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EIA STANDARD

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Statistical Process Control Systems

EIA-557-A

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(From Standards Proposal No. 3378, formulated under the cognizance of the EIA Quality and Reliability Engineering (QRE) Committee and the JEDEC JC-13.5 Hybrid Microcircuit Technology Committee.)

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STATISTICAL PROCESS CONTROL SYSTEMS

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(Formulated under the cognizance of the EIA Quality and Reliability Engineering (QRE) Standards Committee and JEDEC JC-13.5 Hybrid Microcircuit Technology Committee.)

1.0 INTRODUCTION

Continuous quality improvement and the achievement of operational and manufacturing excellence are the essence of the total quality philosophy. One of the major vehicles used for achieving the excellence objective is the application of Statistical Process Control (SPC) techniques.

SPC embraces a management philosophy of continuous process improvement that has a primary focus on prevention of defects. After a process has been characterized using statistical techniques (i.e., design of experiments (DOE), capability studies, etc.), SPC is a tool that can be applied to control and optimize the process and reduce variability. An acceptable approach toward an SPC system involves the use of "end-of-process" data to control the process through the application of SPC techniques. However, the intent of this standard is to emphasize the use of in-process data in order to better control and forecast system quality. This proactive use of SPC in conjunction with other techniques and the appropriate responsiveness to out-of-control situations serves to make SPC techniques critical in continuous process improvement and achieving excellence.

It is well recognized that the implementation of an effective and measurable continuous improvement program, which includes SPC, may take years and is an ongoing process. In order for techniques such as SPC to be firmly established throughout all facets of an organization, a strong management commitment must exist. In addition, all personnel must be trained, involved, and held accountable in this statistical analysis, control and improvement process. The exact nature and sophistication of these techniques may vary from manufacturer to manufacturer, depending on the management concepts involved. In recognition of this tendency, this standard provides the general requirements of SPC, including definitions and terminology to promote standardization.

2.0 PURPOSE

This document describes the general requirements of a statistical process control (SPC) system.

3.0 SCOPE

The general requirements of an SPC system shall encompass, but are not limited to, the following elements:

a. Overall quality system

b. Management commitment

c. SPC system documentation

d. Critical process nodes

e. Gage characterization and capability

f. Process characterization and capability

g. Control system documentation

h. On-line/off-line control

i. Training

j. Supplier SPC systems

k. Calibration

l. Preventive maintenance

m. Self audit

4.0 DEFINITIONS

The definition of SPC terms used in this document, and some additional terms common to the industry, are provided in Annex A.

5.0 REFERENCE PUBLICATIONS

Publications referenced by this document, along with additional references available on this topic, are provided in Annex B.

6.0 GENERAL REQUIREMENTS

The general requirements of an SPC system are provided in the following paragraphs. However, the paragraphs are not provided in any prescribed order.

6.1 Overall Quality System

A prerequisite to the effective implementation of SPC is the existence and adequate application of the basic elements of an overall quality system. A quality system shall be documented and capable of being audited. The basic elements are described in various military and industrial documents such as MIL-Q-9858, MIL-STD-790, MIL-I-38535, and ANSI/ASQC Q9001/Q9002.

The quality system shall comply with the applicable standard/specification requirements.

6.2 Management Commitment

Management shall:

6.2.1 Empower personnel with responsibility, authority, and provide sufficient resources to implement and maintain an SPC system

6.2.2 Periodically review and document the status of the SPC system.

6.3 SPC System Documentation

6.3.1 The SPC system documentation and all other references to documentation in this standard shall be in accordance with the overall quality system of 6.1.

6.3.2 The manufacturer shall document and implement a plan for an SPC system. Annex D may be used as a guideline.

6.4 Critical Process Nodes

6.4.1 All process nodes shall be identified (e.g., process flow or lot traveler operations).

6.4.2 Critical process nodes shall be determined using techniques such as Quality Function Deployment (QFD) or yield analysis.

6.4.3 The critical nodes may change as process flows, process techniques, equipment or other pertinent factors change. When this occurs, node criticality shall be reviewed and new controls determined as appropriate.

6.5 Gage Characterization and Capability

Characterization and capability studies of test equipment and gages shall be performed to show variance, limitations and repeatability of the measurement equipment. All studies shall be documented and substantiated by data.

6.6 Characterize the Critical Process Nodes

The manufacturer determines appropriate characteristics to be measured for each critical process node. Target values for each characteristic chosen shall be determined, with variability about that value to be identified, quantified, and reduced if appropriate. These steps may involve the use of various techniques (e.g., DOE, off-line data analysis, process mapping, customer request, etc.).

Process characterization and capability studies shall describe the process limitations with respect to the critical characteristics. Both short-term and long-term capability studies shall be performed and documented. Results shall be substantiated by data.

Process/product parameters for each node may change as process flows, process techniques, equipment, or other pertinent factors change. In this case, another process capability study may be required.

6.7 Control System Documentation

A system of statistical control procedures shall be implemented for each critical characteristic identified in accordance with paragraph 6.6. As a minimum, the control system documentation shall include:

6.7.1 The control techniques used for each characteristic.

Care should be taken to ensure that appropriate control techniques are used for normal and non-normal distributions.

6.7.2 The individual or functional responsibilities.

6.7.3 A definition of out-of-control conditions.

The out-of-control definition shall address the following situations:

a. Data points that lie outside the statistical control limits,

b. Data points that show significant changes, trends or patterns within the statistical control limits.

NOTE: Decisions on which out-of-control signals to use in this case are determined by the manufacturer and may be based on criteria such as process capability, false alarm rates versus the cost of running out-of-control. This case may be waived for certain types of control charts such as CUSUM or EWMA.

6.7.4 The procedures for recording pertinent facts.

Out-of-control situations shall be documented.

6.7.5 The procedures (e.g., out of control corrective action plan) to search for assignable causes, implement corrective actions and conduct failure analysis including appropriate actions to be taken by inspectors, operators, supervisors, and engineers.

Out-of-control situations should be investigated and the root causes identified, documented, and corrective action implemented as warranted. Corrective actions should be evaluated for timeliness and effectiveness in order to prevent out-of-control conditions from recurring.

6.7.6 The procedures for establishing and adjusting statistical control limits, sample size and frequency.

Statistical control limits should be adjusted when the process has been changed and not routinely as a result of shifts/trends without assignable causes. The objective is to use on-line/real-time techniques to verify that the process is in control.

6.7.7 The procedures for SPC Self-Audit

6.8 On-line/Off-line Control

The appropriate control methods for the critical process nodes shall be identified.

A means of demonstrating on-line and/or off-line control shall be established and implemented for critical operations. The record retention requirements for on-line/off-line data shall be defined. A variety of techniques may be used as appropriate. Some examples are:

6.8.1 Off-line Techniques

a. Histogram

b. Pareto analysis

c. Scatter Plot/Regression Analysis

d. Cause and Effect Diagram

e. Inferential Statistics (e.g., Estimation, Hypothesis Testing, Confidence Intervals)

f. Design of Experiments

g. Process Flow Analysis

h. Gage Studies

6.8.2 On-line Techniques

a. Logs

b. Check Sheets

c. Control Charts (e.g., X-Bar & R, P, etc.)

d. CUSUM Charts

6.9 Training

There shall be adequate and appropriate training to support the SPC system. Training shall be tailored to individual functions and responsibilities within the organization and shall include all techniques utilized. For example, the training program shall provide necessary training to management, engineering/ technical personnel, production supervisors/operators, and support personnel. Suggested training topics are presented in Annex D.

6.10 Supplier SPC Systems

Each manufacturer shall have a documented program to encourage suppliers to use SPC. The SPC methods that suppliers are encouraged to use should be consistent with this standard. The system may vary based on the complexity of the supplier's materials and components, criticality to the manufacturer's processes, and resources of the supplier. Refer to Annex D for an example of a Supplier SPC program.

6.11 Calibration

Any instrument used to monitor critical characteristics shall be calibrated in accordance with military standards, industry standards, or equivalent international standards (e.g., MIL-STD-45662, ANSI/ASQC-M1, etc.).

6.12 Preventive Maintenance

A preventive maintenance program to support an SPC system shall include:

6.12.1 Use of the equipment manufacturer's recommendations during collection of historical data and determination of product/ process relationships.

6.12.2 A preventive maintenance program designed to minimize equipment-induced product and process variability.

6.12.3 Identification of the inter-relationships of equipment and product/process characteristics.

6.12.4 A preventive maintenance schedule derived from operating and historical data using statistical and/or analytical techniques for critical product and process equipment.

6.13 Self-Audit

A self audit of the SPC system shall be conducted once a year, as a minimum. An example of an SPC self-audit check list is provided in Annex C.

ANNEX A

DEFINITIONS AND TERMINOLOGY

ACCURACY: The difference between the sample estimate and the population parameter being estimated.

ATTRIBUTE DATA: Data that result from counting items or classifying items into distinct non overlapping categories. Examples are count data (e.g., the number of nonconforming items), ordinal data (e.g., rank: first, second; classification: excellent, good, poor), nominal data (i.e., unordered groupings such as defect type), or pass/fail data.

AUDIT: The periodic observation of procedures and performed activities to evaluate compliance with requirements.

AVERAGE: The sum of the sample values divided by the number of sample values. A measure of location used to estimate the population mean.

BINOMIAL DISTRIBUTION: A specific discrete probability distribution for attributes data.

CAPABILITY: The natural variation of the process due to common causes.

CAPABILITY INDEX: A measure of the relationship between the specification limits and the capability. See EIA QB6, "Guideline on the Use and Application of Cpk" and "The Use and Abuse of Cpk" by Berton H. Gunter.

CAUSE AND EFFECT DIAGRAM: A tool for individual or group problem-solving that uses a graphic description of the various process elements to analyze potential sources of process variation. Also called a Fishbone Diagram (after its appearance) or Ishikawa Diagram (after its developer).

CENTERLINE: A reference line on a control chart about which the chart points are expected to cluster in the absence of a special cause. It is usually set at the average, median, or mode of the points being plotted, or (for a tunable process) at an achievable target value (to detect deviations from the value thought most desirable).

CHARACTERISTIC: A distinguishing feature of a process or its output on which variables or attributes data can be collected.

CHARACTERIZATION: A description of the characteristics of a product or process by mathematical modeling, design of experiments or statistical data evaluation.

CHECKLIST: A listing of the specified criteria that may be observed and checked off during an audit or inspection.

CHECK SHEET: A form for data collection.

COMMON CAUSE: A source of natural variation that affects all the individual values of the process output being studied. In control chart analysis it appears as part of the random process variation.

CONTROL CHART: A graphic representation of a process characteristic showing plotted values of some statistic gathered from that characteristic; a central line and one or two statistically derived control limits. Two basic uses are to determine whether a process has been operating in statistical control and to aid in maintaining statistical control.

CONTROL LIMITS: The maximum allowable variation of a process characteristic due to common causes alone. Variation beyond a control limit may be evidence that special causes are affecting the process. Control limits are calculated from process data and are usually represented as a line (or lines) on a control chart. They are not to be confused with engineering specification limits.

CONTROL LOOP: A corrective action system based on a feedback procedure.

CRITICAL PROCESS NODE: A node in the process flow whose output has a significant impact on the process.

CUSUM CHART: An SPC charting technique where cumulative deviation from a target is plotted.

DATA POINTS: Values that are either observed or calculated.

DISCREPANT MATERIAL: Material that does not conform to specifications (see nonconforming units).

EWMA (Exponentially Weighted Moving Average) Chart. An SPC charting technique based on assigned weights to past observations.

FAILURE MODE AND EFFECT ANALYSIS (FMEA): A disciplined analysis of possible failure modes on the basis of seriousness, probability of occurrence, and likelihood of detection.

HISTOGRAM: A graph obtained by dividing the range of the data set into equal intervals and plotting the number of data points in each interval.

INDIVIDUAL: A single unit or a single measurement of a characteristic.

INSPECTION: The assessment of a characteristic and its comparison to a standard.

LOCATION: The typical value or central tendency of a distribution.

LONG TERM CAPABILITY: The process capability under normal operating conditions over an extended period of time.

MANUFACTURING: All areas/operations where products or services are processed, stored or handled.

MEAN. The sum of the population values divided by the number of values in the population. A measure of location (central tendency) equal to the center of gravity of the population.

MEDIAN: The middle value in a group of measurements when arranged from lowest to highest. When the number of measurements is an even number, the average of the two middle values is used as the median. A measure of location.

MODE: The most frequently occurring value in a group of measurements. A measure of location.

NODE: A definable point in the process where form, fit or function of the product or service is altered.

NONCONFORMING: Does not conform to specification(s), procedures or requirements.

NONCONFORMING UNITS: Units that do not conform to a specification (see discrepant material).

NONCONFORMITY: A specific occurrence of a condition that does not conform to specification (Sometimes called a discrepancy.).

NORMAL DISTRIBUTION: A continuous, symmetrical, bell-shaped frequency distribution for variables data. When measurements have a normal distribution, about 68.26% of all individuals lie within plus or minus one standard deviation unit of the mean; about 95.44% lie within plus or minus two standard deviation units of the mean; and about 99.73% of all individuals lie within plus or minus three standard deviation units of the mean.

PARAMETER: A numerical characteristic of a population.

PARETO ANALYSIS: A technique for problem-solving where all potential problem areas or sources of variation are ranked according to their contribution.

POISSON DISTRIBUTION: A specific discrete probability distribution for attributes data.

POPULATION: The collection of all possible values of a given characteristic.

PRECISION: The measure of natural variation of repeated measurements.

PROBABILITY: The relative frequency with which an outcome takes place over a very long sequence of trials in which the outcome could have occurred.

PROBABILITY DISTRIBUTION: A collection of all possible outcomes of a random event, together with their respective probabilities.

PROBABILITY DISTRIBUTION FUNCTION: A mathematical representation of a probability distribution.

PROBLEM-SOLVING: The process of moving from effects to causes (special or common) to actions that improve performance.

PROCESS: A combination of people, procedures, methods, machines, materials, measurement equipment, and/or environment for specific work activities to produce a given product or service. A repeatable sequence of activities with measurable inputs and outputs.

PROCESS AVERAGE: The location of the distribution of measured values of a particular process characteristic.

PROCESS CAPABILITY STUDY: The quantification of natural process variability.

PROCESS SPREAD: The extent to which the individual values of a process characteristic vary.

PRODUCT PERFORMANCE: The totality of the capability of characteristics of a product

QUALITY FUNCTION DEPLOYMENT (QFD). A technique for analysis of the inter-relationships between different requirements.

RANDOMNESS: A condition in which individual values are not predictable, although they may come from a definable distribution.

RANDOM SAMPLE: A set of individuals taken from a population in such a way that each possible individual has an equal chance of being selected.

RANGE: The difference between the maximum and minimum values. A measure of spread.

RUN: A consecutive number of points consistently increasing or decreasing, above or below the central line.

RUN CHART: A time-ordered graphic representation of a characteristic of a process showing plotted values of some statistic gathered from the process and a central line that can be analyzed for runs.

SAMPLE: A set of individuals taken from a population.

SCATTER DIAGRAM: A graph of the value of one characteristic versus another characteristic.

SHAPE: A general concept for the overall pattern formed by a distribution of values.

SHORT TERM CAPABILITY: The process capability under controlled conditions over a brief period of time.

SPECIAL CAUSE: A source of variation that is intermittent, unpredictable, or unstable and affects only some of the individual values of the process output being studied. Sometimes called an assignable cause.

SPECIFICATION LIMITS: The requirements for judging acceptability of a particular characteristic.

STABILITY: The absence of special causes of variation; the property of being in statistical control.

STABLE PROCESS: A process that is in statistical control.

STANDARD DEVIATION: A measure of the spread or variation in a probability distribution (population standard deviation) or in a sample of values measured on the output from a process (sample standard deviation).

STATISTIC: A value calculated from or based upon sample data used to make inferences about a parameter of the population from which the sample came.

STATISTICAL CONTROL: The conditions describing a process from which all special causes of variation have been eliminated and only common causes remain.

STATISTICAL PROCESS CONTROL (SPC): The conversion of data to information using statistical techniques to document, correct and improve process performance.

STATISTICAL QUALITY CONTROL (SQC): Statistical methods and procedures used to document and ensure compliance with requirements.

TARGET: The desired value for a statistic of a characteristic or parameter of a process node.

TREND: The movement of a process in a consistently increasing or decreasing direction.

VARIABLES DATA: A measure of a characteristic where every value within a given interval is possible.

VARIATION: The difference among individual outputs of a process. The sources of variation can be grouped into two major classes: common causes and special causes.

YIELD: The number of units that pass some inspection criteria divided by the number submitted.

ANNEX B

REFERENCES

Military Specifications and Requirements

MIL-H-38534	Hybrid Microcircuits, General Specification for
MIL-HDBK-683	Statistical Process Control (SPC) Implementation and Evaluation Aid
MIL-I-38535	Integrated Circuit Manufacturing, General Standard for
MIL-Q-9858	Quality Program Requirements
MIL-S-19500	Semiconductors, General Requirements for
MIL-STD-790	Product Assurance Program for Electronic and Fiber Optic Components
MIL-STD-45662	Calibration System Requirements

Industry Standards

ANSI/ASQC A1	Definitions, Symbols, Formulas and Tables for Control Charts
ANSI/ASQC A3	Quality Systems Terminology
ANSI/ASQC M1	Calibration Systems
ANSI/ASQC Q9000	Quality Systems - Quality Management and Quality Assurance Standards -Guidelines for Selection and Use
ANSI/ASQC Q9001	Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing
ANSI/ASQC Q9002	Quality Systems - Model for Quality Assurance in Production and Installation
ANSI/ASQC Q9003	Quality Systems - Model for Quality Assurance in Final Inspection and Test
ANSI/ASQC Q9004	Quality System and Quality System Elements - Guidelines

ANSI/ASQC Z1.15	Generic Guidelines for Quality Systems
ANSI Z1.1/ASQC B1	Guidelines 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
EIA 599	National Electronic Process Certification Standard
EIA QB6	Guideline on the Use and Application of Cpk
IPC-PC-90	General Requirements for Implementation of Statistical Process Control

American Society for Testing Materials (ASTM)

ASTM STD 15D	Manual on Presentation of Data and Control Chart Analysis

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Part 1: January 1989, vol. XXII, no. 1, pp. 72-73.
Part 2: March 1989, vol. XXII, no. 3, pp. 108-109.
Part 3: May 1989, vol. XXII, no. 5, pp. 79-80.
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ANNEX C

EXAMPLE OF A TYPICAL SPC SYSTEM SELF-AUDIT CHECKLIST

1.0 PURPOSE

The purpose of this annex is to provide a typical set of questions that an auditor may use for evaluating the existence and adequacy of an established SPC system to ensure continuing conformance to the system requirements.

2.0 GENERAL

The manufacturer shall establish an independent, self-audit program to assess the effectiveness of the SPC system. Any deficiencies identified by the audit shall be directed to the appropriate individual(s) assigned the functional responsibility for the specific corrective action(s) required. The attached checklist provides an example for development of an SPC self-audit checklist. The self-audit check list used shall be representative of the SPC system to be audited.

All deficiencies shall be documented and a follow-up procedure used to ensure the corrective actions are implemented in a timely manner.

SPC SYSTEM

SELF-AUDIT CHECKLIST

Auditor: _____

Date: _____

Area: _____

Audited: _____

ITEM	Y/N	QUESTIONS (TEXT REFERENCE)
1	___	Are the general SPC system requirements encompassed in the overall quality system requirements? (3.0)
2	___	Do the general SPC system requirements include a management commitment element? (3.0)
3	___	Are the general SPC system requirements described in the SPC system documentation? (3.0)
4	___	Does the SPC system include requirements for determining and characterizing critical process nodes? (3.0)
5	___	Does the SPC system include requirements for determining gage characteristics and capability? (3.0)
6	___	Does the SPC system include requirements for determining process characteristics and capability? (3.0)
7	___	Does the SPC system include requirements for documenting the process control system? (3.0)
8	___	Does the SPC system include requirements to utilize appropriate on-line and off-line process control methods? (3.0)
9	___	Does the SPC system include requirements for determining SPC training needs and ensuring that those needs are fulfilled? (3.0)
10	___	Does the SPC system include requirements for suppliers to implement and maintain SPC systems? (3.0)

11 ___ Does the SPC system include requirements to calibrate all inspection, measuring and test equipment used to measure process/product parameters? (3.0)

12 ___ Does the SPC system include requirements for determining what preventive maintenance is needed and how frequently it must be performed? (3.0)

13 ___ Does the SPC system include requirements to perform periodic self audits? (3.0)

14 ___ Is the quality system documented and capable of being audited? (6.1)

15 ___ Does the quality system comply with the applicable quality system requirements (e.g., MIL-Q-9858, MIL-STD-790, MIL-I-38535, or ANSI/ASQC Q91/ Q92)? (6.1)

16 ___ Is objective evidence available to demonstrate that management has empowered personnel with the responsibility and authority to implement and maintain an SPC system? (6.2)

17 ___ Is objective evidence available to demonstrate that management has provided sufficient resources to implement and maintain an SPC system? (6.2.1)

18 ___ Is management periodically reviewing and documenting the status of the SPC system? (6.2.2)

19 ___ Is the SPC system documented? (6.3.1)

20 ___ Has an SPC system plan been documented and implemented? (6.3.2)

NOTE: Annex D of this standard provides an example that can be used as a SPC plan guideline.

21 ___ Have all process nodes (e.g., process flow or lot traveler operations) been identified? (6.4.1)

22 ___ Has it been determined which process nodes are critical using techniques such as QFD or yield analysis? (6.4.2)

23 ___ Do the documented SPC procedures provide for reviewing node criticality when process flows, process techniques, equipment or other pertinent factors change? (6.4.3)

24 ___ Are new controls determined and implemented when node criticality changes? (6.4.3)

25 ___ Have characterization and capability studies of test equipment and gages been performed to show variance, limitations and repeatability of the measurement equipment? (6.5)

26 ___ Are the characterization and capability studies documented and substantiated by data? (6.5)

27 ___ Have the critical process nodes been characterized? (6.6)

NOTE: The manufacturer determines appropriate characteristics to be measured for each critical process node.

28 ___ Have target values been determined for each critical characteristic? (6.6)

NOTE: Target value determination may involve the use of various techniques (e.g., DOE, off-line data analysis, process mapping, customer request, etc.).

29 ___ Has the variability about critical characteristic target values been identified, quantified and reduced? (6.6)

NOTE: Characteristic variability determination may involve the use of various techniques (e.g., DOE, off-line data analysis, process mapping, etc.).

30 ___ Do the process characterization and capability studies describe the process limitations with respect to the critical characteristics? (6.6)

31 ___ Have both short and long term capability studies been performed and documented with the results substantiated by data? (6.6)

32 ___ Is the need for a new process capability study evaluated and a new process capability study performed when process and/or product parameters for critical nodes change? (6.6)

NOTE: Process/product changes may occur due to changes in the process flows, process techniques, equipment, or other pertinent factors

33 ___ Has a system of statistical control procedures been implemented for each identified critical characteristic? (6.7)

34 ___ Does the control system documentation include the control techniques used for each characteristic? (6.7.1)

35 ___ Are the appropriate control techniques used for both normal and non normal distributions? (6.7.1)

36 ___ Does the control system documentation identify the individuals or functions responsible for maintaining the system? (6.7.2)

37 ___ Does the control system documentation define the out-of-control conditions? (6.7.3)

38 ___ Does the definition of out-of-control conditions include all data points that lie outside the statistical control limits? (6.7.3a)

39 ___ Does the definition of out-of-control conditions include all data points that show significant changes, trends or patterns within the statistical control limits? (6.7.3b)

40 ___ Are the exceptions and modifications justified when the control system documentation excludes or modifies some of the out-of-control signals? (6.7.3b)

NOTE: The justifications may be based on criteria such as process capability or false alarm rates versus the cost of running out-of-control. This case may be waived for certain types of control charts such as CUSUM or EWMA.

41 ___ Are the procedures for recording pertinent facts and out-of-control situations documented? (6.7.4)

42 ___ Are the procedures to search for assignable causes, implement corrective actions and conduct failure analysis documented and do they include the appropriate actions to be taken by inspectors, operators, supervisors, and engineers? (6.7.5)

43 ___ Are the causes of out-of-control situations investigated and documented? (6.7.5)

44 ___ Are the corrective actions for out-of-control situations documented and, when warranted, implemented? (6.7.5)

45 ___ Are data available showing that evaluations are being performed to verify the timeliness and effectiveness of corrective actions in preventing out-of-control conditions from recurring? (6.7.5)

46 ___ Are the procedures for establishing and adjusting statistical control limits, sample size and frequency documented? (6.7.6)

47 ___ Are the statistical control limits adjusted, if appropriate, when the process has been changed? (6.7.6)

NOTE: The objective of statistical control limits is to use on-line/real-time techniques to maintain process control.

48 ___ Are statistical control limits adjusted due to assignable causes? (6.7.6)

NOTE: Statistical control limits should not be adjusted due to shifts/trends.

49 ___ Are the procedures for SPC self audit documented? (6.7.7)

50 ___ Have the appropriate control methods for the critical process nodes been identified? (6.8)

51 ___ Are data available demonstrating that on-line and/or off-line control has been established and implemented for the critical operations? (6.8)

52 ___ Have the record retention requirements for on-line and off-line data been defined and documented? (6.8)

53 ___ Are a variety of off-line control techniques used when appropriate (Histogram, Pareto analysis, Scatter Plot/Regression Analysis, Cause and Effect Diagram, Inferential Statistics, Design of Experiments, Process Flow Analysis, Gage Studies)? (6.8.1)

54 ___ Are a variety of on-line techniques used when appropriate (Logs, Check Sheets, Control Charts, CUSUM Charts)? (6.8.2)

55 ___ Have the personnel performing product related SPC activities received adequate and appropriate training to perform those activities? (6.9)

NOTE: The training program shall provide the necessary training to management, engineering, technical personnel, production supervisors, operators, and support personnel.

56 ___ Has the training been tailored to individual functions and responsibilities within the organization? (6.9)

NOTE: Suggested training topics are presented in Annex D.

57 ___ Does the training include all of the SPC techniques that are being utilized? (6.9)

58 ___ Does the manufacturer have a documented program to encourage suppliers to use SPC? (6.10)

59 ___ Are the SPC methods that suppliers are encouraged to use consistent with this standard? (6.10)

NOTE: The supplier's SPC system may vary based on the complexity of the supplier's materials and components, criticality to the manufacturer's processes, and resources of the supplier.

60 ___ Are all instruments used to monitor critical characteristics calibrated in accordance with military standards, industry standards, or equivalent international standards (e.g., MIL-STD-45662, ANSI/ASQC-M1, etc.)? (6.11)

61 ___ Does the preventive maintenance program include use of the equipment manufacturer's recommendations during collection of historical data and determination of product and process relationships? (6.12.1)

62 ___ Does the preventive maintenance program contain procedures designed to minimize equipment-induced product and process variability? (6.12.2)

63 ___ Does the preventive maintenance program include identification of the inter-relationships of equipment and product/process characteristics? (6.12.3)

64 ___ Does the preventive maintenance program include a preventive maintenance schedule derived from operating and historical data using statistical and/or analytical techniques for critical product and process equipment? (6.12.4)

65 ___ Is a self audit of the SPC system conducted at least once a year? (6.13)

ANNEX D

EXAMPLE OF AN SPC PLAN OUTLINE
(SPC SYSTEM IMPLEMENTATION PLAN)

The SPC plan is a formal document that defines the system, establishes the methodology, identifies the resources, sets the goals and objectives, and schedules the implementation. As the implementation progresses, performance against the plan is evaluated and adjustments are made as necessary to ensure timely completion. The following may be used as an example:

1.0 PURPOSE

This section should describe the purpose of the document, i.e., to formally define a Statistical Process Control System.

2.0 SCOPE

This section should delineate areas of the company to which this plan applies and indicate that an SPC plan is evolutionary in nature.

3.0 GOAL

This section should describe goals for utilizing SPC and the basic underlying philosophy of applications. Review of the "Introduction" paragraph of this standard (paragraph 1.0) should be of assistance.

4.0 GENERAL

4.1 Definitions

This section should list definitions that are applicable to SPC, common to industry, and the company. The "Definitions and Terminology" annex of this standard (Annex A) should be of assistance.

4.2 References and Publications

This section should list references and publications that are useful in an SPC system. The "References" annex of this standard (Annex B) should be of assistance. Additional specifications and standards may be added to this section, including any in-house quality system specifications, inspection procedures, procedures for non-conforming product, etc.

4.3 SPC Committee

This section should denote, by position, the members of an SPC steering committee or team and their responsibilities for maintaining the SPC system plan. The committee's purpose is to develop and oversee the implementation of an overall SPC plan. This committee or team may use the following approach as a guideline in planning and organizing the SPC system:

4.3.1 Include managers of each function on the committee, including a quality engineer or statistician who thoroughly understands the concepts, technical use and applications of SPC. The committee should be headed by a senior manager or designee.

4.3.2 Provide initial SPC training for the management team to ensure their knowledge of the concepts and philosophy of SPC. Visit other manufacturers that have had success with their SPC systems. Identify potential pitfalls and roadblocks.

4.3.3 Provide overall awareness training to middle management and line supervisors through the use of seminars or group meetings. Present the concepts, organization plans and objectives.

4.3.4 Set the objective of the implementation to install and maintain a Statistical Process Control system across the entire process. The SPC system will focus on maintaining consistent processes and reducing variability to provide continuous quality, reliability, and service improvement through the use of statistical techniques.

4.3.5 From the process flow, group related processes and associated operations so that production, engineering and quality personnel may form into quality improvement teams for a particular process group.

4.3.6 Identify the organizational responsibilities for performing process characterization, capability studies, on and off-line control, documentation, training, etc.

4.3.7 Prepare a timed action plan that commits the involvement of all levels in the organization to the establishment of an SPC system as a major component of the overall operations process.

4.3.8 Determine the resources needed. Use in house experts, external consultants or purchased services as needed to ensure effective execution of the plan.

4.3.9 Develop and document the rationale for determining the critical operations in the overall process flow.

4.3.10 From historical data, use problem-solving techniques such as Pareto analysis, etc., to prioritize problems and causes. Use results of this analysis to select the process group to execute the initial introduction of SPC techniques. Look for a chance for early success to reinforce the benefits of SPC. Provide the in-depth technical training for the appropriate individuals involved in the initial introduction.

4.3.11 Develop quantifiable performance metrics. Determine initial metrics and set targets for improvement. For example, a product quality measure such as quality costs can be used to track overall improvement. Review performance and issues at regularly scheduled staff meetings. Present the concepts, organization plans, and objectives.

4.3.12 Provide operator training just prior to and during the introduction of SPC into their area. Involve the line supervisors in the operator training.

4.3.13 Use the statistical methodology of paragraph 4.6 for implementation of SPC in the selected process group.

4.3.14 Revise existing procedures and develop new procedures as necessary, to include the SPC system in the overall quality system and operations process.

4.3.15 After a successful start with the initial implementation, review the strengths and weaknesses of the implementation process, adjust the strategy as necessary, expand the SPC system implementation to the other areas until the entire process has been included.

4.4 Training

This section should describe the approach to SPC training, including who trains, who receives the training, how often, how the concept of training is approached (i.e., team training, self managed work teams, self study, etc.), and a general listing of topics and techniques for SPC training, (i.e., Pareto charts, basic statistics, problem solving techniques, etc.). Suggested topics for an SPC training program are:

a. Definitions, terminology and philosophy of SPC

b. Basic problem solving

- Pareto analysis
- Cause and effect diagrams
- Check sheets

Histograms·I

Scatter plots

Basic statistics

Team training

Concept of variation

c. Fundamentals of control

Concept control

Control charts

d. Capability analysis

Control versus capability

Short term capability

Long term capability

Capability index/ratio (c/c)

Gage studies

e. Design of experiments

4.5 Organizational Responsibility

In this section, the commitment at different levels throughout the organization should be detailed. The specific responsibilities of management, engineering, technical personnel, support functions, production personnel, etc. should be described. Areas such as maintenance, optimization, and recording of SPC data should be identified by functional job responsibility.

4.6 Methodology

This section should describe how the company embraces the evolutionary process of SPC. A methodology, for example, on how critical process nodes are identified for SPC chart application may be useful here. including a general program description of how and when characterization and capability studies are performed. One statistical methodology approach is outlined below.

4.6.1 Flow Chart the process. Prioritize the critical parameters of each operation, including inputs, outputs, and product requirements at this stage in the process.

4.6.1.1 Indicate the following:

a. Inputs to the operation. Prioritize the critical parameters.

b. Each operation. Prioritize the critical parameters.

c. Output of the operation. Prioritize the product requirements at this stage in the overall process.

4.6.2 Define the cause and effect relationships for each product requirement identified in 4.6.1.1 (i.e., the product requirement is the effect and the critical parameters of the inputs and process operations are the causes).

4.6.2.1 Prioritize the causes for each effect.

4.6.3 Define the data collection points for planned experiments and / or setting up control charts.

4.6.3.1 For each data collection point indicate the following :

a. Subgroup size and sampling plan.

b. Method used to collect data.

c. Responsibility

4.6.4 Perform a gage capability study to validate the measurement system.

4.6.5 Select and implement the appropriate control system and initiate data collection.

4.6.6 Determine if the process is in statistical control.

4.6.7 If the process is not in statistical control, determine and eliminate assignable causes of variation until the process is in statistical control.

4.6.8 Perform a capability study.

4.6.9 If the process is capable, determine the long term stability of the process.

4.6.10 If the process is not capable, refine the process through design of experiments, etc. or revise the specification. Repeat the capability study.

4.6.11 If the process is not stable over the long term, determine and eliminate assignable causes. Repeat the capability study.

4.6.12 Repeat the process for each characteristic.

4.6.13 Prioritize and select projects for variability reduction by determining common causes of variation and implementing action plans for improvement. When changes are made, repeat statistical methodology.

4.6.14 Track improvement progress.

4.6.15 Establish regularly scheduled meetings for individual areas covering cause/ effect relationships, plans for improvement , corrective action, out of control situations, etc. Have the operators involved in the meetings. During each meeting, items should be prioritized and actions assigned.

4.7 Documentation, Charting , and Control

This section should delineate the following areas:

- justification for use of SPC charts (normal, skewed data)
- annotation conventions on charts
- how to set up charts (rules)
- types of charts (n, c, x-bar)
- subgroup sampling plan
- calculations for charts (control limits)
- what to do when out of control (decision trees)
- how to maintain the charts

- archiving charts

- gage studies to validate the measurement system

- product, process, equipment chart application

- continuous improvement loop

- computer enhancements, data links

This section should also describe what to do with a non-conforming product. The location of where to find data used to characterize or qualify a critical node may also be identified in this section.

4.8 Critical Operations Requiring SPC

This section should list critical nodes or operations to be controlled by SPC. A listing of the critical nodes may include , for example, the area, the equipment, the process step or monitor, the variable measured, the measurement method, the inputs to the operation, the unit of measure, the chart type, subgroup size and the sampling plan.

4.9 Calibration and Maintenance

This section should describe the approach to calibration and maintenance. How SPC can be utilized in the company to predict equipment failure or down time and identify root causes may also be addressed in this section.

4.10 Purchased Material and Supplier SPC systems

This section should describe the approach to managing purchased material and suppliers using SPC methodology. A list of critical suppliers who utilize and/ or provide the company with SPC data may be helpful.

4.10.1 The supplier SPC system may consist of the following elements

a. Selection of suppliers that are critical to the SPC process.

b. Early involvement of the suppliers in the design phase to promote concurrent engineering and teamwork with the objective of reducing variation.

c. Determination of procured material and component statistical goals based on the manufacturers process and end product goals.

d. Transition from existing tolerance methods to metrics with nominal, standard deviation and process and product capability indices.

e. Formation of joint customer-supplier material teams to mutually determine critical characteristics, baseline processes, reduce variation through design of experiments, and establish metrics.

f. Identification of the key quality characteristics that, if controlled , would reduce or eliminate inspection and test of the manufacturer's materials, components and assembled devices.

g. Implementation and maintenance of statistical controls for processes and product characteristics.

h. Conduct process and product capability studies to determine a baseline.

i. Reduction of variation through design of experiments to achieve more robust designs, processes and product meeting statistical goals.

j. Implementation of certification programs for those suppliers meeting statistical goals for processes/product, and concurrently reducing or eliminating redundant inspection or test at the manufacturers facility.

k. Establishment of electronic data interchange (EDI) systems that allow the manufacturer to monitor supplier progress on critical material quality characteristics.

l. Ongoing information exchange between the manufacturer and supplier to continuously reduce variability within the supplier's operation.

4.10.2 To support the supplier SPC system, the manufacturer will typically provide the following:

a. Strategies, roadmaps, goals and detailed Supplier Variation Reduction plans.

b. Training and technical support to assist suppliers in variation reduction through experimentation and statistical process controls.

c. Computer communications support to facilitate electronic data interchange of the supplier's statistical data.

4.11 Customer use of SPC

This section should describe customers use of SPC to process incoming data as a feed back mechanism supporting continuous improvement. A

listing of such customers should be provided or this section should indicate where they are listed.

5.0 MILESTONE SCHEDULES AND RESPONSIBILITIES

This section should state the who, what, and when of continuous evolutionary process of the company's SPC system and its implementation. It may state at what intervals this milestone schedule should be evaluated and by whom.

6.0 SELF AUDIT

This section should describe, in detail, the SPC system self audit program. The "Self Audit Checklist" of this standard (Annex C) may be used in whole, as well as delineating other items such as frequency, documentation, and how results are acted upon.