1.0 Purpose

1.1 This procedure defines how Giles Chemical assigns, plans, conducts, and reports internal quality audits and provides Management an independent examination of the Quality System and the effectiveness of corrective actions.

2.0 Scope

2.1 This procedure applies to all internal quality auditing activities. The internal audits will inspect actual practice against documentation.

3.0 Responsibilities

3.1 The cGMP Coordinator or Designee is responsible for managing the program including planning and scheduling internal quality audits.

3.2 The auditor is responsible for completing the audit and the audit report.

4.0 Safety Considerations

1.1 Applicable safety requirements for each audit area will be observed. 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 the community.

5.0 Materials/Equipment

5.1 N/A

6.0 Procedure

6.1 Audit Assignment

6.1.1 The cGMP Coordinator or Designee is responsible for planning and scheduling internal audits using *Internal Quality Audit Schedule* Q12-PR-100-F008a. Each main activity comprising the quality system is audited at least once a year. In addition to the annually scheduled audits, certain activities may be selected for more frequent auditing, depending on their status, importance and past compliance history. The audit schedule is subject to change as circumstances require.

6.2 Audit Planning

6.2.1 Personnel assigned to carry out an audit shall be independent of those having direct responsibility for the audited activity.

6.2.2 Audits will be issued by the cGMP Coordinator or Designee using the *Internal Quality Audit Assignment* Q12-PR-100-F008b.

6.3 Preparing for Audits

6.3.1 Auditors prepare for an audit by fully familiarizing themselves with 21 CFR 210 & 211 regulations and ICH standards, refreshing their knowledge of the quality manual and relevant operating procedures and reviewing the post-nonconformity reports and corrective action files.

6.4 Certified Internal Auditors

6.4.1 The Quality Unit is responsible for identifying candidates for internal auditor training. Training can be produced by Giles Chemical or a third party trainer.

6.4.2 Certification for an internal auditor will be granted upon successful completion of training and assisting with conducting three audits.

6.4.3 Certification will remain valid as long as at least one audit per year is conducted. Otherwise, the auditor must repeat initial training.

6.5 Conducting an Audit

6.5.1 Management responsible for the area being audited is contacted at least one week in advance with the proposed audit date. The manager concerned responds with a confirmation or proposes an alternative date.

6.5.2 The audit is performed using an *Internal Quality Audit Checklist* Q12-PR-100-F008c-k. Checklists are located within the Giles intranet controlled document system for the appropriate area being audited.

6.5.3 While conducting an audit, the auditors seek objective evidence demonstrating whether the audited activities comply with the requirements of the documented quality system. Auditors are encouraged to make observations and discuss ideas that will promote good business practice and process improvement.

6.5.4 The *Internal Quality Audit Checklist* Q12-PR-100-F008c-k will be completed during the audit. Problems or opportunities for improvement will be recorded. This will include a clear reference to what was observed.

6.5.5 When a noncompliance is noted, it is brought to the attention of, and discussed with, the responsible manager. Before the end of an audit, each noncompliance noted during the audit is documented on the *Audit Non-compliance Report* Q12-PR-100-F008l. Auditors fill out only the first part of the form, describing the noted noncompliance. The form is then given to the responsible area/department manager who then uses its second part to propose a corrective action.

6.6 Corrective Action and Follow-Up Audits

6.6.1 Once a noncompliance is identified and documented, further processing of the *Audit Non-compliance Report* Q12-PR-100-F008l is done by the area/department manager responsible. The manager concerned investigated the cause of the problem noted as a noncompliance, proposes a corrective action and indicated a date of implementation. The auditor reviews and approved the proposed corrective actions.

6.6.2 Follow-up audits are performed if the effectiveness of a corrective action was not verified prior to the closing of an audit-originated nonconformance. In addition, follow up audits may be scheduled in the case of repeat nonconformances in a particular area that has been identified with nonconformances.

6.7 Documentation and Record

6.7.1 Internal audits, implementation of resulting corrective action and the follow up audits are documented using Internal Audit Checklists for the appropriate area and *Audit Non-compliance Report* Q12-PR-100-F008l.

6.7.2 Internal Quality Audit documentation shall be filed by the Quality Unit and kept for the time specified in the *Document Retention Policy* Q12-PL-100-001.

7.0 Reference Documents

7.1 *Internal Quality Audit Schedule* Q13-PR-100-F008a
7.2 *Internal Quality Audit Assignment Report* Q12-PR-100-F008b
7.3 *Internal Quality Audit Checklist* Q12-PR-100-F008c-k
7.4 *Audit Non-conformance Report* Q12-PR-100-F008l
7.5 *Document Retention Policy* Q12-PL-100-001

8.0 Amendment Record

Revision Number	Revision Date	Revision Author	Revision Description

1	08/21/2012	DD	Procedure completely revised to reflect ICH recommendations.