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

A. 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 Waynesville Site 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 QA Manager. The documentation database will reside on the computer network within intranet (shown on Documentation System), a back-up hardcopy and revisions will be maintained by the QA/Manager.

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 and 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

All documents must have a designation of one of the following in the header.

1. General Awareness
2. Job Specific
3. Safety

Documents may contain two items.

For Example: A procedure may be General Awareness and a Safety Procedure.

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 filled out completely. 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 must be completely filled out before submission to Quality Manager.
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 Manager. Quality Manager 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.

4. The documents will be submitted to the Quality Manager.

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. A list of delegates for each area must be documented and kept current.
The list as follows:

- HR – HR Manager
- Maintenance – Maintenance Manager
- Manufacturing – Director of Manufacturing
- Manufacturing- Plant Manager
- Manufacturing – Production Manager
- Manufacturing – Process Engineer
- CSR – CSR Manager
- Quality, Safety, Lab – QA/Safety Manager

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 on the electronic network by the QA Manager. A backup hardcopy will be maintained by the QA Manager. 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.

Posted Document
All posted documents will be controlled through the Document Control System.

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). 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 QA Manager 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 if the document is to be held until training is complete. The sponsor is then responsible for notifying the QA Manager when the training is complete so that the procedure can be published

Record Keeping

The completed "Document Approval Form" 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 QA Manager for Document Control.

TRAINING DOCUMENTATION

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Revision Number	Revision Date	Revision Author	Revision Description
00	09/09/2005	CM	New Document
01	07/23/2009	PT/SL	- Changed steps in Requesting Approval of Procedures - Removed items no longer listed in header