

SOP: Identification and Segregation of Non-Conforming Products

This SOP details the process for the **identification and segregation of non-conforming products**, ensuring that products not meeting quality standards are promptly recognized and separated from conforming goods. It covers procedures for inspection, labeling, documentation, and storage of non-conforming items, facilitating effective quality control and preventing the mixing of defective products with acceptable inventory. This protocol aims to maintain product integrity, enhance customer satisfaction, and comply with regulatory requirements.

1. Purpose

To outline the steps for identifying, labeling, documenting, and segregating non-conforming products to prevent their unintended use or distribution.

2. Scope

This SOP applies to all employees involved in the inspection, handling, storage, and documentation of products at all company facilities.

3. Definitions

- **Non-Conforming Product:** Any product that does not meet specified quality requirements or standards.
- **Segregation:** The process of physically separating non-conforming products from conforming products.
- **Disposition:** The action taken regarding non-conforming products (e.g., rework, scrap, return to supplier).

4. Responsibilities

- **Quality Control (QC):** Conduct inspections and identify non-conforming products.
- **Warehouse Staff:** Segregate and store non-conforming products in designated areas.
- **Production Supervisor:** Ensure proper labeling and documentation.
- **Document Control:** Maintain non-conformance records.

5. Procedure

1. **Inspection**
 - Perform visual and/or functional inspection at scheduled checkpoints.
 - Record inspection results on the appropriate checklist or form.
2. **Identification**
 - Clearly label non-conforming products with a “Non-Conforming” tag indicating the nature of the defect, date, and inspector’s initials.
3. **Segregation**
 - Immediately move non-conforming products to a designated, clearly marked quarantine area.
 - Ensure physical barriers or visual indicators are present to prevent accidental mixing.
4. **Documentation**
 - Complete a Non-Conformance Report (NCR) detailing product description, quantity, nature of issue, and proposed disposition.
 - Update inventory management systems to reflect the status change.
5. **Disposition**
 - QC Manager or responsible authority determines whether the product will be reworked, scrapped, or returned to supplier.
 - Update records with final disposition decision and actions taken.

6. Records

- Inspection Checklists
- Non-Conformance Reports (NCRs)
- Inventory Logs
- Disposition Records

7. Related Documents

- Quality Manual
- Inspection and Testing SOP
- Corrective and Preventive Action (CAPA) Policy

8. Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-01	Initial issue	Quality Manager