Standard Operating Procedure (SOP)

Recording Inspection Results and Traceability Requirements

This SOP details the **recording inspection results and traceability requirements**, covering the systematic documentation of inspection findings, procedures for ensuring accuracy and completeness, methods for maintaining traceability of products and processes, and compliance with regulatory standards. The goal is to enhance quality control, enable effective tracking of product history, and support accountability and transparency throughout the production and inspection cycle.

1. Purpose

To define standardized procedures for recording inspection results and ensuring traceability of products and processes.

2. Scope

This SOP applies to all products, materials, and processes subject to inspection within *[Department/Company Name]*.

3. Responsibilities

- **Inspectors:** Perform inspections, accurately complete records, and verify traceability markings.
- **Supervisors:** Review inspection records for accuracy, ensure traceability systems are maintained, and provide training.
- **Quality Assurance:** Audit records and traceability logs for compliance with regulatory and standard requirements.

4. Definitions

- **Inspection Results:** Documented outcomes of product/process examinations, including acceptance or rejection.
- **Traceability:** The ability to track the history, application, or location of an item using recorded data.

5. Procedure

1. **Preparation:**
    - Obtain current inspection forms or electronic records.
    - Verify applicable product identification and batch/lot numbers.
2. **Recording Inspection Results:**
    - Record inspection data immediately upon completion of each inspection step.
    - Include: date/time, inspector's name/signature, product ID, lot/batch number, inspection criteria, results, and observations.
    - For nonconformances, document description and reference the corrective action report.
3. **Ensuring Accuracy and Completeness:**
    - Double-check all entries for legibility and completeness before submission.
    - No blank fields allowed. Use â€œN/Aâ€ if not applicable.
4. **Maintaining Traceability:**
    - Assign unique identifiers (e.g., serial, batch, or lot numbers) to all inspected items.

- Record all identifier information in both inspection and traceability registers/logs.
- Link inspection results to corresponding product and process records.

5. **Retention and Storage:**
   - Store inspection and traceability records in secure, designated locations (physical or electronic).
   - Retain records for the duration specified in *[applicable regulation or company policy]*.

6. Forms and Records

Form/Record	Description	Retention Period	Storage Location
Inspection Record Form	Documents detailed results of each inspection	[e.g., 5 years]	[e.g., Quality Dept. Archive, QMS Database]
Traceability Log/Register	Tracks unique identifiers for lots/batches	[e.g., 5 years]	[e.g., Quality Mgmt. System]
Nonconformance Report	Records details of nonconforming items	[e.g., 5 years]	[e.g., NCR Database]

7. Compliance

All procedures for recording inspection results and maintaining traceability must comply with applicable standards such as ISO 9001, GMP, and other relevant regulatory requirements.

8. Revision History

Revision	Date	Description	Approved by
1.0	[Insert date]	Initial issue	[Name/Title]