

Review of Quality Management Documents related to Inspection and Compliance Processes

The quality management documents to be routed in this fashion include:

1. Standard Operating Policy/Procedures (SOP) – These designate a policy or procedure developed and must include a document review form (**QMFRM0001**, *Document Review Form – Individual Review*).
2. Work instructions (WI) – These provide the details of how a process is done and who does the process. Work instructions DO NOT define or alter the CVB Quality Management System (QMS) policies or procedures or alter any Federal Regulations.
3. Forms (FRM) – These capture information/data. The majority of forms for Inspection and Compliance (IC) are review worksheets for incoming submissions, summary sheets, and inspection notes.
4. Templates (TEM) – These are letters or reports that provide uniform communication.

Any IC employee may develop a SOP, WI, FRM, or TEM.

SOPs must have an IC Section Leader review and concurrence.

WIs, FRMs, and TEMs should be reviewed by IC management to ensure they do not alter current program policy.

IC uses the Mail Log to track the initiation and review of quality management documents prior to the actual submission to the Quality Management Section for final processing.

This process should be used for new and revised quality management documents.

MAIL LOG

1. Create Mail Item

Establishment = NA

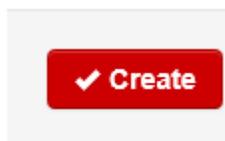
Date Submitted = date mail log is created

Submission Type = Internal Projects - IC

Submission Subtype = QM Document

Brief Description = List the type of document (SOP, WI, FRM, TEM) – New or Revised – If it has a number, include this, and finally the title of the document.

Click on



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2. Create Attachment

Upload quality management document using Browse – only one document per mail log. If several documents should move together for review, the individual mail logs should be functionally linked.

Type = Internally Routed

No comments required.

Click on



3. If Comments are needed from others in the Program – Not Required

Initiate Child Workflow

Program Input

Add Routing Comment

Click on



Personnel can make comments and attach their revised document under Create Attachment, as noted in Section 2.

4. Section Leader Review

After input from colleagues has been gathered (if requested) and a final draft has been written, the Mail Log item is moved forward for Section Leader Review (IC).

The Section Leader will review the process and provide comments. They may give final approval to move the document to Quality Management for processing, or they may require changes to the document. The Mail Log is either given final approval by clicking on “OK” or requests revisions by clicking on “Cancel.”

5. Final Process

Once Section Leader approval has been given, the author moves the Mail Log to Finalization (IC) and chooses Linda Snavely. She then receives the document in her queue for final formatting and processing.

REMEMBER to include in comments what Chapter and Section of the IC Quality Manual the quality management document should reside.