SOP Template: Quarantine and Segregation Guidelines for Non-Conforming Materials

This SOP provides detailed **quarantine and segregation guidelines for non-conforming materials**, ensuring that all materials that do not meet quality standards are properly identified, isolated, and controlled. The procedures include steps for immediate segregation, labeling, documentation, and secure storage of non-conforming items to prevent unintended use or mixing with conforming materials. It also outlines responsibilities for verification, disposition, and corrective action to maintain compliance with quality management systems and regulatory requirements, thereby safeguarding product integrity and operational efficiency.

1. Purpose

To establish procedures for the identification, quarantine, segregation, documentation, and disposition of non-conforming materials to prevent their unintended use and ensure compliance with quality standards.

2. Scope

This procedure applies to all incoming, in-process, and finished materials identified as non-conforming within the facility.

3. Responsibilities

- **Production/Receiving Staff:** Identify and immediately segregate non-conforming material.
- **Quality Assurance (QA):** Verify non-conformance, ensure proper segregation, and oversee labeling and documentation.
- **Warehouse Personnel:** Store non-conforming materials in designated quarantine areas.
- **Quality Manager:** Approve disposition and corrective actions.

4. Procedure

1. **Identification:** Immediately tag or mark any suspected non-conforming material.
2. **Segregation:** Remove and physically separate non-conforming material from conforming material to prevent mix-up.
3. **Quarantine:** Transfer material to a clearly marked, secured quarantine area.
4. **Labeling:** Clearly label materials with a â€œNon-Conformingâ€ tag, including details such as material ID, batch/lot number, date, and reason for non-conformance.
5. **Documentation:** Record all relevant information in the non-conformance log or deviation report.
6. **Verification:** QA verifies proper segregation, quarantine, and documentation.
7. **Disposition Decision:** Quality Manager reviews investigation and decides disposition (rework, return to vendor, scrap, etc.).
8. **Corrective Action:** Document root cause and corrective actions as necessary. Implement changes to prevent recurrence.

5. Documentation

- Non-Conformance Report Form
- Quarantine Log Book
- Corrective and Preventive Action (CAPA) Records
- Label templates for non-conforming items

6. Definitions

- **Non-Conforming Material:** Any material that fails to meet required specifications or quality standards.
- **Quarantine Area:** A secured area designated for holding non-conforming materials separate from conforming stock.

7. References

- ISO 9001:2015 â€“ Quality Management Systems
- Internal Quality Manual
- Applicable Regulatory Requirements

8. Revision History

Version	Date	Description	Approved By
1.0	2024-06-01	Initial release	Quality Manager

Note: Unauthorized movement or use of non-conforming materials is strictly prohibited and may result in disciplinary action.