Standard Operating Procedure (SOP)

Identification and Segregation of Non-Conforming Materials

This SOP describes the process for the **identification and segregation of non-conforming materials** to ensure quality control and prevent defective products from reaching customers. It includes procedures for detecting non-conformities, labeling and isolating affected materials, documenting discrepancies, and initiating corrective actions. The goal is to maintain product integrity, comply with quality standards, and facilitate continuous improvement within the production process.

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Department	Quality Assurance / Production		
Prepared by	[Name]	**Reviewed by**	[Name]
Approved by	[Name]	**Revision**	[Number]

1. Purpose

To establish a standardized procedure for the identification and segregation of non-conforming materials within the production process.

2. Scope

This procedure applies to all incoming, in-process, and finished materials at [Company Name].

3. Definitions

- **Non-conforming Material:** Any material or product that does not comply with specified requirements or quality standards.
- **Segregation:** The process of physically separating non-conforming materials from conforming materials to prevent unintended use.

4. Responsibilities

- **Quality Assurance (QA):** Oversees the identification, documentation, and segregation processes.
- **Production Staff:** Reports detected non-conforming materials and assists with segregation.
- **Warehouse Staff:** Ensures proper labeling and storage of segregated materials.

5. Procedure

1. **Detection of Non-Conformity**
    - Inspect materials during receiving, production, and final inspection stages.
    - Report findings to QA personnel immediately upon detection.
2. **Identification**
    - Clearly label non-conforming materials with a â€œNon-Conformingâ€ tag/sticker indicating:
        - Material Name/Code
        - Date Identified
        - Description of Non-Conformity
        - Inspector's Name
3. **Segregation**
    - Move non-conforming materials to a designated quarantine or rejection area.
    - Restrict access to this area to authorized personnel only.
    - Ensure materials are not used for production until disposition is determined.
4. **Documentation**
    - Record each occurrence in the Non-Conformance Register or appropriate logbook.
    - Attach supporting evidence (photos, inspection reports, etc.).
5. **Corrective Action**
    - Initiate investigation to determine the cause of non-conformity.
    - Implement corrective actions as per the CAPA (Corrective and Preventive Action) procedure.
    - Release, rework, or dispose of non-conforming materials according to management decision and

documented procedures.

6. Records

- Non-Conformance Register
- Material Inspection Reports
- Corrective and Preventive Action Records
- Disposition Forms

7. References

- [Applicable ISO/QMS Standard]
- Company Quality Manual
- CAPA SOP

8. Revision History

Revision	Date	Description of Change	Author
[Number]	[YYYY-MM-DD]	[Initial Release/Update Description]	[Name]