officials are authorized to ensure accreditation bodies provide satisfactory assurances of compliance under Section 354(e)(1)(C) of the PHS Act (42 U.S.C. 263b(e)(1)(c)):

1. Director and Deputy Directors, CDRH, OMPT.
2. Director and Deputy Directors, OIR, CDRH, OMPT.
3. Director and Deputy Director, DMQS OIR, CDRH, OMPT.

F. The following official is authorized to issue regulations under which the Director may withdraw approval of accreditation bodies under Section 354(e)(2)(A) of the PHS Act (42 U.S.C. 263b(e)(2)(A)):

1. Director, CDRH, OMPT.

G. The following officials are authorized to determine the expiration date of a certificate of a facility accredited by an accreditation body after the body's approval is withdrawn, or a State's certification authority has been withdrawn, or a facility's accreditation has been revoked by an accreditation body under Sections 354(e)(2)(B) and 354(e)(5) of the PHS Act (42 U.S.C. 263b(e)(2)(B) and (e)(5)):

1. Director and Deputy Directors, CDRH, OMPT.
2. Director and Deputy Directors, OIR, CDRH, OMPT.

H. The following officials are authorized to determine the applicable standards for a facility for accreditation under Section 354(e)(3) of the PHS Act (42 U.S.C. 263b(e)(3)):

1. Director and Deputy Directors, CDRH, OMPT.
2. Director and Deputy Directors, OIR, CDRH, OMPT.
3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.

- I. The following officials are authorized to ensure accreditation bodies make on site visits and to determine whether other measures are appropriate under Section 354(e)(4) of the PHS Act (42 U.S.C. 263b(e)(4)):
 - 1. Director and Deputy Directors, CDRH, OMPT.
 - 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 - 3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.

- J. The following officials are authorized to evaluate annually the performance of each approved accreditation body as provided by Section 354(e)(6)(A) of the PHS Act (41 U.S.C. 263b(e)(6)(A)):
 - 1. Director and Deputy Directors, CDRH, OMPT.
 - 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 - 3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.

- K. The following officials are authorized to determine the compliance of certified facilities with established standards through annual facility inspections as provided by Section 354(g) of the PHS Act (42 U.S.C. 263b(g)):
 - 1. Director and Deputy Directors, CDRH, OMPT.
 - 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 - 3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.

- L. The following officials are authorized to promote voluntary compliance with established standards instead of taking actions under Section 354(i) of the PHS Act (42 U.S.C. 263b(i)) by imposing directed plans of correction and/or payment of the cost of onsite monitoring under Section 354(h)(1) of the PHS Act (42 U.S.C. 263b(h)(1)):
 - 1. Director and Deputy Directors, CDRH, OMPT.
 - 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 - 3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.

- M. The following officials are authorized to require facilities to notify patients and referring physicians under Section 354(h)(2) of the PHS Act (42 U.S.C. 263b(h)(2)):

1. Director and Deputy Directors, CDRH, OMPT.
 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.
- N. The following officials are authorized to impose civil money penalties under Section 354(h)(3) of the PHS Act (42 U.S.C.263b(h)(3)):
1. Director and Deputy Directors, CDRH, OMPT.
- O. The following officials are authorized to develop and implement the procedures for determining when and how to impose sanctions as provided by Section 354(h)(4) of the PHS Act (42 U.S.C. 263b(h)(4)):
1. Director and Deputy Directors, CDRH, OMPT.
 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.
- P. The following officials are authorized to suspend or revoke individual facility certificates under Section 354(i)(1) and (i)(2) of the PHS Act (42U.S.C. 263b(i)(1) and (i)(2)):
1. Director and Deputy Directors, CDRH, OMPT.
 2. Director and Deputy Directors, OIR, CDRH, OMPT.
- Q. The following officials are authorized under Section 354(i)(3) of the PHS Act (42 U.S.C. 263b(i)(3)) to ensure that no person who owned or operated a facility at the time the cause of revocation occurred may, within 2 years of the revocation of the certificate, own or operate a mammography facility:
1. Director and Deputy Directors, CDRH, OMPT.
 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.
- R. The following officials are authorized to compile and make available to physicians and the general public information determined to be useful in evaluating the performance of mammography facilities as provided by Section 354(l) of the PHS Act (42 U.S.C. 263b(l)):

1. Director and Deputy Directors, CDRH, OMPT.
 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.
- S. The following officials are authorized to ensure that appropriate Federal agencies are consulted in the development of standards, regulations, evaluations, procedures for compliance and oversight as provided by Section 354(o) of the PHS Act (42 U.S.C. 263b(o)):
1. Director and Deputy Directors, CDRH, OMPT.
 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 3. Director and Deputy Director, DMQS, OIR, CDRH, OMPT.
- T. The following officials may authorize a State to carry out certification program requirements and implement quality standards under Sections 354(q)(1) and (q)(2) of the PHS Act (42 U.S.C. 263b(g)(1) and (g)(2)):
1. Director and Deputy Directors, CDRH, OMPT.
 2. Director and Deputy Directors, OIR, CDRH, OMPT.
 3. Director and Deputy Directors, DMQS, OIR, CDRH, OMPT.
- U. The following officials are authorized, after providing notice and opportunity for corrective action, to withdraw the approval of a State's authority to carry out certification requirements and implement quality standards under Section 354(q)(4) of the PHS Act (42 U.S.C.263b(g)(4)):
1. Director and Deputy Directors, CDRH, OMPT.

2. REDELEGATION.

These officials may not further redelegate these authorities.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on July 5, 2013.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/05/2010	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	07/05/2013	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs