1.0 Purpose

The purpose of this procedure is to describe how to manage product that does not conform to standards or specifications and has been approved for rework or reprocessing. Following this procedure will ensure that the reworked or reprocessed product will be of equivalent quality to that which it was originally produced to meet. Properly reworked or reprocessed product may be shipped in a saleable condition and reduces loss.

2.0 Scope

This procedure applies to any in-process or finished product during Repackaging. Sources of product approved for rework or reprocessing may include, but not limited to, product determined to be non-conforming, product that has been returned, or damaged/incorrect packaging.

3.0 Responsibility

Quality Unit- is responsible for quarantining, evaluating and approving all product prior to it being reworked or reprocessed and releasing the product upon a final evaluation.

Plant Management/Supervisor- is responsible for assuring that all personnel involved are properly trained and for ensuring the appropriate steps of this procedure are followed to properly rework or reprocess the identified product.

4.0 Safety Considerations

Always wear facility required PPE including, but not limited to, safety glasses and steel toed boots.

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

1. Any product that is non-conforming, has been returned or has damaged/incorrect packaging will be tagged with *Quality Hold* placards *(Q12-FM-100-002)* and quarantined appropriately by Quality and/or Production.

    - *See Nonconforming Material (Q12-PR-100-017), Returned Products (Q13-PR-100-011), and Quarantine and Auditing of Products (Q12-PR-100-012).*

2. Quality will evaluate the product and assist Production with investigating the issue. If required, a CAPA will be initiated according to *Corrective and Preventive Action System (Q13-PR-100-014).* A determination will be made as to which of the following actions will be carried out:

Rework: *Product that meets all specifications but has a non-conforming packaging issue that can be corrected without impacting the product.*

- The magnesium sulfate heptahydrate in products that is approved for rework must meet all specifications.
- Rework issues must be related to the product's packaging/labeling and/or special customer requirements (i.e. pallet configurations, print, damaged boxes)
- Reworked product must undergo evaluation prior to approval for release.
- The disposition of all reworked product is to be documented so as to maintain traceability.
- USP salt that cannot be used as packaged may be reworked as follows:
  - This material must be free of contaminants and inspected/released by Quality.
  - Once released by Quality, it may be poured back into a super sack labeled with a *Recovered Product Placard (R13-FM-100-061)* to be used in tech grade production, such as scented product or agricultural product which makes no claim for human consumption.
  - If there is no tech grade material to consume this salt, the super sack must be weighed and returned to manufacturing for reprocessing.

Reprocessing: *is a product that meets all specifications but cannot be reworked and must be melted down and reintroduced into the beginning of the process as a Raw Material.*

- The weight of the recovered material is to be recorded on the *Salt Waste Form (R12-FM-100-044)* in the recoverable column and listed on a *Product/Stock Transfer Form.*
- The magnesium sulfate heptahydrate in products that is approved for reprocessing must meet all specifications.
- Reprocessing issues must be related to physical characteristics such as, but not limited to, hard salt, damaged packaging, and crystal size.
- Reprocessed product must undergo evaluation prior to approval for release to ensure that the magnesium sulfate heptahydrate is not OOS.
- The magnesium sulfate heptahydrate will be reintroduced into the process as a Raw material.
- As a Raw Material the product will be subject to repeat all stages of the established manufacturing process from the beginning with the digesters, filtration and crystallization to drying, cooling and packaging.
- The disposition of all reprocessed product is to be documented so as to maintain traceability.

Scrap/Waste: *is any product that does not meet specifications and cannot be reworked or reprocessed.*

- Material that does not meet criteria to be used as tech grade or any other grade of product and must be disposed of.
- The waste is put into appropriately marked wheelbarrows, weighed and disposed of in the dumpster and sent to the land fill while abiding by local environmental codes.
- The weight is to be recorded on the *Salt Waste Form (R12-FM-100-044)* in the unrecoverable column.

7.0 Reference Documents

Quality Hold Placards	*(Q12-FM-100-002)*
Recovered Product Placard	*(R13-FM-100-061)*
Nonconforming Material	*(Q12-PR-100-017)*
Corrective and Preventative Action System	*(Q13-PR-100-014)*
Returned Product	*(Q13-PR-100-011)*
Salt Waste Form	*(R12-FM-100-044)*
Product/Stock Transfer Form	

8.0 Change Information

Updated number two, rework section to include process for recovered salt and added *Recovered Product Placard*, also revised reprocessing section to accurately reflect the process for reprocessing materials.