1.0 Purpose

To describe how raw materials, packaging, finished goods, non-conforming product, out-of-specification product, and returned goods will be quarantined and audited by the Quality Unit. Following this procedure will insure prevention of cross-contamination of materials/products.

2.0 Scope

This procedure applies to all materials/products consumed by or produced by Giles Chemical.

3.0 Responsibility

Quality Unit is responsible for testing, approving and releasing materials/products as mentioned in this procedure.

All Employees are responsible for reporting non-conforming product or any deviations.

4.0 Safety Considerations

PPE requirements are to be observed in designated areas.

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

N/A

6.0 Procedure

There are designated quarantine areas in all facilities. Quarantine areas are clearly marked with one or more of the following: signage, stanchions and chains, Hold or Do Not Ship barrier tape, etc. A bin may be used for quarantining product as long as demarcation clearly defines the area to prevent non-conforming product from being mixed with conforming product.

Identification:

1. All Manufacturing and Repackaging in-coming packaging will be tagged with *Quality Hold* placard *(Q12-FM-100-002)* and placed in designated quarantine area until tested and released by Quality Unit.

2. All Manufacturing in-coming raw materials (Sulfuric Acid and Magnesium Oxide) are quarantined on rail spur until material has been tested and released by the Quality Unit.
3. All Repackaging in-coming raw materials (Fragrance, Salt, etc.) are tagged with *Quality Hold* placard and placed in designated quarantine area until tested and released by the Quality Unit.
4. All non-conforming or out-of-specification product(s) will be tagged with *Quality Hold* placard placed in designated quarantine area and the proper report filled out following SOP's *Non-conforming Material (Q12-PR-100-017)* and *Out-of-Specifications (OOS) (Q12-PR-100-025)*. Product will remain quarantined until evaluated by and released by Quality Unit.
5. All returned goods are tagged with Quality Hold placard and placed in designated quarantine area until evaluated by and released by Quality Unit following SOP *Returned Products (Q13-PR-100-011)*.

Evaluation/Auditing:

1. Manufacturing in-coming packaging will be tested following *In-coming Raw Material – Film Checks (P12-PR-100-074)* and *Super Sacks and Liners (P13-PR-100-075)*.
2. Repackaging in-coming packaging will be tested following *In-coming Raw Material: Pouch - Carton (R12-PR-100-013)*
3. Manufacturing in-coming raw materials will be tested following *In-coming Raw Material – MgO and H2SO4 (P13-PR-100-076).*
4. Repackaging in-coming raw materials will be audited and tested following *In-coming Raw Material: Fragrance Barrel (R12-PR-100-014)* and *In-coming Raw Material: Magnesium Sulfate (R13-PR-100-032).*
5. Non-conforming, out-of-specification and returned product will be audited as follows:
    a. In order to determine the amount of affected product, the auditing process will begin by sampling material/product immediately before and after the non-conformance or out-of-specification causing event. Audit details will be recorded in Quality Audit Notebook.

b. The auditing strategy will follow this format until there is a sequential run of three units of acceptable material/product before and after the beginning of the occurrence of non-conformance or out-of-specification that have been identified.

c. If an investigation is warranted, a CAPA will be opened following *CAPA Procedure (Q12-PR-100-014)*. Process control charts and production batch records will be reviewed by Quality, Production, Engineering and Management to determine root causes of the non-conforming or out of specification product(s).

Disposition/Release:

1. The disposition of product will be approved by the Quality Unit. Disposition may include release, re-route of product to different customer per their quality approval, re-work, or proper disposal.
2. Upon completion of the appropriate testing by QA, in-coming raw materials and packaging will either be released for use or returned to vendor. A supplier complaint will be launched if materials are returned to vendor.
3. If recall is deemed necessary follow *Recall (Q12-PR-100-013).*
4. Quality Hold placards will be removed from approved material/product and filed with the daily Quality records. The Quality Hold placard will then be replaced with quality approval designation and removed from the quarantine area.

7.0 Reference Documents

Quality Hold	*(Q12-FM-100-002)*
Non-conforming Material	*(Q12-PR-100-017)*
Deviation Reporting	*(Q13-PR-100-024)*
Out-of-Specifications (OOS)	*(Q13-PR-100-025)*
Returned Products	*(Q13-PR-100-011)*
Film Checks	*(P12-PR-100-074)*
In-coming Raw Material –Super Sacks, and Liners	*(P13-PR-100-075)*
In-coming Raw Material – MgO and H2SO4	*(P13-PR-100-076)*
In-coming Raw Material: Pouch - Carton	*(R12-PR-100-013)*

In-coming Raw Material: Fragrance Barrel *(R12-PR-100-014)*
In-coming Raw Material: Magnesium Sulfate *(R13-PR-100-032)*
CAPA Procedure *(Q12-PR-100-014)*
Recall *(Q12-PR-100-013)*

8.0 Amendment Record

New Procedure