

Include this clause in Solicitations and Contracts when required on the Contract Clause Selection Worksheet, ARDEC Form 367-E. Fill in information will be included on the form.

52.246.4017

**PROCESS CAPABILITY, CONTROL & IMPROVEMENT
REQUIREMENTS**

MAY 2011

a. The Contractor shall establish a Process Control System that includes, but is not limited to, procedures, systems and software. This Process Control System shall complement the requirements of an ISO 9001-2008 or equivalent Quality Management System as well as all contract quality requirements. Statistical Process Control (SPC), when utilized, shall be implemented in accordance with ISO 11462-1 and ANSI/ASQC B1, B2, and B3 or equivalent. A Process Control Plan (PCP), which describes actions and methods to assure production processes will be in a state of control, shall be submitted to the Government for review and acceptance as stipulated on DD Form 1423 and DI-MGMT-80004. Demonstration of process capability in accordance with the accepted PCP shall be accomplished prior to or at first article (if required) or prior to start of production. Acceptance of product shall be contingent on verification of acceptable process capability in accordance with the accepted PCP, provided all other contractual requirements are met. The Government reserves the right to withhold acceptance of product when there is evidence of noncompliance to the PCP. Should a finding of noncompliance to the PCP be made, a corrective action plan shall be submitted to the Government.

b. Characteristics for process control are as follows:

(1) Characteristics for process control are attributes or features whose variation have a significant effect on product fit, form, function, performance, service life or producibility, that require specific actions for the purpose of controlling variation. Characteristics for process control result from an in depth Government-only review and analysis as specified in Technical Data Package (TDP) documentation as required below:

(1.1) Government selected list, see paragraph g below

(1.2) As listed key characteristics

(2) Characteristics for process control are attributes or features whose variation have a significant effect on product fit, form, function, performance, service life or producibility, that require specific actions for the purpose of controlling variation. Characteristics for process control shall be determined using an in-depth Contractor review and analysis as specified in the PCP documentation. The Government reserves the right to identify any characteristics for process control as well as any additional characteristics identified in paragraph g.

(3) Characteristics for process control are features within a product, subassembly, part and process whose variation from nominal (i.e., target value) significantly impacts safety, performance in terms of customer's requirements, or final cost of a product. Special controls should be applied where the cost of variation justifies the cost of control. These shall be developed from an in depth Government-Contractor review and analysis of design as specified in paragraph g below.

c. The Contractor's analysis shall include processes and operations under the control of the prime Contractor and those under the control of sub-Contractor including subtier suppliers. The Contractor shall create a process flow chart for the entire process (including manufacturing, inspection and material handling) and perform Process Failure Modes and Effects Analysis (PFMEA) for all processes identified on the process flow chart [If option b(3) is selected, a PFMEA and process flow chart will not be necessary]. The Contractor shall identify, define and document specific controls applicable for each process and operation that affects all characteristics required for control by this clause. The Contractor shall: (a) conduct process capability studies on all process and operation parameters affecting characteristics for process control; (b) verify that all automated inspection equipment used to validate process capability has been properly calibrated and certified; and (c) conduct Measurement System

Analysis (MSA) studies on all applicable corresponding measurement systems utilized to monitor process capability.

d. The Contractor shall prepare and implement a PCP. The PCP shall be based upon and include the process flow chart, PFMEA [If option b(3) is selected, a PFMEA and process flow chart will not be necessary], process capability studies and Measurement System Analysis (MSA) for all process and operation parameters affecting characteristics for process control. For each characteristic, the PCP shall describe the entire process (including manufacturing, inspection and material handling), control methods and action plans for all out of control conditions and process capability at the stated production rates. When utilizing statistical methods, a process capability index such as C_{pk} shall be calculated. A characteristic for process control shall be considered to have an acceptable (and capable) process if it has a C_{pk} of at least 2.00 for Critical characteristics, 1.33 for all other characteristics selected for control, or as stated as follows: _____. The Contractor shall notify the Government when the minimum process capability values (C_{pk}) of 2.00 for Critical characteristics and 1.33 for all other characteristics for process control, or the alternative established minimum C_{pk} values, are no longer being maintained.

e. In accordance with MIL-STD-1916 the Contractor may request, in writing, that alternate methods of acceptance be evaluated once the processes and applicable operation parameters have been demonstrated to be both stable and capable. Any alternate methods may not be implemented until accepted by the Contracting Officer.

f. Corrective Action Requests (CARs) and Requests For Deviations (RFDs) generated for identification of product nonconformances shall result in an evaluation of the Process Control Plan (PCP). The evaluation will consider addition of new characteristics for process control to the contractually required process control list and require implementation of actions per paragraphs (c) and (d) above with submittal to the PCO for Government acceptance. If the CARs and RFDs are related to characteristics, processes and / or operations already identified in the PCP then those actions required by paragraphs (c) and (d) will be reassessed and submitted to the PCO for Government acceptance. The Government reserves the right to withhold acceptance of product until the revised PCP is accepted by the Government.

g. If box b(1)[1.1], b(2) or b(3) are checked above, the selected characteristics and applicable tools, techniques, control methods or method of analysis to obtain these are specified as follows: