
POLICY AND PROCEDURES

Office of the Center Director

Continuity of Operations Program (COOP) for CDER

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PURPOSE

The purpose of this MAPP is to ensure compliance with Presidential, FEMA and Federal directives, describe CDER’s Continuity of Operations Program (COOP) including the responsibilities of COOP Members, and the procedures to be followed to ensure the Center is compliant with governing laws, regulations and policies. COOP enables CDER to continue essential functions during a wide range of emergencies. Specific program elements are in individual Super Office COOP plans, posted on the CDER COOP Intranet site.

BACKGROUND

Presidential Decision Directive 67 requires all Federal agencies to develop Continuity of Operations Plans for operations. The subsequent Federal Emergency Management Agency (FEMA) Federal Preparedness Circular 65 and Federal Continuity Directive 1 and 2 detail the mandatory requirements for Federal COOP Plans.

POLICY

CDER’s mission-essential functions shall continue effectively and without interruptions because of CDER’s implemented, maintained and viable Continuity of Operations Program (COOP).

RESPONSIBILITIES**The Center Director:**

- Supports the CDER COOP Program and ensures the program is implemented across CDER.
- Approves lines of succession and delegations of authorities to be included in the CDER Senior Leadership COOP plan.
- Ensures CDER Offices and employees are aware of responsibilities and procedures to be followed during COOP events.

CTECS Director:

- Oversees the CDER COOP program which includes training, testing and exercises, with the partnership of CDER COOP Coordinator.
- Supervises the CDER COOP Coordinator.
- Receives communications from the CDER Center Director regarding activation of COOP plan, in response to an event.
- Advises CDER leadership of significant issues related to the COOP Program.
- Ensures appropriate notification procedures are followed.
- Reviews and clears the annual CDER COOP plan.

CDER COOP Coordinator:

- Coordinates all aspects of CDER's COOP Program with the Agency and other Federal government stakeholders.
- Works with Office Directors and Office COOP Coordinators to develop, maintain and revise the Office COOP Plans.
- Ensures each Office COOP Plan is current, and Agency requirements are met.
- Provides guidance and annual training to all Office COOP Coordinators.
- Initiates quarterly notifications to ensure COOP Coordinators have accurate contact information and practice COOP exercises.
- Maintains an inventory of equipment to be deployed during COOP events. Ensures equipment is operational and located in the appropriate COOP relocation sites.
- Maintains an inventory of emergency relocation sites in FDA buildings.
- Provides activity reports to the CTECS Director, and to the FDA Office of Operations annually, and upon request.
- Posts updated Office COOP plans to CDER's intranet (Inside.FDA).
- Continually improves and enhances the CDER COOP program.
- Ensures SOP for CDER COOP Coordinators is current and posted on the CDER COOP page of Inside.FDA.
- Ensures the COOP page on Inside.FDA is current and accurate.
- Ensures the COOP training applications are current and operational.

CDER Office Directors:

- Designate primary and alternate Office COOP Coordinator and Office COOP Emergency Relocation Group (CERG) members.
- Identify leadership succession, and delegations of authority, to be employed during a COOP emergency.
- Determine organization's essential functions to continue during a COOP emergency.
- Work with the Office COOP Coordinator to maintain or revise the Office COOP Plan annually.
- Sign the most updated version of the Office COOP Plan, prior to posting.
- Participate in COOP training, testing and exercises.
- Ensure all Office staff participate in COOP training, testing, and exercises, if appropriate.
- Communicate updates to Office staff, in the event of a COOP emergency.

Office COOP Coordinators:

- Conduct annual reviews of the Office COOP plan, to ensure the plan is current.
- Activate the Office COOP plan during COOP exercises and events, at the direction of the CDER Office Director.
- Coordinate relocation of CERG members.
- Participate in training provided by the CDER COOP Coordinator.
- Demonstrate familiarity with the current Emergency Notification System (ENS).
- Demonstrate familiarity with the contents of the SOP for COOP Coordinators, and the CDER COOP page posted on inside.FDA.
- Communicate office staff changes to the CDER COOP Coordinator, to ensure the ENS database is current.
- Provide guidance and training to CERG members on ENS use, and the importance of accurate contact information.
- Ensure home use COOP laptops are logged onto the network, monthly.
- Conduct all required quarterly notification activities and annual exercises.

Office COOP Emergency Relocation Group (CERG) Member:

- Is familiar with the Office COOP Plan, the Office COOP Coordinator, and the other Office CERG members.
- Participates in quarterly COOP notifications and annual relocation exercises.
- Is prepared to be fully functional and capable of performing essential functions while working from home or from an alternate relocation site, during an exercise or actual emergency event, for a minimum of 30 days.
- Ensures their personal contact information is entered in the ENS, and available to the Office COOP Coordinator.
- Participates in training provided by CDER COOP Coordinator.
- In the event of a building evacuation during duty hours, is aware of the assembly location.

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- Knows the locations of the CDER Emergency Relocation Sites (ERS) and how to get to them both from the workplace and from their personal residence.
 - Ensures staff contact information, equipment, and databases are current and accurate.
 - Identifies and prepares vital records for use during COOP activation.
 - Maintains telework-ready status, at all times.

CDER Staff:

- Receives COOP Communication from the Office Director.
- Participates in COOP training, testing, and exercises, as appropriate.
- Shares contact information with management.

PROCEDURES

1. Using the most recent CDER COOP Plan template, Office Director and Office COOP Coordinator develop a plan for their Office to include:
 - Identifying essential personnel who must be available during emergencies.
 - Identifying essential functions.
 - Designating orders of succession and delegations of authority.
 - Identifying continuity facilities or work from home locations and providing instructions for CERG personnel.
 - Identifying Emergency Notification System (ENS) procedures.
 - Adhering to Tests, Training, and Exercises (TT&E) requirements.
 - Describing devolution of control and direction.
2. Office COOP Coordinator works with CDER COOP Coordinator to:
 - Finalize and implement the office plan.
 - Update the office plan annually, or as needed.
 - Understand the automated ENS. Ensures the personnel contact information database is current.
 - Provide training to Office CERG members.
 - Coordinate with the CDER Office Director to conduct quarterly call-down and annual relocation exercises for the CDER Office.
 - Prepare and submit quarterly reports of notification exercises to the FDA Office of Operations.
 - Submit the annual review of COOP plans to the FDA Office of Operations.
 - Stay current on COOP issues and participate in all required meetings and trainings.

REFERENCES

1. US Department of Homeland Security, FEMA, 2017, Federal Continuity Directive 1 and 2.
 2. FEMA, 2004, Federal Preparedness Circular (FPC) 65, Federal Executive Branch Continuity of Operations (COOP).
 3. Homeland Security Presidential Directive 7, 2003. Critical Infrastructure Identification, Prioritization, and Protection.
 4. Presidential Decision Directive 67, 1998, Enduring Constitutional Government and Continuity of Government Operations.
 5. SOP for CDER COOP Coordinators, 2/2020, posted on Inside.FDA.
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DEFINITIONS

COOP Event: a condition which requires the relocation of CDER personnel from their normal work location to an emergency relocation site (ERS); specifically, employees would work from home or from a location identified. There are four levels of disasters that may disrupt normal business activities:

- Level 1: Washington, D.C. Metropolitan Area affected.
- Level 2: The White Oak Campus and surrounding area affected.
- Level 3: A CDER White Oak building or an off-campus building is closed or affected.
- Level 4: Part of a White Oak building or other occupied space housing is affected.

CDER Emergency Relocation Sites: An FDA facility or other designated facility to which the CERG moves to continue FDA Essential Functions in the event the organization's building(s), or other occupied space is threatened or incapacitated.

Office COOP Plan: Drafted within the FDA's template by each Office Director and Office COOP coordinator, this document provides lines of succession and delegations of authority to be employed in the event of a COOP event. Each of CDER's Office Directors revisits the plan annually, or more frequently, if required.

CDER Senior Leadership COOP Plan: The formal documentation of the lines of succession and delegations of authorities to be engaged by CDER's Senior Leadership in a COOP event. This plan is updated annually, or as necessary.

Emergency Notification System (ENS): The method of facilitating the one-way dissemination or broadcast of messages to one or many groups of people, alerting them to

a pending or existing emergency. An automated system contacts designated personnel simultaneously via text, email, office and cell phones.

CERG (COOP Emergency Relocation Group) members: Staff assigned responsibility to continue essential functions from an alternate site in the event that their primary operating facilities are threatened or have been incapacitated by an incident.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
07/08/15	Initial	N/A
07/12/21	1	Clarified language, updated web addresses and technology systems. Edits to the Responsibilities section.

ATTACHMENT 1: CDER Senior Leadership Team

Director, Office of the Center Director (OCD)
Director, Counter-Terrorism and Emergency Coordination Staff (CTECS)
Director, Office of Communications (OCOMM)
Director, Office of Compliance (OC)
Director, Office of Executive Programs (OEP)
Director, Office of Generic Drugs (OGD)
Director, Office of Management (OM)
Director, Office of Medical Policy (OMP)
Director, Office of New Drugs (OND)
Director, Office of Pharmaceutical Quality (OPQ)
Director, Office of Regulatory Policy (ORP)
Director, Office of Strategic Programs (OSP)
Director, Office of Surveillance and Epidemiology (OSE)
Director, Office of Translational Sciences (OTS)