1.0 Purpose

1.1 The purpose of the validation process is to provide a high degree of assurance that a specific process will consistently produce a product which meets predetermined specifications and quality attributes set by Giles Chemical.

2.0 Scope

2.1 To validate equipment, methods and processes affecting the critical product attributes of the final product.

3.0 Responsibility

3.1 Process Engineer is responsible for this procedure.

4.0 Safety Considerations

4.1 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

5.1 N/A

6.0 Procedure

1) Procedure

Validation, in simple terms, is documenting that a piece of critical equipment, production process, cleaning procedure, analytical method, in-process control test procedure, or computerized system is capable of producing product that meets specifications under normal circumstances and exhibiting normal process variation. The general steps to complete a typical validation are below:

1. Identify the critical product attributes. These can be identified from historical data, and the necessary ranges for the reproducible operation should be defined. This should include:
   - Defining the product in terms of its critical product attributes
   - Identifying process parameters that could affect the critical quality attributes of the product
   - Determining the range for each critical process parameter expected to be used during routine manufacturing and process control

2. Write a validation protocol. At a minimum, the protocol will include specifics of what parameters will be tested, the acceptance criteria, and the number of process runs. The protocol

will be reviewed and approved by the Quality Department and other affected areas (ie. Production).

3. Document the qualification of equipment and systems. Qualification is usually carried out by conducting the following activities, individually or combined:
    a. Design Qualification (DQ): documented verification that the proposed design of the facilities, equipment, or systems is suitable for the intended purpose
    b. Operational Qualification (OQ): documented verification that the equipment or systems, as installed or modified, perform as intended throughout the anticipated operating ranges
    c. Performance Qualification (PQ): documented verification that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process method and specifications
    d. Installation Qualification (IQ): documented verification that the equipment or systems, as installed or modified, comply with the approved design, the manufacturer's recommendations and/or user requirements

4. Gather data from the process runs.

5. Write a report based on the protocol that summarizes the results, comments on any deviations, draws appropriate conclusions, and includes any recommended changes to correct deficiencies.

2) Validation Review

At the Annual Quality Review, the need for re-validation of equipment or processes based on the data will be determined and assigned through the CAPA list generated at that meeting.

3) Re-validation

When any process critical equipment is modified (ie, changes in physical size, nature of operation, or sequence in the overall process) a new validation should be performed.

7.0 Reference Documents

7.1

8.0 Amendment Record

Revision Number	Revision Date	Revision Author	Revision Description
0	08/20/12	PO	New Document