

SOP: Defect Identification, Segregation, and Reporting Processes

This SOP details the **defect identification, segregation, and reporting processes** to ensure product quality and compliance with industry standards. It covers the systematic inspection of products to detect defects, procedures for segregating defective items to prevent their distribution, and accurate reporting mechanisms to document and communicate defects for corrective action. The objective is to maintain high-quality standards, reduce waste, and improve overall operational efficiency by addressing defects promptly and effectively.

1. Purpose

To establish clear processes for identifying, segregating, and reporting product defects, ensuring timely corrective actions and maintaining product quality.

2. Scope

This SOP applies to all personnel involved in the inspection, handling, and reporting of defective products across all production and warehousing areas.

3. Definitions

| Term | Definition |
|-------------|--|
| Defect | An imperfection or non-conformity in a product that affects its intended function, quality, or compliance with requirements. |
| Segregation | The physical separation of defective items from conforming products to prevent accidental use or distribution. |
| Reporting | The documentation and communication of identified defects for the purpose of corrective and preventive action. |

4. Responsibilities

- Quality Control (QC) Personnel:** Conduct inspections, document findings, and initiate segregation and reporting procedures.
- Production Staff:** Immediately notify QC of suspected defects, isolate defects as directed.
- Supervisors/Managers:** Review defect reports, initiate corrective actions, and ensure compliance with SOP.

5. Procedure

5.1 Defect Identification

- Inspect materials/products at designated checkpoints as per inspection plan.
- Identify visual, dimensional, or functional non-conformities based on specifications and quality standards.
- Tag or mark defective items immediately with a standardized label (e.g., "Defective - Do Not Use").
- Record details of defects found using the Defect Report Form (see Section 6).

5.2 Defect Segregation

- Move tagged/identified defective items to a designated segregation area (clearly marked and secured).
- Ensure segregated items are not accessible for further processing or distribution until disposition is determined.

- 3. Maintain a segregation log, including item description, quantity, date, and defect type.

5.3 Defect Reporting

- 1. Complete the Defect Report Form for each incident, providing comprehensive information.
- 2. Submit reports to the Quality Supervisor/Manager for review and disposition instructions.
- 3. Notify relevant departments (Production, Inventory, Management) as necessary for follow-up actions.
- 4. File completed reports for traceability and audit purposes.

6. Defect Report Form Template

| Section | Details |
|-------------------------|---------|
| Date of Identification | |
| Inspector Name/ID | |
| Product/Batch Details | |
| Defect Description | |
| Quantity Affected | |
| Location of Segregation | |
| Corrective Action Taken | |
| Remarks/Comments | |

7. Records

- Defect Report Forms
- Segregation Log
- Corrective Action Records

8. References

- Quality Manual
- Inspection Plan
- Industry-specific regulations and standards

9. Revision History

| Revision | Date | Description | Approved By |
|----------|------|-----------------|-------------|
| 01 | | Initial Release | |