1.0 Purpose

The purpose of this procedure is to outline the process of handling returned product.

Following this procedure will ensure that employees do not inadvertently use or reship returned product.

2.0 Scope

This procedure applies to all returned products regardless of source at both the Manufacturing and Repackaging facilities. Sources include, but may not be limited to, customer complaint, recall, or withdrawal.

3.0 Responsibility

Customer Service Representative (CSR) / Sales Representative: coordinates the logistics of the return.

Production Employees: Unload returned product, quarantine and placard the return and inform the Quality Unit of its arrival and location.

Quality Unit: Inspects return and approves final disposition of the returned product.

4.0 Safety Considerations

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

Care shall be exercised when unloading customer returned material to the warehouse. The material may have shifted or may not be properly secured to the pallet. Product could have come in contact with contaminated material and should be handled as such.

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

- Barcode scanner
- Barricade Tape/Signage
- Quality Hold Placards, RGA Placards
- Sample Bags

6.0 Procedure

Initiation of Return

- The CSR or Sales will fill out the top portion of the *Returned Products Report (Q12-PR-100-F011a)* and submit the form to the Quality Unit.
- Additionally, in the case of a customer return, the CSR will fill out the *Complaint Intake Information and Initiation* form *(Q13-PR-100-F019)* and submit the form to the Quality Unit.
    - CSR contacts Sales and the customer to determine if a credit is to be issued or if the product needs to be replaced; note on Intake form.
    - Quality Unit begins the complaint process following *Complaint Handling* procedure *(Q13-PR-100-019).*
    - CSR will communicate with the customer to arrange freight for the returned product.

Return of Product

- Once Return is approved and an RGA assigned, the CSR or Sales notifies the Plant Manager and Quality Unit the logistics of the return.
- Plant Manager, Quality Unit and Inventory will determine quarantine location for the return. Operator will be notified where to place the returned product and its expected arrival.
- Once the product is returned, Operator unloading the truck will sign for the return; retain a copy of the Bill of Lading plus any other paperwork involved with the shipment, placard the return with RGA and Quality Hold placards and notify the Quality Unit of arrival.
- Returned product tagged with a *Quality Hold* placards *(Q12-FM-100-002)* must be held under quarantine following *Quarantine and Auditing of Products* procedure *(Q12-PR-100-012).*
- The Quality Unit will then examine, sample and test the returned product as appropriate to evaluate whether a non-conformance or out-of-specification exists.

- 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.

Disposition of Returned Product

- The final 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-process, or proper disposal.

- Records of returned product shall be maintained and shall include the product type, lot number reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned product. All data should be recorded on the *Returned Product Report (Q12-PR-100-F011a)*. All *Returned Product Reports* should be logged on the *Returned Product Log (Q12-PR-100-F011b).*

- If a recall is deemed necessary, follow *Recall (Q12-PR-100-013).*

7.0 Reference Documents

Complaint Intake Information and Initiation Form	*(Q13-PR-100-F019)*
Complaint Handling	*(Q13-PR-100-019)*
Quality Hold	*(Q12-FM-100-002)*
Quarantine and Auditing of Products	*(Q12-PR-100-012)*
CAPA Procedure	*(Q13-PR-100-014)*
Returned Product Report	*(Q12-PR-100-F011a)*
Returned Product Log	*(Q12-PR-100-F011b)*
Recall	*(Q12-PR-100-013)*

8.0 Change Information

Review and general update.