

SMG 1410.602

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - RADIATION CONTROL

**EXEMPTION OF ELECTRONIC PRODUCTS FROM PERFORMANCE STANDARDS
AND PROHIBITED ACTS**

Effective Date: July 05, 2013

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

The following officials 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)):

- 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.

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.

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