SOP: Product Quality Inspection and Conformity Assessment

This SOP details the procedures for **product quality inspection and conformity assessment**, covering the criteria for quality standards, inspection methods, sampling techniques, testing protocols, documentation requirements, non-conformance management, corrective actions, and final product approval. The goal is to ensure that all products meet specified quality requirements and regulatory standards, guaranteeing customer satisfaction and maintaining compliance throughout the production process.

1. Purpose

To define a standardized approach for inspecting and assessing the conformity of products against quality requirements and regulations, ensuring only compliant products proceed to customers.

2. Scope

Applies to all products manufactured or received for distribution within the facility.

3. Responsibilities

- **Quality Assurance (QA):** Oversees inspection processes, reviews records, and verifies corrective actions.
- **Quality Control (QC) Inspectors:** Conduct product inspections, record observations, escalate non-conformities.
- **Production Supervisor:** Ensures compliance with inspection protocols, supports corrective actions.

4. Quality Standards and Criteria

- All products must comply with internal quality specifications and applicable regulatory standards.
- Reference master product specification documents for detailed requirements.

5. Inspection Methods

Inspection Stage	Method	Responsible
Incoming Materials	Visual and dimensional check, certificate review	QC Inspector
In-process	Sample checks, process monitoring	QC Inspector
Final Product	Comprehensive review and testing	QA/QC

6. Sampling Techniques

- Adopt **AQL** (Acceptable Quality Level) sampling plans as per ISO 2859 or custom company criteria.
- Document each lot's sample size and selection method in the inspection record.

7. Testing Protocols

- Perform functional, performance, safety, and reliability tests as per product-specific procedures.
- Calibrate all testing equipment prior to use and maintain calibration records.

8. Documentation Requirements

- Maintain detailed inspection and test records for every batch/lot.
- Use standardized forms/checklists and attach supporting evidence (photos, test results).
- Store records in electronic or hard copy as per company retention policy.

9. Non-Conformance Management

- Immediately identify and segregate non-conforming products from conforming ones.
- Document non-conformities in the Non-Conformance Report (NCR).
- Notify QA and Production Supervisors for disposition.

10. Corrective Actions

- Investigate root causes of non-conformance and document findings.
- Implement corrective and preventive actions (CAPA) and track their effectiveness.
- Re-inspect products after correction before approval.

11. Final Product Approval

- Grant product release only if all inspection and test results meet requirements.
- QA final sign-off required before product dispatch.

12. References and Related Documents

- Master Product Specification
- Inspection and Test Records
- Non-Conformance Report (NCR) Form
- CAPA Procedure
- Applicable Industry Standards (e.g., ISO 9001, ISO 2859)