TM	**The Aerospace and Defense Learning Institute (ADLI)**	**ADLI-Q001:2011** Issued: 12-DEC-2011

The Aviation, Space and Defense Industry

Quality Body of Knowledge (BoK):

General Narrative of the AS&D Quality Profession

0.1 General

The following is a narrative of the Aerospace & Defense Learning Institute (ADLI) Body of Knowledge (BoK) for those processes that are relevant to the Aviation, Space & Defense (AS&D) industry. This Standard is intended to describe the AS&D quality professional BoK, based in the processes that are generally found to be enacted in the AS&D industry, in compliance with KMS 10001:2011.

This Standard does not provide the detailed analysis of tasks nor does it provide the Bloom's taxonomy analysis for knowledge requirements. For profession specific Quality BoK knowledge requirements, refer to the applicable ADLI Quality BoK Standard (e.g., AS&D Supplier QE, AS&D QE, etc.).

In order to further the global standardization of the Quality profession, the ADLI AS&D Quality BoK applies the formatting style and structure of the American Society for Quality (ASQ) BoK. Though independently developed and sustained, the ADLI AS&D BoK organizes major knowledge categories to the ASQ structure. As related to the ASQ BoK structure, ADLI makes no claims to copyright protection. However, the content of the ADLI BoK is owned by the ADLI and is protected by international copyright laws. Any unauthorized reproduction, distribution, and/or inappropriate use will be aggressively protected.

No commercial training course providers may claim compliance to this Standard or any other ADLI Standard without ADLI review and written approval of training material content.

THE AEROSPACE AND DEFENSE INDUSTRY QUALITY BODY OF KNOWLEDGE (BoK) – GENERAL NARRIATIVE – REQUIREMENTS

1.0 SCOPE

1.1 General

This Knowledge Management Standard provides the general requirements for knowledge within the field of Quality in the Aviation, Space and Defense (AS&D) industry. This Standard may be used as a guideline for the development, validation, and sustainment organizational skills and capabilities. Though it is the intent of this Standard to provide standardization of knowledge requirements for the Quality profession in the AS&D industry, each organization must individually ensure their business processes are adequately identified and aligned skills effectively managed.

1.2 Application

The requirements of this Knowledge Management Standard are specific to the AS&D industry and generic to Quality professions. This Standard is intended to be applicable to all organizations and Quality professions, regardless of type, size and product/service provided within the AS&D industry.

2 NORMATIVE REFERENCES

The following referenced documents are relevant for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2005, Quality management systems - Fundamentals and vocabulary

AS/EN/JISQ 9100C, Quality Management Systems - Requirements for Aviation, Space and Defense Organizations

KMS 10001:2011, Development and Sustainment of Process-Based Ontological Engineering based Bodies of Knowledge

3 DEFINITIONS

Reserved.

4. AS&D QUALITY BODY OF KNOWLEDGE REQUIREMENTS

4.1 General Requirements

The following AS&D Quality BoK is provided as a guideline. For profession specific requirements, refer to the applicable ADLI Knowledge Management Standard.

AS&D Relevant Knowledge Areas (Structured to the ASQ BoK criteria)

I.G.1. Contracts

Ensure Contract Terminations: To ensure when a contract is terminated with a customer that the terms and conditions of termination are complied with and quality is maintained throughout the process.

Ensure Contract Terminations – Value stream: To ensure when a contract is terminated with a supplier/partner that the terms and conditions of termination are complied with and quality is maintained throughout the process.

I.J. Knowledge Management

Monitor Changes in Value stream Personnel: To ensure supplier/partner personnel have the appropriate capability and understanding to meet design and contract requirements. Through surveillance and reporting, monitor supplier/partner personnel changes. Evaluate changes of key personnel to ensure appropriate capabilities are maintained.

Monitor Changes in Organizational Personnel: To ensure organizational personnel have the appropriate capability and understanding to meet design and contract requirements. Through surveillance and reporting, monitor organizational personnel changes. Evaluate changes of key personnel to ensure appropriate capabilities are maintained.

I.M. Material Resource Planning (MRP)

Coordinate Scheduling (MRP): To ensure adequate support is provided (e.g., inspection, testing, etc.), ensure critical points in material flow are recognized and planned. The planning process should be a joint effort to identify timing and work scope. This planning may include the identification of critical skills, special equipment, or logistics considerations.

To ensure action is taken at critical points in material flow, as defined in program planning. Ensure skills, equipment and other considerations are available when needed. Document the outcomes of planned activities. In the event that conditions prevent the execution of activities as planned, ensure remedial planning is accomplished to ensure tasks are effectively performed.

II.B. Documentation of the Quality System

Participate in Process/Procedure Ballot (Sign-off) Review: To provide input to changes in policies and procedures. Ensure changes to policies and procedures are appropriate with regards to product design, quality requirements (FAI, QMS, standards, FAR), organizational culture, available resources, and equipment.

Ensure Records & Documentation are Appropriately Maintained: To ensure the documentation required to document traceability, product configuration, and quality acceptance are appropriately maintained. Ensure the retention times and locations of records comply with contract requirements. For electronic records, ensure data is backed-up at appropriate locations and content is protected from derogation, as well as, content is readable utilizing current technology (e.g., absence of floppy disc drives).

Monitor Value stream Documentation Control Processes: Within the value stream, to ensure documentation control processes are appropriately controlled, to include changes reviewed and approved by authorized persons, changes implemented at the appropriate configuration control level, and implemented into appropriate work documents. Ensure documents are retained in accordance with specific requirements.

Monitor Organizational Documentation Control Processes: Within the organization, to ensure documentation control processes are appropriately controlled, to include changes reviewed and approved by authorized persons, changes implemented at the appropriate configuration control level, and implemented into appropriate work documents. Ensure documents are retained in accordance with specific requirements.

II.D.3. Audit Planning and Implementation

Ensure Supplier Self Audit (QMS): To ensure suppliers/partners perform self-assessments to ensure compliance to their QMS and contract requirements (internal audit). Records of self-assessments must be maintained as quality records. Persons performing the self-assessments must be qualified to perform self-assessments. Records shall contain the scope of the assessment, elements of the assessment which were not performed, and findings and observations discovered during the assessment. Ensure past findings and observations are included in audit scope planning. Ensure records are available for review by external auditors.

Ensure Organizational Self Audit (QMS): To ensure the organization performs self-assessments to ensure compliance to their QMS, contract, and regulatory requirements (internal audit). Records of self-assessments must be maintained as quality records. Persons performing the self-assessments must be qualified to perform self-assessments. Records shall contain the scope of the assessment, elements of the assessment which were not performed, and findings and observations discovered during the assessment. Ensure past findings and observations are included in audit scope planning. Ensure records are available for review by external auditors.

Perform Periodic QMS Evaluations – Value stream: To ensure suppliers/partners comply with approved QMS and other stated requirements. Plan, schedule, and perform periodic QMS evaluations at supplier/partner locations. Utilize risk based methods as appropriate. Ensure the results of the audit are documented, to include scope of audit. Where 2nd or 3rd party sources are utilized as a means of determining supplier/partner compliance to their QMS, ensure 2nd and 3rd parties have the appropriate skills and capabilities to perform the scope of the audits.

Perform Full Quality Management System Evaluation: Perform a complete quality management system evaluation of the selected supplier/partner to ensure compliance to all applicable requirements. Ensure the results of the evaluation are appropriately documented, to include any findings or observations.

II.D.4. Audit Reporting and Follow Up

Document QMS Findings: To document noncompliance found during QMS evaluations, ensure such findings and observations are documented to reflect the required condition and the encountered condition and such are documented on appropriate records.

II.H. Control of Customer/Government Material

Ensure Control of Customer Owned Material: To ensure customer-owned material is controlled in accordance with defined requirements. This control shall include identification, proper handling, preservation, and updating as required. May require physical audits of customer-owned materials, understanding of special storage requirements, and traceability and point of usage documentation.

II.I. Control of Customer/Government Equipment/Property

Ensure Control of Customer/Government Furnished Equipment/Materials: To ensure government-owned property and material is controlled in accordance with defined requirements. May require compliance to applicable customer/government standards and/or customer/government contract clauses. This control shall include identification, proper handling, preservation, and updating as required. May require physical audits of customer/government-owned property/materials, understanding of special storage requirements, and traceability and point of usage documentation.

II.J. Capability/Capacity Measurement

Notification of Changes in Capacity and/or Capability: To ensure the organization is aware of any changes (positive or negative) to the capacity and/or capability of a supplier/partner. (Includes all aspects, e.g., engineering, production, maintenance, verification, and facilities.) Ensure there is a notification process in place to make all appropriate parties aware of changes.

Ensure Process Verification (Process Tryout): To ensure processes perform as designed, process verification process is conducted. Ensure processes are adequately defined and operating in a conforming fashion. As processes are submitted for production, ensure a documented process tryout is performed. (Note: The process of process tryout is a Production and/or Servicing process. Only when the process is being applied to verify production/servicing and yields a quality record is it considered a Quality process.)

III.A. Classification of Quality Characteristics

Baseline the Quality and Regulatory Requirements: Combine previous quality requirements review processes performed during the Design Phase and create a baseline quality requirements document. Ensure baseline quality

requirements document are accurate and complete. Ensure consolidated requirements are organized, documented, stored and integrated (decompose to system and subsystem requirements) into the requirements hierarchy using a requirements management tool.

III.B. Design Inputs and Review

Define Customer/Program Requirements: To understand the stated and identify the unstated requirements of the customer/program and document such as a preliminary requirements document. To understand the stated and identify the unstated regulatory requirements and document such as a preliminary requirements document.

Determine Design Capability: To understand the present and potential state of engineering capability and to ensure engineering capability can meet the stated and unstated requirements of the customer/program. To ensure mechanisms exist for design consideration of production capabilities and mitigation of predicted nonconformance activity. (Assessment of risk associated with variation to standard-work.) Also, ensure supplier/partner has sufficient resources to accomplish design requirements.

Establish a Preliminary Design and Production/Servicing Execution Plan: To understand where and how the stated and unstated work is to be performed. Establish a program/project execution plan identifying sources for work scope performance.

Determine Quality Requirements – General: Review customer, design, and process requirements and determine quality requirements for the product/program. This review process should include lessons learned material from other similar programs as well as industry source material. These requirements shall be documented in the appropriate organizational format and stored in a database that facilitates requirement hierarchy navigation, configuration control of requirements, and the development of requirement metrics.

Determine Quality Requirements – Regulatory: Review regulatory requirements and determine quality requirements for the product/program. These requirements shall be documented, stored and integrated into the requirements hierarchy using a requirements management tool. (Examples of such requirements include FAA, EASA, OSHA, DoD, NASA, FMS, and others.)

Determine Quality Requirements - Special Processes: Review design and production requirements and identify special processes associated with program. Determine special process requirements for the product/program. These requirements shall be documented, stored and integrated into the requirements hierarchy using a requirements management tool.

III.B.1. Workmanship Standards

Determine Material Control Laboratory (MCL) Requirements: Review engineering, process, and production requirements and establish the appropriate material control requirements for laboratory review. This may include destructive and non-destructive evaluation.

Identify Applicable Engineering Source Approval (ESA) Requirements: Review engineering (design), process, and production requirements and determine if there are production processes which require engineering review and approval prior to production release and prior to the implementation of any changes (processes declared unchangeable by engineering without subsequent review and approval).

Provide QA/Engineering Interpretation: Provide interpretation of design and quality requirements to other members of the organization to ensure accurate understanding of requirements. Understand functional differences within the organization. Ensure any formal direction is appropriately documented. Ability to understand technical requirements. Ability to understand organizational challenges and recommendations and engage with engineering, procurement, and other functional disciplines to resolve issues.

Monitor Engineering Source Approval (Process Approval - as required): To ensure processes which are designated as controlled by engineering ("frozen process") are effectively controlled. Evaluate engineering source controlled processes to ensure they are performing as approved. Ensure evaluation results are appropriately documented.

III.B.2. Produceability Review

Perform Manufacturability Review of Design: Review engineering, process, and production requirements and assess such against the known capability of manufacturing/servicing to ensure the design can be produced. Aspects of the review include: ability to produce, cost to produce, and ability to produce with an appropriate level of quality.

III.B.3. Inspectability Review

Perform Inspectability Review of Design: Review engineering, process, and production requirements and assess such against the known capability to inspect/test product at the appropriate point of production to ensure conformity to design. In the event the process is found insufficient apply remediation activities such as request for design changes, process changes, or the development of new methods. Design documentation should contain the

appropriate requirements for quality. (e.g., Measurement, Inspection, Key Characteristic Control, and First Article Quality Plans.) Ensure data collection capabilities support the requisite inspection, measurement and control plans.

III.B.4. Design Validation

Ensure Design Validation (Standard Work): To verify that the design validation process is completed and that there is objective evidence of its completion. The design validation process must ensure the design meets all customer and regulatory requirements. If there are variations in the design that have not been previously produced, risk mitigation plans must be developed (variations to standard work).

III.C.2. Computer Produced Design (CPD) Control

Apply CPD Techniques/Methods (solid model): As Computer Produced Designs (CPD) are created, such must be transferable into production and inspection protocol. Ensure such protocol is validated and controlled through all lifecycle aspects. Verify CPD controls include effective control of electronic data, to include retention and retrieval.

III.D. Design Verification

Determine Product Validation Laboratory Testing Requirements (Engineering Tests): Review development, deployment, logistic, customer and usage requirements to determine the appropriate categories and approaches to Product Validation Laboratory Testing.

III.E. Reliability and Maintainability

Determine Production/Servicing Capability: To assess and understand the present and potential state of production/servicing capability of the organization and ensure its capability to produce/service is known and provided as an input to the design process, and to ensure the production base is capable of fulfilling the final stated requirements of design.

Determine Production/Servicing Capacity: To understand the present and potential state of production/servicing capacity to ensure the production base has the capacity to produce/service to the requirements of the customer/program.

Perform Maintainability Review of Design: Review the design for ease of maintaining the product while it is in the possession of the customer/end-user.

Perform Design FMEA: Review design to quantify and categorize the potential areas of design risk and ensure risk mitigation plans are developed.

Perform Process FMEA: Review processes to quantify and categorize the potential areas of process risk and ensure risk mitigation plans are developed.

III.G. Configuration Management

Plan for Configuration Management Process: Review the Configuration Management Processes to be used on the program to ensure compliance with established Systems Engineering (SE) and Configuration Management (CM) practices. Ensure the establishment of a change process for program and design changes is being planned for, and coordination and communication are integral parts of the process's design. (Awareness of common CM tools).

Ensure the Establishment of Configuration Tracking/Status Accounting System: Ensure a system for tracking changes and released configuration status is developed and implemented prior to work authorization.

Ensure Configuration Controls: Ensures a congruence of part configuration with engineering configuration, and that changes to one are adequately coordinated with the other. Implementation of approved changes are planned produceably (e.g., ability to implement the appropriate configuration in production and in servicing) and effectively either in line or through modification kits which are thoroughly coordinated with the affected internal and / or external organizations.

III.G.1. Configuration Baseline

Ensure Configuration Status and Accounting (FCA): Prior to delivery, ensure configuration reconciliation is performed between Engineering Bill of Materials (EBOM) and Manufacturing Bill of Materials (MBOM), complete with a history of Deviation and Waivers, open and pending changes, and objective evidence of change incorporation as applicable. Ensure the capability to successfully perform a Functional Configuration Audit (FCA), if required.

Ensure Configuration Status and Accounting (PCA): Prior to delivery, ensure configuration reconciliation is performed between Engineering Bill of Materials (EBOM) and Manufacturing Bill of Materials (MBOM), complete with a history of Deviation and Waivers, open and pending changes, and objective evidence of

change incorporation as applicable. Ensure the capability to successfully perform a Physical Configuration Audit (PCA) exists if required.

Ensure Engineering Support is Provided (Organizational): To ensure organizational members have accurate technical/design data to include the assurance of configuration management. To ensure understanding of requirements is accurate by assessing the implementation of technical requirements into documented work processes.

Monitor Engineering Change Request Process: To ensure engineering processes are performed in accordance with system requirements. To ensure engineering changes are implemented effectively and configuration management maintained.

Review Engineering Changes (MCL/SQE/QE) (Quality Review): To ensure quality considerations are included in engineering changes, including produceability, inspectability, and production testing requirements.

Ensure Positive Control of Un-validated Engineering Changes: To provide a means of deploying un-validated engineering changes into production while maintaining positive recall control of any product or services in which un-validated changes have been applied.

Ensure Ship in Advance of Completion/Approval Process is Controlled: To provide a means to control product and its production configuration when shipping product without all processes being complete or approved.

III.G.2. Tech Data Management (Incl. Export Control)

Determine Quality Requirements - Export Controls: Review design and production requirements and determine export control considerations such as ITAR and EAR requirements for the product/program. These requirements shall be documented in the appropriate organizational format.

Create Technical Data for Suppliers: In order to effectively communicate to partners/suppliers, create a master file of documents which contain all of the design information required to produce the product/service. Configuration management of applicable revisions must be assured. This may include quality (incl. customer and regulatory), reliability and other related documents.

Apply Export Control Rules (as required): Review technical data and assess if special handling processes are required to ensure compliance with export requirements.

IV.A.2. First Article Inspections (AS/EN/SJAC 9102)

Review and Approve Development of First Article Inspection Report: To ensure the organization is appropriately planning and is compliant to applicable First Article Inspection (FAI) standards (e.g., AS/EN/SJAC 9102). Ensure FAI plans addresses organization's internal requirements as well as higher-level (customer, prime) requirements. Ensure tooling is included in FAI plan. Ensure supplier and sub-tier supplier activities are included in FAI plan.

Ensure Deliverable Software Conformance - 1st Article: To ensure deliverable/embedded software meets design requirements and that production systems will assure conformity. Where code can be verified, ensure the review process is structured and the resulting code is maintained for future review.

Ensure NDT/Special Process Conformance - 1st Article: To ensure NDT and special processes are included in FAI plan and are verified to meet design/specification requirements. Ensure special processes have objective evidence of conformity and that NDTs are performed per requirements. Ensure personnel are qualified to perform special processes and NDT. Ensure personnel at all levels of the supplier/partner base are qualified to perform special processes and NDT.

Ensure Hardware Conformance - 1st Article: To ensure the geometric and physical characteristics are conformed through the FAI process. Ensure appropriate measurement devices (e.g., calibrated, and accuracy) are utilized when making inspection measurements.

Ensure Deviations are Reviewed and Approved: To formally document deviations discovered in pre-production processes and to ensure appropriate review and approval is concluded. Ensure deviation authority is defined and controlled. Ensure deviations are re-planned for a follow up FAI.

Approve Product Conformance - 1st Article Reports: To ensure the entire deliverable product conforms to design and purchasing document requirements and complies with FAI requirements. Verify all lower-level/component-level FAIs are complete and accurate.

IV.A.3. Process/Manufacturing/Servicing/Quality Planning

Verify Production/Servicing Work Instructions: Review production/servicing work instructions and ensure the process of completing work is accurately defined and work definition and verification is appropriately sequenced. Work instruction review will require review of design and process documents and assurance of correlating revisions (configuration management) and the coordination with relevant inspection planning.

Review Product/Servicing Process Planning: Review documented process planning to ensure processes are adequately defined and controlled. Process planning may include statistical process control plans, process control sheets, and other means of process definition. Ensure process planning is controlled by configuration management processes.

Ensure In-Process Inspection/Operator Certification: To ensure inspections are being performed at appropriate points in production/servicing and the inspections are being performed by qualified persons. Where operators are performing inspection functions, ensure a comprehensive operator certification program is in place. If required, ensure organization has approval to perform operator certification. (E.g., Approval may be required by primes and regulatory authorities.) Where special processes are being performed, persons responsible for inspection/verification shall be appropriately qualified and may require special certification (e.g., welding, NDT, chemical processes.)

Ensure Adequacy of In-Process Inspection/Machine Probing: To ensure in-process inspections and machine probing are appropriately planned, sequenced, implemented and controlled. May require process auditing and documentation review. Ensure inspection personnel are appropriately qualified to perform inspection and are available when inspection is required. Ensure the in-line probing equipment has adequate capability to perform the required inspections. Ensure the use of machine probing is incorporated into organizational procedures and work instructions and utilization is documented in the first article inspection (FAI) reports, as appropriate.

Review Supplier Process Planning: Review documented process planning at suppliers/partners to ensure processes are adequately defined and controlled. Process planning may include statistical process control plans, process control sheets, and other means of process definition. Ensure process planning is controlled by configuration management processes.

Verify Supplier Work Instructions: Review supplier/partner work instructions and ensure the process of completing work is accurately defined. Work instruction review will require review of design and process documents and assurance of correlating revisions (configuration management).

Ensure Process Verification (Process Tryout): To ensure processes perform as designed, a process verification process is conducted. Ensure processes are adequately defined and operating in a conforming fashion. As processes are submitted for production, ensure a documented process tryout is performed, when appropriate. (Note: Unless the output of the verification process yields a quality record and is controlled as a Quality process, the Production/Servicing process tryout is not a Quality domain process.)

IV.A.3.a. Mandatory Inspections

Establish Delegated Inspection Process: To provide for organizational personnel to perform delegated governmental/customer inspection functions. Delegation approval may include FAA, EASA, NASA, company/organization, prime, and other entities. Ensure delegation process is well defined, means for delegation process oversight provided, and training for inspectors is available.

Perform Supplier Designee Management: To ensure persons who have been delegated inspection authority are capable to execute inspection responsibilities and are in compliance with applicable requirements.

Provide Operator/Inspector Training/Supervision Support: To ensure personnel have accurate understanding of requirements. To ensure personnel have access to organizational decision-making processes. Ability to provide instruction to operators and/or inspectors in the methods of product/service verification.

Ensure Self Release Program: To provide a means of delegating inspection authority to suppliers/partners and create appropriate quality and shipping documentation. Ensure self-release programs at suppliers/partners are approved, personnel understand requirements, documentation is maintained, and product is conforming.

Monitor Operator Certification Controls: When required, to provide a means of delegating inspection authority to personnel other than quality inspectors. Ensure the integrity of the certification process and the capability of delegated inspections.

IV.B.1. Material Identification, Status, and Traceability

Ensure Traceability Controls: To ensure materials, components, and products are controlled in such a manner that traceability is assured to all specified requirements (Note: Traceability requirements may originate from various sources.). Ensure drawings, process documents, work instructions, and quality records accurately reflect applicable traceability requirements and that traceability is maintained to the level of product definition which requirements specify. Ensure product identification processes are appropriately defined.

Monitor Parts Release Kitting Verification: To ensure parts assembled into kits are effectively identified, documented, and controlled. Parts making up the kit must be identified and controlled with the appropriate revision status.

Monitor Stamp Control: To ensure stamps and signatures utilized to perform acceptance of work processes are effectively controlled and traceable to the individual accepting work. (Includes all media, including electronic.)

IV.B.4. Material Review Board (MRB)

Document Product Nonconformities: To ensure product and process nonconformities are appropriately documented.

Manage Quality Review (MRB Activities) – Product: To ensure appropriate segregation, review, disposition, corrective work, and approvals are made in the event of a product nonconformance. Ensure personnel are authorized (e.g., MRB) personnel and have approved the corrective work activities. (Note: Personnel authorization requirements may be defined by the customer and/or regulatory authorities and such authorizations must be provided in writing.)

Define Material Review Board (MRB) Requirements: Define requirements for material review processes for creation of nonconforming product/services. Ensure the process is documented in a controlled procedure and identifies the responsibilities of the entities involved in the design, procurement, and production of the product/service.

IV.B.4.a. Escape Containment

Perform Escapes (nonconformance to field) Management and Field Notification/Recall Process: To ensure nonconforming materials that have left the quality system are positively controlled in notification/recall processes and/or field management dispositions.

IV.B.4.b. Industry/Government Notification of Escapes and Suspected Escapes

Manage Reportable Nonconformance, Defect, and Malfunction (e.g., FAA CFR 14 Part 21.3) Reporting Process: To ensure discrepancies defined in regulatory requirements (e.g., CFR 14 Part 21.3) are appropriately reported within specified time requirements.

IV.B.4.e. Positive Control of Scrap

Monitor Control of Scrap: To ensure scrap materials are positively controlled.

IV.C. Acceptance Sampling (Non-SPC)

Ensure Sampling Inspection Processes are Appropriate and Controlled: To ensure the sampling plans established and controlled in compliance with

appropriate sampling standards, and plans are appropriately utilized. Ensure personnel utilizing sampling plans understand sampling methods. Verify customer/government approval of sampling methods is/are provided prior to application.

IV.D. Measurement and Test

Perform Source Inspection: To assure product conformity at source of production/servicing. Plan, schedule, and perform product inspection activities and document results in appropriate quality records. Ensure personnel performing source inspection have the appropriate skills and experience to understand and access product/service conformity.

Perform Product Conformity Audits: To ensure the established production/servicing processes continuously produce conforming product. Plan, schedule, perform, and document product conformity audits. Utilize risk based methods as appropriate.

Monitor Inspection Control Processes: To ensure inspection processes are appropriately planned and performed throughout production/servicing processes by qualified persons. Evaluate effectiveness of inspection/testing processes, ensure authorized personnel perform inspection/test functions, and ensure appropriate documentation.

IV.D.2. Destructive and Nondestructive Tests

Ensure Non-Destructive Test Sequences are Appropriately Applied: Review work instructions, process planning, and quality records to ensure nondestructive testing is being performed at the appropriate points in production/servicing. The NDT process shall be documented in appropriate records and define the standards of reference and the limits of acceptance. Ensure the documentation of NDT results are accurately defined in applicable work instructions and quality records.

Ensure Hardware Conformance - NDT Inspection: To ensure physical product qualities are verified by appropriate nondestructive evaluation techniques. Ensure supplier/partner NDT processes are performed to requirements, equipment is appropriately maintained (to include calibration and shelf-life), and personnel performing NDT hold appropriate qualifications.

Perform Special Process and/or NDT Evaluations: When special processes and/or nondestructive testing are to be performed within the supplier/partner base, such shall be evaluated to the applicable specifications and standards to

ensure capability and compliance. These evaluations will include review of people, process and equipment.

IV.D.3. Measuring Techniques

Ensure First Piece Setup: To ensure the first article produced for each production run in recurring production processes is appropriately set-up so that it will yield conforming characteristics and meets all stated requirements.

Ensure Hidden Dimension Verification is Performed (as required): To ensure all required verification characteristics are positively conformed to design and engineering data sets. Ensure required inspections and tests on product characteristics are performed that cannot be verified at a later point. Ensure quality records accurately reflect inspection of hidden characteristics.

Ensure Test and Inspection using Measurement Software, Equipment etc. is Performed (as required): Ensure inspections (NDT and visual) and verification (e.g., testing, software model runs) of product characteristics at appropriate points and with appropriate techniques. Ensure process, people, and equipment are appropriately qualified and controlled. Results of inspection and test activities must be defined and documented.

Ensure Hardware Conformance - Dimensional Inspection - CMM/Layout/Bench: Ensure dimensional inspections are performed utilizing appropriate equipment and gages, utilizing appropriate inspection techniques, utilizing qualified personnel, and are appropriately documented.

Ensure Hardware Conformance - Visual Inspection: To ensure physical product qualities are verified by appropriate visual means. Ensure visual inspection processes are appropriately defined and personnel performing the visual inspection process are qualified to the scope of their responsibilities.

Ensure Internal Receiving Inspection Controls are Adequate: To ensure receiving inspection processes which receive supplier/partner products and services, including customer/government furnished equipment/materials, are capable of performing required verification processes. Inspection requirements must meet the requirements of the customer, design, and production complexity. Receiving inspection processes may include physical inspection, documentation review, and other means of verifying conformity of design and contract requirements.

IV.E. Metrology

Determine Tool & Gage Design Requirements: Review regulatory, engineering, process, and production/servicing requirements (capability, maintainability, reliability, certification, and human factors) and determine requirements for design, production, and maintenance of tools and gages. This may include calibration and traceability (reference to primary standards) requirements.

Monitor Calibration Control: To ensure the calibration system is in compliance with the approved system. Evaluate equipment maintenance, handling methods, calibration standards, use, and storage.

IV.F. Measurement System Analysis (MSA)

Monitor Gage R&R Control: To ensure reliability of equipment used for product acceptance. To ensure equipment used to accept products are appropriate to the level of accuracy required. When performed, ensure gage R&R studies are documented.

Monitor Correlation of Metallurgical Testing: To ensure the standards and equipment utilized for metallurgical testing are accurate. Ensure documentation of correlation studies is available throughout the supplier/partner base. Special verification and monitoring emphasis on should be applied to spectrometers and associated control standards.

IV.G.1. Shop Assist

Ensure Shop Assist Process: To provide for a temporary supplier relationship to perform work which is not intended to be permanently outsourced. Ensure the scope and use of shop assist is limited to the temporary use of production capacity and is not actually an outsourcing of longer-term production and/or services. Ensure supplier/partner has systems in place to perform work in accordance with organizational procedures and process, including the application of computerized numerical control machines and associated programing. Ensure documentation is controlled.

IV.I. Control of Tooling

Ensure Process Tooling Changes: To ensure tooling utilized in the production/servicing processes are conforming to design requirements, including any changes to such tooling (Note: Including electronic media for tooling and inspection.). Ensure references to tooling requirements are

accurately reflected in work instructions, process sheets, and other technical documents.

IV.K.1. Risk Based Acquisition Management

Request Quotes from Suppliers: Ensure a document is created which requests from suppliers/partners formal documents which define their terms, conditions and pricing to perform work which is stated within the technical data package and defined in a statement of work.

Evaluate Quotes from Suppliers: Evaluate the formal offer packages that potential suppliers/partners have provided in response for quotations. Ensure the responses accurately address all of the technical requirements stated in the scope of work. Evaluate all requested deviations/objections noted in the response from suppliers/partners, and assess the impact on quality and schedule.

Make a Supplier Selection: Based on the criteria established by the organization, and the ability of the potential supplier/partner to deliver to the defined scope of work, select a supplier/partner.

IV.K.3. Flow Down of Requirements (Including Purchase Orders)

Create Purchasing Documents: Create formal documents to procure products or services from suppliers/partners. The documents shall contain all applicable information or references to all applicable information related to the procured scope of work.

Provide QA/Engineering Interpretation: Provide interpretation of design and quality requirements to suppliers and to other members of the organization to ensure accurate understanding of requirements. Understand cultural differences within the supplier/partner base. Ensure any formal direction is appropriately documented. Ability to understand technical requirements. Ability to understand supplier challenges and recommendations and engage with engineering, procurement, and other functional disciplines to resolve issues.

Ensure Engineering Support is Provided (Value stream): To ensure suppliers/partners have accurate technical/design data to include the assurance of configuration management. To ensure understanding of requirements is accurate by assessing the implementation of technical requirements into documented work processes.

Identify Flow down of Unique Customer Requirements: To review all applicable customer requirements documents, assess and determine that any and all

applicable customer and/or regulatory requirements are conveyed in the technical data and/or purchasing documents.

Assemble Master Technical Data and Bid Package: To create a master package of technical data, terms and conditions, and other pertinent documents that accurately communicate to the supplier the expectations of the customer.

Apply Unique Requirements to Purchasing Documents: To effectively communicate to the supplier/partner any special or unique requirements. This communication is to be made on applicable purchasing documents and may be included in engineering data.

IV.K.4. Deliverable Data

Issue Purchasing Document: Issue the purchasing documents to the supplier/partner. Ensure the documents are formally controlled within an established system. Purchasing documents shall ensure the correct design configuration is documented.

Verify Master Technical Data and Bid Package: To ensure the contents of the master technical data and bid package are complete and correct.

IV.K.5. Pre-Award/Post-Award Evaluations

Determine Supplier Capability (Assess who has capability): To understand where technical capability resides in the supplier/partner base. For existing suppliers/partners, past performance may demonstrate capability. For new suppliers/partners there should be some objective evidence established to demonstrate technical capability as it relates to the design and production requirements.

Determine Supplier Capacity (Assess who has capacity to take on additional/changed work): To understand where production/servicing capacity resides in the supplier/partner base. This requires recent assessment of supplier/partner workload and an accurate understanding of their total production capacity.

Perform Pre-Award Surveys: For new suppliers/partners, or existing who are potentially assuming work for which they have no previous performance evidence, perform an evaluation at the points where value is added, which may include sub-tier suppliers. This evaluation is to determine if the supplier/partner is potentially qualified to participate in the present procurement. Scope of the evaluation may not be as extensive as full system or process approvals.

Perform Financial Capability Assessment on Supplier/Partner: To the extent a supplier/partner will require extensive resources to perform the stated scope of work, assess the financial capability of the supplier and their sustained ability to conduct business.

Verify Suppliers' Technical Capabilities: To physically evaluate and ensure the supplier/partner can perform to the requirements of the technical data and purchasing documents. This verification shall also ensure the supplier has the ability to interpret the design media provided.

IV.K.6. Supplier Approvals (ASL)

Ensure Organizational Approvals Match Approved Commodity Types: Review the approvals granted to the organization and ensure the approvals match the products or services the organization is capable of providing. The approvals shall note the scope of system approval, product approvals, and special process approvals. (i.e., Unique approvals may include commodities such as forgings, castings, ESD controls, NDT, special processes, etc., as well as, governmental certifications such a production and/or repair approvals.)

Add Supplier to Approved Supplier List: Once a supplier/partner is formally approved, ensure they are listed on the organization's list of approved suppliers. The approved suppliers list should be made available to all points where its use is expected. This may require updating of electronic databases or the reissuance of paper documents. Approved suppliers shall be identified with their specific product and system capabilities (e.g., heat treat, castings, and electronics).

IV.K.7. Sub-tier Supplier Control

Ensure Supplier has an Adequate Supplier Control System: Evaluate the supplier/partner's supplier management processes and ensure the supplier/partners have effective control over the work processes sourced at sub-tier suppliers. This evaluation shall ensure that there is effective control at all levels of the supplier-base. Suppliers/Partners must have capability and capacity to ensure all work subcontracted to sub-tier suppliers. Verification may require the performance of physical audits at sub-tier suppliers.
Supplier/Partner should have formal monitoring systems in place to assess supplier performance. Supplier control processes shall also possesses controls for managing noncompliance and nonconformities, to include disposition and corrective action. (The general expectation is for the organization to substantiate through evaluation compliance to requirements throughout the entire value-stream and the technology capability to transfer product/servicing verification data.)

Ensure Supplier's Utilize Source Approval List for Sub-tier Selection (as required): To ensure suppliers/partners only utilize approved sources when required by design or other formal document. Use of approved suppliers does not absolve suppliers/partners from the responsibility of sub-tier supplier management.

Monitor Supplier Sub-tier Control: To ensure suppliers/partners are effectively controlling their supply base by ensuring requirements are flowed through purchasing documents and complied with.

IV.K.9. Direct/Drop Shipments

Ensure Drop-Ship Approvals (Shipments directly from Supplier to Supplier): To provide for a means to control shipments of product from one supplier to another, which is not directly controlled by the receiving supplier. Ensure appropriate documented approvals are maintained to permit drop-shipments between suppliers. Ensure positive quality control drop-shipments are maintained throughout supplier/partner base.

Ensure Direct-Ship Approvals (Shipments directly from Supplier to Customer): When the organization is not the end-item producer, to provide for a means to control direct shipments of product from the organization's supplier to the end-item customer. Ensure appropriate documented approvals are maintained to permit direct-shipments to the end-item customer or other defined destinations (e.g., customer and regulatory approvals). Ensure positive quality control is maintained over direct-shipments.

IV.K.10. Supplier Support Resources

Determine Support Resource Needs (IPT, SQA, Labs, etc.): To understand the actual and total resource needs to support outsourcing to suppliers/partners. Based on supplier, design, and production maturity, resource needs may vary. Need to understand differences in regional and international influences on required support resources.

Determine Oversight Resources Needs and Plan Surveillance: To understand the on-going surveillance support resource requirements to sustain the outsourcing to suppliers/partners.

IV.K.11. Monitoring of Suppliers *(RCCAPA in Section V.D.)*

Monitor Supplier Resource Capacity: To ensure the effectiveness of the supplier's/partner's production/servicing capacity. Through review of supplier/partner notification of changes in capacity and/or capability, assess the potential impact of those changes on product and system quality. During on-going assessments and communication with supplier/partners, establish awareness of potential capability/capacity changes.

Notification of Changes in Capacity and/or Capability: To ensure the organization is aware of any changes (positive or negative) to the capacity and/or capability of manufacturing and/or servicing of a supplier/partner, including location of suppliers and significant changes in management/ownership. Ensure there is a notification process in place to make all appropriate parties aware of changes, including required notifications to customers/regulatory authorities.

Monitor Financial Condition of Key Suppliers: To ensure the ability of a supplier/partner to sustain production/servicing. Maintain awareness of the financial condition of suppliers/partners by review public information and discussions within industry. Establish awareness through observation in the supplier base of conditions such as material changes, changes in suppliers, equipment condition, employee turn-overs, etc.

Monitor Risk of Ultra-Small Key Suppliers: In the event that the organization engages an ultra-small supplier for services or products which are considered key, ensure risk management plans are in place. (Ultra-small suppliers are organizations that will be adversely affected by the absence of 1 to 2 persons.)

IV.K.13. Supplier Quality Plans

Develop Alternate Supplier Approval Process (as required): To provide a means of outsourcing work to a potential supplier which has not been approved under the required processes. Create a quality plan which defines the specific controls to be in place to effectively manage work to a supplier which is not approved under normal processes. If the quality plan is subject to customer approval prior to implementation, ensure such approval is obtained.

IV.M. Special Process Control

Ensure Chemical/ Metallurgical Processes are Conforming: Ensure chemical and metallurgical processes are conforming to design and process

requirements. May require destructive and/or nondestructive evaluation methods. Personnel must be appropriately qualified to perform special processes.

Perform Periodic Special Processes (Weld, Peen, Plating, etc.) Evaluations: To assure control, capability, compliance and conformity of special processes performed in production/servicing processes. Plan, schedule, perform, and document periodic evaluations of special processes. Utilize risk based methods as appropriate.

IV.M.1. Second and Third Party Surveillance

Monitor Second and Third Party Surveillance Process: To monitor suppliers/partners who have systems and/or special processes approved by a second or third party (e.g., Nadcap) are maintaining their approval as current. For suppliers who allow their certification to expire, engage an alternative means of surveillance and to assure product/service quality.

IV.N.1. Deliverable Software

Ensure Software Conformance – Deliverable: To ensure deliverable software (software which is embedded in a product and is delivered to a customer) conforms to design requirements. Ensure verification processes are performed (e.g., code comparison, run tests, peer review) to verify deliverable software is conforming. Ensure quality records reflect software configuration, conformity, and acceptance. As required, ensure testing tools are provided with the deliverable code or software program.

Monitor Software Quality Plan: To ensure software quality plans are being applied as required.

IV.O. Packaging, Handling & Shipping

Ensure Packaging Controls are in Place: Ensure the organization has processes to protect products and services in packaging to prevent damage during transport. Depending on contractual requirements, may require familiarity with various packaging standards. Ability to understand and interpret packaging specifications and drawing requirements. Ensure shipping documents, to include labeling are legible, applied appropriately, and contain all applicable data required.

Ensure Packaging & Preservation: To prevent deterioration of product during shipping and storage. Evaluate compliance to packaging, handling and preservation requirements.

IV.O.2. Foreign Object Debris

Monitor Handling Practices / Foreign Object Damage Controls: To ensure products are not damaged during handling and processing. Evaluate material handling process to ensure product is effectively protected during processing. Evaluate work practices and ensure there are positive practices to prevent FOD.

IV.P. Product Pedigree Assurance

Ensure Buy Back Processes are Controlled: To provide a means to control product to re-enter a production system which has previously been certified as airworthy. Assurances such as state of airworthiness, regulatory authority approvals, customer approvals, and other product and system requirements must be addressed.

IV.R. Certification of Flight Readiness/Airworthiness Certification

Complete Governmental Forms Related to Production/Servicing and/or Design Conformity: To create the appropriate documentation for product design and production approval by governmental agencies. Ensure authorized persons complete the official forms and that supporting documentation is provided.

IV.R.1. Civil Aviation

Issue Governmental Forms for Documentation of Major Repairs and Alteration (e.g., FAA Form 337): Where appropriate, produce governmental documentation to record and approve major repairs and alternations (e.g., FAA Form 337), and that only authorized persons have signed the forms.

Issue FAA Form 8130-series/EASA Form 1 (Authorized Release Certificate/Airworthiness Certificate): When applicable, produce a civil airworthiness certificate and ensure an authorized person has signed the form.

IV.R.2. Military Products

Issue Governmental Product Acceptance Documentation (e.g., DD Form 250 (USA)): When applicable, produce the U.S. Government documentation to accept products/services and transfer ownership (DD 250). An awareness and understanding of governmental policies, procedures, and regulations related to product and system certification (e.g., U.S. Air Force certification requirements are provided in AFPD 62-6 and AFI 62-601.)

V.A. Quality Control Tools

Apply Continuous Improvement Support: To ensure process waste is removed and quality is improved, utilize data and various quality tools to understand process performance and improvement opportunity. Ensure improvement action does not compromise approved production controls.

V.B. Quality Management and Planning Tools

Establish Appropriate Performance Metrics & Data Analysis: To provide visibility of product, process, and organizational performance establish appropriate performance measurements to assess process performance and quality.

V.D. Corrective Action

Monitor/Approve Root Cause Analysis - Product/Process: Ensure appropriate root cause analysis tools are utilized during analysis of documented findings. Ensure authorized (e.g., MRB) personnel have approved the identification of root cause. Ensure product/services previously produced/provided are reviewed for applicability.

Monitor/Approve Corrective & Preventive Action Processes - Product/Process: To ensure effective corrective and preventative action processes are in place and applied to the root cause of noncompliance/nonconformance in a timely fashion. Verify effectiveness after implementation and prior to closure of the corrective action records.

Take Action Based on Data Analysis: Based on analysis of data, take improvement action to achieve objectives.

Monitor QMS Findings: To ensure noncompliance is documented when found during QMS assessments and are managed for root cause and corrective action.

Monitor Root Cause Analysis - QMS (Root Cause Process): To ensure appropriate root cause analysis tools and such are applied during analysis of documented findings.

Approve Root Cause Analysis - QMS (Individual Root Cause Analysis): To ensure the true root cause of QMS noncompliance is identified and appropriate review and approval provided.

Monitor Corrective & Preventive Action Processes – QMS: To ensure effective corrective and preventative action processes are in place and such are applied to the root cause of noncompliance. Ensure process identifies and contains any potential impact on product.

Approve Corrective & Preventive Action – QMS: To ensure the documented corrective and preventative action determinations effectively address the root cause in a timely fashion.

Follow Up of Corrective & Preventative Action: To verify the effectiveness of corrective and preventative actions by assessing implemented solutions after actions had been taken. Establish appropriate interval for effectiveness assessment; audit the implemented solutions to ensure they reflect the agreed-to arrangements; and that the solution prevents recurrence of the root cause.

Monitor Supplier-QMS Corrective and Preventative Action Process: As noncompliance is identified at suppliers/partners, ensure procedures are in place and the process of effective closed-loop corrective and preventative action is deployed. May include managing the implementation timing of corrective action and the management of deviations.

V.G. Lessons Learned

Capture, Document, and Preserve Lessons Learned: To recognize, understand, and document lessons learned during the application of the previous processes in the relevant phase so that such may be used in future programs/projects.

Apply Lessons Learned: Based on the lessons learned in previous programs/projects, apply lessons learned to ensure previous issues are not repeated.

VI.A. Collecting and Summarizing Data

Collect Performance Metrics & Perform Data Analysis: Collect data related to process performance and quality and perform analysis of data. Present data in visual formats for use in the organization.

VI.F. Statistical Process Control (SPC)

Monitor Process Certification /Statistical Process Control: To ensure statistical techniques and inspection sampling plans are appropriately and effectively applied.