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Single Manager for Conventional Ammunition (SMCA)

Review Guide

Process Capability Control & Improvement (PCCI) Requirements

Process Control Plan (PCP)

http://www.pica.army.mil/PicatinnyPublic/organizations/ardec/orgchart/quality.html

13 October 2011 – Revision 1

(See Revision sheet at end of Guide)

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Table of Contents

A PCCI Review Guide is available to assist Contractors on the ARDEC Public Website in the application of the PCCI Clause. The PCCI 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 PCCI Review Guide is expressly not, nor shall it be construed to be, incorporated either directly or by reference into the terms of the PCCI Clause itself nor into the terms and conditions of any underlying contract which contains the PCCI Clause.

Background

The Process Capability, Control and Improvement (PCCI) clause was developed by the Ammunition Enterprise (AE) in cooperation with the Single Manager for Conventional Ammunition (SMCA) and Military Services as a tool for use in ammunition acquisition and, when applicable, in conjunction with other supplier quality requirements.

The PCCI clause supports and reinforces the expectations of MIL-STD-1916, DOD Preferred Method For Acceptance Of Product.

PCCI requirements are intended to be uniform, integrated requirements for the SMCA or other procuring agencies to aid suppliers in accomplishing the following:

- Perform manufacturing flowcharting and process failure mode and effects analysis
- Identify and assess process risks for characteristics for process control
- Determine process capability for identified processes
- Control identified processes
- Initiate continuous improvement efforts for identified processes
- Utilize commercial best practices
- Interface with Supplier Quality Management System (QMS)

The PCCI clause was developed to manage the requirements for various ammunition acquisition situations, including dissimilar product complexities and quantities being procured. The clause also allows program unique application with knowledge of current ammunition industry capabilities.

The PCCI clause does not mandate the use of Statistical Process Control (SPC) unless specifically stated in paragraph g of the clause. Statistical methods are the preferred method of process control; however, there are many methods to monitor and control a process and these requirements were developed to allow use of any method that can be supported by objective evidence.

The basis for these requirements is that sampling inspection alone does not control or improve quality. Product quality comes from robust product and process design and process control activities. When such activities are effective, sampling inspection may be a redundant effort and an unnecessary cost. This clause requires Contractors to develop an acceptable quality system and proven process controls for identified processes and encourages continuous improvement. The intended result is reduced or eliminated inspection in accordance with MIL-STD-1916.

Introduction

The PCCI and Process Control Plan (PCP) Review Guide is meant to be an aid for:

- Applying the PCCI clause
- Developing a PCP
- Reviewing a PCP

The document is formatted in a fashion where a clause paragraph is followed by a discussion of what should be contained in a PCP for that particular clause requirement. The text contained here reflects the language of the clause. These excerpts are not substitutes for the actual requirements included in a solicitation, purchase order or contract.

There are a variety of approaches/methods/tools that can be utilized in meeting a particular requirement. The goal in developing the review guide is to provide clarification of the requirements and an aid in developing the required documents.

Two considerations:

- Any given PCP will have variety that will distinguish it from other submissions,
- Every PCP submitted must address all applicable requirements contained in the contract.

The goal of this document is to assure a uniform development and review process for the PCP.

The term Contractor is used throughout this document to denote the entity with a Government contract or Government Owned, Government Operated (GOGO) activity.

The Integrated Product Team (IPT) will consist of Government, Contractor and sub-Contractor representatives, as appropriate.

It is recommended that the Contractor participate in Government partnering through IPTs during the analysis. This will facilitate acceptance of the PCP and allow for open discussion of the manufacturing, inspection and material handling processes as well as the product design.

Contracts & Statement of Requirements – COCOs, GOCOs & GOGOs

The normal method of transmission of PCCI requirements for Contractor Owned, Contractor Operated (COCOs) and Government Owned, Contractor Operated facilities (GOCOs) is via a contractual instrument. The method of transmission of PCCI requirements at a GOGO is through a Statement of Requirements (SOR) via a Production Work Directive.

Contract Data Requirements List (CDRL)

The Contractor shall submit the final PCP sixty (60) days prior to the First Article. If a First Article is not required, the Contractor shall submit the final PCP sixty (60) days prior to the start of production. See Attachment 2 below.

If the Contractor revises a previously Government accepted PCP, the revised PCP must be submitted to the Government for acceptance before it is released for use. The Government will respond within 10 working days.

Paragraph a. (Process Capability, Control & Improvement System)

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

Discussion:

Process Control System

Process Control involves ensuring a process is predictable, stable, and consistently operating at the target level of performance with only normal variation using mechanical, optical, or electronic systems that are used to maintain the desired output. A Process Control System is comprised of tools, methodologies, production and inspection equipment, testing devices, standards, computer software, data collection paraphernalia, control charting, data output, processes, work instructions, procedures, etc., utilized for maintaining or managing a manufacturing or production process.

Process controls selected for monitoring/controlling manufacturing processes and/or product characteristics should be widely accepted by industry and capable of demonstrating quality system effectiveness. This should not discourage the use of new or novel techniques that have not yet achieved widespread acceptance if they can provide superior process control.

Control systems include process sensors, data processing equipment, actuators, networks to connect equipment and sampling techniques such as control charts. Types of process control systems may include Statistical Process Control Methods such as x bar, r, p, c or u charts; run charts; visual, optical, camera or laser control sensors; specialized/built-in manufacturing/machining controls (e.g., CNC and robotic); instrumentation control systems (e.g., temperature and humidity controls) and calculations of station and system effectiveness.

Complement to ISO 9001-2008

There is a direct connection between Process Capability, Control & Improvement requirements and ISO 9001-2008 (Quality Management Systems - Requirements). ISO 9001-2008 specifies requirements for a quality management system that is focused on customer needs and requirements, processes, product and continuous improvement. Some examples of this connection are contained in the following ISO 9001-2008 paragraphs:

- General (ISO 9001-2008, paragraph 1.1) - ISO specifies requirements for a quality management system where an organization demonstrates its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements.

- Customer Focus (ISO 9001-2008, paragraph 5.2) – Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

- Resource Management (ISO 9001-2008, paragraph 6)- The organization shall determine and provide the resources needed to a) implement and maintain the quality management system and continually improve its effectiveness and b) to enhance customer satisfaction by meeting customer requirements.

- Product Realization (ISO 9001-2008, paragraph 7.1, 7.5) – In planning product realization, the organization shall determine … (the) need to establish processes, documents and provide resources specific to the product … the required verification, validation, monitoring, inspection and test activities specific to the product and criteria for product acceptance. The organization shall plan and carry out production and service under controlled conditions. The organization shall validate any processes for production … validation shall demonstrate the ability of these processes to achieve planned results.

- Measurement, analysis and improvement (ISO 9001-2008, paragraph 8.1) – The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity to product requirements and to continually improve the effectiveness of the quality management system.

- Analysis of Data (ISO 9001-2008, paragraph 8.4) - Organization shall determine, collect and analyze appropriate data … data analysis includes customer satisfaction, conformity to product requirements and trends of processes and products.

- Continual Improvement (ISO 9001-2008, paragraph 8.5.1) – Organization shall continually improve the effectiveness of the quality management system through … analysis of data.

Other Contract Quality Requirements

When utilized, the Critical Characteristic Control (CCC) requirements in the contract require that the Contractor's processes be designed to prevent the creation or occurrence of any nonconforming critical characteristic. During development and maintenance of any process control system, the Contractor must be mindful of the requirements contained in their Quality Management System and other contractual parameters. Any self-imposed Quality Management System requirements must not conflict with any provision contained in their process control system. The Contractor's ISO system must work in concert with their documented process control system.

SPC Standards

When SPC is utilized for process control, ISO 11462-1 (Guidelines for implementation of statistical process control) and ANSI / ASQC B1-B3-1996: Quality Control Chart Methodologies (Charting and control methods) will be implemented. Other equivalent commercial industry standards may be utilized if accepted by the Government.

ANSI/ASQC B1-1996--Guide for Quality Control Charts This is a guide for handling problems concerning the economic control of quality of materials and manufactured products, with particular reference to methods of collecting, arranging, and analyzing inspection.

ANSI/ASQC B2-1996--Control Chart Method of Analyzing Data This guide gives particular reference to quality data resulting from inspections and tests of materials and manufactured products.

ANSI/ASQC B3-1996--Control Chart Method of Controlling Quality During Production This outlines the control chart method of identifying and eliminating causes of trouble in repetitive production processes in order to reduce variation in the quality of manufactured products and materials.

These standards, along with ISO 9001-2008, contain methodology and assessment tools for use by the Contractor in developing their SPC program for the PCP. The Government should use these standards in the evaluation of the Contractor's process control systems.

Process Control Plan (PCP)

The Contractor will submit the PCP as stipulated in DD1423. Approval/disapproval/required corrective actions should be forwarded through the PCO by the Quality Directorate after coordinating with Integrated Product Team (IPT) team members. DI-MGMT-80004 is a general management data item description. The content of the PCP must meet the requirements of the PCCI clause. Refer to paragraph d of this guide for further information on the contents of a PCP.

Demonstration of Process Capability

This section will describe some of the details that should be included in the Contractor's submission to validate their process capability. The submission demonstrating process capability should include, but is not limited to, the following:

- The process should be identified and described by process flow charts, Process Failure Modes and Effects Analysis (PFMEA), Fault Tree Analysis (FTA), and Cause and Effect (C&E) diagrams.
- The process must be stable (in statistical control) prior to performing capability studies using the process capability indices of C_{pk} and P_{pk}. Objective evidence must be provided to demonstrate that the process is stable.
- When demonstrating process capability using the indices of C_{pk} and P_{pk}, objective evidence must be provided in the form

of Bias/Linearity, Reproducibility and Repeatability, and Stability studies for the measurement system used.

- When demonstrating process capability, objective evidence must be provided to show that nonconforming product cannot be accepted. Acceptance/rejection parts should be run through the planned production system as verification.
- The Contractor will notify the Government when the minimum process capability values (C_{pk}) of 2.00 for Critical characteristics and 1.33 for all other characteristics for process control, or the alternative established minimum C_{pk} values, are no longer achieved/maintained.
- As an exception to normal process capability data, a 100% automated and fool proof capable inspection system along with potential sources of data (such as defect rates) can be used to meet this requirement and must be demonstrated that only conforming product be accepted. This option is to be exercised only when other options have been exhausted.

Paragraph b. (Characteristics for Process Control)

b. Characteristics for process control are as follows:

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

(1.1) ☐ Government selected list, see paragraph g below
(1.2) ☐ As listed key characteristics

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

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

Discussion:

Characteristics for Process Control (CFPC)

This paragraph provides three mutually exclusive options for the required CFPC that need to be addressed by the Contractor. The option selected depends on the acquisition strategy and must be consistent with the Procurement Data Package (PDP) and/or Military Interdepartmental Purchase Request (MIPR) provided by

the Military Service customer(s). JOCG JCAPP 8 states that the Developing Military Service (DMS) (The Service that is the Technical Authority and maintains Configuration Management of the item to be procured) establishes and maintains life-cycle QA requirements for their munitions. Further, JCAPP 8 recognizes that often a Requiring Military Service (RMS) will procure munitions to a TDP owned and managed by another Service (DMS). In this case the RMS may have additional unique QA requirements that will influence the option selected. Therefore the office responsible for the acquisition must work with not only the DMS but also, when applicable, the RMS in selecting the option that assures best value for the procurement.

PCCI was developed with a group of options to provide flexibility to the Military Services when procuring munitions through the SMCA. During the procurement planning phase, including formulation of the solicitation/contract, the office responsible for managing the acquisition is expected to work closely with the RMS/DMS to select the specific option and, if necessary, complete paragraph g of the clause. This is typically accomplished through the Acquisition IPT responsible for the item being procured. It is essential that the Military Service customer(s) and office responsible for acquisition have a consistent vision with regards to implementation of the options within the clause. In addition, stakeholders in the procurement should discuss and clearly understand potential impacts to risk, cost, quality and schedule during the process to determine which option is selected.

Clause Option b(1)

In general, this option is selected when the Government has a high degree of confidence in the accuracy and completeness of the TDP such as firm fixed price contracts. The Contractor is expected to accept the Government selected characteristics in total when planning and implementing the requirements of the PCCI clause. If this option is selected then either sub-option (1.1) or (1.2) must also be selected.

Sub-option (1.1) requires the Government to list the characteristics for process control selected from the TDP in paragraph g of the clause. For noncomplex munitions with relatively few characteristics classified as Critical or Major the DMS/RMS may elect to state in paragraph g: “All product characteristics, features, tolerances, and test requirements classified as Critical or Major in the Technical Data Package.” For complex munitions with many Major characteristics the DMS/RMS working with the Acquisition Office must list the

specific characteristics in paragraph g. Typically, the list will include all Critical characteristics and a subset of essential Major characteristics selected for process control.

Sub-option (1.2) requires the Government to analyze and identify Key Characteristics in the TDP. As of the date of this Review Guide, there is no Military Specification or Standard that defines how Key Characteristics are selected and identified.

Clause Option b(2)

If option b(2) is checked, the Contractor must determine the number of Characteristics For Process Control (CFPC) using an in-depth review and analysis. The Contractor will fulfill this requirement by providing all of the CFPC with objective evidence to the Government for review and acceptance. Each CFPC will be clearly identified and explained. The Government may identify additional CFPC deemed necessary in paragraph g.

In addition, option b(2) is primarily used when the Government does not own or maintain the TDP. This can include Performance Based Contracting or Commercial Off The Shelf (COTS) Acquisitions. This option is applied when the Government and Contractor share TDP management duties as well. For example, in a performance based contract, the specification is owned by the Government while the drawing package that meets the performance specification requirements is owned by the Contractor. In such a case, it is assumed the Contractor has greater knowledge of their processes and CFPC.

When the Government owns the TDP and desires to use this option instead of option b(1), the Government through this option would allow the Contractor to submit their own CFPC after an evaluation of their process based upon a PFMEA and other analysis. When the Government owns the complete TDP, the Government may establish an IPT to ensure both Contractor and Government share knowledge to identify the correct CFPC and process control parameters. This option is useful when the item specified by the TDP has not been produced for a long time, or the TDP is valid, but old and the Government is seeking improvement based upon Contractor input.

Since it is assumed that the Government may not have knowledge of the potential Contractor's process control parameters during the solicitation phase, many characteristics required for process control are determined via a Contractor’s PFMEA after contract award. The Government may identify some CFPC in paragraph g based upon their requirements.

Example
The Government places a performance specification on a request for proposal / solicitation. Three Contractors bid on this RFP. Since the Government has only specified performance requirements, it has identified some characteristics for process control (CFPC) based on those performance requirements, e.g., weapon/ammunition interface dimensions. In this case, the Government has identified length, diameter, and a flange thickness as characteristics that require process control in paragraph g. The Contractors bidding on this RFP must plan on addressing these requirements. Designs for each Contractor meeting performance requirements vary, if awarded a contract. Contractor ABC may identify 5 additional CFPC after a PFMEA is conducted. Contractor XYZ, if awarded the contract, may identify 7 additional CFPC based upon the PFMEA that shows high RPN values associated with the failure modes. Contractor MNO, if awarded the contract, may identify an additional 10 CFPC based upon their PFMEA.

Note
The Contractor, after contract award, conducts a PFMEA and uses information from the PFMEA to identify additional CFPC, which at minimum, should address the highest risk / impact areas. The Government identifies a small number of CFPC up-front (if needed) in paragraph g.

Clause Option b(3)
This option is selected when the Government wants to partner with the Contractor to identify the optimal set of characteristics for process control (CFPC). This set of CFPC is specific for the procured item as well as the manufacturing system used. The focus of the analysis is safety, performance in terms of customer’s requirements and final cost impact of the features and processes. The basis for the analysis will be a systematic approach connecting Warfighter requirements to design features and process capabilities. In paragraph g, the Government will provide a set of requirements to allow Contractors to bid the tasks therein as part of the proposal process.

Table 1 below summarizes the PCCI Options for Government selection.

Table 1 – PCCI Option for Government Selection

Government Decision Matrix	Guidance on PCCI Option Selected			
PCCI Requirements	OPTION B1.1	OPTION B1.2	OPTION B2	OPTION B3
CFPC List	• Govt has knowledge of TDP • TDP is stable • Provide list in paragraph g	TDP has Key Characteristics identified	• Contractor has more knowledge • Performance based / COTS acquisition • Govt has handful of characteristics, e.g., interface dimensions • Old TDPs	• Govt desires to evaluate TDP • Govt / Contractor share knowledge • Old TDPs

Paragraph c (Process Analysis)

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

Discussion:

Flowdown of Process Control Requirements

These requirements are applicable to the prime Contractor. It is the responsibility of the prime Contractor to apply these requirements to sub-Contractors at all levels of manufacturing with emphasis on processes that affect the quality of characteristics for process control (CFPC). The application of these requirements is subject to Government review.

Processes are transformation of inputs (people, material, equipment, methods and environment) into outputs and eventually a finished product. In order to understand the effect of an input and its interrelationships, every process must be understood. Processes at Contractor and sub-Contractor facilities must be included in the review to assure all interrelationships are examined. The Contractor will provide objective evidence of the review and analysis of each process. Objective evidence consists of each element of the PCP (i.e., flowchart, PFMEA, process capability and MSA studies as outlined in paragraph d for each Contractor and sub-Contractor level.

Process Flowchart

Process flow charts of the production process begin with the receiving of components or materials from Contractors and continues until the final product is packaged, labeled and shipped. The flow chart should incorporate every process and action which is directly or indirectly a part of producing the product. Direct processes affect the actual form, fit, or function of the product such as machining, forming, handling, and finishing. Indirect processes do not physically affect the product such as inspection, testing, traceability and non conforming material control.

The more detailed the flow chart, the more likely potential failures in the process can be captured and prevented. The flow chart will have process numbers assigned to each process for ease of reference.

Process flow charts should give a clear representation and description of the processes being accomplished. The flow chart submission must be clear, complete and understandable to someone not familiar with the product or process.

The use of industry standard flow charting techniques is recommended. All non standard symbology should be clearly defined.

Process Failure Modes and Effects Analysis (PFMEA)

A PFMEA assists in the analysis of manufacturing and assembly processes. The PFMEA assumes the product, as designed, will meet the design intent provided the product is manufactured and assembled properly in accordance with its specifications. PFMEAs focus on potential product failure modes that result from manufacturing or assembly process deficiencies and the ability to detect the deficiencies prior to product delivery. Outputs from a PFMEA include recommended corrective actions and process modifications to eliminate the causes of process failures, or reduce the frequency of their occurrence to an acceptable level, and improve the defect detection capability of the manufacturing process.

The PFMEA should be created using the flow chart to capture all processes involved that affect characteristics for process control (CFPC). The potential failure modes should be carefully considered and all failure modes and causes listed in connection with each process step. The possible failure modes and causes

should include all possible scenarios regardless of probability of occurrence as the probability is already considered in the Risk Priority Number (RPN). Do not exclude a mode from the list based solely on its probability.

It may be necessary to establish process boundaries for the PFMEA where there are interfaces with commercial items, sub-Contractors with proprietary processes, or Government Furnished Products/Materials.

The use of the following steps and Attachment 3 below, for product / design and PFMEA's, are recommended:

1. Review the process
2. For each process step brainstorm potential failure modes or how the process could potentially fail to meet the product and process requirements
3. List potential effects of each failure mode on the end item to be delivered
4. Assign a severity rating (S) for each effect which is associated with the most serious effect for a given failure mode for the operation being evaluated
5. Determine the potential cause(s) or how the process failure(s) could occur for each failure mode
6. Determine the likelihood of occurrence during production taking into account the prevention-type process controls and assign an occurrence rating (O) for each failure mode
7. List the controls for the process including prevention and defect or nonconformance detection
8. Assume the failure has occurred then assess the capabilities of all detection type controls and assign a detection rating (D) for each failure mode and/or effect
9. Calculate the RPN (product of S, O, and D) for each effect
10. Prioritize the failure modes for action
11. Take action to eliminate or reduce the high risk failure modes
12. Calculate the resulting RPN as the failure modes are reduced or eliminated

In addition, the use of Classification Codes (CLASS) are optional in a PFMEA. Classification Codes are the result of criticality analysis which ranks each failure mode according to the significance of its impact on product characteristics classified as Critical or Major. Typically, letter codes are used for Classification to highlight high priority failure modes or causes that require further attention.

The PFMEA should be able to discriminate subtleties in total risk by using no fewer than 5 rating levels and up to 10 levels for each of the 3 categories (S, O and D). Five rating levels yield a maximum RPN of 125 whereas 10 allow for a maximum RPN of 1000. Regardless of whether 5 or 10 rating levels are selected the team will have to develop criteria for each rating level of the 3 categories. A severity rating (S) for a potential process failure mode that affects a design characteristic classified as 'Critical' will be given the maximum rating. Occurrence rating (O) criteria is typically based on projected incidents per 1000 items. Detection rating criteria is based on the likelihood of detecting a nonconformance with the highest rating assigned when the defect cannot be detected. RPN ratings are subjective, therefore selecting an RPN threshold for action is not recommended. Establishing thresholds may promote the wrong behavior causing team members to spend time trying to justify lower rating values to reduce the RPN. Typically, process steps with high severity ratings (S) and RPNs should be given special attention when creating the PCP to have good controls and response plans to address occurrences in production.

SAE Aerospace Recommended Practice (ARP) 5580 (Recommended Failure Modes and Effects Analysis (FMEA) Practices for Non-Automobile Applications) issued in July 2001 replaced MIL-STD-1629 which was cancelled in 1998. SAE ARP 5580 describes the basic procedures for performing a FMEA but has very limited information on conducting process FMEAs. A better and more recent resource for PFMEAs is SAE J1739 (Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA) issued January 2009. Although developed for the automobile industry SAE J1739 contains detailed procedures for performing a PFMEA and evaluation criteria tables for rating (S), (O) and (D) that can be modified for application to munitions.

Control Systems

Control systems include process sensors, data processing equipment, actuators, networks, etc. to connect equipment and control charts. Types of process control systems may include Statistical Process Control Methods such as x bar, r, p, c or u charts; run charts; visual, optical, camera or laser control sensors; specialized/built-in manufacturing/machining controls (e.g., CNC and robotic); instrumentation control systems (e.g., temperature and humidity controls) and calculations of station and system effectiveness.

Process Capability Studies

Process capability studies are fundamental to the understanding and control of all processes creating the product. Every process that affects characteristics for process control (CFPC) should attain acceptable levels of control. The level of control should be ascertained initially by careful measurement and analysis of the data to establish acceptable process capability (C_{pk}) levels. Process capabilities can be influenced by factors such as personnel, shift, time of day, lighting conditions, atmospheric conditions, power fluctuations, air supply variations, relocation of equipment, peripheral disturbances, etc. A good understanding of all possible influences should be considered and included in the PFMEA and control plan. Process steps which can influence CFPC should have methods developed for obtaining variables type measurements for use in SPC controls.

Measurement System Analysis (MSA)

MSA, such as Repeatability and Reproducibility (R&R) studies, should be conducted on all applicable manufacturing and inspection processes to determine the possible individual effects due to variability in measurement equipment, methods, operators and other factors with potential to affect the outcome of any identified CFPC. The results of the MSA studies can impact process capability or detection levels especially in highly operator dependent processes. Operator dependent processes should be given special attention in detailing procedures and standards to minimize variation and increase control. Operator dependent processes should be eliminated where possible and tightly monitored and controlled when other alternatives are not practical.

Paragraph d. (Process Control Plan)

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

Discussion:

Process Control Plan (PCP)

The PCP is intended to be the unifying document with respect to controlling the product through product realization process for the characteristics identified for process control (paragraphs b and g). It ties in the requirements for process control, critical characteristics, MIL-STD-1916, ISO 9001:2008, acceptance inspections, etc. It compliments but does not supersede other contract requirements (CCCP, CPOA, Quality Plan, AIE, etc.) All aspects controlling the production processes should be addressed in this document.

The PCP is to be created by incorporation of the results of the in depth analyses required by paragraph c and all potential actions that affect product realization to be taken during the production of the product including:

o Process flow charts

- PFMEAs (with cause and effect diagrams when used)
- Process capability studies
- MSA studies
- Process control methods and tools:
  - Process and inspection equipment
  - Process Plan of Action (PPOA) for out of control conditions
  - Process capability at Contractor stated production rate

Process Control Methods and Tools

Process control methods should be clearly defined. They should outline how each process is controlled, where controlled, whether controlled by equipment or operator, control capability and limits of control at each step. When SPC is utilized to maintain process control it should be located as near and practical to the process as possible and, preferably, provide real-time feedback. To be considered adequate, process controls must be capable of stabilizing processes within the control limits and maintain acceptable C_{pk} values.

Emphasis must be placed on controlling the parameters of the process and not the monitoring methods.

Process and Inspection Equipment

The equipment used in the process should be clearly identified and deemed capable of producing within the process control limits. Inspection equipment producing variables type measurement data is preferred over go / no-go type inspection equipment. Calibration and control of equipment and gauges will be clearly defined and documented and include audit schedules and calibration cycles to ensure equipment and / or gauge accuracy and repeatability.

Mil-A-70625 may be used as a guide when using Automated Acceptance Inspection Equipment (AAIE).

When not specified in the Technical Data Package (TDP) the Contractor should be mindful of the measurement system evaluation requirements (AIE Plan) when developing their PCP.

Elements of the contractually required AIE Plan may fulfill portions of this requirement.

Process Plan of Action (PPOA) for Out of Control Conditions

A PPOA should be developed and included in the PCP for potential out of control manufacturing process conditions that may impact CFPC. The PPOA is not a waiver to the requirements of paragraph a and provides a means of ensuring the process can be controlled and improved when out of control conditions exist.

The PPOA may address other out of control conditions that may occur during planned and unplanned interruptions of production, power outages and any other natural or man made events. PPOAs may address the following:

1. Clearing of product with unknown status.
2. Control of rejected items.
3. Notification of the program IPT, Quality Assurance Specialist and Buying Command, accordingly.
4. Production startup including use of verification and fault-finding standards (i.e., “golden standards” or accept / reject standards) for the purpose of verifying that logic and measurement systems are performing as planned.

Below are the minimum criteria that will trigger implementation of PPOAs:

1. Three consecutive lots with a C_{pk} between 1.0 - 1.33 for non-critical characteristics (this would be applicable when the Contractor is producing at a relatively fast pace, i.e., 1 or 2 lots per week).
2. C_{pk} is between 1.0 – 1.33 for the last 25% of the production lot for non-critical characteristics (this would be determined by the Contractor to be applicable when it is producing lots at a relatively slow pace such as 1 per month)
3. A critical characteristic with a C_{pk} of 1.67 to 2.0 is determined by the Contractor to be applicable (~ 0.5 defects per million parts). Note that a C_{pk} of 2.0 corresponds to 0.00198 defects per million parts while a C_{pk} of 1.33 corresponds to 64 defects per million parts.

   The above criteria are applicable when lotting in accordance with the contract, e.g., MIL-STD-1168.

   NOTE: The above would typically be reviewed during a post award conference by all of the contractually affected Contractors.

A PPOA would not be applicable / accepted for the following conditions:

1. A C_{pk} below 1.67 for critical characteristics
2. A C_{pk} below 1.00 for non critical characteristics

Process Capability at Stated Production Rates

The process capability should be determined at the stated rate of production. The capability of processes can vary widely by rate. The planned production rate is determined by the Contractor. When higher or lower production rates are desired or required, the affected process capabilities will be recalculated.

Process Capability and Government Acceptance of Product

The statistical sampling methods used to infer acceptability of product not 100% inspected requires the samples be representative of the population of product. This is achieved through stratified, random sampling in accordance with contract requirements. The Government requires the Contractor provide objective evidence that product has been produced from stable, capable and controlled processes as a condition of lot acceptance.

Process capability indices (PCI) can be calculated for distributions other than Normal (Weibull, Lognormal, etc.), and for attribute data as well (Binomial, Poisson, etc.). Data transformations (such as Box-Cox and Johnson’s) may also be applied. Most statistical software packages that are commercially available are capable of these calculations. Evidence of the control of processes creating or influencing characteristics for process control of each Lot Acceptance Test (LAT) package will be made available to the Government upon request or as required by a Lot Acceptance Testing CDRL item in the contract or work order using the Worldwide Ammunition-data Repository Program (WARP) residing in the Munitions History Program. The form of objective evidence to be provided for lot acceptance will be documented in the PCP. The lot acceptance data package should include the capability data for each process established with control limits when using an alternate acceptance plan in accordance with MIL-STD-1916. The capability and control data will have the form of a Government accepted metric. If the capability is determined on less than a lot by lot basis, it will be accepted on the frequency established in the Government accepted PCP.

The periodic verification of capability will be outlined in the PCP. The frequency of capability verification will be established with periods appropriate to the process. The control and capability will be determined as frequently as practical to aid in maintaining product integrity / quality. Some processes may be expected to have continuous monitoring while other processes might be monitored on longer cycles depending upon the processes involved. The period should be appropriate to the process, controls and risk with a higher risk suggesting an increased frequency.

The PCCI clause defines a capable process that influences the quality of a characteristic for process control as having a C_{pk} equal to or greater than 1.33 unless otherwise stated in contract or purchase order. Contractor identified processes that influence characteristics for process control must also meet this requirement. MIL-STD-1916, paragraph 4.1.2b defines the minimum values of process capability. The expected standard of performance is to improve all processes to capabilities as high as possible within the bounds of reasonable application of technology and procedural control. Upon approval of the assessment plan, the Contractor may reduce or eliminate inspection sampling when the plan criteria are met or exceeded.

Section 5 of MIL-HDBK-1916 provides details for the application of SPC including how to determine process statistical control and capability. The Government will adhere to the C_{pk} definition provided in MIL-STD-1916.

As an exception to normal process capability data, a 100% automated and fool proof capable inspection system along with potential sources of data (such as defect rates) can be used to meet this requirement and must be demonstrated that only conforming product be accepted. This option is to be exercised only when other options have been exhausted.
Please note that the sampling plans and procedures of MIL-STD-1916 are not intended for use with destructive tests or where product screening is not feasible or desirable. In such cases, the sampling plans to be used will be specified in the contract or product specifications.

Example

Bullet production involves a die forming operation followed by a plating operation. The shape of the bullet and the plating thickness were determined by the customer to be characteristics for process control*. The die forming process used to make the bullet is automated and involves very little human interaction. Through process capability and control and die wear studies it was determined by the customer and Contractor that the bullet forming operation / process is highly capable and adequately controlled. Based upon this information it was decided that the frequency of monitoring the die forming process would be reduced.*

The plating operation, on the other hand, involves numerous interactions with operators and changes of chemical solutions along with bath temperature, pH, electric current and part count. Through process capability and control studies, it was determined by the Contractor that all the process controls listed above are additional characteristics *required to control the plating thickness specified in the TDP. The part counts and electric current need to be controlled and monitored on a batch basis while the pH and temperature need to be continuously monitored to ensure process control and to meet customer defined characteristics for process control.*

The lot acceptance data for each lot of bullets may include the most current process capability data for the bullet forming operation. It may also include the process capability data for each batch of electrical current and part counts relative to the process limits. Since the temperature and pH are continuously monitored and controlled, the data for these two process parameters should show control throughout the process relative to established limits as defined in the PCP. The plating process data may represent less than a lot or more than a lot depending on the size of the lot relative to the process defined batch size. If the batch size is less than a lot, there may be multiple data points showing the process control across all plating batches.

NOTE

All process control elements along with process capability studies will be captured and documented in the PCP. The customer must accept the process capability and controls and any proposed changes.

Table 2 below summarizes the Contractor requirements.

Table 2 – Contractor Requirements

Contractor Requirements	PCCI Option Selected			
PCCI Requirements	OPTION B1.1	OPTION B1.2	OPTION B2	OPTION B3
	• Govt responsible for developing list. • Govt provided list in para g	If identified as Key Characteristics in TDP	• Contractor responsible for conducting analysis on developing optimal set of CFPC. • Govt may provide some in para g	Govt & Contractor responsibilities / deliverables as identified in para g
Process Control Plan (Deliverable)	✓	✓	✓	✓
Process Flow Chart	✓	✓	✓	If para g requests
PFMEA	✓	✓	✓	If para g requests
Process Capability Studies	✓	✓	✓	If para g requests
Measurement System Analysis studies	✓	✓	✓	If para g requests
Process Control Methods and Tools	✓	✓	✓	✓
Process & Inspection Equipment	✓	✓	✓	✓
PPOA for Out of Control Condition, i.e., preventative actions, corrective actions, minimum thresholds for action	✓	✓	✓	✓
Process Capability at Contractor stated production rates	✓	✓	✓	✓
Other requirements as required by contract	✓	✓	✓	✓

Legend:

- ✓ These requirements are mandatory. Compliance with these requirements will vary based upon the CFPC and applicable tools and techniques used to maintain control and prevent defects.

Paragraph e. (Alternate Methods of Acceptance Inspection and Test)

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

Discussion:

Application of this clause is intended to support the implementation of MIL-STD-1916.

Alternate methods of acceptance inspection and test requirements, including but not limited to reduction in sample sizes, may be proposed in accordance with MIL-STD-1916 as stated in the Foreword, paragraph 4.1 (general) and 5.1 (detail) of MIL-STD-1916.

The data resulting from this clause may be used to demonstrate the stability and capability requirements for alternate methods of acceptance inspection and test under the provisions of MIL-STD-1916.

IPT should carefully consider the various factors such as number of lots, lot size, Contractor's quality management system, process control methods, capability and stability of processes, production rates, etc. to see if an alternate method of acceptance proposed is desirable. For example, production quantities on contract may result in lot sizes of a small quantity such that 10 consecutive lots (as required by MIL-STD-1916) may not be feasible to provide the confidence necessary to consider reduction of alternate methods of acceptance inspection and test. In such an instance, the IPT may wish to consider the above factors in assessing the proposed plan.

Following is an excerpt from MIL-STD-1916. However, the Contractor is expected to fully understand the entire standard.

4.1.1 General.

a. This standard, when referenced in the contract or product specifications, requires the Contractor to perform sampling inspection in accordance with paragraph 4.2 and

the product specification. However, it is recognized that sampling inspection alone does not control or improve quality. Product quality comes from proper product and process design and process control activities. When such activities are effective, sampling inspection is a redundant effort and an unnecessary cost. Contractors that have an acceptable quality system and proven process controls on specific processes are encouraged to consider submitting alternate acceptance methods for one or more contractually specified characteristics. In addition, Contractors that have a successful quality system and a history of successful process controls relevant to the products/services being procured in this contract, are encouraged to consider submitting a systemic alternate acceptance method for the contractual sampling inspection requirements associated with paragraph 4.2.

Paragraph f. (Additions to Characteristic for Process Control List)

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

Discussion:

Application of the above paragraph in this clause is intended to support and complement ISO 9001-2008 Paragraph 8.5 and MIL-STD-1916. Corrective Action Requests (CARs) and Requests for Deviations (RFDs) should be looked at as opportunities for continuous improvement. The objective of the requirements in this paragraph is to ensure when opportunities for continuous improvement are identified they are documented, the Process Control Plan (PCP) is reviewed for the potential addition of new characteristics for process control, and process control techniques are applied that addresses how the Contractor will prevent future product non-conformances. These non-conformances may result from new failure modes or currently identified ones with characteristics for process control that lack the appropriate process control once highlighted by a CAR or RFD.

DCMA, Army COR staff at Army Ammunition Plants, or other Government agency issued CARs for product non-conformances are of key importance here. CARs written by Prime Contractors against their sub-Contractors for product non-conformance or RFDs are of interest as well. The Contractor should include their impact from internal CARs if the characteristics for process control and stability of the process are affected.

When CARs and/or RFDs are generated for product non-conformances as a result of new failure modes (unknown causes associated with current process), then this should result in the implementation

of corrective actions after a root cause analysis per the applicable requirements of the quality management system, MIL-STD-1916 and other contract requirements. The Contractor should submit an updated PCP for the Government's review once analysis has been completed and new characteristics for process control are identified per paragraphs c and d of this clause.

If a currently identified failure mode is the root cause for the product non-conformance documented in the CAR and/or RFD, the Contractor must analyze why the process control techniques identified in the PCP did not prevent the defect and provide appropriate controls. This may indicate the types of tools used to control the process will need to be reviewed and actions implemented per paragraphs c and d of this clause.

If updated PCPs submitted to the Government for review do not adequately address the CAR and/or RFD, the Government reserves the right to withhold acceptance of product until the plan is accepted. The Contractor and Government should partner, when appropriate, to ensure product non-conformances can be prevented and processes are appropriately studied with objective data in hand to facilitate a robust PCP and continuous improvement.

NOTE: If characteristics for process control include Critical Characteristics, requirements of the Critical Characteristics Clause (CCC) are to be followed. The PCCI is meant to be complementary to the CCC and actions of updating the Critical Characteristics Control Plan (CCCP) and Critical Plan of Action (CPOA) are complementary to the update of a PCP. Also, the Contractor should review their quality plan, ensure requirements of ISO 9001-2008 or an equivalent QMS are met along with MIL-STD-1916 and contract requirements, when applicable.

Example 1
Contractor is not performing SPC on a particular characteristic for process control, rather, conducting monthly or quarterly capability studies to monitor whether the process was in control or not due to historical data showing very high C_{pk} (4.0-6.0) in accordance with their Government accepted PCP. Contractor decides to install new equipment of a similar design to the older one, for wear/tear replacement purposes. A capability study was not conducted after the new equipment installation as the Contractor did not understand or study the impact of the new machinery, since it was very similar to the equipment being replaced. No procedures or processes were updated. Two weeks later, while conducting MIL-STD-1916 verification level final inspection, a defect is found.

The Government Quality Assurance Representative (QAR - DCMA or Army) issues the Contractor a CAR to address the defect. Per corrective action requirements of ISO 9001-2008 QMS and MIL-STD-1916, the Contractor conducts a root cause analysis and determines procedures required to be updated with the equipment, while practically the same, had minor differences with regards to operations and maintenance. Variation that was introduced was not captured as an SPC system was not in-place to monitor the process via an X-Bar/R chart. The Contractor addresses the CAR via a corrective action to their procedure to ensure SPC is instituted, at minimum, for a month to monitor processes when equipment is being replaced, even if the equipment is practically the same. Since the result of this corrective action was an update to Contractor process control procedures, the PCP was reviewed and updated accordingly and submitted to the Government for acceptance.

Example 2

The Contractor decides to switch sub-Contractors for a machined part. After a First Article is conducted to show the new sub-Contractor meets requirements to produce the new part, the Contractor incorporates this part into their assembly for delivery to the Government. PCCI requirements are flowed to the sub-Contractor in accordance with contract requirements. No major updates were made as all parties assumed the parts were effectively manufactured the same way. Since the item is being delivered on a performance specification, the Government decided to use a list of characteristics for process control generated by the prime Contractor via a PFMEA of the sub-Contractor's process, the PCP was eventually accepted.

However, due to differences in machining techniques between the previous and new Contractors (not addressed to the level necessary in the PFMEA and PCP), several unknown failure modes were introduced into the process. This resulted in non-conforming product produced as indicated by a failed Lot Acceptance Test. The Government QAR issued a CAR and the Contractor also submitted an RFD. In the process of addressing the CAR and RFD, the Contractor evaluates the PCP for inclusion of new characteristics for process control. In order to address the root cause of the problem, the PFMEA is updated for the new sub-Contractor. A characteristic for process control, previously ignored, is now identified as a parameter that when left unchecked, can result in a product non-conformity. The PCP is updated by the prime Contractor to include the new list of characteristics for process control and the appropriate process

control tools (SPC in this case) are implemented to prevent future defects from occurring.

Table 3 below summarizes the potential conditions under which the Government will issue out a CAR.

Table 3 – Government CAR Decision Matrix for PCCI

Potential Conditions	When a CAR is Issued
CFPC not monitored IAW requirements & accepted PCP	X
CFPC doesn't meet C_{pk} of 2.0 for Criticals (para d)	C_{pk} drops below 1.67 & no effective corrective action(s) implemented.
CFPC do not meet C_{pk} of 1.33 for all other characteristics (para d)	1. C_{pk} drops below 1.00 & no effective corrective action(s) implemented. 2. C_{pk} drops below 1.33, but above 1.0 for four consecutive lots and no effective corrective action(s) implemented per PPOA in the PCP. (High volume production of 1 lot or more per week) 3. C_{pk} drops below 1.33, but above 1.0 for greater than last 25% of production and no effective corrective action(s) implemented per the PPOA in the PCP (Low volume production with l lot or so per month)
Other C_{pk} value in the fill-in of para d, para g or as agreed to in the accepted PCP based on Contractor proposal.	X
Lack of compliance to agreed "PPOA for out of control conditions" per accepted PCP.	X
TDP non-conformance	X
Non-conformance to contractual requirements of this PCCI clause.	X
Other PCCI contractual requirements	X

Paragraph g (Selected List of Characteristics for Process control, or Analysis and Selection Techniques)

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

Discussion:

Detailed information is added to this paragraph only when box (1.1), (2) or (3) in paragraph b is checked. The information is typically provided by the Military Service customer to the procuring office during formulation of the solicitation/contract.

When Clause Sub-option b(1)(1.1) is Checked

This option requires the listing of all TDP characteristics that the Contractor will be required to address for process control. If process control is desired for all TDP characteristics classified as Critical or Major the statement provided in the discussion of Clause Option b(1), Sub-option (1.1) may be used in lieu of listing all of the individual characteristics.

“All product characteristics, features, tolerances, and test requirements classified as Critical and / or Major in the Technical Data Package.”

However, if the Contractor will be required to address only selected TDP characteristics then the specific characteristics must be listed in a table that clearly identifies each characteristic or requirement in accordance with the example below:

Drawing No. Spec. No.	Page or Sheet No.	Dwg Zone	Classification	Characteristic or Requirement
1380547	3	A7	M112	6.250-12UNS-2B Thread
923AS331	1	C7	C1	Note 9 Thermal Insulation Shore Hardness D55 Minimum
923AS331	1	D5	C2	Note 13 Explosive Level

The Government may specify tools such as SPC for individual CFPC if desired as well, for example:

Drawing No. Spec. No.	Page or Sheet No.	Dwg Zone	Classification	Characteristic or Requirement	SPC Required	Type of SPC Chart
MIL-DTL-70438A	9		M102	Length of Thread Section	X	X Bar/R
MIL-DTL-70438A	9		M105	Flange Thickness		
MIL-DTL-70438A	9		M106	Diameter of Flange		
MIL-DTL-70438A	9		M107	Diameter of Gasket Groove	X	Contractor Choice
MIL-DTL-70438A	12		M102	Air Pressure Test		

Note: The above tables are merely examples, not recommendations for the referenced drawings or specifications.

When Clause Option b(2) is Checked:

This option requires the Contractor to create a list of CFPC (for example, on an item manufactured with a performance specification). However, the Government may still specify a small CFPC list in certain instances, for example, if the item in question has any key interface dimensions with a weapons system. The following is an example:

Drawing No. Spec. No.	Page or Sheet No.	Dwg Zone	Classification	Characteristic or Requirement
MIL-PRF-32056	6		M111	Cartridge Length, Max
MIL-PRF-32056	6		M112	Rim, Thickness Max
MIL-PRF-32056	6		M113	Head Diameter, Max
MIL-PRF-32056	6		M114	Case Diameter, Max

Note: The above table is merely an example, not recommendations for the referenced drawings or specifications.

When Clause Option b(3) is Checked

This option requires the process to be described that will be used by a joint Government-Contractor team to select CFPC. The description must provide sufficient detail so potential Contractors can formulate a realistic offer to support this effort. For example, the description should clarify the terms used in option b(3) such as “significantly”, “final cost of a product” and “cost of variation justifies the cost of control.”

In addition, sufficient detail is required so potential Contractors clearly understand their role, responsibility and resulting level of effort in the review and analysis of TDP characteristics that leads to the selection of the CFPC.

When Clause Option b(3) is checked the systematic approach for identifying CFPC would require the process that will be used to be described by a joint Government-Contractor team in order to select characteristics for process control. The Request for Proposal (RFP) will include Scope of Work (SoW) language to assist offerors in their response preparations.

The following is an example of a systematic approach for identifying CFPC:

This option requires a joint Government-Contractor team to select CFPC. The efforts will enable both parties to link the customer needs to the manufacturing processes. The effort will integrate the following bodies of knowledge to attain these linkages:

• Systems Engineering discipline,
• Scientific principles expressed in mathematical/chemical equations, and
• Lean/Six Sigma practices.

The Request for Proposal (RFP) will include language in both the Scope of Work (SoW) as well as Request for Proposal Sections L & M to assist Offerors (prospective Contractors) in their response preparations. The following is a synopsis of tasks needed to complete this goal. Notional examples provide an illustration of the data or analysis documents indicated at the step.

Step 1 - Establish Charter

- Establish Government & Contractor key team members' Roles & Responsibilities
- Develop clear, specific & measurable results

Step 2 - Involve Subject Experts

- Allocate Government & Contractor personnel based upon functional competencies and engineering insight
- Ensure best mix of experience and judgment
- Participate on Government-led briefing for chartered Government & Contractor personnel of the item's design and functional allocation.

The purpose of this task is to provide a common frame of reference to all personnel. It entails the item's requirements, design, function, and allocation of characteristics. This provides the rationale explaining what the item does and why the Government specifies it as described in the TDP.

Step 3 - Requirement Clarity & Flow

- Identify processes associated with the features provided in the item's functional allocation matrix.
- Initial identification of focus areas, such as most difficult tolerances or laborious operations.

Notional functional allocation matrix

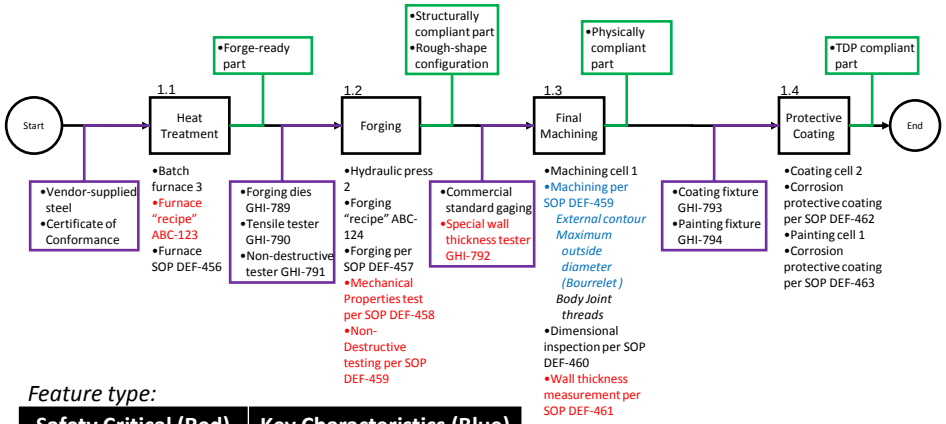
Function	Feature	Process	
Perform calculated flight trajectory	External body profile (contour)	**Machining operation 1.3**	
	Weight	Forging operation 1.1	
		Machining operations 1.2 through 1.3	
	Maximum outside diameter (Bourrelet)	Machining operation 1.2	
Seal propellant combustion chamber	Maximum outside diameter (Bourrelet)	Machining operation 1.2	
Processes in **boldface type** *are considered difficult/laborious*			

Step 4 - Generate Supporting Diagrams

- Develop process maps describing the production operations.
  - Offerors may leverage the Production Process Map (for items with Safety Critical Characteristics in their TDPs) submittal requirements.
  - Note Safety Critical Characteristics are Key Characteristics with production and inspection controls designated upfront by the Government.
- Identify processes associated with the item's functional allocation matrix.

Production Process Map

Notional Example for metal part fabrication



Feature type:

Safety Critical (Red)	Key Characteristics (Blue)
Mechanical properties	External contour
Structural integrity	Maximum outside diameter (Bourrelet)
Wall Thickness	

Black	Process flow
Purple	Process input(s)
Green	Process output(s)

Step 5 – Develop a Key Parameter Tree/Dashboard

- Identify the process capability of each process in the item's functional allocation matrix.
  - Existing vendors need to provide historical data.
  - New entrants need to provide an estimate based on like processes for their other products. An alternative is their Manufacturing Readiness Level process targets.

The purpose of this task is to provide a statistical description of the process in question. The illustration below as well as subsequent ones shows an upper – lower Cpk nomenclature. This readily identifies both process capability and its symmetry. The specific approach to provide the statistical descriptions should be agreed upon by the Government and Contractor Team.

Notional functional allocation matrix with process capability inputs

Function	Feature	Process	Lower - Upper Cpk
Perform calculated flight trajectory	External body profile (contour)	**Machining operation 1.2**	1.4 - 2.8
	Weight	Forging operation 1.1	1.9 - 2.0
		Machining operation 1.2	2.4 - 2.7
	Maximum outside diameter (Bourrelet)	Machining operation 1.2	3.5 - 3.4
Seal propellant combustion chamber	Maximum outside diameter (Bourrelet)	Machining operation 1.2	3.5 - 3.4
Processes in **boldface type** *are considered difficult/laborious.*			

- Conduct initial Risk Analysis
  - Offerors may leverage the Critical Characteristic Control Plan (CCCP) or the Critical Plan of Action (CPOA) Failure Modes and Effects [Criticality] Analysis (FMEA/FMECA) submittal requirements.

  This task is the beginning of a risk assessment pertaining to the identified features or processes. Use of standard tools found in Six Sigma curriculums is encouraged. For example a method for risk identification is the fishbone diagram. A common tool for quantification is the FMEA. Note this risk assessment will evolve as the Government and Contractor Team marches on.

Step 6 - Focus on greater variation contributors

- The Government will employ Modeling & Simulation (M&S) techniques to identify operations with the biggest impact on User requirements. The M&S exercise uses math models correlating the processes' effect on the functional responses described within the functional allocation matrix.

  The M&S exercise intends to help the Government and Contractor Team understand the effects of the production floor's variability on the performance required by the Warfighter/Customer. This shows a clear, definite framework to assess strengths and weaknesses of the Contractor's system. In addition, it lets the Team reduce the impact of

unintended consequences as they select the activities yielding the greatest effect on the delivered product. This M&S exercise's basis is a thorough effort which developed scientifically and validated experimentally those equations. Essential consideration therein is the evaluation of feature variation interactions, whether beneficial or degrading. Otherwise, the model's capability to predict performance is hindered drastically.

- The Government & Contractor personnel assess which processes need further analysis to ensure optimal functional responses.
- Refine Risk Analysis.

Step 7 - Establish Capable Inspection

- Characterize measurement systems within the production processes by means of inspection Repeatability and Reliability [R&R] studies.
  The characterization of inspection equipment is essential to the success of the contract's production efforts. This is a pre-requisite to give full confidence upon the accuracy of inspection information. An unidentified inspection bias or inaccuracy will bring significant risk to both this process and all lots' acceptance.
- Refine Risk Analysis.

Step 8 - Design & Conduct Designs of Experiments [DOEs]

- Identify parameters most likely to influence the above processes.

Notional parameter identification

Forging	• **Pre-forging part temperature** • Forge die wear • Forge die temperature	• Hydraulic dwell time • **Hydraulic dwell pressure**
Final Machining	• **Cutting die profile** • **Cutting die exchange interval**	• **Lathe turning speed** • Lathe coolant flow • Lathe chuck pressure
Parameters in **boldface type** *are considered significant contributors to the operation.*		

- Conduct screening experiments
  - Validation and down-selection of parameters yielding least variation.
- Conduct modeling experiments
  - Develops mathematical models between parameters and design features.
- Perform appropriate analysis of resulting data.
- Establish math models correlating parameters and design features.
- Correlate the influential parameters for each process. *These experiments allow for a statistical validation of a mathematical model which relates the parameters and processes. This is analogous to the models relating performance and processes which support the M&S exercise discussed earlier. In later steps, these new models provide a greater level of correlation between the production floor and the Warfighter/Customer requirements.*

Notional correlation of processes and parameters with process capability inputs

Process	Parameter		
Forging operation 1.1	Pre-forging part temperature		
	Hydraulic dwell pressure		
Machining operation 1.2	Lathe turning speed		
	Cutting die profile		
	Cutting die exchange interval		
Parameters listed herein are considered most influential to the specified process.			

- Identify their corresponding process capabilities.
  - Existing vendors need to provide historical data.
  - New entrants need to provide an estimate based on like processes for their other products. An alternative is their Manufacturing Readiness Level process targets.

Notional correlation of processes and parameters with process capability inputs

Process	Parameter	Lower - Upper Cpk	
Forging operation 1.1	Pre-forging part temperature	1.4 - 1.7	
	Hydraulic dwell pressure	1.8 - 2.1	
Machining operation 1.2	Lathe turning speed	2.4 - 2.8	
	Cutting die profile	4.1 - 4.3	
	Cutting die exchange interval	2.3 - 1.9	
Parameters listed herein are considered most influential to the specified process.			

- Refine Risk Analysis.

Step 9 – Complete variation analysis

- The Government will re-employ Modeling & Simulation (M&S) techniques to identify operations with the biggest impact on User requirements. The M&S exercise will merge the processes' math models with the design ones to further detail the impact.
  This task is the integration of all attained knowledge to complete the correlation between production floor and Warfighter/Customer requirements. This enables the Government and Contractor Team to precisely assess the consequences (direct and unintended) of adjustments in the factory to what the Warfighter/Customer will experience when using the product.
- The Government & Contractor personnel assess which processes need further special controls to ensure optimal functional responses.
  The purpose for all earlier tasks is to provide the necessary insight to assess which parameters introduce the most variation on the Warfighter/Customer performance expectations. These therefore require tighter scrutiny to ensure those expectations are met. This is referred in Clause paragraph b.3 as the "Cost of variation justifies the cost of control".
- Refine Risk Analysis.

Step 10 – Establish & Verify Tolerances

- Define significant contribution parameters' nominal ("target") values.
- Incorporate risk analysis outcomes into the determination of target values.
  - Example: Coolant temperature controls if it can introduce process degradation.
- Verify & validate final nominal values.

Step 11 – Plan to Implement

- Establish production nominal values and tolerances.
- Establish process controls ("control plans") as dictated by Government & Contractor personnel assessments.
  - Establish appropriate screening or sampling approach for significant contribution process parameters.
  - Establish alternate sampling or process control approach for non-significant process parameters.
- Establish Measurement Systems Analysis verification approach to confirm inspection integrity for product deliveries. (I.e., no bias shifts accumulating from lot to lot.)

Step 12 – Complete Statistical Analysis

- Establish control plan agreement.
- Provide lot acceptance data in terms of the control plan. (I.e., upper and lower Cpk for significant contribution parameters.)
- Conduct a Government & Contractor pre- Lot Acceptance Test (LAT) Test Readiness Review.
  - The Government will re-employ Modeling & Simulation (M&S) techniques to forecast Lot Acceptance Test probability of acceptance.
- Identification of improvement opportunities in terms of increase in functional performance and program benefits (e.g., lower cost alternatives).
- Support independent auditors' evaluation of control plans.

References:

1) MIL-STD-1916, *DoD Preferred Methods for Acceptance of Product*, of 1 April 1996

2) MIL-HDBK-1916, *Companion Document to MIL-STD-1916*, 20 April 2004

3) ISO 9001-2008, *Quality Management Systems – Requirements*, 15 November 2008.

4) ISO 11462-1, *Guidelines for implementation of statistical process control (SPC) -- Part 1: Elements of SPC*, 15 June 2001

5) ANSI/ASQC B1, B2, B3, *Guide for Quality Control Charts Control Chart Method of Analyzing Data Control Chart Method of Controlling Quality During Production*, 1 January 1996.

6) DI-MGMT-80004, *Management Plan*, 30 October 2006

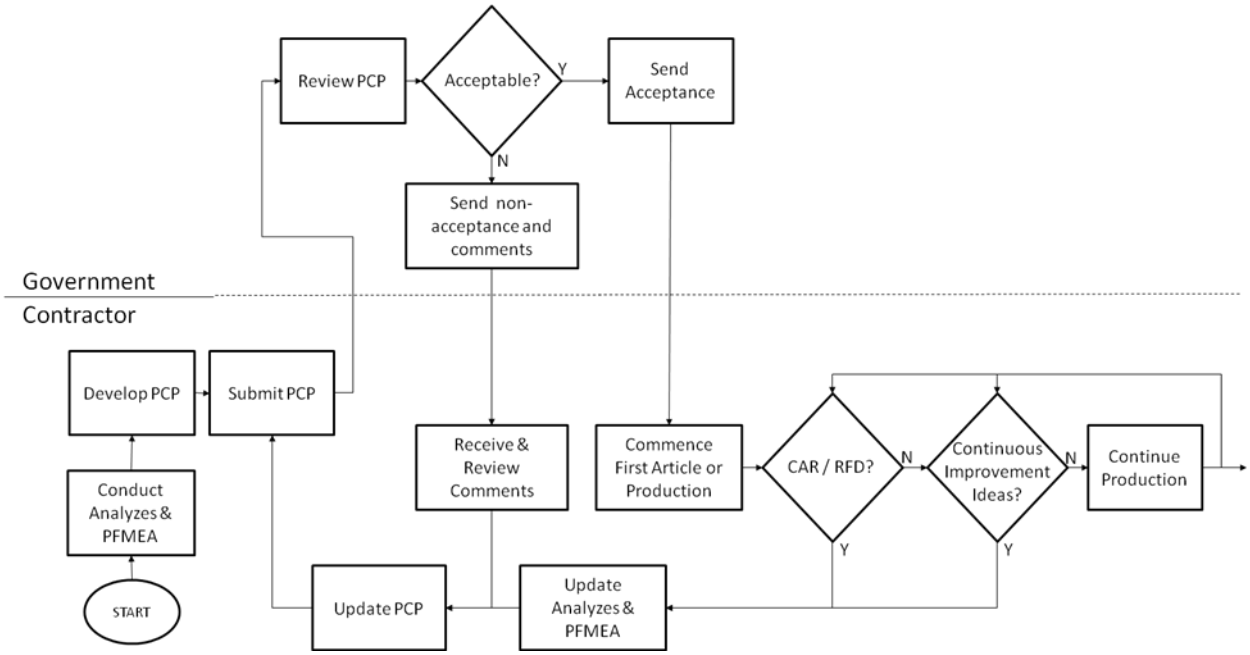
7) SAE ARP 5580, *Recommended Failure Modes Effects Analysis (FMEA) for Non-Automobile Applications*, 1 July 2001

8) SAE J1439, *Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA)*, 1 January 2009

9) MIL-STD-1629A, *Procedures for Performing a Failure Mode Effects and Criticality Analysis*, Cancelled, 4 August 1998

10) Automotive Industry Action Group (AIAG), Potential Failure Mode and Effects Analysis Book (FMEA Third Edition or Fourth Edition), July 2001 or June 2008
https://www.aiag.org/source/Orders/index.cfm?section=orders&activesection=unknown&task=3&CATEGORY=CORETOOLS&PRODUCT_TYPE=SALES&SKU=FMEA%2D4&DESCRIPTION=&FindSpec=FMEA&CFTOKEN=13921338&continue=1&SEARCH_TYPE=FIND&StartRow=1&PageNum=1

Attachment 1 – Process Map for Submission and Approval of PCP



ATTACHMENT 2 – Contract Data Requirements List (CDRL) Example

Contract Data Requirements List (CDRL)

One of the requirements contained in the Contract Data Requirements List (CDRL), also known as a DD Form 1423, requires the Contractor to prepare a Process Control Plan (PCP) using a generic Data Item Description (DID), DI-MGMT-80004. It is advantageous for the Contractor to begin preparing the plan immediately upon successful notification of contract award. When preparing the PCP, the Contractor will meet requirements stipulated in the Process Capability, Control and Improvement (PCCI) Clause and follow guidance contained within this review guide.

Initial submission of the PCP using an electronic format such as Microsoft Word or other comparable software is due 60 days after contract award, with Government response due within 30 days of receipt from the Contractor. Contractor revisions to the PCP, when required, are to be submitted within 15 days of the response from the Government. The Government response should be within 15 days from receipt of PCP revisions.

The Final PCP is due 60 days prior to First Article, or 60 days prior to production if First Article is not applicable to this contractual instrument.

Additionally, if the Contractor wishes to submit an alternate MIL-STD-1916 compliant inspection plan in conjunction with their PCP, the Government has 30 days to review the plan for acceptance. The submission of the plan may not be accepted, and this should be recognized for planning purposes.

NOTE – CDRL Distribution Requirements

Technical Agency POCs may include the Design and Development Agency as well as customer representatives based on MIPR requirements.

CONTRACT DATA REQUIREMENTS LIST

Form Approved
CMB 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 222202-2302, 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

D. System/Item.	E. Contract/PR NO.	F. Contractor

1. Data Item No.	2. Title of Data Item:	3. Subtitle:
	Management Plan	Process Control Plan (PCP)

4. Authority (Data Acquisition Document No.)	5. Contract Reference	6. Requiring Office
DI-MGMT-80004 (Tailored)	Contract Section E Clause	

7. DD 250 Req	9. Dist Statement Required	10. Frequency	12. Date of First Submission	14. Distribution
	N/A	See BLK 16	See BLK 16	
8. APP Code		**11. As of Date**	**13. Date of Subsequent Submission**	a. Addressee / b. Copies (Draft; Final: Reg, Repro)
A			See BLK 16	

16. REMARKS

Blk 12: The Contractor shall submit initial PCP no later than sixty (60) days after contract award. The Government will respond within thirty (30) days of initial submission. If further revisions are necessary, the Contractor shall have fifteen (15) days to generate them and the Government shall have fifteen (15) days to review and respond to them. The final PCP shall be available sixty (60) days prior to the First Article or start of production if a First Article is not required.

Blk 13: The Contractor shall submit the final PCP sixty (60) days prior to the First Article. If a First Article is not required, the Contractor shall submit the final PCP sixty (60) days prior to the start of production.

If Contractor revises a previously Government accepted PCP, the revised PCP must be submitted to the Government for acceptance before it is released for use. The Government will respond within 10 working days.

Government Technical Agency Email Distribution List:

XXXX@us.army.mil

A PCCI Review Guide is available to assist Contractors on the ARDEC Public Website in the application of the PCCI Clause. The PCCI 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 PCCI Review Guide is expressly not, nor shall it be construed to be, incorporated either directly or by reference into the terms of the PCCI clause itself nor into the terms and conditions of any underlying contract which contains the PCCI clause.

a. Addressee	b. Copies: Draft	Final: Reg	Final: Repro
PCO	1	1	
COR	1	1	
Tech Agency	1	1	
PQM	1	1	
PM	1	1	
DCMA	1	1	
15. TOTAL	6	6	

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE

DD Form 1423-1, JUN 90 Previous editions are obsolete Page ___ of ___Pages

PCCI Review Guide
FOR REFERENCE & GUIDANCE PURPOSES ONLY
ATTACHMENT 3 – PROCESS FAILURE MODES AND EFFECTS ANALYSIS (PFMEA)

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 & Target Date	Action Assigned to (Name)	Date Completed	*pS*	*pO*	*pD*	*pRPN*

Legend: *pS* = Post Severity rating determined after action is complete.
pO = Post Occurrence rating determined after action is complete.
pD = Post Detection rating determined after action is complete.
pRPN = New RPN calculated as the product of *pS* x *pO* x *pD*.

13 October 2011 Revision 1 – See changes below

- Page 2, Table of Contents. Added the terms "Revision Sheet" at end of page.

- Page 35, paragraph g

From: "All product characteristics, features, tolerances, and test requirements classified as Critical or Major in the Technical Data Package."

To: "All product characteristics, features, tolerances, and test requirements classified as Critical **and /** or Major in the Technical Data Package."