

Standard Operating Procedure

Title: Quality Documentation - Control, Tracking and Distribution

Department	Quality Management		Document no	QMS-025	
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

Document Owner

Quality Assurance Manager

Affected Parties

All QA colleagues specially the Document Control Officer.

Purpose

To define the procedure and method of control to create, review, maintain and distribute Quality Documentation.

Scope

This procedure primarily describes the role of the **Document Control Officer**. Please see the Appendices for Flowcharts of the Quality Documentation System procedural steps

Definitions

Quality Documents	SOPs, Forms, Policies, Manuals, Visual Display, Audit Reports, Training Session Plans, GMP agreements. (See SOP QMS-010 for listing)
Technical Documents	Documents controlled by the Technical Service Department e.g. In-house Control Method, Raw Material Specification.
Packaging Documents	Packaging Material Specifications created and maintained in the Database by Technical Service Department.
Document Database	A central database to prepare, control and update of Quality Documents, Technical documents and Master file documents.
File Administrator	The team member who has been nominated to administer the area Satellite Document Files.
Prepared By	The person who has written the document. This may be an employee who has current charge of the system/process as described by position description or training.
Checked By	The Team Specialist, Supervisor or Manager who has direct charge of the system/process.
Approved By	The position or department noted in the "Approval Matrix" in SOP QMS-010.
Verified By	This applies to external documents. Person who acknowledges the receipt of documentation in full to Sydco. i.e. Maintenance & Operation Manuals, Manuals – General, Procedural Manuals, Project Files.
Confirmed By	Person who confirms the documents provided are consistent with specifications and accurately reflects the project to date. Applies to External Documents. i.e. Maintenance & Operation Manuals, Manuals – General, Procedural Manuals, Project Files.
Revision History	Brief summary in point form of changes made to a Document during update. Includes references to specific changes to other cross-referenced documentation.
Master Document	A signed, white, hardcopy of the document.
Soft Copy	The electronic copy of the Master Document filed in the applicable, secured directory. Soft copy has the signatory's names and required dates typed into the file prior to issue.

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Procedure

1. Creation and Approval of a New Document

1.1. Initiation

A request for initiation of new document is received via a completed, signed **Form-505**. See **QMS-010** for definition of document types and data required for each type. The Document Administrator is to:

- 1.1.1. Issue a document number from the Documentation Database. See **SOP QMS-015** for SOP numbering system.
- 1.1.2. Raise a new record in the “Quality Documents” area of the Database. See Appendix 1 for flowchart describing process for raising a new record.
- 1.1.3. Complete file properties for the document to be created in the database. Type in the Status box “To be Written”, the author’s name and the date the record was added.
- 1.1.4. External documents i.e. Standards, Compendia, Regulatory Codes etc, utilise the externally derived document number.(See **SOP QMS-015**)
- 1.1.5. Inform the requestor of the document number. The Document Administrator or the requestor is to create the electronic copy of the document using the appropriate template. See **SOP QMS-015** for templates. The requester is to save this document in Draft folder. See **SOP QMS-015**

1.2. Creating Documents

- 1.2.1. All Quality documents are to be based on templates.
- 1.2.2. All templates are given unique Template numbers and controlled via the Documentation Database, e.g. **TEM-095** is for creating SOPs.

1.3. Circulation of a new document for Approval

- 1.3.1. A notification of finalisation of the document is received from the author.
- 1.3.2. Update the Status Box in the Documentation Database with “To Be Confirmed” and the name of the first person who is to sign and date the document is forwarded to them (usually the same day).
- 1.3.3. Transfer the electronic copy of the document into circulation folder. Print a copy on White paper. Make sure the sign off boxes do not have any names and dates typed in, as this copy will be the signed “Master Copy”.

Note: For Forms the Revision History is to be “hidden text” in the final soft copy version, however the Revision History should be printed on the Master Copy.

- 1.3.4. Fill in form **Form-395** for SOPs or **Form-495** for Forms with the names of the signatories. Attach this form to the printed document to be circulated.

Note: There are different sign-off requirements for different document types.

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- 2.1.2. **Copy** the electronic document due to be reviewed or updated into Draft folder for editing.
Note: The current version of the document must remain in the 'live' folder.
 - 2.1.3. Change the Status box in the Database to 'Under Review'. Type in the reviewer's name and the date the electronic copy was placed in Draft folder.
 - 2.1.4. Check that the document is based on the current template for the specific document type.
 - 2.1.5. Remove existing signatures and update the version number.
For SOPs and Forms:
 - In the "Revision History" at the end of the document, type in the Issue Date (see Database record).
 - Then, add a row and type in the new version number, so that the reviewer can add a summary of changes to new version.
 - For Forms, change the Font of the Revision History text so that it is no longer "Hidden" text.
 - 2.1.6. Notify the delegated reviewer that the document is available for editing.
 - 2.1.7. Follow procedure as for New Documents until end of Approval circulation.
 - 2.1.8. Once all required signatures are finalised, the DCO will issue the document. See section 4 for issuing of documents.

3. Updating 'Hard Copy Only' documents

The procedure for change control of hardcopy only documents varies depending on specific document type.

3.1. Operational & Maintenance Manuals, Project Manuals, Procedural Manuals

Changes are to be annotated to ALL hardcopies and the Manual Approval Change form on the front page of each manual is to have the Change Control section completed. The text used to describe the change on the Change Control Form must be the same on all copies of the Manual.

4. Issuing Documents

Once all required signatures are finalised, the DCO will issue the document.

4.1. Saving file to live directory

- 4.1.1. Write in the Issue Date and the Review date on the signed hardcopy Master Document. Type these dates into the electronic copy. Type the signatories' names into the electronic copy.
- 4.1.2. If a version is being superseded following review or updating, rename the previous version's electronic copy to include version number. Move this superseded version into Obsolete folder.
- 4.1.3. Save the updated or new electronic copy into the applicable "live" directory. Delete the copy in the circulation folder. Note that the document is to be saved as the latest version of Word available.
- 4.1.4. Complete the 'File\Properties' data of each document. Make amendments where necessary.

Title	The document number
Subject	The document title. This must be the exact title of the current document.
Author	The person who "prepared" the document.

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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.

6. Logging of Technical Files and Standards in the Documentation Database

6.1. Technical Files

- 6.1.1. Log all Technical Files into the Documentation Database and store the hard copy for future reference.
- 6.1.2. Allocate a number to each file. Follow SOP **QMS-015** for numbering system used for technical files. Label the file with allocated number on the spine and front of the file.
- 6.1.3. Distribution the documents in appropriate compactus.

6.2. Standards

- 6.2.1. Log the documents into the "Standards, Codes and Compendia" sub section.
- 6.2.2. Follow **QMS-015** for numbering system used for standards. Label the file with allocated number on the spine and front of the file.
- 6.2.3. Distribution the documents in appropriate compactus.

Note: Each standard is logged as new, so there could be more than one listing of the same standard. A search is required to ensure the latest amendment/version is found.

7. Quality Assurance (GMP) Agreements

GMP Agreements are prepared by the Quality Assurance Department and are written to outline the basic responsibilities and actions undertaken by Sydco and any contracted party who has direct impact in the manufacturing stages of product.

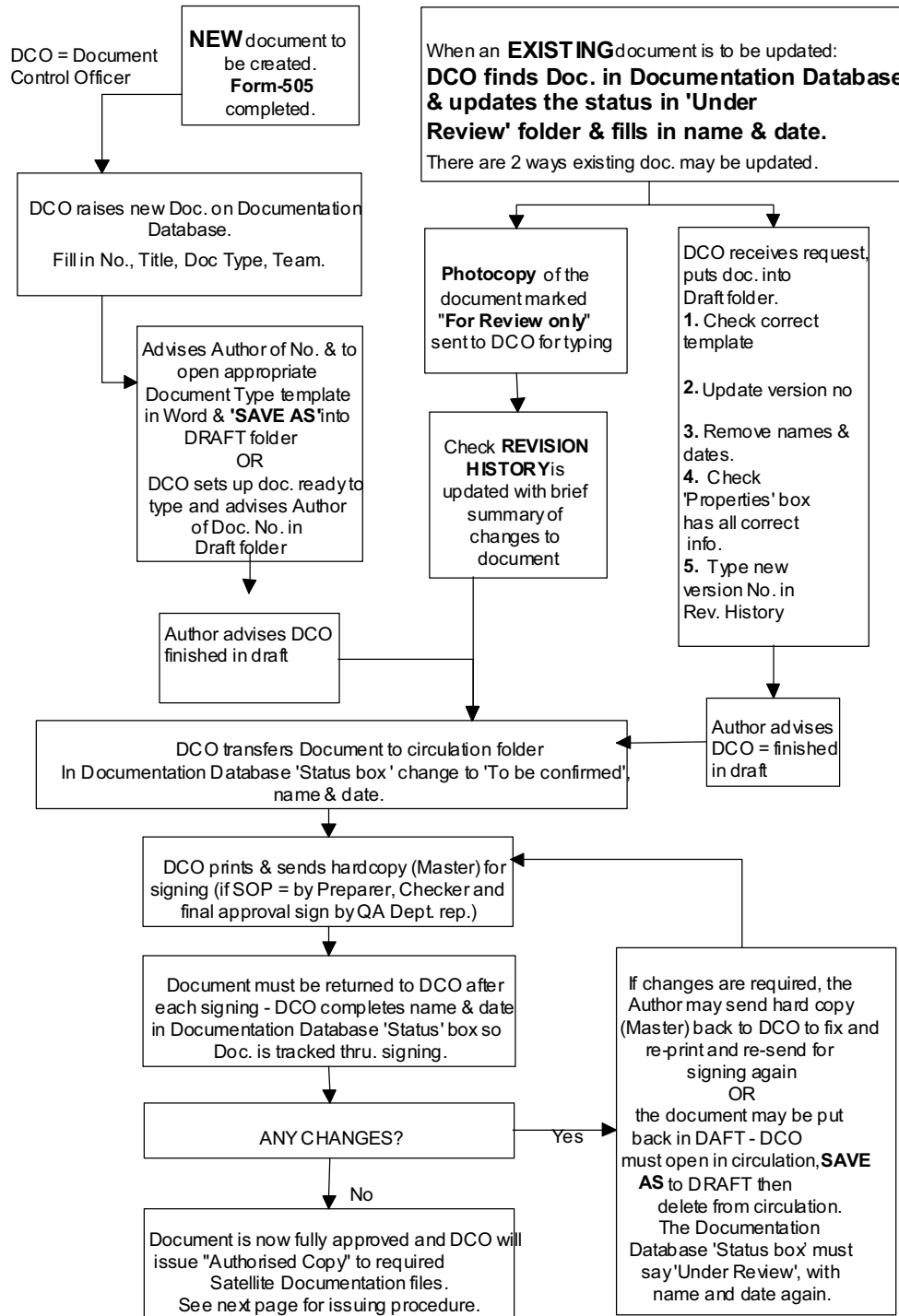
7.1. Control, Tracking and Distribution of QA agreements (between Sydco and contractor)

- 8.1.1. Once the QA agreement is drafted it should be moved from Draft folder to Live Agreements for printing and signing. Two copies should be printed so that one can be given to each of the contracted parties.
- 8.1.2. The tracking of QA agreements is done through QA Agreements folder of the database.
- 7.1.1. Once signed by both parties the Register of Contracts form (**Form-460**) should be filled out to ensure tracking of the agreement follows the requirements set out in **SOP QMS-110**.

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9. Appendix 1 – DCO – Instruction for Updating or Creating Electronic Quality Documents



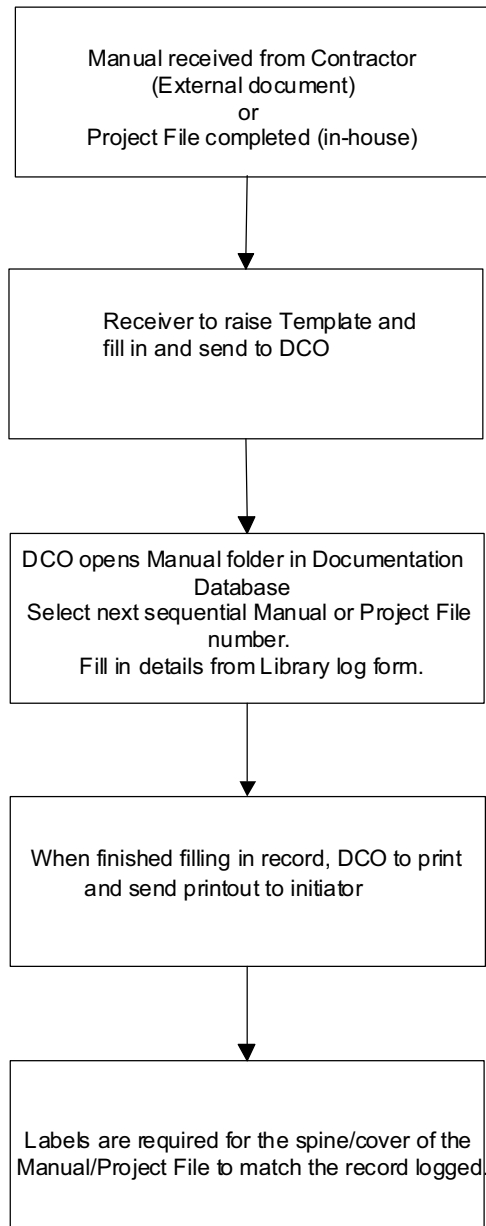
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Appendix 2, cont.

Document Initiation Procedure for Manuals:

7



SOP Ready for Signing

(Ref. SOP QMS-015; QMS-025)

All signatories are to review:

- for correctness, effectiveness and clarity
- the EHS statement
- the document Revision History

"PREPARED BY"	REPEATS													
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">To (Preparer):</td> <td style="width: 50%; padding: 2px;">Dept:</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Is this SOP correct?</td> </tr> <tr> <td colspan="2" style="padding: 2px;"><input type="checkbox"/> No - Mark changes and/or request DCO to put electronic copy back into DRAFT Folder.</td> </tr> <tr> <td colspan="2" style="padding: 2px;"><input type="checkbox"/> Yes - Sign & Date on Page 1 of the SOP in the "Prepared By" box</td> </tr> </table>	To (Preparer):	Dept:	Is this SOP correct?		<input type="checkbox"/> No - Mark changes and/or request DCO to put electronic copy back into DRAFT Folder.		<input type="checkbox"/> Yes - Sign & Date on Page 1 of the SOP in the "Prepared By" box							
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Incident / Investigation Report (Ref. SOP QMS120)

Report No. – YY-INI-XXX or YY-INV-XXX

DR Number:

Investigation Type

This should list the type of investigation
(eg. Process Failure, Operator Error, etc.).

Executive Summary

The executive summary should contain a brief description of the event, root cause found during the investigation and a final summary on product disposition.

Name (Position)	Signature	Date
Prepared by:		
Checked by:		
Authorised by:		
Approved by:		

Incident / Investigation Report (Ref. SOP QMS120)

Report No. – YY-INI-XXX or YY-INV-XXX

DR Number:

1.0 Event

Description of event and details to be added here.

Process Line(s), Product Name(s), Product Code(s) and Batch No.(s) to be added here.

Initial Scope of the investigation and any immediate action/segregation/blocking of stock for sale should be listed here.

2.0 Batch Chronology

This table is an example of events that may need to be documented in a batch investigation chronology. Table can be customised (or even omitted) to fit the sequence of events in an investigation.

Date (dd/mm/yyyy)	Time (24 hrs)	Description
dd/mm/yyyy	00:00	Example – Batch planned / scheduled
dd/mm/yyyy	00:00	Example – Batch commenced filling
	00:30	Example – Shipper No at time of event
	05:00	Example – Line Clearance performed after event
	06:00	Example – DR raised at this point

3.0 Suspect Causes and Rationales

No.	Cause Description	Primary / Contributing / Unlikely
3.1	Enter suspect cause here	Choose one type from above
	Rationale: This is where you enter your rationale as to why a suspect cause is likely to be correct or why you have discounted this particular cause	

Incident / Investigation Report (Ref. SOP QMS120)

Report No. – YY-INI-XXX or YY-INV-XXX

DR Number:

Here is where you outline the risk assessment and impact to product made during the event and rationale as to why it is either acceptable or not.

6.3 Product made after the event

Here is where you outline the risk assessment and impact to product made after the event and rationale as to why it is either acceptable or not.

7.0 Summary

Here is where you write your conclusion to the investigation, you must summarise the overall root cause found during the investigation, the impact on this batch and any other batches and the overall batch disposition.

7.1 Root Cause

State the root cause or suspect cause if root cause was not determined.

7.2 Repeat Event

State if a similar event occurred in the last 12 months and DR reference.

7.3 Batch Disposition

State final batch disposition and reasoning behind the decision.

7.4 Impact on other batches / processes

State if other batches/processes are impacted and reasoning behind the decision.

Incident / Investigation Report (Ref. SOP QMS120)

Report No. – YY-INI-XXX or YY-INV-XXX

DR Number:

Note: Batch release may occur prior to the preventative items being completed

8.2 Attachment - Investigation meeting minutes

8.2.1 Meeting Minutes

If there are multiple meetings or discussions these should be listed on this page

8.3 Attachment - Supporting batch documentation

8.3.1 Attachment – Deviation Report/s

If there are multiple DR associated with this event then these should be listed on this page.

8.3.2 Attachment - Supporting Batch Documentation / Log Books

If there are excerpts from the batch documentation or copies of log book pages associated with this event then these should be listed on this page.

8.3.4 Attachment - Supporting Facilities Data

List copies of in-process checks printed from the production lines.

8.3.5 Attachment - Supporting Analytical Data

Register of Contract

(Ref. SOP QMS-110)

Contract Identifier#	Please complete details in this column										
Prepared by:											
Name & Contact											
Contract Details											
• Contracted ID (alphanumeric)											
• Contracted Party (text)											
• Supplier Contact Name (text)											
• Supplier e-mail address											
• Supplier telephone number											
• Nature of the Agreement											
• Type of Agreement	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Service <input type="checkbox"/></td> <td style="width: 50%;">Maintenance <input type="checkbox"/></td> </tr> <tr> <td>Business contract <input type="checkbox"/></td> <td>Service Level Agreement <input type="checkbox"/></td> </tr> <tr> <td>Operations <input type="checkbox"/></td> <td>Confidentiality Agreement <input type="checkbox"/></td> </tr> <tr> <td>Licence Agreement <input type="checkbox"/></td> <td>Leases <input type="checkbox"/></td> </tr> <tr> <td>QA Agreement <input type="checkbox"/></td> <td></td> </tr> </table>	Service <input type="checkbox"/>	Maintenance <input type="checkbox"/>	Business contract <input type="checkbox"/>	Service Level Agreement <input type="checkbox"/>	Operations <input type="checkbox"/>	Confidentiality Agreement <input type="checkbox"/>	Licence Agreement <input type="checkbox"/>	Leases <input type="checkbox"/>	QA Agreement <input type="checkbox"/>	
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Licence Agreement <input type="checkbox"/>	Leases <input type="checkbox"/>										
QA Agreement <input type="checkbox"/>											
• Date Signed											
• Start Date											
• Term of the agreement (years & months)											
• Critical business implications or actions of the contract											
• Sponsor of the Contract											
• Total VALUE of the contract over the term											
• Value Notes (additional information)											
• Billing Cycle											
Termination											
• Termination Date											
• Termination procedures											
• Critical date to commence re-negotiation or termination											
• Status (select: under negotiation, current or expired)											
• Notes (e.g. open ended contract)											
Administration											
• Date last updated											
• Updated by											
• Where is the physical contract stored?											
• PO or requisition number											
• Division responsible											

Document Creation or Change Request

(Ref. SOP QMS-015)

1. To complete this form:

- a) Print a copy of this form.
- b) Add details in section 2 and in relevant section 3. or 4. (✓ Create or Cancel).
- c) Add details of Line Manager in section 5.
- d) Send to the Line Manager for approval to proceed.
- e) Line Manager is to obtain appropriate approval from Quality Assurance.
- f) On approval/rejection, send this form to Document Management Department who will advise Form Initiator of outcome of request, or request further information, if required.

2. Form Initiator

Date	Area	
Initiator Name	Position	
Line Manager's Name		

3. Create New Document

Document Type (SOP, Form, VD etc.):	(if VD/Form incl. SOP Cross Ref.).....
Title	
Reason for Creation (new machinery; new process, etc.)	

4. Cancel Document

Document Type (SOP, Form, VD etc.)	
Document No	
Reason for Cancellation (obsolete machinery, process or procedure; covered in other SOP, etc.)	
Comments:	

5. Approval: Line Manager

Print Name			
Sign for approval		Date:	

6. Approval (Quality Assurance Dept. Managers)

Note: Cannot be Manager of Stakeholder Area / Dept.

Print Name		Position	
Sign for approval		Date	

If this is a QA area document, ONLY the QA Manager can approve. Send printed, signed form to DCO

7. DCO

Initiator informed?	
Date	