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: July 05, 2013

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

The following officials 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)), to disapprove testing programs upon which certification is based under Section 534(h) of the Act (21 U.S.C. 360kk(h)):

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