Early Manufacturing and Quality Engineering Guide

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Early Manufacturing and Quality Engineering Guide

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Early Manufacturing and Quality Engineering Guide Change Record

Date	Change	Rationale

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1 INTRODUCTION

1.1 Objectives

This guide describes best practices and guidance for Department of Defense (DoD) system developers, project leaders, and manufacturing and quality (M&Q) engineers to consider during early defense system development—the period starting with initial system concept definition before the Materiel Development Decision (MDD) and culminating with the system Preliminary Design Review (PDR). During early development, a program's status and leadership roles may be forming. The decisions regarding early activities, including M&Q, may fall to different persons depending on the stage of development. This guide is intended for the relevant decision makers and their associated M&Q practitioners, so they may consider ways to incorporate M&Q proactively during fundamental early system development activities such as requirements definition, mission engineering (ME), and systems engineering (SE). The guide encourages development project teams to integrate M&Q considerations for warfighter capabilities that can be produced feasibly and that will meet quality requirements. The benefits of including M&Q in this early stage are many, including improvements in schedule, cost, and performance as the system proceeds through development.

M&Q practitioners should proactively support early development activities to:

- Integrate early M&Q considerations into ME and SE processes (e.g., requirements and mission definition, science and technology (S&T), prototyping, early system development, producibility as a design consideration).
- During the Pre-MDD phase, analyze ME and SE trade space and help characterize candidate solutions.
- During the Materiel Solution Analysis (MSA) phase, provide M&Q expertise to the Analysis of Alternatives (AoA) and in maturing the preferred concept.
- During the Technology Maturation and Risk Reduction (TMRR) phase, participate in prototyping, SE trade-off analyses, digital engineering (DE) activities, SE Technical Reviews (SETRs), and acquisition planning (e.g., specifications, acquisition planning, contract requirements).

The guide will:

- Outline how M&Q practitioners should proactively engage with ME, SE, and DE during the "extreme front-end" (before the MDD, referred to as "Pre-MDD" activities) of engineering and technology development.

- Provide guidance for DoD M&Q practitioners and Engineering and Technical Management practitioners to collaborate effectively to identify potential manufacturing and producibility risks early in system development.
- Suggest ways to enable a more producible product and conduct manufacturing maturation planning.
- Provide insight regarding how to include M&Q engineering input to inform early acquisition milestone decisions.
- Recommend consideration of M&Q during early system development to facilitate bridging the "valley of death"[1] to develop producible systems.

This guide addresses early M&Q involvement in the DoD Instruction (DoDI) 5000.02, Adaptive Acquisition Framework (AAF)[2] pathways of Major Capability Acquisition (MCA); Middle Tier of Acquisition (MTA) (Rapid Prototyping, Rapid Fielding); and Urgent Capability Acquisition (UCA). This guide does not address the Software Acquisition, Defense Business System Acquisition, or Defense Acquisition of Services pathways involving fewer traditional manufacturing activities (Figure 1-1).

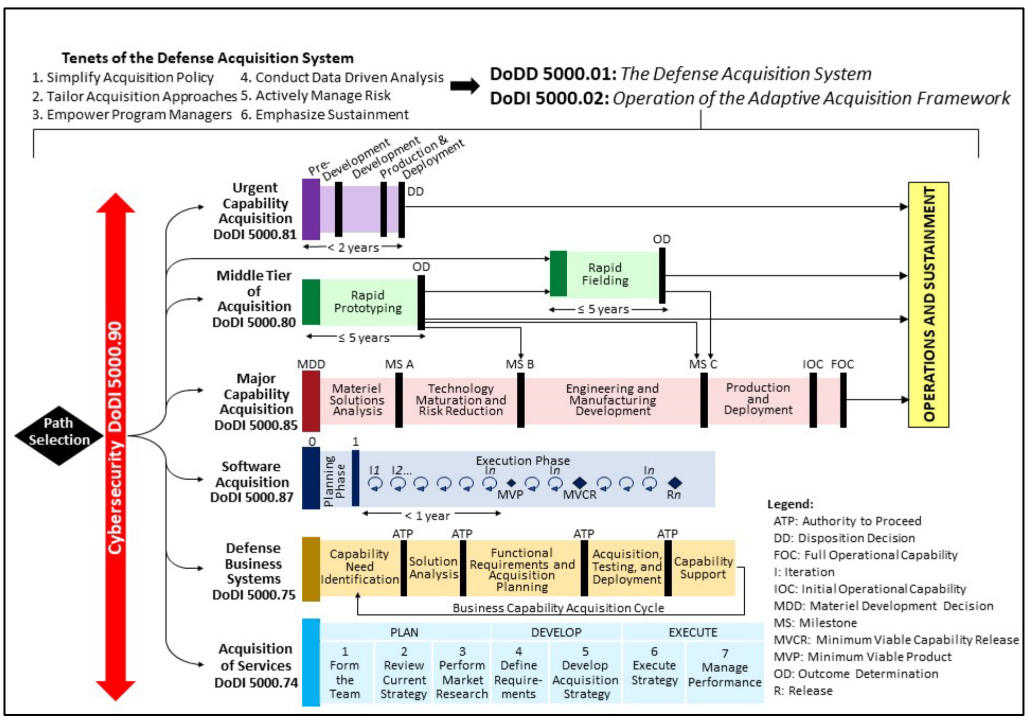

Figure 1-1. AAF Pathways

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[1] The phrase "valley of death" refers to the fate of technology that languishes in laboratories rather than making the transition to programs of record and operational use.

[2] DoD Instruction 5000.02. Operation of the Adaptive Acquisition Framework, Office of the Under Secretary of Defense for Acquisition and Sustainment, January 23, 2020. https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/500002p.pdf

The Office of the Under Secretary of Defense for Research and Engineering (OUSD(R&E)) prepared this guide as a living document that will evolve with engineering best practices in the areas of SE, ME, DE, and advanced manufacturing (Industry 4.0)[3]. This guide is not a directive, standard, or instruction but offers guidance and best practices from experienced M&Q engineers.

Sections 2 through 6 of this guide focus on activities and best practices based on the MCA acquisition pathway framework and should be tailored for other acquisition pathways to meet specific program needs. Section 7 addresses MTA and UCA considerations.

For additional guidance related to engineering processes, see DoDI 5000.88, Engineering of Defense Systems; DoD Engineering of Defense Systems Guidebook; DoD Systems Engineering Guidebook; DoD Mission Engineering Guide; DoD Systems Engineering Plan Outline; and other documents at the Engineering References for Program Offices website: https://ac.cto.mil/erpo/.

Information on detailed M&Q activities during all system life cycle phases can be found in the DoD Manufacturing and Quality Body of Knowledge at https://ac.cto.mil/maq/.

1.2 Early Manufacturing Overview

Although many early system development activities outlined in the following sections are often led by S&T teams and systems engineering practitioners, this guide is intended to assist M&Q practitioners to effectively integrate M&Q considerations into these engineering processes. Early system development teams are encouraged to request M&Q practitioner resources and M&Q input as they develop early concepts.

Early defense system development encompasses a range of processes including:

- Defining operational requirements
- Mission definition
- Development planning (DP)
- Academic research
- Independent research and development (IRAD)
- DoD S&T
- Design trade-off analyses

[3] Fourth Industrial Revolution, referred to as Industry 4.0

- Industrial Base Assessments (IBAs)
- Manufacturing technology (ManTech) investments
- Decomposing operational requirements into functional and allocated baselines
- Experimentation, prototyping, and preliminary design activities

Often M&Q specialists are not involved in these early technical activities until PDR or Milestone B; however, if the program does not consider M&Q during early system development, it may miss the opportunity to influence the system design, production processes, and efficient production. These overlooked issues may result in redesign, schedule delays, producibility risks, and increased program cost during transition from development to production. To improve results, the technical team should define and manage M&Q considerations starting at the earliest project stages and continue throughout the system life cycle.

M&Q involvement should start at the "extreme front-end" of the acquisition process as system concepts are first conceived and analyzed for feasibility. Activities of interest include mission and system requirements definition, AoA, concept and design trade studies, preferred system concept maturation, technical planning, and prototyping. In addition, as systems engineers develop the digital thread approaches, early M&Q involvement allows for a more seamless transition to later-stage preliminary design, product detailed design, and transition from development to production.

On smaller early development projects when the government project team has limited personnel, the technical team lead should budget for and request support from independent sources (i.e., Service M&Q functional leaders, defense agencies, laboratories, Federally Funded Research and Development Centers (FFRDCs), or other government technical resources) to assist in Pre-PDR manufacturing activities or to conduct independent manufacturing feasibility assessments.

For early development projects focused on fielding major weapon systems such as advanced fighter and bomber aircraft, major land combat systems, ships/submarines, space systems, missile defense, or hypersonic weapons, etc., involving large development teams and resources, program technical leadership should include one or more M&Q specialists on the early development project technical team. If suitable resources are not available (similar to smaller development teams), the technical team lead should also budget for and request support from independent sources (i.e., Service M&Q functional leaders, agencies, laboratories, FFRDCs, or other government technical resources) to assist in manufacturing activities or to conduct independent manufacturing feasibility assessments.

As a best practice, M&Q subject matter experts (SMEs) should engage proactively with other system development technical and management stakeholders that lead key processes. For example, they might:

- Assign M&Q engineers to laboratory development teams and prototype development Integrated Product Teams (IPTs).
- Initiate input to early system concept development, for example, Joint Capabilities Integration and Development System (JCIDS) requirements development, AoA, technology development contract requirements, ME and SE planning processes, Acquisition Strategy (AS) development, Systems Engineering Plan (SEP), and design trade-off analysis.
- Participate in early assessments of technology.
- Lead assessments of manufacturing maturity and industrial base capabilities.
- Integrate M&Q considerations and criteria into SETRs.
- Identify potential manufacturing and producibility risks, formulate feasible production solution concepts, and develop comprehensive plans for manufacturing maturation.
- Provide M&Q engineering recommendations to inform acquisition milestone decisions.

1.3 Transition from Development to Production

The transition from development to production is not an event with a readily identifiable starting point in the acquisition process. It is a series of technical processes relying on engineering disciplines, incorporating a number of activities (e.g., design, test, production) that are interrelated and interdependent. During the transition from development to production, a key design consideration is "producibility" (see Section 3.10). During this transition, the development team should create an adequate technical data package to manufacture the required product, and they should establish, monitor, and assess M&Q measures of effectiveness of the manufacturing organization, operations, and processes to identify opportunities for improvement through the entire system life cycle. The early activities should also include manufacturing and quality strategy and management planning.

2 Alignment of Early M&Q and Defense Engineering Activities

Often system development teams overlook M&Q, especially during the earliest stages of system development (starting from early S&T during Pre-MDD activities resulting in PDR design alternatives) when technology development is the primary focus. However, M&Q involvement during early system design and development is important to prevent inadvertent “designed-in” producibility issues, industrial base and supply chain constraints, or inefficiencies that otherwise may not be uncovered until Engineering and Manufacturing Development (EMD) or Production and Deployment (P&D). Lack of attention to M&Q may result in redesign or significant cost and schedule changes. Examples of designed-in production issues include:

- Development of prototype systems based on unproven materials.
- Designs that include manufacturing tolerances or processes that can be achieved only for small quantities or can be produced only by highly skilled workers in a controlled laboratory environment.
- Lack of adequate technical data package documentation to rapidly transition prototypes from system development to production.

Introducing long-lead factors that affect cost and schedule (new materials, complex tooling, new processes, additional workforce training and certification requirements, etc.) can result in cost, schedule, and performance risks and issues. Aligning early M&Q activities with early ME and SE objectives during the “extreme front-end” (i.e., before the MDD), and then during early system development (i.e., MSA to PDR) (Figure 2-1) can help facilitate the transition from development to production.

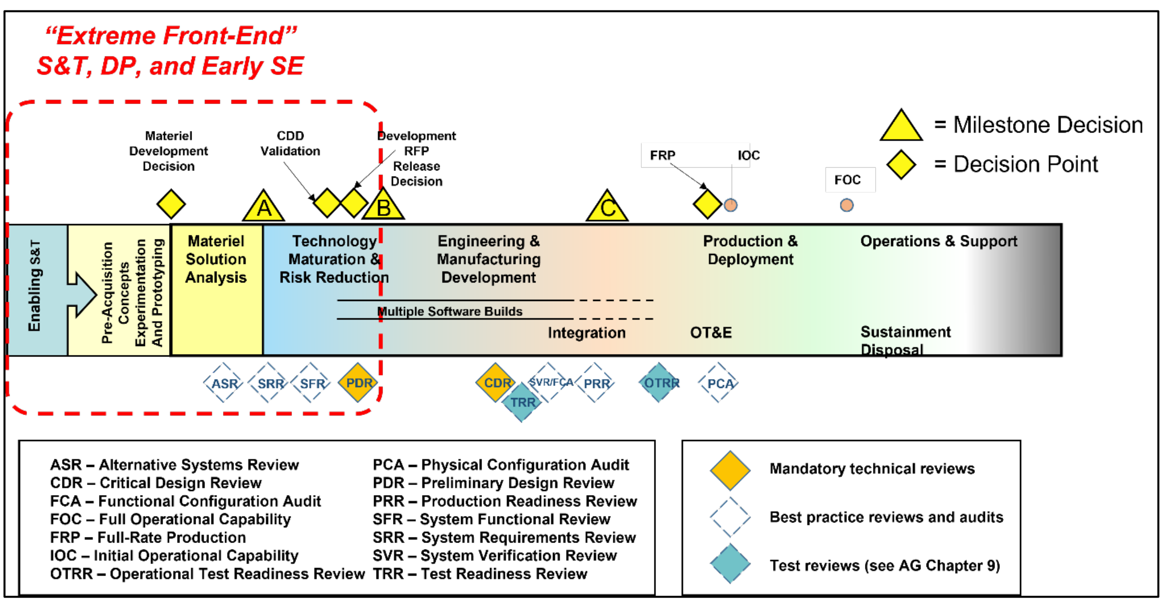


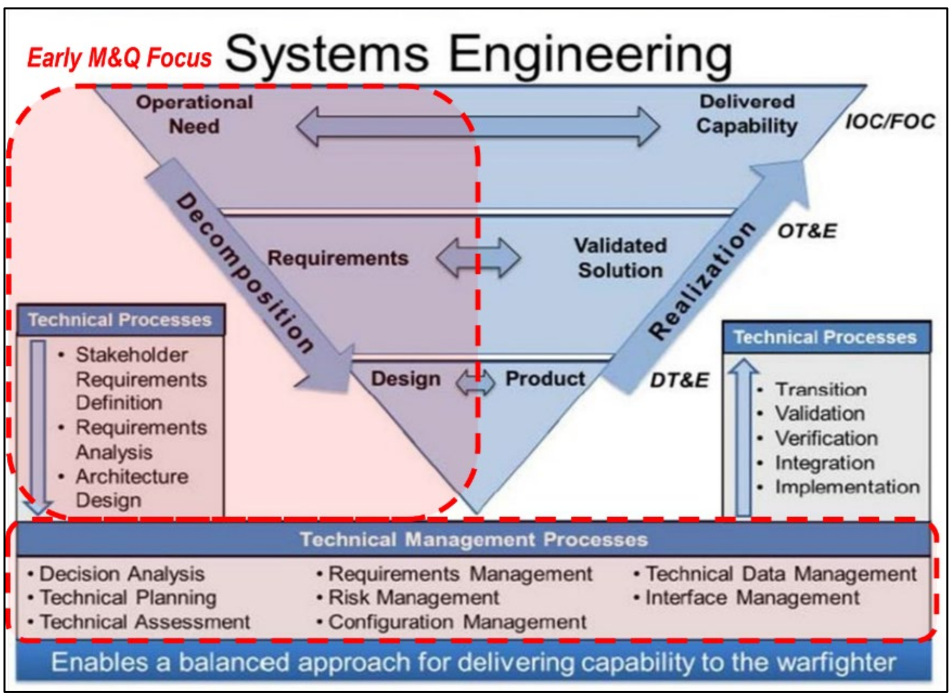
Figure 2-1. Early M&Q Involvement

2.1 Systems Engineering

SE establishes the technical framework for delivering materiel capabilities to the warfighter. Sound SE planning, as documented in the SEP, identifies a disciplined technical path to deliver a capability, from identifying user needs and concepts through delivery and sustainment. For a comprehensive description and guidance for defense SE, see DoDI 5000.88, Engineering of Defense Systems, and the DoD Systems Engineering Guidebook.

As illustrated in Figure 2-2, SE involves both proven "technical processes" and "technical management processes" to translate operational needs into a delivered capability. The SE process depicted in the "V-Diagram" includes top-down design and requirements decomposition processes (left-hand side), and bottom-up integration and realization processes (right-hand side). These engineering processes provide a structured approach to increase the technical maturity of a product and associated production systems as they are conceived, designed, and implemented to consider design, cost, schedule, technical, manufacturing, and sustainment risks.

Although M&Q is most often associated with product realization (right-hand side), this guide outlines best practices and considerations for M&Q on the front end (left-hand side) of technical processes (Operational Need, Requirements, and Design) and in all SE technical management processes.



IOC/FOC: Initial Operational Capability/Full Operational Capability
DT&E: Developmental Test and Evaluation
OT&E: Operational Test and Evaluation

Figure 2-2. Early M&Q in SE Technical and Technical Management Processes

In the "extreme front-end" of the acquisition process, the SE and design teams allocate requirements and defining design approaches. Introducing M&Q considerations during early SE activities can present challenges to the development team:

- Project leadership may not support M&Q involvement during early system development.
- S&T project teams may lack the resources to include M&Q personnel in S&T organizations or on early SE IPTs.
- The project may lack integration of M&Q process improvement approaches with the SE design and analysis processes.
- The project design practices may lack producibility as a design consideration or may lack detailed design review and involvement by M&Q personnel.

By aligning M&Q objectives and major activities with these SE front-end processes, the program can develop and mature production systems in a concurrent manner. Doing so makes it far more likely the program will be able to deliver the expected performance, schedule, and cost.

An important factor for successful integration of early SE activities with manufacturing processes is to include experienced M&Q personnel in S&T, laboratory, and development IPTs. When possible, the project team or IPT should include SE team members with M&Q experience on similar types of systems, or on similarly complex technology programs. For example, including an industrial, manufacturing, or quality engineer in the S&T laboratory environment during prototype development can facilitate the early identification of feasible manufacturing tolerances, geometries, materials selection, consideration of alternative manufacturing processes, and development of adequate technical documentation to transition laboratory assembly processes from development to production. Incorporating M&Q engineering in the early phases of system design ensures a higher probability of using feasible manufacturing processes, resulting in a product that will meet warfighter needs without significant redesign and delay in fielding the system.

2.2 Mission Engineering[4]

Early M&Q activities such as manufacturing feasibility assessments, IBAs, manufacturing maturity assessments, and ManTech investment requirements should inform ME processes and analyses. Integrating M&Q considerations into ME will increase the likelihood of meeting warfighter requirements within cost and schedule constraints.

As outlined in the DoD Mission Engineering (ME) Guide (2020), ME is "…the deliberate planning, analyzing, organizing and integration of current and emerging operational and system

[4] This section includes excerpts from the DoD Mission Engineering Guide at https://ac.cto.mil/wp-content/uploads/2020/12/MEG-v40_20201130_shm.pdf

capabilities to achieve desired warfighting mission effects." ME facilitates the transition from JCIDS processes (requirements definition) to early system analysis and architecture approaches (Pre-MDD concept definition); and ultimately to SE development processes.

During Pre-MDD, ME processes provide mission-based outputs to the requirements process, guide prototypes, offer design options, and inform investment decisions. Pre-MDD ME practices include interaction of the JCIDS as defined in the Joint Chiefs of Staff Instruction (CJCSI) 5123, and the Defense Acquisition System as defined in DoD Directive 5000.01, The Defense Acquisition System.

ME products and artifacts identify and quantify mission capability gaps and help the Engineering and Technical Management team to focus on technological solutions to meet future mission needs; inform requirements, prototypes, and acquisition; and support capability portfolio management.

As illustrated in Figure 2-3, the ME process begins with the end in mind: a carefully articulated problem statement; the characterization of the mission and identification of key measures of value, effectiveness, and performance; and the collection of data and models needed to analyze the mission and document the output results.

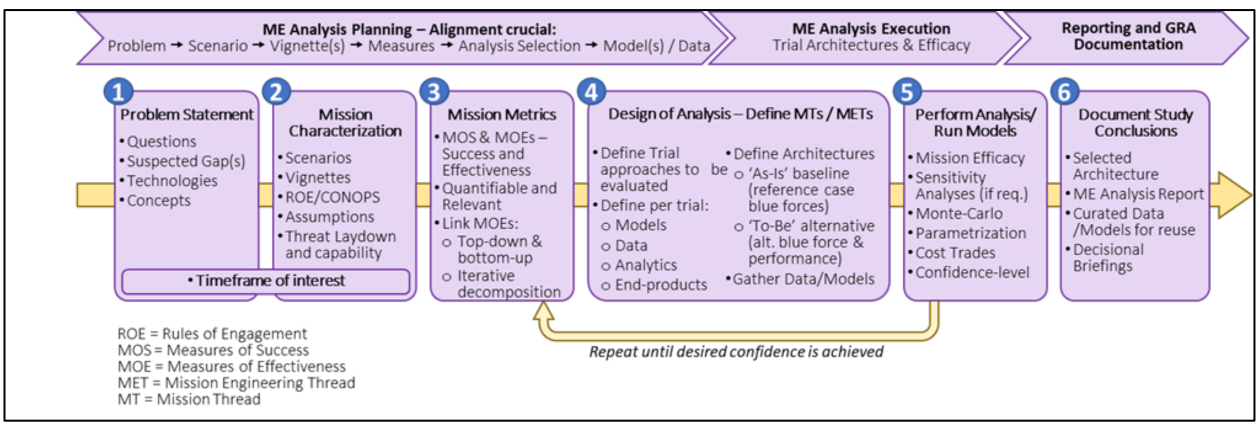
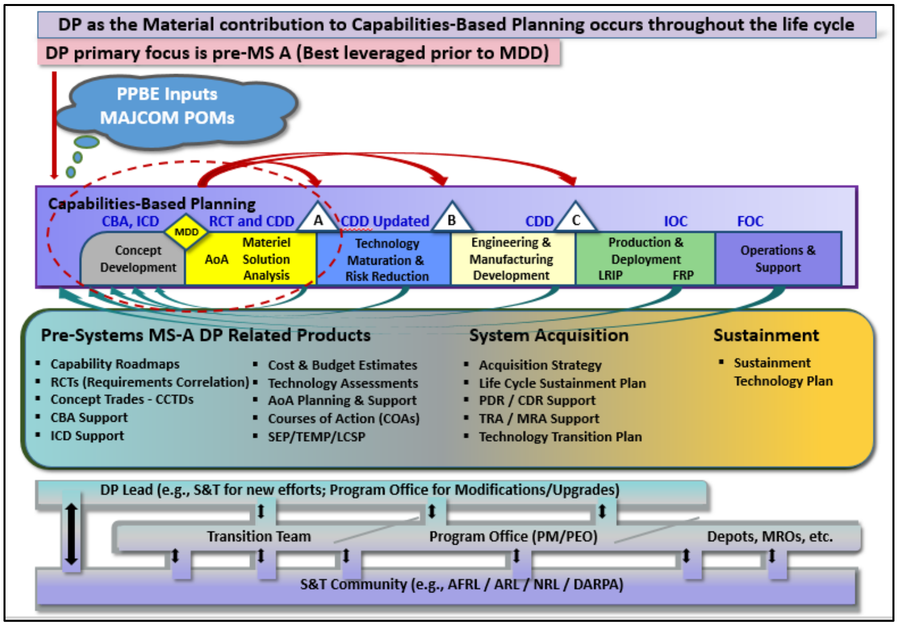


Figure 2-3. ME Process Overview

2.3 Development Planning

In support of early SE and ME, development planning (DP) encompasses engineering analysis and technical planning activities to provide the foundation for informed investment decisions to meet operational requirements and materiel development needs. As depicted in Figure 2-4, key aspects of DP include: analytic support for identification of needs and development of requirements for potential materiel solutions; identifying and assessing technology maturity and risk drivers, initiation of high-confidence acquisition programs via early SE; early test and evaluation strategy development; technology and manufacturing maturity; assessments of life-cycle analyses; life cycle cost estimates; and early acquisition intelligence engagement.



CBA: Capabilities-Based Planning	IOC: Initial Operational Capability
ICD: Initial Capabilities Document	CCTD: Concept Characterization and Technical Description
CDD: Capability Development Document	FOC: Full Operational Capability
PPBE: Planning, Programming, Budgeting and Execution	POM: Program Objective Memorandum
LRIP: Low Rate Initial Production	FRP: Full Rate Production
SEP: System Engineering Plan	TEMP: Test and Evaluation Master Plan
LCSP: Life Cycle Sustainment Plan	TRA/MRA: Technology/Manufacturing Readiness Assessment
PDR/CDR: Preliminary/Critical Design Review	MRO: Maintenance, Repair and Overhaul
DP: Development Planning	ARL: Army Research Laboratory
S&T: Science and Technology	NRL: Naval Research Laboratory
MS: Milestone	AFRL: Air Force Research Laboratory
DARPA: Defense Advanced Research Projects Agency	PM: Program Manager
PEO: Program Executive Officer	RCT: Requirements Correlation Tools

Figure 2-4. Relationship of Development Planning to Acquisition Process[5]

Key DP processes:

- Capability Planning and Analysis: Assess operational capability needs versus the art-of-the-possible regarding existing and potential materiel and concept of operations (CONOPS) solution set.
- Concept Development: Develop concepts during early planning and mature the concept using early SE.
- Cross-cutting Opportunities: Identification and integration of potential solutions across multiple levels, within and across DP efforts, and across capability areas.
- Enabling Processes: Those processes and business practices used across most acquisition programs: cost estimating; early SE; ME; DE; human systems integration; modeling and simulation (M&S); reliability and maintainability; risk, issue, and opportunity (RIO) management; product support; program protection; scheduling; test and evaluation (T&E); and M&Q; etc.

[5] Derived from Air Force Materiel Command, Development Planning Guide, June 17, 2010

As members of the SE IPT, M&Q personnel should participate in DP principal processes. Potential M&Q-related considerations include:

- Review and assess the "art of the possible" to include existing and potential materiel solution sets.
- Support the transition of the Basic Research (budget category 6.1), Applied Research (budget category 6.2), and Advanced Technology Development (budget category 6.3) projects into acquisition programs.
- Support Advanced Technology Development (budget category 6.3) projects in support of concept developments that have a clear and recognized trace back to a stated: technology modernization priority, industrial base capability, deficiency, or manufacturing development project.
- M&Q input during the development of DP-related products (e.g., technology assessments, AoA, and Courses of Action).
- Producibility design criteria (evaluate for cost-effectiveness and ease of manufacture).

2.4 Innovation Opportunities

During DP, M&Q engineers should engage with relevant communities of interest to assist in developing manufacturing capabilities to facilitate the transition of programs from development to production, and mitigate challenges presented by the "valley of death" as shown in Figure 2-5.

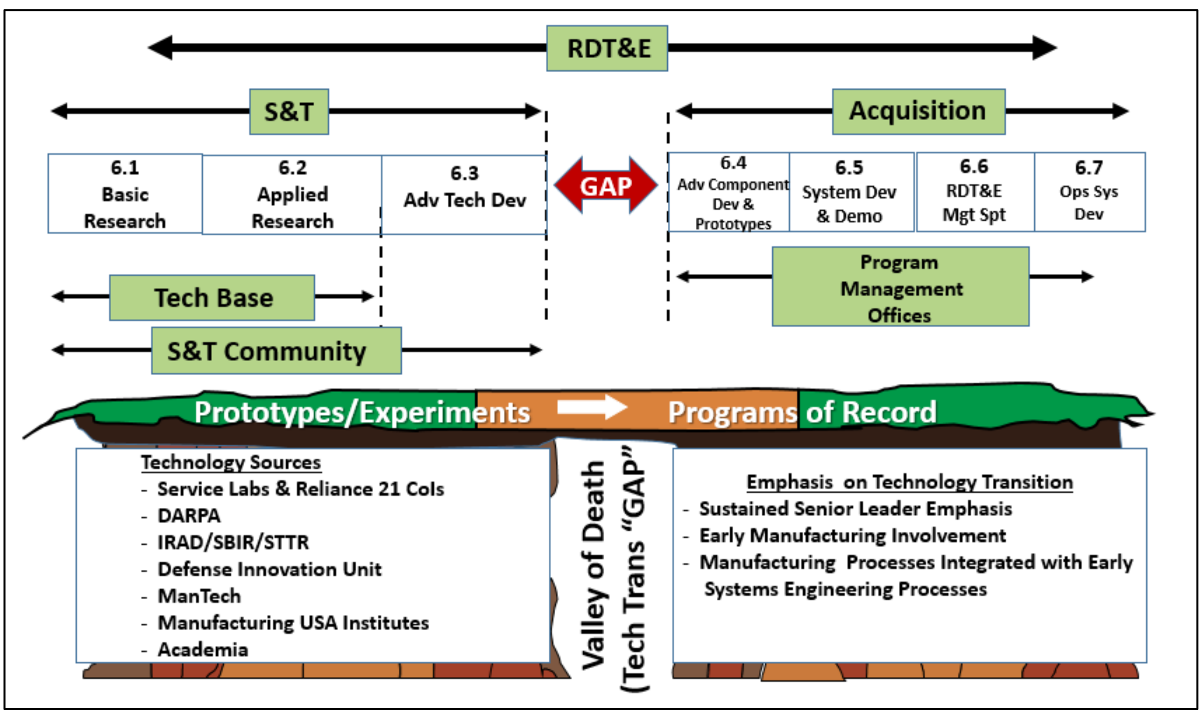


Figure 2-5. Early Manufacturing Support to Bridge the "Valley of Death"

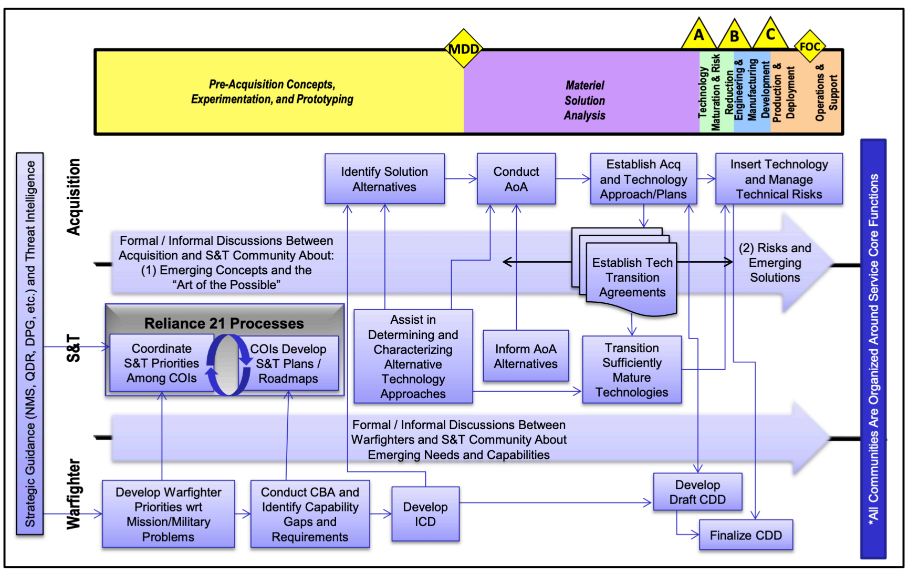
M&Q personnel and program teams should pursue opportunities for technology development, technology transition, and industrial base development and sustainment. These government, academia, and industry resources and programs provide opportunities for manufacturing capability development throughout the entire system life cycle:

- Manufacturing Technology (ManTech) Program (DoDI 4200.15 Manufacturing Technology Program) focuses on the development and application of advanced manufacturing technologies and processes that will reduce the acquisition and sustainment manufacturing/repair cycle times and cost http://www.dodmantech.com.
- Manufacturing USA provides a network of manufacturing innovation institutes that offer opportunities for partnership with DoD, Department of Energy, Department of Commerce, industry, and academia engineering activities on applied manufacturing research https://www.manufacturingusa.com.
- Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) offer competitive programs focused on encouraging small businesses to participate in federal research and development (R&D) programs with commercial potential https://sbir.gov.
- Defense Innovation Unit (DIU) provides opportunities to adopt commercial technologies to rapidly prototype and field commercial solutions https://diu.mil.
- Defense Advanced Research Projects Agency (DARPA) focuses on investment in breakthrough technologies for national security https://darpa.mil.
- Service and federal research laboratories conduct research, technology development, prototyping, and cutting-edge focused research to develop and transition specialized technical capabilities.
  - U.S. Army Research Laboratory
  - U.S. Naval Research Laboratory
  - Air Force Research Laboratory
  - Rapid Capability Offices (RCO)—i.e., Army (Rapid Capabilities and Critical Technologies Office), Navy, Air Force, Marine Corps RCOs
  - Federally Funded Research and Development Centers (FFRDCs)—public-private partnerships to conduct R&D for the U.S. Government
- IRAD provides opportunities for industry investment to develop technology of interest to both industry and government (i.e., manufacturing cost reduction, quality improvements).

- The OSD(A&S) Industrial Policy programs https://businessdefense.gov:
  - Industrial Base Analysis and Sustainment (IBAS) program enables investments to monitor and assess the industrial base, address critical industrial base issues related to urgent operational needs, expand the industrial base, and address supply chain vulnerabilities (10 USC Section 2508, "Industrial Base Fund").
  - Defense Production Act Title III provides the authorities to create, maintain, protect, expand, or restore domestic industrial base capabilities.
  - Industrial Base Assessments (IBAs) can provide information on industrial base risks and mitigation strategies (with Defense Contract Management Agency support).
- National Institute of Standards and Technology (NIST) Manufacturing Extension Partnership—public-private partnership to serve small- and medium-size manufacturers provides opportunities for collaboration on manufacturing technology development https://nist/gov/mep.

2.5 Reliance 21 Communities of Interest

Reliance 21[6] is DoD's framework for Joint S&T planning and coordination to ensure the DoD S&T community provides solutions and advice to DoD's senior decision makers (Figure 2-6).



AoA: Analysis of Alternatives
CBA: Capabilities-Based Assessment
CDD: Capability Development Document
DPG: Defense Planning Guidance
S&T: Science and Technology
NMS: National Military Strategy
ICD: Initial Capabilities Document
QDR: Quadrennial Defense Review
COI: Community of Interest
ICD: Initial Capabilities Document

Figure 2-6. Reliance 21: Warfighter, Acquisition, and S&T Community Interaction

[6] Reliance 21 Operating Principles: Bringing Together the DoD Science and Technology Enterprise. Defense Science and Technology, January 2014. https://defenseinnovationmarketplace.dtic.mil

Reliance 21 uses community of interest teams to facilitate multi-agency coordination and collaboration in cross-cutting technology focus areas with multiple-component investments. Reliance 21 includes the Materials and Manufacturing Processes Community of Interest, whose principal outputs include portfolio reviews, strategic plans/road maps, and identification of common S&T needs, gaps, and future opportunities related to emerging manufacturing technologies. Figure 2-6 depicts Reliance 21 processes.

Under the Reliance 21 framework, the S&T community initiates technology "push" to influence alternative technology approaches for consideration by the acquisition community. This includes leveraging the DP and early SE best practices and benchmarks to effectively integrate early M&Q and manufacturing S&T considerations, https://defenseinnovationmarketplace.dtic.mil/ (select Communities of Interest).

2.6 Digital Engineering

DoD's Digital Engineering Strategy provides guiding principles and promotes consistency in engineering processes through the use and reuse of digital tools, models, and curated data throughout a program's life cycle. As a best practice, the technical team should consider M&Q digital data requirements (e.g., factory floor modeling, digital technical data packages and work instructions, supply chain data) during early establishment and development of the digital thread.

By employing DE approaches to the system architecture, design, evaluation, technical data packages, and manufacturing processes early in system development, a program can avoid the transition from paper-based approaches to a digital thread later in the life cycle.

As a best practice, when conducting early M&Q engineering analysis, the technical team should consider DE principles, methods, and tools. DE best practices and tools are defined in the DE Body of Knowledge (DEBoK), available to DoD Common Access Card users at the Defense Technical Information Center (DTIC) website: https://www.dodtechipedia.mil/dodwiki/pages/viewpage.action?pageId=760447627.

DE tools for manufacturing may require further development to apply to specific projects. The technical team should document capability gaps in the Concept Characterization and Technical Description (CCTD) approach as described in Section 4.2.1.

DE tools can decrease the schedule and cost for tooling and special test equipment, facilitate model-based systems engineering (MBSE) efforts, reduce redesign efforts for producibility, and ultimately reduce risks in transition from development to production. An initial DE step is to determine what data the project requires.

Although there are many types of data related to defense systems, it may be helpful for M&Q practitioners to consider the following categories, or layers:

- Mission Data – Information generated and consumed in the operation of the system (e.g., targeting information passed from a sensor to a weapon). This information is shared across the system's internal network and operational networks (e.g., GPS, GIG).
- Enterprise Data – Information used to manage a program or project (e.g., contracts, acquisition documents, reports, test data, email). This information is shared across information technology (IT) networks (e.g., NIPR, SIPR) and business systems.
- Infrastructure Data – Information used to control and monitor facilities; equipment; industrial control systems; heating, ventilation, and air conditioning systems; programmable logic controllers; inspection tools; material handling equipment; and sensors.
- Product Data – Information and technical data about the item to be manufactured.

Most M&Q data is related to the Infrastructure Data layer, but all four layers outlined above are complementary. The M&Q practitioner should consider the interfaces and the differences in the nature, storage, transmission, and use of each type of data, especially regarding information protection. The following may affect the type, accessibility, and quantity of digital M&Q data available and required and should be considered early in the SE process:

- Acquisition Pathway (e.g., UCA, MTA, MCA)
- Acquisition life cycle phase (e.g., Pre-MDD, MSA, TMRR, EMD, P&D, Operations and Support (O&S))
- Product type (e.g., satellite, ship, fixed-wing, rotary-wing, ground combat vehicle, missile, munition, weapon)
- Product mission/CONOPS (e.g., single-use, reusable, sustainable, maintainable)
- AS (e.g., limited, or single acquisition, commercial off-the-shelf (COTS), non-developmental item (NDI), Government Purpose Rights)
- Product Support Strategy (e.g., Contractor Logistics Support vs. Performance-Based Logistics)

When planning and organizing data, M&Q specialists should keep the end product in mind and consider program needs to connect and involve all stakeholder communities (e.g., S&T, acquisition, production, quality, test, and sustainment) in decisions regarding data approaches.

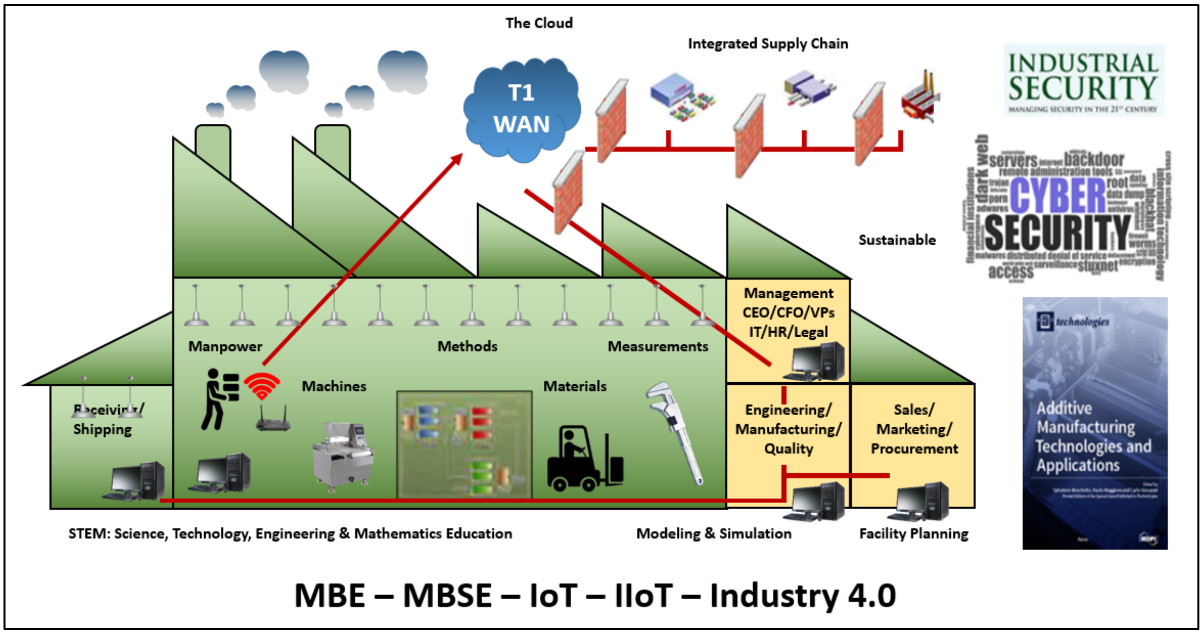
2.7 Industry 4.0

SE teams with M&Q input should consider implementing advanced manufacturing technologies as part of the program's DE ecosystem established during the MSA phase. M&Q personnel should be knowledgeable of rapidly evolving manufacturing technologies since they present opportunities for manufacturing efficiency, producibility, and quality improvements.

Industry 4.0 refers to the Fourth Industrial Revolution, emphasizing the growth in digital technology to automate manufacturing operations with interconnectivity through large-scale machine-to-machine communication, Internet of Things/Industrial Internet of Things (IoT/IIoT), access to real-time data, and the introduction of cyber-physical systems. Industry 4.0 offers potential benefits from a more comprehensive, interlinked, and holistic approach to manufacturing. It connects physical with digital and allows for better collaboration and access across departments, partners, vendors, product, and people. Industry 4.0 empowers managers with increased visibility, understanding, and potentially control of their operation; leverages digital data to increase productivity; and enhances processes improvement, all of which can produce efficiencies. Industry 4.0 focuses on the convergence and application of digital industrial technologies and organizing principles/structures including the following:

- Advanced Robotics
- Additive Manufacturing
- Augmented Reality/Virtual Reality
- Modeling and Simulation
- Horizontal/Vertical Integration
- Industrial Internet of Things
- Cloud Computing/Storage
- Cybersecurity
- Big Data and Analytics
- Block Chain supply chain management

Industry 4.0 advanced manufacturing technologies and capabilities offer opportunities to enhance product system producibility and production system effectiveness and efficiency to promote affordability (Figure 2-7).



MBE: Model-Based Engineering
MBSE: Model-Based System Engineering
IoT: Internet of Things
IIoT: Industrial Internet of Things
CEO/CFO: Chief Executive/Financial Officer
HR: Human Resources
WAN: Wide Area Network

Figure 2-7. Emerging Digital Factory

DE concepts and practices to consider include the following:

- Model-Based Engineering (MBE): Using annotated digital three-dimensional (3D) models of a product and relevant production equipment and processes as the authoritative information source for all activities in that product's life cycle including relevant production equipment and processes.
- Model-Based Systems Engineering (MBSE): An approach to engineering using models as an integral part of the technical baseline, which includes the requirements, analysis, design, implementation, and verification of a capability, system, and/or product throughout the acquisition life cycle.
- Industrial Security and Cybersecurity: Practices that ensure a safe and secure environment to share digital information from government to industry, prime contractor to subcontractor, laboratory to program office, etc., including transfer of digital data within a facility or through the cloud to other facilities (see DoDI 8500.01, Cybersecurity).

2.7.1 Modular Open Systems Approach in Manufacturing

M&Q personnel should be aware that modular open systems approach (MOSA) is mandatory under FY17 NDAA Section 805 as amended by FY21 NDAA Section 804, codified in 10 USC 2320(a) (2)(G), 2446a, and 2446b(c) and (d). These design requirements may affect government rights to manufacturing technical and processes data.

2.8 Technology and Program Protection

The M&Q team should assist the S&T team in technology protection planning and management to include manufacturing technologies and manufacturing operations to support development of cyber resilient systems.

Refer to DoDI 5000.83 for Technology Area Protection Plan (TAPP), Program Protection Plan (PPP) and engineering cybersecurity activities. DoDI 5000.83, "Technology and Program Protection to Maintain Technological Advantage," establishes policy, assigns responsibilities, and provides procedures for S&T managers and engineers to manage system security and cybersecurity technical risks from foreign intelligence collection; hardware, software, cyber, and cyberspace vulnerabilities; supply chain exploitation; and reverse engineering.

Specific to cybersecurity during manufacturing planning and operations, early system development teams should consider cybersecurity for the factory floor and supply chain starting in pre-MDD and throughout the system life cycle—known as operational technology (OT).

NIST SP 800-37, "Risk Management Framework for Information Systems and Organizations" defines OT as:

> "Programmable systems or devices that interact with the physical environment (or manage devices that interact with the physical environment). These systems/devices detect or cause a direct change through the monitoring and/or control of devices, processes, and events. Examples include industrial control systems, building management systems, fire control systems, and physical access control mechanisms."

Other examples of OT systems include numerically controlled machines, automated inspection equipment, sensors, and enterprise management systems collecting manufacturing data.

The term "operational technology" distinguishes manufacturing-related technologies from IT, platform information technology (PIT)/mission data, or other enterprise/business management information systems (MIS). OT may not be controlled by the IT department or evaluated during IT reviews and audits. Therefore, M&Q input is required to focus on cyber-resilient engineering in planning for factory floor and supply chain operations.

As a best practice, early development technical teams, with M&Q personnel input, should assess cybersecurity protections for OT using Manufacturing Readiness Level (MRL) assessment criteria as described in Section 3.1. These OT assessment criteria are applicable starting with early manufacturing maturity assessments, and manufacturing readiness assessments throughout the system life cycle.[7]

[7] The 2022 MRL Deskbook and assessment criteria will include detailed OT cybersecurity criteria

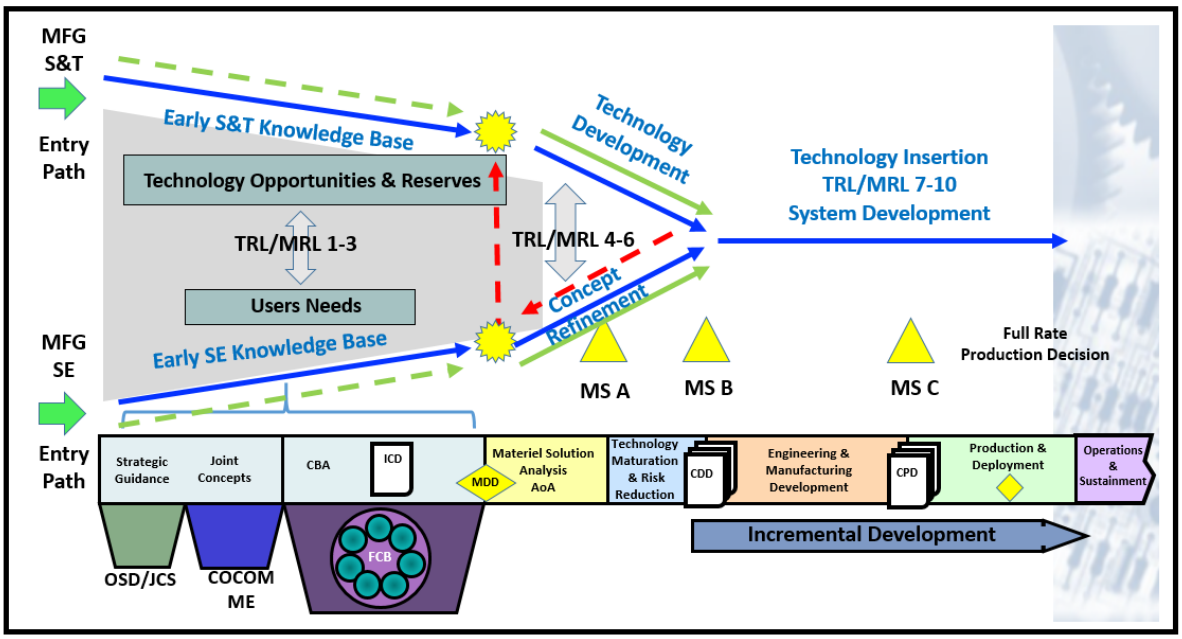
3 M&Q ACTIVITIES DURING EARLY SYSTEM DEVELOPMENT

3.1 Technology and Manufacturing Readiness Levels

During early system development, technical teams often focus only on technology maturity and conduct Technology Readiness Assessments (TRAs) using Technology Readiness Levels (TRLs). However, development teams should be aware that DoDI 5000.88 directs that manufacturing, producibility, and quality risks be identified and managed throughout the system life cycle. Thus, manufacturing maturity and readiness are key considerations starting with early system development.

As a best practice, S&T engineering teams should simultaneously conduct Manufacturing Readiness Assessments (MRAs) using MRL criteria to assess manufacturing maturity and identify potential early M&Q risks.

Figure 3-1 depicts concurrent assessment of technology and manufacturing readiness starting early in the system life cycle and continuing through all life cycle phases.



OSD: Office of the Secretary of Defense	CDD: Capability Development Document
JSC: Joint Chiefs of Staff	CPD: Capabilities Production Document
COCOM: Combatant Command	FCB: Functional Capabilities Board
CBA: Capabilities-Based Assessment	SE: Systems Engineering
ME: Mission Engineering	MS: Milestone
MFG: Manufacturing	S&T: Science and Technology
ICD: Initial Capabilities Document	
TRL/MRL: Technology/Manufacturing Readiness Levels	

Figure 3-1. Relationship of Product/System and Manufacturing Technology Development

Technology Readiness Assessments: TRAs are a method of evaluating the technical maturity of Critical Technology Elements (CTEs), using a TRL scale from 1 to 9, with 9 being the most mature. TRAs provide a consistent assessment approach across a range of technologies. During early system development, technology maturity is usually assessed using TRL 1-6 assessment level criteria (i.e., starting with S&T through PDR as highlighted in Table 3-1). The table provides a brief description of the TRL objectives.

Table 3-1. Technology Readiness Levels

Levels	Brief Description
TRL 1	Basic principles observed and reported
TRL 2	Technology concept and/or application formulated
TRL 3	Analytical and experimental critical function and/or characteristic proof of concept
TRL 4	Component and/or breadboard validation in laboratory environment
TRL 5	Component and/or breadboard validation in relevant environment
TRL 6	System/subsystem model or prototype demonstrated in a relevant environment
TRL 7	System prototype demonstrated in an operational environment
TRL 8	Actual system completed and qualified through test and demonstration
TRL 9	Actual system proven through successful mission operations

Source: Derived from GAO Technology Readiness Assessment Guide (GAO-20-48G)

Additional information on TRL assessments, criteria, and best practices can be found in the DoD Technology Readiness Assessment Guidance (2011; undergoing revision) and Government Accountability Office (GAO) Technology Readiness Assessment Guide (GAO-20-48G) http://www.gao.gov/products/gao-20-48g.

TRLs are a metric used to assess the maturity of technologies from a performance perspective. However, TRLs do not answer major transition to production questions:

- Is the technology producible?
- Can the system be produced at required rates and quantities?
- What is the projected production cost? Is the technology affordable?
- Can the system be made in a production environment or only in a laboratory?
- What investments are required for production facilities and manufacturing processes?
- Are key materials and components available?
- What are the material lead times?

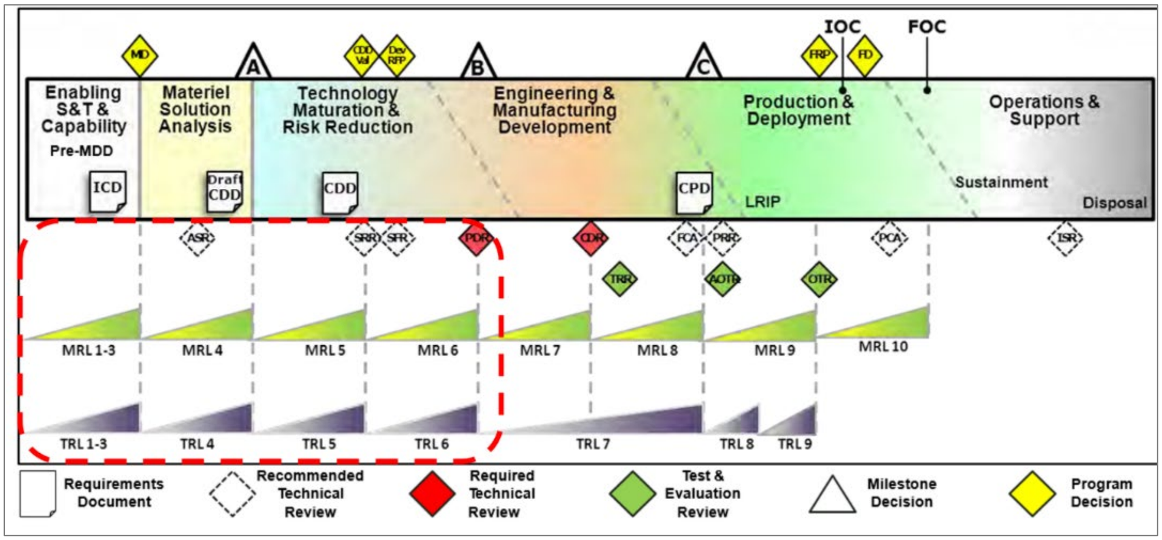
Manufacturing Readiness Assessments: MRAs, using MRL criteria, are a method of evaluating a system's M&Q maturity using a scale from 1 to 10, with 10 being the most mature. MRL criteria provide a structured approach to estimate the current manufacturing maturity. MRAs identify, quantify, and prioritize M&Q risks and mitigation efforts. The assessment process increases value to customers by providing M&Q risk information to support decision points during the entire system life cycle by evaluating the relative maturity of manufacturing technologies, products, and processes. Assessments identify potential risks and are not a "pass/fail" audit but are a best practice across DoD and industry. Information on the complete MRL assessment criteria, MRL Deskbook, and Users Guide are specified at www.dodmrl.org.

During early system development (Pre-MDD and MSA), manufacturing maturity is usually assessed using MRL 1-4 criteria. As a best practice, at PDR the components, subsystems and system-level maturity should meet MRL 6 criteria or higher. These early system development levels and a brief description are highlighted in Table 3.2.

Table 3-2. Manufacturing Readiness Levels

Levels	Brief Description
MRL 1	Basic manufacturing implications identified
MRL 2	Manufacturing concepts identified
MRL 3	Manufacturing Proof of Concept developed
MRL 4	Capability to produce the technology in a laboratory environment
MRL 5	Capability to produce prototype components in a production-relevant environment
MRL 6	Capability to produce prototype system/subsystem in a production-relevant environment
MRL 7	Capability to produce systems/subsystems, or components in a production-representative environment
MRL 8	Pilot Line capability demonstrated; ready to begin Low-Rate Initial Production
MRL 9	Low-Rate Production demonstrated; capability in place to begin Full-Rate Production
MRL 10	Full-Rate Production demonstrated and lean production practices in place

TRLs and MRLs are complementary but are not directly related one to one. The technical team should be aware of both the technology and manufacturing maturity during early system development to enhance the likelihood of successful transition from development to production. As a best practice, starting during Pre-MDD the team should use MRAs in conjunction with TRAs. The system development team may tailor MRL assessments during early system development to meet the S&T project's specific needs to identify and mitigate transition to production risks and to support knowledge transfer between life cycle phases.



ASR: Alternative Systems Review
CDD: Capability Development Document
CDR: Critical Design Review
CPD: Capability Production Document
FCA: Functional Configuration Audit
FOC: Full Operational Capability
FRP: Full-Rate Production
ICD: Initial Capabilities Document
LRIP: Low-Rate Initial Production
MRL: Manufacturing Readiness Level
PCA: Physical Configuration Audit
PDR: Preliminary Design Review
PRR: Production Readiness Review
RFP: Request for Proposal
SFR: System Functional Review
SRR: System Requirements Review
TRR: Test Readiness Review

Figure 3-2. Notional Relationship of MRLs and TRLs

Early Manufacturing Readiness Assessment Teams

As a best practice when conducting early MRAs, the project team should ensure government involvement and oversight of the assessment. The project team should not rely on contractor-only conducted assessments. If a system development contractor performs an MRA, the government project team should coordinate closely with the contractor to develop the assessment approach and closely review the results.

When the government project has limited personnel, the project team should request support from independent sources (e.g., Services, DoD agencies, laboratories, FFRDCs, or other government agencies or government resources such as the Department of Energy) to assist in the assessment or to conduct or participate in independent assessments.

Depending on the complexity and scope, MRA team members or sub-teams can be assigned to evaluate specific technologies, components, products, processes, or subsystems/systems using selected MRL threads and sub-threads, or as appropriate.

3.2 Early Manufacturing Readiness Assessments

Assessment of manufacturing maturity and readiness is an iterative process that may begin before prototype development at the component and subsystems levels. For example, components previously proven on other systems may be more mature than components that have not yet been proven on other systems (Figure 3-3).

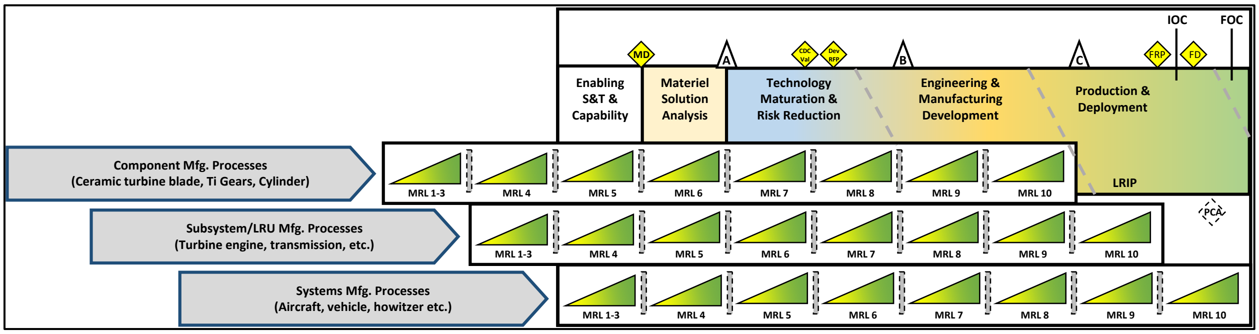


Figure 3-3. Notional MRL Relationships at the Component, Subsystem, and System Levels[8]

3.3 Early System Development MRA (MRA "Lite")

As a best practice during Pre-MDD or prototyping, if the program is not planning to conduct an MRA using the complete MRL assessment criteria matrix, the technical team may use a tailored assessment approach (i.e., MRA "Lite") to identify risks early. This abbreviated version of the MRA allows the development team to focus quickly on specific critical technologies and subsystems with potential manufacturing and producibility issues based on known or perceived risks. The technical team should conduct a follow-on complete MRL assessment as information becomes available.

The goal of performing early-stage MRA Lite evaluations is to identify technology and manufacturing risk proactively during the Pre-MDD and early-stage MSA phase. These assessments support initial AoA trade studies and preferred solution concept down-selection. MRA Lite evaluations should then lead to more rigorous and comprehensive MRL assessments of the preferred solution concept.

The technical team can use certain initial questions to identify potential risk and determine where they should focus early manufacturing maturity assessments. They can then select applicable MRL criteria for a tailored assessment. Following are sample questions:

- **Materials:** Does the item include new and/or unique materials that have not been demonstrated in similar products or manufacturing processes?
- **Diminishing Manufacturing Sources and Material Shortages (DMSMS):** Have the identified parts been evaluated to ensure there are at least 5 years remaining in their life cycle?

[8] Figure 3-3 Source: U.S. Army Combat Capability Development Center Armaments Center, MRA Training, 2020

- **Cost:** Is this item a cost driver that has a significant impact on unit or life cycle cost (development, unit, or O&S costs)? Is the technology new with excessively uncertain cost?
- **Design:** Does the item design contain non-standard dimensions, geometries, or tolerances?
- **Manufacturing Process:** Will the item require use of manufacturing technology, processes, inspection, or capabilities that are unproven in the current environment?
- **Quality:** Does the item have historical or anticipated yield or quality issues; or are there new quality requirements (i.e., inspection techniques, test equipment) that must be developed and proven?
- **Schedule:** Does this item present lead-time issues or manufacturing concerns on the critical path that could significantly impact the program schedule?
- **Facilities:** Does this item require a new manufacturing facility or major updates of existing facilities (e.g., new capability or capacity) to meet production and scale-up requirements?
- **Supply Chain Management:** Does the item have anticipated or historical sub-tier supplier problems (e.g., sole source, foreign source) that could negatively impact cost, quality, or delivery?
- **Industrial Base:** Is the industrial base footprint capable of meeting the program's needs, or are there identified critical shortfalls or gaps in the industrial base?
- **Cybersecurity:** Are there anticipated cybersecurity weaknesses and vulnerabilities associated with manufacturing, supply chain or Operational Technology related to Critical Program Information in the Program Protection Plan or that need to be addressed?

Appendix A includes a more detailed description and a sample approach to MRA Lite criteria.

3.4 Manufacturing Maturation Plans

The Manufacturing Maturation Plan (MMP) addresses identified manufacturing risks and provides a documented mitigation plan for each risk. The MMP is a key product resulting from an assessment of manufacturing readiness. For every assessment of manufacturing readiness in which the MRL has not achieved its target level, the manufacturing lead in collaboration with the SE lead should develop an associated MMP. When required, the project team including M&Q personnel should monitor MMP implementation to mitigate risks, including plans for supplier and sub-tier supplier risks.

MMPs should address the following areas:

- Statement of the problem
  - Describe the element of assessment and its maturity status.
  - Describe how this element of assessment would be used in the system.
  - Show areas where manufacturing readiness falls short of target MRL including key factors and driving issues.
  - Assess type and significance of risk to cost, schedule, or performance.
- Solution options
  - Identify cost/funding necessary to mitigate risks and document anticipated returns on investment (ROIs).
  - Describe the benefits of using the preferred approach.
  - Describe the alternative approaches and the consequences of each option.
- Maturation plan with schedule and funding breakout
- Key activities for the preferred approach
- Preparations for using an alternative approach
- The latest time that an alternative approach can be chosen
- Status of funding to execute the manufacturing plan
- Specific actions to be taken (what will be done and by whom)
- Prototypes or test articles to be built
- Tests to be conducted
  - Describe how the test environment relates to the manufacturing environment.
- Threshold performance to be met
- MRL criteria to be achieved and when they will be achieved

M&Q practitioners should ensure that MMPs are submitted to technical team leadership to be included in the program/project risk, issue, and opportunity plan and further documented in the SEP. The MMP input should also be provided as input to the ITRA team during each review.

3.5 Industrial Base Assessments[9]

An Industrial Base Assessment (IBA) is an assessment of the capabilities of the supplier base to produce the required items. Starting with Pre-MDD, M&Q personnel should support the S&T community to assess and characterize the industrial base capability for the types of commodities expected to solve the warfighters needs.

Early IBA objectives include:

- Identify anticipated industrial base and supply chain.
- Identify the supply chain capability and capacity to produce and the financial stability of key suppliers.
- Identify industrial base capability risks such as single points of failure and unreliable suppliers.
- Assess the industrial base ability to successfully transition prototype systems to production and the ability to meet program quantities, rates, and quality requirements to deliver and sustain operational systems.

3.5.1 Understanding the Industrial Base

A program development team must understand the conditions of the industrial base that will be required to accomplish the program objectives. Concerns include the industrial base capability and capacity to produce and its financial stability:

- **Capability** (i.e., ability to produce) Answers the question, "Does the supplier have the necessary human resources, skills, machines, facilities, material, methods, and other business and technical management processes to produce the item?"
- **Capacity** (i.e., rate and quantity) Answers the questions, "Does the supplier have the ability to produce the item at the rates required by the warfighter (per day, per week, per month, etc.)" and "Can the industrial base meet total requirements, to include potential surge requirements?" In addition, capacity looks at potential conflicting demand requirements (e.g., two DoD projects in the same plant or a mix of DoD and commercial in one plant) to understand if there are competing requirements that might impact capacity.
- **Financial stability** (i.e., financial viability of the firm) Answers the question, "Does the company have the financial resources and financial stability to execute the program through completion?"

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[9] This guide uses the term Industrial Base Assessment (IBA). Sources may use the term Industrial Base Analysis for this activity.

The steps for conducting an assessment are similar to those for other management and technical assessments and could follow the notional process identified in Figure 3-4.

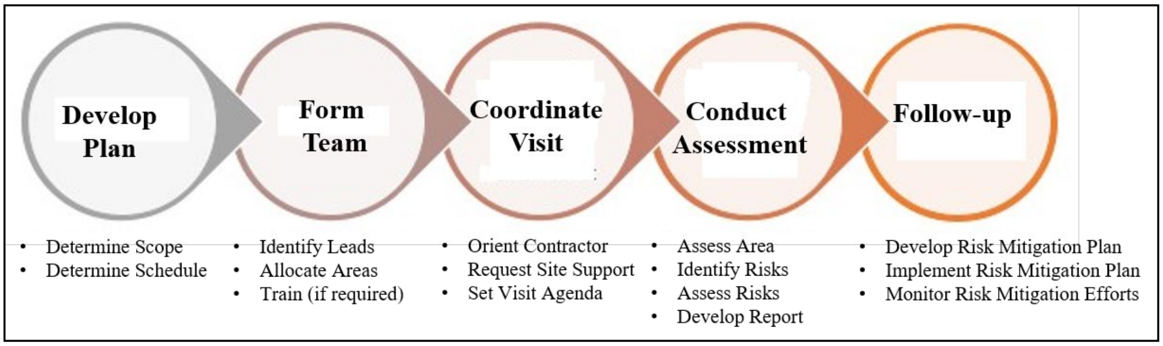


Figure 3-4. Sample Industrial Base Assessment Process

The engineering team should analyze the Work Breakdown Structure (WBS) and identify anticipated suppliers, to include tier 3-5 suppliers when possible. The project team, led by an M&Q specialist, should then conduct an industrial survey to assess the anticipated supply chain.

S&T project teams may consider requesting assistance from the Defense Contract Management Agency (DCMA), Industrial Analysis Division to identify, analyze, and assess the supply chain. This may require a Memorandum of Agreement and funding between the sponsoring agency and DCMA to conduct or support the assessment. To collect data on the supply chain, DCMA and/or the program team may develop questionnaires or surveys, and conduct site visits and interviews for key suppliers. The supply chain assessments identify and analyze risks affecting the industrial base capability to continue development and transition technologies to production. The assessment also may provide recommended courses of action to reduce risk and continue technology development.

Conducting IBAs during early system development also supports transition to production. 10 USC 2440, DFARS Subpart 207.1, and DoDI 5000.85, require IBA results to be documented in acquisition planning and included in the program AS. Early assessments facilitate meeting these requirements.

3.5.2 M&Q Tasks in Support of Industrial Base Assessments

As a best practice, M&Q personnel should engage in conducting IBAs to include these tasks:

- Assist the SE team to identify CTE(s), and assess the WBS to determine the scope of the IBA.
- Review TRL and MRL assessments or supplier quality audits to consider previously identified risks.

- Conduct an IBA to identify sources relevant to the concepts being considered for the Initial Capabilities Document (ICD), AoA study guidance, and the MDD phase.
- Identify and understand potential industrial base sources and needs.
- Conduct industrial base sector studies (e.g., capabilities and capacities) relevant to potential and future needs including design, development, production, operation, and sustainment.
- Identify unique manufacturing capabilities that are not readily accessible.
- Request DCMA support and data for:
    - Assessments survey and interview questions
    - Analytical products (e.g., specific company performance data)
    - Defense business and economic analysis
- Analyze the capabilities of the identified industrial base sources to develop, produce, maintain, and support the concepts being considered for inclusion in the ICD and AoA study guidance.
- Identify the availability of essential raw materials, special alloys, composite materials, components, tooling, and M&Q test equipment required to support the concepts being considered.
- Identify items that are sole or single source, fragile source, or available only from sources outside the National Technology Industrial Base (NTIB) (see 10 U.S.C § 2508, "Industrial Base Fund"). The NTIB consists of the people and organizations engaged in national security and dual-use R&D, production, maintenance, and related activities within the United States, Canada, the United Kingdom, and Australia.
    - Analyze the effects on the sources for the concepts being considered that result from foreign acquisition of firms in the United States.
    - Analyze the military vulnerability that could result from the lack of alternatives if such items become unavailable from sources outside the NTIB.

3.6 Other Management Activities to Support Early Manufacturing

3.6.1 Portfolio Approach

When a new technology, manufacturing process, or industrial base capability is required to support multiple programs, the project team should conduct assessments (e.g., IBA, manufacturing feasibility assessments, MRAs) from a portfolio perspective. This approach should consider total manufacturing capabilities to support the entire portfolio of manufacturing requirements, capabilities, and risks. When assessments consider only individual programs without regard to the entire industrial base, the reviewers may overlook risks such as supply chain constraints, materials shortages, rates and quantities, or resource priorities for the entire portfolio of programs.

3.6.2 Industry Days

The development team may consider holding Industry Days, which offer an opportunity for the development team to present plans for a current or future program and solicit feedback from industry about a potential procurement. Feedback may include potential manufacturing and industrial base risks areas, and manufacturing-related input for the proposed approach.

3.6.3 Special Studies/Tiger Teams/Peer Reviews

The development team may also consider sponsoring independent studies or reviews (e.g., independent consultants, Tiger Teams, SME peer reviews) focused on specific industrial base, materials, and M&Q risks at the system, subsystem, or component levels to assess:

- Supply chain and potential bottlenecks
- Characterization of the health of the industrial base
- Detailed assessment of lower tier suppliers of key components
- Technical workforce and skills challenges/shortfalls
- Industrial base capabilities (e.g., production processes, equipment, facilities, testing, modeling software), challenges, and resource gaps
- Transition to production challenges
- Recommended investments needed to improve the industrial base capability

3.7 Manufacturing Feasibility Assessments

A program team conducts a manufacturing feasibility assessment beginning with alternative concept trade studies during the Pre-MDD and MSA phases. A manufacturing feasibility assessment is a holistic analysis and early evaluation of the practicality of a proposed solution for future production. The program team with M&Q input conducts the assessment to determine whether the proposed concept is feasible and should move forward.

If the assessment identifies gaps, the M&Q team can suggest approaches to close gaps (e.g., 3D printing, digital twins/manufacturing, robotics, adaptive machining) or investments such as IRAD, ManTech, IBAS, or DPA Title III program. The manufacturing feasibility assessment can narrow the scope and range of solution approaches under consideration by identifying the most feasible alternatives.

A manufacturing feasibility assessment answers the question, "Can the system be manufactured at the required rates and quantities, and cost objectives to meet the customers' requirements?" The assessment may address the following questions:

- Is the product adequately defined to enable an assessment?
- Are the design and materials reproducible?
- Can the product be produced to the tolerances specified in the technical data package?
- Are the manufacturing processes to be used stable and in control?
- Can the product be produced to the appropriate process capability requirements?
- Does the facility have the capacity to meet production requirements?
- Do M&Q personnel have the appropriate training, skills, and certifications for all tasks?
- Can the product be produced based on the estimated cost?
- Has a learning curve been established for new processes?
- Can the product be produced to the planned schedule?
- Has a line of balance or critical path been established for production?
- Have appropriate test requirements and qualifications been identified to adequately characterize materials and performance?
- Is the supply chain in place and capable of meeting contract requirements?

The manufacturing feasibility assessment's objective is to narrow the range of solution approaches under consideration by identifying feasible alternatives. The manufacturing feasibility assessment should address operational, technical, economic, and schedule feasibility.

3.7.1 Operational Feasibility

This assessment is customer-focused and concerned with how well the approach under consideration solves the problem. It also assesses the overall producibility of the product and the capability and capacity of the production system concept. It includes asking questions such as: Are there any barriers in the implementation of the system(s)? Is the capacity sufficient to support anticipated production quantities and rates?

3.7.2 Technical Feasibility

This assessment is engineering-focused and concerned with the technical viability of the approach under consideration. It evaluates whether the development team has the technical resources and skills to complete the project; and the feasibility to convert the ideas into a producible product within resource, design, and technical risk constraints. The technical feasibility assessment is also concerned with ascertaining whether needed manufacturing capabilities and production system elements already exist, or can be matured in a timely manner.

3.7.3 Economic Feasibility

This assessment is business-focused and typically involves cost-benefit, cost-capability, cost sensitivity, cost uncertainty, financial stability, and other types of affordability analyses. It consists of product, technology, and industrial base market analysis, economic analysis, business case analysis, trend analysis, and strategic analysis and helps provide information to decision makers to determine the positive economic benefits that the proposed approach provides.

3.7.4 Schedule Feasibility

This assessment is program-focused and examines the likelihood that the technical approach under consideration can be matured and implemented within schedule constraints. It also examines the timeline for R&D efforts to develop or transition required manufacturing capabilities into the proposed product and production system concepts. The assessment examines whether they align with the proposed system development time horizon, including identifying schedule risks and impacts.

3.8 Manufacturing Planning

The purpose of manufacturing planning is to identify and integrate numerous resources to meet production objectives for required rate, quantities, and quality. Manufacturing planning includes measuring the qualitative and quantitative resources required for production.

During early system development, the technical team, with M&Q personnel input, should develop M&Q strategies, including broad M&Q planning for production approaches to be used (e.g., single source, co-production, leader/follower, foreign sources). Program quality approaches also should be developed (e.g., industry standards (i.e., ISO 9001, AS9100), military standards, Federal Aviation Administration standards, nuclear certification, and space qualified parts).

During the transition from development to production, M&Q personnel should establish and maintain a manufacturing plan to include producibility planning, supply chain and material management, manufacturing technology development, manufacturing modeling and simulation, manufacturing costs, manufacturing system verification, workforce, tooling, test equipment, and facilities. MIL-HDBK-896, “Manufacturing Management Program Guide” and the industry standard SAE AS6500A “Manufacturing Management Program” provide details on manufacturing planning and management activities.

3.9 Risk, Issue, and Opportunity

The project team should develop a RIO management approach/plan. The risk management team consisting of the program office, development laboratory prime contractor, field activities, and support contractors, with participation from M&Q personnel (see DoDI 5000.85, DoDI 5000.88, and DoD RIO Guide).

3.10 Systems Engineering Plan

The SEP is a living document that details the execution, management, and control of the technical aspects of an acquisition program from conception to disposal. During early system development, M&Q engineers should collaborate with the technical team to define M&Q approaches for documentation in the SEP. See DoDI 5000.88, Engineering of Defense Systems; and DoD SEP Outline https://ac.cto.mil/erpo/ for additional information.

M&Q SEP inputs should address:

- Manufacturing management approach
- Quality management approach
- IBA
- SETRs including Production Readiness Review(s) (PRR(s))
- Supplier qualifications
- Application of statistical process control
- Manufacturing maturity and readiness

3.11 Technical Performance Measures

Technical Performance Measures (TPMs) describe attributes of a system or a system element and are used to determine how well a system/system element satisfies, or is expected to satisfy, technical requirements. The technical team uses TPMs to assess design progress, compliance to performance requirements, or technical risks. TPMs can include, but are not limited to, accuracy, weight, size, power, timing, and lower-level product quality characteristics related to critical operational and/or technical requirements.

3.11.1 M&Q Technical Performance Measure Development

M&Q metrics provide quantitative data and information to measure, assess, compare, and track performance of the production system. Measurable outputs inform M&Q SMEs to identify potential corrective actions and improve performance. The M&Q team should establish metrics to evaluate the efficiency and effectiveness of M&Q operations.

A critical part of the SE process is the development of hierarchical TPMs used to guide product and production system design/development (Figure 3-5). A key feature of these measures is they are traceable and validated. The measures are derived from Measures of Effectiveness (MOEs).

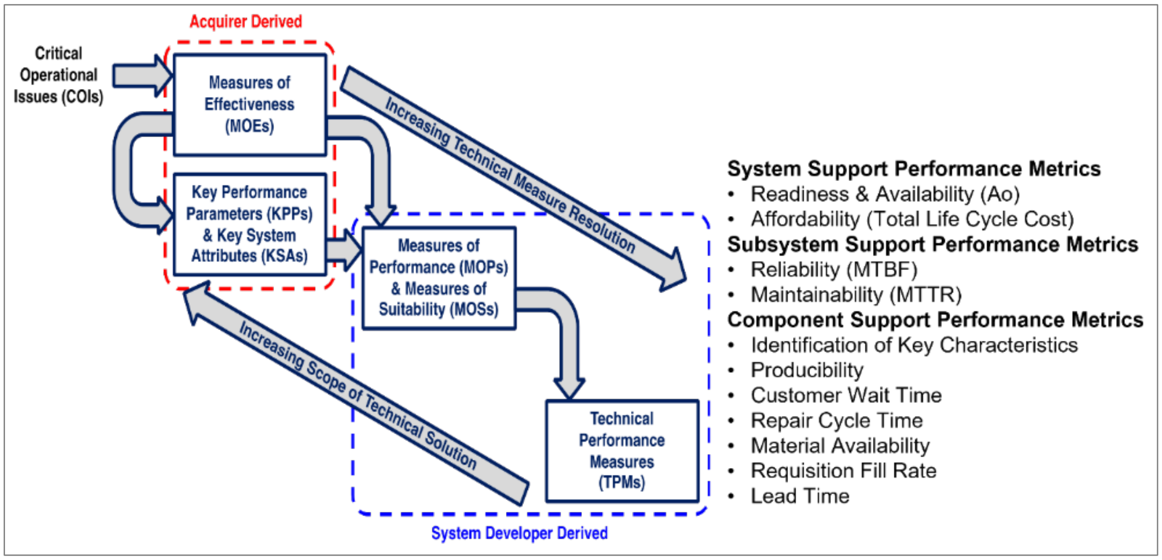


Figure 3-5. Technical Performance Measure Relationships and Hierarchical Linkages

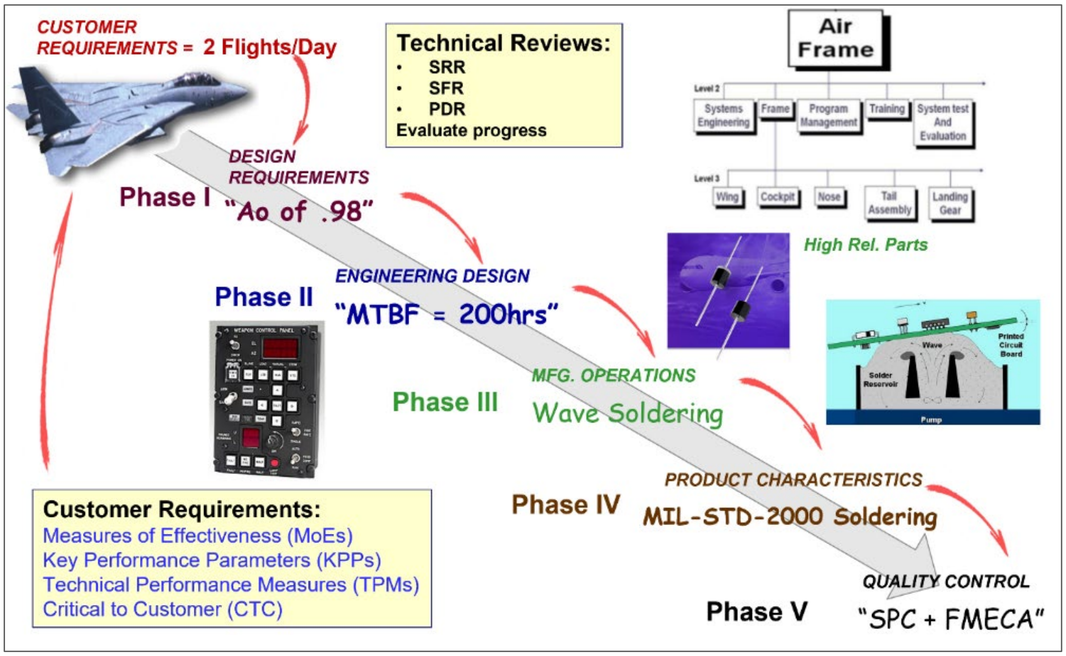
The derived measures include:

- Key Performance Parameters (KPPs)
- Key System Attributes (KSAs)
- Measures of Suitability (MOSs)
- Measures of Performance (MOPs)
- Technical Performance Measures (TPMs)

3.11.2 M&Q Support for TPMs

M&Q considerations can support achievement of performance measures (MOEs, KPPs, KSAs, MOPs, MOSs, and TPMs). As these measures are developed and then translated into the system design, the requirements affect how the system is produced, tested, and supported.

Figure 3-6 depicts a typical aircraft system with a warfighter requirement to support two sorties per day. As an example, the M&Q team could establish an Operational Availability (Ao) metric of 98 percent to support meeting this requirement. This type of metric drives lower-level requirements to meet the top-level requirement. Thus, the navigation system may have a requirement for 400 hours Mean Time Between Failure (MTBF). To achieve this 400-hour MTBF the navigation system design must ensure the navigation system survives the hostile (high-heat, high-vibration) environment. To produce the system, M&Q personnel should consider the manufacturing maturity (e.g., MRL) for required components and processes (e.g., high-reliability parts, and high-reliability soldering techniques).



SPC: Statistical Process Control
FMECA: Failure Modes, Effects and Cause Analysis
MTBF: Mean Time Between Failure
Ao: Operational Availability

Figure 3-6. Example Approach to M&Q Metrics Supporting Achievement of KPPs

To assist in achieving system-level TPMs, the development team should identify and control Key Characteristics (KCs). SAE AS6500A and AS9103 define KCs as "An attribute or feature whose variation has a significant influence on product fit, form, function, performance, service life, or producibility that requires specific actions for the purpose of controlling variation." To control these attributes, at a minimum the manufacturer should place all components with KCs under statistical process control.

3.11.3 M&Q Technical Performance Measures

M&Q TPMs: During early system development, as the technical team is planning for PDR activities and updating the SEP, the M&Q technical team should begin preparing M&Q TPMs to assess production system effectiveness and efficiency. Example M&Q TPMs include the following:

- Quality of Product
  - First Pass Yield planned vs. actual
  - Scrap/Rework/Repair planned vs. actual

  - Cost of Quality
  - Supplier Quality Acceptance Rates
  - Number of Customer Complaints/Returns
- Producibility
  - Architecture elegance
  - Value optimization
  - Assembly elegance
  - Quality improvement
- Process Capability (Cpk) or Process Performance (Ppk)[10]
  - Prediction of process capability (e.g., Cpk = 2.0)
  - Actual process performance (e.g., Ppk = 2.0)
- Design Maturity
  - Class I and 2 Engineering Change Rates vs. planned
- Cost
  - Budgeted Cost of Work Performed (BCWP) vs Actual Cost of Work Performed (ACWP) (Earned Value Management)
- Schedule Performance (Earned Value Management)
  - Planned vs. actual hours
  - Actual drawing release vs. planned
  - Actual purchase orders released vs. planned
  - Actual cycle times to build vs. planned
  - Actual lead times of hardware vs. planned
- Manufacturing Infrastructure
  - Facility utilizations rates
  - Overall equipment effectiveness
  - Manpower, skills, availability, and turnover

[10] Cpk and Ppk examples are notional and may be technology dependent. Refer to Six Sigma guidance.

3.12 Producibility as a Design Consideration

Producibility can be defined as "the relative ease by which a product can be manufactured in terms of yield, cycle times, and the associated costs of options in product designs, manufacturing processes, production and support systems, and tooling." NAVSO-P-3687, Producibility System Guidelines, provides best practices for producibility.

Producibility is a design consideration resulting from a coordinated effort by design engineers and functional engineering specialties to create a design approach that optimizes the ease and economy of fabrication, assembly, inspection, test, and acceptance of the hardware, without sacrificing desired function, performance, or quality. M&Q personnel need to influence the design for producibility considerations. Producibility is one of the most important determinants of product cost as producibility, or lack thereof, affects both the product and the sustainment or life cycle cost.

Design for producibility principles include:

- Simplicity of design
- Use of economical materials
- Use of feasible and economical manufacturing processes
- Use of standard materials and components
- Optimized design tolerances
- Process repeatability
- Product inspectability
- Use of acceptable materials (e.g., non-hazardous)

Producibility steps and elements are listed in Table 3-3.

Producibility begins with Producibility Engineering Planning and the use of producibility engineering tools and techniques. Key tools and techniques identified for producibility analysis:

- Design guidelines
- Process capability guidelines and process capability benchmarking
- Design for Manufacturing and Assembly (DFMA) analyses
- Process Failure Modes and Effects Analysis (PFMEA)
- Identification of Key and Critical Characteristics
- Modeling and simulation (M&S) tools

- Rapid prototyping techniques
- Product and process complexity analyses
- Lean/Six Sigma tools

Table 3-3. Producibility Steps and Elements

Producibility Steps and Elements	Product Phase			
	Initial Concept	Preliminary Design	Detailed Design	Production
Step 1 – Establish a Producibility Infrastructure				
1.1 Recognize the Need for Management Commitment	X	●	●	●
1.2 Organize for Producibility	X	●	●	●
1.3 Implement a Risk Management Program	X	●	●	
1.4 Incorporate Producibility into New Product	X			
1.5 Employ Producibility Design Guidelines		X	●	
1.6 Instill a Commercial Best Practices Philosophy	X	●	●	●
Step 2- Determine Process Capability				
2.1 Understand Current Process Capabilities	X	●	●	●
2.2 Predict Future Process Capabilities		X	●	●
Step 3 - Address Producibility During Concept				
3.1 Identify Product Goals	X	●		
3.2 Identify Key Characteristics	X	●		
3.3 Perform Trade Studies on Alternative Designs/Processes		X	●	
3.4 Develop a Manufacturing Plan		X	●	●
3.5 Perform a Complexity Analysis		X	●	
Step 4 – Address Producibility During Detailed Design				
4.1 Conduct Producibility Engineering Review			X	
4.2 Error-Proof the Design			X	
4.3 Optimize Manufacturing			X	●
Step 5 - Measure Producibility				
5.1 Measure Processes	X	●	●	●
5.2 Measure Products				X
5.3 Measure Producibility System				X
X - Denotes the phase where implementation begins ● - Denotes continuing implementation of the producibility element				

3.13 Systems Engineering Technical Reviews

Technical reviews and audits are necessary SE activities performed to assess technical progress within a program, relative to contractual requirements and development maturity. IEEE 15288.2 – Standard for Technical Reviews and Audits on Defense Programs is the primary standard and best practice for conducting a technical review or audit.

Technical reviews are event-driven and conducted when the system under development meets the review entrance criteria as documented in the SEP. The technical reviews and audits should include participation by SMEs to include M&Q personnel.

Key technical reviews objectives:

- Determine the developer's technical progress achieved to date.
- Compare the end item performance against the requirements.
- Identify potential impediments and risks to each end item's design execution.
- Determine mitigation plans to avert program schedule delays and unplanned resource expenditures.

The project team should integrate early M&Q considerations in the development of the IPT structure, trade study analysis, SEP, and SETR processes to include formal entrance and exit criteria.

During early system development, M&Q personnel should provide input to the following Pre-Milestone B SETRs as described in the following sections of this guide:

- Alternative Systems Review (ASR)
- System Requirements Review (SRR)
- System Functional Review (SFR)
- Preliminary Design Review (PDR)

3.14 Reliability, Availability, and Maintainability

Design Failure Modes and Effects Analysis (DFMEA) is a design analysis technique used to identify potential problems with the product design and to eliminate or mitigate these problems before the design is final. Of note, starting with the DFMEA process, M&Q personnel should work with the system design team to identify KCs. If incorrectly specified, or if the product is not built to the characteristic specification, these special product characteristics (key characteristics) significantly influence product safety, performance, fit, and service life. M&Q

engineer SMEs should contribute to DFMEAs early in development. Outputs from the DFMEA should feed into the Process Failure Modes and Effects Analysis (PFMEA).

In transition from TMRR to preliminary design, M&Q personnel should emphasize the need to conduct PFMEA as manufacturing processes are developed. This analysis determines potential product failure modes caused by manufacturing processes. In particular, the technical team should require a PFMEA for ordnance, and critical safety or mission-critical processes. Requirements to conduct a PFMEA should be included starting with EMD contract requirements. The technical team should initiate PFMEA analysis when the product design has progressed far enough to initiate manufacturing process development. PFMEAs should be repeated or updated whenever there is a new process, a modification to an existing process, or when an existing process will be used in a new environment, location, or application.

Additional information on the topic of PFMEAs is included in SAE J1739, Potential Failure Modes and Effects Analysis in Design, and Potential Failure Mode and Effects in Manufacturing and Assembly Process; and MIL-HDBK-896A Manufacturing Management Program Guide.

3.15 Corrosion Control Planning

As a best practice, to prevent sustainment issues and increased cost issues later in the system life cycle, corrosion control planning should be included explicitly during early M&Q engineering processes. Corrosion must be considered when selecting materials (e.g., addressing non-chrome concerns and potential sustainability issues), manufacturing of pieces and parts (e.g., welding, dissimilar metals concerns), and throughout early system development engineering processes. Doing so during producibility analysis will prevent cost burdens later in the system life cycle (DoDI 5000.67, Prevention and Mitigation of Corrosion on DoD Military Equipment and Infrastructure).

3.16 Contracting for M&Q Activities

M&Q personnel should support the development of the Request for Proposal (RFP) by identifying M&Q considerations and criteria for inclusion in the RFP and subsequent contract. RFP considerations should ensure linkage between M&Q considerations and be specified in source selection evaluation factors and sub-factors.

Appendix E provides M&Q tasks, best practices, and sample RFP language to contract for M&Q requirements. DE requirements and considerations are evolving. As example best practices, refer to the Air Force Digital Campaign RFP guidance https://wss.apan.org/af/aflcmc.

For further DMSMS contracting considerations refer to the Defense Standardization Program Office guide, SD-26, DMSMS Contract Language Guidebook.

4 PRE-MDD M&Q ACTIVITIES AND CONSIDERATIONS

4.1 Objectives

The pre-MDD SE objectives are to obtain a clear understanding of user needs, identify a range of technically feasible candidate materiel solution approaches, consider near-term opportunities to provide a more rapid interim response, and develop a technical plan for the next acquisition phase including identifying the required resources. This knowledge base supports the characterization of the design and manufacturing trade space, risks, and product and production system interdependencies. An important aspect of the Pre-MDD effort is narrowing the field of candidate solutions to a reasonable set included and analyzed in the AoA.

The role of M&Q is to influence the design for producibility, to plan for production, and to execute the production plan. These roles are critical to achieving program success; as such, M&Q personnel should:

- Ensure the design process includes M&Q. The role of manufacturing is to influence the design so it is producible. The role of quality is to influence the design so it is reliable and robust.
- Assess manufacturing feasibility and quality risks for the materiel solutions identified.
- Support the reduction of M&Q risks and demonstrate producibility.

For example, candidate geometry and material combinations from engineering design trade-offs may inadvertently constrain manufacturing processes. Manufacturing personnel should keep this in mind and identify alternative product geometries, materials (e.g., composites vs. lightweight metals, easier to process super-alloys) based on more cost-effective or robust alternative manufacturing processes (e.g., hog-outs vs. castings vs. additive manufacturing) or advanced manufacturing capabilities (e.g., smart manufacturing, advanced robotics) that could be used.

As the design team identifies and develops new concepts, the technical team has an opportunity to add M&Q representatives to the S&T prototyping or design engineering team. M&Q specialists support S&T by identifying design-driven producibility issues and manufacturing risks, performing MRAs, and identifying ManTech and advanced manufacturing R&D projects to address affordability.

4.2 Pre-MDD Documentation

M&Q personnel should provide input to the development or review of the following documents:

- Initial Capabilities Document (ICD)
- Analysis of Alternatives (AoA)

In particular, the draft ICD and AoA should include M&Q perspectives on industrial base capability and manufacturing feasibility.

4.2.1 Concept Characterization and Technical Description[11]

As a best practice during early system development, M&Q practitioners can use CCTD approaches to initiate M&Q planning and to develop input for the ICD and AoA. The CCTD approach summarizes technical planning and analysis and identifies areas where further work is required to mature the concept. The information within the CCTD approach represents the analytic basis upon which a materiel concept was developed, the rationale for decisions made during that development, and the relevant technical documentation that results from early application of SE processes and activities.

The project technical team should conduct initial technical planning to include M&Q considerations during pre-MDD activities. The team should refine the analysis during the MSA phase and AoA to include the following topics:

- Critical Technology Elements (CTEs): Technologies identified as critical to the concept. The technical team should describe the CTE maturity level in terms of TRLs and should recommend which CTEs require additional technology maturation.
- Critical Design Constraints: Constraints that limit choices for the concept design (e.g., cost, immature technologies, requirements that exceed current technological capabilities). When applicable the technical team should provide recommendations to alleviate those constraints (e.g., a technology maturation program, ManTech or other program, requirement changes).
- Program Characterization/Implementation Analysis: Efforts envisioned to develop, test and evaluate, manufacture, and sustain the materiel concept. This analysis should include early M&Q considerations such as producibility evaluations, manufacturing technology development, and other advanced manufacturing opportunities.
- Technology Maturation Approach: Approach to address the identified technology gaps such as new projects, prototyping, and planned technology development.
- Manufacturing/Producibility Approach: Approach to ensure the concept can be produced at the required scale by assessing the manufacturing readiness of the overall concept and key components. As efforts to improve manufacturing readiness are completed, they should be documented or referenced. MRLs 1-3 highlight M&Q issues requiring attention prior to the end of the MSA phase (unless the concept is an off-the-shelf product or system, or based on one currently in inventory, it will likely be at MRL 1-3 at MDD).

[11] The Office of Aerospace Studies AoA Handbook, August 2017, and Air Force Materiel Command Development Planning Guide, 2010, outline CCTD considerations and best practices for Development Planning and AoAs.

  - The technical team should identify gaps in the manufacturing assessment to meet the needs of the concept and recommend approaches to address the gaps (e.g., ManTech program or other investment efforts) along with event-driven opportunities to re-assess the manufacturing readiness.
  - As it determines whether the concept is producible or not, the Milestone Decision Authority should consider the manufacturing readiness of the concept to determine where the concept enters the acquisition cycle.

4.2.2 Analysis of Alternatives

The AoA involves three principal artifacts: (1) the AoA Study Guidance, (2) the AoA Study Plan, and (3) the AoA Final Report. M&Q perspectives should be incorporated in AoA activities and documents.

The AoA is an analytical comparison of the operational effectiveness, suitability, and life cycle cost of alternatives that could satisfy identified user capability needs. The AoA requires the development of an AoA Study Plan, a road map for the conduct of the AoA. M&Q personnel need to be engaged in the assessment of the alternative solutions to assess M&Q impacts and plan for future implementation. M&Q considerations include:

- Schedule and Technology/Manufacturing Readiness Assessment: The AoA should include estimated schedules for each alternative, as well as an assessment of existing technology and manufacturing readiness (TRL/MRL) for critical technologies that may influence the likelihood of completing development, integration, and operational testing on schedule and within budget. Where significant risks are identified, the assessment should outline practical mitigation strategies to minimize impact to delivering the operational capability to the warfighter, and, if applicable, notional work-arounds in the event the risks are realized.

Early M&Q activities should identify candidate production system concepts and technologies to address industrial base capability gaps. In addition, M&Q personnel should:

- Provide analyses of the M&Q requirements and feasibility contained in the draft ICD, the AoA Study Guidance, and the preliminary CONOPS for the AoA.
  - Analyses should verify adequacy, relevance, and completeness.
  - Analyses should identify and quantify M&Q risks.
- Update IBAs and market analyses to address concepts included in the AoA.
  - IBAs should illustrate the differences between alternatives based on the industrial and manufacturing capabilities and the required resources during the AoA.

    - Manufacturing feasibility should answer the question, “Can it be built at the required scale?”
- Ensure assessments of manufacturing feasibility for the AoA preferred concepts are up to date, including engineering trade studies, early prototypes, models or data, and the industrial capabilities required to design, develop, manufacture, and maintain each (conduct if not previously accomplished).
    - Identify M&Q risks.
        - Include materials, processes, and technology.
        - Identify new or high-risk manufacturing processes or capacity requirements.
    - Identify manufacturing, quality, materials, and unique requirements that are cost drivers for the AoA.
    - Ensure the phase-by-phase requirements for M&Q skills and training are updated for the AoA preferred materiel solutions.
    - Ensure the facilities and capital equipment requirements for each AoA preferred concept are updated.
    - Ensure that each AoA preferred concept includes and is analyzed for quality management requirements.
    - Ensure each AoA preferred concept includes and is analyzed for M&Q management requirements.

4.3 M&Q-Related Activities

M&Q personnel should provide the Milestone Decision Authority with M&Q information by supporting the various assessment and strategy/planning activities to include the following:

- MRA: A structured evaluation of a technology, component, manufacturing process, weapon system, or subsystem using best practice tools.
- TRA: A systematic, evidence-based process that evaluates the maturity of technologies (hardware, software, and processes) critical to the performance of a larger system or the fulfillment of the key objectives of an acquisition program, including cost and schedule.
- IBA: A comprehensive assessment of industrial base capabilities required to meet current and future requirements and that the capabilities are available and affordable.
- Manufacturing Strategy: The strategy outlines the manufacturing approach in support of the AS and SEP. The strategy should identify general manufacturing management standards approaches such as: SAE AS 6500, MIL-HDBK-896A, identification of major suppliers, critical suppliers, manufacturing workforce skills/needs, manufacturing

maturity, producibility; technical data package requirements, and manufacturing approaches (dual source, single source, leader-follower, etc.).

- Quality Strategy: The quality strategy outlines the quality approach in support of the AS and SEP. The strategy should identify general approaches for quality standards to be used such as: ISO 9000/9001, AS 9100, Federal Aviation Administration quality/inspection standards, space or nuclear certification, supplier management; Parts and Materials, and Process Controls, first article test, and approaches for contractor surveillance activities.

In summary, the pre-MDD M&Q major activities include:

- Achieving an in-depth understanding of the production system capability and gaps. The development team with input from M&Q personnel should include findings in the Capabilities-Based Assessment (CBA), further documented in the ICD. The basic CBA process can be applied to identify and characterize industrial base capability gaps.
- Identifying an appropriate range of candidate production system solutions.
- Identifying production system solution opportunities to provide a more rapid response.
- Analyzing the design and manufacturing trade space to determine alternative product and production system solution concepts.
- Planning the production system capability development for the subsequent technical efforts required during the MSA phase.
- Evaluating risks associated with the alternative production system concepts to be analyzed during the MSA phase.
- Identifying critical product and production system technologies and associated technology maturation and prototyping approaches, performing TRL and MRL evaluations, and documenting these in the AoA. These preliminary manufacturing readiness evaluations are not as rigorous as formal MRAs performed in support of the MSA phase Milestone A decision and TMRR phase maturation.
- Identifying M&Q management approaches for follow-on program phases.

Appendix B includes detailed M&Q tasks to support the above activities.

5 MSA M&Q ACTIVITIES AND CONSIDERATIONS

5.1 Objectives

The MSA phase includes two major activities:

- AoA development, during which the program considers and iteratively refines a range of materiel solution concepts under consideration.
- Post-AoA operational analysis, requirements development, and technical planning for the next program phase after the sponsor selects a preferred concept to pursue.

MSA outputs include the system model or architecture, DE planning, and system performance specification, and the definition of the system to be prototyped.

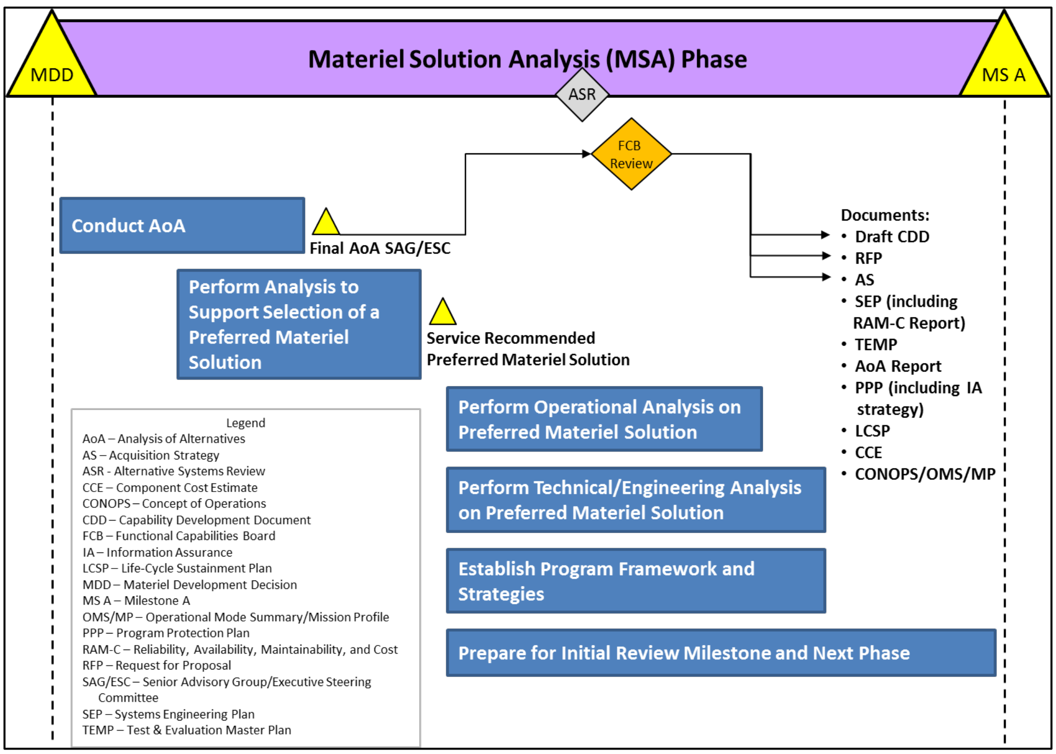


Figure 5-1. MSA Phase Activities Overview

5.2 MSA Documentation

To meet these MSA phase objectives, M&Q personnel should provide input to the development and review of the following documents:

- AS
- SEP

  - Manufacturing Strategy
  - Quality Strategy
  - SETR Entrance and Exit Criteria
- Analysis of Alternatives (AoA)
- Capability Development Document (CDD)
- Foundation for DE Ecosystem definition
- TMRR Request for Proposal

MSA phase documents and artifacts provide confidence that a technically feasible product, and production system approach, will satisfy user needs and is affordable with reasonable risk.

Potential M&Q artifacts should include:

- Manufacturing Readiness Assessment (MRA)
- Manufacturing Feasibility Assessment (MFA)
- Manufacturing facility and processes models and simulations
- Market research to identify potential solutions appropriate for maturing the concept in the next phase

5.3 MSA Reviews/Assessments

M&Q personnel should engage in the organization and execution of numerous formal reviews and assessments during this phase, which could include:

- Alternative Systems Review (ASR)
- Manufacturing Readiness Assessment (MRA)
- Technology Readiness Assessment (TRA)
- Manufacturing Feasibility Assessment (MFA)
- Industrial Base Assessment (IBA)
- Independent Technical Risk Assessment (ITRA)

5.3.1 Alternative Systems Review (ASR)

The purpose of the ASR is to review the technical and programmatic plans (SEP included) to transition the preferred system concept, down-selected during the AoA process, into a program at Milestone A and to ensure the concept is ready to proceed into the next phase. The ASR ensures that the preferred system alternative is cost-effective, affordable, operationally effective, and suitable, and can be feasibly developed/manufactured to provide a timely solution to the need at an acceptable level of risk. Example questions for M&Q personnel to consider at ASR include:

- What are the production limits on the number of prototype units that might be developed?
- Have facility requirements been identified to support the prototype build?
- Have material requirements been identified, and are all materials available (long lead, sole source, foreign source, etc.)?
- Are hazardous materials embedded in the system or used in manufacturing processes?
- Has Programmatic Environmental, Safety, and Occupational Health Evaluation (PESHE) and National Environmental Policy Act (NEPA) compliance planning been initiated?
- Has the schedule been evaluated for M&Q impacts?
- Has a project plan been developed with a critical path identified for design build?
- Have cost estimates been developed, and do they identify M&Q cost drivers?
- Has the WBS been evaluated, and have risks been identified to include M&Q risks?
- Have design alternatives been identified and evaluated for M&Q risks?
- Has the program office conducted any modeling and simulation on the preferred concept?
- Have any trade studies been identified, and do they include M&Q concerns?

5.3.2 Independent Technical Risk Assessment (ITRA)

For Major Defense Acquisition Programs (MDAPs), starting with Milestone A, ITRAs are conducted before each acquisition milestone. The ITRA approval authority must be independent and may not be in the program's chain of command. The project technical team should be aware that they may need to support and participate in ITRA activities beginning prior to Milestone A.

DoDI 5000.88, Engineering of Defense Systems, states an ITRA will "consider the full spectrum of technology, engineering, and integration risk. These areas could include mission capability, technology, system development, MOSA (Modular Open Systems Approach), software, security, manufacturing, sustainment, and their potential impacts to cost, schedule, and performance. For ITRAs conducted before Milestone A, identifies critical technologies and manufacturing processes that need to be matured. Subsequent ITRAs will re-assess technology and manufacturing process maturity, accounting for demonstrations in relevant environments."

DoDI 5000.88 further outlines that OUSD(R&E) is the ITRA approval authority for ACAT 1D programs, and determines ITRA approval authority for ACAT IB/IC programs. ITRAs are not required for non-MDAP programs, but if conducted, they will follow the OUSD(R&E) published ITRA policy and guidance at https://ac.cto.mil/itra/.

Pursuant to 10 USC 2448b (FY17 National Defense Authorization Act (NDAA) Sections 807 and 808) the following are required at Milestone A:

- Submissions to Congress on Milestone A—(1) Brief ITRA summary report.— Not later than 15 days after granting Milestone A approval for a major defense acquisition program, the MDA should provide to the congressional defense committees…a brief summary report that contains the following elements:
    - A summary of the technical or **manufacturing risks** associated with the program, as determined by the military departments concerned, including identification of any critical technologies or **manufacturing processes that need to be matured**
    - A summary of the independent technical risk assessment conducted or approved under Section 2448b of this title, including identification of any critical technologies or **manufacturing processes that need to be matured**

According to DoDI 5000.88, "For programs for which an ITRA is conducted, a technology readiness assessment report is not required. Programs will continue to assess and document the technology maturity of all critical technologies consistent with the technology readiness assessment guidance. ITRA teams may leverage technology maturation activities and receive access to results in order to perform independent technical reviews and assessments."

The Defense Technical Risk Assessment Methodology (DTRAM) defines ITRA assessment criteria and categories https://ac.cto.mil/wpcontent/uploads/2021/01/DTRAM-0-1.

5.4 MSA Phase M&Q Activities

During the MSA phase, M&Q activities should focus on evaluating CTEs identified by engineering, estimating the manufacturing readiness, and screening all components in the level 4 program WBS for potential manufacturing maturity deficiencies, ManTech investment needs and opportunities, potential producibility issues, and production system cost drivers. M&Q personnel should incorporate these considerations into SE and program planning efforts.

Early M&Q objectives are to support the AoA and to evaluate design concepts in terms of producibility, analyze production system performance and manufacturing feasibility, and optimize advanced manufacturing solution alternatives.

Post-AoA early M&Q objectives are the technical planning for TMRR phase activities, to include identifying critical production technologies, developing a competitive and risk reduction process and production prototyping strategy, and establishing other plans that support risk-reduction efforts and lay the foundation for the TMRR phase contract award(s). M&Q activities include establishing a producibility engineering plan and establishing technical production system requirements for development specifications placed on contract for the TMRR phase, and documenting these in both the SEP.

Appendix C includes additional information on M&Q tasks to support MSA activities.

6 TMRR M&Q ACTIVITIES AND CONSIDERATIONS

6.1 Objectives

A primary objective of the TMRR phase is to reduce technical risk and develop a sufficient understanding of the materiel solution to support sound investment decisions at the pre-EMD review and at Milestone B regarding whether to initiate a formal acquisition program. Major efforts associated with the TMRR phase include:

- Determining the appropriate technologies to integrate the full system.
- Maturing and demonstrating technologies in a relevant environment.
- Conducting prototyping of the system and/or system elements.
- Performing trade studies and using the results to refine requirements and revise the design concept(s).
- Developing the preliminary design including establishing the functional and allocated baselines and associated specifications.
- Performing Development test activities as appropriate.

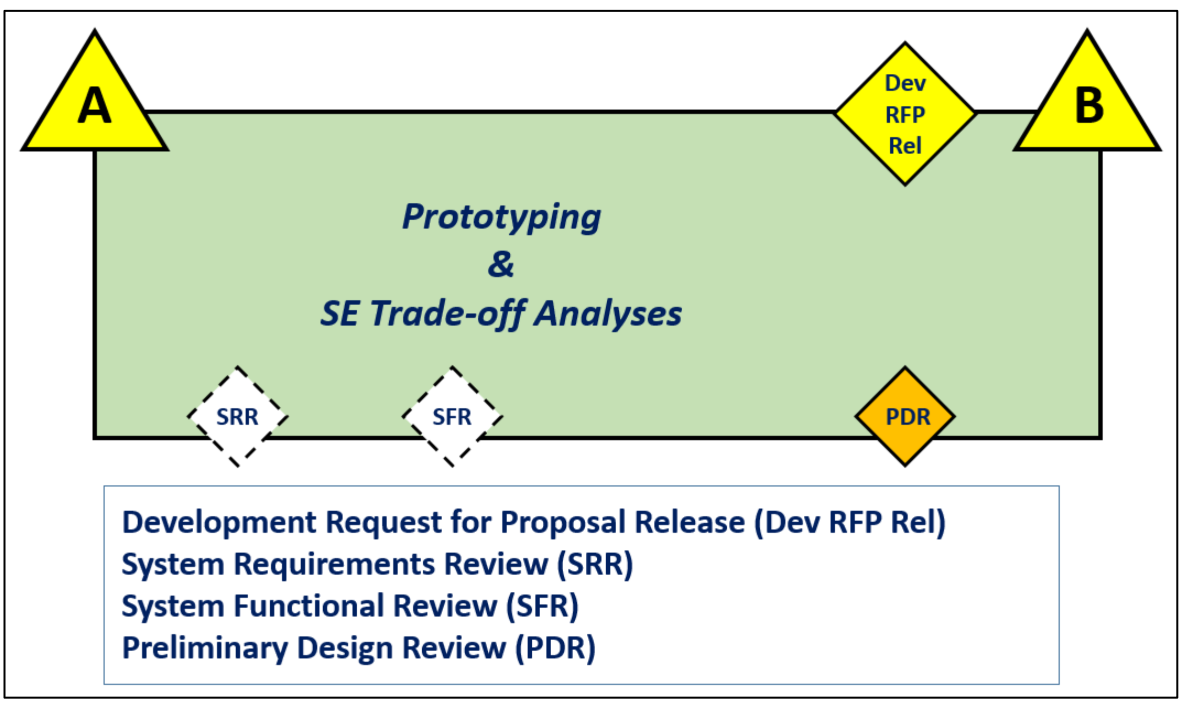


Figure 6-1. TMRR Phase Activities

For TMRR, M&Q technical objectives include the following:

- Technical risk reduction
- Initial product and production system design and development activities that culminate in the preliminary design of these systems
- The build of prototype components, subsystems, or systems for testing

6.2 TMRR Documentation

M&Q personnel need to be engaged in the development and update of numerous documents, including the following:

- SEP
    - Manufacturing Plan
    - Quality Plan
- Test and Engineering Master Plan (TEMP)
- Integrated Master Plan/Integrated Master Schedule (IMP/IMS)
- Core Logistics Determination/Core Logistics and Sustaining Workloads Estimate
- Life Cycle Sustainment Plan (LCSP)
- DMSMS Management Plan (see DoDI 4245.15)
- PESHE and NEPA Compliance Schedule
- Corrosion Prevention (see DoDI 5000.67)

These products of the TMRR phase support the technical recommendation at Milestone B that the program has found an affordable product and production system solution for the identified need with acceptable risk, scope, and complexity. SE and M&Q artifacts include a product and production system preliminary design and allocated design-to baselines; updated functional and allocated baselines; updates to product and production system architectures, models, and simulations; market research of potential solutions; and trade-off analysis results, along with the associated rationale for all assumptions, ground rules, and constraints that form the basis for the trades.

M&Q provides expertise to support design and management decisions about product and production system trades for inclusion in the SEP and Manufacturing Management Plan.

Appendix D list applicable M&Q tasks to support TMRR SE activities.

6.3 TMRR Reviews/Assessments

SETRs provide a venue to establish the technical baselines, assess the system's technical maturity, and review and assess technical risks. In accordance with DoDI 5000.88, at each technical review the PM will, to the extent practicable, use information from the digital authoritative source of truth to assess key risks, issues, opportunities, and mitigation plans to understand cost, schedule, and performance implications.

M&Q personnel should participate in several reviews and assessments during this phase in preparation for the Milestone B decision review for entry to EMD:

- System Requirements Review (SRR)
- System Functional Review (SFR)
- Preliminary Design Review (PDR)
- Manufacturing Readiness Assessment (MRA)
- Independent Technical Risk Assessment (ITRA)
- Industrial Base Assessment (IBA)

6.3.1 System Requirements Review (SRR)

The SRR is a formal review by the technical team to ensure system requirements are identified, and to ensure a mutual understanding between the government and contractor. The SRR ensures that the system under review can proceed into initial systems development and that all system and performance requirements derived from the ICD or draft CDD are defined, testable, and consistent with cost, schedule, risk, technology readiness, and other system constraints.

Completion of the SRR should provide the following:

- An approved system performance specification, or System Requirements Document with sufficiently conservative requirements to provide for design trade space for the EMD phase
- A preliminary allocation of system requirements to hardware, human, and software subsystems
- A preliminary identification of all software components (tactical, support, deliverable, non-deliverable, etc.)
- A comprehensive risk assessment for EMD
- An approved EMD phase SEP that addresses cost and critical path drivers
- An approved Life Cycle Sustainment Plan (LCSP)

6.3.2 System Functional Review (SFR)

The SFR is a technical review to ensure the system's functional baseline is established and can satisfy the requirements of the ICD or draft CDD within the currently allocated budget and schedule. The SFR also determines whether the system's lower-level performance requirements are fully defined and consistent with the system concept and whether lower-level systems requirements trace to top-level system performance requirements.

Completion of the SFR should provide the following:

- An established system functional baseline with traceability
- An updated risk assessment for EMD
- An updated Cost Analysis Requirements Description (CARD)
- Updated program development schedule including system and software critical path drivers

SRR and SFR planning should include M&Q analyses and input. Key M&Q inputs include: manufacturing feasibility assessments, traceability of M&Q requirements to the CDD, IBAs, IMP/IMS input, risk assessments, recommendations for the manufacturing management system and quality management systems, and input to PDR entrance/exit criteria required for the PDR process.

6.3.3 Preliminary Design Review (PDR)

The PDR is a technical assessment that establishes the allocated baseline of a system to ensure a system is operationally effective. A successful PDR will inform requirements trades, improve cost estimation, and identify remaining design, integration, and M&Q risks. The PDR should determine whether critical technologies are matured to at least TRL 6 and manufacturing technologies and processes to at least MRL 6.

As the design team develops initial design approaches for PDR, M&Q personnel should engage in the planning, organization and execution of the review. Example M&Q tasks include the following:

- Assess the preliminary system-level design for producibility and production costs.
- Provide M&Q support to identify preliminary key characteristics and critical processes.
- Review and assess M&Q DE approaches, technical data storage, and configuration control.
- Provide an assessment of long-lead materials and production requirements.

- Provide an updated assessment and analysis of the M&Q processes and metrics included in the contractor's Systems Engineering Management Plan (SEMP) for completeness, adequacy, and alignment with those processes and metrics included in the program SEP.
- Review manufacturing maturity information (i.e., MRL).
- Review contractor manufacturing facility and workforce plans.
- Assess the preliminary system design and M&Q management information, including the following:
  - Results and data from building and testing prototypes
  - Parts, materials, and processes management
  - Design testability (e.g., built-in test)
  - Tooling design, testing (special tooling and test equipment)
  - Hazardous materials
  - Variability reduction plans
  - Diminishing Manufacturing Sources and Material Shortages
  - Use of COTS, government off-the-shelf (GOTS), and government-furnished equipment (GFE)
  - Products or components (known and/or projected) from sole, single, fragile, or foreign sources

Additional information on M&Q tasks to support SFR, SRR, and PDR activities are outlined in the DoD Manufacturing and Quality Body of Knowledge https://www.ac.cto.mil/maq/.

6.4 TMRR Phase M&Q Activities

M&Q activities in this phase should focus on quantifying product producibility characteristics and production system characteristics using the system technology demonstration as part of the advanced development and prototyping. These activities should lead to definition of the final product and to production system concepts optimized in terms of both producibility and industrial base considerations.

These activities include using the results of the prototyping activities to finalize the product and production system concepts to balance consideration of performance, cost, schedule, quality, long-lead item, tooling complexity, specialized test and inspection equipment, specialized and niche industrial base capabilities, etc. These early-stage TMRR phase M&Q activities provide a sound technical foundation for the final product and production system concepts going into the PDR or Milestone B decision, informing the Manufacturing Management Plan. Applying effective early SE and M&Q in accordance with the SEP, gated by SETRs and the associated checklists, reduces program risk, reveals potential management issues in a timely manner, and supports decisions aimed at achieving a balanced product and production system design. The TMRR phase early SE and early M&Q major activities include the following:

- Conduct product and production system technology maturation activities (e.g., design, integration, production) and assess the results of the activities by participating in TRAs and MRAs.
- Support product and production system prototyping to reduce engineering and manufacturing development risk.
- Perform product and production system design and trade-off analyses to assess alternatives with respect to performance, cost, schedule, and risk.
- Establish associated functional baselines, allocated baselines, preliminary design concepts, and allocated TPMs.
- Identify major affordability drivers from both a design and manufacturing perspective.
- Conduct SETRs and audits to assess whether preplanned technical maturity points are reached.
- Support the EMD RFP requirements development.

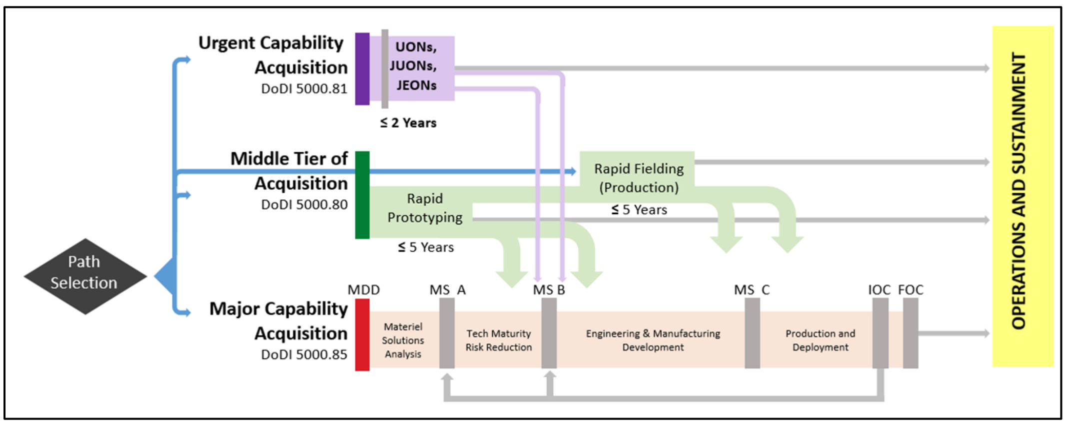
Appendix D provides additional information on M&Q tasks to support TMRR activities.

7 MTA AND UCA M&Q ACTIVITIES AND CONSIDERATIONS

7.1 Middle Tier of Acquisition

The Middle Tier of Acquisition (MTA) is a rapid acquisition approach that focuses on delivering capability in a period of 2-5 years with rapid prototypes and rapid fielding of proven technology. Refer to DoDI 5000.02, Operation of the Adaptive Acquisition Framework, and DoD 5000.80, Operation of the Middle Tier of Acquisition.

The MTA pathway (Figure 7-1) fills a gap in the Defense Acquisition System for those capabilities that have a level of maturity to allow them to be either rapidly prototyped within an acquisition program or fielded within 5 years of program start. The MTA pathway may be used to accelerate capability maturation before transitioning to another acquisition pathway, or may be used to minimally develop a capability before rapidly fielding.[12]



UON: Urgent Operational Need	MS A, B, C: Milestone A, B, C
JUON: Joint Urgent Operational Need	IOC: Initial Operational Capability
JEON: Joint Emergent Operational Need	FOC: Full Operational Capability
MDD: Materiel Development Decision	

Figure 7-1. Middle Tier of Acquisition

7.1.1 Rapid Prototyping

Rapid prototyping provides an acquisition pathway for use of innovative technologies to rapidly develop and field prototypes to demonstrate new capabilities to meet emerging military needs.

The program team should use technologies and manufacturing processes that are significantly mature and assessed using the appropriate TRL/MRL criteria based on acceptable program risk. Conducting a PRR is a recommended best practice before entering production.

[12] DoDI 5000.80 Operation of the Middle Tier of Acquisition, para 1.2.b

M&Q personnel, working with the Program Manager, Lead Systems Engineer, and other IPT members, should ensure that manufacturing, quality, and producibility requirements and risks are identified and managed throughout the rapid prototyping process. M&Q personnel should:

- Support the development of program documentation to include acquisition strategies.
    - Develop SEP with planned M&Q management activities, and document manufacturing readiness and risk.
- Support the development and implementation of efficient and cost-effective M&Q activities and processes.
    - Estimate cost (identify M&Q cost drivers).
    - Track and improve cost.
- Support demonstration and evaluation of prototype design, build, and test activities.
    - Support the identification, tracking, and management of technical risks.
    - Support all SETRs, to ensure the program addresses M&Q considerations early.

The manufacturing of prototype(s) for proposed components, production, and integration of subsystems and systems should follow M&Q best practices. The government team should ensure that contractors are operating under a documented M&Q management system based on accepted standards such as:

- SAE AS6500A, Manufacturing Management Program
- MIL-HDBK-896A, Manufacturing Management Program Guide
- AS9001, Quality Management System, or
- ISO 9001, Quality Management System

Prototyping contractors should have developed and provided to the government their Manufacturing and Quality Plans for the proposed prototype system or subsystems. The government team should assess these plans for completeness and adequacy.

M&Q personnel should engage in rapid prototyping efforts by:

- Supporting the development of program documentation (AS, SEP, PESHE, NEPA and compliance schedule, Market Research, IBA, etc.).
- Supporting program reviews (technical reviews, program reviews, etc.).
- Supporting the evaluation and assessment of proposed prototyping projects and technologies to include assessments of manufacturing maturity.

- Supporting the evaluation and assessment of program risks (cost, schedule, and performance) from an M&Q perspective.
- Identifying M&Q best practices and continuous improvement processes to support prototype design, development, and testing.
- Supporting the use of DE best practices to shorten the time and risk for prototype design, development, and testing.
- Supporting the development of metrics and plans for the transitioning of the prototype to existing acquisition programs for production, fielding, and O&S.

7.1.2 Rapid Fielding

Rapid fielding provides an acquisition path for use of proven technologies to field production quantities of new or upgraded systems with minimal development required. Rapid fielding efforts should consider the potential of existing products, proven technologies, and/or demonstrated processes to meet an existing or emerging capability gap or create future operational opportunities.

To begin production within 6 months, the technologies and manufacturing processes used to implement the final system configuration should be significantly mature and assessed at a very mature TRL/MRL based on acceptable program risk. A manufacturing risk assessment is required during all phases of the system life cycle.

In accordance with DoDI 5000.88, M&Q personnel, working with the Program Manager, Lead Systems Engineer, and other IPT members, will ensure that manufacturing, quality, and producibility requirements and risks are identified and managed throughout the program's lifecycle. M&Q personnel should:

- Support the development of program documentation to include acquisition strategies.
    - Develop the SEP with planned M&Q management activities, and document manufacturing readiness and risk.
- Support the development and implementation of efficient and cost-effective M&Q activities and processes.
    - Estimate cost (identify M&Q cost drivers).
    - Track cost and reduce manufacturing cost.
- Support demonstration and evaluation of prototype design, build, and test activities.
    - Support the identification, tracking, and management of technical risks.

  - Support all system engineering technical reviews, to ensure manufacturing and quality considerations are addressed early.

Manufacturing of the proposed rapid fielding system to include proposed components, subsystems, and systems should follow M&Q best practices, thus the government teams should ensure that any proposed contractors are operating under a documented M&Q management system such as:

- SAE AS6500A, Manufacturing Management Program
- MIL-HDBK-896A, Manufacturing Management Program Guide
- AS9001, Quality Management System, or
- ISO 9001, Quality Management System

Contractors involved in Rapid Fielding acquisition pathway efforts should have developed and provided to the government their Manufacturing and Quality Plans for the proposed system or subsystems. The technical team should assess the plans should for completeness and adequacy.

M&Q personnel need to engage in rapid fielding efforts by:

- Supporting the development of program documentation (AS, SEP, PESHE, NEPA and Compliance Schedule, Market Research, IBA, etc.).
- Supporting program and technical reviews.
- Supporting the evaluation and assessment of proposed rapid fielding projects to include manufacturing maturity of the proposed projects.
- Supporting the evaluation and assessment of program risks (cost, schedule, and performance) from an M&Q perspective to include demonstrations of the proposed products.
- Identifying M&Q best practices and continuous improvement processes to support project development, integration, and testing.
- Supporting the use of DE best practices, where appropriate, to shorten the time and risk for project development, integration, and testing.

7.2 Urgent Capability Acquisition

To field an urgent capability to meet immediate warfighter needs, the engineering team should assess the planned technology and manufacturing processes using the appropriate TRL/MRL criteria based on acceptable program risk.

Programs teams should tailor M&Q efforts to address identified risk. Since the nature of the urgent capability program implies that a capability is required on an accelerated timeline, use of existing documentation and manufacturing plans, etc., is encouraged. As a best practice, a tailored PRR is recommended before entering production.

M&S personnel, working with the Program Manager, Lead Systems Engineer, and other Integrated Product Team (IPT) members, should ensure that manufacturing, quality, and producibility requirements and risks are identified and managed throughout the process of fielding an urgent capability. M&Q personnel should:

- Support a review of Courses of Action for M&Q implications and risks.
- Support the development of program documentation to include acquisition strategies.
    - Develop the SEP with planned M&Q management activities.
- Support the development and implementation of efficient and cost-effective M&Q activities and processes.
    - Estimate cost (identify M&Q cost drivers).
    - Track cost and cost improvements.
- Support demonstration and evaluation of prototype design, build, and test activities.
    - Support the identification, tracking, and management of technical risks.
    - Support all SETRs to ensure the program addresses M&Q considerations early.

The manufacturing of the proposed urgent capability to include components, subsystems, and systems should follow M&Q best practices, thus any proposed contractors should be operating under a documented manufacturing and quality management system such as:

- SAE AS6500A, Manufacturing Management Program
- MIL-HDBK-896A, Manufacturing Management Program Guide
- AS9001, Quality Management System
- ISO 9001, Quality Management System

Contractors should have developed and provided to the government their Manufacturing and Quality Plans for the proposed system or subsystems. The government project team should assess the plans for completeness and adequacy.

APPENDIX A: MRA "LITE"

MRA "Lite" Approaches[13]

The goal of performing pre-MDD MRA "Lite" evaluations is to identify manufacturing risk proactively and as early as possible in the program. The government project team should limit MRA Lite evaluation approaches to early screening of system concepts and prototypes during early pre-MDD candidate solution set development. This allows the development team to more quickly focus on specific critical technologies/subsystems early in the process to identify critical manufacturing elements with potential manufacturability and producibility issues based on known or perceived risks. A follow-on more rigorous MRA and development of manufacturing maturation plans should be conducted as additional information becomes available.

The MRA Lite approach uses high-level manufacturing, quality, and producibility risk identification questions to identify specific potential risk areas for further assessment. Example risk areas of components or subsystems include:

- Design configurations and materials that have a high level of geometric complexity, processing, assembly, and/or inspection complexity.
- Known affordability, availability, or producibility issues for the baseline concept and other relevant "similar to" systems.
- Known quality control problems, high scrap, and rework; low first pass yield, etc.; issues for the baseline concept and other relevant "similar to" systems.
- Exotic or specialty materials or manufacturing processes for the baseline concept and other relevant "similar to" systems.
- Machine capability issues for producing the required rate; quality and capability of the quality system planned to be employed.
- Materials that are hard to machine, join, form, mold, fabricate, process, post-process, etc., and require specialized manufacturing sources or processes.
- Materials requiring the use of advanced or specialized processes or emerging manufacturing technologies under development.
- Design configurations with stringent engineering-driven tolerances linked to system flow-down requirements.
- Complex tooling or manufacturing processes requiring multiple setup operations during their manufacture or hand-offs to other suppliers to produce for "similar-to" designs.

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[13] MRL Lite approach in this section highlight best practice approaches from U.S. Navy development and prototyping efforts

- High levels of manually intensive or artisan processing to meet design requirements for prototypes and "similar-to" designs.
- Specialized industrial base manufacturing capabilities or workforce skill sets to produce them.
- Materials and/or manufacturing processes under development where characterization is ongoing and not yet mature.
- Known material availability issues, limited sources, or non-domestic sources; DMSMS issues, etc.
- Known process repeatability issues or high levels of process variability for the baseline design concept and "similar-to" designs.
- Systems that require highly specialized or complex tooling, fixtures, inspection, or test equipment.
- Manufacturing processes for prototypes that cannot be later automated for production.
- Major system recertification and/or requalification efforts to retrofit.

Using select MRA criteria referenced at www.dodmrl.org, the assessment team can select appropriate criteria for the early assessment. Table A-1 provides an example MRA-Lite evaluation approach using select criteria.

Table A-1. Sample MRA Lite Criteria

MRL "LITE" EVALUATION QUESTIONS (CHECK ALL THAT APPLY)		
MRL 1-2 DESIGN THREAD	MRL 3-4 DESIGN THREAD	MRL 5-6 DESIGN THREAD
Producibility and manufacturability issues identified and correlated to key product/technology variables	Producibility and manufacturability criteria established and used to identify improvement opportunities	Producibility and manufacturability assessments used to guide system element optimization activities
Part family design, material, and process capability gaps identified and characterized	Part family design, material, and process requirements traceable to system-level operational requirements	Prototype part key characteristics identified with sensitivities correlated to system performance requirements
MRL 1-2 MATERIALS THREAD	MRL 3-4 MATERIALS THREAD	MRL 5-6 MATERIALS THREAD
Material process-property-structure cause-effect relationships and key variables have been characterized	Material process-property-structure relationships can be analytically or computationally predicted	Material properties are adequately characterized and preliminary material specifications are in place
Material availability and/or obsolescence issues identified along with potential solutions to address	Material availability, obsolescence, and long lead time mitigation plans in place to support prototype builds	Material availability, obsolescence, and long lead time scale-up plans in place for transition to production
Supply chain capability and capacity gaps identified along with potential solutions to address	Supply chain gap closure solution strategies defined with potential additional sources identified	Critical supply chain suppliers identified with additional qualified sources being developed

MRL “LITE” EVALUATION QUESTIONS (CHECK ALL THAT APPLY)		
MRL 1-2 PROCESSES THREAD	MRL 3-4 PROCESSES THREAD	MRL 5-6 PROCESSES THREAD
Process stability and repeatability cause-effect relationships and key variables have been characterized	Process control variability limits defined and statistically monitored for critical process variables	Process capability data from prototype builds used to establish production requirements
Process yield drivers and capacity bottlenecks identified along with potential solutions to address	Process yield and capacity improvement strategies defined with plans in place to address gaps	Process yield, scrap, rework, and capacity utilization metrics and improvement targets defined
Process modeling and simulation analysis tool gaps identified along with potential solutions to address	Process modeling and simulation analysis tools utilized to define manufacturing and quality requirements	Process modeling and simulation analysis tools utilized to guide prototype process optimization
MRL 1-2 QUALITY THREAD	MRL 3-4 QUALITY THREAD	MRL 5-6 QUALITY THREAD
Quality management system gaps identified along with potential solutions to address	Quality management system business processes established for prototype and production scale-up	Quality management system used to establish quality plans for prototype and production sale-up
Product quality drivers identified for prototype builds along with potential solutions to address	Product quality criteria and inspection and acceptance test methods defined for prototype builds	Product key characteristics and acceptance test verification criteria defined for prototype builds
Supplier quality management business process gaps identified with potential solutions to address	Supplier quality management business processes established for supplier requirements flow down	Supplier quality management business processes established for supplier development initiatives
MRL 1-2 WORKFORCE THREAD	MRL 3-4 WORKFORCE THREAD	MRL 5-6 WORKFORCE THREAD
Engineering workforce skill set gaps identified along with potential solutions to address	Engineering workforce skill set development requirements defined along with training solutions	Engineering workforce skill sets and talent pipeline sufficient to support prototype and production scale-up
Production workforce skill set gaps identified along with potential solutions to address	Production workforce skill set development requirements defined along with training solutions	Production workforce skill sets and talent pipeline sufficient to support prototype and production scale-up
MRL 1-2 FACILITIES THREAD	MRL 3-4 FACILITIES THREAD	MRL 5-6 FACILITIES THREAD
Plant capacity and equipment modernization gaps identified along with potential solutions to address	Plant capacity and equipment modernization requirements defined to meet production scale-up requirements	Plant capacity and equipment modernization plans in place to meet production scale-up requirements
Specialized tooling, inspection, and test equipment gaps identified along with potential solutions to address	Specialized tooling, inspection, and test equipment requirements defined along with implementation strategies	Specialized tooling, inspection, and test equipment in place to support prototype and production scale-up
MRL 1-2 TECHNOLOGY THREAD	MRL 3-4 TECHNOLOGY THREAD	MRL 5-6 TECHNOLOGY THREAD
Manufacturing technology gaps identified and gap closure solutions and investment needs defined	Manufacturing technology requirements and maturation/implementation projects defined	Manufacturing technology maturation/implementation projects funded, staffed, and under way

APPENDIX B: M&Q SUPPORT FOR PRE-MDD SE ACTIVITIES

Manufacturing and Quality Tasks

M&Q personnel should engage in the early SE management and technical management processes. This engagement includes developing early plans, identifying risks, and developing risk mitigation plans. Pre-MDD M&Q tasks include:

- Conduct a gap analysis for manufacturing feasibility to eliminate unfeasible materiel solutions based on factors such as timeliness, sustainability, cost-effectiveness, etc. The gap analysis of manufacturing feasibility should include the use of near-term, commercial, or current systems as a materiel solution for rapid fielding.
- Analyze industrial base capabilities and manufacturing feasibility as part of a Capabilities-Based Assessment.
- Draft a top-level plan that includes scheduling, workforce, and cost projections based on the results of manufacturing feasibility assessment of materiel solutions.
- Support the Milestone Decision Authority MDD process to authorize entry into the acquisition life cycle and pursue a materiel solution.
- Provide M&Q input to identify a range of materiel solutions across the entire solution space including user input as appropriate.
- Develop technical planning with respect to performance characteristics and analysis of capability gaps in manufacturing as part of the analysis of materiel solutions.
- Assess materiel solutions for external dependencies and integration impacts on the industrial base.
- Analyze materiel solutions for producibility and manufacturability and associated costs for the Analysis of Alternatives Study Guidance.
- Analyze the potential alternatives that address the feasibility of a rapid interim response to the need.

APPENDIX C: M&Q SUPPORT OF MSA SE ACTIVITIES

Manufacturing and Quality Tasks

- Update the assessment of manufacturing feasibility for the preferred concept, if not completed; conduct an assessment, for inclusion in the SEP.
- Provide M&Q inputs to the SEP on industrial base, design, manufacturing, production, and quality risks and risk reduction and mitigation efforts.
  - Identify critical technologies and M&Q process areas requiring risk reduction and mitigation efforts for the SEP, including the following activities:
    - Initial M&Q approaches for system requirements and system design concepts
    - M&Q trade studies
    - Potential M&Q solutions
  - Identify M&Q risks, issues and opportunities from existing architectures, capabilities, and external dependencies.
  - Maintain up-to-date status on all key M&Q inputs to the SEP.
- Provide M&Q plans and support to assist in development of the SEP and the program schedule based on the M&Q strategies in the AS, to include:
  - Inputs on required M&Q products (e.g., assessment, metrics) for all SETRs
  - Inputs on specific and detailed M&Q entry and exit criteria metrics for technical reviews and MSA, TMRR, and subsequent phase decision points
    - Metrics should include current and projected M&Q maturity of identified critical technologies and manufacturing processes
    - Metrics should also include the planned MRL target for system, subsystems, components, and items
  - M&Q criteria, metrics, and frequency for SE reviews
  - Planned significant M&Q activities and tools (e.g., modeling and simulations, M&Q assessments, long lead or advanced procurements, prototype builds, production lots/phases)
  - Specifications for the M&Q organization, billets, and leadership positions
  - Specification of the roles, responsibilities, and organization of the Manufacturing Working Group to support SE
  - M&Q roles and responsibilities within other program IPTs (e.g., Design, Risk Management, SE, T&E, Sustainment, Facilities)
- Provide M&Q requirements, risks, issues, and opportunities (e.g., design, producibility, manufacturing technology, facilities, sustainment, cost, and schedule), for the SEP to be addressed by all IPTs.

- Identify M&Q inputs on technical reviews/audits (e.g., PDR, CDR, PRR) to be conducted at the sub-tier level on Configuration Items to be developed by a sub-tier supplier.
- Plan for M&Q activities for the next phase:
  - Summarize key M&Q engineering, integration, and verification processes and activities established or modified since the previous phase, including updated:
    - Risk and risk mitigation strategies
    - Technical and manufacturing maturity
    - M&Q metrics to support key management focus areas
- Support the update of the Industrial Base Assessments for concepts included in the Analysis of Alternatives (conduct if not previously accomplished), for example:
  - Ensure identification of relevant sources including identification of unique manufacturing capabilities that are not readily accessible or available (e.g., capability is at maximum capacity, materials from a constrained source).
  - Determine the likelihood that a proposed materiel solution can be produced using existing manufacturing capabilities while meeting quality, production rate and cost requirements.
  - Ensure the concept requirements and capabilities assessments are updated to include:
    - Identification of all known gaps, risks, and potential sources for key processes, technologies, and components
    - Identification of all potential and future M&Q needs inclusive of design, development, production, operation, and sustainment, and eventual disposal
    - All technological developments, market trends, processes, environmental factors, and policies, etc., that could potentially impact M&Q of the preferred concepts
- Conduct manufacturing risk assessments to identify gaps and high-risk in manufacturing processes needed for the preferred concept(s):
  - Analyze identified advanced manufacturing capabilities to confirm requirements.
  - Analyze the gaps for potential manufacturing technology solutions to mitigate risks.
- Develop plans for identified gaps and high-risk manufacturing processes that require investments in ManTech or other manufacturing programs.
- Develop Initial Producibility Plans to support prototype design efforts with a focus on the realism, completeness and clarity of the planning accomplished by the contractor.
- Provide M&Q support to Technical Reviews to include:
  - Alternative Systems Review
  - Independent Technical Risk Assessment using DTRAM
  - Technology Readiness Assessment

APPENDIX D: M&Q SUPPORT OF TMRR SE ACTIVITIES

Manufacturing and Quality Tasks

- Provide M&Q analyses and support to SE functions by:
  - Conducting manufacturing feasibility assessments including cost and schedule.
  - Providing M&Q requirements mapped to the hardware and software functional baseline.
  - Providing traceability of M&Q requirements to the draft Capability Development Document.
  - Providing results of Industrial Base Assessments.
  - Conducting assessments of risks, issues, and opportunities and associated mitigation planning (e.g., industrial base, manufacturing technology gaps, quality).
  - Assessing Manufacturing and Technology Maturation Plans.
  - Providing M&Q inputs to the program Preliminary Design Review planning to include sustainment and life cycle planning.
  - Providing analysis of the contractor's SEMP.
  - Providing inputs to the detailed plan and schedule (e.g., Integrated Master Plan/Integrated Master Schedule).
  - Providing results of assessments of contractor(s) and supply chain capability to mature the proposed design(s).
  - Providing results of M&Q design producibility analyses:
    - Specialized manufacturing requirements (extreme complexity, multiple or very tight tolerances, precision assembly, handling of fragile components, etc.)
    - Key Characteristics
    - Diminishing Manufacturing Sources and Material Shortages
  - Conducting analyses of materials availability, maturity, and characterization.
  - Conducting assessments and providing estimates of process maturity and capability for manufacturing and production processes.
  - Assessing contractor initial plans for manufacturing workforce requirements, skills, capabilities, training, and certifications.
  - Providing analyses of the contractor's tooling and facilities strategies.
- Assess the contractor's Manufacturing Management System and plans.
  - Identify M&Q Management program requirements (e.g., SAE AS6500A, ISO 9000, SAE AS9100, IEEE 15288).
- Provide M&Q support to various Technical Reviews to include:
  - System Requirements Review

  - System Functional Review
  - Preliminary Design Review
  - Manufacturing Readiness Assessment
  - Independent Technical Risk Assessment using DTRAM
  - Technology Readiness Assessment
- Identify program office M&Q workforce billets and M&Q leadership positions.
- Provide M&Q requirements in support of:
  - Hazardous materials management
  - Environmental Safety and Occupational Health
  - Industrial facilities (factory floor) physical and cyber security (physical and cyber) for both hardware and software
  - Data management and software (including collection, analysis, testing, and methods of analysis, storage, retrieval of M&Q data)
  - Use of commercial off-the-shelf, government off-the-shelf, and government-furnished equipment
    - Modeling and simulation plans to include design, production, processes, costing, etc.
  - Corrosion Prevention such as parts selection to mitigate corrosion (see DoDI 5000.67)

Appendix E: Contracting for M&Q Activities

Manufacturing and Quality Tasks

- Ensure M&Q personnel are included in RFP writing and review teams.
- Analyze M&Q results from the AoA and system concepts trade-off as a basis for RFP requirements.
  - Use results from relevant M&Q feasibility and industrial base studies as additional data for RFP requirements.
- Specify appropriate requirements for Contract Data Requirements Lists items (CDRLs), Data Item Descriptions (DIDs), etc., to support M&Q processes and the requisite approval process.
  - Include requirements for reporting of manufacturing, quality, and supplier management metrics.
- Specify requirement for the contractor to describe best practices it will use for the Manufacturing Management System and Quality Management System (e.g., AS6500A, ISO 9001, AS9100).
  - Specify the requirements for the contractors to identify and describe their proposed specific processes, methods, and actions to address manufacturing feasibility, producibility, and M&Q risks associated with the proposed solutions.
- Analyze design for manufacturing:
  - Conduct producibility analyses.
  - Identify and manage key and critical characteristics in the Technical Data Package.
  - Implement Variability Reduction to reduce part-to-part variation of key and critical characteristics.
  - Identify and manage key and critical manufacturing processes.
  - Conduct Process Failure Modes and Effects Analysis (PFMEA) on critical manufacturing processes.
- Identify manufacturing risk:
  - Integrate manufacturing risk management activities into the program RIO management process.
  - Conduct and document manufacturing feasibility assessments for each competing design alternative under consideration.

  - Identify MRL targets and document manufacturing risks through the MRL assessments.
- Plan M&Q:
  - Establish and maintain a manufacturing plan that includes supply chain and material management, manufacturing technology development, manufacturing modeling and simulation, manufacturing costs, manufacturing system verification, manufacturing workforce, and tooling, test equipment, and facilities.
- Manage M&Q operations:
  - Production Scheduling and Control
  - Manufacturing Surveillance
  - Continuous Improvement
  - Process Control Plans
  - Process Capabilities
  - Production Process Verification
  - First Article Inspections and First Article Tests
  - Supplier Management and Quality
- Specify industry best practices for SE to be used (e.g., IEEE 15288, -1, -2) in the RFP
- Specify contractual M&Q requirements for:
  - Implementing a M&Q variability reduction program
  - Managing materials and subcontractors
  - Using COTS, GOTS, and NDIs

Appendix F: Recommended Contracting Approach for M&Q Activities

Recommended Manufacturing and Quality Assurance Request for Proposal Inputs

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Introduction

This document provides examples for Manufacturing and Quality Request for Proposal (RFP) inputs, including the Statement of Work (SOW), Sections L and M for competitive acquisitions, and Federal Acquisition Regulation (FAR)/Defense Federal Acquisition Regulation (DFAR) requirements.

The Core SOW requirements should be used on all Acquisition Category (ACAT) I programs. They may be used on other programs but should be tailored as needed to match the scope and needs of each program. For all of the requirements and other inputs in this guide, program team with input from manufacturing and quality specialist should conduct specific tailoring to ensure requirements are appropriate to meeting the unique needs and circumstances of each program.

If possible, developing contractual requirements should be a collaborative process between the government program office and the prime contractor.

Data Item Descriptions (DIDs):

- Prior to using a DID, ensure the most current version is being referenced.
- Use caution when calling out DIDs: Some requirements in the SOW do not have DIDs that directly correspond to them. In those cases, the closest, related DID is suggested. In other cases, some DIDs may be significantly outdated. They were provided to serve as a potential starting point and may need to be tailored. These will be discussed in each section, if applicable.

Manufacturing and Quality RFP Guide Summary Applicability Matrix

The following table is provided for general guidance only. Specific determinations of program and contract applicability should be made on a case-by-case basis.

All requirements are applicable to land, sea, air, and space-based systems. The only exception is for Aviation Critical Safety Items, which are applicable only to air and space systems.

Where checkmarks are shown, that requirement should be considered for inclusion in a SOW. Requirements may still be tailored to meet program needs.

Manufacturing and Quality Input to RFP

Manufacturing/Quality RFP Inputs	MSA	TMRR	EMD	P&D	O&S	Design Change	NDI/COTS
Core SOW Inputs							
Manufacturing Management Program		✓	✓	✓	✓	✓	
Quality Management System Requirements		✓	✓	✓	✓	✓	✓
Manufacturing Readiness Levels and Assessments (MRLs)	✓	✓	✓	✓	✓	✓	✓
Quality and Manufacturing Metrics		✓	✓	✓	✓	✓	✓
Counterfeit Parts Prevention		✓	✓	✓	✓	✓	✓
First Article Inspections/First Article Tests			✓	✓	✓	✓	✓
GIDEP Participation			✓	✓	✓	✓	
Production Readiness Review			✓	✓		✓	✓
Other SOW requirements to consider							
Aviation Critical Safety Items		✓	✓	✓	✓	✓	
Manufacturing Modeling and Simulation		✓	✓	✓	✓	✓	
Calibration			✓	✓	✓	✓	
Configuration Management		✓	✓	✓	✓	✓	
Risk Management		✓	✓	✓	✓	✓	
Parts, Materials, and Processes Control Program		✓	✓	✓	✓	✓	
Environmental Stress Screening		✓	✓	✓	✓	✓	
Key Characteristics and Variation Reduction		✓	✓	✓	✓	✓	
Advanced Product Quality Planning (APQP) & Production Part Approval Process (PPAP)			✓	✓	✓	✓	

1. Core SOW Inputs

1.1. Manufacturing Management Program

The contractor shall establish and maintain a Manufacturing Management Program that meets the requirements of SAE AS6500A and flow this requirement down to major/critical suppliers. The contractor shall document this program as part of their Manufacturing Plan. The contractor shall include its plans for Production Readiness Reviews (PRRs) and Manufacturing Readiness Level (MRL) Assessments in the Manufacturing Plan.

Suggested Data Item Description (DID):

- DI-MGMT-81889B, Manufacturing Plan

Guidance:

1. Major and critical suppliers are defined in AS6500A:

Critical Supplier: A contractor whose performance could seriously jeopardize the successful achievement of a program's cost, schedule, technical, or supportability requirements if not satisfactorily managed (e.g., a sole source supplier or supplier of critical parts, strategic and critical materials, or unique or special processes.)

Major Supplier: A supplier, distributor, vendor, or firm that furnishes supplies or services to or for the prime contractor whose total costs are a significant portion of the total purchased value for the program.

2. While the requirement for a manufacturing management system is applicable during the TMRR phase, it may be too early to require a deliverable manufacturing plan.

3. The DID for a Manufacturing Plan, DI-MGMT-81889B, was updated to be consistent with AS6500A.

1.2. Quality Management System Requirements

The contractor shall establish and maintain a Quality Management System (QMS) that meets the requirements of AS9100. The quality system shall ensure delivery of product that complies with all technical requirements. The Contractor shall document how the QMS is implemented with any unique requirements within the Quality Assurance Program Plan. Major/critical suppliers and suppliers with design authority shall be required to establish and maintain a Quality Management System (QMS) in accordance with requirements of AS9100. Suppliers without design authority shall be compliant to SAE AS9003, Inspection and Test Quality System, as a minimum.

Suggested DID:

- DI-QCIC-81794A, Quality Assurance Program Plan, contractor format acceptable

Guidance:

1. AS9100 is the preferred requirement for a Quality Management System for ACAT I programs in Aviation, Space, and Defense Organizations. The Federal Acquisition Regulation, Part 46, also recognizes overarching quality management system standards such as ISO 9001, ASQ/ANSI E4; ASME NQA-1, SAE AS9003, and ISO/TS 16949. If applying any of these other standards, ensure they are appropriate to the complexity and criticality of the product.

2. The most recent version of AS9100 (or equivalent standard) shall be specified.

3. While the requirement for a quality management system is applicable during the TMRR phase, it may be too early to require a deliverable quality plan.

1.3. Manufacturing Readiness Levels and Assessments (MRLs)

The contractor shall conduct assessments of manufacturing readiness in accordance with AS6500A and use the definitions, criteria, and processes defined in the Manufacturing Readiness Level Deskbook as a guide. Assessments will be conducted at the locations and frequencies specified in Appendix TBD. They will be led by the government program office at the prime contractor's facilities. The prime contractor shall lead the assessments at suppliers and include government participants. The selection of supplier assessments should be determined by the government and prime contractor using the MRL Deskbook, Section 4.3 as a guide. The contractor shall develop and implement Manufacturing Maturation Plans or their equivalent for criteria in which the MRL is lower than the target MRL. The contractor shall monitor and provide status at all program reviews for in-house and supplier MRLs and shall re-assess MRLs in areas for which design, process, source of supply, or facility location changes have occurred that could impact the MRL.

Suggested DIDs:

- DI-SESS-81974, Assessment of Manufacturing Risk and Readiness
- DI-ADMIN-81249B, Conference Agendas
- DI-ADMIN-81250B, Conference Minutes
- DI-MISC-80508B, Technical Report – Study/Services

Guidance:

1. Ensure DIDs are current and appropriate.

1.4. Quality and Manufacturing Metrics

In accordance with AS6500A, the contractor shall maintain a manufacturing surveillance process. The contractor shall submit quality and manufacturing metrics at the agreed upon frequency that report the contractor's and major/critical suppliers' performance and progress. Metrics shall include cost, schedule, and quality metrics to monitor the effectiveness of the contractor's manufacturing, quality, and supplier management programs. Metrics shall be presented at design, technical, and program management reviews. The contractor shall provide on-line access of these metrics to the government.

Suggested DIDs:

- DI-QCIC-82323, Manufacturing and Quality Assurance Status Report

Guidance:

1. Tailor the list of metrics in the DID to meet your specific program needs.

2. On-line access to contractor metrics may be desired, but not feasible. Discuss this with the prime contractor before including this as a requirement.

1.5. Counterfeit Parts Prevention

The contractor shall develop and implement a Counterfeit Parts Prevention (CPP) program in compliance with SAE AS5553 and AS6174 to prevent the inclusion of counterfeit parts or parts embedded with malicious logic into products intended for sale to the Government. These requirements shall be flowed to suppliers to ensure requirements are met. As part of CPP, the contractor shall make available to the government Certificates of Conformance (CoC) as well as supply chain traceability for all electronic part purchases.

Suggested DID:

- DI-MISC-81832, Counterfeit Prevention Plan

Guidance:

1. The RFP could request the elements of DI-MISC-81832 be included in the contractor's Program Protection Implementation Plan (PPIP), DI-ADMN-81306. Another good reference source is SAE-AS6081; Parts, Electronic, Fraudulent/Counterfeit: Avoidance, Detection, Mitigation, and Disposition.

2. The DID may be significantly out of date. Review for appropriateness prior to use.

1.6. First Article Inspections (FAI)/First Article Tests (FAT)

The contractor shall establish an FAI/FAT process and perform FAIs/FATs on new and modified product in accordance with AS9102, "Aerospace First Article Inspection Requirement." First article inspections shall be conducted on new products representative of the first production run and when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes). The contractor shall notify the Government program office, and designated representative(s) of first article inspection events to allow for participation. An FAI/FAT report shall be generated for each product as evidence that the engineering requirements have been met.

Suggested DIDs:

- DI-NDTI-81307A, First Article Qualification Test Plan and Procedures
- DI-NDTI-80809, Test/Inspection Report

Guidance:

1. The DIDs may be out of date or not related exactly to the SOW requirement. Review for appropriateness prior to use.

2. Applicability to O&S phase is based on new designs, suppliers, or other changes.

1.7. Government Industry Data Exchange Program (GIDEP) Participation

The contractor shall implement procedures and processes for their participation in GIDEP, including the submission of alerts/advisories to GIDEP when warranted. The processes and procedures shall describe how the contractor (a) receives alerts and advisories from GIDEP and other sources, (b) determines any impact to their product design and already manufactured hardware, (c) implements corrective action procedures when design and/or produced hardware are affected, and (d) includes supplier participation.

Suggested DID:

- DI-QCIC-80125B, Government Industry Data Exchange Program (GIDEP) Alert/Safe-Alert Report
- DI-QCIC-80126B, Government Industry Data Exchange Program (GIDEP) Alert Response

1.8. Production Readiness Review (PRR)

The contractor shall perform PRRs in support of the Milestone C/FRP Decision in accordance with IEEE 15288.2. These requirements shall be flowed to the contractor's major and critical suppliers.

Suggested DIDs:

- DI-ADMIN-81249B, Conference Agendas
- DI-ADMIN-81250B, Conference Minutes
- DI-MISC-80508B, Technical Report – Study/Services

Guidance:

1. The requirement for a PRR is a Core requirement for contracts that will result in a Milestone C or FRP Decision

2. Ensure deliverable plans, minutes, etc., are not already required in another section of the SOW for technical reviews and audits. Ensure DIDs are compatible with IEEE 15288.2 requirements, if imposed.

2. Other SOW Requirements to Consider

2.1. Aviation Critical Safety Items (CSIs)

The contractor shall identify, establish and manage aviation CSIs using the Joint Aeronautical Logistics Commanders (JALC) Critical Safety Item Management Handbook and SAE AS9017, “Control of Aviation Critical Safety Items,” as guides. The contractor shall develop a list of Critical Safety Items, their Key or Critical Characteristics (KCs/CCs), and associated Critical Manufacturing Processes. The contractor shall identify, measure and reduce variability of KCs/CCs and provide a formal method to manage and monitor all critical processes associated with CSIs. The contractor shall flow requirements to the lowest level of the supply chain.

Suggested DIDs:

- DI-SAFT-81932, Critical Safety Item (CSI) / Critical Application Item (CAI) List
- DI-SAFT-80970A, Critical Safety Item, Characteristic and Critical Defect Report

Guidance:

1. Requirements for CSI management should be balanced against the costs.

2. The DIDs may be out of date. Review for appropriateness prior to use.

2.2. Manufacturing Modeling and Simulation

The contractor shall analyze manufacturing processes using Modeling & Simulation (M&S) techniques to identify potential bottlenecks or constraints and confirm the achievability of planned cycle times, etc., and provide the government access to the model and data. The model should use commercially available simulation software used to evaluate scenarios and impacts of process variabilities, plant optimizations, production rate changes, capacity planning, and estimate required quantities of tooling, personnel, and inventory. The contractor shall update the production simulation model for facility modifications and other significant changes.

Suggested DID:

DI-MISC-80508B, Technical Report – Study/Services

Guidance:

1. While AS6500A requires the use of Modeling & Simulation, this additional requirement should be imposed if the government program office needs to obtain the contractor’s manufacturing model(s) as a deliverable item. This would enable the program office to conduct independent capacity and schedule assessments and to better identify risks independently from the contractor.

2. The DID may be out of date. Review for appropriateness prior to use.

2.3. Calibration

The contractor shall maintain a calibration system in accordance with ANSI/NCSL Z540.3. The calibration system shall control the accuracy of measuring and test equipment, and measurement standards, used to ensure that products delivered to the Government comply with all contract technical specifications. The calibration system shall prevent inaccuracy by ready detection of deficiencies and timely positive action for their correction. Contractors who operate and maintain calibration laboratories or subcontract to outside calibration laboratories shall ensure compliance with requirements of ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories.

2.4. Configuration Management

The contractor shall establish, document, and maintain a Configuration Management (CM) system for control of all configuration documentation, physical media, and physical parts representing or comprising the product, which includes all hardware, software, and firmware. The contractor's configuration management system shall consist of these elements:

a. Configuration management and planning.
b. Configuration identification.
c. Configuration change management.
d. Configuration status accounting.
e. Configuration audit.
f. Configuration management of digital data.

The contractor may use MIL-HDBK-61A as additional guidance for CM.

Guidance:

1. Applicability during TMRR should be determined on a case-by-case basis. Consult Configuration Management Subject Matter Experts for guidance.

2.5. Risk Management

The contractor shall establish and maintain a risk management program to continuously identify, analyze, mitigate, monitor, and report systems engineering process, product, technology, cost, schedule, and other program risks. Risk management process results shall be used for continual improvement and risk reduction. Program risks must be assessed and managed at the appropriate level. The contractor shall establish and maintain risk management programs consistent with the DoD Risk, Issue, and Opportunity Management Guide for Defense Acquisition Programs.

2.6. Parts, Materials, and Processes Control Program

The contractor shall establish, document, and maintain a Parts, Materials, and Processes Control Program (PMPCP) to ensure selection and use of parts, devices, and materials, including commercial and non-developmental items, meet specified performance, quality, reliability, safety, supportability, and configuration management requirements throughout the life cycle of the system. The program shall include provisions for mitigating the impact of counterfeit parts and parts obsolescence on product integrity.

The contractor shall flow down applicable PMPCP requirements to applicable lower-tier suppliers.

The contractor may use SD-22, MDA-QS-003-PMAP, MIL-STD-3018, or SMC Standard SMC-S-009 as additional guidance for control of Parts, Materials, and Processes.

Suggested DID:

- DI-MGMT-81949, DMSMS Implementation Plan

2.7. Environmental Stress Screening

The contractor shall implement an Environmental Stress Screening (ESS) program to surface defects by stressing the item without degrading its inherent reliability. Environmental stresses (i.e., thermal cycling and random vibration) may be applied in sequence or in combination, with the intent of stimulating hardware defects. The ESS program should not be used to simulate an operational environment. Results of ESS shall be used to continually improve manufacturing processes. The contractor may use MIL-HDBK-344 as additional guidance for planning, controlling, and measuring the effectiveness of the ESS program.

Guidance:

1. Imposing ESS requirements should be a joint determination by engineering, manufacturing, Quality, and Reliability functional experts. Consider using ESS on major and critical suppliers of electrical, electronic, electro-optical, electromechanical or electrochemical components in demonstration & validation, engineering & manufacturing development and production phases.

2.8. Key Characteristics and Variation Reduction

The contractor shall identify Key Characteristics and implement a Variation Reduction program in accordance with AS9103.

2.9. Advanced Product Quality Planning (APQP) & Production Part Approval Process (PPAP)

The contractor shall implement APQP and PPAP programs in accordance with AS9145.

3. Suggested Section L and M inputs

3.1. Instructions to Offerors Guidance (Section L):

1. Manufacturing Readiness Level Demonstration. The offeror's proposal shall identify those elements (systems, subsystems, suppliers, and/or processes) being assessed for manufacturing risk and their current Manufacturing Readiness Levels using the criteria and process identified in the Manufacturing Readiness Level Deskbook (Link http://www.dodmrl.com). The contractor shall describe the approach used to assess the MRLs. For any element that is assessed to be below the target MRL of 'X', the offeror shall identify the current MRL and the plan to achieve the target MRL.

(Note: DFARS Subpart 215.304 requires that the manufacturing readiness of offerors be considered during source selection for ACAT I programs.)

2. Manufacturing Plan. The offeror shall describe:

a. How their manufacturing management system meets the requirements of AS6500A.
b. The major assembly sequence chart and anticipated manufacturing process flow.
c. The manufacturing build schedule, including drawing release; tooling design, build, and proofing; key supplier deliveries; and fabrication, assembly, and delivery schedules.
d. Facility requirements and layouts.
e. The offeror's plans to provide the needed manpower, facilities, and equipment for expected delivery rates.

3. Quality Systems. The offeror shall describe how their quality system assures product quality; achieves stable, capable processes; prevents defects; and employs effective methods for conducting root cause analyses and implementation of corrective actions.

4. Supplier Management. The offeror shall describe their:

a. Approach to selecting and managing key suppliers.
b. Processes for integration of key supplier activities into the overall program plan to assure that supplier activities support the overall program performance.
c. Specific supplier risks to the program and plans for mitigating those risks.
d. Plan for preventing the intrusion of counterfeit parts in factory equipment and delivered products.

3.2. Evaluation Criteria Guidance (Section M):

1. Manufacturing Readiness Level Demonstration. The offeror's proposal will be evaluated on the maturity of their proposed manufacturing capability, the adequacy of their supporting documentation to justify this capability, and the adequacy of the offeror's process and plans to achieve the target MRL as described in the Manufacturing Readiness Level Deskbook.

This sub-factor is met when the offeror's proposal identifies the elements being assessed for manufacturing readiness and their current MRLs. As described in the proposal, the offeror's

MRL assessment process is consistent with the MRL Deskbook. For elements that are below the target MRL, the proposal describes an achievable plan to meet the target MRL.

2. Manufacturing Plan. This sub-factor evaluates the proposed methods, schedules, and resources for producing the required products. This sub-factor is met when the offeror's proposal:

a. Describes how their manufacturing management system meets the requirements of AS6500A.
b. Describes the major assembly sequence and manufacturing process flows.
c. Includes an integrated, achievable schedule incorporating design, tooling, supplier, fabrication, assembly, and delivery milestones.
d. Describes facility requirements and layouts.
e. Describes achievable plans to provide the needed manpower, facilities, and equipment for expected delivery rates.

3. Quality Systems. This sub-factor evaluates the offeror's planned quality assurance system. This sub-factor is met when the offeror's proposal describes policies and practices that will:

a. Assure product quality.
b. Achieve stable, capable processes.
c. Prevent defects.
d. Result in effective root cause analyses and corrective actions.

4. Supplier Management. This sub-factor evaluates the offeror's proposed supplier management program. This sub-factor is met when the offeror's proposal:

a. Describes how key suppliers are selected and managed.
b. Describes how supplier activities will be integrated into the overall program plan.
c. Lists specific supplier risks and achievable plans for mitigating those risks.
d. Describes effective plans for preventing the intrusion of counterfeit parts in factory equipment and delivered products.

4. FAR/DFARS Clauses

Although the Contracting Officer is ultimately responsible for applying the appropriate FAR and DFARS clauses to the contract, the following sections address topics relevant to the Manufacturing and Quality function. Manufacturing and Quality Subject Matter Experts should be familiar with the requirements of these sections and offer their support and recommendations to the Contracting Officer.

4.1. Higher Level Quality Requirements

FAR Part 46, "Quality Assurance," prescribes the use of various FAR clauses that address quality and inspection requirements, depending upon the nature of the contract. For critical or complex items, clause 52.246-11 must be included in the contract. This clause requires the identification of a specific higher-level contract quality standard. Section 46.202-4 lists examples, such as ISO 9001 and AS9100. The Manufacturing/Quality Subject Matter Expert should work with the Contracting Officer to ensure the appropriate clause is included in the contract and the appropriate higher-level quality requirement is included in 52.246-11.

4.2. Counterfeit Parts Prevention

DFARS 246.870-3 prescribes the use of clauses 252.246-7007, "Contractor Counterfeit Electronic Part Detection and Avoidance System," and 252.246-7008, "Sources of Electronic Parts" when procuring electronic parts or end items that contain electronic parts.

4.3. First Article Approvals

FAR Subpart 9.3 governs First Article Testing and Approval and describes when this testing is required. When it is required, Subpart 9.3 requires either FAR clause 52.209-3 for contractor testing or 52.209-4 for government testing.

4.4. Contract Administration Functions

FAR Subpart 42.302, "Contract Administration functions," lists the activities performed by the Contract Administration Office (typically DCMA.) Manufacturing & Quality-related functions include activities such as performing production surveillance and status reporting, conducting pre-award surveys, monitoring industrial labor relations, ensuring contractor compliance with contractual quality assurance requirements, and reviewing waivers and deviations.

4.5. Labor Relationships

FAR Part 22 describes the government's policies and practices regarding labor relations at contractor facilities. Subpart 22.103-5 prescribes the use of Clause 52.222-1 to require the contractor to notify the government of labor disputes.

4.6. Government Property

FAR Part 45 governs the use of government property. Subpart 45.107 prescribes the use of Clause 52.245-1 when government property is being used.

4.7. Records Retention

FAR Subpart 4.7 governs records retention. Many Manufacturing and Quality-related items, such as receiving and inspection reports, purchase orders, and quality control and inspection records must be retained for four years.

4.8. Contractor Debarment, Suspension, and Ineligibility

FAR Subpart 9.4 discusses reasons that contractors may not be allowed to obtain government contracts. This includes limitations on subcontracting (Subpart 9.405-2). Most contracts must include Clause 52.209-6 that protects the government's interests when subcontracting with debarred (or soon to be debarred) or suspended suppliers.

ACRONYMS

3D	Three-Dimensional
A_o	Operational Availability
AAF	Adaptive Acquisition Framework
AFRL	Air Force Research Laboratory
AM	Additive Manufacturing
AoA	Analysis of Alternatives
ASR	Alternative Systems Review
CARD	Cost Analysis Requirements Description
CBA	Capabilities-Based Assessment
CCTD	Concept Characterization and Technical Description
CDD	Capability Development Document
CoI	Community of Interest
CONOPS	Concept of Operations
COTS	Commercial Off-the-Shelf
Cpk	Process Capability
CSI	Critical Safety Item
CTE	Critical Technology Element
DARPA	Defense Advanced Research Projects Agency
DID	Data Item Description
DCMA	Defense Contact Management Agency
DTIC	Defense Technical Information Center
DE	Digital Engineering
DFARS	Defense Federal Acquisition Regulation Supplement
DFMA	Design for Manufacturing and Assembly
DFMEA	Design Failure Modes and Effects Analysis
DIU	Defense Innovation Unit
DMSMS	Diminishing Manufacturing Sources and Material Shortages
DoD	Department of Defense
DoDD	DoD Directive
DoDI	DoD Instruction
DP	Development Planning
DTRAM	Defense Technical Risk Assessment Methodology

EMD	Engineering and Manufacturing Development
ESOH	Environment, Safety, and Occupational Health
FFRDC	Federally Funded Research and Development Center
FMEA	Failure Modes and Effects Analysis
FOC	Full Operational Capability
FRP	Full-Rate Production
GAO	Government Accountability Office
GFE	Government Furnished Equipment
GOTS	Government off-the-shelf
IB	Industrial Base
IBA	Industrial Base Assessment or Industrial Base Analysis
ICA	Industrial Capability Assessment
ICD	Initial Capabilities Document
IMP/IMS	Integrated Master Plan/Integrated Master Schedule
IoT	Internet of Things
IIOT	Industrial Internet of Things
IOC	Initial Operational Capability
IPT	Integrated Product Team
ISO	International Organization for Standardization
IT	Information Technology
ITRA	Independent Technical Risk Assessment
JCIDS	Joint Capabilities Integration and Development System
KC	Key Characteristic
KPP	Key Performance Parameter
KSA	Key System Attribute
LCSP	Life Cycle Sustainment Plan
LRIP	Low-Rate Initial Production
M&S	Modeling and Simulation
M&Q	Manufacturing and Quality
ManTech	Manufacturing Technology
MBE	Model-Based Engineering
MBSE	Model-Based Systems Engineering
MCA	Major Capability Acquisition
MDA	Milestone Decision Authority

MDAP	Major Defense Acquisition Program
MDD	Materiel Development Decision
ME	Mission Engineering
MFA	Manufacturing Feasibility Assessment
MOE	Measure of Effectiveness
MOP	Measure of Performance
MOS	Measure of Suitability
MOSA	Modular Open Systems Approach
MTBF	Mean Time Between Repair
MTTR	Mean Time To Repair
MMP	Manufacturing Maturation Plan
MRA	Manufacturing Readiness Assessment
MRL	Manufacturing Readiness Level
MS A	Milestone A
MS B	Milestone B
MS C	Milestone C
MSA	Materiel Solution Analysis
MS&T	Manufacturing Science and Technology
MTA	Middle Tier of Acquisition
NDAA	National Defense Authorization Act
NEPA	National Environmental Policy Act
NIST	National Institute of Standards and Technology
NRL	Naval Research Laboratory
NTIB	National Technology and Industrial Base
O&S	Operations and Support
OT	Operational Technology
OT&E	Operational Test and Evaluation
PDR	Preliminary Design Review
PESHE	Programmatic Environmental, Safety, and Occupational Health Evaluation
PFMEA	Process Failure Modes and Effects Analysis
PM	Program Manager or Program Management
Ppk	Process Performance
PPP	Program Protection Plan
Pre-MDD	Pre-Materiel Development Decision

P&D	Production and Deployment
PRR	Production Readiness Review
QA	Quality Assurance
QMS	Quality Management System
R&D	Research and Development
RAM	Reliability, Availability and Maintainability
RCO	Rapid Capability Office
RCT	Requirements Correlation Table
RFP	Request for Proposal
RIO	Risk, Issue, and Opportunity
ROI	Return on Investment
SBIR	Small Business Innovation Research
SE	Systems Engineering
SEMP	Systems Engineering Management Plan
SEP	Systems Engineering Plan
SETR	Systems Engineering Technical Review
SFR	System Functional Review
SME	Subject Matter Expert
SRD	System Requirements Document
SRR	System Requirements Review
STTR	Small Business Technology Transfer
S&T	Science and Technology
TAPP	Technology Area Protection Plan
T&E	Test and Evaluation
TEMP	Test and Evaluation Master Plan
TMRR	Technology Maturation and Risk Reduction
TPM	Technical Performance Measure
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level
UCA	Urgent Capability Acquisition
WBS	Work Breakdown Structure

BIBLIOGRAPHY

Resources related to the guide are listed below and contain links to the referenced document. As many of these resources are revised frequently, readers are advised the documents may change or may be updated, replaced, or cancelled. Readers may need to conduct an Internet search to find the most recent version.

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