
OFFICE OF REGULATORY POLICY

Editing Procedures

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PURPOSE

This MAPP describes the procedures in the Office of Regulatory Policy (ORP) for moving documents through the editing process.

BACKGROUND

A variety of documents are developed and edited in ORP. Examples include rules, guidances (including ICH guidances), notices (including notices of availability, meeting notices, part 15 hearing notices, withdrawal notices), MAPPs, user fee letters, citizen petition responses, and other miscellaneous documents. The procedures described in this MAPP explain how documents can be submitted to the editors for review. The procedures also clarify the editing process for all involved.

POLICY

- An ORP editor must review all documents developed in ORP before they are submitted for clearance.
- An ORP editor must review any documents that have changed substantially since their most recent editorial review before they can be submitted for clearance.
- An ORP editor must review any documents that have not been edited in the last 6 months before they can be submitted for clearance.
- Generally, documents will be edited on a first-come-first-served basis. With the approval of an ORP division or office director, documents can receive a high-priority edit. Document length will be taken into consideration when prioritizing documents for edit.
- An editor who removes a document from the editing box should try to complete the edit within 10 working days.

- Documents must be assigned a COMIS number (and an FRDTS number if needed) and be tracked as they move through the editing process.
 - Unless there is a reason to do otherwise, editors who perform a first review of a document should perform all subsequent reviews.
 - It will be ORP's goal to return guidance documents submitted for editing to the author, or document lead, within 30 days of receipt in ORP. Our goal for MAPPS will be to return them to the author, or lead, within 10 working days of receipt in ORP.
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RESPONSIBILITIES

When documents are ready for editing, **ORP Staff** have the following responsibilities:

- Make sure a document has been logged into the COMIS system and has COMIS and FRDTS numbers if needed (guidances are processed on the j:\!guidance directory according to their COMIS numbers).
- Complete the green editing request form (Attachment) and make a copy. Attach the copy of the form to the document and place the document in the editing box.
- Include all backup documents so the editor doesn't have to ask for it later.
- Place the original (green) copy of the request form in the editing log — most recent entry on top.
- If a document needs a high-priority review, give the document to an office or division director for referral to an editor as high priority.

The ORP Office Director and Division Directors have the following responsibilities:

- Give high-priority documents to an editor and provide the necessary due date.
- Monitor the editing box on a regular basis to ensure that high-priority documents have not been put there in error.
- Monitor editor workload.
- Function as the contact person for ORP staff or editors with regard to concerns about any documents undergoing editorial review.

Editors have the following responsibilities:

- Take documents from the editing box in chronological order based on the editing log book unless given a high-priority document by a division or office director. Keep an eye out for short documents that won't take much time.
- Fill in the requested information on the green editing request form in the editing log each time a document is removed from the box for editing or returned to the author, or lead, after editing.
- Edit all documents consistent with the CDER Style Guide.
- Try to return documents taken from the editing box to the author, or document lead, within 10 working days.

- If documents come to an editor through a source other than the editing box (e.g., from a division or office director), fill out a green editing request form, make a copy, attach the copy to the document, and place the original in the editing log.
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EFFECTIVE DATE

This MAPP is effective upon date of publication.

EDITING REQUEST FORM

Originator: _____

Document Title/Type: _____

Number of Pages: _____

COMIS/FRDTS #s: _____ / _____

Date Submitted: _____

Date Requested: _____

Comments: _____

Editor/1st Review
Pickup Date: _____

Return Date: _____

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Editor/2nd Review
Pickup Date: _____

Return Date: _____

*

Editor/3rd Review
Pickup Date: _____

Return Date: _____

Comments
