Standard Operating Procedure (SOP)

Non-conformance Identification and Segregation Procedure

This SOP details the **non-conformance identification and segregation procedure**, emphasizing the systematic process for detecting products or materials that do not meet specified quality standards. It includes steps for recognizing non-conforming items, segregating them from conforming products to prevent unintended use or shipment, documenting discrepancies, and initiating corrective actions. The objective is to maintain product integrity, ensure compliance with quality requirements, and prevent the distribution of defective goods.

1. Purpose

To establish a standardized procedure for identifying, segregating, and managing non-conforming products or materials to ensure only products meeting quality standards are used or shipped.

2. Scope

This procedure applies to all personnel involved in the manufacturing, inspection, storage, and distribution of materials and products at *[Company Name]*.

3. Definitions

- **Non-conforming Item:** Any material, component, or product that fails to meet specified requirements or quality standards.
- **Segregation:** The process of physically separating non-conforming items from conforming ones.
- **Corrective Action:** Steps taken to eliminate causes of detected non-conformity and prevent recurrence.

4. Responsibilities

- **Production/Inspection Staff:** Identify and report non-conformances immediately.
- **Quality Assurance (QA):** Verify non-conformances, manage segregation, documentation, and initiate corrective actions.
- **Warehouse/Logistics:** Ensure segregated items remain isolated and are properly labeled.
- **Management:** Review non-conformance records and approve corrective actions.

5. Procedure

1. **Identification of Non-conformance**
    - During production or inspection, personnel must inspect materials/products for conformity to specifications.
    - Any deviations found must be reported to QA immediately.
    - Non-conforming items should be marked/tagged with a red label or other designated identifier.

2. **Segregation of Non-conforming Items**
    - Non-conforming items must be moved to a clearly marked and designated segregation area.
    - Ensure that segregated items are physically separated from conforming stock to prevent unintended mixing or usage.
    - Document the segregation in relevant logbooks or digital systems.

3. **Documentation**
    - Complete a Non-conformance Report (NCR) detailing the type and extent of non-conformance, items affected, date, and personnel involved.
    - Record all information accurately in the Non-conformance Register.

4. **Disposition and Corrective Action**
    - QA reviews NCR and investigates the root cause of non-conformance.
    - Determine appropriate disposition: rework, scrap, return to supplier, or acceptance with concession (if applicable).
    - Initiate corrective and preventive actions as necessary, assigning responsibilities and deadlines.
    - Verify and document completion of corrective actions.

5. **Release or Disposal**
    - Only upon QA approval may items be reprocessed or disposed of.
    - Update inventory and records to reflect the final status of the non-conforming items.

6. Records

- Non-conformance Reports (NCR)
- Non-conformance Register
- Corrective Action Logs
- Segregation Area Inventory Logs

7. References

- Quality Manual
- ISO 9001:2015, Section 8.7: Control of Nonconforming Outputs
- Internal Quality Control Procedures

8. Revision History

Version	Date	Description	Approved By
1.0	[YYYY-MM-DD]	Initial Release	[Name/Title]