

GILES CHEMICAL CORPORATION		
COMPANY PROCEDURE		
Standard Operating Procedure	Page : 1 of 7	Revision : Date : 9/9/2005
Author: Carl Mooney, Jr.	Title: (00) DOCUMENT CONTROL	

Purpose

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

Attachment

Controlled Document Approval Form

Giles Quality System Documents

The following documents make up Giles' quality system.

A. Quality Manual

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. Quality/Lab procedures, work instructions and forms
8. Equipment description and documents related to equipment

External Documents

Externally generated documents may be referenced 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. At a minimum, it will consist of the document title, the document number, and the effective date of the document's current version. The documents database will reside on the computer network withintranet, a backup 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

Document Number

Area

Date

Page Number (Page # of #)

Document Control Notice (for on-line Procedures and Work instructions)

- Subsequent pages

Document Title

Document Number

Effective Date

Page Number (Page # of #)

Document Control Notice (for on-line Procedures and Work instructions)

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. 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.
2. 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.

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.

3. Retrieve and complete a copy of the Document Approval Form being careful to check or fill in all appropriate blanks.
4. The QA Manager will determine and select the document reviewers prior to implementation and route the approval form to the appropriate people
5. Send the form and a printed copy of the entire document to the QA Manager. The Manager will assign a number to new documents.

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In addition an electronic copy of documents revised or created electronically may be E-mailed to Document Control.

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 is as follows:

- HR – HR Manager
- Maintenance – Maintenance Manager
- Manufacturing – Operations Manager
- Repack – Repack Manager
- CSR – HR Manager
- Safety, Quality, 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 system. 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 satisfied. 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.

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Temporary Posted Document

When temporary instructions are required on a short term or emergency basis, temporary posted documents are allowed under the following conditions:

1. The document is not used to make changes to Limits, or Specifications.
2. The document is posted and approved by individuals designated by Area Management.
3. The approver's signature, posting location, effective date and expiration is included on the document.
4. If more than one copy of the document is issued, each copy must meet conditions 1, 2 and 3.
5. The approver is responsible for posting, removing and making revision to the document. Any revisions must be clearly marked, initialed and dated by the approver.
6. Expired temporary documents shall not be used for operation. Any employee can remove them.

Document Review

All controlled documents shall be reviewed at least every 2 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.

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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 5 years by the QA Manager for Document Control.

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REVISION HISTORY

Effective

Date

Revision

Changes

9/9/2005

00

New Document

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TRAINING DOCUMENTATION

	EMPLOYEE	TITLE	SIGNATURE	DATE
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