

**FDA Staff Manual Guides, Volume II – Delegations of Authority**

**Regulatory – Mammography Facilities**

**Ensure Mammography Facilities Meet Quality Standards**

Effective Date: 12 January 2023

**1. Authority Delegated and To Whom Delegated.**

- A. The officials listed below are authorized to ensure mammography facilities obtain certificates under section 354(b) of the Public Health Service Act (PHS Act) (42 U.S.C. 263b(b)):
  - (1) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
  - (2) CDRH/Office of Product Evaluation and Quality (OPEQ) Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
  - (3) CDRH/OPEQ/Office of Health Technology VIII (OHT VIII) Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
  - (4) CDRH/OPEQ/OHT VIII/Division of Health Technology VIIIA (DHT VIIIA) Director and Deputy Director.
- B. The officials listed below are authorized to accept an application, and issue, renew, and extend certificates to mammography facilities under sections 354(c) and 354(d)(1) of the PHS Act (42 U.S.C. 263b(c)) and (42 U.S.C. 263b(d)(1)):
  - (1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
  - (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
  - (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
  - (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.
- C. The officials listed below 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) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

D. The officials listed below 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) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

E. The officials listed below may withdraw approval of accreditation bodies consistent with regulations promulgated under section 354(e)(2)(A) of the PHS Act (42 U.S.C. 263b(e)(2)(A)):

- (1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

F. The officials listed below 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), 354(e)(5), and 354(q)(4)(B) of the PHS Act (42 U.S.C. 263b(e)(2)(B), (e)(5), and (q)(4)(B)):

- (1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

G. The officials listed below 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) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

H. The officials listed below 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) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

I. The officials listed below are authorized to evaluate annually the performance of each approved accreditation body as provided by section 354(e)(6)(A) of the PHS Act (42 U.S.C. 263b(e)(6)(A)):

- (1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/ OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

J. The officials listed below 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) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.

- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

K. The officials listed below 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 costs of onsite monitoring under section 354(h)(1) of the PHS Act (42 U.S.C. 263b(h)(1)):

- (1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

L. The officials listed below 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) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

M. The officials listed below are authorized to impose civil monetary penalties under section 354(h)(3) of the PHS Act (42 U.S.C. 263b(h)(3)):

- (1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

N. The officials listed below 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) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.

- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

O. The officials listed below are authorized to suspend or revoke individual facility certificates under sections 354(i)(1) and 354(i)(2) of the PHS Act (42 U.S.C. 263b(i)(1) and (i)(2)):

- (1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

P. The officials listed below are authorized to ensure that no person who owned or operated a facility at the time the cause of revocation occurred may, within two years of the revocation of the certificate, own or operate a mammography facility under section 354(i)(3) of the PHS Act (42 U.S.C. 263b(i)(3)):

- (1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

Q. The officials listed below are authorized to compile and make available to physicians and the general public information determined to be useful in evaluating performance of mammography facilities as provided by section 354(l) of the PHS Act (42 U.S.C. 263b(l)):

- (1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

R. The officials listed below 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) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

S. The officials listed below are authorized to authorize a State to carry out certification program requirements and implement quality standards under sections 354(q)(1) and 354(q)(2) of the PHS Act (42 U.S.C. 263b(q)(1) and (q)(2)):

- (1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/OPEQ Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
- (3) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, and Chief Medical Officers.
- (4) CDRH/OPEQ/OHT VIII/DHT VIIIA Director and Deputy Director.

T. The officials listed below 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(q)(4)):

- (1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

## **2. Redellegation.**

These officials may not further redelegate this authority.

## **3. Effective Date.**

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 12 January 2023.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	08/16/2003	N/A	OC/ OA OM/OMP	Mark Barr McClellan, M.D., Ph.D. Commissioner of Food and Drugs
Revision	01/05/2010	N/A	OC/ OA/ OM/OMP	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	07/05/2013	N/A	OMPT/ CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	01/12/2023	N/A	CDRH/ OMO/ DWM	Robert M. Califf, M.D., MACC Commissioner of Food and Drugs