1.0 Purpose

To provide the information needed to ensure that all Non-conforming material is documented and managed effectively. This procedure will explain how and when to use a *Non-conforming Material Report (Q12-PR-100-F017)* versus a *Deviation Report (Q13-PR-100-F024)* or *Out-of-Specification (OOS) Report (Q13-PR-100-F025).*

2.0 Scope

This procedure applies to any material including, but not limited to, raw materials, product or packaging where a special cause variation exists that is not the result of a deviation or change control. The product meets specifications but may not meet control limits or possess characteristics that are undesirable for the customer for whom it was produced (hard salt, crystal size, color, etc.).

3.0 Responsibility

The Quality Unit is responsible for ensuring that non-conforming product is documented and its disposition approved. When applicable, QA will oversee an investigation in order to determine root causes and the associated actions to prevent recurrence. All employees are required to inform their supervisor whenever they identify nonconforming material.

4.0 Safety Considerations

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

Identification

Identification of non-conforming material can occur at any stage from in-coming raw materials through production to final packaging. It can originate from internal auditing or a customer complaint.

All returned product will be initially classified as non-conforming unless later determined to be Out of Specifications (OOS). See *Out of Specifications Reporting (OOS) (Q13-PR-100-025)*

Segregation

When non-conforming product or material is discovered by an employee, he will immediately report it to the Production Manager and/or Quality. The non-conforming material must be tagged with a "Quality Hold" placard *(Quality Hold Q12-FM-100-002)* and placed in the designated areas in Manufacturing and Repackaging. Non-conforming material may be held in a bin as long as the bin is taped off with yellow tape and tagged with a "Quality Hold" placard. All placards must state the reason for being held and be appropriately signed.

Evaluation

The Quality Unit will perform the initial evaluation of non-conforming product in accordance with approved test and inspection procedures. Additionally, the risk to human health will be evaluated. A determination will be made as to whether an investigation will be required. If so, the CAPA process will be initiated by the Quality Unit.

Disposition

"Quality Hold" placards shall not be removed nor shall the material be moved from the non-conforming product area until a suitable disposition is developed. The Production Manager (or Designee) is authorized to remove "Quality Hold" placards if reviews indicate that the reported non-conformance is not legitimate or the product is acceptable. The Quality Unit carries ultimate authority as to whether a product is fit for use or shipment to an alternate customer. When required, the responsible Sales personnel will consult with the customer.

The results of the evaluation and resultant disposition determination will be documented using the *Non-conforming Material Report (Q12-PR-100-F017).* Dispositions resulting from the evaluation of nonconforming product/material may include:

- rework/reprocess to meet stated requirements
- scrap or other disposal (in accordance with applicable environmental controls)
- obtain (from relevant authority) a waiver of or deviation from requirements
- return to supplier
- put into inventory for possible future use for another application
- use as is (under customer concession or other required approval authority)

Documentation

Once a disposition has been determined, all applicable parties are to sign-off on the *Non-conforming Material Report (Q12-PR-100-F017)*. "Quality Hold" placards shall be returned to the Quality Unit for filing.

The current year of completed *Non-conforming Material Reports* that have been closed by the Quality Unit will be filed in the *Non-conforming Material Reports* binder. Thereafter, reports will be filed in the cGMP library and maintained for a period of 4 years.

7.0 Reference Documents

Non-conforming Material Report	*(Q12-PR-100-F017)*
Deviation Report	*(Q13-PR-100-F024)*
Out-of-Specification (OOS) Report	*(Q13-PR-100-F025b)*
Out-of-Specification Investigation (OOS)	*(Q13-PR-100-025)*
Quality Hold	*(Q12-FM-100-002)*

8.0 Change Information

Updated document to broaden the understanding of the classification of non-conforming material; used new format and numbering.