**Purpose**:

This procedure provides a system for controlling documents defined within the site Quality System.

**Giles Quality System Documents**

The following documents make up Giles’ quality system

1. **Documentation System**
   1. HR Procedures and Forms
   2. Safety Procedures and Forms
   3. Manufacturing Procedures, working instructions, and forms
   4. Maintenance Procedures, MP’s, work instructions, manuals, and forms
   5. Repack Procedures, work instructions, and forms
   6. CSR Procedures, work instructions, SCR’s and Forms
   7. Equipment description and documents related to equipment

**External Documents**

Externally generated documents may be reference in the Giles Quality system as the need arises. This information becomes a quality system requirement only when specified by another Controlled Document. Consequently, control of referenced documents is limited to the extent deemed necessary to assure effective operation of the Quality System.

**Document Listing**

A database of all internal controlled documents will be maintained by the Quality Department. The documentation database will be maintained by the Quality Department.

**Format**

The general format for documents will be outline form; however, tables, sketches, and other illustrations may be used to enhance the clarity of instructions. Header or Footer information shall include as a minimum:

**-First Page**

Document Title

Page Number (Page # of #)

Revision #

Date of Revision

Original Author

**-Subsequent Pages**

Document Title

Page Number (Page # of #)

Revision #

Date of Revision

Original Author

**Requesting Approval of Revisions, Deletions, and New Documents**

Any person knowledgeable of the process in question may submit a request to revise an existing document or to implement a new one by following the steps below:

1. All documents submitted as new procedures or revised procedures must have a Document Approval Form (QA-01-F01) filled out. If an employee writes a new procedure or makes a revision of a procedure the procedure must be taken to their supervisor who will fill out proper documentation for submission. Document Approval Forms (QA-01-F01) must be filled out before submission to Quality Department.
2. New documents may be legible written or typed. Review Document for clarity of instructions prior to submission for approval. If necessary, let a co-worker review it.
3. Changes must be easy to locate and read. Revisions may be made electronically as long as they are easy to locate and easy to read even when the document is printed. Original word documents for electronic correction must be requested from the Quality Department. Quality Department keeps PDF hardcopy of original procedure.

Note: Review the document in its entirety to ensure that the revisions are valid in the context of the entire document and that it is still applicable for the current operation. Check referenced document to avoid conflicting information.

1. The documents will be submitted to the Quality Department.

**Document Approval**

All controlled documents shall be approved. The same approvals are required for revisions as for new documents. A list of approvers must be kept. Approval authority may be delegated to others.

The list as follows:

* HR – HR Manager
* Maintenance – Maintenance Manager
* Manufacturing- Plant Manager
* CSR – CSR Manager
* Quality, Safety, Lab – Director of Quality

**Document Distribution**

Distribution of controlled documents shall be managed so that they are available wherever necessary for the effective functioning of the quality systems. Documents will be maintained by the Quality Department. Hard copies may be printed from the network to satisfy an immediate need, but shall be destroyed after use specified. Computer access is restricted to read only and print, for those persons authorized.

**Document Review**

All controlled documents shall be reviewed every 3 years to determine if they are applicable for current operation and revised immediately if they are not. The review must be thorough and must involve individuals who are knowledgeable of the described task, product, or process. A walk through might be required to verify equipment ID, valve numbers, etc. Get additional technical resources as needed. The reviewer must ensure that any reference documents are also considered.

The reviewer must submit a request for approval of the necessary changes (Document Approval Form QA-01-F01). The form shall also be used to document the review even when no changes are necessary so that the effective date of the document can be revised.

**Training/Communication**

The sponsor of new or revised documents is responsible for describing training requirements. The requirements can range from a mail notification, routing of the document for reading and signoff, classroom lecture, on the job, hands-on training, etc., based on the effect of the change on the product or process. The Quality Department or area Manager can identify qualified trainers. Any training or notification method must be documented for training records, in a way that the subject, trainer, trainee and training date is recorded.

The sponsor should indicate on the Document Approval Form (QA-01-F01) if the document is to be held until training is complete. The sponsor is then responsible for notifying the Quality Department when the training is complete so that the procedure can be published

**Record Keeping**

The completed Document Approval Form (QA-01-F01) shall be maintained as a record of document revisions and reviews. Other supporting information may also be included but is not required. Document management records are kept for a minimum of 3 years by the Quality Department for Document Control.

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| Revision  Number | Revision  Date | Effective  Date | Revision  Author | Quality  Approval | Production Approval | Revision Description |
| 00 | 9/9/2005 | 9/9/2005 | Carl Mooney | Carl Mooney | J. Bumgarner | New Document |
| 01 | 7/23/2009 | 7/23/2009 | Paul Teleki | Paul Teleki | J. Bumgarner | Review, changed steps in Requesting Approval of Procedures |
| 02 | 8/23/2012 | 8/23/2012 | P. Owen | D. Durbin | J. Bumgarner | 3 year review, new header |
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