1.0 Purpose

The purpose of this procedure is to describe how documents are controlled from cradle to grave.

2.0 Scope

This procedure applies to all documents that define the Giles Quality System.

3.0 Responsibility

The Quality Unit is responsible for ensuring that all document control activities including, but not limited to, the preparation, approval, review and archival of documents are carried out in accordance with this procedure.

4.0 Safety Considerations

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

N/A

6.0 Procedure

6.1 Document Generation

All procedures must be written using the standardized format described in *SOP Template Instructions (Q12-PR-100-004).* Other documents are not necessarily required to follow this format but must use the same header and footer as the template.

6.2 Document Submission

All documents, new or revised, must be submitted in hard copy form to the Quality Unit accompanied by a completed *Document Approval* form *(Q12-PR-100-F002).* In the case of revisions, the current document along with the revised document is to be included with the submission. Changes must be easy to locate and read and be noted on the *Document Approval* form.

The new or revised document being submitted for approval must also be submitted to the Quality Unit electronically in Word. The Quality Unit will convert it to a controlled PDF

and upload to the Documentation System upon final approval. The original Word document of the controlled PDF document is to be obtained through the Quality Unit.

The document owner should indicate on the *Document Approval* form if the document is to be held until training is complete.

The document owner will obtain relevant approval signatures from their supervisor (if applicable) and from the appropriate personnel in the departments affected by the new or revised document.

The Quality Unit will assign a unique identification number to new documents generated from the *Master Controlled Document List* (*Q12-PR-100-F003)* in accordance with *Document Numbering* (*Q12-PR-100-003).*

The Quality Unit will assign a Revision number. Revision numbers will be issued sequentially where the original document will be designated as Revision 0 (zero).

6.3 Document Training

The document owner of new or revised documents is responsible for describing training requirements. The requirements can range from an email notification, routing of the document for reading and sign-off, classroom lecture, on the job, hands-on training, etc., based on the effect of the change on the product or process. Any training or notification method must be documented and recipients' signatures recorded on a *Training Roster* (*Q12-PR-100-F006).* Training records will be maintained and filed by the Quality Unit.

The document owner is then responsible for notifying the Quality Unit when the training is complete.

6.4 Document Approval

The Quality Unit will review the submitted documents for clarity and completeness. The new or revised document will be reviewed for being fit for purpose and in compliance with regulatory requirements. Any questions or concerns will be directed to the document owner. Upon successful completion of the review process, the document will be approved and made available on the Documentation System.

6.5 Document Distribution

Approved documents will be converted from Word to PDF and uploaded to the Documentation System located on Giles Intranet replacing the previous revision if one

exists. This allows for all Giles employees to have access to the most current and accurate documents without access to make unauthorized changes to the documents; access is limited to read only and print. Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for the accuracy of the document. Hard copies may be printed from the network to satisfy an immediate need but shall be destroyed after use specified.

The electronic Documentation System is backed up regularly by IT; the backup copy will be securely stored off site.

A hard copy of all quality documents and their accompanying approval forms will be managed and filed by the Quality Unit for the purpose of maintaining revision history and change information. These documents will be securely stored in the cGMP Library.

.

6.6 Document Review

The Quality Unit is responsible for scheduling a review of all quality controlled documents to determine if they are applicable for current operations. Due to the static nature of our business, this review will occur every five years from the document effective date. The document owner will be notified to conduct a thorough review of the identified documents.

If revisions are deemed necessary, the Quality Unit will determine if the revisions need to go through the Change Control System.

Upon completion of the review, the document owner must submit a completed *Document Approval* form with the document regardless if changes or revisions are needed.

6.7 Document Archival

Original documents and subsequent revisions leading up to the current revision uploaded to the Documentation System will be retained and filed in a secure location for the life of the document.

Documents no longer in use, including the original and revisions, will be considered obsolete. These documents will be retained and securely stored for a minimum of three years.

7.0 Reference Documents

SOP Template Instructions (*Q12-PR-100-004)*
Document Approval (Q12-PR-100-F002)
Master Controlled Document List (*Q12-PR-100-F003)*
Document Numbering (Q12-PR-100-003)
Training Roster (*Q12-PR-100-F006)*

8.0 Change Information

Due to the static nature of our business, the document review period was extended from three years to five years.