# Review Guide
# for
# Critical Characteristics Control Plan
# and
# Critical Plan of Action

## Per the
## Single Manager for Conventional Ammunition
## Critical Characteristics Contract Clause

## Revision A with Amendment 1

## October 07, 2015

**Disclaimer**: The review guide's content in its entirety is provided solely for reference and guidance purposes only; it is not, nor is it intended to be, contractually binding. Accordingly, the information contained within the review guide is expressly not, nor shall it be, construed to be incorporated, either directly or by reference, into the terms of the Critical Characteristics Clause itself nor into the terms and conditions of any underlying contract which contains the Critical Characteristics Clause.

**Distribution Statement A:** Approved for public release; distribution is unlimited.

# Revision History

| Revision | Date | Description |
|---|---|---|
| -- | 8 March 2006 | Initial Release |
| A | 10 May 2012 | CCC Guide Update Effort to provide greater clarity for CCCP and CPOA including addition of Appendices C, D, E, F and G. |
| A, Amd 1 | 07 October 2015 | Updates for corrections, clarity, and typos:<br>• Para c(3), 1, 2nd para: Clarify that inspection system shall not accept defects.<br>• Para c(3), 1, 3rd para: Clarify that VL-VII inspections are not included in inspection reliability/escape risk calculations.<br>• Example 4: Delete "minimum" in title and correct 0.356 to 0.390 in final answer.<br>• App A3: Correct DID to "DI-SAFT-80970A"<br>• App C, para 2.c(1)(a): Clarify wording to emphasize that CPOA thresholds used to evaluate escape risk<br>• App C, para 2.c(2)(a): Clarify wording by changing sentence order. |

Changes from previous issue. The margins of this document are marked with vertical lines to indicate where changes from the previous issue were made. This was done as a convenience only and the Government assumes no liability whatsoever for any inaccuracies in these notations. Bidders and contractors are cautioned to evaluate the requirements of this document based on the entire content irrespective of the marginal notations and relationship to the last previous issue.

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# Critical Characteristics Clause
# CCCP & CPOA Review Guide

## Introduction

The critical characteristics clause Critical Characteristic Control Plan (CCCP) and Critical Plan of Action (CPOA) review guide is meant to be an aid as follows:

- For contractors, suppliers, or any entities that produce assemblies, parts, or components with critical characteristics, including Government Owned Government Operated (GOGO) facilities, who are developing a CCCP and/or CPOA.
- For individuals who are reviewing a CCCP or a CPOA which has been submitted.
- For individuals who are the disposition authority of a CCCP or CPOA.

The goal of this document is to assure a uniform review process for CCCPs and CPOAs. The objective in developing the review guide is to provide a common methodology that prescribes the development and review of Critical Characteristic documents.

The document is set up in a fashion where each clause paragraph is duplicated and then followed by what should/shall be addressed in a CCCP or CPOA for that particular clause paragraph. These excerpts do not substitute for the actual clause included in a solicitation, production order, or contract. Additionally, there are appendices to provide further information and guidance.

### Notes

- Any given CCCP or CPOA will have variety in it that will distinguish it from other submissions,
- Every CCCP or CPOA submitted shall address every requirement contained in the clause.

The latest revision of this guide is available at the following web site:
http://www.pica.army.mil/PicatinnyPublic/organizations/ardec/orgchart/quality.html

# Paragraph a - CCCP

a. The contractor's processes shall be designed with the objective of preventing the creation or occurrence of non-conformance of a critical characteristic (see paragraphs d and 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

## Review Points

Critical non-conforming material includes any material that does not meet critical characteristic requirements per the contract, including material for which an approved standard rework procedure exists.

The CCCP forms a part of the contractor's quality system and addresses how a contractor and their subcontractors will PREVENT the creation of a critical non-conformance (defect), but in the event of its occurrence, assure its detection and control (paragraph f). This entails those aspects of the manufacturing process that can influence the creation of a critical non-conformance including, but not limited to, the production process, work instructions/procedures, process controls, mistake proofing/Poka-Yoke (see MIL-HDBK-1916, paragraph 6.1.1), inspection systems (Acceptance Inspection Equipment (AIE), Automated Acceptance Inspection Equipment (AAIE)), materials, material handling, personnel, training, and quality management system (calibration, corrective/preventive action, control of non-conforming product, supply chain management).

Requirements of the clause apply to wherever a critical non-conformance can be created and/or detected, whether at the contractor's facility, their subcontractor's facility, or any subsequent location. The CCCP may reference existing documents for systems currently in place that may be related to non-conforming material controls. It is good practice to include any referenced documents as a part of the CCCP submission to enable effective review and expedite approval of the plan. This plan can be supplemented with CPOAs for specific critical characteristics which a contractor may elect to develop/submit (paragraph g).

There shall be one comprehensive product specific CCCP submitted by the contractor for the contract. The contractor may divide the CCCP into sections by the different subcontractors, suppliers, or facilities. However, the CCCP must address overarching requirements including how the prime contractor will manage and coordinate the CCC requirements throughout the supply chain as well as continuously monitor and track inputs used to establish the overall product specific escape risk. Factors such as caliber, processes, materials, technical data package (TDP) requirements, manufacturing location, and other contractual requirements may be used to define "product specific". If any questions exist on what "product specific" means, a request for clarification should be submitted to the PCO.

## Key Elements of a CCCP

For details, please reference Appendix C.

The CCCP shall identify and describe all product realization processes which can affect the creation, handling, movement, and/or detection of critical non-conformances anywhere within the supply chain. This shall include:

1. Procedures of the process and work instructions: This section should describe the manufacturing process, including (or referencing) all operating procedures of the manufacturing system, under all conditions (e.g., normal operation, power failure, recall, etc.). This can be addressed through a detailed production process map incorporating failure modes identified by a Process Failure Mode and Effects Analysis (P-FMEA) (for an sample format, please see Appendices E & F). Procedures should specifically address what controls are in place to mitigate failure modes such as a power failure, tool breakage, dropped/mishandled parts, etc. (See process controls.)

2. Handling instructions: Material handling system for an item is defined as all operations (e.g., manufacturing, inspection, material transport, storage, marking, rework, repair, disposal, etc.) which affect the feature classified as a critical characteristic defined by the contract (Detail Specification, Performance Specification, Critical Item Characteristic List (CICL), etc.). The contractor should assure that the documentation has positive procedures in effect for identifying and controlling material with features identified as critical characteristics. Additionally, it should address material handling to ensure that items do not bypass critical manufacturing and/or inspection processes.

3. Process controls: Tools such as Statistical Process Control (SPC) or other process control tools should be applied to ensure processes are capable and under control.

4. Mistake proofing techniques: Failure modes of the material handling and inspection systems should be assessed and mistake proofing techniques implemented to reduce the risk of a critical nonconformance creation, introduction, or the possibility of an escape.

5. Inspection systems: Description of inspection systems used to verify/validate critical non-conformances shall be included in the plan. This applies to Automated Acceptance Inspection Equipment, Acceptance Inspection Equipment, In-Process Inspection, Standard Measuring Equipment, gages, visual inspection, defect masters/salters (known critical non-conformance samples use to verify reliability of the inspection system, whether AIE, AAIE, or visual), referee gages, etc. For example, in the event of a power failure it must be assured that the machine logic is not affected thereby preventing a reject from being "remembered" and kicked out; or a procedure which requires clearing the indexing table and evaluating the material.

   *Note:* The above elements (1-5) should include the specific locations/facilities that apply e.g. different buildings, production lines, or subcontractors.

CCCP shall be updated with a new revision and corresponding date and resubmitted for approval when:

- the critical nonconformance threshold rates are re-calculated.
- the location of production changes.
- there are any major process changes.
- there are any major equipment changes.
- there are any inspection system changes.
- any new failure modes are identified or eliminated.
- there are any change in subcontractors affecting or influencing critical characteristics.
- there are any changes in technical data requirements (new specifications/drawings, Engineering Change Proposals, Request for Deviations, etc.) affecting or influencing critical characteristics.
- the established schedule within the CCCP requires an update.

## CCCP Approval Process

Initial submissions and revisions of the CCCP shall be submitted for approval per DD Form 1423 (sample Contract Data Requirements List format provided in Appendix A). Revisions to documents referenced by the CCCP (such as control of non-conforming material, material handling, etc.) can be requested by the government to determine if the CCCP is materially affected and requires re-approval.

For the internal government approval flow chart, please refer to Appendix B.

## Notes

The CCCP is a supplementary document to the Quality Management Plan required by the Higher Level Quality Requirements clause.

MIL-STD-1916 also addresses requirements for critical characteristics, control of non-conforming product, inspection, and process controls. This clause is intended to supplement and work with these requirements, or any other contract requirements. Additional requirements regarding critical characteristics may be included from the item's TDP (including drawings and specifications), additional referenced or included specifications (such as MIL-A-48078, MIL-A-70625, etc.) and the contract.

# Paragraph b - Production Process Robustness

> 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.

For the necessary elements of a CCCP, please reference Appendix C.

## Review Points

A process is robust if:

- Performance will be insensitive to variation in factors internal and external to the process.
- Flexible.
- Easy to operate.
- Easy to error-proof.
- Anticipates changes in material, environment, operators, etc.

Capable and Controlled Process: A capable process for critical characteristics should have a minimum process capability of 2.0 or as defined by the contract (MIL-STD-1916 or other contract quality clauses – SPC or Process Capability, Control and Improvement, etc.). ISO 9001:2008 paragraph 7.5.1 also describes elements of a controlled process.

To prevent critical non-conformances, the contractor's CCCP shall address the methodology to assess the reliability and effectiveness of the production processes throughout their entire supply chain that influences creation of critical non-conformances. This is generally addressed by:

- Documentation and identification of the processes (flow charts, work instructions, procedures, FMEA methodology, key process parameters - pressure, temperature, environmental controls, etc.) and mistake proofing techniques.
- Calculating relevant data for critical characteristic processes (non-conformance rates, process capability, first pass yield, etc.).
- A schedule to assess relevant metrics and process documentation and take corrective action when needed. This schedule should consider production rates

and volume. The assessment should ensure that the reliability and effectiveness of the system is evaluated and maintained to prevent the creation of critical non-conformances, and determine the critical non-conformance rate and impact on end item escape rate risk (see paragraph c for further details). Tools such as SPC, process capability studies, and audits can be utilized for the assessment.

The process reliability and effectiveness is the first pass *production* yield of product (with respect to critical characteristics) prior to inspection (by contractor/subcontractor). This addresses the incoming non-conformance rate going into any inspection process (in-process or final). This paragraph applies to the production process, while paragraph c addresses the inspection system. Production entails the transformation of materials and parts with input from personnel and equipment into a finished product.

What constitutes “routinely” for an individual item or characteristic would be based upon production rates and volume. If a process produces a million parts a month, an annual frequency would not meet the standards of “routinely”. For example, a high rate manufacturing system with an SPC frequency of a daily basis would not meet the intent of “routinely”. Inadequate periodic verification will impact the approval of a CCCP.

## Notes

The goal is to continually drive the critical non-conformance rate to zero, but must realize it will require time and resources to eliminate some non-conformances.

# Paragraph c - Inspection System Robustness

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.

For the necessary elements of a CCCP, please reference Appendix C.

## Review Points

An escape is a critical non-conformance identified past its designated inspection point; whether it is discovered at a subsequent operation or facility, or is delivered to the government. This will result in a shutdown of the process controlling the identified critical characteristic and the inspection process that allowed the escape. Acceptance of any critical non-conformance or any critical non-conformance master by AAIE or the inspection system constitutes an escape and shall result in shutdown.

The contractor's CCCP shall identify the methodology used to assess the reliability and effectiveness of the inspection and verification system. It shall include:

- Documentation and identification of the inspection and verification processes at both the contractor and subcontractor facilities. This includes AIE, AAIE, in-process inspection, and when accepting on process control (per MIL-STD-1916), the process control measuring and monitoring systems.
    - Inspection systems provide feedback on production and compliance to requirements, but do not comprise part of the production system. Production entails the transformation of materials and parts with input from personnel and equipment into a finished product.
    - MIL-STD-1916 (see paragraph 4.4) requires that "unless otherwise specified in the contract or product specifications, the contractor is required for each critical characteristic to implement an automated screening or a fail-safe manufacturing operation and apply sampling plan VL-VII to verify the performance of the screening operation."
    - The MIL-STD-1916 requirement for screening and VL-VII verification should occur at the same facility and the VL-VII verification is required whether the 100% screening is performed by AAIE or visual/manual inspection.

- Definition of the designated inspection points and any proposed referee gages/procedures to validate critical non-conformance.

- Definition of how the inspection system reliability will be calculated.

    - For purposes of calculating inspection system reliability, where visual inspections are called out as the inspection system, the individual inspections should not be separated. In addition, visual inspection stations must have documented inspection procedures (generally including visual standards) and maintain inspection records.

- Conditions (location, environment, rate) under which the inspection system is qualified to run.

- A schedule (frequency) to routinely assess inspection system reliability and take corrective action. This schedule should consider production rates and volume to ensure that reliability and effectiveness of the system can be assessed to prevent the escape of a critical non-conformance, to assess the inspection system error rate and determine impact on end item escape rate risk. The use of defect masters or salters to assess reliability is a standard practice. These masters are typically run through several times a day to validate system control.

## Paragraph c(1) - Calculated Non-Conformance Escape Risk

(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: _____

Unless otherwise approved by the PCO, the non-conformance escape rate 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.

### Review Points

The non-conformance rate is an estimate of the capability of the process and is determined as a upper confidence limit of the number of non-conformances produced and the number of items manufactured (which would correspond to one minus the 90% lower confidence bounds of the rate of manufacturing conforming material). It is independent of where the non-conformance is identified or found. Non-conforming material includes any material that does not meet requirements; including material for which an approved standard rework procedure exists.

The contractor may omit GFM escape risks from their calculations unless actions by the contractor upon receipt or during subsequent processing affect those risks.

Functional critical characteristic non-conformances found during destructive testing (e.g., functional testing, Ballistic Lot Acceptance Testing (BLAT), etc.) should not be included from the overall critical characteristic escape risk calculation. However it does not exclude the other provisions of the clause (shutdown, notification, etc.).

The following example provides a simplified example of calculating Escape Risk; it uses the assumption of attributes inspection to give inspection system error rate demonstration quantities. See paragraph c(3) discussion for information on alternatives.

Example 1. SIMPLIFIED EXAMPLE FOR CALCULATING ESCAPE RISK FOR SEVERAL CRITICAL CHARACTERISTICS DEMONSTRATING MEETING 1/1 MILLION ESCAPE RISK REQUIREMENT

An item's specification lists three (3) critical characteristics and the default requirement is for not worse than 1 in 1 million total escape risk.

Recent, relevant, history includes creation of 2 critical non-conformances for Critical Characteristic #1 (C1), 6 critical non-conformances for Critical Characteristic #2 (C2), and 0 critical non-conformances for Critical Characteristic #3 (C3) out of 78,000 items manufactured. Accordingly, determination of the 90% upper confidence bounds for the non-conformance creation rates would yield rates of 0.000068 (C1), 0.000135 (C2), and 0.000030 (C3).

If the inspection system error rate (risk) for C1 has been demonstrated to be not greater than 1 in 500 (0.002), and C2 and C3 have been demonstrated to 1 in 750 (0.0013333) each with successful running and detection of 1150 (C1) and 1725 (C2 and C3) of each non-conformance master accordingly (see paragraph c3, Review Point 2) than the overall escape risk would be determined as follows:

(C1) $Mfr\_rate_{C1} * Insp\_Error\_Rate_{C1} = Esc\_Risk_{C1}$
(C2) $Mfr\_rate_{C2} * Insp\_Error\_Rate_{C2} = Esc\_Risk_{C2}$
(C3) $Mfr\_rate_{C3} * Insp\_Error\_Rate_{C3} = Esc\_Risk_{C3}$

(Total) $Esc\_Risk_{C1} + Esc\_Risk_{C1} + Esc\_Risk_{C3} = Esc\_Risk_{Total}$

Therefore:
(C1) 0.000068 * 1/500 = 0.000000136
(C2) 0.000135 * 1/750 = 0.000000180
(C3) 0.000030 * 1/750 = 0.000000040

(Total) 0.000000136 + 0.000000180 + 0.000000039 = 0.000000356

= 0.356 per million which meets the total escape risk requirement for less than 1/1 million.

## Paragraph c(2) - Allowance for Phased-In Approach

(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.

### Review Points

Request for phased in approach is not part of the CCCP. This request requires a separate submission and approval from the PCO. If the request is approved, then the phased-in approach needs to be addressed within the CCCP.

Some contractors may not be able to meet the calculated critical non-conformance escape risk right at the start of production. Contractors are given the option to propose a phased-in approach to comply with the clause paragraph c(1) requirement. This option would only be approved where it is in the best interests of the government.

A contractor's request for a phased in approach will include the following:

1. Current Process capability and any supporting data available.
    a. Current non-conformance rate for each critical characteristic.
    b. Current inspection equipment error rate for each critical characteristic.
    c. Current Individual escape risk.
    d. Current total escape risk.
2. Commitment to meet their current total escape risk for the requested time period.
3. Justification for the requested relief period addressing the specific limitations.
4. An improvement plan which identifies strategies for meeting the contractual requirement and includes a milestone chart with key phases and dates. The plan should include, at a minimum, activities such as:
    a. Process capability improvement studies.
    b. Inspection system reliability studies and implementation.

c. SPC implementation strategies.

d. Material handling system improvements.

e. Modification or purchase of process equipment or inspection equipment.

f. Training of personnel and/or acquisition of new competencies.

g. Software implementation.

## Paragraph c(3) - Inspection System Error Rate

> (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.

### Review Points

1. Error Rate

The error rate (risk) of the inspection system is determined as a upper confidence level (bound) based upon the number of non-conforming parts accepted and the number of parts inspected during prove-outs and/or historical data. The minimum upper confidence level shall be 90% (with zero non-conformances), unless otherwise approved by the PCO as part of a phased in-approach when requested.

The contractor shall develop a test procedure (referenced to or included within the CCCP) to demonstrate inspection system error rate which shall be performed using non-conforming parts or reject standards (representing the full spectrum of non-conformances). No part or standard shall be accepted during the test. If a part or standard is accepted, the cause of the failure shall be isolated and corrected and the test rerun to demonstrate efficacy.

If redundant (series) inspection equipment is utilized, the overall inspection system error rate shall be calculated by multiplying the error rate of the first inspection point by the error rate of the following inspection point(s) (e.g., overall inspection system error rate = error rate of 1st inspection station * error rate of the 2nd, etc.). Verification Level VII inspections IAW MIL-STD-1916 verify the performance of the screening operation (100% inspection) and shall not be included in calculations assessing the overall inspection system reliability or escape risk. Defects identified by the VL-VII inspection are, by definition, escapes.

The prove-out of inspection equipment for critical characteristics using a confidence level of 90% can be accomplished either via attribute or variable data. For attribute inspections the test quantities can get quite large. Great reductions in test quantities are typical for tests utilizing variables data when feasible.

2. For assessment of inspection reliability using attribute data:

The following formula in MS Excel™ will provide prove-out test quantities for attributes:

Quantity of test samples = ROUND(CHIINV(1-*c*,2*(x+1))/((1- θ)*2),0)

where c = confidence level (0.90), x = failures allowed (zero in our case) and θ = reliability required.

An adequately accurate simplification of this formula for 90% confidence and 0 defectives accepted is:

Quantity of test samples = 2.3 / (1-θ)

Visual inspections performed after the AAIE should not be considered in the calculation of inspection system error rates.

When allowed by the TDP, visual inspection of a single characteristic is considered by industry standards to be 80% reliable and can be negatively affected by production rates, lighting, and other factors. Visual inspections of multiple characteristics by the same individual or under adverse conditions are less than 80% reliable. Data should be provided by the contractor to document the reliability of multiple visual inspections and any deviations from the above. Two independent visual inspections of a single characteristic in series are considered to be 96% reliable (see below for calculation).

1 – ((1 - 0.8) x (1 - 0.8)) = 0.96

To obtain this higher inspection reliability, multiple sequential visual inspections should not be separated by other manufacturing processes, operations, or locations.

3. <u>For assessment of inspection reliability using variable data</u>:

If a measurement system must meet reliability with respect to a single critical limit, the working limit may be biased to assure that measurement repeatability does not enable critical non-conforming product to be accepted. The k factor or Tolerance Factor can be used to determine the minimum bias. If, for example, a maximum inspection system error rate of 1:200 (or point estimate reliability of 0.995) is assigned to the measurement system, based upon a sample of 30 measurements at a confidence level of 90%, the bias would be to restrict the limit by 3.16 times the standard deviation determined for the repeatability.

The k factor can be found in statistical tables or calculated. Using the single tailed formula for approximate values of $k_1$, acquired from the NIST/SEMATECH Engineering Statistics Handbook, the function in MS Excel™ would look like:

= (NORMSINV(θ)+SQRT((NORMSINV(θ)^2)-((1-((NORMSINV(*c*)^2)/(2*(n-1))))*
((NORMSINV(θ)^2)-((NORMSINV(*c*)^2)/n)))))/(1-((NORMSINV(*c*)^2)/(2*(n-1))))

where θ = reliability requirement, n = sample size, and *c* = confidence level. (*Note:* cell locations in Excel need to be substituted for θ, n, and *c*).

The use of variables data then potentially reduces the required prove-out test quantities from 460 that would be required for attributes data to 30 for the above example.

Automated measurement equipment would require fail-safe electro-mechanical and software design and regular maintenance to assure that those design features continue to function properly. Otherwise the reliability of identifying product deemed to be non-conforming would also need to be assessed including special causes of failure in the inspection system.

4. Additional methods to reduce qualification sample quantities or time.

Methods of reducing the number of samples or time required to prove-out the AAIE include:

- Use of redundant, independent inspection stations in series.
- Use of multiple non-conformance standards containing the same non-conforming characteristic to reduce cycle time.
- Accumulation of historical data from periodic verification.

5. Scheduling of review of inspection error rate.

The contractor in their CCCP shall identify an adequate frequency for monitoring inspection system error rates to ensure that escape risk remains better than one in one million. This monitoring can be accomplished by routinely running of defect masters. Objective verification shall be available at any time.

The following example provides a simplified example of determining inspection system error rate demonstration quantities for attribute inspections.

Example 2. SIMPLIFIED EXAMPLE FOR CALCULATING NUMBER OF REQUIRED SAMPLES FOR DEMONSTRATION OF INSPECTION RELIABILITY USING ATTRIBUTE DATA

An item's specification lists two (2) critical characteristics and the default requirement is for not worse than 1 in 1 million total escape risk. The inspection systems for both of these characteristics are going to use attribute data for the decisions of their AAIE.

Based upon requirements to meet overall escape risks requirements and/or other contractual requirements, the inspection error rate (risk) for Critical 1 (C1) needs to be demonstrated at least 1/500 (.002) and for Critical 2 (C2) at least 1/750 (0.0013333) each at a 90% upper confidence bound. We can determine the minimum number of defect masters that the system must successfully reject without incorrectly accepting any defect masters by using the 2.3 factor shown above where $\theta$ is the inspection system reliability and $(1-\theta)$ is the inspection system error rate.

(C1) # Samples = $2.3 / (1-\theta_1)$
(C2) # Samples = $2.3 / (1-\theta_2)$

Therefore:
(C1) # of Samples = 2.3 / (1/500) = 2.3 * 500 = 1150
(C2) # of Samples = 2.3 / (1/750) = 2.3 * 750 = 1725

Therefore:
The inspection system for C1 must demonstrate its minimum inspection reliability by successfully rejecting 1150 of the specific defect master (or of each defect master if there are multiple) while accepting none (0). The inspection system for C2 must demonstrate its minimum inspection reliability by successfully rejecting 1725 of the specific defect master (or of each defect master if there are multiple) while accepting none (0).

It should be noted that this is the method solely for demonstration of inspection system reliability. Additional qualification may be required to demonstrate and qualify an inspection system to meet other additional contractual requirements.

# Paragraph d - Previous Practices

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 non-conformances" includes those non-conformances 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.

## Review Points

Paragraph d provides definitions and does not require contractor input with the exception of properly identifying all the characteristics which fall under the auspice of the critical characteristics clause. All criticals and "Specials" are to be considered critical until changed by Engineering Change Proposals (ECPs) in the TDP.

# Paragraph e - CICL

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.html and shall be submitted to and approved by the PCO prior to production (DI-SAFT-80970A).

For the necessary elements of a CCCP, please reference Appendix C.

## Review Points

This paragraph applies to the contractor's technical data (performance based acquisition, Commercial Off the Shelf (COTS), Non-Developmental Item (NDI), etc.) as well as if the contractor chooses to review a government TDP for additional critical characteristics. Additional failure modes leading to destructively tested critical non-conformances can be identified as part of the CICL and included within the CCCP and CPOA accordingly.

The contractor shall establish a review process for identifying additional critical characteristics. If, as part of this process, a contractor identifies any additional critical characteristics, they shall be submitted to the government as a part of a CICL. Additional critical identified by the contractor will be included and addressed in the CCCP. Development and submission of a CICL list does not supersede any other contractual requirements. When referenced within the TDP, the definition of a critical characteristic is per DOD-STD-2101 or MIL-STD-1916.

Common tools used to generate a CICL:

- Cause and Effect Analysis.
- Fault Tree Analysis.
- Failure Modes Effects Analysis.

- Design of Experiments.
- Historical data including experienced failures leading to occurrences of critical non-conformances.

For the internal government approval flow chart, please refer to Appendix B.

# Paragraph f - Critical Non-Conformances

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:

For the necessary elements of a CCCP, please reference Appendix C.

## Review Points

The phrase “anywhere in the production process” means the critical non-conformance is found at or after the operation that produces that characteristic. It is a critical non-conformance, even if found prior to the designated inspection point.

The following are examples of some unique “production processes” consisting of a multiple step operation which must be fully completed to create a conforming part:

- If “depth to explosive filler” is a critical characteristic and depth is controlled by drilling out the explosive to a specified height, the critical characteristic would not apply until the projectile had completed the drilling and vacuuming processes.
- If “explosive residue on exterior of body” was a critical characteristic and it is known and documented in the CCCP that the drilling operation causes explosive dust to get onto the outside of the projectile, this critical characteristic would not apply until after the operation designed to clean the outside of the projectiles.
- In either of these examples, parts which bypassed or were found downstream of the process would be considered as critical non-conformances but not those found between the operations.

In a system where redundant (series) inspection stations are utilized to achieve the needed inspection reliability the product determined to be non-conforming by the first inspection station will be considered a critical non-conformance and counted as such. Additionally, any critical non-conformance found at any other location including in-process inspection stations shall be counted as well.

## Paragraph f(1) - Identification, Segregation and Disposition

> (1) The non-conformance is positively identified and segregated to ensure the non-conforming 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.

### Review Points

As part of the CCCP, the contractor will identify the specific procedures and individuals who will:

1) Identify the critical non-conformance; e.g., tagged, color coded, marked, placed in a marked sealed bag.

2) Segregate the critical non-conformance to prevent reintroduction; e.g., placed in a locked container or other positive control method.

3) Maintain auditable custody chain with objective evidence to ensure accountability and traceability of the critical non-conformance through final disposition.

## Paragraph f(2) - Operation Stoppage

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

### Review Points

The CCCP shall require that all critical non-conformances, when found, will result in immediate stoppage of the appropriate operation(s). The operators, supervisors, and appropriate management personnel shall take actions as prescribed in the CCCP to ensure the operation(s) that produced the non-conformance are immediately stopped and relevant data is collected for notification to the government.

The term “any other operations” includes operations at subcontractor facilities and operations downstream (in-plant or external to the contractor) as well. In situations where multiple machines or stations perform a similar/identical operation in parallel, and a critical defect is found originating from one of those machines/stations, all of the machines/stations shall be immediately stopped. Exceptions to this must be approved by the government on a case-by-case basis.

## Paragraph f(3) - Notification

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

### Review Points

The CCCP will document the process and personnel involved in the notification to the government including notification time. Notification must occur for all critical non-conformances, without exceptions.

"Immediate" means no longer than 24 hours unless otherwise stated in the DD Form 1423. Notification shall be in accordance with the distribution list of the DD Form 1423.

An approved CPOA does not relieve the contractor from this notification requirement when a critical non-conformance is found even though the approved threshold has not been exceeded, an escape has not occurred, or it was the result of a known failure mode. However, the notification may be conducted through an agreed upon periodic report.

## Paragraph f(4) - Suspect Material

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

### Review Points

The CCCP shall address the methodology by which suspect material will be identified, segregated and suspended from further processing and shipment.

As an example, when the inspection method employed is AAIE the material considered suspect will be, at a minimum, that quantity of material which has been produced since last successful verification with the appropriate reject masters. Typically this is 2-4 hours of production depending upon inspection and production throughput. If a visual or manual inspection method is used, the CCCP should identify how the contractor determines what would be considered suspect material.

Any critical escapes beyond the designated inspection point(s) would expand the scope of what is considered to be suspect material. All suspect material, regardless of location, should be properly identified, segregated and suspended from use. Examples of potential scenarios which need to be addressed in the CCCP include: Where is the suspect product? Has any suspect product left the plant? Has it been delivered to the customer?

## Paragraph f(5) - Root Cause and Corrective Action

(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.

### Review Points

The CCCP should identify the contractor's process for determining root cause and required corrective actions including evaluation and disposition of suspect material. It should include the contractor's internal review and approval process in addition to the process for the submission of these findings to the government.

The contractor's documentation shall provide sufficient detail on exactly what steps constitute an investigation, including adequate validation of corrective action. The contractors' documentation shall also assure adequate depth of root cause analysis has been conducted.

## Paragraph f(6) - Operation Restart and Disposition of Suspect Material

> (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 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.

### Review Points

CCCP shall state that the contractor will not utilize suspect material or restart production without PCO approval and provide the methodology for requesting approval.

The request to restart will include information, per DI-SAFT-80970A (paragraph 4.3).

The contractor is not relieved from any of the obligations of this clause including control of non-conforming material, root cause analysis, and corrective/preventive action if a proposed self-restart process is approved. Approval of such self restart is the exception to the rule, which will seldom be approved without significant negative programmatic impact to a major government program milestone. It is solely at the government's discretion as to what constitutes a major government program. All material and production under such a self restart shall be withheld from acceptance until PCO approval of the request to restart is provided. The government is under no obligation to accept any product manufactured under a self restart.

### Notes

- PCO will respond to the contractor after coordination with customers and technical community. The government's time frame for initial response to the contractor will be established in the clause and DD 1423.

- Government has the right and authority to confirm and verify the effectiveness and efficiency of the implemented corrective actions IAW ISO 9001:2008 or equivalent QMS requirements.

For the internal government approval flow chart, please refer to Appendix B.

## Paragraph f(7) - Right of Refusal

(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.

### Review Points

See previous sections including paragraphs f(5) and f(6).

# Paragraph g - CPOA

> 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.

For the necessary elements of a CPOA, please reference Appendix D.

### Review Points

The CPOA is not a waiver to the requirements of this clause. The CPOA gives a contractor a methodology to address known failure modes within approved critical non-conformance creation rates (also referred to as CPOA thresholds), appropriate corrective actions and continuous improvement to reduce critical non-conformances. For a stable and in-control production process with well understood non-conformance creation rates and failure modes, it provides a means to maintain operational continuity while avoiding delays due to mandated shutdown.

CPOAs are independent for each critical characteristic and do not require government mandated shutdown (per paragraph f(2)) and restart (per paragraph f(6)) procedures where evidence is provided that the contractor has adequate knowledge of the failure modes, root causes and associated corrective/preventive actions with critical non-conformances and is able to show that their processes are under control.

The goal of this clause and tools such as the CCCP and CPOA are to continually improve processes, prevent critical non-conformances, and manage them ensuring escape risk is less than as defined in paragraph c(1).

While each CPOA for individual critical characteristics stand on their own, they may be submitted to the government for review in a single document, or separate documents. However, government may approve/disapprove CPOAs for each critical characteristic separately; e.g., product has 20 critical characteristics, therefore it is acceptable that the contractor submits one or more documents that address the CPOAs for each critical

characteristic. However, government reserves the right to accept/reject each CPOA for the 20 critical characteristics (therefore 20 CPOAs) on an individual basis.

The contractor shall review CPOAs at minimum on an annual basis and submit the results to the PCO. It is encouraged that review of CPOAs be performed more frequently.

When the CPOA or its referenced documents are revised and the revision will affect the requirements specified in the clause, the contractor will resubmit for government re-approval and make the revised reference documents available to the government upon request.

CPOA thresholds should be established based on the rate of occurrence within some limited, logical production interval (per day/hour/shift/week/etc.) or quantity. They should include only those non-conformances created by assignable, controllable, and correctable failure modes with processes running under stable, controlled production and inspection conditions.

CPOA thresholds shall be used in the determination of escape risk and shall ensure that overall escape risks requirements are still maintained.

CPOAs shall be updated with a new revision and corresponding date and resubmitted for approval when:

- the critical nonconformance threshold rates are re-calculated.
- the location of production changes.
- there are any major process changes.
- there are any major equipment changes.
- there are any inspection system changes.
- any new failure modes are identified or eliminated.
- there are any change in subcontractors affecting or influencing critical characteristics.
- there are any changes in technical data requirements (new specifications/drawings, Engineering Change Proposals, Request for Deviations, etc.) affecting or influencing critical characteristics.)
- the established schedule within the CCCP requires an update.

Development and assignment of threshold rates for a CPOA requires appropriate balancing of multiple considerations while at the same time, continuing to ensure that the default (1in 1 million) escape rate is maintained. The CPOA threshold should reflect the capability (defect creation rates) of the current process when running under "normal", well understood, controlled conditions. Too low (infrequent) a threshold rate subjects the supplier to excessively frequent shutdowns, restricting continuity of production, while an artificially high threshold rate (too lenient) masks degradation and loss of control of the manufacturing processes increasing risks of defect creation and escapes.

If the supplier selected to use as the threshold the historical average of defect creation rates, then by random occurrence (MTBF) they would fall above that rate about 50% of the time, breaching the CPOA. On the other hand, if too lenient a threshold is allowed or too large of a window is provided over which a larger number of defects is allowed, then it risks of masking spikes in the defect creation rate exposing the process to escapes. Instead, a suggested method is to take into account supplier risk (alpha risk ($\alpha$)) and assess an upper confidence limit to determine the CPOA threshold while ensuring that overall escape risks are appropriately maintained. A supplier risk ($\alpha$) of 0.10 or 0.05 should be used unless a specific reason is identified and the impact is considered;; levels which are significantly higher or lower may be either ineffective or expose too much risk of not detecting process deviation. This threshold can be calculated using following formula in MS Excel™

$$= \text{CHIINV}(\alpha, 2*(x+1)) / (2*n)$$

where $\alpha$ equals the supplier risk, x equals the number of critical defects created and n equals the number of units produced base upon recent, relevant production history (Note: cell locations in Excel need to be substituted for $\alpha$, n, and x). The following examples provides a simplified examples of calculating and using CPOA thresholds:

Example 3. EXAMPLE OF CPOA THRESHOLD CALCULATIONS BASED UPON HISTORICAL DEFECT RATES

| # of Units Produced(n) | # of Defects(x) | | Creation Rate | |
|---|---|---|---|---|
| | | | $\alpha$ = 0.10 | $\alpha$ = 0.05 |
| | | | | |
| 48,910 | 0 | | 0.000047 (1/21241) | 0.000061 (1/16326) |
| 52,000 | 3 | | 0.000128 (1/7783) | 0.000149 (1/6706) |
| 370,000 | 5 | | 0.000025 (1/39893) | 0.000028 (1/35194) |

Example 4. EXAMPLE OF INCORPORATING CPOA THRESHOLD INTO DEMONSTRATION OF OVERALL ESCAPE RISK (EXPANSION OF EXAMPLE 1)

This example is based upon example 1 with three (3) critical characteristics and the default requirement is for not worse than 1 in 1 million total escape risk. Recent, relevant, history includes creation of 2 critical non-conformances for Critical Characteristic #1 (C1), 6 critical non-conformances for Critical Characteristic #2 (C2), and 0 critical non-conformances for Critical Characteristic #3 (C3) out of 78,000 items manufactured. Initial plans are to demonstrate the inspection system error rate for at not greater 1 in 500 for C1 and 1 in 750 for C2 and C3. The supplier desires to submit CPOAs for Critical Characteristics C2 and C3 and utilize a supplier risk ($\alpha$) of 0.05 and will determine manufacturing rate as above in Example 3. At this time, they do not desire to submit a CPOA for C1 and will calculate manufacturing rate following Example 1.

| Critical Defect | # of Units Produced(n) | # of Defects(x) | | Creation Rate | |
|---|---|---|---|---|---|
| | | | | w/o CPOA (Example 1) | using CPOA w/ $\alpha = 0.05$ |
| | | | | | |
| C1 | 78,000 | 2 | | .000068 (1/14655) | -- |
| C2 | 78,000 | 6 | | -- | 0.000152 (1/6586) |
| C3 | 78,000 | 0 | | -- | 0.000038 (1/26037) |

(C1) $Mfr\_rate_{C1} * Insp\_Error\_Rate_{C1} = Esc\_Risk_{C1}$
(C2) $Mfr\_rate_{C2\text{-}CPOA} * Insp\_Error\_Rate_{C2} = Esc\_Risk_{C2}$
(C3) $Mfr\_rate_{C3\text{-}CPOA} * Insp\_Error\_Rate_{C3} = Esc\_Risk_{C3}$

(Total) $Esc\_Risk_{C1} + Esc\_Risk_{C1} + Esc\_Risk_{C3} = Esc\_Risk_{Total}$

Therefore:
(C1) 0.000068 * 1/500 = 0.000000136
(C2) 0.000152 * 1/750 = 0.000000202
(C3) 0.000038 * 1/750 = 0.000000051

(Total) 0.000000136 + 0.000000202 + 0.000000051 = 0.000000390

```
          = 0.390 per million which meets the total escape risk
                  requirement for less than 1/1 million.**

Resulting from the implementation of the CPOA, the supplier
would be able to resume production upon experiencing of a
critical defect (not an escape, and of known failure mode, etc.)
in processes C2 and C3 so long as they occurred, separated by
6586 (C2) or 26037 (C3) defects.  The occurrence of any escapes
or C1 defects, the experiencing of any C2 or C3 defects by new
failure modes, or the occurrence of C2 or C3 defects more
frequently than permitted would be cause for production shutdown
requiring Government approval for restart in accordance with
paragraphs f & h and the clause.

**Note:  If the overall total escape risk did not meet the 1/1
million requirement then either a lower threshold (rate) would
be required or the reliability of the inspection system(s) would
be required to be higher to support the approval of the CPOA(s).
```

For the internal government approval flow chart, please refer to Appendix B.

### Notes

CPOAs from subcontractors should be evaluated by the prime contractor before submission to the government for review/approval and statement to that effect should be included in submission letter to the PCO.

# Paragraph h - Production Continuity

```
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.
```

For the necessary elements of a CPOA, please reference Appendix D.

## Review Points

This paragraph provides permission to continue production despite finding a critical non-conformance provided that there is an approved CPOA. However, if a critical non-conformance is found, the CPOA should address how the contractor will analyze the affected production process in order to investigate and verify that the root cause is consistent with an approved failure mode (including a temporary pause/shutdown of the affected process when appropriate) in the CPOA and that the non-conformance rate is within the approved threshold before continuing with production.

Production may only continue with contractor validation that a critical non-conformance is within accepted failure mode(s) and rate(s) of the approved CPOA and that it has not escaped the designated inspection point. Production shall cease if the non-conformance has a previously unidentified or unaddressed failure mode, exceeds the approved non-conformance rate, or escapes the designated inspection point.

## Notes

In a systems contract environment, it is the responsibility of the prime contractor to ensure CPOA requirements are met and verified through the product realization process, including subcontractors that may produce/control critical characteristics with an approved CPOA.

It is good practice for contractors to ensure objective evidence is readily available to local government QAR or other government representatives to validate whether critical non-conformances are consistent with known failure modes and rates documented in the CPOA, in accordance with requirements of this clause.

# Paragraph i - Responsibility for Escapes

> 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.

For the necessary elements of a CCCP, please reference Appendix C.

## Review Points

The CCCP plan shall address actions to be taken if critical non-conformance escapes occur either within the contractor's control or delivered to the government. It should include at a minimum:

- The actions of paragraph f.
- Investigating the cause of the critical non-conformance and implementing corrective action.
- Investigating the cause of the critical non-conformance escape and implementing corrective action.
- Updating the overall escape risk calculation.

# Appendix A: Contract Data Requirements Lists

The following three pages contain suggested template Contract Data Requirements Lists (CDRLs) to be used with this clause. These provide the timeline requirements for document submittal and evaluation.

# Appendix A1: Example CDRL for Submission of CCCP

**CONTRACT DATA REQUIREMENTS LIST**
*(1 Data Item)*

*Form Approved*
*OMB No. 0704-0188*

Public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503. Please DO NOT RETURN your form to either of these addresses. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

| A. CONTRACT LINE ITEM NO. | B. EXHIBIT | C. CATEGORY: TDP ___ TM ___ OTHER ____ |
|---|---|---|
| | | |

| D. SYSTEM/ITEM | E. CONTRACT/PR NO. | F. CONTRACT |
|---|---|---|
| PROGRAM NAME | | |

| 1. DATA ITEM NO. | 2. TITLE OF DATA ITEM | 3. SUBTITLE |
|---|---|---|
| A000 | Management Plan | Critical Characteristics Control (CCC) Plan |

| 4. AUTHORITY (Data Acquisition Document No.) | 5. CONTRACT REFERENCE | 6. REQUIRING OFFICE |
|---|---|---|
| DI-MGMT-80004 (Tailored) | Insert Contract Clause Here | Insert Office Symbol Here |

| 7. DD 250 REQ | 9. DIST STATEMENT | 10. FREQUENCY | 12. DATE OF 1ST SUBMISSION |
|---|---|---|---|
| LT | N/A | SEE BLK 16 | SEE BLK 16 |

| 8. APP CODE | 11. AS OF DATE | 13. DATE OF SUBSEQUENT |
|---|---|---|
| A | | SEE BLK 16 |

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

**16. REMARKS**

Tailoring: Ignore DID paragraphs 10.3.6 and 10.3.7. Contractor's electronic format using Microsoft Word or comparable software is acceptable.

Additional guidance on content of the CCC Plan is available at :
<http://www.pica.army.mil/PicatinnyPublic/organizations/ardec/orgchart/quality.html>

BLK 10: Contractor shall submit Plan covering all critical characteristics as Required in contract clause reference.

BLK 12: Contractor shall submit 60 days prior to First Article or production if a FA is not applicable. Government will respond within 45 days of receipt of original and any required revisions. Unless otherwise specified, contractor shall submit revisions within 10 days of receipt of Government response.

BLK 13: Unless otherwise specified, If CCC Plan changes after initial Government approval, contractor shall resubmit revised plan for Government approval.

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PCO Email Address

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| PCO | 1 | 1 | |
| Tech Agency POCs | 1 | 1 | |
| DCMA QAR | 1 | 1 | |
| **15. TOTAL ---------→** | 3 | 3 | |

| G. PREPARED BY | 2. DATE | I. APPROVED BY | J. DATE |
|---|---|---|---|
| NAME | 00-00-0000 | | |

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# Appendix A2: Example CDRL for Submission of CPOA

**CONTRACT DATA REQUIREMENTS LIST**
*(1 Data Item)*

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| A. CONTRACT LINE ITEM NO. | B. EXHIBIT | C. CATEGORY: TDP ___ TM ___ OTHER ____ |
|---|---|---|
| D. SYSTEM/ITEM: PROGRAM NAME | E. CONTRACT/PR NO. | F. CONTRACTOR |

| 1. DATA ITEM NO. | 2. TITLE OF DATA ITEM | 3. SUBTITLE |
|---|---|---|
| A000 | Management Plan | Critical Plans of Action (CPOA) |

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

| 4. AUTHORITY (Data Acquisition Document No.) | 5. CONTRACT REFERENCE | 6. REQUIRING OFFICE |
|---|---|---|
| DI-MGMT-80004 (Tailored) | Insert Contract Reference Here | Insert Office Symbol Here |

| 7. DD 250 REQ | 9. DIST STATEMENT | 10. FREQUENCY | 12. DATE OF 1ST SUBMISSION |
|---|---|---|---|
| LT | N/A | See BLK 16 | See BLK 16 |
| **8. APP CODE** | | **11. AS OF DATE** | **13. DATE OF SUBSEQUENT** |
| A | | | See BLK 16 |

**16. REMARKS**

**Tailoring:** Ignore DID paragraphs 10.3.6 and 10.3.7. Contractor's electronic format using Microsoft Word or comparable software is acceptable.

Additional guidance on content of the CCC Plan is available at :
http://www.pica.army.mil/PicatinnyPublic/organizations/ardec/orgchart/quality.html

BLK 10: Contractor may voluntarily submit a CPOA for all critical characteristics as specified in the contract clause reference.

BLK 12: Contractor shall submit the CPOA for approval prior to use. Government will respond within 45 days of receipt of original and any required revisions.
Unless otherwise specified, contractor shall submit revisions within 10 days of receipt of Government response. Unless otherwise approved by the PCO, the CPOA is not authorized for use prior to Government approval.

BLK 13: Unless otherwise specified , if the CPOA changes after initial Government approval, Contractor shall resubmit revised plan for Government approval.

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| PCO | 1 | 1 | |
| Tech Agency POCs | 1 | 1 | |
| DCMA QAR | 1 | 1 | |
| 15. TOTAL ---------→ | 3 | 3 | |

| G. PREPARED BY | H. DATE | I. APPROVED BY | J. DATE |
|---|---|---|---|
| NAME | 00-00-0000 | | |

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# Appendix A3: Example CDRL for Submission of CICL; Notification of Occurrence of a Critical Defect; Root Cause and Corrective Action; Segregated Suspect Material Use; and Request to Restart Operations

**CONTRACT DATA REQUIREMENTS LIST**
*(1 Data Item)*

*Form Approved*
*OMB No. 0704-0188*

Public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503. Please DO NOT RETURN your form to either of these addresses. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

| A. CONTRACT LINE ITEM NO. | B. EXHIBIT | C. CATEGORY: TDP ___ TM ___ OTHER ____ |
|---|---|---|
| D. SYSTEM/ITEM: PROGRAM NAME | E. CONTRACT/PR NO. | F. CONTRACTOR |

| 1. DATA ITEM NO. | 2. TITLE OF DATA ITEM | 3. SUBTITLE | 17. PRICE GROUP |
|---|---|---|---|
| A000 | Critical Safety Item Characteristic and Defect Report | CICL,Notification,Investigation,Segregated, Material Use and Restart Request | 18. ESTIMATED TOTAL PRICE |

| 4. AUTHORITY (Data Acquisition Document No.) | 5. CONTRACT REFERENCE | 6. REQUIRING OFFICE |
|---|---|---|
| DI-SAFT-80970A | Insert Contract Reference Here | Insert Office Symbol Here |

| 7. DD 250 REQ | 9. DIST STATEMENT | 10. FREQUENCY | 12. DATE OF 1ST SUBMISSION |
|---|---|---|---|
| LT | N/A | See BLK 16 | See BLK 16 |
| **8. APP CODE** | | **11. AS OF DATE** | **13. DATE OF SUBSEQUENT** |
| A | | | See BLK 16 |

**16. REMARKS**

Critical Item Characteristics List (CICL) ( DID paragraph 3.3)

BLK 12 and 13: If applicable, contractor shall submit 60 days prior to First Article or production if FA is not applicable. Government will respond within 45 days of receipt of original and any required revisions. Unless otherwise stated, contractor shall submit revisions within 10 days of receipt of Government response.

Notification of a critical defect (DID paragraph 4.1)

BLK 12 and 13 : Unless otherwise approved by the PCO, notification of the occurrence of any critical defects shall be made to government, see distribution list, within 24 hours of event, by the most expeditious means available.

Root Cause Investigation and Corrective Action (DID paragraph 4.2)

BLK 12 and 13: Contractor shall submit to the Government, see list, for approval. Government will respond within 45 days of receipt of original and any required revisions. Unless otherwise stated, contractor shall submit revisions within 10 days of receipt of Government response.

Segregated Suspect Material Use (DID paragraph 4.3)

BL12 and 13: Contractor shall submit to the Government, see list, for approval. Government will respond within 45 days of receipt of original and any required revisions. Unless otherwise stated, contractor shall submit revisions within 10 days of receipt of government response.

Request to Restart Operations (DID paragraph 4.3)

BLK 12 and 13: Contractor shall submit to Government, see list, for approval. Government will respond within 10 days of receipt.

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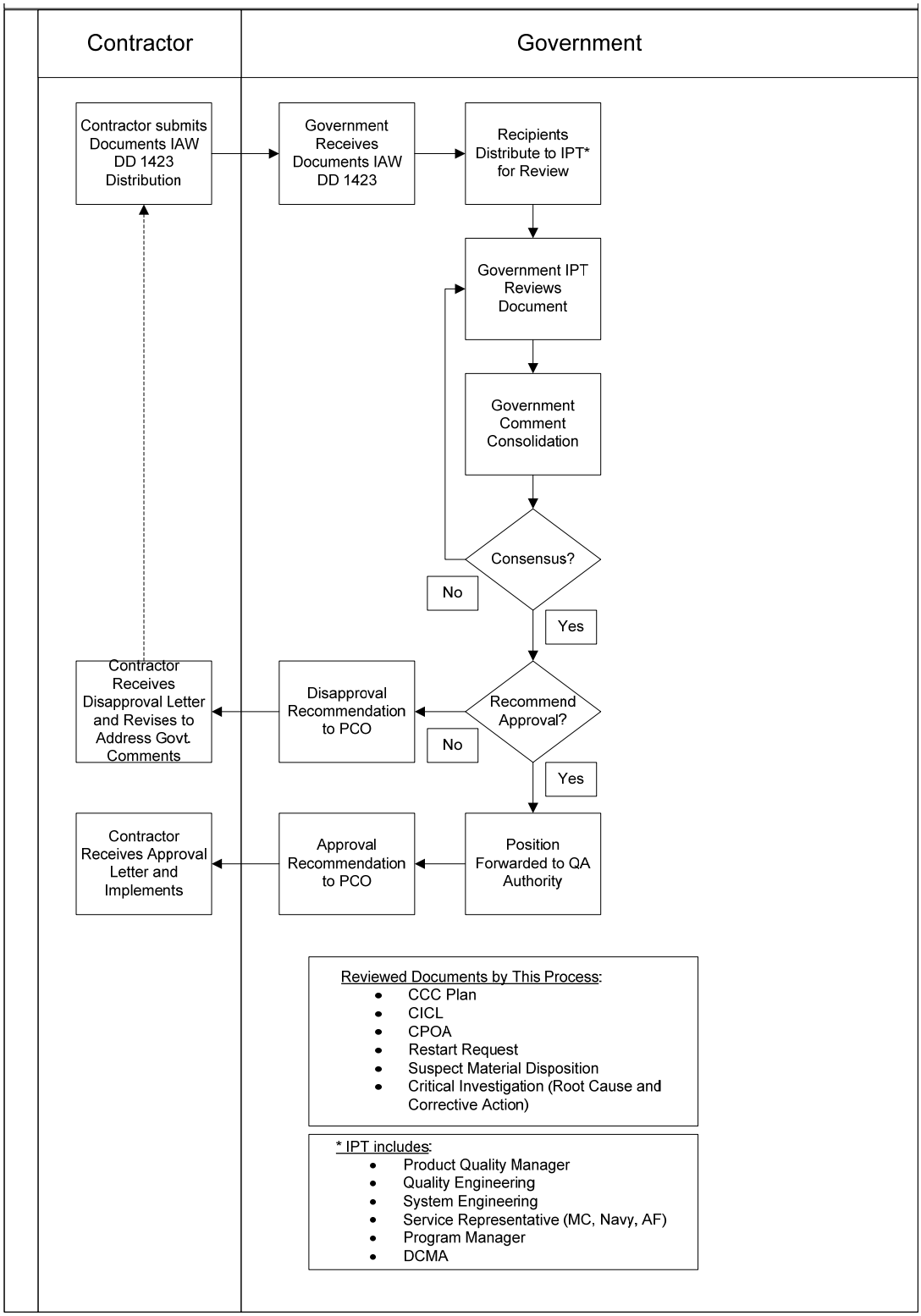
# Appendix B: Process for Internal Government Review of Critical Documents



# Appendix C: Recommended Elements and Format of a CCCP

Plan shall be submitted IAW with DD 1423 and DI-MGMT-80004.

The following are items that should be addressed in a CCCP:

1. General information
    a. Cover Sheet
        (1) Contractor's name
        (2) Contract number
        (3) Revision and date
        (4) Product identification (item or applicable family)
        (5) Security classification and/or distribution restrictions as appropriate
    b. Table of Contents (if more than 30 pages in length)
    c. List of the applicable critical characteristics and associated documents specifying the requirement – specification or Quality Assurance Provision (QAP) number, drawings and the revisions.
    d. Critical characteristics management structure and roles/responsibilities.
        (1) An organization chart addressing the critical characteristics control structure should include, at a minimum:
            (a) Personnel performing QA inspections and verification inspections.
            (b) Relevant QA Inspection validation (running of masters/salters).
            (c) Material Review Board (MRB) authority (departments, subcontractors, root cause/corrective action, etc.).
            (d) Access/disposition to critical non-conformances, accountability, traceability.
            (e) Work stop authority.
            (f) Restart authority.
            (g) Notification to government authority.
        (2) The plan should address program management responsibilities, see paragraph 3.4 of DI-MGMT-80004.

e. Reference to the appropriate critical process documents (when referenced, copies should be provided upon request for review or included as an appendix to the plan). This can include process control, inspection, accountability/traceability of non-conforming materials documentation and associated quality records maintaining an audit trail. They include such things as, but not limited to:

(1) Manufacturing Process and Procedures

(2) Work Instructions

(3) Handling Instructions

(4) Process Controls

(5) Inspection Systems and Procedures

f. Specify the location/facility which produces the material affected by the critical characteristics (listed in paragraph c).

2. Detail information

a. Prevention of critical non-conformances (Production process related)

(1) Describe process and how it is robust with high capability and adequate controls.

(a) Process description.

(b) Detailed flow chart including Inputs, Outputs, and Key Process Parameters.

(c) How key process parameters are identified, defined, and controlled.

(d) Failure Modes analysis methodology such as FMEA, Fault Tree Analysis, etc.

(e) Type of mistake proofing/Poka-Yoke techniques.

(f) Process control tools.

(g) Feedback or in-process inspections.

(h) Material handling.

(2) Calculate, document and identify how process is capable, reliable, and effective.

(a) Identification of failure modes and frequency of occurrence.

(b) Method to assess that the system is robust, capable, and under control (process prove-out; recent, relevant production data, SPC, etc.).

(3) Schedule to ROUTINELY assess reliability and effectiveness.

(a) Frequency of verification (SPC, process capability, and audit schedules.)

(b) Monitor appropriate metrics and reactions to trends.

(c) Documentation and identification of actions to ensure process is reliable and effective.

(d) Define the frequency for assessing the reliability and effectiveness of the production processes.

Note: What constitutes "routinely" for an individual item or characteristic would be based upon production rates and volume. If a process produces a million parts a month, an annual frequency would not meet the standards of "routinely". For example, a high rate manufacturing system with an SPC frequency of a daily basis (rather than at least hourly with the appropriate sub-group sample size) would not meet the intent of "routinely". Inadequate periodic verification will impact the approval of a CCCP.

b. Prevention of critical non-conformance escapes (inspection system).

(1) What is the inspection system, including equipment, and how will it prevent an escape.

(a) Contractor's process to verify that the design of the inspection system is robust, capable, and effective to ensure that non-conformances are identified and correctly dispositioned ensuring no escapes.

(b) Inspection/verification system process description to include material handling and accountability of non-conforming material. For example:

1) Describe the methodology of inspection utilized (AIE, AAIE, visual, acceptance based on process control, etc.).

2) Identify MIL-STD-1916 VL VII validation system or alternate proposed method.

3) Personnel involved in inspection and their required qualifications.

4) Throughput of inspections utilized (AIE, AAIE, visual inspections, etc.).

5) Identify any proposed referee gages and associated processes to include re-introduction of conforming material into the production process and maximum rates and quantities permitted for referee gages.

(c) Detailed flow chart including Inputs, Outputs, and Key Process Parameters (may be incorporated with the manufacturing flow chart).

(d) Failure Modes of the inspection system.

(e) Fail-safe methods, mistake proofing/Poka-Yoke techniques and assurance that the inspection system is not bypassed.

(2) Calculate, document, and identify reliability and effectiveness of the inspection system.

(a) Provide formula, methodology, or industry standard used to determine the inspection system reliability.

i. Defect masters/salters or other inspection process parameters can be used to calculate inspection reliability.

(3) For each inspection system, provide the results of the demonstrated reliability based upon the verification/validation.

(4) Schedule to ROUTINELY assess reliability and effectiveness.

(a) Frequency and method of routine verification (when and how many times defect masters/salters are run through and/or audit schedules). Plan shall quantify inspection system error rates. This data can be collected through a prove-out of the system with equipment, personnel, procedures, and materials used in production at the appropriate sample size or running calibrated defect masters/salters at the appropriate sample size. MIL-A-70625 has further information on automated inspection equipment prove-out.

Note: Procedures should address (based upon production rates and volume) how objective verification of the process is conducted within a reasonable timeframe. Defect masters/salters should be inserted into the inspection system at established frequencies (planned and random) to validate system reliability. Inadequate periodic verification will impact the approval of a CCCP. It is good business practice to run these defect masters/salters through at production start-up, shift changes, breaks, and randomly throughout the shift to validate the inspection systems.

(b) The plan should address actions to be taken if the inspection system accepts a defect master/salter. This constitutes a failure of the inspection system which would require the following actions:

i. Segregate all material since the last successful verification.

ii. Investigate and implement corrective action to the inspection system.

iii. Verify suspect material does not contain any critical non-conformances.

iv. Update the inspection system's error rate and overall escape risk calculation.

(5) Test procedure(s) should exist to demonstrate the error rate (reliability) of the inspection system. When referenced, this procedure should be provided for review along with the CCCP submission. This procedure can also be included as a part of the CCCP.

(a) Sufficient test quantities/samples sizes should be identified to assure minimum 90% statistical confidence (unless otherwise approved by the PCO).

i. Contractor shall have a schedule identified in the plan to routinely monitor the non-conformance and inspection system error rates to assure they do not exceed maximum rates allowed.

c. Escape Risk Calculation:

(1) Plan shall quantify critical non-conformance rates entering the inspection systems. This can be calculated based upon historical data or limited production runs for new processes/production lines (or no history of producing the product).

(a) If a CPOA is submitted and approved, the CPOA threshold(s) for the characteristic(s) is used as the incoming non-conformance rate into the inspection system; however, the overall escape risk requirements shall be met using the most frequent (worst case) relevant defect creation rate(s).

(2) Plan should list individual escape rates for the critical characteristics and address how escape risk is the sum of all individual escape rates. This is a cumulative number – the summation of ALL critical escape rates shall not exceed the overall escape risk specified in the contract clause.

(a) Critical non-conformances discovered during performance testing based upon samples (for example ballistic testing) are considered to

be escapes and they shall be reported and dispositioned in accordance with contract requirements. They should, however, not be included in calculations of overall escape risk.

d. When phased in approach is requested by the contractor, the plan should explain methodology and milestones for this phased in approach on how non-conformance escape risk will be achieved over a period of time not to exceed 180 days from date of first article approval or initiation of production when first article is not required. Phased in approach is subject to PCO approval.

3. Document the review process for development of the CICL in the CCCP.

   a. Contractor shall identify any additional critical characteristics that result in hazardous or unsafe conditions associated with material, components, subassembly and assemblies identified by the contractor for technical data developed by the contractor. These additional critical characteristics shall be documented in a CICL. These CICLs are to be treated just like any other critical characteristic identified in a TDP or contract. All requirements of the CCCP apply to these CICLs.

      Note: This is only applicable to the contractor's technical data (performance-based acquisition, COTS, NDI, etc.) as well as if the contractor chooses to review a government TDP for additional critical characteristics.

4. The CCCP shall have procedures in place to address the necessary actions to be taken if a critical non-conformance is found anywhere in the production process and shall include:

   a. Plan shall address how a non-conformance will be identified and segregated.

   b. All personnel/positions responsible for identifying, segregating, and maintaining accountability/traceability for the critical non-conformances.

   c. Identify the appropriate documentation, including records for disposition/accountability for tracking a critical non-conformance.

   d. Plan shall address how the operation that produced the non-conforming component or assembly operations and any other operations incorporating suspect product will be immediately stopped. This should include personnel/positions responsible for the shutdown process and records documenting the shut-down.

   e. Plan shall identify a process to immediately notify the government per the CDRL. Identify personnel responsible for reporting critical non-conformances to the government.

f. Plan shall identify how suspect material is identified, segregated, and prevented from additional processing or shipment to the customer. Any critical non-conformance escape will expand the quantity of suspect material.

g. Plan shall address how and by whom an investigation will be conducted to determine the root cause of a non-conformance and required corrective actions. The plan shall address how the report will be submitted to the government.

h. Plan shall address the restart request process or use of any suspect material, including objective evidence of the failure analysis investigation, which will be provided to the government as part of the restart request.

5. Plan should address what actions and by whom are taken for any critical non-conformance escape found beyond the designated inspection point prior to government acceptance. In addition to the actions required per paragraph (f) of the clause, the contractor should:

   a. Conduct a root cause analysis and corrective action on the inspection system that allowed the critical nonconformance to escape.

   b. Update the inspection system reliability rates (error rates) and re-calculate total escape risk.

# Appendix D: Recommended Elements and Format of a CPOA

Plan shall be submitted IAW with DD Form 1423 and DI-MGMT-80004 and include:

1. Cover Sheet

    a. Contractor's name
    b. Contract number
    c. Revision and date
    d. Product Identification (item or applicable family)
    e. Security classification and/or distribution restrictions as appropriate

2. Table of Contents (if more than 30 pages in length)

3. List of the applicable critical characteristic(s) and associated documents specifying the requirement – specification or QAP number, drawings and the revisions.

4. Reference to the specific associated CCCP and revision.

5. Management structure: Roles/responsibilities, and procedures to ensure that CPOA(s) are evaluated for currency and process improvements. In addition to the management structure identified in the CCCP, contractor should identify:

    a. Position(s) responsible for monitoring and reporting the CPOA thresholds.

    b. Position(s) responsible for confirming that critical non-conformance is from a known/approved failure mode and execute root cause failure analysis.

    c. Position(s) responsible for implementing corrective actions and determining that they adequately address the critical non-conformance based upon known/approved failure modes.

    d. Position(s) responsible for controlling access to critical non-conformances as well as maintaining accountability and traceability through final disposition.

    e. Position(s) responsible for controlling access to material suspected of having critical non-conformances as well as maintaining accountability and traceability through final disposition.

6. Failure Modes and Effects Analysis: Failure modes associated with each critical characteristic, including Failure Modes and Effects Analysis (FMEA) (for an sample format, please see Appendices E & F), Cause and Effects diagrams, and data from any other tool used to establish a baseline of known failure modes for the CPOA.

    a. CPOA should include the failure mode, frequency of occurrence, applicable key process parameters, and how they are specifically monitored. It should

identify short term corrective action(s) and long term preventive action(s) for each failure mode.

b. CPOA should include procedures and objective evidence used to confirm that the failure mode of a critical non-conformance is that identified in the CPOA.

c. CPOA should address how an occurrence of a new failure mode not previously identified, exceeding the established threshold, or occurring after the inspection point (an escape) shall result in actions prescribed per paragraph (f) of the clause.

7. Key Process Parameters: Key process parameters include the maximum subject critical non-conformance rate and inspection equipment error rate. It also includes those parameters which are used to control the quality of the listed critical characteristic (i.e., dwell time, temperature, pressure, humidity, etc.).

   a. Monitoring Key Process Parameters: Once established the CPOA shall provide for effective monitoring of the non-conformance and inspection system error rates to assure that they do not exceed the maximum rates allotted. What evidence will be monitored to determine each of these rates?

8. Activities upon occurrence of a critical non-conformance:

   a. Operation Shutdown: The supplier's plan must state, in some manner, that the operation will be shut down and an investigation IAW stated procedures will ensue if the threshold in the CPOA is exceeded or a non-conformance is generated from a previously unidentified mode.

   b. Material Controls: Action to be taken when a critical non-conformance occurs and a description of controls to ensure the non-conforming item does not inadvertently remain in or reenter the production process. Final disposition of non-conforming material must be traceable and auditable.

   c. Verification: Method to immediately verify that a produced critical non-conformance is consistent with the identified failure mode(s) and key process parameter limits.

   d. Notification: An approved CPOA does not relieve the supplier from the notification requirement even though the approved threshold has not been exceeded; however, the notification may be through a periodic report. The reporting period would be coordinated with the government and approved as part of the CPOA.

   e. Process Improvement: Process improvement plans with milestones will be specific in nature and will be tied to FMEA results for each characteristic and failure modes for that characteristic. A previously approved CPOA must be updated with timely, relevant data that incorporates any process improvements, to be considered for continued use. At a minimum, current

historical data must be provided. Inspection processes, process capabilities, and key process parameters must be reviewed for improvement. The goal is to reduce the failure rates and the number of failure modes. The supplier's CPOA should show improvement over the previous contract or production order.

9. CPOA Threshold Calculation: When calculating the CPOA thresholds, the following guidance applies:

    a. Provide rationale for selection of data population from which threshold is derived (what type of data was selected historical/limited production runs, how far the data goes back, why the particular time-frame was selected, any process changes/improvements over that timeframe, etc.).

    b. Provide an explanation on how the threshold was calculated based upon the factors above.

    c. Provide a methodology on how the threshold rate applied to a particular quantity of production (# critical non-conformances allowed per # of items produced) is monitored and managed.

    d. Provide explanation and justification for establishing amount of product or time frame within which the threshold frequency is calculated (e.g., per 10,000 vs. per 100,000; per week vs. per month, etc.).

    e. Ensure that CPOA threshold matches the non-conformance rate for that critical characteristic in the CCCP Escape risk calculation and the overall escape risk requirement is maintained.

10. CPOA shall address plans to ensure currency and process improvements:

    a. Planned improvements and/or corrective actions to reduce occurrences and/or eliminate failure modes.

    b. Resubmission of the updated CPOA to the PCO for approval in accordance with the approved schedule (at minimum on an annual basis).

11. Any proposed alternate reporting structure for critical non-conformances. Clause requires 24 hour notification for ALL critical non-conformances, even when a CPOA is approved. However, alternate reporting arrangements can be made with PCO approval when non-conformance rate is under the threshold rate.

# Appendix E: Example FMEA Format

Prime Contract No. _____ Team Members _____ _____ Date _____

Prime Contractor _____ _____ _____ Rev _____

End Item _____ _____ _____

Team Leader _____ _____ _____

| | | | | | | | | | | | | Actions Results | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Process Step No./ Functional Description | Potential Failure Mode | Potential Effect(s) of Failure | SEV (S) | CLASS | Potential Cause(s) of Failure | OCC (O) | Controls (Detection & Prevention) | DET (D) | RPN | Planned Actions (Short & Long Term) & Target Date | Action Assigned to (Name) | Date Completed | *pS* | *pO* | *pD* | *pRPN* |
| | | | | | | | | | | | | | | | | |
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# Appendix F: Example Scales for Severity, Occurrence Rate, and Detection for Assessing Risk Priority Number in a FMEA

| | Assigned #: | Severity (S): | Occurrence Rate (O): | Detection (D): |
|---|---|---|---|---|
| Of Greatest Concern: | 5 | Catastrophic (Death, Serious Injury) | Frequent (~1/10) | Highly Unlikely (~10%) |
| | 4 | | Probable (~1/100) | Unlikely (~50%) |
| | 3 | Marginal | Occasional (~1/1000) | Marginal (~90%) |
| | 2 | | Remote (~1/10,000) | Likely (~99%) |
| Of Least Concern: | 1 | Inconsequential | Improbable (~1/1,000,000) | Highly Likely (~99.9%) |

Note: Risk Priority Number (RPN) is assessed as the product of the Severity (S), Occurrence Rate (O), and Detection (D) such that: S * O * D = RPN.

For example, if a failure mode is identified as having a catastrophic severity (S=5), an occasional rate of occurrence (O=3), and is unlikely to be detected (D=4), then the RPN would be assessed as 60. If, after process and inspection improvements, the severity remains unchanged but the rate of occurrence is improved to Remote (pO=2) and the detection improved to likely (pD=2) then the improved process would have an improved RPN (pRPN) of 20.

# Appendix G: Referenced Documents

| | |
|---|---|
| 1. JMC ES6550 | Critical Characteristics (Six Sigma) |
| 2. JM&L 173 | Critical Characteristics (Six Sigma) |
| 3. MIL-STD-1916 | DoD Preferred Methods for Acceptance of Product |
| 4. MIL-HDBK-1916 | DoD Handbook Companion Document to MIL-STD-1916 |
| 5. ISO 9001:2008 | Quality Management Systems - Requirements |
| 6. NIST/SEMATECH | Engineering Statistics Handbook |
| 7. DI-SAFT-80970A | Critical Safety Item, Characteristic and Defect Report |
| 8. DI-MGMT-80004 | Management Plan |
| 9. DOD-STD-2101 | Classification of Characteristics |
| 10. MIL-A-70625 | Military Specification for Automated Acceptance Inspection Equipment Design Testing and Approval |
| 11. MIL-A-48078 | Military Specification for General Specification for Standard Quality Assurance Provisions |