SOP: Defective Sample Handling and Storage Instructions

This SOP provides detailed **defective sample handling and storage instructions**, covering procedures for identifying, segregating, labeling, and securely storing defective samples. It emphasizes maintaining sample integrity, preventing cross-contamination, documenting sample details accurately, and ensuring compliance with quality control standards. The instructions aim to facilitate proper management of defective samples to support accurate analysis, traceability, and appropriate disposal or reprocessing.

1. Purpose

To define standardized procedures for the identification, handling, segregation, labeling, storage, documentation, and disposition of defective samples, ensuring integrity, traceability, and compliance with quality standards.

2. Scope

This SOP applies to all laboratory/production staff involved in the handling, storage, and management of defective samples within the facility.

3. Responsibilities

- **All Personnel:** Follow procedures described in this SOP.
- **Supervisors/Quality Control:** Ensure compliance, monitor adherence, provide training, and authorize sample disposition.
- **Records Keeper:** Maintain accurate documentation regarding defective samples.

4. Definitions

- **Defective Sample:** Any sample that does not meet pre-established quality, integrity, or specification criteria.
- **Segregation:** Physical separation of defective samples from non-defective or usable samples.

5. Procedure

1. **Sample Identification:**
    - Visually and/or analytically inspect each sample to identify defects.
    - Mark identified defective samples immediately.
2. **Segregation:**
    - Move defective samples to a designated 'Defective Sample Area' away from compliant samples.
3. **Labeling:**
    - Affix a red â€œDEFECTIVEâ€ label or tag with the following information:
        - Sample ID/Batch Number
        - Date and time of identification
        - Name/initials of inspector
        - Description of defect
4. **Storage:**
    - Store in containers appropriate to the sample type and potential hazard.
    - Ensure containers are sealed, clearly labeled, and stored in restricted-access locations.
    - Prevent exposure to contaminants, moisture, extreme heat/cold, or direct sunlight as applicable.
5. **Documentation:**
    - Record each defective sample in the Defective Sample Log (see template below).
    - Maintain traceability from identification to final disposition.
6. **Prevention of Cross-Contamination:**
    - Use dedicated tools and PPE when handling defective samples.
    - Clean and disinfect any surfaces or equipment used.
7. **Disposition:**
    - Dispose of or reprocess defective samples as per approved protocols and after QC review/authorization.
    - Document actions taken and retain records for audit purposes.

6. Defective Sample Log Template

Sample ID/Batch No.	Date Identified	Inspector Name/Initials	Description of Defect	Storage Location	Disposition Action	Date of Disposition

7. References

- Company Quality Manual
- ISO 9001:2015 - Quality management systems
- Internal SOPs on sample disposal and reprocessing

8. Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-01	Initial release	[Approver Name]