

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

Medical Device Reporting Procedures

Effective Date: 23 May 2024

1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized under 21 CFR section 803.15 to request the submission of additional information:

- (1) Center for Devices and Radiological Health (CDRH) Director and Deputy Directors.
- (2) CDRH/Office of Product Evaluation and Quality (OPEQ) Director and Deputy Directors.
- (3) CDRH/OPEQ/CSPS Chief Medical and Science Officer.
- (4) CDRH/OPEQ/RPGS Deputy Director for Regulatory Policy
- (5) CDRH/OPEQ/Office of Clinical Evidence and Analysis (OCEA) Director, Deputy Directors, Associate Directors, and Chief Medical Officer.
- (6) CDRH/OPEQ/OCEA/Division of Clinical Evidence and Analysis 1 (DCEA1) Director and Deputy Directors.
- (7) CDRH/OPEQ/Office of Health Technology I (OHT I) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (8) CDRH/OPEQ/Office of Health Technology II (OHT II) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (9) CDRH/OPEQ/Office of Health Technology II1 (OHT III) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (10) CDRH/OPEQ/Office of Health Technology IV (OHT IV) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (11) CDRH/OPEQ/Office of Health Technology V (OHT V) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (12) CDRH/OPEQ/Office of Health Technology VI (OHT VI) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.

- (13) CDRH/OPEQ/Office of Health Technology VII (OHT VII) Director, Deputy Directors, Associate Director for Strategic Initiatives, Chief Medical Officers, Division Directors, Deputy Division Directors, Associate Division Directors, and Assistant Division Directors.
- (14) CDRH/OPEQ/Office of Health Technology VIII (OHT VIII) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (15) CDRH/OPEQ/Office of Regulatory Programs (ORP) Director, Deputy Directors, and Chief Medical Officer.
- (16) CDRH/OPEQ/ORP/Division of Regulatory Programs 3 (DRP3) Director, Deputy Director, and Assistant Division Directors.

B. The officials listed below are authorized under 21 CFR section 803.19 to grant or revoke exemptions from, variances to, or alternatives to reporting requirements:

- (1) CDRH Director, Deputy Center Director for Policy, and Deputy Center Director for Science.
- (2) CDRH/OPEQ Director and Deputy Directors.
- (3) CDRH/OPEQ/CSPS Chief Medical and Science Officer.
- (4) CDRH/OPEQ/RPGS Deputy Director for Regulatory Policy.
- (5) CDRH/OPEQ/OCEA Director, Deputy Directors, Associate Directors, and Chief Medical Officer.
- (6) CDRH/OPEQ/OCEA/DCEA1 Director and Deputy Directors.
- (7) CDRH/OPEQ/OHT I Director, Deputy Directors, Associate Director, Chief Medical Officer, and Division Directors.
- (8) CDRH/OPEQ/OHT II Director, Deputy Directors, Associate Director, Chief Medical Officer, and Division Directors.
- (9) CDRH/OPEQ/OHT III Director, Deputy Directors, Associate Director, Chief Medical Officer, and Division Directors.
- (10) CDRH/OPEQ/OHT IV Director, Deputy Directors, Associate Director, Chief Medical Officer, and Division Directors.
- (11) CDRH/OPEQ/OHT V Director, Deputy Directors, Associate Director, Chief Medical Officer, and Division Directors.
- (12) CDRH/OPEQ/OHT VI Director, Deputy Directors, Associate Director, Chief Medical Officer, and Division Directors.
- (13) CDRH/OPEQ/OHT VII Director, Deputy Directors, Associate Director for Strategic Initiatives, Chief Medical Officers, Division Directors, Deputy Division Directors, and Associate Division Directors.
- (14) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Director, Chief Medical Officer, and Division Directors.

- (15) CDRH/OPEQ/ORP Director, Deputy Directors, and Chief Medical Officer.
- (16) CDRH/OPEQ/ORP/DRP3 Director and Deputy Director.

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 23 May 2024.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/23/2009	N/A	OC/ OA/ OM/OMP	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	03/22/2012	N/A	OMPT/ CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	11/22/2013	N/A	OMPT/ CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	11/13/2018	N/A	OMPT/ CDRH/ OMO/ DEMO	Scott Gottlieb, M.D. Commissioner of Food and Drugs
Revision	05/23/2024	N/A	CDRH/ OM/ DWM	Robert M. Califf, M.D., MACC Commissioner of Food and Drugs