Sampling Inspection Planning Procedure

Role	Position/Department	Name	Date
Author			DD YYYY
Reviewer			DD YYYY
Approver			DD YYYY

[Company Name], Inc.

Revision History

Ver.	Effective Date^p^pRevision Details (Reason, Changes, Affected Documents)^p^pAuthor/Reviewer/Approver
Version^p1.0	Effective Date^p20XXMMDDYYYY^p^pReason^pInitial Release (For subsequent versions, describe the reason for revision here)^p^pContent^pInitial Release (For subsequent versions, describe the revision content here)^p^pAffected Documents^pN/A (For subsequent versions, list affected documents here)^p^pRole^pAuthor: XXX^pReviewer: XXX^pApprover: XXX

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1. Purpose

The purpose of this procedure is to ensure that sampling inspection methods employed by [Company Name], Inc. (hereinafter referred to as the Company) are established based on statistically sound principles. This procedure defines the methodology for developing and implementing sampling plans that provide objective evidence of product conformance to specified requirements while optimizing inspection resources.

2. Scope

This procedure applies to all sampling methods used in conducting inspections throughout the Company's quality system, including but not limited to receiving inspection, in-process inspection, and final inspection. This procedure is applicable when acceptance sampling by attributes is used as specified in ANSI/ASQ Z1.4-2008.

3. Definitions

Term	Definition
Receiving Inspection	Inspection conducted to determine whether purchased items from external suppliers conform to specified requirements.
In-Process Inspection	Inspection conducted during the manufacturing process to determine whether in-process work-in-progress meets specified requirements. This includes controlling products through required inspection, testing, or other verification activities until completion and documentation, or until necessary approval is obtained.
Final Inspection (Product Inspection)	Inspection conducted to determine whether finished products meet specified product requirements before release.
AQL^p(Acceptance Quality Limit)	The maximum percent nonconforming (or the maximum number of nonconformities per hundred units) that, for purposes of acceptance sampling, can be considered satisfactory as a process average. As defined in ANSI/ASQ Z1.4-2008 (ISO 2859-1:1999), the AQL is expressed as percent defective or defects per hundred units.
Lot	A collection of units of product from which a sample is to be drawn and inspected to determine conformance with the acceptability criteria. As defined in ANSI/ASQ Z1.4-2008.
Sample Size	The number of units of product from the lot to be inspected. As defined in ANSI/ASQ Z1.4-2008.
Acceptance Number (Ac)	The maximum number of nonconforming units or nonconformities that can be found in a sample while still permitting acceptance of the lot. As defined in ANSI/ASQ Z1.4-2008.
Rejection Number (Re)	The minimum number of nonconforming units or nonconformities found in a sample that will cause rejection of the lot. As defined in ANSI/ASQ Z1.4-2008.

4. Roles and Responsibilities

Role	Responsibilities
Inspector	- Prepare the Sampling Inspection Plan Sheet (Form ID: MD-QMS-F2501)^p- Review the Sampling Inspection Plan Sheet^p- Conduct sampling inspection based on approved sampling plan
Inspection Manager	- Approve the Sampling Inspection Plan Sheet (Form ID: MD-QMS-F2501)^p- Ensure

	sampling plans comply with statistical principles and regulatory requirements

5. Procedure

5.1 Sampling Plan Development

The Company employs acceptance sampling by attributes in accordance with ANSI/ASQ Z1.4-2008 (Sampling Procedures and Tables for Inspection by Attributes), which is the U.S. adoption of ISO 2859-1:1999. This internationally recognized standard provides statistically valid sampling procedures for lot-by-lot inspection.

When destructive testing or economic considerations necessitate deviation from ANSI/ASQ Z1.4-2008, alternative statistically valid sampling methods may be employed. In such cases, a separate sampling plan document shall be prepared with full statistical justification, limited to the specific inspection application, and approved by the Inspection Manager.

Responsible Party	Activity	Deliverable	Notes
Inspector	Prepare Sampling Inspection Plan Sheet for each inspection type or product category.^p^pDetermine:^p- Lot size range^p- Inspection level (I, II, or III)^p- AQL value^p- Sample size code letter^p- Sample size^p- Acceptance number (Ac)^p- Rejection number (Re)	Sampling Inspection Plan Sheet^p(MD-QMS-F2501)	- Create separate plan sheets for each inspection type (receiving, in-process, final) or product category as appropriate^p^p- Apply ANSI/ASQ Z1.4-2008 standard for statistically valid sampling^p^p- Reference Attachment 1 for sample size code letters and master sampling tables^p^p- General Inspection Level II is typically used unless specified otherwise^p^p- Document rationale for any deviation from standard sampling plans
Inspector^p(different from preparer)	Review the Sampling Inspection Plan Sheet for:^p- Correct application of ANSI/ASQ Z1.4-2008^p- Appropriate AQL selection^p- Proper sample size determination^p- Completeness and accuracy	Reviewed Sampling Inspection Plan Sheet^p(MD-QMS-F2501)	- Reviewer must be different from preparer^p^p- Verify calculations match standard tables^p^p- Confirm plan meets inspection requirements^p^p- Document review findings
Inspection Manager	Approve the Sampling Inspection Plan Sheet.	Approved Sampling Inspection Plan Sheet^p(MD-QMS-F2501)	- Final approval authority^p^p- Ensure plan compliance with quality system requirements and regulatory standards^p^p- Approved plan becomes effective for inspection