

Include this clause when checked on the Contract Clause Selection Worksheet, ARDEC Form 367-E. To be included in all solicitations, contracts and purchase orders where the Government TDP, specification(s) or purchase description(s) contain one or more critical characteristics. Selected by the PQM in same manner as current SOW language.

**52.246-4011**

**CRITICAL CHARACTERISTICS (SIX SIGMA)**

**OCT/2010**

a. The contractor's processes shall be designed with the objective of preventing the creation or occurrence of non-conforming critical characteristics (see paragraphs d & e). The contractor shall establish, document and maintain a product specific, critical characteristics control (CCC) plan that shall be submitted to and approved by the Procuring Contracting Officer (PCO) IAW DD Form 1423 and DI-MGMT-80004. The CCC plan shall include or reference all procedures, work and handling instructions and process controls relating to any critical characteristics. Mistake Proofing techniques of the material handling and inspection systems shall be a part of the CCC Plan. Guidance for developing this plan and submitting Critical Plans of Action (CPOA) (paragraph g) can be found at <http://www.pica.army.mil/PicatinnyPublic/organizations/ardec/orgchart/quality.html>.

b. The contractor shall assure its critical processes are robust in design, capable and under control, with the objective of not generating any critical non-conformances. The contractor shall calculate, document, clearly identify, and have a schedule that routinely assess the reliability and effectiveness of its critical processes to prevent generating critical non-conformances as identified in the CCC Plan.

c. An inspection and verification system shall be employed that will verify the robustness of all critical processes. The contractor shall calculate, document, clearly identify, and have a schedule that routinely assess the reliability and effectiveness of its inspection and verification system to detect and prevent critical non-conformance escapes as identified in the CCC Plan. The Government expects that a contractor will allow zero critical escapes. To demonstrate its critical escape risk the contractor will utilize the non-conformance escape risk goal provided below.

(1) Unless otherwise specified immediately below, the calculated critical non-conformance escape risk is 1 in a million (.000001) items delivered. Or:

Alternate calculated Critical Non-conformance Escape risk (fill-in -1-):

Unless otherwise approved by the PCO, the non-conformance escape risk is the sum of the individual characteristic escape rates. The probability of escape for a single characteristic shall be calculated by multiplying the non-conformance rate(s) entering the inspection system(s) by the error rate of the inspection system(s). These escape rates are then summed and shall not exceed the tolerable critical non-conformance escape risk.

(2) Within 45 days after award, the contractor can elect to submit a phased-in approach on how the non-conformance escape risk will be achieved over a period of time not to exceed 180 days from the date of first article approval, or from initiation of production when first article is not required. Submission will require approval by the Government and is subject to a technical review and analysis. Allowance for a phased-in approach will then become a part of the contract. Disapproval of the contractor's submission does not relieve the contractor of its obligation to comply with the terms of this clause.

(3) Based on the maximum error rate defined for the inspection system, the contractor shall develop a test procedure to demonstrate the error rate. As part of the test plan the contractor shall include sufficient test quantities to assure 90% statistical confidence in the resultant rates unless otherwise approved by the PCO. Once established, the contractor shall have a documented schedule to routinely monitor the non-conformance and inspection system error rates to assure they do not exceed the maximum rates allotted.

d. As a result of previous practices, the government's technical data may refer to "Critical I", "Critical II", and "Special" characteristics. The use of the term "critical characteristics" within this clause includes Critical I, Critical II and Special characteristics and the use of the term "critical nonconformances" includes those nonconformances

pertaining to Critical I, Critical II and Special characteristics. Unless otherwise stated in Section C, these characteristics shall be subject to all requirements of this clause.

e. In addition to critical characteristics defined in the government's technical data (drawings, specifications, etc.), the contractor shall also identify and document in their contractor developed technical data all known material, component, subassembly and assembly characteristics whose non-conformances would likely result in hazardous or unsafe conditions for individuals using, maintaining or depending upon the product. All additional critical characteristics identified by the contractor shall comply with the critical characteristic requirements of the technical data package, supplemented herein. The Critical Item Characteristic List (CICL) review process shall be included in the CCC Plan. The contractor's additional critical characteristics shall be classified in accordance with guidance located at <http://www.pica.army.mil/PicatinnyPublic/organizations/ardec/orgchart/quality.shtml> and shall be submitted to and approved by the PCO prior to production (DI-SAFT-80970A).

f. In the event that a critical non-conformance is found anywhere in the production process, the contractor, as part of its CCC Plan, shall have procedures in place to ensure:

(1) The non-conformance is positively identified and segregated to ensure that nonconforming product does not inadvertently remain in or reenter the production process. This control shall be accomplished without affecting or impairing subsequent non-conformance analysis. Final disposition of non-conforming product shall be documented and audited for traceability.

(2) The operation that produced the non-conforming component or assembly and any other operations incorporating suspect components or assemblies are immediately stopped. (See para h. for exceptions)

(3) The government (PCO) is immediately notified of the critical non-conformance (electronic mail)(DI-SAFT-80970A).

(4) Any suspect material is identified, segregated and suspended from any further processing and shipment.

(5) An investigation is conducted to determine the root cause of the non-conformance and the required corrective actions. An evaluation shall also be conducted with regard to suspect material to ensure that no additional critical non-conformances are present. A report of this investigation shall be submitted to the government (DI-SAFT-80970A). The use of the DID report shall not delay notification to the government as required in f(3) above.

(6) A request to restart manufacturing or to use any suspect material associated with the critical non-conformance is submitted to the government (DI-SAFT-80970A). Restart of production shall not occur until authorized by the PCO, unless previously addressed in the approved CCC Plan. The Government will respond to a restart request within 3 working days. All objective evidence of the investigations to date shall be available for review at the time of restart. Suspect material shall not be used without PCO approval.

(7) The procuring activity reserves the right to refuse acceptance of any suspect material until the root cause or reasonably likely cause of the critical non-conformance has been identified, corrective action has been fully implemented and sufficient evidence has been provided to exclude non-conforming material from the conforming population.

g. The contractor may develop alternative plans and provisions, collectively referred to as a Critical Plan of Action (CPOA), relative to government or contractor identified critical characteristics. All CPOAs are independent and shall be evaluated by the government for this contract. The CPOA and any subsequent revisions submitted IAW DD Form 1423 and DI-MGMT-80004 require PCO approval prior to implementation. Unless otherwise specified at time of approval, contractor shall review and evaluate CPOAs for currency and process improvements at least on an annual basis and submit results to the PCO. Unless otherwise approved by the PCO, each critical characteristic shall require a separate CPOA. If the CPOA includes other documents by reference they shall be submitted upon request. Guidance for the development of a CPOA can be found in the referenced guidance located at paragraph a of this clause.

h. The contractor may continue production with an approved CPOA provided that the critical non-conformance is consistent with the failure mode(s) and rates established in the CPOA. Failure to meet all CPOA requirements will require the contractor to revert back to paragraph f requirements.

i. If a critical non-conformance is discovered beyond its designated inspection point and prior to Government acceptance the contractor shall take actions specified in paragraph f above. If a critical non-conformance is discovered after Government acceptance the Government has the right to invoke the requirements of paragraph f with respect to the contractor's remaining production under this contract.