

SMG 1410.601

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Radiation Control

Variances from Performance Standards for Electronic Products

Effective Date: 12 January 2023

1. Authority Delegated and To Whom Delegated.

A. The officials listed below, for medical devices and electronic products assigned to their respective organizations, are authorized to grant, deny, and withdraw variances under 21 CFR 1010.4, and issue notices of availability of any approved variance, or any amendment or extension thereof, from the provisions of performance standards for electronic products established in 21 CFR 1000:

- (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, Division Directors, and Assistant 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 12 January 2023.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	03/22/2005	N/A	OA/ OM/ OMP	Lester M. Crawford, D.V.M., Ph.D. Acting Commissioner of Food and Drugs
Revision	01/05/2010	N/A	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