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GEIA STANDARD

STATISTICAL PROCESS CONTROL SYSTEMS

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1 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 Purpose

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

3 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 Definitions

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

5 Reference Publications

Publications referenced by this document, along with additional references available on this topic, are provided in [Annex B](#).

6 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-STD-790, MIL-PRF-38535, and ANSI/ISO/ASQ Q9001.

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, runs, 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 actions 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.