

POLICY

OFFICE OF MANAGEMENT

Developing, Issuing, and Maintaining Standard Operating Procedures for CDER

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PURPOSE

This Manual of Policies and Procedures (MAPP) specifies the factors to consider when determining whether to develop a MAPP or a standard operating procedure (SOP) to delineate CDER policies and procedures. The MAPP also addresses requirement for maintaining access to, and currency of, SOPs.

BACKGROUND

A CDER MAPP is the official repository for CDER directives (internal policies and procedures) and meets all Office of Management and Budget (OMB) and National Archives and Records Administration (NARA) requirements for developing and archiving directives. However, many CDER offices have chosen to compile SOPs either as stand-alone documents or as supplements to their MAPPs. SOPs have greater flexibility in format, structure, content, and clearance requirements. CDER does not generally make SOPs available to the public, although they may be releasable under the Freedom of Information Act (FOIA), unless they contain content that is FOIA-exempt (see Attachment), which would be redacted before release.

Existing legal and transparency considerations require that CDER offices carefully consider what content should be published as MAPPs. Offices may then consider what other matters may be incorporated into the office’s internal documents (SOPs). Guidelines are provided to help offices assess the suitability of utilizing these alternative forms of

documentation based on several considerations.

SOPs may be appropriate if one or more of the following criteria apply:

- The content is specifically exempt from disclosure under FOIA. (Contact CDER Office of Regulatory Policy/Division of Information Disclosure Policy for information on identifying FOIA-Exempt content.)
 - The content involves only internal information of a relatively routine nature, and not of obvious interest to the public.
 - The content includes only internal office procedures that may require frequent updates as new systems or new technologies are created and adapted.
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POLICY

- MAPP 4000.1 *Developing and Issuing MAPPs for CDER* establishes a system for issuing directives within CDER for the purpose of documenting and dissemination CDER policies and procedures, using the format described in the official MAPP templates.
- **MAPPs are:**
 - High level documents that define office or center policy, mission, and goals.
 - Formal statements about CDER's operating principles that are established by statute, regulations, or other controlling authority.
 - Descriptions of official steps necessary to implement CDER or office policy.
 - Often coordinated between or among multiple offices or multiple centers because of shared work or interests.
 - Of interest to the general public and available to the general public, to ensure transparency.
 - Compliant with section 508 of the Rehabilitation Act of 1973.
 - In rare instances, temporary and not published on the FDA Internet website (interim MAPPs or internal MAPPs) when it is important to provide MAPP-level guidance to staff before the MAPP is ready for publication on the FDA Internet website.

- Alternate documentation of procedures, including SOPs or the equivalent, is allowable within the scope of this MAPP.

- **SOPs are:**
 - Formatted according to the preference of the originating office and distinguishable from MAPPs to reduce inadvertent public disclosure.
 - Designed to include, at a minimum, responsibilities of parties to the SOP, and dates of issuance, revision, and cancellation. SOPs may also contain reference material and definitions.
 - Detailed documentation including, for example, descriptions of the minutia of processing documents, running reports, organizing meetings, populating databases, or sending and receiving communications.
 - Initiated, cleared, managed, and archived by the issuing office.
 - Specific to the internal functioning of a single office.
 - Consistent with MAPPs and Staff Manual Guide (SMG) documentation on the same subject matter.
 - Ideally, evaluated for continued relevance and accuracy every 3 years after clearance.
 - Maintained in a repository of the office's choice that is readily accessible to office staff.
 - Provided to staff, with appropriate training on the system of SOPs at New Employee Orientation and on individual SOPs, as needed, thereafter.
 - Compliant with section 508 of the Rehabilitation Act of 1973.
 - Not known to be of interest to the general public.
 - Not necessarily privileged information. May be available to the public, by request, unless FOIA-Exempt (see Attachment).

RESPONSIBILITIES

Super Office or Office Director (or designee(s))

- Understands the differences between MAPPs and SOPs and their appropriate use.

- Ensures the office has a system for considering the need for new or revised SOPs.
 - Ensures all SOPs originating in the office meet the requirements listed in the Policy section of this MAPP.
 - Ensures office staff members can locate and follow the office’s SOPs that impact their work.
 - Ensures employees follow their office records management plans that align with NARA records management requirements.
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REFERENCES

1. FDA, 2021, Center for Drug Evaluation and Research, MAPP 4000.1 Rev. 6: Developing and Issuing MAPPs for CDER.
 2. OMB, 2004. Circular A-123, Revised, Management’s Responsibility for Internal Control.
 3. Freedom of Information Act, Revised, 2000.
 4. Plain Writing Act of 2010.
 5. Rehabilitation Act of 1973 (29 U.S.C. § 794d), Sec. 508
 6. FDA, 2019, Center for Drug Evaluation and Research, MAPP 7610.1 CDER Records Management
 7. Staff Manual Guides
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DEFINITIONS

Manual of Policies and Procedures (MAPP) – A compilation of policies and procedures in CDER, designed to guide staff in the conduct of its work. Each numbered entry is commonly referred to as a “MAPP.” CDER's MAPPs are federal directives and documentation of internal policies and procedures. Such directives are required by law and are published on the FDA Internet website. MAPPs are maintained by the CDER Office of Management, Immediate Office.

Standard Operating Procedure (SOP) – A policy or procedure that generally applies to the internal functioning of a single office and refers to subject matter that is presumably of negligible interest to the public. SOPs often include information that changes frequently. SOPs are cleared at the office or division level. An example is a description of an office’s process for answering mail. SOPs are published internally on SharePoint sites, but they may be available to the public by request (unless exempt under the FOIA, see Attachment 1). SOPs are initiated, cleared, maintained, and archived by the issuing office.

Staff Manual Guides (SMG) - Directives developed and maintained at the FDA level. The SMGs are located on the FDA Internet website or FDA Intranet InsideFDA. SMGs are maintained by the FDA Office of Human Resources.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.
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CHANGE CONTROL TABLE

| Effective Date | Revision Number | Revisions |
|----------------|-----------------|--|
| 1/12/15 | N/A | Initial |
| 2/1/2023 | 1 | Format update and include records management |
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ATTACHMENT: Documents that include non-public information (FOIA-Exempt):

- Cannot be published on the FDA Internet website or otherwise publicly disclosed without redaction of exempt information.

- Contain non-public information that includes the following, for example:
 - Trade secret or confidential commercial information
 - Personal privacy information
 - Classified information
 - Any information that could reasonably be expected to endanger the life or physical safety of an individual

Contact CDER Office of Regulatory Policy, Division of Information Disclosure Policy if you have questions on whether specific content included in a document is exempt from public disclosure under FOIA.