

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Radiation Control

Exemption of Electronic Products from Performance Standards and Prohibited Acts

Effective Date: 2 June 2025

1. Authority Delegated and To Whom Delegated.

A. The officials listed below, for medical devices assigned to their respective organizations, are authorized to exempt from performance standards any electronic product intended for use by departments or agencies of the United States under section 534(a)(5) of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. 360kk(a)(5)) and to exempt an electronic product or class of products from all or part of the provisions of section 538(a) of the Act (21 U.S.C. 360oo(a)) under section 538(b) of the Act (21 U.S.C. 360oo(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 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, Chief Medical Officers, and Division Directors.

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 2 June 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	06/02/2025	N/A	CDRH/ OP	Martin A. Makary., M.D., M.P.H. Commissioner of Food and Drugs