

SMG 1410.22

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

REGULATORY – GENERAL REDELEGATIONS OF AUTHORITY

**EMERGENCY FUNCTIONS AND DELEGATIONS FOR INCIDENT
MANAGEMENT TEAMS**

Effective Date: May 12, 2017

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

- A. Each District Director (DD), Office of Regulatory Affairs (ORA), Office of Global Regulatory Operations and Policy (OGROP) is delegated the following:
- 1) During any period when normal channels of direction are disrupted between the Food and Drug Administration (FDA) Headquarters and a field office to:
 - a. Fully represent FDA within their jurisdiction in accordance with the Department of Health and Human Services (HHS) regional emergency plans.
 - b. Exercise the authority of the Commissioner of Food and Drugs for supervision of, and direction to all, FDA activities and use of resources within their jurisdiction for continuity and for Federal Emergency Health Service operations.
 - 2) Provide Emergency Plans for the delegation of FDA district authorities to heads of field activities when such activities are cut off from National Headquarters.
- B. Each District Director, Program Director, or Program Division Director during a time that FDA has established an Incident Management Team in response to an incident, emergency, or event,¹ is authorized to act as the

¹ Under this Delegation of Authority (DoA), the term “incident” is as defined in the FDA Emergency Operations Plan (EOP) as “An occurrence, natural or manmade, that requires a response to protect life or property. Incidents can, for example, include major disasters, emergencies, terrorist attacks, terrorist threats, civil unrest, wild land and urban fires, floods, HazMat spills, nuclear accidents, aircraft accidents, earthquakes, hurricanes, tornadoes, tropical storms, tsunamis, war-related disasters, public health and medical emergencies, and other occurrences requiring an emergency response.”

Incident Commander under the National Incident Management System and Incident Command System within their jurisdiction. This delegation includes the authority to direct field activities of FDA personnel assigned to incidents, emergencies, or events. These authorities may be redelegated.

- C. For large scale incidents, such as National Special Security Events and natural or man-made disasters, impacting multiple districts, the following officials are delegated the authority to act as the Incident Commander under the National Incident Management System and Incident Command System and to direct field activities of FDA personnel:
- 1) Assistant Commissioner for Human and Animal Food Operations (ACHAFO), ORA, OGROP.
 - 2) Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO), ORA, OGROP

The ACHAFO and ACMPTO may redelegate this authority.

2. REDELEGATION.

- A. These officials may not further redelegate these authorities except as provided in Sections 1.B. and 1.C.
- B. The authorities in Sections 1.B and 1.C. may be redelegated as follows:
- 1) In writing, using the Memorandum for Redefinition Authority for Emergency/Incident/Event Management in the FDA Incident Management Handbook.
 - 2) A copy of any redelegation of this authority must be provided to the Associate Commissioner for Regulatory Affairs, the Office of Crisis Management, and FDA's Principle Delegation Officer.
 - 3) The authority may only be redelegated to FDA employees. Within a Unified Command scenario, in which there are multiple Incident Commanders from multiple agencies, Program Directors, District

Under this DoA, the term "emergency" is as defined in the EOP as "Any incident, whether natural or manmade, that requires responsive action to protect life or property. Under the Stafford Act, an emergency means any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States.

Under this DoA, the term "event" is as defined in the FDA Incident Management Handbook as "A planned, nonemergency activity (e.g., sporting event, concert, parade)."

Directors, Program Division Directors may redelegate authority solely to their own Incident Commander (i.e., not to the Unified Command as a group).

- 4) All redelegations to the Incident Commander must be consistent with FDA statutory and regulatory authority and applicable procedures.
- 5) The personnel to whom authority is redelegated must have the requisite knowledge, skills and abilities pertaining to the legal, regulatory, policy and performance requirements regarding the National Incident Management System and the Incident Command System.

3. EFFECTIVE DATE.

The delegations become effective upon date of signature.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on May 12, 2017.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	04/04/2011	N/a	ORA/ORM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	05/12/2017	N/a	OGROP/ORA/OM	Scott Gottlieb, M.D., Commissioner of Food and Drugs

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