

**SMG 1410.601**

**FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY**

**REGULATORY - RADIATION CONTROL**

**VARIANCES FROM PERFORMANCE STANDARDS  
FOR ELECTRONIC PRODUCTS**

Effective Date: July 05, 2013

**1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.**

The following officials are authorized to grant, deny and withdraw variances 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 Title 21, Code of Federal Regulations, Part 1000, subchapter J:

- A. Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), Office of Medical Products and Tobacco (OMPT).
- B. Director and Deputy Directors, Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH, OMPT.
- C. Director, Division of Radiological Health, OIR, CDRH, OMPT.

**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 July 5, 2013.

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
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