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 *Incoming Raw Material* placard *(Q15-FM-100-012)* and placed in designated quarantine area until tested and released by Quality Unit.

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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 *Incoming Raw Material* 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 (Q12-FM-100-002)* 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

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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

Incoming Raw Material	*(Q15-FM-100-012)*
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)*

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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 Change Information

General review and added *Incoming Raw Material* placard.

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