

Standard Operating Procedure Requesting Official Documentation and Binders	SOP No. 1.006
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- 1 Purpose
 - 1.1 To establish a system for requesting official documentation.
- 2 Scope
 - 2.1 This procedure applies to requesting documentation and assigning numbers to registered binders containing official documentation under quality control such as SOP's, attachments, and forms.
- 3 Definition
 - 3.1 Official documents are copied on non-photo blue paper by the QA department. To maintain quality control of documentation, copies of official documents will only be distributed to registered binders.
 - 3.2 Binders contain official documentation and will be assigned to individuals who will be responsible for maintaining and updating the documentation contained within their registered binder.
 - 3.3 Official documentation marked "*Reference Copy*" will not fall under the authority of the QA department.
 - 3.4 Each new binder issued will have a table of contents with the latest document revisions on the front cover.
- 4 Responsibility
 - 4.1 The QA manager is responsible for assigning each binder a registered number.
 - 4.2 All registered binders are subject to annual audits by the QA department.
 - 4.3 The QA department is responsible for gathering the requested documentation as needed for new binder(s), existing binder(s) and/or reference copies.
 - 4.4 Revised documents will be issued to registered binders by QA once a document has become effective.
- 5 Procedures

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- 5.1 The requester will complete the information requested in the Document Request (DR) form (FN 1.006.3). Include the document number and title for each SOP, form, and attachment.

Note: The document request form is used when requesting the following: adding or deleting existing documentation from binders, adding or deleting binders from the quality control system, or for requesting reference copies of official documentation.

- 5.2 The DR form is returned to the QA department for approval.

Note: If a binder is requested, proceed to step 5.3. If documents only are requested, proceed to step 5.4.

- 5.3 A file number is assigned to each binder by logging the appropriate information into both tracking forms FN 1.006.1 (Binder Numbering Assignment Sheet) and FN 1.006.2 (Binder Table of Contents).

5.3.1 FN 1.006.1 is used to track who is assigned a registered binder.

5.3.2 FN 1.006.2 is used to track the contents of each binder issued.

5.3.3 Each binder is assigned an identification number as follows: five digits--first and second represent the year, and third-fifth are sequentially assigned. Example: Binder # 96001 is the first binder of 1996.

- 5.4 The DR form with the requested documentation is routed to the requester.

- 5.5 The requester reviews the pack of information for completeness and accuracy.

- 5.6 If all of the requested documentation is received and error free, the requester signs the DR form and returns it to QA.

- 5.7 If the documents requested are damaged or missing, the DR form is returned to QA for completeness and steps 5.4 to 5.6 are repeated.

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6 Audit

- 6.1 For each binder audited, review the corresponding table of contents with the most up-to-date revision number and check the documents for completeness and accuracy. Update the binders as needed.
- 6.2 Number a list of issued binders sequentially, beginning with the numbers 000.
- 6.3 Compare the list with the number of binders that have been distributed. Any deviation of a 1-to-1 correspondence with these two lists will be noted and explained as part of the annual report.
- 6.4 The number of binders to audit equals the square root of the total number of binders plus one.
- 6.5 A random audit equal to the number of binders from step 6.4 will be performed.
- 6.6 On an annual basis, QA will issue a return receipt notification to each person issued a registered binder to perform an audit.
 - 6.6.1 Each return receipt will list a table of contents and a revision number (of the most recent document) for each official document issued to a registered binder.
 - 6.6.2 The contents of the binder is cross-referenced for a 1-to-1 correspondence against the return receipt notification. Once the audit has been performed the individual signs and returns the receipt to QA.

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