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VALIDATION PLAN

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Abstract:
This document describes validation of processes or products.

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1.0 Scope

Procedures [redacted] may be used to validate conformance to requirements of the following:

a. End items
b. Components or basic materials
c. Operations or services
d. Materials in process (cleaning, sterilization, preservation, etc)
e. Supplies in storage
f. Maintenance operations
g. Data or records
h. Administrative procedures

Note: use of the word "product" [redacted] also refers to processes, services and other deliverables.

1.1 Product Requirements

The Company is required to produce and submit product that meets all contract and specification requirements. Each step of the manufacturing process must be controlled to [redacted] The Company's quality system must be established and operated to consistently produce products that meet all requirements. Absence of any inspection or process control requirement in the contract does not relieve the Company of its responsibility for assuring that all products submitted for acceptance conform to all requirements of the contract.

1.2 Limitations

The procedures [redacted] are not intended for use with destructive tests or when product screening is not feasible or desirable and/or when [redacted] In such cases, validation procedures will be defined in the product specification. There are too many products, devices, processes and manufacturing facilities to list all validation functions. Several broad concepts have general applicability that manufacturers can use successfully as a guide in validating a product. Although the particular requirements of validation will vary according to such factors as [redacted] the broad concepts stated [redacted] have general applicability and provide an acceptable framework for building a comprehensive approach to the validation process.

2.0 Recommended Reading

ANSI/NCSL Z540-1 - General Requirements for Calibration Laboratories and Measuring and Test Equipment
ANSI Z1.1/ASQC B1 - Guide for Quality Control Charts.
ANSI Z1.2/ASQC B2 - Control Chart Methods of Analyzing Data.
ANSI Z1.3/ASQC B3 - Control Chart Method of Controlling Quality During Production.
ASME Y14.5M - Dimensioning and Tolerancing
ISO 10012 - Quality Assurance Requirements for Measuring Equipment

2.1 Order of precedence

Nothing in this document supersedes applicable laws and regulations unless a specific exemption has been obtained.

3.0 Definitions

-Acceptance

The act of an authorized representative of the Customer by which the Customer, for itself or as agent of another, assumes ownership of supplies tendered or approves specific services rendered as partial or complete performance of the contract.

-Alpha risk (a)

This is also known as the producer's risk. When referring to lot acceptance sampling, it is the probability that an acceptable lot will be rejected. When applied to control charts, the alpha risk is the probability that an out-of-control signal will be observed when the process is actually in control.

-ANOVA (Analysis of Variance)

A technique that subdivides the total variation of a set of data into meaningful component parts associated with specific sources of variation for the purpose of testing some hypothesis on the parameters of the model or estimating variance components. The technique, in conjunction with the F ratio, is used to provide a test of significance for the effects of these sources of variation and/or to obtain estimates of the variances attributable to these sources. The basic assumptions are that the effects due to all the sources of variation are additive and that the experimental errors are independently and normally distributed with zero mean and have equal variances throughout all subdivisions of data.

-Benchmarking

A continuous, systematic process for evaluating the products, services and work processes of organizations that are recognized as representing best practices for the purpose of organizational improvement.

-Beta risk (b)

This is also known as the consumer's risk. When referring to lot acceptance sampling, it is the probability that a lot of rejectable quality will be accepted. When applied to control charts, the beta risk is the probability that an out-of–control condition will not be observed when it actually exists.

-Bonus Tolerance (also known as "Increase in Positional Tolerance")

Where the actual size of a feature is at maximum material condition (MMC), the geometric tolerance is zero. Where the actual size of the feature has departed from MMC, an increase in the geometric tolerance is allowed (bonus tolerance) equal to the amount of such departure.
The total permissible variation is maximum at least material condition (LMC). Bonus tolerancing is applied on an MMC, LMC or 'regardless of feature size" (RFS) basis. The bonus tolerance, datum and symbols are contained within feature control frames. This tolerance is in addition to the feature tolerance and permits the feature location and form to vary from true (theoretically exact) position. Basically, while maintaining the specified size limits of the feature, the center, axis or feature surface may not exceed the boundary established by the bonus tolerance. This may produce a distribution that is not centered on nominal and/or skewed. A detailed explanation is available in ASME Y14.5M, Dimensioning and Tolerancing.

-Cause and Effect Diagram

A method that graphically illustrates the factors (Causes) that impacts on a quality characteristic or contributes to some problem (the Effect). The causes are categorized under general headings that relate to the effect. Commonly used headings are; "Materials, Methods, People, Machines, Measurement and Environment". This technique is used to aid in determining and ranking the severity or impact of the causes on the effect.

-Central tendency

Central tendency is the tendency of a set of measurement data to cluster or to center about certain numerical values.

-Check Sheets

A check sheet is a data collection sheet where categories or ranges of possible measurements are printed on the sheets. The data collector records tally or tick marks across from the appropriate category or measurement. It allows the user to systematically record and compile data from historical sources or observations as they happen so that patterns and trends can be clearly detected and shown.

-Chi-square test (goodness of fit test)

This is a statistical test that provides confidence levels and intervals to describe whether or not the data truly approximates a particular distribution such as the normal distribution.

-Common Cause

Factors that contribute to variation and are inherent to the process. When a process is in statistical control, the only variation existing comes from common causes. Common cause variation can only be reduced by management action on system components, e.g., improving equipment capability, better training, etc. (Also called chance cause).

-Continuous process improvement

This is a goal of quality driven organizations to continually improve and optimize their processes.

-Contract quality requirements

The technical requirements relating to the quality of the product - contract clauses prescribing inspection - other quality controls incumbent on the Company to assure that the product conforms to contractual requirements.

-Critical characteristic

A characteristic that experience and judgment indicate must be met to avoid hazardous or unsafe conditions for individuals using, maintaining or depending upon the product; or that experience and judgment indicate must be met to assure performance of the end product.

-Critical nonconforming unit

A unit of product that fails to conform to specified requirements for one or more critical characteristics.

-Customer quality assurance

The various functions performed by the Customer to determine whether a Company has fulfilled the contract obligations pertaining to quality and quantity.

-Cycle variation

This is the variation from piece to piece with no time element involved. The pieces could have been made in any time order.

-Histogram

A Histogram is plot of frequency distribution in the form of a bar chart whose bases are equal to the cell interval and whose areas are proportional to the frequencies. It is used to summarize data from a process that has been collected over a period of time and graphically presents its frequency distribution.

-Inspection

Examining and testing supplies or services including raw materials, components and intermediate assemblies to determine whether they conform to requirements.

- Installation qualification

Establishing confidence that process equipment and ancillary systems are capable of consistently operating within established limits and tolerances.

-Key characteristic

The feature of a material, part or process whose variation has a significant influence on product fit, performance, service life or manufacturability.

-Major characteristic

A characteristic, other than critical, that must be met to avoid failure or reduced usability of a product. Major characteristics will require more verification effort than minor characteristics.

VL-VII requires the highest level of effort and the effort decreases as the VL decreases to the lowest level VL-I.

-Major nonconforming unit

A unit of product that fails to conform to specified requirements for one or more major characteristics but conforms to all critical characteristics.

-Minor characteristic

A characteristic, other than critical or major, whose departure from its specification requirement is not likely to reduce the usability of a product or whose departure from established standards has little bearing on the effective use or operation of the unit.

-Minor nonconforming unit

A unit of product that fails to conform to specified requirements of one or more minor characteristics but conforms to all critical and major characteristics.

-Nonconformance

A departure from a specified requirement for any characteristic.

-Nonconforming unit

A unit of product that has one or more nonconformances.

-Normal probability paper

Paper that is scaled to show graphically how close a variables data distribution approximates a normal distribution is called normal probability paper.

-Normality

This is the tendency of variables data to pattern itself in a bell shaped curve. Many processes innately behave in this manner. Some processes do not produce output whose measurements can be characterized by the normal distribution; therefore, before performing operations that depend on assumptions of normality, it is wise to test those assumptions.

-Pareto Analysis

A Pareto Analysis is used to graphically focus efforts on the problems that offer the greatest potential for improvement by showing their relative frequency, cost or other metric in a descending bar graph. It is based on the proven Pareto principle: approximately 20% of the sources cause approximately 80% of any problem.

-Poka-Yoke

Poka-Yoke is Japanese for “mistake proofing”. These devices are used either to prevent the special causes that result in defects or to inexpensively inspect each item that is produced to determine whether it is acceptable or defective. A Poka-Yoke device is any mechanism that either prevents a mistake from being made or makes the mistake obvious.

-Positional variation

This is the within piece variation. (e.g., measuring the paint thickness on the fender of a truck.)

-Process performance qualification

Establishing confidence that the process is effective and reproducible.

-Product performance qualification

Establishing confidence through appropriate testing that the finished product produced by a specified process meets all release requirements for functionality and safety.

-Production interval

A period of production under continuous sampling assumed to consist of essentially homogeneous quality. It is normally a single shift. It can be a day if it is reasonably certain that shift changes do not affect quality of product but shall not be longer than a day.

-Prospective validation

Validation conducted prior to the distribution of either a new product, or product made under a revised manufacturing process, where the revisions may affect the product's characteristics.

-Quality

The composite of material attributes including performance features and characteristics of a product to satisfy a given need.

-Quality assurance

A planned and systematic pattern of all actions necessary to provide adequate confidence that adequate technical requirements are established; products conform to established technical requirements and satisfactory performance is achieved.

-Quality audit

A systematic examination of the acts and decisions with respect to quality in order to independently verify or evaluate the operational requirements of the quality program or the specification or contract requirements of the product.

-Quality program

A program which is developed, planned and managed to cost effectively carry out all efforts to affect the quality of materials from concept through validation, full-scale development, production, deployment and disposal.

-Quality system

This is a documented procedure, written by the supplier explaining just how the organization will control quality in its processes and/or production of product.

-Rational subgroup

These are subgroups that are rationally or logically selected to only include common cause variability.

-Retrospective validation

Validation of a process for a product already in distribution based upon accumulated production, testing and control data.

-Run/Trend Charts

A run (or trend) chart is a line graph of the data, with time units represented on the x-axis and the data values on the y-axis. This type of chart is used to show visual signals in the 'behavior' of the process data with time; it is not a control chart per se and typically does not include any form of limits.

-Scatter Diagram

A scatter diagram is an X-Y plot of paired data from two variables. It is used to examine the strength of the relationship between a variable plotted on the horizontal axis and a second variable plotted on the vertical axis. A scatter diagram provides visual information that should be used in conjunction with investigations such as correlation analyses.

-Screening inspection

An inspection process whereby every unit is checked and all nonconforming units are removed; also referred to as 100 percent inspection.

-Shapes of distributions

These are the patterns formed by data when placed on a histogram.

-Shapiro-Wilk Test

The Shapiro-Wilk Test is a quantitative test for normality. It is designed for sample sizes less than or equal to 2000 and it computes the Shapiro-Wilk statistic (W). The statistic measures the strength of linear relationship between the set of data and the expected Normal distribution.

-Short run SPC

Short run SPC is a method for using control charts when a small number of items are manufactured; too few to use traditional control charts.

-Skewness

This is an indication of asymmetry of the data distribution. If skewed, a distribution is skewed to the right or left. If skewed to the right, the distribution has a long "tail" to the right and if skewed to the left, the distribution has a long "tail" to the left.

-Special Cause

A factor that contributes to variation and that is feasible to detect and identify. Examples are operator error or a faulty set-up.

-Stratified Sampling

The process of selecting units deliberately from various locations within a lot or batch or from various phases or periods of a process to obtain a sample. An attempt is made with stratified sampling to select known homogeneous areas within a lot that is not homogeneous - random samples are then taken from these various locations, usually proportional in number to the size of the strata. If the strata are known, stratified random sampling will reduce the sampling variability.

-Taguchi loss function

A formula that assigns a monetary value to the loss to society incurred due to a quality characteristic deviating from its optimum (target) value.

-Temporal variation

This is the measured piece to piece variation of a characteristic over time.

-Traceability

The ability to trace the history, application or location of an item or activity, or similar items or activities by means of recorded identification.

-Transformations

A mathematical process that changes data into a desired distribution (e.g., a normal distribution).

-Type I Error

The incorrect decision that a process is unacceptable when, in fact, perfect information would reveal that it is located within the zone of acceptable processes. (Ex. The decision to reject a lot of material that does not contain enough nonconformities to be classified as unacceptable).

-Type II Error

The incorrect decision that a process is acceptable when, in fact, perfect information would reveal that it is located within the zone of rejectable processes. (Ex. The decision to accept a lot of material that contains enough nonconformities to be classified as unacceptable).

-Validation

Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.

-Validation protocol

A written plan stating how validation will be conducted, including test parameters, product characteristics, production equipment, and decision points on what constitutes acceptable test results.

-Verification level (VL)

Prescribes the level of significance or utility of a characteristic to the user. The amount of effort to assure conformance can be allocated on the basis of importance to the user.

-Worst case

A set of conditions encompassing upper and lower processing limits and circumstances, including those within standard operating procedures, which pose the greatest chance of process or product failure when compared to ideal conditions. Such conditions do not necessarily induce product or process failure.

-ZBA

Zero Based Acceptance (ZBA) plans are sampling plans in which the acceptance number is zero for any sample taken. They are also referred to as C=0 and Accept on Zero (AoZ) sampling plans.

4.0 General

4.1 Quality System

The Company shall establish and implement an internal prevention-based quality system as a means of ensuring that all products conform to requirements specified by the contract and associated specifications and standards. The acceptability of the quality system is dependent on compliance with ISO 9001 or equivalent - demonstration of its process focus - and the availability of objective evidence of its implementation and effectiveness. Using ISO 9001 will not in itself assure quality products; however, it will assure [redacted]

4.1.1 Quality system plan

The quality system shall be documented and shall be subject to on-site Customer review throughout the contract. It shall include, at a minimum, [redacted]

4.1.2 Prevention-based quality system

The quality system shall demonstrate its prevention-based outlook by meeting the following objectives throughout all areas of contract performance:

a. [redacted]
b.
c.
d.
e.
f.
g.

4.1.3 Process focus of quality system

To demonstrate a process focus, the Company shall demonstrate that the manufacturing process and its related processes have [redacted] to show that they are:

a. [redacted]
b.
c.
d.
e.
f.
g.

4.1.4 Objective evidence of quality system implementation and effectiveness

4.1.4.1 Examples of evidence regarding process improvement.

a. [redacted]

b. [redacted]
c.
d.
e.

4.1.4.2 Examples of evidence regarding process control.

a. [redacted]
b.
d.
e.
f.
g.
h.
i.
j.

4.1.4.3 Examples of evidence regarding product conformance

a.
b.
c.
d.
e.

4.2 Validation Overview

It is recognized that sampling inspection alone does not control or improve quality. Product quality comes from [redacted] When such activities are effective, sampling inspection is a redundant effort and an unnecessary cost. This [redacted] provides a selection of tools that can be used to determine [redacted] Tools [redacted] must be selected and used according to the technical requirements of the product – not all tools are applicable to every project but their use will give more meaningful results than just determining if all test results fall within

specifications. Meeting technical specifications alone may not guarantee that requirements will be consistently met. A validation program must quantify the assurance level by [redacted] The tools [redacted] can support product and process validation by scientific rationale to determine the variables/parameters that are critical or not for the process criteria - specifications to be met - and/or the parameters that must be strictly controlled within a tighter range than others. It is now widely recognized that the practice of detection is the most costly approach to quality control and prevention is the most economic approach - problems that are prevented never have to be solved. This [redacted] focuses on statistically valid sampling and statistical process control (SPC) to achieve product validation. SPC can benefit [redacted] The goal is to determine the correct set of conditions that will always produce conforming product with the least amount of variability. This [redacted] provides an overview of the tools that are essential for establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes. In addition, the sampling provisions [redacted] provide [redacted]

4.3 Elements of a Validation Program

A typical validation program includes [redacted] The validation process may include [redacted] It is important to prepare a written validation program that specifies [redacted] The program should specify [redacted] The test conditions for these runs should [redacted] Validation documentation should include [redacted] Analysis of the data collected from monitoring will establish the variability of process parameters for individual runs and will establish whether or not the equipment and process controls are adequate to assure that product specifications are met. Finished product and in-process test data can be of value in process validation, particularly in those situations where [redacted] Written manufacturing specifications and processing procedures shall be established, implemented and controlled to assure [redacted] Validation is an essential element in the establishment and implementation of a process procedure and product specification, as well as in determining [redacted]

A. Prospective Validation

Prospective validation includes [redacted] The following are considered as key elements of prospective validation.

A.1 Equipment and Process

[redacted]

A.1.a Equipment - Installation Qualification

Installation qualification studies establish confidence that the process equipment and ancillary systems are capable of [redacted]

This phase of validation includes [redacted] In assessing the suitability of a given piece of equipment, it is usually insufficient to rely solely upon [redacted] It is important that equipment qualification simulate actual production conditions, including those which are "worst case" situations.

Tests and challenges should be repeated a sufficient number of times to assure reliable and meaningful results. All acceptance criteria must be met during the test or challenge. If any test or challenge shows that the equipment does not perform within its specifications, an evaluation should be performed to identify the cause of the failure. Corrections should be made and additional test runs performed, as needed, to verify that the equipment performs within specifications. The observed variability of the equipment between and within runs can be used as [redacted] The installation qualification should include [redacted] The objective is [redacted] In addition, special post-repair cleaning and calibration requirements should be developed to prevent [redacted]

A.1.b Process: Performance Qualification

The purpose of performance qualification is to provide rigorous testing to demonstrate the effectiveness and reproducibility of the process. In entering the performance qualification phase of validation, it is understood that [redacted] Each process should be defined and described with sufficient specificity so that employees understand what is required. Parts of the process that may vary so as to affect important product quality should be challenged. In challenging a process to assess its adequacy, it is important [redacted]

Each specific manufacturing process should be appropriately qualified and validated. There is an inherent danger in relying on [redacted]

A.1.c Product - Performance Qualification

These steps should be viewed as pre-production quality assurance activities. Before reaching the conclusion that a process has been successfully validated, it is necessary to demonstrate [redacted] Where possible, product performance qualification testing should include [redacted]

After actual production units have successfully passed product performance qualification, a formal technical review should be conducted and should include:

- [redacted]
- [redacted]

[redacted]

A.2 System to Assure Timely Revalidation

There should be a quality assurance system in place that requires revalidation whenever there are changes in [redacted] Furthermore, when a change is made in raw material supplier, the manufacturer should consider [redacted]

A determination of adverse differences in raw material indicates a need to revalidate the process. One way of detecting the kind of changes that should initiate revalidation is [redacted]

Such tests and methods usually yield specific results that go beyond the mere pass/fail basis, thereby detecting variations within product and process specifications and allowing determination of whether a process is slipping out of control. The quality assurance procedures should establish the circumstances under which revalidation is required. These may be based upon [redacted] The extent of revalidation will depend upon [redacted] It may not be necessary to revalidate a process from scratch merely because [redacted]

A.3 Documentation

The validation program must be documented and properly maintained. Approval and release of the process for use in routine manufacturing should be based upon [redacted] For routine production, it is important to [redacted] A maintenance log can be useful in performing failure investigations concerning a specific manufacturing lot. Validation data (along with specific test data) may also determine expected variance in product or equipment characteristics.

B. Retrospective Process Validation

In some cases a product may have been on the market without sufficient pre-market process validation. In these cases, it may be possible to validate, in some measure, the adequacy of the process by [redacted] In such cases, preliminary prospective validation should have been sufficient to warrant product marketing.

As additional data is gathered on production lots, such data can be used to build confidence in the adequacy of the process. Conversely, such data may indicate a declining confidence in the process and a commensurate need for corrective changes. Test data may be useful only if [redacted] It is important to maintain records that describe the operating characteristics of the process, e.g., [redacted]

4.4 Factors that affect product quality

All factors that affect product quality should be evaluated when designing and undertaking a process validation study. These factors may vary considerably among different products and manufacturing technologies and could include, for

example, [redacted]

4.4.1 R&D

During the research and development (R&D) phase, the desired product should be carefully defined in terms of its characteristics, such as [redacted]

4.4.2 Changes

Documentation of changes made during development help to provide traceability to information that can later be used to pinpoint solutions to future problems. Once a specification is demonstrated as acceptable, it is important that any changes to the specification be made according to documented change control procedures.

4.4.3 End Use

The product's end use should be a determining factor in the development of product (and component) characteristics and specifications. All pertinent aspects of the product that impact [redacted] These ranges should be expressed in readily measurable terms.

4.4.4 Acceptance Specifications

The validity of acceptance specifications should be verified through testing and challenge of the product on a sound scientific basis during the initial development and production phase.

4.4.5 Operator Control

It is highly desirable that production operators should make decisions on conformance. They are already in the mainstream of the product flow and are most familiar with the nature of the product characteristics. To require others to make measurements and judge conformance adds costs and delays and reduces the sense of responsibility of the operators. When work is organized in a way that enables a person to have full mastery over the attainment of planned results, that person is said to be in a state of self-control. Self-control is [redacted] To achieve a state of self-control, the operator must be provided with:

a. [redacted]

b. [redacted]

c. [redacted]

If all the parameters have been met, the person is said to be in a state of self-control and can properly be held responsible for any deficiencies in performance. If any of the parameters have not been met, the person is not in a state of self-control and cannot be held responsible for deficiencies.

5.0 Process Validation Tools

5.1 Process Improvement

5.1.1 Design of experiments

Design of Experiments (DOE) is a planned strategy to systematically test combinations of variable elements of a process and analyze the results. The elements of the process to be adjusted are called ‘factors”; the different settings of those factors for the purposes of the experiment are called “levels.” Carefully designed and analyzed experiments can [redacted]

5.1.2 Determining optimum process settings

Statistically designed experiments should be conducted for systematically identifying optimum levels, as well as any interactions that may exist. Experimentation can also help to identify those process parameters that do not need to be rigidly controlled. Using experimental results, parameters can be set to optimum levels. Results can be verified by [redacted] Design of Experiments (DOE) is a systematic approach to answer the question, "How do changes in process parameters impact the final product characteristics?" Most processes involve many variables that can be established at a multitude of levels. Designed experiments involve choosing [redacted]

5.1.3 Quality Function Deployment

A strategic view starts with quality as a part of the overall business plan. This plan identifies how Customer requirements and desires are translated into the design of quality products and production processes. Quality Function Deployment (QFD) is a disciplined methodology which begins with Customer needs and then translates them into lower and lower levels in the design tree. The end result of QFD is the identification of the specific manufacturing process parameters needed to ensure Customer requirements are met. QFD consists of at least four phases called [redacted] QFD also defines how complementary techniques such as [redacted] can be used to ensure a quality product is designed and manufactured. It is a disciplined approach to strategically improving market share. In essence, QFD is [redacted]

5.1.4 Failure Mode and Effects Analysis

FMEA is a systematic, analytical approach to properly plan for defect prevention and mistake-proofing. It is a technique for identifying and focusing on those areas in the design and manufacturing process for the prevention, reduction and elimination of non-conformances in the product or production. During this team-oriented process, each potential defect or failure mode in a system is analyzed to determine [redacted]
Thus, FMEA is a defect prevention tool that can formalize product reliability planning prior to design or production, and a direct method for identifying process points for installing SPC. The FMEA procedure is to [redacted]
This is followed by [redacted]

The failure modes are then ranked by RPN, prioritized and corrective action taken to eliminate or mitigate them.

5.2 SPC

a. [redacted]
b. [redacted]
c. [redacted]

d. [redacted]

e. [redacted]

f. [redacted]

5.2.1 Service and administrative SPC

SPC for service and administrative processes refers to the application of statistical techniques to improve performance. Statistical analysis methods are just as effective in an office environment as they are on the factory floor.

5.2.2 Customer requirements

"Customer" in this document includes [redacted]

a. [redacted]

b. [redacted].

c. Suppliers should meet with the Customers and ask:

(1) [redacted]

(2) [redacted]

(3) [redacted]

d. [redacted]

Operator Control

It is highly desirable that production operators should make decisions on conformance. They are already in the mainstream of the product flow and are most familiar with the nature of the product characteristics. To require others to make measurements and judge conformance adds costs and delays and reduces the sense of responsibility of the operators. When work is organized in a way that enables a person to have full mastery over the attainment of planned results, that person is said to be in a state of self-control. Self-control is [redacted] To achieve a state of self-control, the operator must be provided with:

a. [redacted]

b. [redacted]

c. [redacted]

If all the parameters have been met, the person is said to be [redacted]

5.3 SPC Planning

5.3.1 Approach

Knowledge of statistical procedures alone is not sufficient to ensure improvements in product quality and process productivity. A structured approach for implementing SPC is needed. Organizational team structures, such as self-managed work teams, cross-functional teams and project teams will facilitate and enhance the use of SPC with its many internal and external benefits. Because each supplier's situation is unique, actual implementation will require [redacted]

[redacted]

5.3.2. Preliminary planning

The following factors contribute significantly to effective SPC implementation:

5.3.2.1. Senior management

[redacted]

5.3.2.2 Quality system

[redacted]

5.3.2.3 Steering committee

[redacted]

5.3.2.4 SPC facilitator

[redacted]

5.3.2.5 SPC policy

[redacted]

5.3.2.6 Goals

[redacted]

5.3.2.7 Milestones

[redacted]

5.3.2.8 SPC plan

A written SPC implementation plan (SPC Plan) should be developed which does the following:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

Procedures should specifically define what decisions (with regard to the product and process) are appropriate and allowable under such conditions and who is authorized to make those decisions. Procedures should also address [redacted] The SPC Plan should provide for [redacted]

[redacted]

The supplier should also provide for the appropriate review of vendor SPC plans and offer to assist vendors in establishing an SPC program, including training, if necessary.

5.3.2.9 SPC verification

The verification of effective internal and vendor SPC programs has its basis in an effective SPC audit program. Once an effective SPC plan has been established, it is recognized that the full implementation of the events defined in the plan may [redacted]

Some of the more important aspects of SPC practices to be evaluated during an audit will be:

a. [redacted]
b.
c.
d.
e.
f.
g.
h.
i.
j.
k.
l.
m.
n.
o.
p.

Some or all of these items will be included in each SPC audit. The intent of the audits is to [redacted]

A typical audit checklist for a production operation:

DATE/SHIFT:							
The operator has provided date, time and initials.							
[redacted]							
Calculations are performed correctly.							
[redacted]							
No columns are skipped.							
[redacted]							
Adjustments are made in accordance with SPC Management Plan.							
[redacted]							
Blade changes and down-times are noted.							
[redacted]							
Reasons for out-of-control Range chart noted.							
[redacted]							
INSPECTOR							

5.3.3 Training

Initial SPC training should be provided for all supplier personnel who will be involved in the program to impart knowledge of the philosophy and concepts of SPC. Visiting similar facilities that exemplify the type of commitment required can be beneficial. An overall training strategy should [redacted] A training plan should consider:

a. [redacted]
b. [redacted]
c. [redacted]
d. [redacted]
e. [redacted]
f. [redacted]
g. [redacted]

5.4 Process knowledge

5.4.1 Flow diagramming

In order to optimize and control a process and maximize the benefits from SPC implementation, a thorough knowledge of the process is of paramount importance; therefore, prior to implementing SPC, it is very helpful to systematically diagram (flowchart) the overall process. Often, flow-charting will [redacted] Flow diagrams may consider:

a. [redacted]
b. [redacted]
c. [redacted]
d. [redacted]
e. [redacted]
f. [redacted]
g. [redacted]

5.4.2 Additional tools and techniques to gain knowledge of the process

Upon completion of flow diagramming, several other problem solving tools and techniques may also be used to analyze, study, control and optimize the processes. These techniques, described in Appendix C, include:

a. Pareto analysis
b. Cause and effect diagram
c. Check sheets
d. Run/Trend charts
e. Histograms
f. Scatter diagrams

Inputs for the above techniques may be [redacted] Such factors may affect not only the operation of the actual process but may contribute to variations in process inputs as well.

5.4.3 Characterizing variation

There are, in general, three main mechanisms of variation:

a. [redacted]
b. [redacted]
c. [redacted]

It is important that the relative contribution of these sources is investigated - SPC control charting, subgroup formulation and sampling procedures are based on this information. The use of multi-vari charts is very beneficial in tracking down the sources of variation. Multi-Vari charts use vertical lines to represent the range of variation of one unit of product. The resulting vertical lines are [redacted]

5.5 What to measure

5.5.1 Key characteristics to control

The flow diagram may be used as a "road map" in the selection of the most advantageous or key characteristics for SPC application. By following the flow "upstream", the supplier can [redacted]

While upstream operations may promise the greatest cost savings, both the Customer and the supplier are keenly interested in controlling those key characteristics throughout the entire process that most significantly impact the functionality of the finished product - key characteristics may also be dictated by [redacted]

5.5.2 Process variables to control product characteristics

While SPC data usually results from the direct measurement of product characteristics, using SPC to control variable process input and environmental conditions is often more beneficial. Controlling variables in a plating process to control the product plating thickness is an example. This should be done whenever possible as the control of process variables is a real-time system, whereas the control of the characteristic is an after-the-fact system. SPC should be applied to the process variables that have [redacted] Common process variables to consider include:

a. [redacted]
b.
c.
d.
e.
f.
g.
h.
i.
j.
k.
l.

5.6 Normality

5.6.1 When and why normality is important

When using $\overline{X}$ - R control charts, sample means are plotted and the central limit theorem is very helpful. This theorem states that the sample means tend toward normality as the subgroup size increases, regardless of the population distribution of individual values. Because of this theorem, plotting control charts for means, whose limits are based on the normal curve, is usually not dependent on [redacted] Normality is important here because if the individual values are not normally distributed, the percent of the population expected outside the control limits, due to chance, is not the same as for an $\overline{X}$ chart. Normality is also important when [redacted]

5.6.2 Tests for normality

Methods of testing for normality include:

a. [redacted]
b. [redacted]
c. [redacted]
d. [redacted]

It is recommended that the first three tests be used when [redacted]

5.6.3 Transformations/Curve-fitting

Many SPC software packages are now available with statistical tools that will determine if a distribution is normal or not. These packages provide the most expeditious way to evaluate distributions. In the event the distribution is non-normal, additional tools provide for a transformation of data or a determination of the best fitting distribution to the data. Once a suitable transformation is made, or a determination has been made as to the actual distribution type, a valid calculation of a process capability can be made, and valid control limits for an individual X chart can be plotted. Some types of transformations that may be used are:

a. [redacted]
b. [redacted]
c. [redacted]

5.7 Control charting

The control chart has been utilized to enhance process control and process improvement capabilities since its introduction in the late 1920's by W.A. Shewhart. It has become the cornerstone of the time proven methods and practices of SPC.

5.7.1 The basic control chart and its use

The control chart is [redacted]

5.7.2 Types of control chart

There are two major types of control charts:

a. [redacted]
b. [redacted]

5.7.2.1 Variable chart

Variable charts are concerned with three characteristics:

a. [redacted]
b. [redacted]
c. [redacted]

Table A – Sample size rules for variables control charts

Control Chart Type	Sample Size (n)
Average & Range ($\overline{X}$, R)	10 or fewer, usually 2 to 5
Average & Standard Deviation ($\overline{X}$, s)	10 or greater
Moving Average & Moving Range (m $\overline{X}$, mR)	10 or fewer, usually 2 to 5
Individuals & Moving Range (X, mR)	1

[redacted]

5.7.2.2 Attributes charts

Attribute control charts may be applied to quality characteristics that can be observed only as attributes or those that are actually recorded as attributes even though they might have been measured as variables. Attributes charts are concerned with:

a. [redacted]

b. [redacted]

Table B – Sample size rules for attributes control charts

Control Chart Type	Sample Size
Fraction nonconforming (p)	50 or greater, Variable sample size
Number nonconforming (np)	50 or greater, Constant sample size
Number of nonconformities (c)	Constant inspection unit
Number of nonconformities per unit (u)	Variable inspection unit

5.7.3 Rationale for subgroup size

The following points should be considered in selecting the subgroup size.

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

5.7.4 Rationale for sampling frequency

Selecting the appropriate sampling frequency (i.e., the interval between subgroups) is as important a decision as selecting the subgroup size. Sampling frequency may be expressed in terms of [redacted]

[redacted] The following factors should be considered:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

5.7.5 SPC for short run production

Because current SPC methods require 20-25 subgroups of data (typically 2-5 items per subgroup) to be collected before calculating control limits, many suppliers have difficulty in applying traditional SPC methods. A production run may not produce enough data to generate meaningful control limits. Several SPC concepts that work well with very short production runs (some with a lot size of only one piece) allow every organization to take advantage of the power of SPC methods, even when lot sizes are small. Different part numbers may be monitored on the same chart. Multiple process streams or characteristics can be plotted together on one chart, minimizing paperwork for the operator and maximizing process understanding. Short Run charts work with [redacted] This assumption must be periodically verified.

5.7.5.1 Control charts for short run production - variables data

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

5.7.5.2 Control charts for short run production - attribute data

The traditional SPC charts for attribute data suffer from the same problems as do the traditional variable data charts in that they are [redacted]

5.7.6 Control chart auditing

a. [redacted]

b. [redacted]

5.8 Assess stability, capability and performance

5.8.1 Stability

5.8.1.1 Introduction

A process is said to be operating in a stable manner (that is, in statistical control) when all special causes have been eliminated from the production process to the extent that [redacted]

5.8.1.2 Criteria (interpretation)

Interpreting control charts involves determining when special causes are present and diagnosing the reasons for them so that they can be removed, or if beneficial, incorporated into the process. Examples of the latter include [redacted] Not all criteria have to be used in all cases. Other criteria may also be used.

Test 1. [redacted]

Test 2.

Test 3.

Test 4.

Test 5.

Test 6.

Test 7.

Test 8.

5.8.1.3 Verification

A stable process can be verified by drawing the data points on a control chart and examining its statistical behavior. If the chart does not manifest any of the criteria in paragraph 5.8.1.2, the process is [redacted] Improvement comes from [redacted]

5.8.2 Capability

In the past, Cp and Cpk were both called Capability indices. More recent practitioners have labeled Cp as a capability index (which answers the question, "Is the process capable of meeting the specification?") and Cpk as a performance index (which answers the question, "[redacted]"). [redacted]

5.8.2.1 Introduction

Process capability is determined by the variation that comes from common causes. Capability refers to what can be predicted from a stable process. The capability index of a process compares the process variation to the specification limits. The capability index alone does not [redacted]
A capability value should only be calculated from data that is in statistical control and from a known distribution. Capability indices can be broadly grouped into two categories: [redacted] This type of study is often used to validate the initial parts produced from a process for Customer submission. Another use, sometimes called a machine capability study, is to validate that a new or modified process actually performs within the engineering parameters. When a process has been found to be stable and capable of meeting requirements in the short-term, a long-term capability study can then be made. This involves [redacted] One use for this study is to [redacted]

5.8.2.2 Process capability index = Cp = (USL-LSL)/(6 sigma)

This index of capability requires two specification limits and assumes a normal distribution of individuals. The calculation of this index does not require [redacted]

5.8.2.3 Capability of non-normal distributions

In the strict sense of a capability study, the shape of the distribution is not as important as how it compares to the engineering specification; however, when expressing process capability as a numeric value, like Cp or Cpk, it should be understood [redacted]
These methods should only be used after an investigation of the special sources (causes) of variation has been conducted and documented: [redacted]

5.8.2.4 Capability for one-sided specifications

Cp has meaning only for two-sided specifications. Potential capability could be spoken of if there exists a target value and one specification limit. For example, if Cpt is calculated as Cpt = (spec limit – Target)/(3 sigma), this would yield [redacted]

5.8.2.5 Verification

The Cp values should be verified as often as is necessary. If the Cp values are equal to or less than [redacted] If the Cp's are greater than one and one-half times the minimum values, significant changes can be determined by [redacted]

5.8.3 Performance

5.8.3.1 Introduction. The performance index determines how well the process is actually performing relative to the specification limits.

5.8.3.2 Index

One common performance index for a normal distribution is Cpk = the minimum of (process average – lower spec limit)/(3 sigma) and (upper spec limit – process average)/(3 sigma).

Cp and Cpk should be used together. If a process has a good Cp and a poor Cpk, it may only require a shift in the process average. If both are poor, then [redacted] "All values" means all of the individual values sampled.

For example, these individual values can come from [redacted]

5.8.3.3 Performance for non-normal data distributions

Method 1. The parameters of the distribution which best fits the data are estimated first. Then a check for goodness of fit is made. If fit is not rejected, [redacted]

Method 2. The data is transformed into a normal distribution (see paragraph 5.6.3).

The resulting numbers will then be normally distributed and the performance can be calculated using the Cpk formula above.

Method 3. If enough attribute data has been collected, an estimate of the performance can be calculated by [redacted]

5.8.3.4 Verification

Cpk values should be verified as often as is necessary. If the Cpk values are equal to or less than [redacted] If the Cpk's are greater than [redacted]

5.8.3.5 Economic positioning of process

Sometimes targeting the process in the middle of the specification limits is not practical. Process owners must often make decisions to target their process where an optimum economic condition is achieved. This decision is sometimes based on [redacted]

A statement that covers the rationale for making this kind of economic positioning decision should [redacted]

5.8.3.6 Continuous improvement prioritization

The goal of an organization should be to continually improve and optimize its processes. This is accomplished through [redacted] Part of the knowledge of the continuous improvement process is knowing when [redacted]

5.8.4 Other measures

Other indices used in describing capability/performance include Cpm, CPU, CPL, Cr, and more. In general, both the producer and the consumer should [redacted]

5.9 Gaging and measurement

It is very important to have valid measurement studies to ensure [redacted] Some of the commonly used techniques are:

a. [redacted]
b. [redacted]
c. [redacted]
d. [redacted]

The Company should state the method to be used and the acceptable limits of variation of the measurement system. Measurement standards deteriorate in accuracy and precision during use. Maintaining the required amount of accuracy requires a continuing system of calibration control. Examples of calibration programs can be found in ANSI/NCSL Z540-1 and ISO 10012.

5.10 Final Acceptance using SPC

5.10.1 Requirements for acceptance

Prior to utilization of SPC for Final Acceptance of a characteristic, the controlling process(es) should have demonstrated statistical control and a minimum Cpk (or equivalent) of [redacted] The process(es) should be in control for a period long enough to assure [redacted]

5.10.2 Actions for acceptance by SPC

a. [redacted]

These results should be submitted to the customer for review.

b. [redacted]
c. [redacted]
d. [redacted]
e. [redacted]

5.10.3 Customer report generation

A myriad number of SPC activities can be tracked to develop internal metrics and generate statistical reports. Internal metrics are typically calculated and published on a monthly basis. This data is then accumulated into a statistical report and attached to the validation report. Examples of validation reports are as follows:

a. [redacted]
b. [redacted]
c. [redacted]

d. [redacted]

e. [redacted]

6.0 Alternate Methods for Process Validation

[redacted]

When SPC is not possible, it is recognized that other product acceptance methodologies are also viable. Examples of these other acceptance techniques include [redacted]

The acceptability of the validation plan is dependent upon [redacted]

6.1 Poka-Yoke or mistake-proofing

Poka-Yoke is a Japanese term that generally translated means “mistake-proofing” or “fail-safing”. Poka-Yoke is an approach that uses [redacted]

The types of Poka-Yoke devices are:

a. [redacted]

b. [redacted]

c. [redacted]

6.2 Calibrated fixtures as a media of inspection - Production Tooling Used as Media of Inspection

When production jigs, fixtures, tooling masters, templates, patterns and such other devices are used as media of inspection, they shall [redacted]

These devices shall be proved again for accuracy at intervals formally established in a manner to cause their timely adjustment, replacement or repair prior to [redacted]

Sometimes an election is made to use production tooling for inspection and gaging - in such cases, special precautions must be taken to assure accuracy. This involves [redacted]

6.3 100% automated inspection

This system must be verified as to the accuracy of the inspection and its fail-safe feature.

7.0 Sampling Inspection

7.1 Sampling

It is through careful design and validation of both the process and process controls that the Company can establish a high degree of confidence that all manufactured units from successive lots will be acceptable. Successfully validating a process may [redacted]

7.1.1 Preferred sampling plans

[redacted]

7.1.2 Formation and identification of lots or batches

The product shall be assembled into identifiable lots, sublots or batches or in such other manner as may be prescribed. Each lot or batch shall, as far as practicable, consist of [redacted] Although lot or batch size is not used to select a continuous sampling plan, the formation of lots or batches may remain desirable for reasons of [redacted]

7.1.3 Determination of sampling plan

A sampling plan is determined by:

a. [redacted]
b. [redacted]
c. [redacted]
d. [redacted]

For lot acceptance situations (attributes or variables), the occurrence of one or more nonconformances shall result in [redacted]

7.1.4 Sampling of lots or batches

7.1.4.1 Selection of units

Units of product drawn from a lot for a sample shall be selected at random from the lot without regard to their quality. Random sampling requires that each unit in the lot, batch or production interval has the same probability of being selected for the sample.

7.1.4.2 Representative (stratified) sampling

When appropriate, the number of units in the sample shall [redacted]

When representative sampling is used, the units from each sublot, sub-batch or part shall be selected at random.

7.1.4.3 Process of sampling

A sample may be drawn after all units comprising the lot or batch have been assembled or sample units may be drawn during [redacted]

7.1.4.4 Non-conforming product

When sample units are drawn during lot or batch assembly and nonconforming units are found, the Company shall [redacted] For lots or batches withheld from acceptance, the Company shall take the following actions:

a. [redacted]
b.
c.
d.

7.2 Acceptance using Sampling

7.2.1 Sampling inspection

When acceptance is accomplished using the sampling tables provided [redacted] the following considerations apply.

7.2.1.1 Verification level specification

A VL may be specified for individual characteristics, for a group of characteristics or for subgroups of characteristics within the group. The VL and code letter (CL) from Table I determine the sampling plan required for assessing product compliance to specification requirements. The Company is expected to [redacted]

TABLE I. Code letters (CL) for entry into the sampling tables

Lot or production interval size	Verification Levels						
	VII	VI	V	IV	III	II	I
2–170	A	A	A	A	A	A	A
171–288	A	A	A	A	A	A	B
289–544	A	A	A	A	A	B	C
545–960	A	A	A	A	B	C	D
961–1632	A	A	A	B	C	D	E
1633–3072	A	A	B	C	D	E	E
3073–5440	A	B	C	D	E	E	E
5441–9216	B	C	D	E	E	E	E
9217–17408	C	D	E	E	E	E	E
17409–30720	D	E	E	E	E	E	E
30721 and larger	E	E	E	E	E	E	E

7.2.1.2 Sampling procedures

Sampling is performed at one of three stages called normal, tightened and reduced. For Critical Characteristics - [redacted] Majors Characteristics should typically use [redacted] Minor Characteristics should typically use [redacted] The more important the characteristic is, the higher the VL. Lower VL's may also be considered where [redacted] If no VL is specified, then [redacted] for majors and [redacted] for minors should be used. The tightened and the reduced stages are then defined as the stages to the immediate left and right, respectively, of the initial stage. The sampling inspection stage in effect shall continue unchanged for each group of characteristics or individual characteristic except where [redacted]

7.2.1.3 Switching procedures

The procedures for switching among normal, tightened and reduced inspection are given as Note (2) in Tables II, III and IV. The switching procedures are independent of the results of any remedial action, such as [redacted] Some Table IV switching criteria depend upon a corresponding Table II entry. These entries have been denoted by $n_a(N)$ and $n_a(T)$ in the descriptions that follow. $n_a(N)$ represents the Table II sample size used for normal sampling at the VL and CL currently in effect. Likewise, $n_a(T)$ represents the tightened sample size.

7.2.1.3.1 Normal to tightened

When normal inspection is in effect, tightened inspection shall be instituted when one of the following conditions occurs, depending on the type of sampling plan being used:

[redacted]

7.2.1.3.2 Tightened to normal

When tightened inspection is in effect, normal inspection may be instituted when the following conditions are both satisfied:

a. [redacted]

b. [redacted]

7.2.1.3.3 Normal to reduced

When normal inspection is in effect, reduced inspection may be instituted when the following conditions are all satisfied:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

7.2.1.3.4 Reduced to normal

When reduced inspection is in effect, normal inspection shall be instituted when one of the following conditions occur.

a. [redacted]

b.

c.

d.

7.2.1.4 Discontinuation of acceptance

If sampling inspection of lots or batches remains in tightened inspection due to discovery of nonconformances or when, on continuous sampling plans, there are long periods of screening due to discovery of nonconformances, the Company must discontinue acceptance of the product until [redacted]

7.2.2 Preferred sampling inspection tables

See the Appendix for methods of computing sampling results, using switching rules and determining compliance with requirements using the attributes, variables and continuous sampling plans contained in this section.

7.2.2.1 Attributes sampling plans for lot or batch inspection

The preferred attributes sampling plans for lots or batches are described in [redacted]

7.2.2.1.1 Acceptability criterion

The lot or batch shall be considered acceptable only if [redacted]

TABLE II - Attributes sampling plans

Code letter	Verification levels								
	T	VII	VI	V	IV	III	II	I	R
	Sample size (n_a)								
A	3072	1280	512	192	80	32	12	5	3
B	4096	1536	640	256	96	40	16	6	3
C	5120	2048	768	320	128	48	20	8	3
D	6144	2560	1024	384	160	64	24	10	4
E	8192	3072	1280	512	192	80	32	12	5

NOTES:
(1) [redacted]
(2) [redacted]

7.2.2.2 Variables sampling plans for lot or batch inspection
The preferred variables sampling plans for lots or batches are described in [redacted]

7.2.2.2.1 Limitations on use
Variables sampling is not to be used indiscriminately. Its use shall depend upon [redacted]

7.2.2.2.2 Nonconforming unit
For the purposes of variables sampling, a unit of product shall be considered nonconforming if [redacted]

7.2.2.2.3 Acceptability criteria
The lot or batch shall be considered acceptable if [redacted] If the sample contains any nonconforming unit or if the sample does not meet the "k" criterion or if the sample does not meet the "F" criterion (when applicable), the lot does not meet the acceptability criteria.

a. [redacted] $\bar{x}$ [redacted] ec [redacted]

b. [redacted] $\bar{x}$ [redacted] L [redacted] U [redacted] $\bar{x}$ [redacted]

c. [redacted]

[redacted] $\overline{U}$ [redacted] L [redacted]

[redacted]

TABLE III - Variables sampling plans

Code Letter	Verification Levels								R
	T	VII	VI	V	IV	III	II	I	
A	113	87	64	44	29	18	9	4	2
B	122	92	69	49	32	20	11	5	2
C	129	100	74	54	37	23	13	7	2
D	136	107	81	58	41	26	15	8	3
E	145	113	87	64	44	29	18	9	4
	K values (one- or two-sided)								
A	3.51	3.27	3.00	2.69	2.40	2.05	1.64	1.21	1.20
B	3.58	3.32	3.07	2.79	2.46	2.14	1.77	1.33	1.20
C	3.64	3.40	3.12	2.86	2.56	2.21	1.86	1.45	1.20
D	3.69	3.46	3.21	2.91	2.63	2.32	1.93	1.56	1.20
E	3.76	3.51	3.27	3.00	2.69	2.40	2.05	1.64	1.21
	F values (two-sided)								
A	.136	.145	.157	.174	.193	.222	.271	.370	.707
B	.134	.143	.154	.168	.188	.214	.253	.333	.707
C	.132	.140	.152	.165	.182	.208	.242	.301	.707
D	.130	.138	.148	.162	.177	.199	.233	.283	.435
E	.128	.136	.145	.157	.174	.193	.222	.271	.370

NOTES:
(1) [redacted]
(2) [redacted]

7.2.2.3 Continuous attributes sampling inspection plans
The preferred continuous sampling plans for inspection by attributes are described in [redacted]

TABLE IV - Continuous sampling plans

Code Letter	T	Verification Levels VII	VI	V	IV	III	II	I	R
	Screening Phase: clearance number (*i*)								
A	3867	2207	1134	527	264	125	55	27	*NA*
B	7061	3402	1754	842	372	180	83	36	*NA*
C	11337	5609	2524	1237	572	246	116	53	*NA*
D	16827	8411	3957	1714	815	368	155	73	*NA*
E	26912	11868	5709	2605	1101	513	228	96	*NA*
	Sampling phase: frequencies (*f*)								
A	1/3	4/17	1/6	2/17	1/12	1/17	1/24	1/34	1/48
B	4/17	1/6	2/17	1/12	1/17	1/24	1/34	1/48	1/68
C	1/6	2/17	1/12	1/17	1/24	1/34	1/48	1/68	1/96
D	2/17	1/12	1/17	1/24	1/34	1/48	1/68	1/96	1/136
E	1/12	1/17	1/24	1/34	1/48	1/68	1/96	1/136	1/192

NOTES:
(1) [redacted]
(2) [redacted]
(3) [redacted]

7.2.2.3.1 Conditions for continuous sampling procedures

The following conditions must exist before the continuous attributes sampling procedures of this section may be used for inspection.

a. [redacted]
b. [redacted]
c. [redacted]

7.2.2.3.2 Continuous sampling inspection procedure

At the start of production, all units are inspected. Sampling inspection may be initiated at frequency "*f*" when the following conditions are satisfied:

a. [redacted]

b. [redacted]

Sampling inspection shall be terminated and 100 percent inspection resumed if either of the following conditions occur:

a. [redacted].

b. [redacted]

c. [redacted]

7.2.2.3.3 Acceptability criterion

In continuous sampling, units of product are determined to be acceptable or not on essentially an individual basis. While 100 percent inspection is being performed, each unit is individually inspected and categorized as a conforming or a nonconforming unit and accepted or not accepted accordingly. While inspection is being performed on a sampling basis, each unit that is inspected is categorized as [redacted]

7.2.2.3.3.1 Special reservation for critical nonconforming unit

In addition to the provisions of paragraph 7.5, if a critical nonconforming unit is found while on sample inspection, [redacted]

7.3 Disposition of nonconforming product

All units of product found to be nonconforming shall [redacted]

The Company may rework these units unless [redacted]

7.4 Critical characteristics

Unless otherwise specified in the contract or product specifications, the Company is required to implement an automated screening or a fail safe manufacturing operation and apply sampling plan VL-VII to verify the performance of the screening operation. The occurrence of one or more critical nonconformances requires corrective action as specified in paragraph 7.5.

7.5 Special reservations for critical nonconformance

When a critical nonconformance is discovered at any phase of production or during any inspection, the following immediate actions are required:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

Records of corrective actions shall be maintained and made available to the Customer representative.

APPENDIX A - EXAMPLES OF SAMPLING PLAN USE

A.1 SCOPE

A.2 General

This Appendix is not [redacted]

A.3 Purpose

This Appendix illustrates how to implement the three types of sampling plans described in paragraphs 4 and 5 [redacted] The examples explain how to use the four tables, how to apply the switching rules and how to do some of the requisite calculations. In addition, this Appendix explains how the Company can modify Table IV to some extent by calculating and using other "*i*" and "*f*" values.

A.4 APPLICABLE DOCUMENTS

This section is not applicable to this Appendix.

A.5 EXAMPLES

A.5.1 Attributes sampling

[redacted]

Lot #	Lot Size	Code Letter	Sample Size	Non-conform-ances	Lot Disposition	Stage T/N/R	Action
1	5000	D	160	2	Withhold Acceptance	N	Begin with normal sampling, VL-IV.
2	900	A	80	0	Accept	N	
3	3000	C	128	1	Withhold Acceptance	N	2 lots out of 5 fail to pass. Switch to tightened VL-IV. Check process.
4	1000	B	256	0	Accept	T	
5	1000	B	256	0	Accept	T	
6	900	A	192	0	Accept	T	
7	2000	C	320	0	Accept	T	
8	2500	C	320	0	Accept	T	Process corrected and 5 consecutive lots accepted. Switch to normal VL-IV.
9	3000	C	128	0	Accept	N	
10	5000	D	160	0	Accept	N	

FIGURE 1 - Attributes sampling inspection log

A.5.2 Variables sampling (single-sided specification limit case)

[redacted]

Line	Information Needed	Symbol	Formula	Result	Explanation
1	Sample size	n_v		4	See Table III
2	Sum of measurements		$\sum x$	774	
3	Sum of squared measurements		$\sum x^2$	150034	
4	Correction factor	CF	$(\sum x)^2 / n_v$	149769	$774^2 / 4$
5	Corrected sum of squares	SS	$\sum x^2 - CF$	265	150034-149769
6	Sample variance	V	$SS / (n_v - 1)$	88.333	265/3
7	Sample standard deviation	S	$\sqrt{V}$	9.399	$\sqrt{88.333}$
8	Sample mean	$\overline{X}$	$\sum x / n_v$	193.500	774/4
9	Lower specification limit Upper specification limit	L U		Not applicable 209	
10	Lower quality index Upper quality index Quality Index	Q_L Q_U Q	$(\overline{X} - L) / s$ $(U - \overline{X}) / s$ $min(Q_L, Q_U)$	Not applicable 1.649 1.649	(209-193.5)/9.399
11	Sample F value	F	$S / (U - L)$	Not applicable	
12	Number of nonconformances k value F value	C k F		0 1.210 Not applicable	See Table III See Table III
13	C acceptability criterion k acceptability criterion F acceptability criterion		$C = 0$? $Q \geq k$? $\widehat{F} \leq F$?	Yes Yes Not applicable	1.649 ≥ 1.21
NOTES: The k value is the minimum allowable value for the quality index, Q. The F value is the maximum allowable value for the sample F value, $\widehat{F}$.					

FIGURE 2 - Computations for single specification limit case

A.5.3 Variables sampling (double-sided specification limit case)

[redacted]

Line	Information Needed	Symbol	Formula	Result	Explanation
1	Sample size	n_v		4	See Table III
2	Sum of measurements		$\sum x$	774	
3	Sum of squared measurements		$\sum x^2$	150034	
4	Correction factor	CF	$(\sum x)^2 / n_v$	149769	$774^2 / 4$
5	Corrected sum of squares	SS	$\sum x^2 - CF$	265	150034-149769
6	Sample variance	V	$SS / n_v - 1$	88.333	265/3
7	Sample standard deviation	s	$\sqrt{V}$	9.399	88.333
8	Sample mean	$\bar{X}$	$\sum x / n_v$	193.500	774/4
9	Lower specification limit Upper specification limit	L U		180 209	
10	Lower quality index Upper quality index Quality Index	Q_L Q_U Q	$(\bar{X} - L) / s$ $(U - \bar{X}) / s$ $min(Q_L,Q_U)$	1.436 1.649 1.436	(193.5-180)/9.399 (209-193.5)/9.399
11	Sample F value	$\hat{F}$	$s / U - L$	0.324	9.399/(209-180)
12	Number of nonconformances k value F value	C k F		0 1.210 0.370	See Table III See Table III
13	C acceptability criterion k acceptability criterion F acceptability criterion		$C = 0$? $Q \geq k$? $\hat{F} \leq F$?	Yes Yes Yes	 1.436 ≥ 1.210 0.324 ≤ 0.370
NOTES: The k value is the minimum allowable value for the quality index, Q. The F value is the maximum allowable value for the sample F value, $\hat{F}$.					

FIGURE 3 - Computations for double specification limit case

A.5.4 Continuous sampling

[redacted]

Product Item Number	Code Letter	Frequency or 100%	Stage T/N/R	Event/Action
1	C	100%	N	Start production: Begin screening phase with *i* = 116.
8	C	100%	N	Find a defective unit: Reset counter.
124	C	100%	N	*i* =116 consecutive conforming units cleared: Begin sampling phase with *f* = 1/48.
170	C	1/48	N	First random sample selected: Found it to conform.
9697	C	1/48	N	200 consecutive conforming sampled units observed: Switch to reduced inspection with *f* = 1/68. Here, 200 equals 10 times the Table II sample size entry for CL-C and VL-II.
9769	C	1/68	R	Next sample randomly selected with *f* = 1/68.
13982	C	1/68	R	Production interval size tripled (2100 to 2400 units): End CL-C and begin CL-E sampling phase, *f* = 1/136, since VL-II and reduced sampling inspection are in effect.
14121	E	1/136	R	First random sample taken with new *f* = 1/136: Found it to conform. Continue random sampling.
16290	E	1/136	R	A nonconforming unit observed: Switch to normal inspection. Initiate screening phase with *i* = 228, since CL-E and VL-II are in effect.
16518	E	100%	N	*i* = 228 consecutive conforming units cleared: Begin sampling phase with *f* = 1/96.

FIGURE 4 - Continuous sampling inspection log

A.5.5 Continuous sampling - plan tailoring

The Company may opt to use another continuous sampling plan instead of the one specified in Table IV. The only restrictions are [redacted]

Certain circumstances make such choices desirable. Sometimes the selection of a clearance number or frequency is application dependent, e.g., [redacted]

[redacted] Producers willing to sample at rates larger than *f* can reduce *i* substantially. The procedure that allows choice is presented by [redacted]

Line	Information Needed	Symbol	Formula	Result	Explanation
1	Clearance number	i		116	Table IV
2	Target *i* number	i_t	$i_t < i$?	Yes	50 < 116
3	Attribute sample size	n_a		20	Table II, same VL, CL
4	Compute f_0: Step 1 Step 2 Step 3 Step 4	 S_1 S_2 S_3 f_0	 $(n_a + 1)(1 + 1/n_a)^{n_a}$ $(i_t + 1)(1 + 1/i_t)^{i_t}$ $[S_1 / (S_1 - 1)]^{i_t}$ $(S_1 - 1) / [(S_2)(S_3)]$	 55.7193 137.2710 2.4732 0.1612	
5	Valid *f*		*Any* $f > f_0$	1/6	1/6 > 0.1612

FIGURE 5 - Procedure to determine a valid *f*

[redacted]

APPENDIX B - SPC SOFTWARE CONSIDERATIONS

B.1 SCOPE

This appendix provides some factors that should be considered in the acquisition of SPC software.

B.2 PURPOSE OF SPC SOFTWARE.

B.2.1 Software and management objectives

SPC Software should [redacted]

B.2.2 Assessing effectiveness

No matter what SPC software a organization uses, the key to assessing its effectiveness is objective evidence that [redacted]

B.2.3 Convenience

SPC software is used for convenience factors, speed, and accuracy.

B.2.4 Successful usage

The key to successful SPC software usage is real time data gathering, analysis, and action. Ultimately, reliance should be placed upon [redacted]

B.3 SOFTWARE EVALUATION

B.3.1 End user. Who will be using it?

B.3.2 End use. How will it be used?

a. [redacted]
b. [redacted]
c. [redacted]
d. [redacted]
e. [redacted]
f. [redacted]

B.4 SUGGESTED MINIMUM FEATURES

An excellent reference is the annual software issue of [redacted]

B.4.1 Control charts

As a minimum, the SPC software should be able to produce these control charts:

a. [redacted]
b. [redacted]

B.4.2 Out-of-control conditions

As a minimum, the SPC software should [redacted]

B.4.3 Variable size subgroups

The SPC software should [redacted]

B.4.4 Control limits

Control limits should [redacted]

B.4.5 Subgroups used

User should define [redacted]

B.4.6 Out-of control conditions

The software should [redacted]

B.4.7 Histogram

Software should [redacted]

B.4.8 Process capability

During a capability study, the system should [redacted]

APPENDIX C - SELECTED PROCESS IMPROVEMENT TOOLS

C.1 Scope

This appendix lists some tools that are useful for process improvement.

C.2 Brainstorming

[redacted]

C.3 Cause and effect diagram

[redacted]

C.4 Check sheets

[redacted]

C.5 Flow charts

[redacted]

C.6 Force Field Analysis

[redacted] Force Field Analysis helps make change happen because:

a. [redacted]
b. [redacted]
c. [redacted]

C.7 Histogram

[redacted]

C.8 Hoshin Planning Techniques

[redacted] the techniques include:

a. [redacted]
b. [redacted]
c. [redacted]
d. [redacted]
e. [redacted]
f. [redacted]
g. [redacted]

C.9 Nominal Group Technique

[redacted] Nominal Group Technique assists in:

a. [redacted]

b. [redacted]

C.10 Pareto chart

[redacted]

C.11 Plan-Do-Check-Act (PDCA) Cycle. (Also known as the Shewhart Cycle, Plan-Do-Study- Act Cycle)

[redacted]

C.12 Run/trend charts

[redacted]

C.13 Scatter diagram

[redacted]

C.14 Stratification

[redacted]

APPENDIX D – PROCESS MODELING

D.1 Process Qualification Sequence

D1.1 Acceptance Criteria

Develop acceptance criteria such as the maximum allowable nonconformance probability and the net sensitivity.

D1.2 Confidence Limit

Base the acceptance criteria on the 90% upper confidence limit for the fraction nonconforming (tail probabilities).

D1.3 Net Sensitivity

Net sensitivity acceptance should be based on cost according to a Defect per Million (DPM) value, which can be used to establish the maximum allowable increase in nonconformance probability for the process.

D1.4 Control Chart

Produce a control chart to determine the stability of the process.

D1.5 Modeling

Establish a model for the observed process distribution:

[redacted]

These types of modeling require [redacted]

D1.6 Process Parameters

Determine the effect of possible changes in the mean and/or standard deviation.

D1.7 Projections

Compare the worst-case projections from the model with the acceptance criteria and make a decision on the acceptability of the process.

D.2 Estimating Shift Effects

D.2.1 Left and Right Tail Nonconformances

[redacted]

D.2.2 Theoretical Shift

[redacted]

D.2.3 Comparisons

Compare the results of D2.1 and D2.2 with the acceptance criteria. If the results satisfy the criteria then the process is considered robust enough to be released to production.

D.3 Net Sensitivity (NS)

The NS for a Normally distributed process is given by:

[redacted]

D.4 Process Capability

It should be noted that the classic process capability indices Cpk, Cpl or Cpu can be very insensitive to [redacted]