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MONTEREY, CALIFORNIA

THESIS

**SELECTION OF AN ALTERNATIVE PRODUCTION
PART APPROVAL PROCESS TO IMPROVE WEAPON
SYSTEMS PRODUCTION READINESS**

by

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September 2017

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**SELECTION OF AN ALTERNATIVE PRODUCTION PART APPROVAL
PROCESS TO IMPROVE WEAPON SYSTEMS PRODUCTION READINESS**

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ABSTRACT

This thesis conducted an examination related to Department of Defense (DOD) weapons systems production-approval practices. Current practices result in poor weapons systems production outcomes that reduce fleet readiness in DOD weapons systems acquisition. The Government Accountability Office (GAO) has reported concerns related to a lack of manufacturing knowledge at production start as causal to poor production outcomes. A comparison of DOD practices against non-DOD industrial production approval processes addressing causality and improvement opportunity provided new insight not found in acquisition research. An analysis of alternatives identified best practices to improve production capability and readiness. Key findings revealed that the automotive production approval process followed industry best practices that fully addressed problems identified by the GAO. Non-DOD industries used a more prescriptive Quality Management System (QMS) that enabled a more disciplined manufacturing development and demonstration of production capability prior to production commitment. Commercial surveys in the literature confirmed the benefits of the automotive prescriptive QMS. The more successful QMS approach can be applied to DOD acquisition practices reducing costs and improving fleet readiness.

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LIST OF ACRONYMS AND ABBREVIATIONS

AIAG	Automotive Industry Action Group
AOA	analysis of alternatives
APQP	advanced product quality planning
AS	aerospace standard
ASD(R&E)	Assistant Secretary of Defense for Research and Engineering
ASQ	American Society for Quality
AT&L	Acquisition, Technology, and Logistics
CFR	Code of Federal Regulations
COCOM	combatant commander
CONOPS	concept of operations
CPD	capabilities production document
Cpk	process capability index
DAG	<i>Defense Acquisition Guidebook</i>
DAS	Defense Acquisition System
DAU	Defense Acquisition University
DFMEA	Design Failure Modes and Effects Analysis
DOD	Department of Defense
DODAF	Department of Defense Architectural Framework
DON	Department of the Navy
DODR&E	Defense of Defense Research and Engineering
DOT	Department of Transportation
DSB	Defense Science Board
DT&E	Development Test and Evaluation
EMD	Engineering and Manufacturing Development
FAA	Federal Aviation Administration
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FRP	Full-Rate Production
GAO	Government Accountability Office
ICOM	input/controls/output/methods
INCOSE	International Council on Systems Engineering
ISO	International Standards Organization
JCIDS	Joint Capability Integration and Development System
LRIP	Low-Rate Initial Production

MANTECH	Manufacturing and Technology
MDA	Milestone Decision Authority
MOP	measure of performance
MRL	manufacturing readiness level
MSA	Measurement System Analysis
MS C	Milestone C
MTB_	mean-time-between-
NAVAIRINST	Naval Air Systems Command Instruction
NAVSEA	Naval Sea Systems Command
NDIA	National Defense Industrial Association
OEM	original equipment manufacturer
OMB	Office of Management and Budget
OSD	Office of the Secretary of Defense
PARL	Product Assurance Readiness Level
PCA	Physical Configuration Audit
PD	Production and Deployment
PDR	Preliminary Design Review
PFMEA	Process Failure Modes and Effects Analysis
PM	program manager
PPAP	production part approval process
Ppk	Process Performance Index
PRR	Production Readiness Review
PSW	Part Submission Warrant
QMS	Quality Management System
SAE	Society of Automotive Engineers
SE	systems engineering
SECNAV	Secretary of the Navy
SEDP	Systems Engineering Design Process
SETR	System Engineering Technical Review
SPC	Statistical Process Control
SYSCOM	system command
TA	technical authority
TMRR	Technology Maturation and Risk Reduction
TRL	technical readiness level
TS	technical specification
TTP	transition-to-production
UTC	United Technologies Corporation
USD	Under Secretary of Defense

EXECUTIVE SUMMARY

Poor production outcomes in Department of Defense (DOD) weapon systems acquisition are costly and adversely affect fleet readiness. National security demands a highly capable and ready fleet to respond to a complex global threat environment. One agency charged with oversight of weapon systems acquisition is the Government Accountability Office (GAO). Annual GAO reports on select weapon programs show a persistent and troubling observation revealing poor production outcomes in DOD acquisition (Dodaro 2013). Dodaro identified three reasons for DOD weapons systems poor production outcomes: 1) knowledge gaps in technology, 2) design instability and 3) manufacturing knowledge gaps. Only manufacturing knowledge gaps lacked DOD attention. Additional details reported by Dodaro concerning manufacturing causality included: 1) use of non-standard processes, 2) failure to identify critical manufacturing processes, and 3) failure to apply statistical process control.

The current state of DOD acquisition of weapon systems follows the defense acquisition system consisting of law, policy, instruction and other guidance documents. A current-state system operational view is shown in Figure 1. DOD guidance pays little attention to manufacturing during engineering and manufacturing development (EMD). The acquisition process related to manufacturing development relies upon a contractor's discretion. The DOD provides oversight by using risk-based assessments. Dodaro (2013) pointed out that non-DOD industries followed a standard and more knowledge-based approach, confirming production readiness. As a result, the GAO recommended that the DOD deploy a more disciplined approach to manufacturing development and production approval pointing to the success in non-DOD industries.

The GAO findings provided motivation for this research, which examined the DOD acquisition process against alternative, non-DOD, industrial production approval processes. This study fills a significant gap in the research with respect to weapon systems' poor production outcomes. An analysis of alternatives (AOA) comparing the production approval processes of DOD and non-DOD industries identified an opportunity for improvement over the current-state DOD production approval process. Key findings

revealed that the automotive approach followed industry best practices that fully addressed the GAO concerns of a lack of manufacturing knowledge at production start. The non-DOD industries used a more prescriptive set of quality standards that enabled a more disciplined development and demonstration of production capability prior to production commitment.

The AOA relied upon the identification of industry best practices. A set of high-level stakeholder needs were identified and related to a set of best-practice attributes for production approval processes. Characteristics found within the non-DOD production approval practices were not observed within the DOD processes, giving an indication why non-DOD industries enjoyed more successful production outcomes:

- Third-party compliance to quality system standards
- Prescriptive advanced quality practices
- Common quality requirements levied to the entire supply network
- Knowledge-based demonstration of production capability
- Certification warrant demonstrating production readiness
- Quality metrics assessing user satisfaction

Central to the findings in support of the study AOA was an assessment of two fundamental types of Quality Management Systems (QMS) that are used in industry. There were remarkable differences in production success depending on the type of QMS used by an organization. While all industrial sectors incorporated the International Standards Organization's (ISO) ISO-9000 family of commercial standards, only the automotive sector applied a more prescriptive quality standard. The automotive sector used the QS-9000 family of standards published by the Automotive Industry Action Group. The more prescriptive QMS provided structure for the disciplined development and demonstration leading to a certification of production capability. The QS-9000 requirements identified by an automotive original equipment manufacturer (OEM) were flowed to the entire automotive supply network. In contrast, the DOD sector was found to

apply the ISO-9000 type QMS lacking the prescriptive nature of the automotive standards.

There were three alternative industrial sectors examined in this study. All three of the non-DOD sectors studied used a certification process for production approval. Only the DOD did not use a certification process.

Commercial surveys confirmed the benefits of the prescriptive quality standards. The benefits reported were pivotal to this study's preferred solution selection. The adherence by suppliers to the automotive QMS showed improved quality and better production outcomes. Data obtained from the Department of Transportation supported the benefits in product reliability growth over time in the automotive sector. The assessment of alternate production approval processes provided compelling evidence in favor of the prescriptive automotive production approval process.

An example that could be followed by the DOD is the approach taken by the automotive industry when they deployed the implementation of a prescriptive QMS process. The automotive supply base used the services of the Automotive Industry Action Group (AIAG) to prepare to meet new quality requirements. The AIAG was a consortium formed by the American OEMs to communicate, train and enable the implementation of the QS-9000 set of prescriptive standards.

The automotive QS-9000 standard (later renamed ISO/TS-16949) is consistent with the DOD's requirement to use voluntary consensus standards and is identified in the Federal Acquisition Regulations (FAR §46.202-4). A new aerospace standard released by the Society of Automotive Engineers, AS-9145, describes an advanced product quality planning and production part approval process. This standard captures the intent of the automotive production approval process available for DOD application.

It is the recommendation of this research that the DOD adopt the automotive production approval approach. The automotive QMS success experience can be applied to the DOD to reduce acquisition costs and improve fleet readiness. A future ideal-state operational view is shown in Figure 2. This figure highlights the integration of best practices found in non-DOD organizations. The non-DOD industries have developed a

more disciplined manufacturing model with product and process verification required prior to the start of production.

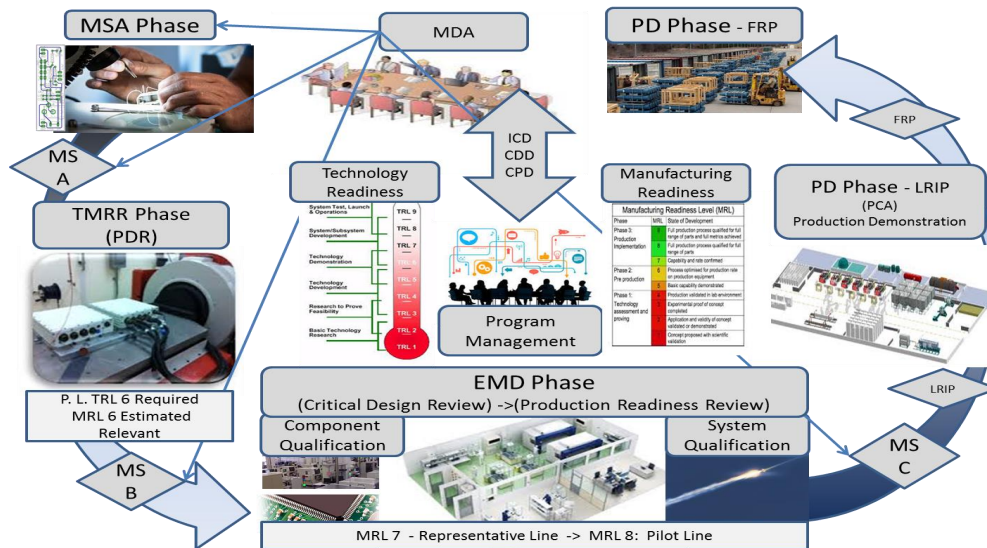


Figure 1. (OV-1) DOD Descriptive (Current) State

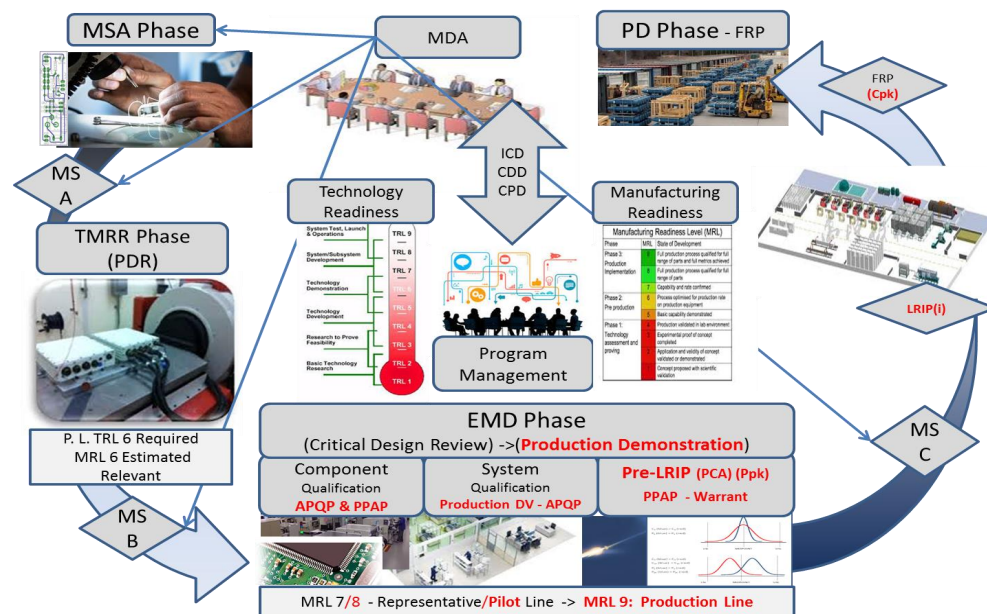


Figure 2. (OV-1) DOD Normative (Ideal) State

Reference

Dodaro, Gene L. 2013. *Assessments of Selected Weapon Programs*. (GAO-13-294SP). Washington, DC: General Accountability Office.

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I hope the findings of this research will contribute to acquisition improvement and provide a competitive advantage to the U.S. military. As I move forward in my career, know that I will express the benefits of continuous education at Naval Postgraduate School and share the impact it has on improving acquisition in support of our liberties.

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I. INTRODUCTION

A. OVERVIEW

National security requires an ability to develop military capability in a complex political and economic global environment. Given the nature of an ever-changing military threat coupled with challenging economic pressures, there is a clear need to ensure that best-value outcomes occur within the federal weapon systems acquisition process. However, this has not always been the case. Certain manufacturing readiness issues in particular have resulted in poor production outcomes. An analysis of alternatives (AOA) to investigate Department of Defense (DOD) and non-DOD production approval processes may identify an opportunity to improve production outcomes in defense acquisition. The Government Accountability Office (GAO) reporting has provided insight towards understanding specific deficiencies found in weapons system acquisition.

1. Poor Production Outcomes

Annual GAO reports on select weapon programs show a persistent and troubling observation revealing poor production outcomes in DOD acquisition (Dodaro 2013). Dodaro identified three reasons behind the poor production outcomes: 1) knowledge gaps in technology, 2) design-instability and 3) knowledge gaps in manufacturing. Of these three causes, only knowledge gaps in manufacturing lacked DOD attention. Additional details reported by Dodaro concerning manufacturing causality of poor production outcomes included: 1) use of non-standard processes, 2) failure to identify critical manufacturing processes and 3) failure to apply statistical process control prior to production start (2013, 170).

According to Dodaro, the DOD acquisition process lacked a standard and systematic knowledge-based transition-to-production (TTP) in support of a production decision occurring at Milestone C (MS C). Key findings in the 2013 GAO report revealed that the acquisition of weapon systems often fail to deliver reliable and mature technologies into the Production and Deployment (PD) phase from the Engineering and Manufacturing Development (EMD) phase. The consequence of this acquisition approach

has been poor production outcomes after MS C. Such outcomes adversely affect cost, schedule, performance and related military readiness in the field of operations. A look at the manufacturing causality invites further review (Figure 1).

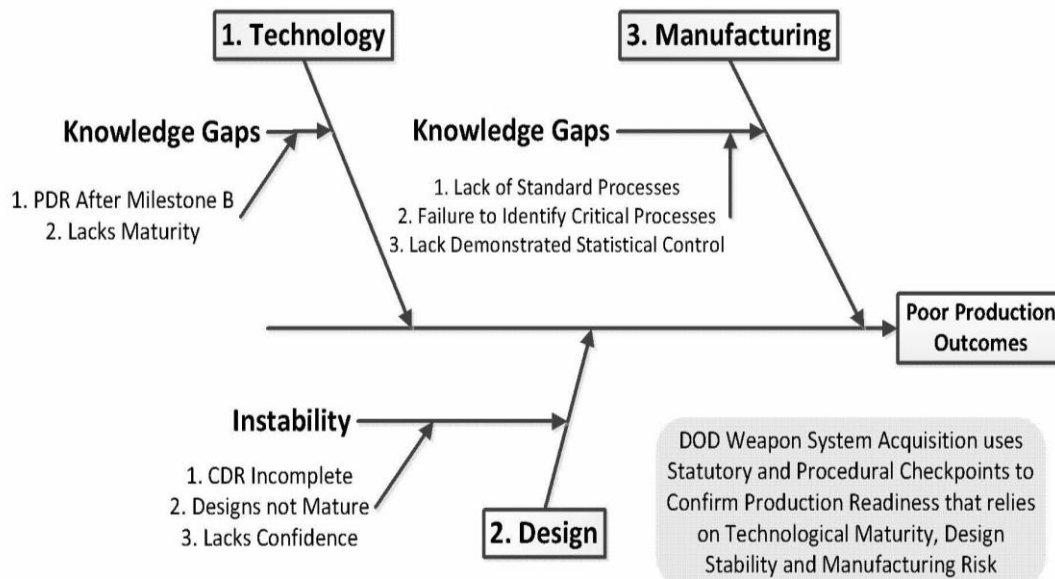


Figure 1. GAO's Three Factors Resulting in Poor Production Outcomes.
Adapted from Dodaro (2013).

2. GAO Questions the DOD Production Approval Process

The GAO found prime contractors in DOD acquisition lacked a standard approach to achieve a stable and mature production process at the MS C decision point. In 2002, the GAO had reported their observation that there was a lack of a systematic and standard knowledge-based production readiness approach in DOD acquisition (Schinasi 2002). This lack of discipline was not characteristic of other industries the GAO reviewed. These findings led the GAO to recommend that the DOD look to other industries in hopes of finding improvement opportunity.

The DOD acknowledged the GAO's finding that there were no standard methods followed related to manufacturing development and production capability verification prior to MS C. This finding establishes why many programs fail to reach performance goals in production. One characteristic found in non-DOD manufacturing acquisition

processes was the observation of a more disciplined product development and production demonstration process (Schwartz 2013, 27) and (USD[AT&L] 2015). However, there were no significant policy actions taken by the DOD concerning the GAO's findings towards a more knowledge-based manufacturing development approach.

3. DOD Acquisition and Production Approval

The DOD's requirements related to manufacturing development are found in the Joint Capabilities Integration and Development System (JCIDS) reference manual. The JCIDS describes requirements on how a program development is conducted and outlines the requirements for a life cycle phased acquisition process. With respect to manufacturing development, the JCIDS requires a risk-based assessment of a program's manufacturing maturity but does not require an actual production line demonstration. According to the JCIDS instruction, a program manager (PM) will report manufacturing risk to the Milestone Decision Authority (MDA) through the capabilities production document (CPD) at MS C. However, if the risk-based assessment does not rise to a significant level of concern a PM is not required to report on manufacturing risk (JCS 2015b).

In contrast, non-DOD industry practices use a disciplined knowledge-based production approval process that demonstrates a manufacturing capability based on product from an actual production line to report product and process capability running at production rates. As such, it is easy to see a stark difference contrasting the DOD's risk assessment approach that does not rely upon an actual production line experience to assess production capability to show readiness to produce (USD[AT&L] 2015, 26–29, 84). This is why the GAO made recommendations to consider a knowledge-based production capability demonstration approach to determine production manufacturing readiness at the end of the EMD phase (Dodaro 2013).

Defense acquisition using the JCIDS calls out a manufacturing risk assessment tool to evaluate a product's production environment to measure manufacturing readiness level (MRL). The establishment and maintenance of the MRL tool is directed by the Office of the Secretary of Defense (OSD) within the OSD's Department of Research &

Engineering's DOD Manufacturing Technology (MANTECH) (OSD 2012). The MRL procedure guides an evaluation that interrogates a contractor's production environment's maturity. Manufacturing assessments in this approach fail to identify actual production line performance capability. Therefore, the MRL risk assessment provides little insight into critical manufacturing data to support production decisions.

Additional guidance within the defense acquisition system (DAS) related to manufacturing development and approval processes are found in the DOD Instruction (DODI) DODI-5000.02 (USD[AT&L] 2015). The DODI and JCIDS guidance falls far short of the discipline of non-DOD organizations where there is a requirement to validate an actual production capability. Of concern is the absence of manufacturing process capability data in MRL risk assessment reporting. A manufacturing readiness assessment does not rely upon a demonstration of production capability. Contractor fabricated product built in support of EMD only requires a contractor assert that a production environment is "production relevant." This MRL assessment of relevant does not mean that the early production or fabrication of product for Low-Rate Initial Production (LRIP) or Full Rate Production (FRP) is fully defined and validated.

The DOD acquisition guidance, described in the *Defense Acquisition Guidebook* (DAG) on systems engineering (SE), stated that use of the OSD *MRL Guidebook* is but "one way" to assess manufacturing risk (USD[AT&L] 2013, chapter 4). The DAG did not go on to discuss any other ways of identifying manufacturing risk or point to any other best practices to inform how a program should assess production readiness. In DOD acquisition, the decision to go into a production contract allows a contractor to continue manufacturing development in PD with inherent manufacturing risk. Even if EMD fabricated items are successfully qualified to functional requirements little is known about an intended production line definition or its degree of manufacturing robustness in sustaining as-built product requirements.

The JCIDS DODI 5000.02 and DAG confirm this minimalist approach to production definition and reporting of manufacturing risk (USD[AT&L] 2013). The DOD will conduct its last technical review in EMD as a final assessment of production readiness before PD. The production readiness review (PRR) is an assessment that guides

this final inquiry based upon a checklist to measure program and manufacturing risk. This PRR is part of a program's reporting to the MDA at MS C to gain approval for a production go-ahead. Early production will start with manufacturing development incomplete. During PD is when a contractor finally completes development of the manufacturing environment for production where the government acquisition process attempts to confirm production capability. The post-production assessment is a technical review called a Physical Configuration Audit (PCA).

The PCA is a standard DOD practice that occurs after LRIP and prior to Full-Rate Production (FRP). The PCA event is used to legally define the saleable production baseline of the configured item for on-going production. According to the JCIDS, the PCA serves as a graduation event to enter FRP (USD[AT&L] 2015, 29).

4. The Study Production Approval Process AOA

The AOA conducted in this study relied upon the identification of industry best practices related to manufacturing development and process verification. A set of high-level stakeholder needs were identified and related to a set of best practice attributes as used in disciplined production approval processes. Certain production approval process characteristics found within non-DOD production approval practices were not observed within the DOD processes. The additional production approval practices found in non-DOD industries provided an indication why non-DOD industries enjoyed more successful production outcomes. Some of these differences in non-DOD organizations included:

- Third-party compliance to quality system standards
- Prescriptive advanced quality practices
- Common quality requirements levied to the entire supply network
- Knowledge-based demonstration of production capability
- Certification warrant demonstrating production readiness
- Quality metrics used to assess user satisfaction

B. CONTEXT OF THE PROBLEM

The problem space of poor production outcomes related to manufacturing causality can be defined through the audit reports of the GAO, a review of the literature related to weapons system acquisition, DOD policy, DOD workforce capability and DOD actions that try to improve production outcomes. One observation within the DOD acquisition policy shows favoritism toward product performance development and verification and fails to provide the necessary guidance concerning knowledge-based manufacturing readiness. This is particularly significant at MS C where manufacturing readiness is assessed but production capability is not assessed. This failure to require a demonstrated production capability prior to MS C coupled with a contractor's lack of discipline to develop key manufacturing knowledge during EMD transfers manufacturing risk into LRIP/FRP.

One of the contributing factors related to poor production outcomes is DOD workforce competency. The lack of a broadly skilled workforce hinders the ability to develop and assess production maturity and capability. This occurs in DOD contracting and oversight because manufacturing expertise is not fully staffed or understood within DOD SE community. As such, the DOD lacks a standard and systematic method in developing manufacturing maturation and has failed to require verified process stability and control (Sullivan 2008). The DOD's lopsided focus on product over process performance can also be seen by a review of the many product performance related technical reviews in acquisition (see Figure 2) (USD[AT&L] 2013). Conversely, non-DOD organizations are staffed to develop and manage their manufacturing development that requires a certification of readiness prior to entering production.

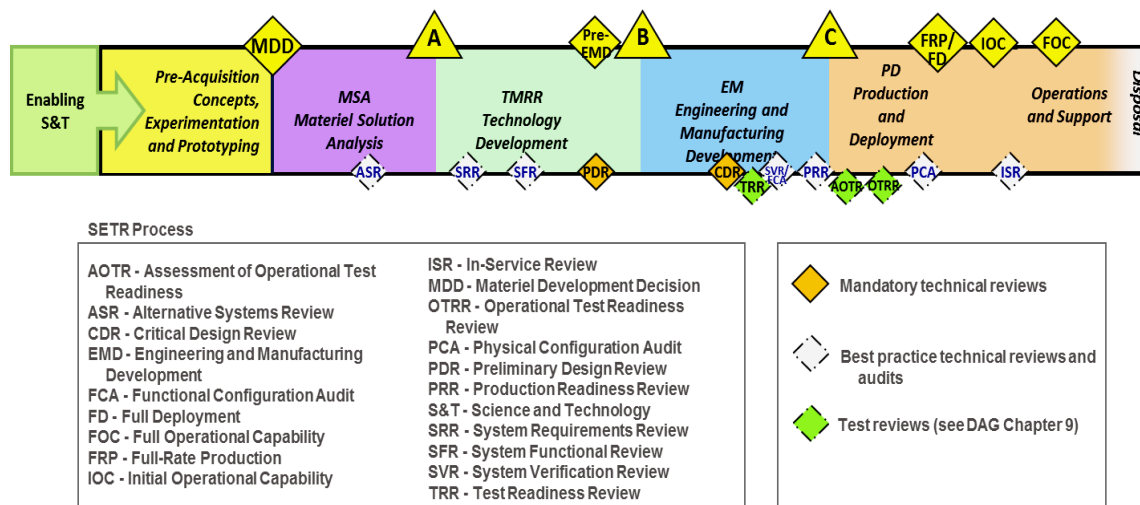


Figure 2. Life Cycle Development. Adapted from (USD[AT&L] 2013).

The weakness related to a lack of a skilled professional manufacturing oversight can be traced to a memo (Perry 1994) that eliminated most prescriptive military standards (see “Appendix A. Perry Memo”). In 1994, the DOD moved to a Performance Based Acquisition (PBA) practice setting in motion the use voluntary consensus standards. When the PBA practice commenced, the DOD divested itself of the skills to assess integration and manufacturing development. Recently, the DOD recognized this loss of know-how and initiated a hiring of 20,000 acquisition professionals by the end of fiscal year 2015 (Erwin 2010). In National Defense Industrial Association (NDIA)’s Sandra Erwin’s blog, there was a posting concerning the 2009 Weapon Systems Acquisition Reform Act (WSARA) Progress Report. Here, Erwin chronicled GAO Director Sullivan’s response to a question from the House Oversight and Government Reform chairman, Rep. John Tierney, D-Mass:

The law alone won’t result in substantial change unless there are leaders within the department enforcing it, he [Tierney] said. “It will take considerable and sustained leadership and effort to change the incentives and inertia that reinforce this status quo. And I think the Congress has a role in that as well.”

Sullivan then posed an obvious and uncomfortable question: “One has to ask why extraordinary actions are needed to force practices that should occur normally.” Realistic cost estimates and assessments of the maturity

of technology should have been part of the standard modus operandi and not required major legislation, he noted.

Much of the blame for the shocking cost overruns and performance of major programs has been laid on the shortage of contracting personnel and technical experts at the Defense Department. WSARA reinforces the issue and calls for the Pentagon to beef up its in-house skills. Defense Secretary Gates last year announced plans to hire 20,000 acquisition professionals (ID 134).

This communication captured by Erwin appears to identify one concern at the root of the manufacturing knowledge gap reported by the GAO: manufacturing expertise within the government acquisition process lacks experienced personnel resources. If fortified with manufacturing expertise, then there would likely be improved oversight and ability to assess a contractor's manufacturing maturity accurately. In the short term, the DOD had developed a set of expert questions in the MRL and PRR checklists and communicated them to the combatant commanders (COCOMs) and PMs.

The release of the DOD MRL guidebook indicated that the DOD was not satisfied with its current state of problems, in part, due to manufacturing issues (OSD 2012). The MRL process came about the same time as the WSARA hiring initiative in hopes that the assessment tool would improve manufacturing readiness and better document manufacturing risk. Unfortunately, the GAO findings since 2010 still discuss the problem of poor production outcomes from manufacturing workforce deficiencies. The manufacturing knowledge-gap problem is then related to the acquisition process and workforce expertise.

The DOD also took steps to augment manufacturing expertise by the development of centers of manufacturing excellence. One center setup is the Department of Defense Research and Engineering (DODR&E). In support of the MRL, the DODR&E discussed the need to apply the MRL process in a development program (Dunn 2010). This recommendation was implemented by the DOD and is now specified as a required practice in the 2015 JCIDS.

Another, but long-standing, center of excellence developed was the NDIA as a partnership between the United States government and the defense industry. In a 2010

report on Air-Launched Tactical Weapons, the NDIA called for a certification of a product's production readiness (NDIA Gulf Coast Chapter 2010, 19). It would be a novel approach for the DOD to use a knowledge-based certification for manufacturing readiness as recommendation by the NDIA.

The DOD acquisition guidance initiative to monitor how a production line develops and matures using the MRL risk assessment process showed increased attention given to the manufacturing competency yet these actions only served to continue the DOD's risk-based approach to manufacturing readiness. The DOD's lack of response to the NDIA and GAO recommendations related to manufacturing improvement opportunity ignored the value placed on process verification used by non-DOD industries. The applications of best practices are the disciplined focus in a knowledge-based manufacturing development. Failing to identify and improve production processes were missed opportunities for DOD acquisition to reduce problems related to production risk. Brock and Walker pointed out that product knowledge is obtained late in DOD acquisition as compared to organizations that follow best practices in non-DOD organizations (see Figure 3) (Brock 2003; Walker 2005).

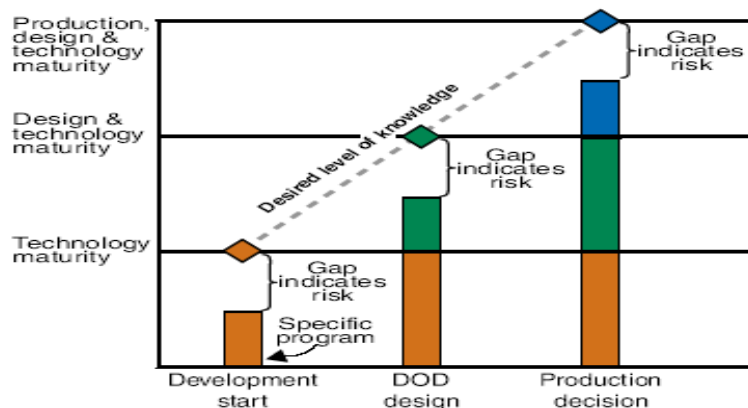


Figure 3. Risk Vice Production Knowledge. Adapted from Walker (2005).

1. Problem Space Source Data Robustness

Confidence in background information related to the problem space comes from examining the reliability of the reports used to describe DOD acquisition deficiencies. One question to answer was the degree of integrity of the findings as published by the GAO. To answer this, the GAO assured integrity based on long-standing ethics they apply to their investigative reporting (see “Appendix B”). An additional strength in the quality of the information dealing with the problem space definition was found in the GAO’s reporting and the DOD responses to GAO recommendations. In one responsive letter, the DOD took some exception to the GAO’s findings but indicated that the DOD would conduct their own report on the issues discussed. See Appendix G - DOD Memo to GAO. At times, the GAO reports discussed how the DOD implemented or planned to implement various actions to satisfy the GAO recommendations. The GAO would provide a status in the following year’s report if the DOD acted upon any recommendation. Therefore, these periodic reports provided a continuum of objective observations on issues identified through the GAO reporting.

Consider the problem space represented by manufacturing deficiencies resulting from a lack of manufacturing requirements definition. Since manufacturing development has not had much attention in DOD acquisition, there is an omission of process capability requirements definition. Non-DOD manufacturing development follows an approach that prevents poor production outcomes by addressing manufacturing requirements early.

Objective manufacturing and quality requirements in non-DOD organizations are typically defined through customer or regulatory guidance and is explicitly expressed in the execution of an organization’s quality management system (QMS). Adhering to the practices outlined in a QMS helps define a contractor’s business practices related to manufacturing and quality policy. DOD acquisition practices have customarily invoked the International Standards Organizations ISO-9000 or similar AS-9000 family of quality standards that do not require customer or regulatory requirements to be defined. The automotive supply base followed specific customer requirements given in the QS-9000 QMS published by the Automotive Industry Action Group (AIAG). The AIAG has been a key enabler supporting the deployment of the automotive QMS. The AIAG served the

automotive supply network as a consortium formed by the American original equipment manufacturers to communicate, train and enable the implementation of the QS-9000 set of prescriptive standards.

The ISO technical specification (TS) ISO/TS-16949 (successor to the original QS-9000 QMS) is related to the automotive industry. It is interesting that the CFR references these QMS; however, the DOD has not taken an active role to invoke these more disciplined QMS (Appendix H - CFR, Title 48, 46.202.4) and (Walker 2006). In addition, the National Institute of Standards reported on the problem space with its recommendation to use the automotive QMS (Breitenberg 1999). While these references indicate that DOD could elect to include production requirements characteristic of the automotive prescriptive standards it is not followed. The DOD tends to shy away from how-to requirements based upon acquisition practices since the Perry memo giving attention to product performance rather than manufacturing development and process capability verification.

Even with several initiatives in workforce development, the DOD does not seem to address the root cause of poor production results related to manufacturing. The DOD had not required contractors to follow a disciplined development of manufacturing requirements likely due to the absence of an accepted prescriptive standard. Assessments of risk to determine the state of readiness to produce did not lend itself to process improvement for manufacturing capability in defense acquisition. Even contractual incentive type contracts have been problematic to improve the state of contracting or in validation of manufacturing development and capability knowledge. According to one review of incentive based contracts there has been an \$8-billion-dollar giveaway not achieving results (Calvaresi-Barr 2005).

1. Supporting Data Concerning Poor Production Outcomes

Given that there is a lack of manufacturing knowledge at production decision in the DOD acquisition process, what impact is there on fleet readiness? This question can be answered by the examination of several reports and problem related datasets concerning field performance that gives attention to the size of the problem.

First, the problem space of poor production related to manufacturing and quality are chronicled in a GAO report to Congress that reviewed 11 major weapon systems (Figure 4) (Sullivan 2008). The Senate also looked for answers by asking the GAO to consider a review of best practices in 2002 and to look for alternatives to improve (Schinasi 2002). The highlights section of the GAO report by Sullivan (2008) spoke to these type results with industries outside of the DOD stating: “In contrast, leading commercial companies GAO contacted use more disciplined systems engineering, manufacturing, and supplier quality practices.” In summary, the most meaningful way to look at the DOD product approval process problem space is by examining the GAO findings within their basis for improvement recommendations. Interestingly, the GAO recommendations did not provide a clear path for improvement.

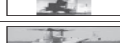
System		Source of quality problem			Impact of quality problem	
		Systems engineering	Manufacturing	Supplier quality	Cost (dollars in millions)	Schedule
Advanced SEAL Delivery System ^a		✓		✓	\$87	Program halted
Advanced Threat Infrared Countermeasure/ Common Missile Warning System		✓	✓		\$117	5-year delay
Expeditionary Fighting Vehicle		✓			\$750	4-year extension to system development
F-22A		✓	✓	✓	\$400	No schedule impact to program
Global Hawk ^a		✓		✓	\$239	4-month production slip for sensor suite
Joint Air-to-Surface Standoff Missile			✓	✓	\$39	Program deferred
LPD 17 Amphibious Transport Dock ^a		✓	✓	✓	\$846	3-year delay
MH-60s Fleet Combat Support Helicopter			✓		No cost impact to program	6-month production slip
Patriot Advanced Capability-3		✓	✓	✓	\$26	6-month delay
V-22 Joint Services Advanced Vertical Lift Aircraft		✓			\$165	Flight operations halted for 17-months
Wideband Global SATCOM			✓	✓	\$10	18-month delay for initial operating capability

Figure 4. Weapon System Quality Problems. Source: Sullivan (2008).

Second, the Department of the Navy (DON) Red Stripe data that tracks failures that ground the fleet and data provided by the Defense Science Board (DSB) concerning ARMY programs failing to meet reliability targets measures the problem scale (DSB 2008).

The Red Stripe data set presents a proportional contribution of failure causes from the individual failure events that grounded aircraft. See Figure 5. The data segregates causal factors into five categories on a percentage basis: manufacturing/quality (33.6%), age/fatigue (27.3%), design (12.5%), maintenance (22.4%) and those not yet determined (4.2%).

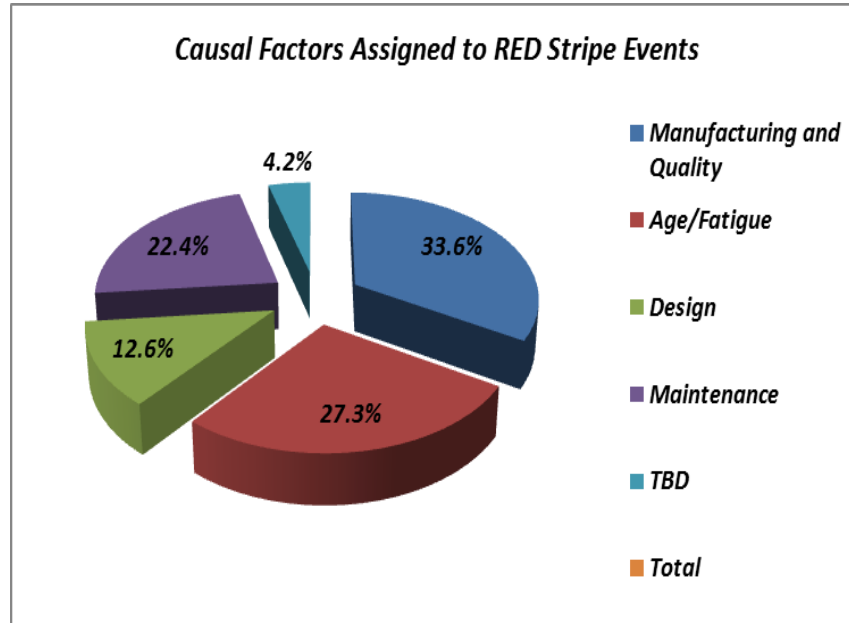


Figure 5. Causal Factors Assigned to Red Stripe Events.

ARMY development program results provided by the DSB Taskforce on Development Test and Evaluation (DT&E) “Final Report of DSB Taskforce on DT&E” observed that almost two thirds of the programs monitored fell below planned reliability performance. Reliability is expressed as an average such as, mean-time-between_ (MTB_). Here, MTB_ is a measure such as the mean time between - operational failures expressed in usage units. See Figure 6. These are alarming statistics.

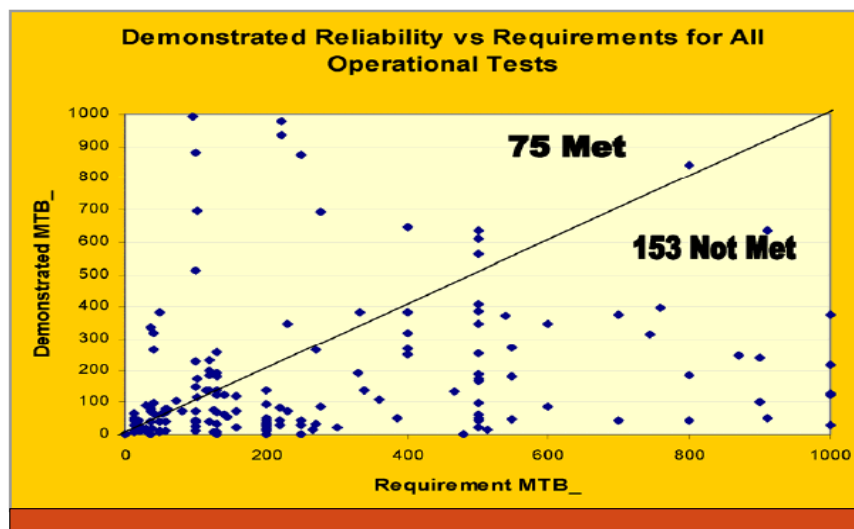


Figure 6. Demonstrated Reliability versus Requirements. Source: DSB (2008).

2. Risk and Knowledge-Based Decision Models

Government Accountability Office reporting has characterized poor production outcomes due to an acquisition approach that focuses on risk over knowledge. This bounds the GAO argument as they make assertions about the DOD's need for improvement. Since the GAO looked at better performing production outcomes in non-DOD industries it became important to focus on manufacturing and production approval processes in those industries. The primary conclusion of the GAO involved the need for a more knowledge-based decision process.

a. *Contrasting Risk and Knowledge-Based Decisions*

When the GAO discusses a knowledge-based approach to characterize the success of non-DOD producers, it is useful to review what they meant by knowledge-based decisions (Figure 7). Between the years 1996 and 2013 the GAO developed its assessment framework consistent with its former findings. Later reporting by the GAO added specific criteria to assess DOD programs against certain non-DOD best practices.

Knowledge Point Observations	
1.	Many of the programs that began in the last 5 years had mature technologies and held a preliminary design review prior to the start of development (knowledge point 1), providing a better foundation to avoid future cost and schedule problems.
2.	Less than one-third of the programs that provided data on design drawings released actually reported having a stable design at their critical design review (knowledge point 2), and the use of other knowledge-based practices to ensure design stability at this critical juncture varied.
3.	Many of the programs we assessed have taken or plan to take steps to capture critical manufacturing knowledge prior to the start of production (knowledge point 3), although the methods used varied.

Figure 7. Knowledge Point Observations. Source: Dodaro (2013).

The GAO reported that non-DOD programs followed a disciplined production development and process demonstration practice that achieved better product reliability. The GAO indicated that non-DOD best practices required a demonstration of production capability using statistical control prior to production commitment. The GAO defined three knowledge points in their weapons program assessment framework. Knowledge point three was concerned with manufacturing (Dodaro 2014) (Figure 8).

Knowledge Point 3: Production meets cost, schedule, and quality targets. Decision to produce first units for customer
Demonstrate manufacturing processes
Build and test production-representative prototypes to demonstrate product in intended environment
Test production-representative prototypes to achieve reliability goal
Collect statistical process control data
Demonstrate that critical processes are capable and in statistical control
Conduct independent cost estimate
Conduct independent program assessment
Conduct major milestone decision review to begin production

Figure 8. Knowledge Point 3 Criteria. Source: Dodaro (2014).

The Acquisition Community Connection website managed by the Defense Acquisition University (DAU) provided a definition of a knowledge-based acquisition approach (DAU 2015a):

Knowledge-Based acquisition is a management approach which requires adequate knowledge at critical junctures (i.e., knowledge points)

throughout the acquisition process to make informed decisions. DOD Directive 5000.1 calls for sufficient knowledge to reduce the risk associated with program initiation, system demonstration, and full-rate production. DOD Instruction 5000.2 provides a partial listing of the types of knowledge, based on demonstrated accomplishments that enable accurate assessments of technology and design maturity and production readiness (ID 24660).

and

E1.14. Knowledge-Based acquisition. PMs [Program Managers] shall provide knowledge about key aspects of a system at key points in the acquisition process. PMs shall reduce technology risk, demonstrate technologies in a relevant environment, and identify technology alternatives, prior to program initiation. They shall reduce integration risk and demonstrate product design prior to the design readiness review. They shall reduce manufacturing risk and demonstrate producibility prior to full-rate production (ID 24660).

A knowledge-based approach related to manufacturing readiness assessment in the DOD is deferred to full-rate production. There is a risk versus knowledge struggle that favors risk by allowing a broad flexibility for PMs to satisfy programmatic manufacturing risk reporting at MS C in DOD acquisition. The current direction towards a DOD production decision uses knowledge points to assess readiness but still largely operates as if it is a risk-based decision process contrary to the updated policy and DAG guidance. With a lack of manufacturing process definition and a lack of data from process controls on early fabrication of product in EMD it is unlikely that decision makers will have assurances for successful achievement of production rates and a desired production capability in PD. This contributes to the weakness observed by the GAO in the DOD production approval process. The May 2015 *MRA Guidebook* (version 2.3) states that

the final stage of EMD is producing products that look and operate like they are production units from LRIP. These units need to be built on a pilot production line to adequately demonstrate the ability to migrate from EMD to LRIP. Without this realism it would be very difficult to obtain confidence that the production process will be able to meet cost, schedule, and performance (e.g., quality) requirements for production (15).

b. GAO Assesses Contractor Improvement Effort

The GAO (2013) reported that contractors did improve their manufacturing readiness by demonstrating manufacturing product knowledge. However, a scorecard review, as published by the GAO, revealed there was a lack of process control and demonstration. The GAO use of “scorecards” failed to show that contractors complied with the GAO’s former recommendations for a statistical demonstration of production processes and controls across the programs the GAO reviewed. However, the GAO scorecards did not fully support Dodaro’s assessment (2013) with the findings that things were improving over prior years with respect to production maturity knowledge: “Many of the programs are capturing critical manufacturing knowledge prior to production, but their methods vary.”

Fact checking the scorecards did not show evidence of the GAO’s assertion that programs improved over the prior years. What was observed is that the scorecards refute these claims—an example from AIM 9X Block II’s assessment (2013). The repudiation of “scorecard” success found that the data collected indicated that a contractor would be scored favorably by the GAO when audited but the contractor only planned to control the process at some future time (Figure 9).

Attainment of Product Knowledge	
As of January 2013	
Resources and requirements match	
• Demonstrate all critical technologies in a relevant environment	●
• Demonstrate all critical technologies in a realistic environment	●
• Complete preliminary design review	●
Product design is stable	
• Release at least 90 percent of design drawings	●
• Test a system-level integrated prototype	
Manufacturing processes are mature	
• Demonstrate critical processes are in control	○
• Demonstrate critical processes on a pilot production line	●
• Test a production-representative prototype	●
● Knowledge attained	■ Information not available
○ Knowledge not attained	Not applicable

Figure 9. Product Knowledge Score Card. Source: Dodaro (2013).

3. Problem Statement

National defense is affected by any reduction in fleet readiness caused by poor production outcomes. The lack of a production capability demonstration at production start is one of those detractors. The DOD's inability to address manufacturing capability issues reported by the GAO stems from policy inadequacies and a lack of a standard means to assure there is a readiness to produce.

4. Research Questions

The following research questions helped develop the study problem statement. A listing of specific research questions to be answered by this study follows:

- How is production readiness defined in DOD acquisition?
- How does the DOD manage manufacturing maturity and risk prior to MS C?
- Why is there a lack of production readiness evidence for a decision at MS C?
- Are non-DOD production approval processes more successful than comparable DOD processes and in what ways?
- How can an alternative production approval process improve success in the DOD acquisition environment?

C. PROJECT OBJECTIVES

The deficiencies in DOD production outcomes, identified by the GAO's Dodaro, provided a motivation for this research that intends to identify a more successful TTP not found in the current state of the DOD production approval process (2013). Coming at the problem space from many directions helped identify how to translate that discussion into a set of statements representing the study purpose:

- Identify specific deficiencies and causal factors for poor production outcomes in DOD acquisition practices

- Provide a SE approach to study alternative industry production approval processes as compared to DOD production approval process
- Develop assessment criteria for an analysis of alternatives for a production approval process
- Conduct analysis with discriminating measures of performance attributes
- Report to stakeholders the findings and recommendations from this study
- Identify potential future research to exploit the research conclusions

D. SCOPE

While the GAO pointed to three high-level factors contributing to poor production outcomes in DOD acquisition only manufacturing causal factors became the focus of this study. This study found that there had been little research addressing the acquisition consequences due to the lack of a standard approach to manufacturing development and demonstration. An examination of DOD manufacturing development, readiness and the production approval process created the domain of the manufacturing knowledge gap pointed out by the GAO (Table 1).

Table 1. Selecting the Study Domain: Manufacturing Knowledge Gaps

Causal Factors Poor Production Outcomes	Research Novelty	Trends in Acquisition Reform	Study Significance	Study Scope
Technological Knowledge gaps	Not Novel, many research publications, one technical journal alone citing 32 other related research items.	DODI 5000.02 included significant reforms to address this gap. GAO has observed more successes in recent reviews. Other policy guidance also reviewed showing reform and improvement.	Related, but not significant. There is a high degree of independence with respect to technological maturity.	Excluded (gray row)

Causal Factors Poor Production Outcomes	Research Novelty	Trends in Acquisition Reform	Study Significance	Study Scope
Design-instability	Not Novel, many research publications.	DODI 5000.02 included significant reforms to address this gap. GAO has reported more successes in recent reviews. One example is conducting a Preliminary Design Review in Technology Maturation and Risk Reduction.	Related, but not significant. There was a high degree of independence with respect to technological maturity.	Excluded (gray row)
Manufacturing Knowledge gaps	Novel study field with little research outside of the GAO addressing the production approval prior to MS C.	GAO reported that there was a lack of production knowledge in DOD acquisition as compared to other more successful commercial development programs.	DOD policy documents and guidelines in 2015 do not require a manufacturing demonstration of capability prior to MS C.	Included

E. REPORT ORGANIZATION

This report is organized in five chapters and an appendix. The remaining chapters are described as follows:

Chapter II includes the background section, which addresses the study domain with respect to SE as a tool to analyze alternatives as applied to production approval processes contrasting DOD and non-DOD industries. The literature review section develops important elements of the study context related to production approval processes from the point of view of poor production outcome causality focusing the study on the issue of a lack of manufacturing knowledge.

The study's analytic approach is discussed in Chapter III. Lower-level details for measurable performance used in the AOA are developed. An operational view of the problem definition and role of stakeholders provides a construct that models the current DOD and "Ideal State" based on industrial sector best practices. The development of the

six-step Systems Engineering Development Process (SEDP) is described and is applied to this study.

Chapter IV discusses the study's analytic approach using the measurable performance evaluation criteria developed. Commercial surveys investigated confirmed the benefits of the prescriptive quality standards. The study identified a preferred solution selection.

Chapter V, the last chapter of the thesis, discusses the findings, summarizes the results, and provides recommendations. In addition, there is a brief discussion related to an opportunity for future study. Key enablers in support of a DOD process improvement are highlighted.

The appendices support certain complex discussions found in the thesis. The items expand an understanding for practices that are typically unfamiliar to a DOD acquisition audience. A whitepaper is provided that treats the subject of a DOD technical warrant for use in any implementation of a standardized advanced product quality planning (APQP) / production part approval process (PPAP) for DOD acquisition.

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II. BACKGROUND AND LITERATURE REVIEW

A. BACKGROUND

The background section is a discussion of general SE principals and then a careful development of the issues in the problem of poor production outcomes in manufacturing causality in DOD acquisition practices. This requires a development of the current-state of the DOD production approval practices and its shortcomings. Insight gained by studying the DOD process of manufacturing development provides a basis for evaluation for process improvement.

B. SYSTEM ENGINEERING METHODS

Systems engineering methods can provide a problem solving framework to examine issues surrounding the manufacturing knowledge gap that has resulted in poor production outcomes in DOD acquisition. In this study, an AOA assessment relied upon the selection of candidate alternatives and the development of assessment criteria that was used to study process improvement potential. A definition of systems engineering is a starting point that helped define the problem solving process of the study AOA. The development and application of the AOA model lead to the identification of a coherent SE approach aiding in the selection of a preferred solution.

1. General Systems Engineering Definition

The developing practice of SE and its body of knowledge includes the work of the International Council on Systems Engineering (INCOSE). Two popular definitions of SE help to provide a context for the use of SE for problem solving related to a process as significant as production approval in weapons procurement. According to INCOSE (2007),

systems engineering is an interdisciplinary approach and means to enable the realization of successful systems. It focuses on defining customer needs and required functionality early in the development cycle, documenting requirements, and then proceeding with design synthesis and system validation while considering the complete problem. Systems engineering considers both the business and the technical needs of all

customers with the goal of providing a quality product that meets the user needs (introduction). According to the *Defense Acquisition Guidebook* (DAG),

systems engineering is an interdisciplinary approach encompassing the entire technical effort to evolve and verify an integrated and total life cycle balanced set of system, people, and process solutions that satisfy customer needs. Systems engineering is the integrating mechanism across the technical efforts related to the development, manufacturing, verification, deployment, operations, support, disposal of, and user training for systems and their life cycle processes. Systems engineering develops technical information to support the program management decision-making process. (OSD 2009, Chapter 4.0.2)

From these definitions there is a need to apply the systems engineering discipline to manufacturing. A manufacturing process definition, like a product definition, can approach manufacturing development as a series of problem solving activities that identifies process functionality in relation to the satisfaction of product requirements. System Engineering works to evolve a preferred production solution that will create a product that reliably meets user needs. DOD weapons system acquisition does include manufacturing development and production approval process. Manufacturing engineering is therefore a concurrent partner with engineering development sharing a goal of delivering an affordable and producible engineered design.

2. System Engineering Development Process (SEDP)

The SEDP is a SE problem-solving approach focusing on system needs and continues toward an implementation of a supporting solution (Gibson, Scherer and Gibson 2007, 29–34). The SEDP approach defines an ideal (or normative) state related to a desired outcome. In production approval processes the normative state would be “good” production outcomes. Similarly, the SEDP approach assesses the as-is descriptive state of the DOD production approval process with the related undesired poor production outcome. An excellent graphical illustration, not intended to show details, captures visually the nature of the SEDP approach that considers product or process alternatives while moving the development along interpretively to a solution (Figure 10) (Sullivan, Broulette and Joles 1998).

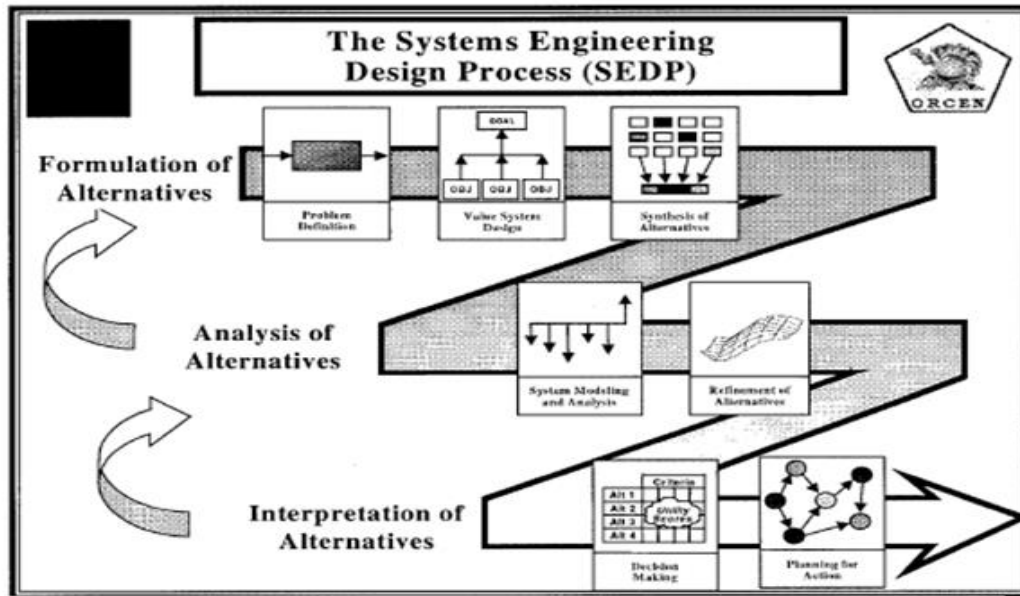


Figure 10. System Engineering Design Process (SEDP).
Source: Sullivan, Broulette and Joles (1998).

In addition, the early engineering effort characterizes requirements and provides a problem definition in relation to the goals associated with that of an ideal solution. The process of establishing meaningful criteria used to assess the benefits of one alternative over another can involve a criteria ranking scheme allowing the analysis to discriminate between candidates. The resulting assessment uses numerical scoring comparing alternatives to support a recommendation towards a preferential option that best aligns with stakeholder needs and overall program goals.

The SEDP can be further described as a sequential method of iterating around a solution space over variances in the factors of analysis moving engineering effort towards a preferred solution. See Table 2. Gibson notes that this approach can be controversial in its rating and ranking of metrics that are hard to characterize for comparison purposes (Gibson, Scherer and Gibson 2007, 33). Inhibiting issues may include political implications or a lack of sufficient background to substantiate the impact of factors influencing design or process.

Table 2. Six Steps on How to Do a Systems Analysis

Step	
1	Determine the (values) goals of the system
2	Establish criteria for rating alternative candidates
3	Identify or develop candidate alternative solutions
4	Rank alternative candidates
5	Iterate as necessary
6	Action

Adapted from Gibson, Scherer and. Gibson (2007).

C. DOD ACQUISITION POLICY AND PROCESSES

The lack of clear policy and guidance with respect to manufacturing development and demonstration in DOD weapons acquisition is a finding frequently identified in GAO's annual reports to Congress (Dodaro 2013). This omission of clear guidance for manufacturing demonstration is an obstacle to realizing the benefits of best practices found in non-DOD industries.

Prior to the Perry memo military standards were more prescriptive and included manufacturing requirements. The Office of Management and Budget's (OMB) conducts annual compliance reporting to assure military standards are only used when vital (OMB 1998). The dramatic change brought on by the Perry memo still limits the use of how-to standards. Consider the policy statement from DOD Instruction No. 4120.24 (Breitenberg 1999, 1):

3. POLICY. It is DOD policy that:

- a. The Department of Defense shall maintain a single, integrated DSP [Document Standardization Program] to promote standardization of materiel, information technology, facilities, and engineering practices in accordance with Reference (c).
- b. Non-government standards shall be used in preference to developing and maintaining Government specifications and standards as required by

section 12(d) of Public Law 104–113 (Reference (d)), unless they fall under one of the exceptions specified in section 12(d) of Reference (d).

In the Perry approach, there is the reduced use of military standards in favor commercial consensus standards. An unintended consequence has been the loss of manufacturing requirements and know-how in DOD acquisition (policy and workforce). Today, there are no suitable consensus standards found in policy guidance. In addition, there is a legacy resistance to change current policy and practices given the established contractor-defined performance-based acquisition approach. The omission of manufacturing requirements in development programs with the removal of prescriptive military standards gave rise to the use of non-standard contractor developmental practices. The various contractor approaches to manufacturing development drives uncertainty into DOD oversight and inhibits improvement due to an omission of standard practices in manufacturing development and knowledge.

The DOD has been slow to move towards defining a more objective treatment of manufacturing in development. For example, if reference is given to the DAU definition of “knowledge-based” acquisition then there should be a discussion and policy that supports producibility and affordability activities. Producibility is a design activity primarily concerned with making an item more affordable based on a design’s ease of manufacturing. This simple statement shows how interrelated designing and manufacturing are as partners in development. However, the DOD guidance documents do not standardize or require a prescriptive process of manufacturing development and demonstration. Manufacturing development lacks requirements specification in DOD acquisition and does not find itself as an equal development partner with product design and verification requirements.

Generally, the DOD production readiness methods provide visibility to prime contractor behaviors with limitations on oversight into the supply network. There exists a contracting challenge in DOD acquisition to gain insight into the entire supply network. This was discussed in one GAO report pointing to the automotive sector’s QMS approach that is flowed to all tiers in the supply network consistently. It was not clear if the intent

of this reference was a recommendation to apply the prescriptive automotive QMS to the entire supply network as a requirement (Schinasi 1996).

Another difference illustrating contrast between the DOD and automotive OEMs is the automotive response to the global economic environment is uninhibited where the DOD prime contractors may be restrictive in global sourcing opportunities given obvious security issues in defense acquisition. Such examples as these can negatively impact acquisition outcomes, but they would be exceptions to the basic approach non-DOD manufacturers follow in their production approval processes.

D. DOD PRODUCTION DECISION AND ACQUISITION POLICY

The DOD acquisition guidance comes from four main policy documents and one guidebook used principally to define the acquisition approach for DOD weapons acquisition. Table 3 lists each of these key documents with a brief description of the associated sponsoring organization, document number, issuance date, and a comment derived to capture the purpose of the document. One significant finding from a review of these policy documents is that they describe a risk-based assessment and not a knowledge-based demonstration of production capability. As a result, programs proceed into production with significant production risk entering the PD phase. Poor production outcomes are the undesired consequence given the findings as reported by the GAO Dodaro (2013). The understanding conveyed is that the DOD process is deferring development of critical manufacturing knowledge by waiting until after early production experience.

Table 3. Primary Governing Policy Documents for DOD Acquisition

Sponsor	Document Number	Date of Issuance	Document Title	Comment-Purpose
Joint Chiefs of Staff	CJCSI 3170.011	23-Jan-15	<i>Joint Capabilities Integration And Development System (JCIDS)</i>	“The JCIDS process provides organizations with the guidance and ability to validate Capabilities documents: ICD, CDD, CPD” (2)
Joint Chiefs of Staff	<i>JCIDS Manual</i>	12-Feb-15	<i>JCIDS Manual</i>	“This manual provides information regarding activities including mandatory training for personnel involved in the requirements processes, capability requirement portfolio management, identification of capability requirements and associated capability gaps, development of capability requirement documents, gatekeeping, and staffing procedures.” (1)
Department of Defense	DODD 5000.01	12-5-2003 Cert 1 2 - Nov-2007	DOD Directive - <i>The Defense Acquisition System</i>	“The Defense Acquisition system is intended to acquire quality products satisfying user needs that achieve mission capability at a fair and reasonable price.” (3)
Department of Defense	DODI 5000.02	7-Jan-15	DOD Instruction - <i>Operation of the Defense Acquisition System</i>	“The overarching management principles and mandatory policies that govern the Defense Acquisition System...” (1)
Acquisition Technology & Logistics	DAG	15-May-2013	<i>Defense Acquisition Guidebook</i>	“The Defense Acquisition Guidebook is intended to complement policy documents with discretionary best practice that should be tailored to program needs.” (DAU 2015b, ID=654219)

1. Knowledge-Based Acquisition and Technical Authority

The DOD acquisition process includes program authorities that are the actors in a program’s management. Recent DOD acquisition reforms expressed in the DAS describe the intention to develop a weapons system using a stated paradigm shift in the supported SE approach from “risk-based” management to a “knowledge-based” acquisition strategy. Specifically, there is a discussion of a basic acquisition approach calling for a process capability assessment aligned to the new knowledge-based strategy. While noted in the DAG the knowledge-based approach is not operationalized in practice in DOD acquisition. Consider the following from the DAG:

Positive acquisition outcomes require the use of a knowledge-based approach to product development that demonstrates high-levels of knowledge before significant commitments are made. In essence, knowledge supplants risk over time (chapter 4).

An example brings some clarity to the difference between knowledge-based and risk-based approaches in SE. Manufacturing risk management is documented through a system engineering technical review (SETR) that is accomplished by the use of formal checklists that have been developed as guidance in support an acquisition milestone review. In the case of the MRL assessments, they are not used as entrance or exit requirements at acquisition milestones. Instead, DOD guidance describes manufacturing risk assed by the MRL simply as a status report.

In addition to the MRL assessments the NAVY will often use the OSD SETR checklist tool to report overall program risk. The ARMY supports a gated SE review process with a checklist called the Product Assurance Risk Level (PARL) assessment. The ARMY Aviation & Missile Research, Development & Engineering Center maintains the PARL and is not a publicly accessible web product. In each case, manufacturing reviews consider the risk to manufacture and do not require any validation or demonstration of process capability knowledge prior to production decisions. These risk assessments do not follow the DAG paradigm shift to knowledge-based acquisition.

The DAG downplays the advocacy of the MRL checklists within the policy documents and guidebooks questioning the value of a checklist's ability to capture actual manufacturing program risk. This posture implies that the use of checklists is not adequate to the task of assuring process capability. If so, the DAG is correct in calling for a knowledge-based acquisition approach but does not actually integrate this process approach into best practices as found in the non-DOD industries. The DAG recognizes that a demonstration of process capability requires the use of statistical control from an assessment of key characteristics but the DOD approach lacks policy or standardization in production decisions acquisition. The DOD's current risk assessment guidance describing manufacturing readiness is therefore favored over a knowledge-based readiness assessment (USD[AT&L] 2013).

Examining authorities involved in the assessment and approval process in DOD acquisition provides a potential construct for understanding the current state and any improvement potential in determination of DOD manufacturing readiness at MS C. The PM as a program authority is assigned the responsibility for executing a SE approach in accordance with acquisition policy and guidance. The PM is assisted by the appointment of a technical authority (TA). These authorities are two but not equal authorities. The manifestation of this is important to the production-readiness approach found in the automotive and regulatory industries. The non-DOD industries employ the use of a certified production readiness document called a Product Submission Warrant (PSW) assuring conformance to product and process requirements. The certified warrant is signed by a producer's production authority as an industry best practice. The DOD does not have a similar certification process for production readiness for PD start.

If the DOD TA structure supported a PSW type policy it would first require an accepted standard for production readiness demonstration. A white paper by Ireland (2017) provides a detailed discussion for such a TA approach. Ireland's paper discusses how a certificated warrant for production readiness could be created by identifying a production readiness demonstration as a key performance parameter (Appendix E – DOD Technical Warrants). In brief, the organizational construct of a Technical Warrant Holder derives within a DOD system command (SYSCOM) workforce grouping the authority to manage a certification process to demonstrated production readiness. This workforce grouping represents a Competency-Aligned Organization that holds the recognized TA group. The certification warrant for production readiness is then the evidence and confirmation demonstrating production capability.

Additional supporting justification for the PSW being a best practice can be found in the recently released Society of Automotive Engineer (SAE) standard, AS-9145 Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP) (SAE 2015). The warrant process provides a commitment by the producer that a production process is effective and suitable at production start.

2. Manufacturing Development and Consensus Standards

Since 1996, the GAO had reported poor production outcomes and related this to a lack of a demonstrated process capability. At the time, the DOD acquisition system of 1996 eliminated most military standards due to the post Perry memo period. Here, the force of law required the use of commercial consensus standards (Breitenberg 1996) and (Perry 1994). Consider the discussion taken from this 1996 GAO report:

In December 1995, DOD began the Single Process Initiative, managed by: DCMC that allows contractors with military contracts to transition their quality management system from MIL-Q 9858A to their best practice, such as a quality management system based on ISO 9000, the basic commercial standard. The response to date has been slow; as of June 5, 1996, 38 contractors had submitted proposals to change their quality management systems, 5 of which had been approved (15).

The National Institute of Standards and Technology/GAO (1996) report stopped short of recommending the newly commercialized automotive family of standards over the ISO-9000 family of standards. The ISO-9000 QMS had been the accepted practice for contractors in DOD acquisition. The DOD acceptance of the aerospace standard (AS) AS-9100 was not a significant change due to the similarity in content to the ISO-9000 QMS. The adoption of these QMS replaced the use of military standards for contractor quality practices that prior had many prescriptive manufacturing related requirements.

Given the two types of QMS (prescriptive and non-prescriptive), one finds that the difference between ISO-9000 and AS-9100 is minor, but the difference between ISO-9000 and QS-9000/ISO/TS-16949 was significant. The hallmark difference is found in the prescriptive methods of the automotive QS-9000 family of standards and guidebooks. A key tenant of the QS-9000 QMS was the application of a PSW or certification for product and process conformance verification. The PSW requirement included customer specific requirements such as statistical process control of the manufacturing processes. Dimensional requirements would be satisfied if a demonstration to a specified threshold performance was achieved utilizing the indices process performance index (Ppk) or process capability index (Cpk). Demonstration of process capability knowledge at

production decision would overcome the patchwork of checklists that rely upon the risk-based approach of the DOD.

A significant operational difference found in the standard automotive OEM customer quality requirements was the passing of their common requirements on to lower tier suppliers as an enabling factor towards the success of the automotive sector. The enhanced set of automotive quality requirements included how-to manuals as guidance for APQP with a PPAP requirement (Table 4). As manufacturing processes developed under the guidance of APQP best practices the expectation of a supplier's validation of product and production readiness completed by showing empirically any supplier's readiness.

Table 4. Automotive Prescriptive Guidance and PPAP Quality Standards

Global Automotive Standards For the OEM Supply Network	Source	G-Guide R - Required
ISO/TS 16949 - Quality Management Systems Particular requirements for the application of ISO 9000:2008 for automotive production and relevant service part organizations	ISO.org	R
Advanced Product Quality Planning and Control Plan (APQP) The APQP and Control Plan is a reference manual that streamlines the entire quality & manufacturing process control approach in support of a development program. Provides a means to communicate requirements to suppliers.	AIAG.org	G
Design/Process Failure Mode & Effects Analysis (DFMEA/PFMEA) As part of the APQP family of reference manuals this guide answers how-to perform a DFMEA and PFMEA.	AIAG.org	G
Measurement Systems Analysis (MSA) This guide assists in the assessment of a measurement system that supports a manufacturing process.	AIAG.org	G
Statistical Process Control (SPC) This guide provides includes a wide range of statistical methods for effective monitoring and control of manufacturing processes.	AIAG.org	G
Production Part Approval Process (PPAP) The supply network is required to comply with the requirements of the PPAP. Consistent quality demonstrated in an actual production run at production rates. The PPAP integrates production readiness including the design, qualification, process capability with a certification warrant.	AIAG.org	R

E. PRODUCTION AND PROCESS CAPABILITY DISCUSSION

In order to place into context the specialized understanding of production and process capability there is a need to draw from experience and research to develop a basic treatment on the subject. This understanding will help enable the reader to benefit from this study's assessment method of critical criteria used in the AOA. This is of concern to this research because of the lack of guidance in DOD acquisition when contrasted to the more disciplined and robust manufacturing development practices present in non-DOD organizations (Schinasi 2002).

This section discusses a context of production and process capability to show linkages to some of the manufacturing causal knowledge gaps that lead to poor production outcomes. Several definitions have been created to give additional clarity to the discussion on manufacturing environments and related contractor capabilities:

- Manufacturing development - associates the development of a production environment to be used in the fabrication or production of an item.
- Production capability - is used as a term that associates the totality of an organization's ability to produce an item: man, machine, equipment, facilities and methods.
- Process capability - is a term used that is specifically related to the ability of a given process to satisfy a design tolerance in a stochastic manner.

A discussion on production capability examines manufacturing development as a producer's ability to define, demonstrate and offer its ability to manufacture a product under a given operational strategy that gives that organization a position in their chosen industrial market place. The maturity of a manufacturing development that defines the fabrication of a given product is related to the manufacturing planning needed to process and demonstrate that ability to produce at a desired production rate. Each item produced under this manufacturing development is to meet that item's design requirements. The evidence that a manufacturing process is production capable is the knowledge-based approach used in non-DOD organizations to show readiness.

It is the DOD and non-DOD production approval processes that can be studied for their approach to measure a new production capability and underlying process capability. The pre-production approval results are used to show the importance and impact of production capability and therefore readiness at production start.

When process capability knowledge is lacking then poor outcomes may occur as decisions are made without sufficient evidence of production or process capability. When a production decision is primarily based on a functional qualification, as in DOD production readiness decisions, there is a manufacturing knowledge gap. The DOD approach to manufacturing development may show production feasibility from early fabrication experience but leave decision makers uninformed about process capability. Most non-DOD industries favor a manufacturing development similar to the approach in the APQP guidance standards published by the AIAG culminating in a demonstration of their production system (AIAG 2008a).

1. What Is Process Capability?

An item's technical performance qualification is no guarantee that the developed manufacturing process used to fabricate that item is capable. A process that is required to manufacture an item has its own process-dependent performance measures to substantiate that there is a capable process. When a qualified item's functional performance meets requirements it cannot confirm that the same item was made under manufacturing process that is stable and in control. For instance, an individual process step can have a high-degree of part-to-part variation due to equipment, operators, instructions, and measurements. When a fabricated part is shown to meet requirements inference cannot be made as to its underlying production environment's capability.

From a designer's view, there is a technical data package with drawings that seldom are inclusive of any specific description regarding how that item is fabricated. The producibility aspects of a design are beyond the given design feature specified. Consider a hole specified on a drawing with its dimensions and tolerance that is sufficient to communicate a designer's intent. However, if one wanted to create that hole they could select from a myriad of fabrication methods unrelated to the drawing definition.

Whether drilling, stamping or a water jet fabrication method is chosen it is vitally important to assure manufacturing method translates into a capable process. For example, water pressure could vary at the time of processing or the water jet's effective size may vary with age so resulting features may be too large or off-center - all of which impact precision and accuracy to the design intent. Process capability studies are the typical way to provide confidence that a given fabrication method of a design feature would be producible, affordable and process capable. These processes should be fully designed and verified by MS C in DOD acquisition as they are in non-DOD counterparts as a pre-production demonstration requirement.

In another case, manufacturing planning and execution for any process step under some level of process control must involve suitable tools and fixtures that meet the quantity and quality challenges. Functional features that are difficult to measure at the point of fabrication may rely upon a downstream process functional test or an upstream process characteristic validation.

For example, a fastener is required to reach a certain torque with the intent to assure, indirectly, a clamp load that engineering defines. If the clamp load characteristic is critical, then certain in-process features may be critical to the process for controlling fastened torque. A process action may define a critical characteristic for fastener position (Soft start, thread engagement and angle) during torque achievement in-station. This process may need to be inspected by a functional downstream test using a wrench that measures breakaway torque. Indirect measurement studies can support critical product characteristics defined as supporting process tolerances in fabrication. Items made as manufacturing representative prototypes or early production may not have adequate production controls applied in the manufacturing processes in DOD acquisition in the EMD phase. The relationship of functional performance and part fabrication controls is fundamental in achieving production and process capability. This is why product qualification testing cannot substantiate process qualification directly.

The need to identify and measure critical characteristics in the process under manufacturing control is a best practice in non-DOD production organizations as pointed out by Sullivan (2008). Over time, process capability needs periodic assessment to

demonstrate process stability, homogeneity and measurable achievement of product performance at a production demand rate. Statistical Process Control (SPC) performance can show a stable process exists demonstrating that parts are in conformance with design tolerances and can be correlated to product performance. Statistical Process Control reveals the degree of process capability and assures part-to-part variation is acceptable to a threshold quality level and may show an as-built item meets design performance.

2. Process Capability Measurement

In any manufacturing development process, capability determination may include the identification of some risk and uncertainty related to late design changes anticipated from early test results and production methods used in qualification. Assessing a production readiness of an item solely upon a risk-based PRR technical review falls short when trying to establish a production maturity level. This approach is insufficient in contrast to the evidence of compliance that assesses part-to-part variation in a demonstration of process capability.

In the DOD acquisition guidance, a contractor's production plans may be complete but not realized in EMD where manufacturing development should complete. The DAS allows manufacturing development to continue during LRIP. This can be up to ten percent of a production order and be repeated. Therefore, production capability is not known and is a risk at the end of EMD. This would be unacceptable and woefully incomplete in most non-DOD industries and would not be allowed in regulatory industry environments. This lack of assessing actual production knowledge is a typical omission in the government readiness assessments.

Non-DOD industries follow standard formulas to measure process capability. A manufacturing process can be addressed by the use of Cpk defined in the AIAG's SPC reference manual (AIAG 2005). These capability indices are to verify the ability of a process to meet design tolerance requirements in a repeatable manner and at production rates. These indices can be correlated to measures of non-conformance such as defects per thousand produced. The probability of violating design tolerances are set as threshold indices and are correlated by a process measure of variation.

Manufacturing assessments are needed as on-going measures of process capability. The use of SPC under a given process control can signal adverse trends with excessive part-to-part variation that would lead to a non-conformance condition. Active capability assessments allow an ability to prevent non-conformances by in-station adjustments preserving process standards. When part tolerance limits are established and measurement systems are suitable then this approach is an industrial best practice. Yang discusses the approach to automation control characteristics in quality planning in computer-aided design and relies on the following basic steps (Yang 2007, 30):

Here are the steps to follow when implementing SPC:

- Take periodic samples from process
- Plot sample points on control chart
- Determine if process is within limits
- Prevent quality problems

While Yang's research developed a systematic approach to analyze the tolerance stack-up for complex multi-spec processes, his outline of action is central to using a knowledge-based QMS to assure quality targets are achieved. Process capability viewed through the analytics of Cpk and Ppk measures are related to on-going process capability verification. The use of quality metrics, such as Cpk and Ppk, help to verify process control achievement of design tolerances and avoids adverse product effects from process variation. These measures defined and validated early in support of production approval would give support to continuous improvement initiatives in LRIP and FRP rather than continuing uncertain manufacturing development capability. This would pull back fleet readiness risk into manufacturing development prior to MS C.

It is important to note how the GAO advocated for this practice of calculating process control indices. The GAO discussed best practices that included measurement of defect expectation to avoid adverse findings on DOD acquisition of weapon systems. The GAO found recently that DOD acquisition practices still did not confirm production readiness with a demonstration as a best practice (Dodaro 2014):

To assess production maturity, we asked program officials to identify the number of critical manufacturing processes and, where available, to quantify the extent of statistical control achieved for those processes as a part of our data-collection instrument. In most cases, we did not verify or validate the information provided by the program office. We clarified the number of critical manufacturing processes and the percentage of statistical process control where information existed that raised concerns. We used a standard called the process capability index, a process-performance measurement that quantifies how closely a process is running to its specification limits. The index can be translated into an expected product defect rate, and we have found it to be a best practice (159).

3. Measurement System Analysis

Dimensional control in a manufacturing process requires an understanding of the associated measurement systems that are used to confirm a manufactured item meets a given design feature's specified engineering tolerance. Common within a DOD contractor's production facility are the inclusion of test and measurement devices to show fabrication and assembly processes are satisfying functional design requirements. The process capability to be demonstrated and maintained requires a suitable calibrated test and measurement system's precision and accuracy — meaning that the gage or measuring device's error is typically designed around a 10:1 ratio with the error of measurement being at most 10% of the tolerance of interest as a best practice (AIAG 2010). The ability to measure and replicate a manufacturing process part after part says more about a manufacturing process capability than a qualification-only approach. Production process capability measures demonstrate the confidence or likelihood that a production process will sustain its ability to make product that meets product functional requirements.

One experience in a measurement study considered a relationship between a measurable design feature and its measuring device. That measuring device was a calibrated tape measure. The tape measure had graduated markings of measurement every 1/32nd inch. As a rule of thumb the error of measurement of a trained operator has an accuracy of ½ the marked division. When the process called for a measurement of 1/32nd inch tolerance this meant every part would have to measure nominal to the center of a design tolerance with no margin. Here, the error of measurement (+/- 1/64th inch) used the entire engineering specified design tolerance. The measuring device was not suitable.

Stochastically the probability of being nominal is zero and therefore every part was non-conforming.

4. Process Definition

In addition to the quantitative aspects of a process capability, there is also the fidelity of the manufacturing development definition that ultimately defines the production capability of an organization including enabling structures listed:

- manufacturing plans
- work instructions
- production methods
- production machines
- production tooling
- test equipment
- facilities

These items are all a part of the production capability context prior to one part being ready to build under the challenge of production. These items are integral to the homogeneity of process relied upon prior to understanding if a functioning part is from a well-defined and well-behaved production process under process control (AIAG 2005).

5. Advanced Product Quality Planning and Risk

The advanced product quality planning process is directly related to the automotive QMS and concerns itself with the development of product and production capability. APQP has four core product and manufacturing development strategies and are referenced in Table 4. The APQP guidance is standard practice in most non-DOD industries and includes the definition manufacturing knowledge at production start not found in DOD practices. For example, the DOD use of the MRL assessment does not identify any process capability requirements and gives no guidance on DOD oversight

with respect to demonstrating critical characteristics from an actual production line when completing EMD at MS C.

On a scale of one (not ready) to ten (experienced), the MRL of 8 is the maturity level desired at the end of EMD (OSD 2012). MRL practitioners find that there is a limitation in the use of the MRL preset questions when interrogating a manufacturing process as to its maturity level. The MRL approach is not necessarily able to identify project-specific risks.

A process study serves to identify any associated risk or non-conformance potential in a manufacturing process which might otherwise go undetected. In contrast, trying to document manufacturing risk, from the interrogation approach of the MRL assessment, lacks the specificity to address a given production or process capability. The MRL level associated with a production capable process is set at MRL 9 where process controls would be evaluated. In the DOD assessment of manufacturing maturity an MRL of 9 is not required until prior to FRP. In contrast, if a non-DOD industry would apply the MRL process it would have an MRL goal of 10 with process improvement behaviors at production start. See “Appendix M. MRL Levels 6 to 10” and (OSD 2015).

A non-DOD manufacturing development best practice uses a process study approach to assess specific manufacturing risk that results in the identification of a potential need for a process control as a mitigation of process risk. One such approach is the Process Failure Modes and Effects Analysis (PFMEA) identified in the automotive APQP (AIAG 2008b). Analyzing and addressing a manufacturing process for potential ways a production process might fail is a robust study into good production process analysis and should be completed prior to production start and is not a typical tool used in DOD acquisition.

The design related risk assessment is found in the application of the Design Failure Modes and Effects Analysis (DFMEA) and the PFMEA is for the process failure mode assessment (AIAG 2008b, AIAG 1992). According to the AIAG’s FMEA manual, the DFMEA is conducted ahead of the PFMEA to identify design risk. Design risk found in a DFMEA can potentially be mitigated by actions going back to design (as in selecting

different materials) or in considering a manufacturing control if design tolerance margin is small in proportion to desired process capability.

The power of the PFMEA analysis is in its ability to identify potential ways a specific process may fail and then to capture actionable process changes that may assure a part processed under statistical control meets requirements (AIAG 2008b). The PFMEA is a preferred non-DOD best practice for identifying manufacturing risk and utilizes three risk parameters. Risk assessed in this way identifies potential non-conformance concerns by severity, occurrence and detection risk factors. Here, a finding of risk allows an evaluation for acceptance, mitigation or elimination of potential failure modes at the root cause level early in manufacturing development towards a robust manufacturing process.

Another core strategy found the AIAG's APQP is the use of SPC. This would be the in-process measurements that are to be tracked and stochastically evaluated for trends that might threaten achievement of a characteristic of design due to a manufacturing process or methods variability. A fourth core APQP strategy is the Measurement System Analysis (MSA) process that evaluates the underlying measurement system used in manufacturing whether special test equipment or gages and tools. A key tenet of any MSA is a calibration process affirming equipment accuracy is maintained to assure a process measurement tool is calibrated to known standards. In non-DOD industries it is a best practice to use the error of measurement to amend process acceptance criteria to be more restrictive than a design tolerance—a guard band. This adjustment is rarely used by contractors in DOD programs and without this guidance quality defects escape the factory unlike non-DOD industries that guard band measurement error.

F. PRODUCTION APPROVAL PROCESSES

Non-DOD organizations interviewed by the GAO had industrial sector influences that guided organizational use of specific QMS with an associated production approval practice. Organizations followed a product development strategy according to their associated OEM or related regulatory agency with their unique requirements. An organization's industrial sector provided the larger influence that guided the type of QMS adherence (Table 5).

Applying the selection filter of Table 5 there are three alternate production approval processes that emerge for study as industrial sectors. These alternatives are grouped into the industrial sectors governed by Federal Aviation Administration (FAA), the Food and Drug Administration (FDA) and the automotive industry. These three, non-DOD industrial sectors were determined to be suitable alternatives because of scale and product complexity for comparison to the DOD acquisition practices.

Table 5. Identification of Alternate Production Approval Processes

Sources	Company	Sector	Organizational Motivation	Study Significance	Within Study
(Sullivan 2008)	Boeing Commercial Airplanes	Aerospace	Initial payment and % withheld until final delivery functions properly AS9100	AS9100 FAR Part 14	Yes, By Sector - FAA
(Sullivan 2008)	Intelsat Satellites	Telecom	High Reliability favorable terms from the underwriters incentivize good quality outcomes	Mature Technologies	No
(Sullivan 2008)	American Airlines	Aerospace	incentivize good quality outcomes AS9100	AS9100 FAR Part 14	Yes, By Sector - FAA
(Sullivan 2008)	Siemens Medical Solutions	Medical Devices	measures process yields	FAR Part 21	Yes, By Sector - FDA
(Sullivan 2008)	Kenworth	Heavy Equipment	requires their own investment Six Sigma	Supply Chain Tier 1	No
(Sullivan 2008)	Cummins	Heavy Equipment	Poor Quality Motivated Large Change in Development Process requires their own investment Six Sigma	Warranty	No

Sources	Company	Sector	Organizational Motivation	Study Significance	Within Study
(Schinasi 1996)	Texas Instruments Defense Systems & Electronics, Dallas	Defense	DOD accepts monetary risks in development (Often pays for quality issues)	Little Supply Knowledge	Yes, By Sector - DOD
(Schinasi 1996)	Texas Instruments, Lubbock	Electronics Semiconductor	NA	NA	No
(Schinasi 1996)	Delco Electronics	Automotive	(QS-9000, APQP, PPAP)	Supply Chain	Yes, By Sector - Auto
(Schinasi 1996)	John Deer Horicon Works	Lawn & Ground Care	reduce defects, reduced suppliers, reduced inspection	Supply Chain	No
(Schinasi 1996)	Varian	Electronics Medical Devices	Malcom Baldrige with advanced quality systems	Supply Chain	Yes, By Sector - FDA
(Schinasi 1996)	Motorola Paging Products	Electronics Telecom	Malcom Baldrige with advanced quality systems	Supply Chain	No
(Schinasi 1996)	Cherry Electronics Products	Automotive	(QS-9000, APQP, PPAP)	Supply Chain	Yes, By Sector - Auto

While there are examples of DOD contractors who applied the automotive type QMS to their supply network, it is rare. United Technologies Corporation (UTC) is one example. The history of UTC included an automotive division's influence observed by the application by Sikorsky (Appendix L - Links to Quality Practices).

Table 6 illustrates the three industrial sectors rough scaling of business metrics and associated financial data. A gross comparison revealed each industry's economic statistics in terms of 1) number of employees; and 2) revenue (Department of Commerce 2015a; Department of Commerce 2015b; Ibisworld 2015). The scalable comparison of economic factors showed that each industry sector had definable quality systems. The non-DOD industries studied included a certification process as part of their production approval process not observed in the DOD approach.

Table 6. Rough Scaling of Industry Sectors

Rough Scaling of Industry Sectors (Selected for AOA - Production Part Approval Processes)			
Sector	Direct	Billions	Billions
	Employees	Revenue	Export
Commercial Aerospace	500,000	\$216	\$118
Automotive Industry	786,000	\$225	\$75
Medical Devices	411,000	\$40	
DOD - three largest Contractors	400,000	\$100	

With the assumption that better production outcomes in non-DOD industries resulted from the use of their best practices the reader is left asking what differentiated these processes from DOD production approval practices? A review of these non-DOD QMS applications found that they all used a more prescriptive type of QMS. The QMS groupings provided the insight needed to conduct the AOA which appears in detail in chapter III of this report. This supports why a quality management system's characteristics and benefits need to be explored in this study. The GAO report (2010) demonstrates the direction the DOD selected.

The DOD's response to the GAO report of 2010, found in "Appendix G," did not satisfy the GAO's hopes that a consistent or standard approach might emerge in DOD production approval with a demonstration, including statistical process control (SPC) (Sullivan 2010). Capturing the key response from the DOD memo:

While the Department [DOD] notes that all manufacturing processes do not warrant the same level of process capability and control, appropriate levels of control are certainly warranted on a case by case basis (66).

and

The Department [DOD] will examine strengthening the manufacturing readiness criteria related to process capability and control of critical components and/or interfaces prior to the MS C low rate initial production decision. However, program offices and contractors should continue to have the latitude to jointly agree on the targets and specific process control demonstrations required on the pilot production line during the Engineering and Manufacturing Development to ensure success (66).

G. PRODUCTION APPROVAL PROCESS ATTRIBUTES

Given the comparative groupings of the FAA, FDA and the auto industry, the next goal of the study focused on the development of an analysis tool to differentiate between alternate production approval processes. A review of each industrial sector's approach to production approval practices provided a producer's respective manufacturing development knowledge and attributes of each production readiness decision process.

The comparative study criteria developed performance and cost benefits. A comparison of each industrial sector, selected for study, followed a discoverable and formal production approval process. The comparison to the DOD production readiness process used high-level criteria developed from the industrial best practices. A summary categorizing production process characteristics as best practice attributes are presented in Table 7 as observed in the researcher's commercial experience.

Each statement found in Table 7 is a best practice attribute that expresses a robust matured practice. For example, there is a considerable amount of professional effort in developing consensus standards and then to deploy them throughout an entire industrial sector supply network. It is not unusual for a commercial standard to take several years to gain consensus and then another decade to maintain and discover its effectiveness.

Table 7. Input and Output Best Practice Attributes

Production Process Input / Output Best Practice Attributes		
Input	1	Common engineering language
	2	Common quality standards
	3	Common customer requirements
	4	Third party compliance to quality system standards
	5	Prescriptive advanced quality planning practices
	6	Quality requirements flowed to the entire supply network
	7	Certification of demonstrated capability prior to production
Output	1	Quality system administrative efficiencies
	2	Knowledge-based demonstration of manufacturing capability
	3	Measurable system of quality metrics for user satisfaction
	4	Improved product reliability and durability

H. QUALITY MANAGEMENT SYSTEMS (QMS)

Quality management system standards were found to influence an organization's effectiveness as a manufacturer. Basic production capability depended upon an organizational approach to production approval. The two basic types of QMS applications included the ISO-9000 family of standards and the Automotive Industry Action Group (AIAG) QMS QS-9000 family of standards. Depending on which QMS an organization followed, there were different quality outcomes observed (ISO 2008; AIAG 2006).

The ISO-9000 related standards remain the core of all QMS in the study. A QMS serves as an industry best practice employed by organizations as an assurance to customers that their systems and processes followed good management principles and quality practices that influence product and service results. The QS-9000's release followed closely after the publication of the ISO-9000 standards but added customer specific guidance documents requiring prescriptive requirements directed at the automotive industry OEM supply chain.

The QS-9000 family of standards unified a myriad of automotive OEM standards used by the entire automotive supply base (Bandyopadhyay 1996, 7, 12). Bandyopadhyay observed that registering compliance to the earlier released ISO-9000 family of standards was not satisfactory for the automotive OEMs and the additional requirements of the auto industry that contributed to higher quality production outcomes.

The AIAG consortium, formed by the American automotive OEMs, enabled and managed the newer enhanced quality standards of the QS-9000. As reported by Bandyopadhyay, the supply network implementation of the unified OEM automotive approach was facilitated by the AIAG assisting in educating, enabling and guiding suppliers as to the necessary means to have a common production approval process.

The supply base QMS implementation relied upon AIAG training and third party compliance registration. The instrumental role of the AIAG and the formulation of common standards in the United States have now grown to include most automotive

OEMs globally and are practiced by the entire supply chain and avoiding multiple QMS requirements. See Appendix F..

A review of the automotive-unique requirements distinguished the two QMS standards (ISO-9000 and QS-9000) as materially different. The automotive enhanced quality standards (QS-9000) required many prescriptive OEM quality practices and how to conduct a demonstration. Process capability required the identification of critical characteristics during their disciplined process development. The additional requirements were essential to confirm production readiness through a production capability demonstration prior to a production decision. The automotive QS-9000 standards transferred control from the AIAG to the SAE and preserved the automotive OEM customer specific requirements to reflect the global supply base managed by ISO. This was done in collaboration with an international automotive taskforce (AIAG 2006). The ISO rebranding of the QS-9000 QMS used the TS prefix designation now rendered as ISO/TS-16949. This allowed the ISO construct to include detailed customer specific requirements of a prescriptive nature.

After a decade of use, the ISO-9000 QMS type was assessed by a survey conducted by McGraw-Hill in 1999 (Naveh, Marcus and Koo Moon 1999). Similarly, for the QS-9000 QMS type there were two similar surveys by the AIAG and the American Society of Quality (ASQ) (AIAG/ASQ 1997) and (AIAG 1998). The ISO-9000 standards, absent of prescriptive practices, served as a management system of quality related policy statements that identified manufacturing best practices. The DOD version of ISO-9000 was the AS-9000 QMS. The more prescriptive QS-9000 standards with a certification of production demonstration represented the evidentiary difference between standards (SAE 2009). Discussion on the results of the ASQ/AIAG QS-9000 QMS and McGraw-Hill ISO-9000 QMS application surveys are in the AOA section, IV.B.

There was a finding of ineffectiveness showing little improvement when adopting the QMS from the ISO-9000 series. In contrast, the QS-9000 series of prescriptive standards showed significant improvement in a producer's business and quality. The difference found between QMS types was pivotal in providing insight and reliability in

the study findings. The QMS type used and its impact on quality were highly correlated in each survey due to the numerous respondents.

The application of a QMS and how oversight is applied in DOD weapon systems acquisition follows policy level guidance where the various SYSCOMs flow requirements to acquisition teams. Consider the AS version of the ISO 9000 QMS (AS-9100) (SAE 2009). The Secretary of the Navy (SECNAV) endorsed the AS-9100 QMS in SECNAVINST 5000.2D/E (“Appendix D”).

The DOD acquisition leads can select higher level quality standards such as a QMS for compliance to a contractor’s conduct of an engineering development and execution of a production system. Acquisition teams have some guidance as to which consensus standards can be levied against a contract. The usage of a particular QMS, such as the ISO/TS-16949 reference within the CFR, would be to provide a more prescriptive set of requirements to weapons contracting. The GAO report (1996), discussed the use of the ISO/TS-16949 quality standard as a supplement to ISO-9000 but no finding of its use has been shown in subsequent GAO reports (Schinasi 1996, 13).

The CFR called out the need for each agency desiring to specify a higher quality standard to create a procedure to assess when such a need would exist. Unfortunately, the DOD acquisition legacy and policies only guide program teams to follow performance-based acquisition favoring a contractor’s individual approach. Additionally, DOD acquisition policy and guidance does not indicate when to use the enhanced QMS like ISO/TS-16949 or the AS-9100 D release that will likely be required after 2018 that also includes the AS-9145 APQP and PPAP manufacturing development and quality production approval standard in the overall QMS family.

While it is not found in any guidance, the current AS-9100 revision C QMS does allow for a customer’s special or discretionary requirements (Table 8). Invoking the special requirements clause allows regulatory requirements to be defined to satisfy supplementary agency requirements to be levied by the FAA and the FDA. The DOD does not engage on this level of requirements as a standard practice or even selectively. DOD Prime contractors act as the OEMs in acquisition with the DOD being the end user.

Non-DOD supplier contracting relationships develop differently and more directly defining the relation between a prime and a subcontractor (SAE 2009). A summary of AS-9100, clause 3.2, given by the Long Island chapter of ASQ has discretionary language almost identical to that shown in the instruction given by the Navy policy guidelines but still leans toward contractor discretion (ASQLONGISLAND 2015).

Table 8. AS-9100 C: 2008 Clause 3.2 – Special Requirements

3.2 Special Requirements	Insight
Those requirements identified by the customer, or determined by the organization, which have high risks to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.	Why: Ensure that such requirements are systematically addressed and linked to risk management activities by the organization Impact: A formal approach to identifying special requirements and connecting them to the risk management process

Adapted from American Society of Quality - Long Island Division, (2015).

I. LITERATURE REVIEW

Reviews of certain DOD policy documents, academic publications, technical publications and oversight reports help identify the current state of DOD acquisition practice. This information confirms the manufacturing knowledge gaps identified by the GAO as deficiencies and causal factors for poor production outcomes. This literature review provides sufficient detail with respect to establishing the alternate process knowledge to build the development of the AOA approach. Observations concerning alternative production approval processes established a solid foundation for process comparison in the AOA. Collectively, this information provided the development of the study focus and the process performance factors for the AOA assessment.

There are three factors of poor production outcomes assessed in the literature review and are taken from Figure 1 identifying the reason for the study focus on lack or manufacturing knowledge:

1. Lack of Technical Readiness

a. Technical Readiness in the TMRR Phase

Technology knowledge gaps and the value of technology readiness in DOD acquisition are explored in a thesis by Coble et al. (2014). This work addressed a need to identify a better modeling approach in requirements definition during the Technical Maturity and Risk Reduction (TMRR) phase. The thesis study team reported an improved requirements modeling approach related to prototyping. The authors believed that improved modeling of requirements and the prototyping process would help more accurate and timely facilitation of technology.

Here, Coble et al.'s report failed to identify manufacturing technology knowledge gaps as being of any concern during the TMRR phase. The work by Coble's team is part of a large body of published work focusing on technological maturity in DOD acquisition. The omission of manufacturing development in Coble's team thesis is similar to other research ignoring manufacturing causality on poor production outcomes.

b. A Broad Meta Study Review on Technical Readiness

The technical report by Azizian, Sarkani and Mazzuchi (2009), "A Comprehensive Review and Analysis of Maturity Assessment Approaches for Improved Decision Support to Achieve Efficient Defense Acquisition," discussed the need to address poor production outcomes of major weapon system programs. Azizian, Sarkani and Mazzuchi's article cited many of the same GAO reports referenced in this study with the same causal issues for poor production outcomes. They specifically mention all three of the GAO causal factors (including manufacturing knowledge gaps) but only reported on issues related to short comings of technological maturity. This team joins other researchers omitting the manufacturing causal factor.

According to Azizian, Sarkani and Mazzuchi, there exists confusion in the literature with respect to saying a technology is mature or if a technology possesses a readiness to the extent that they use the terms interchangeably. This researcher does not agree with the Azizian team's interchangeability of terms. In studying production approval there needs to be clarity between maturity and readiness. Maturation is to be

viewed as a process and readiness is the assessment of maturity at a point in time against a goal or standard. The confusion can be resolved by the context given in the respective Technical Readiness Level (TRL) and MRL guidebooks. A given “readiness” level is the result of using the related maturity assessment process asking progressive questions interrogating a product’s performance or a production environment’s definition.

c. Technical Readiness Contrasted with Manufacturing Readiness

A review of the DOD acquisition policy and guidance documents identified the DOD instruction, DODI 5000.02, which describes detailed acquisition policy requirements (USD[AT&L] 2015). These DOD policy documents deal objectively with technology readiness in acquisition. The JCIDS manual states that for any critical technology element identified, the technical maturity measurement must satisfy a TRL 6 prior to entry to the EMD phase (JCS 2015b). The JCIDS manual shows that technology maturation is to be determined by a demonstration of a TRL requirement (JCS 2015b); (USD[AT&L] 2015).

There is no complementary MRL readiness level required as a milestone entrance or exit requirement. As a measure of risk, the MRL would be reported to the MDA only if the PM considered that risk significant. The absence of a complimentary manufacturing readiness requirement demonstration inhibits knowing if a program is ready to proceed from EMD to the PD phase. A production environment is the focus of the desired MRL level and is not based on a production environment’s execution under production control. The MRL guidebook actually de-emphasizes the MRL “number” in favor of a maturity assessment and any plan to mature any discovery of shortcomings (OSD 2012). Therefore, there is a lack of manufacturing readiness knowledge by DOD guidance.

2. Lack of Design Stability

The DOD acquisition policy reformers released DOD 5000.02 in 2008 wherein a formal Preliminary Design Review (PDR) occurs prior to Milestone B at the end of the TMRR phase. See Figure 2 (USD[AT&L] 2008). The DOD acquisition process, as amended in 2008, inserted the PDR technical review into the earlier TMRR phase instead of at the start of the EMD phase.

Therefore, a design definition in EMD is now definable in TMRR to assure a more stable PDR product definition in the build-to configuration with its allocated baseline realized prior to EMD. At this point, a contractor will specify a design level that defines the PDR's allocated baseline and apply configuration management for the associated item(s) developed. Having configuration management and a design definition from a successful PDR in the TMRR phase is discussed as addressing the GAO concern related to design-instability by the Office of the DODR&E, Systems Engineering Department (Dahmann and Kelley 2009).

While the Dahmann and Kelley paper offered guidance on the approach used by system engineers during development phases the guidance offered failed to establish an approach with respect to manufacturing even though the manufacturing competency belongs within the domain of SE. There is no mention given to the establishment of manufacturing requirements or capabilities in the early phases leading to EMD or exiting from EMD to enter PD start.

There is ample evidence in the published literature and the current DAS showing that the two causal factors identified by the GAO for poor production outcomes related to technological readiness and design-instability have been addressed. Therefore, current acquisition policy, in general, closed two of the three deficiencies advocated by the GAO reports as related to the causality of poor production outcomes after MS C. On the other hand, the DOD acquisition reformers have not shown improvement over the prior policies with respect to manufacturing in DOD acquisition (JCS 2008); (USD[AT&L] 2013); (JCS 2015a); (JCS 2015b) and (USD[AT&L] 2015).

3. Lack of Manufacturing Knowledge

This section examines various selections of the DAS guidance and provides a detailed look at the treatment of the production approval processes in DOD acquisition. One key observation is that there are no standards that require a demonstration of statistical control of a manufacturing process prior to MS C. Consider the DOD acquisition manufacturing policy guidance in the JCIDS manual that states that the CPD should be "informed" with a manufacturing readiness assessment requirement completed

in accordance with the Joint Service/Industry MRL Working Group's published MRL Deskbook (OSD 2012). The review of the 2015 JCIDS manual also identifies the need for manufacturing knowledge to support a production decision. In addition, it should be noted that the MRL Deskbook identifies itself as a best practice and not a DOD requirement in conflict with the 5000.02 instruction calling for its use in weapons acquisition as a requirement (OSD 2012, i) and (OSD 2015, i).

The discussion that follows considers selections of the DAS taken from certain policy documents with the relevant part to this thesis giving a brief assessment:

a. *Reference Appendix E Selections from DOD Acquisition Policy: Item 4 Selection 1, Selection 2 and Selection 3*

Guidance from the DODI 5000.02 includes a call to have an effective demonstration of production capability. However, when more detail in this requirement is presented in the instructions there is a demotion from a rigor associated with a demonstration to a discussion on risk to support CPD reporting requirements to satisfy an MDA. These passages advocate for a manufacturing demonstration at the end of EMD and also prior to FRP. The need for a manufacturing demonstration at the end of EMD is subsequently deconstructed from a knowledge-based demonstration of process control to a risk assessment process not requiring actual evidence of production process capability.

b. *Reference Appendix E Selections from DOD Acquisition Policy: Item 4 Selection 4*

When contrasting the manufacturing demonstration and product qualification required for reporting technological and performance requirements at the end of EMD one finds that the manufacturing demonstration does not occur and is deferred until after LRIP instead of being verified as an exit requirement for EMD. Functionally defined technical requirements appear in various detailed programmatic documents such as the TEMP, statements of work or specification documents and lists of performance based requirements to be demonstrated. These functional requirements for demonstration and qualification prior to production decision are only product based and not process based. Any manufacturing readiness is effectively a paper study with readiness being reported as

risk to the contractor's manufacturing plan. Any expectation for a production capability demonstration does not factor into DOD acquisition at MS C.

The character "M" found in the abbreviation EMD is to represent a program's manufacturing development as a partner of design. When comparing non-DOD development the M is properly represented with respect to assessing manufacturing design and development with a verification and demonstration. DOD acquisition waits to assess production capability as a post-production consideration at the PCA event (USD[AT&L] 2015, 29).

One rationale behind the omission of a manufacturing demonstration in DOD acquisition is by mistakenly relying upon functional product qualification to substitute product performance and manufacturing capability. In a non-DOD production approval demonstration there is a requirement to show verification from a controlled and defined production environment, at a production rate, from production tooling, with product built under SPC (AIAG 2005).

In addition, the DOD policy documents do not engage the supplier network to assure that the government's interest in being production ready at MS C. In this case, a supplier's part only requires a functional qualification. The flow down requirement to show that manufacturing processes will be under statistical control in the supply base is significant and different than accepting a part's qualification results as representing the capability of the manufacturing process. Therefore, any program that fails to secure production capability knowledge at production commitment has a built-in manufacturing knowledge gap that is a causal condition for poor production outcomes.

The DAS higher-level guidance flows down in DOD acquisition definition to the SYSCOMs. Individually, SYSCOMs may structure a responsive instruction to achieve production readiness knowledge. One SYSCOM instruction directed attention to a functional performance demonstration and production process readiness and planning asking for "a satisfactory basis" for determining readiness as found in the Naval Air System Command Instruction (NAVAIRINST) in NAVAIRINST 4355.19D, (NAVAIR 2008)

c. *Reference Appendix E Selections from DOD Acquisition Policy: Item 4 Selection 5*

In the current NAVAIRINST 4355.19E there is far less guidance given with respect to manufacturing readiness and removes any notion of an objective basis for proceeding to LRIP (NAVAIR 2015). Clearly, the writers of the D revision anticipated some basis of satisfaction to be determined but did not clearly define the basis or require an objective demonstration or certification of production readiness as recommended by the NDIA in 2010. Between revisions of the instruction from D to E, there is a scaled down PRR criteria offered by the SYSCOM instruction NAVAIRINST 4355.19E (NAVAIR 2015).

d. *Reference Appendix E Selections from DOD Acquisition Policy: Item 4 Selection 6*

Here, the E revision referring to the PRR technical review process, establishes less content rich manufacturing assessment criteria through the Critical Design Review (CDR) and as represented in production readiness assessments in keeping with the reporting of risk approach in the higher guidance of the JCIDS. The conclusion from this literature review is to recognize that a contractor establishes its own manufacturing requirements separate from DOD oversight and verifies compliance to produce an item by product functional qualification. The acquisition guidance then assumes the risk of a contractor's production capability at MS C. The manufacturing process knowledge that may be concurrently developed in EMD is lacking objectivity and may be misleading or incomplete from the PRR conducted in support of MS C.

Decision authorities lack an empirical conformance and demonstration of production capability in the DOD. Even the GAO manufacturing knowledge score card approach lacked an actual demonstration giving credit in favor of the contractor to proceed to LRIP on a promise that manufacturing will be under statistical control at some future time – effectively an unsecured I-Owe-You to exit the EMD phase (Dodaro 2013).

This is similar to that reported by the Congressional Research Service's report stating "At Milestone C, the MDA authorizes the beginning of low-rate initial production,

which is intended to prepare manufacturing and quality control processes for a higher rate of production and provide test models for operational test and evaluation (OT&E). Upon completion of OT&E, demonstration of adequate control over manufacturing processes, and with the approval of the MDA, a program can go into full rate production” (Schwarz 2013, 10). Therefore, actual manufacturing knowledge is not required in establishing a developed manufacturing capability at MS C.

The DAS never discusses directly that product qualification is a substitute for a manufacturing process capability demonstration but many program SOWs have stated this in the author’s experience. The manufacturing verification that eventually is assessed is deferred until the PCA and still fails to gain insight to supplier parts. Consider further the significance that the supply network is over 65% of content purchased or developed (Sullivan 2010). This means that manufacturing process knowledge is nearly invisible to DOD oversight in the sub-tier supply network. Beyond view are quality factors that indicate production capability such as, scrap rates, process variability and first-pass-yield. As long as deliveries are met and a part had been qualified then no additional supplier insight is required – including any production capability.

e. Reference Appendix E Selections from DOD Acquisition Policy: Item 4 Selection 7

The TRL process and technical risk of critical elements is considered a rigorous process in the TMRR acquisition phase that identifies and manages product technology needing insight as it matures through development. The critical elements are required to have an assessment by statutory requirement. Specifically, this is referenced in DODI 5000.02.

Sullivan (2010) also reported the welcoming of the MRL assessment process to improve manufacturing knowledge and to improve production outcomes. The new MRL process was to consider relevant manufacturing environment development in a similar manner to TRL assessments appropriate to the life cycle acquisition process. Sullivan expressed hope that after 14 years of reporting negatively about production outcomes that

the DOD acquisition process would realize a knowledge-based approach over the risk-based approach decried by the GAO:

A serious concern is that DOD's in-house manufacturing workforce has been diminishing for decades and that, therefore, could hamper successful implementation of MRLs. Unless DOD develops long-range plans to build its in-house manufacturing workforce, it may not be able to realize the full potential of integrating manufacturing readiness levels into its processes (47).

and

Direct the Office of the Director, Defense Research and Engineering to examine strengthening the MRL criteria related to the process capability and control of critical components and/or interfaces prior to MS C, or equivalent, for low-rate initial production decision (47).

With the on-going findings of the GAO and the review of the DAS documents, a clear picture of what is absent in DOD manufacturing knowledge compared to non-DOD industries reveals weaknesses in the DOD approach. Acquisition practices in the DOD at MS C do not demonstrate production capability or producibility performance to any specified standards. Therefore, the DOD weapons acquisition process fails to provide a means to gain confidence in a contractor's ability to produce a given design.

III. PROJECT APPROACH

A. VALUE-HIERARCHY DEVELOPMENT AND THE ICOM MODEL

Systems engineering methods and tools can help define a development path hoping to satisfy a system's requirements. The SE approach endeavors to establish a value-hierarchy representing the desired state of process or product. In support of this thesis SE analysis, there are simple process definition tools used to introduce evaluation characteristics for the more detailed AOA discussed in Chapter III, Section C.

One tool that helps explore this space is the input/controls/output/methods (ICOM) model (KBSI 2014). The ICOM model can provide a visual and contextual view of the DOD production approval process. The content of the current DOD process is defined by the manufacturing development and approval process. This can be defined further by the development of the DOD acquisition system's concept of operations (CONOPS) giving a one page pictorial view of a system's broad conceptual operation. The definition of simplified ICOM structure of the DOD manufacturing development and approval process is represented in Figure 11.

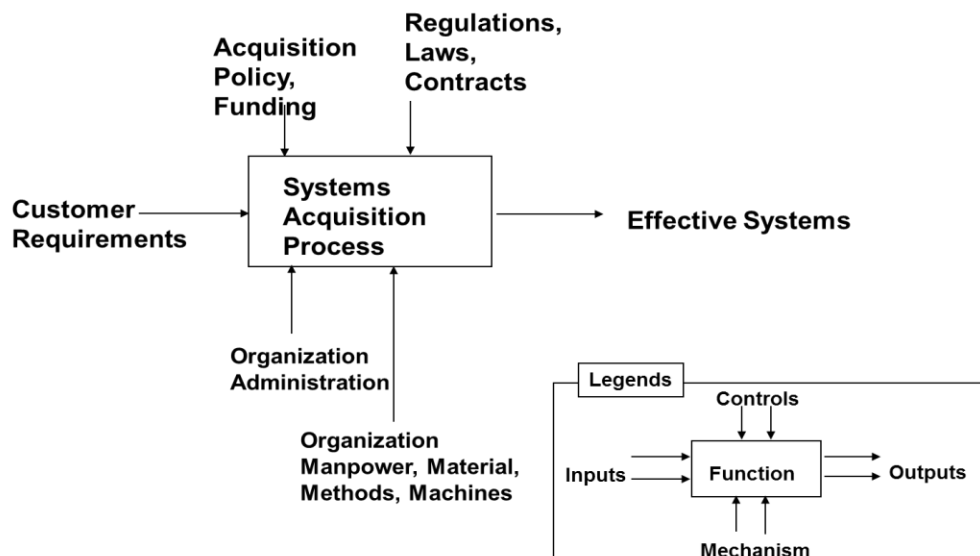


Figure 11. Weapon Systems Acquisition Process Using ICOM Modeling

In general, the ICOM representation provides an understanding of basic requirements, methods and inputs needed to describe high level production acquisition process activities and show output, as in our case, as either a future effective state or a current ineffective state. At this stage of modeling, the ICOM highlights the key elements of a production system that include: manpower, material, methods, and machines.

B. REQUIREMENTS DEFINITION IN THE SEDP METHOD

System engineering practices will define requirements in early phases of a project. These requirements are refined through a capture of stakeholder and user needs to understand desired customer usage and avoid potential problems in system definition. High-level user needs and lower-level derived requirements are developed to help achieve a robust solution against competing alternatives. The SEDP process follows guidance found in a published handbook given by the Air Force Materiel Command (AFMC 2014). In this study there is a development of a hierarchical functional valuing of the manufacturing production approval processes to support a modeling and assessment objectively contrast alternative best practices.

C. AOA USED IN THE SEDP APPROACH

An AOA approach provides decision makers with a well-reasoned assessment describing the factors and modeling criteria that can be used as the basis for selection of a preferred alternative. The AOA approach guides the problem solving process towards a selection from alternatives that might best achieve desired capabilities. The preferred solution can emerge out of a complex fog of potential resources.

The comparative approach of the AOA establishes a reasonable story showing how best practices are able to satisfy a preferred process outcome from the alternatives under study. When a preferred solution emerges from an AOA there is an opportunity for decision makers to consider improvement potential, innovation, cost reduction and risk reduction for the problems they are trying to solve. It is often a prudent approach in the SE selection process to devise a verification test to evaluate any proposed solution confirming the preferred alternative. In SEDP, this execution step is an initial action step. When adopting a recommendation from and AOA some tailoring due to complexity, cost

or time may be required to reach a better alternative that balances between competing goals of cost, performance and schedule.

D. STAKEHOLDERS

This study recognizes there are various stakeholder interests. Identifying and understanding stakeholder interest leads to refinement of higher-level requirements and their associated value-functions with process and quality objectives. Identifying these objectives operationally is a precursor to associating appropriate and measurable process best practices. The development of measurable objectives to achieve improved production outcomes are intended to satisfy customer expectations as developed in the CONOPS discussion in this chapter, section E.

This researcher used the literature review and experience to develop a mapping of stakeholder interests to manufacturing related business practices. This mapping is used to translate stakeholder values into process objectives. Process objectives can be related to best practices. With any best practice there is a presumption of quality when they come from successful organizations. In other words, successful organizations achieve their success by their business practices. Using the best practice presumption, one can assert that if an industrial practice is in use by an organization, then that organization derives value with its practice likely satisfying stakeholder needs.

Stakeholder value streams can be associated with more clarity by looking into stakeholders as actors and with transactional roles within the context of the acquisition activities in production part approval with the intention of achieving ideal production outcomes. In DOD acquisition, stakeholders who are the users of the acquisition products are the COCOM. The associated operational attributes of stakeholder values present as suitability factors (Table 9).

Table 9. Stakeholder to Process Improvement Suitability Factors

Stakeholder	Suitability Factors for Best Practices
Supplier	Improved business efficiencies
Supplier	Improved requirements definition
Supplier	Improved production capability
Supplier	Improved process capability
User/OEM	Improved production outcomes
OEM & Supplier	Improved customer satisfaction

In defining some differences between DOD and non-DOD stakeholders there are factors specifically related to the production approval process as used in non-DOD practices. Suitability factors for production approval stakeholders are related to DOD acquisition as factors important to end-item users. In the DOD acquisition environment prime contractors are the OEMs and in non-DOD acquisition development environments users are the customers who purchase products from OEMs.

There is a need to further develop the identification of high level stakeholder values to measurable objectives. A functional hierarchy can describe a value stream from user need to lower-level functional and sub-functional values for modeling measurable attributes as measures of performance (MOP). Analytically, the lowest measurable behavior for each best practice becomes a key measure of performance for scoring in the AOA. The creation of a hierarchy then provides the means to assess alternatives and creates elements to define a preferred concept of operations in production approval processes. In the next section, a discussion of stakeholders and their relationship to the context of production approval use-cases fully form an operational concept. Two cases will be described to explain the descriptive and normative approval process CONOPs.

E. OPERATIONAL CONCEPT

The DOD's Architectural Framework (DODAF) can communicate a view of a system's CONOPS at a glance. The system level view of key transactional relationships reveals a system's actors in their interactive behaviors. A complex problem under the treatment of an AOA can use the development of an operational concept to clarify the descriptive and normative use cases and associated process outcomes. The variation found in alternatives assists the robustness of an AOA assessment of study alternatives to satisfy system needs. The identification of process attributes and MOPs in the various approaches provides differentiating criteria found in an alternative and its ability to provide improvement potential.

With the identification of three operationally different industrial alternatives the study was able to construct for comparison the operational concepts contrasting non-DOD to DOD production approval process. These alternatives were different with respect to the types of knowledge required to make production decisions for their associated commercial production processes. The DOD approach tended to focus on product technology and functional requirements and the non-DOD organizations had an additional focus upon manufacturing development and demonstration of manufacturing capability. Identifying two non-DOD alternative production approval processes came from regulatory agencies: 1) the FAA (commercial aircraft industry) and 2) the FDA (medical industry). The automobile industry was a third commercial industry used to compare acquisition alternatives for production approval processes.

In the non-DOD sectors, the part suppliers required a PSW approval allowing that supplier to enter production. The supplier had to certify that an item demonstrated functional and manufacturing process capability together with any unique requirements and regulatory compliance prior to gaining approval to market those products. In the automotive industry the OEMs directly managed the requirements for compliance in support of a vehicle's production. The FDA and FAA, as regulatory agencies, govern compliance by law; ("Appendix C. FAA Memo"), ("Appendix I. FDA Procedures, Premarket Approval"), ("Appendix N. Understanding the Automotive QMS") and ("Appendix J. FAA Production Approval Process").

The non-DOD industries assure production-approval conformance by their certification requirement. The requirements did not allow a supplier to change its manufacturing process or location of manufacturing without reevaluation of the changed process and recertification. In addition, the readiness certification required a compliant company's QMS to show a registration to their QMS by a third party, a configuration managed design definition for product and process, product qualification, a working production environment and a process capability demonstration as determined at production rates. In contrast, the DOD accepts supply network parts into inventory when that supplier passes a qualification based on performance of a part's functionally.

The DOD production approval process for suppliers asserts, by policy, that a part can enter inventory if that part is subject to a functional qualification without any verification that a supplier is capable to produce based on any process verification. The significance of a demonstrated process control in the supply network is to achieve sustained quality compliance and prevent poor product outcomes. At times, the DOD may on a case-by-case basis include additional verifications of a supplier's parts through a first article inspection and acceptance test. This type of added contractor activity relates to unique and non-standard purchase agreements with their suppliers.

The lack of a standard approach to production approval identifies why non-DOD producers have solved the issues reported by the GAO. A demonstrated repeatable production process that includes the entire supply network ensures the desired consistent production outcomes. In general, the DOD does not consider the supply network of the prime contractor beyond part qualification unless by exception.

1. The Current DOD Production Approval Process CONOP

Developing the graphical representation of the DOD production approval process defines a depiction of the actors and activities with communications and decisions points. This operational view (OV) provides a means to describe the interworking and execution of the DOD production approval process. The high-level contextual operational view, OV-1, provides a visualization of a system in a static sense with various nodal interactions, activities and actors. This study's DODAF OV-1 follows a sequence starting

at the top and moving counter-clockwise to show the life-cycle acquisition process of the activities leading up to production approval and concluding with FRP.

The current state of the DOD production approval process is referred to as the descriptive state of operations of the production approval process in review. This acquisition environment shown by the OV-1 captures the actors with key organizational elements. The transactional nature of program management includes the production approval event at MS C with the milestone decision authority involvement.

The DOD acquisition technical review event that considers production readiness is the PRR technical review conducted just prior to MS C. The PRR assesses the pre-production baseline. This approach has a high degree of variation in the absence of formal standards and relies on a checklist approach that has inherent weaknesses if not outright omission in determining a given process capability. The results of a PRR reports manufacturing risk to the PM and the PM may inform the CPD about manufacturing risk. The CPD is the reviewable document given to the Defense Acquisition Board (DAB) to affect production approval.

The PRR review is to assure that a production readiness has been achieved with any reported risk when a program is to transition from the EMD to the PD phase. The information used to formulate the graphical OV-1 came from Table 10. See Figure 12.

Table 10. Descriptive—DOD Actors / Stakeholders DOD Roles and Activities

Actor	Organization	Transaction
Congress	Congress	Funding; Law; Oversight
Sponsor; User; Fleet; Government Acquisition	OT&E/OPTVFORE/ COCOM	Manage program/funding; Apply JCIDS - KPPs / KSAs-> COIs/MOEs/TPMs); Use -Case for System for fulfilling unrealized capability need Evaluate Suitability and Effectiveness to meet the need – Present to Congress
OEM - Producer/Prime	Contractor	From MS B - Provide Development of Product and Process (TMRR/EMD); Establish product baseline and provide readiness to produce for LRIP/FRP at MS C - Risk-based Acquisition.
Maintainer I/O/D	Flight Line/Logistics Contractor	Provide Support Services for Product In Operational Environment/Intermediate; Organizational; Depot Services
Congress /OSD / Milestone Decision Authority	Acquisition Authority	Provide Funding; JCIDS High-level requirements – KPP; KSA; Periodic Program Approval
Supply Network	Supplier tiers	Provides items/services to prime; qualified parts required.
3 rd Party Auditors DCCA; DCMA Authority	QMS Auditor; Contracts	Assessment of Compliance; e.g. AS9100 Completes DD250 to approve of payment for compliant deliveries
Panel Members Executives PM and Program Office Technical Manager Authorities	Contractor Executives COCOM Government Executives	Provide Recommendation to decision authorities at Project Milestones; Provide Project Oversight at Technical Reviews

Here, a program determines if requirements from the JCIDS process have been satisfied. The CPD is the document that reports the support for a decision to advance to production. In brief, these requirements cover: 1) production items that are purchased at the contracted price and delivery schedule and 2) production items that meet the design requirements through qualification. The end goal of the DOD production approval process is to ensure that items produced are suitable and effective as observed by the Operation and Test Evaluation (OT&E) and qualification.

supply base. The FAA and FDA use an agency-acceptable QMS such as the AS-9100 or ISO-9000 standards. The FDA and FAA append the addition of regulatory specific requirements and a demonstration to production approval requirements making their production approval processes more like the automotive process. The intended production capability is resolved by the use of the non-DOD prescriptive standards and requirements following their QMS. Contextual information is shown from the automotive perspective to create the transactional relationships from their best practices. See Table 11. These transactions describe how compliance for production readiness leads to a production decision in non-DOD industries.

The description of actors, organizations and transactions for the automotive industry production approval process is very similar to the other non-DOD production approval processes. The context, shown by the automotive production approval process develops and demonstrates production readiness from their best practices from a disciplined manufacturing development and demonstration approach using their industry standards. These unique non-DOD acquisition elements capture the knowledge-based production approval processes observed by the GAO reporting (Sullivan 2008).

Table 11. Automotive Actors and Activities Using a PPAP Certification

Actor	Organization	Transaction
Producer	Original equipment manufacturers	Requirements; Integrator; Producer; Sell/Warrant /Service; Product Sold to Users
User / Customer	Individual or Organization	Buy / Use Vehicle
Dealer – Service	OEM or Independent	Sell / Service Vehicle
Government / Legal	National Transportation and Safety Board	Requirements Homologation; Regulations
Supplier Producer	Component / Subsystem Supplier Tier 1 – to OEM	Design Responsible ; APQP; PPAP; Delivery
Supply Network	Tier 2; Tier 3 and ...	Supplies to Tier 1

Actor	Organization	Transaction
3 rd Party Certifier	Certification Bodies – Quality System;	OEM Directed Compliance to Supply Network
3 rd Party Training	AIAG/SAE/ASQ/SE	Related Training; supply base enablers

3. Normative DOD Production Approval Process

A normative state production approval process for DOD implementation considers the integration of non-DOD best practices. The transactional actors and actions are described by synthesizing necessary elements of the current DOD process and merging non-DOD production approval processes. This normative (or ideal) state for DOD production approval would then describe actors, organizations and transactions of both QMS based systems. The modifications formed in this way use the current DOD actors of Table 10 and those best practices of non-DOD industries found in Table 11. The combined actors and transactional behavior from the synthesis and integration of commercial best practices with the DOD transactions are in Table 12.

Table 12. Normative—DOD Actors / Stakeholders DOD Roles and Activities

Actor	Organization	Transaction	Comment
Congress /OSD / MDA	Acquisition Authorities	Provide Funding; JCIDS High-level requirements determined – KPP; KSA; Periodic Program Approvals	Same
Sponsor; User; Fleet (Customer)	OT&E/OPTVFO RE/COCOM Government Acquisition Strategy & Oversight	Manage program/funding; Apply JCIDS - KPPs / KSAs-> COIs/MOEs/TPMs); Use -Case for System for fulfilling unrealized capability need Evaluate Suitability and Effectiveness to meet the need. Knowledge-Based Acquisition.	Modified

Actor	Organization	Transaction	Comment
Integrating Contractor - Producer/Prime	Contractor	Provide Development of Product and Process – Technical Maturity and Risk Reduction and (EMD); Establish product baselines and provide demonstrated process capability at MS C, follow PPAP, LRIP,FRP	Modified
Supply Network	Tier 1; Tier 2 and ...	Supply network provides evidence for APQP and PPAP – to higher tier. Tier 1 to Prime Contractor PPAP.	Modified
3 rd Party Certifier	Certification Bodies – Quality System	OEM Directed Compliance to Supply Network	Modified
<u>3rd Party Training</u>	<u>AIAG/SAE/ASQ/SE</u>	Related Training; supply base enablers	New
Legal / Agency	Certifications; Boards	Requirements Demonstration, Report to decision authorities	Modified
1st Party Auditors DCCA; DCMA	Agency, Contract Administration	Assessment of Contract Compliance; Completes DD250 to approve of payment for compliant deliveries; Oversight	Same
Panel Members; Program Manager and Program Office; Technical Manager	Government: COCOM; (PMA)/(PEO) & Subject Matter Experts Contractor	Provide Recommendation to decision authorities at Project Milestones; Provide Project Oversight at Technical Reviews	Same
Maintainer I/O/D (Government)	Flight Line/Logistics/ COCOM	Provide Support Services for Product In Operational Environment/Intermediate; Organizational; Depot Services	Same
Maintainer I/O/D Supply Network	Contractor	Provide Support Services for Product In Operational Environment/Intermediate; Organizational; Depot Services Provides items/services to prime; Follows PPAP – as needed in PD. Follow ISO/TS16949 /AS9145 PPAP/APQP	Modified

The integration of non-DOD best practices into the DOD acquisition process visually represents the normative operational concept. The normative operational view, at

a glance is shown in Figure 13. It is important to point out that the knowledge-based manufacturing method recommended by the GAO is fully captured in the synthesis of DOD with non-DOD standards providing a production commitment at MS C.

The normative model reveals key changes over the current state DOD OV-1 by pulling the DOD PCA ahead prior to MS C. The PRR, in EMD, would then include the demonstration of process capability using the DOD PCA demonstration of process capability prior to MS C. This would pull the nature of the MRL ratings to a higher level of MRL 9 at the end of EMD. The necessary evidence of a functional production line at the end of EMD incorporates a full development and verification of the production line prior to production commitment at the end of EMD.

This CONOPS review sets up the development and analysis conducted in the thesis AOA. This synthesis would likely have to assure that development funding incorporates the manufacturing development fully prior to LRIP to launch a completed production line. In the alternative the full manufacturing development and demonstration could require long lead funding of a production contract that is pulled into EMD to build production items in the pre-PD phase rather than using LRIP to develop the final FRP manufacturing process.

Gardner (chapter 9.7), describes a two-part strategy—first to research potential best practices and secondly to provide an evaluation and implementation activity. Gardner’s approach is in agreement with the SEDP approach to problem solving. Improvement opportunity needs to be ingrained in organizational culture by including and empowering an improvement council to provide a way to evaluate and manage change. Each of the non-DOD best practices was at some point identified and was found to contribute to operational success and business improvements. This aligns with the SAE’s purpose to serve its members by developing standards to improve the industries they serve.

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IV. ANALYSIS OF ALTERNATIVES

A. DEVELOPING THE STUDY AOA MODEL

The study AOA forms a part of a SE problem solving effort examining a process that needs improvement in DOD acquisition practices with respect to production approval. This AOA captures an improvement potential by comparing the alternate production approval processes of the FDA, FAA, and automotive industry to the DOD approach and assesses industry best practices and that have shown superior results. Using the Air Force AOA handbook helped to model the assessment of best practices as found in an industry's QMS (such as the QS-9000 family of standards for the automotive industry), those practices of the FAA (aircraft sector), and the FDA (medical devices sector) (AFMC 2014). QMS best practices were identified and described by each of the study QMS types as ISO-9000 non-prescriptive and QS-9000 prescriptive QMS. The FAA and FDA regulatory process construct has been described by their respective federal regulations are found on agency websites. From the FAA website - FAA.gov and the FDA website FDA.gov respectively a high degree of fidelity their production approval processes are outlined. The government websites contained the relevant information in support of a comparative analysis needed for the AOA.

B. QUALITY MANAGEMENT STANDARDS COMPARISON

The differences between QMS approaches of ISO-9000 and QS-9000 were significant for the unique U.S. requirements driven by Ford, General Motors and Chrysler and the more global ISO standards development. The QS-9000 included additional business processes such as planning, customer satisfaction, continuous improvement, manufacturing capabilities and advanced quality planning. The automotive industry needed a uniformly prescriptive set of instructions as best practices using their experience and influence to advantage. The desired improvements in manufacturing capabilities needed to be confirmed by a PPAP submission of a warrant prior to production. The American OEMs also knew that improved production outcomes needed manufacturing development best practices as an enabling companion to the PPAP. The development

standards for manufacturing employed the APQP, a synergistic partner communicated by guidelines as advanced by the AIAG consortium.

The aerospace and defense sectors adopted the ISO-9001 standard and embedded it into the aerospace QMS AS-9000 and conforming later the release of the AS-9100 QMS. Aerospace (including National Aeronautics and Space Administration, Aerospace, and Defense) unified their approach, but unlike the automotive QMS, the aerospace standards stayed more aligned to the generic best practices found in the ISO-9000.

The DOD could invoke by contract the use of the AS-9100 QMS for prime contractors but did little to standardize this application of a QMS in supply networks leaving supply chain management to each prime contractor. The DOD did not require any customer specific or prescriptive practices differentiating DOD contractors as adherents of the ISO-9000 type of QMS.

The adoption of the QS-9000 standards as a requirement for suppliers found over time that there were considerable quality, economic and customer satisfaction gains. The AIAG and the ASQ had an interest in measuring the impact of the constituent supplier application in the new automotive QMS. Specifically they wanted to measure if the OEM's quest to improve product quality and regain market share through applying the QS-9000 QMS was working. Many participating organizations were interviewed and captured these results in an ASQ survey. This survey was conducted ten years after QS-9000 introduction in 1997 with a confirming follow-on survey in 1998.

Subsequently the McGraw-Hill company conducted a survey of ISO-9000 companies (comparable to the DOD AS9100 QMS application). The comparison and basic affect is given in stark contrast showing significant differences in quality in application of those suppliers adopting the QS-9000 standards and the McGraw-Hill survey (see Table 13) (AIAG/ASQ 1997;Naveh, Marcus and Koo Moon 1999).

The automotive industry standards established a common product and process development language between OEM and supplier. There were common expectations following the common QMS for design and production authority within the supply chain at the global sourcing level. OEMs were able to have requirements flow down to supplier

organizations dendritically. The intent to have one QMS identified with proven methods paid-off. Suppliers were required to satisfy OEM minimum requirements and submit evidence that products would meet product and production performance targets prior to an OEM's production commitment.

Table 13. Survey Benefit Results—ISO Vice QS-9000 QMS

Survey	Number of Respondent	Cost to Register	Maintenance Costs	Economic Benefits	Quality Defect Rate
QS 9000	Combined	\$120,000	\$40,000	3 to 1 return on total costs	50% of respondents 50% reduction in defect rate due to
ASQ/AIAG1997 & 1998	800			improvement 6% of sales	QS 9000
ISO 9000	1100	\$156,000	Unreported	1.3 to 1 return on total cost	6% of respondents indicated a reduction in defect rate due to ISO 9000
McGraw-Hill 1999					

Member companies were required to conduct a third-party audit to establish compliance costing an average of \$40,000; see Table 13. Bandyopadhyay (1996, 12) confirmed this approximate fee averaged about \$50,000 to register including most preparation fees not expressly recorded in the survey findings.

1. Statistical Significance and Quality Standard Type

If an organization is to seek to improve business processes then various alternatives can be competed to find a better approach. A selection between two processes could be evaluated by a comparison of two treatments. If each treatment had many trials that expressed results as success or failure then a best process could emerge based on this performance. In this study of production approval process alternatives the ISO-9000 QMS as one treatment – characterized by its non-prescriptive approach and the QS-9000 QMS as a second treatment – characterized by its prescriptive approach. The DOD acquisition approach considers a prime contractor that adheres to the ISO-9000 or AS-9100 type QMS. Then non-DOD organizations that use a prescriptive QMS like the automotive QS-9000 or the regulated FAA and FDA acquisition processes.

To contrast the survey results the key question asked in each trial group (survey respondent) was to assess if there was an improvement observed under the treatment application of their respective QMS types. The ISO QMS type showed quality improvement in just 6% of 1100 cases. In the Automotive type QMS they recorded an improvement in 50% of respondents in 800 cases. The results of these trials were able to show a significant difference with the automotive QS-9000 QMS had better quality results than the ISO-9000 QMS. In this way, a reviewer could discriminate between processes if the differences observed were sufficient to recommend one treatment as better than the other where the differences were not due to randomness and change from sampling alone. Data was analyzed from the commercial surveys providing the production outcomes by QMS type. A test of significance at the $(1 - .05 \text{ alpha})$ level was conducted. See Table 14. The results confirm that there is a significant difference observed at the alpha .05 level with a p-value of 0.000. Those respondents that used the ISO-9000 standard of Treatment A versus those that used the QS-9000 of treatment B were found different favoring the QS-9000 QMS as providing superior quality improvement.

Table 14. Survey Benefit Results—ISO Vice QS-9000 Test of Significance

Two Sample Proportions - TEST ISO-9000 QMS vs QS-9000 QMS				
P value at the alpha .05 level = 0.000				
Quality System	Sample Size	Companies Reporting Improvement	Fraction of Companies Improved - Sample (P)	Survey Source
Treatment A ISO-9000*	1100	66	0.06	McGraw-Hill 1999
Treatment B QS-9000**	800	400	0.5	AIAG/ASQ 1997/8
Note: 95% CI for $p(QS) - p(ISO)$: (0.402618, 0.477382) Estimate for $p(QS) - p(ISO)$: 0.44 Test for $p(QS) - p(ISO) = 0$ (vs not = 0): $Z = 23.07$ P-Value = 0.000 * ISO companies reported only 6% improved due to ISO 9000 as their QMS (no degree of improvement reported) ** QS companies reported that 50% improved at least 50% due to QS 9000 as their QMS				

In any survey study it is important to make an assessment regarding validity and reliability. Environmental factors show that each QMS matured in use about ten years. Each QMS type standard had at its core the same ISO 9000 elements. The primary difference between QMS standards was the enhancement defined by the guidance of the APQP and requirement of a PPAP. The PPAP used SPC to demonstrated process capability prior to production commitment. In addition, there was a global nature of each supply network surveyed with the ISO 9000 type QMS favoring more European respondents with both QMS used in a global economy. The repeat nature of the QS-9000 survey showed similar, in position, results of respondents being just separated by time. Therefore, the commercial surveys cited were found to have validity and reliability.

2. Benefits of Prescriptive Quality Standards

The published surveys by ASQ/AIAG and McGraw Hill indicated that the automotive industry's ISO enhanced standards (QS-9000 /ISO/TS-16949) performed remarkably better with respect to quality outcomes than the ISO based QMS as used in the DOD. The QS-9000 based QMS surveys revealed a benefit analysis captured in a presentation by Ireland (2000), citing that AIAG/ASQ 1998 Quality Survey, "Cost Benefit Summary with 600 Respondents":

Of the 600 survey respondents using the QS-9000 automotive quality management systems standards it was reported that sales increased by 6% or \$10,000,000 per company on average. The supply network applied the quality standards, received third party registration and followed the production approval approach of the automotive OEMs (Ireland 2000).

Ireland also reported (2009) that there was an increase in vehicle durability over that same period where vehicles improved their durability by more than 1.5 years; now averaging 8 years (Ireland 2009). *USA Today* agreed with Ireland in that the automotive vehicle reliability was increasing and that it continued to increase showing the average age of a vehicle on the road now exceeds 11.4 years (Bomey 2015).

Further study on vehicle durability over time showed that there was a correlation aligned to the adoption of the QS-9000 family of standards and the data published from the Office of the Assistant Secretary for Research and Technology, Bureau of

Transportation Statistics , (USDTOASR & TBOT), showing calendar year versus average age of vehicle on the road from 1980 to 2000 (USDTOASR & TBOT 2014). What is noticeable is that durability growth was flat from 1985 to 1990 prior to QS-9000. There was a continuation of sustained growth through 2000 based on the DOT reporting. The linear best line fit to the DOT age data from 1990 to 2000 can be projected at this same rate of growth linearly through 2015 (Figure 14).

The nature of these results shows mathematical correlation that the production approval process for the automotive industry was supported. Ireland (2009) reported that there were a number of organizational benefits from the use of the automotive standards:

- Suppliers realized cost efficiencies by the use of a common standard
- Suppliers realized product quality and reliability improvement
- OEM realized vehicle quality and reliability improvement
- OEM realized cost efficiencies by use of a common standard, 23

There were no similar quality improvements reported by the McGraw-Hill survey under the use of the ISO-9000 standard from 1100 respondents (Naveh, Marcus and Moon 1999). The benefits of a prescriptive QMS as used in the auto industry provided the compelling reason for the development of a detailed functional analysis for AOA comparing alternate production approval processes.

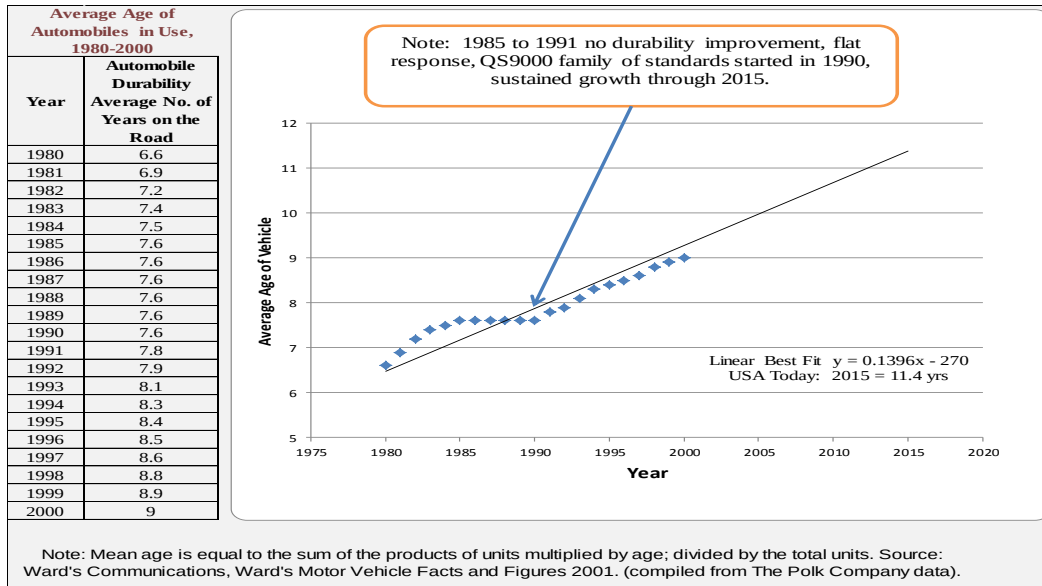


Figure 14. Automobile Durability Average No. of Years on the Road. Adapted from USDTOASR&TBOT (2014).

C. FUNCTIONAL ANALYSIS

Information concerning stakeholder needs leads to an identification of functional values and sub-values that develop discrimination criteria for the exercise of the AOA. The functional analysis helps define factors of a measurable effectiveness against identifiable alternative best practice behaviors.

A process of functional analysis starts with the higher-level requirements in stakeholder needs. Building upon the simple ICOM model the additional description with the DOD acquisition process can show the current and ideal state output (Figure 15). The output side of the ICOM model shows that there is a difference in expectations for poor and ideal production performance. By using the findings from the AIAG/ASQ and McGraw-Hill QMS surveys a case supporting a normative outcome was developed.

The underlying performance improvement in the automotive industry best practices is traced to the use of prescriptive quality standards. Production approval process alternatives could then address the gap between descriptive and the normative production process outcomes. Consider the supporting quote: “It must be possible to estimate how well a system is doing in its drive toward the goal or how closely one

option or another approaches the ideal” (Gibson, Scherer, and Gibson, 2007, 2). As shown in the ICOM diagram and the OV-1 model there is a contrast of results by organizational QMS type. See the descriptive OV-1 in Figure 12 and the normative OV-1 in Figure 13.

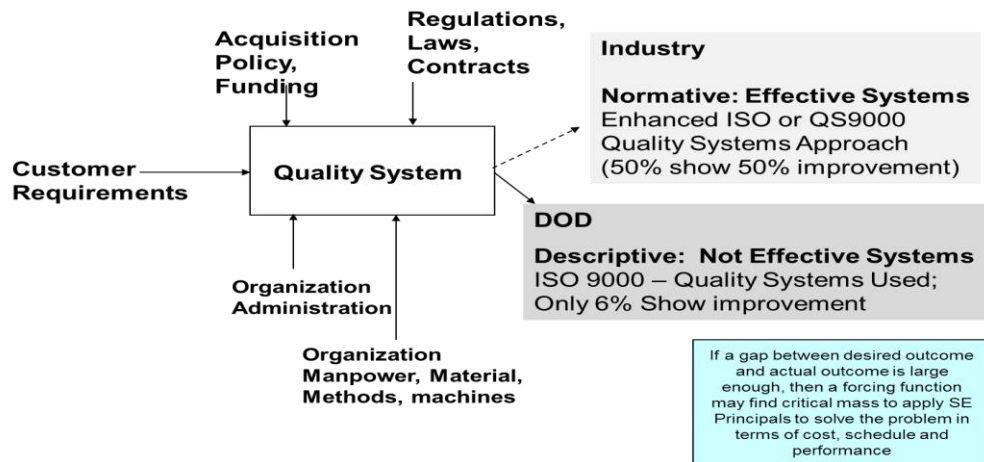


Figure 15. ICOM Model with Normative and Descriptive Output.

The value system for a production approval process has its genesis in the GAO’s reporting of the manufacturing related causal factors for poor production outcomes. When examining the manufacturing causal factors the study identified six key objectives for evaluation. See Table 15. The study value system of hierarchical functions and sub-functions are reviewable starting in Figure 16. The value system continues as derivative elements into measurable evaluation factors within the value stream establishing increasing fidelity into sub-functions. See Figure 17. For completeness of the study problem space, the shaded “gray box” items include notionally the two additional causal factors reported by the GAO related to poor production outcomes as excluded items in the study.

A structure tracing six binning categories for the higher-level objectives to various counting lower-level measurable sub-functions under each bin that applies. These lower level objectives are the countable measures of performance aligned to individual best practices in industry production approval processes. The element as a measurable

best practice under value element 1.1 is “QMS ISO-9000; AS-9100; ISO/TS-16949 w/ Certification” (Figure 17). The element 1.1 is then the lowest measure of performance (MOP) under study as a measurable objective. Reviewing all measurable objectives starts with objective 1.0 through objective 6.0 showing 37 identifiable evaluation items in the AOA. The MOP elements define a discrete listing of best practices in production part approval processes. The study MOPs are the countable number of individual best practices aligned in relation to the six objectives. For all 37 MOPs; see Figure 17 through Figure 22. Definitions for each measurable best practice MOP is found in the appendix. For more information see “Appendix K. MOP Rationale and Weighting Factors.”

The AOA’s ability to discriminate between alternatives under review is by the use of the six objectives defined as logical groupings of the countable best practices found in the non-DOD industry practices. These practices are articulated in the QS-9000 (ISO/TS-16949) family of automotive standards and guidance manuals. The reason these MOPs represent the normative best practices is from the accounting that these quality system standards produced the best production outcomes observed by the GAO and the assessments from the commercial surveys in review. These best practices align to the 11 normative production part approval best practice attributes and represent the prescriptive quality system captured in stakeholder needs (Table 15).

Table 15. SEDP Objective Binning for Countable Measures of Performance

Objective	Objective Description	Comment
1	Quality Systems	Type of quality system
2	Requirements Definition	The degree of specific requirements communicated for product and process
3	Design: Product / Process & Risk	Measurable Design Activities & Risk measurement
4	Product / Process Qualification	From the requirements, key measurable performance of product and process
5	Product / Process Quality Metrics	Measurable items of capability for product and process
6	Customer Satisfaction	Measurable feedback and status of customer satisfaction factors

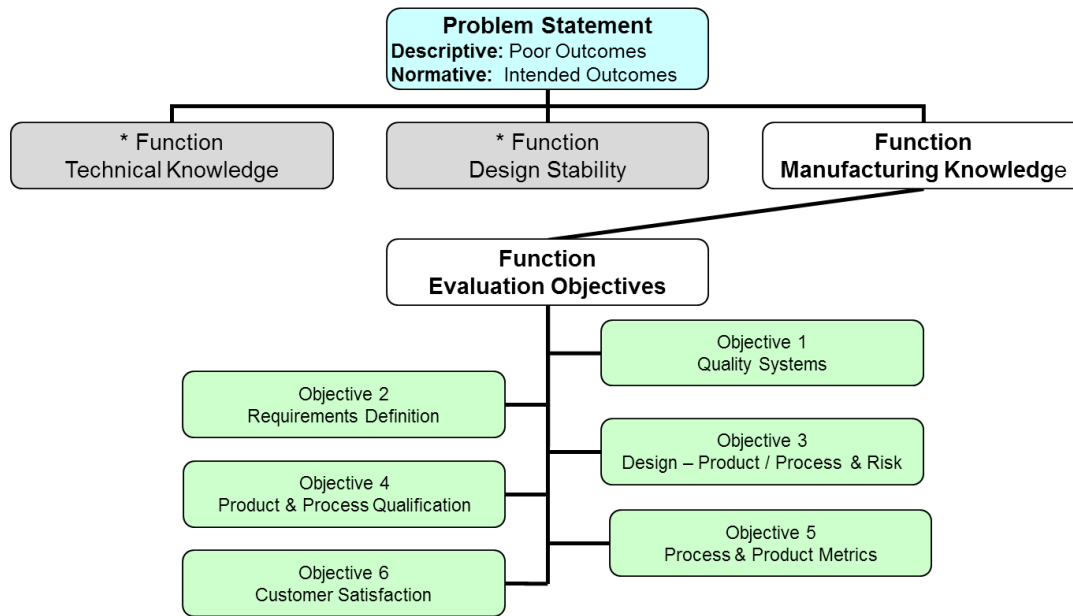


Figure 16. SEDP Value Stream—Key Study Objectives

The modeling of weighting factors was developed for the six high level objectives in the scoring system. Each objective is weighted by the mapping of the 37 individual MOPs and their association with 11 normative attributes. See Appendix K MOP Rationale and Weighted Factors. An aggregate total score sums across each of the six objective categories. If a given alternative under study did not use a listed best practice attribute, then it would not receive a counting value in the aggregate of the objective measure. An example of a notional raw data matrix worksheet shows how scores roll into the raw data matrix for each alternative (Table 16). By applying these weighting factors to the countable score of the assessment criteria, then a selection from the alternatives may emerge as a preferred best practice overall.

Table 16. .Notional AOA Excel Tool Raw Data Matrix Development.

Value Hierarchy Function (Measures of Performance)	Alternatives								Points Available	Weighting
	Alt 1		Alt 2		Alt 3		Alt 4		Points X Weighting is Score	
	Points	Score	Points	Score	Points	Score	Points	Score		
Obj 1	#	#	#	#	#	#	#	#	Obj Points	Weighting
Obj...										
Obj N	#	#	#	#	#	#	#	#	Obj Points	Weighting
TOTAL		0		0		0		0		

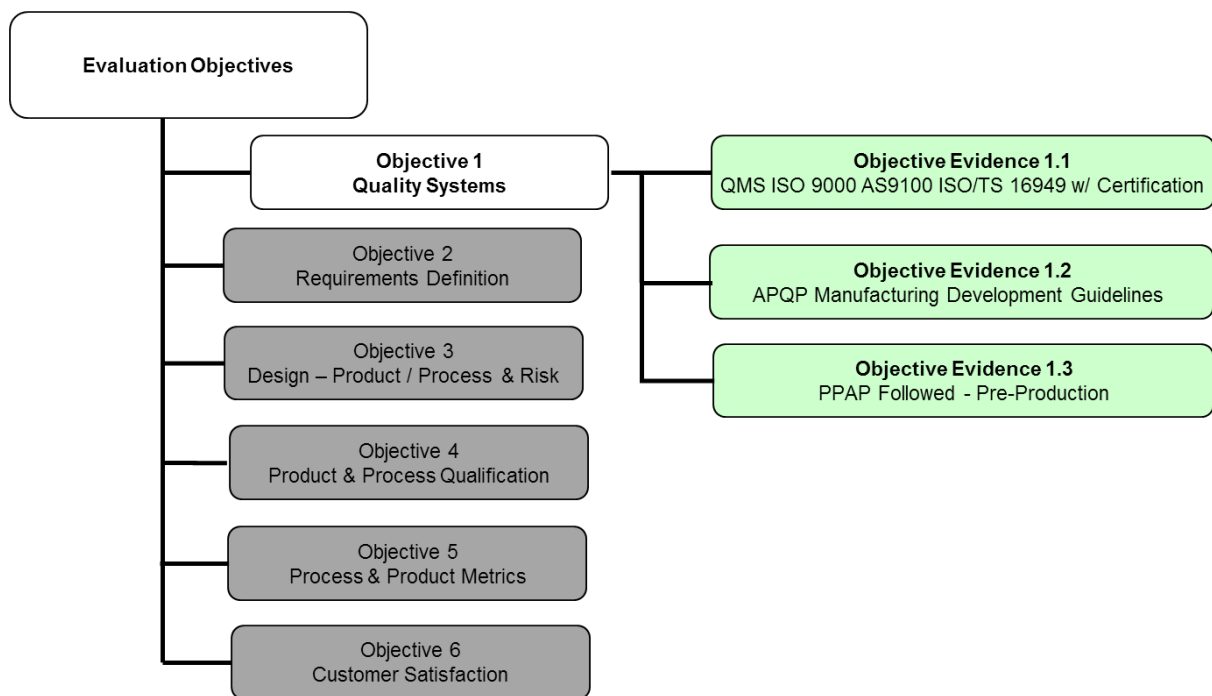


Figure 17. Objective 1 - Value Hierarchy—Quality Systems.

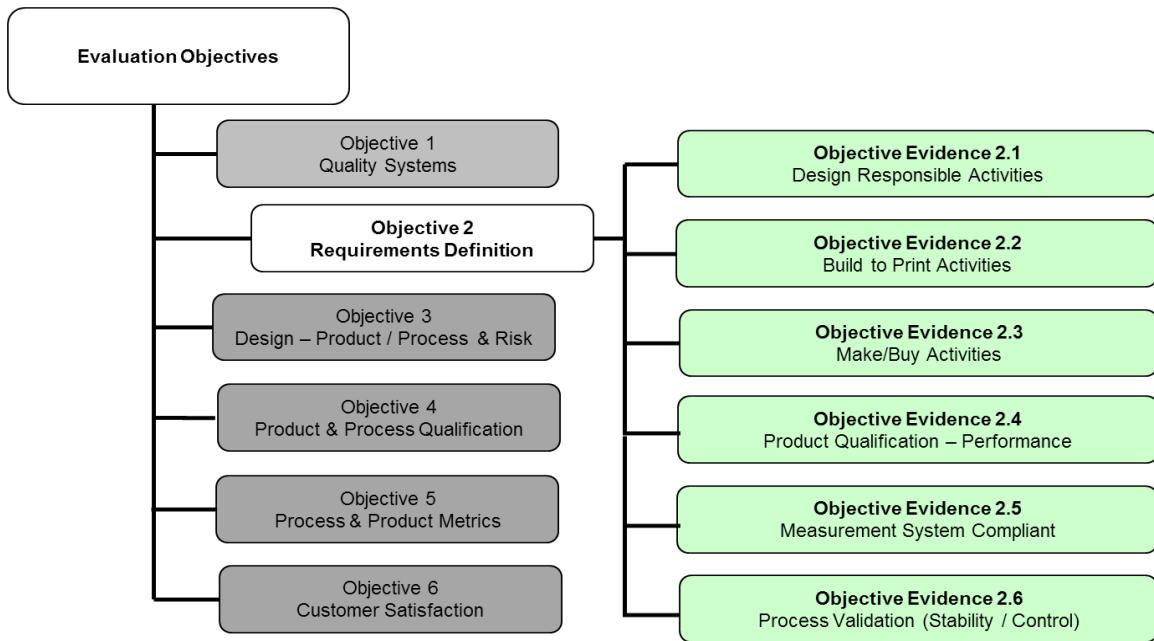


Figure 18. Objective 2 - Value Hierarchy—Requirements Definition.

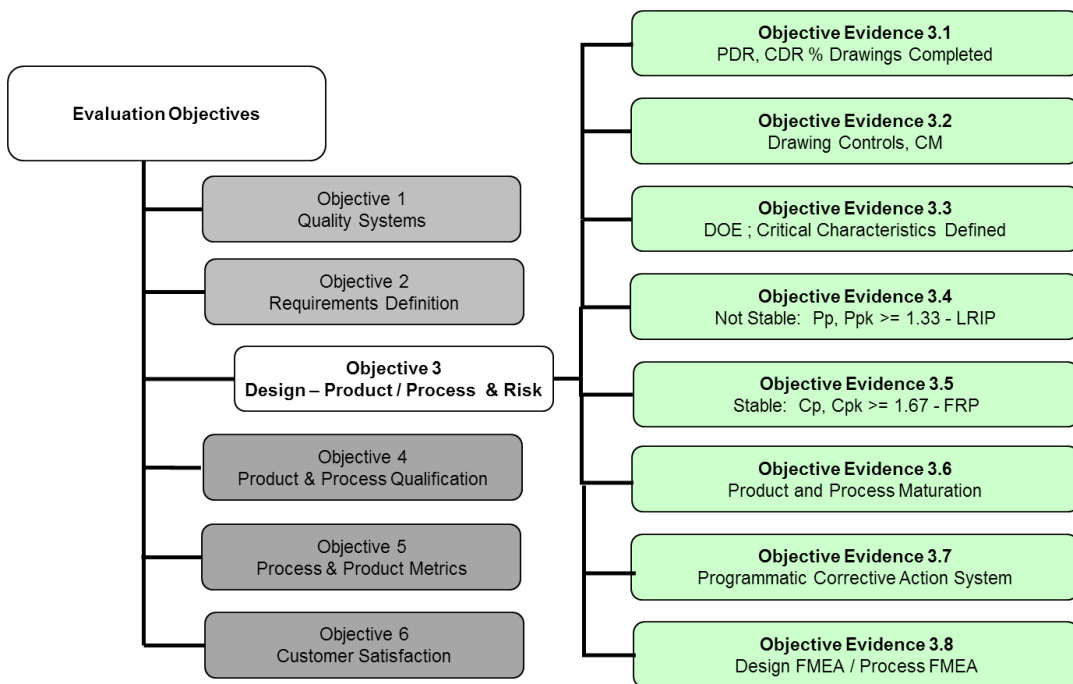


Figure 19. Objective 3 - Value Hierarchy—Design – Product / Process Risk.

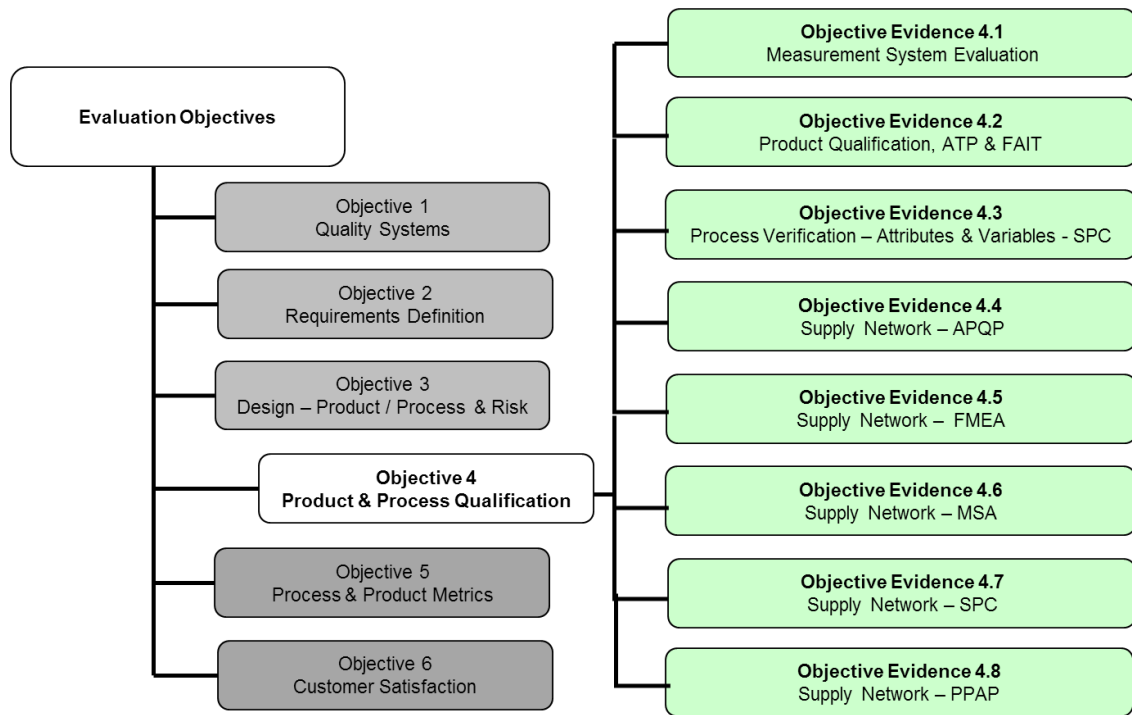


Figure 20. Objective 4 - Value Hierarchy—Product and Process Qualification.

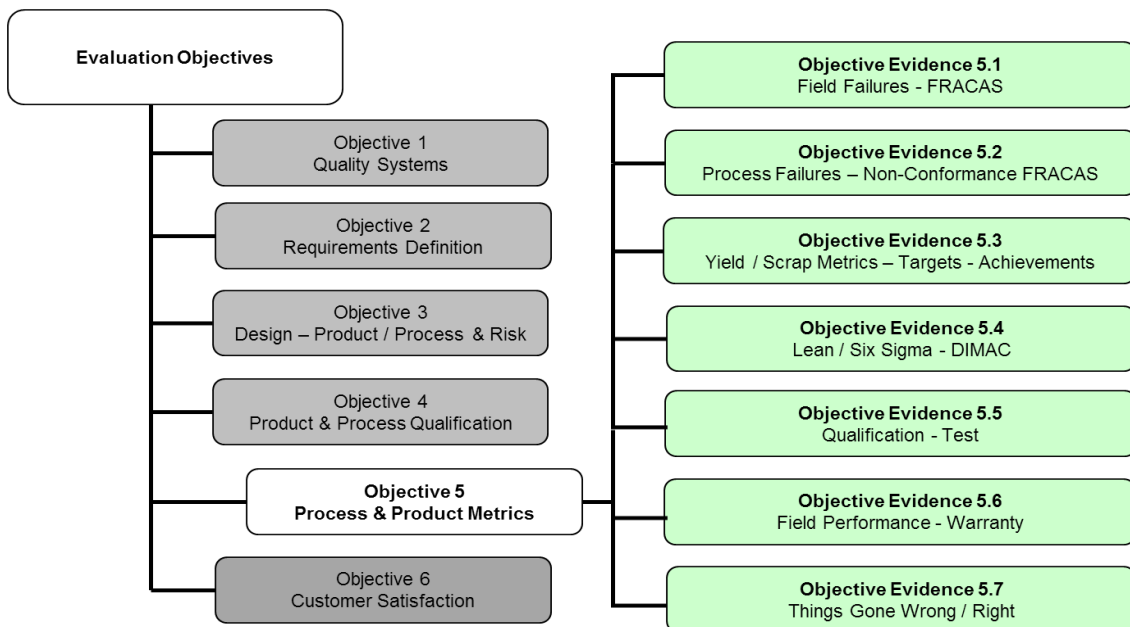


Figure 21. Objective 5 - Value Hierarchy—Product and Process Metrics.

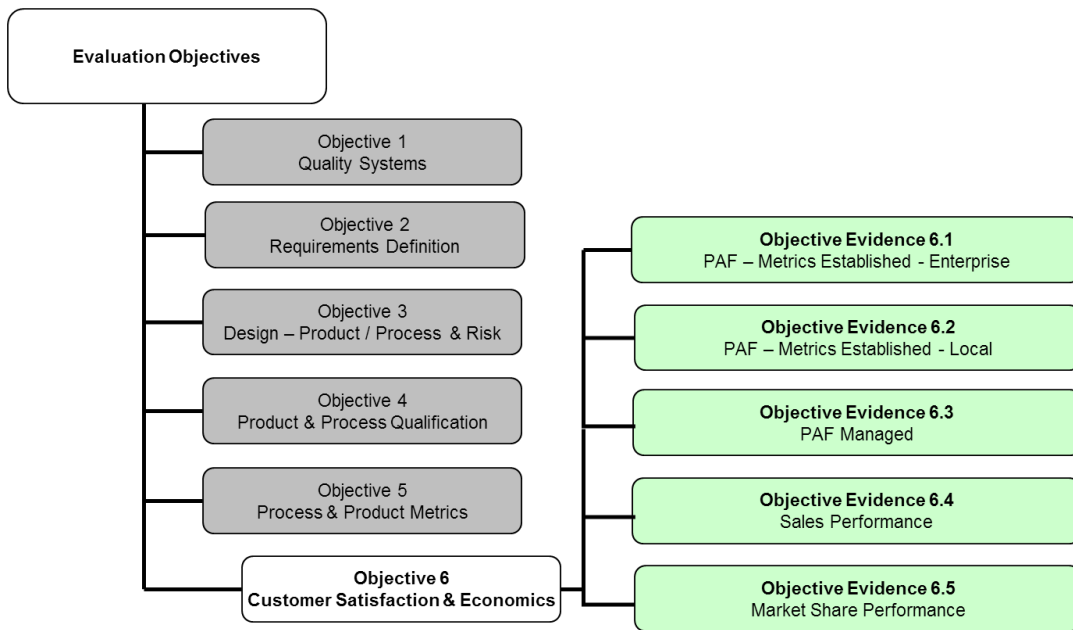


Figure 22. Objective 6 - Value Hierarchy—Satisfaction and Economics.

D. AOA DETAILS

The AOA with its objectives and defined MOPS allows a comparative scoring based upon an alternative's use of individual best practices. If the alternative production approval process utilizes a lower-level MOP best practice then a countable score would be awarded (Table 17).

Table 17. SEDP Detailed Lower-Level Measures of Performance

Manufacturing Knowledge Gaps and Measures of Performance	
Objective 1. Quality Systems	Sub-Function Measures of Performance
QMS, APQP & PPAP w/ 3rd Party Compliance	1. QMS - ISO 9000/ AS9100 / ISO/TS 16949 2. APQP Manufacturing Development Guidelines 3. PPAP Followed - Pre-Production
Objective 2. Requirements	Sub-Function Measures of Performance
Product & Process w/ PPAP Warrant	1. Common Training - infrastructure 2. Development Activities - APQP 3. Warrant Approach - PPAP 4. Product /Process - Performance – DFMEA/PFMEA 5. Measurement System Analysis 6. Process Validation (Stability & Control - SPC)
Objective 3. Design & Risk	Sub-Function Measures of Performance

Manufacturing Knowledge Gaps and Measures of Performance	
Product Definition, Maturity	1. PDR, CDR % Drawings Completed 2. Drawing Controls CM 3. DOEs - Critical Characteristics Defined
Process Definition - Stability and Control	4. Not Stable: Pp Ppk ≥ 1.33 - LRIP 5. Stable: Cpk ≥ 1.67 - FRP
Risks Mitigated & Issues Resolved	6. Product & Process Maturation 7. Programmatic Corrective Action System 8. DFMEA/PFMEA
Objective 4. Qualification	Sub-Function Measures of Performance
Product & Process Qualification Integration Supply Network	1. Measurement System Evaluation 2. Product Qualification - Qualification, Acceptance Test Procedure & First Article Inspection and Test 3. Process Verification - Attributes & Variables 4. Supply Network APQP 5. Supply Network DFMEA/PFMEA 6. Supply Network MSA 7. Supply Network SPC 8. Supply Network PPAP
Objective 5. Metrics	Sub-Function Measures of Performance
Corrective Action System Non-Conformance / Yield / Scrap	1. Field Failures - FRACAS 2. Process Failures – Non-Conformance FRACAS 3. Yield / Scrap Metrics - Targets - Achievements 4. Lean / Six Sigma Results - DIMAC
Reliability / Durability	5. Qualification - Test 6. Field Performance - Warranty 7. Things Gone Wrong / Right
Objective 6. Customer Satisfaction	Sub-Function Measures of Performance
Quality Economics	PAF Model of Quality Improvement 1. Metrics Established - Enterprise 2. Metrics Established - Local 3. PAF Managed
Business Economics	4. Sales Performance 5. Market Share Performance

In the SEDP approach, the AOA has a focus centered on high-level objectives and deriving lower-level functional requirements. These lower-level requirements challenge the solution space. In this study, the AOA identified functional requirements by first creating a value stream functional analysis. The input of the best practice tally goes into the tabular form to capture scores by alternative by objective. The scoring possible, for

each objective, is just the number of lower-level countable MOPs under that objective (See Table 18 through Table 20).

Table 18. SEDP AOA Results: Objective 1 and 2—Raw Evidence Tally.

Evaluation Category: Manufacturing Knowledge Gaps and Associated Measures of Performance Category by Alternative		MOPs Performed by Alternative			
		DOD Weapons	FDA Medical Devices	FAA Aviation	Auto Vehicles
1. Quality Systems	Objective MOP 1 Roll up ----->	1	3	3	3
QMS, APQP & PPAP w/ 3rd Party Compliance	1. QMS - ISO 9000/ AS9100 / ISO/TS 16949 2. APQP Manufacturing Development Guidelines 3. PPAP Followed - Pre-Production	1	1,2,3	1,2,3	1,2,3
2. Requirements Understood	Objective MOP 2 Roll up ----->	3	4	4	6
Product & Process w/ PPAP Warrant	1. Common Training - infrastructure 2. Development Activities - APQP 3. Warrant Approach - PPAP 4. Product /Process - Performance - FMEA 5. Measurement System Compliant (MSA) 6. Process Validation (Stability & Control - SPC)	2,5	2,4,5,6	2,4,5,6	1,2,3,4,5,6

Table 19. SEDP AOA Results: Objective 3 and— Raw Evidence Tally.

Evaluation Category: Manufacturing Knowledge Gaps and Associated Measures of Performance Category by Alternative		MOPs Performed by Alternative			
		DOD Weapons	FDA Medical Devices	FAA Aviation	Auto Vehicles
1. Quality Systems	Objective MOP 1 Roll up ----->	1	3	3	3
QMS, APQP & PPAP w/ 3rd Party Compliance	1. QMS - ISO 9000/ AS9100 / ISO/TS 16949 2. APQP Manufacturing Development Guidelines 3. PPAP Followed - Pre-Production	1	1,2,3	1,2,3	1,2,3
2. Requirements Understood	Objective MOP 2 Roll up ----->	3	4	4	6
Product & Process w/ PPAP Warrant	1. Common Training - infrastructure 2. Development Activities - APQP 3. Warrant Approach - PPAP 4. Product /Process - Performance - FMEA 5. Measurement System Compliant (MSA) 6. Process Validation (Stability & Control - SPC)	2,5	2,4,5,6	2,4,5,6	1,2,3,4,5,6
3. Design-Product/Process & Risk	Objective MOP 3 Roll up ----->	4	4	4	7
Design Definition, Maturity	1. PDR, CDR % Drawings Completed 2. Drawing Controls CM 3. DOEs - Critical Characteristics Defined	1,2	1,2	1,2	1,2,3
Process Definition - Stability and Control	4. Not Stable: Pp Ppk >= 1.33 - LRIP 5. Stable: Cp Cpk >= 1.67 - FRP	0	0	0	4,5
Risks Mitigated & Issues Resolved	6. Product & Process Maturation 7. Programmatic Corrective Action System 8. Design FMEA & PFMEA	6,7	6,7	6,7	7,8
4. Product & Process Qualification	Objective MOP 4 Roll up ----->	4	4	5	8

Table 20. SEDP AOA Results: Objective 5 and 6 – Raw Evidence Tally.

		MOPs Performed by Alternative			
Evaluation Category: Manufacturing Knowledge Gaps and Associated Measures of Performance Category by Alternative		DOD Weapons	FDA Medical Devices	FAA Aviation	Auto Vehicles
5. Process & Product / Metrics	Objective MOP 5 Roll up ----->	3	5	5	7
Corrective Action System Non-Conformance / Yield / Scrap	1. Field Failures - FRACAS 2. Process Failures – Non-Conformance FRACAS 3. Yield / Scrap Metrics - Targets - Achievements 4. Lean / Six Sigma Results - DIMAC	1,2	1,2,3	1,2,3	1,2,3,4
Reliability / Durability	5. Qualification - Test 6. Field Performance - Warranty 7. Things Gone Wrong / Right	5	5,6	5,6	5,6,7
6. - Customer Satisfaction	Objective MOP 6 Roll up ----->	2	4	4	4
Quality Economics	PAF Model of Quality Improvement 1. Metrics Established - Enterprise 2. Metrics Established - Local 3. PAF Managed	1,2	1,2	1,2	1,2
Business Economics	4. Sales Performance 5. Market Share Performance	0	4,5	4,5	4,5

The weighting factors are derived by the number of best practice attributes assigned to each of the six objectives. The score would just be the countable scored points times the weighting factor. The sum of the aligned weighting factors times the objective aggregate points for each alternative is the accumulated score for an alternative under study. The largest score would be the preferred solution.

An individual score was the result of counting the MOPs by alternative then rolling up the tallies as points. These tallies entered into the AOA Scoring matrix. The Microsoft Excel tool then multiplied the weighting factor against the points accumulated for each objective and for each alternative. The summation of the objective scores would be a total for the alternative. The preferred solution after scoring would be the alternative with the largest score. See Table 21. The study AOA fully assessed shows the results that differentiate upon the preferred solution. The study points to the automotive production approval process with a score of 127. The next closest competing alternative achieved a score of 89.

The results for the more prescriptive quality system, or QMS type, was significance given the finding of the AOA results involving the DOD, FAA, FDA and automotive industry. The production approval processes showing that the automotive industry approach was superior to all others for cost, schedule and performance over time. This analysis is one factor in determining the desirability of a new solution space for DOD acquisition practices. The APQP/PPAP process in the automotive industry demonstrated that there is a method in non-DOD industries that would satisfy the deficiencies pointed out by the GAO: 1) lack of standard and systematic methods and 2) lack of knowledge in contractor demonstration of production readiness prior to production commitment.

Table 21. SEDP AOA Results: Scored / Weighted and Preferred Solution

Value Hierarchy Function 3: Manufacturing (Measures of Performance)	Alternatives - Production Part Approval Processes								Points Available	Weighting
	DOD Points Score		FDA Points Score		FAA Points Score		Auto Points Score			
Obj 1 Evaluation 3.1 Quality Systems	1	7	3	21	3	21	3	21	3	7
Obj 2 Evaluation 3.2 Requirements Understood	3	9	4	12	4	12	6	18	6	3
Obj 3 Evaluation 3.3 Design-Product/Process & Risk	4	8	4	8	5	10	7	14	8	2
Obj 4 Evaluation 3.4 Product & Process Qualification	4	24	4	24	4	24	8	48	4	6
Obj 5 Evaluation 3.5 Process & Product / Metrics	3	6	5	10	5	10	7	14	7	2
Obj 6 Evaluation 3.6 - Customer Satisfaction	2	6	4	12	4	12	4	12	5	3
TOTAL		60		87		89		127		
Selection Based on Highest Score								Selected		

This research used the findings from the various commercial quality standards, the literature review and personal experience as a subject matter expert to develop the study assessment criteria. Each criterion defined needed to have the qualities as having a sustained and widespread use throughout its constituent industrial sector.

The application of these criteria differentiated among candidates that one alternative practice would be most effective. A best practice improvement for DOD application would close the knowledge gap as reported by the GAO concerning manufacturing practices. The inference is that an improved process that has proven to achieve better production outcomes for the automotive sector would similarly improve poor production outcomes in DOD acquisition. This assessment approach is part of a method for a comparison of perspective best practices as discussed separately by Gardner with his process focused organizational approach and Gibson with respect to the SEDP process (Gibson, Scherer and Gibson 2007; Gardner 2004).

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V. FINDINGS

A. SUMMARY

Acquisition costs and fleet readiness have been affected adversely by poor production outcomes related to a lack of manufacturing knowledge at MS C. An examination of DOD and non-DOD production approval processes identified an opportunity to improve affordability and military readiness by improving the DOD's approach to weapon systems production approval.

In this thesis, an analysis of alternatives examined a family of commercial best practices used by non-DOD industries that followed a more disciplined approach to manufacturing development than DOD acquisition. Quality standards used by the non-DOD industrial sectors validated manufacturing development and production capability with better production outcomes. The prescriptive QMS used by the automotive industry was significantly better than other alternatives. The AOA identified that the automotive approach is a preferred solution enjoying superior quality and improved product reliability.

Specifically, the application of the American automotive production approval process helped suppliers see a gain in market share, a reduction in costs and a doubling of fielded reliability as a result of implementing a unified and prescriptive QMS. Automotive development required a more disciplined approach to product and process realization than DOD acquisition practices. The prescriptive QMS of the automotive industry used a knowledge-based production approval process with a production submission warrant leading to production approval. The degree of improvement was evident by findings reported in commercially conducted surveys. A listing of supporting findings from this research includes:

- Department of Defense weapon systems production outcomes fall short of program goals with up to 34% of poor production outcomes coming from manufacturing and quality issues.

- Department of Defense acquisition policy provides minimal direction with respect to manufacturing development and verification of a production capability at MS C.
- Non-Department of Defense a production part approval processes helped identify industrial best practices that demonstrated that a prescriptive QMS (QS-9000) would improve quality and reliability better than non-prescriptive QMS (ISO-9000).
- Manufacturers experienced significant improvements in quality and reliability based on the applying the automotive QMS. This QMS guided manufacturing development with a prescriptive manufacturing development process - APQP and then required a demonstration of production capability prior to production start using a certification process - PPAP.
- The aerospace standards committee of the SAE realized in 2014 that the automotive approach would improve quality outcomes for the DOD and aerospace industry and added to the AS-9000 family of standards with the release of AS-9145 APQP and PPAP on November 8, 2016.
- Department of Defense technical authority structure could invoke the AS-9145 as a certification process to warrant production readiness compliance similar to non-DOD industries.

The DOD is able to invoke these or related standards through the applicable Code of Federal Regulations. See Title 48, sec. 46, higher QMS requirements (Code of Federal Regulations, title 48, sec. 46.202.4).

B. CONCLUSIONS

This study was significant in that it addressed a gap in the research with respect to manufacturing causality of poor production outcomes in DOD acquisition. The findings are significant identifying critical processes behind a more disciplined manufacturing development and demonstration of production capability in non-DOD industries. Non-

DOD industrial sectors required a certified demonstration of production readiness prior to production commitment and addressed the DOD's poor production outcome causal factors. Non-DOD production approval processes studied used a more prescriptive QMS where compelling evidence of improvement potential was confirmed by commercial surveys comparing industry QMS. Industries that followed quality standards that address manufacturing development using an advanced product quality planning process with a warranted production part approval process preformed significantly better as contrasted with non-prescriptive QMS as found in the AS-9100 and ISO-9000 standards.

C. RECOMMENDATIONS

The automotive industry has relied upon the APQP/PPAP as part of a disciplined SE application to the manufacturing development process and has been highly effective for decades. The PPAP warrant process, as required by the automotive OEMs, is flowed down to the lowest-level supplier showing consistency of process and production results. The DOD should adopt the APQP/PPAP process to support a disciplined manufacturing development toward an earlier demonstrated production capability at the end of EMD. This would likely bring the pre-FRP PCA into EMD as a process improvement in DOD acquisition.

The DOD should continuing developing workforce enhancement in their competency aligned organizations with respect to manufacturing expertise. Additional workforce enhancement could be realized by using a third party organization such as the AIAG to train and enable all suppliers across the industrial base adjunct to being compliant to a required prescriptive QMS. The DOD should update the manufacturing related policy documents needed to implement the preferred prescriptive QMS as a requirement for the DOD supply base. Updated acquisition guidance should be developed in support of the APQP and PPAP. The DOD application of AS-9100 revision D should be required with its related AS-9145 standard that calls for APQP and PPAP.

This study supports the standardization of production readiness demonstration for use in DOD acquisition. Prime contractors would engage their supply networks to apply the prescriptive QMS as a standard practice. Program management responsibility would

change from a reporting of manufacturing risk to a reporting of process capability in a knowledge-based approach. Technical authorities should identify production capability as a “critical performance parameter” that would be required to establish a certification process in acquisition and appropriately update the JCIDS to include guidance for a PPAP approach. Here, the TA serving as a chief engineer (CHENG) within a program would represent process capability demonstration under a warrant process. Finally, a pilot program on large scale would better assess the impacts and benefits in a DOD application of an APQP / PPAP.

The list of DOD acquisition structural enablers for APQP/PPAP implementation comes from an operational approach to include:

- Engage Stakeholders: (OSD[AT&L], DDRE, MANTECH, NDIA, COCOMs, AIAG, SAE, ISO, ASQ) Identify training roles and responsibilities.
- Synthesize Comparative Processes: DOD/SETR process with PCA to the ISO/TS 16949/AS9145 and the requirements of the PPAP with Technical Warrant / Certification – through Supply Management; SE Manufacturing and Quality.
- Engage the Policy Document Owners: Define Roles and Responsibilities – Within DOD policy, instructions and COCOMs (e.g., Naval Air Systems Command / Naval Sea System Command, Air Force and Army).
- Engage a third party expertise to enable the supply network, such as the role found in the AIAG automotive consortium with respect to training and implementation of the APQP/PPAP.
- Consider Acquisition Reform in contracting for DOD Weapon’s System programs where the role of enhanced QMS is standard and by exception if not used.
- Consider identifying pilot contracts for implementation using AS9100 C Clause 3.2 for APQP and PPAP customer requirements according to FAR

46.202-4 (see AS-9100:2016 with attachment of AS9145 - - November 2016 release) to impact the entire supply network of a prime contractor.

- Strengthen the workforce competency, experience, and requirements to address what is the current state of DOD acquisition practices covering poor production outcomes impact related to manufacturing and a transition to the use of AS9145.
- Apply a warrant process for production readiness as described in the SAE standard, AS-9145 APQP and PPAP with its PSW requirement. The purpose of the warrant leverages the benefits of this research as a best practice (Appendix E – DOD Technical Warrants).

The DOD should examine the APQP/PPAP approach from any wide spread pilot program within the DOD acquisition process as a pathfinder for deploying a knowledge-based acquisition for production approval. There is a presumption that this best practice from the automotive industry is now accepted by the SAE through the new AS-9145 standard as modeled after the automotive best practices (SAE 2015).

DOD would develop results using a knowledge-based production readiness approach while lowering the current risk-based manufacturing readiness practices. Results of production readiness demonstration would inform the MDA acquisition executives with confidence in an actual system at MS C.

D. FUTURE STUDY

Future study could include other items that would support this thesis that could not be employed due to lack of time or funding. The following list includes potential relevant ideas which do not fall within the scope of this thesis.

- Develop detailed policy change documents covering the DAS including:
- JCIDS; DAG; SYSCOM Instructions; MIL-HDBK-896 with AS9145
- Interview the SAE G-14 members that developed the AS9145 APQP / PPAP and their constituents

- Develop Interview Questions; Identify Subjects; Submit to IRB for review; Conduct Interview; Analyze Results
- Develop an operational implementation strategy and templates for all SYSCOM implementation: Contract Language; CDRLS; DIDs; SOWs; TEMP; CDP
- Define Manufacturing Requirements for DOD Specification application Cpk; Ppk; Yield; PSW format and content
- Develop strategy for Technical Warrant issuance for PSW in DOD contracting

APPENDIX A. PERRY MEMO

The William Perry memo is presented in its entirety and is provided verbatim.

THE SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1000
29 Jun 94

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
COMPTROLLER
ASSISTANT SECRETARY OF DEFENSE (COMMAND, CONTROL,
COMMUNICATIONS, AND INTELLIGENCE)
GENERAL COUNSEL
INSPECTOR GENERAL
DIRECTOR OF OPERATIONAL TEST AND EVALUATION
DIRECTORS OF THE DEFENSE AGENCIES
COMMANDER-IN-CHIEF, U.S. SPECIAL OPERATIONS
COMMAND

SUBJECT: Specifications & Standards - A New Way of Doing Business

To meet future needs, the DOD must increase access to commercial state-of-the-art technology and must facilitate the adoption by its suppliers of business processes characteristic of world class suppliers. In addition, integration of commercial and military development and manufacturing facilitates the development of dual-use processes and products and contributes to an expanded industrial base that is capable of meeting defense needs at lower costs.

I have repeatedly stated that moving to greater use of performance and commercial specifications and standards is one of the most important actions that DOD must take to ensure we are able to meet our military, economic, and policy objectives in the future. Moreover, the Vice President's National Performance Review recommends that agencies avoid government-unique requirements and rely more on the commercial marketplace.

To accomplish this objective, the Deputy Under Secretary of Defense (Acquisition Reform) chartered a Process Action Team to develop a strategy and a specific plan of action to decrease reliance, to the maximum extent practicable, on military specifications and standards. The Process Action Team report, "Blueprint for Change," identifies the tasks necessary to achieve this objective. I wholeheartedly accept the Team's report and approve the report's primary recommendation to use performance and commercial specifications and standards in lieu of military specifications and standards, unless no practical alternative exists to meet the user's needs. I also accept the report of the Industry Review Panel on Specifications and Standards and direct the Under Secretary of Defense

(Acquisition and Technology) to appropriately implement the Panel's recommendations.

I direct the addressees to take immediate action to implement the Team's recommendations and assign the Under Secretary of Defense (Acquisition and Technology) overall implementation responsibility. I direct the Under Secretary of Defense (Acquisition and Technology) to immediately arrange for reprogramming the funds needed in FY94 and FY95 to efficiently implement the recommendations. I direct the Secretaries of the Military Departments and the Directors of the Defense Agencies to program funding for FY96 and beyond in accordance with the Defense Planning Guidance.

Policy Changes

Listed below are a number of the most critical changes to current policy that are needed to implement the Process Action Team's recommendations. These changes are effective immediately. However, it is not my intent to disrupt on-going solicitations or contract negotiations. Therefore, the Component Acquisition Executive (as defined in Part 15 of DOD Instruction 5000.2), or a designee, may waive the implementation of these changes for on-going solicitations or contracts during the next 180 days following the date of this memorandum. The Under Secretary of Defense (Acquisition and Technology) shall implement these policy changes in DOD Instruction 5000.2, the Defense Federal Acquisition Regulation Supplement (DFARS), and any other instructions, manuals, regulations, or policy documents, as appropriate.

Military Specifications and Standards: Performance specifications shall be used when purchasing new systems, major modifications, upgrades to current systems, and non-developmental and commercial items, for programs in any acquisition category. If it is not practicable to use a performance specification, a non-government standard shall be used. Since there will be cases when military specifications are needed to define an exact design solution because there is no acceptable non-governmental standard or because the use of a performance specification or non-government standard is not cost effective, the use of military specifications and standards is authorized as a last resort, with an appropriate waiver.

Waivers for the use of military specifications and standards must be approved by the Milestone Decision Authority (as defined in Part 2 of DOD Instruction 5000.2). In the case of acquisition category ID programs, waivers may be granted by the Component Acquisition Executive, or a designee. The Director, Naval Nuclear Propulsion shall determine the specifications and standards to be used for naval nuclear propulsion plants in accordance with Pub. L. 98-525 (42 U.S.C. §7158 note). Waivers for procurement of items already in the inventory are not required. Waivers may be made on a "class" or items basis for a period of time not to exceed two years.

Innovative Contract Management: The Under Secretary of Defense (Acquisition and Technology) shall develop, within 60 days of the date of this memorandum, Defense

Federal Acquisition Regulation Supplement (DFARS) language to encourage contractors to propose non-government standards and industry-wide practices that meet the intent of the military specifications and standards. The Under Secretary will make this language effective 180 days after the date of this memorandum. This language will be developed for inclusion in both requests for proposal and in on-going contracts. These standards and practices shall be considered as alternatives to those military specifications and standards cited in all new contracts expected to have a value of \$100,000 or more, and in existing contracts of \$500,000 or more having a substantial contract effort remaining to be performed.

Pending completion of the language, I encourage the Secretaries of the Military Departments and the Directors of the Defense Agencies to exercise their existing authority to use solicitation and contract clause language such as the language proposed in the Process Action Team's report. Government contracting officers shall expedite the processing of proposed alternatives to military specifications and standards and are encouraged to use the Value Engineering no-cost settlement method (permitted by FAR 48.104-3) in existing contracts.

Program Use of Specifications and Standards: Use of specifications and standards listed in DOD Instruction 5000.2 is not mandatory for Program Managers. These specifications and standards are tools available to the Program Manager, who shall view them as guidance, as stated in Section 6-Q of DOD Instruction 5000.2.

Tiering of Specification and Standards: During production, those system specifications, subsystem specifications and equipment/product specifications (through and including the first-tier reference in the equipment/product specifications) cited in the contract shall be mandatory for use. Lower tier references will be for guidance only, and will not be contractually binding unless they are directly cited in the contract. Specifications and standards listed on engineering drawings are to be considered as first-tier references. Approval of exceptions to this policy may only be made by the Head of the Departmental or Agency Standards Improvement Office and the Director, Naval Nuclear Propulsion for specifications and drawings used in nuclear propulsion plants in accordance with Pub. L. 98-525 (42 U.S.C. §7158 Note).

New Directions

Management and Manufacturing Specifications and Standards: Program Managers shall use management and manufacturing specifications and standards for guidance only. The Under Secretary of Defense (Acquisition and Technology) shall develop a plan for canceling these specifications and standards, inactivating them for new designs, transferring the specifications and standards to non-government standards, converting them to performance-based specifications, or justifying their retention as military specifications and standards. The plan shall begin with the ten management and manufacturing standards identified in the Report of the Industry Review Panel on Specifications and Standards and shall require completion of the appropriate action, to the

maximum extent practicable, within two years.

Configuration Control: To the extent practicable, the Government should maintain configuration control of the functional and performance requirements only, giving contractors responsibility for the detailed design.

Obsolete Specifications: The “Department of Defense Index of Specifications and Standards” and the “Acquisition Management System and Data Requirements Control List” contain outdated military specifications and standards and data requirements that should not be used for new development efforts. The Under Secretary of Defense (Acquisition and Technology) shall develop a procedure for identifying and removing these obsolete requirements.

Use of Non-Government Standards: I encourage the Under Secretary of Defense (Acquisition and Technology) to form partnerships with industry associations to develop non-government standards for replacement of military standards where practicable. The Under Secretary shall adopt and list in the “Department of Defense Index of Specifications and Standards” (DoDISS) non-government standards currently being used by DOD. The Under Secretary shall also establish teams to review the federal supply classes and standardization areas to identify candidates for conversion or replacement.

Reducing Oversight: I direct the Secretaries of the Military Departments and the Directors of the Defense Agencies to reduce direct Government oversight by substituting process controls and non-government standards in place of development and/or production testing and inspection and military-unique quality assurance systems.

Cultural Changes

Challenge Acquisition Requirements: Program Managers and acquisition decision makers at all levels shall challenge requirements because the problem of unique military systems does not begin with the standards. The problem is rooted in the requirements determination phase of the acquisition cycle.

Enhance Pollution Controls: The Secretaries of the Military Departments and the Directors of the Defense Agencies shall establish and execute an aggressive program to identify and reduce or eliminate toxic pollutants procured or generated through the use of specifications and standards.

Education and Training: The Under Secretary of Defense (Acquisition and Technology) shall ensure that training and education programs throughout the Department are revised to incorporate specifications and standards reform.

Program Reviews: Milestone Decision Authority (MDA) review of programs at all levels shall include consideration of the extent streamlining, both in the contract and in the

oversight process, is being pursued. The MDA (i.e., the Component Acquisition Executive or his/her designee, for all but ACAT 1D programs) will be responsible for ensuring that progress is being made with respect to programs under his/her cognizance.

Standards Improvement Executives: The Under Secretary the Secretaries of the Military Departments and the Director of the Defense Logistics Agency shall appoint Standards Improvement Executives within 30 days. The Standards Improvement Executives shall assume the responsibilities of the current Standardization Executives, support those carrying out acquisition reform, direct implementation of the military specifications and standards reform program, and participate on the Defense Standards Improvement Council. The Defense Standards Improvement Council shall be the primary coordinating body for the specification and standards program within the Department of Defense and shall report directly to the Assistant Secretary of Defense (Economic Security). The Council shall coordinate with the Deputy Under Secretary of Defense (Acquisition Reform) regarding specification and standards reform matters, and shall provide periodic progress reports to the Acquisition Reform Senior Steering Group, who will monitor overall implementation progress.

Management Commitment

This Process Action Team tackled one of the most difficult issues we will face in reforming the acquisition process. I would like to commend the team, composed of representatives from all of the Military Departments and appropriate Defense Agencies, and its leader, Mr. Harold Griffin, for a job well done. In addition, I would like to thank the Army, and in particular, Army Materiel Command, for its administrative support of the team.

The Process Action Team's report and the policies contained in this memorandum are not a total solution to the problems inherent in the use of military specifications and standards; however, they are a solid beginning that will increase the use of performance and commercial specifications and standards. Your leadership and good judgment will be critical to successful implementation of this reform. I encourage you and your leadership teams to be active participants in establishing the environment essential for implementing this cultural change.

This memorandum is intended only to improve the internal management of the Department of Defense and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the Department of Defense or its officers and employees.

/signed/
William J. Perry

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APPENDIX B. GAO MEMO

This memo from the GAO describes the ethics and professional standards that underpin their reports.



Memorandum

Date: June 2, 2015

To: GAO's Financial Management and Assurance Team (FMA)
CIGIE Financial Audit Community

From: James R. Dalkin, Director, FMA
Jessica Boucher, Eric Holbrook, William Lowrey, Greg Ziombra

Subject: Professional Standards Update No. 62
February 2014 through May 2015

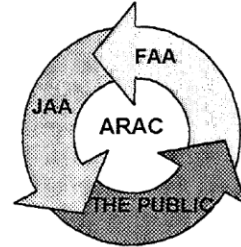
We issue Professional Standards Updates (PSU) to alert staff of changes in professional standards and related guidance. The PSUs highlight some key points concerning recent activity at standard-setting organizations. PSUs are not intended to provide comprehensive information on all standards. Those affected by a new standard should refer that standard for details.

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APPENDIX C. FAA MEMO

This memo from the FAA is an advisory in support of the regulations regarding production approval.

AVIATION RULEMAKING ADVISORY COMMITTEE



March 26, 2002

Mr. Nicholas A. Sabatini
Associate Administrator for Regulations and Certification
Federal Aviation Administration
800 Independence Avenue, S.W.
Washington, DC 20591

Subject: Transmittal of Documents in Support of ARAC 21 Production Certification and Parts Approval Tasking

Dear Mr. Sabatini:

This forwards the following documents, which have been prepared in support of the ARAC 21 Production Certification and Parts Approval tasking:

- Means of Compliance with Proposed Quality System Requirements; 2-20-02
- PAH Transition to New Quality System Requirements; 2-20-02
- Quality System Guidance; 11-26-01
- Proposed AC on Standard and Commercial Parts; 3-21-02
- ODAR; 3-21-02
- PDA Document; 11-26-01

This is the culmination of a long effort to enhance the safety of the production certification system for aeronautical products and those parts needed for continued operational safety.

FAA first began this effort in 1986. In 1993, FAA tasked ARAC 21 to develop recommendations for proposed regulations and guidance materials that would accomplish this safety objective. The preponderance of ARAC 21 recommendations on this tasking were submitted to FAA in 1999 and

would have enabled the FAA to proceed with the development of an Notice of Proposed Rulemaking. However, since an NPRM has not yet been developed, the ARAC 21, in anticipation that an NPRM would be forthcoming, continues to support the FAA with the development of additional recommended guidance for important aspects of this safety effort.

The industry and ARAC 21 respectfully request the FAA consider assigning a higher priority to this safety rulemaking effort.

Very truly yours,

A handwritten signature in black ink, appearing to read 'W. H. Schultz', with a stylized, cursive script.

W. H. Schultz
Assistant ARAC Chair
ARAC 21 Issues

Attachments

Copies:
John Hickey, AIR-1
Frank Paskiewicz, AIR-200

Recomm.

002
 Aircraft Cert. Procedures
 Production Cert. WG
 AIR-93-769-A
 59 FR 60185
Duplicate

Multiplato

	CONCURRENCES
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	INITIALS/SIGNATURE mrueller
	DATE 5/31/02
	ROUTING SYMBOL HWA
	INITIALS/SIGNATURE COURTNEY
	DATE 5/31/02
	ROUTING SYMBOL HWA
	INITIALS/SIGNATURE TF
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g	ROUTING SYMBOL
r	INITIALS/SIGNATURE
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- As indicated in a letter to you earlier this year, rulemaking in this area is important for several reasons. Most important are enhancements in safety and system efficiencies for industry and Federal Aviation Administration. Our Rulemaking Council has asked the program office to define the issues that should be in this rulemaking effort and present a plan to the Council for approval and assignment of resources. The Council will address this action at its next meeting.

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Sincerely,
Original Signed By
Margaret Gilligan

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APPENDIX D. SELECTIONS FROM DOD ACQUISITION POLICY

Item 1 - Selected portion of SECNAVINST 5000.2D

SECNAVINST 5000.2D
October 16, 2008

Chapter 7 Systems Engineering and Human Systems Integration

- References:
- (a) [DOD Directive 5000.1, The Defense Acquisition System, of 12 May 03](#)
 - (b) [DOD Instruction 5000.2, Operation of the Defense Acquisition System, of 12 May 03](#)
 - (c) [OPNAVINST 3960.16A](#)
 - (d) [SECNAVINST 4140.2](#)
 - (e) [DOD 4140.1-R, DoD Supply Chain Material Management Regulation, of 23 May 03](#)
 - (f) [ISO 9001 Quality Management Systems - Requirements](#) Supplemented by [AS9100 International Aerospace Quality Standard](#)

<u>Chapter 7</u>	Systems Engineering and Human Systems Integration
<u>7.1</u>	Systems Engineering
<u>7.1.1</u>	Manufacturing and Production
<u>7.1.2</u>	Quality
<u>7.1.3</u>	Acquisition Logistics and Sustainment
<u>7.1.4</u>	Open Architecture
<u>7.1.5</u>	Reliability, Availability, and Maintainability (RAM)
<u>7.1.6</u>	Interoperability and Integration
<u>7.1.6.1</u>	IT Design Considerations
<u>7.1.6.2</u>	DoD Architecture Framework/Defense Information

Item 2 - Selected portion of SECNAVINST 5000.2D, paragraph 7.1.2:

7.1.2 Quality

The quality program should ensure the use of best engineering, design, manufacturing and management practices that emphasize the prevention of defects. Quality should be designed into the product through the systems engineering design process to define the product and process quality requirements. Contractors should propose a quality management process that meets required program support capabilities. The quality management system may be based on the fundamentals described in the ISO-9001 series supplemented by AS9100, International Aerospace Quality Standard, which provide a basic minimum quality management system model.

Additional advanced quality requirements should be considered for systems based on factors such as risk, design complexity, and maturity, process complexity and

maturity, safety, and economics. An advanced quality management system builds on a basic quality management system, especially during the design / development phase, by identifying critical product and process characteristics, design-to-manufacturing process capabilities, design for assembly and manufacturing, design to control process variability, process controls, continuous improvements, etc. The quality management approach should include an assessment of the contractor's quality management process and its implementation, including those related to assessments or oversight of subcontractors, suppliers, and special process facilities (e.g., heat treatment). The quality management system should provide timely notification and feedback to contracting and program offices in areas such as major and critical deficiencies, potential manufacturing process problems, and subcontractor, supplier, or special process facilities problems that potentially impact the program.

Item 3 - Selected portion of SECNAVINST 5000.2E, paragraph 6.1.2:

6.1.2 Quality

A process shall be in place to assure product quality during design, development, manufacturing, production, and sustainment. Quality is determined by the extent that products and services meet requirements and satisfy the customer at an affordable cost. A quality management system should monitor, measure, analyze, control and improve processes. Quality practices and quality requirements consistent with program complexity and criticality shall be used to assist in reducing risk, assuring quality, and controlling costs.

Reference (f) is a model for quality management systems. Contractors may propose alternative systems, as long as they are found technically acceptable by the SYSCOM technical authority and accomplish program objectives.

Item 4 – Select portions of the Defense Acquisition System

DODI 5000.02 policy statements related to manufacturing development with the underlined portions added for emphasis: (USD[AT&L] 2015)

Selection 1

(d) EMD Phase Completion. The EMD Phase will end when: (1) the design is stable; (2) the system meets validated capability requirements demonstrated by developmental and initial operational testing as required in the TEMP; (3a) manufacturing processes have been effectively demonstrated and are under control; (3b) software sustainment processes are in place and functioning; (4) industrial production capabilities are reasonably available; and (5) the system has met or exceeds all directed EMD Phase exit criteria and MS C entrance criteria. EMD will often continue past the initial production or fielding decision until all EMD activities have been completed and all requirements have been tested and

verified (26).

Selection 2

(10) MS C

(a) MS C and the Limited Deployment Decision are the points at which a program or increment of capability is reviewed for entrance into the P&D Phase or for Limited Deployment. Approval depends in part on specific criteria defined at Milestone B and included in the Milestone B ADM. The following general criteria will normally be applied: demonstration that the production/deployment design is stable and will meet stated and derived requirements based on acceptable performance in developmental test events; an operational assessment; mature software capability consistent with the software development schedule; no significant manufacturing risks; a validated Capability Production Document (CPD) or equivalent requirements document; demonstrated interoperability; demonstrated operational supportability; costs within affordability caps; full funding in the FYDP; properly phased production ramp up; and deployment support (27).

Selection 3

(12) Full-Rate Production Decision or Full Deployment Decision. The MDA will conduct a review to assess the results of initial OT&E, initial manufacturing, and limited deployment, and determine whether or not to approve proceeding to Full-Rate Production or Full Deployment. Continuing into Full-Rate Production or Full Deployment requires demonstrated control of the manufacturing process, acceptable performance and reliability, and the establishment of adequate sustainment and support systems (29).

Selection 4

Selection 4 comes from the DODI 5000.02 and the SE section found in this document's enclosure 3, paragraph 10 entitled "Manufacturing and Producibility." The DODI5000.02 states:

During the Engineering and Manufacturing Development Phase, program managers will assess the maturity of critical manufacturing processes to ensure they are affordable and executable. Prior to a production decision, the Program Manager will ensure manufacturing and producibility risks are acceptable, supplier qualifications are completed, and any applicable manufacturing processes are or will be under statistical process control (84).

Selection 5

Naval Air System Command Instruction (NAVAIRINST) in NAVAIRINST 4355.19D, (NAVAIR 2008) (underlining for emphasis added):

The Production Readiness Review (PRR) is an examination of a program to determine if the design is ready for production and the producer has accomplished adequate production planning without incurring unacceptable risks that will breach thresholds of schedule, performance, cost, or other established criteria. The full, production-configured system is evaluated to determine that it correctly and completely implements all system requirements, and whether the traceability of final system requirements to the final production system is maintained. **At this review the IPT shall also review the readiness of the manufacturing processes, the Quality System, and the production planning, i.e., facilities, tooling and test equipment capacity, personnel development and certification, process documentation, inventory management, supplier management, etc. A successful review is predicated on the IPT's determination that the system requirements are fully met in the final production configuration, and that production capability form a satisfactory basis for proceeding into LRIP and FRP** (124).

Selection 6

Naval Air System Command Instruction (NAVAIRINST) in NAVAIRINST 4355.19E, (NAVAIR 2015)

Criteria PRR:

Production baseline, Manufacturing, Producibility and Quality requirements are producible as verified by the results of the Incremental Production Readiness Reviews (iPRR)

Rationale:

Ensures that test data indicate readiness for production; ensures the specified manufacturing and quality requirements are captured in the production plans.

Selection 7

DODI 5000.02. See selection 6 and Table 2:

TECHNOLOGY READINESS ASSESSMENT (TRA)
SEC. 205, P.L. 111-23 (Ref. (an)) ASD(R&E)

STATUTORY A preliminary assessment is due for the Development RFP Release Decision Point. The Assistant Secretary of Defense for Research and Engineering (ASD(R&E)) will conduct an independent review and assessment of the TRA conducted by the Program Manager and other factors to determine whether the technology in the program has been demonstrated in a relevant environment. The assessment will inform the 2366b CERTIFICATION MEMORANDUM at Milestone B (in accordance with 10 U.S.C. 2366b (Reference (g))). The TRA at MS C is a Regulatory requirement when MS C is Program Initiation (57).

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APPENDIX E. DOD TECHNICAL WARRANTS

The following is a white paper written by William Ireland, at the Naval Postgraduate School and submitted on April 2, 2017, in support of his thesis, “Selection of an Alternative Production Part Approval Process to Improve Weapon Systems Production Readiness.”

Discussion

In the DOD, there is technical authority (TA) that interacts with programmatic authority over the life cycle phased weapons systems acquisition process. The manner of this interaction is through organizational alignment by competencies. Tomaiko, in his 2008 thesis, discusses the TA framework within the NAVSEA SYSCOM and the development of a new specialized certification. The SYSCOM TA comes from a competency-aligned delegation of authority. The effectiveness of introducing a new TA is explored:

In 2006, the Assistant Secretary of the Navy for Research, Development and Acquisition, ASN (RD&A), mandated the transformation of Naval Sea Systems Command (NAVSEA) into a Competency-Aligned Organization (CAO). A CAO fosters a competency-based approach to mission performance. A key objective of NAVSEA’s new CAO is to improve program management authority and contract authority through more effective technical authority. A key challenge facing NAVSEA in establishing a new CAO is aligning program management, contract, and technical competencies. This will require a common alignment of the engineering workforce across the Navy, as well as common policy development and implementation.¹

The TA approach is the subject of SECNAVINST 5400.15C dated September 13, 2007 and as updated and changed December 2, 2011.² The organizational construct representing TA is defined along technical workforce competencies. These organizational constructs are delegated authorities. Each competency is recognized as an authority that flows down through its supervisory chain. These chains of authority are further described in various policy documents and practices within the respective SYSCOMs. The Secretary of the Navy (SECNAV) delegates the TA through the operational Navy (OPNAV) and the SYSCOMs to lower level experts identified as Technical Warrant Holders (TWH) for certain key performance areas. The NAVAIR SYSCOM uses a CAO that follows their technical workforce competencies with few actual TWHs while NAVSEA SYSCOM follows a more commodity based designation with many TWHs.

Core beliefs in the technical authorities construct, as discussed by Tomaiko, is based on an assumption that asserts that a well behaved process will result in quality

¹ IMPROVING THE U.S. NAVY’S EXECUTION OF TECHNICAL AUTHORITY THROUGH A COMMON RISK MANAGEMENT AND TECHNICAL ASSESSMENT PROCESS by Thomas Andrew Tomaiko, 2008.

² SECNAVINST 5400.15C CH-, 1 ASN (RD&A), September 13, 2007 and 2 December 2011

acquisition outcomes. Enablers of the CAO TA approach is found in required periodic training and commitment levied on key acquisition personnel in order to maintain continuity of program oversight and execution.

Practices within certain valued threads of authority, such as safety, requires an independent communication path to leadership and milestone decision authorities. Typically, there is a reporting of status of significant technical issues to the SYSCOM commander. One example of a critical assessment related to safety examines flight worthiness. The flight worthiness assessment is a requirement that informs leadership by issuing a certificate of conformance or its denial. In this case, the NAVAIR SYSCOM conducts gate reviews over an item's life cycle acquisition development and assures the proper certificates are completed prior to Initial Operational Capability (IOC).

Certifications used to communicate compliance to key performance capabilities is based upon the item being able to show compliance objectively to accepted standards and reporting policies. SECNAVINST 5400.15 C states the certificate responsibility as coming from the CNO / CMC and delegated to the SYSCOMs, PEOs and DRPMs.

Technical, Programmatic and Certification Authority

Authorities, technical or programmatic, are described in the key policy documents defining the requirements for each SYSCOM derived from the SECNAVINST 5400-C, dated 2 DEC 2011. The instruction defines TA with its roles and responsibilities. The use of the terms that describe the role of a TA and certification follows closely a dictionary definition giving the common meaning of warrant. The actual exercise of granting a warrant and communicating compliance requires standards that show required adherence evidence in order to adjudicate a specific certification's requirements. Those involved in the technical and programmatic authority chain are responsible for issuing and communicating any warrant to decision makers. Refer to the definitions of authorities in DOD acquisition and the general meaning of warrant:

Definition 1:

(3) Technical authority (TA). TA is the authority, responsibility, and accountability to establish, monitor and approve technical standards, tools, and processes in conformance with applicable Department of Defense (DOD) and DON policy, requirements, architectures, and standards.

Definition 2:

Technical authority is the authority, responsibility and accountability to establish, monitor and approve technical products and processes are in conformance to higher authority policy, requirements, architectures and standards.

Programmatic authorities manage all aspects of assigned programs from concept to disposal, including oversight of cost, schedule and performance, and direction of life cycle management.

Certification authority is a special case of technical authority where there is authority to certify that products meet established standards. Specific certification authority is defined by the technical process documentation established by the cognizant technical authority.

Definition 3:

Select portions for the definition of “warrant”³
war·rant (wôr’ənt, wŏr’-) n.

Something that provides assurance or confirmation; a guarantee or proof

Authorization or certification; sanction, as given by a superior.

a. A warrant officer.

b. A certificate of appointment given to a warrant officer.

To capture briefly the dual role of a TWH there is the definition of a technical authority as associated to a workforce competency or office and the reporting of compliance to technical standards for key performance areas with certification or warrants:

Technical Warrant Holder: Significant delegated chain of authorities to a lead office/officer.

Certification or Warrant Process: Actions that lead to documenting compliance to the related authority and resultant certification or warrant granted within the domain of the authority.

Types of Technical Authority as Warrant Holders

With respect to types of authorities in this discussion is the TA that is delegated. Consider the SECNAVINST 5400.15C:

The SYSCOM Commanders are responsible for: providing for in-service support; providing support services to PEOs and DRPMs without duplicating their management functions; and serving as the technical authority and operational safety and assurance certification authorities for their assigned areas of responsibility.

As a practical matter, this delegation of TA is conferred to certain Chief Systems Engineers (CSEs) or the SYSCOM’s Chief Engineer (CHENG) by the commanders of the SYSCOMS to:

“(5) Exercise Technical Authority and certification authority for weapon and IT systems.”

One example of delegated TA is from the NAVAIR SYSCOM, where the CHENG for aviation manages the aviation baseline for Ship Design Managers (SDMs). In another case, the Cost Engineering Managers (CEMs) ensure independent cost

³ The Free Dictionary: URL: <http://www.thefreedictionary.com/warrant>, 9/29/2016.

engineering and estimating in support of Navy programs. Lastly, there is the Technical Area Expert (TAE) acting under the top CHENG as the Navy's expert in the assigned technical domain (e.g. NAVAIR - Air Vehicles; NAVSEA – Shipboard Pumps). Further, there have been Technical Process Owners (TPOs) who provide definition and documentation for the assigned technical processes (e.g. NAVAIR - Air Worthiness Certification). NAVSEA will define Waterfront and Depot Chief Engineers (CHENGs) and lead the technical efforts of the SYSCOMs from the waterfront and depots.

Technical Authority Policy and Manufacturing Competency

TA, as it applies to NAVAIR, NAVSEA, SPAWAR, NAVFAC, and NAVSUP, is derived by DOD TA policy that defines various types of Technical Warrant Holders (TWH). There are specific policies and instructions that define the roles for these technical, programmatic and certification authorities within the SYSCOMs. First, a TA is conferred upon through a competency office holder or individual who is considered a Technical Warrant Holder (TWH).

The TWH is chartered with establishing specific policy for resolving conflicts on technical decisions within their domain of delegated expertise and oversight responsibility. In addition, these authorities are assigned to support DOD acquisition to assure products meet requirements and obtain any necessary certifications and approvals to advance a product's development through the various gated technical reviews over the DOD life cycle acquisition phases. As stated in the OPNAV Instruction (OPNAVINST 5450.350), this TA is deployed to the NAVAIRSYSCOM stating the TWH responsibility:⁴

(5) Exercise Technical Authority and life cycle management for assigned programs and oversee core processes, operational safety, and assurance certification required to support the acquisition, in-service support, and disposal of weapon and IT systems.

In addition, the OPNAV INST confirms the relation to a competency as long as it is not chartered to another organization in the requirement stating:

(b) Management of shore activities, industrial management of depot maintenance activities, administration of DOD policies on manufacturing methods and technology and metrification;

Technical Authority for Manufacturing in DOD Acquisition

The SYSCOMs are similar to one-another in their application of TA within their respective CAO structures. The NAVAIR TA for manufacturing is derived from the systems engineering competency. The NAVAIR CHENG further delegates the TA for manufacturing to the division head of the Manufacturing and Quality organization as the workforce expertise for manufacturing. In this chain of authority, representing specifically the TA for manufacturing, the instruction does not identify a requirement for certification to warrant a contractor's readiness to produce. When a warrant or certification of compliance is defined within the TA there are associated standards and

⁴ OPNAVINST 5450.350 dated 24 Apr 2012

requirements that must be satisfied representing a key performance area. However, for Manufacturing and Quality it has fallen short of being a key performance area requiring certification. There are no standards related to manufacturing or a production readiness decision requiring a certification for production approval in the DOD acquisition. This lack of a standard manner to demonstrate process capability was observed by the GAO report on “Select Weapon Systems reporting that there was a lack of a standard approach for contractor’s compliance for production readiness. A standard would be needed for production readiness if process capability would become a key performance area for TA certification.

Current approval for production, in the NAVSEA case, acquisition practices follow a technical review process providing technical ownership across commodities of interest for its production readiness oversight. Presently, in NAVSEA, there are about 250 different specific TWHs representing particular commodities. In the NAVAIR case, the acquisition review process relies upon an approach that assesses an end item’s Production Readiness Review (PRR). The technical review process at PRR uses relatively few TWHs associated with workforce competencies, relying primarily on the TWH for manufacturing as to reviewing and reporting of risk with respect to production readiness.

In either case, the technical assessments of production readiness occur prior to Milestone C’s production decision. At MS C, a programmatic authority will then report if there are any significant manufacturing risks to decision authorities in a program’s capabilities production document (CPD) given to the MDA. While there is a Production Readiness Review used to report readiness risk, there are no policies, instructions or standards of compliance within the DOD manufacturing competency that could be used to certify, with a warrant, such readiness.

It is important to note that the Secretary of Defense (SECDEF), through the chain of Technical Authorities, identified “Manufacturing,” Integrated Logistics Support and T&E as equals in its instruction and guidance but only the manufacturing domain does not require a warrant as evidence demonstrating a compliance for readiness. The manufacturing performance area for oversight, by a TWH, was taken from the SECNAVINST 5400.15C dated September 2007:

(1) Oversee the core processes required to support the acquisition, in-service support, and disposal of weapon and IT systems. Core processes include: (a) Realistic and reasonable cost estimating; (b) Technology development and technical readiness assessment; (c) Systems engineering (acquisition and in-service) and development, including Environment, Safety and Occupational Health (ESOH) management; (d) Manufacturing; (e) Test and evaluation; (f) ILS (acquisition and in-service); (g) Installation; (h) Maintenance and modernization planning; (i) Configuration management;

In the current instruction, 2 December 2011 release, the manufacturing thread is somewhat ambiguous to TA delegation and oversight responsibility. On the other hand, technical readiness of an item relies upon qualification testing that demonstrates key functional performance and holds a much higher standard of review that is observed. One

example is the Technological Readiness Level (TRL) required by public law requiring a TRL level 6 prior to EMD.⁵ Additional functional performance verification prior to production often requires a demonstration of functional requirements under qualification testing and Operational Test and Evaluation (OT&E). Representative functional performance requirements and certifications are required to be documented in order to satisfy a production decision leading to Initial Operation Capability (IOC) and will include special certifications related to that end item.

Requirements, in the MRL and PRR sense, are not under certification reporting and there is no warrant to report readiness compliance demonstrating a production system's process capability. One aspect of the 2 December 2011 change to the SECNAVINST 5400.15 that shows the technical manufacturing thread in the TA obligation removed:

(1) Exercise management authority, including selection and application, over core capabilities that support the SECNAVINST 5400.15C acquisition, in-service support, and disposal of assigned weapons and IT systems. These capabilities include: (a) Business and financial management; (b) Life cycle logistics; (c) Test, evaluation and certification; (d) Technology evaluation(s); (e) Systems engineering (including ESOH management); (f) Installation, maintenance, and modernization; (g) Configuration management; and (h) Demilitarization and disposal.

When contrasting the DOD production readiness practices, to the automotive industry, one finds the automobile industry uses a model of compliance requiring a manufacturing readiness / production readiness defined by a certificated warrant process for production approval. Other industries, such as FDA and the FAA, all require a producer to demonstrate production readiness knowledge prior to production commitment by issuing a warrant as part of a Production part approval process (PPAP). The notion of issuing a certification that warrants a demonstrated capable production process is not a structure in the DOD CAO. As a model, the PPAP is a long standing best practice in the automotive industry and serves as a key performance area standard. The GAO 013 report was in support of creating a production readiness standard for DOD production approval, stating there is a need to look at process capability demonstration in a standardized manner.⁶ In 2010, this process of certification for production readiness was also recommended for use in the DOD by the National Defense Industrial Association (NDIA) (NDIA 2010, p19).⁷ Consider what is said by Tomaiko with regards to the need to develop and standardize the TA process on interoperability in DOD acquisition - Quoted directly (Tomaiko, 2008):

⁵ Manual for the Operation of the Joint Capabilities Integration and Development System (JCIDS)

⁶ Defense Acquisitions - Assessments of Selected Weapon Programs. RTC (Report No. GAO-13-294SP) Washington, DC: General Accountability Office, 2013.

⁷ NDIA Gulf Coast Chapter, 2010. Acquisition Excellence through Effective Systems Engineering; Systems Engineering Deficiencies and Corrections for Air-Launched Tactical Weapons. Panel Report, Arlington, VA: NDIA.

This thesis achieved its purpose of improving execution of Technical Authority by defining the relationship between program authority and Technical Authority and describing how to assess and improve the state of Technical Authority through common policy development and implementation. Still, more work needs to be done. Future research necessary to help the SYSCOMs implement a common risk management process includes development and deployment of an Integrated Assessment Tool (IAT). Future research also needs to include promulgating a common policy for developing Systems Engineering Plans, a common technical review process, a common total platform and interoperability certification process, and a common systems engineering training program.

In the case brought by Tomaiko, a more effective TA process was desired for the key performance area of interoperability. Fortunately, the TA on interoperability followed the recommendation discussed by Tomaiko. Now there is a complete certification process improvement in practice. Compliance for the certificated Interoperability requirements are given in the Interoperability Process Guide, dated 10 September 2012. The guide is managed by the Defense Information Systems Agency (DISA).⁸

Rationale for a DOD PPAP Warrant / Certificate

The automotive industry production approval process observes a stable commercial best practice giving acquisition oversight assuring a production part is ready to start production based on a set of PPAP standards. In the commercial case, a PPAP warrant holder represents that a production system of interest produces parts meeting requirements. This process is applied throughout an entire supply network in the exact same manner. The PPAP can be assembled from a bottom-up approach providing consistent evidence of compliance.

The automotive industry has relied upon the PPAP as a performance of a disciplined systems engineering application to the manufacturing development process and production ready demonstration. The PPAP warrant process is flowed from the original equipment manufacturer down to the lowest level supplier prior to production approval. A review of one reference in DOD guidance issued by the NAVAIR SYSCOM in the NAVAIRINST 4355.19D one finds that the instruction considered a very limited view of certification associated only to personnel in support of production readiness.⁹ There was attention to functional performance demonstration and production process readiness and planning (highlighted selections by the author). Production capability was to be assured at PRR. The requirements do not develop any description of what is meant by a “satisfactory basis for determining readiness.” If it was to be from objective manufacturing requirements demonstrated, no such production capability requirements are shown to be required. Reference the quote from NAVAIRINST:

⁸ Interoperability Process Guide, Version 1.0, dated 10 September 2012, Defense Information Systems Agency

⁹ NAVAIRINST 4355, 19E FEB 06 2015.

*The Production Readiness Review (PRR) is an examination of a program to determine if the design is ready for production and the producer has accomplished adequate production planning without incurring unacceptable risks that will breach thresholds of schedule, performance, cost, or other established criteria. The full, production-configured system is evaluated to determine that it correctly and completely implements all system requirements, and whether the traceability of final system requirements to the final production system is maintained. **At this review the IPT shall also review the readiness of the manufacturing processes, the Quality System, and the production planning, i.e., facilities, tooling and test equipment capacity, personnel development and certification, process documentation, inventory management, supplier management, etc. A successful review is predicated on the IPT's determination that the system requirements are fully met in the final production configuration, and that production capability form a satisfactory basis for proceeding into LRIP and FRP,** p. 124.*

In the current NAVAIRINST 4355.19E, the PRR requirements related to production and manufacturing readiness do not include a “basis of satisfaction” to be determined towards a production capability. The writers of version D anticipated some “basis of satisfaction” to be determined or assured but did not go as far as requiring an objective demonstration or certification as recommended by the NDIA in 2010. Reference the table on PRR requirements from NAVAIRINST 4355.19E:¹⁰

Criteria PRR	Rationale
c. Production baseline, Manufacturing, Producibility and Quality requirements are producible as verified by the results of the Incremental Production Readiness Reviews (iPRR)	Ensures that test data indicate readiness for production; ensures the specified manufacturing and quality requirements are captured in the production plans.

In the DOD technical review process, there is a system engineering review establishing a stable and manufacturable design at the Critical Design Review (CDR). The subsequent PRR review is the technical review leading to production start at MS C. The CDR and PRR reviews are conducted to ensure that functional test data and manufacturing risk indicate readiness. The specified manufacturing and quality readiness, that span CDR and PRR, rely solely upon manufacturing and quality planning and not on production capability that had a basis of being satisfied in the earlier version of the instruction. With a focus on the manufacturing review requirements, the CDR and PRR are simply defined:

CDR:

System and subsystem level analyses of producibility, manufacturing process, and process controls, [in] support [of] the product baseline

¹⁰ NAVAIRINST 4355.19E, 19E FEB 06 2015 p 42.

Ensures that contractors have processes and process controls in place to manufacture systems per the product baseline

PRR:

Product baseline, manufacturing, producibility and quality requirements are producible as verified by the results of the incremental production readiness reviews (IPRR- without a special definition)

Summary of Technical Authority Discussion in Manufacturing

The manufacturing solution that historically led the automotive industry to devise one standard approach for a PPAP warrant was the industry's response to poor automotive production outcomes in the 80's and foreign competition. This is similar to the GAO's findings that reported poor production outcomes, in the DOD, due to a lack of standard and demonstrated process capability at MS C. The need for a common approach for the automotive OEMs limited a proliferation of OEM standards that were a burden on the supply network. A common approach emerged that employed a set of prescriptive quality guidelines and a production approval requirement standard. These prescriptive standards were deployed with four overlapping activities called advanced product quality planning (APQP).¹¹

The APQP is used to guide best practices in the development of a manufacturing process. If this approach would be applied, within the DOD acquisition and TA constructs, it would serve to significantly reduce time and costs that are hard to assess with the endless different readiness approaches taken by contractors and their suppliers. One common approach would streamline and enhance production oversight and be able to use the PPAP standard for a certification warrant to realize quality improvement. The adaptation of the process capability using APQP and PPAP are described in brief:

APQP

Advanced Manufacturing – Prototype (where critical characteristics were identified) & Production Planning through final equipment validation (facilities planning & execution / equipment & process including sub-tier entity oversight – all PPAP) early process prove-out – (relied upon process potential).

PPAP

Transitions from the development phase to the production phase by a warranted production readiness demonstration. Customer acceptance (relied upon process capability – where critical characteristics were controlled).

The PPAP serves as the evidence of readiness to produce and is conducted prior to production. The PPAP is a handshake from advanced manufacturing to plant operations. A simplification of the PPAP requirement: a production part that meets functional requirements, has been manufacturing from a defined production environment,

¹¹ AIAG. 2008. Advanced Product Quality Planning and Control Plan (APQP) 2nd ed. Reference Manual, Advanced Product Quality Planning Working Group, Southfield: AIAG.

is produced under manufacturing controls, is run at production rates, parts show statistical a demonstrated capability and thereby assure production readiness at production start.

Benefits of the PPAP Warrant Process Surveyed

Surveys in the late 1990s by the American Society of Quality and McGraw-Hill allowed a comparison of the prescriptive quality systems known as the QS 9000 quality standards and the ISO 9000 quality standards (including AS9100) (ISO 9000 was common to DOD acquisition).¹² The prescriptive standards of the automotive industry revealed compelling evidence that the knowledge-based approach demonstrating process capability was superior to non-prescriptive quality standards based on the ISO 9000 series alone. The automotive prescriptive quality system achieved at least 50% improvement 50% of the time based on reduced scrap, improved reliability and improved profits. The ISO 9000 family of quality standards showed that only 6% of respondents improved quality by adherence to the standards.¹³¹⁴

Aerospace Standard - AS 9145

The success of the automotive industry best practices, of APQP and PPAP, had not gone unnoticed and is the reason why there is a new aerospace standard, released 11/2016, to adopt the APQP and the PPAP, reference SAE – AS9145.¹⁵ The APQP and PPAP are processes that show a solution space that has demonstrated success for over 25 years as a best practice in the automotive industry and has been largely adopted by the FAA and the FDA. Therefore, there is a need to develop a certification process for process capability, as a key performance area, in the DOD using the CAO and the TA construct to close the manufacturing knowledge gap reported by the GAO. This would close the knowledge gap in manufacturing tied to poor production outcomes from given the current lack of standard disciplined demonstration of process capability prior to production start.

Conclusion

The success of the automotive approach relies upon a third party consortium - Automotive Industry Action Group (AIAG). The AIAG has trained and maintained the knowledge base over the entire supply network on behalf of OEMs since the early 1990s. This success of APQP and PPAP has been given stature for consideration as a prescriptive standard for the aerospace industry by the Society of Automotive Engineers. The significantly more prescriptive standard AS9145 with certification warrant is now proposed by the Society of Automotive Engineers on behalf of the aerospace industry

¹² Naveh, Eitan, Alfred Marcus, and Hyoungh Koo Moon. 1999. ISO 9000 Cost - Benefit Survey. Quality management systems Update and Plexus Corporation, New York: McGraw-Hill Inc.

¹³ AIAG/ASQ. Quality Survey Results. Survey Workshop, Novi: Automotive Industry Action Group/American Society of Quality, 1997.

¹⁴ AIAG. 1998. 1998 Annual Quality Survey Report. Survey, Southfield: Automotive Industry Action Group.

¹⁵ Society of Automotive Engineers. 2015. Advanced Product Quality Planning (APQP) / Production Part Approval Process (PPAP). Issuing: G-14 Americas Aerospace Quality Standards Committee SAE International. Host: SAE.org URL: <http://standards.sae.org/as9145> (accessed April 3, 2017).

because that standards body recognized the superior production outcomes over the use of the ISO and AS9100 quality systems standards.

Therefore, this paper urges the adaptation of APQP and PPAP for DOD acquisition process improvement identifying Production Readiness as a key performance area requiring a certification warrant at MS C. These standards and guidelines for quality and manufacturing readiness are able to be applied within the framework of the Code of Federal Regulations but would need the DOD to update their policy and guidance with respect TA roles and responsibilities for manufacturing.

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APPENDIX F. DEALING WITH MULTIPLE QMS

When there is more than one quality management system, to satisfy multiple customer requirements, a supplier may adopt an approach that addresses each. This can occur when they serve customers that cross industries such as FAA, FDA and automotive that has industry specific standards for their quality management approach. If a supplier serves a DOD contractor, then there are unique requirements that, in general, follow either ISO 9000 or AS 9000 requirements for Quality Management Systems. One quality system may try to satisfy all such standards by a consolidation approach first addressing the common requirements of ISO 9000 and then with additional requirements treated in some unique manner such as:

The Company Quality Management System shall meet the requirements of the International Standard ISO-9001:2008.

Additional, for products sold to automotive application, the company quality management system shall comply with the requirements of the ISO/TS 16949 standard, as it appears in italic type with a (TS) preceding the statement.

Additional, for products sold as an aerospace application, the company quality management system shall comply with the requirements of the AS-9100 standard, as it appears in italic type with an (AS) preceding the statement.

Note: How to address multiple quality management systems given by the author's personal knowledge.

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APPENDIX G. DOD MEMO TO GAO

This memo from the DOD to the GAO is an example response to the findings of a GAO report on weapon programs.

DoD Response to GAO-10-439 Recommendations

GAO DRAFT REPORT DATED MARCH 12, 2010
GAO-10-439 (GAO CODE 120793)

**“BEST PRACTICE: DOD CAN ACHIEVE BETTER OUTCOMES BY
STANDARDIZING THE WAY MANUFACTURING RISKS ARE MANAGED”**

DEPARTMENT OF DEFENSE COMMENTS TO THE GAO RECOMMENDATIONS

RECOMMENDATION 1: The GAO recommends that the Secretary of Defense require the assessment of manufacturing readiness across DoD programs using consistent MRL criteria as a basis for measuring, assessing, reporting, and communicating manufacturing readiness and risk on science and technology transition projects and acquisition programs.

DOD RESPONSE: Partially concur. The Department of Defense recognizes that mature manufacturing processes and readiness are critical to achieving predictable and successful program outcomes. It also recognizes the value in assessing manufacturing risks during science and technology research on technologies planned to be incorporated into acquisition programs. Department of Defense Instruction (DoDI) 5000.02, Operation of the Defense Acquisition System, dated 8 December 2008 reflects an increased focus on manufacturing throughout the acquisition lifecycle for programs of all acquisition categories. Specifically, it establishes a framework to continually assess and mitigate manufacturing risks during the Analysis of Alternatives, 2366b certifications to Congress, Preliminary and Critical Design Reviews; and acquisition milestones.

The Department's new manufacturing readiness criteria will form the basis for assessing pertinent science and technology efforts, and acquisition programs throughout the acquisition lifecycle on programs of all acquisition categories. These criteria will be a tool to identify relevant manufacturing risks which require mitigation. These manufacturing readiness criteria are expected to be tailored for programs and will be included in the Department's criteria for systems engineering technical reviews; the Department's templates for Preliminary Design Review/Critical Design Review reports; and acquisition phase exit criteria. These manufacturing readiness criteria will also be assessed as part of the Program Support Reviews which the Department conducts on Major Defense Acquisition Programs. These reviews evaluate manufacturing as part of an overall integrated program assessment. These manufacturing readiness criteria and products will be made available to government and industry. Their use by the Services on lower ACAT programs will also be encouraged. The Navy's Gate Review process currently assesses manufacturing risks but is being updated with the new manufacturing readiness criteria.

DoD Response to GAO-10-439 Recommendations

RECOMMENDATION 2: The GAO recommends that the Secretary of Defense direct the Office of the Director, Defense Research and Engineering to examine strengthening the MRL criteria related to the process capability and control of critical components and/or interfaces prior to the Milestone C low rate initial production decision.

DOD RESPONSE: Concur. Department of Defense Instruction 5000.02 directs that programs at Milestone C have no significant manufacturing risks; that manufacturing processes have been effectively demonstrated in a pilot line environment; and manufacturing processes are under control (if Milestone C is full-rate production). While the Department notes that all manufacturing processes do not warrant the same level of process capability and control, appropriate levels of control are certainly warranted on a case by case basis.

The Department will examine strengthening the manufacturing readiness criteria related to process capability and control of critical components and/or interfaces prior to the Milestone C low rate initial production decision. However, program offices and contractors should continue to have the latitude to jointly agree on the targets and specific process control demonstrations required on the pilot production line during the Engineering and Manufacturing Development to ensure success.

RECOMMENDATION 3: The GAO recommends that the Secretary of Defense direct the Office of the Director, Defense Research and Engineering to assess the need for analytical models and tools to support MRL assessments.

DOD RESPONSE: Concur. The Department will collaborate with government services, contractors, and academia to capture knowledge and provide improved tools for government and contractor usage in conducting assessments of manufacturing readiness as part of systems engineering technical reviews and milestone reviews.

RECOMMENDATION 4: The GAO recommends that the Secretary of Defense assess the adequacy of the manufacturing workforce knowledge and skills base across the military services and defense agencies and develop a plan to address current and future workforce gaps.

DOD RESPONSE: Concur. We agree that the production, quality and manufacturing (PQM) career field has suffered erosion, as have other DoD career fields. The USD (AT&L) Director of Human Capital has launched a review of the PQM career field design to identify the skills, knowledge and training required at each level of career progression in order to develop training courses and evaluate progression of anticipated DoD planned new hires. The Department has started to implement hiring and retention strategies to mitigate the potential loss in experienced, senior-level PQM talent and increase the size of the manufacturing workforce. As part of the Secretary's growth strategy and other initiatives, the PQM career field is projected to grow approximately

APPENDIX H. CFR, TITLE 48, 46.202.4

Code of Federal Regulations

FAR Part 46

Code of Federal Regulations, title 48, 46.202.4 is the Federal Acquisition Regulations (FAR) for Higher-level contract quality requirements 46.202-4.

eCFR Electronic Code of Federal Regulations, 2015.

48CFR46.202.4(2015)

Date accessed 8/2/15

e-CFR data is current as of August 28, 2015

URLs:

<https://www.acquisition.gov/?q=browsefar>

http://www.ecfr.gov/cgi-bin/text-idx?SID=b3db0004232a54dfb141afc9ee3a86af&mc=true&node=se48.1.46_1202_64&rgn=div8

Host:

<http://www.gpo.gov/>

Code of Federal Regulations (CFR) annual edition is the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government produced by the Office of the Federal Register (OFR) and the Government Publishing Office.

Higher-level quality standards

URLs:

<http://www.bizfilings.com/toolkit/sbg/run-a-business/govt-contracts/govt-contractors-quality-assurance-standards.aspx>

host:

www.bizfilings.com

Higher-level quality standards - All government quality assurance requirements are spelled out in Part 46 of the Federal Acquisition Regulation (FAR).

Any language that you will see in a bid or contract related to quality control consists of clauses extracted from this Part.

When a contract is for complex or critical items, higher-level requirements are applicable.

The contracting officer is responsible for identifying the higher-level standard(s) that will satisfy the government's requirement.

Title 48 → Chapter 1 → Subchapter G → Part 46 → Subpart 46.2 → §46.202-4

Higher-level quality standards 46.202-4 Higher-level contract quality requirements.

(a) Agencies shall establish procedures for determining when higher-level contract quality requirements are necessary, for determining the risk (both the likelihood and the impact) of nonconformance, and for advising the contracting officer about which higher-level standards should be applied and included in the solicitation and contract. Requiring compliance with higher-level quality standards is necessary in solicitations and contracts for complex or critical items (see 46.203) or when the technical requirements of the contract require—

(1) Control of such things as design, work operations, in-process controls, testing, and inspection; or

(2) Attention to such factors as organization, planning, work instructions, documentation control, and advanced metrology.

(b) Examples of higher-level quality standards include overarching quality management system standards such as ISO 9001, ASQ/ANSI E4, ASME NQA-1, SAE AS9100, SAE AS9003, and ISO/TS 16949, and product or process specific quality standards such as SAE AS5553.

Quality Requirements May Apply for Subcontractors

(Applicable to complex or critical items; contracts may be for less than \$100,000).

You may be thinking to yourself, “If I am just a subcontractor, I won’t have to do all this quality stuff, will I?” Guess again. In many instances, a prime contractor will find it necessary or desirable to pass along the quality requirements to the subcontractor. Why? The prime contractor is responsible for the quality of materials supplied by the subcontractors or suppliers, and it is in its best interest to assure that all suppliers are capable of providing the materials and meeting the quality requirements of the prime contract.

The only way that the prime can assure itself that you can do quality work, on time and within budget, is to inspect your systems and get them approved. The day of the “pal” or “buddy” at the prime level that will issue a contract just on an owner’s assurance that the company can deliver the required product is becoming a thing of the past. Many a small business that had this type of relationship has found, to their woe, that it must still have some kind of quality control system in place. So you must market your company in ways that you might not have had to before.

To the surprise of many contractors and subcontractors, government contract quality assurance at the subcontractor level does not relieve the prime contractor of any responsibilities under the contract nor does it establish a contractual relationship between the government and the subcontractor. So, if you think that you are getting out of some of the quality “stuff” by being a sub, think again.

The prime might, under a special exception or for a particular job, let you slide by without a QA program for a while, but it will eventually want to see a formal program in place or it won’t want to work with you. Therefore, you may as well start creating your own program now, and do it to your satisfaction, without having the pressure of having to create one on the eve of a bid contract that you really want.

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APPENDIX I. FDA PROCEDURES, PREMARKET APPROVAL

This item represents specific FDA regulatory guidance documents for selected medical devices and their respective production part approval process—REGULATIONS: ISO 9000, FAR PART 15.

Guidance Documents (Medical Devices and Radiation-Emitting Products) > Real-Time P... Page 1 of 3

[Home](#) [Medical Devices](#) [Device Advice: Comprehensive Regulatory Assistance Guidance Documents \(Medical Devices and Radiation-Emitting Products\)](#)

Medical Devices

Real-Time Premarket Approval Application (PMA) Supplements

1

 [PDF Printer Version](#)

Document issued on: April 28, 2006

This document supersedes and replaces, the "Real-Time" Review Program for Premarket Approval Application (PMA) Supplements document last updated April 22, 1997 and Section II C, "PMA Supplements Definitions – Real Time Supplements" of the February 2003 guidance entitled, "Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products; Guidance for Industry and FDA"

For questions regarding this document, contact Thanh Nguyen (CDRH) at 240-276-4010 or by e-mail at Thanh.Nguyen@fda.hhs.gov. For questions regarding the application of this guidance to devices regulated by the Center for Biologics Evaluation and Research (CBER), contact Leonard Wilson at 301-827-0373 or by email at leonard.wilson@fda.hhs.gov.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologic Evaluation and Research**

Contains Nonbinding Recommendations

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet.² You may also send an e-mail request to dsrnica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (673) to identify the guidance you are requesting.

Table of Contents

- I. Purpose
- II. Background
- III. Which modifications are appropriate for a Real-Time PMA Supplement?
- IV. How do I request a Real-Time review?
- V. Is there a user fee for a Real-Time PMA Supplement?
- VI. How do I submit a Real-Time PMA Supplement?
- VII. What should a Real-Time PMA Supplement contain?
- VIII. What is the format of a Real-Time review meeting?

Attachment I. Sample Real-Time Review Request

Guidance for Industry and FDA Staff

Real-Time Premarket Approval Application (PMA) Supplements

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Purpose

This guidance provides information about the real-time review process for premarket approval application (PMA) supplements and outlines the procedures for requesting and submitting these types of documents. This guidance supersedes the document entitled "Real-Time" Review Program for Premarket Approval Application (PMA) Supplements, issued April 22, 1997 (the 1997 document) and Section II C, "PMA Supplements Definitions – Real Time Supplements" of the February 2003 guidance entitled, "Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products; Guidance for Industry and FDA."

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

II. Background

On February 4, 2003, FDA published a Federal Register notice entitled, "Medical Device User Fee and Modernization Act of 2002, Establishment of a Public Docket¹ to provide an opportunity for interested persons to share information and views on the implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).² Subsequently, FDA issued a guidance entitled "Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products³ and invited comments on its topics, which included Real-Time PMA Supplements. FDA received no comments on Real-Time PMA Supplements in either docket.

In revising the 1997 document, FDA considered the comments submitted on it and other comments about Real-Time review presented at the MDUFMA Annual Stakeholder Meetings.⁴ Our revision incorporates the criteria for Real-Time PMA Supplements set forth in section 737(4)(D) of the Federal Food, Drug, and Cosmetic Act (the act) and clarifies the kinds of device modifications we believe are appropriate for real-time review. We continue to invite comments on this guidance.

The Least Burdensome Approach

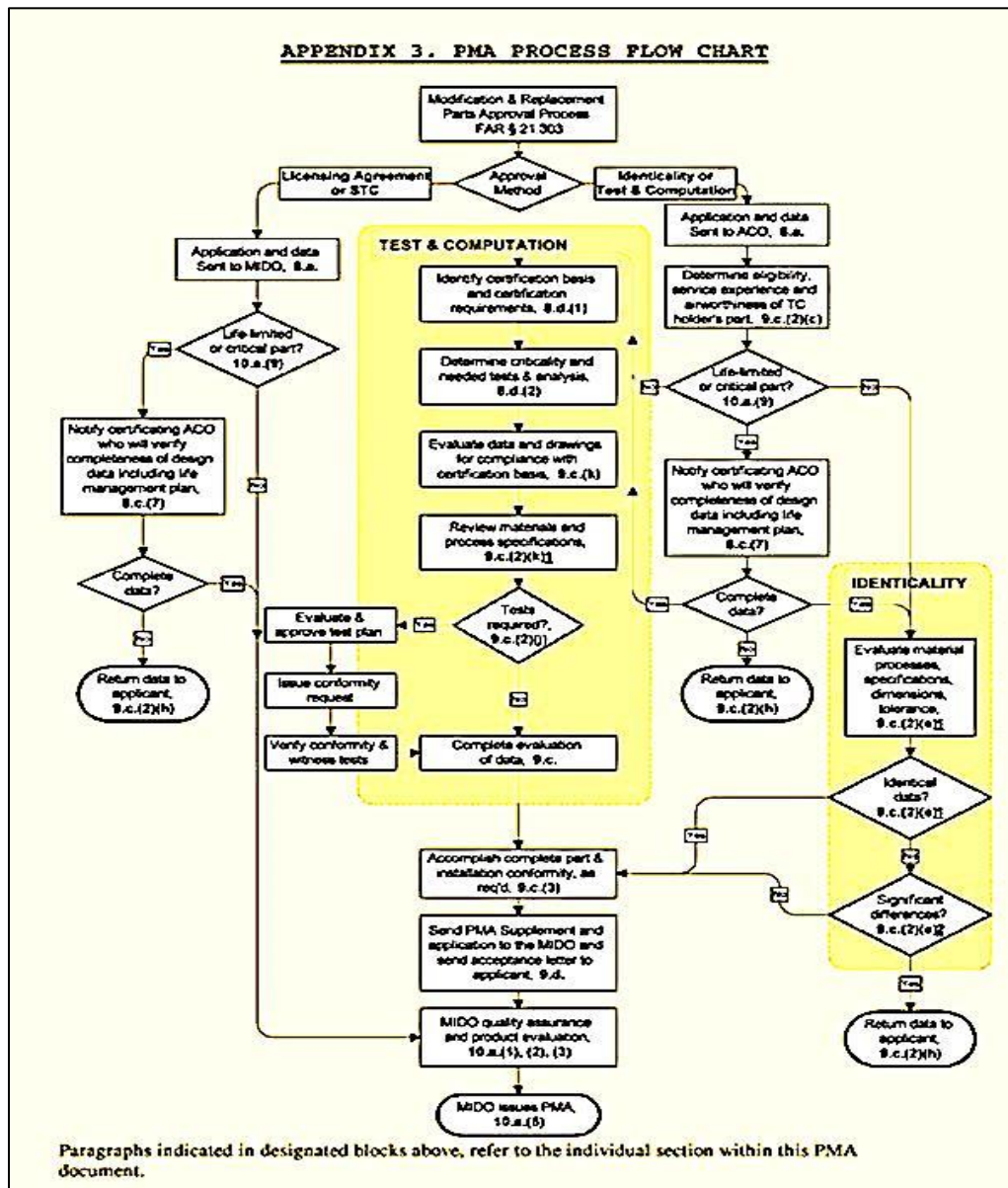
We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH or CBER Ombudsman. [Comprehensive information on CDRH's Ombudsman⁵](#), including ways to contact him, can be found on the Internet and CBER's Ombudsman can be reached at (301) 827-0379.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/...> 4/18/2014

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APPENDIX J. FAA PRODUCTION APPROVAL PROCESS

These selections represent specific regulatory guidance from the FAA for production part approval certifications showing the PMA process flow chart and then the reference to FAR PART 21; ISO 9000/ AS 9100 and includes unique FAA requirements.



FAA – Aviation Production Approval, FAA.gov – FAR Part 21; ISO 9000/ AS 9100, includes unique FAA requirements.

Parts Manufacturer Approval (PMA) – Production Approval

Page 1 of 1



**Federal Aviation
Administration**

Parts Manufacturer Approval (PMA) Production Approval

A PMA production approval allows you to produce and sell FAA approved aircraft articles that are eligible for installation on FAA type certificated products.

A PMA is not transferable. A PMA is valid until surrendered, withdrawn or terminated. One may sell PMA data to another, but the buyer must get a separate PMA.

Withdrawing Your PMA

If you no longer want to produce and sell PMA articles, send a letter to your local [Manufacturing Inspection District Office \(MIDO\)](http://www.faa.gov/about/office_org/field_offices/mido/) (http://www.faa.gov/about/office_org/field_offices/mido/) stating that you wish to withdraw your PMA. Then you will turn in your original PMA letter and supplements to the FAA. Contact your local MIDO about your remaining inventory of material and articles.

Page last modified: July 03, 2012 1:15:19 PM EDT

This page was published at: http://www.faa.gov/aircraft/air_cert/design_approvals/pma/pma_prod/

http://www.faa.gov/aircraft/air_cert/design_approvals/pma/pma_prod/

4/17/2014

APPENDIX K. MOP RATIONALE AND WEIGHTING FACTORS

The following table provides detailed measure of performance rationale used in the analysis of alternatives concerning various industry best practices and then a summary of the weighting criteria applied to each of the six identified key items.

Evaluation Category: Manufacturing Knowledge gaps and Associated Measures of Performance Category with Best Practice Rationale		
Item	MOP	----- Rationale -----
1. Quality Systems	Objective MOP	Best Practice Rationale
QMS, APQP & PPAP w/ 3rd Party Compliance	1.1. QMS - ISO 9000/ AS9100 / ISO/TS 16949	Formal Quality Management System maintained by producer, a) adjudged to be compliant by an auditor internal or DCMA or b) 3rd party registration. Prescriptive quality systems are superior to general guidance (TS 16949 is more prescriptive than ISO 9000)
	1.2. APQP Manufacturing Development Guidelines	Advanced product quality planning: Consensus Standard, Guidelines are superior to unique planning processes. This is acknowledged in the aerospace standard AS 9145 that is to supplant less disciplined manufacturing development guidelines.
	1.3. PPAP Followed - Pre-Production	Production part approval process: Consensus Standard, Required in Automotive Industry and the subject of a pending aerospace standard AS 9145. Certification or Warrant Issued prior to production demonstrating production capability is superior to production approval based on risk models.
2. Requirements	Objective MOP	Best Practice Rationale
Product & Process w/ PPAP Warrant	2.1. Common Training - infrastructure	Common standards precede best practice training. Institutional training external is preferred above internal as variation is reduced. The absence of standards reduces effectiveness

Evaluation Category: Manufacturing Knowledge gaps and Associated Measures of Performance Category with Best Practice Rationale		
	Item MOP	----- Rationale -----
	2.2. Development Activities - APQP	Manufacturing development best practices requires a standard disciplined approach. If there are prescriptive external standards they are superior to heuristic non-standard practices of development.
	2.3. Warrant Approach - PPAP	Production approval is warranted by a qualified agent. A Standard approach to PPAP is superior to ad-hoc processes. Demonstration prior to production approval is a best practice.
	2.4. Product /Process - Performance – DFMEA/PFMEA	Product Design Failure Modes and Effects Analysis to the component level are superior to functional level. Process Failure Modes and Effects Analysis to the process step with controls for causes are superior. Causes need to be actionable not being able to ask why any further. Process is used to identify key characteristics is a best practice.
	2.5. Measurement System Compliant	Measurement Systems must be calibrated, repeatable, have high reliability and suitable to the item tolerance. A rule of thumb is to have error be less than 1/10th the tolerance. Error is used to create error bands inside design tolerance limits.
	2.6. Process Validation (Stability & Control - SPC)	Purposefully and statistically define, manage and interpret key process parameters using SPC. Process must show that it is first stable and in control.
3. Design & Risk	Objective MOP	Best Practice Rationale
Design Definition, Maturity	3.1. PDR, CDR % Drawings Completed	Product Development practices assures technologies are mature, designs are stable. One measure is percent of drawings released. (Example: 85% at PDR and 100% at CDR). Another measure is having drawing standards that use geometric tolerances. Having high skill reviews helps to remove ambiguity and outside reviews is a best practice.

Evaluation Category: Manufacturing Knowledge gaps and Associated Measures of Performance Category with Best Practice Rationale		
	Item MOP	----- Rationale -----
	3.2. Drawing Controls CM	Configuration control is important to a technical data package defining the design record. The same care applied to the manufacturing process definition is a superior best practice.
	3.3. DOEs - Critical Characteristics Defined	Once design characteristics are understood and key characteristics identified, robust design use parameter design experimentation as a best practices to understand complex tolerances, finds interactions, and makes recommendations to improve design record.
Process Definition - Stability and Control	3.4. Not Stable: Pp Ppk ≥ 1.33 - LRIP	If a new process has not demonstrated statistical stability or homogeneity for manufacturing or fabrication then determining a processes potential Ppk is applied as a best practices.
	3.5. Stable: Cpk ≥ 1.67 - FRP	If a more mature process has demonstrated statistical stability and homogeneity for a manufacturing process a more rigorous demonstration to a Cpk is a best practice.
Risks Mitigated & Issues Resolved	3.6. Product & Process Maturation	Manufacturing readiness level assessment Conducted or Manufacturing Process Matured in Development. A best practice is to use a knowledge-based approach as compared to a risk-based approach showing evidence of the maturation. Using an actual production line running at rate with parts that meet requirements is a best practice.
	3.7. Programmatic Corrective Action System	When inspection, test or field failure occurs then a disciplined corrective action process begins to prevent recurrence. FMEAs are updated and Non-recurrence is monitored. A closed loop corrective action system is a best practice.
	3.8. Design FMEA & PFMEA	After FMEAS are completed then using Risk Priority Numbers that guide improvement recommendations to achieve higher quality systems is a best practice.
4. Qualification	Objective MOP	Best Practice Rationale

Evaluation Category: Manufacturing Knowledge gaps and Associated Measures of Performance Category with Best Practice Rationale		
	Item	MOP ----- Rationale -----
Product & Process Qualification Integration Supply Network	4.1. Measurement System Evaluation	This guide assists in the assessment of a measurement system that supports engineering and manufacturing process.
	4.2. Product Qualification, Acceptance Test Procedure & First Article Inspection and Test	Product functional requirements that demonstrate product performance and reliability are part of verification of a compliant system. Dimensional compliance that follows AS9102 periodically assessed is a best practice.
	4.3. Process Verification - Attributes & Variables - SPC	Following an SPC reference guide that provides a wide range of statistical methods for effective monitoring and control of manufacturing processes is a best practice.
	4.4. Supply Network - APQP	Manufacturing development best practices requires a standard disciplined approach. If there are prescriptive external standards then they are superior to heuristic non-standard practices for development of manufacturing. Supplier requirements for APQP and Control Plan guide are a best practice that streamlines the quality & manufacturing process control approach in support of a development program.
	4.5. Supply Network - FMEA	This guide assists in the assessment of a design or a process that supports eliminating or reducing the effects of failure modes identified. Product Design Failure Modes and Effect Analysis to the component level are superior to functional level. Process Failure Modes and Effects Analysis to the process step with controls for causes are superior. Causes need to be actionable not being able to ask why any further. Process is used to identify key characteristics is a best practice.

Evaluation Category: Manufacturing Knowledge gaps and Associated Measures of Performance Category with Best Practice Rationale		
Item	MOP	----- Rationale -----
	4.6. Supply Network - MSA	This guide assists in the assessment of a measurement system that supports engineering and manufacturing process. Measurement Systems must be calibrated, repeatable, have high reliability and suitable to the item tolerance. A rule of thumb is to have error be less than 1/10th the tolerance. Error is used to create error bands inside design tolerance limits.
	4.7. Supply Network - SPC	This guide describes how SPC provides a wide range of statistical methods for effective monitoring and control of manufacturing processes. Purposefully and statistically define, manage and interpret key process parameters using SPC. Process must show that it is first stable and in control.
	4.8. Supply Network - PPAP	The supply network is required to comply with the requirements of the PPAP. Consistent quality is demonstrated in an actual production run at production rates. The Production part approval process integrates production readiness including the design, qualification, process capability with a certification warrant.
5. Metrics	Objective MOP	Best Practice Rationale
Corrective Action System Non-Conformance / Yield /Scrap	5.1. Field Failures - FRACAS	Field failures in development, qualification, field test should be following a failure reporting and corrective action system. Problems could be design or manufacturing. Having cross functional teams review failure items should help identify root cause and mitigate the problems as a best practice. Reliability improvement and fix effectiveness are expected outcomes.
	5.2. Process Failures – Non-Conformance FRACAS	Same as for field failures, but process events.

Evaluation Category: Manufacturing Knowledge gaps and Associated Measures of Performance Category with Best Practice Rationale		
	Item	MOP ----- Rationale -----
	5.3. Yield / Scrap Metrics - Targets - Achievements	Processes should have a full complement of metrics that establish targets, measure and monitor results and report to management. Best Practice quality metrics help identify causes for shortcomings and have executive leadership involved in the management of the improvement processes.
	5.4. Lean / Six Sigma Results - DIMAC	Six-sigma is a data driven analysis process that quantifies problems and improvement change process. A best practice uses six-sigma to eliminate waste at the enterprise level of management as a best practice.
Reliability / Durability	5.5. Qualification - Test	Design Requirements have been defined and the configured baseline has been tested in field usage conditions demonstrating those requirements. A best practice uses production representative or actual production items.
	5.6. Field Performance - Warranty	Post production field usage data is maintained for items that fail in the field. Items manage durability risk through warranty. The post production data is used to confirm or improve reliability over time as a best practice, particularly for durable goods.
	5.7. Things Gone Wrong (TGW) / Right (TGR)	Customer feedback is actively understood by user and internal data streams using items like surveys, warranties, peer reviews and lessons learned. There is an active activity to use these feedback systems to identify TGW and TGR to improve product and process performance at the Enterprise and project levels as a best practice.
6. Satisfaction	Objective MOP	Best Practice Rationale

Evaluation Category: Manufacturing Knowledge gaps and Associated Measures of Performance Category with Best Practice Rationale		
	Item	MOP ----- Rationale -----
Quality Economics	6.1 PAF Model of Quality Improvement 1. Metrics Established - Enterprise	Cost of Quality metrics is defined at the enterprise level and is a best practice. Quality metrics are financial and product related and are aligned to prevention, appraisal and failure activities (both internal and external). An ABC cost accounting practice is aligned to PAF at the local project level is a best practice.
	6.2 PAF Model of Quality Improvement 2. Metrics Established - Local	Cost of Quality metrics is defined at the local level and is a best practice. Quality metrics are financial and product related and are aligned to prevention, appraisal and failure activities (both internal and external). An ABC cost accounting practice is aligned to PAF at the local project level is a best practice.
	6.3 PAF Model of Quality Improvement 3. PAF Managed	Cost of Quality metrics including prevention, appraisal and failure activities (both internal and external) are used to influence product improvements and ROI by activity in a balanced way between PAF.
Business Economics	6.4. Sales Performance	Enterprise level sales performance can be traced to product performance over time and can be related to quality economics as a best practice. ROI are related to improvement actions and can be readily determined based on item performance and from internal actions, field activity or warranty systems.
	6.5. Market Share Performance	Enterprise and local level understanding of market share is known and related to Enterprise and project performance. Effects of Quality Economics can be related to market share performance as a best practice.

II. Weighting Factor Mapping of 11 Attributes to 37 Best Practices

AOA Weigting factors determination based on how many Best Practice Attributes can be associated with an Evaluation Category

Normative Production Part Approval Process – Best Practice Attributes			Evaluation Category	
Input			Manufacturing Knowledge Gaps and Measures of Performance	
	A common engineering language.	1	1. Quality Systems	Objective Measures of Performance
	A common set of quality standards.	2	QMS, APQP & PPAP w/ 3rd Party Compliance	1. QMS - ISO 9000/ AS9100 / ISO/TS 16949 2. APQP Manufacturing Development Guidelines 3. PPAP Followed - Pre-Production
	A common set of customer requirements.	3	2. Requirements Understood	Objective Measures of Performance
	A common 3rd party compliance to quality system standards.	4	Product & Process w/ PPAP Warrant	1. Common Training - infrastructure 2. Development Activities - APQP 3. Warrant Approach - PPAP 4. Product /Process - Performance - FMEA 5. Measurement System Compliant (Calibration, Gage R&R-MSA) 6. Process Validation (Stability & Control - SPC)
	A common set of prescriptive advanced quality practices.	5	3. Design-Product/Process & Risk	Objective Measures of Performance
	A flow down of quality requirements to the entire supply network.	6	Design Definition, Maturity	1. PDR, CDR % Drawings Completed 2. Drawing Controls CM 3. DOEs - Critical Characteristics Defined
Output	A warrant / certification of demonstrated capability prior to production.	7	Process Definition - Stability and Control	4. Not Stable: Pp Ppk $\geq$ 1.33 - LRIP 5. Stable: Cp Cpk $\geq$ 1.67 - FRP
	A single quality system assures administrative efficiencies.	8	Risks Mitigated & Issues Resolved	6. Product & Process Maturation 7. Programmatic Corrective Action System 8. Design FMEA & PFMEA
	A knowledge based demonstrated of manufacturing capability.	9	4. Product & Process Qualification	Objective Measures of Performance
	A system of quality metrics demonstrates measurable user satisfaction.	10	Product & Process Qualification Integration Supply Network	1. Measurement System Evaluation 2. Product Qualification - Qual, ATP & FAIT 3. Process Verification - Attributes & Variables - SPC 4. Supply Network - APQP 5. Supply Network - MSA 6. Supply Network - SPC 7. Supply Network - MSA 8. Supply Network - PPAP
	A product's reliability and durability with field performance tracking.	11	5. Process & Product / Metrics	Objective Measures of Performance
			Corrective Action System Non-Conformance / Yield /Scrap	1. Field Failures - FRACAS 2. Process Failures – Non-Conformance FRACAS 3. Yield / Scrap Metrics - Targets - Achievements 4. Lean / Six Sigma Results - DIMAC
			Reliability / Durability	5. Qualification - Test 6. Field Performance - Warranty 7. Things Gone Wrong / Right
			6. Customer Satisfaction	Objective Measures of Performance
			Quality Economics	PAF Model of Quality Improvement 1. Metrics Established - Enterprise 2. Metrics Established - Local 3. PAF Managed
			Business Economics	4. Sales Performance 5. Market Share Performance

APPENDIX L. LINKS TO QUALITY PRACTICES

A standard Google search was made to identify any relevant links to quality management systems that use a Production Part Approval Process (PPAP). The United Technologies Corporation (UTC) was one organization identified as noted in this selection.

I. UTC Production-part-approval-process (UPPAP)

www.utc.com/Suppliers/Documents/asqr09_2.pdf

Production-part-approval-process (PPAP) ... property of United Technologies Corporation (UTC). You may not possess, use, copy or disclose this document or any • [PDF]

II. UPPAP Basics issued: 1–13-2016 - United ...

supplierdiversity.utc.com/Suppliers/Documents/ppap_asqr09_2_faq.pdf

United Technologies Corporation Farmington, CT 06032 UPPAP FAQ UPPAP Basics issued: 1–13-2016 What is UPPAP? The UPPAP process is used to ensure that parts ...

III. • UPPAP Toolbox | Suppliers | United Technologies

www.utc.com/Suppliers/Pages/UPPAP-Toolbox.aspx

Download documents in the UPPAP Toolbox. ... We are a company founded by people who invented technologies, turned them into businesses and, through innovation, built ... • [PDF]

IV. TITLE UTC Production-part-approval-process (UPPAP)

utcaerospacesystems.com/sites/kiddeaerospace/Documents/asqr09_2...

which produces parts for a United Technologies Corporation (UTC) Member Company. ... Note: UPPAP is modeled after AIAG's PPAP (Production-part-approval-process...

• [PDF]

V. SUPPLIER QUALITY MANUAL Exhibit 1

<https://files.ccs.utc.com/ccs/en/worldwide/contentimages/SQM-BIS...>

Further the SQM applies to internal suppliers within United Technologies ... PPAP submission should be made as far in advance of production start-up as possible, ... • [PDF]

VI. Process Sheets / Supplier ... - United Technologies

utc.aws-stage.com/Suppliers/Documents/asqr09_1.pdf

Business Entities need not be re-submitted, for new approval, until such time ... Unpublished Work - © UNITED TECHNOLOGIES CORPORATION 2012

VII. • Home | UTC Aerospace Systems

utcaerospacesystems.com/Pages/Default.aspx

UTC Aerospace Systems provides innovative aerospace technologies and integrated systems that advance the performance, safety and efficiency of commercial...

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APPENDIX M. MRL LEVELS 6 TO 10

This selection describing the MRL levels 6 to 10 are directly taken from the OSD's MRL Deskbook, version 2.3.

Manufacturing Readiness Level (MRL) Deskbook

Version 2.3

May 2015

Prepared by the OSD Manufacturing Technology Program

In collaboration with The Joint Service/Industry MRL Working Group

Material Solution Analysis (MSA)	Technology Maturation and Risk Reduction (TMRR)		Engineering & Mfg Development (EMD)		Low-Rate Initial Production (LRIP)	Full-Rate Production (FRP)					
ASR	A	SRR/SFR	PDR	B	CDR	PRR/SVR	C	PCA	FRP		
MRL 4		MRL 5		MRL 6		MRL 7		MRL 8		MRL 9	MRL 10

MRL 6: Capability to produce a prototype [parts] in a production relevant environment

This MRL is associated with readiness for a Milestone B decision to initiate an acquisition program by entering into the Engineering and Manufacturing Development (EMD) Phase of acquisition. Technologies should have matured to at least TRL 6. It is normally seen as the level of manufacturing readiness that denotes acceptance of a preliminary system design. An initial manufacturing approach has been developed. The majority of manufacturing processes have been defined and characterized, but there are still significant engineering and/or design changes in the system itself. However, preliminary design has been completed and producibility assessments and trade studies of key technologies and components are complete. Prototype manufacturing processes and technologies, materials, tooling and test equipment, as well as personnel skills have been demonstrated on systems and/or subsystems in a production relevant environment. Cost, yield and rate analyses have been performed to assess how prototype data compare to target objectives, and the program has in place appropriate risk reduction to achieve cost requirements or establish a new baseline. This analysis should include design trades. Producibility considerations have shaped system development plans. The Industrial Capabilities Assessment (ICA) for Milestone B has been completed. Long-lead and key supply chain elements have been identified.

MRL 7: Capability to produce [parts] in a production representative environment

This level of manufacturing readiness is typical for the mid-point of the Engineering and Manufacturing Development (EMD) Phase leading to the Post-CDR Assessment. Technologies should be on a path to achieve TRL 7. System detailed design activity is nearing completion. Material specifications have been approved and materials are available to meet the planned pilot line build schedule. Manufacturing processes and procedures have been demonstrated in a production representative environment. Detailed producibility trade studies are completed and producibility enhancements and risk assessments are underway. The cost model has been updated

with detailed designs, rolled up to system level, and tracked against allocated targets. Unit cost reduction efforts have been prioritized and are underway. Yield and rate analyses have been updated with production representative data. The supply chain and supplier quality assurance have been assessed and long-lead procurement plans are in place. Manufacturing plans and quality targets have been developed. Production tooling and test equipment design and development have been initiated.

MRL 8: Pilot line capability demonstrated; Ready to begin Low Rate Initial Production

This level is associated with readiness for a Milestone C decision, and entry into Low Rate Initial Production (LRIP). Technologies should have matured to at least TRL 7 or 8. Detailed system design is complete and sufficiently stable to enter low rate production. All materials, manpower, tooling, test equipment and facilities are proven on pilot line and are available to meet the planned low rate production schedule. Manufacturing and quality processes and procedures have been proven in a pilot line environment and are under control and ready for low rate production. Known producibility risks pose no significant challenges for low rate production. Cost model and yield and rate analyses have been updated with pilot line results. Supplier qualification testing and first article inspection have been completed. The Industrial Capabilities Assessment for Milestone C has been completed and shows that the supply chain is established to support LRIP.

MRL 9: Low rate production demonstrated; Capability in place to begin Full Rate Production

At this level, the system, component or item has been previously produced, is in production, or has successfully achieved low rate initial production. Technologies should have matured to TRL 8 or 9. This level of readiness is normally associated with readiness for entry into Full Rate Production (FRP). All systems engineering/design requirements should have been met such that there are minimal system changes. Major system design features are stable and have been proven in test and evaluation. Materials, parts, manpower, tooling, test equipment and facilities are available to meet planned rate production schedules. Manufacturing process capability in a low rate production environment is at an appropriate quality level to meet design key characteristic tolerances. Production risk monitoring is ongoing. LRIP cost targets have been met, and learning curves have been analyzed with actual data. The cost model has been developed for FRP environment and reflects the impact of continuous improvement

MRL 10: Full Rate Production demonstrated and lean production practices in place.

This is the highest level of production readiness. Technologies should have matured to TRL 9. This level of manufacturing is normally associated with the Production or Sustainment phases of the acquisition life cycle. Engineering/design changes are few and generally limited to quality and cost improvements. System, components or items are in full rate production and meet all engineering, performance, quality and reliability requirements. Manufacturing process capability is at the appropriate quality level. All materials, tooling, inspection and test equipment, facilities and manpower are in place and have met full rate production requirements. Rate production unit costs meet goals, and funding is sufficient for production at required rates. Lean practices are well established and continuous process improvements are ongoing.

APPENDIX N. UNDERSTANDING THE AUTOMOTIVE QMS

A collection of personal notes by William Ireland concerning the history of the QS-9000 Quality Management System from personal experience and prior publications and presentations that are given under Ireland in the List of References of this thesis. Notes compiled on 5/29/2017:

The QS-9000 automotive QMS transferred into the ISO/TS-16949 under SAE management and are used interchangeably for this research. These standards focused on the identification and application of customer specific requirements. In the global automotive industry the ISO/TS-16949:2009 through: 2016 continues a compatibility with the specifications of Ford, General Motors (GM), Chrysler domestically and internationally the German automaker's VDA6.1 standard, French EAQF standard and the Italian automotive standard AVSQ. The ISO/TS-16949 standard is the automotive industry's uniform consensus QMS (AIAG 2006).

The motivation and implementation of the automotive PPAP provided context to assist in the identification of relevant similarities between the alternative non-DOD industrial sectors and the DOD. Historically, the American automotive sector faced a dual challenge in the 1970s and 1980s. First, poor vehicle quality and reliability resulted in a rapid decline of market share. The poor quality was associated with the lack of attention OEMs gave to quality in design and manufacturing. In addition, the industry was ignoring methods employed by the Japanese auto manufacturers who were adhering to statistical quality methods in production.

Actions to improve production outcomes in the automotive industry came from detailed prescriptive requirements and standardization of their QMS. The automotive standards required suppliers to follow prescriptive quality practices to satisfy two key elements: APQP, representing the development phase of a manufacturing process and 2) PPAP, as validating manufacturing process requirements. The GAO did characterize non-DOD organizations as more successful when they followed a more disciplined manufacturing knowledge-based development and production-approval approach. This contrasted to the DOD production approval process that was non-standard and risk-based. The deficiencies related to DOD acquisition practices represented a knowledge gap in process capability failing to be objectively determined as part of production readiness by a demonstration prior to production start.

Insight into the enhancement and unification in automotive quality standards was a trend moving key technologies out of the OEMs to create a burgeoning supply base where those entities became global suppliers. Examples are companies such as Visteon, Bendix Allied Signal, Delphi and TRW. Early attempts by each OEM to manage this emerging supply network resulted in the creation of individual OEM QMS requirements.

A confirming report given by Timothy J. Sturgeon and Richard K. Lester, in their February 2003 paper to the World Bank Project on East Asia's Economic Future stated: "The entry of GM's and Ford's former component divisions into the merchant market for

vehicle components, modules, and systems has, almost overnight, created the world's two largest, most diversified, and geographically extensive automotive suppliers" (Sturgeon and Lester 2003).

Here, the globalization strategies were enablers to overcome the challenges of an Asian invasion into the American automotive sector supporting the divesting of component technologies within the OEMs to the supply network. Just prior to the automotive industry adoption of their common set of standards, individual OEMs had unique QMS requirements for suppliers. Suppliers found themselves burdened with the need to comply with three different QMS while essentially producing for a common customer with nearly common production technologies - - an onerous cost burden within the supply base. The auto industry realized a need to improve their practices in the supply network and required an adherence to a common set of standards with the hopes to improve production outcomes.

As the automotive OEMs updated their global QMS they also became system integrators. This has similarly occurred in DOD's prime contractors. This meant that the design expertise moved deeper into the supply base. As suppliers became larger global enterprises the OEMs and prime government contractors pushed component know-how down into the supply chain (Ireland 2000). What Ireland reported establishes a concern that there is increased risk to the OEMs and prime contractors requiring a need to assure production readiness can be maintained at lower supply tiers.

These first efforts by the OEMs failed to provide the desired results and led to a collaborative effort in the automotive sector. With the formation of the AIAG in 1982, the OEMs consolidated the various QMS requirements into a unified set of practices with the goal to unburden suppliers and build a consistency in development of product and process. The AIAG delivered a unified body of standards applying development and support for a common "production approval process."

Historically, it may be important to put the movement for a unified QMS standard in perspective. The push for standards in manufacturing goes to the war effort in World War II. The ISO formation occurred shortly after, in 1947. It was not until the mid-1970s that standards became more international. An international view of quality standards was launched in 1987 with trading partners globally adopting the European based common set of quality management standards known as the ISO-9000 QMS.

The state of standards prior to this uniform approach included the adaptation of national standards. The AIAG used the platform of the ISO-9000 standards to forward the automotive industry quality standards from a global perspective. While the core of the ISO approach was notionally accepted it did not address the peculiarities of the automotive industry. The release of the QS-9000 family of standards was mandated with its prescriptive measures of compliance for production demonstration and control. Insightfully, the automotive standards approach preserved the belief that the global supplier network would have to be ISO-9000 certified by the mid-90s to trade with Europe. Therefore, the American automotive effort of standards development used ISO-9001 as its core to its QMS requirement and then added their unique requirements. This would minimize any cost for implementation in DOD acquisition being able to build on the existing QMS framework that is based on the ISO-9000.

LIST OF REFERENCES

- AFMC. 2014. *Analysis of Alternatives (AOA) Handbook*. Kirtland AFB: Office of Aerospace Studies, Air force Materiel Command.
- AIAG. 1992. *Failure Modes and Effects (FMEA)*, 1st ed., Southfield, MI: AIAG.
- . 1998 *Annual Quality Survey Report*. Southfield, MI: Automotive Industry Action Group.
- . 2005. *Statistical Process Control (SPC)*, 2nd ed. Process Control Working Group, Southfield, MI: AIAG.
- . 2006. *Production Part Approval Process (PPAP)*, 4th ed. Southfield, MI: AIAG.
- . 2008 a. *Advanced Product Quality Planning and Control Plan (APQP)*, 2nd ed. Advanced Product Quality Planning Working Group, Southfield, MI: AIAG.
- . 2008b. *Failure Modes and Effects (FMEA)*, 4th ed. Southfield, MI: AIAG.
- . 2010. *Measurement Systems Analysis (MSA)*, 4th ed. Southfield, MI: AIAG.
- AIAG/ASQ. 1997. *Quality Survey Results.*, Novi, MI: AIAG/ASQ.
- ASQLONGISLAND. 2015. “AS9100 ‘B’ to ‘C’ Revision.” http://www.asqlongisland.org/seminars/AS9100_B_to_C_Revision.pdf, (accessed August 1st, 2015).
- Azizian, Nazanin, Shahram Dr. Sarkani, and Thomas Dr Mazzuchi. 2009. In *A Comprehensive Review and Analysis of Maturity Assessment Approaches for Improved Decision Support to Achieve Efficient Defense Acquisition*, edited by S. I. Ao and Craig Douglas and W. S. Grundfest and Jon Burgstone. *World Congress on Engineering and Computer Science 2009 Vol II WCECS*. San Francisco: IAENG 1150–1157.
- Bandyopadhyay, Jayanta K. 1996. “Quality System Requirements QS-9000: The New Automotive Industry Standards.” *International Journal of Quality and Productivity Management* (International Society for Quality & Productivity Management).
- Bomey, Nathan. 2015. “Average Age of Cars on U.S. Roads Hits Record 11.5 Years.” *USA Today*, July 30, 2015.
- Breitenberg, Maureen. 1999. *A Century of Excellence in Measurements, Standards, and Technology, A Chronicle of Selected NBS/NIST Publications 1901–2000*;

- Questions and Answers on Quality*. NIST Special Publication 958 Gaithersburg, MD: National Institute of Standards and Technology.
- Brock, Jack L. 2003. *Defense Acquisitions—Assessments of Major Weapon Programs*. (RTC Report No. AO-03-476) Washington, DC: General Accountability Office.
- Calvaresi-Barr, Ann M. 2005. *Defense Acquisitions—DOD Has Paid Billions in award and Incentive Fees Regardless of Acquisition Outcomes*. Report to the Subcommittee on Readiness and Management Support, Committee on Armed Services (GAO-06-66). Washington, DC: Government Accountability Office.
- Coble, Mar, Doug Glandon, Phi Pham, Jeremy Royster, John Stewart, and Brandon Taylor. 2014. *Improving the Prototyping Process in Department of Defense Acquisition*. Master's thesis, Monterey: Naval Postgraduate School.
- Dahmann, Judith S., and Mike Kelley. 2009. *Systems Engineering During the Materiel Solution Analysis and Technology Development Phases*. Washington, DC: Director of Defense Research and Engineering (DDR&E).
- DAU. 2009. Acquisition Community Connection: Systems Engineering. Chapter 4.02. <https://acc.dau.mil/CommunityBrowser.aspx>.
- . 2015a. Acquisition Community Connection: Systems Engineering, ID 24660. <https://acc.dau.mil/CommunityBrowser.aspx?id=24660&lang=en-US>.
- . 2015b. Acquisition Community Connection: Systems Engineering, ID 654219. <https://acc.dau.mil/CommunityBrowser.aspx?id=654219&lang=en-US>.
- . 2016. Acquisition Community Connection: Systems Engineering, ID 638297. <https://acc.dau.mil/CommunityBrowser.aspx?id=638297&lang=en-US>.
- Department of Commerce. 2015a. Automotive Spotlight. <http://selectusa.commerce.gov/industry-snapshots/automotive-industry-united-states>.
- . 2015b. Industry Subsectors. <http://selectusa.commerce.gov/industry-snapshots/aerospace-industry-united-states.html>.
- Dodaro, Gene L. 2013. *Assessments of Selected Weapon Programs* (GAO-13-294SP). Washington, DC: General Accountability Office.
- . 2014. *Assessments of Select Weapon Programs* (GAO-14-340SP). Washington, DC: Government Accountability Office.

- DSB. 2008. *Final Report of Defense Science Board Taskforce on DT&E*. Washington, DC: DOD, Office of the Under Secretary of Defense for Acquisition, Technology and Logistics.
- Dunn, Michael. 2010. *OSD Manufacturing Technology*. Workshop Presentation, 42nd Annual Defense Manufacturing Conference, OUSD[AT&L], DDR&E Research Directorate, Nov. 29.
- Erwin, Sandra. 2010. *Weapons Acquisition Reform Act: One-Year Anniversary Not Cause for Celebration*. May 27, 2010. NDIA, <http://www.nationaldefensemagazine.org/blog/Lists/Posts/Post.aspx?ID=134> (accessed August 23, 2015).
- Gardner, Robert. 2004. *The Process-Focused Organization: A Translation Strategy for Success*. Milwaukee: ASQ Quality Press.
- Gibson, John E., William T. Scherer, and William F. Gibson. 2007. *How to Do a Systems Analysis*. Edited by Andrew P. Sage. Hoboken, NJ: John Wiley & Sons.
- Ibisworld. 2015. *Medical Device Manufacturing in the US: Market Research Report*. Market Research, Melbourne: IBISWorld.
- INCOSE. 2007. *Systems Engineering Handbook, version 3.1.*, Report No. INCOSE-TP-2003-002-03.1, August 2007, Seattle: INCOSE.
- Ireland, William C. 2000. "Quality System QS9000 and NAFTA." *Symposium of Industrial Engineering*. Aguascalientes: Instituto Tecnológico de Aguascalientes.
- . 2009. *Automotive Design-to-Life-Cycle Criteria for Lowering Warranty Costs and Improving Ownership Experience through the use of a new Binary Decision Model and Application of a Warranty Index*. Master's thesis, University of Maryland.
- ISO. 2008. *Quality Management Systems—Requirements*. Standard No. ISO 9001:2008 4th ed., Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC 2, International Standards Organization, Geneva: International Standards Organization.
- JCS. 2008. *Manual for the Operation of the Joint Capabilities Integration and Development Documents*. Washington, DC: Joint Chiefs of Staff.
- . 2015a. *Joint Capabilities Integration and Development System (JCDIS)*. Instruction No. CJCSI_3170_01I for DOD, Washington, DC: Department of Defense.

- . 2015b. *Manual for the Operation of the Joint Capabilities Integration and Development System (JCIDS)*. Washington, DC: Department of Defense.
- KBSI. 2014. “IDEF0 Functional Modeling Method.” http://www.idef.com/idefo-function_modeling_method/.
- NAVAIR. 2008. *NAVAIR Instruction 4355.19D System Engineering Technical Review Process*. NAVAIR Instruction, Washington, DC: DON.
- . 2015. *NAVAIR Instruction 4355.19E Systems Engineering Technical Review Process*. NAVAIR Instruction, Washington, DC: DON.
- Naveh, Eitan, Alfred Marcus, and Hyoung Koo Moon. 1999. *ISO 9000 Cost–Benefit Survey*. New York: McGraw-Hill.
- NDIA Gulf Coast Chapter. 2010. *Acquisition Excellence through Effective Systems Engineering; Systems Engineering Deficiencies and Corrections for Air-Launched Tactical Weapons*. Arlington, VA NDIA.
- NIST. 1999. *On the Implementation of the OMB Circular A-119 and P.L. 104–113*. Annual Report to the Office of Management and Budget, United States Department of Commerce, National Institute of Standards and Technology, Gaithersburg: Technology Services Office of Standards Services.
- OMB. 1998. *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*. Washington, DC: Office of Management and Budget.
- OSD. 2012. *Manufacturing Readiness Level Deskbook*. Vers. 2.2.1. <http://www.dodmrl.com>. October 2012. http://www.dodmrl.com/MRL_Deskbook_V2_21.pdf
- OSD. 2015. *Manufacturing Readiness Level Deskbook*. Vers. 2.3. http://www.dodmrl.com/MRL_Deskbook_V2_21.pdf.
- Perry, William J. 1994. *Specifications & Standards—A New Way of Doing Business*. Washington, DC: Department of Defense.
- Schwartz, Moshe. 2013. *Defense Acquisitions: How DOD Acquires Weapon Systems and Recent Efforts to Reform the Process* (CRS Report No. RL34026). Washington, DC: Congressional Research Service.
- SAE. 2009. *AS9100C Quality Management Systems—Requirements for Aviation, Space and Defense Organizations*. Commercial Technical Standard, G-14 Americas Aerospace Quality Standards Committee, SAE, www.sae.org.

- . 2015. *Advanced Product Quality Planning (APQP) / Production Part Approval Process*. Issuing: G-14 Americas Aerospace Quality Standards Committee SAE International. <http://standards.sae.org/wip/as9145>.
- Schinasi, Katherine V. 1996. *Best Practices—Commercial Quality Assurance Practices Offer Improvements for DOD* (NSIAD-96-162). Washington, DC: Government Accounting Office.
- . 2002. *Best Practices—Capturing Design and Manufacturing Knowledge Early Improves Acquisition Outcomes* (GAO-02-701). Washington, DC: Government Accountability Office.
- Sturgeon, Timothy J., and Richard K. Lester. 2003. *World Bank Project on East Asia's Economic Future*. MIT Working Paper IPC-03-006, Cambridge: MIT.
- Sullivan, LTC James F. Jr. 1998. MAJ Gregory Broullette, and MAJ Jeffery K. Joles. *1998 Army After Next Unmanned Aerial Vehicle Studies*. Technical Report No. 98-X, West Point: United States Military Academy.
- Sullivan. 2008. *Best Practices—Increased Focus on Requirements and Oversight Needed to Improve DOD's Acquisition Environment* (GAO-08-294). Washington, DC: Government Accountability Office.
- . 2010. *DOD Can Achieve Better Outcomes by Standardizing the Way Manufacturing Risks Are Managed*. Report to Congressional Requestors, Report No. GAO-10-439, Washington, DC: Government Accountability Office.
- USD[AT&L]. 2008. *Operation of the Defense Acquisition System*. Instruction No. DODI 5000.02, Washington, DC: Department of Defense.
- . 2013. "Defense Acquisition Guidebook." <https://dag.dau.mil/pages/default.aspx>.
- . 2015. *Operation of the Defense Acquisition System*. Department of Defense Instruction No. DDOI 5000.02, Washington, DC: Department of Defense.
- USDTOASR&TBOT. 2014. *The Changing Face of Transportation*. Office of the Assistant Secretary for Research and Technology, Bureau of Transportation Statistics United States Department of Transportation. http://www.rita.dot.gov/bts/sites/rita.dot.gov/bts/files/publications/the_changing_face_of_transportation/html/appendix_a.html
- Walker, David. 2005. *Defense Acquisitions - Assessments of Select Weapon Programs* (GAO-05-301). Washington, DC: Government Accountability Office.
- . 2006. *Contracting for Better Outcomes* (GAO-06-800T). Washington, DC: Government Accountability Office.

Yang, Yihong. 2007. *Integrated Quality Control Planning in Computer-Aided Manufacturing Planning*. Dissertation, Worcester Polytechnic Institute.

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