SMG 1410.603

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Radiation Control

Testing Programs and Methods of Certification and Identification for Electronic Products

Effective Date: 30 May 2025

1. Authority Delegated and To Whom Delegated.

A. The officials listed below, for medical devices assigned to their respective organizations, are authorized to review and evaluate industry testing programs under Section 534(g) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360kk(g)), and to disapprove testing programs upon which certification is based under Section 534(h) of the Act (21 U.S.C. 360kk(h)):

(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 and Deputy Directors.

(3) CDRH/OPEQ/Clinical and Scientific Policy Staff (CSPS) Chief Medical and Science Officer.

(4) CDRH/OPEQ/Compliance and Quality Staff (CQS) Associate Director for Compliance and Quality.

(5) CDRH/OPEQ/Regulation, Policy, and Guidance Staff (RPGS) Deputy Director for Regulatory Policy.

(6) CDRH/OPEQ/Office of Health Technology VIII (OHT VIII) Director, Deputy Directors, Associate Directors, and Chief Medical Officers.

2. Redelegation.

These officials may not further redelegate this authority.

3. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 30 May 2025.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	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	05/30/2025	N/A	CDRH	Martin A. Makary, M.D., M.P.H. Commissioner of Food and Drugs