

SOP 01 CONTROL OF QUALITY SYSTEM DOCUMENTATION

1.0 PURPOSE AND SCOPE

1.1 Purpose and Scope

This SOP specifies the requirements for the control of Quality System documentation. This SOP specifies the requirements for the preparation, approval, and maintenance of Quality System documents. These documents are the QA Manual (including SOPs), documentation of internal audits, and associated forms.

2.0 REQUIREMENTS

- 2.1 The format of each SOP shall be similar to the format of this SOP.
- 2.2 For the first issue of this QA Manual, the revision and change number shall be zero. Each revision and change shall follow a sequential number, as applicable.
- 2.3 Other SOPs shall be prepared as determined.
- 2.4 When an activity described in this QA Manual (including SOPs) takes a significantly different direction, this QA Manual shall be revised/changed, as required.
- 2.5 This Quality Manual (including SOPs), documentation of internal audits, and associated forms shall be reviewed annually and revised/changed, as required. The compliance officer shall conduct this review at the same time as the annual review of the Quality System. The conduct of this review shall be documented.
- 2.6 Revisions/changes to this Quality Manual shall be approved.



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