Standard Operating Procedure (SOP)

Non-conforming Material Identification and Quarantine Steps

Purpose:

To outline procedures for detecting, labeling, documenting, and quarantining materials that do not conform to specified quality standards. The intent is to control non-conforming materials and prevent their unintended use or shipment until proper corrective actions are taken.

Scope:

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

Responsibilities:

- **Quality Assurance (QA):** Oversees the identification, documentation, and quarantine process.
- **Production/Receiving Staff:** Report and assist in identifying non-conforming materials.
- **Warehouse Personnel:** Move and store materials in designated quarantine areas.

Definitions:

- **Non-conforming Material:** Any material or product failing to meet required specifications or quality standards.
- **Quarantine:** Physical or procedural isolation of materials to prevent unintended use or shipment.

Procedure:

1. **Identification of Non-conforming Material**
    - Inspect materials at receiving, during process, or after production for compliance with quality standards.
    - Criteria for non-conformance may include visual defects, incorrect labeling, out-of-specification results, or incomplete documentation.
2. **Labeling of Non-conforming Material**
    - Attach a "Non-conforming" or "Quarantine" label to each affected item or batch.
    - Labels must include: date, description of non-conformance, identified by, and reference to the non-conformance report number.
3. **Quarantine**
    - Physically segregate non-conforming materials in a clearly marked quarantine area.
    - Restrict access to only authorized personnel.
4. **Documentation**
    - Complete a Non-conformance Report (NCR) or similar documentation.
    - Record material details, nature of non-conformance, location, and quarantine status in the appropriate logbook or electronic system.
5. **Control**
    - Ensure non-conforming materials are not used, processed, or shipped until reviewed and dispositioned by QA or relevant authority.

Records:

- Non-conformance Report (NCR)
- Quarantine area log
- Corrective action records, if applicable

References:

- Company Quality Manual
- ISO 9001:2015 (Section 8.7 Control of Nonconforming Outputs)
- Internal forms/templates as applicable

Note: Review this SOP annually or upon relevant process changes.