

# SOP: Segregation of Non-Conforming Materials

This SOP describes the process for **segregation of non-conforming materials** to ensure that defective or non-compliant products are properly identified, isolated, and prevented from entering the production line or reaching customers. It outlines steps for identification, labeling, separation, and storage of non-conforming items, roles and responsibilities for handling these materials, and procedures for documenting and reporting incidents to maintain product quality and compliance with regulatory standards.

## 1. Purpose

To establish a systematic process for identifying, isolating, withholding, and reporting non-conforming materials to prevent their inadvertent use or shipment and to maintain compliance with applicable regulatory requirements.

## 2. Scope

This procedure applies to all materials, components, sub-assemblies, and finished goods within the facility found or suspected to be non-conforming during receipt, storage, production, or inspection.

## 3. Definitions

Term	Definition
Non-Conforming Material	Any material or product that does not meet specified requirements or quality standards.
Segregation	Physical and systemic separation of non-conforming items from conforming materials.
NC Material Hold Area	Designated area for storing non-conforming materials until disposition.

## 4. Responsibilities

- **Quality Control (QC)/QA:** Identify and document non-conforming materials, initiate segregation, and complete required records.
- **Warehouse/Production Personnel:** Physically segregate and label non-conforming materials; report any suspected non-conformances immediately.
- **Supervisors/Managers:** Oversee compliance with this SOP; authorize disposition decisions.

## 5. Procedure

1. **Identification:**
  - Inspect incoming, in-process, or finished goods for defects or non-compliance.
  - Mark any suspected non-conforming items for review.
2. **Labeling:**
  - Clearly label non-conforming materials with a unique **NC tag/label** (e.g., red tag).
  - Include details such as part number, batch/lot number, date, reason for non-conformance, and initials of examiner.
3. **Segregation:**
  - Immediately move labeled non-conforming materials to a designated NC Material Hold Area.
  - Ensure non-conforming areas are distinctly marked and physically separated from conforming stock.
4. **Documentation:**
  - Complete a Non-Conformance Report (NCR) or similar record for each incident.
  - Record details of material, description of defect, quantity, and disposition status.
5. **Notification & Review:**
  - Notify relevant supervisors and QA personnel for further investigation and disposition determination (e.g., rework, scrap, return to vendor).

6. **Release/Disposal:**
- Release, rework, scrap, or return materials only after documented approval by authorized personnel.

◦ Update records to reflect final disposition of the material.

## 6. Documentation & Records

- Non-Conformance Reports (NCR)
- NC Material Log/Inventory Records
- Disposition/Corrective Action records
- Retain all records per company policy and regulatory requirements.

## 7. Training

All relevant personnel must receive initial and periodic training on this SOP and the proper handling of non-conforming materials.

## 8. References

- Company Quality Manual
- Applicable Regulatory Guidelines (e.g., ISO, GMP)

## 9. Revision History

Version	Date	Description	Approved By
1.0	2024-06-15	Initial Release	[Name/Signature]