Quality Assurance Program Plan Guidebook

July 2026

Office of the Under Secretary of War for Research and Engineering

Office of the Assistant Secretary of War for Mission Capabilities

Washington, D.C.

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1 Introduction

This guidebook provides recommendations and best practices for Department of War (DoW) program managers (PMs), manufacturing and quality (M&Q) engineers and practitioners, systems engineers, and other technical managers responsible for placing a Quality Assurance (QA) Program Plan (QAPP) on contract for a DoW acquisition program. It supports the DoW Acquisition Transformation Strategy (ATS), which states:

> *The Department will restore innovation, accelerate production, gain negotiating leverage, and more effectively manage cost and schedule growth by promoting competition with lowered barriers to entry and diversification of prime and subcontractor sourcing without sacrificing quality.*

By providing a framework for robust QAPPs, this guide helps ensure that as the Department accelerates acquisition, it does so without compromising the technical excellence and performance superiority characteristic of U.S. military systems. The principles outlined herein empower the acquisition workforce to implement data-driven, risk-based quality management that is essential for developing, producing, and sustaining high-performance systems that meet the warfighter's needs at the speed of relevance.

A QAPP is a document a contractor prepares to describe how the contractor will meet the Government's QA performance requirements for a specific system or aspect of a program. The Data Item Description (DID) DI-QCIC-81794, Quality Assurance Program Plan, outlines the requirements for a QAPP.

Government personnel are responsible for identifying contract quality requirements, supporting the systems engineering (SE) process, monitoring contractor performance against contract requirements, and supporting quality responsibilities as identified in Federal Acquisition Regulation (FAR) 42.302, Contract Administration Functions. DoW contractors are responsible for developing, implementing, managing, evaluating, and continuous improvement of their QAPPs. All FAR references have been reviewed as part of the 2026 FAR overhaul and are current per the date of publication.

This guidance outlines the roles, responsibilities, and activities Government QA managers may be required to perform while developing and overseeing Government contracts. For example, the Defense Federal Acquisition Regulation Supplement (DFARS) Subpart 246.1 requires acquisition programs to develop a QA program:

> *Departments and agencies shall also–*
>
> *(1) Develop and manage a systematic, cost-effective Government contract quality assurance program to ensure that contract*

> *performance conforms to specified requirements. Apply Government quality assurance to all contracts for services and products designed, developed, purchased, produced, stored, distributed, operated, maintained, or disposed of by contractors.*
>
> *(2) Conduct quality audits to ensure the quality of products and services meet contractual requirements.*
>
> *(3) Base the type and extent of Government contract quality assurance actions on the particular acquisition.*
>
> *(4) Provide contractors the maximum flexibility in establishing efficient and effective quality programs to meet contractual requirements. Contractor quality programs may be modeled on military, commercial, national, or international quality standards.*

When contractually required, this guide addresses requirements for a higher-level Quality Management System (QMS), an overall system or approach an organization develops to manage a range of QA activities, of which QAPPs are a part. The International Organization for Standardization (ISO) 9001, Quality Management Systems–Requirements; and the Society of Automotive Engineers (SAE) AS9100, Quality Management Systems–Requirements for Aviation, Space both require organizations to develop and implement a QMS. SAE AS9100 includes all of the ISO 9001 QMS requirements and specifies additional aviation, space, and defense industry requirements. Additional references are cited throughout this guidebook and in the reference list at the end.

Certain activities outlined in this guidance may apply to contractors only, to Government personnel only, or to both contractors and Government personnel. The guidance is not mandatory but makes recommendations on the basis of recognized standards and the contribution of experts in the field. The QAPP format is up to the developer, but the plan must meet the contract requirements.

This guidebook is intended to promote timely design, development, production, modification, fielding, and sustainment of cost-effective and capable weapon systems and other complex or critical products by addressing QA risks and issues throughout the acquisition life cycle. DoW and Service-level sources may provide additional guidance for individual DoW acquisition programs.

The Office of the Under Secretary of War (OUSW) for Research and Engineering (R&E) prepared this guide and will revise the document periodically to address comments and changes in the field.

2 Contracting for Quality

The contract is the vehicle used to establish a formal relationship between the Government and a prime contractor. Requirements for DoW acquisition and contracting activities are determined by the FAR and DFARS as well as by DoW, Service, and agency regulations, policies, and guidance documents.

FAR Part 46, Quality Assurance, spells out Government policies for quality and provides the following:

- Subpart 1: General section with definitions, policies, Contracting Office (CO) responsibilities, Contract Administration Office (CAO) responsibilities, Contract and Administration Services (CAS), and contractor responsibilities.
- Subpart 2: Contract Quality Requirements identifies the types of contract quality requirements that are available to the Government to put on contract. The most widely used for large or complex acquisitions are the Higher-Level quality requirements.
- Subpart 3: Identifies various contract quality clauses.
- Subpart 4: Identifies Government contract quality activities and where they may occur.
- Subpart 5: Discusses Government's acceptance of products.
- Subpart 6: Outlines material inspection and receiving reports.
- Subpart 7: Discusses warranties.
- Subpart 8: Discusses contractor liabilities for loss or damaged Government property.

FAR Part 46 and FAR Part 52 operate in a strict prescriptive relationship. FAR Part 46 contains the instructions telling the contracting officer when a specific quality rule applies. Once Part 46 determines a rule is necessary for a specific procurement, it directs the contracting officer to insert the corresponding clause from FAR Part 52.

Table 2-1. Comparison of FAR Part 52 and FAR Part 46

Feature	FAR Part 46 (Quality Assurance)	FAR Part 52 (Provisions & Clauses)
Primary Function	Acts as the policy and procedural framework for quality.	Acts as the legal text repository for contracts.
Content Type	Instructions, guidelines, and rules for contracting officers.	Verbatim legal paragraphs (terms and conditions).
Application	Guides acquisition planning and contract administration.	Inserted directly into solicitations and final contract awards.
Scope	Strictly limited to quality assurance, inspection, and acceptance.	Covers every topic in the FAR (ethics, labor, payments, etc.).

DI-QCIC-81794 outlines the role of a QAPP:

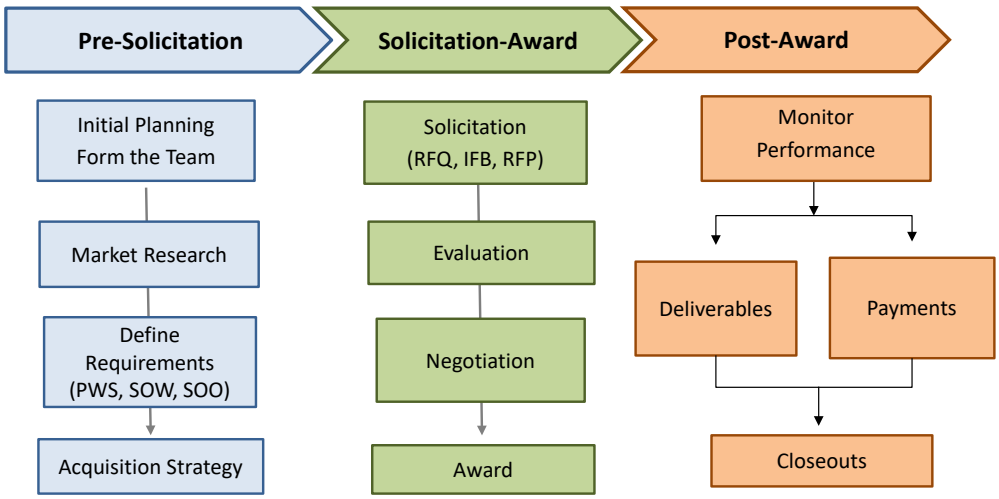
> *"The Quality Assurance Program Plan (QAPP) will be used as a stand-alone document, but it is intended to be a part of an integrated strategy, including: Manufacturing Management; Software Quality; Reliability; Parts, Materials, and Processes; and other related disciplines. The purpose of the QAPP is to describe how the Quality Management System complies with the program's contractual requirements and how the contractor ensures products are designed and produced to meet the program's contractual requirements. The QAPP describes how contractor quality policies and procedures are implemented at the program level."*

DoW contracts may cite a higher-level QMS requirement (as described is 2.1) such as ISO 9001 or SAE AS9100 as a program contract requirement. DoW contractors and other organizations are then responsible for the development, documentation, implementation, management, evaluation, and continuous improvement activities needed to meet the QMS and other requirements. Government personnel are responsible for monitoring contractor performance against the identified requirements to include risk assessment and management.

DoW does not dictate how to implement a QMS, but contractors should provide evidence that they are meeting the intent of the contract. Government personnel should use contractor data as evidence when available and should accept contractor format for most documentation.

Government business processes include the business strategy or acquisition strategy, contracting approach, contracting strategies, contract language, and financial strategies.

The contracting process belongs to the contracting community; however, quality personnel may be asked to support various contracting activities such as inputs to the Statement of Objectives (SOO) or Statement of Work (SOW), Section L and M criteria, technical evaluations, etc. The DoW contracting process is divided into three major contracting processes and is identified in the graphic below.



Source: WarU.

Figure 2-1. DoW Contracting Process

Organizations may be required to provide evidence that QA managers are participating in the following activities:

- Form the Team
- Develop/Review the Contract Strategy
- Conduct Market Research
- Conduct Requirements Analysis:
  - Draft/Update Requirements Roadmap
  - Performance Work Statement
  - Statement of Work (SOW) or Statement of Objectives (SOO)
  - Develop a Government Cost Estimate
- Develop/Review the Source Selection Plan
- Develop/Review the Request for Proposal and then Issue
- M&Q Inputs to the Contract (Section C, E, L and M) (refer to MIL-HDBK-245E)

- Manage the Contract from Contract Evaluation, Negotiation, Award, and entire Lifecycle

2.1 Higher-Level Quality Contract Requirements

Higher-level contract quality requirements should be used for complex or critical items, and these requirements should flow down to subcontractors and vendors as applicable. FAR 46.202-4 identifies when higher-level quality requirements may be required to be put on contract, stating the following:

> *"(a) Agencies shall establish procedures for determining when higher-level contract quality requirements are necessary, for determining the risk (both the likelihood and the impact) of nonconformance, and for advising the contracting officer about which higher-level standards should be applied and included in the solicitation and contract. Requiring compliance with higher-level quality standards is necessary in solicitations and contracts for complex or critical items (see 46.203)or when the technical requirements of the contract require-*
>
> *(1) Control of such things as design, work operations, in-process controls, testing, and inspection; or*
>
> *(2) Attention to such factors as organization, planning, work instructions, documentation control, and advanced metrology.*
>
> *(b) Examples of higher-level quality standards include overarching quality management system standards such as ISO 9001, ASQ/ANSI E4, ASME NQA-1, SAE AS9100, SAE AS9003, and ISO/TS 16949, and product or process specific quality standards such as SAE AS5553."*

2.2 Quality Data Item Descriptions

Data Item Descriptions (DIDs) are standardized documents that the Government uses to define the data that is required by the contractor. The DID specifically defines the data content, format, and intended use. Government QA managers need to review these DIDs and identify which ones should be used. These DIDs can be accessed at the DoD ASSIST Quick Search link.

The following is a list of active quality related DIDs that may be useful to have on contract:

- Quality Assurance Program Plan, DI-QCIC-81794
- Quality Status Report, DI-MGMT-82186
- Quality Assurance Provisions, DI-SESS-80789A

- Quality Management System, DI-MGMT-82184
- Manufacturing Non-Conformance Report, DI-MGMT-81937
- First Article Test/Inspection Procedures and Plan, DI-NDTI-82327

The Data Item Description: Quality Assurance Program Plan (QAPP) (DI-QCIC-81794B, July 2025) describes requirements for a QAPP. The QAPP is developed by the contractor or organization implementing the quality requirements as identified in the contract.

Organizations are given flexibility in choosing how to meet the standards for the QMS and for specific QAPPs, but the QMS should meet the contract requirements.

2.3 Request for Proposal

A request for proposal (RFP) is a formal negotiated solicitation resulting in a contract that includes the contract form, contract clauses, work statements, specifications, the delivery schedule, and payment terms.

The RFP is an opportunity to communicate to the contractor the Government's quality and other requirements for a specific proposal. The RFP should identify the information required in the contractor's proposal and the criteria that will be used to evaluate the proposal and the relative importance of those criteria. M&Q managers typically support the development of the Request for Proposal by identifying M&Q considerations and criteria for inclusion in the REP and subsequent contract. These considerations need to ensure that there is linkage between the M&Q consideration, warfighter requirements, and evaluation factors and sub-factors. Evaluation factors often include cost or price, and quality of product or service which includes technical, past performance and others.

The RFP should specify the requirements for best practices for the contractor's QMS (per Section I (contract clauses) and per FAR 52.246-11, Higher-Level Contract Quality Requirement) to be used (e.g., ISO 9000, SAE AS9100, etc.).

Contractor personnel should document quality policies, standards, practices, and resources needed to meet the requirements of a customer. DoW contractors need to have a complete understanding of the requirements documented in the Government's RFP. The contractor then should develop a quality plan focused on delivering product on time, in the right condition, at the right place, and at the right price and costs.

DoW contracts, Section L outlines instructions to offerors, including specific quality requirements that should be addressed in their proposals. These requirements are crucial for ensuring the contractor's ability to meet the Government's quality standards for the product or

service being acquired. Offerors should carefully review Section L to understand what quality-related information they need to include in their proposals. Section L quality requirements could include:

- Quality Plan
- Inspection and Testing Requirements
- Compliance with higher-level quality standards
- Documentation Requirements or DIDs

2.4 Contract Administration Services

Government quality personnel may be required to support or accomplish the following Contract Administration Services (CAS) functions:

- Pre-award surveys
- Evaluate contractor proposals for quality considerations
- Quality surveillance and compliance with quality requirements
- Status reporting
- Review preservation, packaging, and packing
- Evaluate for adequacy and perform surveillance of contractor engineering efforts and management systems that relate to design, development, production, engineering changes, subcontractors, testing, management of engineering resources, reliability and maintainability, data control systems, configuration management, and independent research and development (R&D)
- Monitor the contractor's environmental practices for adverse impact on contract performance or contract cost, and for compliance with environmental requirements specified in the contract
- Maintain surveillance of flight operations. Government flight operations are often a QA function
- Support the program, product, and project offices regarding program reviews, program status, program performance and actual or anticipated program problems
- Post-award conferences
- Review progress or performance payments
- Price and technical negotiations

- Review engineering change proposals for proper classification, and when required, for need, technical adequacy of design, producibility, and impact on quality, reliability, schedule, and cost; submit comments to the contracting office
- Assist in evaluating and make recommendations for acceptance or rejection of waivers and deviations
- Evaluate and monitor the contractor's procedures for complying with procedures regarding restrictive markings on data
- Monitor the contractor's value engineering program
- Review and maintain surveillance of the contractor's purchasing system
- Administrative contract closeout

3 Quality Management System

This section discusses attributes of a higher-level QMS at an organizational, facility, or program level. Sometimes QMS requirements fall under the umbrella of a functional area such as engineering, manufacturing, sustainment, supply chain management, or contracting. Organizations should ensure QA personnel are involved in activities as necessary.

3.1 Purpose of the QMS

The QMS is an organization's overall set of quality management practices intended to promote delivery of uniform, defect-free products that are cost-effective and meet the weapon system requirements of the warfighter. The QMS may then be tailored to create QA plans that are put on contract for specific systems or parts of a program. The QMS should specify organizational roles and responsibilities for each requirement in the standard.

Organizations should define the scope and extent of the QMS and monitor the impact of the QMS on business practices, product and process quality, and customer satisfaction. Organizations contracted with the Government are free to decide how to implement their QMS provided they meet the contract requirements.

Organizations may be required to provide evidence demonstrating a higher-level QMS and have documented the following:

- Procedures for identifying the needs and expectations of customers and stakeholders
- Procedures for ensuring customer satisfaction to include the use of feedback to address complaints
- Organizational policies, procedures, processes, records, and controls used to achieve quality policies and objectives and to maintain consistent product and process quality
- Identified statutory and regulatory requirements
- Identified safety, security, and risk management activities
- Procedures for monitoring, measuring, and controlling products to include audit activities
- Processes for promoting and achieving continuous improvement

Government organizations should establish contractual quality requirements consistent with FAR 52.246-11, Higher-Level Contract Quality Requirement and FAR 46.2, Contract Quality Requirements. The contracting officer should include in the solicitation and contract the appropriate quality requirements. Government program office personnel should then monitor contractor compliance to those requirements. See section 2, Contracting for Quality, for further information.

Organizations that perform on complex and critical Government contracts should develop and document the manner in which their QMS meets higher-level quality requirements such as those called out in SAE AS9100 or other Government or industry documents. Organizations should provide evidence that their QMS is meeting the intent for a higher-level QMS requirements and other contract requirements and have identified, implemented, and are managing the requirements. Government personnel should use the organizations' own data to assess and manage the following requirements:

- Have a policy that describes the organizations' approach to quality and strategic objectives
- Have determined the scope of the QMS
- Have identified internal and external risks to their QMS and its ability to support the organizations' purpose and strategic direction
- Has the organization identified internal and external stakeholders along with the needs and expectations of the stakeholders
- Show leadership and commitment to supporting the QMS
- Have identified roles and responsibilities for every element of their QMS
- Have identified all of the resources necessary to implement the QMS
- Have a quality manual that addresses all elements of the higher level contract quality requirements (ISO 9001 or SAE AS9100)
- Have a process approach (Suppliers, Process, Inputs, Outputs, and Customers (SIPOC) is one approach)
- Have procedures, instructions, and records
- QMS processes should be identified, documented, managed and controlled
    - Document approval process
    - Review and update process
    - Current revisions only are available
    - Ensure obsolete documents are not available
- Have determined process sequencing
- Have identified process interactions
- Show that they are using evidence-based decision making
- Have established quality performance metrics
- Have established and are using and maintaining internal processes
- Are capturing and managing records and data management

- Are conducting quality analysis to include internal and external audits
- Have implemented subcontractor quality management processes and procedures
- Have a customer focus focusing on customer satisfaction
- Are working to evaluate and continuously improve the QMS

3.2 Leadership

The aim of leadership should be to set the direction of the organization and motivate people toward improving quality and customer satisfaction, while increasing output and efficiency and improving employee involvement in order to achieve success.

QMSs are often successful when management is committed and communicates that commitment to the entire workforce and to subcontractors. Lack of genuine commitment to the QMS may result in poor product quality on the factory floor, poor quality in the supply chain, and poor quality in the field in the form of degraded performance and burdensome sustainment requirements.

3.2.1 Commitment

Organizations should provide evidence of how top management provides leadership and guidance and demonstrates commitment to achieve quality results that are integrated into strategic objectives and business practices. These executives should provide quality policies and regularly communicate those policies to the workforce and review the status and adequacy of the quality program. Top leadership needs to show how their efforts help to influence behavior and motivate employees to achieve organizational goals and quality excellence while ensuring customer satisfaction. Organizations should provide evidence that they are meeting the intent for a higher-level QMS such as SAE AS9100 and have identified, implemented, and are managing the requirements listed below.

M&Q management program standards and best practices including maintaining a QMS may require an up-front investment in early development, with returns not realized until later in development and production; however, the potential returns on investment can include the following:

- Shorter development schedules
- More robust product designs
- Faster lead times
- Easier transition of designs to production
- Better product quality and reliability

- Improved field metrics
- Reduced variation and waste
- Improved thruput and reduced cycle times
- Reduced cost of quality
- Lower inventory
- Increased factory floor efficiency and productivity
- Increased employee engagement
- Improved customer satisfaction
- More effective risk management
- Improved regulatory and statutory compliance
- Improved supplier product integration
- Improved competitive advantage

Achieving the full range of benefits available from the many quality and Lean practices requires cultural changes within the organization and throughout the supply chain, from end-users through lower-tier suppliers.

3.2.2 Deming's 14 Points

W. Edwards Deming (1986) identified 14 Points for Management that leadership should embrace and promote to achieve quality and organizational excellence. The 14 points appear in many variations that could be paraphrased as follows:

1. Create a constancy of purpose for improving products and services
2. Adopt a new philosophy prioritizing quality over short-term profits
3. Cease dependence on inspection
4. End price-based supplier selection
5. Never cease to improve
6. Institute on-the-job training
7. Adopt and institute leadership
8. Drive out fear
9. Break down barriers between departments and staff areas

10. Eliminate slogans, exhortations, and targets for the workforce
11. Eliminate work standards and quotas
12. Eliminate management by numbers and numerical goals
13. Institute a vigorous program of education and self-improvement
14. Make quality transformation everyone's job

Organizations may be required to provide evidence they are managing the following activities:

- (Leadership) Take accountability for the effectiveness of the QMS
- Identify the roles and responsibilities of people engaged in the QMS
- Develop a quality policy and objectives for the QMS that support and are compatible with strategic objectives
- Integrate the QMS into the business processes
- Demonstrate a customer focus and managing customer satisfaction
- Promote the use of the process approach
- Promote risk-based thinking
- Ensure QMS resources are available and are contributing to the effectiveness of the QMS
- Review and assess the effectiveness of the QMS
- Communicate the effectiveness of the QMS
- Ensure that the QMS achieves its intended results and customer satisfaction
- Promote continuous improvement
- Identify opportunities for investments
- Demonstrate quality leadership

3.2.3 Organizational Knowledge

Organizational knowledge refers to the collective knowledge, skills, and experience that exists within an organization that is required by individuals in order to perform their roles and responsibilities in an effective and efficient manner. This knowledge should be understood and managed to accomplish tasks, make intelligent decisions, motivate and empower people, encourage productivity and efficiency, and create new opportunities.

Organizational knowledge consists of the following:

- **Explicit Knowledge** refers to the clearly documented and readily available information about policies, processes, data, and other operational information. Explicit knowledge includes policies, standard operating procedures, product specifications, blueprints or digital engineering data, other product information, machine operating instructions and maintenance manuals, quality assurance and control protocols, training and education materials, etc.
- **Tacit Knowledge** refers to knowledge that exists within individuals and is often not codified and not available to others. One example may be grandma's secret recipe for cookies. This type of knowledge is gained through experience based on trial and error and observation. In quality it may be the ability to detect a visual defect that is learned over time or knowing the best settings for operating a machine. Often this knowledge is difficult to capture or put into words.
- **Implicit Knowledge** refers to knowledge that is gained through experience and on-the-job training. Implicit knowledge if often lost when a key employee retires or moves on to another job and organizations fail to capture and pass on this information.
- **Collective Knowledge** or tribal knowledge refers to the knowledge that includes the combined experience of a group of individuals. This knowledge may exist within a specific group, function, or department.
- **Individual Knowledge** refers the tacit and explicit knowledge an individual possesses.

Organizational knowledge should include the use of knowledge management, the systematic process of creating, capturing, storing, sharing, and applying knowledge in order to achieve organizational goals.

Organizations may be required to provide evidence that QA managers are participating in the following activities:

- Create a database accessible to all employees
- Capture, store, share, and use that knowledge
- Establish a training and education program
- Establish a mentoring program
- Employee discussion groups
- Provide opportunities for learning new skills

3.2.4 Organizational Competence

The three key components of competence include knowledge, skills, and abilities (KSAs) to perform roles and responsibilities to defined standards that support the achievement of organizational goals.

- **Knowledge** refers to the theoretical understanding relevant to a specific task or function
- **Skills** refers to the application of knowledge that allows individuals to perform their tasks and responsibilities to a defined standard (It is the ability to apply specific knowledge)
- **Abilities** refers to natural skills and talents that can be used in the performance of roles and responsibilities

KSAs are often used when developing job descriptions, during performance evaluations, in the development of a hierarchy of skill requirements (entry, midlevel, etc.), which can be for training or advancement purposes.

The Department of War has developed an Engineering and Technical Management Competency model that includes training for quality practitioners (Figure 3-1) through Warfighting Acquisition University. Competencies circled in red address quality topics. In addition, as part of the ETM competency model, credentials are offered in the Quality Assurance topic area.

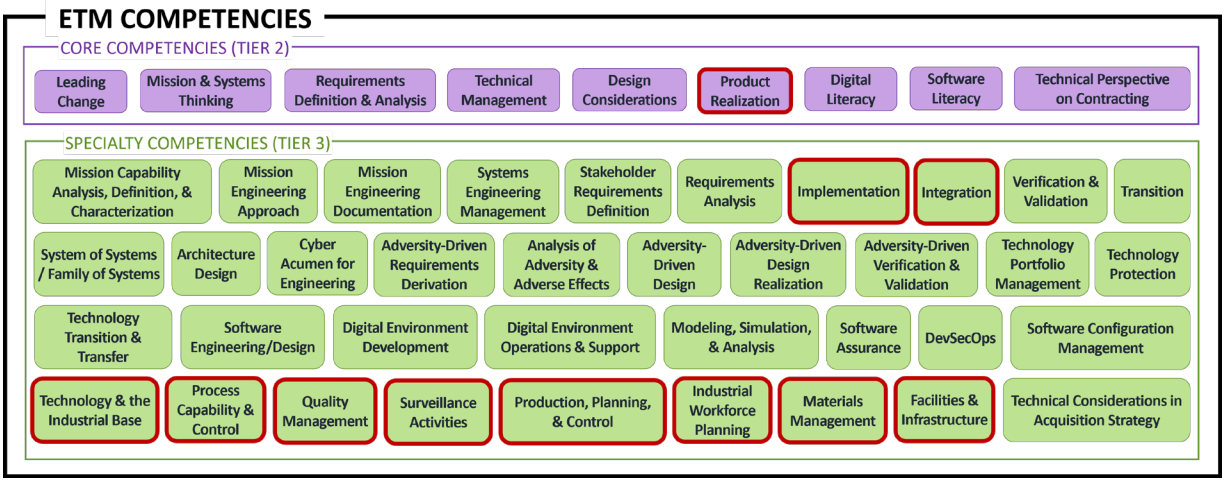
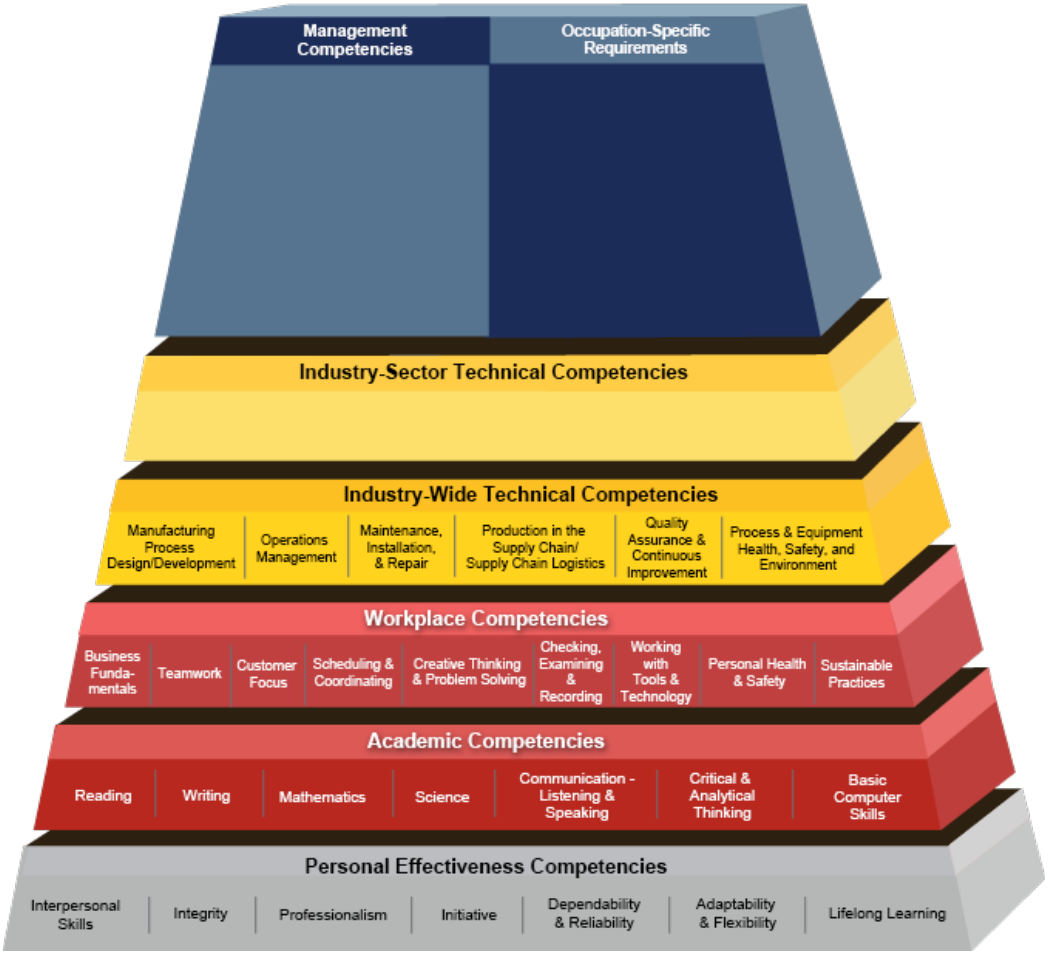


Figure 3-1. ETM Competency Model

The Department of Labor developed an Advanced Manufacturing Competency Model that defines essential skills and knowledge that have been identified for personnel involved in advanced manufacturing (Figure 3-2). While the model was developed for advanced manufacturing, it can be used for evaluating organizations doing business with the DoW. These competencies range from industry specific, workplace, occupation, academic, and personal skills.



Source: CareerOneStop.

Figure 3-2. Advanced Manufacturing Competency Model

Organizations may be required to provide evidence they are managing the following activities:

- Identify: Every organization needs to identify what KSAs are required to establish quality foundational knowledge requirements, those KSAs that support factory floor operations, KSAs for supply chain management, and ongoing improvement and excellence
- Hire: Organizations need to have in place hiring practices that match competent personnel with specific roles and responsibilities (This could include developing effective job descriptions, having a pipeline of candidates, often from referrals, and the use of technology to help identify potential candidates)
- Develop: Competent employees do not just appear; organizations need to make provisions for hiring employees with the requisite KSAs or have plans for ensuring that their personnel achieve the required KSAs (KSA may require certification or other requirements, and those requirements may need to be renewed on a regular basis)

- Monitor Compliance: Organizations need to have a process that ensures their personnel have achieved the required KSAs and provided documented evidence of that achievement and any requirements with ongoing or required annual or other recertification
- Assess Gaps: Organizations should assess gaps in KSAs that are required for meeting organizational goals

Competencies or KSAs can be achieved in many ways:

- Formal training and education
- Online training and education
- Independent study (library research, and other means)
- Certification programs
- On-the-job training and experience
- Mentoring and coaching

3.2.5 Customer Focused

A customer-focused organization should be able to identify and respond to a customer's needs and expectations to satisfy those requirements. Look to see if the organization is tracking customer satisfaction as a Key Performance Indicator (KPI), this may include measuring on-time delivery, number of late deliveries, customer complaints, customer reject rates or returns, warranty claims, field failures, etc.

- Determine, understand, and consistently meet customer and stakeholder requirements
- Identify any customer special requirements
- Provide quick response to customer feedback, inquiries and complaints
- Determine, understand and consistently meet customer and stakeholder statutory and regulatory requirements
- Determine and address the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction
- Maintain the focus of enhancing customer satisfaction
- Measure product and service conformity and on-time delivery performance
- Plan for contingencies and take appropriate action if planned results are not, or may not be achieved

Both Lean and Six Sigma are customer-focused quality initiatives that could be used to support many of the requirements of their QMS system.

- Lean begins with an understanding of the customer using Lean's five-step process:
  1. Specify value from the customer's perspective
  2. Focus on the value stream to find and eliminate waste
  3. Create continuous flow
  4. Respond to the pull of the customer not the push
  5. Work toward perfection
- The Six Sigma process is data driven and customer focused and uses the DMAIC (define, measure, analyze, identify, and control) problem-solving process to focus on reducing variation:
  - Define what is important to the customer
  - Measure the current state
  - Analyze sources of problems
  - Identify and implement corrective action
  - Control (stabilize) the process and pursue continuous improvement

Customers include the primary customer, which includes the person or organization receiving the product, and secondary customer, the person or organization that has a vested interest in the product but is only indirectly involved.

Customer focus requires organizations to systematically gather and analyze the VoC (Voice of the Customer) in order to understand the needs and expectations of the customer. This should enable the organization to better plan for the delivery of products and services that delight the customer. The VoC is primarily a market research tool that gathers and analyzes customer wants, needs, and expectations that are then translated and organized into actionable product requirements. VoC is the first step in the Quality Function Deployment (QFD) process and is used to identify critical-to-quality (CTQ) characteristics.

Customer satisfaction should permeate the entire organization down to the factory floor worker. Workers on the line should know where the product goes, who is at the next workstation, if they are satisfied with the work. Workers should also know the end customer and be provided feedback on that satisfaction.

3.2.6 Support Resources

Support resources should be considered to effectively plan for and manage a QMS and the resulting product and process quality and to foster continuous improvement. These resources provide the organization with the ability to deliver uniform, defect-free products and provide consistent performance that are cost-effective while meeting customer contractual requirements.

Manufacturing is the process of transforming raw materials, components, and subsystems into finished goods. Manufacturing resources are those resources that are required for an organization to complete the transformation process. Organizations should determine what resources are needed to support their programs and then provide those resources from the beginning of a product's life cycle until the end of its life.

Organizations may be required to provide evidence they are managing the following activities:

- Workforce/labor (skilled and unskilled)
- Buildings, facilities, and space management
- Equipment/machines
- Tooling and test equipment
- Maintenance and repairs
- Materials and components from internal and external providers
- Utilities, water, electricity, heat, and air conditioning
- Environmental, Safety, and Occupational Health (ESOH)
- Security (physical and cyber)
- Disaster planning

Resource management begins with an understanding of the demand, requirements, and tasks.

Organizations may be required to provide evidence they are managing the following activities:

- Identification of resource requirements needed to meet contractual requirements
- Planning and scheduling of resources are needed to complete the tasks
- Allocation of resources to assign the right resources to the right tasks and the right time
- Use of resources to ensure the most efficient use of resources. Use should seldom reach 100 percent as then the organization is constrained
- Monitoring and adjusting resources as necessary

3.2.7 People

The organization should determine and provide the personnel necessary for the effective implementation of its QMS and for the operation and control of its processes and products. Organizations should identify their planned approach to acquiring and training the workforce to include skills or certifications required and should provide a forecast of manpower loading over the intended period of performance.

A higher-level QMS should require organizations to determine and provide the processes necessary for the effective implementation of the QMS and for the operation and control of processes. This clause in the QME also should require organizations to ensure that the people performing tasks are competent to perform their assigned tasks, that they have the necessary knowledge, skills, and experience, have the authority and freedom and have unrestricted access to top management.

Organizations may be required to provide evidence they are managing the following activities:

- Conduct a skills and competency assessment of all employees: This assessment should identify the skills and competencies that are required for each job role and the gaps between the current skills and competencies of employees and the required skills and competencies
- Conduct an assessment of the availability of personnel: Currently there is a significant shortage of manufacturing and quality personnel with over 20 percent of U.S. plants operating under their full capacity; the shortage is forecasted to last well into 2033 according to a study by Deloitte and The Manufacturing Institute (2024)
- Develop and implement a training plan to address the gaps identified in the skills and competency assessment: This training plan should be tailored to the specific needs of the organization and should be delivered in a way that is effective for the employees
- Create a culture of continuous learning and development: This culture should encourage employees to take on new challenges and to develop skills and competencies
- Provide employees with the resources they need to perform their jobs effectively: These resources may include tools, equipment, training, and information
- Create a positive work environment that is supportive of employee development: This environment should be characterized by trust, respect, and collaboration (Deming would tell managers that they need to “drive out fear” -- point # 8)

Workforce requirements, planning, and analysis cover a range of KSAs from a competency perspective. A concern is many companies face shortfalls in personnel. In addition to specific labor skills (welding, machining, fabrication, assembly, inspection, testing, etc.) associated with production processes, there is a need for M&Q personnel to understand the requirements for fabrication and assembly of countless numbers of types of materials.

3.2.8 Infrastructure

The plant infrastructure encompasses all of the essential facilities, equipment, and systems required to operate and support production. Infrastructure includes:

- Buildings, structures, and space management (production, storage, transportation and other facilities)
- Equipment, machinery, tools, test equipment, inspection equipment, etc.
- Material handling, storage, and movement equipment
- Safety equipment, fire suppression, first aid, etc.
- Information systems, networks, computers, data storage, etc.
- Industrial ventilation, heating, cooling, air quality, etc.
- Electrical and water systems
- Security (physical and cyber)

Organizations may be required to provide evidence they are managing the following activities:

- Strategies of infrastructure investments
- Plans for infrastructure management and maintenance
- Establishing processes and procedures for facilities management
- Ensuring that the physical environment supports factory operations and provides a safe, clean, and healthy environment
- Plans for the safe operation of all facilities
- Plans for facilities sustainment

3.3 Plan (Organizing for Quality)

To have a successful QMS, organizations should plan for, execute, and manage all of the requirements for a higher-level QMS to meet customer and stakeholder requirements.

Organizing could be achieved by implementing a comprehensive PDCA process (Figure 3-3).

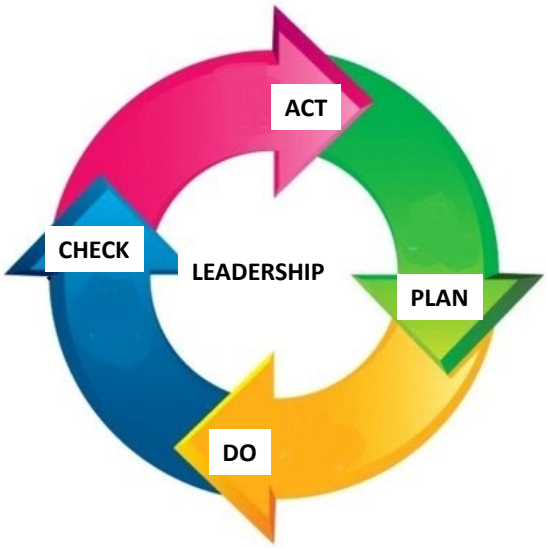


Figure 3-3. PDCA Model for a QMS

Plan: Define objectives, identify processes, and develop a plan to achieve the desired results. This includes understanding customer requirements, defining responsibilities, and identifying resources.

Do: Implement the plan and execute the processes. This involves putting the plan into action and carrying out the necessary activities.

Check: Monitor and measure the results of the implemented plan and processes. This involves assessing whether the plan is working as expected and identifying any deviations or areas for improvement.

Act: Analyze the results, identify areas for improvement, and take action to address any issues or deviations. This may involve implementing corrective actions, preventative actions, or improving the processes.

Organizational quality planning begins with a thorough contract review to understand the specific quality activities to be performed. QA personnel involved in the program should be working with the technical IPT and have already been exposed to the requirements by supporting the development of the Acquisition Strategy, Systems Engineering Plan, and the other activities prior to contract award. While M&Q personnel are not directly involved in requirements, they should be able to provide evidence that quality personnel are involved in:

- Supporting market research
- Providing inputs to the contract strategy
- Providing inputs to the Source Selection Plan

- Providing inputs to the Request for Proposal
- Supporting contract evaluation and award
- Supporting Pre-Award Surveys

Organizations should be able to provide evidence that quality personnel are involved in:

- Roles and responsibilities
- Documented standards
- Goals and objectives
- Key Performance Indicators (KPIs)
- Training and personnel qualifications
- Quality assurance and control processes
- Inspection and testing requirements
- Control of nonconforming material requirements
- Root cause analysis
- Auditing requirements (internal and external)
- Supplier quality requirements
- Continuous improvement of the QMS
- Change control of the QMS
- Ongoing risk assessment and management

Quality plans should be integrated into the Systems Engineering Plan and into the Acquisition Strategy. The SE process includes eight Technical Processes and eight Technical Management Processes (Table 3-1). Organizations should be able to provide evidence that quality personnel are involved with the following:

Table 3-1. Systems Engineering Technical Processes and Technical Management Processes

Technical Processes	Technical Management Processes
Stakeholder Requirements Definition	Technical Planning
Requirements Analysis	Decision Analysis
Architecture Design	Technical Assessment
Implementation	Requirements Management
Integration	Risk Management
Verification	Configuration Management
Validation	Technical Data Management
Transition	Interface Management

The 16 processes provide a structured approach to increasing the technical maturity of a system, thereby increasing the likelihood that the capability being developed balances mission performance with cost, schedule, risks, and design considerations. QA personnel should be involved with most of these activities at some level. The following documents detail engineering and manufacturing processes that M&Q personnel should support (see References):

- Systems Engineering Guidebook, Section 7.14
- Early Manufacturing and Quality Engineering Guide
- DoD Producibility and Manufacturability Guide
- Manufacturing and Quality (M&Q) Body of Knowledge (BoK)

The following design tools are useful in managing the SE process:

- DMADV (Define, Measure, Analyze, Design, and Verify)
- Quality Function Deployment (QFD)
- Design for Six Sigma (DFSS)
- Design for Manufacturing and Assembly (DFMA)
- Design for Reliability, Maintainability, or Sustainability
- Design Failure Mode and Effects Analysis (DFMEA)
- Design of Experiments (DoE)
- Process Failure Mode and Effects Analysis (FMEA)
- Producibility and Manufacturability Engineering

Table 3-2 lists examples of QA activities that occur during the various acquisition phases of a Major Capability Acquisition program.

Table 3-2. Manufacturing and Quality Participation

SE Activity	M&Q SME Participation
Pre-MDD (Materiel Development Decision)	• Support the Source Selection process • Identify quality contract requirements • Develop a program quality strategy and plan • Identify product quality requirements and goals • Identify technical data requirements • Support program and technical reviews • Identify key technologies and processes needing development • Support the 16 Systems Engineering processes • Support QA risk assessments including MRAs
Materiel Solution Analysis	• Support the Source Selection process • Identify quality contract requirements • Develop a program quality strategy and plan • Identify product quality requirements and goals • Identify technical data requirements • Identify supplier quality requirements • Support program and technical reviews • Identify key technologies and processes needing development • Support the 16 Systems Engineering processes • Support Manufacturing Feasibility assessment • Support QA risk assessments including MRAs • Support Milestone Decision Reviews
Technology Maturation and Risk Reduction	• Support the Source Selection process • Identify quality contract requirements • Update a program quality strategy and plan • Update product quality requirements and goals • Identify technical data requirements • Support Material Review Board (MRB) process • Conduct Quality Audits • Assess and manage supplier quality • Support program and technical reviews • Support Configuration reviews and changes • Identify, implement, and manage ManTech programs • Support the 16 Systems Engineering processes • Support QA risk assessments including MRAs • Support Milestone Decision Reviews

SE Activity	M&Q SME Participation
Engineering and Manufacturing Development	• Support the Source Selection process • Identify quality contract requirements • Update a program quality strategy and plan • Update product quality requirements and goals • Identify technical data requirements • Support the Material Review Board (MRB) process • Conduct Quality Audits • Assess and manage supplier quality • Support program and technical reviews • Support Configuration reviews and changes • Identify, implement, and manage ManTech programs • Support the 16 Systems Engineering processes • Support QA risk assessments including MRAs • Validation of Production Process • Support testing (FAT, FAI, PPAP, etc.) • Production Qualification Testing • Measurement System Analysis • Statistical Process Control (SPC) • Support Milestone Decision Reviews
Production and Deployment	• Identify quality contract requirements • Update a program quality strategy and plan • Update product quality requirements and goals • Identify technical data requirements • Support the Material Review Board (MRB) process • Conduct Quality Audits • Assess and manage supplier quality • Support program and technical reviews • Support Configuration reviews and changes • Identify, implement, and manage ManTech programs • Support the 16 Systems Engineering processes • Support QA risk assessments including MRAs • Final Inspection and Acceptance • Continuous Process Improvements • Support process audits and inspections • Support finding solutions for Diminishing Manufacturing Sources and Material Shortages (DMSMS) • Support Configuration Mgt reviews and Changes • Finalize Design

3.3.1 Quality Policy

A quality policy is a document or statement outlining the organization's vision and commitment to providing high-quality products and services. The policy guides employees in day-to-day activities with a goal of delivering uniform, defect-free products that satisfy the customer and relevant stakeholders. The policy should ensure organizations provide evidence that they are meeting the intent for a higher-level QMS and have identified, implemented, and are managing the requirements listed in sections 3.3.1.1 through 3.3.1.4.

The quality policy should provide strategic direction and set realistic strategic quality objectives (e.g., continuous improvement). The policy should identify how the organization is going to develop, initiate, manage, and continuously improve the QMS quality results.

3.3.1.1 Establish the Policy

Organizations may be required to provide evidence they are managing the following activities:

- Supports the strategic direction
- Provides a framework for establishing, setting, and managing quality goals and objectives
- Prevention oriented not appraisal
- Achieving the intended purpose and satisfying the customer
- Identify customers and stakeholders
- Establish quality business practices and procedures
- Identify how leadership communicates the policy and engage with the quality function
- Identify how the organization adheres to statutory and regulatory requirements
- Identify organizational goals
- Establish roles and responsibilities
- Identify quality tools and techniques that can be used to monitor, assess, and manage quality
- Identify assessment and audit techniques (internal and external) Management review of audits and assessments
- Identify quality risk management processes

3.3.1.2 Communicate the Policy

Communication at all levels of an organization is extremely important, and good communication reduces many risks while fostering teamwork and improved customer relationships.

Communication can be either internal or external. Internal communication is within an organization and goes to every person at every level. External communication goes outside of the organization to all customers and interested stakeholders up and down the organizational chain. Communication needs to be two ways, with a feedback loop to ensure the communication was understood or whether there are any questions or ambiguities.

Communication needs to be:

- Relevant: Tied to corporate strategies, goals, and objectives and is useful to customers and interested parties
- Accurate: Factual, free from bias, errors and omissions
- Consistent: Has the same message over time, cannot say one thing and do another
- Controlled: Information needs to get to people who need it, and not get to people who do not need it
- Understood: Do all the parties involved in communication have the same understanding from the message

Organizations need to have developed a communication strategy, plans, and procedures with communication goals and objectives. The communication strategy should ensure that communications contribute to:

- Building employee morale, satisfaction and engagement
- Helping employees understand the requirements of the job and drives commitment to organizational goals
- Giving employees a voice and improving employees' satisfaction with their employer
- Helping to lessen chances for misunderstandings
- Improving processes/procedures, creating greater efficiency and reducing costs

Organizations should provide evidence that they have identified, implemented, and are managing a quality policy that meets the requirements listed below.

- What to communicate: Organizations need to ensure that corporate strategies, goals, plans, progress, milestones etc., are being communicated, and not just quality strategies, goals, plans, etc. (An effective communication plan should document these requirements)
- When to communicate: All communications may have a different time period in which the communication takes place (Some communications should take place every day, for example safety reminders. Some communication may be a one-time event, for example an email about an upcoming quality meeting. Some information may be periodic, for

example monthly reports, or annual certification requirements. Communications may also be based upon the frequency, urgency/importance, significance, scheduled meetings, ad-hoc briefings, staff shift patterns.)

- With whom to communicate: Deciding with whom to communicate can be challenging (Sometimes people are left out of the loop because they are not the primary audience, but as interested stakeholders, they may require the information. Other times information is sensitive and needs to be kept with a select group of people. Remember communication can be either internal or external)
  - Internal includes those within an organization
  - External includes customers, suppliers, regulators, stakeholders, Government agencies, local community, investors, external providers, and the media
- How to communicate: Requires the identification of which communication technology or channel should be used for specific types of communications
- Where communication comes from: Where or who the communication comes from could include senior leadership, line managers, department supervisors, team leaders, team members, employee representatives, public relations, marketing, customers, and external agencies

The quality policy should be communicated throughout the organization, its supply chain, and to customers and stakeholders as appropriate. It is important that everyone involved with the implementation and execution of the QMS understand the importance of adhering to the standard and its requirements. Organizations may be required to provide evidence they are managing the following activities:

- Distributing the policy to all employees
- Ensuring the policy is available to employees and to customers through the organizations website
- Ensuring that the policy is understood and correctly applied

Methods of communication:

- Newsletters
- Training and education
- Social networking (internet, intranet, emails, etc.)
- Posters and other printed material
- Meetings

3.3.1.3 Awareness of the Policy

Awareness is not just about knowing or understanding that there is a QMS policy, it is about employees knowing their role in establishing an effective QMS, and in achieving organizational goals. Organizations may be required to provide evidence they are managing organizational awareness which should include ensuring that the people within the organization are aware of:

- The quality policy – its contents and objectives
- The QMS requirements and individual roles in implementing the QMS
- Quality measures or metrics for success
- How each team member fits into the successful implementation of the QMS and quality policy
- How individual and team efforts contribute to the implementation of the QMS
- How a team fits into the successful implementation of the QMS and quality policy
- How important the execution of the quality policy and QMS are to the success of the organization
- The impact of the quality policy and QMS have on business outcomes
- How committed the organization and leadership are to implementing the quality policy
- Who are the customers (internal and external)
- Who the suppliers are (internal and external)
- Individual roles in preventing defects
- Individual roles in managing non-conformances
- The need to document inspections and test
- The need to manage documentation
- Improving the quality culture can improve safety
- Industry specific quality requirements
- How to assess quality and quality risks
- The need to continuously improve quality
- Various quality tools
- The need to behave ethically

3.3.1.4 Roles and Responsibilities

All personnel performing quality functions have sufficient, well-defined responsibility, authority and organizational freedom to identify and evaluate quality problems and to initiate, recommend or provide solutions.

Quality management is structured around:

- Quality planning
- Quality assurance
- Quality control
- Quality reporting and improvement
- Quality training and awareness
- Quality audits and inspections
- Management of nonconforming products and processes
- Management of requirements (customer, stakeholder, statutory and regulatory compliance
- Customer and stakeholder satisfaction

Organizations may be required to provide evidence they are managing the following activities:

- Define and clearly describe the roles and responsibilities of all personnel involved in the performance of the contract
- Set measurable objectives that are specific, measurable, achievable, relevant, and time-based
- Foster a quality culture that is focused on the customer and encourages risk-based thinking
- Foster a culture of continuous improvement based on the PDCA cycle
- Support workforce training and engagement

3.3.2 Quality Management Plan

A quality management plan (QMP) or strategy is a top-level document that lays out the process for ensuring quality measures are taken to implement the QMS. The QMP serves as the foundation for quality management on any project and addresses quality planning (QP), quality assurance (QA), quality control (QC), and quality improvement (QI).

The purpose of the QMP is to describe how quality should be managed throughout the project's lifecycle. Quality management planning determines the scope of the QMS and sets quality policies and procedures relevant to the project for deliverables and processes and defines quality responsibilities for what, and documents compliance.

Government contractors should already have an established quality organization and an established QMS, and they should have a history of successfully performing under that QMS.

Developing a quality plan therefore should focus on specific activities directed toward satisfying a specific contract or customer.

Organizations may be required to provide evidence they are managing the following activities:

- Quality Policy and Objectives:
  - Identify what should be done
  - Who is responsible for each defined activity
  - When the activities take place
  - Identify who should document and verify the results
- QMS Planning: The QMP should identify risks and opportunities so key goals and measures can be achieved
- Quality Standards/Metrics: The quality standards are the “measures” used to determine a successful outcome for a deliverable (These standards may vary depending on the type of product and organization)
  - Quality Key Performance Indicators (KPIs): KPIs are measurable values used to track, assess, and verify the quality of the products, processes, and services that are provided by an organization (Quality metrics should be Specific, Measurable, Achievable, Relevant, and Time-Bound (SMART))
- Customer Satisfaction: The customer satisfaction criteria describe when each deliverable is complete and acceptable as defined by the customer
- Quality Control Activities: The quality control activities monitor and verify that the project deliverables meet defined quality standards
- Process Quality Standards: The quality standards are the “measures” used to determine if project work processes are being followed
- Stakeholder Expectations: Stakeholder expectations describe when a project process is effective as defined by the project stakeholders (An example is the review and approval of all high-impact changes to the project)
- Quality Assurance Activities: The quality assurance activities monitor and verify that the processes used to manage and create the deliverables are followed and are effective
- Quality Improvement: Ensure that quality is constantly improving
- Roles and Responsibilities: Ensure everyone understands and knows their role in the quality management process
- Develop Metrics: Metrics for the above activities that are specific, measurable, achievable, relevant, and time-bound (SMART)

- Auditing and Monitoring: The implementation of the QMS should be monitored and audited on an ongoing basis both internally and externally

3.3.3 Supplier Quality Plan

Supplier quality refers to the processes an organization goes through to assess, select, monitor and manage the quality of the products and services it procures. The management of supply chains is key to the success of any organization. On many programs, suppliers provide 70 to 80 percent of product content. Many factors can disrupt supply chains as evidenced by the COVID pandemic.

Organizations may be required to provide evidence they are managing for the control of supplier products, processes, and services as listed below.

- Supplier Selection and Evaluation
  - Criteria-Based Selection: Organizations select suppliers based on many factors to include cost, capability, capacity, quality, reliability, location, delivery performance, product performance features, financial stability, and past performance (These criteria are especially important for items that are critical, complex, and/or expensive)
  - Supplier Qualification: A systematic assessment of a potential supplier to ensure that the supplier is capable of meeting the organizations contractual requirements
  - Organizations seek to select suppliers based on a balance between many factors to include cost, schedule, and performance
- Supplier Requirements and Agreements
  - Contractual Requirements: Should be clear and understood by both parties (The agreement or contract should outline the terms and conditions of their business relationship. This could include specifying the product to be supplied, pricing and payment terms, delivery schedules, quality standards, intellectual property rights, warranties, non-disclosure agreements. dispute resolution, termination clauses, and special considerations such as the implementation of Lean/Six Sigma programs.)
  - Contractual Flow Down Requirements: Includes the requirement for suppliers to flow down to suppliers any applicable contract requirements to include quality clauses as appropriate
- Supplier Monitoring and Management
  - Supplier Inspection
  - Supplier Audits (see section 3.5.4 Audits: Internal and External), Supplier Communication, and Collaboration: Supply chain management practices emphasize a proactive approach to partnership in which both parties share information by

identifying clear expectations, fostering open and transparent communication, timely (daily) communication of the demand schedule, and the leveraging of communication technology to foster improved communication

- Supplier Quality Control and Inspection
  - Incoming material inspection
  - Inspection at the suppliers during production, prototype build, and in-process
- Corrective and Preventive Action
  - Address incoming non-conforming material
  - Address field failures, reliability issues, and warranty items
- Supplier Quality Metrics or Key Performance Indicators (KPIs)
  - On-time Delivery
  - First-time Quality Rates
  - Defect/Yield Rates
  - Cost of Quality
  - Lead times
  - Corrective Action Rates
  - See the DoD Supply Chain Metrics Guide
- Supplier Continuous Improvement based on the PDCA cycle
- Supplier Risk Management: The DoD Risk Management Process can be used to identify and manage high risk suppliers. (This could include sole source, single source, foreign owned, and a myriad of other risk concerns.)
  - Risk Planning
  - Risk Identification
  - Risk Analysis
  - Risk Mitigation/Correction
  - Risk Monitoring
  - See the DoD Risk, Issue, and Opportunity Management Guide for Defense Acquisition Programs
- See AS9133: Qualification Procedure for Aerospace Standard Parts

3.3.4 Changes to the QMS

The QMS is a living system and may require changes for a variety of reasons (changes to standards, laws, regulations, etc.). As risks arise, the QMS may need to be updated. Audit

findings or customer feedback may indicate a need to change or update to the QMS. Statutory or regulatory requirements may change, requiring a change to the QMS.

Organizations may be required to provide evidence they are managing changes to the QMS and can show that they have:

- Identified and documented the change
- Identified the reason for the change
- Assessed possible positive and negative impacts due to the change
- Identified the resources required to implement the change
- Identified who the process owners are and how the change is implemented and communicated
- Identified who and how the change is approved or authorized

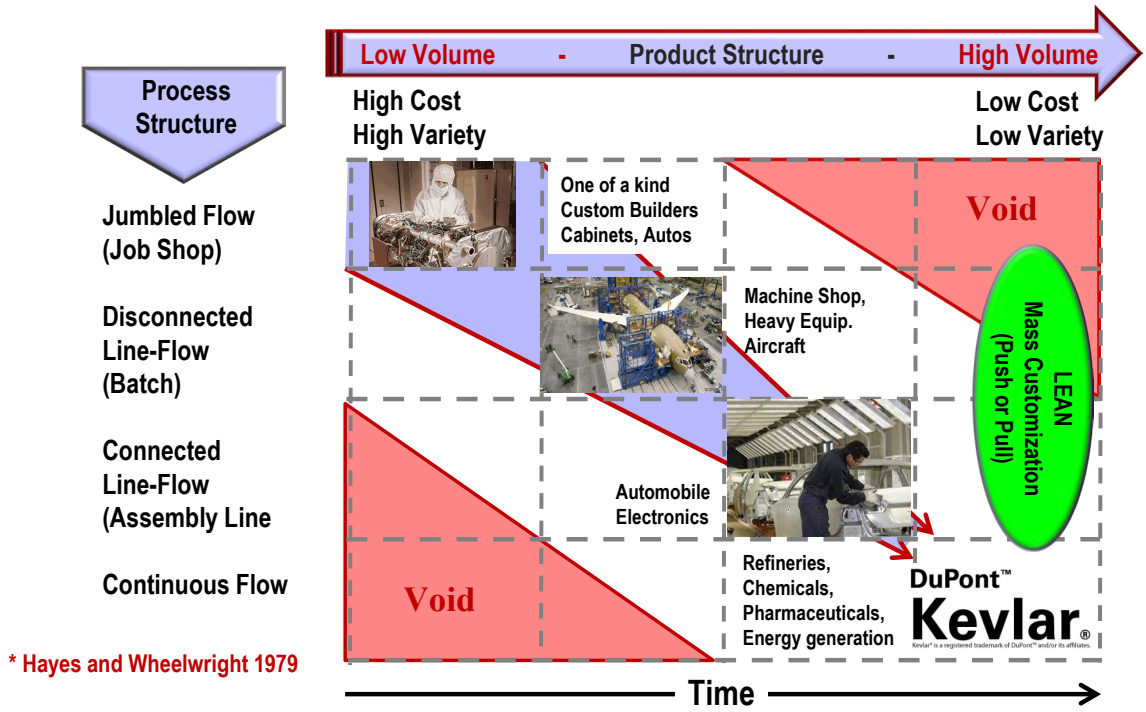
3.4 Do (Execute)

The factory floor environment plays a crucial role in facility outcomes, including product quality. There are several types of factory environments that are often based on the rate of production, total production, and complexity of the product.

For example:

- **Jumbled Flow or Job Shop:** Used for low-volume production but ability to produce a high variety of product, based on a make-to-order and has a functional layout where the product flows from shop to shop (milling, drilling, welding, etc.) within the factory
- **Disconnected or Batch:** Used for volumes higher than the job shop model and produces the items in discrete batches (These batches are more cost effective than job shops but require setups and teardowns when switching between products. The variety of products is less than the job shop but more than the connected line.)
- **Connected Flow or Assembly Line:** Used for a small variety of products that are produced within a network of machines, processes, and workstations (assembly line) (As the product moves down the line the product is progressively assembled. The restrictions of the line limit the types of products that flow down the line, but the process is very efficient.)
- **Continuous Flow:** Used to produce one product in a continuous stream (There is no room for variety, but the process produces the product very efficiently. The pace of the plant is consistent with the product flowing from one process to the next with little to no interruptions.)

Figure 3-4 shows that as product volume increases the unit costs go down and the ability to create a variety of product decreases. This impacts the factory floor by identifying which process structure should be used in production.



Source: Developed for PQM 301, Manufacturing Systems Design.

Figure 3-4. Manufacturing Product-Process Matrix

Quality operations include many activities; however, it is impossible to separate manufacturing and quality operations as they are intertwined at all levels, functions and processes. The manufacturing role is to transform raw materials, components, and subsystems into a deliverable product. The goal of manufacturing is to deliver uniform, defect-free products that are affordable, perform as expected, delivered on-time, and is affordable. These goals are often reflected in manufacturing KPIs such as improving productivity, efficiency, and quality while reducing costs.

The role of quality overlaps many of the roles of manufacturing and is to ensure that the products produced meet or exceed customer requirements and expectations, resulting in customer satisfaction. Quality goals are to achieve customer satisfaction, comply with customer, regulatory, and statutory requirements, while continuously improving.

Many quality activities are embedded in manufacturing activities and outcomes including:

- Production Planning
- Resource Planning and Management

- Production Control
- Quality Management and Control
- Continuous Improvement
- Inventory Management and Control
- Supply Chain/Logistics Management
- Distribution Management

Quality operations include:

- Quality Planning
- Quality Management
- Quality Assurance
- Supplier Quality
- Quality Control
- Continuous Improvement

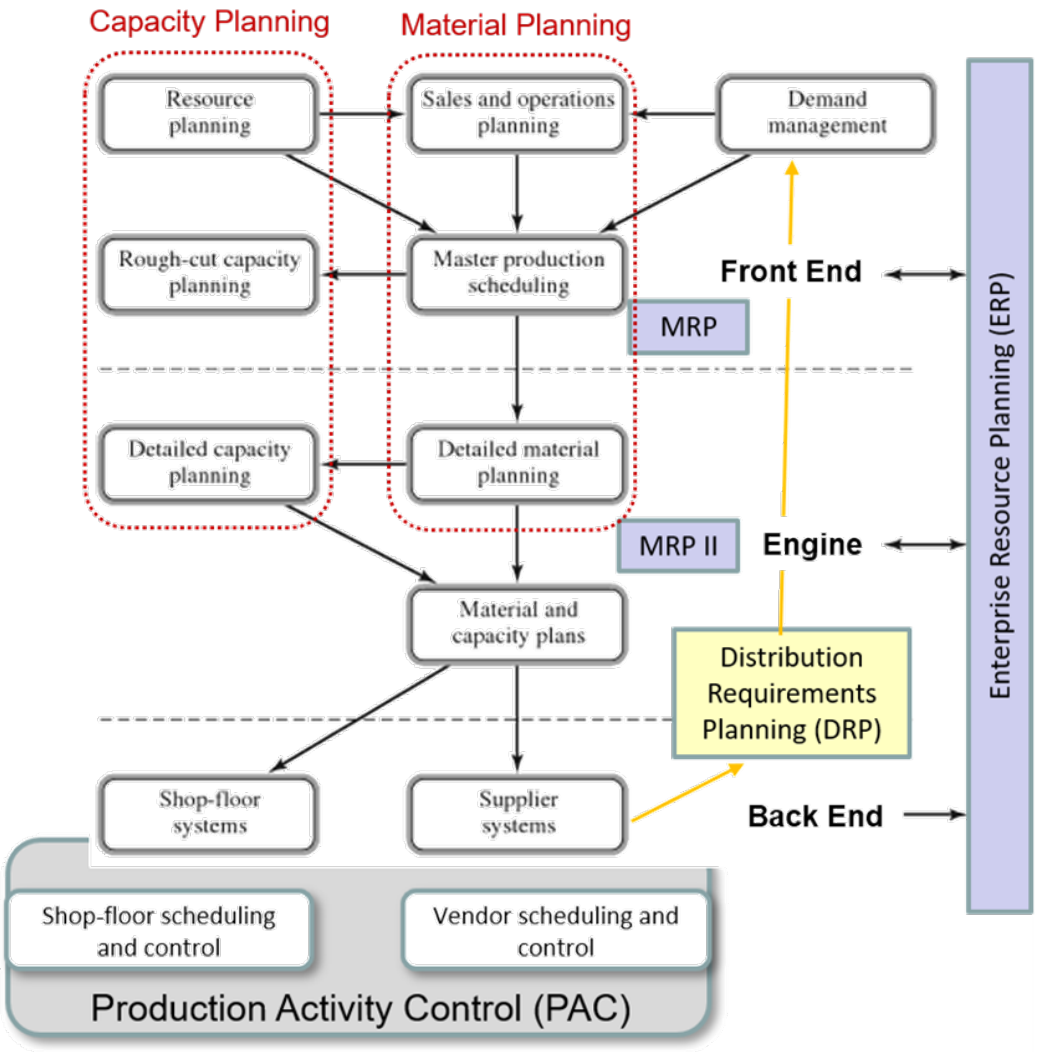
Many organizations use software programs to help in the planning and execution of their M&Q functions, often under the umbrella of software programs called Enterprise Resource Planning (ERP). Those organizations that do not have software tools use paper-based processes. ERP systems are a suite of integrated software modules that manage the day-to-day business operations to include:

- Forecasting/Demand Management
- Finance and Accounting
- Human Resources
- Customer Relationship Management
- Manufacturing Management
- Quality Management
- Material/Inventory Management
- Purchasing
- Supply Chain Management
- Order Processing and Fulfillment

These ERP modules play a crucial role in managing M&Q functions and processes through the automation of the functions listed below:

- Centralization of Data and Data Management provide a central repository for M&Q data such as audit reports, inspection data, calibration data, supplier quality, etc.
- Data Analytics and Reporting provide the ability to capture and analyze M&Q data to identify trends, track performance, and drive continuous improvement
- Automation of Quality Processes reduce manual activities by automation functions such as scheduling of inspections from receiving inspection, in process and final inspection, documenting and managing nonconforming activities, tracking and managing calibration, training and certification, auditing functions, and documentation control
- Risk Management helps identify, assess, and manage M&Q-related risks
- Real Time Visibility and Tracking as the data is imported ensure data is readily available and tracked
- Traceability and Accountability enable all functions and activities to demonstrate a clear record of actions, decisions, and outcomes, allowing for transparency and the ability to track and verify information throughout the process

Manufacturing planning and control (MPC) systems are built on a hierarchy of planning and control that starts with front end planning, where the strategy and vision are set; the engine of planning, where detailed plans emerge; and the back-end planning, where the execution takes place (Figure 3-5):



Source: Developed for WarU Supply Chain Management Workshop.

Figure 3-5. Manufacturing Planning and Control Model

Strategic or Front-End Planning:

- Strategy and vision set
- Sales and operations plans developed
- Resource plans developed
- Demand management requirements are estimated

Detailed Plans or the Engine:

- Detailed capacity plans are developed
- Detailed resource plans are developed
- Integrated capacity and material plans are developed

Execution or Back-End Planning:

- Execution of production and supply plan
- Shop floor controls

Manufacturing Execution Systems (MES) are concerned with planning and controlling all of the elements of M&Q processes embedded in the following software modules:

- **Operations Management:** Management of all manufacturing processes to include planning, scheduling, executing, and controlling activities
- **Production Processes:** Management of the specific methods, processes, and techniques that are used to convert material into finished goods
- **Resource Management:** Management of all resources needed to produce a product
- **Quality Management:** Management of the quality function requirements needed to ensure delivery of a product that meets customer requirements
- **Inventory Management:** Management of raw materials vendor supplied components, work-in-progress, and finished goods
- **Distribution Management:** Management of the process of getting the product to the customer

Quality personnel may be involved in all or just some of these functions. Organizations should provide evidence that they are meeting the intent for a higher-level QMS and are able to identify, implement, and manage the requirements listed in the subsections below.

3.4.1 Operational Planning and Control

Operational planning and control requires the organization to implement processes, procedures, and controls needed to meet QMS contract requirements.

Organizations need to know what products and services they are providing and the quality tools needed to complete the various tasks associated with those products and processes. See the list of Tools identified at Appendix D that could be used by quality personnel to conduct the various activities listed below:

- Determining the requirements for products and services. Organizations should ensure that they have a clear understanding of the requirements for the products and services, including any applicable statutory and regulatory requirements. This information can be obtained from a variety of sources, such as customer contracts, specifications, and drawings.
    - Identifying customer requirements for products and services

  - Identifying product characteristics (shape, size, color, etc.) for the product
  - Understanding any legal, statutory, and safety requirements
- Establishing criteria for processes and products. Once the requirements for products and services have been determined, organizations should establish criteria for processes and products. These criteria should be measurable and objective, and they should be used to ensure that products and services meet the requirements to include:
  - Design verification
  - Process controls and verification
  - Identification of KCs
    - KCs can be identified by using DoE, DFMEA, Process Failure Modes and Effects Analysis (PFMEA), Criticality Analysis, etc.
  - Process capability studies
  - SPC of KCs
- Establishing and providing resources that are required to achieve conformity (Organizations should ensure they have the resources needed to achieve conformity to the requirements for products and services. This includes resources such as people, equipment, tooling, measurement systems, and materials.)
- Establishing and controlling processes in accordance with established criteria (Organizations need to control processes in accordance with the established criteria. This includes monitoring and measuring processes, SPC, taking corrective action when necessary, and maintaining records of the results of monitoring and measurement.)
- Identifying and controlling outsourcing processes for those manufacturing processes that are not accomplished in-house (If an organization outsources any of its processes, it should ensure the outsourced processes are controlled in accordance with the organization's QMS.)

Organizations should consider the following as well:

- Personal and product safety
- Producibility, manufacturability, testability, and inspectability
- Reliability, availability, and maintainability
- Suitability of parts and materials used in the product
- Selection and development of embedded software
- Product obsolescence and counterfeit parts
- Prevention, detection, and removal of foreign objects

- Handling, packaging, and preservation
- Recycling or final disposal of the product at the end of its life

3.4.1.1 Operational Risk Management

Many organizations encounter significant operational disruptions. These risks can come from several sources:

- Supply Chain: COVID-19 drastically altered the landscape, driving some out of business
- Weather: The tsunami that hit Japan or the hurricane that hit New Orleans caused severe disruption for many businesses
- Cybersecurity Threats: The U.S. Government considers cybersecurity as a key aspect of national security
- Compliance: Laws, regulations, directives, and other sources of compliance can change, for example, changes to environmental regulations
- Workforce: Workforce risks can suddenly appear, for example, the sudden retirement or illness of a key person, or inability to find qualified workers
- Equipment: A simple but unplanned equipment failure can disrupt a line

Organizations should provide evidence that they are meeting the intent for a higher-level QMS and are able to plan for, identify, analyze, mitigate, and monitor their risks.

3.4.1.2 Configuration Management

Configuration Management is a part of the systems engineering process and was originally defined in MIL-HDBK-61, which has been replaced by SAE GEIA-HDBK. Various functional organizations have a role to play in managing the configuration of a product throughout its life cycle. DoDI 5000.88, Engineering of Defense Systems, directs that the "The LSE [lead systems engineer], under the direction of the PM, will implement a digital CM approach and automated tools to establish, control, and curate product attributes and technical baselines across the total system life cycle. Organizations should provide evidence that they are meeting the intent for a higher level QMS and that QA managers are supporting the activities listed below.

- Identify, document, audit, and control schedule, cost, functional, physical, and performance characteristics of the system design
- Specifically, track any changes (e.g., use dynamic change logs for in and out of scope changes, formal engineering change proposals) and provide an audit trail of program design decisions and design modifications

- Provide for traceability of mission capability to system requirements to performance and execution metrics

Configuration management consists of the following sub-processes:

- Configuration Planning and Management - delineates the specific CM application methods and their levels of emphasis in the contest and environment of the product to which the CM process is applied; identifies and applies resources and assigns responsibilities to perform CM activities; provides management of supplier configuration management program activities
- Configuration Identification - the basis from which the configuration of products are defined and verified; products and their product configuration information are labeled; changes are managed; and traceability is maintained throughout the product's life cycle
- Configuration Change Management - changes to a product are accomplished using a systematic, measurable change process
- Configuration Status Accounting - provides an accurate, timely information base concerning a product and its product configuration information throughout the product life cycle
- Configuration Verification and Audit - verifies a product's compliance with the physical, functional and interface requirements in approved product definition information confirms the basis for managing product configuration

QA managers support the process for ensuring the integrity and consistency of the products configuration by verifying and validating changes, auditing compliance, testing and inspection, and collaboration with other functional teams. Configuration Management is evaluated throughout the lifecycle, and especially during the following reviews:

- Functional Configuration Audit (FCA): The Functional Configuration Audit (FCA) is the technical audit during which the actual performance of a system element is verified and documented to meet the requirements in the system element performance specification in the allocated baseline.
- Physical Configuration Audit (PCA): The Physical Configuration Audit formally examines the as-built configuration of each configuration item to ensure that it is consistent with its detail specification and technical data package (TDP) of the final product baseline

3.4.1.3 Product Safety

Product safety follows the risk management process to plan, identify, analyze, mitigate, and monitor risks. Product safety begins with an SE process that focuses on ensuring products and systems are safe for their intended use, encompassing the entire life cycle from design to disposal. It involves identifying potential hazards, assessing risks, and implementing safety measures to minimize or eliminate those risks. Systems safety should be embedded in the SE process to incorporate safety considerations into the design process to minimize risks and protect users. The QMS and QA managers should provide evidence that they are involved in:

- Design and development planning for system safety
- Evaluating design and development inputs/outputs
- Design and development verification and validation through rigorous testing to ensure the product meets safety standards
- Risk, issue, and opportunity management

3.4.2 Customer Product Requirements

Products are intended to meet the needs and requirements of the customer and interested parties or stakeholders. This requires close communication with the customers. If the requirements are wrong, the product will not satisfy their needs. This information may come in the form of a contract or other agreement, a technical data package, drawings, specifications or standards.

The Requirements Analysis Process is the method to decompose user needs (usually identified in operational terms at the system level during implementation of the Stakeholder Requirements Definition Process) into clear, achievable, and verifiable high-level requirements. Requirements Analysis activities support allocation and derivation of requirements down to the system elements representing the lowest level of the design.

Organizations should provide evidence that they are managing the requirements process and that QA managers are part of that process or have insight into that process.

3.4.2.1 Determine Customer Product Requirements

Organizations need to provide evidence that they have determined the customers' requirements. The DoW process includes identifying customer requirements with a focus on understanding and translating stakeholder needs into initial requirements.

3.4.2.2 Review Customer Product Requirements

Organizations need to provide evidence that they are reviewing customers' requirements. The DoW requirements process may include:

- **Requirements Analysis:** Breaks down user needs into clear, achievable, and verifiable high-level requirements, allocated and derived down to the system elements
- **Requirements Management:** Ensures a current and approved set of requirements are maintained throughout the acquisition lifecycle, tracking changes and ensuring traceability of end-user needs
- **Requirements Development:** Involves developing requirements by understanding customer needs and stakeholder expectations, refining and documenting them as formal specifications
- **Requirements Verification and Validation:** Ensures the system meets the defined requirements through testing and evaluation

3.4.2.3 Manage Changes to Customer Product Requirements

Customer requirements often change, and organizations need to provide evidence that they are managing changes to the customers' requirements. The systems engineer is responsible for managing changes to requirements and maintains traceability of end-user needs to the system performance specification and the delivered capability. As the system design evolves to lower levels of detail, the systems engineer traces the high-level requirements down to the system elements through the lowest level of the design. The change management should involve QA managers as part of the Systems Engineering IPT. Organizations need to provide evidence that they are managing and controlling changes to meet requirements.

3.4.3 Design and Development

Products need to meet the requirements of the customer and interested parties or stakeholders. This requires close communication with the customers. The capturing of requirements is the first step in the SE process and is an essential activity. If the requirements are wrong, the product may not satisfy their needs. Customer requirements usually come in the form of a contract or other agreement. Organizations should provide evidence they are involved in design and development processes. The following concerns occur during the design and development process:

- Producibility
- Manufacturability
- Inspectability
- Testability

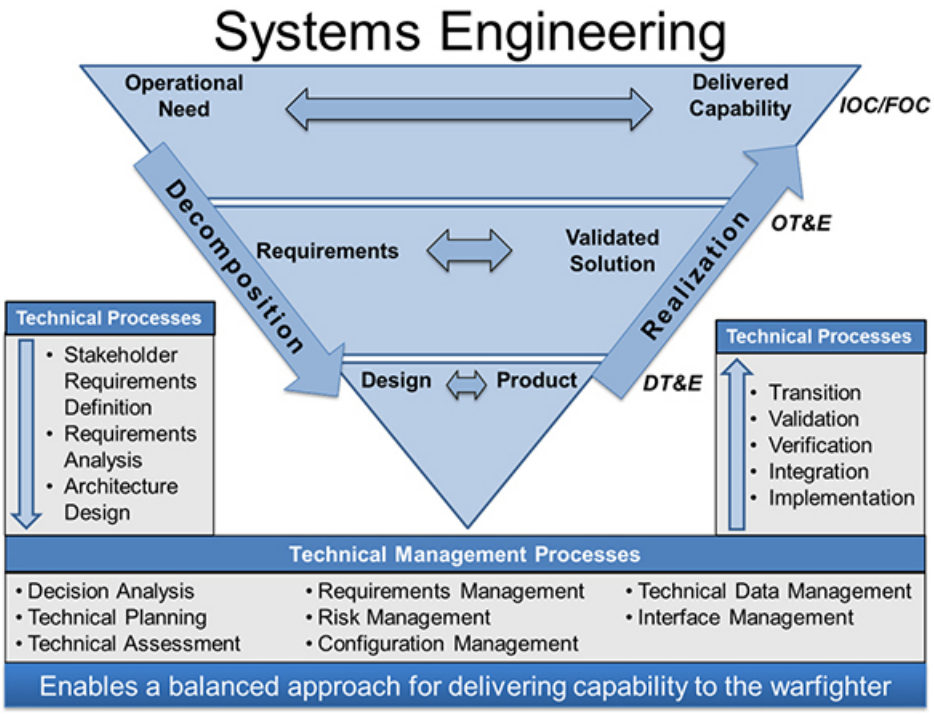
3.4.3.1 Design and Development Planning

Product design and development planning is the process of creating, designing, and developing a product to meet user requirements and is accomplished using the SE process. Product design process encompasses several key elements: aesthetics, usability, functionality, reliability, product safety, and engineering.

Design and development planning involves research, brainstorming, development, testing, and iteration to plan for and create products that meet user needs and align with business goals.

Product development is the process of taking the design and transforming it into a useful product. Product development may require taking the design through prototyping, user testing, Low-Rate Initial Production (LRIP), and Full-Rate Production (FRP). This also means that the design gets pushed down into the Work Breakdown Structure (WBS) down to the third or fourth level.

Organizations should provide evidence that they are following a structured design and development (systems engineering) process and that QA personnel are involved in design and development planning. One example is the DoW Systems Engineering process model or process as seen below (Figure 3-6). The SE process establishes the technical framework for delivering materiel capabilities to the warfighter. All organizations performing SE should scale their application of the processes, further described in Section 7.14 of the DoW Systems Engineering Guidebook, to reflect the unique needs of the program and the type of product or system being developed. The SE process is an end-to-end life cycle process that is ongoing and iterative and follows a natural progression starting with a need and ending when the system is fully capable and operational.



Source: SE Guidebook 2026.

Figure 3-6. Systems Engineering Model

The SE process provides a structured approach to increasing the technical maturity of a system, increasing the likelihood that the capability being developed balances mission performance with cost, schedule, risks, and design considerations. Quality assurance personnel should be involved with most of the eight technical and eight technical management activities at some level. The SE process begins with technical planning which should reflect the context of the organization and comply with all applicable policies. The PM, Lead Engineer, and other technical management personnel supporting the IPT should consider all relevant constraints when identifying technical tasks, sequencing these tasks and estimating resources and budgets. Inputs into the technical planning process vary over time as the program evolves and the system matures.

Technical Planning activities include:

- Define the scope and objectives of the technical effort to include cost and schedule
- Define and develop performance evaluations of product as it progresses through the design and development lifecycle
- Identify constraints and risks
- Establish roles and responsibilities
- Divide the program scope and objective into discrete elements (see WBS)
- Identify technical reviews and audits as well as their timing

- Establish schedules and costs
- Prepare or update planning and other program documentation
- Scale SE processes based on the scope and complexity of the program/system
- Identify areas for potential tailoring (including rationale) for Milestone Decision Authority (MDA) approval

Key factors that the systems engineer and the technical IPT should consider when accomplishing technical planning include:

- Capability needs (requirements, gaps, threats, operational context, CONOPS/OMS/MP, Target Audience Description)
- The system concept or materiel solution
- Key interfaces and interdependencies that exist or need to be developed
- The acquisition approach and strategy, from both a business and a contract perspective
- The chosen SE approach includes design considerations, development strategy, and modularity and standard interfaces in product designs where feasible and cost-effective
- The strategy and approach for T&E, for both developmental and operational testing (See T&E Enterprise Guidebook (2022) for additional information regarding interactions with the Chief Developmental Tester)
- Manufacturing and quality planning
- Program management approach, including organization, processes and products
- External dependencies and agreements with other systems or organizations that may be in place
- Need date
- Availability of resources, including funds, personnel, facilities, etc.
- Program risks
- Risk management strategies

Technical Processes:

- Requirements development process takes all inputs from users and stakeholders, clarifies them as necessary and translates these inputs into Technical Requirements
- Logical analysis process via functional analysis, improves understanding of the defined Technical Requirements and the relationships among them (e.g., functional, behavioral, time-related) by creating and analyzing functional architectures

- Design solution process translates the outputs of the Stakeholder Requirements Definition and Requirements Analysis processes into alternative design solutions, physical architectures and a final design solution (set of Solution-Specified Requirements)
- Implementation process includes the detailed design down to the lowest level system elements in the system architecture, and the fabrication/production procedures of forming, joining, and finishing, or coding for software
- Integration process incorporates lower-level system elements into higher-level subsystems and systems
- Verification process confirms that a system element meets its design-to or build-to specifications
- Validation process confirms that a system element meets its Stakeholder Requirements
- Transition process moves the system element to the next stage of development, or for the end-item system, to the user

Technical Management Processes:

- Technical planning process ensures the proper application of SE processes
- Requirements management process provides traceability, back to user-defined capabilities and needs
- Interface management process ensures interface definition and compliance among the elements that compose the system as well as with other systems with which the system or system elements must interoperate
- Risk management process examines the technical risks of deviating from the program plan
- Configuration management process establishes and maintains consistency of a product's attributes with its requirements and product configuration information
- Technical data management process plans for acquiring, accessing, managing, protecting and using data of a technical nature to support the total life cycle of the system
- Technical assessment process measures technical progress and the effectiveness of plans and requirements (Key technical assessment tools include earned value management (EVM), technical performance measurement (TPM) and Technical Reviews.)
- Decision analysis process provides the basis for evaluating and selecting technical alternatives when decisions need to be made

3.4.3.2 Systems Engineering Inputs, Outputs, and Controls

Organizations should be able to provide evidence that quality personnel are involved with the SE process for the development of inputs, outputs, and controls and can meet the requirements for a higher-level QMS. A good source of information on Inputs and Outputs comes from the Advanced Product Quality Planning process. Inputs, outputs, and controls change over time as product development moves from user requirements identified and defined, to concept development, prototyping, testing, and then to production.

Inputs include the requirements or information which define the performance, safety, reliability, maintainability, producibility, manufacturability and other capabilities that the design team needs to create the design and plan for the development of the product. These inputs can come from many sources.

- Customer requirements which get translated into product design (The product design evolves into functional, physical, and performance inputs and outputs)
- Product and technical information from like products or adversary capabilities
- Laws, regulations, guidance and technical standards as applicable
- Technical risk to include design constraints

Outputs are often the product of Input activities

- The design, drawings, technical data packages,
- Test and other verification results
- Change documentation
- Improvement plans

Controls include all of the verification and validation activities that are used to ensure that the product meets the contractual and technical requirements. Technical Reviews and Audits are formal activities that are performed throughout the life cycle of a products development and deployment. Organizations should provide evidence that they are managing and controlling their design and development processes and have established key performance metrics with goals they are tracking. Technical reviews and audits are described in ISO/IEC/IEEE 24748-8. Technical reviews and audits include:

- Program and technical documentation
- Testing and test results
- Initial Technical Review (ITR)
- Alternative System Review (ASR)

- System Requirements Review (SRR)
- Technology Readiness Assessment (TRA)
- Integrated Baseline Review (IBR)
- System Functional Review (SFR)
- Preliminary Design Review (PDR)
- Pre-Engineering, Manufacturing & Development (EMD) Review
- Critical Design Review (CDR)
- Test Readiness Review (TRR)
- Flight Readiness Review (FRR)
- System Verification Audit (SVA)
- Functional Configuration Review (FCR)
- Production Readiness Review (PRR)
- Operational Test Readiness Review (OTRR)
- Physical Configuration Audit (PCA)
- In-Service Review (ISR)

See also the DoW Systems Engineering Guidebook and the DoD Producibility and Manufacturability Engineering Guide.

3.4.4 Subcontractor/Vendor Control

The contractor (prime and below) is responsible for ensuring that all supplies and services procured for their suppliers conform to the contract requirements. This includes subcontractors and vendors to have a quality system that conforms to contract and subcontract requirements, and for controlling product and service and offering to the Government for acceptance only those products and services that meet all requirements. Organizations should provide evidence that quality personnel are involved with the organization's subcontractor/vendor process described below and can meet the requirements for a higher-level QMS.

Subcontractor/vendor quality control is often delegated to the Defense Contract Management Agency (DCMA) for on-site surveillance.

3.4.4.1 Supplier Evaluation and Selection

Subcontractor, supplier, and vendors control is a key operation since these organizations often provide 70-80 percent of the final product. The process of identifying, assessing, and selecting

suppliers is key to the success of the organization and to balancing, cost, schedule, and performance. Organizations should provide evidence that they are using:

- Criteria-based Selection: Organizations select suppliers based on many factors to include cost, capability, capacity, quality, reliability, location, delivery performance, product performance features, financial stability, and past performance (These criteria are especially important for items that are critical, complex, and/or expensive. See Appendix C, Dimensions of Quality, for other potential selection criteria.)
- Supplier Qualification: Is a systematic assessment of a potential supplier to ensure that the supplier is capable of meeting the organizations contractual requirements
- A balance between many factors to include cost, schedule, and performance to select suppliers

3.4.4.2 Supplier Contractual Requirements and Agreements

Organizations should provide evidence that they have analyzed their product quality requirements at the subcontractor and vendor level and issue contracts with the appropriate contract quality clauses.

- Contractual Requirements: Must be clear and understood by both parties (The agreement or contract should outline the terms and conditions of their business relationship.)
    - A higher level of quality may be required and put on contract
    - Agreements could include specifying the product to be supplied, pricing and payment terms, delivery schedules, quality standards, intellectual property rights, warranties, non-disclosure agreements, dispute resolution, termination clauses, and special considerations such as the implementation of Lean/Six Sigma programs

Contractual Flow Down Requirements: Ensure that the appropriate contract requirements are flowed down to suppliers to include quality clauses as appropriate.

3.4.4.3 Supplier Monitoring and Management

Organizations should provide evidence that they are monitoring and managing product quality requirements at the subcontractor and vendor level.

- Supplier Inspections and testing are conducted, documented and managed as necessary (see section 3.5.3, Inspection and Testing)
- Supplier Audits are conducted, documented, and managed as necessary (see section 3.5.4, Audits: Internal and External)

3.4.4.4 Supplier Corrective Action and Preventions

Organizations should provide evidence that they are monitoring and managing the supplier's processes for taking corrective action and promoting prevention instead of appraisal. Organizations at the subcontractor and vendor level need to issue contracts with the appropriate contract quality clauses.

- Address incoming non-conforming material (see section 3.6.1 Nonconforming Material Control)
- Address field failures, reliability issues, and warranty items

3.4.4.5 Supplier Quality Metrics and Key Performance Indicators

Organizations should provide evidence that they have developed and implemented a process for identifying and assessing supplier quality metrics and KPIs. Below is a list of some quality and quality related KPIs that could be used to assess and manage supplier quality:

- Customer Satisfaction
- On-time Delivery
- First time Quality or First Pass Yield Rates
- Defect/Yield Rates
- Process Efficiency
- Cost of Quality
- Lead times
- Corrective Action Rates, and others
- Supplier Performance
- Return Rates
- Field Complaints
- Warranty Costs
- Audit Findings
- Employee Satisfaction and Retainment
- Quality Risk Reduction Efforts

For more information, refer to the DoD Supply Chain Metrics Guide.

3.4.4.6 Supplier Continuous Improvement

Organizations should provide evidence that they have initiated, are analyzing and managing requirements for continuous improvement of their QMS at the subcontractor and vendor level. One way is to use the PDCA cycle as described in section 3.3.

3.4.4.7 Supplier Risk Management

Organizations should provide evidence that they have initiated and are analyzing supplier risk management requirements at the subcontractor and vendor level and are accomplishing the following:

- Risk Planning
  - Assigned roles and responsibilities
  - Documented policies, processes and procedures
  - Established traceability of risk to technical and program requirements
  - Determined and are providing resources
- Risk Identification
  - Understands the nature of the product and requirements
  - Has identified and are using various risk methodologies
  - Review various sources of data (previous assessments, cost/schedule/performance information, field data, etc.)
- Risk Analysis
  - Quantify the cost, schedule, and performance impacts
  - Assess the likelihood of the risk being realized
  - Periodically analyze the risk area
- Risk Mitigation
  - Organizations can choose to accept, avoid, transfer, or control the risk
  - Implement the best risk mitigation option
  - Ensure that customers and interested parties are aware of the risk and mitigation efforts
- Risk Monitoring
  - Track the progress of risk mitigation efforts
  - Include appropriate technical performance measures
  - Conduct regular status reviews
  - Document results of risk mitigation efforts

- See the DoD Risk, Issue, and Opportunity Management Guide for Defense Acquisition Programs for additional information on risk management

3.4.5 Production Requirements

Production is the process of transforming raw materials and components into a finished product based on a design or technical data package that meets a specific need or requirement. This process requires an understanding of the capabilities and capacities of the factory floor and the subcontractors and vendors that supply the raw materials and components. Capacity deals with how many units can be produced in a given time period. Thus, if the demand is for 100 units a week, then the capacity needs to be more than 100 a week and the organization should show that the resources are available for production. Capability is the ability to fabricate and assemble the end product. The manpower, machines, materials, methods, and measurement systems should have the capability to produce an end item that meets all of the customers' requirements.

The factory floor environment consists of the 5Ms (manpower, machinery, material, methods, and measurement systems). Production is accomplished in different factory floor environments. These environments include a job shop, disconnected line flow, connected line flow, or continuous flow. The complexity and rate of production should dictate which production environment should be used for production. Production planning begins early in the life cycle of a product and continues through operations and support.

Production also requires a plan that details how the product should be fabricated, assembled, inspected, tested, and delivered. This plan should include cost, schedule, and performance measures in order to assess the efficiency of the production process.

Production planning requires knowledge of the product to include how and where production should take place for the various WBS elements. Planning requires a bill of material or BOM in order to know what is needed (raw materials, components, etc.) and how many are needed to meet production rates and quantities. Organizations need to decide what they should make and what they should buy or purchase from a subcontractor or vendor. Developing an efficient manufacturing flow should be driven in part by the plant layout. The flow should require the development of work instructions or route sheets, to include inspection and testing requirements.

Organizations should provide evidence that they understand the product and are managing production process and that QA managers are a part of these processes as appropriate. The production process consists of several elements of planning, execution, analysis, and follow-up.

3.4.5.1 MRP and ERP Software Tools

Planning and execution activities are often accomplished using Manufacturing Resource Planning (MRP) or Enterprise Resource Planning (ERP) software tools. These tools include:

- Demand Forecasting and Planning
- Sales and Operations Planning
- Master Production Plan and Schedule
    - Rough Cut Capacity Planning: Assesses if there are enough resources (manpower, machines, materials, methods (throughput capacity), and measurement (inspection and testing) capacities to meet planned production requirements
- Material Requirements Planning
    - Capacity Requirements Planning
- Bill of Material Analysis
- Inventory Management
- Production Scheduling and Shop Floor Controls
    - Scheduling/Loading: Allocates jobs to specific work centers; route sheets include the following information:
        - Sequence of Operations
        - Setup
        - Labor and Machine Requirements
        - Queueing and Moving
        - Cycle Time
    - Sequencing: Lays out the flow of the work within the facility
    - Dispatching: Releases the jobs to the work centers
    - Monitoring: Manage the process and understand the planned work vs the actual and take corrective action if necessary
- MRP/ERP Reports
    - Capacity Planning
    - Production Schedule
    - Performance Measures
    - Quality Reports
    - Cost Reports
    - Labor Reports

3.4.5.2 Advanced Product Quality Program

Advanced Product Quality Program (APQP) is a quality planning tool, a structured approach to ensure product quality throughout development and production. APQP begins with initial design and uses cross-functional teams to identify and manage quality throughout the products life. APQP consists of a standardized set of requirements (IATF 16949) for a QMS for the automotive industry for contractors and suppliers to design a product and bring a product to pilot production that satisfies the customer.

Organizations may use some of the following tools to aid in managing and accessing the various activities conducted during the design and build process to include:

- Value Stream Mapping
- Process Failure Modes and Effects Analysis (PFMEA)
- Process Flow Diagrams
- Measurement System Analysis (MSA)
- Process Capability Studies and Statistical Process Control (SPC)
- Control Plans
- 8 Dimensions of Quality
- First Article Inspection (FAI)

APQP consists of five phases that often overlap and run concurrently and include ongoing feedback assessment and corrective action (see also Appendix B).

Each phase of the APQP process has a series of inputs and outputs with the outputs of a phase becoming the inputs to the next phase.

The purpose APQP s to establish:

- Common APQP expectations for the internal and external suppliers
- Common APQP process metrics
- Common program status reporting format
- Roles and responsibilities for APQP elements
- A better understanding of how the APQP elements relate to Product Development and to the development of milestones and the timing

See Appendix B for additional information on the APQP.

3.4.5.3 Production Part Approval Process

The Production Part Approval Process (PPAP) is an output of APQP and provides evidence that the organization properly understands engineering design records and specification requirements, and that contractor's manufacturing processes are capable of producing products that consistently meet all requirements during an actual production run at the quoted production rate.

PPAP is a standardized process developed by the Automotive Industry Action Group (AAIG) to ensure that products from suppliers meet all contract and specification requirements and provides documentation demonstrating conformance to requirements. The PPAP process is required prior to first production pf a new product, or production that involves changes to materials, processes, suppliers, product modifications, of restart of production after twelve months.

PPAP includes 18 elements. Organizations should be able to provide evidence that they are following the PPAP process below to include:

- Design Records and Documentation
- Authorized Engineering Change Documents
- Customer Engineering Approval
- Design Failure Modes and Effects Analysis (DFMEA)
- Process Flow diagrams
- Process Failure Modes and Effects Analysis (PFMEA)
- Control Plan
- Measurement System Analysis Studies (includers Gage R&R studies)
- Dimensional Records
- Records of Material/Performance Test Results
- Initial Process Studies (includes SPC charts on Critical Characteristics or KCs)
- Qualified Laboratory Documentation
- Appearance Approval Report
- Sample Production Parts
- Master Sample
- Checking Aids
- Customer Specific Requirements
- Part Submission Warrant

3.4.5.4 Materials and Material Control

Materials and material control is concerned with ensuring that the materials used in the production of a product ensure that the product meets customer requirements and satisfy its intended purpose. This includes having the right materials, at the right time, in the right quantities, and the right qualities.

Organizations should provide evidence that they are managing the material planning and execution process.

Material planning and executing includes:

- Make/Buy Decisions
- Subcontract/Purchase Order Provisions
- Inspection and Testing
- Inventory Control
- Material Handling
- Material Release
- Material KPIs

3.4.5.5 Production Fabrication and Assembly

Fabrication and assembly are distinct terms that are related to the process of creating an end item.

Fabrication is the transformation of raw materials into components that are used during the assembly process. Fabrication creates components. Fabrication involves many different processes used to cut, bend, weld, machine or otherwise shape raw materials into components.

Assembly is the process of joining components or subassemblies into higher-level products. Assembly puts together the components.

Organizations should be able to provide evidence that they are managing and controlling production fabrication and assembly.

- Production Scheduling and Shop Floor Controls
  - Scheduling/Loading: Allocates jobs to specific work centers
- Sequence of Operations
  - Setup

  - Labor and Machine Requirements
  - Queueing and Moving
  - Cycle Time
- Sequencing: Lays out the flow of the work within the facility
- Dispatching: Releases the jobs to the work centers
- Monitoring: Manage the process and understand the planned work vs the actual and take corrective action if necessary
- MRP/ERP Reports
  - Capacity Planning
  - Production Schedule
  - Performance Measures
  - Quality Reports
  - Cost Reports
  - Labor Reports
- Shop Floor Environmental Controls (HVAC, water, electricity, etc.,)
- Environmental, Safety, and Occupational Health Compliance
  - NEPA and NEPA Compliance Schedule
  - Pollution Prevention
  - Systems Safety
  - Hazardous Material Management
  - Programmatic ESHO Evaluation (PESHE)
- FOD control

3.4.5.6 Inspection, Testing, and Traceability

Inspection means examining and testing supplies or services (including, when appropriate, raw materials, components, and intermediate assemblies) to determine whether they conform to contract requirements.

Production Inspection and testing should include a systematic approach to verifying that all products meet specified criteria, starting with incoming materials, including in-process checks, and final release and acceptance. This approach should include an assessment of quality plans, calibration procedures and equipment, rained personnel, and documented records of conformity, ensuring consistent quality across the entire lifecycle.

Organizations should provide evidence that they are managing and controlling inspection and testing and are able to provide traceability of the inspection and test results.

When and where to inspect/test:

- Pre-production with receiving inspection of incoming parts or at the supplier's facility
- In-process inspections and testing during the manufacturing process
- Acceptance inspection and testing or end item or final inspection

Inspection or testing methods:

- Visual Inspection: A non-destructive method of examining products using human senses using simple aids like magnifiers, cameras, lights, etc., to detect surface defects, damage, or irregularities for quality control, safety, and maintenance, ranging from basic naked-eye checks to advanced
- Dimensional Inspection: Involves the measuring a part or product's physical geometric characteristics to ensure they comply with the specified standards and tolerances outlined in engineering drawings or CAD models
- Sampling Inspection: Involves the assessment of a random subset (sample) of items from a large batch (lot) which is inspected to determine the quality of the entire lot and uses established plans (like ISO 2859 with AQLs) with acceptance/rejection criteria for single or multiple samples, adjusting for good or bad quality to protect consumers and producers
- Functional Testing: Focuses on verifying features against requirements using methods like unit tests, boundary value analysis, and risk-based approaches to ensure product quality, safety, and performance in real-world scenarios
- Non-destructive Testing: Involves assessing materials, components, or structures for flaws and defects without causing damage, using methods such as ultrasound, radiography, magnetic particle, eddy current, and liquid penetrant testing to find cracks, voids, or corrosion invisible to the eye, crucial for quality control and preventing failures
- Compliance Testing: Involves verifying that a system, product, or organization adheres to contractual requirements or industry standards (like SAE AS9100) ensuring controls are effective through risk assessment, structured testing, issue management, and continuous monitoring
- First Article Inspection (FAI): Involves a rigorous quality assessment on the first part (or sample) from a new production run to confirm it meets all design, engineering, and specification requirements before mass production starts, verifying tooling, processes, and materials, and preventing costly errors, common in aerospace/automotive, triggered by new parts, design changes, or process shifts

- First Article Testing (FAT): Involves a rigorous contractor assessment of a first product sample (the “first article”) against all design specs before full production, ensuring the process works, documentation is correct, and quality is consistent (The assessment confirms the ability to meet requirements, involves detailed measurement, testing, documentation and results in official approval or rejection before mass production begins.)
- Production Lot Testing: Used to validate quality conformance of products prior to lot acceptance (The product specialist should review the ESA testing requirements for completeness, accuracy, and applicability; coordinate any changes with the ESA; and enter the testing requirements in the material master.)
- Final Inspection: Used as a critical last check ensuring finished products meet all specified requirements before shipment, confirming all prior checks (raw materials, in-process) were done and documented, involving performance, appearance, and completeness checks, and preventing customer dissatisfaction by verifying conformance to quality plans and standards

Product quality should be assessed against predefined standards, which may be based on customer requirements, industry norms, or regulatory compliance and the status of inspections and tests should be documented, evident, and traceable throughout the production process.

Inspection and Test Records (ITRs) are the documented results of inspections or tests that are conducted during production and should include appropriate records at subcontractor and vendor facilities. Organizations should be able to provide all inspection and test records, identify when and where they were performed, what item, component, or WBS level the inspection or test relates to, and the status of the inspection or test (pass/fail/etc.).

Inspections and tests are conducted against drawings and technical data packages (TDP) to ensure that the product is manufactured according to the design specifications and requirements. The TDP defines the physical and functional characteristics of a configuration item and lower-level items. The TDP is a set of documents that define the design, configuration, performance requirements, and manufacturing processes for a specific product. The TDP could include 2D drawings, 3D models, specifications, bill of materials or parts lists, material requirements, work instructions, quality assurance criteria, and packaging information.

Inspection/Test traceability is the requirement to be able to document and trace inspection and test results from the origination to end-use, thus creating an audit trail of materials, processes, and quality checks. The Warfighting Acquisition University (WarU) addresses traceability during inspection and testing as follows:

- Requirements Management: WarU promotes bi-directional traceability in Requirements Management to link system-level requirements to lower-level requirements and system element designs; this allows for an analytical understanding of the impact of changes and ensures that all requirements are addressed
- System Performance Specifications: WarU recommends that System Performance Specifications include a “Verification” section outlining inspections needed to verify conformance to requirements; this verification can be done through analysis, demonstration, examination, or testing, and should be traceable back to the requirements
- Test and Evaluation: WarU’s guidance on test and evaluation (T&E) focuses on characterizing system capabilities, verifying requirements, and informing decision-makers; this process involves planning, execution, and evaluation, where traceability is crucial for linking test results back to the original requirements
- Quality Assurance: WarU’s resources on Quality Assurance emphasize the importance of ensuring that supplies or services conform to contract quality requirements through inspection and testing; the Government relies on the contractor to perform this function, highlighting the importance of contractor traceability in these processes
- Traceability Documentation: WarU guidance on traceability documentation, such as DLAD 11.392, specifies the need for proper documentation to support the tracing of items and activities; this is particularly relevant for situations where there are traceability concerns or when product verification testing is invoked

Measuring and Test Equipment (M&TE) refers to the tools, gauges, instruments, devices, or systems used to inspect, test, calibrate, or measure parameters during the development, production, and maintenance of defense systems. This includes both general-purpose and special-purpose equipment, as well as Automatic Test Equipment (ATE). The proper selection, calibration, maintenance, and use of M&TE are crucial for ensuring the quality and reliability of defense products.

MIL-STD-1839D outlines the requirements to provide a means for calibration and measurement traceability of all system, subsystem, and equipment to ensure accuracy and traceability. Organizations should provide evidence that they are managing and controlling M&TE. All M&TEs need to be identified and managed.

Identification includes:

- A unique identification: All M&TE should have a unique identification number for proper tracking

- Calibration status is evident: Equipment should be identified with a label or sticker indicating its calibration status, including the date of calibration and the next due date (This identification should be clear and visible to users.)
- Non-conforming M&TE s: Instruments that do not meet calibration requirements should be identified (e.g., with a red sticker) and segregated

Management:

- Calibration: M&TE should be calibrated regularly to maintain accuracy within specified limits and according to industry standards (The frequency of calibration depends on factors like usage frequency, criticalness of measurements, and industry regulations.)
- Documentation and record-keeping: Maintain detailed records for each M&TE, including purchase orders, maintenance records, calibration data, standard operating procedures, and usage logs
- Maintenance: Implement a program of routine maintenance actions (cleaning, lubrication, adjusting, etc.) to keep M&TE in good working order
- Proper handling and usage: Train personnel on the correct procedures for handling and using equipment to prevent damage and ensure accurate results
- Traceability: Ensure that calibration for each M&TE is traceable to national or international standards
- Secure storage: MTEs should be stored properly in a designated area (e.g., a gauge room) to prevent M&TE damage and unauthorized use

3.4.5.7 Nonconforming Material Control

Nonconforming material refers to any product, component, or material that fails to meet the specified requirements, whether defined by design, process, or standards.

Organizations should provide evidence that they are managing and controlling products that do not conform to specified requirements. Organizations should address the identification, documentation, evaluation, segregation, and disposition of NCM products. The evaluation of nonconformance should include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance.

Organizations should provide and maintain an inspection system acceptable to the Government and should tender to the Government for acceptance only supplies that have been inspected in accordance with the inspection system and have been found by the Contractor to be in conformity with contract requirements. As part of the system, the Contractor should prepare records, evidencing all inspections made under the system and the outcome. These records

should be kept complete and made available to the Government during contract performance and for as long afterwards as the contract requires. The Government may perform reviews and evaluations as reasonably necessary to ascertain compliance with this paragraph. These reviews and evaluations should be conducted in a manner that should not unduly delay the contract work.

Supplies are nonconforming when they are defective in material or workmanship or are otherwise not in conformity with contract requirements. The Government has the right either to reject or to require correction of nonconforming supplies.

Organizations should have a plan to effectively control and reduce nonconforming material which could include:

- Identification of Nonconformance: Nonconforming material should be identified through inspections, quality audits, customer complaints, or employee reports
- Documentation: Nonconforming material needs to be documented which should include details about the nature and extent of the nonconformance, its location and the individuals or processes involved
- Evaluation and Investigation: Organizations should investigate the root causes of the nonconformance. This involves conducting a thorough analysis to determine why the nonconformance occurred
- Containment: Nonconforming material should develop procedures to prevent NCM from reaching customers or continuing in the manufacturing process
- Corrective Actions: Organizations should implement corrective actions to address deficiencies and prevent similar nonconformances in the future
- Verification of Effectiveness: Corrective actions should be assessed to ensure that the nonconformance has been resolved or mitigated
- Preventive Actions: Organizations should develop and implement preventive actions to proactively address potential sources of nonconformance and prevent future occurrences
- Documentation and Reporting: Nonconforming materials should be documented and maintained for compliance purposes and future reference

3.4.5.8 Production Acceptance and Release

Product acceptance constitutes acknowledgment that the product conforms to contract requirements, is fit for use, and conforms to product specifications. Acceptance criteria should be predefined conditions or requirements that a product should fulfill to gain acceptance from both the customer and the user.

Organizations should provide evidence that they have a process for managing and controlling production acceptance and release.

Product acceptance and release often occur at the end of the line, after the product has finished fabrication, assembly, inspection, and testing and is ready for delivery to the customer. In order to do this, the organization should provide documented evidence that the product conforms to all requirements defined by the customer, often contained in the contract or TDP. The documented evidence should be traceable to the individual making the acceptance decision and that individual has the training and authority to make the acceptance decision. Traceability also includes the need to be able to trace the production process from start to finish, detailing in some cases the identification of raw material and tracking of that raw material by lot to the final customer. This could include the tracking of serial numbers, batches, or other methods of identification allowing the ability to trace what parts, processes, materials, etc. went into a specific product.

Note: Final acceptance usually involves many in-process inspections, tests, and reviews.

3.4.5.9 Government-Owned or Government-Furnished Property

Government owned or furnished property is any property that the Government has furnished to the organization for performance of a contract. This includes:

- Government-Furnished Property (GFP): Property provided by the government to a contractor
- Government-Furnished Equipment (GFE): Equipment provided by the government to a contractor
- Government-Furnished Material (GFM): Material provided by the government to a contractor
- Contractor Acquired Property (CAP): Property that the contractor has purchased or fabricated but the government retains title

Organizations should be able to provide evidence that they are identifying, managing, and controlling government owned material or property, this includes the requirement to:

- Identify: Government owned property or material should identify the owner and maintain traceability to the property or material throughout the production cycle and must be authorized for use on the product being produced
- Protect: Government owned property or material should be protected from any damage, loss, or misuse while in the control of the organization (This includes the requirement to ensure that the property or material is stored, moved, handled, and used correctly.)

- Document: Organizations need to document and maintain records the detain the receipt, usage, and return of Government owned property or material
- Return Instructions: Government-owned property or material should be returned to the Government after completion of the contract or when it is determined to be excess or unused

3.4.5.10 Document Control

Document control refers to the processes and systems in place for managing and controlling documents related to acquisition programs. This includes creating, storing, organizing, tracking, and distributing documents to ensure they are readily available and accurate throughout the acquisition lifecycle. Document control is a key aspect of effective program management and acquisition.

Organizations should provide evidence that they are managing, maintaining, controlling, and making available to the Government all appropriate documents.

Document control procedures should consider the following:

- Procedures should ensure that the document numbering system includes the process number, document type, incremental number, and revision number
- The procedures should describe the approval process and ensure that the right approval levels are based on the document type and/or change content
- The procedure should describe how revisions should be controlled and disseminated
- The procedure should describe how documents should be made available at the point of use. This could include documents that are electronic or hard copy
- The procedure should describe how the content of a document is not altered or changed
- The procedure should describe how documents should be managed, the retention period, and record retention
- The procedure should describe how to handle obsolete documents and retirement of documents

Documents that should be managed and controlled include:

- Policies and Procedures
- Calibration and Metrology of Measuring and Test Equipment
- Employee Records for Training and Competence
- Design and Development Inputs, Outputs, and Controls

- Key/Critical Manufacturing Processes
- Government Property or Material
- Inspection and Test Results
- Nonconforming Material Records
- Corrective Actions and Continuous Improvement
- Internal/External Audits
- Management and Program Reviews and Audits

Every day, businesses deal with countless documents, such as contracts, invoices, vendor agreements and employee information that come in various file formats. Document control is the establishment of a systematic process for managing documents throughout the life cycle. This includes the creation, review, approval, revisions, storage, distribution, access, version control, and document governance, including disposal.

Documents control includes the following:

- Identifying what documents need to be controlled
- Identifying who controls the documents
- Identifying when the documents are created
- Identifying where the documents should be stored
- Identifying how the documents should be accessed or distributed

Documents and the document control are important for the following reasons:

- Provides evidence of conformance to quality standards and regulatory requirements
- Ensures the traceability of a product through all stages of production, from receiving inspection to delivery
- Validates supplier documentation of product quality
- Ensures the review and feedback of field documenting performance over time
- Demonstrates continuous improvement
- Captures audits results, deficiencies and corrective actions

Documents need to be controlled in order to ensure that:

- People who need access to the information have access to it
- People who do not need the information do not have access to it

Organizations may be required to provide evidence that QA managers are participating in the following activities:

- Quality Policy
- Quality Assurance Plan
- Quality Manuals
- Quality Objectives
- Standard Operating Procedures and Work Instructions
- Inspection and Test Records
- Nonconforming Material Control Processes
- Corrective Action Records
- Manufacturing Change records
- Bill of Materials (BOM)
- Master Production Records
- Training Manuals and Other Material
- Audit Reports
- Engineering and Design Records
- Detailed Drawings and Specifications
- Engineering And Design Change Requests
- Control of proprietary and classified information

3.4.5.11 Special Topics

Special Topics are areas of interest that are not covered by many quality system requirements but are areas of interest and are covered below.

DMSMS/Obsolescence Management

Diminishing Manufacturing Sources and Material Shortages (DMSMS) The loss, or impending loss, of manufacturers of items or suppliers of items or of raw materials. This can be caused by many factors including new or evolving science, detection limits, toxicity values, and regulations related to chemicals and materials resulting in significant impact on the DoW's supply chain and industrial base. This situation may cause shortages that endanger the life-cycle support and capability of the weapon system or equipment or that cause shortages that may endanger an ongoing production capability and/or the life-cycle support of a weapon system or any training, support, or test equipment already in the field. DMSMS issues affect materiel readiness and

operational availability, which, in turn, affect both combat operations and safety. This situation also may cause shortages that endanger the life-cycle support and capability of the weapon system or equipment.

Obsolescence is the lack of availability of an item or raw material resulting from statutory and process changes, as well as new designs. Obsolescence deals with the process or condition by which a piece of equipment becomes no longer useful, or a form and function is no longer current or available for production or repair. Implementation of new technology causes older technology to become less supportable because of the diminished availability of parts and suppliers. Mitigation practices include reviewing proposed parts lists for obsolescence and being proactive in the engineering design process prior to production

DMSMS/Obsolescence is a risk to the life-cycle support and operational availability of weapon systems. Effective DMSMS management requires proactive solutions of obsolescence problems before they adversely affect system availability or total ownership cost (TOC).

Organizations should provide evidence that they are able to identify, implement and manage the DMSMS practices listed below.

- Prepare for DMSMS management operations
- Identify DMSMS issues and create cases to track their status
- Assess the need, timing, and level of resolution for DMSMS issues
- Analyze DMSMS cases to determine the optimal resolutions
- Implement the resolutions

See SD-22 DMSMS Guidebook and SD-26 DMSMS and Parts, Materials, and Process Management Contracting Guide.

Counterfeit Parts or Material

The Counterfeit parts or materiel refers to items that are unauthorized copies or substitutes that have been identified, marked, or altered by a source other than the items' legally authorized supplier or have been misrepresented to be authorized items of the legally authorized supplier. Examples include but are not limited to:

- Used material that is sold as new
- Material represented as having specific capability (e.g., speed, power, temperature, capacity) outside what the Original Manufacturer (OM) specified the part

- Material construction (e.g., anodization, composition) other than the materiel's advertised construction
- Material containing additional features or capabilities not intended by the OM (e.g., added malicious functions, modified firmware, etc.)

Organizations may be required to provide evidence that QA managers are participating in the following activities:

- Prevent the acquisition of counterfeit materiel in the DoW supply chain
- Protect the DoW supply chain prior to delivery of materiel
- Identify and protect counterfeit detection capabilities and mitigation procedures through application of the operations security process, in accordance with DoDM 5205.02; ensure essential information and indicator lists are reviewed and updated in accordance with DoDD 5205.02
- Require remediation for counterfeit materiel discovered after delivery of materiel
- Seek restitution and recover costs incurred from all failures and damages caused by counterfeit materiel

See DoDI 4140.67 DoD Counterfeit Prevention Policy and numerous industry Counterfeit Prevention standardization documents.

Environmental, Safety, and Occupational Health

ESOH encompasses the processes and approaches for addressing laws, regulations, DoW policies, environmental compliance, and hazards associated with environmental impacts, system safety, occupational safety and health, hazardous materials management, and pollution prevention.

ESOH provides a framework which is embedded throughout DoW today in response to several laws:

- Occupational Safety and Health Act of 1970
- NEPA and the NEPA Compliance Schedule
- Pollution Prevention Program – DODI 4715.4
- Systems Safety Program – MIL-STD-882E
- Hazardous Material Management Program – NAS 411
- Toxic Substances Control Act 1976
- Resource Conservation and Recovery Act 1977

- Programmatic Environmental Safety and Health Evaluation Program (PESHE)

Organizations should provide evidence that they are able to plan for, identify, implement and manage the various ESOH programs listed above. These actions should include:

- Identification, assessment, mitigation, and acceptance of ESOH program risks
- Ongoing evaluation of ESOH risks
- Documentation and mitigation of ESOH risks
- ESOH considerations should be included in the Systems Engineering Plan

See DoDD 4715.1E Environmental, Safety, and Occupational Health and other policy documents.

Other

There may be other QA related considerations that should be planned for, managed, assessed, mitigated, and documented that are not listed here but are a concern for the organization. Organizations should be able to provide evidence of their management of the following:

- Corrosion Prevention and Control: The rigorous application of management principles, engineering design and analysis, QA, non-destructive inspection (NDI), manufacturing, operations, and support technologies and practices to prevent the start of corrosion, avoid functional impairment due to corrosion, and define processes for the tracking and repair of corrosion problems (Although not required as an element (e.g., Logistics, T&E, Manpower, Personnel, and Training (MP&T) of DoW Risk Management (RM)), incorporating CPC as part of risk management is an effective way to provide tracking and mitigation of corrosion for the system/equipment)
- Additive Manufacturing includes various processes for the joining materials to make parts from three-dimensional model data, usually layer by layer, also known as three-dimensional printing
- Advanced Manufacturing is a concept that further encompasses the areas listed below:
    - Advanced Materials: Any new or significantly improved material that provides a distinct advantage in (physical or functional) performance when compared to conventional materials
    - Advanced Composite Materials: Materials that are characterized by unusually high strength fibers with unusually high stiffness, or modulus of elasticity characteristics, compared to other materials, while bound together by weaker matrices.

- Robotics and Automation: Automation is the process of using technology to perform tasks without direct human intervention, while robotics is the design and use of robots to perform tasks; automation is a broader concept that includes robotics, but the two are often used together to improve productivity, quality, and safety
- Laser, Machining and Welding (Laser technologies that enable manufacturers to create products with high accuracy and efficiency for cutting, engraving, marking, welding, or other industrial applications. Advanced machining processes are those machining processes that are different from current conventional machining processes. Advanced welding is the use of new techniques including plasma welding, which has four times the energy density of TIG welding, and electron beam welding, which uses an electron gun to melt and bond workpieces together. Other advanced welding processes include friction stir welding, explosive welding, ultrasonic welding, and laser welding)
- Nanotechnology: The study and manipulation of matter at the nanoscale, which is a size range of about 1 to 100 nanometers; at this scale, matter exhibits unique physical, chemical, and biological properties

Organizations should provide evidence that they are able to plan for, identify, implement, and manage the various considerations listed above. These actions should include:

- Identification, assessment, mitigation, and acceptance of risks
- Ongoing evaluation of risks
- Documentation and mitigation of risks

3.5 Check (Performance Evaluation)

Performance evaluation can go by many names, such as checking, measuring, etc., and is the process of assessing the effectiveness of the many manufacturing and quality processes. These assessments should be based on established performance goals, objectives of other requirements criteria, and should measure the progress to the goals, objectives, or requirements. These assessments may be one time or ongoing.

Performance evaluations may be focused on objective or subjective goals, objectives or other requirements.

- Objective evaluations are factual and used to assess products and processes that can be proved through observation, measurement, or testing (These evaluations are consistent using standard tools and methods and do not vary based on the observer. Data captured

on the factory floor, such as quality inspection records, are usually objective. Thus, different people using a standard process should all produce the same results.)

- Subjective evaluations use personal experience to assess products and processes based on feelings, opinions, or perceptions (These evaluations may vary between individuals and might not be observed the same by other individuals. Many measurements related to leadership, commitment to the customer and other QMS elements are subjective. It is difficult to measure or assess employee satisfaction or commitment to quality for example.)

Organizations may be required to provide evidence that QA managers are managing performance evaluations and are meeting the requirements listed below. These evaluations may include KPIs.

Appendix D includes a list of tools that quality personnel can use to conduct various performance evaluations.

3.5.1 Product Quality

Product quality provisions are called out by contract, agreement, specification, or other customer documentation. Product quality includes the characteristics and features of a product that determine the products ability to meet and satisfy customer requirements and perform its intended function. Product quality should include identifying and defining the acceptable product standards. Organizations should provide evidence that they are meeting the intent of contract quality requirements for product quality and are meeting the requirements listed below.

- Conformity to product specifications
- Conformity to testing requirements
- Conformity to performance requirements
- Product durability and reliability
- Product maintainability and sustainability

Product quality evaluations may include some of the following metrics, and data.

- Dimensional measurements
- Performance measurements
- Material properties
- Inspection and testing data
- Statistical process control (SPC) data
- Scrap, rework and return

- Cost of quality
- Etc.

Product quality evaluations may include some of the following KPIs (many of these apply to process quality also).

- Throughput
- Cycle Time or Takt Time
- Changeover Time
- Production Downtime
- Overall Equipment Efficiency
- Cost of Quality
- First Time Quality
- Yield Rate
- Scrap, Rework and Repair Rate
- Receiving Inspection Acceptance Rate
- Customer Satisfaction
  - On-time Delivery
  - Customer Complaint Rate
- Nonconformities
- Audit Findings
- Reportable Incidents

3.5.2 Process Quality

Process quality provisions are called out by contract, agreement, specification, standards, procedures, work instructions, or other customer documentation. Process quality refers to the ability of a process to effectively and efficiently produce an end item that meets customer needs or requirements. Process quality follows the SIPOC (Supplier, Input, Process, Output, and Customers) model. The graphic below shows just some of the potential elements of the SIPOC model for a factory environment. These SIPOC elements should be evident in all four factory floor process models (Job Shop, Batch, Connected, and Continuous lines).

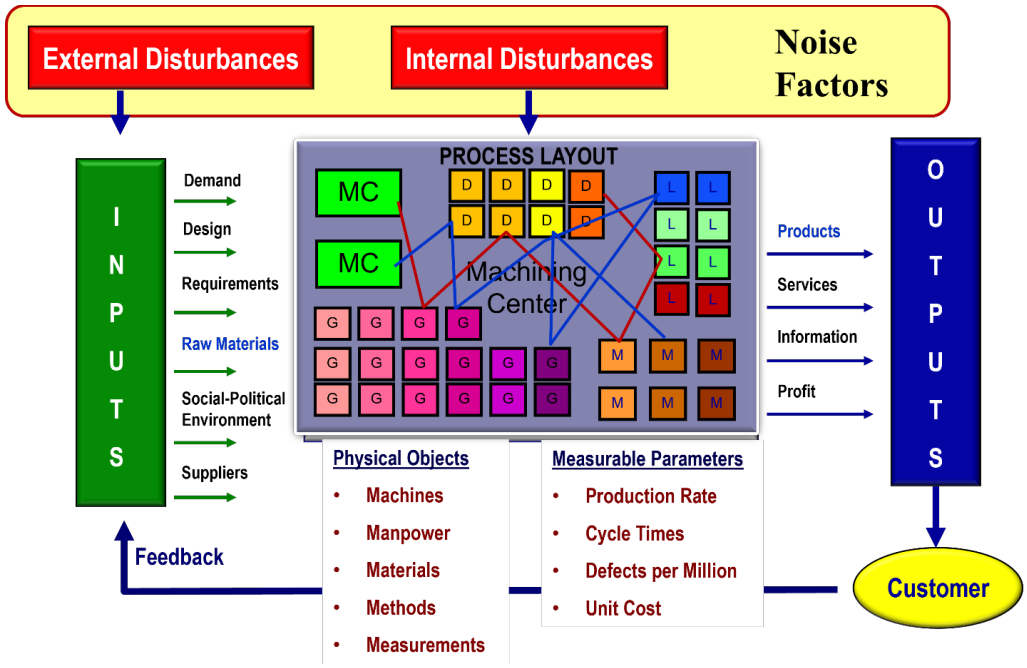


Figure 3-7. Factory Inputs, Processes, and Outputs

A manufacturing process is not, by nature, in a state of statistical control. Control can only be achieved through dedicated effort. One of the requirements of a manufacturing organization is to study a process and see what that process yields. By collecting data and arranging that data into a histogram, the engineer is able to get a picture of the process. A process has three features: how much variation (spread), where (centering), and shape (normal, skewed, bimodal, etc.). If the process is stable, then these features should remain constant and predictable over time. If the process is unstable, then these features should change, and the output should become unpredictable. If the goal of manufacturing is to achieve uniform, defect-free products, then it becomes the job of the engineering team to reduce or eliminate the sources of variation.

Process quality focuses on the methods and procedures used to create that product or service, aiming for efficiency, consistency, and adherence to standards. Organizations should provide evidence (data) that they are meeting the intent of contract quality requirements for process quality. Process quality evaluations may include some of the following process areas, metrics, data, and KPIs:

- Process quality provisions and system performance
- Process knowledge
- Process controls
- Acceptable process standards and adherence to procedures
- Product quality is driven by the processes used to create the product

- Covers the entire quality system and production processes

3.5.2.1 Risk-Based Thinking

Defense programs encounter risks and issues that should be anticipated and addressed on a continuing basis. Risk is the chance that a future event could result in loss, injury, or other adverse circumstances that could impact cost, schedule, and/or performance. Risk and issue management are closely related and use similar processes. Opportunity management is complementary to risk management and helps achieve should-cost objectives. Risks, Issues and Opportunities may be in areas including, but not limited to, technology, integration, cybersecurity, quality, manufacturing, logistics, requirements, software, test and reliability

Organizations should provide evidence that they are meeting the intent of contract quality requirements and are applying the risk management process to the program and product.

The DoD Risk Management Model is composed of five stages:

1. Risk Planning: Does the organization have a risk management process and is it effective?

2. Risk Identification: Does the organization have a risk identification process and is it continuously updated?

3. Risk Analysis: Does the organization conduct risk analysis to assess the likelihood of occurrence and consequence of the risk?

4. Risk Handling (Mitigation): Does the organization identify their process for determining how the risk should be managed (accept, avoid, transfer, or mitigate)?

5. Risk Monitoring: Does the organization track the progress of risk mitigation to ensure that the risk is changing in a positive direction?

The DoD risk management process examines all of the potential sources of risks and for manufacturing and quality it includes assessments of risks as often accomplished using the Manufacturing Readiness Level (MRL) assessment model and criteria.

3.5.3 Inspection and Testing

The FAR 52.246-2 Inspection of Supplies discusses inspection and testing requirements and states:

> *"The Contractor shall provide and maintain an inspection system acceptable to the Government covering supplies under this contract and shall tender to the Government for acceptance only supplies that have been inspected in accordance with the inspection*

system and have been found by the Contractor to be in conformity with contract requirements. As part of the system, the Contractor shall prepare records evidencing all inspections made under the system and the outcome. These records shall be kept complete and made available to the Government during contract performance and for as long afterwards as the contract requires. The Government may perform reviews and evaluations as reasonably necessary to ascertain compliance with this paragraph. These reviews and evaluations shall be conducted in a manner that will not unduly delay the contract work. The right of review, whether exercised or not, does not relieve the Contractor of the obligations under the contract."

Inspection is an examination of the item (hardware and software) and associated descriptive documentation that compares appropriate characteristics with predetermined standards to determine conformance to requirements without the use of special laboratory equipment or procedures.

Testing is a technical means for examining the properties or elements of products, or components, including functional operation, by applying established scientific principles and procedures.

Organizations should provide evidence that they are meeting the intent of contract quality requirements and are applying inspection and testing to verify products at various stages of production and to accept products at the end of production. Examples of inspection and testing activities include:

- Indication of inspection status
- Identification and control of nonconformances
  - Type 1 and Type 2 errors
- Receiving/Incoming inspection
  - Kind, Count, and Condition
- First Article Test (FAT) See AS9102 *Aerospace First Article Inspection Requirement or other*
- Production Lot Test (PLT) (May be called Lot Acceptance Test (LAT) or Ammo Lot Test)
- Visual inspection
- Measurement with tools/gauges/instruments
- Witness events (test, torque, destructive test)
- Non-Destructive Testing (NDT)

- Review of contractor inspection records (Verification)

3.5.4 Audits (Internal and External)

Organizations should provide evidence that quality planning activities include the conduct of audits.

3.5.5 Airworthiness Assessment

Airworthiness certification data should include the following:

- Reliability, quality, and manufacturing program plans
- Contractor policies and procedures
- Durability and damage tolerance control plans
- Work instructions
- Process specifications
- Production/assembly progress reports
- Quality records
- Defect/failure data
- Failure modes, effects, and criticality analysis (FMECA) documentation
- Tech data package
- As-built list to include part numbers/serial numbers for all critical components
- List of deviations/waivers and unincorporated design changes
- List of approved class I engineering change proposals (ECPs)
- Proposed DD Form 250, Material Inspection and Receiving Report
- Configuration management plans/process description documents
- Test reports and Test plans

M&Q functions should:

- Verify that key product characteristics (including CCs) have been identified
- Verify that all critical process capabilities exist to meet key product characteristic requirements
- Verify that all critical process controls exist to assure key product characteristic requirements (including CCs) are met
- Verify that the as-built configuration matches the as-designed configuration

- Verify that nondestructive inspection (NDI) processes have been validated to assure conforming parts

3.5.6 Monitoring and Measuring (Systems and Processes)

Measuring is essential to ensuring that product conforms to requirements. In order to accomplish this the organization needs equipment, tools, and processes needed to establish, manage, and manage reliable measurement resources that are calibrated and capable of measuring and monitoring product and processes. Monitoring and measuring equipment, tools, and processes are essential to ensuring that produce meets product and quality requirements. M&M requirements are integral to evidence-based decision making. These processes include:

- Monitoring: Is a process used to collect, observe, record, and store/manage data (Monitoring is a form of surveillance that involves the continuous observation of data to identify trends, changes and identify risks and issues. Monitoring could employ such quality tools as pareto charts, fishbone charts, control charts, etc.)
- Measuring: Is a physical process used to collect, observe, and record actual physical values and characteristics (Measuring requires the use of instruments to take readings, conduct tests, and collect data for analysis and action.)

M&M requires the establishment of processes that use measurement systems to capture measurements and document measurements in order to ensure products meet customer requirements. M&M processes require the implementation of inspection, testing, and evaluations using measurement equipment that has been calibrated, and is traceable to known standards. Organizations should provide evidence that they are managing their M&M procedures by:

- Identifying what and where M&M should be required
- Identifying what M&M equipment or other resources are required
- Identifying the processes that should be used to M&M to include calibration
- Ensuring that the M&M resources are calibrated and able to verify the data
- Ensuring that M&M resources are appropriate for the type of measurements that should be required
- Ensuring that M&M resources have the necessary accuracy and precision needed for all required measurements and those resources should be calibrated and maintained over determined periods
- Ensure that M&M resources are maintained
- Identifying how M&M data should be collected, who should be collecting the data

- Identifying how the calibration and measurement data should be managed, and that the data is traceable to known standards, and traceable over time
- Ensuring that all M&M resources have provisions for the proper storage, handling, and protection of those resources from loss of accuracy due to damage, negligence, or deterioration over time
- Ensuring that the calibration status for all M&M resources is clearly identified
- Identifying how M&M data should be collected, reviewed and analyzed, and who should do it
- Ensure that all records associated with M&M processes are documented and traceable
- Ensuring that there are procedures for the management of M&M resources that are found to be nonconforming
- Ensuring that there are procedures for getting those nonconforming resources back into conformance
- Evaluating all products and processes that were evaluated using nonconforming M&M resources
- Identifying how M&M data should be used to control processes and output to satisfy customer requirements

Process control plans should also address the measurement system and its ability to accurately ensure product conformance to specifications.

3.5.6.1 Measurement System Analysis

Measurement Systems Analysis (MSA)/Gage R&R: All manufacturing processes and products exhibit variation. Variation that in some instances could cause the product to be rejected and reworked or replaced at great expense. The assumption is that the variation is in the product, but that is not true, some of the variation exists within the measurement system. If the measurement system is not assessed, then it is possible to reject the product is compliant or to accept a product that is nonconforming.

It is the role of the quality organization to determine if the product and associated processes can deliver conforming products. Measurement systems analysis is a scientific method of determining how much of the variation measured exists withing the measurement process or tool as opposed to the variation that exists within the product itself.

Organizations should provide evidence that they are managing the following:

- Accuracy: Measures how close the measurements are to the true value

- Precision: Measures how close the measurement systems are to each other when repeated
- Repeatability: Measures the variation within a single operator's measurements
- Reproducibility: Measures the variation between different operators
- How much of the variation exists within the tool or equipment
- How much of the variation exists within the individuals performing the measurements
- How much of the variation exists within the measurement process

MSA is a data driven process. Decision making and data go hand-in-hand, and the quality of the measurements from which the data is derived is important. Factors like measurement selection, calibration, and gage repeatability and reproducibility directly influence the process output and should be evaluated as part of overall process capability and control planning. MSA evaluates the test method, measuring instruments, and the entire measurement process to ensure the integrity of the data used for analysis and to understand the implications of measurement error on decisions made about a product or process. These MSA techniques are often called Gage R&R (repeatability and reproducibility) studies.

3.5.7 Management Reviews

Senior leadership and management are responsible for the performance of the organization and the success of the product in meeting customer requirements. During the design, development, production, and sustainment of the product, there are numerous program and technical reviews and audits, as well as other activities that may be documented on a daily, weekly, or monthly basis. Many of these documents may be called out by contract as a requirement or a Data Item Description (DID) (see Section 2).

Organizations should provide evidence that they are reviewing the program and technical performance of the organization. Failure of QA managers to participate in the following documents could result in important QA requirements not being considered. Documentation associated with product lifecycle could include:

- Acquisition Strategy
- Systems Engineering Plan
- Contracting Strategy
  - Request for Proposals
  - Source Selection Plans
- Product Support Strategy
- Acquisition Program Baseline
- Integrated Master Plan

- Test and Evaluation Master Plan
- Life Cycle Sustainment Plan
- Environmental Safety and Occupational Health (ESOH) Plans
- Programmatic Environmental Safety and Health Evaluation (PESHE)
- NEPA and NEPA Compliance Schedule
- Pollution Prevention Program
- Systems Safety Program
- Hazardous Material Management Program
- Technology Readiness Assessment (TRA)
- Manufacturing Readiness Assessment (MRA)
- Alternative System Review (ASR)
- System Requirements Review (SRR)
- System Functional Review (SFR)
- Preliminary Design Review (PDR)
- Critical Design Review (CDR)
- Test Readiness Review (TRR)
- System Verification Review (SVR)
- Functional Configuration Audit (FCA)
- Production Readiness Review (PRR)
- Physical Configuration Audit (PCA)
- In-Service Review (ISR)

This includes documentation from the five QMS subareas identified in this document to include:

- The QMS System, Scope, Guidance, and Leadership (section 4.1)
  - Quality Policies and Guidance (QMS)
  - Quality Objectives and Performance
  - Supplier Quality Performance
- Planning and Organizing for Quality (section 4.2)
  - Quality Policy
  - Quality Plans
  - QMS Updaters
- Executing the Plans (Design, Development, Production, and Sustainment) (section 4.3)

    - Customer Product Requirements
    - Operational Planning and Control
    - Design and Development Processes
    - Production Requirements and Processes
    - Subcontractor and Vendor Management
- Performance evaluation and assessment of products and processes (section 4.4)
    - Product Quality
    - Process Quality
    - Inspection, Testing, and Acceptance
    - Auditing
    - Monitoring and Measuring
- Continuous Improvement (section 4.5)
    - Management Reviews Outputs
    - Nonconformity and Control
    - Corrective Action
    - Continuous Improvement

3.6 Act (Improvement)

Continuous improvement is a systematic, ongoing effort to improve products, processes, and services by identifying and eliminating waste, improving efficiency, and increasing overall value. Improvement can be incremental or major and should be focused on customer satisfaction. Improvement involves monitoring and measuring processes, products, and the QMS itself to identify areas for improvement.

Organizations should provide evidence that they are meeting the intent for a higher-level QMS and are able to identify, implement and manage the requirements for continuous improvement. Organizations need to provide evidence that they have established metrics, are collecting relevant data, analyzing trends, and use this information to drive continuous improvement initiatives.

3.6.1 Nonconforming Material Control

The FAR 46.105 Contractor Responsibilities states:

> *"The contractor is responsible for carrying out its obligations under the contract by:*
>
> - *Controlling the quality of supplies or services;*

- *Tendering to the Government for acceptance only those supplies or services that conform to contract requirements;*
- *Ensuring that vendors or suppliers of raw materials, parts, components, subassemblies, etc., have an acceptable quality control system; and*
- *Maintaining substantiating evidence, when required by the contract, that the supplies or services conform to contract quality requirements, and furnishing such information to the Government as required."*

Additionally, the FAR 46.407 Nonconforming supplies or service discusses non-conforming material stating:

> *"The contracting officer should reject supplies or services not conforming in all respects to contract requirements. In those instances where deviation from this policy is found to be in the Government's interest, such supplies or services may be accepted only as authorized in this section."*

The contractor may be required to provide and maintain an inspection system or program for the control of quality that is acceptable to the Government.

The control of quality by the contractor may relate to, but is not limited to:

- Manufacturing processes, to ensure that the product is produced to, and meets, the contract's technical requirements
- Drawings, specifications, and engineering changes, to ensure that manufacturing methods and operations meet the contract's technical requirements
- Testing and examination, to ensure that practices and equipment provide the means for optimum evaluation of the characteristics subject to inspection
- Reliability and maintainability assessment (life, endurance, and continued readiness)
- Fabrication and delivery of products, to ensure that only conforming products are tendered to the Government
- Technical documentation, including drawings, specifications, handbooks, manuals, and other technical publications
- Preservation, packaging, packing, and marking
- Procedures and processes for services to ensure that services meet contract performance requirements

FAR 52.246-26 mandates contractors report certain major/critical nonconformances and suspect counterfeits to GIDEP to ensure safety, reliability, and avoid costly failures. GIDEP (Government-Industry Data Exchange Program) is a system for U.S. and Canadian

Government/industry to share data on critical and major nonconforming materials, counterfeit parts, and product issues to prevent use in critical systems like aerospace and defense with a specific focus on electronic components and items containing them,

Organizations should provide evidence that they have established processes for identifying and addressing nonconformities and meeting the FAR requirements identified above. When nonconformity occurs, organizations should take corrective actions to eliminate the root cause and prevent its recurrence. This involves investigating the cause of the nonconformity, determining appropriate corrective actions, implementing those actions, and verifying their effectiveness. Organizations need to conduct root cause analyses in order to identify issues, ensuring corrective actions address underlying causes rather than symptoms. These implementing actions need to focus on “prevention” not “detection” as a method of control.

Organizations should establish and maintain an effective and positive system for controlling nonconforming material. Those procedures should include provisions for the identification, segregation, and disposition of the nonconforming material. All nonconforming material should be identified to prevent use, shipment, and intermingling with conforming material to include areas for the storage of the nonconforming material until disposition.

Documentation of nonconforming material should contain:

- Identification
  - Identification of the nonconforming material (name, part number, lot number, etc.)
  - Identification that the part is in a nonconformance state (tagging or other method of identification)
  - Identification should ensure that the nonconforming material does not get reintroduced into the system
- Documentation
  - Written documentation of the nonconformance (paper or electronic)
  - Description of the nonconformance
  - Documentation includes nature of the nonconformance
  - Affected products or processes
  - Date, time and personnel involved
  - Severity of the nonconformance
  - Date and time of nonconforming material
- Evaluation
  - Identification of root cause

    - Material Review Board Evaluation
- Control and Disposition
- Corrective Action
    - Corrective action or disposition
    - Effectiveness of the corrective action monitored

3.6.2 Corrective Action

FAR 52.246-2(f) *"The Government has the right either to reject or to require correction of nonconforming supplies."*

Organizations are required to take prompt action to correct assignable conditions which have resulted in the production of nonconforming material or could result in the submission of nonconforming material to the Government that does not meet contractual requirements.

Organizations should implement corrective actions to address non-conformities and prevent their recurrence. Corrective actions occur after an event has happened or after a nonconforming product has been produced. Preventive actions focus on anticipating potential issues before they occur and to take action to prevent the occurrence of a nonconforming product.

Corrective Action could include:

- Identification and Description of the Problem:
    - Date of Quality Assurance Report: The initial quality assurance report or audit where the issue was identified
    - Describe the specific quality issue, deviation, or non-conformance that needs to be addressed
    - Identify the impact on quality, processes, or products
- Root Cause Analysis: Explains the underlying reasons why the problem occurred (This might involve techniques like the "5 Whys" or a Fishbone Diagram)
- Corrective Action Plan:
    - Proposed actions
    - Detail steps needed to resolve the problem
    - Identify necessary process adjustments, training programs, equipment upgrades, or policy changes.
    - Identify a timeline for the plan
    - Timeline:
- Responsibilities: Assigns ownership for each action to specific individuals or teams

- Resource Allocation: Outlines the resources (personnel, materials, budget) needed to implement the corrective actions
- Verification and Follow-up:
  - Specifies how the effectiveness of the corrective actions should be evaluated, ensuring the problem is truly resolved and should not recur.
  - Defines any necessary follow-up activities to monitor the sustained effectiveness of the corrective actions.
  - Establish a timeline for reviewing the implemented actions to ensure they have addressed the root cause and prevent future occurrences.

3.6.3 Continuous Improvement

A higher-level QMS requires the improvement of the QMS, products, processes, and customer satisfaction. Continuous Process Improvement (CPI) is an integrated system of improvement that focuses on doing the right things right. CPI is also an enterprise-wide "way of thinking" for achieving lower cost, shorter lead and cycle times, and higher quality. CPI has a focus on enhancing the satisfaction of the customer, often the warfighter, by improving the processes that are used to develop and deliver the product or service.

There are many tools that organizations can use to continuously improve. See Appendix D for a list of tools. Identified below are a few of the most common and useful tools that organizations may use to support quality and continuous improvement.

Value engineering is primarily governed by FAR Part 48, which prescribes the policies and procedures for using and administering value engineering techniques in federal contracts.

The intent of Value Engineering (VE) is to utilize a systematic, function-oriented methodology to optimize the "value" of a system—mathematically defined as the ratio of performance to cost—by ensuring essential mission functions are achieved at the lowest life-cycle cost without sacrificing quality, reliability, or safety often with cost-sharing benefit to the industrial base.

Within the Department of War mission environment, SD-24 (Value Engineering: A Guidebook of Best Practices and Tools) serves as the primary implementation manual that translates high-level statutory requirements and DoD Instruction 4245.14 into actionable, standardized procedures for the workforce. While the FAR provides the regulatory framework for contract clauses, SD-24 provides the operational "how-to," equipping practitioners with the tools necessary to identify cost-avoidance opportunities, process Value Engineering Change Proposals (VECPs), and reinvest those savings directly into modernization and warfighter lethality.

Organizations should provide evidence of continuous improvement that may include some of the following:

- Seven Quality Tools
  - Check Sheet
  - Cause and Effect Diagram or Fishbone Chart
  - Stratification
  - Histogram
  - Pareto Chart
  - Scatter Diagram
  - Control Chart
- Seven New or Advanced Quality Management Tools
  - Affinity Diagram
  - Interrelationship Diagraph
  - Tree Diagram
  - Matrix Diagram
  - Matrix Data Analysis
  - Process Decision Program Charts
  - Arrow Diagram
- Lean focuses on workflow, customer value, and eliminating process waste. It is unique from traditional process improvement strategies in that its primary focus is on eliminating non-value-added activities.
- Value Stream Mapping (VSM) is a technique for mapping processes and is used to create a visual representation of the steps in a process in order to optimize that process. VSM looks for waste in processes. Value stream mapping involves four steps:
  - Identify the product value stream to map
  - Develop the current state map of materials, processes, and flow of information
  - Diagnose problems, identify opportunities for improvement and define a future state
  - Implement improvements
- Waste can include the following:
  - Unnecessary Transportation
  - Unnecessary Inventory
  - Unnecessary Motion
  - Unnecessary Waiting

  - Over Production
  - Over Processing
  - Defects
- Six Sigma focuses on satisfying customer requirements while minimizing waste by reducing and controlling variation.
- DMAIC phases direct a process improvement team from problem definition to implementing solutions linked to root causes
- Value Engineering Change Proposals (VECPs)

4 Quality During the Acquisition Phases

Organizations should have quality activities to perform during each phase of acquisition, and the PDCA cycle is recommended. Specific PDCA activities under each phase may vary. In the early stages of a program there may not be a need for a full up QMS, but as the program moves through the various phases the requirements get more rigorous. It is up to the QA managers to determine the activities that they should be focusing on. See Section 3 for more information on all the higher-level QMS requirements.

> Integrating quality activities at every stage is essential for realizing the vision of the Acquisition Transformation Strategy, which requires an overhaul of the acquisition system to create flexibility, delegate responsibility, and enable responsive execution.

Many acquisition activities fall under the purview of other functional areas such as contracting, SE, testing, logistics and sustainment, cost estimating, etc., but may require QA support.

Quality involvement facilitates data-driven, risk-based quality management that is essential for developing, producing, and sustaining high-performance systems that meet the warfighter's needs at the speed of relevance.

- Inputs to acquisition activities
  - Provide input to the Initial Capabilities Document (ICD)
  - Provide input to the Analysis of Alternatives (AoA)
  - Identify range of potential solutions
  - Support milestone decisions
- Provide input into the various program documents
  - Acquisition Strategy
  - Systems engineering
  - Quality Strategy and Plan
- Inputs to contracting activities
  - Market research
  - Source Selection Plan
  - Request for Proposal
  - Contract evaluation and award
  - Post-award activities
- Performance of surveillance activities
  - Identify and perform required Contract Administration Services (CAS) functions

  - Develop agreements with DCMA for surveillance support
  - Implement and monitor their CAS requirements and activities
  - Monitor and Track Business, Technical, Program Risks, and Program Reviews
- Monitor, assess, and manage the industrial base
  - Capabilities
  - Capacities
  - Activities
  - Risks
- Identify critical technologies and processes that need development
  - New materials
  - Machines
  - New skills
  - New inspection and testing equipment
  - New processes and procedures
- Identify and implement manufacturing technology (ManTech) or other science and technology (S&T) projects to mature needed technologies and processes
- Support the 16 SE technical and technical management processes as necessary
- Support SE activities
  - Systems Engineering Plan
  - Producibility Plan
  - Technical Reviews and Audits
  - Identify and Manage Key Characteristics
  - Assess Design Maturity
- Support Cost and Funding Activities
  - Cost Estimating
  - Budget Estimates
  - Identify cost drivers
  - Cost Risks and Mitigation
- Identify potential higher-level contract quality requirements
- Define and manage a Quality Management System
  - Develop and implement program quality strategy and plans
  - Identify product quality requirements and goals
  - Identify and manage quality Key Performance Indicators (KPIs)

  - Identify and manage Key and Critical Characteristics
  - Identify and manage key processes
  - Demonstrate process capability
  - Support variability reduction and yield enhancement activities
  - Plan for and manage continuous improvement activities
- Support various program reviews and technical assessments
  - Technology Readiness Assessment (TRA)
  - Manufacturing Readiness Assessment (MRA)
  - Alternative System Review (ASR)
  - System Requirements Review (SRR)
  - System Functional Review (SFR)
  - Preliminary Design Review (PDR)
  - Critical Design Review (CDR)
  - Test Readiness Review (TRR)
  - System Verification Review (SVR)
  - Functional Configuration Audit (FCA)
  - Production Readiness Review (PRR)
  - Physical Configuration Audit (PCA)
  - In-Service Review (ISR)
- Identify potential producibility and manufacturability requirements
  - Develop and implement producibility and manufacturability plans
  - Support producibility and manufacturability activities
- Identify and manage material risks
  - Development and/or testing of new materials
- ESOH considerations for new materials and processes
- Identification of the need for new facilities, tooling, and test equipment
  - Development of facility, tooling, inspection, and test equipment plans
  - Assess and manage facility activities
  - Assess and manage tooling, inspection, and test
- Development and/or testing of processes and procedures
- Identification of potential new workforce requirements and risks (e.g., for training, etc.)
- Collection and assessment of initial manufacturing process quality data
- Identify their organizational structure, roles, and responsibilities

- Identify potential supply chain risks and issues
- Identify how they will identify, manage, and mitigate risks
- Identify their inspection and testing requirements and acceptance process
- Identify how they will manage nonconforming materials and processes
- Identify how they address customer satisfaction
- Identify how they will manage quality after delivery to include field failures, warranties, returns, and other sustainment indicators

4.1 Pre-Materiel Development Decision

Pre-Materiel Development Decision (Pre-MDD) is not a phase but can be considered the front-end of the DoW acquisition process. Pre-MDD refers to the initial stage of analysis and planning that occurs before the MDD.

Pre-MDD activities may involve the identification of a military capability gap, and the analysis needed to determine if a materiel solution is merited. Pre-MDD objectives include obtaining a clear understanding of user needs, identify a range of technically feasible materiel solutions, consider near-term opportunities to provide a more rapid interim response, and develop a plan for the next acquisition phase—including the required resources.

The result of Pre-MDD is the MDD, which directs execution of the Analysis of Alternatives (AoA) and authorizes the DoW Component to conduct the MSA phase. This decision point is the entry point into the acquisition process for all defense acquisition products.

Pre-MDD may require quality managers to proactively collaborate with the S&T and user communities to develop understanding of materiel solutions, understand the potential gaps in manufacturing and quality processes, begin planning on how to fill those gaps, and make necessary and substantive inputs to future contracts and acquisition planning.

Pre-MDD activities may occur in a lab environment. The MRL Deskbook (2025) defines a laboratory environment as follows:

> *Laboratory Environment – An environment in which scientists, design engineers, manufacturing engineers, quality engineers, and production personnel develop and test processes, procedures, and equipment for making a product. (MRL Deskbook 2025, p. 9)*

Typically, Pre-MDD equates to MRLs 1 through 3.

There are a broad range of technology programs that could be used to satisfy current or potential DoW needs during this period to include contractor-funded R&D, or DoW-funded projects like Basic Research, Applied Research, and Advanced Technology Demonstrations.

- Basic Research is a 6.1 Budget Activity directed toward a greater understanding of the fundamental aspects of phenomena and/or observable facts without specific applications toward processes or products
- Advanced Research is a 6.2 Budget Activity directed toward gaining greater knowledge necessary to determine how a recognized and specific need may be met (It connects the technology with a user.)
- Advanced Technology Development is a 6.3 Budget Activity directed toward efforts that will move the development and integration of hardware for field experiments and tests

At this point, M&Q personnel should assess QA implications to determine the feasibility of a proposed concept or materiel solution and to influence the design for producibility and manufacturability. The concept may be just a paper study or may involve some development and testing of new or improved materials, new or improved processes or methods, new or improved machines, new or improved manpower skills, or new or improved products.

The activities or concepts that an organization may be developing may not require higher-level QA requirements but should still address QA considerations such as the following:

- Inputs into acquisition activities
  - Provide input to the Initial Capabilities Document (ICD)
  - Provide input to the Analysis of Alternatives (AoA)
  - Identify range of potential solutions
- Inputs into contracting activities
  - Market research
  - Source Selection Plan
  - Request for Proposal
  - Contract evaluation and award
  - Post-award activities
- Performance of surveillance activities
  - Identify and perform required Contract Administration Services (CAS) functions
  - Monitor and Track Business, Technical, Program Risks, and Program Reviews
- Monitor, assess, and manage the industrial base
  - Capabilities

  - Capacities
  - Activities
  - Risks
- Identify critical technologies and processes that need development and potential ManTech or other S&T efforts
  - New materials
  - Machines
  - New skills
  - New inspection and testing equipment
  - New processes and procedures
- Support the 16 SE technical and technical management processes as necessary
- Support cost and funding activities
  - Estimate cost
  - Prepare budget estimates
  - Identify cost drivers
  - Determine cost risks and mitigation
- Define and manage quality
  - Identify product quality requirements and goals
- Identify potential producibility and manufacturability requirements
  - Develop and implement producibility and manufacturability plans
  - Support producibility and manufacturability activities
- Identify and manage material risks
  - Develop or test new materials
- Consider ESOH for new materials and processes
- Identify the need for new facilities, tooling, and test equipment
  - Develop facility, tooling, inspection, and test equipment plans
  - Assess and manage facility activities
  - Assess and manage tooling, inspection, and test
- Identify potential new workforce requirements and risks (e.g., for training)
- Identify potential supply chain risks and issues

4.2 Materiel Solution Analysis

The purpose of the Materiel Solution Analysis (MSA) phase is to conduct analysis and other activities needed to choose a concept that may be acquired. It involves analyzing various concepts, technologies, and alternatives to determine the best approach for meeting specific needs. Milestone A is an investment decision to pursue a specific product or design concept and to commit the resources required to mature technology and/or reduce any risks that should be mitigated. The MSA phase is an opportunity for M&Q to influence the design by balancing producibility, manufacturability, quality, and affordability and then to begin identifying M&Q requirements for planning, executing the plan, monitoring, and continuous improvement.

An important aspect of the MSA effort is narrowing the field of possible solutions to a reasonable set that will be analyzed during the AoA. Early recognition of constraints, combined with analysis of technical feasibility, can identify potential risks and eliminate some initial ideas because they lack the potential to meet the need in a timely, sustainable, and cost-effective manner. Conversely, the range of alternatives analyzed in the AoA needs to be selected from a sufficiently broad solution space.

Key MSA activities include:

- Identify and evaluate alternative solutions
- Conduct the Analysis of Alternatives (AoA)
- Perform engineering and technical analysis on the preferred materiel solution
- Identify technology gaps and maturation
- Draft Capability Development Document (CDD)
- Materiel Development Decision (MDD)

During the AoA, the various alternative solutions are analyzed for key trades among affordability analyses, risk analyses, and planning for risk mitigations that affect cost, schedule, and performance. M&Q should provide inputs to the AoA process with respect to feasibility and industrial base analyses, performed as part of the AoA Study Guidance, the validated ICD, and the AoA Study Plan, which guide the AoA and MSA phase activities. The analysis focuses on identification and AoA; measures of effectiveness; key trades between cost and capability; life cycle cost, including sustainment; schedule; concepts of operations; and overall risk. The AoA will include affordability analyses, cost analyses, early SE analyses, threat projections, and market research.

The AoA should address the M&Q feasibility and technology maturity of the proposed alternatives including the risks, issues, and opportunities associated with varying production

rates; industrial base health and needs; manufacturing technology research; facilities and tooling, special test equipment, and special inspection equipment; manufacturing skill sets; and maturity of new materials and novel processing methods.

At this point, M&Q personnel are trying to determine the feasibility of the proposed concept or material solution, which is the capability to produce prototype components in a lab environment. The concept or materiel solution will involve some development and testing in a laboratory environment. Typically, MSA equates to MRL 4.

Many acquisition activities fall under the purview of other functional areas such as contracting, SE, testing, logistics and sustainment, cost estimating, etc. but may require QA support. Organizations should provide evidence of QA involvement in the following

- Inputs into acquisition activities
- Provide input to the Initial Capabilities Document (ICD)
- Provide input to the Analysis of Alternatives (AoA)
- Identify a range of potential solutions
- Support milestone decisions
- Provide inputs to the various program documents
    - Acquisition Strategy
    - Systems Engineering Plan
    - Quality Strategy and Plans
- Inputs into contracting activities
    - Market Research
    - Source Selection Plan
    - Request for Proposal
    - Contract Evaluation and Award
    - Post-Award Activities
- Performance of surveillance activities
- Identify and perform required Contract Administration Services (CAS) functions
    - Develop agreements with DCMA for surveillance support
    - Implement and monitor CAS requirements and activities
    - Monitor and manage business, technical, and program risks
- Monitor, assess, and manage the industrial base
    - Capabilities

  - Capacities
  - Activities
  - Risks
- Identify critical technologies and processes that need development
  - New materials
  - Machines
  - New skills
  - New inspection and testing equipment
  - New processes and procedures
- Identify and implement ManTech or other S&T projects to mature needed technologies and processes
- Support the 16 SE technical and technical management processes as necessary
- Support SE activities
  - Systems Engineering Plan
  - Producibility Plan
  - Technical Reviews and Audits
  - Identify and Manage Key Characteristics
  - Assess Design Maturity
- Support cost and funding activities
  - Cost estimating
  - Budget estimates
  - Identify cost drivers
  - Cost risks and mitigation
- Identify potential higher-level contract quality requirements
- Define and manage QMS
  - Develop and implement program quality strategy and plans
  - Identify product quality requirements and goals
  - Identify and manage quality Key Performance Indicators (KPIs)
  - Identify and manage Key and Critical Characteristics
  - Identify and manage key processes
  - Demonstrate process capability
  - Support variability reduction and yield enhancement activities
  - Plan for and manage continuous improvement activities

- Support various program reviews and technical assessments
  - Technology Readiness Assessment
  - Manufacturing Readiness Assessment
  - Alternative System Review (ASR)
- Identify potential producibility and manufacturability requirements
  - Develop and implement producibility and manufacturability plans
  - Support producibility and manufacturability activities
- Identify and manage material risks
- Identify and manage ESOH considerations for new materials and processes
- Identify need for new facilities, tooling, inspection, and test equipment
- Development of facility, tooling, inspection, and test equipment plans
- Assess and manage facility activities
- Assess and manage tooling, inspection, and test
- Development and/or testing of processes and procedures
- Identification of potential new workforce requirements and risks (e.g., for training, etc.)
- Collection and assessment of initial manufacturing process quality data
- Identify their organizational structure, roles, and responsibilities
- Identify potential supply chain risks and issues
- Identify how they will identify, manage, and mitigate risks
- Identify their inspection and testing requirements and acceptance process
- Identify how they will manage nonconforming materials and processes
- Identify how they address customer satisfaction
- Identify how they will manage quality after delivery to include field failures, warranties, returns, and other sustainment indicators

4.3 Technology Manufacturing and Risk Reduction

Technology development is the application of scientific methods to achieve a DoW, commercial, or industrial technology objectives. The Technology Maturation and Risk Reduction (TMRR) phase is used to develop and demonstrate prototype designs to reduce technical risk, validate designs, validate cost estimates, evaluate manufacturing processes, and refine requirements.

This phase includes a mix of activities intended to reduce program risks. These include the design and requirements trades necessary to ensure the product or program is cost-effective and

an executable development and production program. Close collaboration with the requirements community is essential and should inform development and validation of the CDD.

At this point, M&Q personnel are trying to determine the feasibility of the proposed concept or material solution, and produce prototype components, subsystems, and systems in a production relevant environment. The MRL Deskbook (2025) describes a production-relevant environment as follows:

> *Production-Relevant Environment – An environment with some shop floor production realism present (e.g., facilities, personnel, tooling, processes, materials, etc.). There should be minimum reliance on laboratory resources during this phase. Demonstration in a production relevant environment implies that assessed organizations [contractor(s)] must demonstrate their ability to meet the cost, schedule, and performance requirements of the EMD Phase based on their production [manufacturing] of prototypes. The demonstration must provide the program with confidence that these targets will be achieved but does not require a production line. Furthermore, there must be an indication of how the program intends to achieve the requirements in production-representative and pilot environments. (MRL Deskbook 2025, p. 9)*

Typically, TMRR equates to MRLs 5 through 6.

Manufacturing is concerned with the conversion of raw materials into products based upon a detailed design. This conversion is accomplished through a series of M&Q procedures and processes. It includes the following major functions manufacturing planning, cost estimating and scheduling, engineering, fabrication and assembly, installation and checkout, demonstration and testing, and quality assurance. Many acquisition activities listed below fall under the purview of other functional areas such as contracting, SE, testing, logistics and sustainment, cost estimating, etc. but may require QA support as a best practice.

- Inputs into acquisition activities
  - Provide input to the Initial Capabilities Document (ICD)
  - Provide input to the Analysis of Alternatives (AoA)
  - Identify range of potential solutions
  - Support milestone decisions
- Provide inputs into the various program documents
  - Acquisition Strategy
  - Systems Engineering
  - Quality Strategy and Plan

- Inputs into contracting activities
  - Market research
  - Source Selection Plan
  - Request for Proposal
  - Contract evaluation and award
  - Post-award activities

Organizations should provide evidence of QA involvement in the following:

- Performance of surveillance activities
  - Identify and perform required Contract Administration Services (CAS) functions
  - Develop agreements with DCMA for surveillance support
  - Implement and monitor their CAS requirements and activities
  - Monitor and track business, technical, program risks, and program reviews
- Monitor, assess, and manage the industrial base
  - Capabilities
  - Capacities
  - Activities
  - Risks
- Identify critical technologies and processes that need development and potential ManTech or other S&T efforts
  - New materials
  - Machines
  - New skills
  - New inspection and testing equipment
  - New processes and procedures
- Support Systems Engineering activities
  - Systems Engineering Plan
  - Producibility Plan
  - Technical reviews and audits
  - Identify and manage Key Characteristics (KCs)
  - Assess Design Maturity
- Support Cost and Funding Activities
  - Cost estimating

  - Budget estimates
  - Identify cost drivers
  - Cost risks and mitigation
- Identify potential higher-level contract quality requirements
- Define and manage Quality Management System
  - Develop and implement program quality strategy and plans
  - Identify product quality requirements and goals
  - Identify and manage quality Key Performance Indicators (KPIs)
  - Identify and manage Key and Critical Characteristics
  - Identify and manage key processes
  - Demonstrate process capability
  - Support variability reduction and yield enhancement activities
  - Plan for and manage continuous improvement activities
- Support various program reviews and technical assessments
  - Technology Readiness Assessment (TRA)
  - Manufacturing Readiness Assessment (MRA)
  - System Requirements Review (SRR)
  - System Functional Review (SFR)
  - Preliminary Design Review (PDR)
- Identify potential producibility and manufacturability requirements
  - Develop and implement producibility and manufacturability plans
  - Support producibility and manufacturability activities
- Identify and manage material risks
  - Development and/or testing of new materials
- ESOH considerations for new materials and processes
- Identification of the need for new facilities, tooling, and test equipment
  - Development of facility, tooling, inspection, and test equipment plans
  - Assess and manage facility activities
  - Assess and manage tooling, inspection, and test
- Development and/or testing of processes and procedures
- Identification of potential new workforce requirements and risks (e.g., for training, etc.)
- Collection and assessment of initial manufacturing process quality data

- Identify their organizational structure, roles, and responsibilities
- Identify potential supply chain risks and issues
- Identify how they will identify, manage, and mitigate risks
- Identify their inspection and testing requirements and acceptance process
- Identify how they will manage nonconforming materials and processes
- Identify how they address customer satisfaction
- Identify how they will manage quality after delivery to include field failures, warranties, returns, and other sustainment indicators

4.4 Engineering and Manufacturing Development

The purpose of the Engineering and Manufacturing Development (EMD) phase is to develop, build, test, and evaluate a materiel solution to verify that all operational and implied requirements, including those for security, have been met, and to support production, deployment and sustainment decisions.

The program should complete all needed hardware and software detailed designs. A Critical Design Review (CDR) assesses design maturity, design build-to risks, and establishes the initial technical baseline. The CDR should be used as the decision point that the system design is ready to begin pre-production prototype hardware fabrication and assembly with acceptable risk.

An objective of the EMD phase is to develop the initial product baseline, verify it meets the functional and allocated baselines and transform the preliminary design into a producible design, all within the schedule and cost constraints of the program.

The EMD phase should end when the design is stable; the system meets validated capability requirements demonstrated by developmental, live-fire (as appropriate) and early operational testing; manufacturing processes have been demonstrated and are under control; software sustainment processes are in place and functioning; industrial production capabilities are reasonably available; program security remains uncompromised; and the program has met or exceeds all directed EMD phase exit criteria and Milestone C entrance criteria per the MDA's direction.

At this point, M&Q personnel are trying to determine the capability to produce the item in a production-representative and establish a pilot line with plans to build to LRIP. The MRL Deskbook (2025) provides the following definitions:

> *Production-Representative Environment – An environment that has as much production realism as possible, considering the maturity of the*

> *design. [Production] personnel, equipment, processes, and materials that will be present on the pilot line should be used to the maximum extent possible. The work instructions and tooling should be of high quality, and the only changes anticipated on these items are associated with design changes downstream that address performance or [production] rate issues. There should be no reliance on laboratory environment or personnel.*
>
> *Pilot Line – An environment that incorporates all of the key production realism elements (e.g., equipment, personnel skill levels, facilities, materials, components, work instructions, processes, tooling, temperature, cleanliness, lighting) required to manufacture production configuration items, subsystems or systems that meet design requirements in LRIP. To the maximum extent practical, the pilot line should use FRP processes.*
>
> *Production Line – An environment that incorporates all capabilities required to manufacture production configuration items, subsystems, or systems that meet design requirements using manufacturing processes and procedures that are under control and capable of meeting required rates and quantities. (MRL Deskbook 2025, p. 10)*

Typically, EMD equates to MRLs 7 through 8.

Many acquisition activities listed below fall under the purview of other functional areas such as contracting, SE, testing, logistics and sustainment, cost estimating, etc., but may require QA support as a best practice.

- Inputs into acquisition activities
  - Provide input to the Initial Capabilities Document (ICD)
  - Provide input to the Analysis of Alternatives (AoA)
  - Identify range of potential solutions
  - Support Milestone Decisions
- Provide inputs into the various program documents
  - Acquisition Strategy
  - Systems Engineering
  - Quality Strategy and Plan
- Inputs into contracting activities
  - Market research
  - Source Selection Plan
  - Request for Proposal
  - Contract evaluation and award

  - Post-award activities

Organizations should provide evidence of QA involvement in the following:

- Performance of surveillance activities
  - Identify and perform required Contract Administration Services (CAS) functions
  - Develop agreements with DCMA for surveillance support
  - Implement and monitor their CAS requirements and activities
  - Monitor and track business, technical, program risks, and program reviews
- Monitor, assess, and manage the industrial base
  - Capabilities
  - Capacities
  - Activities
  - Risks
- Identify critical technologies and processes that need development and potential ManTech or other S&T efforts
  - New materials
  - Machines
  - New skills
  - New inspection and testing equipment
  - New processes and procedures
- Support SE activities
  - Systems Engineering Plan
  - Producibility Plan
  - Technical reviews and audits
  - Identify and manage Key Characteristics (KCs)
  - Assess design maturity
  - Support the 16 SE technical and technical management processes as necessary
- Support Cost and Funding Activities
  - Cost estimating
  - Budget estimates
  - Identify cost drivers
  - Cost risks and mitigation
- Identify potential higher-level contract quality requirements

- Define and manage Quality Management System (QMS)
  - Develop and implement program quality strategy and plans
  - Identify product quality requirements and goals
  - Identify and manage quality Key Performance Indicators (KPIs)
  - Monitor and manage SPC activities
  - Collect, share, use SPC data to foster continuous improvement
  - Identify and manage Key and Critical Characteristics
  - Identify and manage key processes
  - Demonstrate process capability
  - Support variability reduction and yield enhancement activities
  - Plan for and manage continuous improvement activities
- Support various program reviews and technical assessments
  - Technology Readiness Assessment (TRA)
  - Manufacturing Readiness Assessment (MRA)
  - Critical Design Review (CDR)
  - Test Readiness Review (TRR)
  - System Verification Review (SVR)
  - Functional Configuration Audit (FCA)
  - Production Readiness Review (PRR)
- Identify potential producibility and manufacturability requirements
  - Develop and implement producibility and manufacturability plans
  - Support producibility and manufacturability activities
- Identify and manage material risks (Development and/or testing of new materials)
- ESOH considerations for new materials and processes
- Identify the need for new facilities, tooling, and test equipment
  - Development of facility, tooling, inspection, and test equipment plans
  - Assess and manage facility activities
  - Assess and manage tooling, inspection, and test
- Develop or test processes and procedures
- Identify potential new workforce requirements and risks (e.g., for training)
- Collect and assess initial manufacturing process quality data
- Identify their organizational structure, roles, and responsibilities

- Identify potential supply chain risks and issues
- Identify how they will identify, manage, and mitigate risks
- Identify their inspection and testing requirements and acceptance process
- Identify how they will manage nonconforming materials and processes
- Identify how they address customer satisfaction
- Identify how they will manage quality after delivery to include field failures, warranties, returns, and other sustainment indicators

4.5 Production and Deployment

The purpose of the Production and Deployment (P&D) phase is to produce and deploy materiel solutions to receiving operating organizations. In this phase, the product is produced and fielded for use by operational units and encompasses a number of events: LRIP, personnel training, completion of developmental T&E (if required), Initial Operational Test and Evaluation, and the FRP Decision or Full Deployment Decision.

At this point, M&Q personnel are trying to demonstrate LRIP and FRP.

Low-Rate Initial Production (LRIP): At this level, all SE and design requirements should have been met such that there are minimal system changes. Major system design features are stable and have been proven in operational test and evaluation. Materials, parts, manpower, tooling, test equipment, and facilities are available to meet planned rate production schedules. STE/SIE are validation are maintained, as necessary. Manufacturing process capability in an LRIP environment is at an appropriate quality level to meet KC tolerances. Risks and issues are managed with monitoring ongoing. LRIP cost targets have been met, and learning curves have been analyzed with actual data. The cost model has been updated for FRP and reflects the impact of continuous improvement.

Full-Rate Production (FRP): At this level, manufacturing is normally associated with the P&D or Operations and Support (O&S) phases of the acquisition life cycle. Engineering or design changes are few and limited to continuous improvement changes or obsolescence issues. System, components, and items are in FRP and meet all engineering, performance, quality, and reliability requirements. Manufacturing process capability is at the appropriate quality level. All materials, tooling, inspection and test equipment, facilities, and manpower are in place and have met FRP requirements. STE/SIE validation is maintained and revalidated, as necessary. Rate production unit costs meet goals, and funding is sufficient for production at required rates. Continuous process improvements are ongoing.

Many acquisition activities listed below fall under the purview of other functional areas such as contracting, SE, testing, logistics and sustainment, cost estimating, etc. but may require QA support as a best practice.

- Provide inputs into the various program documents
  - Acquisition Strategy
  - Systems Engineering Plan
  - Quality Strategy and Plan
- Inputs into contracting activities
  - Market research
  - Source Selection Plan
  - Request for Proposal
  - Contract evaluation and award
  - Post-award activities

Organizations should provide evidence of QA involvement in the following:

- Performance of surveillance activities
  - Identify and perform required Contract Administration Services (CAS) functions
  - Develop agreements with DCMA for surveillance support
  - Implement and monitor their CAS requirements and activities
  - Monitor and Track Business, Technical, Program Risks, and Program Reviews
- Monitor, assess, and manage the industrial base
  - Capabilities
  - Capacities
  - Activities
  - Risks
- Identify critical technologies and processes that need development and potential ManTech or other S&T efforts
  - New materials
  - Machines
  - New skills
  - New inspection and testing equipment
  - New processes and procedures
- Support SE activities

  - Systems Engineering Plan
  - Producibility Plan
  - Technical reviews and audits
  - Identify and manage key characteristics
  - Assess design maturity
  - Support the 16 SE technical and technical management processes as necessary
- Support Cost and Funding Activities
  - Cost estimating
  - Budget estimates
  - Identify cost drivers
  - Cost risks and mitigation
- Identify potential higher-level contract quality requirements
- Define and manage Quality Management System
  - Develop and implement program quality strategy and plans
  - Identify product quality requirements and goals
  - Identify and manage quality Key Performance Indicators (KPIs)
  - Identify and manage Key and Critical Characteristics
  - Identify and manage key processes
  - Demonstrate process capability
  - Support variability reduction and yield enhancement activities
  - Plan for and manage continuous improvement activities
- Support various program reviews and technical assessments
  - Technology Readiness Assessment (TRA)
  - Manufacturing Readiness Assessment (MRA)
  - Physical Configuration Audit (PCA)
  - In-Service Review
- Identify potential producibility and manufacturability requirements
  - Develop and implement producibility and manufacturability plans
  - Support producibility and manufacturability activities
- Identify and manage material risks
  - Development and/or testing of new materials
- ESOH considerations for new materials and processes
- Identification of the need for new facilities, tooling, and test equipment

  - Development of facility, tooling, inspection, and test equipment plans
  - Assess and manage facility activities
  - Assess and manage tooling, inspection, and test
- Development and/or testing of processes and procedures
- Identification of potential new workforce requirements and risks (e.g., for training)
- Collection and assessment of initial manufacturing process quality data
- Identify their organizational structure, roles, and responsibilities
- Identify potential supply chain risks and issues
- Identify how they will identify, manage, and mitigate risks
- Identify their inspection and testing requirements and acceptance process
- Identify how they will manage nonconforming materials and processes
- Identify how they address customer satisfaction
- Identify how they will manage quality after delivery to include field failures, warranties, returns, and other sustainment indicators

4.6 Operations and Support

The objective of the Operations and Support (O&S) phase is to execute a support program that meets operational support performance requirements and sustains the system in the most cost-effective manner over its total life cycle.

During O&S, the PM should measure, assess, and manage system readiness using sustainment metrics, and implement corrective actions for trends diverging from the required performance outcomes defined in the Product Support Strategy (PSS).

Product support management includes planning, cost estimating and budgeting, developing, implementing, and managing an effective PSS that addresses all 12 Integrated Product Support elements listed below to accomplish material and system readiness. Many of these elements include the need for support from QA personnel.

- Product support management
- Design interface
- Facilities and infrastructure
- Information technology
- Maintenance planning and management
- Manpower and personnel

- Packaging, handling, storage, and transportation
- Supply support
- Sustaining engineering
- Technical data
- Training and support

Over the program life cycle, operational needs change and may require changes to systems or subsystems which could include the need for changes to training requirements, technology advances, process improvements, service life extensions, changes to the industrial base, or disposal and demilitarization.

At this point, M&Q personnel are trying to support sustainment activities to include:

- Trade studies to support system modifications, technology insertions, and technology refresh activities
- M&Q risk assessments
- Review of Engineering Change Proposals (ECP) and value engineering (VE) efforts
- Analysis of Failure Reporting, Analysis, and Corrective Action (FRACAS) and impact to design, production and quality activities
- Analysis of Diminishing Manufacturing Sources and Material Shortages (DMSMS) and Obsolescence
- Support demilitarization and disposal activities

Many acquisition activities fall under the purview of other functional areas such as contracting, SE, testing, logistics and sustainment, cost estimating, etc., but may require QA support. Organizations should provide evidence of QA involvement in the following:

- Provide inputs into the various program documents
  - Systems Engineering Plan
  - Quality Strategy and Plan
- Inputs into contracting activities
  - Market research
  - Source Selection Plan
  - Request for Proposal
  - Contract evaluation and award
  - Post-award activities

- Performance of surveillance activities
  - Identify and perform required Contract Administration Services (CAS) functions
  - Develop agreements with DCMA for surveillance support
  - Implement and monitor their CAS requirements and activities
  - Monitor and track business, technical, program risks, and program reviews
- Monitor, assess, and manage the industrial base
  - Capabilities
  - Capacities
  - Activities
  - Risks
- Identify critical technologies and processes that need development and potential ManTech or other S&T efforts
  - New materials
  - Machines
  - New skills
  - New inspection and testing equipment
  - New processes and procedures
- Support SE activities
  - Systems Engineering Plan
  - Producibility Plan
  - Technical reviews and audits
  - Identify and manage Key Characteristics
  - Assess design maturity
  - Support the 16 SE technical and technical management processes as necessary
- Support Cost and Funding Activities
  - Cost estimating
  - Budget estimates
  - Identify cost drivers
  - Cost risks and mitigation
- Identify potential higher-level contract quality requirements
- Define and manage the Quality Management System (QMS)
  - Develop and implement program quality strategy and plans
  - Identify product quality requirements and goals

  - Identify and manage quality Key Performance Indicators (KPIs)
  - Identify and manage Key and Critical Characteristics
  - Identify and manage key processes
  - Demonstrate process capability
  - Support variability reduction and yield enhancement activities
  - Plan for and manage continuous improvement activities
- Support various program reviews and technical assessments
  - Technology Readiness Assessment (TRA)
  - Manufacturing Readiness Assessment (MRA)
  - Physical Configuration Audit (FCA)
  - In-Service Review
- Identify potential producibility and manufacturability requirements
  - Develop and implement producibility and manufacturability plans
  - Support producibility and manufacturability activities
- Identify and manage material risks (Development and/or testing of new materials)
- ESOH considerations for new materials and processes
- Identification of the need for new facilities, tooling, and test equipment
  - Development of facility, tooling, inspection, and test equipment plans
  - Assess and manage facility activities
  - Assess and manage tooling, inspection, and test
- Development and/or testing of processes and procedures
- Identification of potential new workforce requirements and risks (e.g., for training, etc.)
- Collection and assessment of initial manufacturing process quality data
- Identify their organizational structure, roles, and responsibilities
- Identify potential supply chain risks and issues
- Identify how they will identify, manage, and mitigate risks
- Identify their inspection and testing requirements and acceptance process
- Identify how they will manage nonconforming materials and processes
- Identify how they address customer satisfaction
- Identify how they will manage quality after delivery to include field failures, warranties, returns, and other sustainment indicators

Appendix A: Quality Gurus

The following engineers and businessmen created the foundations of modern quality principles.

A.1. Walter A. Shewhart (1891-1967)

Walter A. Shewhart, an American physicist, engineer, and statistician, is widely regarded as the father of statistical quality control (SQC). His extensive research on process variation led to the development of the first control chart. His work centered on the importance of identifying and reducing variation to achieve quality improvement.

In 1918, Shewhart joined the Western Electric Company to assist their engineers in improving the quality of telephone hardware. Western Electric produced hardware for the Bell Telephone Company, which became the American Telephone and Telegraph Company (AT&T). Western Electric manufactured telephone equipment and its major plant was the Hawthorne Plant in Cicero, a suburb of Chicago.

Shewhart's legacy includes the fundamental concepts of assignable and common causes of variation. All production processes exhibit some level of variation, which intuitively leads to decreased quality with increased variability. Assignable variation arises from identifiable and addressable causes, such as employee error, software malfunction, or equipment failure. In contrast, common variation, also known as chance variation, is inherent to the process and expected. Minimizing or eliminating either type of variation directly translates to enhanced product quality.

Statistical process control (SPC) was classified as a secret and adopted during World War II to improve production and productivity.

A.2. W. Edwards Deming (1900-1993)

W. Edwards Deming was an American engineer, statistician, professor, and prolific author. Following World War II, his expertise in SPC led him to Japan, where he was involved with the training thousands of Japanese engineers, managers, and academics in fundamental SPC techniques. This pivotal role is widely credited with propelling Japan to become a global leader in quality manufacturing. In recognition of Deming's profound impact, the Deming Prize, Japan's most prestigious quality award, was named in his honor.

While Deming wrote numerous publications, and his enduring legacy is secured through Deming's 14 Points and the Deming Cycle (PDCA cycle), both of which continue to be foundational principles within quality management. Deming emphasized system-wide improvement, not just inspection, and believed poor quality stems from the system, not

individual employees. Demings 14 points include the following general ideas, which may be paraphrased in different sources and contexts:

1. Create constancy of purpose
2. Adopt the new philosophy
3. Cease dependence on inspection to achieve quality
4. Award contracts based on minimizing total cost
5. Improve every process constantly
6. Institute training on the job
7. Institute leadership
8. Drive out fear
9. Break down barriers
10. Eliminate exhortations
11. Eliminate arbitrary numerical targets
12. Permit pride of workmanship
13. Encourage education
14. Make quality everybody's job

A.3. Joseph M. Juran (1904-2008)

Joseph M. Juran, a Romanian-born American engineer, established himself as a giant in the quality management field defining quality as "fitness for use." Juran is credited with the concept of the cost of poor quality building on Fiegenbaum's work, developing a framework for understanding and managing the financial implications of quality. His foundational work includes the widely influential *Quality Control Handbook* (1951).

Juran identified three building blocks of quality management that he called the Quality Trilogy:

- Quality Planning (Quality of Design): Requires a clear understanding of the customer and the customers' requirements. Tools like Quality Function Deployment (QFD) can assist

organizations in identifying the VoC and with developing plans to achieve customer satisfaction.

- Quality Control: A system of procedures used to ensure that products meet all customer contractual and regulatory requirements.
- Quality Improvement (Lean/Six Sigma): Despite best efforts, there is always room for improvement. Successful organizations recognize this and are on a journey of continuous product and process improvement.

Table A-1. Juran's Quality Management Building Blocks (Quality Trilogy)

Quality Planning	Quality Control	Quality Improvement
• Identify Customers • Determine Customer Requirements • Develop Product Features • Set Quality Goals • Develop Production Processes • Validate Process Capabilities • Identify Suppliers • Develop Audit Plans	• Identify Control Subjects • Identify Units of Measurement • Establish Measurement • Establish Performance Standards • Measure Actual Performance • Take Action on Performance Deviations	• Identify Improvement Opportunities • Plan and Organize for Improvement • Establish Improvement teams • Provide Improvement Resources • Identify Causes and Plans for Improvement • Implement and Monitor Improvement Activities

A.4. Philip B. Crosby (1926-2001)

Philip B. Crosby championed the "zero defects" approach, arguing that it is better to do the job right the first time than to deal with the costs of poor quality. Crosby is known for emphasizing the importance of prevention over inspection in quality management. Crosby is also known for his Four Absolutes of Quality, paraphrased as follows:

1. The definition of quality is conformance to requirements.
2. The system of quality is prevention.
3. The performance standard is zero defects.
4. The measurement of quality is the price of non-conformance.

Crosby also introduced the idea of "quality is free," which is the notion that the cost of preventing defects is always lower than the cost of dealing with defects after they occur.

A.5 Armand V. Feigenbaum (1920-2014)

Armand V. Feigenbaum, an American quality engineer and businessman, served as the Director of Manufacturing Operations at General Electric from 1958 to 1968. He is credited with pioneering the concept of total quality control, which later evolved into the widely adopted total quality management (TQM) philosophy. Feigenbaum introduced the idea of the "cost of quality" as a way to measure the impact of quality on an organization. Feigenbaum also introduced the concept of the "hidden plant," which refers to the productive capacity lost due to inefficiencies, defects, and rework. Many of these costs are undocumented, thus hidden, and this concept is often depicted as an iceberg where much of the costs is below the surface. His work highlighted the significant potential for improvement that lies within existing operations.

A.6 Kaoru Ishikawa (1915-1989)

Kaoru Ishikawa is known as the father of Japanese quality because of the many concepts and quality tools he developed, including the "fishbone diagram," a problem-solving model that helps determine root causes of problems. When the Japanese industrial sector changed after World War II, Ishikawa met Deming and Juran, and they worked together to develop management concepts that are still in use.

Ishikawa also introduced the concept of total quality control, involving all employees in the quality control process and using data and statistical analysis to drive continuous improvement. This concept later evolved into Total Quality Management (TQM), which was popular in the 1980s.

Ishikawa wrote *An Introduction to Quality Control* (1990) and other books that outlined how to use 7 Basic Quality Tools. He also popularized the use of quality circles or groups of people trained in quality skills of problem identification, data gathering, and analysis and generation of solutions. These groups of people meet voluntarily to improve organizational performance.

A.7. Genichi Taguchi (1924-2012)

Just after World War II, Genichi Taguchi was working to reduce spiraling manufacturing cost in the automotive industry and discovered that many costs were due to external factors that he identified as "noise." He developed methods to isolate noise factors at the source, reduce variations in quality, and improve costs.

Taguchi also introduced the idea of using "robust design" to create products that were insensitive to variations in manufacturing processes by pushing quality and reliability back into the design process and then iterating it through system design, parameter design, and tolerance design.

A.8. Taiichi Ohno (1912-1990)

Taiichi Ohno was a Japanese industrial engineer and businessman known as the father of the Toyota Production System (TPS). The TPS is a manufacturing methodology focusing on maximizing efficiency and minimizing waste and is based on two pillars.

- Jidoka: Automation with a human touch or a process whereby the machine or equipment can detect the abnormality and stop automatically, or the operator can stop the line by pulling the stop cord themselves allowing them time to correct the error before it can go any further.
- Just-in-Time: Making only what is needed, when it is needed, and in the exact amount needed, with no overproduction or inventory. Taiichi Ohno's concept of waste, or "muda" in Japanese, is central to Lean manufacturing. He identified seven types of waste that can occur in any production process:
    - Overproduction
    - Waiting
    - Transportation
    - Over-processing
    - Inventory
    - Motion
    - Defects

A.9. Shigeo Shingo (1909-1990)

Shigeo Shingo was a Japanese industrial engineer who created the Poka-Yoke (mistake-proofing) system to prevent human error or mistakes are difficult or impossible to make. He emphasized the importance of eliminating waste and increasing efficiency in the production process. Shingo is also known for his contributions to Lean manufacturing, including working at Toyota during the 1960s, supporting the development of the TPS, focusing on the reduction of machine setup times. He also developed and popularized the term Single Minute Exchange of Die (SMED).

Appendix B: Quality Concepts

This section summarizes several quality-related concepts with which DoW program personnel should be familiar. Organizations may define terms differently or use terms interchangeably. This guidebook uses the following.

B.1 Quality Management System

A Quality Management System (QMS) is the overall set of coordinated activities a program uses to direct and control quality policy, quality objectives, quality planning, QA, and quality improvement for an organization, including the supply chain. The QMS focuses on results and quality objectives, which are used to identify and satisfy the needs, expectations, and requirements of customers and stakeholders.

A QMS is intended to help an organization provide the following:

- Uniform, defect-free products
- Products and services that meet customer expectations and perform as expected
- Enhanced operational efficiency and affordability
- Compliance with contract and regulatory requirements
- Risk-based thinking as a way to manage every stage of the development process

QMS processes and procedures are formalized in tailored supporting documents to ensure products or services consistently meet customer and regulatory requirements.

The first documented QMS was MIL-Q-9858A, developed by the Department of Defense in 1959. In the 1970s and 1980s, other countries began establishing standards, and the North Atlantic Treaty Organization (NATO) developed a QMS, the Allied Quality Assurance Publication (AQAP).

As countries began encountering many different standards, there was a push to develop an international standard, resulting in ISO 9001 published in 1987. SAE AS9100 was developed and issued in 1999 to meet the unique requirements of the aerospace industry, specifying additional requirements beyond ISO 9001. Many DoW programs now require contractors to implement a higher-level QMS such as ISO 9001 or SAE AS9100.

B.2 Quality Assurance

Quality assurance (QA) is the part of quality management focused on providing confidence that quality requirements will be fulfilled. QA is a planned and systematic pattern of actions

necessary to provide confidence that adequate technical requirements are established, that products and services conform to established technical requirements, and that satisfactory performance is achieved.

QA focuses on processes and how they are performed and how the product is made. QA looks to build quality into the product and process rather than inspect for defects after the product is built. Building in quality begins with understanding customer requirements and influencing the design process. QA seeks to ensure the right things are done the right way.

B.3 Quality Control

Quality control (QC) is a line function and refers to the activities used during the production of a product that are designed to verify that the product conforms to the customer's requirements. QC is product focused and reactive and depends on an inspection system that is appraisal or inspection oriented. QC focuses on the process of producing the product or service with the intent of eliminating problems that might result in defects. QC begins as the product is being produced, seeking to ensure that what is produced meets customer requirements.

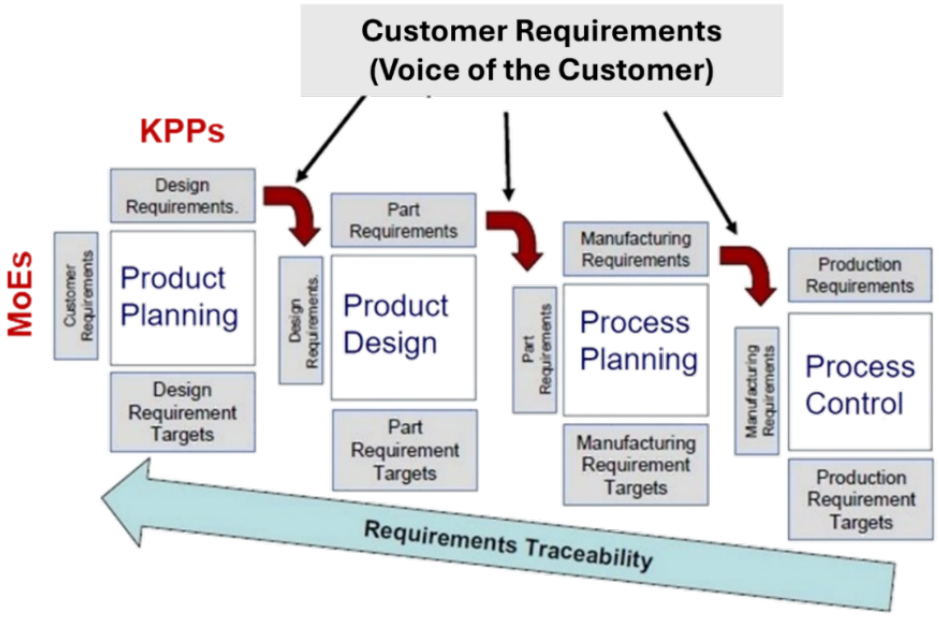
During the design process, engineers develop specifications, targets, and tolerances that are required for the part or component to function optimally. The goal of manufacturing is to achieve the target value while staying within the tolerances set by the engineers.

QC may be referred to as quality of conformance (QoC), the degree to which a product meets or exceeds its design specifications and is free of defects or other problems that could degrade its performance and answers the question "is it fit for use?" QoC can be verified through inspection and testing. Inspection involves the examination of products for defects or deviations from specifications, while testing is a systematic process to assess functionality, performance, or to the characteristics of the product. Activities could include first article inspection (FAI), first article testing (FAT), receiving inspection and testing, in-process inspection and testing, final inspection and testing, and supplier installation and testing.

B.4 Quality of Design

Quality of design (QoD) is a proactive approach to product design that uses integrated product and process teams (IPPTs) that focus on designing quality into a product. These activities start from the earliest stages of planning and design in order to ensure a product meets customer requirements while optimizing the design. This approach involves the process of understanding the product and processes in order to identify and then control critical quality attributes (CQAs) and critical process parameters (CPPs).

QoD refers to how well a product is designed to meet customer requirements and includes the features, specifications, and functionality that are designed and built into the product or system. QoD uses technical tools to assist technical personnel with ensuring that QoD is considered during the SE process as conceptualized in Figure B-1.



KPP: Key Performance Parameter; MOE: Measure of Effectiveness.

Figure B-1. Customer Requirements Flowdown

Product Planning (Functions)

- Define and prioritize customer needs
- Analyze competition and opportunities
- Plan for a product to respond to the needs (Allocations)
- Establish target values (Critical to Customer)

Product Design

- Identify parts and assemblies
- Flow-down Key Product Characteristics
- Translate into critical part/assembly characteristics and target values

Process Planning

- Determine key manufacturing processes and process flow
- Develop production equipment requirements
- Establish key process parameters

Process/Quality Control

- Determine key part and process characteristics (KCs)
- Establish process parameters
- Establish inspection and test methods and parameters (Critical to Quality)

The objectives of QoD efforts are to:

- Design a product that is robust to meet customer and stakeholder requirements
- Influence and enhance the product and process design
- Increase process capability while reducing process variability and defects
- Transition to production with no significant quality process and reliability risks that could lead to cost and performance problems.

M&Q and other technical managers' role during the design is to influence the design for producibility and plan for production, then execute the plans to achieve uniform, defect-free product that meets the designers' intent and satisfies customer expectations.

During the detailed design, technical managers need to influence the design so it is producible and manufacturable (see DoD Producibility and Manufacturability Guide). Design engineers and technical personnel need to understand and consider many factors, including factory floor process capabilities and other quality attributes, if they are going to achieve cost, schedule, and performance goals. Following is a partial list of tools that can be used to support these efforts:

- Design guidelines
- Design of Experiments (DoE)
- Design for Six Sigma (DFSS)
- Process capability guidelines and process capability measurement/benchmarking
- Design for Manufacturability and Assembly (DFMA) analyses
- Multivariate Data Analysis (MVDA)
- Design for Ergonomics (DFE) for manufacturing processes and workforce
- Process Failure Modes and Effects Analysis (PFMEA)
- Identification of KCs and Critical Characteristics (CCs)
- Modeling and simulation (M&S) tools
- Rapid prototyping
- Product and process complexity analyses
- Diminishing Manufacturing Sources and Material Shortages (DMSMS) Program

- Counterfeit Parts Management Program
- Six Sigma tools

As a design emerges from the system, decisions are being made continuously on thousands of characteristics. Which material will provide the best performance at the lowest cost? Which process characteristics are important and should be controlled? Which processes should be used to fabricate parts? What factors need attention to control the process?

Engineers work to design a product to achieve the right performance parameters. This includes product characteristics, tolerance, and process parameter design. The factory floor may produce parts with high defect rates and low yields. Engineers should work to make the design robust, that is, a design that takes into consideration the inherent variations of the factory floor in a way that does not negatively affect product performance.

B.5 Quality Audits

A quality audit is a planned, independent, and documented assessment to determine whether agreed-upon requirements are being met. Contractors and production organizations should provide the majority of audits; however, the following organizations may also conduct quality audits: Government facilities, Government personnel from a program office, or the Defense Contract Management Agency (DCMA).

Quality audits may focus on a specific context; for example:

- Product Audit: Evaluation of a finished item that has been previously accepted for characteristics being audited.
- Process Audit: Evaluation of M&Q processes or test operations against documented instructions and standards to measure conformance.
- Quality System Audit: Evaluation of system processes, work instructions, checklists, and other objective evidence that applicable QMS elements are being applied and are effective in meeting requirements.

In addition, quality audits may relate to a category of stakeholder, for example:

- Internal Audit: A first-party audit to measure conformity of the product to a standard and conformity of the QMS
- Customer Audit of a Supplier: A second-party audit conducted to measure the conformance of a subcontractor or vendor to product standards and the QMS

- External Independent Audit: A third-party audit or independent audit that measures conformance to a product standard of the QMS

The need to conduct quality audits is a requirement of a higher-level QMS such as ISO 9001 and SAE AS9100 and is part of the “Check” of the PDCA cycle.

The prime contractor is responsible for the quality of its entire supply chain even though it might not have contractual authority. This requires the flow-down of quality requirements and a plan for assessing quality risks at the lower levels of the supply chain.

Quality auditing begins in the planning cycle, and Government auditing may require the support of DCMA personnel. If the audit requires DCMA personnel, then agreements should be put in place to accomplish this effort.

B.6 Detection to Prevention

Detection to prevention (D2P) is a strategic initiative that shifts from simply finding defects (detection) to proactively preventing them by focusing on contractor accountability and process capability. D2P involves risk assessment, process surveillance, and data-driven analysis to mitigate risks before they lead to non-conforming products, rather than relying solely on end-product inspections. This approach aims to improve efficiency and quality, providing better value for the Government and ensuring warfighters receive the supplies and services they need.

Key components of the D2P strategy include the following:

- **Process-focused surveillance:** Instead of just inspecting the final product, DCMA evaluates the contractor’s entire system, processes, and outputs to ensure they are capable of producing quality work from the start.
- **Risk assessment and mitigation:** The strategy emphasizes identifying and mitigating risks early in the acquisition process through data-driven insights and proactive measures.
- **Contractor accountability:** D2P places greater emphasis on holding contractors accountable for their processes, encouraging them to prevent issues before they occur.
- **Data-driven insights:** Centralized data systems, like the Program and Contract Administrative Services Data Repository (PDREP), provide the information needed for analysis, risk assessment, and the development of more efficient surveillance plans.
- **Reduced redundancies:** By focusing on process capability, D2P reduces the need for redundant end-product inspections and can lead to reduced inspection holds, saving time and resources for both DCMA and the contractor.

B.7 Airworthiness

Airworthiness is the property of an air vehicle or aircraft system configuration to safely attain, sustain, and terminate flight in accordance with the approved usage limits. All manned aircraft should be airworthy.

Airworthiness certification is a repeatable process implemented to verify that a specific air system can be, or has been, safely maintained and operated within its described flight envelope. The two necessary conditions for issuance and maintenance of an airworthiness certification are:

- The air system must conform to its type design
- The air system must be in a condition for safe operation

Airworthiness certification is covered in part by Service guidance and MIL-HDBK-516, Airworthiness Certification Criteria, which establishes the airworthiness certification criteria, standards and methods of compliance to be used in the determination of airworthiness of all manned and unmanned, fixed and rotary wing air systems.

- Airworthiness Assessment: All air systems owned, leased, or operated undergo an airworthiness assessment. This assessment evaluates the configuration, usage, and operating environment of the aircraft to support the issuance of an airworthiness certificate.
- Technical Airworthiness Authority: The Technical Airworthiness Authority is responsible for conducting these assessments and ensuring that all air systems meet the necessary safety and operational standards before they can be flown.
- Joint Service Specification Guides (JSSGs): The JSSGs provide a framework for developing program-specific requirements for air systems. They include candidate references, requirements, verification criteria, and guidance for program teams to ensure compliance with airworthiness standards.

Airworthiness addresses logistics, product support, sustainment, and systems/sustaining engineering considerations. Organizations should establish and implement airworthiness processes to ensure air system configurations are maintained in accordance with the airworthiness assurance requirements in MIL-HDBK-516. Continuing airworthiness processes include the following:

- Inspections: [DoW] Components should establish inspection intervals and criteria to assess the status of the materiel condition of the air system.

- Life Limits: [DoW] Components should establish life limits, wear limits, and conditions for mandatory replacement or overhaul as necessary to sustain operations of the air system
- Maintenance and Overhaul: [DoW] Components should document maintenance and overhaul requirements, including physical standards of the materiel, process standards, and personnel training.
- Critical Safety Items: [DoW] Components should control critical safety items in compliance with Section 3243(g) of Title 10, U.S.

B.8 Key Characteristics

A Key Characteristic (KC) is a characteristic of a material or part whose variation has a significant impact on product fit, performance, service life, or manufacturability. KCs can be either:

- **Key Product Characteristics:** specific attributes of a product that directly affect safety, compliance, performance, and customer satisfaction within a QMS. These characteristics require enhanced control measures, systematic monitoring, and rigorous documentation throughout the product lifecycle to ensure regulatory compliance and operational excellence.
- **Key Process Characteristics:** critical features, parameters, or variables within a process that significantly impact the quality, performance, and reliability of the final product or service. Identifying and controlling these characteristics is vital for achieving operational efficiency, meeting customer requirements, and reducing costs, as variations in these elements directly influence the outcome and customer satisfaction.

The identification and management of KCs is considered a best practice because any variation in KCs heavily affects all of the factors listed above and provides a way for focusing design and production resources on things that matter. When identifying and reducing KCs, organizations should:

- Identify which of the thousands of products or process parameters contribute the most to variation.
- Understand the factors that contribute the most variation using tools such as Design of Experiments (DoE) and the Taguchi Loss Function.
- Reduce variation and control KCs using tools such as measurement system analysis, statistical process control (SPC), and control plans.
- Develop a process control plan

Organizations need to identify and manage KCs by controlling the variation of those KCs, leading to improved performance and affordability. Control and management of KCs may be accomplished using SPC to measure and monitor and the KCs to ensure that variation is tightly controlled.

KCs should be identified on drawings. One method is to use a flag on the drawing. A unique identifying number or label should be assigned to each KC so that related data can be tracked and mapped to the production processes that create the KCs.

Once identified, KCs should be mapped to manufacturing processes and Critical Characteristics (CCs) mapped to critical processes. The contractor should maintain documentation depicting this relationship between KCs and the associated key processes. For each critical manufacturing process, a Process Failure Modes and Effects Analysis (FMEA) should be performed, and process control plans should be developed and implemented.

B.9.1 Identifying Key and Critical Characteristics

KCs and CCs can be identified by using one of several techniques:

- Design Failure Modes and Effects Analysis (DFMEA): a design analysis technique used to identify potential problems with the product design and to eliminate or mitigate those problems before the design is finalized and for identifying Key Product Characteristics. M&Q Engineers should contribute to DFMEAs early in development. Outputs from the DFMEA should feed into the PFMEA to provide the most robust transition to production.
- Process Failure Modes and Effects Analysis (PFMEA): a structured risk-based methodology for analyzing and preventing failures in manufacturing and assembly processes and for identifying Key Process Characteristics. The PFMEA is a process design risk analysis tool, and it should be performed continuously from conceptual design through development. PFMEAs are not intended to take the place of DFMEAs, since they cannot improve the quality or reliability of an inherently poor design. The objectives of PFMEAs are:
    - Identify the potential failure modes of a process and the effects of those failure modes
    - Rank risk probability and consequence associated with failure modes
    - Develop actions that should mitigate or eliminate the probability and/or consequences of the potential failures
- Failure Modes and Effects Analysis (FMEA): a systematic approach used to identify and describe potential failure modes and the effects of those failures. Failure Modes, Effects, and Criticality Analysis (FMECA) take the analysis further to quantify the effects of

failures and to prioritize and manage failure modes that could impact mission success, safety, or maintainability.

- Design of Experiments (DoE): a statistical approach to planning, conducting, analyzing, and interpreting controlled tests in order to determine the relationship between factors affecting a process and the output of that process. DoE provides for the manipulation of various input variables (factors) to determine what effect they could have on the desired output (responses) allowing for engineers and process managers to better control and improve quality.

B.9.2 Mapping KCs to Manufacturing Processes

Organizations can use several techniques for mapping KCs to manufacturing processes, to include:

- Process Characterization: Mapping KC use involves creating a visual representation of a process to identify and analyze the KCs that impact product quality. This is done by creating a process flow diagram, defining KCs, and using the map to find areas for improvement, such as reducing variation, eliminating bottlenecks, or managing the lifecycle of the KC.
- Process Mapping Tools: Flowcharts, swimlane map, and Value Stream Maps are used to represent the sequence of activities within a process and identify areas for improvement.
- Quality Control Tools: Total Quality Management (TQM), SPC, Six Sigma, and DoE help identify, analyze, and control variation in manufacturing processes by focusing on KCs.
- Data Analysis: Collecting and analyzing data on process performance and KC measurements helps determine the relationships between process parameters and product quality.

See SAE AS9103, Variation Management of Key Characteristics, for more guidance.

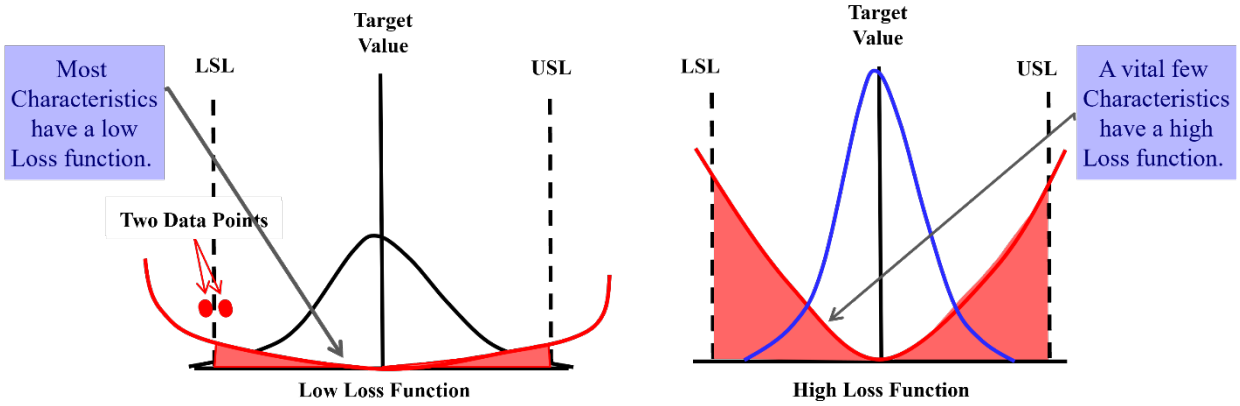
B.10 Taguchi Loss Function

Quality achievement has at times been reduced to the act of simply “meeting specs.” Consistent with this mindset, if a product characteristic lies within the design tolerances, the product is considered “good” and accepted. If the product lies outside of the design limits, the product is considered “bad” and is rejected.

Taguchi’s (see Appendix A) approach conceptualizes financial loss due to any deviation from the design feature’s target value. Taguchi showed that failure to meet nominal values for KCs can result in value lost even when the feature’s measurement falls within the specification limits,

while other characteristics can vary more from the target value and have little impact on cost, fit, function or service life.

Figure B-2 illustrates how a characteristic with a "low loss function" does not experience much of an impact as the feature deviates from the target value while the characteristic with a "high loss function" experiences a significant impact on fit, performance, service life, or manufacturability, even when it is still within the specification limits.



Source: Developed for WarU PQM 301, Advanced Quality.

Figure B-2. Taguchi Loss Function

Parameter design involves the identification and optimization of control factors that engineers can adjust to minimize variation of KCs, thereby improving product robustness. Robust parameter design exploits the interaction between controllable and uncontrollable noise variables by robustification—finding the settings of the control factors that minimize response variation from uncontrollable factors. This allows engineers to manage those control factors and improve quality.

Tolerance design is the process of defining acceptable amounts of variations in dimensions and characteristics that can be allowed while balancing performance and costs. Dimensional characteristics may include the target value, upper control limit, and lower control limit.

B.11 Statistical Process Control

SPC is a method using statistical techniques to monitor and control a process by identifying and reducing variation in order to ensure the process is producing products that meet design requirements. SPC is based on the premise that all processes exhibit variation and that variation is bad and should be minimized. Organizations collect SPC data from products or processes based on measurements. That data is presented in the form a control charts which presents the data over time, showing upper and lower control limits and used to identify "out of control" conditions.

B.11.1 SPC Goals

Any assessment of SPC data should be based on the original source of that data. The goal of SPC is to:

- Achieve consistency by reducing overall variation in the process by implementing corrective action.
- Simplify procedures, methods, and tools.
- Measure the long-term performance level after the process has been brought under control.
- Obtain the best performance from current equipment without major capital expenditure.
- Provide information for better cost estimation, feedback, a common language for discussing process performance, and reliable permanent records and reports of actual performance.
- Identify when a process is moving in a way that may result in the production of defective material.
- Provide opportunity to improve the process

The control chart in Figure B-3 shows how a typical part will have dimensional characteristics that are defined by a target value with an upper and lower control limit. Control charts are similar in that they contain the same data listed above but the data is presented as a graph that is laid on its side and data is collected and plotted over time. QA specialists monitor this data to ensure that they are producing parts that comply with the specification or drawing requirements.

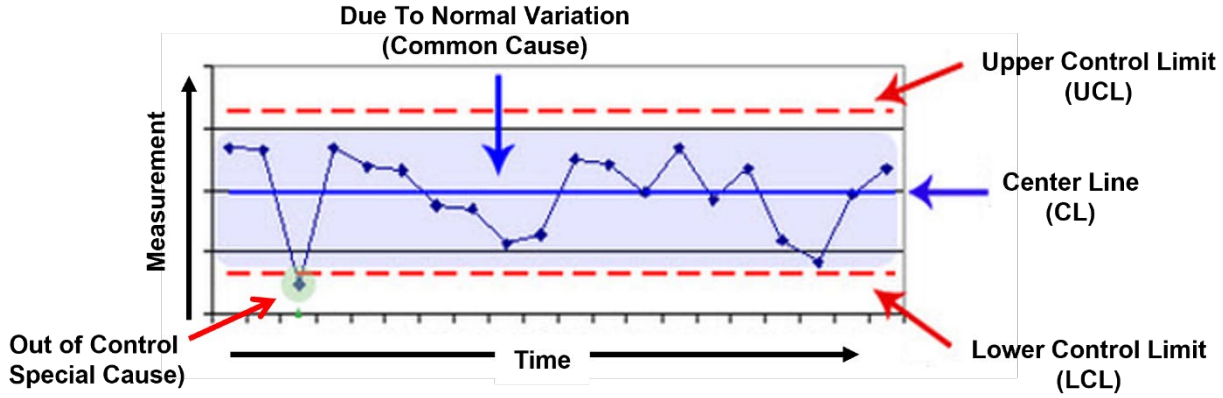


Figure B-3. Control Chart

B.11.2 SPC Principles

- Understand Variation: Variation comes from two sources common cause and special cause. Common cause variation is inherent or predictable variation that is expected in any

process that is operating under stable conditions. A process is stable or in control when variation is within the control limits and most of the variation is coming from common causes.

- Understand Special Cause Variation: Special cause variation is unexpected or unpredictable and comes from a specific and identifiable factor that is outside the normal process or system. A process is capable when special causes are present, and common causes have been eliminated to the point that the process is now producing conforming products. Special cause variation requires immediate attention, while common cause can be dealt with using SPC techniques such as:
- Understand Process Stability and Capability: Process capability is the ability of a process to meet specifications and is first calculated using process capability studies and measured using a process capability index. These studies and indices provide an awareness of a process's potential and if the process is capable of meeting spec.
- Foster Continuous Improvement: Continuous is an ongoing process, striving for perfection. Six Sigma
- Focus on Prevention not Detection: Inspection is at the end of the line and is detection oriented. SPC is prevention oriented and focuses on techniques like control charts to identify if a process is in control or out and if the process is drifting out of control.

B.12 Process Capability

A state of perfect control does not exist on any factory floor. Things happen that cause variation. All processes have inherent variation, and companies need to know if variation in their processes is causing them to produce bad products. They obtain this information by conducting a process capability study.

Process capability studies are performed to determine if a process is stable (predictable) (Figure B-4) or unstable (unpredictable) (Figure B-5) and to measure the extent to which a process can meet the expectations of the customer. Process capability studies compare the output or Voice of the Process (VoP) against the Voice of the Customer (VoC) as identified by a requirement or specification. If the current process is wider than the specification, the process is said to be unstable and is therefore unpredictable. A process is unstable and unpredictable because "special causes of variation" are present. Special causes of variation are sporadic and are not a part of the normal process. They are a result of a specific change (e.g., a car accident that slows traffic) in a process resulting in an unusual problem.

In B-5, both the top and bottom images show an unstable process. The top is unstable and unpredictable and is making bad product; however, the lower graphic shows a process that is

unstable and unpredictable but making good product because the specification limits are wider than the current process variation.

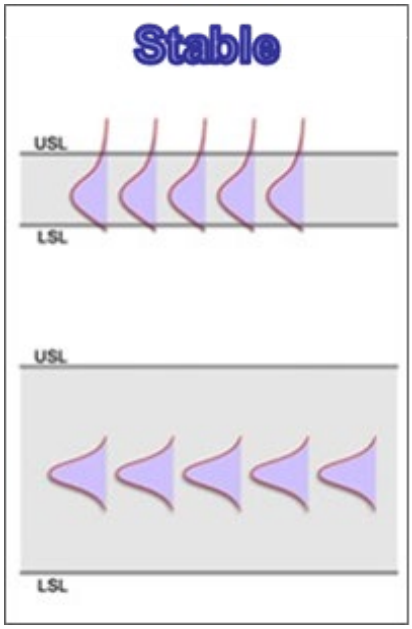


Figure B-4. Stable Process

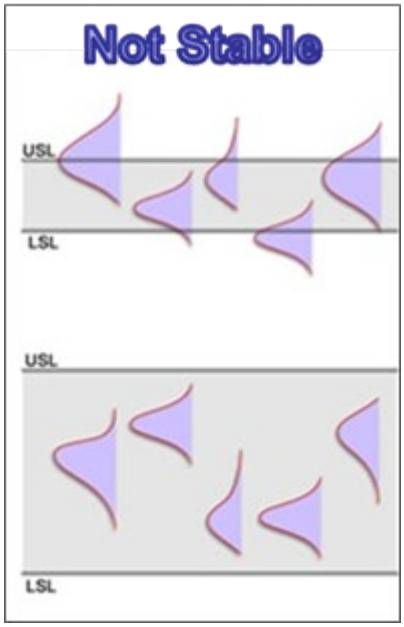


Figure B-5. Unstable Process

The organization needs to make the process stable (predictable), which requires removing all "special causes" of variation. Most companies do so by applying one or more variability reduction tools to include Six Sigma and by adopting the Plan- Do-Check-Act (PDCA) cycle. Once the special causes of variation have been removed, the process becomes stable and predictable over time.

B.12.1 Process Capability Index

A Process Capability Index is a statistical measure used to assess how well the manufacturing processes are meeting customer requirements. Process capability looks at both the amount of variation or spread in the process and the centering of the process.

- Voice of the Customer (VoC): Defines what the customer wants and is often expressed as a specification.
- Voice of the Process (VoP): Defines how well the system does in meeting the customer requirements.

Process capability studies are accomplished in order to:

- Determine the potential capability of a process

- Assess the actual performance of the process over time
- Identify areas that need improvement

These measurements can be expressed as Process Capability Indices (Cp or Cpk), or as Process Performance Indices (Pp or Ppk).

B.12.2 Process Control Studies

Process Control Studies leading to process improvement consist of four major steps.

1. Use of control charts to bring the process into statistical control.
2. Determine if the process is capable of meeting specifications.
3. If capable, determine if the process is meeting specifications.
4. Make decisions on how to change, adjust, and/or improve the process.

B.13 Lean, Six Sigma, and Theory of Constraints

B.13.1 Lean

Lean is the Toyota Production System (TPS) process. Lean involves organizations using less of everything: getting the right product or service to the right place and the right time, in the right quantities, at the right cost, and with the right performance.

Lean in the production environment is about finding and removing the seven forms of waste listed below:

- Excess Transportation: Unnecessary movement of material from one location to another. This could include moving material more often than necessary or further than necessary, inefficient delivery routes. Excessive transportation can lead to damage from the extra movement and handling.
- Excess Inventory: A result of overproduction and requires increased transportation and storage of the material at great costs and may be caused by a poor forecasting system, excessive setup times, or unbalanced production.
- Excess Motion: Unnecessary movement of people or equipment often exhibited as unnecessary or repetitive motion, excessive reaching when items could be closer, poor workstation layout, or any other unnecessary movement that does not add value.
- Excess Waiting: Idle time waiting for people, machines, material, for the next process step or on the previous process step, testing, etc. Idle time is not productive time.

- Overproduction: Making more than is needed, before it is required; an indication of a push system. Overproduction often leads to excess inventory, transportation, and costs.
- Overprocessing; Performing unnecessary process steps that do not add value. Overprocessing could be the need for a secondary operation because the first operation was not able or capable of completing the entire task.
- Defects: Anything that results in scrap, rework, or repair.

Lean adds value by eliminating waste identified above, being responsive to change, focusing on quality and enhancing the effectiveness of the workforce. Lean focuses on maximizing the value stream while eliminating waste. A value stream is the sequence of activities needed to deliver a product or service to a customer, from initial concept to final delivery. It encompasses both the flow of materials and the flow of information.

Lean focuses on optimizing production and combines the best aspects of craft and mass production allowing for high volume and low costs while producing a great variety.

The “House of Lean” (Figure B-6) focuses on:

- Roof that represents the goal of an organization and that is Customer Satisfaction
- Foundation that provides stability to the entire house focusing on Standard and Stable processes and Continuous Improvement
- Pillars that support the roof (goals) and drive processes including Just-in-Time (JIT), Jidoka (autonomation), and People and Teamwork

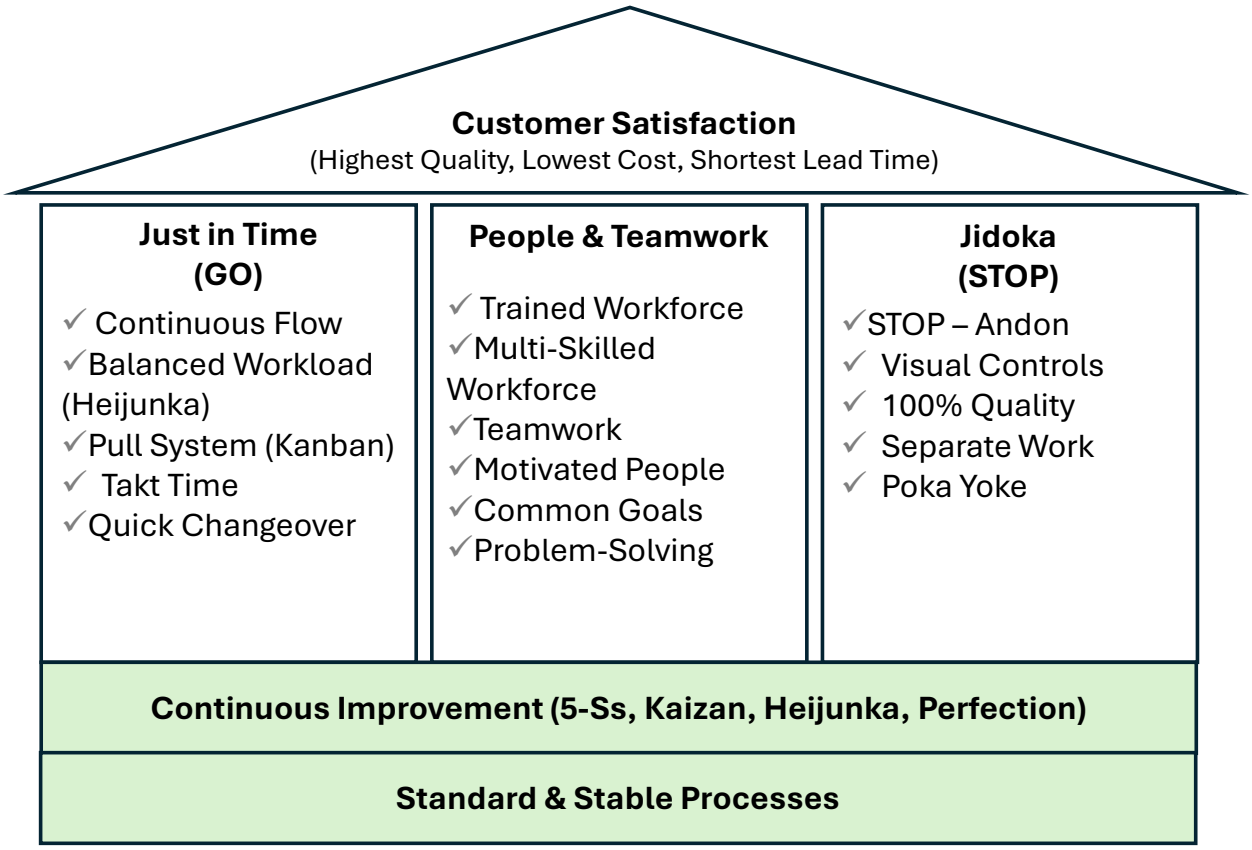


Figure B-6. House of Lean

B.13.2 Six Sigma

Six Sigma in production is a data-driven methodology focused on improving manufacturing processes by reducing defects and variation, leading to higher quality and efficiency.

Various Six Sigma approaches that can be used for manufacturing, design, and other activities. The Six Sigma process for production typically follows five steps known as DMAIC:

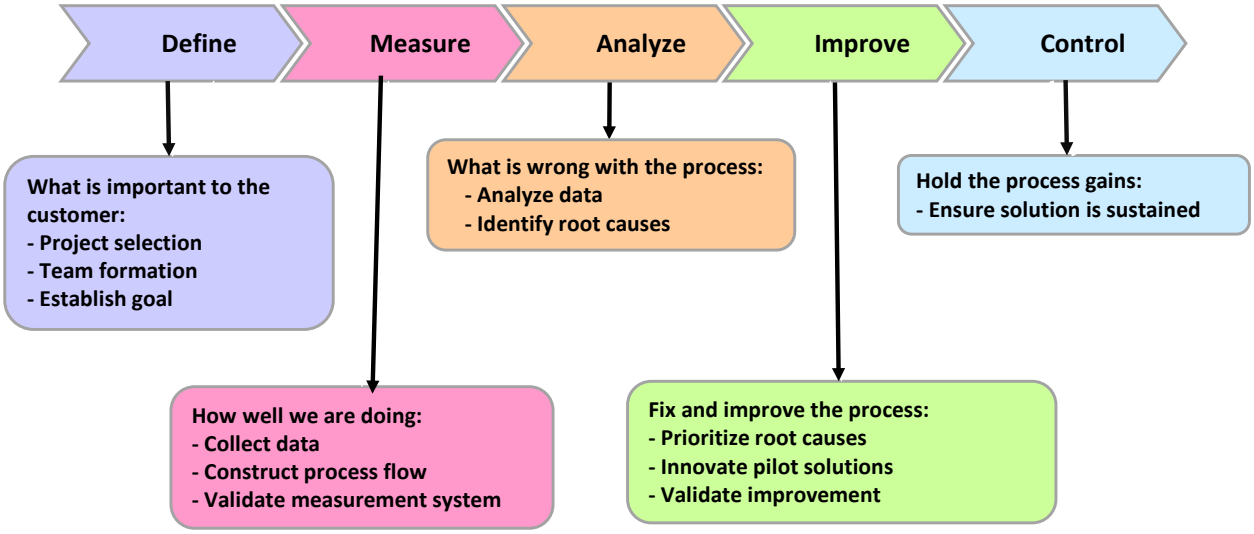
1. **Define:** Clearly define the project scope, objective, and timeframe. Tools to help with defining include benchmarking, value stream mapping, the Kano model, VoC, process flow maps, and stakeholder analysis.

2. **Measure:** Identify the state by collecting data on important metrics. Tolls to help with measure include the seven basic quality tools, (Pareto charts, histograms, check sheets, run charts, flow chart, and control chart).

3. **Analyze:** Is to identify the root cause of source of the problem that is leading to waste. Tools for this include Pareto charts, Fishbone charts, 5-why's, flow charts, Failure Modes and Effects Analysis, capability studies, and others.

4. **Improve:** Is to take the process from the "as is" condition to a more efficient condition, Tools for improve include flow charts, Kaizen, DoE, process mapping, developing standard procedures, measurement system analysis. etc.

5. **Control:** Is to manage the process at the new "current state." Tools for control include control charts, SPC charts, mistake proofing, standard operating procedures, failure mode and effects analysis, lessons learned, etc.



Source: Developed for PQWM 301, Six Sigma.

Figure B-7. DMAIC Process

Six sigma employs many tools to identify and continuously improve. A few of the more important tools are the following:

- Value Stream Mapping: Is a virtual representation of the flow of materials and information that is needed to deliver a product.
- Suppliers, inputs, processes, outputs, and customer (SIPOC): Is another form of a flow chart used to map, understand, and improve processes by diagramming the flow of product and information.
- Kaizen: Kaizen is a Japanese term meaning continuous improvement by focusing on incremental and ongoing improvements. These incremental improvements eventually lead to significant long-term benefits. Kaizen follows a five-step process:
  - Identify areas for improvement
  - Analyze the current state
  - Develop solutions
  - Implement solutions
  - Evaluate results and continue to improve

- Statistical process control (SPC)
- Root Cause Analysis (Ishikawa diagram): Is a tool that is used to identify root or potential causes of a problem by sorting ideas into useful categories. Those categories are often defined as one of the 5Ms (manpower, machines, material, methods, and measurement).

Six Sigma programs seek to continuously improve product and processes to the degree that there are fewer than 3.4 defects per million opportunities (DPMO).

Many DoW suppliers have process capabilities between 3 and 6 Sigma, but certain critical processes, including micro electro-optical integrated circuits, and other micro integrated circuits, do not. Those low yield processes with capabilities below 3 Sigma require screening and inspection processes that are 6 Sigma or better. Suppliers and programs to identify those processes and focus on those screening and inspection processes to ensure only conforming parts make it into production.

B.13.3 Theory of Constraints

Theory of Constraints (TOC) is not a quality tool but is used to improve production performance and gain faster thruput but identifying and eliminating constraints or bottlenecks. TOC is a thinking process that looks at:

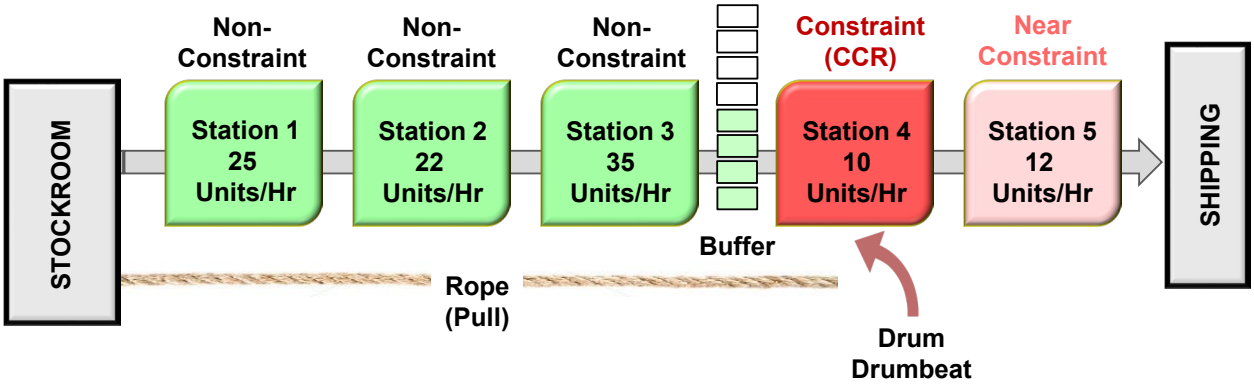
- What needs to be changed?
- What actions are required to cause the change?
- What is the goal of the change?

The TOC process follows these five focusing steps:

1. Identify the constraint or bottleneck (called the drum)
2. Exploit the constraint (use and protect the bottleneck aby getting the most out of the constraint without adding additional resources)
3. Subordinate all other processes (use non-bottleneck operations in front of the drum only to keep pace with the bottleneck, do not overproduce in front of the drum)
4. Elevate the constraint by reducing the load, improving capacity and reducing variability at the bottleneck
5. Repeat the cycle looking for new constraints (find and improve the next bottleneck)

TOC includes three components:

- Drum: The drum is the pace of the system and is the constraint or bottleneck that needs to be eliminated
- Buffer: The buffer is calculated amount of inventory put in front of the drum to prevent the bottleneck from becoming idle.
- Rope: The rope is a demand signal that tells all processes in front of the drum when to produce more material.



Source: Developed for PQM 301, Theory of Constraints.

Figure B-8. Theory of Constraints Drum - Buffer - Rope

Any changes to the processes to eliminate bottlenecks should improve throughput, decrease inventory, improve flow, and decrease operating expenses.

Table B-1 shows how each process is applied in theory, application guidelines, basic assumptions, and the primary effect of each process.

Table B-1. Comparison of Lean, Six Sigma, and Theory of Constraints

Program	Lean Thinking	Six Sigma	Theory of Constraints
Theory	**Remove Waste**	**Reduce Variation**	**Manage Constraints**
Application Guidelines	1. Identify value 2. Identify value stream 3. Flow 4. Pull 5. Perfection	1. Define 2. Measure 3. Analyze 4. Improve 5. Control	1. Identify constraints or bottlenecks 2. Exploit constraint 3. Subordinate the process 4. Elevate constraint 5. Repeat cycle
Focus	Flow Focused	Problem Focused	System Constraints
Assumptions	Waste removal will improve business performance Many small improvements are better than system analysis	A problem exists Data is valued System output improves if process variation is reduced	Emphasis on speed and volume Uses existing systems Process interdependence
Primary Effect	Reduced flow time	Uniform process output	Fast throughput

B.14 Cost of Quality

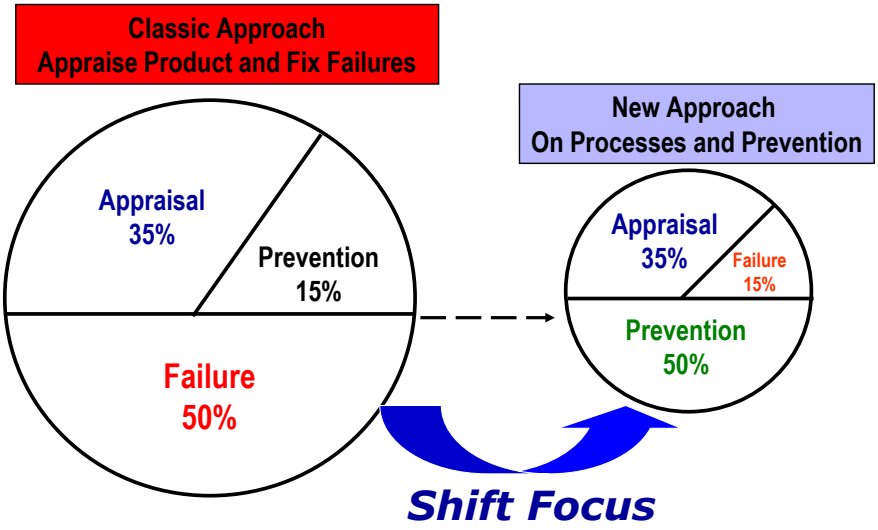
The Cost of Quality (CoQ) comprises three elements:

- Appraisal costs: Cost associated with determining, assessing, or measuring a product to ensure it meets requirements. This could include various forms of audits, various inspection activities, supplier rating systems,
- Failure costs (Internal and External): Costs associated with defective products and could include scrap, rework, repair, return-to-vendor warranty costs, repair costs, customer complaints, and lost customers.
- Prevention costs: Costs associated with "doing it right the first time," to design and build in quality, not inspect it in.

The CoQ is just the "tip of the iceberg" and extends beyond the cost of scrap, rework, and repair. CoQ includes many wasteful activities that lead to customer dissatisfaction. Quality costs show up in the plant as excessive motion, over-production, over-processing, excessive warranty costs,

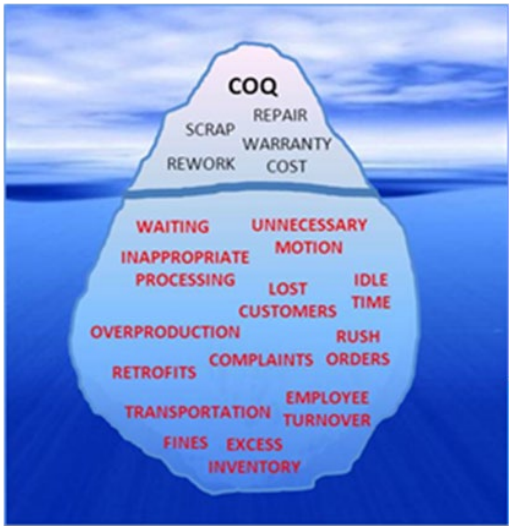
idle time, retrofits, employee turnover, and others. Quality costs show up in the field in the form of degraded performance, low availability, excessive maintenance, etc.

The classic approach to quality for years was to appraise the product and then fix the failures. This "find it and fix it" approach led to a very high Cost of Poor Quality with 35 percent of the CoQ associated with Appraisal, 50 percent with Failure, and only 15 percent spent on Prevention. The move from D2P changed the dynamics so that the new approach focused on processes not product and on prevention not detection. Under this model, Prevention accounted for 50 percent of the CoQ, Appraisal 35 percent, and Failure only 15 percent.



Source: Developed for PQM 301, Advanced Quality Management System.

Figure B-9. Detection to Prevention



Source: Developed for PQM 301, Advanced Quality Management System.

Figure B-10. Cost of Quality Iceberg

Many organizations estimate their CoQ at 15-20 percent of sales; if that accurately translates into program costs, it represents considerable lost operational capability. A high CoQ indicates that the organization tends toward being appraisal driven, relying on a detect (poor quality after it has already happened) and correct mode of operation. A low CoQ indicates that the organization is prevention oriented, actively designing in, planning for, and managing quality.

Organizations may want to request prime contractors to capture and report CoQ data via a Contract Data Requirements List (CDRL).

B.15 Plan-Do-Check-Act Cycle

The PDCA cycle was developed by Shewhart and later popularized by Deming and goes by the name Shewhart Cycle, Deming Cycle, Deming Wheel, or PDCA cycle. The idea was developed as a continuous improvement methodology that involves the use of four iterative steps that can be used to improve both product and processes; it is one of the most fundamental quality tools used for planning purposes.

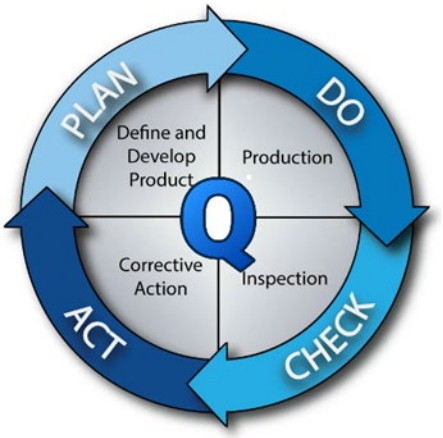
The PDCA cycle is a valuable tool for capturing knowledge about products, processes, or services in order to improve and achieve customer satisfaction. The PDCA cycle is often used in the development of new products or for defining and managing ongoing work looking for improvements, and is represented as follows:

The PDCA cycle can be used to:

- Enhance or improve production efficiency
- Ensure compliance with regulations and standards
- Improve product design
- Improve quality levels and standards required for aerospace products

The PDCA cycle should be accomplished by contractors or organizations doing production activities (Arsenals, Plants, Depots, etc.) with oversight being conducted by Government activities. Oversight activities should rely on contractor or organizational data as their primary source of information and should accept contractor format for that data unless that data is insufficient to meet assessment needs.

The PDCA cycle is illustrated in Figure B-11 with each PDCA step summarized below.



Source: Developed for PQM 301.

Figure B-11. PDCA Cycle

The PDCA cycle may be used implement and assess a QMS as follows.

B.15.1 Plan: Develop a Plan for QMS

- Identify requirement for a QMS at a program or facility level
- Identify all QMS requirements to implement
- Review existing plans, procedures and other QA documentation
- Perform a gap analysis to identify implementation needs
- Identify solutions and priorities
- Gain management support for implementation
- Identify customers and stakeholders

B.15.2 Do: Implement the QMS Plan

- Identify success criteria
- Test possible solutions
- Develop plans to achieve goals
- Gain stakeholder approval
- Implement the solution

B.15.3 Check: Analyze Quality Products and Processes

- Gather and analyze data
- Measure results of implementation actions

- Validate the results of those

B.15.4 Act: Improve

- Assess results against improvement goals
- Document the results and verify effectiveness
- Implement systematic changes (prevention oriented)
- Monitor and adjust as needed
- Identify other improvement activities

B.16 Advanced Product Quality Program

The Advanced Product Quality Program (APQP) originated in the automotive industry and is used during product development. It is a structured approach to product and process design using cross-functional teams. APQP consists of a standardized set of requirements defined in AS9145: Aerospace Series – Requirements for Advanced Product Quality Planning and Production Part Approval Process. APQP was developed to create a proactive structured approach for the product development processes used throughout the aviation, space, and defense industries. APQP is designed to ensure that organizations have fully integrated processes, extending from concept and design to manufacturing process, into product use, service, and customer feedback.

APQP uses many tools to aid in accomplishing the design process, to include:

- Process Failure Modes and Effects Analysis (PFMEA)
- Process Flow Diagrams
- Measurement System Analysis (MSA)
- Process Capability Studies and Statistical Process Control (SPC)
- Control Plans
- Run Rate
- 8 Dimensions of Quality
- First Article Inspection (FAI)

The purpose APQP is to establish:

- Common APQP expectations for the internal and external suppliers
- Common APQP process metrics
- Common program status reporting format
- Roles and responsibilities for APQP elements

- A better understanding of how the APQP elements relate to Product Development and to the development of milestones and the timing

APQP consists of five phases: Concept Approval, Program Approval, Prototype, Pilot, and Launch

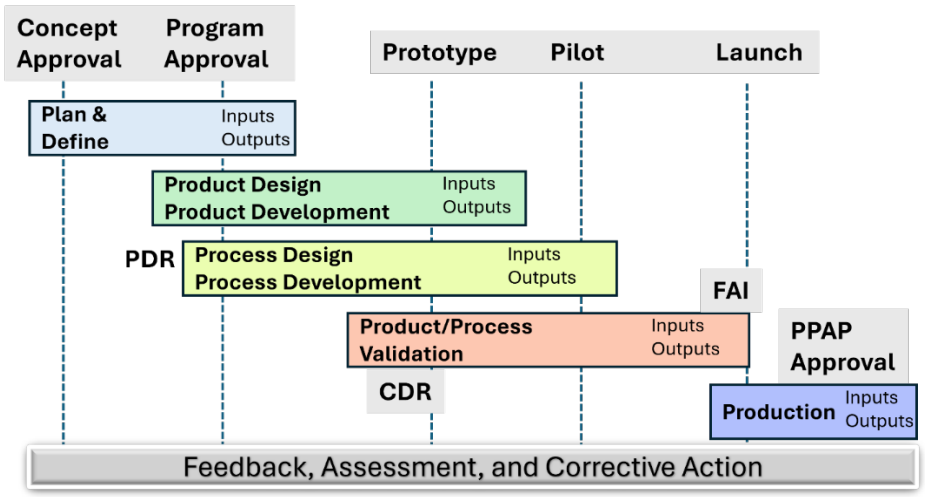


Figure B-12. APQP Phases

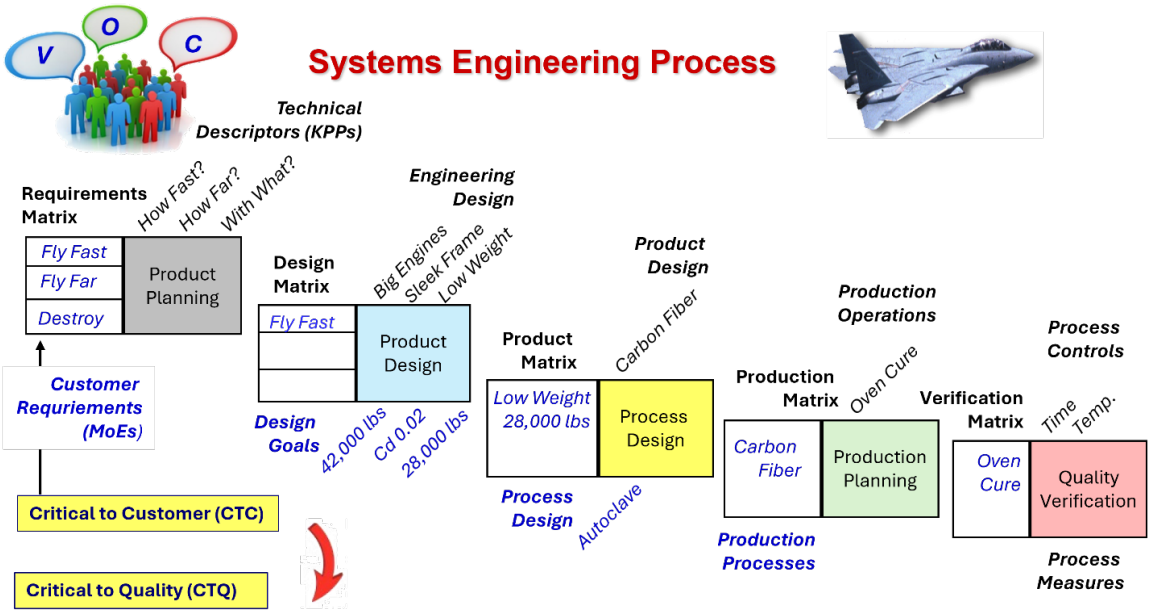
Each phase of the APQP process has a series of inputs and outputs with the outputs of a phase, becoming the inputs to the next phase.

APQP begins with an operational need, through to a delivered capability, and finally to disposal. The SE process begins with the development and capturing of customer and stakeholder requirements from the VoC. These requirements are then analyzed and the functions allocated or decomposed into the system configuration or work breakdown structure. These functions are then translated into design solutions as the functions are driven down from the system to subsystems, and lower-level items. The design is then implemented, meaning a prototype or other configuration item is produced, verified (confirming that the system element meets its design-to or build-to specification, validated or tested to ensure the system element meets stakeholder performance and other requirements, and finally transitioned to the customer or warfighter.

The SE top-down process is depicted below for the design-build of an aircraft using Quality Function Deployment. Quality Function Deployment (QFD) is a structured methodology for translating customer needs into specific technical design requirements and process plans to ensure products and services effectively satisfy those needs. QFG planning includes:

- Product Planning: Gathering the VoC to identify and prioritize requirements)
- Product Design: At the system, subsystem and component level.

- Process Design or Planning: Identify the important processes and flows required for meeting production requirements
- Production Planning or Operations: Involves setting and maintaining quality control throughout the product's production process.
- Quality or Process Controls: Determine the critical part and process characteristics and establish control methods and parameters.



Source: SE Guidebook 2026.

Figure B-13. Systems Engineering Process Flowdown

B.16.1 Plan and Define

Planning links customer requirements to product and resource planning. Planning and defining should include capturing customer requirements and incorporating high-level cost, technical, and quality data into a product concept and realization plan. Integrated Product Teams (IPTs) plan the activities of the first phase of APQP with the customers' needs and expectations in mind. The goal of planning is to establish the framework of the project and product. The activities in this phase should capture the building of the technical, quality, and manufacturing requirements, the identification of the parts to be outsourced, the building of the sourcing plan, and finally the building of the APQP timeline plan which describes all APQP activities, and the schedule aligned with the project needs.

B.16.2 Product Design and Development

The SE process translates requirements into design solutions including a detailed design, geometry, and tolerances. During Product Design and Development design goals, reliability goals, and quality goals that were developed in the planning phase are translated into a product

design to be used in development. Product design defines “what” is to be made and is often captured in a technical data package (TDP) at the following levels per MIL-STD-31000C:

- “Conceptual level - A level (1) Conceptual TDP defines design concepts and includes the appropriate information required for analysis and evaluation of those concepts. The data will consist of simple sketches/models, artist renderings and/or basic textual data. The data may consist of the system performance specification and conceptual design data as specified by the contract.
- Developmental level - A level (2) Developmental TDP provides sufficient data to support the analysis of a specific design approach, the fabrication of prototype material for test or experimentation, and limited production by the original design activity or with assistance from the original design activity. The data may consist of the unique item specifications for all system Configuration Items (CIs) and developmental design data and any required associated lists as specified by the contract.
- Product level - A level (3) Product Level TDP provides the information necessary to fully define the item and enables the procurement or manufacture of an item. The product shall be defined to the extent necessary for a competent manufacturer to produce an item, which duplicates the physical, interface, and functional characteristics of the original product, without additional design engineering effort or recourse to the original or current design activity. Product data shall reflect the approved, tested, and accepted configuration of the defined delivered item. The key components of a TDP may include:
- Design sketches or drawings (2D or 3D)
- Specifications to include references, materials, processes, military standards, packaging etc.
- Product characteristics that require verification and used during a first article inspection”

B.16.3 Process Design and Development

Process design and development address the manufacturing processes and controls that are developed or used to produce and mature the product. Manufacturing processes should be capable of delivering products that meet customer and stakeholder requirements while achieving operational efficiency. Process design defines “how” a product is to be made and may include process flow charts, work instructions, process or route sheets, factory floor layout, production and quality workstations, process instructions, inspection, testing, material movement and kitting, packaging, and distribution.

B.16.4 Product and Process Validation

Product and process validation ensures that the design and production can achieve design requirements and goals and that it can consistently produce uniform, defect-free product at the rate, quantity, and quality required by the customer. During product and process validation, the customer may validate the product and the manufacturing process and accept the product based on initial product samples and contractor documentation. This is often accomplished through FAI and FAT. Technical IPTs to include QA management should ensure that contractor process control documents, such as the Process Flow Diagram (PFD), Process Failure Mode and Effects Analysis (PFMEA), Control Plan, and Operator Instructions are being followed. Technical IPTs to include QA management should ensure that organizations monitor and assess the design and development process throughout the life cycle of the product. These assessments may include:

- Initial Technical Review (ITR)
- Alternative System Review (ASR)
- System Requirements Review (SRR)
- Technology Readiness Assessment (TRA)
- Integrated Baseline Review (IBR)
- System Functional Review (SFR)
- Preliminary Design Review (PDR)
- Pre-Engineering, Manufacturing & Development (EMD) Review
- Critical Design Review (CDR)
- Test Readiness Review (TRR)
- Flight Readiness Review (FRR)
- System Verification Audit (SVA)
- Functional Configuration Review (FCR)
- Production Readiness Review (PRR)
- Operational Test Readiness Review (OTRR)
- Physical Configuration Audit (PCA)
- In-Service Review (ISR)

B.16.5 Feedback and Corrective Action

The feedback, assessment, and corrective action phase is the only phase that runs from start to finish of the program and illustrates the need to apply corrective actions and course corrections throughout the program to ensure the on-time delivery of a quality product. Feedback is used to

ramp up production and improve manufacturing processes while reducing variation, defects, and enhancing product delivery quality and customer satisfaction.

B.16.6 Production Part Approval Process

The Production Part Approval Process (PPAP) can be used to implement the fourth phase of APQP and provide evidence that the organization producing the item has the ability to meet all design and quality requirements consistently. The evidence is provided through five submission levels:

- Level 1: Part Submission Warrant only submitted to the customer.
- Level 2: PSW with product samples and limited supporting data.
- Level 3: PSW with product samples and complete supporting data.
- Level 4: PSW and other requirements as defined by the customer.
- Level 5: PSW with product samples and complete supporting data available for review at the supplier's manufacturing location.

PPAP is a standardized process developed by the Automotive Industry Action Group (AAIG) to ensure that products from suppliers meet all contract and specification requirements and provides documentation demonstrating conformance to requirements. The PPAP process is required prior to first production pf a new product, or production that involves changes to materials, processes, suppliers, product modifications, of restart of production after 12 months.

PPAP includes 18 elements (see section 3.4.5.3).

B.16.7 Act: Implement New Activities Based on Previous Results

- Implement the best solution
- Evaluate results
- Modify plan to continuously improve

Appendix C: Dimensions of Quality

Quality should be aligned with program and corporate strategies, with quality as an enabler leading to successful program management. The achievement of program goals often depends on ensuring that the following dimensions of quality are articulated in the contract and system design and achieved on the program. See also the Early Manufacturing and Quality Guidebook and the Producibility and Manufacturability Engineering Guide.

C.1 Performance: Will the product do its intended function?

Performance refers to a product's primary operating characteristics. For an Abrams tank, performance would include traits like speed, mobility, firepower, protection, and advanced technologies. Because this dimension of quality involves measurable attributes, competing and adversarial systems can be ranked objectively on individual aspects of performance. Performance rankings require product developers to develop clear objectives that align with strategic goals and establishing specific targets, such as focusing on modernizing technology or enhancing cybersecurity capabilities to better address emerging threats and vulnerabilities.

C.2 Features: What does the product do?

Features are additional characteristics that also enhance the value of a product or service and can be considered secondary requirements or a want or need. Features may be difficult to describe or evaluate because they blur the lines with customer performance requirements. Features can be objective or measurable attributes such as sustainability, interoperability, and cybersecurity or features that enhance customer experience like seat warmers.

C.3 Reliability: How often does the product fail?

Within the DoW reliability also includes availability and maintainability (RAM).

- Reliability is the probability an item will perform a required function under stated conditions for a specified period of time. Reliability is further divided into mission reliability and logistics reliability. Metrics that significantly affect reliability include mean time between failure (MTBF), mean time to repair (MTTR), and mission capable (MC) rate.
- Availability is a measure of the degree to which a system is in an operable state and can be committed at the start of a mission when the mission is called for at an unknown (random) point. A system's MC rate is the best metric for availability. Three basic elements drive a weapon system's availability: reliability, maintainability, and supportability.

- Maintainability is the measure of the ability of the system to be brought back to a readiness status and state of normal function. This involves maintenance personnel having specified skill levels and using prescribed procedures and resources, at each prescribed level of maintenance and repair.

C.4 Conformance: Does the product meet the design requirements?

Conformance is the degree to which a product's design and operating characteristics meet contract and regulatory requirements. Conformance is often measured as defect rates in the factory and, once a product is in the hands of the customer, the incidence of service calls.

C.5 Durability: How long does the product last?

The ability to withstand wear and tear over its lifespan determines the durability of a product. Durability is a measure of product life and can be defined as the amount of use one gets from a product before it deteriorates or breaks down and where replacement is preferable to continued repair. Durability can be measured at the system, subsystem or component level. Examples include an oil filter that needs to be replaced after 5,000 miles or the need to replace brake pads after 50,000 miles. Durability can be measured by the MTBF.

C.6 Serviceability: Is the product easy to maintain?

Serviceability is the speed and ease of repair. Serviceability can be measured by the MTTR, which looks at the average time it takes to diagnose and bring the product back to a useful operating condition using skilled workers and trained maintenance personnel

C.7 Aesthetics: Does the product look good?

Aesthetics is a subjective dimension of quality. How a product looks, feels, sounds, tastes, or smells is a matter of personal preference. Therefore, when two or more people look at a product, they may judge that product to be better or worse than a competing product. This is why some people prefer one car or house style over another.

C.8 Perceived Quality: What is the reputation of the product?

People often have perceptions about a product or service's attributes such as quality, reliability or performance and perceptions may be based on different factors that might bias those perceptions. For example, automobile reliability can be measured but often people do not look at the data but rely on their own opinion, the opinion of others or are biased by advertising. Perceived quality is seldom observed directly and may be based on images, advertising, and brand names that provide inferences about quality rather than the actual quality.

Appendix D: Tools

DoW programs could use tools including but not limited to the following to help incorporate M&Q activities into acquisition technical, business, and management processes. Most of these tools support systems engineering technical and technical management processes, but a few can be used to support business processes such as cost estimating, contract language, acquisition strategies, etc. Some tools could be used by a contractor, some by Government personnel, and by people in different functional specialties. Most tools are available from on-line sources, some tools may need to be purchased to use, and many are free.

- 3Ps - Production Preparation Process
- 5S's (Sort, Straighten, Shine, Standardize, Sustain
- 5-Whys
- 7 - Basic Tools for Quality Improvement (includes the following which are also discussed separately):
  - Cause and Effect Diagram
  - Check Sheet
  - Control Chart
  - Histogram
  - Pareto Chart
  - Run Chart
  - Scatter Diagram
  - Stratification or Flowchart or
- 7 - Management and Planning Tools, or Advanced Tools for Quality Improvement (includes the following which are also discussed separately):
  - Affinity Diagram
  - Relations Diagram or Interrelationship Diagraph
  - Tree Diagram
  - Matrix Diagram
  - Matrix Data Analysis
  - Arrow Diagram
  - Process Decision Program Chart (PDPC)
- 8D/PSP (Eight Disciplines/Problem Solving Process)
- A3 Problem Solving Chart
- Acceptable Quality Levels (AQL)

- Acceptance Sampling
- Active Risk Manager (ARM)
- Affinity Diagram
- Advanced Product Quality Planning (APQP) Core Tools
- Arrow Diagram (Chart)
- AS6500 Manufacturing Management System (MMS)
- SAE AS9100 Advanced Quality Management Systems (QMS)
- SAE AS9103 Variation Management of Key Characteristics
- SAE AS9110 Maintenance
- SAE AS9120 Distributors
- SAE AS9102 FAI
- SAE AS9115 Software QA
- SAE AS9131 N/C Document
- SAE AS9132 Marking
- SAE AS9133 Supplier QA
- SAE AS 9137 AQAP Align
- SAE AS 9138 Statistical Process Control
- SAE AS9162 Self Verification
- Axiomatic Design
- Balanced Scorecard
- Baldrige Performance Excellence Criteria
- Bekidou Rate
- Benchmarking
- Bill of Materials (BOM)
- Bone Diagram
- Bottleneck Analysis
- Box and Whisker Plot
- Bubble Chart
- Capacity Matrix
- Capacity Analysis
- Cause and Effect Diagram (Fishbone or Ishikawa)
- Cause and Effect Matrix

- CFMEA – Concept Failure, Mode, and Effect Analysis
- Check Sheet
- Chokko Rate
- Computer-Aided Design (CAD)
- Computer-Aided Manufacturing (CAM)
- Computer Aided Process Planning (CAPP)
- Computer-Aided Three-Dimensional Interactive Application (CATIA)
- Computer Integrated Manufacturing (CIM)
- Consensogram
- Contingency Planning
- Control Chart - C-chart for Attribute Data (Go/No Go, Good/Bad, etc.)
    - Control Chart - C-chart for Attribute Data (Go/No Go, Good/Bad, etc.)
    - Control Chart -U-chart for Attribute Data
    - Control Chart - NP-chart for Attribute Data
    - Control Chart - P-chart for Attribute Data
    - Control Chart - X-barR chart for Variable Data (measurable)
    - Control Chart - X-bar-S chart for Variable Data
    - Control Chart - X-MR/I-MR chart for Variable Data
- Correlation Chart (Scatter Diagram)
- Cost/Benefit Analysis
- Cost of Quality Analysis
- Cost of Quality (COQ)
- Cost Modeling (Estimating)
- Criteria Testing
- Critical Chain Project Management
- Critical Design Review Checklist (DoD)
- Critical Path/PERT
- Critical to the Customer (CTC)
- Critical to Quality (CTQ) Tree
- Customer Contingency Table
- DCOV – Define, Characterize, Optimize and Verify
- Departmental Purpose Analysis

- Design of Experiments (DoE)
- DFMEA - Design Failure Mode and Effects Analysis
- DFMA - Design for Manufacturing and Assembly
- Design to Cost (DTC)
- DFSS - Design for Six Sigma
- DMAIC - Define, Measure, Analyze, Improve and Control
- DMADV (see DCOV)
- Factory Modeling and Simulation
    - Factory Modeling and Simulation
    - Producibility Analysis & Ergonomics
    - Process Planning
    - Production Planning & Scheduling
    - Line Balancing & Bottleneck Analysis
    - Capacity Planning
    - Predictive Analytics & Optimization
    - Facility Planning, Layout and Design
    - Virtual Factory Mock-up
- Failure Mode and Effects Analysis (FMEA)
- Fault Tree Analysis
- First Article Inspection
- First Article Testing
- Flow Chart or Process Flow Chart
- Force Field Analysis
- Gage R&R Studies
- Gantt Chart
- Histogram (Frequency or Bar Chart)
- Hoshin Kanri (Quality Policy Deployment)
- Interrelationship Diagraph (see also Relations Diagram, Network Diagram)
- ISO 9001 Quality Management Systems (QMS)
- Kano Model
- KJ model - Kawalota Jiro (see affinity diagram)
- Lead Time Analysis

- Learning Curve
- Learning Curve Analysis
- Line of Balance (LOB)
- Taguchi Loss Function
- Lotus Diagram
- Manufacturing Cost Estimating
- Manufacturing Plan
- Manufacturing Readiness Assessment (MRA)
- Manufacturing Readiness Level (MRL) Criteria
- Matrix Diagram
- Matrix Data Analysis Diagram
- Measurement Systems Analysis (MSA)
- MIL-HDBK-896A Manufacturing and Quality Program
- Multi-Vari Charts
- Network Diagram
- Nominal Group Technique
- One Piece Flow
- Operations Process Chart
- Overall Equipment Effectiveness (OEE)
- Pareto Charts (Template)
- Part-Family Analysis
- Paynter Chart
- Plan-Do-Check-Act (PDCA) Cycle
- P-Diagram or Parameter Design
- PERT Chart (Program Evaluation Routine Technique)
- PFMEA – Process Failure, Mode and Effect Analysis
- Pie Chart
- Preliminary Design Review Checklist (DoD)
- Preliminary Hazards List (PHL)
- Process Capability Studies (Cp and Cpk)
- Process Performance Studies (Pp and Ppk)
- Process Decision Program Chart (PDPC)

- Producibility Analysis/Assessments
- Producibility Assessment Worksheet
- Producibility Engineering and Planning (PEP) Program
- Production Part Approval Process
- Production Readiness Review (PRR) Checklist
- Program and Contract Administrative Services Data Repository (PDREP)
- Programmatic Evaluation of ESOH (PESHE)
- Pugh Matrix
- Quadrant Chart
- Quality Function Deployment (QFD)
- Queuing Theory/Waiting Line Analysis
- Radar Chart
- Rational DOORS
- Relation Diagram
- Reliability Growth Analysis
- Requirements Verification (Traceability) Matrix (RVM)
- Risk Management Assessment Tool
- Route Sheet
- Run Chart
- Scatter Diagram (Mind Mapping)
- SIPOC – System, Input, Process, Output and Customer
- Six Sigma
- SMART – Specific, Measurable, Attainable, Resources, Time
- Spaghetti Diagram
- Spider Diagram
- Stratification
- Statistical Process Control (SPC)
- Supply Chain Management Risk Assessment
- Swim Lane Chart (sometimes called a Deployment Flow Chart)
- SWOT Model (Strength, Weaknesses, Opportunities and Threats
- Systems Engineering Plan
- Takt Time Analysis

- Technical Risk Identification and Mitigation System (TRIMS)
- Technology Readiness Level (TRL) Checklist
- Theory of Constraints Analysis
- Throughput Analysis Tool
- Throughput Accounting
- Tolerance Analysis
- Tolerance Design
- Total Productive Maintenance (TPM)
- Trade Studies/Analysis
- Transition to Production (Willoughby Templates)
- Tree Diagram
- TRIZ Matrix
- Value Stream Mapping (VSM)
- Variability Reduction Program
- Venn Diagram
- Work Center
- Work Measurement
- X-Matrix
- Yamazumi Chart

Acronyms

See also M&Q BoK and other references.

2D	2 Dimensions
3D	3 Dimensions
5Ms	Manpower, Material, Machines, Methods, and Measurements
AAIG	Automotive Industry Action Group
ACA	Associate Contractor Agreement
AFB	Air Force Base
ALC	Air Logistics Center
ANSI	American National Standards Institute
AoA	Analysis of Alternatives
APQP	Advanced Product Quality Program
AQAP	Allied Quality Assurance Publication
ASR	Alternative System Review
ASQ	American Society for Quality
ATE	Advanced Test Equipment
BOM	Bill of Materials
BPR	Business Process Reengineering
BS	British Standard
CAD	Computer Aided Design
CAP	Contractor Acquired Property
CAS	Contract Administration Services
CC	Critical Characteristic
CCP	Critical Process Parameter
CDD	Capability Development Document
CDR	Critical Design Review
CDRL	Contract Data Requirements List
CFR	Code of Federal Regulations
CLIN	Contract Line Item Number
CM	Configuration Management
CMP	Critical Manufacturing Process
CNC	Computer Numerical Controlled
CoC	Certificate of Conformance
CONOPS	Concept of Operations
CORRS	Cost of Rework, Repair, and Scrap
CoQ	Cost of Quality
COTS	Commercial Off-The-Shelf

Cp	Process Capability Index (assumes process is centered)
Cpk	Process Capability Index (allows possibility process may not be centered)
CPARS	Contractor Performance Assessment Reporting System
CPI	Continuous Process Improvement
CPP	Counterfeit Parts Prevention
CPP	Critical Process Parameter
CQA	Critical Quality Attribute
CSI	Critical Safety Item
CTQ	Critical to Quality
DA	Determinant Assembly
DAU	Defense Acquisition University. *See* WarU.
DCMA	Defense Contract Management Agency
DE	Digital Engineering
DFARS	Defense Federal Acquisition Regulation Supplement
DFE	Design for Ergonomics
DFMA	Design for Manufacturing and Assembly
DFMEA	Design Failure Mode and Effects Analysis
DFSS	Design for Six Sigma
DID	Data Item Description
DLA	Defense Logistics Agency
DMADV	Define, Measure, Analyze, Design, and Verify
DMAIC	Define, Measure, Analyze, Improve, and Control
DMSMS	Diminishing Manufacturing Sources and Material Shortages
DoD	Department of Defense
DoE	Design of Experiments
DoW	Department of War
DPMO	Defects per Million Opportunities
DSMC	Defense Systems Management College
DTC	Design to Cost
ECP	Engineering Change Proposal
EMD	Engineering and Manufacturing Development
EPA	Environmental Protection Agency
ERAI	Electronic Resellers Association International
ERP	Enterprise Resource Planning
ESOH	Environment, Safety, and Occupational Health
FAI	First Article Inspection
FAR	Federal Acquisition Regulation
FAT	First Article Test

FCR	Functional Configuration Audit
FMEA	Failure Mode and Effects Analysis
FMECA	Failure Mode, Effects, and Criticality Analysis
FOD	Foreign Object Debris
FRP	Full-Rate Production
FRR	Flight Readiness Review
Gage R&R	Gage Repeatability and Reproducibility
GAO	Government Accountability Office
GFM	Government Furnished Material
GFP	Government Furnished Property
GIDEP	Government-Industry Data Exchange Program
GT	Group Technology
HDBK	Handbook
HQA	Hardware Quality Audit
IATF	International Automotive Task Force
IBR	Initial Baseline Review
ICD	Initial Capabilities Document
IEEE	Institute of Electrical and Electronics Engineers
IMP	Integrated Master Plan
INST	Instruction
IPPD	Integrated Product and Process Development
IPPT	Integrated Product and Process Team
IPS	Integrated Product Support
IPT	Integrated Product Team
IRT	Independent Review Team
ISO	International Organization for Standards
ISR	In-Service Review
JDMTP	Joint Defense Manufacturing Technology Panel
JDRS	Joint Deficiency Reporting System
JSSG	Joint Service Specifications Guide
KC	Key Characteristic
KMP	Key Manufacturing Process
KPI	Key Performance Indicator
KSA	Knowledge, Skills, and Abilities
LAT	Lot Acceptance Testing
LCD	Liquid Crystal Display
LCL	Lower Control Limit
LOB	Line of Balance

LRIP	Low-Rate Initial Production
LSL	Lower Specification Limit
M&Q	Manufacturing and Quality
M&S	Modeling and Simulation
M&TE	Measuring and Test Equipment
MC	Mission Capable
MDA	Missile Defense Agency
MDD	Material Development Decision
M&E	Manufacturing and Test Equipment
MES	Manufacturing Execution System
MII	Manufacturing Innovation Institute
MIT	Massachusetts Institute of Technology
M&M	Monitoring and Measuring
MM	Manufacturing Management
MOA	Memorandum of Agreement
MP	Mission Profile
MPC	Manufacturing Planning and Control
MRA	Manufacturing Readiness Assessment
MRB	Material Review Board
MRL	Manufacturing Readiness Level
MRO	Maintenance, Repair, and Overhaul
MRP	Material Requirements Planning
MRP	Manufacturing Resource Planning
MSA	Materiel Solution Analysis (phase)
MSA	Measurement System Analysis (MM program requirement)
MSV	Manufacturing System Verification
MTBF	Mean Time Between Failure
MTTR	Mean Time to Repair
MVDA	Multi-Variant Data Analysis
NADCAP	National Aerospace and Defense Contractors Accreditation Program
NATO	North Atlantic Treaty Organization
NEPA	National Environmental Policy Act
NCM	Nonconforming Material
OCM	Original Component Manufacturer
OEM	Original Equipment Manufacturer
OM	Original Manufacturer
OMS	Operational Mode Summary
OTTR	Operational Test Readiness Review

OUSD(R&E)	Office of the Under Secretary of Defense for Research and Engineering
OUSW(R&E)	Office of the Under Secretary of War for Research and Engineering
PAC	Production Activity Control
PC	Production Certificate
PCA	Physical Configuration Audit
PCM	Production Cost Model
PDCA	Plan-Do-Check-Act
PDR	Preliminary Design Review
PESHE	Programmatic Environmental Safety and Health Evaluation Program
PFMEA	Process Failure Mode and Effects Analysis
PFMECA	Process Failure Mode, Effects, and Criticality Analysis
PLT	Production Lot Testing
PM	Program Manager
PMS	Production Management System
PO	Purchase Order
PPAP	Production Part Approval Process
PPP	Pollution Prevention Program
PPP	Program Protection Plan
PPV	Production Process Verification
PRR	Production Readiness Review
PSS	Product Support Strategy
PWS	Performance Work Statement
QA	Quality Assurance
QC	Quality Control
QCP	Quality Control Plan
QFD	Quality Function Deployment
QMP	Quality Management Plan
QMS	Quality Management System
QoC	Quality of Conformance
QoD	Quality of Design
RAM	Reliability, Availability, and Maintainability
R&D	Research and Development
RF	Realization Factor
RFP	Request for Proposal
RMS	Reliability, Maintainability, and Supportability
ROM	Rough Order of Magnitude
RPN	Risk Priority Number
SAE	Society of Automotive Engineers

SE	Support Equipment
SE	Systems Engineering
SEP	Systems Engineering Plan
SFR	System Functional Review
SIE	Special Inspection Equipment
SIPOC	Supplier, Input, Process, Output, and Customers
SLA	Stereolithography Apparatus
SLS	Selective Laser Sintering
SMART	Specific, Measurable, Achievable, Relevant, and Time-Bound
SME	Subject Matter Expert
SOO	Statement of Objectives
SOW	Statement of Work
SPA	Supplier Process Audit
SPC	Statistical Process Control
SRP	Standard Repair Procedure
SRR	Scrap, Rework, and Repair
SRR	System Requirements Review
S&T	Science and Technology
ST	Special Tooling
STD	Standard
STE	Special Test Equipment
SVA	System Verification Audit
TDP	Technical Data Package
TLCSM	Total Life-Cycle Systems Management
TMRR	Technology Maturation and Risk Reduction
TOC	Total Ownership Cost
TPM	Total Preventive Maintenance
TPS	Toyota Production System
TQM	Total Quality Management
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level
TRR	Test Readiness Review
UCL	Upper Control Limit
UID	Unique Identification Data
USL	Upper Specification Limit
VE	Value Engineering
VIN	Vehicle Identification Numbers
VoC	Voice of the Customer

VoP	Voice of the Process
VR	Variability Reduction
VSA	Variation Simulation Analysis
VSM	Value Stream Map
WarU	Warfighting Acquisition University
WBS	Work Breakdown Structure
WIP	Work In Process (Work in Progress)

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