

Standard Operating Procedure

Title: Quality Documentation - Control, Tracking and Distribution

Authorised Copy	A printed hardcopy photocopied version of the Master Document, which is authorised by a signed, dated and stamped in red.
Uncontrolled copy	Any document, which is printed from the electronic copy or photocopied version without having red stamp on it. Each quality document has a footer statement of "This is not an approved copy unless stamped red"
Hardcopy Only Documents	Documents that are not maintained electronically. Documents are generally of externally derived origin but are being incorporated into Site's Quality System.
Satellite file Location	A set of relevant hardcopy documents remotely located to ensure ready access to the documents by all employees. These locations have designated numbers that are included in the Database record for each document.
TPM Dispatch Records	Third Party Manufacturing Dispatch Records.
GMP	Good Manufacturing Practice.

Related Documents

Form-395	SOP Ready for Signing
Form-410	Document Location in Satellite File
Form-455	Incident or Investigation Report Form
Form-460	Registrar of contracts
Form-495	Form Ready for Signing
Form-505	Document Creation or Cancel Request
Form-530	Reading Compliance Form
TEM-080	Internal Audit Report Template
TEM-085	Training Report Template
TEM-090	Form, VD Template
TEM-095	SOP Template
TEM-100	Quality Assurance Agreement Template
TEM-110	In-House Manual Template
TEM-120	Vendor Audit Report Template
QMS-005	How to Write Standard Operating Procedure
QMS-015	Quality Documentation Management and Change Control.
QMS-030	Preparation, Maintenance and Change Control of Master Documents
QMS-020	Documentation Rule for GMP Documents
QMS-110	Management and Control of Contract Work
QMS-080	Audits
MAN-030	Production Logbook.

EHS Statement

This SOP covers documentation systems only – there is no EHS impact.

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- Next version number (remains 0 if new document, or next number for existing documents)
 - Check the title is exactly the same as in the document
 - Applicable names and dates
 - Issue date
 - Review date
 - Document status - "Current"
 - Cross Reference to other type documents recorded in "Document Cross Reference" table in the document.
 - Any other comments or change in location.
 - The required distribution to the satellite file locations.
- 4.2.3. Generate "Reading Compliance" forms (**Form-530**) from the Documentation Database by running the "Reading Compliance" reports in the Quality Documentation Reports section of the Documentation Database.
- "Reading Compliance" forms will be printed for each satellite file nominated in the Distribution section of the database record. A copy will also be printed for attachment to the Master File document.

4.3. Issuing hardcopy

- 4.3.1. Print a copy of the document on the appropriate paper type for each Satellite Document file. Count the "Reading Compliance" forms to determine the number of copies required.
- Note:** In general, Quality Documentation is printed on white paper with a Red "Authorised Copy" stamp, sign and date.
- 4.3.2. Write the relevant Satellite Document File number on the reading compliance form and attach the corresponding "Reading Compliance" form to the back.
- 4.3.3. The Authorised Copy should be printed without Revision History.
- 4.3.4. File the signed Master document in the appropriate Master file. Make sure this copy also has a "Reading Compliance" form attached.
- 4.3.5. Send the SOPs to the Satellite File Administrators.
- 4.3.6. Retain and file the "Reading Compliance" and then destroy the superseded hardcopy Master. Use secure shredding.
- Note:** The returned "Reading Compliance" forms are filed according to SOP **QMS-010**. (They are regarded as training records).
- 4.3.7. Generate and distribute a new index to the affected Satellite Document Files.

4.4. Return of Superseded Copies of Documents

The File Administrators will return all superseded copies of documents, which have been updated.

- 4.4.1. Mark off the return of the superseded copies on the appropriate printout of the Document Database record filed in the "Superseded SOPs Returned" file. VDs are marked off on return of superseded copy. No "Reading Compliance" is applied to VDs.
- 4.4.2. Retain and file the "Reading Compliance" and then destroy the superseded hardcopy. Use secure shredding.
- 4.4.3. Destroy the printout of the Document Database record when all copies of the superseded documents have been retrieved and destroyed.

5. Cancellation of Documents

Form-505 must be completed and signed before a document may be cancelled. Follow SOP **QMS-010** to cancel a document.

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10. Appendix 2 - Required Data for Document Initiation in Database Record

10.1. SOP, Form, Policy, Position Papers, Packaging Specifications, Standards, GMP agreements (as per section 8.1)

Document Title
Document Type (See SOP A.4.1 for Prefix ID)
Document Owner
Distribution
Cross References
Location

10.2. Training Session Plan

Document Title
Document Type
Document Owner
Distribution
Skills Level
Cross references
Location

10.3. Operational / Maintenance Manuals

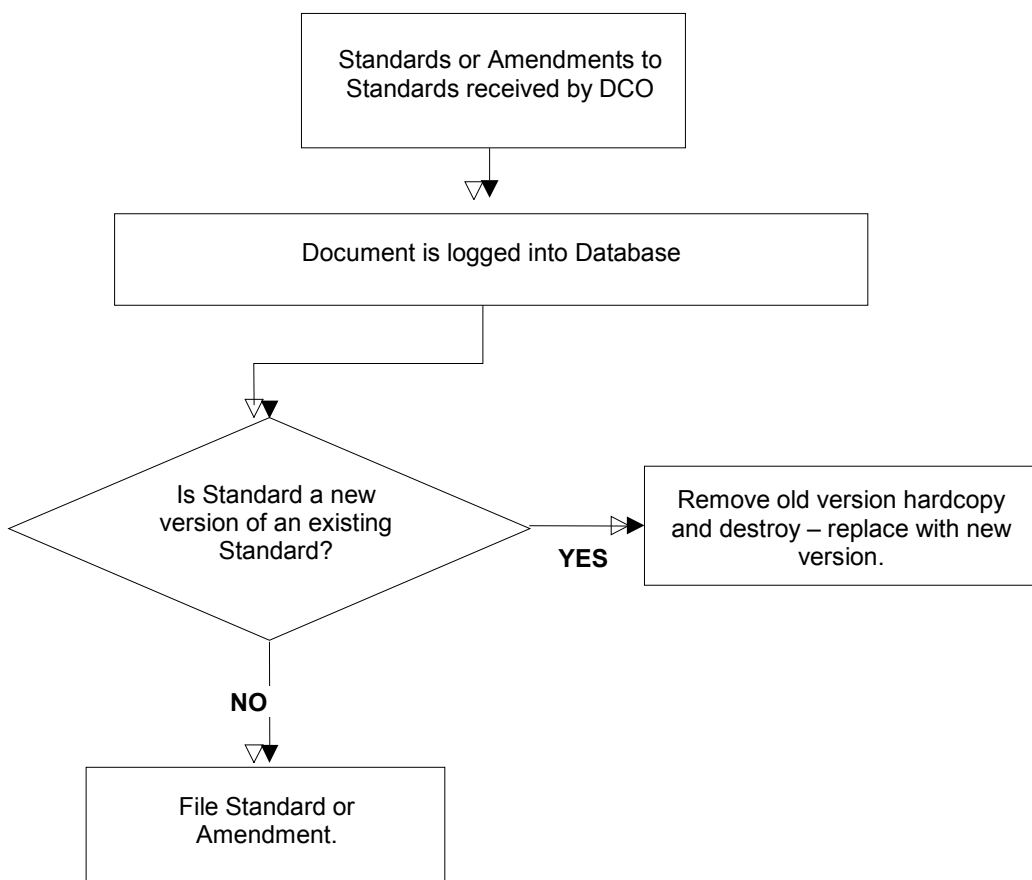
See Flowchart below - Document Initiation Procedure for:
Operations & Maintenance Manuals (MO), Procedural Manuals (PR) & Project Files (PF).

Template
Document Title
Document Type
Owner
Distribution
Site
Service
Person who will conduct Verification
Person who will conduct Confirmation
Contractor
Contractor Project Number (if applicable)

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11. Appendix 3 - Process control Regulatory Standards



12. Summary of Changes

Version #	Revision History
QMS-025	New