

Include the following in solicitations/contracts whenever selected on the Contract Clause Selection Worksheet, ARDEC Form 367-E. This clause should not be used in conjunction with the "Alternatives to Lot Acceptance Sampling (Including Statistical Process Control (SPC))" local clause. At contract award, fill-in the "Date of Acceptance" and "Contract Number(s)" information that was provided by the Contractor in paragraph I (b).

52.246-4014

STATISTICAL PROCESS CONTROL (SPC)

OCT/2010

Part I – General Statistical Process Control Requirements

(a) In addition to the quality requirements of the technical data package, the Contractor shall implement Statistical Process Control (SPC) in accordance with a government accepted SPC Program Plan. Control chart techniques shall be in accordance with the American National Standards Institute (ANSI) B1, B2 and B3. Alternate SPC charting methods may be proposed and submitted to the Government for review.

(b) The SPC Program Plan developed by the contractor shall consist of a general plan and a detailed plan. The plans shall be structured as delineated on the Data Item Description referenced in the DD Form 1423. The general and the detailed plans shall be submitted to the government for review per DD Form 1423 requirements. Notification by the Government of acceptance or nonacceptance of the plans shall be provided in accordance with the timeframes specified on the DD Form 1423. Once a general plan for a facility has been approved by this Command, the approval remains in effect for subsequent contracts as long as the contractual requirements remain substantially unchanged from contract to contract. Therefore, resubmission of a previously accepted general SPC plan is not required if current SPC contract clause and Data Item Description (DID) requirements are fulfilled. If this Command has previously accepted the general SPC plan under essentially the same SPC contractual requirements, so indicate by providing the Contracting Officer with the following information:

Date of Acceptance _____

Contract Number(s) _____

(c) The contractor is responsible for updating the general plan to current SPC contractual requirements. If errors or omissions are encountered in a previously accepted SPC general plan, opportunities for improvement will be identified by the Government, and corrective action shall be accomplished by the contractor.

(d) A milestone schedule will be submitted for those facilities that do not have, or have never had, a fully implemented SPC program and will not have a fully operational SPC program once production is initiated. The milestones shall provide a time phased schedule of all efforts planned relative to implementation of an SPC program acceptable to the Government. A milestone schedule shall include implementation start and complete dates for those SPC subjects addressed in Part II of this clause. The milestone schedule shall only include those actions that cannot be accomplished prior to first article or the initiation of production, if a first article is not required. Milestones shall be developed for each commodity identified for SPC application. Milestones shall be submitted through the Government Quality Assurance Representative to the Contracting Officer for review and acceptance. Any deviations from the accepted milestones, to include justification for such deviations, shall be resubmitted through the same channels for review. The Government reserves the right to disapprove any changes to the previously accepted milestones. Notification by the Government of the acceptance or non-acceptance of the milestones shall be furnished to the Contractor by the Contracting Officer.

(e) The Contractor shall review all process and operation parameters for possible application of SPC techniques. This review shall include processes and operations under the control of the prime contractor and those under the control of subcontractor or vendor facilities. A written justification shall be included in the detailed plan for each process and operation parameter that controls or influences characteristics identified as critical, special, or major which have been deemed impractical for the application of SPC techniques. A pamphlet on application of SPC for short production runs is available through the Contracting Officer.

(f) Statistical evidence in the form of control charts shall be prepared and maintained for each process or operation parameter identified in the detailed plan. These charts shall identify all corrective actions taken on statistical signal. During production runs, control charts shall be maintained in such a manner to assure product is traceable to the control charts. At the conclusion of the production run, a collection of charts traceable to the product, shall be maintained for a minimum of three years. The control charts shall be provided to the Government for review at any time upon request.

(g) When the process or operation parameter under control has demonstrated both stability and capability, the Contractor may request, in writing, through Administrative Contracting Officer (ACO) and Contracting Officer (CO) channels to the Product Assurance and Test Directorate, that acceptance inspection or testing performed in accordance with contract requirements be reduced or eliminated. Upon approval by the CO, acceptance shall then be based upon the accepted SPC plan, procedures, practices and the control charts.

(h) The Government will not consider requests for reduction or elimination of 100% acceptance inspection and testing of parameters or characteristics identified as critical in the technical data package, specifications or drawings of this contract if any one of the following conditions exists:

(1) The existing process currently utilizes a fully automated, cost effective, and sufficiently reliable method of 100% acceptance inspection or testing for an attribute type critical parameter or characteristic.

(2) The Contractor utilizes attribute SPC control chart methods for the critical parameter or characteristic.

(3) The critical parameter or characteristic is a first order, single point safety failure mode (nonconformance of the critical parameter or characteristic in and of itself would cause a catastrophic failure).

(i) The Government will only consider reduction or elimination of the 100% acceptance inspection or test requirement for other critical parameters or characteristics if either of the following conditions is met:

(1) The process is in a state of statistical control utilizing variable control chart methods for the critical parameter or characteristic under control and the process performance index (Cpk) is at least 2.0. The Contractor shall maintain objective quality evidence through periodic audits that the process performance index is being maintained for each production delivery.

(2) The critical parameter or characteristic is conclusively shown to be completely controlled by one or more process or operation parameters earlier in the process, and those parameters are in a state of statistical control utilizing variable data, and the product of the probability of the conformance for each earlier parameter associated to the critical characteristic is better than or equal to a value equivalent to that provided by a Cpk of at least 2.0. The Contractor shall maintain objective quality evidence through periodic audits that the process performance indexes are being maintained for each production delivery.

(j) For characteristics other than critical, requests for reduction or elimination of acceptance inspection and testing shall be considered when the process performance index is greater than or equal to a Cpk of 1.33 for variables data. Requests shall be considered for attributes data when the percent beyond the specification limits is less than or equal to .003 (Cpk=1.33).

(k) Process or operation parameters under reduced or eliminated inspection or testing that undergo a break in production less than 6 months in length, may continue to operate under reduced or eliminated inspection or testing provided there has been no degradation below a Cpk of 1.33 (2.0 for criticals). Any break in production greater than 6 months shall require resubmission of the request for reduction or elimination of inspection or testing through the same channels cited in paragraph (g) above.

(l) Not used.

(m) Immediately following a change to a process or operation parameter under reduced or eliminated inspection, the process capability (Cp) or process performance indexes (Cpk) shall be recalculated and documented

for variable data; the grand average fraction defective shall be recalculated for attribute data. If any of these values have deteriorated, immediate notification shall be made to the Government along with the associated documentation. Return to original inspection and test requirements may be imposed as stipulated in paragraph n below.

(n) The Government reserves the right to withdraw authorization to reduce or eliminate final acceptance inspection or testing and direct the Contractor to return to original contract inspection or test procedures at any indication of loss of process control or deterioration of quality.

Part II – Detailed requirements pertaining to plan submittal

In accordance with DI-MGMT-80004 and Part I of this clause, the following supplemental information shall be considered and used when designing your general and detailed SPC plans.

1.0 General Management Plan

This section shall define management's SPC responsibilities and involvement and shall include management's commitment to continuous process improvement. The plan shall embrace a total commitment to quality and shall be capable of standing on its own merit.

1.1 Policy/Scope:

Describe the Contractor's policy for applying SPC, including goals and management commitment to SPC.

1.2 Applicable Document:

List documents that are the basis for the contractor's SPC program (i.e., ANSI standard, textbooks, Government documents).

1.3 SPC Management Structure:

Define the SPC management structure within the organization. Identify and include interrelationships of all departments involved in SPC (i.e., Production, Quality, Engineering, Purchasing, etc.) Identify by job title or position all key personnel within departments involved in the application of SPC. Describe which functions are performed by key personnel and when these functions are performed (i.e., include personnel responsible for performing inspections/audits, charting and interpreting data; personnel responsible for determining, initiating and implementing corrective action upon detecting assignable causes, etc.)

1.4 SPC Training:

Identify by job title or position the primary individual responsible for overseeing that SPC training is accomplished. Describe the qualification program required and in use for all personnel utilizing SPC techniques, including the qualification of trainers. Identify who is to be trained and the type, extent and length of such training (i.e., on-the-job, classroom, etc.). Identify when refresher training is required and how personnel using SPC techniques are monitored.

1.5 Manufacturing Controls:

Identify the criteria for performing SPC gage capability studies and describe how and when these studies are applied. Repeatability and accuracy of gages should be addressed.

1.6 Determination of SPC Use:

Describe how the process/operation parameters are determined appropriate for SPC application and explain what actions are taken if SPC is not deemed appropriate for critical, special and major process/operation parameters (i.e., Pareto analysis; analysis of characteristics with tight tolerances, etc.)

1.7 Process Stability and Capability:

a. Identify the criteria for performing process capability studies and describe how and when these studies are applied. Describe how the process capability index is calculated and include the frequency of these calculations. Describe what actions are taken as a result of each process capability study. Describe the contractor's methodologies when process capability is for variable and attribute data. To determine a capable process, the process/operation parameters shall meet the following requirements:

(1) Variable Data. Process capability (C_p) shall be determined. Process performance index shall be greater than or equal to 1.33 (C_{pk}). For critical parameters/characteristics, the process performance index shall be greater than or equal to 2.0 (C_{pk}).

(2) Attribute Data: Process capability/performance shall be the percent beyond the upper/lower specification limit less than or equal to .003 percent ($C_{pk}=1.33$).

b. Describe what actions will be taken if process/operation is sub-marginal or marginal. (C_{pk} less than 1.33 or 2.0 for criticals) or grand average fraction defective is greater than .003 percent).

c. Include analysis of statistical distributions and define all formulas and symbology utilized.

1.8 Control Chart Policy:

a. Type of charts to be used (i.e., \bar{x} bar/R \bar{x} bar/S, etc.) and rationale for use; the criteria for selection of sample size, frequency of sampling and rational subgroups.

b. Procedures for establishing and updating control limits, including frequency of adjustments.

c. Criteria for determining out-of-control conditions (i.e., trends, points beyond control limits, etc.) and the corrective action taken; to include failure analysis when the process is unstable or when nonconforming product has resulted from unstable processes. Illustrate out-of-control tests.

d. Describe the method of recording pertinent facts on control charts such as changes in raw material, machines, manufacturing methods and environment, and corrective actions taken and describe how control charts are traceable to the product.

1.9 Vendor/Subcontractor Purchase Controls:

Identify whether suppliers are required to utilize SPC and describe the extent the vendor's policies and procedures are consistent with in-house procedures of the prime contractor. Describe the following: methods utilized to determine that suppliers have adequate controls to assure defective product is not produced and delivered; the system utilized to audit suppliers, what will be audited and how often; what action will be taken when out-of-control conditions exist at subcontractor/vendor facilities.

1.10 SPC Audit System:

At a minimum, the contractor's SPC Audit System shall consist of auditing compliance with the planned arrangements specified in the general and detailed SPC plans followed by a review and analysis of the outcome to include implementation of necessary corrective action.

1.11 SPC Records:

Identify various records to be used in support of SPC and describe their use. Identify retention periods.

2.0 Detailed Plan:

This section shall detail specific manufacturing process/operation parameters under control.

2.1 Control of Process/Operation Parameters or Characteristics:

a. Identify the following for each process/operation by name or characteristic under control:

(1) Identify process/operation by name or characteristic and provide rationale for selection; justification for non-selection if the parameter or characteristic is identified as critical, special and/or major.

(2) Describe how the characteristic is produced; the chain of events, type and number of machines involved, location of manufacturing facility, tolerances maintained, etc.

(3) Production and inspection machinery used. Include the production rate, number of shifts and length of shifts plus whether inspection is fully or semi-automatic or manual. If manual, identify the type of gages in use.

(4) Identify the type of charts to be maintained and whether the process/operation is performed in-house or subcontracted out; identify facility/vendor where process/operation parameters are targeted for SPC.

2.2 Reduction or Elimination of Inspection/Test: The Procuring Contracting Officer (PCO) will accept submissions of requests for reduction or elimination of final acceptance inspection/testing when the requirements of the SPC contract clause and this SOW are met. Each request shall contain and/or address the following: control charts documenting twenty (20) consecutive production shifts or more for the same process/operation parameter under control; type of control chart utilized; control chart limits and process average or grand average fraction defective (as applicable); definition of out-of-control condition and corrective actions taken during out-of-control conditions; specification and part number.