DEPARTMENT OF DEFENSE

Technology Readiness Assessment (TRA) Deskbook

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Prepared by the
Deputy Under Secretary of Defense for Science and Technology
(DUSD(S&T))

This version of the TRA Deskbook accounts for policy and guidance provided by Directive DoDD 5000.1, dated May 12, 2003; Instruction DoDI 5000.2, dated May 12, 2003; and the *Defense Acquisition Guidebook*, dated October 2004.

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EXECUTIVE SUMMARY

The body of this document is a concise description of suggested best practices, responsibilities, roles, and procedures for meeting the Technology Readiness Assessment (TRA) requirements of the Defense Acquisition System. The intent is to provide those involved with TRAs a greater understanding of how TRAs fit into defense acquisition and what is expected by the DUSD(S&T), which serves as the staff proponent for TRAs for the Director of Defense Research and Engineering (DDR&E). The potential benefit to other Office of the Secretary of Defense (OSD) and Service Component participants is also recognized.

The Department of Defense (DoD) acquisition system is addressed in the following documents:

- DoD Directive 5000.1 (DoDD 5000.1), *The Defense Acquisition System*, dated May 12, 2003
- DoD Instruction 5000.2 (DoDI 5000.2), *Operation of the Defense Acquisition System*, dated May 12, 2003
- *Defense Acquisition Guidebook,* dated October 2004.

These documents are available at http://www.akss.dau.mil/darc/darc.html. The *Defense Acquisition Guidebook* replaced the *Interim Defense Acquisition Guidebook* (October 2002) referenced in the September 2003 version of this *Technology Readiness Assessment (TRA) Deskbook*.

A central theme of the acquisition process is that the technology employed in system development should be "mature" before system development begins. Normally, for technology to be considered mature, it must have been applied in a prototype article (a system, subsystem, or component), tested in a relevant or operational environment, and found to have performed adequately for the intended application. This implies a need for a way to measure maturity and for a process to ensure that only sufficiently mature technology is employed. The *Defense Acquisition Guidebook* provides an outline of a process and suggests activities for performing TRAs; however, this guidance is not mandatory. The *Guidebook* introduces Technology Readiness Levels (TRLs) as an accepted way to describe technology maturity and suggests activities that could be carried out by Program

Managers (PMs), Component Science and Technology (S&T) Executives, Component Acquisition Executives (CAEs), and the DUSD(S&T).

The body of this document includes the following:

- A description of the overall systems acquisition process in DoD, with particular emphasis on the roles of people conducting the TRA (Section 2)
- A description of the TRA process (Section 3)
- A description of the TRA format (Section 4)
- A description of the best practices for managing technology maturation (Section 5).

The appendixes provide the following information:

- Extracts from the DoD 5000 Series of Documents and the *Defense Acquisition Guidebook* relevant to TRAs (Appendix A)
- Extracts from relevant Government Accountability Office (GAO) and DoD reports (Appendix B)
- Guidance, best practices, and examples for assessing technology maturity, including tables that provide TRL definitions for hardware, software, and manufacturing technology (Appendix C)
- Guidance and best practices for identifying Critical Technology Elements (CTEs) (Appendix D)
- Policy statements relevant to the TRA process (Appendix E)
- A Technology Development Strategy (TDS) template(Appendix F)
- Technology Transition Agreement (TTA) elements and a template (Appendix G)
- Specialized definitions and descriptions of TRLs for biomedical technology (drugs, vaccines, and medical devices) (Appendix H)
- A discussion of Manufacturing Readiness Levels (MRLs) (Appendix I).
- Easy-reference displays of the TRA Activities Time Line and the Hardware/ Software TRLs (Appendix J). These 11 × 17 copies can be removed from the hard copy or printed from the soft copy.

The expectation is that the basic architecture of the TRA process will remain relatively stable over time, whereas the details implementing the process will evolve and become more or less explicit over time. As changes occur, adapting the appendixes or adding new appendixes will provide an effective way for the *Deskbook* to accommodate these changes.

SECTION 1.
INTRODUCTION

1.1 BACKGROUND

The Department of Defense (DoD) acquisition system is addressed in the following documents:[1]

- DoD Directive 5000.1 (DoDD 5000.1), *The Defense Acquisition System*, dated May 12, 2003
- DoD Instruction 5000.2 (DoDI 5000.2), *Operation of the Defense Acquisition System*, dated May 12, 2003
- *Defense Acquisition Guidebook,* dated October 2004.[2]

DoDD 5000.1 and DoDI 5000.2 provide management principles and mandatory policies and procedures for managing all acquisition programs. The *Guidebook* contains recommended guidance on best practices, lessons learned, and expectations.

A central acquisition process theme is that the technology should be "mature" before system development begins.[3] Normally, for technology to be considered mature, it must have been applied in a prototype article (a system, subsystem, or component), tested in a relevant or operational environment, and found to have performed adequately for the intended application. This implies a need for a measure of technology maturity and for a process to ensure that only sufficiently mature technology is used.

These needs are met by DoDI 5000.2, which establishes a requirement for Technology Readiness Assessments (TRAs), and by the *Defense Acquisition Guidebook,* which suggests a process and a methodology for performing TRAs. The *Guidebook* also introduces Technology Readiness Levels (TRLs) as an accepted way to describe

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1 These documents are available at http://www.akss.dau.mil/darc/darc.html. Appendix A contains relevant extracts from these documents.

2 This *Guidebook* replaced the *Interim Defense Acquisition Guidebook* (October 2002) referenced in the September 2003 version of this *Technology Readiness Assessment (TRA) Deskbook*.

3 This reflects a major conclusion of a study performed by the Government Accountability Office (GAO) (see Appendix B).

technology maturity.[4] The National Aeronautics and Space Administration (NASA) has defined TRLs and has used these TRLs in its program reviews. The NASA definitions are the basis for the DoD definitions.

Regulatory requirements mandate TRAs at the Milestone B and Milestone C reviews for all acquisition programs.[5] This *Deskbook* describes actions to carry out TRAs that would normally be taken by Program Managers (PMs), Component Science and Technology (S&T) Executives, Component Acquisition Executives (CAEs), and the Deputy Under Secretary of Defense for Science and Technology (DUSD(S&T)). TRAs for Acquisition Category (ACAT) ID[6] or ACAT IAM[7] programs must be submitted to the DUSD(S&T).

1.1.1 TRA Definition and Purpose

A TRA is a systematic, metrics-based process and accompanying report that assesses the maturity of certain technologies [called Critical Technology Elements (CTEs)][8] used in systems. The report includes information about how the CTEs are identified, why they are important to the program, and an *independent* (from the program) assessment of their maturity.

The purpose of the TRA is to surface data and assess information relevant to the maturity of the CTEs in acquisition programs. This assessment does not predict future

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4 Appendix C addresses the topic of assessing technology maturity in some detail.

5 Milestone B initiates system development. It is the most common point for formal program initiation in the Defense Acquisition System. However, regulatory requirements mandate a TRA for ships at program initiation—typically Milestone A. Milestone C approves low rate initial production (LRIP) for hardware systems and initial deployment for automated information systems (AISs). Section 2 presents an overview of the Defense Acquisition System.

6 ACAT ID is a subcategory of ACAT I. ACAT I programs are Major Defense Acquisition Programs (MDAPs) or programs that the Milestone Decision Authority (MDA) designates ACAT I. An MDAP is an acquisition program that is not a highly sensitive classified program (as determined by the Secretary of Defense) but is designated by the Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)) as an MDAP based on several factors, including research, development, test, and evaluation (RDT&E) expenditures and procurement expenditures. The MDA for ACAT ID programs is the USD(AT&L).

7 ACAT IAM is a subcategory of ACAT IA. ACAT IA programs are Major Automated Information System (MAIS) programs or programs designated by the Assistant Secretary of Defense for Networks and Information Integration (ASD(NII)) [formerly the Assistant Secretary of Defense for Command, Control, Communications, and Intelligence (ASD(C3I)] to be ACAT IA. The MDA for ACAT IAM programs is the ASD(NII), who is also the Department of Defense Chief Information Officer (DoD CIO).

8 Appendix D addresses CTEs in some detail.

performance of the technologies or the system nor does it assess the quality of the system architecture, design, or integration plan. It is simply a report on what has been accomplished to date for an important subset of technologies in the program. The TRLs reported in the TRA are part of the program's technical risk assessment. Elements of technical risk also include design, architectures, interoperability, cost, schedule, manufacturability and producibility, and so forth. Thus, although the PM should find the output of a disciplined TRA process useful in highlighting technology items and shaping the risk mitigation plans, the TRA should not be the sole means of discovering technology risk.

To conduct a TRA, the PM identifies the CTEs by looking across the established program work breakdown structure (WBS) (or equivalent) for technology components that are essential to the system and are either new or novel or are being applied in a new or novel way. Data concerning the performance of the CTEs are collected and presented to reviewers (or teams) who are independent from the program and expert in the technologies. The independent reviewers assess the maturity of the CTEs against established TRL metrics. This assessment is approved by the Service or Agency S&T Executive and forwarded to the CAE or Agency Head, who then transmits it to the DUSD(S&T). The DUSD(S&T) either concurs with the TRA, concurs with reservation, or does not concur. If DUSD(S&T) does not concur, it can either send the TRA back to the Service or Agency for changes or elect to conduct another Independent Technical Assessment (ITA). In all cases, the DUSD(S&T) forwards recommendations to the Milestone Decision Authority (MDA) as input to the decision process.[9] Section 4 contains a suggested format for the TRA submitted from the Service or Agency S&T component to the DUSD(S&T).

1.1.2 The Importance of the TRA

The Defense Acquisition System strives to integrate advanced technology into producible systems and deploy these technologies in the shortest time practicable. The TRA and the recommendations from the DUSD(S&T) are two elements of the MDA decision to transition high-interest programs between the Defense Acquisition System milestones.

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[9] For instance, the DUSD(S&T) may recommend remedial action (e.g., requiring a TRA update at a later time or using alternative technologies to replace immature CTEs) to be included in the Acquisition Decision Memorandum (ADM).

Money is saved by adhering to the DoDI 5000.2 policy on technology maturity, which requires CTEs to be demonstrated in a relevant environment *before* system development. On those occasions when programs have been initiated with immature technologies, DoD has often suffered the consequences of enormous cost growth and schedule slippages.

Congress has also voiced its concern about technology maturity in acquisition programs. Each year, the DUSD(S&T) is required to submit to Congress a report that describes and justifies each case in which an Major Defense Acquisition Program (MDAP) entered system development with a CTE that had not been demonstrated in a relevant environment.[10] The TRAs submitted by the Services and Agencies are the primary sources of data and information for that report.

PMs have found TRAs useful in trying to understand the maturity of their programs. The TRA can help the PM by identifying immature and important components and tracking the maturity development of those components. Some programs use TRAs as an important component of their risk assessment. The TRA highlights critical technologies and other potential technology risk areas that require the PM's attention.

For Information Technology (IT) systems, which rely heavily on off-the-shelf components, TRAs have increased the focus of management attention on CTEs that lie outside of hardware and software. For example, CTEs may relate to IT issues, such as interfaces, throughput, scalability, external dependencies, and information assurance, depending on how the system architecture drives system interdependencies and complexities. Since many IT systems have experienced problems with these issues, the TRA has proven useful in understanding potential problems earlier in the process when solution options are easier to adopt and less costly to implement.

1.2 PURPOSE OF THIS DOCUMENT

This *Technology Readiness Assessment (TRA) Deskbook* gives defense organizations involved with TRAs a greater understanding of how TRAs fit into defense acquisition approval process and what is expected by the DUSD(S&T). [11] For conducting TRAs, it also contains advice and best practices obtained from interviews with people who have

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[10] See Appendix E.

[11] The DUSD(S&T) serves as the staff proponent for TRAs for the Director of Defense Research and Engineering (DDR&E).

been involved in the TRA process. In addition, this document provides the DUSD(S&T) staff a working appreciation of the overall TRA process, with enough detail to allow them to meet their staff responsibilities.

1.3 ORGANIZATION OF THIS DOCUMENT

The body of this document is a concise description of suggested best practices, responsibilities, roles, and procedures for meeting the TRA requirements of the Defense Acquisition System. It provides

- A description of overall systems acquisition process in DoD, with particular emphasis on the roles of people conducting the TRA (Section 2)
- A description of the TRA process (Section 3)
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1.4 CHANGES FROM THE PREVIOUS VERSION

This document replaces the *Technology Readiness Assessment (TRA) Deskbook* published September 2003. This current version provides a more up-to-date discussion of the process and best practices for performing a TRA. It also provides much greater detail in identifying and assessing CTEs and the readiness of critical manufacturing technologies, conducting TRAs for Major Automated Information System (MAIS) programs and the IT aspects of MDAPs, and defining software TRLs.

SECTION 2.
SYSTEMS ACQUISITION OVERVIEW

2.1 SYSTEMS ACQUISITION FRAMEWORK

Figure 2-1 depicts the defense acquisition process. TRAs are conducted just before Milestones B and C and at program initiation (typically Milestone A) for ships. The TRAs are a component of the Milestone decisions.

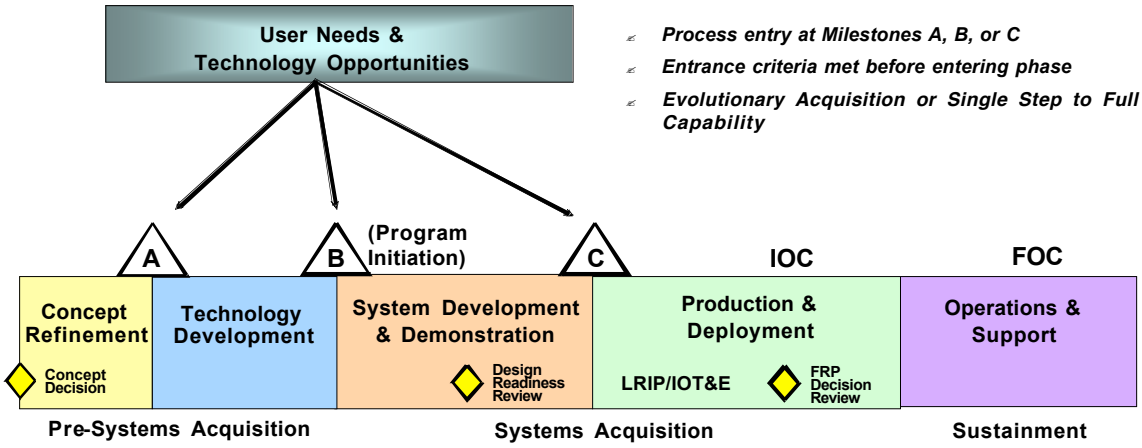

Figure 2-1. Defense Acquisition Management Framework (Source: DoDI 5000.2)

The acquisition process is progressive, proceeding from desired operational capabilities to system concepts and then successively to systems, subsystems, and components that are more sharply and more completely defined. The following description of the acquisition system focuses on the elements that impact technology selection, development, and use in defense system acquisition. DoDI 5000.2 and the *Defense Acquisition Guidebook* contain a more complete description of the acquisition system.

2.2 PRE-CONCEPT DECISION

The Joint Capabilities Integration and Development System (JCIDS) identifies current and future gaps in our ability to carry out Joint warfighting missions and

functions.[12] The identification process begins before the Concept Decision point shown in Figure 2-1 at the start of the acquisition management framework.

Analysis conducted as a part of the JCIDS process results in doctrine, organization, training, materiel, leadership and education, personnel, and facilities (DOTMLPF) change recommendations and/or an Initial Capabilities Document (ICD), along with an associated Analysis of Alternatives (AoA) plan. The ICD, as approved by the Joint Requirements Oversight Council (JROC), validates the capability need and includes a list of alternative materiel approaches. These approaches establish boundary conditions for the subsequent AoA, which analytically compares these material approaches. Materiel approaches are elements of the system concepts discussed in DoDI 5000.2.[13]

Before planning the AoA, robust analyses of the technology[14] needed by each of the candidate concepts must be conducted to provide assurance that the technology is available or can be developed. Therefore, before concept decision, CTE identification should be a major effort. Studies must be carried out in enough detail to reveal those features that will be difficult or impossible to achieve with currently mature technology. This includes a thorough consideration of alternative technologies, with focus on their maturity, risk, and maturation needs.

2.3 CONCEPT DECISION AND THE CONCEPT REFINEMENT PHASE

The ICD and a plan for an AoA are presented to the MDA at a Concept Decision review. The MDA designates the lead DoD component(s), grants approval to proceed into Concept Refinement, approves a selected concept, approves the AoA plan, and establishes a date for a Milestone A review.

Paragraph 3.5.3 of DoDI 5000.2 states that the "AoA shall assess the critical technologies associated with these concepts, including technology maturity, technical risk, and, if necessary, technology maturation and demonstration needs." Therefore, the system concept should become more definitive as the AoA progresses. This narrowing of

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12 This discussion has been extracted from the Chairman of the Joint Chiefs of Staff Instruction (CJCSI) 3170.01E, *Joint Capabilities Integration and Development System,* 11 May 2005, and the Chairman of the Joint Chiefs of Staff Manual (CJCSM) 3170.01B, *Operation of the Joint Capabilities Integration and Development System,* 11 May 2005.

13 The term "concepts," as used in DoDI 5000.2, refers to more than materiel concepts.

14 DoDI 5000.2, paragraph 3.4.1 states that the JCIDS process "shall include robust analyses that consider affordability, technology maturity, and responsiveness."

choices should be based on the availability of mature technology and many other considerations. It is an essential ingredient of the Technology Development Strategy (TDS), which is a plan for maturing the promising but still unproven technologies that are key to the system concept. The TDS is a requirement for Milestone A. It is the basis not only for the Technology Development phase of the acquisition process, but also for the program's acquisition strategy at Milestone B.[15]

2.4 MILESTONE A AND THE TECHNOLOGY DEVELOPMENT PHASE

At Milestone A, the program enters the Technology Development phase and begins execution of the MDA-approved TDS. **Note:** *At this point in the process, the program is still not considered an acquisition program.*[16]

As stated in DoDI 5000.2, paragraph 3.6.1, "the purpose of this phase [the Technology Development phase] is to reduce technology risk and to determine the appropriate set of technologies to be integrated into a full system." In DoD, "sufficiently mature for product development" normally requires the technologies to be demonstrated in a relevant environment, [17] so that after detailed design, these items should be suitable for integration into the full system.

Technology Development is often executed with a Technology Transition Agreement (TTA). This document is a commitment of the requirements/resource sponsor, S&T activity (developer and provider of the technology/product), and acquisition program sponsor (intended receiver of a technology or capability) to develop, deliver, and integrate a technology/product into an acquisition program.[18]

Near the completion of the Technology Development phase, a TRA is conducted. The purpose of this TRA is to ensure that a program does not enter System Development and Demonstration (SDD) relying on technologies that fail to meet the maturity criterion. This means that technologies important to the system development and production have been identified through a credible process and that the maturities of these technologies have been demonstrated at an appropriate level. The Milestone B TRA includes primarily

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15 The TDS describes how the program will be divided into technology spirals and development increments, what prototypes will be built and tested, and specific exit criteria. Appendix F contains a TDS template used by the Defense Acquisition University (DAU).

16 Shipbuilding acquisition programs can be initiated at Milestone A (see DoDI 5000.2, paragraph 3.6.3).

17 The relevant environment is described in detail in Appendix D.

18 See Appendix G for a TTA template.

technical information about the system, such as a WBS, and a system architecture with CTEs and results from tests that included prototypes or models.

2.5 MILESTONE B AND THE SDD PHASE

A favorable Milestone B decision authorizes a program or an increment of a program to enter SDD.[19] The SDD phase consists of two major efforts (System Integration and System Demonstration) and a mid-phase Design Readiness Review (DRR) per Figure 2-1. During System Integration, the chosen technologies and subsystems are integrated into a detailed system design. This effort typically includes the demonstration of prototype articles or Engineering Development Models (EDMs) that result from the integration of some or all of the subsystems. The DRR marks the transition to System Demonstration. During System Demonstration, system-level prototypes are demonstrated in the intended environment to show that the system can meet approved requirements.[20] This effort must also establish that no significant manufacturing risks exist and the needed industrial capabilities will be available.

A new or revised TRA is required before Milestone C. This TRA should

- Reflect the resolution of any technology deficiencies that arose during SDD
- Establish that all critical manufacturing technologies are mature for hardware systems
- Document successful development, test, and evaluation (DT&E) for MAIS acquisitions and software-intensive systems.

2.6 MILESTONE C: ENTRY TO PRODUCTION AND DEPLOYMENT

Milestone C authorizes Low Rate Initial Production (LRIP) for MDAPs or limited deployment in support of operational testing for MAIS programs or software-intensive systems that have no production components. LRIP produces production-representative

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19 The Joint Staff finalizes a Capability Development Document (CDD) that is validated and approved before Milestone B. The CDD captures the information necessary to develop a proposed program. The CDD outlines an affordable increment of militarily useful, logistically supportable, and technically mature capability.

20 After DRR, the Joint Staff finalizes a Capability Production Document (CPD). The CPD is validated and approved before Milestone C. Key performance parameters (KPPs) from the CPD are inserted verbatim into the acquisition strategy and the Acquisition Program Baseline (APB). See CJCSM 3170.01B, *Operation of the Joint Capabilities Integration and Development System,* dated 11 May 2005, Enclosure G, paragraphs 1 and 2. This manual should be available at http://www.dtic.mil/cjcs_directives/cjcs/manuals.htm.

articles for Initial Operational Test and Evaluation (IOT&E) and completes manufacturing development to ensure efficient manufacturing capability. After LRIP, approval for Full Rate Production (FRP) depends on demonstrating that critical manufacturing processes are under control in a production environment, statistical process control data are being collected, and design-to-cost (DTC) goals have been met. [21]

2.7 TAILORING THE ACQUISITION PROCESS

The acquisition process framework can be tailored to a specific acquisition program structure. For example, the program does not have to start at Concept Refinement. It can start at any point consistent with phase-specific entrance criteria and statutory requirements. However, any program that enters the acquisition process mid-phase must meet the *entrance* requirements of that phase. In practice, this means that programs starting at or beyond Milestone B must conduct an associated TRA to ensure that the technology is ready for the upcoming phase of acquisition.

DoDI 5000.2 establishes evolutionary development as the strategy that DoD prefers:

> **3.3.2.** The approaches to achieve evolutionary acquisition require collaboration between the user, tester, and developer. They include
>
> **3.3.2.1. Spiral Development.** In this process, a desired capability is identified, but the end-state requirements are not known at program initiation. Those requirements are refined through demonstration and risk management; there is continuous user feedback; and each increment provides the user the best possible capability. The requirements for future increments depend on feedback from users and technology maturation.
>
> **3.3.2.2. Incremental Development.** In this process, a desired capability is identified, an end-state requirement is known, and that requirement is met over time by developing several increments, each dependent on available mature technology.

To ensure that the technology is mature, a TRA should be conducted for each increment or spiral under either approach to evolutionary acquisition.[22]

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[21] From DoDI 5000.2, paragraph 3.8.3.4: "Software shall have demonstrated the maturity level required in the CPD prior to deploying it to the operational environment."

[22] DoDI 5000.2, paragraph 3.7.2.4 and Table E3.T2.

SECTION 3.
THE TRA PROCESS

3.1 INTRODUCTION

This section describes the overall TRA process. While the focus is on the general procedures and best practices for ACAT ID and IAM programs, much of the material is also applicable to smaller programs. Figure 3-1 portrays a suggested time line for TRA activities. Subsections 3.2 and 3.3 discuss activities, roles, and responsibilities of key players within the two broad functional areas that make up the overall TRA process. Examples of some best practices for each of these functional areas are as follows:

- **Identifying CTEs**
  - The PM is responsible for identifying CTEs. Technologies may be critical from a *performance* perspective, a *manufacturing* process, or from a material, measurement, or tooling/infrastructure perspective.
- **Assessing CTE Readiness**
  - The Component S&T Executive should direct the TRA and decide how it will be conducted. Typically, much of the *information* used in a TRA comes from the PM; however, the *assessment* should be independent of the PM. TRLs provide the metric for a technology's maturity.

This *Deskbook* provides guidance on best practices observed across the board. Each Component has its own procedures for conducting TRAs. Refer to the Service or Agency S&T Component for details.

3.2 IDENTIFYING CTEs[23]

Figure 3-2 shows a representative schedule of activities to identify CTEs for a TRA. The "weeks" shown across the top of the figure represent the number of weeks before a milestone decision. Depending on the size and complexity of the program, the start point and activity length may vary greatly. ACAT ID and IAM programs should

[23] See Appendix D for more details.

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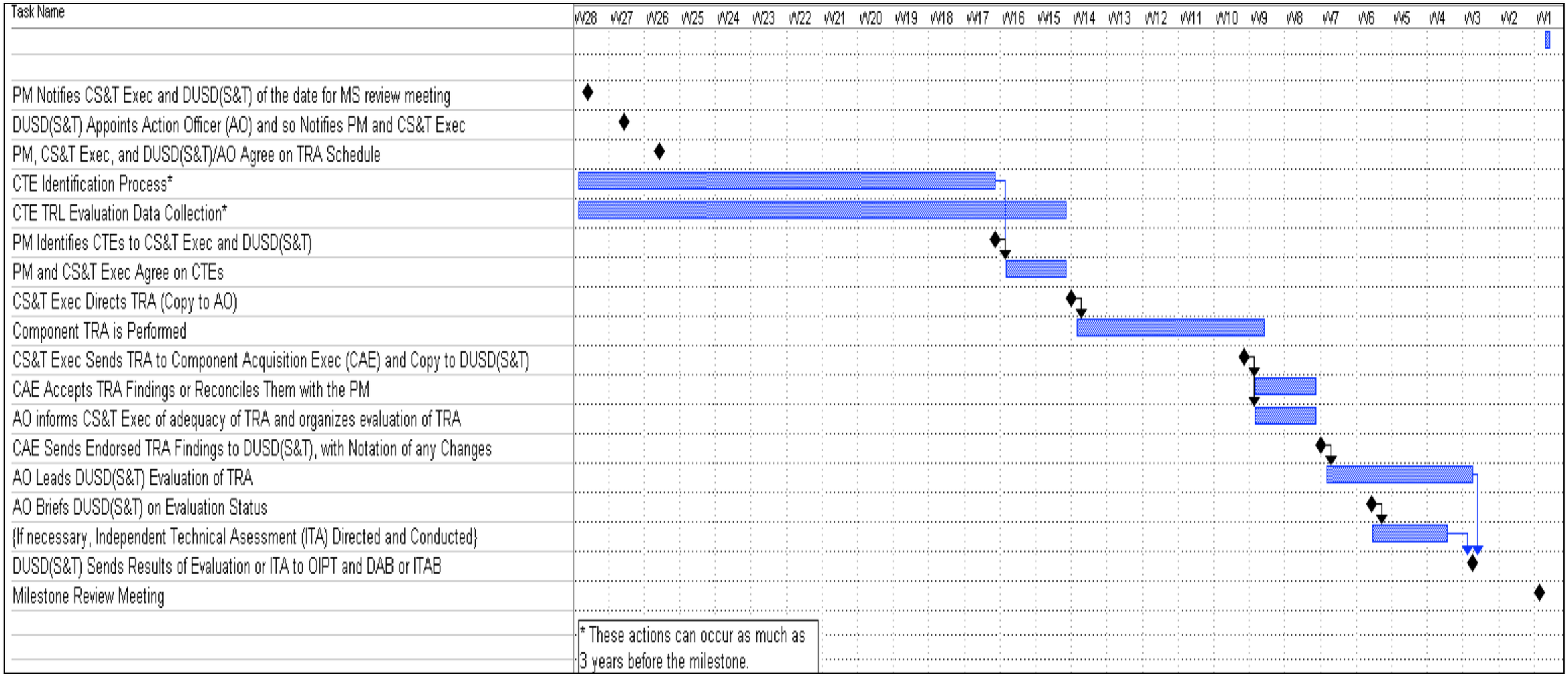

Figure 3-1. Suggested Time Line for TRA Activities for ACAT ID and IAM Programs

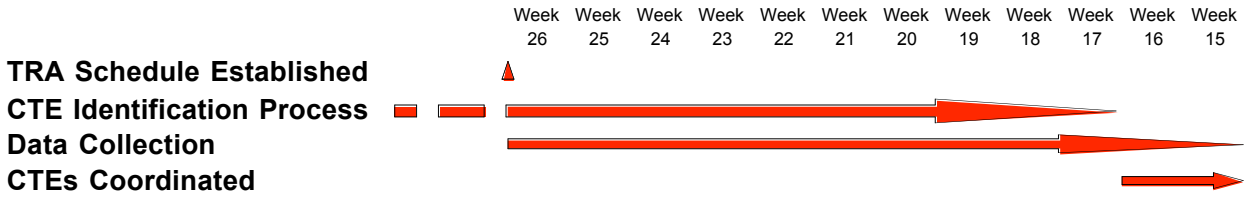

Figure 3-2. Representative Schedule for Identifying CTEs

begin the TRA process a minimum of 26 weeks (preferably 52 weeks) before the milestone decision. The following subsections describe the activities for each line in Figure 3-2. These descriptions include key player roles and responsibilities and the most important best practices.

3.2.1 TRA Schedule Established

Six to 12 months[24] before a Milestone B or C review (or program initiation in the case of ships), the TRA process begins when the Component S&T Executive, working closely with the PM, establishes a schedule for conducting the TRA. The schedule should be consistent with the program's integrated master schedule. The TRA should be completed at least 6 weeks before the Milestone review to allow sufficient time for the DUSD(S&T) to conduct its review and, if needed, to request TRA revisions and/or an ITA.

Key Player Roles and Responsibilities in Establishing the TRA Schedule

- **Component S&T Executive.**[25] Develop the TRA schedule jointly with the program office. The schedule should be coordinated with the DUSD(S&T) for ACAT ID and ACAT IAM acquisitions. This not only allows the Office of the Secretary of Defense (OSD) adequate time to prepare, but also provides an opportunity for OSD to share information on high-interest items. Provide training and support to the program office concerning its roles and responsibilities in the TRA process.

Best Practice

Coordinate the TRA schedule with the DUSD(S&T).

- **Agency Head.** When a program is not managed by one of the Components, the head of the lead Agency should designate a person (e.g., the CIO) to

24 The time varies as a function of Component procedures and the complexity of the program.

25 The Component S&T Executive can delegate his (or her) roles and responsibilities to a TRA coordinator elsewhere in the organization.

carry out the Component S&T Executive's TRA roles and responsibilities if that position does not exist in the Agency. The person selected should be competent in the technical area of the program, independent of the program, and knowledgeable about the DoD acquisition process.

- **PM.** Support the Component S&T Executive in developing and coordinating the schedule. Designating a responsible individual in the program office to organize all TRA activities is helpful. That individual should be the interface point between the Component S&T Executive and the DUSD(S&T).

3.2.2 The CTE Identification Process

The working definition for a CTE is as follows:

> A technology element is "critical" if the system being acquired depends on this technology element to meet operational requirements (with acceptable development, cost, and schedule and with acceptable production and operation costs) *and* if the technology element or its application is either new or novel. Said another way, an element that is new or novel or is being used in a new or novel way is critical if it is necessary to achieve the successful development of a system, its acquisition, or its operational utility.

CTE identification is fundamental to the TRA concept. For a readiness assessment to be useful, it must include all CTEs. CTEs should be identified in the context of the program's systems engineering process based on a comprehensive review of the program's established WBS. For IT/MAIS systems, the system architecture should be used.

In the CTE identification process line of Figure 3-2, the dashed line to the left of "Week 26" indicates that much of this CTE identification should occur well before the formal TRA process. In fact, most CTEs should be identified during Concept Refinement. The TDS should reflect the result of a process sufficiently thorough and disciplined to identify those technologies (including CTEs) that have a realistic potential to be exploited beneficially in the Technology Development phase. Failure to recognize the CTEs at this stage will usually result in wasting resources—time, money, facilities, and so forth—and could result in an unfavorable Milestone B decision. As system development proceeds, the possibility exists, through necessity or opportunity, for the exploitation of technologies not previously considered. These technologies must be given careful consideration to decide whether they are critical and whether they are mature enough to be included in the detailed design.

It may require 10 weeks or more to finalize the list of CTEs for the TRA because CTE identification takes place in two stages.[26] The PM should prepare an initial list of possible CTE candidates. An independent panel should be used to determine which of the candidate technologies included in the original list are "truly" critical based on the CTE definition (see shaded box on page 3-6).

Several useful questions have been developed to facilitate this process:

1. Does the technology directly impact an operational requirement?
2. Does the technology have a significant impact on an improved delivery schedule?
3. Does the technology have a significant impact on the affordability of the system?
4. If this is a spiral development, is the technology essential to meet the spiral deliverables?
5. Is the technology new or novel?
6. Has the technology been modified?
7. Has the technology been repackaged such that a new relevant environment is realized?
8. Is the technology expected to operate in an environment and/or achieve a performance beyond its original design intention or demonstrated capability?

For a technology to be critical, the answer to one of the first four questions (1–4) must be "yes," and the answer to one of last four questions (5–8) must also be "yes." In questions 5 to 8, the environments could include the following:

- **Physical Environment**. For instance, *mechanical components, processors, servers, and electronics; kinetic and kinematic; thermal and heat transfer; electrical and electromagnetic; climatic—weather, temperature, particulate; network infrastructure*
- **Logical Environment.** For instance, *software (algorithm) interfaces; security interfaces; Web-enablement*
- **Data Environment.** For instance, *data formats and databases; anticipated data rates, data delay and data throughput; data packaging and framing*

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[26] Two stages: preparing a list of potential CTEs and conducting a review to determine which CTEs are really critical.

- **Security Environment.** For instance, *connection to firewalls; security appliqués; rates and methods of attack*
- **User and Use Environment.** For instance, *scalability; upgradability; user behavior adjustments; user interfaces; organizational change/realignments with system impacts; implementation plan.*

Therefore, additional questions that can help guide the definition of environment for the CTE candidates include the following:

- Is the physical/logical/data environment in which this CTE has been demonstrated similar to the intended environment? If not, how is it different? Is the difference important?
- Is the CTE going to be operating at or outside of the usual performance envelope? Do the design specifications address the behavior of the CTE under these conditions? What is unique or different about this proposed operations environment?
- Do test data, reports, or analyses that compare the demonstrated environment to the intended environment exist? If modeling and simulation (M&S) is an important aspect of that comparison, are the analysis techniques common and generally accepted?

CTEs may also include high-leverage and/or high-impact manufacturing technologies that enable faster delivery of affordable systems if there is something not well characterized or understood about them or their use for producing the system. For a manufacturing technology, the following questions replace previous questions 5 to 8. The answer to a least one of them must be "no" for the technology to be considered a CTE.

1. Has the manufacturing technology been successfully integrated into a product line?
2. Is the industrial base[27] capable of design, development, production, maintenance and support, and disposal of the system?
3. Is the intended design producible?
4. Have the materials been characterized in a manufacturing environment?
5. Are the materials available to meet quantity and schedule demands?
6. Are the DTC goals achievable?
7. Are the key manufacturing processes characterized, capable, and controllable with respect to achieving the system requirements?

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[27] Depending on the circumstances, this may be limited to the National industrial base.

Key Player Roles and Responsibilities in the CTE Identification Process

- **PM.** Within the context of the program's systems engineering approach and based on a comprehensive review of the program's established WBS or system architecture, use the CTE definition to prepare an initial list of possible CTE candidates. When competing designs exist, identify CTEs separately for each one. At Milestone C, begin with CTEs identified at Milestone B. However, unplanned performance and especially manufacturing technologies could have been incorporated in the design during SDD, so a careful review should be conducted at Milestone C to find any newly emergent CTEs.

Best Practice

Apply the CTE definition across the system WBS or system architecture to identify CTE candidates.

Some programs rely heavily on commercial-off-the-shelf (COTS) or government-off-the-shelf (GOTS) components and may have little-to-no technology development before Milestone B. Also, these programs often plan for a competitive acquisition strategy, and, consequently, the design approach(es) and the associated CTEs will not be finalized until the SDD contract is awarded. Such a situation is contrary to good systems engineering. According to the *Defense Acquisition Guidebook*, the Systems Requirements Review (SRR) conducted before Milestone B is a multifunctional technical review. The purpose of this review is to ensure that all system and performance requirements are defined and consistent with cost (program budget), time frame (program schedule), risk, and other system constraints. Among other things, the SRR is intended to ensure consistency between the system requirements and the preferred system solution and available technologies. It includes a preliminary allocation of system requirements to hardware, human, and software subsystems and an identification of all software components (tactical, support, deliverable, nondeliverable, and so forth).

Best Practice

To the extent possible, exploit the SRR before Milestone B as a contributor to the CTE identification process.

If some overriding circumstance dictates that the program has a Milestone B review before SDD proposals are received, discuss the options with the DUSD(S&T) as early as

Best Practice

When the CTEs are uncertain, discuss options with the DUSD(S&T) as early as possible.

possible. If a decision on contract award is made before Milestone B, use the winning proposal as the basis for a TRA. If proposals have been received but the contract award decision will occur during or after the Milestone B review, identify and assess any CTE bid in any of the proposals.[28] In either case, the TRA may be proprietary and/or competition sensitive.

If a program integrates critical systems or subsystems being developed in other programs, the PM of the higher order program (in preparation for a TRA) should identify the CTEs—including interface technologies—used on his/her side of the interfaces. This PM should request [through the appropriate Program Executive Office (PEO) or CAE, as necessary] and obtain the identification of any CTEs in the lower order programs. The CTEs of the higher order system and all lower order systems or subsystems should be included in the list of CTEs that the PM of the higher order system submits to the Component S&T Executive and the DUSD(S&T).

- **Component S&T Executive.** In conjunction with the PM, form an independent panel to review the candidate technologies included in the original PM-generated list and, based on the CTE definition, make recommendations on which of these technologies are "truly" critical elements.

  Best Practice

  Obtain advice from an independent expert panel on which CTE candidate technologies should be included on the final CTE list.

  An Action Officer (AO), appointed by the Component S&T Executive, should participate in the identification process to the extent that his/her participation is considered useful and valuable. The AO can provide beneficial TRA process and policy experience and information and can also minimize the chance that an unexpected problem will delay the process. The AO should understand the reasons for the inclusion and exclusion of technologies from the initial candidate list before the list is shown to the DUSD(S&T).

- **Independent Panel.** On the basis of the CTE definition, the PM's answers to questions, and personal experience of panel members, make final recommendations (with associated rationale) on which CTEs should be assessed in the TRA.

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[28] Another circumstance in which CTEs may not be firmly understood is the program initiation TRA for ships. Similar best practices apply. If decisions on technology development agreements and contracts have been made, use them as the basis for a TRA. Otherwise, identify and assess any critical technology bid in any of the Technology Development proposals.

3.2.3 Data Collection

Relevant data and information are needed to assess the TRL for each CTE. The process of collecting and organizing the material for each CTE should begin as early as possible. Figure 3-2 shows this process as being concurrent with CTE identification. Data collection should be complete when the CTEs have been finalized. The assessment process will be disrupted and delayed if relevant data are not easily accessible at the time these data are needed.

Key Player Roles and Responsibilities in Data Collection

- **PM.** Compile component or subsystem test descriptions, environments, and results in the context of the system's functional needs. Any other analyses and information necessary to assess and rationalize the maturity of the CTEs should also be included.

3.2.4 CTEs Coordinated

At this point, any disagreements on identifying CTEs should be resolved within the Component. A DUSD(S&T) agreement on the CTEs should also be obtained so that any concerns can be raised early and addressed in a timely manner.

Key Player Roles and Responsibilities in Coordinating CTEs

- **PM.** After reviewing the recommendations of the independent panel, submit the final CTE identification data to the Component S&T Executive and request a TRA. An information copy should be sent to the DUSD(S&T) for ACAT ID and ACAT IAM programs. As part of this submission, explain the function of each CTE at the component, subsystem, and system levels and describe the rationale and criteria for declaring this technology critical. Also, briefly explain the process and criteria used to eliminate the CTE candidates that were not judged to be critical. Provide any additional information requested by the Component S&T Executive or the DUSD(S&T).

Best Practice

CTE identification data should include a brief description of the rationale for declaring a CTE to be critical and of the process and criteria for eliminating a CTE candidate.

- **Component S&T Executive.** Review the CTEs and coordinate with the PM and the DUSD(S&T) on any additions or deletions and on any additional information needed for the TRA.

3.3 ASSESSING CTE READINESS[29]

Figure 3-3 is extracted from the bottom of Figure 3-1. It shows a possible schedule of activities to assess CTE readiness as a continuation of the schedule shown in Figure 3-2. The following subsections describe the activities for each line in Figure 3-3.

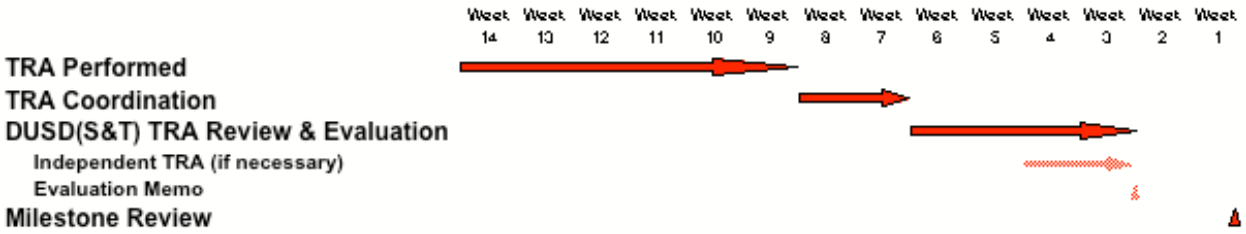

Figure 3-3. Representative Schedule for Assessing CTE Readiness

3.3.1 TRA Performed

Depending on the number of CTEs to be assessed and the complexity of the system, completing the process may require several months. Given all the data, assessing the maturity of a technology does not take very long. However, the amount of time needed to complete the process is also a function of iterative data-collection efforts, obtaining answers to questions, scheduling meetings, and so forth.

Key Player Roles and Responsibilities in Performing the TRA

- **Component S&T Executive.** Conduct the TRA in accordance with Component guidelines and procedures. Appoint and train an independent team[30] to make the assessments. Training should include an overview of the system, an overview of the TRA process, criteria for identifying CTEs, and examples and instructions for the application of the TRLs. Keep DUSD(S&T) informed, as appropriate.[31]

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29 See Appendix C for more details.

30 This may or may not be the same team used to provide a recommendation on CTEs.

31 The Component S&T Executive is not required to agree to any monitoring or participation beyond oversight; however, greater DUSD(S&T) involvement facilitates quicker concurrence. The DUSD(S&T) AO should review the CTEs and the identification process, negotiate any perceived deficiencies, and provide oversight on the overall process while the Component TRA is conducted. The AO should coordinate with the Component S&T Executive to determine to what extent he/she and/or technology specialists designated by the DUSD(S&T) could or should monitor or participate in the Component TRA.

- **Independent Team.** Assess the TRL for all CTEs. Prepare the TRA for submission once the assessment is made. The TRA assessment should explain the function of each CTE at the component, subsystem, and system level. It should also describe the rationale and criteria for declaring these technologies to be critical and for declaring any candidate technology not to be critical.[32] The TRA should also include the basis for the assessment. Evidence could include records of tests or applications of the technology, technical papers, reports, presentations, and so forth. Explain how the material was used or interpreted to make the assessment. The TRA at Milestone C should highlight the assessment of CTEs that did not attain a TRL 6 at Milestone B and additional CTEs that were identified during SDD—especially any manufacturing CTEs. For MAIS acquisition and software-intensive systems at Milestone C, describe the results of DT&E for all CTEs.

Best Practice

The TRA should include the CTE identification rationale and the basis for the assessment.

The Component should use TRLs to communicate TRA findings. Tables 3-1 through 3-4 show TRL definitions, descriptions, and supporting information for hardware, software, and manufacturing technologies.[33]

3.3.2 TRA Coordination

The TRA should be submitted to the DUSD(S&T) according to the agreed-upon schedule—normally, at least 6 weeks before a scheduled Milestone B or Milestone C. Allow at least 2 weeks for the coordination process within the Component before TRA submission. See Figure 3-3.

The coordination should take into account more than agreement on the value of the TRL. The effect of immature technology on programmatics is an even more important consideration. DoD policy on technology maturation is clear. One of the entry

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[32] This represents the minimum requirement for a TRA if no technology was identified as being critical using the criteria described in Subsection 3.2, as supplemented by Appendix D.

[33] See Appendix H for a discussion of biomedical TRLs and Appendix I for a discussion of Manufacturing Readiness Levels (MRLs).

Table 3-1. Hardware TRL Definitions, Descriptions, and Supporting Information (Source: *Defense Acquisition Guidebook*)

TRL	Definition	Description	Supporting Information
1	Basic principles observed and reported.	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development (R&D). Examples might include paper studies of a technology's basic properties.	Published research that identifies the principles that underlie this technology. References to who, where, when.
2	Technology concept and/or application formulated.	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.	Publications or other references that outline the application being considered and that provide analysis to support the concept.
3	Analytical and experimental critical function and/or characteristic proof of concept.	Active R&D is initiated. This includes analytical studies and laboratory studies to physically validate the analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.	Results of laboratory tests performed to measure parameters of interest and comparison to analytical predictions for critical subsystems. References to who, where, and when these tests and comparisons were performed.
4	Component and/or breadboard validation in a laboratory environment.	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared with the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.	System concepts that have been considered and results from testing laboratory-scale breadboard(s). References to who did this work and when. Provide an estimate of how breadboard hardware and test results differ from the expected system goals.
5	Component and/or breadboard validation in a relevant environment.	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment. Examples include "high-fidelity" laboratory integration of components.	Results from testing a laboratory breadboard system are integrated with other supporting elements in a simulated operational environment. How does the "relevant environment" differ from the expected operational environment? How do the test results compare with expectations? What problems, if any, were encountered? Was the breadboard system refined to more nearly match the expected system goals?

Table 3-1. Hardware TRL Definitions, Descriptions, and Supporting Information (Source: *Defense Acquisition Guidebook*) (Continued)

TRL	Definition	Description	Supporting Information
6	System/subsystem model or prototype demonstration in a relevant environment.	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in a simulated operational environment.	Results from laboratory testing of a prototype system that is near the desired configuration in terms of performance, weight, and volume. How did the test environment differ from the operational environment? Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level?
7	System prototype demonstration in an operational environment.	Prototype near or at planned operational system. Represents a major step up from TRL 6 by requiring demonstration of an actual system prototype in an operational environment (e.g., in an aircraft, in a vehicle, or in space). Examples include testing the prototype in a test bed aircraft.	Results from testing a prototype system in an operational environment. Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level?
8	Actual system completed and qualified through test and demonstration.	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.	Results of testing the system in its final configuration under the expected range of environmental conditions in which it will be expected to operate. Assessment of whether it will meet its operational requirements. What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before finalizing the design?
9	Actual system proven through successful mission operations.	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation (OT&E). Examples include using the system under operational mission conditions.	OT&E reports.

Table 3-2. Additional Definitions of TRL Descriptive Terms
(Source: *Defense Acquisition Guidebook*)

Term	Definition
Breadboard	Integrated components that provide a representation of a system/subsystem and that can be used to determine concept feasibility and to develop technical data. Typically configured for laboratory use to demonstrate the technical principles of immediate interest. May resemble final system/subsystem in function only.
High Fidelity	Addresses form, fit, and function. A high-fidelity laboratory environment would involve testing with equipment that can simulate and validate all system specifications within a laboratory setting.
Low Fidelity	A representative of the component or system that has limited ability to provide anything but first-order information about the end product. Low-fidelity assessments are used to provide trend analysis.
Model	A functional form of a system, generally reduced in scale, near or at operational specification. Models will be sufficiently hardened to allow demonstration of the technical and operational capabilities required of the final system.
Operational Environment	Environment that addresses all the operational requirements and specifications required of the final system to include platform/packaging.
Prototype	A physical or virtual model used to evaluate the technical or manufacturing feasibility or military utility of a particular technology or process, concept, end item, or system.
Relevant Environment	Testing environment that simulates the key aspects of the operational environment.
Simulated Operational Environment	Either (1) a real environment that can simulate all the operational requirements and specifications required of the final system or (2) a simulated environment that allows for testing of a virtual prototype. Used in either case to determine whether a developmental system meets the operational requirements and specifications of the final system.

Table 3-3. Software TRL Definitions, Descriptions, and Supporting Information
(Source: *IT TRL Working Group Minutes,* November 9, 2004)

TRL	Definition	Description	Supporting Information
1	Basic principles observed and reported.	Lowest level of software technology readiness. A new software domain is being investigated by the basic research community. This level extends to the development of basic use, basic properties of software architecture, mathematical formulations, and general algorithms.	Basic research activities, research articles, peer-reviewed white papers, point papers, early lab model of basic concept may be useful for substantiating the TRL level.

Table 3-3. Software TRL Definitions, Descriptions, and Supporting Information (Source: *IT TRL Working Group Minutes,* November 9, 2004) (Continued)

TRL	Definition	Description	Supporting Information
2	Technology concept and/or application formulated.	Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies using synthetic data.	Applied research activities, analytic studies, small code units, and papers comparing competing technologies.
3	Analytical and experimental critical function and/or characteristic proof of concept.	Active R&D is initiated. The level at which scientific feasibility is demonstrated through analytical and laboratory studies. This level extends to the development of limited functionality environments to validate critical properties and analytical predictions using non-integrated software components and partially representative data.	Algorithms run on a surrogate processor in a laboratory environment, instrumented components operating in laboratory environment, laboratory results showing validation of critical properties.
4	Module and/or subsystem validation in a laboratory environment (i.e., software prototype development environment).	Basic software components are integrated to establish that they will work together. They are relatively primitive with regard to efficiency and robustness compared with the eventual system. Architecture development initiated to include interoperability, reliability, maintainability, extensibility, scalability, and security issues. Emulation with current/ legacy elements as appropriate. Prototypes developed to demonstrate different aspects of eventual system.	Advanced technology development, stand-alone prototype solving a synthetic full-scale problem, or standalone prototype processing fully representative data sets.
5	Module and/or subsystem validation in a relevant environment.	Level at which software technology is ready to start integration with existing systems. The prototype implementations conform to target environment/ interfaces. Experiments with realistic problems. Simulated interfaces to existing systems. System software architecture established. Algorithms run on a processor(s) with characteristics expected in the operational environment.	System architecture diagram around technology element with critical performance requirements defined. Processor selection analysis, Simulation/ Stimulation (Sim/Stim) Laboratory buildup plan. Software placed under configuration management. COTS/GOTS in the system software architecture are identified.

Table 3-3. Software TRL Definitions, Descriptions, and Supporting Information (Source: *IT TRL Working Group minutes,* November 9, 2004) (Continued)

TRL	Definition	Description	Supporting Information
6	Module and/or subsystem validation in a relevant end-to-end environment.	Level at which the engineering feasibility of a software technology is demonstrated. This level extends to laboratory prototype implementations on full-scale realistic problems in which the software technology is partially integrated with existing hardware/software systems.	Results from laboratory testing of a prototype package that is near the desired configuration in terms of performance, including physical, logical, data, and security interfaces. Comparisons between tested environment and operational environment analytically understood. Analysis and test measurements quantifying contribution to system-wide requirements such as throughput, scalability, and reliability. Analysis of human-computer (user environment) begun.
7	System prototype demonstration in an operational high-fidelity environment.	Level at which the program feasibility of a software technology is demonstrated. This level extends to operational environment prototype implementations where critical technical risk functionality is available for demonstration and a test in which the software technology is well integrated with operational hardware/software systems.	Critical technological properties are measured against requirements in a simulated operational environment.
8	Actual system completed and mission qualified through test and demonstration in an operational environment.	Level at which a software technology is fully integrated with operational hardware and software systems. Software development documentation is complete. All functionality tested in simulated and operational scenarios.	Published documentation and product technology refresh build schedule. Software resource reserve measured and tracked.
9	Actual system proven through successful mission-proven operational capabilities.	Level at which a software technology is readily repeatable and reusable. The software based on the technology is fully integrated with operational hardware/software systems. All software documentation verified. Successful operational experience. Sustaining software engineering support in place. Actual system.	Production configuration management reports. Technology integrated into a reuse “wizard”; out-year funding established for support activity.

Table 3-4. Manufacturing Technology TRL Definitions, Descriptions, and Supporting Information
[Source: *Joint Defense Manufacturing Technology Panel (JDMPT) Manufacturing Readiness Level Subgroup*]

TRL	Definition	Description	Supporting Information
1	Basic principles observed and reported.	NA	
2	Technology concept and/or application formulated.	NA	
3	Analytical and experimental critical function and/or characteristic proof of concept.	NA	
4	Component and/or breadboard validation in a laboratory environment.	The new technology has been demonstrated in a laboratory environment on simple design parts using similar types of materials that would be used in the intended application.	This is the lowest level of production readiness. Component technologies must have matured to at least TRL 4. At this point, few requirements have been validated, and there will be a large number of engineering/design changes. Component physical and functional interfaces have not been defined. Materials, machines, and tooling have been demonstrated in a laboratory environment. Inspection and test equipment have been demonstrated in a laboratory environment. Manufacturing cost drivers are identified. Producibility assessments have been initiated.
5	Component and/or breadboard validation in a relevant environment.	The new technology has been demonstrated in a laboratory environment on design parts of the same level of complexity and using the same types of materials that would be used in the intended application.	Component technologies must have matured to at least TRL 5. At this point, all requirements have not been validated, and there will be significant engineering/design changes. Component physical and functional interfaces have not been defined. Materials, machines, and tooling have been demonstrated in a relevant manufacturing environment, but most manufacturing processes and procedures are in development (or ManTech initiatives are ongoing). Inspection and test equipment have been demonstrated in a laboratory environment. Production cost drivers/goals are analyzed. System-level DTC goals are set. Producibility assessments are ongoing.

Table 3-4. Manufacturing Technology TRL Definitions, Descriptions, and Supporting Information (Source: *JDMTP Manufacturing Readiness Level Subgroup*) (Continued)

TRL	Definition	Description	Supporting Information
6	System/subsystem model or prototype demonstration in a relevant environment.	The new technology has been demonstrated in a pre-production environment on design parts of the same level of complexity and using the same types of materials that would be used in the intended application. Appropriate quality levels have been achieved.	During the prototype demonstration, phase requirements are validated and defined. However, there will still be many engineering/design changes, and the physical and functional interfaces are not yet fully defined. Component technologies must have matured to at least TRL 6. Raw materials are initially demonstrated in relevant manufacturing environment. Similar processes and procedures have been demonstrated in a relevant manufacturing environment. At this point, there are likely major investments required for machines and tooling. Inspection and test equipment should be under development. Producibility assessments are ongoing, and trade studies have been conducted. A production Cost Reduction Plan is developed. Production goals are set.
7	System prototype demonstration in an operational environment.	The new technology has been demonstrated in a relevant production environment on design parts of the same level of complexity and using the same types of materials that would be used in the intended application. Appropriate quality and throughput levels have been achieved.	Component technologies must have matured to at least TRL 7. At this point, engineering/design changes should decrease. Physical and functional interfaces should be clearly defined. All raw materials are in production and available to meet planned LRIP schedule. Pilot line manufacturing processes and procedures set up and under test. Processes and procedures are not yet proven or under control. During this phase, initial producibility improvements should be underway. DTC estimates are less than 125 percent of goals. Detailed production estimates are established.
8	Actual system completed and qualified through test and demonstration.	The new technology has been demonstrated in a pilot production environment on production-representative parts of the same level of complexity and using the same types of materials that would be used in the intended application. Appropriate quality and throughput levels have been achieved. Process has been proven and is under control for LRIP.	Component technologies must have matured to at least TRL 8. At this point, engineering/design changes should decrease significantly. Physical and functional interfaces should be clearly defined. All raw materials are in production and available to meet the planned LRIP schedule. Manufacturing processes and procedures have been proven on the pilot line, are under control, and are ready for LRIP. During this phase, initial producibility risk assessments should be completed. Production cost estimates meet DTC goals.

Table 3-4. Manufacturing Technology TRL Definitions, Descriptions, and Supporting Information (Source: *JDMTP Manufacturing Readiness Level Subgroup*) (Continued)

TRL	Definition	Description	Supporting Information
9	Actual system proven through successful mission operations.	The new technology has been demonstrated in an LRIP environment on intended parts and using the intended types of materials. Process has been proven and under control for production.	During LRIP, all systems engineering/design requirements should be met and there should only be minimal system engineering/design changes. Technologies must have matured to at least TRL 9. Materials are in production and available to meet planned production schedules. Manufacturing processes and procedures are established and controlled in production to three-sigma or some other appropriate quality level. Machines, tooling and inspection and test equipment deliver three-sigma or some other appropriate quality level in production. Production risk monitoring is ongoing. LRIP actual costs meet estimates.

criteria for SDD is that all CTEs should have been demonstrated in a relevant environment. Therefore, if the TRA indicates otherwise, the Component has three choices:[34]

1. Request a delay of the Milestone review until all CTEs are at the requisite maturity level
2. Use alternative, mature technologies in the program
3. *As a last resort,* carry immature technologies into the Milestone review and submit a Technology Maturation Plan (TMP) along with the TRA.

Key Player Roles and Responsibilities in TRA Coordination

- **Component S&T Executive.** For ACAT ID and ACAT IAM programs, approve the TRA, accept responsibility for its accuracy based on established standards and expectations for quality, submit (e.g., sign a forwarding memorandum) the TRA to the CAE or Agency Head and, at the same time, send an information copy to the DUSD(S&T).
- **Component Acquisition Executive or Agency Head.** For ACAT ID and ACAT IAM programs, submit a report to the DUSD(S&T), with an assessed TRL for each CTE. This report can consist of a cover letter or memorandum endorsing the Component TRA and officially transmitting that TRA. The report endorses an agreement with the assessed readiness levels and, if any of the CTEs are immature, a commitment to a TMP.

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[34] See Section 5 for a more complete discussion of this topic.

3.3.3 DUSD(S&T) TRA Review and Evaluation

The DUSD(S&T) evaluates the Component TRA in cooperation with the Component S&T Executive and the PM. An AO, designated by the DUSD(S&T), will normally lead the evaluation effort.[35] After an initial evaluation, the AO can either concur or request that revisions be made. In the latter case, the TRA will be updated and returned to the AO for further review.

If the DUSD(S&T) does not concur with the findings of the Component TRA, an independent technical assessment can be conducted. This independent assessment should be a positive contribution to the acquisition program. For example, it could result in a revised, more realistic schedule, in the use of an alternative technology, or in a revised, evolutionary acquisition strategy. The independent assessment should be conducted as quickly as possible—whether this requires one day or several months. Typically, the Component funds the independent assessment.

The AO prepares a memorandum for DUSD(S&T) signature. This memorandum contains the evaluation results of the Component TRA and of the independent technical assessment (if an independent technical assessment was conducted). It indicates either concurrence or concurrence with reservations concerning the findings of the Component TRA, or it contains the findings of the independent technical assessment. If the AO deems any CTE to be insufficiently mature for the coming milestone, he/she informs the Component S&T Executive and the PM so that all involved have an opportunity to reach agreement on appropriate action. The memorandum is sent to the Overarching Integrated Product Team (OIPT) and the Defense Acquisition Board (DAB) or to the Information Technology Overarching Integrated Product Team (IT OIPT) and the Information Technology Acquisition Board (ITAB). The evaluation memorandum should be signed at least 15 days before a Milestone B or Milestone C review meeting.[36] This memo is forwarded to the MDA and, if there is nonconcurrence, to the OIPT/ITOIPT and the DAB/ITAB. Concurrence with reservation is handled on a case-by-case basis.

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[35] The AO calls for assistance, as necessary, to obtain a competent assessment of the CTEs and to determine whether all the CTEs have been identified.

[36] If this 15-day window is not possible, the date of the review meeting should be reconsidered so the OIPT and DAB members or the IT OIPT and ITAB members have ample time to review all the relevant information. As appropriate, the memorandum should address recommendations to the MDA for issues to be raised at the Milestone review and for items to be included in the ADM.

SECTION 4.
SUBMITTING A TRA

4.1 SKELETAL TEMPLATE FOR A TRA SUBMISSION

The following outline is a skeletal template for anticipated TRA submissions:

1.0 Purpose of This Document

2.0 Program Overview

2.1 Program Objective

2.2 Program Description

2.3 System Description

3.0 Technology Readiness Assessment

3.1 Process Description

3.2 CTEs

3.3 Assessment of Maturity

3.3.1 First CTE or Category of Technology

3.3.2 Next CTE or Category of Technology

3.4 Summary of TRLs by Technology

4.0 Conclusion

4.2 ANNOTATED TEMPLATE FOR A TRA SUBMISSION

The following outline is an annotated version of the TRA template. [37]

1.0 Purpose of This Document

Should be short and should give the program name, the system name if different from the program name, and the milestone or other decision point for which the TRA was performed. For example, "This document presents an independent Technology Readiness Assessment (TRA) for the UH-60M helicopter program in support of the Milestone B decision. The TRA was performed at the direction of the Army S&T Executive."

2.0 Program Overview

2.1 Program Objective

States what the program is trying to achieve (e.g., new capability, improved capability, lower procurement cost, reduced maintenance or manning, and so forth). Refers to the Capability Development Document (CDD) (for Milestone B) or the Capability Production Document (CPD) (for Milestone C) that documents the program objectives.

2.2 Program Description

Briefly describes the program, not the system. Does the program provide a new system or a modification to an existing operational system? Is it an evolutionary acquisition program? If so, what capabilities will be realized in Increment 1? When is the initial operational capability (IOC)? Does it have multiple competing prime contractors? Into what architecture does it fit? Is it a system-of-systems? Does its success depend on the success of other acquisition programs?

2.3 System Description

Describes the overall system, the major subsystems, and components, as necessary, to give an understanding of what is being developed and to show what is new, unique, or special about it. This should include the systems, components, and technologies that will later be declared Critical Technology Elements (CTEs) Describes how the system works (if this is not obvious).

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[37] People who directly contribute to the generation of TRAs can obtain examples of TRA reports from Mr. Jack Taylor. Mr. Taylor's contact information is as follows: DDR&E, 1777 North Kent Street, Rosslyn, VA 22209. Phone number: 703-588-7405; e-mail address: jack.taylor@osd.mil.

3.0 Technology Readiness Assessment (TRA)

3.1 Process Description

Tells who led the TRA and what organizations or individuals performed the TRA. Identifies the special expertise of participating organizations or individuals. This should establish the competence and the independence of the TRA. In this context, "independence" means that the assessors are not unduly influenced by the opinions of the developers (government or industry). Usually, the PM or the System Program Office (SPO) will provide most of the data and other information that form the basis of a TRA. Nevertheless, the *assessment* should be *independent* of the PM or SPO.

Tells how CTEs were identified (i.e., the process and criteria used and who identified them). Describes the scale used for the assessments [usually Technology Readiness Levels (TRLs)].

States what analyses and investigations were performed when making the assessment (e.g., examination of test setups, discussions with test personnel, analysis of test data, review of related technology, and so forth).

This is only a broad description of the process. Paragraph 3.3 presents an opportunity to include more detail.

3.2 CTEs

Shows the work breakdown structure (WBS) or systems architecture and the CTEs. Lists the technologies included in the TRA. Explains the criterion for technologies that were included on the list of CTEs. Describes the environment surrounding each CTE. A table that lists the technology name and includes a few words that describe the technology, its function, and the environment is appropriate. The names of these CTEs should be used consistently throughout the remainder of the document.

Any additional technology elements that the Component S&T Executive considers critical should be included.

3.3 Assessment of Maturity

3.3.1 First CTE or Category of Technology

Describes the technology (subsystem, component, or technology). Describes the function it performs and, if needed, how it relates to other parts of the system. Provides a synopsis of development history and status. This can include facts about related uses of the same or similar technology, numbers or hours of testing of breadboards, numbers of prototypes built and tested, relevance of the test conditions, and results achieved.

Describes the environment in which the technology has been demonstrated. Provides a brief analysis of the similarities between the demonstrated environment and the intended operational environment.

Finally, applies the criteria for TRLs and assigns a readiness level to the technology. States the readiness level (e.g., TRL 5) and the rationale for choosing this readiness level.

Provides extensive references to papers, presentations, data, and facts that support the assessment. Includes data tables and graphs that illustrate that a key fact is appropriate.

If the CTEs presented are in categories (e.g., airframe or sensors), the information specified in the previous paragraph (e.g., describing the technology, describing the function it performs, and so forth) should be provided for each CTE within a category.

3.3.2 Next CTE or Category of Technology

For the other CTEs, this paragraph and the following paragraphs (e.g., 3.3.3, 3.3.4, and so forth) present the same type of information that was presented in paragraph 3.3.1.

3.4 Summary of TRLs by Technology

Presents a table that lists the CTEs and presents the TRL assigned, along with a short explanation (one sentence or a list of factors).

4.0 Conclusion

States the Component S&T Executive's position concerning the maturity of the technologies and whether this maturity is adequate for the system to enter the next stage of development. If the position supports entering the next stage even though some CTEs are less mature than would ordinarily be expected, explains what circumstances or planned work justifies this position. Includes references to a separately submitted Technology Maturation Plan (TMP) for each immature CTE.

The TRA should be signed "Approved By" the Component S&T Executive, or it should be transmitted with a cover memorandum that clearly states that the TRA represents the position of the Component S&T Executive. In effect, the Component S&T Executive must certify that he/she stands behind the statements in the conclusion.

Finally, the TRA should be signed by the Component Acquisition Executive (CAE).

SECTION 5.
GUIDANCE AND BEST PRACTICES FOR THE USE OF TMPs

5.1 INTRODUCTION

DoD has a long history of accepting high technology risk and suffering the consequences. "Excessive optimism in drawing up performance specifications can make the development so difficult that it must fail or take much longer and cost much more than planned, or require a downgrading of the requirements. It is not unusual for weapon system requirements to be so optimistic that several inventions or advances in the state of the art are needed on schedule if the development is to succeed."[38] More than 40 years after this observation, the situation has not changed substantially. The current defense acquisition system attempts to solve this problem by requiring that technologies for a new system be mature before being used in Systems Integration, the first part of SDD.

5.2 THE PROPER TIME TO MATURE TECHNOLOGY

DoD policy on technology risk is quite clear: "PMs shall reduce technology risk, demonstrate technologies in a relevant environment, and identify technology alternatives, prior to program initiation" (DoDI 5000.1, paragraph E1.14). Program initiation is normally at Milestone B.

> The management and mitigation of technology risk, which allows less costly and less time-consuming systems development, is a crucial part of overall program management and is especially relevant to meeting cost and schedule goals. Objective assessment of technology maturity and risk shall be a routine aspect of DoD acquisition. Technology developed in S&T or procured from industry or other sources shall have been demonstrated in a relevant environment or, preferably, in an operational environment to be considered mature enough to use for product development in systems integration. Technology readiness assessments and, where necessary, independent assessments, shall be conducted. If technology is not mature, the DoD Component shall use alternative technology that is mature and that can meet the user's needs. (DoDI 5000.2, paragraph 3.7.2.2)

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[38] C.J. Hitch and R.N. McKean, *The Economics of Defense in the Nuclear Age*, Atheneum Press, New York, 1965, cited in E.H. Conrow, *Effective Risk Management: Some Keys To Success* (p. 4), American Institute of Aeronautics and Astronautics, Inc., Reston, VA, 2000.

All acquisition personnel, especially PMs, should understand that acquisition programs are to use mature technology. The overall acquisition management framework is designed to provide time for identifying the technology needed and time for developing the needed technology. These intervals are designated Concept Refinement and Technology Development.

The TDS formulated during the Concept Refinement phase should show how the technologies (those known at Milestone A to be critical to the successful realization of the chosen concept) will be demonstrated in a relevant environment before they are used in System Development. Any exception to this approach should be brought to the attention of the MDA, and this departure from DoD policy should be fully justified before asking the MDA to approve entry into the Technology Development phase for potential ACAT ID and IAM programs.

Best Practice

For ACAT ID and IAM programs, the sponsoring Component should ensure that the TDS (at Milestone A) includes activities, schedule, and funding to demonstrate the identified CTEs of the chosen concept in a relevant environment.

The chosen concept continues to evolve and become better defined throughout the Technology Development phase. This process can lead to a different set of preferred technologies, some of which might be CTEs. When this occurs, the program should consider technology maturity in making the technology choices and should execute a program to mature all CTEs before reaching Milestone B. DoDI 5000.2 makes it clear that programs should be planned so that System Development can use only mature technologies.

> The project shall exit Technology Development when an affordable increment of militarily useful capability has been identified, the technology for that increment has been demonstrated in a relevant environment, and a system can be developed for production within a short time frame (normally less than 5 years); or when the MDA decides to terminate the effort. … A Milestone B decision follows the completion of Technology Development." (DoDI 5000.2, paragraph 3.6.7).

5.3 TMPs AT MILESTONE B[39]

Best Practice

All CTEs should be identified and successfully demonstrated in a relevant environment (a TRL 6 or higher) before Milestone B.

DoD policy for technology maturation at Milestone B is unambiguous. Either schedule Milestone B for a date after the CTEs will be mature or use other technologies that are already mature. Nevertheless, PMs have taken programs to Milestone B with immature CTEs (i.e., not demonstrated in the relevant environment). In this case, the MDA decision options include rescheduling Milestone B, directing the use of an alternative technology (perhaps only in the initial increment), or conditionally approving entry into SDD.

Conditional approval to enter SDD implies that certain critical conditions have been met, namely:

- A sound technical basis exists for expecting the immature technology to prove adequate after a demonstration.
- A substitute *mature* technology exists, and this technology can be used in case the demonstration is unsuccessful.
- The program plan can accommodate use of either technology from funding, performance, and schedule perspectives.

According to the *Defense Acquisition Guidebook* these conditions must be captured in a TMP. "If the system does not meet pre-defined Technology Readiness Level scores, then a Critical Technology Element maturation plan is identified. This plan explains in detail how the Technology Readiness Level will be reached prior to the next milestone decision date or relevant decision point" (Section 4.3.2.4.3).

The TMP is different from the TDS that was prepared before Milestone A. The TMP should be more specific regarding what is going to be done, what test articles will be made, the TRL levels that will be achieved, the schedule of demonstrations, the fall-back technology and its maturity, and the decision date for choosing between the preferred technology and the fall-back technology. Section 5.5.1 of this document provides an outline for a TMP.

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[39] In an evolutionary acquisition program, a separate Technology Development phase and Milestone B are required for each increment. The reason for a new increment might be to introduce new technology or to extend the operating environment, either of which could result in the use of immature technology. Consequently, each increment should be examined individually.

The TMP is a commitment by the PM and the Component. It should be approved or certified by the CAE and included with the TRA for ACAT ID and IAM programs to give the MDA a basis for the Milestone B decision.

When the MDA authorizes a program to enter SDD with immature technology, the Acquisition Decision Memorandum (ADM) usually calls for greater than normal oversight by the OSD staff. It also sometimes requires additional reporting—possibly even a new TRA—to be provided by a specified time during System Integration.

Best Practice

If some overriding circumstance causes the program to have a Milestone B review before all CTEs are at TRL 6 or above, include, as part of the TRA, a TMP for each deficient technology and a rationale for proceeding to SDD while maturation continues.

5.4 TMPs AT MILESTONE C

A TRA is also required before approval to enter LRIP at Milestone C for hardware systems or limited deployment in support of operational testing for MAIS programs or software-intensive systems that have no production components. Just as TRL 6 is usually required for Milestone B, TRL 7 is usually required for Milestone C. By Milestone C, prototypes have been tested in field trials under conditions that simulate the operational environment. Success in these tests can usually be taken as demonstration at TRL 7 for the performance technologies.[40] However, unplanned technologies could have been incorporated in the design during SDD, so a careful review of the design should be conducted to find any such technologies and then to assess their maturity. Under no circumstances should a critical performance technology be less than TRL 7 at Milestone C.

The TRA at Milestone C is most important for manufacturing technologies. Prototypes are often built by methods that are not suitable for production, so the testing of prototypes does not usually tell much about the maturity of the manufacturing technologies that must be used to achieve the production rate, production cost, and low defect rate that are needed.

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40 "Performance technologies" influence the performance of the produced system, as distinguished from "manufacturing technologies," which influence construction of that system.

At TRL 7, the maturity of a manufacturing technology should be as follows:

- Manufacturing processes, materials and assembly methods have been developed for a production environment—ideally in a pre-production facility or better.
- The design is maturing, key materials and process characteristics have been identified, and planning is taking place for managing process controls, as appropriate.
- A detailed manufacturing risk assessment has been performed. This assessment covers industrial base infrastructure (facilities and manpower), materials (availability, producibility characteristics), methods (mature processes), measurement (inspection and test equipment), and costs.
- A quality management structure has been identified.
- Initial goals have been set for yields, quality, and reliability.

Best Practice

If the critical manufacturing technologies have not been successfully qualified through test and demonstration (TRL 8) by Milestone C, include with the Milestone C TRA a TMP for the immature manufacturing technologies.

FRP (post LRIP) should not be initiated if a critical manufacturing technology has not reached TRL 8—successfully qualified through test and demonstration—or TRL 9. This implies the following:

- Manufacturing processes, materials, and assembly methods demonstrated on production-representative articles with no known significant manufacturing risk
- Yields, quality, and reliability within 25 percent of goals
- Design mature (process requirements proven and validated)
- Quality management structures in place.

5.5 PREPARING TMPs

Figure 5-1 shows a possible schedule of activities to mitigate technology risk. While this is a continuation of the schedules shown in Section 3, the time scaling is different. TMP oversight is a continuous activity over a long period of time. Arbitrary locations have been used for the three technical reviews that occur during Systems

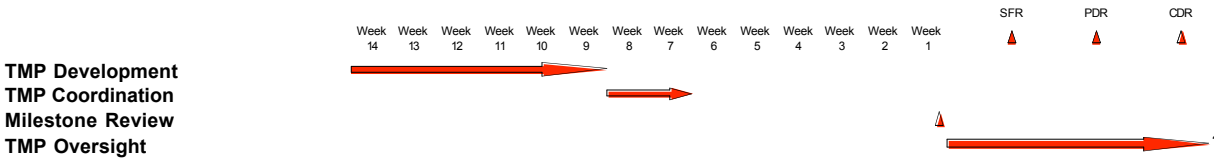

Figure 5-1. Representative Schedule for TMP Preparation and Oversight

Integration: the System Function Review (SFR), the Preliminary Design Review (PDR), and the Critical Design Review (CDR). The following subsections describe the template, activities, and key player roles and responsibilities.

5.5.1 TMP Development

The following outline for a TMP includes the most essential items:

- Title
- Statement of the problem
  - Describe the technology and its maturity status
  - Say how this technology would be used in the system
- Solution options
  - Benefits of using the preferred technology
  - Fall-back options and the consequences of each option
- Maturation program plan with schedule
  - Describe key activities for the preferred technology
  - Describe preparations for using an alternative technology
  - Show the latest time that an alternative technology can be chosen
- Specific actions to be taken (what will be done and by whom)
  - What prototypes or EMDs will be built?
  - What tests will be run?
  - How does the test environment relate to the operational environment?
  - What threshold performance must be met?
  - What TRL will be achieved?
- Status of funding to perform this technology maturation.

Key Player Roles and Responsibilities in TMP Development

- **PM.** The PM is responsible for developing the TMP. When a PM anticipates that a CTE will be less mature than TRL 6 at Milestone B or a critical manufacturing technology is less than TRL 8 at Milestone C, prepare a TMP and submit that plan through the Component S&T Executive to be included with the Component TRA.
- **Component S&T Executive.** Assign an AO to participate in the process to the extent that his/her participation is considered useful and valuable.

5.5.2 TMP Coordination

The TMP coordination should be concurrent with the TRA coordination.

Key Player Roles and Responsibilities in TMP Coordination

- **PM.** Submit the plan to the Component S&T Executive. An information copy should be sent to the DUSD(S&T) for ACAT ID and ACAT IAM programs. Provide any additional information requested by the Component S&T Executive or the DUSD(S&T).
- **Component S&T Executive.** Review the plan and coordinate with the PM on any additions or deletions and on any additional information needed. For ACAT ID and ACAT IAM programs, approve the TMP, accept responsibility for its accuracy, submit the plan (e.g., sign a forwarding memorandum) to the CAE or Agency Head and, at the same time, send an information copy to the DUSD(S&T).
- **CAE or Agency Head.** For ACAT ID and ACAT IAM programs, certifies that the plan is a commitment of the Component and submits the plan to the DUSD(S&T).

5.5.3 TMP Oversight

Technical reviews provide the PM an integrated technical assessment of program technical risk and the readiness to proceed to the next technical phase. These technical reviews are conducted between the Program Management Office (PMO) and the system developer.

The *Defense Acquisition Guidebook* identifies three such reviews during System Integration: SFR, PDR, and CDR. These reviews provide opportunities to assess the progress of the technology maturation activities and to inform OSD of the results. Close attention to the maturation progress is important because any delay or failure could jeopardize a program's schedule.

Key Player Roles and Responsibilities in TMP Oversight

- **PM.** Notify the DUSD(S&T) and the Component S&T Executive whenever a decision is made to use a mature, alternative technology or whenever any deviation from the schedule in the TMP occurs. Report the status and results at OIPT meetings.
- **Component S&T Executive.** Monitor all technology maturation efforts and demonstration activities included in the plan. Support the maturation efforts as required by the plan.
- **DUSD(S&T).** Monitor the technology maturation status at technical reviews and OIPT meetings.

GLOSSARY

ACAT	Acquisition Category
ADM	Acquisition Decision Memorandum
AIS	Automated Information System
AKSS	AT&L Knowledge Sharing System
AO	Action Officer
AoA	Analysis of Alternatives
APB	Acquisition Program Baseline
ASD(C3I)	Assistant Secretary of Defense for Command, Control, Communications, and Intelligence
ASD(NII)	Assistant Secretary of Defense for Networks and Information Integration
CAE	Component Acquisition Executive
CDD	Capability Development Document
CDR	Critical Design Review
CIO	Chief Information Officer
CJCSI	Chairman of the Joint Chiefs of Staff Instruction
CJCSM	Chairman of the Joint Chiefs of Staff Manual
COTS	commercial-off-the-shelf
CPD	Capability Production Document
CS&T	Component Science and Technology
CTE	Critical Technology Element
DAB	Defense Acquisition Board
DARC	Defense Acquisition Resource Center
DAU	Defense Acquisition University
DDR&E	Director of Defense Research and Engineering
DoD	Department of Defense
DoDD	DoD Directive
DoDI	DoD Instruction

DOTMLPF	doctrine, organization, training, materiel, leadership and education, personnel, and facilities
DRR	Design Readiness Review
DT&E	development, test, and evaluation
DTC	design-to-cost
DUSD(S&T)	Deputy Under Secretary of Defense for Science and Technology
EDM	Engineering Development Model
FOC	full operational capability
FRP	Full Rate Production
GAO	government Accountability Office
GOTS	Government-off-the-shelf
ICD	Initial Capabilities Document
IOC	initial operational capability
IOT&E	Initial Operational Test and Evaluation
IT OIPT	Information Technology Overarching Integrated Product Team
IT	Information Technology
ITA	Independent Technical Assessment
ITAB	Information Technology Acquisition Board
JCIDS	Joint Capabilities Integration and Development System
JDMTP	Joint Defense Manufacturing Technology Panel
JFCOM	Joint Forces Command
JROC	Joint Requirements Oversight Council
KPP	key performance parameter
LRIP	Low Rate Initial Production
M&S	modeling and simulation
MAIS	Major Automated Information System
MDA	Milestone Decision Authority
MDAP	Major Defense Acquisition Program
MRL	Manufacturing Readiness Level
MS	Milestone
NASA	National Aeronautics and Space Administration

OIPT	Overarching Integrated Product Team
OSD	Office of the Secretary of Defense
OT&E	Operational Test and Evaluation
PDR	Preliminary Design Review
PEO	Program Executive Office
PM	Program Manager
PMO	Program Management Office
R&D	research and development
RDT&E	research, development, test, and evaluation
S&T	Science and Technology
SAIC	Science Applications International Corporation
SDD	System Development and Demonstration
SFR	System Function Review
Sim/Stim	Simulation/Stimulation
SPO	System Program Office
SRR	Systems Requirements Review
TDS	Technology Development Strategy
TEAO	Test, Evaluation, Analysis, and Operation
TMP	Technology Maturation Plan
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level
TTA	Technology Transition Agreement
USD(AT&L)	Under Secretary of Defense for Acquisition, Technology, and Logistics
WBS	work breakdown structure

APPENDIXES

APPENDIX A.
EXTRACTS FROM THE DEPARTMENT OF DEFENSE (DoD) 5000 SERIES OF DOCUMENTS AND THE *DEFENSE ACQUISITION GUIDEBOOK* RELEVANT TO TECHNOLOGY READINESS ASSESSMENTS (TRAs)

The DoD documents relevant to TRAs are

- Department of Defense Directive (DoDD) 5000.1, *The Defense Acquisition System,* dated May 12, 2003
- Department of Defense Instruction (DoDI) 5000.2, *Operation of the Defense Acquisition System,* dated May 12, 2003
- *Defense Acquisition Guidebook.*

For background and reference, the portions of these documents relevant to technology readiness are shown below. These documents appear on Internet Web site http://akss.dau.mil/darc/darc.html in their entirety.

A.1 EXTRACTS FROM DoDD 5000.1, DATED MAY 12, 2003

A.1.1 Section 4. Policy

- **4.3.** The following policies shall govern the Defense Acquisition System:

  4.3.1. Flexibility. There is no one best way to structure an acquisition program to accomplish the objective of the Defense Acquisition System. MDAs and PMs shall tailor program strategies and oversight, including documentation of program information, acquisition phases, the timing and scope of decision reviews, and decision levels, to fit the particular conditions of that program, consistent with applicable laws and regulations and the time-sensitivity of the capability need.

  4.3.2. Responsiveness. Advanced technology shall be integrated into producible systems and deployed in the shortest time practicable. Approved, time-phased capability needs matched with available technology and resources enable evolutionary acquisition strategies. Evolutionary acquisition strategies are the preferred approach to satisfying operational needs. Spiral development is the preferred process for executing such strategies.

A.1.2 Enclosures

- **Enclosure 1: Additional Policy**

  E1.14. Knowledge-Based Acquisition. PMs 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.

E1.28. Technology Development and Transition. The Science and Technology (S&T) program shall:

E.1.28.1. Address user needs;

E.1.28.2. Maintain a broad-based program spanning all Defense-relevant sciences and technologies to anticipate future needs and those not being pursued by civil or commercial communities;

E1.28.3. Preserve long-range research; and

E.1.28.4. Enable rapid, successful transition from the S&T base to useful military products.

A.2 EXTRACTS FROM DoDI 5000.2, DATED MAY 12, 2003

A.2.1 Section 2. Applicability and Scope

- **2.2.** All defense technology projects and acquisition programs. Some requirements, where stated, apply only to Major Defense Acquisition Programs (MDAPs) and Major Automated Information System (MAIS) programs.

A.2.2 Section 3. Procedures

- **3.4. User Needs and Technology Opportunities**

  3.4.1. The capability needs and acquisition management systems shall use Joint Concepts, integrated architectures, and an analysis of doctrine, organization, training, materiel, leadership, personnel, and facilities (DOTMLPF) in an integrated, collaborative process to define desired capabilities to guide the development of affordable systems. The Chairman of the Joint Chiefs of Staff, with the assistance of the Joint Requirements Oversight Council, shall assess and provide advice regarding military capability needs for defense acquisition programs. The process through which the Chairman provides his advice is described in Chairman of the Joint Chiefs of Staff Instruction 3170.01 (reference (g)). Representatives from multiple DoD communities shall assist in formulating broad, time-phased, operational goals, and describing requisite capabilities in the Initial Capabilities Document (ICD). They shall examine multiple concepts and materiel approaches to optimize the way the Department of Defense provides these capabilities. The examination shall include robust analyses that consider affordability, technology maturity, and responsiveness.

- **3.5. Concept Refinement**

  3.5.2. Concept Refinement begins with the Concept Decision. The MDA designates the lead DoD Component(s) to refine the initial concept selected,

approves the AoA plan, and establishes a date for a Milestone A review. The MDA decisions shall be documented in an Acquisition Decision Memorandum (ADM). This effort shall normally be funded only for the concept refinement work. The MDA decision to begin Concept Refinement DOES NOT mean that a new acquisition program has been initiated. The tables in enclosure 3 identify all statutory and regulatory requirements for the Concept Refinement decision.

3.5.3. The ICD and the AoA plan shall guide Concept Refinement. The focus of the AoA is to refine the selected concept documented in the approved ICD. The AoA shall assess the critical technologies associated with these concepts, including technology maturity, technical risk, and, if necessary, technology maturation and demonstration needs. To achieve the best possible system solution, emphasis shall be placed on innovation and competition. Existing commercial-off-the-shelf (COTS) functionality and solutions drawn from a diversified range of large and small businesses shall be considered.

- **3.6. Technology Development**

3.6.1. Purpose. The purpose of this phase is to reduce technology risk and to determine the appropriate set of technologies to be integrated into a full system. Technology Development is a continuous technology discovery and development process reflecting close collaboration between the S&T community, the user, and the system developer. It is an iterative process designed to assess the viability of technologies while simultaneously refining user requirements.

3.6.2. The project shall enter Technology Development at Milestone A when the MDA has approved the TDS. The tables in enclosure 3 identify all statutory and regulatory requirements applicable to Milestone A. This effort normally shall be funded only for the advanced development work. For business area capabilities, commercially available solutions shall be employed. (A toolkit of best practices is available at http://deskbook.dau.mil). A favorable Milestone A decision DOES NOT mean that a new acquisition program has been initiated.

3.6.3. Shipbuilding programs may be initiated at the beginning of Technology Development. The information required in the tables at enclosure 3 shall support program initiation. A cost assessment shall be prepared in lieu of an independent cost estimate (ICE), and a preliminary assessment of the maturity of key technologies shall be provided.

- **3.7. System Development and Demonstration**

  3.7.1. Purpose

  3.7.1.2. SDD has two major efforts: System Integration and System Demonstration. The entrance point is Milestone B, which is also the initiation of an acquisition program. There shall be only one Milestone B per program or evolutionary increment. Each increment of an evolutionary acquisition shall have its own Milestone B. The tables in enclosure 3 identify the statutory and regulatory requirements that shall be met at Milestone B. For Shipbuilding Programs, the required program information shall be updated in support of the Milestone B decision, and the ICE shall be completed. The lead ship in a class shall normally be authorized at Milestone B. Technology readiness assessments shall consider the risk associated with critical subsystems prior to ship installation. Long lead for follow ships may be initially authorized at Milestone B, with final authorization and follow ship approval by the MDA dependent on completion of critical subsystem demonstration and an updated assessment of technology maturity.

  3.7.2. Entrance Criteria. Entrance into this phase depends on technology maturity (including software), approved requirements, and funding. Unless some other factor is overriding in its impact, the maturity of the technology shall determine the path to be followed. Programs that enter the acquisition process at Milestone B shall have an ICD that provides the context in which the capability was determined and approved, and a CDD that describes specific program requirements.

  3.7.2.2. The management and mitigation of technology risk, which allows less costly and less time-consuming systems development, is a crucial part of overall program management and is especially relevant to meeting cost and schedule goals. Objective assessment of technology maturity and risk shall be a routine aspect of DoD acquisition. Technology developed in S&T or procured from industry or other sources shall have been demonstrated in a relevant environment or, preferably, in an operational environment to be considered mature enough to use for product development in systems integration. Technology readiness assessments, and where necessary, independent assessments, shall be conducted. If technology is not mature, the DoD Component shall use alternative technology that is mature and that can meet the user's needs.

A.2.3 Enclosures

- **Enclosure 3: Statutory, Regulatory, and Contract Reporting Information and Milestone Requirements**

  E.3.1. Tables E3.T1, E3.T2, and E3.T3,[41] below, show the information requirements for all milestones and phases, both statutory and regulatory, to include contract reporting. MDAs may tailor regulatory program information to fit the particular conditions of an individual program. A non-mandatory guidebook shall support this Instruction to provide best practices, lessons learned, and expectations for the information required by these tables. Issues regarding the intent of the expectations described in the guidebook shall be resolved by the MDA. The AT&L Knowledge Sharing System (formerly Defense Acquisition Deskbook) contains a library of mandatory policy and regulations and discretionary practices and advice. The Internet Web site address is http://deskbook.dau.mil/.

Table E3.T1. Statutory Information Requirements

Information Required	Applicable Statute	When Required
The following information requirements are statutory for both MDAPs and MAIS acquisition programs		
Consideration of Technology Issues	10 U.S.C. 2364, reference (q)	Milestone (MS) A MS B MS C
The following information requirements are statutory for MDAPs and are applicable to MAIS acquisition programs by this Instruction		
Technology Development Strategy (TDS)	Sec. 803, Pub.L. 107-314, reference (an)	MS A MS B MS C

Table E3.T2. Regulatory Information Requirements

Information Required	Source	When Required
Technology Readiness Assessment	This Instruction	Program Initiation for Ships (preliminary assessment) MS B MS C
Independent Technology Assessment (ACAT ID only) (if required by DUSD(S&T))	This Instruction	MS B MS C
Command, Control, Communications, Computers, and Intelligence Support Plan (C4ISP) (also summarized in the acquisition strategy)	DoD Instruction 4630.8 and DoD Directive 4630.5, references (ar) and (as)	Program Initiation for Ships MS B MS C

[41] The parts of Tables E3.T1 and E3.T2 relevant to this discussion are included. Table E3.T3 is not included in this appendix.

A.3 EXTRACTS FROM THE *DEFENSE ACQUISITION GUIDEBOOK*

A.3.1 Chapter 4. Systems Engineering

- **4.3. Systems Engineering Activities in the System Life Cycle**

  4.3.2. Technology Development Phase

  4.3.2.5. Outputs of the Systems Engineering Processes in Technology Development

  – Preliminary System Performance Specification;

  – Live-Fire T&E Waiver request;

  – Test and Evaluation Master Plan;

  – Systems Engineering Plan;

  – Programmatic Environment, Safety, and Occupational Health Evaluation (PESHE);

  – NEPA Compliance Schedule (as required);

  – Program Protection Plan;

  – Technology Readiness Assessment;

  – Validated System Support and Maintenance Objectives and Requirements;

  – Footprint Reduction;

  – Inputs to Integrated Baseline Review;

  – Inputs to the Information Support Plan;

  – Inputs to the System Threat Assessment;

  – Inputs to the Capability Development Document;

  – Inputs to the Acquisition Strategy;

  – Inputs to the Affordability Assessment;

  – Inputs to the Cost and Manpower Estimate; and

  – Review and update Designated Science and Technology Information, the Security Classification Guide, and the Counterintelligence Support Plan.

  4.3.2.4.3. Technology Readiness Assessment (TRA)

  Per DoD Instruction 5000.2, the TRA is a regulatory information requirement for all acquisition programs. The TRA is a systematic, metrics-based process that assesses the maturity of Critical Technology Elements. The TRA should be conducted concurrently with other Technical Reviews, specifically the

Alternative Systems Review, System Requirements Review, or the Production Readiness Review. If a platform or system depends on specific technologies to meet system operational threshold requirements in development, production, and operation, and if the technology or its application is either new or novel, then that technology is considered a Critical Technology Element. The TRA should not be considered a *risk* assessment, but it should be viewed as a tool for assessing program risk and the adequacy of technology maturation planning. The TRA scores the current readiness level of selected system elements, using defined Technology Readiness Levels. The TRA highlights critical technologies and other potential technology risk areas that require program manager attention. The TRA essentially "draws a line in the sand" on the day of the event for making an assessment of technology readiness for critical technologies integrated at some elemental level. If the system does not meet pre-defined Technology Readiness Level scores, then a Critical Technology Element maturation plan is identified. This plan explains in detail how the Technology Readiness Level will be reached prior to the next milestone decision date or relevant decision point. Completion of the TRA should provide:

(1) A comprehensive review, using an established program Work Breakdown Structure as an outline, of the entire platform or system. This review, using a conceptual or established baseline design configuration, identifies program Critical Technology Elements;

(2) An objective scoring of the level of technological maturity for each Critical Technology Element by subject matter experts;

(3) Maturation plans for achieving an acceptable maturity roadmap for Critical Technology Elements prior to critical milestone decision dates; and

(4) A final report documenting the findings of the assessment panel.

After the final report is written, the chairman submits the report to the appropriate Service officials and the program manager. Once approved, the report and cover letter are forwarded to the service acquisition official. For Acquisition Category ID or IAM programs, the service acquisition official provides a recommendation to DDR&E for DUSD(S&T) final approval. If deemed necessary, the DDR&E can conduct an Independent Technical Assessment (ITA) in addition to, and totally separate from, the program TRA.

4.3.3. System Development and Demonstration Phase

4.3.3.9.4. Technology Readiness Assessment (TRA)

The program manager should normally conduct a second TRA prior to Milestone C. The TRA may be held concurrently with other technical reviews, specifically System Requirements Review, Critical Design Review, System

Verification Review, or Production Readiness Review. Completion of this TRA should provide:

(1) An evaluation of system technology maturity based on the Work Breakdown Structure;

(2) An objective scoring of the level of technological maturity; and

(3) Mitigation plans for achieving acceptable maturity prior to milestone decision dates.

4.3.3.10. Outputs of the Systems Engineering Processes in System Development and Demonstration

– Initial Product Baseline;

– Test Reports;

– Test and Evaluation Master Plan;

– Elements of Product Support;

– Systems Engineering Plan;

– Technology Readiness Assessment;

– Programmatic Environment, Safety, and Occupational Health Evaluation;

– Inputs to the Capability Production Document;

– Inputs to System Threat Assessment;

– Inputs to the Information Support Plan;

– Inputs to Cost and Manpower Estimate; and

– Review and update Designated Science and Technology Information, the Security Classification Guide, and the Counterintelligence Support Plan.

A.3.2 Chapter 10. Decisions, Assessments, and Periodic Reporting

- **10.3. Role of Integrated Product Teams (IPTs)**

10.3.1. Overarching IPT (OIPT) Procedures and Assessment

For Acquisition Category ID decision points, the OIPT leader will provide the Defense Acquisition Board chair, co-chair, principals, and advisors with an integrated assessment using information gathered through the IPPD process. The OIPT assessment should focus on core acquisition management issues and should consider independent assessments, including technology readiness assessments, which the OIPT members normally prepare. These assessments typically occur in context of the OIPT review, and should be

reflected in the OIPT leader's report. There should be no surprises at this point-all team members should work issues in real time and should be knowledgeable of their OIPT leader's assessment. OIPT and other staff members should minimize requirements for the program manager to provide pre-briefs independent of the OIPT process.

- **10.5. Role of Independent Assessments**

  Assessments, independent of the developer and the user, ensure an impartial evaluation of program status. However, requirements for independent assessments (for example, the independent cost estimate or technology readiness assessment) must be consistent with statutory requirements and good management practice. Senior acquisition officials should consider these assessments when making acquisition decisions. Staff offices that provide independent assessments should support the orderly and timely progression of programs through the acquisition process. IPTs should have access to independent assessments to enable full and open discussion of issues.

  10.5.2. Technology Maturity and Technology Readiness Assessments

  Technology maturity is a measure of the degree to which proposed critical technologies meet program objectives; and, is a principal element of program risk. A technology readiness assessment examines program concepts, technology requirements, and demonstrated technology capabilities in order to determine technological maturity.

  The program manager should identify critical technologies via the Work Breakdown Structure. In order to provide useful technology maturity information to the acquisition review process, technology readiness assessments of critical technologies and identification of Critical Program Information (CPI) must be completed prior to Milestone Decision points B and C.

  The DoD Component Science and Technology (S&T) Executive directs the technology readiness assessment and, for Acquisition Category ID and Acquisition Category IAM programs, submits the findings to the CAE who should submit his or her report to the DUSD(S&T) with a recommended technology readiness level (TRL) (or some equivalent assessment) for each critical technology. When the DoD Component S&T Executive submits his or her findings to the CAE, he or she should provide the DUSD(S&T) an information copy of those findings. In cooperation with the DoD Component S&T Executive and the program office, the DUSD(S&T) should evaluate the technology readiness assessment and, if he/she concurs, forward findings to the OIPT leader and DAB. If the DUSD(S&T) does not concur with the technology readiness assessment findings, an independent technology readiness assessment, under the direction of the DUSD(S&T), should be required. A summary table of TRL descriptions, Table 10.5.2.1, follows:

Table 10.5.2.1. TRL Descriptions

Technology Readiness Level	Description
1. Basic principles observed and reported.	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include paper studies of a technology's basic properties.
2. Technology concept and/or application formulated.	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.
3. Analytical and experimental critical function and/or characteristic proof of concept.	Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.
4. Component and/or breadboard validation in laboratory environment.	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.
5. Component and/or breadboard validation in relevant environment.	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so it can be tested in a simulated environment. Examples include "high fidelity" laboratory integration of components.
6. System/subsystem model or prototype demonstration in a relevant environment.	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in simulated operational environment.
7. System prototype demonstration in an operational environment.	Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment such as an aircraft, vehicle, or space. Examples include testing the prototype in a test bed aircraft.
8. Actual system completed and qualified through test and demonstration.	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.
9. Actual system proven through successful mission operations.	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. Examples include using the system under operational mission conditions.

The use of TRLs enables consistent, uniform, discussions of technical maturity across different types of technologies. Decision authorities will consider the recommended TRLs (or some equivalent assessment methodology, e.g., Willoughby templates) when assessing program risk. TRLs are a measure of technical maturity. They do not discuss the probability of occurrence (i.e., the likelihood of attaining required maturity) or the impact of not achieving technology maturity.

A.4 REFERENCES

- **From DoDI 5000.2, *Operation of the Defense Acquisition System*, dated May 12, 2003 (see Subsections A.2.2 and A.2.3 of this appendix)**
  - (g) Chairman of the Joint Chiefs of Staff Instruction 3170.01 Series, "Requirements Generation System," April 15, 2001. **Note:** *DoDI 5000.2 actually referenced an April 15, 2001, version of this document. The most current version of this manual, CJCSI 3170.01E, Joint Capabilities Integration and Development System, 11 May 2005, should be available at http://www.dtic.mil/cjcs_directives/cjcs/manuals.htm.*
  - (q) Section 2364 of title 10, United States Code, "Coordination and Communication of Defense Research Activities."
  - (an) Section 803, Public Law 107-314, "Bob Stump National Defense Authorization Act for Fiscal Year 2003," "Spiral development under major defense acquisition programs."
  - (ar) DoD Instruction 4630.8, "Procedures for Interoperability and Supportability of Information Technology (IT) and National Security Systems (NSS)," May 2, 2002
  - (as) DoD Directive, Number 4630.5, "Interoperability and Supportability of Information Technology (IT) and National Security Systems (NSS)," January 11, 2002.

ACRONYMS AND ABBREVIATIONS FOR APPENDIX A

ACAT	Acquisition Category
ADM	Acquisition Decision Memorandum
AoA	Analysis of Alternatives
AKSS	AT&L Knowledge Sharing System
AT&L	Acquisition, Technology, and Logistics
C4ISP	Command, Control, Communications, Computers, and Intelligence Support Plan
CAE	Component Acquisition Executive
CDD	Capability Development Document
CJCSI	Chairman of the Joint Chiefs of Staff Instruction
COTS	commercial-off-the-shelf
CPI	Critical Program Information
DAB	Defense Acquisition Board
DARC	Defense Acquisition Resource Center
DAU	Defense Acquisition University
DDR&E	Director of Defense Research and Evaluation
DoD	Department of Defense
DoDD	Department of Defense Directive
DoDI	Department of Defense Instruction
DOTMLPF	doctrine, organization, training, materiel, leadership, personnel, and facilities
DUSD(S&T)	Deputy Under Secretary of Defense for Science and Technology
ICD	Initial Capabilities Document
ICE	independent cost estimate
IPPD	Integrated Product and Process Development
IPT	Integrated Product Team
IT	Information Technology
ITA	Independent Technical Assessment

MAIS	Major Automated Information System
MDA	Milestone Decision Authority
MDAP	Major Defense Acquisition Program
MS	Milestone
NEPA	National Environmental Policy Act
NSS	National Security Systems
OIPT	Overarching Integrated Product Team
PESHE	Programmatic Environment, Safety, and Occupational Health Evaluation
PM	Program Manager
S&T	Science and Technology
SDD	System Development and Demonstration
T&E	test and evaluation
TDS	Technology Development Strategy
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level

APPENDIX B.
SUMMARY OF GOVERNMENT ACCOUNTABILITY OFFICE (GAO)[42] REPORTS AND DEPARTMENT OF DEFENSE (DoD) IMPLEMENTATION

[42] Formerly the General Accounting Office (GAO). Effective July 7, 2004, the GAO's legal name became the Government Accountability Office.

Several GAO reports addressed the DoD acquisition system and made recommendations that influenced the DoD 5000 series of publications. The following presents a brief summary of GAO-related work, along with references for the source documents.

B.1 GAO REPORTS

The subcommittee on Readiness and Management Support of the Committee on Armed Services, U.S. Senate, which has oversight on acquisitions policy, enlisted the GAO in a study of best commercial practices related to defense acquisition. A series of GAO reports and related testimony assessed how best commercial practices could improve the way DoD incorporates new technology into weapon system programs and reduces risk. These reports, issued from 1996–2000 (the principals of which are listed as References 1, 2, 3), offered DoD some guidance and had significant influence on the current versions of the DoD 5000 series of documents: Department of Defense Directive (DoDD) 5000.1, Department of Defense Instruction (DoDI) 5000.2, and the *Defense Acquisition Guidebook* (Refs. 4, 5, 6).

The weapon system acquisition cycle for DoD major weapon systems before the incorporation of best commercial practices could be illustrated as shown in Figure B-1.[43] Technology, design, and manufacturing knowledge was obtained concurrently.

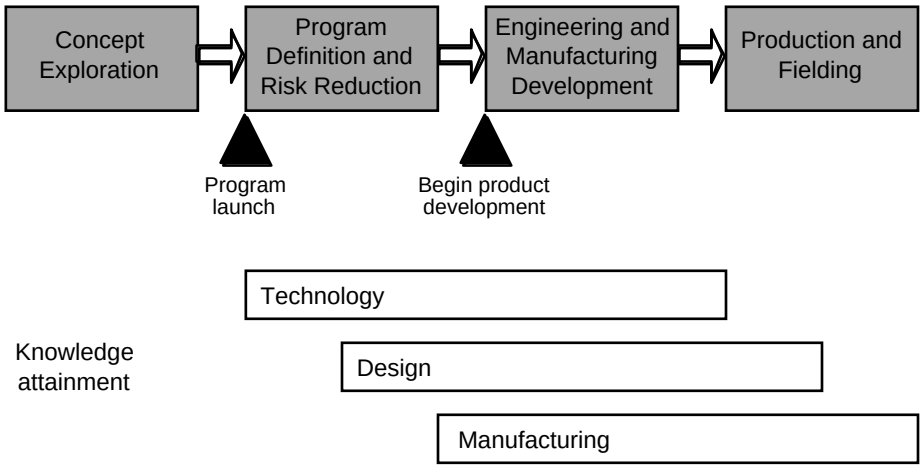

Figure B-1. DoD's Current Weapon System Acquisition (Source: Ref. 3)

[43] Figure B-1 depicts the weapon system acquisition cycle for DoD major weapon systems in the year 2000. Figure B-5 outlines the current Defense Acquisition Management Framework.

The major GAO recommendation, which followed best commercial practice, was to minimize technology development during product development and match requirements with technological capability before product development is launched. Proof that the technology will work and can be demonstrated to a high level of maturity is critical to lowering risk and avoiding large cost overruns. Associated with this principle are the needs to develop high standards for finding the maturity and readiness of technology, to establish disciplined paths that technology must take to be included in products, and to provide strong gatekeepers to decide when to allow the technology into a product development program. GAO recommended that DoD not launch a program until the technologies needed to meet a new weapons requirement are mature. To separate this technology development from the program, GAO best practices' recommendations suggest that a technology and concept maturation phase follow concept exploration and precede program launch, as illustrated in Figure B-2.

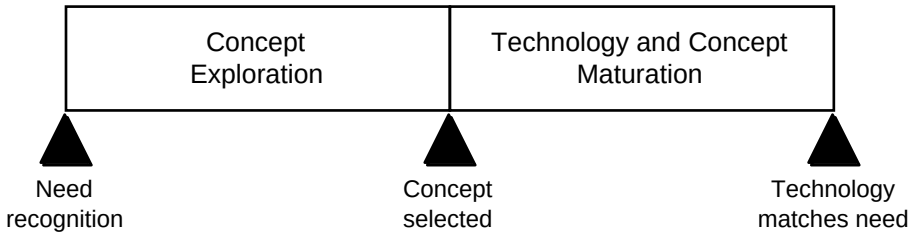

Figure B-2. Weapon Acquisition Phases That Should Precede the Launch of a New Program (Source: Ref. 3)

The GAO review of best practices for including new technology in products (see Ref. 2) applied a scale of Technology Readiness Levels (TRLs) pioneered by the National Aeronautics and Space Administration (NASA) and adapted by the Air Force Research Laboratory (AFRL). "TRLs proved to be reliable indicators of the relative maturity of the 23 technologies reviewed, both commercial and military, and their eventual success after they were included in product development programs" (Ref. 2, p. 22).

To show that a design is mature, the GAO studies suggest that a product development phase should include a distinct system integration effort *before* system demonstration effort to demonstrate the effectiveness of the product and processes (see Figure B-3).

Figure B-4 shows GAO's final proposal for a potential DoD technology and product development process based on commercial best practices. It should be noted that

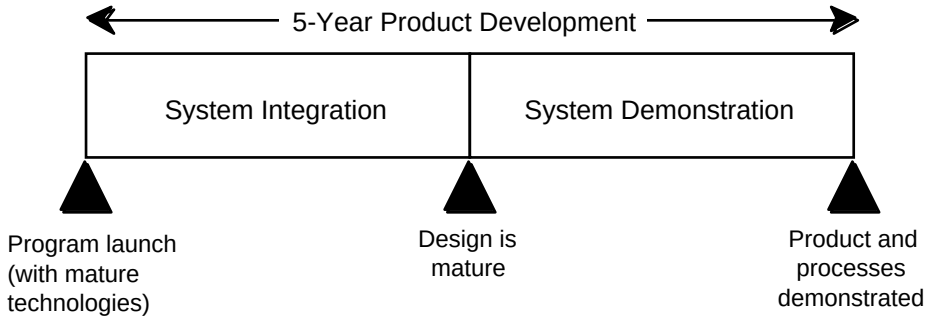

Figure B-3. Product Development Phase To Deliver a Mature Design and Key Processes (Source: Ref. 3)

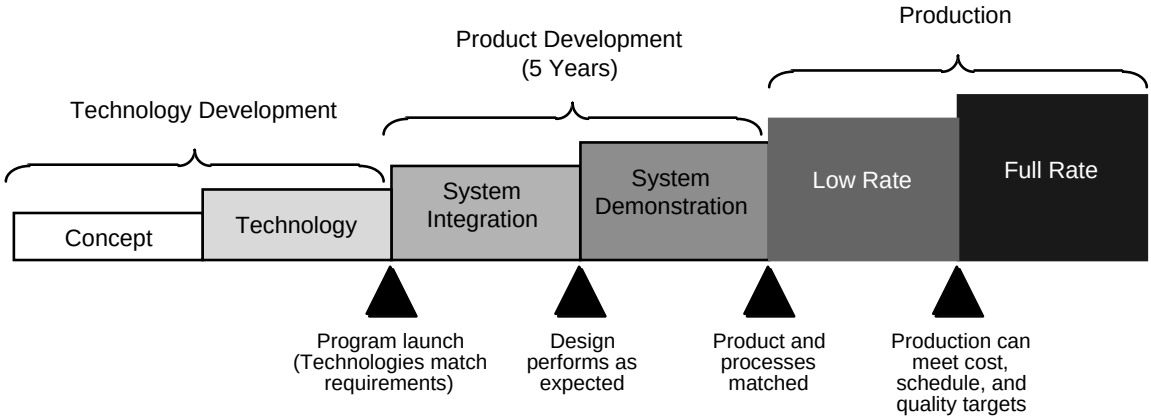

Figure B-4. Potential DoD Technology and Product Development Process Incorporating Best Practices (Source: Ref. 3)

leading commercial firms launch a new product later—after technology is complete—than DoD launches a new product. Paragraphs B.2 and B.3 of this appendix provide the GAO recommendations for DoD management of Technology Development and the DoD response as reported in Reference 2. DoD did not agree entirely with GAO's recommendations and is willing to accept more risk. DoD considered TRL 6 as an acceptable readiness-level risk for a weapon system entering the program definition stage (see Figure B-1) and TRL 7 as an acceptable readiness-level risk for the Engineering and Manufacturing Development (EMD) stage. GAO accepted this.

Figure B-5 outlines the current Defense Acquisition Management Framework. The relationship to the GAO recommendation of Figure B-4 is evident.

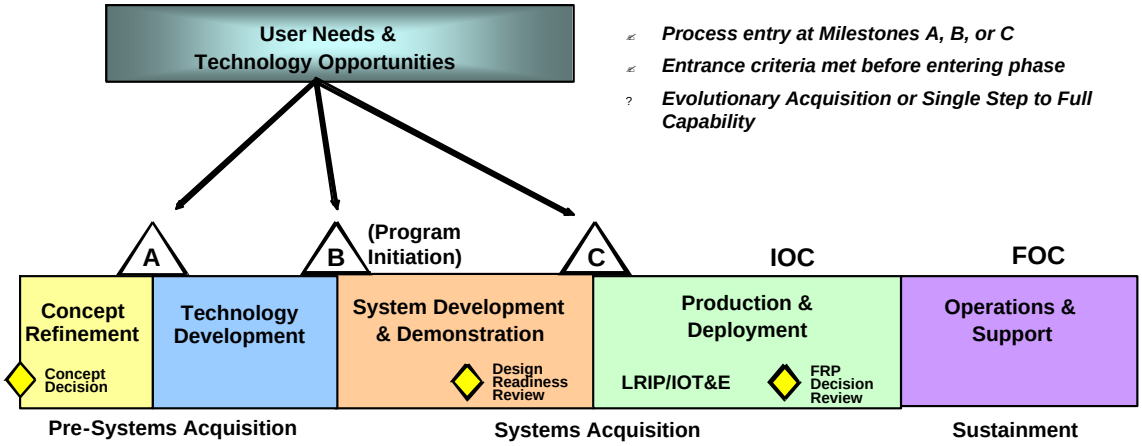

Figure B-5. Defense Acquisition Management Framework (Source: Ref. 5)

B.2 GAO RECOMMENDATIONS

The following paragraphs are direct quotations from Chapter 5 of Reference 2:

We have previously recommended that DOD separate technology development from weapon system programs. That recommendation was made without prejudice toward the necessity of technology development but rather with the intent that programs could be better managed if such development was conducted outside of a program manager's purview. Similarly, the recommendations that follow are made without prejudice toward or the intention of compromising-the basic research and other activities that S&T organizations perform. We recognize that implementation of these recommendations will have organizational, funding, and process implications and will require the cooperation of the Congress. (p. 63)

To help ensure that new technologies are vigorously pursued and successfully moved into weapon system programs, we recommend that the Secretary of Defense adopt a disciplined and knowledge-based method for assessing technology maturity, such as TRLs, DOD-wide. This practice should employ standards for assessing risks of handoff to program managers that are based on a technology's level of demonstration and its criticality to meeting the weapon system's requirements. (p.64)

With these tools in hand, we recommend that the Secretary (1) establish the place at which a match is achieved between key technologies and weapon system requirements as the proper time for committing to the cost, schedule, and performance baseline for developing and producing that weapon system and (2) require that key technologies reach a high maturity level—analogous to TRL 7—before making that commitment. This would

approximate the launch point for product development as practiced by leading commercial firms. (p. 64)

We recommend that the Secretary find ways to ensure that the managers responsible for maturing the technologies and designing weapon systems before product development are provided the more flexible environment that is suitable for the discovery of knowledge, as distinct from the delivery of a product. Providing more flexibility will require the cooperation of requirements managers and resource managers so that rigid requirements or the threat of jeopardizing the funding planned to start product development will not put pressure on program managers to accept immature technologies. Such an environment may not be feasible if the program definition and risk reduction phase remains the effective launch point for an entire weapon system program. (p. 64)

An implication of these recommendations is that S&T organizations will have to play a greater role in maturing technologies to higher levels and should be funded accordingly. Therefore, we recommend that the Secretary of Defense evaluate the different ways S&T organizations can play a greater role in helping technologies reach high levels of maturity before product development begins. For example, given that a technology has sufficient potential for application to a weapon system, at a minimum, an S&T organization should be responsible for taking a technology to TRL 6 before it is handed off to a program office at the program definition and risk reduction phase. During this phase, the program manager would be responsible for maturing the technology to TRL 7 before it is included in an engineering and manufacturing development program. In a situation where a single, design-pacing technology is to be developed for a known application—like the nonpenetrating periscope—an S&T organization should be required to mature that technology to TRL 7 before it is turned over to a product development manager. S&T organizations could play a similar role when a significant new technology is being prepared for insertion into an existing weapon system. Finally, when multiple new technologies are to be merged to create a weapon system, S&T organizations should be required to bring key technologies to TRL 6 and then become part of a hybrid organization with product developers to integrate the technologies and bring them to TRL 7 before handing full responsibility to a product development manager. (pp. 64–65)

To help guard against the possibility that the more basic research and technology development activities would be compromised by having S&T organizations routinely take key technologies to TRL 6 or higher, we recommend that the Secretary extract lessons from the nonpenetrating periscope, the AAAV, and the Army's Future Scout programs, and other ATD and ACTD programs. Specifically, the Secretary should assess whether

the resources needed to enable S&T organizations to play a leading role in the development of technologies and, in some cases, preliminary system design, detracted from or displaced more basic research and technology development programs. (p. 65)

Finally, we recommend that the Secretary empower managers of product development programs to refuse to accept key technologies with low levels of demonstrated maturity. The Secretary can encourage this behavior through supportive decisions on individual programs, such as by denying proposals to defer the development of key technologies and by favoring proposals to lengthen schedules or lessen requirements to reduce technological risk early. (p. 65)

B.3 DoD COMMENTS AND GAO EVALUATION

The following paragraphs are direct quotations from Chapter 5 of Reference 2:

DOD generally concurred with a draft of this report and its recommendations, noting that the traditional path to new weapon system development is no longer affordable or necessary (App. I).[44] DOD stated that it has embarked upon a "Revolution in Business Affairs" that will enable new technologies to be developed more efficiently and effectively. It believes that the first steps in this direction have already been taken but agrees that more progress needs to be made. DOD agreed that TRLs are necessary in assisting decision-makers in deciding on when and where to insert new technologies into weapon system programs and that weapon system managers should ensure that technology is matured to a TRL 7 before insertion occurs. DOD concurred that S&T organizations should be involved in maturing technologies to high levels, such as TRL 6, before transitioning to the engineering and manufacturing development phase and agreed to assess the impact of this involvement on other S&T resources. We note that the best practice is to mature technology to at least a TRL 7 before starting the engineering and manufacturing development phase, whether the technology is managed by an S&T organization, a weapon system program manager, or a hybrid of the two organizations. (pp. 65–66)

DOD noted that while TRLs are important and necessary, the increasing projected life for new weapon systems, total ownership costs, and urgency based upon threat assessments are also important considerations for system development decisions. We agree and note that our recommendations are not intended to cover all aspects of weapon system development decisions or to suggest that technology maturity is the only factor in

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[44] Appendix I of GAO/NSIAD-99-162 is called "Technology Readiness Levels and Their Definitions."

such decisions. Rather, the recommendations are in keeping with the purpose of the report, "to determine whether best practices offer methods to improve the way DOD matures new technology so that it can be assimilated into weapon system programs with less disruption." We believe that a knowledge-based approach to maturing technology, such as TRLs, can benefit other considerations as well. For example, decisions on what technologies to include in a weapon system and when to include them can have a significant bearing on its total ownership costs. (pp. 66)

DOD stated that there should be an established point for the transition of technologies and that it plans to supplement its milestone review process with additional guidance in the next revisions to DOD 5000.2-R.[45] It also stated that its policy on the evolutionary approach to weapon acquisitions should be developed in consonance with the technology transition strategy. We cannot comment on the revisions to the directive or the evolutionary acquisition policy because they have yet to be published. However, under the current milestone review process, the pressures placed on a program during the program definition and risk reduction phase—when much technology development occurs—can operate against the flexibility and judgments that are needed to mature technologies. If the revisions to the directive supplement the current milestones without relieving the pressures brought to bear on programs as they are launched in the program definition and risk reduction phase, it will remain difficult to discourage the acceptance of immature technologies in the design of new weapon systems. To relieve these pressures, we encourage DOD, as it develops the directive and the evolutionary acquisition policy, to separate technology development from product development and to redefine the launch point for a program as the point at which enough knowledge has been gained to ensure that a match is reached between the maturity of key technologies and weapon system requirements. (pp. 66–67)

DOD also stated that program managers already have the ability to reject inappropriately mature technologies, and to the extent technology immaturity affects acquisition baselines, to advise acquisition executives of feasible alternatives. We did not find this to be the case in our review. Rather, we found that the program managers' ability to reject immature technologies is hampered by (1) untradable requirements that force acceptance of technologies despite their immaturity and (2) reliance on tools for judging technology maturity that fail to alert the managers of the high risks that would prompt such a rejection. As noted in the report, once a weapon system program begins, the environment becomes inflexible and

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[45] DoD 5000.2R was revised and evolved into the *Interim Defense Acquisition Guidebook (October 2002)*. The *Interim Defense Acquisition Guidebook* was then revised and is now called the *Defense Acquisition Guidebook*, October 2004.

deviations to program baselines can attract unwanted attention. This reality limits the program managers' ability to reject immature technologies. (p. 67)

B.4 REFERENCES

1. GAO/T-NSIAD 99-116, *Defense Acquisition: Best Commercial Practices Can Improve Program Outcomes*, March 1999.
   (See http://www.gao.gov/archive/1999/ns99116t.pdf).
2. GAO/NSIAD-99-162, *Best Practices: Better Management of Technology Development Can Improve Weapon System Outcomes*, July 1999.
   (See http://www.gao.gov/archive/1999/ns991620.pdf).
3. GAO/T-NSIAD-00-137, *Defense Acquisition: Employing Best Practices Can Shape Better Weapon System Decisions*, April 26, 2000.
   (See http://www.gao.gov/new.items/ns00137t.pdf).
4. DoDD 5000.1, *The Defense Acquisition System*, May 12, 2003.
   (See http://akss.dau.mil/darc/darc.html).
5. DoDI 5000.2, *Operation of the Defense Acquisition System*, May 12, 2003.
   (See http://akss.dau.mil/darc/darc.html).
6. *Defense Acquisition Guidebook*, October 2004.
   (See http://akss.dau.mil/darc/darc.html).

ACRONYMS AND ABBREVIATIONS FOR APPENDIX B

AAAV	Advanced Amphibious Assault Vehicle
ACTD	Advanced Concept Technology Demonstration
AFRL	Air Force Research Laboratory
AKSS	AT&L Knowledge Sharing System
ATD	Advanced Technology Demonstration
DARC	Defense Acquisition Resource Center
DAU	Defense Acquisition University
DoD, DOD	Department of Defense
DoDD	Department of Defense Directive
DoDI	Department of Defense Instruction
EMD	Engineering and Manufacturing Development
FOC	full operational capability
GAO	General Accounting Office Government Accountability Office
IOC	initial operational capability
LRIP	Low Rate Initial Production
NASA	National Aeronautics and Space Administration
NSIAD	National Security and International Affairs Division (GAO)
S&T	Science and Technology
TRL	Technology Readiness Level

APPENDIX C.
GUIDANCE, BEST PRACTICES, AND EXAMPLES FOR ASSESSING TECHNOLOGY MATURITY

C.1 OVERVIEW: TECHNOLOGY READINESS LEVEL (TRL) CONCEPT

The *Defense Acquisition Guidebook* establishes technology maturity as "a measure of the degree to which proposed critical technologies meet program objectives. A Technology Readiness Assessment [TRA] examines program concepts, technology requirements, and demonstrated technology capabilities in order to determine technological maturity" (Section 10.5.2.). The TRA results in a recommended readiness level (i.e., TRL) for the Critical Technology Elements (CTEs) being evaluated.

Using TRLs to describe maturity of technology elements originated with the National Aeronautics and Space Administration (NASA) in the 1980s. The levels spanned the earliest stages of scientific investigation (Level 1) to successful use in a system (Level 9), which typically means having successfully flown in space for NASA. The Department of Defense (DoD) has adopted the NASA definitions—with only minor modifications—for the nine TRLs.

TRLs are not a measure of design validity. CTEs should be identified and assessed under the assumption that the design, developed as part of the systems engineering approach, is adequate for the performance of the required functions. However, supporting TRL 5 or higher without a detailed design or architecture is difficult and problematic.

A CTE is classified as either a hardware, software, or a manufacturing technology. The remainder of this appendix discusses best practices and provides examples for assessing technology maturity for each of the three classes of technology.[46]

C.1.1 The TRL Concept for Hardware

Many TRAs evaluate hardware CTEs that are being developed for weapons systems, communications systems, soldier systems, and so forth. In evaluating hardware, a strong grasp of the TRL concept is important. Table C-1 shows the TRLs used to assess hardware. It also lists typical documentation that should be extracted or referenced to support a TRL assignment. Table C-2 includes a set of additional definitions that help provide a uniform interpretation of the levels.

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[46] Development and use of TRLs for medical-related items, specifically drugs, vaccines, and medical devices must adhere to Food and Drug Administration (FDA) and DoD statutes and policy. In recognition of this situation, the Army took the initiative to establish biomedical TRLs, which have been included in Appendix H.

Table C-1. Hardware TRL Definitions, Descriptions, and Supporting Information (Source: *Defense Acquisition Guidebook*)

TRL	Definition	Description	Supporting Information
1	Basic principles observed and reported.	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development (R&D). Examples might include paper studies of a technology's basic properties.	Published research that identifies the principles that underlie this technology. References to who, where, when.
2	Technology concept and/or application formulated.	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.	Publications or other references that outline the application being considered and that provide analysis to support the concept.
3	Analytical and experimental critical function and/or characteristic proof of concept.	Active R&D is initiated. This includes analytical studies and laboratory studies to validate physically the analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.	Results of laboratory tests performed to measure parameters of interest and comparison to analytical predictions for critical subsystems. References to who, where, and when these tests and comparisons were performed.
4	Component and/or breadboard validation in a laboratory environment.	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared with the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.	System concepts that have been considered and results from testing laboratory-scale breadboard(s). References to who did this work and when. Provide an estimate of how breadboard hardware and test results differ from the expected system goals.
5	Component and/or breadboard validation in a relevant environment.	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment. Examples include "high-fidelity" laboratory integration of components.	Results from testing a laboratory breadboard system are integrated with other supporting elements in a simulated operational environment. How does the "relevant environment" differ from the expected operational environment? How do the test results compare with expectations? What problems, if any, were encountered? Was the breadboard system refined to more nearly match the expected system goals?

Table C-1. Hardware TRL Definitions, Descriptions, and Supporting Information (Source: *Defense Acquisition Guidebook*) (Continued)

TRL	Definition	Description	Supporting Information
6	System/subsystem model or prototype demonstration in a relevant environment.	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in a simulated operational environment.	Results from laboratory testing of a prototype system that is near the desired configuration in terms of performance, weight, and volume. How did the test environment differ from the operational environment? Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level?
7	System prototype demonstration in an operational environment.	Prototype near or at planned operational system. Represents a major step up from TRL 6 by requiring demonstration of an actual system prototype in an operational environment (e.g., in an aircraft, in a vehicle, or in space). Examples include testing the prototype in a test bed aircraft.	Results from testing a prototype system in an operational environment. Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level?
8	Actual system completed and qualified through test and demonstration.	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.	Results of testing the system in its final configuration under the expected range of environmental conditions in which it will be expected to operate. Assessment of whether it will meet its operational requirements. What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before finalizing the design?
9	Actual system proven through successful mission operations.	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation (OT&E). Examples include using the system under operational mission conditions.	OT&E reports.

Table C-2. Additional Definitions of TRL Descriptive Terms
(Source: *Defense Acquisition Guidebook*)

Term	Definition
Breadboard	Integrated components that provide a representation of a system/ subsystem and that can be used to determine concept feasibility and to develop technical data. Typically configured for laboratory use to demonstrate the technical principles of immediate interest. May resemble final system/subsystem in function only.
High Fidelity	Addresses form, fit, and function. A high-fidelity laboratory environment would involve testing with equipment that can simulate and validate all system specifications within a laboratory setting.
Low Fidelity	A representative of the component or system that has limited ability to provide anything but first-order information about the end product. Low-fidelity assessments are used to provide trend analysis.
Model	A functional form of a system, generally reduced in scale, near or at operational specification. Models will be sufficiently hardened to allow demonstration of the technical and operational capabilities required of the final system.
Operational Environment	Environment that addresses all the operational requirements and specifications required of the final system to include platform/ packaging.
Prototype	A physical or virtual model used to evaluate the technical or manufacturing feasibility or military utility of a particular technology or process, concept, end item, or system.
Relevant Environment	Testing environment that simulates the key aspects of the operational environment.
Simulated Operational Environment	Either (1) a real environment that can simulate all the operational requirements and specifications required of the final system or (2) a simulated environment that allows for testing of a virtual prototype. Used in either case to determine whether a developmental system meets the operational requirements and specifications of the final system.

C.1.2 The TRL Concept for Software

Hardware technology may include software that executes on the hardware if (1) the software is not being developed or modified as part of the acquisition or (2) the software is not the reason for placing the element on the CTE list. If the system engineering process develops the software and the software is a CTE, it should appear as a software CTE—with the hardware appearing as a hardware CTE.

Table C-3 shows the TRLs used to assess software. These TRLs are a consolidation of the software TRLs used by the Navy and the Army and approved by the Information Technology TRL Working Group. Although the overall definitions are similar to the TRLs for hardware, the examples and the documentation needed to support the assessment differ.

Table C-3. Software TRL Definitions, Descriptions, and Supporting Information (Source: *IT TRL Working Group Minutes,* November 9, 2004)

TRL	Definition	Description	Supporting Information
1	Basic principles observed and reported.	Lowest level of software technology readiness. A new software domain is being investigated by the basic research community. This level extends to the development of basic use, basic properties of software architecture, mathematical formulations, and general algorithms	Basic research activities, research articles, peer-reviewed white papers, point papers, early lab model of basic concept may be useful for substantiating the TRL level.
2	Technology concept and/or application formulated.	Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies using synthetic data.	Applied research activities, analytic studies, small code units, and papers comparing competing technologies.
3	Analytical and experimental critical function and/or characteristic proof of concept.	Active R&D is initiated. The level at which scientific feasibility is demonstrated through analytical and laboratory studies. This level extends to the development of limited functionality environments to validate critical properties and analytical predictions using non-integrated software components and partially representative data.	Algorithms run on a surrogate processor in a laboratory environment, instrumented components operating in laboratory environment, laboratory results showing validation of critical properties.
4	Module and/or subsystem validation in a laboratory environment (i.e., software prototype development environment).	Basic software components are integrated to establish that they will work together. They are relatively primitive with regard to efficiency and robustness compared with the eventual system. Architecture development initiated to include interoperability, reliability, maintainability, extensibility, scalability, and security issues. Emulation with current/ legacy elements as appropriate. Prototypes developed to demonstrate different aspects of eventual system.	Advanced technology development, stand-alone prototype solving a synthetic full-scale problem, or standalone prototype processing fully representative data sets.

Table C-3. Software TRL Definitions, Descriptions, and Supporting Information (Source: *IT TRL Working Group Minutes,* November 9, 2004) (Continued)

TRL	Definition	Description	Supporting Information
5	Module and/or subsystem validation in a relevant environment.	Level at which software technology is ready to start integration with existing systems. The prototype implementations conform to target environment/ interfaces. Experiments with realistic problems. Simulated interfaces to existing systems. System software architecture established. Algorithms run on a processor(s) with characteristics expected in the operational environment.	System architecture diagram around technology element with critical performance requirements defined. Processor selection analysis, Simulation/ Stimulation (Sim/Stim) Laboratory buildup plan. Software placed under configuration management. COTS/GOTS in the system software architecture are identified.
6	Module and/or subsystem validation in a relevant end-to-end environment.	Level at which the engineering feasibility of a software technology is demonstrated. This level extends to laboratory prototype implementations on full-scale realistic problems in which the software technology is partially integrated with existing hardware/software systems.	Results from laboratory testing of a prototype package that is near the desired configuration in terms of performance, including physical, logical, data, and security interfaces. Comparisons between tested environment and operational environment analytically understood. Analysis and test measurements quantifying contribution to system-wide requirements such as throughput, scalability, and reliability. Analysis of human-computer (user environment) begun.
7	System prototype demonstration in an operational high-fidelity environment.	Level at which the program feasibility of a software technology is demonstrated. This level extends to operational environment prototype implementations where critical technical risk functionality is available for demonstration and a test in which the software technology is well integrated with operational hardware/software systems.	Critical technological properties are measured against requirements in a simulated operational environment.
8	Actual system completed and mission qualified through test and demonstration in an operational environment.	Level at which a software technology is fully integrated with operational hardware and software systems. Software development documentation is complete. All functionality tested in simulated and operational scenarios.	Published documentation and product technology refresh build schedule. Software resource reserve measured and tracked.

Table C-3. Software TRL Definitions, Descriptions, and Supporting Information (Source: *IT TRL Working Group Minutes,* November 9, 2004) (Continued)

TRL	Definition	Description	Supporting Information
9	Actual system proven through successful mission-proven operational capabilities	Level at which a software technology is readily repeatable and reusable. The software based on the technology is fully integrated with operational hardware/software systems. All software documentation verified. Successful operational experience. Sustaining software engineering support in place. Actual system.	Production configuration management reports. Technology integrated into a reuse "wizard", out-year funding established for support activity.

C.1.3 The TRL Concept for Manufacturing

The TRL framework should also be used to assess the readiness of a critical manufacturing technology. Similar to a hardware or software technology, a manufacturing technology will mature through TRLs 1, 2, and 3. However, in most cases, this maturation will occur independently of a specific component for a specific system. For a manufacturing technology to be identified as critical from a TRA perspective, it must be critical in the *program* context of cost, schedule, and performance as described in Appendix D. Therefore, a TRA for a critical manufacturing technology will begin with TRL 4, where the associated critical performance technology will have been validated in a laboratory environment at the component and/or breadboard level.

Table C-4 shows the TRLs used to assess manufacturing technologies. The manufacturing technology may be related to any combination of infrastructure, materials, processes or methods, and measurement.

Table C-4. Manufacturing Technology TRL Definitions, Descriptions, and Supporting Information [Source: *Joint Defense Manufacturing Technology Panel (JDMPT) Manufacturing Readiness Level Subgroup*]

TRL	Definition	Description	Supporting Information
1	Basic principles observed and reported.	NA	
2	Technology concept and/or application formulated.	NA	
3	Analytical and experimental critical function and/or characteristic proof of concept.	NA	

Table C-4. Manufacturing Technology TRL Definitions, Descriptions, and Supporting Information [Source: *Joint Defense Manufacturing Technology Panel (JDMPT) Manufacturing Readiness Level Subgroup*] (Continued)

TRL	Definition	Description	Supporting Information
4	Component and/ or breadboard validation in a laboratory environment.	The new technology has been demonstrated in a laboratory environment on simple design parts using similar types of materials that would be used in the intended application.	This is the lowest level of production readiness. Component technologies must have matured to at least TRL 4. At this point, few requirements have been validated, and there will be a large number of engineering/design changes. Component physical and functional interfaces have not been defined. Materials, machines, and tooling have been demonstrated in a laboratory environment. Inspection and test equipment have been demonstrated in a laboratory environment. Manufacturing cost drivers are identified. Producibility assessments have been initiated.
5	Component and/ or breadboard validation in a relevant environment.	The new technology has been demonstrated in a laboratory environment on design parts of the same level of complexity and using the same types of materials that would be used in the intended application.	Component technologies must have matured to at least TRL 5. At this point, all requirements have not been validated, and there will be significant engineering/design changes. Component physical and functional interfaces have not been defined. Materials, machines, and tooling have been demonstrated in a relevant manufacturing environment, but most manufacturing processes and procedures are in development (or ManTech initiatives are ongoing). Inspection and test equipment have been demonstrated in a laboratory environment. Production cost drivers/goals are analyzed. System-level DTC goals are set. Producibility assessments are ongoing.
6	System/subsystem model or prototype demonstration in a relevant environment.	The new technology has been demonstrated in a pre-production environment on design parts of the same level of complexity and using the same types of materials that would be used in the intended application. Appropriate quality levels have been achieved.	During the prototype demonstration, phase requirements are validated and defined. However, there will still be many engineering/ design changes, and the physical and functional interfaces are not yet fully defined. Component technologies must have matured to at least TRL 6. Raw materials are initially demonstrated in relevant manufacturing environment. Similar processes and procedures have been demonstrated in a relevant manufacturing environment. At this point, there are likely major investments required for machines and tooling. Inspection and test equipment should be under development. Producibility assessments are ongoing, and trade studies have been conducted. A production Cost Reduction Plan is developed. Production goals are set.

Table 3-4. Manufacturing Technology TRL Definitions, Descriptions, and Supporting Information (Source: *JDMTP Manufacturing Readiness Level Subgroup*) (Continued)

TRL	Definition	Description	Supporting Information
7	System prototype demonstration in an operational environment.	The new technology has been demonstrated in a relevant production environment on design parts of the same level of complexity and using the same types of materials that would be used in the intended application. Appropriate quality and throughput levels have been achieved.	Component technologies must have matured to at least TRL 7. At this point, engineering/design changes should decrease. Physical and functional interfaces should be clearly defined. All raw materials are in production and available to meet planned LRIP schedule. Pilot line manufacturing processes and procedures set up and under test. Processes and procedures are not yet proven or under control. During this phase, initial producibility improvements should be underway. DTC estimates are less than 125 percent of goals. Detailed production estimates are established.
8	Actual system completed and qualified through test and demonstration.	The new technology has been demonstrated in a pilot production environment on production-representative parts of the same level of complexity and using the same types of materials that would be used in the intended application. Appropriate quality and throughput levels have been achieved. Process has been proven and is under control for LRIP.	Component technologies must have matured to at least TRL 8. At this point, engineering/design changes should decrease significantly. Physical and functional interfaces should be clearly defined. All raw materials are in production and available to meet the planned LRIP schedule. Manufacturing processes and procedures have been proven on the pilot line, are under control, and are ready for LRIP. During this phase, initial producibility risk assessments should be completed. Production cost estimates meet DTC goals.
9	Actual system proven through successful mission operations.	The new technology has been demonstrated in an LRIP environment on intended parts and using the intended types of materials. Process has been proven and under control for production.	During LRIP, all systems engineering/design requirements should be met and there should only be minimal system engineering/design changes. Technologies must have matured to at least TRL 9. Materials are in production and available to meet planned production schedules. Manufacturing processes and procedures are established and controlled in production to three-sigma or some other appropriate quality level. Machines, tooling and inspection and test equipment deliver three-sigma or some other appropriate quality level in production. Production risk monitoring is ongoing. LRIP actual costs meet estimates.

C.2 ASSESSING HARDWARE CTEs

Applying the TRL definitions to assess the maturity of hardware technologies appears to be straightforward. For a particular technology, the level of technical readiness that best describes the accomplishments and evidence in light of the TRL definitions

should be assigned. In practice, this approach is more difficult than it appears because the TRL definitions often fail to account for all real-life situations.

TRL definitions involve several dimensions. One could be called the application level, which assumes values of device, component, subsystem, system, and system of systems. Another could be the environment, which assumes values of laboratory, mathematical model, physical simulation, field test, and operational use. Scale and performance levels are still other dimensions.

Some of these dimensions are used explicitly in the TRL definitions, and some are not. In any event, the level of technical readiness is determined by a combination of these dimensions. When the accomplishment and evidence fail to match the definition, the assessor must use judgment regarding the relevance of what has been accomplished and ask whether the accomplishment is equivalent to the TRL definition.

Of these dimensions, environment is perhaps the most difficult to interpret. Both TRL 5 and TRL 6 depend on demonstration in a relevant environment. While the specifics of a relevant environment depend on the technology, the criterion is as follows:

> A *relevant environment* for the demonstration of a technology is a set of test conditions that provide confidence that skillful application of that technology to an item (component, subsystem, or system) will support the required (threshold) functionality of that item across the full spectrum of required operational employments.

This criterion intentionally avoids the word "prove" because that would establish a higher, sometimes unreasonable, standard. However, the need to support the full range of required operational employments implies that one or a few demonstrations conducted under the most favorable conditions are not adequate. If a body of data or accepted theory supports with confidence that the efficacy of a technology, though demonstrated only in some useful environment, can be extended to the full spectrum of employments, the demonstration can be considered to have been employed in a relevant environment.

> Demonstration of a technology in a relevant environment requires successful trial testing that either
>
> (1) shows that the technology satisfies functional need across the full spectrum of operational employments, or
>
> (2) shows that the technology satisfies the functional need for some important operational employment and uses accepted techniques to extend confidence over all required operational employments.

The steps or activities in system development programs differ with the type of system. However, some of the steps and some of the terminology are generally applicable. Table C-5 lists numerous steps typical of hardware system development programs and indicates the TRL that is supported by this accomplishment. In this table, "supported" means that the step is at least partial justification for assigning the indicated TRL. "Tested" means not just that a test was run, but also that the test results are consistent with the needs of the application. Note that the items under Accomplishment usually include an application level and an environment and sometimes include a scale or performance level. The accomplishments that support TRLs of 4 through 7 are of particular relevance to TRAs for Milestone B.

Table C-5. Attainment of Technical Readiness for Hardware CTEs

Accomplishment	TRL Supported								
	1	2	3	4	5	6	7	8	9
Discovery of physical or mathematical principle	X								
Characterization of the principle	X								
Application envisioned and described		X							
Concept of application analyzed		X							
Critical functionality empirically confirmed			X						
Proof of concept demonstrated in laboratory			X						
Scale-up or other extension as needed by concept			X	X					
Breadboard or component tested in laboratory				X					
Producibility and cost estimated				X	X				
Engineering Development Model (EDM)[47] of component tested in laboratory				X					
EDM of component tested in relevant environment					X				
Prototype component integrated into a system[48] EDM				X	X				
System EDM tested in simulated environment				X					
System[49] tested in limited field experiments				X	X				
System[50] tested in relevant environment[51]						X			

47 A pre-prototype used for engineering development, functionally the near-equivalent of a prototype but differing from a prototype in noncritical features.

48 System or subsystem.

49 Either EDM or prototype at the system or subsystem level.

50 Prototype or high-fidelity model at system or subsystem level.

Table C-5. Attainment of Technical Readiness for Hardware CTEs (Continued)

Accomplishment	TRL Supported								
	1	2	3	4	5	6	7	8	9
System tested in operational environment[52]							X		
Production system tested in operational environment								X	
Production system proven in mission operations									X

C.2.1 Aircraft

Aircraft are likely to have CTEs in aerodynamic configuration and controls, airframe structure and aeroelasticity, flight control systems, and propulsion. In addition, rotary wing aircraft have CTEs in power transfer, rotor hub, and blades. CTEs could also be factors in mission equipment, secondary power, environmental control, and other systems, depending on the aircraft's missions. A variety of methods and facilities are used to demonstrate these different technologies.

For example, demonstrations such as analysis, computational fluid dynamics (CFD) investigations, wind tunnel tests[53], and flight tests are normally used for the aerodynamic configuration and controls. When aerodynamic configurations indicate large departures from existing aircraft, free-flight models (manned or unmanned) are sometimes used. Similarly, a variety of methods and facilities are used for airframe, flight control, and other aeronautical disciplines. Table C-6 shows a few of the most often used means to demonstrate aircraft technologies and indicates the TRLs that can be supported by these demonstrations.

Table C-6. Aircraft Demonstrations and Supported TRLs

Demonstration	TRL Supported								
	1	2	3	4	5	6	7	8	9
Aerodynamic Configuration and Controls									
Analysis using theory and data	X	X	X						
Computational fluid dynamics		X	X						
Exploratory wind tunnel tests		X	X						

51 Meeting the most significant requirements.

52 Proving operational requirement can be met.

53 Often with a variety of scale models tested in several different wind tunnels to obtain data for different flight conditions and mission phases.

Table C-6. Aircraft Demonstrations and Supported TRLs (Continued)

Demonstration	TRL Supported								
	1	2	3	4	5	6	7	8	9
Wind tunnel tests of specific configuration				X	X	X			
Flight control wind tunnel tests				X	X				
Free flight of scaled aircraft					X	X			
Flight tests of EDM[54] aircraft						X			
Airframe Structure and Aeroelasticity									
Analysis	X	X	X						
Finite element analysis		X	X						
Laboratory tests of structural elements		X	X	X					
Loads tests of major structure (e.g., wing)[55]					X				
Flutter tests in wind tunnel				X	X				
Flight tests of prototype aircraft to g limits						X			
Flight Control System									
Analysis (stability margins, control authority)	X	X	X						
6 Degrees of Freedom (DOF) simulations		X	X						
Laboratory tests of sensors and actuators				X	X				
Flight tests with surrogate aircraft					X	X			
Flight test of EDM or prototype aircraft						X			
Propulsion									
Hot section material tests in laboratory	X	X							
Test cell testing of components[56]			X	X					
Test cell testing of engine core					X				
Wind tunnel tests of prototype engine and inlet					X	X			
Flight test of prototype engine						X			
Integrated Aircraft									
Flight tests of EDM aircraft						X			
Flight tests, EDM with mission equipment						X			

54 EDM functionally near equivalent to prototype.

55 These tests determine the strength and rigidity of the major structure.

56 Blade tests, combustion chamber tests, compressor and turbine tests, gear box and power transfer tests, and so forth, perhaps conducted with surrogate engines.

Table C-6. Aircraft Demonstrations and Supported TRLs (Continued)

Demonstration	TRL Supported								
	1	2	3	4	5	6	7	8	9
Flight tests of complete prototype aircraft[57]							X		
Qualification tests of early production aircraft								X	
Operational use of production aircraft									X

C.2.2 Ground Vehicles

Most new military vehicle concepts/systems can be expected to involve CTEs. Combat and tactical vehicles face new requirements driven by new threats and new or extended performance needs of operational forces. Utility and general-purpose vehicles, many of which are adapted versions of commercial vehicles, also can be required to provide special performance characteristics that exploit new technologies or novel application of existing technologies. Table C-7 is a sampling of military vehicle demonstrations and indicates the TRLs that can be supported by these demonstrations.

Table C-7. Ground Vehicle Demonstrations and Supported TRLs

Demonstration	TRL Supported								
	1	2	3	4	5	6	7	8	9
Power Package									
Analysis using theory and data	X	X	X						
Computational chemistry, heat transfer, and mechanics		X	X						
Laboratory proof of principle experiments		X	X						
Propulsion component small-scale bench tests			X	X					
Propulsion package scaled test stand tests simulating representative environments				X	X				
Full-scale test stand testing representative of operational environments					X	X			
Propulsion package proving ground tests in a representative surrogate vehicle						X			
Armament (Gun and Ammunition)									
Preliminary concept development using top-level analysis, data collection, and experience	X	X	X						

[57] Tests throughout flight envelope and missions.

Table C-7. Ground Vehicle Demonstrations and Supported TRLs (Continued)

Demonstration	TRL Supported								
	1	2	3	4	5	6	7	8	9
Thorough computational analysis			X						
Propellant chemistry			X						
Interior ballistics for gun and ammunition			X						
Flight dynamics			X						
Warhead and penetrator performance			X						
Scaled laboratory tests of system components				X					
Full-scale laboratory tests under operationally relevant conditions				X	X				
Full-scale tests of gun and ammunition integrated with mount and recoil system						X			
Protection (Passive and Reactive Components)									
Materials development	X	X	X						
Armor configuration concept development and preliminary analysis		X	X						
Computational analysis simulating relevant threats			X	X					
Scaled laboratory tests of generic configurations against simulated relevant threats				X					
Full-scale tests of generic configurations against simulated relevant threats					X				
Full-scale tests of combat system representative configurations against relevant threats.						X			

The automotive features of any class of military vehicles are likely to exploit critical technologies in propulsive power, drive trains, platform stability, suspension systems, and endurance. Demonstration of critical technology efficacy requires various means of analysis, test, and verification. In most cases, these analyses and tests are unique to the military environment.

The protection requirements and features of combat and tactical vehicles are unique aspects driven by combat environments. CTEs should be anticipated in vehicle integrated passive protection against diverse weapon and munitions threats. Similarly, as threats increase and become more sophisticated, CTEs appear that have reactive (e.g., explosive armor) or active (e.g., detection and attack of threat munitions) aspects. Evaluation of the maturity of these technologies is often made by developing extensions to existing analysis and test capabilities.

Battlefield dominance continually demands that weaponry improve to meet growing and changing threat capabilities. Technology improvement, development, and exploitation are the principal means to meet the demand. Most new weapons involve a gun or a missile and all their associated technologies. Assessing the maturity of these technologies requires strong analysis, test, and demonstration.

C.2.3 Missiles and Guided Weapons

The development program for a missile or other guided weapon is quite different from that of a "platform" vehicle, and the program for a solid propellant rocket is different from that of a liquid propellant rocket. Most military missiles have structure, propulsion, guidance, flight control, and payload. Each of these comprises numerous elements that must function together to meet the objectives of the system, and any of these elements can depend upon CTEs. To assess the maturity of these technologies, issues that should be considered in performance demonstrations include how the environments compare with the environments of the intended uses and how the performance exposes what is required.

Missile structural integrity and flight control are highly interdependent. Structural bending modes, placement of accelerometers, control system time constants, aerodynamic loads and control moments, and reaction controls must all work together to achieve stable, controlled flight. Structural rigidity and inertial properties can first be computed during computer-aided design (CAD) and confirmed by ground tests. Aerodynamics can be determined by analysis and wind tunnel tests. High-fidelity, 6 DOF simulations can represent the complete missile in its intended flight environment. Components that are tested in hardware-in-the-loop (HWIL) simulations can reasonably be considered to be TRL 4. Assuming that flight accelerations and vibrations are important to the functioning of a component and then testing that component while it is carried on a surrogate missile could achieve TRL 5. After the components are integrated into an EDM dynamically correct missile and flown, perhaps on a flight with pre-programmed maneuvers, the components can be considered TRL 6 if the environment is relevant for those components.

Missile guidance systems can include a variety of sensor types. Several types of test environments have been found to be useful for particular types of sensors. These include anechoic chambers for radars and other radio frequency (RF) systems, terrain tables for visual and infrared (IR) detectors, towers overlooking tactical targets, captive carry on aircraft and missiles, and free flight. The maturity associated with these sensors

depends on the fidelity of the relevant features of the environment and on the fidelity of the test article when compared with the final product. If a tower can provide the correct viewpoint and range to a target and if motion is not important, perhaps a tower test of a prototype sensor can be adequate to assess TRL 5. However, if motion is important, a captive carry test might be necessary to achieve TRL 5. Since motion is almost always important to missile guidance systems, captive carry for TRL 5 and demonstration on a prototype or surrogate missile for TRL 6 are suggested as the norms.

The missile payload will usually be a warhead, but it could be a sensor or a communications system. The warhead requires a safe and arm function and a fuze function, and these functions might be performed by separate devices, possibly integrated with the guidance system or a central processor. The warhead fill (the explosive material) can be characterized in a laboratory—first in small samples and then in larger samples. Numerous tests are required for effectiveness and safety to bring the fill to TRL 3. If, as is usually the case, the fill has been used successfully in other warheads, it might be considered TRL 6 or 7 depending upon the similarity of the present application's environment to that of the earlier applications. Prototype cases loaded with the intended fill should be tested for application-specific requirements (drop tests, projectile-impact tests, cook-off tests, fragment pattern, and so forth) to reach TRL 5. The devices providing the safe and arm and fuse functions should follow a similar development, finally being integrated with a prototype warhead and flown on a missile that can create a near-operational environment to demonstrate TRL 6.

For all these subsystems, the developer should ensure that none of the potential critical items are overlooked. To illustrate this point, the missile propulsion subsystem will be considered in more detail. Table C-8 shows some typical development activities for solid-fuel propulsion systems (solid rockets) and the TRL that can be supported by these activities. A rocket of this type has propellant that must meet requirements for energy, burn rate, strength, stability, and safety, among others. The propellant in a rocket, the "grain," must be supported so that it does not separate from the motor case under shock or high acceleration. The case usually must be insulated from the grain to preserve the strength of the case material, and, of course, the nozzle must not erode excessively during motor firing. The table lists important activities for determining the maturity of the technologies needed for these functions. "Test" normally means a series of trials and not a single trial.

Table C-8. Typical Steps in Development of a Rocket Motor and the TRLs Supported

Accomplishment	TRL Supported								
	1	2	3	4	5	6	7	8	9
Grain									
Discovery of an energetic material	X								
Laboratory synthesis of sample formulations	X	X							
Chemical properties of propellant established[58]	X	X							
Physical properties of propellant established[59]	X	X							
Test of grain in laboratory motor surrogate			X						
Grain Support and Case Insulation									
Static test of heavy case motor[60]				X					
Shock and vibration tests				X					
Sled test of heavy weight motor				X	X				
Case									
Case material properties established[61]		X							
Trial cases built			X	X					
Hydro burst test of prototype case					X				
Nozzle									
Erosion tests of nozzle materials		X							
Nozzle gimbal test			X	X					
Erosion test of prototype nozzle					X				
Motor									
Static test of prototype motor				X					
Flight test of prototype motor[62]					X	X			
Flight test of prototype motor on prototype missile							X		
Flight test of production motor on objective missile[63]								X	
Operational use of motor in missile system									X

58 For example, specific energy, burn rate, sensitivity, chemical stability.

59 For example, density, strength, ductility, rheology.

60 Having grain support and insulation of objective motor.

61 Strength at temperature, ductility, machinability, weld strength, and so forth.

62 On dynamic surrogate of objective missile or on developmental flight test of objective missile.

63 Demonstrating full operational envelope.

For liquid fuel rockets, different items are important. There must be movement and metering of fuel and oxidizer. There might be throttling or multiple starts. There might be cooling of the nozzle with fuel. Relevant conditions can include very low ambient pressures and longitudinal and lateral accelerations that can be achieved only in flight.

Air-breathing rockets have the additional needs to establish inlet performance and flammability limits over a wide range of Mach numbers and ambient pressures. Demonstrations can include connected tests (inlet connected to an air source) and free-flow tests including inlet, captive carry, and free-flight tests. These could merit TRLs of 4, 5, 5, and 6, respectively, if the test articles of the free-flight tests are functionally representative prototypes.

C.2.4 Ships and Ship Systems

Ships are likely to have CTEs in hydrodynamic hull form, materials and structures, propulsion, drag reduction, and motion controls. Ship systems such as sensors (radar/sonar), weapons (torpedoes/missiles), hotel (waste disposal/desalination/material movement), and aircraft interfaces (elevators) will require some additional CTEs. Ships also have CTEs related to survivability, such as signatures, countermeasures, and intact and damaged stability. A wide variety of methods and facilities are used to demonstrate these different technologies.

Ships are usually large and complex; therefore, prototyping of a complete system, such as a new hull form, is expensive and time consuming. The types of demonstrations used normally for ship hull-form technologies include analysis, CFD investigations, towing tank model scale tests, and land-based subsystem tests. For ship configurations that represent large departures from the existing base of knowledge, large-scale prototypes are sometimes used. For example, submarine signature improvements are always evaluated at least at the 1/4 scale in water.

Similarly, a variety of methods and facilities are used for structures and materials, motion control, and other ship-related disciplines. Table C-9 shows a few of the most often used means to demonstrate ship and ship systems technologies and indicates the TRLs that can be supported by these demonstrations. For ship-based missile systems, see Section C.2.3. Torpedo development would follow an approach similar to that of a missile system. The ship signatures, hydrodynamics, and hull form development usually run in parallel, so the demonstrations are linked as indicated in Table C-9. The technologies

Table C-9. Ship-Related Demonstrations and Supported TRLs

Demonstration	TRL Supported								
	1	2	3	4	5	6	7	8	9
Hull Form, Hydrodynamics, and Signatures									
Analysis using theory and data	X	X	X						
Computational hydroacoustics and hydrodynamics		X	X						
Exploratory tow tans and water tunnel tests		X	X						
Model scale tests of specific configurations				X	X				
Reanalysis using empirical data				X	X				
1/4-scale tests in a realistic environment					X	X			
Final full-scale predictions						X			
Ship Materials and Structures									
Initial theoretical analysis	X	X							
Finite element analysis		X	X						
Stress tests of structural elements		X	X	X					
Structural model tests in a tow tank				X	X				
At-sea material evaluation					X	X			
Large-scale evaluation in a seaway									
Motion Control System									
Stability and control analysis	X	X	X						
6 DOF simulations		X	X						
Subsystem tests of sensors and actuators				X	X				
Free-running model scale tests					X	X			
Prototype evaluations						X			
Propulsion									
Concept development and analysis	X	X							
Proof-of-concept tow tank component tests			X	X					
Prime mover land-based tests					X				
Integrated propulsion scale model tests					X	X			
Full-scale prediction of propulsion efficiency						X			
Ship Sensors and Hotel Systems									
Concept development in a laboratory									
Component evaluations			X	X					
Prototype development and testing					X	X			
Evaluation on an existing ship						X	X		

Table C-9. Ship-Related Demonstrations and Supported TRLs (Continued)

Demonstration	TRL Supported								
	1	2	3	4	5	6	7	8	9
Integrated Ship Concept									
Integration of system into ship concept						X			
Integrated prototype at-sea testing							X		
Production ship first-of-class trials								X	
Production ship in mission environment									X

of active drag reduction are treated similar to those of a propulsion subsystem, such as a new propeller, and would follow the propulsion approach. Passive drag reduction systems, such as hull shaping, are treated similar to the hull form development approach.

C.2.5 Hardware for IT Applications

The two examples presented describe the approach for assessing the technical readiness of hardware CTEs used in IT applications.

C.2.5.1 Effective Information Displays for Soldiers on the Battlefield

Infantry soldiers on the battlefield operate in an extremely demanding environment. While soldiers are expected to carry the equivalent of a laptop computer, the form and fit of a conventional laptop is awkward. This CTE example is concerned with the display technology of an integrated computer system having an ergonomic fit and form for use by infantry soldiers.

A high-tech monocle [based on Microelectromechanical Systems (MEMS) technology] to project images directly onto the retina has been selected.[64] The military has tested early prototypes of this technology. Commanders of Stryker vehicles have the

64 Such a system is expected to be more rugged than conventional approaches, to be able to be read in the daylight, and to have higher resolution than a conventional display. Furthermore, because essentially all the light generated enters the eye, the device is extremely energy efficient and thereby reduces demand on the local power supply.

option of viewing the onboard battlefield computer with a helmet-mounted display (HMD). Another prototype system has experimented with this technology to increase situational awareness by providing helicopter pilots a digital display of the battlespace.

The experience gained from testing the display with soldiers in Stryker vehicles and helicopter pilots provides a technical readiness of no higher than TRL 6 based on evidence from these field trials. The operational environment of the infantry soldier is quite different from the two tested applications. Achieving a TRL 7 or higher would require testing the display in the operational environment of the infantry solider.

C.2.5.2 Data Centers for Medical Records

The complete medical records for members of the Services will be located in a distributed computer database and be readily accessible on demand throughout the world. Owing in part to the size of images generated by diagnostic instruments, this database will quickly grow in size to become one of the largest DoD databases. As a consequence, the data centers hosting these data will push the limits for storage size and bandwidth for data transport within the data center. This example compares two technologies: the use of an interconnect technology *expected* to become the default choice for high-performance systems and a conventional, established technology.

Data centers consisting of a cluster of servers, persistent storage, and networked connections to clients often use many network and transport technologies for interconnecting these elements. Replacing these multiple networking technologies with a unified interconnection technology, such as InfiniBand, is desirable for satisfying this range of requirements.[65] The technology is available and has been used previously to build a robust, high-capacity interconnection fabric for a data center with similar requirements. Sufficient evidence exists for a TRL of 7 or higher.

Conventional 10-gigabit Ethernet is a mature alternative that has had significant historical success. Unfortunately, Ethernet's performance is severely limited because it presently does not have the quality of service (QoS) and fault tolerance found in Infiniband.

A dimension of "relevant environment" includes, in this case, the capability to maintain and expand the data center. This will present a problem if the interconnect

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[65] Having multiple networking technologies at the level of box-to-box connection increases system complexity and reduces reliability.

technology fails to meet market acceptance expectations and, consequently, disappears from the marketplace. In that case, a TRL of 7 would no longer be appropriate for Infiniband, whose market acceptance, to date, is not assured. Often, no clear choices exist in these situations between balancing the old and proven approaches (though of limited capability) with emerging approaches (whose long-term survivability has yet to be established). The best practice is to expose the issues and evaluate conservatively.

C.3 ASSESSING SOFTWARE CTEs

As in hardware systems, the definitions of TRLs as applied to software involve several dimensions. At the application level are values of device, component, subsystem, system, and system of systems for hardware and algorithms, software components, software programs, and software packages for software. Another dimension, discussed at length in Appendix D, includes environment (or application) with values of integration laboratory, user environment, logical relationships, data environment, and possibly interfaces. Other system-wide dimensions include obsolescence, scalability, and throughput and are usually expressed in terms of system-wide requirements, but the hardware components often contributes to meeting these requirements. As in the hardware TRLs, some of these terms are used explicitly in the TRL definitions, and some are not. The combination of these dimensions determines any TRL. When the accomplishment and the definition do not match, the assessor must use his/her judgment regarding the relevance of what has been accomplished and ask whether the accomplishment is equivalent to the TRL definition.

In assessing software's technical readiness, one must be aware of the proper use of the terms "relevant environment" and "operational environment." Claiming technical readiness in a relevant environment (TRL 7 or higher) requires a detailed architecture that fully exposes all components and elements affecting the operation of the critical software element. Claiming technical readiness in an operational environment (TRL 6 or higher) requires evidence of the acceptable performance of the software element under operational factors, including, for example, system loading, user interaction, and realistic communications environment (e.g., bandwidth, latency, jitter). In other words, claiming a TRL 5 or higher requires a detailed architecture, and claiming a TRL 7 or higher requires, in addition to the detailed architecture, defining the operational environment and evidence of acceptable performance in the operational environment.

In practice, assessing the maturity of the software components of IT systems can be difficult. Table C-10, adapted from Table C-5 for the hardware technology, can be used as a guide of the type of data needed in support a given maturity level. This table lists the numerous steps typical of software system development programs and indicates the TRLs that can be supported by these accomplishments.

Table C-10. Attainment of Technical Readiness for Software CTEs

Accomplishment	TRL Supported								
	1	2	3	4	5	6	7	8	9
Discovery of mathematical principle or algorithm	X								
Characterization of the principle	X								
Application envisioned and described		X							
Concept of application analyzed		X							
Critical functionality empirically confirmed and implemented software			X						
Proof of concept demonstrated in simulation			X						
Scale-up or other extension as needed by concept			X	X					
Component tested in simulation				X					
Producibility and cost estimated				X	X				
Software component tested in an integration laboratory				X					
Software component tested in a relevant environment					X				
Prototype component integrated into a system prototype				X	X				
System tested in a simulated environment				X					
System tested in a limited field experiments				X	X				
System tested in a relevant environment						X			
System tested in an operational environment							X		
Production system tested in an operational environment								X	
Production system proven in mission operations									X

Brief examples estimating the level of technical readiness for software elements follow.

C.3.1 Information Integration of Unstructured Data (See Figure C-1)

This situation highlights CTE assessment considerations in programs that interface with many semi-autonomous organizations at the information, data, and processing level but have little or no design influence within the organizations beyond the interface.

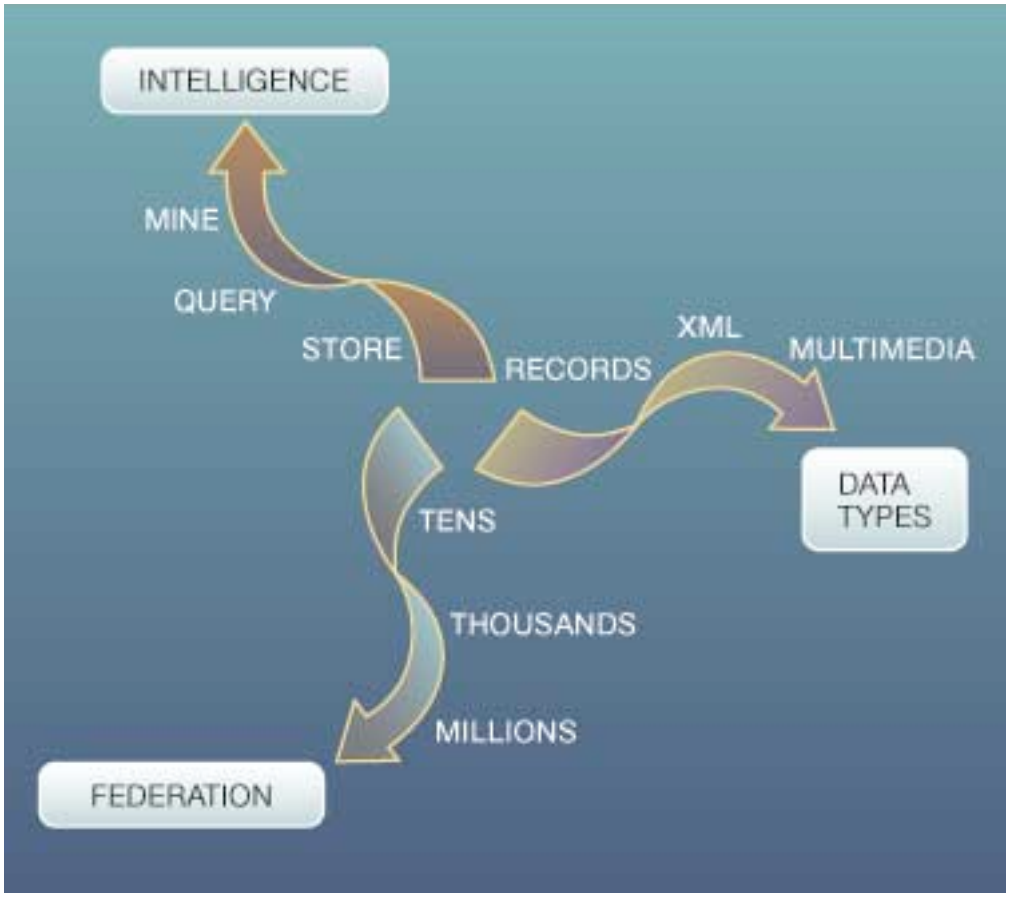

Figure C-1. Three Dimensions of Information Integration (Source: A.D. Jhingran, N. Mattos, and H. Pirahesh, "Information Integration: A Research Agenda," *IBM Systems Journal,* Vol. 41, No. 4, 2002)

In such as system, eXtensible Markup Languuage (XML) can be used to access structured and unstructured data.[66] XML would describe unstructured data through XML schemas, and data access would be provided via XQuery and XPath standards.

If the application were a mission planning system, several DoD-unique concerns would have to be considered:

- Because of the limited control over design and operation internal to the organization hosting the data sources, an increased emphasis is placed on the

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66 The data in a structured data source are strongly typed, and relationships are described by a schema. The data are organized in tables and accessed via a relational database. Structured Query Language (SQL) is supported for accessing information in the database. Unstructured data consists of practically everything else, including documents, images, data sets, field reports, and maps. While some of these unstructured data types are semi-structured, which can be exploited for organization and accessibility, these heterogeneous data sets have begun to be unified only recently. A query should transparently combine data from relational tables, the XML database, and data retrieved from external servers.

inter-organization interface for delineating areas of responsibility (i.e., functional allocation) and standards for representing data using XML.

- The system needs to accommodate the restrictive nature of highly classified data sources while providing access to less classified and most likely unclassified sources. For this system to be useful, the security model, along with its implementation, must successfully provide access while enforcing security policies in a manner that still allows for automated and efficient operation.
- Although base standards have been issued for XQuery and XPath, it is not clear that they have achieved sufficient maturity for this application.

CTEs would be found in the XML data models and their interaction with XQuery; in the interface definitions, including functional allocation among the organization; and in the implementation of security policy. Without any documented, relevant DoD experience, a TRL of 4 is the highest level that should be assigned.

C.3.2 Distributed Resource Sharing (See Figure C-2)

This example discusses CTEs associated with the capability to process, interpret, and distribute an unprecedented quantity of data collected from sensor networks, overhead assets, and other technical collection means in a timely manner—a netcentric warfare scenario. The technical approach is to implement a grid service architecture that is currently being developed in a consortium environment for coordinated resource sharing and problem solving in a dynamic, multiorganizational setting.[67]

CTEs are mostly confined to the suitability and performance of the architecture in a military environment. Specifically, concern involves accommodating DoD security policy and performance over a network of limited bandwidth, including response to unexpected events that causes resources to disappear temporarily (e.g., severance of a communications link).

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[67] Storage, computational, and communication resources will be shared by providing standard, open, and general-purpose protocols and interfaces for capabilities, including authentication, authorization, resource discovery, and resource access. This includes direct and managed access to sensors, processors, software, communications bandwidth, storage, file systems, database, and servers. These resources can be used collectively on existing standard Web service components in a coordinated fashion to deliver negotiated qualities of service, relating for example to response time, throughput, availability, and security. The thrust is to provide a capability for dynamically establishing resource-sharing arrangements with any interested member and thus create something more than a plethora of balkanized, incompatible, noninteroperable distributed systems.

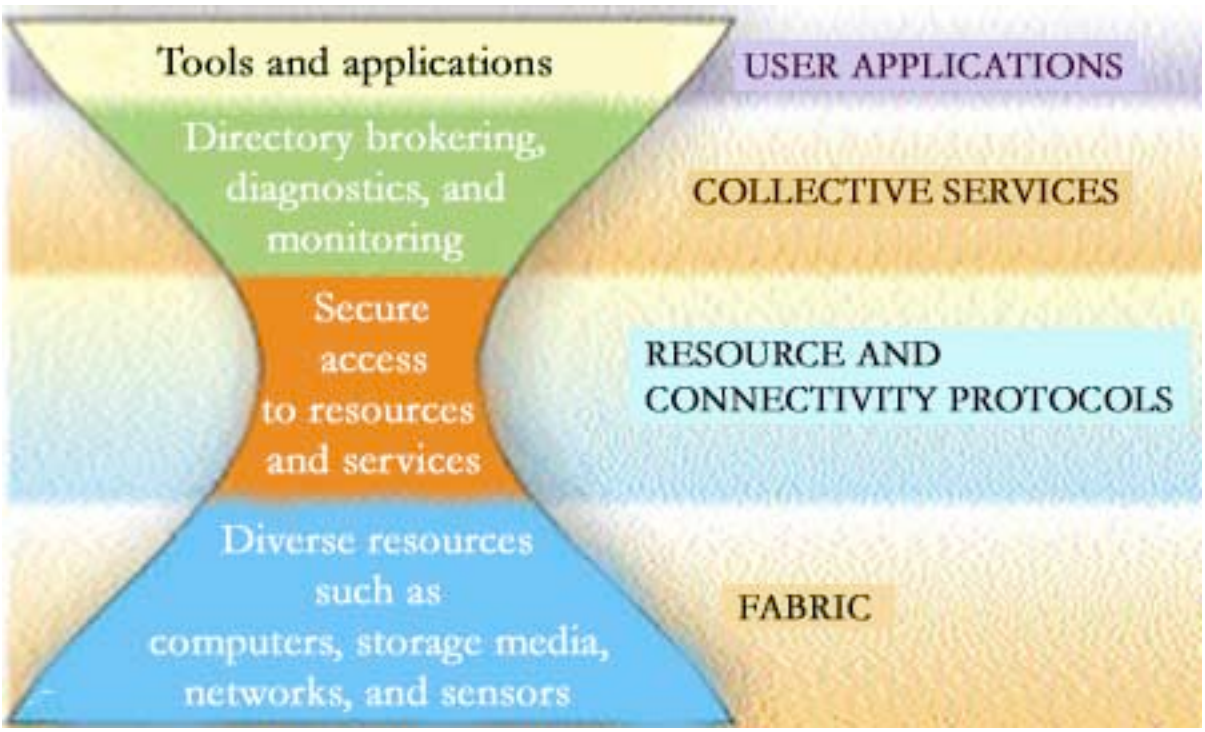

Figure C-2. Elements Involved in Resource Sharing
(Source: Ian Foster, "The Grid: A New Infrastructure for 21st Century Science," ***Physics Today,*** **Vol. 55, Issue 2, 2000)**

A highly promoted way of developing software and standards is via a consortium with wide participation from commercial, governmental, and academic organizations. This is becoming an accepted approach in the software and communications sectors to promote open standards and accommodate user needs better. In the present example, grid technology has undergone continuous development for more than 10 years and has resulted in several standards and released software packages. Through active participation, the program intends to use the standards as they currently exist and influence their evolution to accommodate currently unsatisfied needs.

Because the selected architecture has only established its viability in primarily scientific and limited commercial domains, a TRL of no higher than 4 should be assigned. Achieving a higher level of technical readiness is possible only in the context of a detailed architecture and within a distributed military environment. For example achieving the required QoS level is critical to the viability of this system. QoS is difficult—if not impossible—to assess accurately without an operational system. The difficulty in assessing QoS arises because QoS degrades as a system is stressed from workload, dynamic reconfiguration, and component failures.

C.3.3 Autonomic Computing[68] (See Figure C-3)

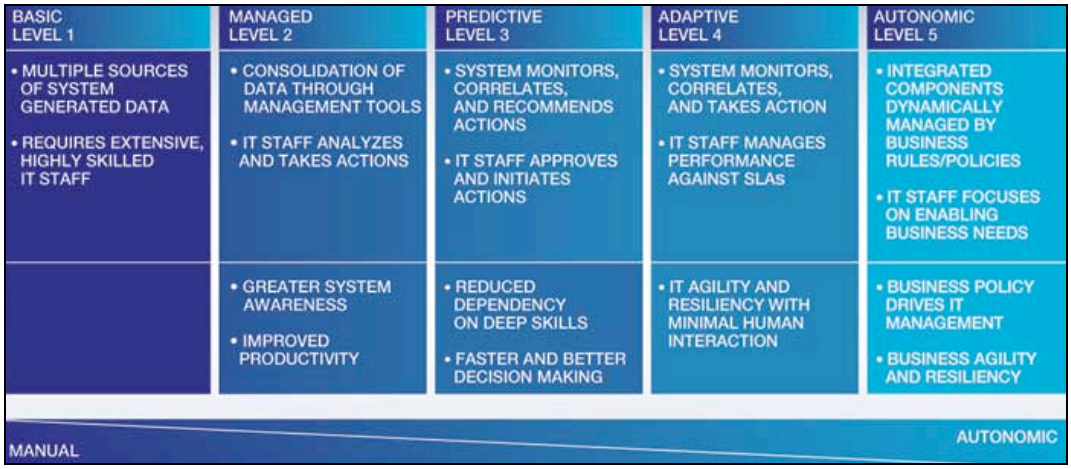

Figure C-3. Evolving to Autonomic Operations
(Source: IBM Global Services and Autonomic Computing, IBM White Paper, October 2002)

Dependence on IT systems during critical tactical operations places exceedingly high requirements on their reliability, availability, and security. A new strategy for increasing IT system reliability and availability while at the same time, reducing dependence on human intervention, incorporates an autonomic system to manage system operation dynamically.[69]

Most of the technology required to build automatic systems either does not exist or exists at a research level/early prototype stage. Procurement of a fully autonomic system is not technically viable at present. A TRL of 3 is the maximum assessment.

In the larger context of a well-defined, incremental approach for achieving a fully autonomic capability, technology selection and evaluation should be focused on the

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68 Much as the autonomic nervous system in humans frees our conscious brain from the burden of controlling low-level but vital functions and coping with deviations from normal operation (e.g., infection), an autonomic system as part of an IT system makes the IT system self-managing. That is, the system become self-configuring, self-healing, self-optimizing, and self-protecting with minimal human intervention.

69 An autonomic system is implemented as a collection of interacting, automatically managed elements. These elements include hardware resources (e.g., storage, processing, or communications) or software resources (e.g., application program, database, or operating system) or even other automatically managed IT systems. Each autonomic element is responsible for managing its own internal state and behavior. Through interacting with other automatically managed elements and the external world, the state of the system is driven toward consistency with the given goals.

capabilities required for the current increment.[70] The current strategy calls for evolving the system though five increments (basic, managed, predictive, adaptive, autonomic) that progress from manually managed to automatically managed.

As an example, consider a program undergoing development of its second increment, which is focused on consolidation and presentation of state and performance data through management tools.[71] The software technology for functions of consolidation and presentation is available and has been demonstrated to operate in a relevant operational environment. Hence, the evidence will likely support a TRL of 5 or higher.

C.3.4 Radio Frequency Identification (RFID) Tags for Material Assets Management

Management of military supplies and equipment is exceedingly complex because current inventory accounting systems are outdated, have limited interoperability, and are implemented with poorly documented software. Knowing the status of these material assets (e.g., current location, expected date of delivery for new assets, condition, and ownership) reduces costs and improves capability.

RFID tags provide automatic identification of tagged assets as they pass through locations equipped with interrogators. The military has used selective RF tagging of large or expensive items for many years. However, as spurred by commercial organizations such as Wal-Mart in managing their supply chain, RFID tagging will reach the point where it is technically and economically possible to tag practically all levels of material objects. Furthermore, not only will the tags identify the object type, but they can also encode item-specific information such as expiration date and lot number.

DoD will probably be in a position to use a commercially proven technology with an inherently low technical risk. While this will certainly be true for several common technology issues (e.g., the cost of tags and good readability by fixed interrogators), military IT systems for collecting, processing, and using RFID tags are expected to face many technical challenges. For example,

- It is common to want to know where the object is and not where it was when the RFID tag was last read. Knowing an object's whereabouts requires the

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[70] It is the designer's responsibility to select and develop technologies that naturally build toward future increments and this is not a consideration of technical readiness for the current increment.

[71] The first increment defined and collected the data that is being consolidated.

integration of tag information with the in-transit visibility (ITV) server. Other asset management systems that will need to interoperate with the RFID system include the Government Freight Management (GFM) system, the Global Air Transportation Execution System (GATES), the Surface Transportation Management System (STMS), and the Movement Tracking System (MTS).

- If objects are tagged at multiple levels (e.g., the item itself, a box of items, a pallet of boxes of items, a shipping container housing the pallet, and so forth), not all tags will necessarily be interrogated at the same time. As the contents of shipping containers get rearranged and distributed and the pallets get broken down, mechanisms and procedures must be put in place to determine the whereabouts of the material assets.
- RFID only works when interrogators are in place to read the tags. Since deployment destinations are not always known in advance, either interrogators must be in place and operational before tagged assets are moved or a way to accommodate a loss of contact must be developed.

While these problems do not appear to require new technology as part of their solution, they do require a careful consideration of interactions, interoperability with other systems, and sensible use of the RFID capability. Until systems have been developed and real-world experience has been gained, a TRL of 5 or less is appropriate.

In addition, RFID tagging presents other technical challenges. DoD will potentially use RFID tags and receptors in extreme environmental conditions that most commercial firms do not face. Potential wireless security concerns also exist if sensitive material is being tracked. These issues require new technology as part of their solution, and, therefore, a TRL of 4 is more appropriate.

C.4 ASSESSING MANUFACTURING CTEs

The readiness of a manufacturing technology is evaluated in context of understanding the risks associated with the industrial process and then developing and implementing risk mitigation plans. The risk elements can be classified over the following areas:

- Technology and industrial
- System design
- Materials
- Cost and funding
- Process capability and control

- Quality management
- Personnel skills and availability
- Facility capability and capacity
- Manufacturing planning, scheduling, and control.

Table C-11 indicates accomplishments that should occur consistent with these threads for a manufacturing technology to achieve a given TRL. The following examples demonstrate these concepts.

Table C-11. Attainment of Technical Readiness for Manufacturing CTEs

Accomplishment	TRL Supported					
	4	5	6	7	8	9
Emerging breadboard design options provide insight into potential manufacturing problems with the industrial base infrastructure (facilities and manpower), materials, methods, and measurement (inspection and test equipment)	X					
Breadboard design options provide insight needed to validate characteristics and potential geometries		X				
Various strategies are identified to mitigate technical and cost risk		X				
Prototype brassboard design has actual components, subsystems, or systems that have associated manufacturing processes, materials, and methods			X			
Preliminary assessment of manufacturing assembly sequences			X			
Industrial base infrastructure (facilities and manpower) capabilities along with measuring and test equipment initially are evaluated			X			
Cost accounted for on high-risk manufacturing areas and plans are developed to mitigate risk			X			
Quality management model understood			X			
Manufacturing processes, materials, and assembly methods have been developed for a production environment—ideally in a pre-production facility or better				X		
Design maturing; key materials and process characteristics have been identified, and planning is taking place for managing (process control as appropriate)				X		
Detailed manufacturing risk assessment covering industrial base infrastructure (facilities and manpower), materials (availability, producibility characteristics), methods (mature processes), measurement (inspection and test equipment), and costs				X		
Quality management structure is identified				X		

Table C-11. Attainment of Technical Readiness for Manufacturing CTEs (Continued)

Accomplishment	TRL Supported					
	4	5	6	7	8	9
Appropriate throughput levels have been achieved				X		
Initial goals set for yields, quality, and reliability				X		
Manufacturing processes, materials, and assembly methods have been demonstrated on production-representative articles, with no known significant manufacturing risk					X	
Yields, quality, reliability and cost are within 25 percent of goals					X	
Design mature. Process requirements are proven and validated					X	
Quality management structures are in place					X	
Manufacturing processes are efficient and acceptable in factory environment						X
Design producible. Used to produce production articles for IOT&E and the field						X
Design-to-cost (DTC) and production goals are met						X

C.4.1 Example: Manufacturing Technology for Laser Diode Arrays

Laser diode arrays are critical components for high-efficiency and reliable solid-state lasers that are used in laser rangefinders and laser designators. Manufacturing technologies were pursued to reduce the manufacturing cost by a factor of two. Major steps in the manufacturing process are as follows:

- Epitaxial growth of laser structure on gallium arsenide (GaAs) substrates
- Wafer processing to define individual elements through photolithography and metallization processes
- Wafer cleaving to produce 1 cm × 1 mm rectangular bar elements
- Optical coating on bar facets to produce high-reflectivity mirror on one edge and partially reflecting mirror on opposite edge
- Bond/solder bars in heat sink package
- Test the completed laser diode array for specified performance.

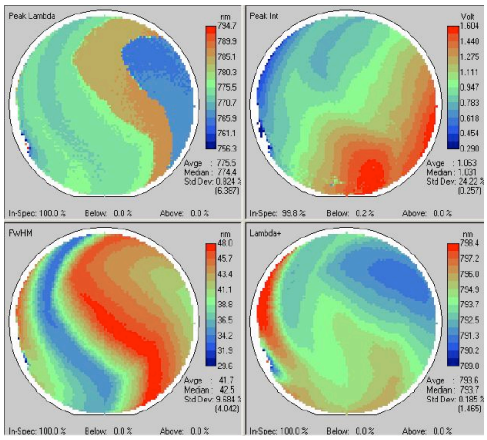
TRL	Example Descriptions
4	**Manufacturing concepts identified from producibility studies:** Initial studies indicated that the cost drivers in bar production are wafer processing and touch labor in cleaving and coating bars. An increase in wafer size will increase throughput and reduce processing cost per bar. The automation of bar stacking in coating fixtures will reduce touch labor and improve yields. New package materials and assembly techniques are expected to increase laser diode array reliability.

TRL	Example Descriptions
5	**Strategies identified to mitigate technical and cost risk:** Change from 2-in. to 4-in. wafers for Molecular Beam Epitaxy (MBE) growth. Identify machines to automate bar stacking in coating fixtures. Preload bars in bonding fixtures to reduce solder thickness in laser diode array package and improve reliability and thermal performance.

MBE Machine for Fabrication of Laser Diode Wafers

4-in., 3-in., and 2-in. Wafers Shown for Comparison (Compared Against the Size of a Quarter)

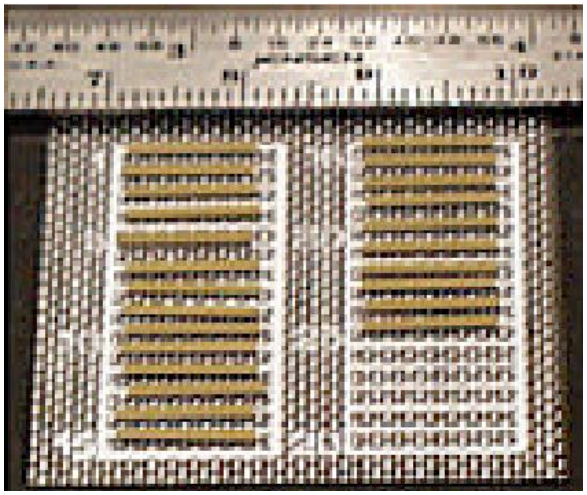
TRL	Example Descriptions
6	**Manufacturing process developed and applied:** Initial 4 in.-wafer growth and evaluation of laser performance and wavelength uniformity. The yield of specification lasers is dependent on the uniformity of material and device wavelength. Design, build, and evaluate automated bar stacking machines for function and yield of good devices. Develop bar bonding techniques to improve yield and the reliability of devices. Demonstrate 4-in. wafer MBE growth meeting center wavelength and wavelength variation specifications across full wafer. Complete automated bar stacking machine and demonstrate improved yield in test lots. Demonstrate array package with reduced solder thickness process and evaluate thermal performance and reliability.



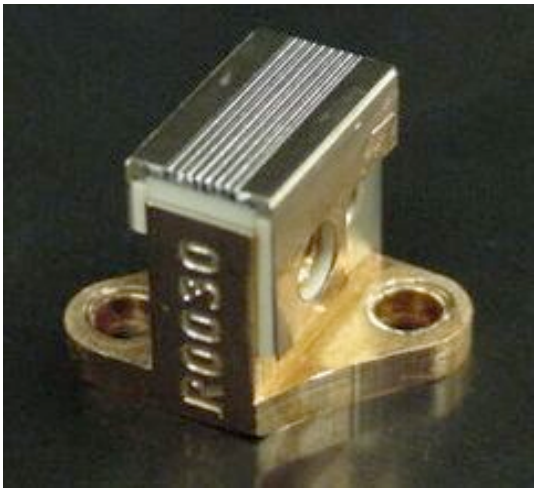
Maps Showing Wavelength Uniformity Initial 4-In. Wafer Growth

Machine To Stack Bars In Coating Fixtures To Reduce Touch Labor

TRL	Example Descriptions
7	**Prototype pre-manufacturing system:** Initial evaluation of individual manufacturing processes for growth and fabrication of wafers. Evaluate automated bar stacking, coating, and unstacking steps for quantity of devices. Initial evaluation of producing new laser diode array packages including performance tests.
8	**Manufacturing process maturity demonstration:** Pilot line demonstration of manufacture of laser diode bars from 4-in. wafers and using automated bar handling machines. Determine yield for each process. Determine yield of laser diode array packages that meet specifications for power and wavelength.
9	**Manufacturing processes proven:** Laser diode bars manufactured in quantity with target yields and cost. Laser diode array packages are manufactured in quantity, with required yields for specified performance and proven reliability.



Unmounted 807-nm Laser Diode Bars

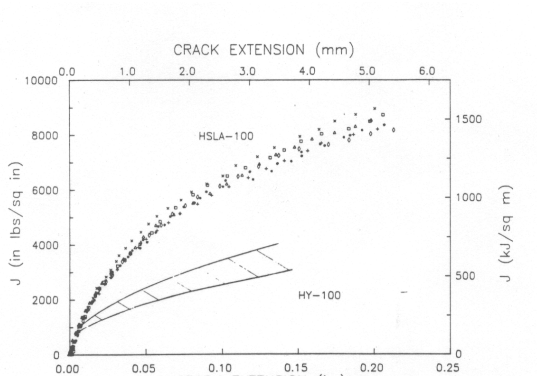


8-Bar Laser Diode Array

C.4.2 Example: Metal Joining Technologies [High-Strength Low-Alloy (HSLA)-100 Steel]

The importance manufacturing technology for metal joining, especially welding, was driven home on April 10, 1963, with the sudden and catastrophic sinking of the *USS Thresher* (SSN-593) off the New Hampshire coast, killing all aboard. As technologies and capabilities improved, the demand on submarines (i.e., deeper, faster, and quieter) grew. Similar demands were also placed on surface ships. These performance improvements required new materials and processes that were often a variation on existing materials and processes. However, even minor changes to a material's properties or a manufacturing process should require extensive manufacturing proofing before production, as was the case with HSLA-100 steel.

C.4.2.1 TRL 4



What Occurred: For the trial plate production phase of the HSLA-100 steel project, an initial 150-ton production of HSLA-100 steel was melted and rolled by Phoenix Steel Corporation in 1986 to the interim specification. This process used a conventional electric furnace and ingot casting practice, conducted to achieve a very low carbon composition. The minimum strength and toughness requirements of the interim specification were met in the initial production of HSLA-100 steel plates in gages from 1/4 to 2 in. Optimum properties in HSLA-100 steel plate resulted from aging temperatures from 1,150 to 1,275 °F. Upon receipt of the HSLA-100 steel plate from the trial productions, an review commenced to evaluate HSLA-100 steel plate and welding using the processes and procedures for High Yield Strength (HY)-100 steel ship and submarine structural applications—but with reduced heat or no preheat. The evaluation of HSLA-100 steel plate properties and welding demonstrated that HSLA-100 steel met the mechanical property requirements of HY-100 steel and was able to be welded, with reduced preheat requirements and using the same welding consumables as those for HY-100 steel fabrication. When compared with HY-100 steel, the tensile and impact toughness properties of the plates met or exceeded the requirements.

Manufacturing Perspective: Trial productions were run—but on a limited basis and mainly to determine if performance could be met. For example, the initial production

of HSLA-100 steel was rolled by the Phoenix Steel Corporation. However, from a manufacturing perspective, Phoenix Steel's success did not mean that other manufacturers would also be successful. First, other manufacturers would have used different people who had slightly different skills. Second, even though these manufacturers may have used the same machines, these machines would have been calibrated and set differently. Third, the specification was interim, indicating that it was not fully proven or tested. This is a significant manufacturing concern. Finally, the manufacturing was migrating from a process that required pre-heating to processes that required little or no pre-heating. While the initial findings were positive, these findings did not indicate that they could have been replicated easily by other production houses. The major issue is this: Just because an item can be produced in limited quantities or in a lab environment, the transition to production will not necessarily be low risk.

C.4.2.2 TRL 5

What Occurred: Lukens Steel Company produced a second melt of HSLA-100 steel, again by electric furnace and ingot casting. Most of the plate produced from the heat was greater than 2 in. thick, primarily for ballistic resistance evaluation. The minimum strength and toughness requirements were met in plate thicknesses that ranged from 1/2 to 3-3/4 in. A double austenitization and quench process was used for an HSLA-100 steel plate in gages over 1-1/4 in. to refine the heavy-plate grain structure for optimum toughness. The HSLA-100 steel was the primary material used in the certification program, from the production to the interim specification. The certification evaluation included continued characterization of production the HSLA-100 steel plate's mechanical, physical, and fracture properties. However, the main focus was the evaluation of weldability and welding process limits for structures of high restraint, studies of fatigue properties, and effects of marine environments on HSLA-100 steel. The results of low-cycle fatigue crack initiation tests of HSLA-100 steel and weldments and high-cycle fatigue tests in air and seawater indicated properties

equivalent to HY-100 steel in every case. The steels showed similar fatigue crack growth rate properties. General corrosion, crevice corrosion, galvanic corrosion, and high-velocity seawater parallel flow and cavitation tests of HSLA-100 in seawater showed that the corrosion behavior of HY-100 and HSLA-100 steels was comparable.

Manufacturing Perspective: With advanced lab testing/development, the performance capabilities continued to mature; however, these performance capabilities differ. For example, the second melt of HSLA-100 steel was by Lukens Steel Corporation. They have a different factory floor plan and different processes than those of Phoenix Steel. Again, product evaluations continued, but no analysis of the industrial base was conducted. No producibility analysis was conducted to identify potential manufacturing process improvements that would lower cost and risk. As the specifications emerged, they probably did not identify the material and process tolerances and the key characteristics of those processes because they were not put under statistical process control to ensure uniform quality.

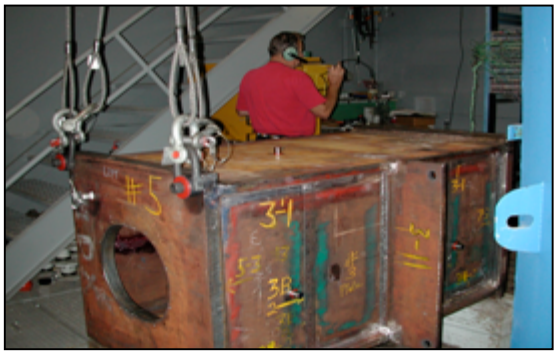
C.4.2.3 TRL 6

What Occurred: The evaluation of HSLA-100 steel production plates concluded that the mechanical properties of production plate, welding and weldability screening tests, fatigue properties, and corrosion properties demonstrated that the system was viable for certification for combatant ship structure. System evaluation by explosion bulge and crack-starter bulge tests, fragment penetration resistance tests, and ballistic property tests were successfully conducted. In 1987, the Naval Sea Systems Command (NAVSEA) initiated projects at General Dynamics Electric Boat and Newport News Shipbuilding (NNS) to evaluate the weldability of HSLA-100 steel under various preheat conditions in a production environment. The results of the weldability evaluation demonstrated that HSLA-100 steel could be welded at up to 1.25-in. thick at 60 ºF minimum preheat, with the same processes and consumables being used for HY-80/100 steels. Ballistic evaluations demonstrated that HSLA-100 steel was equivalent to HY-100 steel and weldments in ballistic resistance.

Both steels were comparable to Army Rolled Homogeneous Armor. In March 1989, NAVSEA certified HSLA-100 for surface ship construction in thicknesses up to 4 in.

Manufacturing Perspective: With prototyping in a relative environment, the analysis and characterization of materials and processes are expanded. For example, the prototyping included testing of both Gas Metal Arc Welding (GMAW) and Submerged Arc Welding (SAW) welding of HSLA-100, and from a thickness of 1 in. to 1 5/8 in. and then up to a thickness of 4 in. Also, the prototype evaluations were taking place in multiple industrial facilities. Each of these facilities had different personnel, slightly different processes, and different vendors of materials and consumables. As they were prototyping, they were validating their processes and capturing that information for incorporation into Military Specifications (MIL-SPECS). The need for capturing quality and manufacturing planning and the related costs to validate against cost targets is implied.

C.4.2.4 TRL 7



What Occurred: The fabrication of a series of structural performance models was completed under shipyard welding conditions. Holding bulkhead panel models, foundation models, and a full-scale foundation were evaluated and demonstrated satisfactory structural performance. Electric Boat fabricated the full-scale foundation and a small, heavy-gage tank model. NNS partially completed the fabrication of a full-scale hard tank; however, a funding shortage precluded tests. In these shipyard fabrication exercises, all weld cracking was related to Shielded Metal Arc Welding (SMAW) and SAW consumables (where cracking occurred even when HY-100 preheat temperatures were used) or to improper welding practices. No heat-affected zone (HAZ) cracking occurred in HSLA-100. Hydrostatic tests of full-gage bulkhead panel models are an extreme test of plating-to-stiffener strength and HAZ ductility. The HSLA-100 panel models exceeded anticipated holding pressure levels, withstanding over twice the holding pressure of identical HY-100 panel models. A series of foundation beam elements (full-scale) and the full-scale SSN 688-type AC foundation were installed and tested on a floating shock platform. The structures were subjected to a series of underwater explosion (UNDEX) shock tests. For a series of 3 UNDEX events, the structural response of

the HSLA-100 items indicated no cracking or excessive deformation in any structural joint.

Manufacturing Perspective: With the onset of prototyping in an operational environment and with subsystem components, the actual or planned manufacturing environment is mirrored. Notice that production testing continued at both Electric Boat and NNS and on some full-scale parts. The one red flag is the lack of full testing at NNS because of funding shortages, especially when some manufacturing problems still had to be isolated and resolved (e.g., the cracking caused by small differences in consumables from different vendors). This indicates that key characteristics were still not fully identified because there were interactions between material factors causing the cracking. The improper welding practice indicates that manufacturing had not gotten control of those processes or did not adequately identify those process steps or were not controlling them from a quality perspective.

C.4.2.5 TRL 8

What Occurred: In 1989, NAVSEA certified HSLA-100 steel for surface ship construction in thicknesses up to 4 in. At that time, the *USS John C. Stennis* (CVN 74) was approved, indicating that HSLA-100 steel was a qualified substitute for HY-80/100 steel in CVN construction. The experience base for welding HSLA-100 steel was too limited to allow the wholesale substitution for all HY-80/100 steel in the unrestricted areas of the carrier. Therefore, an implementation plan for incorporating the HSLA-100 steel was submitted, and NAVSEA approved this plan. NNS used HSLA-100 steel during CVN 74 construction. Approximately 700 tons of HSLA-100 steel plate in 7/8- and 1-in. thicknesses were used for main deck panel assemblies with longitudinal and transverse stiffeners without preheat (65 to 80 ºF shop temperature). One hundred percent magnetic particle inspection was performed on all HSLA-100 butt welds. In 1,400 feet of 7/8-in. thick HSLA-100 butt weld inspected by Magnetic Particle Testing (MT), only 2 repairs (8 in. total) were required (not related to hydrogen-

type defects). The same length of 1-in. thick HSLA-100 butt weld inspected by MT showed no defects. A total of 1,250 tons of HSLA-100 were used in CVN 74, with over 4,000 ft of weldment inspection requiring 32 in. total repair (less than 0.01 percent). The flight deck of the *USS Bataan* (LHD 5) was successfully fabricated with HSLA-100 plate (in place of HY-100 steel) for cost savings, as were subsequent vessels of the same class.

Manufacturing Perspective: With technology being demonstrated in an operational environment (i.e., HSLA-100 welding at NNS on CVN 74), the technology and manufacturing processes are mature enough to transition. The Navy was transitioning slowly because of the still many unknowns related to large-scale welding efforts. Thus, initial production was limited to the deck area only and to 1-in. thick plate. As production and testing progressed, quality data came in and further supported production increases to larger thicknesses and other areas below the deck. At this point, yield data should support the use of selected processes, and the processes should be stable enough to allow others to replicate the results.

C.4.2.6 TRL 9

What Occurred: Because of the experience gained on CVN 74, wholesale changes to HSLA-100 steel were made on CVN 75. Approximately, 10,500 long tons (LTs) of HSLA-100 steel were inserted into CVN 75. Most of the replacement was for decks and bulkheads and some built-up stiffeners. The HSLA-100 stiffeners were short spans with heavy web/flange members. HSLA-100 steel was selected to replace HY-100 steel for fabrication cost reduction, and, as a consequence, HSLA-100 steel has been used in place of HY-100 steel in the construction of *USS John C. Stennis* (CVN 74), *USS Harry S. Truman* (CVN 75), and *USS Ronald Reagan* (CVN 76). On the CVN 76, NAVSEA 08 approved the substitution of HSLA-100 steel for HY-80/100 steel structures outside the primary shield tank, opening another area for substitution. On CVN 77, expended use of HSLA-100 steel plate continues. NNS expects to qualify reduced preheat for welding up to 2 in., adding over 4,000 LT of HSLA-100 steel where significant fabrication cost reduction is gained over HY-100 steel in this thickness range.

Depending on the complexity of the structure, estimated cost savings for HSLA-100 steel vs. HY-100 steel fabrication in CVN 74 construction range from $500 to $3,000 per ton of fabricated structure.

Manufacturing Perspective: With the transition from low rate production (LRP) to full-scale production (FSP), manufacturing and quality processes should be well documented, and efforts should be put into place to improve quality and productivity.

ACRONYMS AND ABBREVIATIONS FOR APPENDIX C

CAD	computer-aided design
CFD	computational fluid dynamics
COTS	commercial off-the-shelf
CTE	Critical Technology Element
CVN	Carrier Vessel Nuclear
DoD	Department of Defense
DOF	degrees of freedom
DTC	design-to-cost
EDM	Engineering Development Model
FDA	Food and Drug Administration
FSP	full-scale production
GaAs	gallium arsenide
GATES	Global Air Transportation Execution System
GFM	Government Freight Management
GMAW	Gas Metal Arc Welding
GOTS	government off-the-shelf
HAZ	heat-affected zone
HMD	helmet-mounted display
HSLA	High-Strength Low-Alloy
HWIL	hardware-in-the-loop
HY	High Yield Strength
IR	infrared
IT	Information Technology
ITV	in-transit visibility
JDMPT	Joint Defense Manufacturing Technology Panel
LHD	Amphibious Assault Ship
LRIP	Low Rate Initial Production
LRP	low rate production
LT	long ton

MBE	Molecular Beam Epitaxy
MEMS	Microelectromechanical Systems
MIL-SPECS	Military Specifications
MT	Magnetic Particle Testing
MTS	Movement Tracking System
NASA	National Aeronautics and Space Administration
NAVSEA	Naval Sea Systems Command
NNS	Newport News Shipbuilding
OT&E	operational test and evaluation
QoS	quality of service
R&D	research and development
RF	radio frequency
RFID	radio frequency identification
SAW	Submerged Arc Welding
Sim/Stim	Simulation/Stimulation
SMAW	Shielded Metal Arc Welding
SQL	Structured Query Language
SSN	Attack Submarine (Nuclear Propulsion)
STMS	Surface Transportation Management System
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level
UNDEX	underwater explosion
XML	eXtensible Markup Languuage

APPENDIX D.
GUIDANCE AND BEST PRACTICES FOR IDENTIFYING CRITICAL TECHNOLOGY ELEMENTS (CTEs)

D.1 INTRODUCTION

CTE Defined

A technology element is "critical" if the system being acquired depends on this technology element to meet operational requirements with acceptable development cost and schedule and with acceptable production and operation costs *and* if the technology element or its application is either new or novel. Said another way, an element that is new or novel or being used in a new or novel way is critical if it is necessary to achieve the successful development of a system, its acquisition, or its operational utility.

Disciplined identification of CTEs is important to a program. If a CTE is overlooked and not brought to the requisite maturity level for exploitation at the start of System Design and Development (SDD), the system performance, program schedule, and cost could be jeopardized. On the other hand, if an overly conservative approach is taken and a plethora of technologies are categorized as critical, energy and resources are likely to be diverted from the few technologies that deserve an intense maturation effort. If a disciplined process with due diligence does lead to an inordinate number of CTEs, this should be an indication that the proposed development is reaching too far for its goals.

CTE identification begins in the early stages of systems acquisition.[72] Although final identification of CTEs is not expected before the Concept Decision, the team developing the Initial Capabilities Document (ICD) should include people who have technical and technology backgrounds to ensure that materiel elements for the needed capabilities are plausible. Restricting the capabilities to those likely to be achievable will prove beneficial for any program that intends to exploit advanced technology.

Best Practice

CTE Identification should be a continuing element of every program. An initial determination of CTEs should be completed during Concept Refinement.

A major part of the CTE identification process should occur during Concept Refinement. The Technology Development Strategy (TDS), a product of the Concept Refinement phase, should reflect the result of a process sufficiently thorough and disciplined to identify those technologies, including CTEs, that have a realistic potential to be improved beneficially in the Technology Development phase and exploited in the SDD phase.

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72 See Section 2 for an overview of the systems acquisition process.

Failure to recognize the CTEs at this stage will result in wasting resources—time, money, facilities, and so forth—and could result in an unfavorable Milestone B decision.

As system development proceeds, the likelihood exists, through necessity or opportunity, for exploitation of technologies not previously considered. These technologies deserve full consideration to decide whether they are critical and whether they are mature enough to be included in the detailed system design.

The original Department of Defense (DoD) Technology Readiness Level (TRL) definitions and supporting information (see Section 3, Table 3-1 of this *Deskbook)* were developed primarily with performance-related hardware technologies in mind. In identifying CTEs and assessing their maturity, the distinction between hardware and software technologies became important because different, but related, procedures and metrics are used to identify and assess the maturity of hardware and software CTEs. The original set of definitions suited hardware technologies but was inadequate for software technologies.

Another shortcoming of the original set of definitions was distinguishing between performance-related technologies and technologies for affordable production. The CTE definition includes the phrases "with acceptable development cost and schedule and with acceptable production and operation costs." Thus, a technology that "does the job" but is not affordable is an *unacceptable* technology. It may be that a manufacturing technology will provide the required affordability, in which case it should be identified as a CTE if it is "new or novel."

The following sections of this appendix provide suggestions about how to identify CTEs—hardware, software, and manufacturing—for a variety of systems.[73] These discussions apply equally to Major Defense Acquisition Programs (MDAPs) and Major Automated Information System (MAIS) programs. Section D.2 discusses system engineering as the program context for identifying CTEs, Section D.3 covers procedures and practices for CTE identification, and Section D.4 contains representative questions/ inquiries to use when making a detailed examination of a system to identify CTEs.

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[73] Distinct technology maturity metrics for drugs, vaccines and medical devices have also been established are detailed in Appendix H).

D.2 SYSTEMS ENGINEERING CONTEXT FOR IDENTIFYING CTEs

CTE identification should be integral to the systems engineering approach for defense acquisition programs. The following definition is extracted from paragraph 4.4.1 of the *Defense Acquisition Guidebook*:[74]

> 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, 0and user training for systems and their life cycle processes. Systems engineering develops technical information to support the program management decision-making process. For example, systems engineers manage and control the definition and management of the system configuration and the translation of the system definition into work breakdown structures.

Figure D-1 depicts one approach to systems engineering during design. It portrays how *requirements analysis*, *functional analysis*, and *design* take place iteratively and recursively. Each element influences and is influenced by the others as tradeoffs are made to discover the best system solution. System operational requirements, operational effectiveness/utility, and cost are all considered. The functional analysis describes and evaluates the system in qualitative and quantitative terms for the functions that must be done to meet the required performance characteristics. Functional analysis forms the bridge between requirements and system design where selections are made among alternative designs—allocating scarce resources (such as cost, weight, power, and space) and guiding the choice of optimal design points. As part of this selection process, different technologies are evaluated for maturity, performance, cost, and manufacturability. This overall systems engineering approach is the sensible place to identify the CTEs and to understand their maturity (i.e., their readiness for application to the system design).

Two outcomes of the systems engineering approach are important to CTE identification: (1) the functional architecture, which allocates functional and technical performance requirements and (2) the physical architecture (design), which shows the system design broken down into all its constituent elements (i.e., subsystems and components). Figure D-2 displays the idea. The functional architecture establishes what the system

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74 Chapter 4 of the *Defense Acquisition Guidebook* provides a thorough coverage of systems engineering.

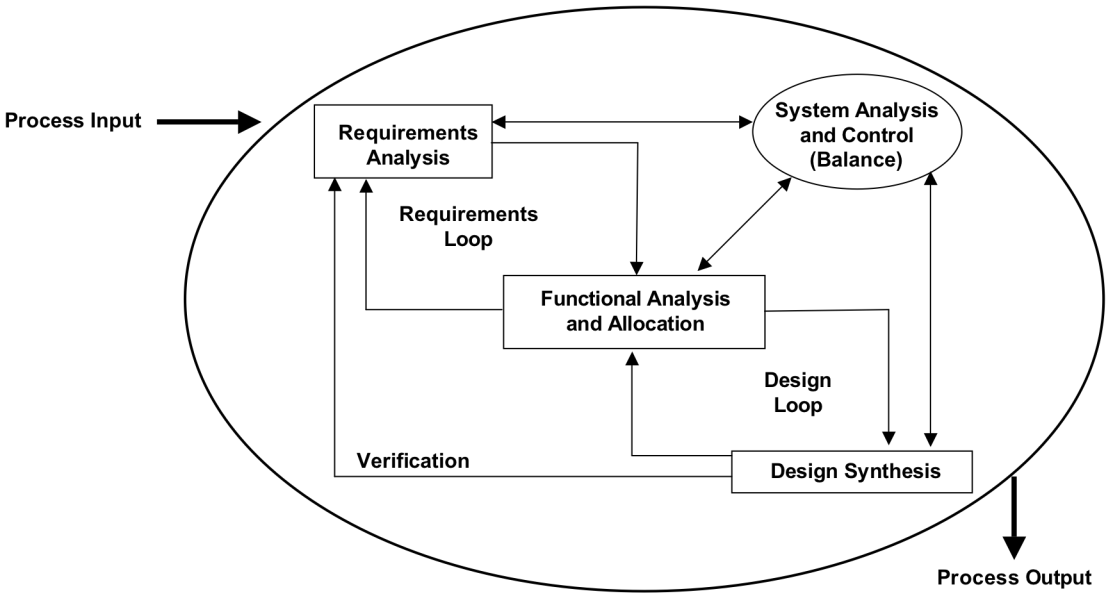

Figure D-1. An Approach for Performing Front-End Systems Engineering (Source: DoD Systems Management College, *Systems Engineering Fundamentals,* Defense Acquisition University (DAU) Press, Fort Belvoir, VA, 2000)

PHYSICAL ARCHITECTURE

FUNCTIONAL ARCHITECTURE

	Aircraft				
	Air Frame	Engine	Communications	New System	Fire Control
Function Performed					
Preflight Check	X	X	X	X	X
Fly					
Load	X				
Taxi	X	X	X		
Take-off	X	X			
Cruise	X	X	X	X	
Recon	X	X	X	X	
Communicate			X		
–					
–					
Surveillance					
–					
–					

Figure D-2. The Relationship of the Functional and Physical Architectures/Designs (Source: DoD Systems Management College, *Systems Engineering Fundamentals,* Defense Acquisition University (DAU) Press, Fort Belvoir, VA, 2000)

accomplishes in descriptive and quantitative terms. It provides the well-defined framework around which the physical architecture is conceived and designed and the basis against which the system and its various subelements are tested. The physical architecture

includes a representation of the software and hardware "products" necessary to realize the concept. The physical architecture forms the basis for design definition documentation [e.g., specifications, baselines, and the work breakdown structure (WBS)].

The WBS tool and generic WBSs applicable to seven specific categories of defense materiel items are provided in DoD MIL-HDBK-881, *Work Breakdown Structure*, dated 2 January 1998. Figure D-3 is a generic WBS for aircraft. It or any of the other six generic WBSs can be adapted to the specific needs of many system concepts.

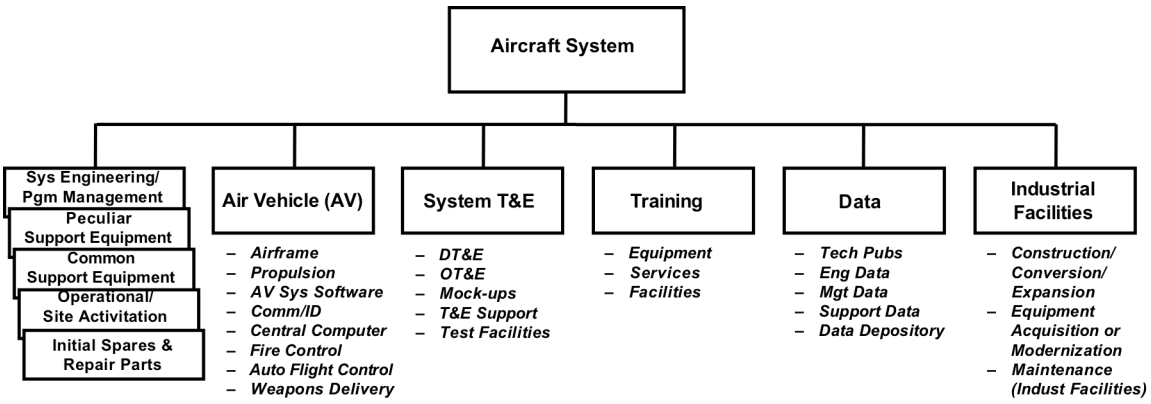

Figure D-3. Generic Aircraft WBS
[Source: Adapted from the material ion Appendix A of MIL-HDBK-881 and from DoD Systems Management College, *Systems Engineering Fundamentals,* Defense Acquisition University (DAU) Press, Fort Belvoir, VA, 2000 (Figures 8-1 and 9-3]

The *Defense Acquisition Guidebook* specifically calls for use of the WBS for identifying the CTEs for the Milestones B and C TRAs.[75] The WBS has several beneficial attributes for this purpose:

- It is readily available when system-engineering practices are used.
- It evolves with the system concept and design.
- It is composed of all products that constitute a system and, thus, is an apt means to identify all the technologies used by a system.
- It relates to the functional architecture and, therefore, to the environment in which the system is intended to be employed.
- It reflects the system design/architecture and the environment and performance envelope for each product in the system.

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75 See Sections 4.3.2.4.3 and 4.3.3.9.4.

While the previous discussion has been for a hardware-centric system, similar approaches are present in the systems engineering of Information Technology (IT) systems, though the terminology differs. The functional analysis and design synthesis portrayed in Figure D-1 are encompassed in the IT architectural design process.

The DoD Architecture Framework (DoDAF)[76] defines a common approach for DoD architecture description, development, presentation, and integration. It describes three related views of architecture:

1. The Operational View (OV) identifies what needs to be accomplished and who does it.
2. The Systems View (SV) relates systems and characteristics to operational needs.
3. The Technical Standards View (TV) prescribes standards and conventions.

Products within this framework can be associated with the systems engineering functional and physical architectures described in this section.

According to Buede, a systems engineering functional architecture "contains a hierarchical model of the functions performed by the system, the system's components, and the system's configuration items (CIs); the flow of informational and physical items from outside the system through the transformational process of the system's functions and on the waiting external systems being serviced by the system; a data model of the system's items; and a tracing of input/output requirements to both the system's functions and items." [77] IT systems engineering creates a data model that exposes data types and their relationships. This data model includes a description of data flow (i.e., how the activities of the IT system affect the data) and the distribution of computational processes over the system. This is analogous to the functional architecture for a hardware-centric system. There are seven associated DoDAF products:

1. OV-2, Operational Node Connectivity Description
2. OV-3, Operational Information Exchange Matrix
3. OV-5, Operational Activity Model
4. OV-6, Operational Activity Sequence and Timing Description

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76 *DoD Architectural Framework,* Version 1.0, "Volume I: Definitions and Guidelines," "Volume II: Product Descriptions," 9 February 2004.

77 Dennis M. Buede, *The Engineering Design of Systems: Models and Methods*, John Wiley & Sons, Inc., 2000, p. 175.

5. OV-7, Logical Data Model
6. SV-4, Systems Functionality Description
7. SV-5, Operational Activity to System Functionality Traceability Matrix.

Buede describes the systems engineering physical architecture as "a hierarchical description of the resources that comprise the system. … [It] provides resources for every function identified in the functional architecture." [78] The IT analog is captured in several DoDAF products in the SV:

- SV-1, Systems Interface Description
- SV-2, Systems Communications Description
- SV-3, Systems-Systems Matrix
- SV-7, System Performance Parameters Matrix.

This hardware technology is typically described as a systems architecture and often exists at several levels of detail, ranging from a prototype architecture through a detailed architecture.

D.3 PROCEDURES AND PRACTICES FOR IDENTIFYING CTEs

D.3.1 Overall Description

Best Practice

Use the WBS or system architecture to identify CTEs.

The management process/ procedure for CTE identification is as important as the technical task because it adds to the credibility of the resulting CTE list. While the Program Manager (PM) holds the basic responsibility for identifying the CTEs, ultimately, the Component Acquisition Executive (CAE) endorses this list to the Office of the Secretary of Defense (OSD) as part of the information forwarded before the Milestone B and Milestone C reviews.

From a management process/procedure perspective, CTE identification should be a two-step process. In the first step, the CTE definition is applied across the system's WBS or architecture to identify critical technology *candidates*. This process should be

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[78] Dennis M. Buede, *The Engineering Design of Systems: Models and Methods*, John Wiley & Sons, Inc., 2000, pp. 215–216.

thorough, disciplined, and conservative. Any questionable technology should be identified as a candidate CTE. For these questionable technologies, the information required to resolve their status should be documented. The PM, the government program office staff, and the system contractors—the people best informed about the system—should lead the first step. The second step consists of resolving, where possible, the status of technologies in question by filling the information gaps noted in the first step. An independent panel of experts convened by the Component Science and Technology (S&T) Executive should conduct the second step.

All individuals involved in these steps should be familiar with

- CTE identification in the context of a TRA and its importance to the technical and programmatic success of the program
- The concept of the WBS or systems architecture as a complete description of the products/things that comprise a system
- The distinction between hardware, software, and manufacturing technologies and the metrics that evaluate their maturity (as described in Appendix C)
- The affordability and production criteria for CTEs
- The role that "environment" has in identifying CTEs.

The technical task involves the use of a series of questions to test whether the CTE definition applies. For a technology to be critical, the answer to one of the following questions must be "yes":

- Does the technology directly impact an operational requirement?
- Does the technology have a significant impact on an improved delivery schedule?
- Does the technology have a significant effect on the system's affordability?
- If this is a spiral development, is the technology essential to meet the spiral deliverables?

In addition, the answer to one of the following questions must also be "yes":

- Is the technology new or novel?
- Is the technology modified?
- Has the technology been repackaged so that a new relevant environment is realized?
- Is the technology expected to operate in an environment and/or achieve a performance beyond its original design intention or demonstrated capability?

The environment in which the system will operate plays a significant role in answering these last four questions. Subsection D.3.2 provides a more detailed explanation of that role.

D.3.2 Environments

Consideration of the environment is important for CTE identification. For a CTE to be assessed at TRL 6, the required level at Milestone B, it must have been demonstrated in a *relevant environment*. For a CTE to be assessed at TRL 7, the required level at Milestone C, it must have been demonstrated in an *operational environment*. [79]

Best Practice

Information for CTE identification should include results of design analyses that define performance expectations of components and the data and physical conditions in which they operate.

Generally, the requirement statement for the system will provide some description of the environment in which the system is expected/required to operate. This can be called the *external* or *imposed environment*. It may be natural or man-made, friendly or hostile (e.g., weather, terrain, friendly and hostile jamming, enemy fire, and so forth). Another environment—the one generally more important for identifying and evaluating CTEs—can be called the *internal* or *realized environment*. It is derived from the performance required of each design item (product, subsystem, component, WBS element). The design analysis should include the required or expected performance envelope and conditions for each WBS element.

Categories of environment and their identification are discussed below briefly. The intent is to provide some ideas for factoring environments into CTE identification.

Environments will likely include

- **Physical Environment**. For instance, *mechanical components, processors, servers, and electronics; kinetic and kinematic; thermal and heat transfer; electrical and electromagnetic; climatic—weather, temperature, particulate; network infrastructure*
- **Logical Environment.** For instance, *software (algorithm) interfaces; security interfaces; Web-enablement*

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79 Section 3 and Appendix C of this *Deskbook* present a more detailed discussion of TRLs.

- **Data Environment.** For instance, *data formats and databases; anticipated data rates, data delay and data throughput; data packaging and framing*
- **Security Environment.** For instance, *connection to firewalls; security appliqués; rates and methods of attack*
- **User and Use Environment.** For instance, *scalability; upgradability; user behavior adjustments; user interfaces; organizational change/realignments with system impacts; implementation plan.*

Various environments not listed previously are almost certain to be relevant to any specific system. If the SV and OV of the design/architecture have been used to identify potential CTEs, they can also be used to help identify the environment, especially the Logical and Data Environments. Requirements can also be used to help identify the environment. In addition, interoperability documents and Interface Control Documents (ICDs) should be used to identify the environments in which the candidate CTEs will operate. Key questions that can help guide the definition of the environment for the CTE candidates might include the following:

Best Practice

People with the requisite technical knowledge and the independence needed to make a good judgment should guide the actual set of questions asked for each CTE candidate. The PM and the suppliers should present clear, convincing, and succinctly summarized data that show what is known/not known about the environment and should explain the similarities and dissimilarities between the expected/demonstrated environments.

- Is the physical/logical/data environment in which this CTE has been demonstrated similar to the intended environment? If not, how is it different? Is the difference important?
- Is the CTE going to be operating at or outside of the usual performance envelope? Do the design specifications address the behavior of the CTE under these conditions? What is unique or different about this proposed operations environment?
- Do test data, reports, or analyses that compare the demonstrated environment to the intended environment exist? If modeling and simulation (M&S) is an important aspect of that comparison, are the analysis techniques common and generally accepted?

The following subsections give more examples of the kinds of questions and sources of information that can be used to help define the environment.

D.3.2.1 Defining the Physical Environment

Representative questions that will be helpful in identifying the physical environment (and whether it is new or novel) for the candidate CTE include the following:

- What are the expected conditions (vibration, movement, exposure to heat, and so forth) in which the candidate CTE will reside? Do any data or analysis show how the demonstrated environment resembles the expected extremes?
- What is the electromagnetic environment in which the candidate CTE will reside? Has it been tested or demonstrated in that full environment?
- What is the server/processor/network environment? How does the designer know that the CTE will operate in that environment?
- What interfaces will be used? How do they compare with interfaces used previously?
- What network infrastructure will be used? How will the load over this infrastructure be affected by the new system?

D.3.2.2 Defining the Logical and Data Environments

Operational and systems architectures can be used to help determine the Logical and Data Environments in which the CTE will operate. Designs or WBSs can also be useful. Whether the CTE is a commercial off-the-shelf/government off-the-shelf (COTS/GOTS) software package or is a network card, the CTE has a logical relationship to other systems and to the outside world. Those logical relationships—the Logical Environment—may or may not be similar to the proposed DoD environment. Furthermore, the databases and their configuration (e.g., partitioned, replicated, standalone) and the anticipated transaction rates in the proposed DoD system may be different from previous environments in which the CTE has been used. These differences should be documented and evaluated for relevance. Sometimes, a developer may use an interface simulation or ersatz data to try to replicate the logical and data environments.

Relevant questions that may be helpful in identifying and evaluating the logical and data environments for the candidate CTE include the following:

- What are the expected logical relationships between the CTE and the rest of the system? The outside world?
- What are the expected data rates? the expected data formats?

D.3.2.3 Defining the Security Environment

Frequently, the security environment will differ from the environment in which a CTE has been demonstrated, especially in COTS systems. Thus, every CTE candidate system should include a careful definition of the security environment in which it will reside.

The security environment includes hardware components (e.g., firewalls, network gateways), logical components, (e.g., potential virtual circuits), and data. Requirements for the security environment can often be derived from IA requirements. In addition, the systems architecture can be a source of information.

The rates and methods of attack during wartime and peacetime may also be elements of the security environment. Technical experts in IT and network security can be helpful in defining and evaluating the security environment. An important question is the anticipated differences in environment in wartime as compared with the environments in peacetime. Often, the security requirements tighten during wartime, and evaluators should take care in defining those differences.

D.3.2.4 Defining the User and Use Environment

The user and use environments are closely tied to the physical environments. They deal with the interactions between the human users and the physical system over a collection of many possible scenarios and sequences. Relevant questions for better understanding the user and use environment for identifying CTEs include the following:

- What is the expected user environment? How do the number of users and the way in which they will use the system compare with what has been done before?
- What are the expectations for growth over time? Is it likely that usage will increase significantly beyond those expectations?
- What organizational changes are anticipated? What are the foreseeable system impacts based on a new organizational structure?
- How will users' jobs be affected? Will the changes be gradual or abrupt? What is the expected user reaction?
- How much resistance to change is anticipated? Are plans in place to mitigate such resistance?
- Has the learning curve for adapting to the new system been anticipated and have preparations been made to address this issue? Is training in place?

- Have all interfaces between existing processes and the new system changed correspondingly?
- Has an implementation or roll-out plan been considered for the new system?

D.4 REPRESENTATIVE QUESTIONS FOR IDENTIFYING CTEs

Identifying CTEs depends on effective questioning. While a universal list of "right" questions does not exist, the following discussion provides typical questions for several categories of systems and suggests the nature of what is intended. Every actual system should use a relevant set of questions tailored to its application.

D.4.1 Aircraft

A few of the pertinent questions to ask when trying to identify the CTEs for aircraft development are as follows:.

- **Aerodynamic configuration.** Does the design incorporate a configuration that has not been used in flight? How similar is the configuration to that of aircraft that are successful? Does the configuration impose limitations on control authority, stability, structural rigidity, or strength? Is stability acceptable at high angles of attack? Are stability and control acceptable during configuration changes in flight?
- **Flight performance.** Is the lift-to-drag (L/D) ratio being used in range calculations consistent with that being achieved by operating aircraft? Has this L/D ratio been confirmed by wind tunnel tests corrected to full-scale, trimmed conditions? Are takeoff and landing distances based on achievable lift coefficients and installed thrust?
- **Airframe structure and weight.** Is the structural weight fraction consistent with operating aircraft of the same type? Are lower fractions justified by use of more efficient materials or structural designs? Do the materials and structures have stiffness and fatigue properties suitable to the application? Has this been demonstrated with full-scale sections and representative loads?
- **Propulsion.** Do the engine hot sections rely on new materials? Have these been tested to the temperatures, loads, and dynamic environment of expected flight? Are the results for thrust and specific fuel consumption (SFC) from ground tests consistent with the estimates? Have the inlets been tested at flight flow rates?
- **Rotors and hubs.** Has the rotor type been used before in a similar application? Has testing been limited to static conditions? Has a similar type of rotor been tested at a relevant scale? Is there a test basis for the durability estimates

for the rotor and hub? Do the cyclic and collective control mechanisms differ from common practice? How have they been tested?

- **Mission equipment.** The appropriate questions differ greatly for the different roles aircraft play. Advanced technology might be incorporated in weapon carriage and employment, in cargo handling, in surveillance, in communications, and elsewhere. General questions include the following: What limits the operational effectiveness of this design? How is advanced technology contributing to more effective performance of the aircraft mission? Are any of these technologies unproven in this application?
- **Manufacturing technology.** The identification of manufacturing technology CTEs will require an analysis to determine the availability of essential raw materials, special alloys, composite materials, components, tooling, and production test equipment required for (1) the sustained production of a system fully capable of meeting performance objectives established for the system, (2) the uninterrupted maintenance and repair of the system, and (3) the sustained operation of the system. Pertinent questions include the following: Will the technology require the use of advanced manufacturing technology, processes, and systems during the research and development (R&D) and the production phases of the program? Has the technology been characterized in a manufacturing environment? Has the manufacturing technology been demonstrated on a similar system? Will the manufacturing technology require a scale-up effort for the proposed system being developed and produced?

D.4.2 Ground Vehicles

Some suggestions are provided to indicate ways to undertake the task of identifying CTEs for ground vehicles. Usually (but not necessarily) the vehicle system under consideration is similar to an existing class of vehicles and their functions. Military systems are usually categorized as combat vehicles (e.g., tanks), tactical vehicles [e.g., High Mobility Multipurpose Wheeled Vehicles (HMMWVs)], or utility vehicles (e.g., sedans or special-purpose vehicles). A first step for CTE identification is to exploit the association and the functional similarities that exist between existing systems and the proposed system by characterizing (quantitatively wherever possible) the functions of the new system and those of comparative existing systems. The second step is to carry out comparisons of the proposed technologies of the new system to identify whether these technologies are new or just new or novel in application. Of course, the possibility exists that this comparison process does not cover all new technologies. In those instances, the technologies not covered will require alternative ways to assess whether they are critical. The

fact that they have not been used previously is a good indicator that they are candidate CTEs.

As an example, a few useful questions for a new fighting vehicle system are listed. These questions address the principal functions of mobility, firepower, and protection. In an actual case, a set of questions could/should be developed around a WBS built upon the template for vehicles found in MIL HDBK-881. Of course, special mission equipment and other items should also be considered.

- **Mobility (e.g., WBS elements: power package/drive train, suspension/ steering).** How do mobility characteristics (range, speed, agility, endurance and so forth) compare with existing vehicles? Is the suspension system proven for the weight and mobility required of the concept system? Has the suspension system been proven to provide a robust, reliable, and stable platform for stationary and on-the-move firing for the type of armaments systems intended for the concept vehicle? Are the engine characteristics (power per unit weight, SFC, cooling and thermal signature characteristics, and so forth) proven in service? Are the power train elements new or in new environments or with extended performance envelopes?
- **Firepower (e.g., WBS elements: armament, fire control, automatic loading).** Are the weapons new? Is new ammunition to be developed? Are the natures of ammunition to be developed new? Will there be an autoloader? If so, is it new? Has ammunition and autoloader compatibility been established? Has a weapon that has the intended characteristics ever been mated with a platform of the weight and structure characteristics of the vehicle platform? Are firing data available on force and motion characteristics of the weapon for all the intended natures of ammunition?
- **Protection (e.g., WBS elements: hull/frame, turret assembly).** Are full-scale data available to demonstrate that the intended passive protection is adequate for all features and required aspects of the design configuration? If not, what are the alternative approaches and what data are available to demonstrate that they meet the need? Are reactive armor applications intended and are data available to allow a flexible design that meets system needs? Does the reactive armor meet logistic requirements (e.g., are there insensitive explosive mandates)? Is the use of an active protection system intended? If so, what data are available to demonstrate its efficacy?
- **Manufacturing technology.** The identification of manufacturing technology CTEs will require an analysis to determine the availability of essential raw materials, special alloys, composite materials, components, tooling, and production test equipment required for (1) the sustained production of a system fully capable of meeting performance objectives established for the system,

(2) the uninterrupted maintenance and repair of the system, and (3) the sustained operation of the system. Pertinent questions include the following: Will the technology require the use of advanced manufacturing technology, processes, and systems during the R&D and the production phases of the program? Has the technology been characterized in a manufacturing environment? Has the manufacturing technology been demonstrated on a similar system? Will the manufacturing technology require a scale-up effort for the proposed system being developed and produced?

D.4.3 Missiles

To discover CTEs in a missile development, the following questions might be helpful:

- **Guidance and control.** Has the type of guidance under consideration been used before? If so, was it successful in the similar application? Does the field of view (FOV), field of regard (FOR), scan rate, slew rate, sensitivity, acuity, or any other performance parameters exceed what has been achieved in affordable guidance systems? Has the guidance system been tested in prototype form? Has it been tested from a tower, in captive carry, or in flight? Has it been tested against realistic targets in realistic environments? Are the sensor range and the missile control time constant compatible with the dynamics of the end game? How has this been established?
- **Propulsion and structure.** Is there a propellant that can meet the specific impulse requirement and have acceptable safety characteristics, burn rates, physical characteristics, and cost? What size batches of this propellant have been made? What size test motors have been fired? Has the combination of case, insulation, grain support, and grain configuration ever been used in a rocket motor? Does the design have any special features (e.g., multiple burn, throttling, air-burning, case-consuming, throatlessness)?
- **Manufacturing technology.** The identification of manufacturing technology CTEs will require an analysis to determine the availability of essential raw materials, special alloys, composite materials, components, tooling, and production test equipment required for (1) the sustained production of a system fully capable of meeting performance objectives established for the system, (2) the uninterrupted maintenance and repair of the system, and (3) the sustained operation of the system. Pertinent questions include the following: Will the technology require the use of advanced manufacturing technology, processes, and systems during the R&D and the production phases of the program? Has the technology been characterized in a manufacturing environment? Has the manufacturing technology been demonstrated

on a similar system? Will the manufacturing technology require a scale-up effort for the proposed system being developed and produced?

D.4.4 Ships, Submarines, and Naval Weapons Systems

The at-sea environment poses unique challenges to new technologies and systems. The new system will have some questions that apply to all combat systems and other questions that are appropriate for all hull, mechanical, and electrical systems. There will also be unique questions for all surface ship systems and others that apply to all submarine systems.

- **Combat systems.** Has the weapon system been tested at sea to establish its firing accuracy in a realistic environment? Has the affect of ship motion and weather variables on targeting been taken into account? Has the weapon been cleared to be placed on board a ship or submarine by the Weapon Systems Explosive Safety Review Board (WSERB)? Does the weapon warhead meet insensitive munitions requirements? Has the sensor system been tested in realistic at-sea conditions for wave motions and accelerations? Are batteries and power supplies needed by the sensor system compatible with the ship's power grid? Is the system safe or does it present hazards in case of fire or shock?[80] Has the weapon or sensor system been evaluated for maintenance requirements and logistics needs since the ship is a closed system that must carry its own spares?
- **Ship and submarine hull, mechanical, and electrical systems.** Does the new system or hull itself use new materials? Have these materials been evaluated for corrosion at sea? How does the weight of a new hull compare with previous designs?[81] If the new hull system comes from a commercial application, has it been evaluated for military usage? In the case of a subsystem, has it been to sea on a ship or submarine previously? For a new hull or a new material, can it withstand the effect of a collision or grounding incident? Does the new system add to the vulnerability of the ship to withstand damage without sinking?[82] For new propulsion systems, does the new system provide an improvement in propulsive efficiency? Does it increase or decrease the ship or submarine signature? Does the new system increase the draft of the ship, thus limiting the ports in which it can operate? Does the propulsion system cavitate during operation, thus reducing efficiency?

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80 Some batteries are not allowed on submarines because of their reaction to fire.

81 The structural weight fraction should be within historical bounds.

82 Strict rules apply to new hulls and major subsystems.

- **Submarine-specific issues.** Has the new system been tested at depth? Does it meet the Submarine Safety Certification Program (SUBSAFE) requirements?[83] Does the new system add to the submarine acoustic or nonacoustic signature in any way? Does the system generate underwater sound that is detrimental to marine life?
- **Surface-ship-specific issues.** Will the system or subsystem stand up to the motions and accelerations caused by waves? Will the system or subsystem increase the ship's drag in any way? Will the system or subsystem have an environmentally unacceptable discharge?
- **Manufacturing technology.** The identification of manufacturing technology CTEs will require an analysis to determine the availability of essential raw materials, special alloys, composite materials, components, tooling, and production test equipment required for (1) the sustained production of a system fully capable of meeting performance objectives established for the system, (2) the uninterrupted maintenance and repair of the system, and (3) the sustained operation of the system. Pertinent questions include the following: Will the technology require the use of advanced manufacturing technology, processes, and systems during the R&D and the production phases of the program? Has the technology been characterized in a manufacturing environment? Has the manufacturing technology been demonstrated on a similar system? Will the manufacturing technology require a scale-up effort for the proposed system being developed and produced?

D.4.5 Information Systems

- **General questions (particularly for COTS).** Does this CTE claim to implement standards that provide critical functionality? How was the compliance to these standards verified? Is there familiarity with the element from other projects? What aspects of the system design are dependent on unique features or particular versions of the CTE? Will these unique features be sustained in future versions of the CTE? Will this CTE be modified, tailored, extended, or enhanced from its original state? Who will perform these modifications? How complex are these modifications? Does this CTE depend on other systems? Does the CTE conform with size, weight, and power requirements?
- **Terminal hardware.** Terminal hardware consists of video displays, audio/sound systems, keyboards, touch-screen terminals, personal digital assistants (PDAs) and so forth. Are there extenuating physical environment considerations for size, weight, visibility in daylight, usability?

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[83] SUBSAFE is a specific and rigorous testing procedure.

- **Processing hardware.** Processing hardware consists of processors, memory, servers, supercomputers, mainframes, blade servers, and so forth. Are needed software development environments supported? Are there any significant changes to the operating system and other systems software? Are processors able to handle average and peak processing loads?
- **Storage hardware.** Storage hardware consists of disk drives, magnetic tapes, redundant array of inexpensive disks (RAID), controllers, and so forth. How is storage being connected to the processing hardware? Is storage balanced with processing capacity? How will storage scale with increasing processing capacity?
- **Networking hardware.** Networking hardware consists of routers, switches, access points, network interface cards (NICs), local area network/wide area network (LAN/WAN) components, storage area network (SAN) components, and so forth. Do requirements for bandwidth, delay, loss, and availability imply that new or modified hardware is required? Is wireless performance acceptable in the expected electromagnetic environment? Is the network able to grow in physical size and bandwidth while still satisfying key performance requirements?

D.4.6 Networked Communications Systems

The following questions can help identify CTEs in a networked communications system:

- Do the requirements for throughput, data latency, security, or reliability imply that a new or novel technology is required? Have the network routers been used before within the required performance envelope? Are new or novel media access control, coding, or routing algorithms needed? Is the multiplexing schema new? Is the topology (logical and hardware) new? Do the peak and average data rates require new hardware or algorithms in the system?
- If the network includes wireless technology, have the wireless devices been used in the anticipated electromagnetic environment? Does the way in which data sources or uses interface to the network imply a need for a new interface (logical or hardware)? Does the ICD identify any interfaces that are new or novel?
- If the network includes commercially available elements, such as Asynchronous Transfer Mode (ATM)[84] and optical components, or Ethernet, and so

[84] Broadband switching and transmission technology.

forth, have these elements been demonstrated for their intended use? That is, do they support the data rates, switching schema, routing, and so forth? Do the IA requirements create a new or novel security environment?

- Do requirements for scalability and the capability to upgrade imply the need for new algorithms? Does the scale of the system imply a new environment for the network?

D.4.7 Business Systems

DoD business systems often use COTS products assembled together to achieve a new capability. Some relevant questions are as follows:

- Are the logical and data environments for each COTS element new or novel? Are there special data synchronization requirements or needs that imply the need for new wrapper algorithms? Has the COTS system run in the operating system environment or on the target workstations and servers?
- Is a new suite of hardware (servers, networks, and so forth) needed to run the business system? Will the interfaces for the server require a new or novel hardware or software technology? Will new processors be required? If so, will these processors support the anticipated speeds?
- Does the IA requirement imply a new security environment? Have the selected COTS products been demonstrated or tested with the IA technologies chosen for the system? Do the data rates and reliability requirements in war vs. peacetime imply a new or novel environment for the system?
- What consideration does the acquisition have for the responsiveness and timeliness across the system? If there is a requirement, what information and activities are available to show that the entire suite of IT (COTS applications, networks, servers, and so forth) will meet those expectations? If there are no such requirements, how will the installers understand and judge the ability to provide a system that the users will find acceptable?
- How will the consistency and timeliness of data be ensured by the selected suite of COTS products? Do the COTS products have mechanisms or techniques by which users can be assured that they have the latest data from an authoritative source? How will the authoritative data set be promulgated and managed across the system? How will it be maintained to ensure that it is updated in a timely fashion? Does the system have enough capacity to handle the anticipated data storage and communication requirements?
- How do issues of scalability impact the selected COTS products? Have the products been run in organizations that have similar numbers of users, similar sizes of data sets, and similar suites of applications? Is the system scalable to

an organization commensurate with its anticipated use in DoD? Is that scalability affected by any other chosen technologies (e.g., IA)?

- Have all the software and hardware components been used together in a similar manner with similar interfaces? How does the DoD environment differ from the environments where the components have been used previously?
- Does the IA requirement imply a new or significantly modified security environment? Do the data rates and reliability requirements in war vs. peacetime imply a new or novel environment for the system? Can the existing network infrastructure handle the anticipated data flow requirements?

D.4.8 Mission Planning Systems

Mission planning systems often include a combination of COTS/GOTS and developmental software to integrate software systems. For these systems, usually the components are mature in their *original* environment. What needs to be determined is how the new integration environment differs. Thus, questions might include the following:

- Are there new logical or data relationships for each component? Are the algorithms used to create interfaces new or novel? Are new hardware components needed to enable interoperability?
- Do the information exchange requirements (IERs) require many more interfaces than previously achieved? Does this imply a new logical or security environment?
- Will the components run on a new hardware system? On a new network?
- Will the need to upgrade the components introduce new algorithms or technologies?

D.4.9 Embedded IT in Tactical Systems

Embedded IT or software in tactical systems is most similar to developmental hardware. Thus, the questions would include the following:

- Have the algorithms been proven to work in a simulated environment? How is that environment different from the operational environment?
- Does the data dissemination requirement imply a new or novel technology or environment?
- Does timeliness imply new or novel algorithms or hardware? Does the quality of the data (e.g., engagement quality) imply special processing that has not been done previously?

- Are the number of software systems or lines of code unprecedented? Do the IERs imply a new or novel technology?

D.4.10 Manufacturing

The following questions indicate whether a manufacturing technology is new or novel:

- Has the manufacturing technology been successfully integrated into a product line?
- Is the industrial base[85] capable of design, development, production, maintenance and support, and disposal of the system?
- Is the intended design producible?
- Have the materials been characterized in a manufacturing environment?
- Are the materials available to meet quantity and schedule demands?
- Are the design-to-cost (DTC) goals achievable?
- Are the key manufacturing processes characterized, capable, and controllable for achieving the system requirements?

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[85] Depending on the circumstances, this may be limited to the National industrial base.

ACRONYMS AND ABBREVIATIONS FOR APPENDIX D

ATM	Asynchronous Transfer Mode
CAE	Component Acquisition Executive
CI	configuration item
COTS	commercial off-the-shelf
CTE	Critical Technology Element
DAU	Defense Acquisition University
DoD	Department of Defense
DoDAF	DoD Architecture Framework
DTC	design-to-cost
FOR	field of regard
FOV	field of view
GOTS	government off-the-shelf
HMMWV	High Mobility Multipurpose Wheeled Vehicle
IA	Information Assurance
ICD	Interface Control Document
ICD	Initial Capabilities Document
IER	information exchange requirement
IT	Information Technology
L/D	lift-to-drag
LAN	local area network
M&S	modeling and simulation
MAIS	Major Automated Information System
MDAP	Major Defense Acquisition Program
MIL-HDBK	Military Handbook
NIC	network interface card
OSD	Office of the Secretary of Defense
OV	Operational View

PDA	personal digital assistant
PM	Program Manager
R&D	research and development
RAID	redundant array of inexpensive disks
S&T	Science and Technology
SAN	storage area network
SDD	System Design and Development
SFC	specific fuel consumption
SUBSAFE	Submarine Safety Certification Program
SV	Systems View
TDA	Technology Development Strategy
TRL	Technology Readiness Level
TV	Technical Standards View
WAN	wide area network
WBS	work breakdown structure
WSERB	Weapon Systems Explosive Safety Review Board

APPENDIX E.
POLICY STATEMENT

107TH CONGRESS
1st Session

HOUSE OF REPRESENTATIVES

REPORT
107–333

NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2002

CONFERENCE REPORT

TO ACCOMPANY

S. 1438

DECEMBER 12, 2001.—Ordered to be printed

SEC. 804. REPORTS ON MATURITY OF TECHNOLOGY AT INITIATION OF MAJOR DEFENSE ACQUISITION PROGRAMS.

(a) REPORTS REQUIRED.—Not later than March 1 of each of years 2003 through 2006, the Secretary of Defense shall submit to the Committees on Armed Services of the Senate and the House of Representatives a report on the implementation of the requirement in paragraph 4.7.3.2.2.2 of Department of Defense Instruction 5000.2, as in effect on the date of enactment of this Act, that technology must have been demonstrated in a relevant environment (or, preferably, in an operational environment) to be considered mature enough to use for product development in systems integration.

(b) CONTENTS OF REPORTS.—Each report required by subsection (a) shall—

(1) identify each case in which a major defense acquisition program entered system development and demonstration during the preceding calendar year and into which key technology has been incorporated that does not meet the technological maturity requirement described in subsection (a), and provide a justification for why such key technology was incorporated; and

(2) identify any determination of technological maturity with which the Deputy Under Secretary of Defense for Science and Technology did not concur and explain how the issue has been or will be resolved.

(c) MAJOR DEFENSE ACQUISITION PROGRAM DEFINED.—In this section, the term "major defense acquisition program" has the meaning given that term in section 139(a)(2) of title 10, United States Code.

APPENDIX F.
TECHNOLOGY DEVELOPMENT STRATEGY (TDS) TEMPLATE

Note: *The Technology Development Strategy (TDS) is a precursor to the Acquisition Strategy; thus, the responsible parties for oversight are part of Acquisition Oversight, not part of Science and Technology (S&T) Oversight. The template is included here as reference because the TDS is an important prerequisite to the Technology Readiness Assessment (TRA).*

TDS Template

(Five (5) Page Maximum)

A. Project/program title: (A unique title specifically identifying this proposed project)

B. General description of the technology solution: Brief overview description of this technology and to whom it will provide increased capability if developed

C. Identify the development strategy (evolutionary or single-step-to-full-capability) and provide a rationale for adopting this concept and technology development approach. For evolutionary strategy,

   1. Describe how the program will be divided into

      a. Technology spirals

      b. Development increments

   2. Identify an appropriate limitation on number of prototype units that can be produced

   3. Describe how these units will be supported (up to transition to the customer)

   4. Describe the specific performance goals and exit criteria that must be met before exceeding the number of prototypes

D. Project/program strategy: Describe the total research and development (R&D) program strategy, including all spirals and so forth, to include the following:

   1. Overall cost

   2. Schedule

   3. Performance goals

E. First spiral demonstration

1. Specific cost

    a. Development cost: estimate from project start to transition to the customer)

    b. Transition and integration cost: estimate from when the customer receives the project for integration into the system until it is provided to the user

    c. Total life-cycle cost: an estimate that adds operations and support (O&S) and disposal costs to the above

2. Schedule: indicate number of months to reach each Technology Readiness Level (TRL) from project start to transition

3. Performance goals for the prototype demonstration

4. Exit criteria for the prototype demonstration phase

5. Test plan: overview concept of how the prototype will be tested and how the results will be analyzed for Measures of Effectiveness (MOEs)

6. Risk strategy

    a. Specify the technology advancement degree of difficulty with respect to "state of the art" (1–well within, 2–within, 3–pushing, 4–hard push, 5–breakthrough required)

    b. Identify program risks for the first spiral

    c. Describe mitigation strategy

7. Transition strategy: an overview description of when, to whom, and under what general conditions the technology solution will be transitioned

ACRONYMS AND ABBREVIATIONS FOR APPENDIX F

MOE	Measure of Effectiveness
O&S	operations and support
R&D	research and development
S&T	Science and Technology
TDS	Technology Development Strategy
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level

APPENDIX G.
TECHNOLOGY TRANSITION AGREEMENT (TTA)
ELEMENTS AND TEMPLATE

TTA Elements

A TTA documents the commitment of the requirements/resource sponsor, the science and technology (S&T) activity (developer and provider of the technology/product), and the Acquisition Program Office (intended receiver of a technology or capability development) to develop, deliver, and integrate a technology/product into an acquisition program. The following elements should be considered for inclusion in the TTA. Not every one of these elements is appropriate for every agreement, but each element should be considered for inclusion.

Agreements, to be effective, must be reviewed periodically with each of the key partners: the requirements/resource sponsor, S&T activity and the Acquisition Program Office representatives. These reviews should address technical progress and future directions.

Elements To Be Provided by the Program Office

A. Target acquisition program. Provide a brief description of the acquisition program to receive the technology/product. Include the

    1. Major program objectives.

    2. Current phase of the acquisition life cycle.

    3. Projected initial operational capability date.

B. Program Manager (PM)/Project Officer (PO). Identify personnel responsible for day-to-day program/project management.

    1. PM and contact information.

    2. PO and contact information.

C. Acquisition program technology need. Identify the technology needs of the acquisition program that S&T is expected to provide. Briefly describe the benefit that the technology/product will bring to the acquisition program.

    1. Relate the benefit to the Initial Capabilities Document (ICD), Capability Development Document (CDD), key performance parameters (KPPs), and so forth.

2. Include need dates for specific capabilities.

3. Provide an estimate of the Technology Readiness Level (TRL) for each technology/product need identified using a systems approach for hardware and software as the measure of technical maturity and as an indication of transition readiness. Coordinate the TRL with the S&T activity.

D. Integration strategy. Describe the process for integrating the technology/product into the acquisition program. Include the following elements of acquisition strategy:

1. Evolutionary acquisition, block upgrade, and so forth.

2. Required contractor-to-contractor agreements.

3. Acquisition program element (PE) numbers funding the transition.

4. Annual PE funding levels committed to the transition program.

5. Transition Fiscal Year (FY).

6. Statement conveying the level of commitment. For example,

i. Commitment: "Upon successful demonstration of key performance requirements (*exit criteria*), PM XXX (*Acquisition Program Office*) will integrate YYY *(technology product delivered*) into XXX (*acquisition program that will integrate the technology deliverable*) commencing in FYXX (*transition year*)." This integration effort will be funded under PE XXXXXXX, Project XXXX (*FYDP budget profile for this acquisition line should be included*).

ii. Intent: "Upon successful demonstration of key performance requirements *(exit criteria)*, PM XXX *(Acquisition Program Office)* intends to integrate *YYY (technology product to be delivered)* into XXX *(acquisition program that will integrate the technology deliverable)* commencing in FYXX *(transition year)* under PE XXXXXXX Project XXXX *(FYDP budget profile)."*

Elements To Be Provided by the S&T Activity

A. Development. What the S&T activity intends to develop for transition to the acquisition program. Include capability delivery dates.

B. Technology manager. Identify the individual designated by the S&T activity to coordinate day-to-day management of the technology/product development and list contact information.

C. Current status of technology/product. Show

1. Status summary. Summarize current state of development. Identify:

   a. Primary areas where additional development is required.

   b. Estimate of current TRL.

2. Risk analysis. Prioritize and discuss major areas of technical risk. Identify planned mitigation activities to address technical risk (e.g., producibility, affordability, sustainability).

D. Technology Development Strategy (TDS). Outline planned approach. Include

1. Efforts required beyond those currently underway.

2. Integration plans if multiple projects are planned.

3. Planned Advanced Technology Demonstration (ATD) or Advanced Technology Concept Demonstration (ACTD) developments, if applicable.

E. Exit criteria (key technical measures of readiness) for transition. Identify quantifiable criteria that will be used to measure whether the technology/product development effort is proceeding appropriately. Provide

1. Definitive, complete, measurable parameters to be tracked, to include performance, physical attributes.

2. Conditions under which technology/product will be tested/demonstrated before delivery to acquisition.

3. Current performance of the technology/product.

4. Minimum acceptable performance threshold.

5. Desired final goal/objective.

6. Estimate of the transition TRL, coordinated with the program office.

F. Program plan. Show major activities/efforts planned for the technology/product development. with milestones. Include both S&T and acquisition tasks/elements/

Elements To Be Provided by Resources/Requirements Code

A. Capability requirement basis. Identify the governing source of the capability requirement (e.g., the ICD, CDD, or other official reference documenting the capability need).

B. Resource sponsor/requirements officer. Identify the resource sponsor and requirements officer responsible for resourcing and establishing requirements for the capability. Include contact information.

Signatures and Dates

TTAs should be signed to commit participating organizations to the plan outlined in the agreement.

ACRONYMS AND ABBREVIATIONS FOR APPENDIX G

ACTD	Advanced Concept Technology Demonstration
ATD	Advanced Technology Demonstration
CDD	Capability Development Document
FY	Fiscal Year
FYDP	Future Years Defense Plan
ICD	Initial Capabilities Document
KPP	key performance parameter
ONR	Office of Naval Research
PE	Program Element
PM	Program Manager
PO	Project Officer
S&T	science and technology
TDS	Technology Development Strategy
TRL	Technology Readiness Level
TTA	Technology Transition Agreement

APPENDIX H.
BIOMEDICAL TECHNOLOGY READINESS LEVELS (TRLs)

Biomedical Technology Readiness Levels (TRLs)

Note: *Medical-related items require Technology Readiness Level (TRL) definitions and descriptions that are appropriate to the technologies upon which they are based and that account for the statues and regulations that govern their development and use. In recognition of these factors, the United States Army Medical Research and Materiel Command (USAMRMC) took the initiative to establish appropriate definitions, descriptions, and processes in the context of military medical research and development (R&D) and Food and Drug administration (FDA) statutory and regulatory requirements. This appendix provides the results of their effort.*

H.1 BACKGROUND

Department of Defense (DoD) policy mandates the use of U.S. FDA-approved products for force health protection,[86] and the USAMRMC has always adhered to the regulatory requirements of the FDA for its studies of drugs, biologics, and devices in humans. To ensure compliance with the clinical phases of the FDA-regulated process and to reduce technological risk, the USAMRMC developed and recently updated their general guidelines for assigning TRLs to drug, vaccine, and medical device development programs.[87] These guidelines are not considered absolutes, and characterization of activities associated with TRLs can and does vary at times.

The science and technology (S&T) and acquisition program managers (PMs) work together in exercising discretion in the selection, progression, and timing of specific activities to be accomplished in the attainment of particular TRLs. Such flexibility and tailoring are needed to align the TRL decision criteria appropriately with the maturation and risk characteristics of a particular technology, including consideration of the associated investment strategy and transition procedures that may vary among PMs.

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[86] For example, Department of Defense Directive (DoDD) 6200.2, *Use of Investigational New Drugs for Force Health Protection,* August 1, 2000, or Health Affairs Policy 95-011, *Tri-Service Pharmacy Policy Guidance,* July 26, 1995.

[87] *Biomedical Technology Readiness Levels (TRLs)*, prepared for the Commander, U.S. Army Medical Research and Materiel Command, under Contract DAMD17-98-D-0022, Science Applications International Corporation, 3 June 2003.

When transitioning from technology development to product development, the risks are greater if the TRL of a Critical Technology Element (CTE) is low. For medical technologies, risk reduction is not linear across TRLs. The rate of risk reduction remains very low until very late. Historically, FDA-regulated products, such as vaccines, do not achieve significant risk reduction (i.e., greater than 50 percent) until completion of Phase 3 clinical trials and approval of a biologics license application by the FDA (TRL 8). Industry's experience is that only one in four vaccines going into Phase 3 trials is licensed. Similarly, whereas technology maturation is commonly perceived as a sequential continuum of activities from basic research, through development, to production and deployment, the evolution of the TRL for a biomedical CTE may not be sequential, especially in those cases where FDA anchors are undefined. In cases of success or failure, the incremental change in the level of technology readiness may be greater than a single TRL. For example, upon successful completion of a pivotal study, biomedical information readiness levels may move from TRL 3 or 4 to TRL 9.

Biomedical TRL descriptions provide a systematic way for the S&T community to assess and communicate to the Milestone Decision Authority (MDA) the maturity level of a particular technology or combination of technologies and the maturity necessary for successful product development. This appendix provides equivalent TRL descriptions applicable to biomedical technologies in four categories:

1. Pharmaceutical (i.e., drugs)
2. Pharmaceutical (i.e., biologics/vaccines)
3. Medical Devices
4. Medical Information Management/Information Technology (IM/IT) and Medical Informatics.

The TRLs for the first three categories have been developed from the DoD's generic definitions, the applicable FDA regulatory process, and industry practices and experience with its R&D processes (discovery through manufacturing, production, and marketing). The last category includes elements of formal regulatory processes and logical events in deriving comparable levels of maturity. Wherever practical, the USAMRMC intends to use external anchors such as "FDA events" to define each TRL decision criterion. Furthermore, activities described as occurring between successive TRL decision criteria are intended to exemplify the kinds of activities that routinely take place when maturation is sequential and stepwise. However, these examples are neither mandatory nor all-inclusive.

Figure H-1 and Table H-1 build upon this work by providing examples of supporting information and documentation required to support the assignment of TRLs as the program progresses.

The proponent for this document is the **Deputy for Research and Development: Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-ZC, 504 Scott Street, Fort Detrick, MD 21702-5012.**

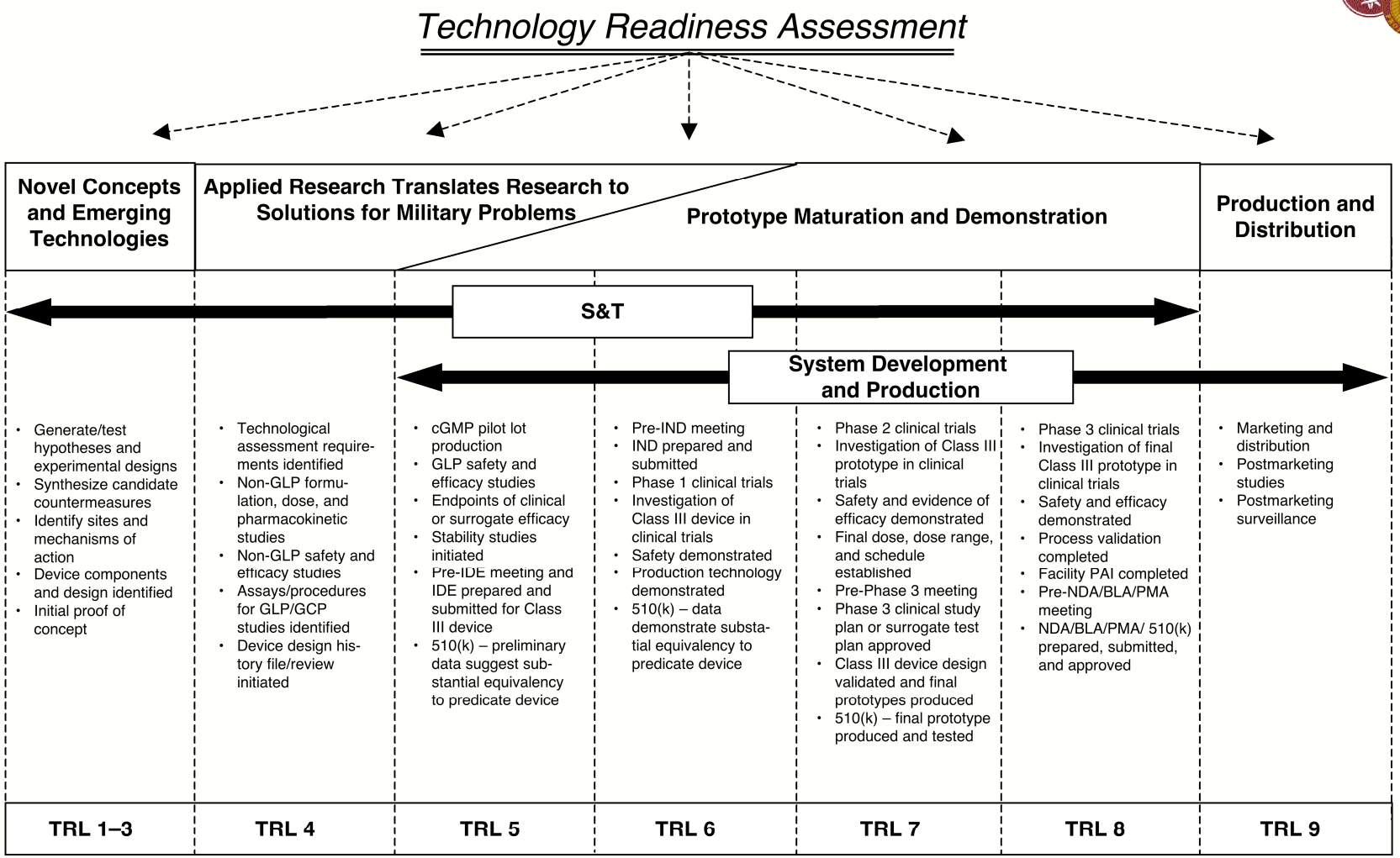

Figure H-1. TRLs in the Medical Materiel Regulatory Process

Note for Figure H-1: *The TRL descriptions are not considered absolutes, and characterization of activities associated with TRLs can and does vary at times. The S&T and acquisition PMs work together in exercising discretion in the selection, progression, and timing of specific activities to be accomplished, particularly with regard to TRL 5. Such flexibility and tailoring are needed to align the TRL decision criteria appropriately with maturation and risk characteristics of a particular technology, including consideration of the associated investment strategy and transition procedures that may vary among PMs.*

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General Note for Table H-1: *The N1, N2, N3, and N4 superscripts refer to the Notes that are listed at the end of Table H-1.*

Table H-1. Proposed TRLs for Medical Research, Development, Test, and Evaluation (RDT&E)

TRL 1 **National Aeronautics and Space Administration (NASA)/*Defense Acquisition Guidebook*[88] TRL Definition:** Basic principles observed and reported				
NASA/ *Defense Acquisition Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs)[N1, N2]	**Pharmaceutical (Biologics, Vaccines)[N1, N2]**	**Medical Devices[N3, N4]**	**Medical IM/IT & Medical Informatics**
Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include paper studies of a technology's basic properties.	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies. **TRL 1 Decision Criterion:** Scientific literature reviews and initial market surveys are initiated and assessed. Potential scientific application to defined problems is articulated.	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies. **TRL 1 Decision Criterion:** Scientific literature reviews and initial market surveys are initiated and assessed. Potential scientific application to defined problems is articulated.	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies. **TRL 1 Decision Criterion:** Scientific literature reviews and initial market surveys are initiated and assessed. Potential scientific application to defined problems is articulated.	Hardware/software (HW/SW) system technology explored. Basic theories applied to IM/IT field suggesting promise. **TRL 1 Decision Criterion:** Identification of the potential medical solution to mission need. Medical Informatics data and knowledge representation issues are defined.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	Reviews of open, published scientific literature concerning basic principles. Findings from market surveys of the open literature. **Note:** *Privately funded research findings or market surveys are proprietary and rarely available to the public.*	Reviews of open, published scientific literature concerning basic principles. Findings from market surveys of the open literature. **Note:** *Privately funded research findings or market surveys are proprietary and rarely available to the public.*	Reviews of open, published scientific literature concerning basic principles. Findings from market surveys of the open literature. **Note:** *Privately funded research findings or market surveys are proprietary and rarely available to the public.*	

[88] The *Defense Acquisition Guidebook,* dated October 2004, contains nonmandatory guidance on best practices, lessons learned, and expectations.

Table H-1. Proposed TRLs for Medical RDT&E (Continued)

TRL 2 **NASA/*Defense Acquisition Guidebook* TRL Definition:** Technology concept and/or application formulated

NASA/ *Defense Acquisition Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs)[N1, N2]	**Pharmaceutical (Biologics, Vaccines)**[N1, N2]	**Medical Devices**[N3, N4]	**Medical IM/IT & Medical Informatics**
Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.	Intense intellectual focus on the problem, with generation of scientific “paper studies” that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. **TRL 2 Decision Criterion:** Hypothesis(es) is generated. Research plans and/or protocols are developed, peer reviewed, and approved.	Intense intellectual focus on the problem, with generation of scientific “paper studies” that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. **TRL 2 Decision Criterion:** Hypothesis(es) is generated. Research plans and/or protocols are developed, peer reviewed, and approved.	Intense intellectual focus on the problem, with generation of scientific “paper studies” that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. **TRL 2 Decision Criterion:** Hypothesis(es) is generated. Research plans and/or protocols are developed, peer reviewed, and approved.	HW/SW system invention begins. Overall system concepts are documented by flowcharting or other system-descriptive techniques. **TRL 2 Decision Criterion:** Identification of the potential medical solution to mission need. Medical Informatics data and knowledge representation issues are defined.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	Focused literature reviews are conducted and scientific discussions are held to generate research plans and studies that identify potential targets of opportunity for therapeutic intervention and to facilitate strategic planning. Supporting analyses provide scientific information and data for developing research proposals for filling in data gaps and identifying candidate concepts and/or therapeutic drugs. Documented by peer-reviewed approved protocol(s) or research plan(s).	Focused literature reviews are conducted and scientific discussions are held to generate research plans and studies that identify potential targets of opportunity for therapeutic intervention and to facilitate strategic planning. Supporting analyses provide scientific information and data for developing research proposals for filling in data gaps and identifying candidate concepts and/or therapeutic drugs. Documented by peer-reviewed approved protocol(s) or research plan(s).	Focused literature reviews are conducted and scientific discussions are held to generate research plans and studies that identify potential targets of opportunity for therapeutic intervention and to facilitate strategic planning. Supporting analyses provide scientific information and data for developing research proposals for filling in data gaps and identifying candidate concepts and/or devices. Documented by peer-reviewed approved protocol(s) or research plan(s).	

Table H-1. Proposed TRLs for Medical RDT&E (Continued)

TRL 3 **NASA/*Defense Acquisition Guidebook* TRL Definition:** Analytical and experimental critical function and/or characteristic proof-of-concept				
NASA/ *Defense Acquisition Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs)[N1, N2]	**Pharmaceutical (Biologics, Vaccines)[N1, N2]**	**Medical Devices[N3, N4]**	**Medical IM/IT & Medical Informatics**
Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.	Basic research, data collection, and analysis begin in order to test the hypothesis, explore alternative concepts, and identify and evaluate technologies supporting drug development. Initial synthesis of countermeasure candidate(s) and identification of their sites and mechanisms of action. Initial characterization of candidates in preclinical studies.	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate critical technologies and components supporting candidate biologic/vaccine constructs research and eventual development of a candidate countermeasure. Agent challenge studies are conducted to support models based on presumed battlefield conditions. Research-scale process initiation and evaluation is conducted, as are studies to identify site(s) and mechanism(s) of action, potential correlates of protection for vaccines, and initial physical/chemical characterization of constructs.	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate component technologies. Initial tests of design concept and evaluation of candidate(s). Study endpoints defined. Animal models (if any) are proposed. Design verification, critical component specifications, and tests [if a system component or necessary for device test and evaluation (T&E)].	Separate elements of HW/SW system components are investigated and developed but not yet integrated or representative.
	TRL 3 Decision Criterion: Initial proof-of-concept for candidate drug constructs is demonstrated in a limited number of *in vitro* and *in vivo* research models.	**TRL 3 Decision Criterion:** Initial proof-of-concept for biologic/vaccine constructs is demonstrated in a limited number of *in vitro* and *in vivo* research models.	**TRL 3 Decision Criterion:** Initial proof-of-concept for device candidates is demonstrated in a limited number of laboratory models (may include animal studies).	**TRL 3 Decision Criterion:** Medical Informatics data and knowledge representation schema are modeled.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	Documentation of the results of laboratory studies demonstrates preliminary proof-of-concept in *in vitro* and animal studies.	Documentation of the results of laboratory studies demonstrates preliminary proof-of-concept with candidate biologic/vaccine constructs in *in vitro* and animal studies.	Documentation of the results of laboratory studies demonstrates preliminary proof-of-concept in laboratory models.	

Table H-1. Proposed TRLs for Medical RDT&E (Continued)

TRL 4 **NASA/*Defense Acquisition Guidebook* TRL Definition:** Component and/or breadboard validation in laboratory environment				
NASA/ *Defense Acquisition Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs)[N1, N2]	**Pharmaceutical (Biologics, Vaccines)[N1, N2]**	**Medical Devices[N3, N4]**	**Medical IM/IT & Medical Informatics**
Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.	Non-Good Laboratory Practice (GLP) laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of candidate drugs [e.g., formulation, route(s) of administration, method of synthesis, physical/chemical properties, metabolic fate and excretion or elimination, and dose ranging]. Candidate drugs are evaluated in animal model(s) to identify and assess potential safety and toxicity problems, adverse events, and side effects. Assays to be used during nonclinical and clinical studies in evaluating candidate drugs are identified.	Non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of critical technologies for effective integration into candidate biologic/vaccine constructs [e.g., environmental milieu (pH, adjuvant, stabilizers and preservatives, buffers, and so forth), route(s)/ methods of administration, proposed production/ purification methods, further physical/chemical characterization, metabolic fate and excretion or elimination, dose ranging, and agent challenge studies for protection]. Candidate biologic/vaccine constructs are evaluated in animal model(s) to identify and assess safety and toxicity, biological effects, adverse effects, and side effects. Assays, surrogate markers, and endpoints to be used during nonclinical and clinical studies to evaluate and characterize candidate biologic/vaccine constructs are identified.	Non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of candidate device(s)/systems (e.g., initial specification of device, system, and subsystems). Candidate devices/systems are evaluated in laboratory and/or animal models to identify and assess potential safety problems, adverse events, and side effects. Procedures and methods to be used during nonclinical and clinical studies in evaluating candidate devices/systems are identified. The design history file, design review, and, when required, a Device Master Record (DMR), are initiated to support either a 510(k)[89] or Premarket Approval (PMA).	Prototype produced. HW/SW system components are integrated to establish that the pieces will work together. This is relatively "low fidelity" compared to the eventual system.
	TRL 4 Decision: Criterion: Proof-of-concept and safety of candidate drug formulation(s) are demonstrated in defined laboratory/animal model(s).	**TRL 4 Decision Criterion:** Proof-of-concept and safety of candidate biologic/vaccine constructs are demonstrated in defined laboratory/animal model(s).	**TRL 4 Decision Criterion:** Proof-of-concept and safety of candidate devices/systems are demonstrated in defined laboratory/animal models.	**TRL 4 Decision Criterion:** Medical Informatics data and knowledge representation models are instantiated with representative data or knowledge from applicable domain.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	Documented proof-of-concept and safety of candidate drug formulations are demonstrated by results of formulation studies, laboratory tests, pharmacokinetic studies, and selection of laboratory/animal models.	Documented proof-of-concept and safety of candidate biologics/vaccines are demonstrated by results of proposed production/purification methods, laboratory tests, pharmocokinetic studies, and selection of laboratory/animal models.	Reviewers confirm proof-of-concept and safety of candidate devices/systems from laboratory test results, laboratory/animal models, and documentation of the initial design history file, design review, and, when required, a DMR. The documented initial design history file, design review, and, when required, a DMR support either a 510(k) or PMA.	

89 A 510(k) is a premarket notification for medical devices.

Table H-1. Proposed TRLs for Medical RDT&E (Continued)

TRL 5 **NASA/*Defense Acquisition Guidebook* TRL Definition:** Component and/or breadboard validation in a relevant environment				
NASA/ *Defense Acquisition Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs)[N1, N2]	**Pharmaceutical (Biologics, Vaccines)[N1, N2]**	**Medical Devices[N3, N4]**	**Medical IM/IT & Medical Informatics**
Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment. Examples include "high-fidelity" laboratory integration of components.	Intense period of nonclinical and preclinical research studies involving parametric data collection and analysis in well-defined systems, with pilot lots of candidate pharmaceuticals produced and further development of selected candidate(s). Results of research with pilot lots provide basis for a manufacturing process amenable to current Good Manufacturing Practice (cGMP)-compliant pilot lot production. Conduct GLP safety and toxicity studies in animal model systems. Identify endpoints of clinical efficacy or its surrogate. Conduct studies to evaluate the pharmacokinetics and pharmacodynamics of candidate drugs. Stability studies initiated.	Intense period of nonclinical and preclinical research studies involving parametric data collection and analysis in well-defined systems with pilot lots of candidate biologics/vaccines produced and further development of selected candidates. Research results support proposing a potency assay, proposing a manufacturing process amenable to cGMP-compliant pilot lot production, identifying and demonstrating proof-of-concept for a surrogate efficacy marker in an animal model(s) applicable to predicting protective immunity in humans, and demonstrating preliminary safety and efficacy against an aerosol challenge in a relevant animal model. Conduct GLP safety and toxicity studies in animal model systems. Identify endpoints of clinical efficacy or its surrogate in animal models that may be applicable to predicting protective immunity in humans. Conduct studies to evaluate immunogenicity, as well as pharmacokinetics and pharmacodynamics when appropriate. Stability studies initiated.	Further development of selected candidate(s). Devices compared to existing modalities and indications for use and equivalency demonstrated in model systems. Examples include devices tested through simulation, in tissue or organ models, or animal models if required. All component suppliers/vendors are identified and qualified; vendors for critical components are audited for cGMP/Quality System Regulation (QSR) compliance. Component tests, component drawings, design history file, design review, and any DME are verified. Product Development Plan is drafted. Pre-Investigational Device Exemption (IDE) meeting is held with Center for Devices and Radiological Health (CDRH) for proposed Class III devices, and the IDE is prepared and submitted to CDRH. For a 510(k), determine substantially equivalent devices and their classification, validate functioning model, ensure initial testing is complete, and validate data and readiness for cGMP inspection.	First technical test of prototype. HW/SW system components are integrated, and realistic supporting elements are employed so that the system can be tested in a simulated environment. Actual interfaces to supporting systems are specified and development begins.
	TRL 5 Decision Criterion: A decision point is reached at which it is determined that sufficient data on the candidate drug exist in the draft technical data package to justify proceeding with preparation of an Investigational New Drug (IND) application.	**TRL 5 Decision Criterion:** A decision point is reached at which it is determined that sufficient data on the candidate biologic/vaccine exist in the draft technical data package to justify proceeding with preparation of an IND application.	**TRL 5 Decision Criterion:** IDE review by CDRH results to determine if the investigation can begin. For a 510(k), preliminary findings suggest the device will be substantially equivalent to a predicate device.	**TRL 5 Decision Criterion:** Medical Informatics data and knowledge representation models are implemented as data and/or knowledge management systems and tested in a laboratory environment.

Table H-1. Proposed TRLs for Medical RDT&E (Continued)

TRL 5 **NASA/*Design Acquisition Guidebook* TRL Definition:** Component and/or breadboard validation in a relevant environment (Continued)

Pharmaceutical (Drugs)[N1, N2]	Pharmaceutical (Biologics, Vaccines)[N1, N2]	Medical Devices[N3, N4]
Supporting Information	**Supporting Information**	**Supporting Information**
Reviewers confirm adequacy of information and data on candidate drug in a draft technical data package to support preparation of IND application. Documentation in the draft technical data package contains data from animal pharmacology and toxicology studies, proposed manufacturing information, and clinical protocols for Phase 1 clinical testing.	Reviewers confirm adequacy of information and data on candidate biologic/vaccine constructs in draft technical data package to support preparation of an IND application. Documentation in the draft technical data package contains data from animal pharmacology and toxicology studies, proposed manufacturing information, and clinical protocols suitable for Phase 1 clinical testing.	For investigation of a Class III device to begin in humans, the following are needed: (1) the FDA's and sponsor's summary minutes of pre-IDE meeting document agreements and general adequacy of information and data to support preparation and submission of IDE application and (2) an FDA letter acknowledging receipt of IDE by CDRH. The investigational plan (clinical trials) can begin after 30 days (barring a clinical hold from the FDA) or sooner if CDRH approves the IDE within 30 days. In the latter case, CDRH will provide written notification. The submitted IDE includes information regarding the sponsor, intended use of device, rationale for use of device, investigational plan, instructions for use of device, labeling, and informed consent. For a 510(k) device, reviewers confirm preliminary claim that the medical device appears substantially equivalent to a predicate device, the proposed classification is consistent with 21CFR860, there is a functioning model, and testing results support substantial equivalency.

Table H-1. Proposed TRLs for Medical RDT&E (Continued)

TRL 6 **NASA/*Defense Acquisition Guidebook* TRL Definition:** System/subsystem model or prototype demonstration in a relevant environment

NASA/ *Defense Acquisition Guidebook* TRL Description	*USAMRMC Equivalent TRL Descriptions*			
	Pharmaceutical (Drugs)[N1, N2]	**Pharmaceutical (Biologics, Vaccines)[N1, N2]**	**Medical Devices[N3, N4]**	**Medical IM/IT & Medical Informatics**
Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in a simulated operational environment.	Pre-IND meeting (Type B) held with the Center for Drug Evaluation and Research (CDER). IND application is prepared and submitted. Phase 1 clinical trials are conducted to demonstrate safety of candidate in a small number of humans under carefully controlled and intensely monitored clinical conditions. Evaluation of pharmacokinetic and pharmacodynamic data to support the design of well-controlled, scientifically valid Phase 2 studies. Production technologies are demonstrated through production-scale cGMP plant qualification. **TRL 6 Decision Criterion:** Data from Phase 1 trials meet clinical safety requirements and support proceeding to Phase 2 clinical studies.	Pre-IND meeting (Type B) held with the Center for Biologics Evaluation and Research (CBER). IND application is prepared and submitted. Phase 1 clinical trials are conducted to demonstrate safety of candidates in a small number of subjects under carefully controlled and intensely monitored clinical conditions. Evaluation of immunogenicity and/or pharmacokinetics and pharmacodynamics data to support design of Phase 2 clinical trials. Surrogate efficacy models are validated. **TRL 6 Decision Criterion:** Data from Phase 1 clinical trials meet clinical safety requirements and support proceeding to Phase 2 clinical trials.	Clinical trials are conducted to demonstrate safety of candidate Class III medical device in a small number of humans under carefully controlled and intensely monitored clinical conditions. Component tests, component drawings, design history file, design review, and any DMR are updated and verified. Production technology demonstrated through production-scale cGMP plant qualification. For 510(k), component tests, component drawings, design history file, design review, and any DMR are updated and verified. Manufacturing facility is ready for cGMP inspection. **TRL 6 Decision Criterion:** Data from the initial clinical investigation demonstrate that the Class III device meets safety requirements and support proceeding to clinical safety and effectiveness trials. For a 510(k), information and data demonstrate substantial equivalency to predicate device and support production of the final prototype and final testing in a military operational environment.	Advanced technical testing of prototype HW/SW system, to include interfaces to actual supporting systems, is conducted in a relevant or simulated operational environment. Out-product is final prototype. **TRL 6 Decision Criterion:** Medical Informatics data and knowledge management systems are tested with target applications in a laboratory environment. Configuration management approach developed.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	For Phase 1 Clinical Trials to begin, the following are needed: the FDA's and sponsor's summary minutes of pre-IND meeting document agreements and general adequacy of information and data to support submission of IND application. Review of the submitted IND application does not result in a FDA decision to put a clinical hold on Phase 1 clinical trials with the candidate drug. For entry into Phase 2 clinical trials, the results from Phase 1 clinical studies have to demonstrate safety of candidate drug. An updated IND application, amended with a new clinical protocol to support Phase 2 clinical trials or a surrogate test plan and submitted to the FDA, documents the achievement of this criterion.	For Phase 1 Clinical Trials to begin, the following are needed: the FDA's and sponsor's summary minutes of pre-IND meeting document agreements and general adequacy of information and data to support submission of an IND application. Review of the submitted IND does not result in an FDA decision to put a clinical hold on Phase 1 clinical trials with the candidate biologic/vaccine. For entry into Phase 2 clinical trials, the results from Phase 1 clinical studies have to demonstrate safety of candidate biologic/vaccine. An updated IND, amended with a new clinical protocol to support Phase 2 clinical trials or surrogate test plan and submitted to the FDA, documents achieving this criterion.	Documentation from clinical study results shows the candidate device is safe. Changes to the investigational plan that require FDA approval (21CFR812.35) are submitted as a supplemental IDE application to the FDA. For a 510(k), reviewers confirm adequacy of documented component tests, component drawings, design history file, design review, and any DMR to support claim of substantial equivalency and readiness for final testing in a military operational environment.	

Table H-1. Proposed TRLs for Medical RDT&E (Continued)

TRL 7 **NASA/*Defense Acquisition Guidebook* TRL Definition:** System prototype demonstration in an operational environment				
NASA/ *Defense Acquisition Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs)[N1, N2]	**Pharmaceutical (Biologics, Vaccines)[N1, N2]**	**Medical Devices[N3, N4]**	**Medical IM/IT & Medical Informatics**
Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment (e.g., in an aircraft, in a vehicle, or in space). Examples include testing the prototype in a test bed aircraft.	Phase 2 clinical trials are conducted to demonstrate initial efficacy and capture further safety and toxicity data. Product activity (e.g., preliminary evidence of efficacy) is determined. Product final dose, dose range, schedule, and route of administration are established from clinical pharmacokinetic and pharmacodynamic data. Phase 2 clinical trials are completed. Data are collected, presented, and discussed with CDER at pre-Phase 3 meeting (Type B) in support of continued drug development. Clinical endpoints and/or surrogate efficacy markers and test plans agreed to by CDER. **TRL 7 Decision Criterion:** Phase 3 clinical study plan or surrogate test plan has been approved.	Phase 2 safety and immunogenicity trials are conducted. Product immunogenicity and biological activity (e.g., preliminary evidence of efficacy) are determined. Product final dose, dose range, schedule, and route of administration are established from vaccine immunogenicity and biologic activity and, when necessary, from clinical pharmacokinetics and pharmacodynamics data. Phase 2 clinical trials completed. Data are collected, presented, and discussed with CBER at pre-Phase 3 (or surrogate efficacy) meeting (Type B) in support of continued development of the biologics/vaccines. Clinical endpoints and/or surrogate efficacy markers and test plans agreed to by CBER. **TRL 7 Decision Criterion:** Phase 3 clinical study plan or surrogate test plan has been approved.	Clinical safety and effectiveness trials are conducted with a fully integrated Class III medical device prototype in an operational environment. Continuation of closely controlled studies of effectiveness and determination of short-term adverse events and risks associated with the candidate product. Functional testing of candidate devices is completed and confirmed, resulting in final down-selection of prototype device. Clinical safety and effectiveness trials are completed. Final product design is validated, and final prototype and/or initial commercial scale device is produced. Data are collected, presented, and discussed with CDRH in support of continued device development. For a 510(k), final prototype and/or initial commercial-scale device are produced and tested in a military operational environment. **TRL 7 Decision Criterion:** Clinical endpoints and test plans are agreed to by CDRH. For a 510(k), information and data demonstrate substantial equivalency to predicate device and use in a military operational environment and support preparation of 510(k).	Prototype HW/SW system is near or at planned operational system. Actual system prototype is demonstrated in an operational environment with end-users (first cut user test). **TRL 7 Decision Criterion:** Medical Informatics data and knowledge management systems are operationally integrated and tested with target applications in an operational environment.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	FDA's summary minutes of pre-Phase 3 meeting with sponsor discussing results of Phase 1 and Phase 2 trials and protocols or test plans provide a record of agreements and basis for sponsor to proceed with Phase 3 clinical study or surrogate test plan. An updated IND application, amended with a new clinical protocol to support Phase 3 clinical trials or surrogate test plan and submitted to the FDA, documents the achievement of this criterion.	FDA's summary minutes of pre-Phase 3 meeting with sponsor discussing results of Phase 1 and Phase 2 trials, as well as clinical protocols or test plans, provide record of agreements and basis for sponsor to proceed with Phase 3 clinical study or surrogate test plan. An updated IND application, amended with a new clinical protocol to support Phase 3 clinical trials or surrogate test plan and submitted to the FDA, documents achieving this criterion.	The FDA's and sponsor's summary minutes of their meeting documents any agreements reached regarding continued development of the Class III medical device. PMA shell modules (e.g., sections of PMA) are submitted to CDRH by sponsor if such submissions were previously approved by CDRH. For a 510(k), documented results of testing in an operational environment support safety, effectiveness, and use of device in a military operational environment.	

Table H-1. Proposed TRLs for Medical RDT&E (Continued)

TRL 8 **NASA/*Defense Acquisition Guidebook* TRL Definition:** Actual system completed and qualified through test and demonstration

NASA/ *Defense Acquisition Guidebook* TRL Description	*USAMRMC Equivalent TRL Descriptions*			
	Pharmaceutical (Drugs)[N1, N2]	**Pharmaceutical (Biologics, Vaccines)[N1, N2]**	**Medical Devices[N3, N4]**	**Medical IM/IT & Medical Informatics**
Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.	Implementation of expanded Phase 3 clinical trials or surrogate tests to gather information relative to the safety and effectiveness of the candidate drug. Trials are conducted to evaluate the overall risk-benefit of administering the candidate product and to provide an adequate basis for drug labeling. Process validation is completed and followed by lot consistency/ reproducibility studies. Pre-NDA [New Drug Application] meeting (Type B) held with CDER. NDA is prepared and submitted to CDER. Facility PAI is completed. **TRL 8 Decision Criterion:** Approval of the NDA for drug by CDER.	Implementation of expanded Phase 3 clinical trials or surrogate tests to gather information relative to the safety and effectiveness of the candidate biologic/vaccine. Trials are conducted to evaluate the overall risk-benefit of administering the candidate product and to provide an adequate basis for product labeling. Process validation is completed and followed by lot consistency/reproducibility studies. Pre-BLA [Biologics License Application] meeting (Type B) held with CBER. BLA is prepared and submitted to CBER. Facility PAI is completed. **TRL 8 Decision Criterion:** Approval of the BLA for biologics/vaccines by CBER.	Implementation of clinical trials to gather information relative to the safety and effectiveness of the device. Trials are conducted to evaluate the overall risk-benefit of using the device and to provide an adequate basis for product labeling. Confirmation of QSR compliance, the design history file, design review, and any DMR are completed and validated, and device production is followed through lot consistency and/or reproducibility studies. Pre-PMA meeting held with CDRH. PMA prepared and submitted to CDRH. Facility PAI [cGMP/ QSR/Quality System Inspection Technique (QSIT)] is completed. For 510(k), prepare and submit application. **TRL 8 Decision Criterion:** Approval of the PMA [or, as applicable, 510(k)] for device by CDRH.	Technical testing of final product. HW/SW system has been proven to work in its final form and under expected conditions. **TRL 8 Decision Criterion:** Developmental test and evaluation of the HW/SW system in its intended environment demonstrate that it meets design specifications. Fully integrated and operational medical informatics data and knowledge management systems are validated in several operational environments.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	FDA issuance of an Approval Letter after their review of the NDA submitted by the sponsor for the drug documents this criterion.	FDA issuance of an Approval Letter after their review of the BLA application submitted by the sponsor for the pharmaceutical (biologic/vaccine) documents this criterion.	FDA issuance of an Approval Order after their review of PMA application submitted by the sponsor for the Class III medical device. The submitted PMA includes general information, summary of safety and effectiveness data, device description and manufacturing information, summaries of nonclinical and clinical studies, labeling, and instruction manual. For a 510(k), FDA issuance of a Marketing Clearance Letter (also referred to as a "substantially equivalent letter") after their review of 510(k) application submitted by the sponsor for the medical device.	

Table H-1. Proposed TRLs for Medical RDT&E (Continued)

TRL 9 **NASA/*Defense Acquisition Guidebook* TRL Definition:** Actual system proven through successful mission operations

NASA/ *Defense Acquisition Guidebook* TRL Description	*USAMRMC Equivalent TRL Descriptions*			
	Pharmaceutical (Drugs)[N1, N2]	**Pharmaceutical (Biologics, Vaccines)[N1, N2]**	**Medical Devices[N3, N4]**	**Medical IM/IT & Medical Informatics**
Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. Examples include using the system under operational mission conditions.	The pharmaceutical (i.e., drug) or medical device can be distributed/marketed. Postmarketing studies (nonclinical or clinical) may be required and are designed after agreement with the FDA. Postmarketing surveillance.	The pharmaceutical (i.e., biologic or vaccine) or medical device can be distributed/marketed. Postmarketing studies (nonclinical or clinical) may be required and are designed after agreement with the FDA. Postmarketing surveillance.	The medical device can be distributed/marketed. Postmarketing studies (nonclinical or clinical) may be required and are designed after agreement with the FDA. Postmarketing surveillance.	Operational testing of the product. HW/SW system is in its final form and under mission conditions, such as those encountered in operational test and evaluation. Medical Informatics knowledge maintenance and verification of data integrity are ongoing. Military requirements met for transportation, handling, storage, and so forth.
	TRL 9 Decision Criterion: None. Continue surveillance.	**TRL 9 Decision Criterion:** None. Continue surveillance.	**TRL 9 Decision Criterion:** None. Continue surveillance.	**TRL 9 Decision Criterion:** Product successfully used during military mission as component of initial operational test and evaluation (IOT&E) phase. Logistical demonstration successfully conducted.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	FDA transmits any requirement for postmarketing studies. Begin postapproval reporting requirements. Maintain cGMP compliance.	FDA transmits requirements for any postmarketing studies. Begin postapproval reporting requirements. Maintain cGMP compliance.	FDA transmits requirements for any postmarketing studies. Begin postapproval reporting requirements. Maintain cGMP compliance.	

Note 1 for Table H-1: *These guidelines are not considered absolutes, and characterization of activities associated with TRLs can and does vary at times. For example, experience to date in applying the guidelines for biomedical TRLs indicates considerable variation in the timing, activities, and programmatic events associated with TRLs 5 and 6 for pharmaceuticals. Hence, the S&T and acquisition PMs work together in exercising discretion in the selection, progression, and timing of specific activities to be accomplished in the attainment of TRL 5. Such flexibility and tailoring are needed to align the TRL decision criteria appropriately with the maturation and risk characteristics of a particular technology, including consideration of the associated investment strategy and transition procedures that may vary among PMs.*

Note 2 for Table H-1: *Descriptions and decision criteria are from Biomedical Technology Readiness Levels (TRLs), prepared for the Commander, U.S. Army Medical Research and Materiel Command under Contract DAMD17-98-D-0022, Science Applications International Corporation, 3 June 2003.*

Note 3 for Table H-1: *These guidelines are not considered absolutes, and characterization of activities associated with TRLs can and does vary at times. For example, experience to date with application of the guidelines for biomedical TRLs indicates considerable variation in the timing, activities, and programmatic events associated with medical devices that follow a 510(k) vis-à-vis PMA path. Hence, the S&T and acquisition PMs work together in exercising discretion in the selection, progression, and timing of specific activities to be accomplished in the attainment of particular TRLs. Such flexibility and tailoring are needed to align the TRL decision criteria appropriately with the maturation and risk characteristics of a particular technology, including consideration of the associated investment strategy and transition procedures that may vary among PMs.*

Note 4 for Table H-1: *Descriptions and decision criteria are from Biomedical Technology Readiness Levels (TRLs), prepared for the Commander, U.S. Army Medical Research and Materiel Command under Contract DAMD17-98-D-0022, Science Applications International Corporation, 3 June 2003. Definitions pertain predominately to Class II and Class III devices (see 21CFR860.3 or Glossary of this appendix for device class definitions) that are subject to approval via the PMA process. Devices that are subject to approval via the 510(k) process (Market clearance; generally limited to certain Class I and Class II devices) may not require all of the studies described and only require an IDE if human studies are necessary.*

H.2 THE FDA REGULATORY PROCESS

To protect U.S. public health, the FDA regulates products by ensuring that human pharmaceuticals (drugs and biologics/vaccines) are safe and effective and that reasonable assurance exists concerning the safety and effectiveness of medical devices intended for human use. Three FDA centers are charged with this mission:

1. **The Center for Drug Evaluation and Research (CDER).** CDER regulates drugs and some biologic products (antibodies, cytokines, growth factors, enzymes, and proteins extracted from animals or microorganisms).

2. **The Center for Biologics Evaluation and Research (CBER).** CBER regulates vaccines, blood and plasma products, viral-vectored gene therapy, products composed of human or animal cells, antitoxins, and select *in vitro* diagnostics. CBER also holds regulatory authority over Human Immunodeficiency Virus (HIV) test kits and medical devices involved in collecting, processing, testing, manufacturing, and administering blood products.

3. **The Center for Devices and Radiological Health (CDRH).** CDRH is responsible for regulating manufactured, repackaged, relabeled, and/or imported medical devices that are sold in the United States (except those devices regulated by CBER).

H.2.1 Pharmaceuticals

Drugs and biologics/vaccines follow parallel developmental regulatory pathways (see Table H-1). During preclinical development, the sponsor evaluates the toxicology and pharmacology of the new drug or biologic through *in vitro* and animal testing. Preclinical test results and any available past human experiences of the drug or biologic are incorporated in an IND (Investigational New Drug Application) and submitted to the FDA for review. If no safety issues are found, human clinical testing of the new drug or biologic can be initiated after 30 days. Clinical testing proceeds in three successive phases, starting with a small group of human subjects (Phase 1) and progressing to a larger population of human subjects (Phase 3). Only qualified investigators, selected by the sponsor in accordance with GCP (Good Clinical Practice) (21CFR312.53 and 21CFR312.62), conduct clinical trials. The safety and effectiveness results of clinical testing comprise the most important factor in the approval or disapproval of the new drug or biologic. All active INDs require submission of an annual IND report to the FDA. The results of the human clinical tests and all chemistry and manufacturing information are submitted either in an NDA (New Drug Application) for drug products or a BLA (Biologics License Application) for biologic products. The appropriate FDA center reviews the NDA or BLA, and, upon approval, the drug or biologic product can be entered into interstate commerce or marketed in the United States. FDA approval is for the specific indication(s) identified in the marketing application. Additional or modified medical indications require the submission of an amendment or a new marketing application. A new marketing application may require additional human clinical data acquired through IND

regulations. With some new drugs or biologics/vaccines, the FDA may require additional reporting requirements after approval, termed Phase 4 or postmarketing surveillance. Manufacturers are required to track and report the number and severity of adverse events attributable to each product for a specified time period. Severe adverse events detected during postapproval can lead to a product recall or mandatory withdrawal from the market. All drugs and biologics/vaccines must comply with cGMP (current Good Manufacturing Practice) and labeling regulations.

With certain drugs or biologic products, human clinical studies are not ethical or feasible because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers. In 2002, the FDA addressed this issue with new regulations that allow for the approval of new drug and biologic products based on evidence of effectiveness in animals (21CFR314 and 21CFR601). In February 2003, under the new federal regulations, DoD was able to gain approval of pyridostigmine bromide for prophylaxis against the lethal effects of the soman nerve agent.

H.2.2 Medical Devices

The FDA CDRH regulates most medical devices, and they have classified each device in the Code of Federal Regulations (CFR). Classification of devices into one of three classes is based on the level of regulatory control that is necessary to ensure the safety and effectiveness of a medical device, with Class I and Class III devices being the least and most regulated, respectively. The sponsor normally proposes the classification level of a device using 21CFR860 as a guide. Most importantly, the classification of the device will identify, unless exempt (e.g., most of the Class I devices), the marketing process [either premarket notification (510(k)) or PMA (Premarket Approval)] that the manufacturer must complete to obtain FDA clearance/approval for marketing. All classified medical devices are subject to cGMP and labeling requirements. An approved 510(k) or PMA allows an applicant to market a particular device for its intended purpose.

The FDA approves most medical devices for marketing in the United States through a premarket notification [510(k)]. The applicant must show that the new device is substantially equivalent to one or more predicate devices legally marketed in the United States. A description of all tests conducted and the results obtained must be provided in sufficient detail to allow the FDA to determine substantial equivalence. If the medical device is found to be substantially equivalent, the FDA will send the manufacturer a "substantially equivalent letter" to clear the device for marketing. If the FDA finds the device not to be substantially equivalent, the FDA sends the manufacturer a "not substantially equivalent letter," and the device cannot be marketed. At this point, the manufacturer can submit another 510(k) with new and/or additional information to support substantial equivalence or may be required to submit a PMA.

To allow a Class III medical device (devices that support or sustain human life or present a potential risk of serious illness or injury) into interstate commerce or marketing, a PMA is required. A PMA is the most stringent regulatory submission for medical devices. Class III

devices follow somewhat different development and regulatory paths compared with those for drugs and biologics/vaccines (see Table H-1). For example, if human clinical information is required to establish safety and efficacy, the regulatory application that allows human clinical trials is called an IDE (Investigational Device Exemption). Approval of an IDE allows the initiation of human clinical trials of an investigational device. Qualified principal investigators (PIs), selected by the sponsor in accordance with 21CFR812.43, conduct clinical trials. All active IDEs require submission of an annual report to the FDA. Safety and efficacy information acquired during the IDE process is used to support the submission of a PMA, and the FDA must approve the PMA before the device can be marketed. As with drugs and biologics/vaccines, the FDA may mandate a period of postmarketing surveillance during which device-related adverse events must be tracked and reported.

H.3 WEB SITES

FDA Center for Devices and Radiological Health (CDRH):
http://www.fda.gov/cdrh/

FDA Center for Drug Evaluation and Research (CDER):
http://www.fda.gov/cder/

FDA Center for Biologics Evaluation and Research (CBER):
http://www.fda.gov/cber/

H.4 ADDITIONAL INFORMATION

Federal Food, Drug, and Cosmetic (FD&C) Act
United States Code, Title 21 – Food and Drugs (21USC)
Chapter 9: Federal Food, Drug, and Cosmetic Act
http://www.access.gpo.gov/uscode/title21/chapter9_.html

FDA Regulations
CFR: Title 21 – Food and Drugs (21CFR)
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm or
http://www.gpoaccess.gov/cfr/index.html

Drug Approval
The CDER Handbook: http://www.fda.gov/cder/handbook/
CDERLearn: http://www.fda.gov/cder/learn/CDERLearn/default.htm

Medical Device Approval
Device Advice: http://www.fda.gov/cdrh/devadvice/index.html

Laws Enforced by the FDA

http://www.fda.gov/opacom/laws/

Protection of Human Subjects

32CFR219- *Protection of Human Subjects* (also referred to as the "Common Rule") (http://www.access.gpo.gov/nara/cfr/waisidx_02/32cfr219_02.html)

DoDD 3216.2 (March 25, 2002) *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*
http://www.dtic.mil/whs/directives/corres/pdf/d32162_032502/d32162p.pdf

GLOSSARY FOR APPENDIX H[90]

Approval Letter: A written communication to an applicant from the FDA approving an application or an abbreviated application to market a drug. [21CFR314.3]

Approval Order: A written communication to an applicant from the FDA approving a PMA for a Medical Devices application. [21CFR814.44]

Biologic or Biological Product: Any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of man. [21CFR600.3]

Biologics License Application (BLA): An application to the FDA for approval to market a biological product. [21CFR601.12]

current Good Manufacturing Practice (cGMP): Regulations that cover the methods used in and the facilities and controls used for the design, manufacture, packaging, storage, and installation of devices. [21CFR820]

Class (Device): One of the three categories of regulatory control for medical devices. [21CFR860.3]

Class I Device: The class of devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. In the absence of sufficient information to make that determination, the device is not life supporting and does not present a potential unreasonable risk of illness or injury. [21CFR860.3]

Class II Device: The class of devices for which general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and for which there is sufficient information to establish special controls, including the promulgation of performance standards. For a device that is purported to be for use in supporting human life, the Commissioner (FDA) shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness. [21CFR860.3]

[90] Complete definitions and explanations of terms can be found in the source cited in brackets. CFR is an acronym for the Code of Federal Regulations.

Class III Device: The class of devices for which premarket approval is or will be required. A device is in Class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness, if the device is life supporting, or if the device presents a potential unreasonable risk of illness or injury. [21CFR860.3]

Classification Name: The term used by the FDA and its classification panels to describe a device or class of devices for purposes of classifying devices under section 513 of the Federal Food, Drug, and Cosmetic (FD&C) Act. [21CFR807.3]

Approximately 1,700 different generic types of devices are grouped into 16 medical specialties [21CFR862–892], as follows:

862: Clinical chemistry and clinical toxicology devices
864: Hematology and pathology devices
866: Immunology and microbiology devices
868: Anesthesiology devices
870: Cardiovascular devices
872: Dental devices
874: Ear, nose and throat devices
876: Gastroenterology-urology devices
878: General and plastic surgery devices
880: General hospital and personal use devices
882: Neurological devices
884: Obstetrical and gynecological devices
886: Ophthalmic devices
888: Orthopedic devices
890: Radiology devices
892: Banned devices.

Clinical Hold: An FDA order to delay proposed clinical investigation or to suspend an ongoing investigation.

Clinical Investigation: Any experiment in which a drug that involves one or more human subjects is administered, dispensed, or used. For this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. [21CFR312.3]

Clinical Trial/Clinical Study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or identify any adverse reactions to an investigational product(s), and/or study absorption, distribution, metabolism, and excretion of an investigational product(s) with

the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous. [62 FR 25692][91]

Cosmetic: (1) Articles intended to be rubbed, poured, sprinkled or sprayed on, or introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering appearance and (2) articles intended for use as a component of any such article. This term shall not include soap.

Device Master Record (DMR): A compilation of records containing the procedures and specifications for a finished device. [21CFR820.3]

Drug or Drug Substance: An active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body. [21CFR314.3]

Drug Product: A finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients. [21CFR314.3]

FD&C Act: The Federal Food, Drug, and Cosmetic Act. [21USC301-397]

FDA-Approved: An FDA designation given to drugs, biologics, and medical devices that have approved marketing applications. Additional or modified medical indications for use require the submission of an amendment or a new marketing application. A new marketing application may require additional human clinical data acquired through IND regulations.

General Controls: The baseline requirements of the FD&C Act that apply to all medical devices. In addition to prohibiting adulteration, misbranding, and banned devices, the general controls contain requirements for device manufacturers. These requirements include device listing, proper labeling, (manufacturing) establishment registration, and premarket notification [510(k)].

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials. It provides assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected. [62 FR 25692]

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[91] 62 FR 25692 (May 9, 1997) is an International Conference on Harmonisation (ICH) document called *Good Clinical Practice: Consolidated Guideline*. This document addresses GCP principles that were adopted for use as guidance for industry. ICH is a joint initiative involving both regulators and industry as equal partners in the scientific and technical discussions of the testing procedures that are required to ensure and assess the safety, quality and efficacy of medicines.

Good Laboratory Practice (GLP): Practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the FDA. [21CFR58.1]

Investigational Device Exemption (IDE): Allows the investigational device to be used in a clinical study to collect safety and effectiveness data required to support a PMA application or a Premarket Notification [510(k)] submission to the FDA. [21CFR50, 56, 812]

Investigational New Drug (IND): A new drug or biologic that is used in a clinical investigation. The term also includes a biological product that is used *in vitro* for diagnostic purposes. [21CFR312.3]

IND Application: Allows a pharmaceutical (drug/biologic) to be used in a study under carefully controlled and intensely monitored conditions in order to collect safety and effectiveness data required to support an NDA or BLA. [21CFR312.3]

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator (or PI). [62 FR 25692]

Label: Any display of written, printed, or graphic matter on the immediate container or package of, or affixed to any article.

Labeling: Any written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment in interstate commerce. This includes manuals, brochures, advertising, and so forth.

License: The terminology used for FDA's approval to market a biological pharmaceutical for a given set of indications (see also **FDA Approved**).

Life-Supporting or Life-Sustaining Device: A device that is essential to or that yields information that is essential to the restoration or continuation of a bodily function important to the continuation of human life. [21CFR860.3]

Medical Device: An instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory that is

- Recognized in the official National Formulary or U.S. Pharmacopoeia or any supplement to them
- Intended for use in diagnosing disease or other conditions or in curing, mitigating, treating, or preventing disease in man or other animals
- Intended to affect the structure or any function of the body of man or other animals and does not achieve any of its primary intended purposes through chemical action

within or on the body of man or other animals and is not dependent upon being metabolized for achievement of any of its primary intended purposes [Section 201(h) of the FD&C Act].

New Drug Application (NDA): An application to the FDA for approval to market a new drug. [21CFR314.50]

Preapproval Inspection (PAI): An FDA inspection of a facility to

- Verify the integrity (truthfulness, accuracy, and completeness) of data submitted in support of an application
- Evaluate the manufacturing controls for the preapproval batches upon which the application is based to be certain that the company can actually meet the commitments in the chemistry, manufacturing, and controls (CMC) section of the application
- Evaluate the capability of the manufacturer to comply with GMPs
- Collect samples for analysis.

Postmarketing Surveillance: Tracking and reporting the number and severity of adverse events attributable to each product. This may be a requirement for licensure for a defined period of time following licensure.

Premarket Approval (PMA) for Medical Devices: Because of the level of risk associated with Class III devices, an applicant must receive FDA approval of its PMA application before marketing the device. PMA approval is based on the FDA's determination that the PMA contains sufficient valid scientific evidence to ensure that the device is safe and effective for its intended use(s). [21CFR814]

Premarket Notification [510(k)]: An application submitted to the FDA to demonstrate that a device is substantially equivalent [see 21USC513(I)(1)(A)] to a device that is legally in commercial distribution in the United States before May 28, 1976, or to a device that has been determined by FDA to be substantially equivalent. [21CFR807.81]

Quality System Inspection Technique (QSIT): An FDA inspection technique that focuses on the first four elements of the seven inspectional subsets of the Quality System Regulation (QSR).

Quality System Regulation (QSR): The 1996 rewrite of the device section of the cGMPs. [21CFR820]

Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (ADR): Any untoward medical occurrence that at any dose

- Results in death
- Is life threatening

- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Causes a congenital anomaly/birth defect.

Special Controls: Class II devices include any device for which reasonable assurance of safety and effectiveness can be obtained by applying "special controls." Special controls can include special labeling requirements, mandatory performance standards, patient registries, and postmarket surveillance.

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial. [62 FR 25692]

Subject: A human who participates in an investigation, either as a recipient of the IND or as a control. [21CFR312.3]

Substantial Equivalence (SE): A device is substantially equivalent if, in comparison to a legally marketed device, it has the same intended use as a predicate device and has the same technological characteristics as the predicate device. SE does not mean the devices are identical. [21CFR807.87]

Type B Meeting: Type B meetings are (1) pre-IND meetings (21CFR312.82), (2) certain end of Phase 1 meetings (21CFR312.82), (3) end of Phase 2/pre-Phase 3 meetings (21CFR312.47), and (4) pre-NDA/BLA meetings (21CFR312.47).

ACRONYMS AND ABBREVIATIONS FOR APPENDIX H

510(k)	Premarket Notification for Medical Devices
ADR	Adverse Drug Reaction
BLA	Biologics License Application
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiologic Health
CFR	Code of Federal Regulations
cGMP	current Good Manufacturing Practice
CMC	chemistry, manufacturing, and controls
CTE	Critical Technology Element
DMR	Device Master Record
DoD	Department of Defense
FD&C	Federal Food, Drug, and Cosmetic
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
HIV	Human Immunodeficiency Virus
HW/SW	hardware/software
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IM/IT	Information Management/Information Technology
IND	Investigational New Drug Application
IOT&E	initial operational test and evaluation
MDA	Milestone Decision Authority
NASA	National Aeronautics and Space Administration
NDA	New Drug Application

PAI	Preapproval Inspection
PI	principal investigator
PM	program manager
PMA	Premarket Approval
POC	point of contact
QSIT	Quality System Inspection Technique
QSR	Quality System Regulation
R&D	research and development
RDT&E	research, development, test and evaluation
S&T	science and technology
SAE	Serious Adverse Event
SE	Substantial Equivalence
T&E	test and evaluation
TRL	Technology Readiness Level
USC	United States Code
USAMRMC	United States Army Medical Research and Materiel Command

APPPENDIX I.
MANUFACTURING READINESS LEVELS (MRLs)

I.1. BACKGROUND

Manufacturing readiness and producibility are as important to the successful development of a system as are readiness and the capabilities of the technologies intended for the system. Their importance has long been recognized in Department of Defense (DoD) acquisition. They remain central to achieving the Secretary of Defense's transformational goals to realign support to the warfighter by reducing acquisition cycle times and eliminating cost growth.[92]

DoD Manufacturing Readiness Levels (MRLs) are designed to be measures used to assess maturity from a manufacturing perspective. The purpose of MRLs is to provide decision-makers (at all levels) a common understanding of the relative maturity (and attendant risks) associated with manufacturing technologies, products, and processes being considered to meet DoD requirements.

A Transition Working Group, comprised of representatives from the Military Services, Defense Logistics Agency (DLA), Missile Defense Agency (MDA), and industry, recently addressed the issue of the rapid, affordable transition of technology to acquisition. This group also generated an initial set of definitions and descriptions for MRLs. Subsequently, the Joint Defense Manufacturing Technology Panel (JDMTP)[93] chartered a working group to refine the initial set of MRL definitions and descriptions, to deploy MRLs within existing DoD acquisition doctrine, policy guidance, and functional critical processes, and to institutionalize MRLs within the DoD Acquisition, Technology, and Logistics (AT&L) community.

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92 2003 Secretary of Defense *Annual Report to the President and the Congress,* pp. 60–62.

93 The JDMTP vision is to rapidly transition science and technology (S&T) from discovery and invention, through engineering development, onto the factory floor, and into the hands of the warfighter. The mission is to provide a common set of terms and conditions [consistent with acquisition policy and doctrine and reconciled with Technology Readiness Levels (TRLs)] by which program management teams (at all levels) can assess the relative maturity and risks associated with technologies being considered to meet DoD requirements. The goal is to empower all members of the acquisition team with pertinent knowledge of the risks—knowledge that is needed to make informed decisions. The objectives are to provide suggested resources (including functional concepts, activities, tools, and resources) available for program risk mitigation. These resources include most-promising technologies, manufacturing S&T voids, engineering challenges, industrial shortfalls, program risks, and risk mitigation tools and processes.

This appendix provides an overview of the processes, functional communities, programs, and challenges associated with identifying and mitigating manufacturing-associated risks in DoD acquisition programs. Also, where possible, it lists sources that can provide information about strategies or approaches. More complete guidance on DoD MRLs will be forthcoming in a DoD *MRL Guidebook*.

I.2 MANDATORY/STATUTORY REQUIREMENTS AND DoD POLICY GUIDANCE

DoD Directive (DoDD) 5000.1, *The Defense Acquisition System*, dated May 12, 2003, specifies the following:

> **E.1.14. Knowledge-Based Acquisition.** PMs 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.

DoD Instruction (DoDI) 5000.2, *Operation of the Defense Acquisition System*, dated May 12, 2003, also specifies the requirements for assessing and demonstrating the manufacturing readiness of a system at various stages of its development. Industrial capability assessments are mandatory requirements at Milestones B and C. In addition to mandatory/statutory requirements, DoDI 5000.2 provides guidance on addressing manufacturing and production-related risks to a program. These sections provide the acquisition manager practical guidelines to implement the laws and policies relative to industrial capabilities. They also provide steps a manager should follow to integrate defense industrial capabilities considerations into the acquisition process effectively and to employ the industry in acquisition programs effectively. Table I-1 provides key sections on production, quality, manufacturing, and industrial capabilities-related acquisition policy issues.

Table I-1. Key Sections From DoDI 5000.2

Section	Subject
3.4	User Needs and Technology Opportunities
3.4.2	Untitled paragraph. Discusses technology opportunities
3.7	System Development and Demonstration
3.7.1.1	Untitled paragraph. Discusses the purpose of the SDD phase
3.7.4	Proceeding Beyond the Design Readiness Review
3.7.5	System Demonstration

Table I-1. Key Sections From DoDI 5000.2 (Continued)

3.8	Production and Deployment
3.8.2	Entrance Criteria
3.8.3	LRIP
3.8.4	Full-Rate Production Criteria
E3. Enclosure 3	Statutory, Regulatory, and Contract Reporting Information and Milestone Requirements
Table E3.T1	Statutory Information Requirements
E5. Enclosure 5	Integrated Test and Evaluation
E5.1.5	Developmental Test and Evaluation (DT&E)
E5.1.5.10	Untitled paragraph. Discusses how to demonstrate the maturity of the production process

Defense Federal Acquisition Regulations Supplement (DFARS) 207.105(b)(19) specifies that, as part of the acquisition strategy, program managers (PMs) shall perform an analysis of the capabilities of the National Technology and Industrial Base to support the design, development, sustained production, and uninterrupted maintenance of the system. Specific contents of the industrial capability assessment include

- The availability of essential raw materials, special alloys, composite materials, components, tooling, and production test equipment for the sustained production of systems fully capable of meeting performance objectives established for those systems; the uninterrupted maintenance and repair of such systems; and the sustained operation of such systems
- Consideration of requirements for efficient manufacture during the design and production of the systems to be procured under the program
- The use of advanced manufacturing technology, processes, and systems during the research and development (R&D) phase and the production phase of the program.

The *Defense Acquisition Guidebook* provides policy guidance on production, quality, manufacturing, and industrial capabilities functional topics and on their integration with acquisition critical processes. Section 2.3.16.1.4.5, Industrial Capability, provides additional guidance on elements of the industrial capability assessments. Table I-2 shows other key sections.

Table I-2. Key Sections From the *Defense Acquisition Guidebook*

Chapter	Subject
2.3.7	Systems Engineering Plan
2.3.16.1.4	Potential Sources
2.3.16.3	Contract Approach

Table I-2. Key Sections From the *Defense Acquisition Guidebook* (Continued)

Chapter	Subject
2.3.17	Accounting Review
2.3.19	Additional Acquisition Strategy Topics
3.1.4	Implications of Evolutionary Acquisition
3.2.4	Cost As An Independent Variable
3.7.4.2	Assess Risk and Sensitivity
3.7.5	System Demonstration
4.1.1	Systems Engineering
4.1.5	The Integrated Product and Process Development (IPPD) Framework and Systems Engineering
4.2.3.2	Technical Planning
4.2.3.6	Configuration Management
4.2.4.4	Implementation
4.2.5.1	The Use of Standards versus Capability and Maturity Models
4.2.5.2	Capability Reviews
4.3.3	System Development and Demonstration Phase
4.3.3.4.5	Critical Design Review (CDR)
4.3.3.5	Outputs of the Systems Engineering Processes/Inputs to the Design Readiness Review
4.3.3.6	Purpose of Systems Engineering in System Demonstration
4.3.3.8.4	Combined Developmental Test and Evaluation, Operational Test and Evaluation, and Live Fire Test and Evaluation Demonstrate System To Specified User Needs and Environmental Constraints
4.3.3.9.2	System Verification Review (SVR)
4.3.3.9.3	Production Readiness Review (PRR)
4.3.4.1	Purpose of Systems Engineering in Production and Deployment
4.3.4.4.3	Physical Configuration Audit (PCA)
4.3.5.1	Purpose of Systems Engineering in Operations and Support
4.4.4	Software
4.4.6	Manufacturing Capability
4.4.6.2	Manufacturing Readiness Levels
4.4.7	Quality
4.4.8	Reliability, Availability, and Maintainability (RAM)
4.5.6	Trade Studies
4.5.7.3	Modeling and Simulation (M&S) in Systems Development and Demonstration
4.5.7.4	Modeling and Simulation (M&S) in Production and Development
5.2.1.5	Continuous Technology Refreshment and Obsolescence
5.2.2	Pre-Acquisition and Acquisition (Design for Support)

Table I-2. Key Sections From the *Defense Acquisition Guidebook* (Continued)

Chapter	Subject
5.4.1.1.2	Life-Cycle Logistics (LCL) Considerations During Concept Refinement
5.4.2.1	System Development and Demonstration Leading to Milestone C
6.4.1	Integrated Product and Process Development and Integrated Product Teams
6.4.5.2	Technology Development and System Development and Demonstration
7.8.3.3	Redesigning the Processes That the Acquisition Supports
8.4.4.1	Risk Management in Systems Engineering
8.4.5.1	Critical Program Information (CPI)
9.1.3.3	Capability Production Document (CPD)
9.3	Developmental Test and Evaluation
9.10	Test and Evaluation Master Plan Recommended Format
11.2.1.1	International Considerations and Program Strategy
11.3.5	Quality
11.5	Knowledge-Based Acquisition
11.8	Integrated Product and Process Development (IPPD)
11.13	Simulation-Based Acquisition (SBA) and Modeling and Simulation (M&S)

Guidance on the transition from development to production can be found at the AT&L Knowledge Sharing System (AKSS) Web site. AKSS, which is part of the Defense Acquisition University Knowledge System,[94] was launched in October 2002 to replace the *Defense Acquisition Deskbook (DAD)*. Like its predecessor, AKSS continues to provide acquisition information for all DoD Service components and across all functional disciplines. It emphasizes the need for a rigorous, disciplined application of fundamental engineering principles, methods, and techniques and the identification and assessment of program risk elements throughout the acquisition cycle. Finally, it provides "templates" designed to introduce discipline into the acquisition process, to identify and give visibility to high-risk factors, and to provide the tools by which risk can be minimized progressively in major risk categories (funding, design, test, production, transition plan, facilities, logistics, and management).

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94 AKSS is one part of the Defense Acquisition University Knowledge System. The two sites are the Acquisition Knowledge Sharing System (http://www.deskbook.osd.mil/jsp/default.jsp) and the Acquisition Community Connection (http://www.deskbook.osd.mil/jsp/AkssPage.jsp?fName=../jsp/community_central.jsp&title=AKSS%20Community%20Central).

I.3 KEY ELEMENTS (THREADS) OF THE INDUSTRIAL PROCESS

Understanding the risks associated with the industrial process in DoD acquisition and developing risk mitigation plans and action are central to successful acquisition program management. These risk elements are discrete (for each phase) and constitute nine threads that transcend the transition from discovery and invention, through engineering and development, to production and deployment, and eventual disposal.

I.3.1 Technology and Industrial Base Thread

This thread requires an analysis of the capabilities of the national technology and industrial base to support the design, development, production, operation, uninterrupted maintenance support of the system, and eventual (environmentally conscious) disposal.

Key issues for the Technology and Industrial Base Thread include

1. Technology base maturity [Technology Readiness Level (TRLs)]
2. Technology leadership (domestic vs. foreign and commercial vs. Government)
3. Manufacturing technology voids
4. Industrial sector structure, trends, capabilities, and capacities (including potential subcontractors, suppliers, and vendors).

I.3.2 Design Thread

This thread requires an analysis of the degree to which the identified/evolving system design will meet user requirements and the degree to which the design is new and unproven.

Key issues for the Design Thread include

1. Design approach, maturity (percentage of design that is new), and stability
2. Design analyses and tools, Design for Excellence (DFX) (X = producibility engineering, design for manufacturing and assembly, testability, cost effectiveness, and other planning efforts)
3. Use of multifunctional Integrated Process Teams (IPTs) (includes manufacturing considerations as tradeoffs)
4. Configuration and block change management
5. Manufacturing, testability, and methods improvement
6. Manufacturing management issues in design reviews and manufacturing-specific reviews (including Manufacturing Feasibility Reviews, Manufacturing Capability Risk Reviews, Producibility Trade Studies and Reviews, and Production Readiness Reviews).

I.3.3 Materials Thread

This thread requires and analysis of the risks associated with materials (including basic/raw materials, components, semi-finished, parts, and subassemblies).

Key issues for the Materials Thread include

1. Availability and degree of competition
2. Sources (domestic/foreign/single/sole/diminishing) and Make/Buy Plan
3. Use of commercial-of-the-shelf/non-developmental items/commercial items
4. Costs, lead times, and capacity constraints and scale-up challenges
5. Understanding materials' basic properties and environmental considerations
6. Characterization in a manufacturing environment
7. Storage, handling, and parts control.

I.3.4 Cost and Funding Thread

This thread requires an analysis of the risk that the system development and deployment will not meet the DoD cost and funding goals.

Key issues for the Cost and Funding Thread include

1. Early manufacturing involvement in technology development and selection
2. Establishment of design-to-cost (DTC) and manufacturing cost goals
3. Cost-reduction activities
4. Progress toward meeting goals
5. Availability of necessary funding
6. Plans for cost mitigation.

I.3.5 Process Capability and Control Thread

This thread requires an analysis of the risk that the manufacturing processes may not be able to reflect (repeatably and affordably) in the design of key characteristics.

Key issues for the Process Capability and Control Thread include

1. Process characterization
2. Variation and variability reduction
3. Identification of key characteristics and process capability indexes
4. Sigma levels.

I.3.6 Quality Management (QM) Thread

This thread requires an analysis of the risk and management efforts to control quality and foster continuous quality improvement.

Key issues for the QM Thread include

1. Planning for quality
2. The quality organization and strategy
3. Prime contractor QM plan
4. Key supply chain QM structures
5. Understanding the contractor's quality model
6. Deployment of risks into contract language
7. Coordination with Defense Contract Management Agency (DCMA) resources.

I.3.7 Personnel Thread

This thread requires the assessment of the skills and availability of the people required to support the manufacturing effort.

Key issues for the Personnel Thread include

1. Involvement with the S&T and Manufacturing Technology programs
2. Manufacturing involvement in the systems engineering and IPPD processes
3. Manufacturing planners, schedulers, and control personnel
4. Tooling and industrial engineers
5. Process operators (including training plans and required certifications).

I.3.8 Facilities Thread

This thread requires an analysis of the capabilities and capacity (prime, subcontractor, supplier, vendor, maintenance, and repair) that are key risks in manufacturing.

Key issues for the Facilities Thread include

1. Location (domestic or foreign)
2. New or existing lines
3. Dedicated or shared
4. Commercial or traditionally defense
5. Government or contractor owned/operated (organic, commercial, or core)
6. Local environmental laws and regulations
7. Labor unions
8. Capacity utilization
9. Use of manufacturing development centers/pilot lines.

I.3.9 Manufacturing Planning, Scheduling, and Control Thread

This thread requires an analysis of the integration of all the elements needed to translate the design into an integrated and fielded system (meeting program goals for affordability and availability).

Key issues for the Manufacturing Planning, Scheduling, and Control Thread include

1. Adequacy of the manufacturing strategy
2. Integration with the acquisition strategy
3. Maturity of the manufacturing plan
4. Integration with the risk management plan
5. Scheduling tooling
6. Capital equipment installation and maintenance
7. Personnel
8. Deliveries (i.e., materiel management)
9. Product flow and test equipment
10. Supply chain management.

In support of these threads, the AT&L production, manufacturing, and quality function has promulgated a set of core activities designed to address associated risks and mitigation activities (see Figure I-1). Within each acquisition phase, a mature body of knowledge, doctrine, and tools for critical processes supports these activities.

I.4 MRLs

MRLs are designed to provide a standard set of functional definitions and terms for the AT&L community so that it can accomplish its tasks and reporting requirements. These MRLs provide a common language for the S&T and acquisition communities in the following areas:

- **DoD investments in Basic Research [i.e., Program Element (PE) 6.1)].** An early understanding of the basic principles observed and reported could benefit from knowledge of ongoing research activities into the understanding of basic manufacturing sciences and theories.
- **DoD investments into Exploratory Research (i.e., PE 6.2).** DoD S&T PMs would benefit from a knowledge of advanced manufacturing technologies (including materials, processes, and systems). This knowledge will assist them in making informed decisions on selections of the most promising technologies and materials being considered for DoD (from an eventual manufacturing cost and schedule baseline perspective for early tradeoffs).

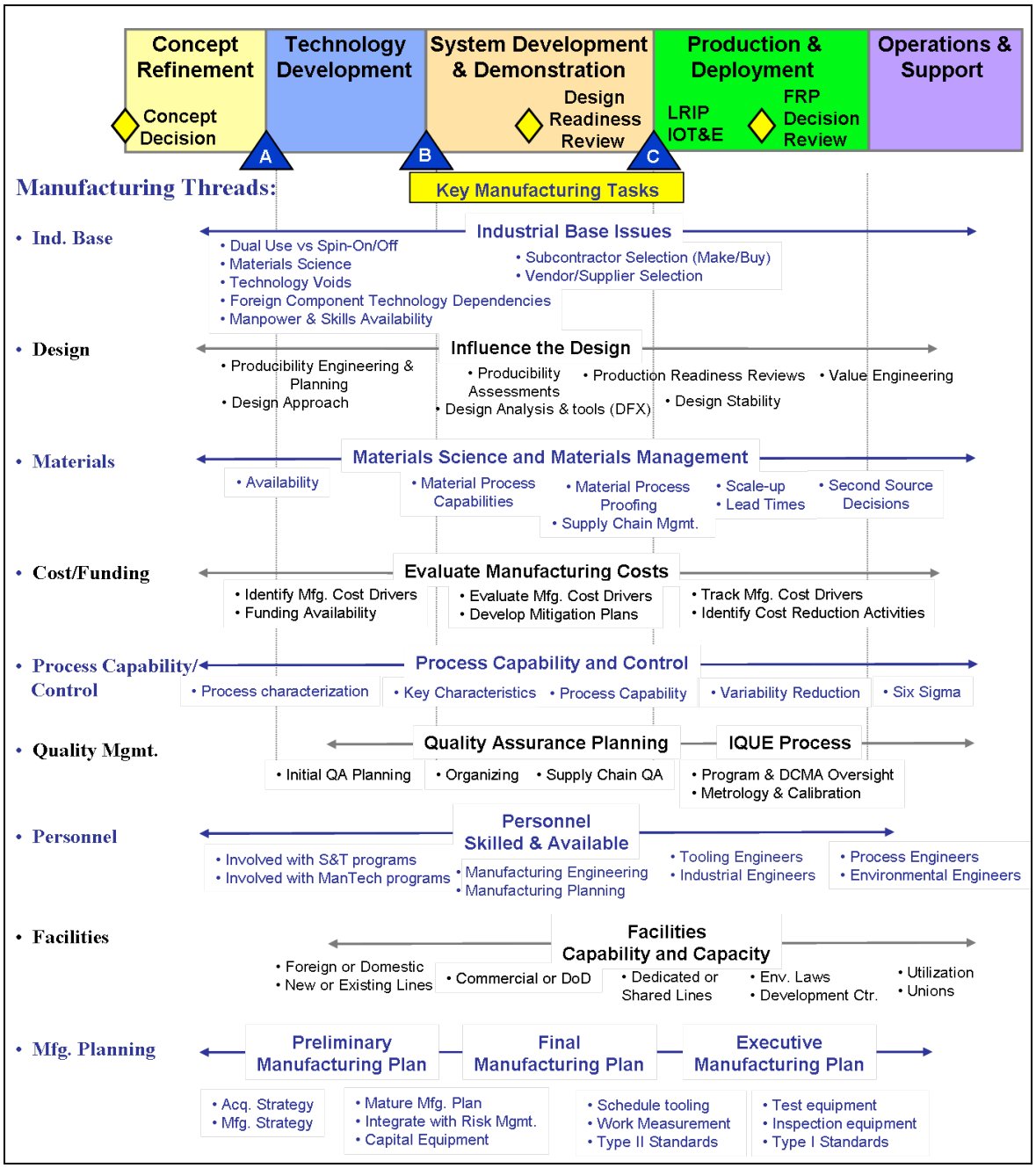

Figure I-1. Associated Risks and Mitigation Activities
[Source: Defense Acquisition University (DAU) Course Materials]

- **Upon approval for entry into, for example, Advanced Technology Demonstration (ATD), Advanced Concept Technology Demonstration (ACTD), or Milestone B.** DoD R&D activities must address the industrial and manufacturing capabilities (and risks) needed to support programs. Technical issues include design performance (including reliability and product

variation). Business issues include cost (i.e., design, producibility, contractor methods, and improvement incentives), schedule (i.e., facility manufacturing capabilities and capacities), and performance (i.e., contractor quality and environmental safety and health considerations).

- **Sustaining the operational system**. This includes a knowledge of industrial technologies, capabilities, capacities, and (eventual) disposal risks.

I.4.1 MRL Levels, Definitions, Descriptions, and Acquisition Phases

Table I-3 shows the current iteration of proposed DoD MRLs. The MRL definitions and descriptions are based on the integration of existing industry, government, and technical coalition standards and recommendations. MRLs 1 to 3 have been added to tie ongoing DoD investments and activities in manufacturing science and advanced manufacturing technology explorations to corresponding TRLs. MRL 10 has been added to emphasize continuous process improvement in the industrial environment. MRL definitions have been refined to incorporate DoD S&T and acquisition doctrinal standard phraseology. MRL descriptions have been organized to provide a comprehensive set of core risk categories (threads) that transcend all levels of manufacturing readiness.

Table I-3. Current Iteration of Proposed DoD MRLs

MRL	Definition	Description	Acquisition Phase
1–3	Manufacturing concepts Identified.	Identification of current manufacturing concepts or producibility needs based on laboratory studies.	Pre-Concept Refinement.
4	System, component, or item validation in a laboratory environment.	This is the lowest level of production readiness. Technologies must have matured to at least TRL 4. At this point, few requirements have been validated, and there are large numbers of engineering/design changes. Component physical and functional interfaces have not been defined. Materials, machines, and tooling have been demonstrated in a laboratory environment. Inspection and test equipment have been demonstrated in a laboratory environment. Manufacturing cost drivers are identified. Producibility assessments have been initiated.	Concept Refinement leading to a Milestone A decision.
5	System, component, or item validation in initial relevant environment. Engineering application/ breadboard, brassboard development.	Technologies must have matured to at least TRL 5. At this point, all requirements have not been validated, and there are significant engineering/design changes. Component physical and functional interfaces have not been defined. Materials, machines, and tooling have been demonstrated in a relevant manufacturing environment, but most manufacturing processes and procedures are in development (or ManTech initiatives are ongoing). Inspection and test equipment have been demonstrated in a laboratory environment. Production cost drivers/goals are analyzed. System-level DTC goals are set. Producibility assessments ongoing.	Technology Development leading to a Milestone B decision.

Table I-3. Current Iteration of Proposed DoD MRLs (Continued)

MRL	Definition	Description	Acquisition Phase
6	System, component or item in prototype demonstration beyond breadboard, brassboard development.	During the prototype demonstration phase, requirements are validated and defined. However, there are still many engineering/design changes, and physical and functional interfaces are not yet fully defined. Technologies must have matured to at least TRL 6. Raw materials are initially demonstrated in relevant manufacturing environment. Similar processes and procedures have been demonstrated in relevant manufacturing environment. At this point, there are likely major investments required for machines and tooling. Inspection and test equipment should be under development. Producibility risk assessments ongoing and trade studies conducted. A production Cost Reduction Plan is developed. Production goals are met.	System Development and Demonstration (SDD) leading to Design Readiness Review (DRR).
7	System, component or item in advanced development.	Technologies must have matured to at least TRL 7. At this point, engineering/design changes should decrease. Physical and functional interfaces should be clearly defined. All raw materials are in production and available to meet planned Low Rate Initial Production (LRIP) schedule. Pilot line manufacturing processes and procedures set up and under test. Processes and procedures not yet proven or under control. During this phase, initial producibility improvements should be underway. DTC estimates are less than 125 percent of goals. Detailed production estimates are established.	SDD; post DRR.
8	System, component or item in advanced development. Ready for LRIP.	Technologies must have matured to at least TRL 8. At this point, engineering/design changes should decrease significantly. Physical and functional interfaces should be clearly defined. All raw materials are in production and available to meet planned LRIP schedule. Manufacturing processes and procedures have been proven on the pilot line and are under control and ready for LRIP. During this phase, initial producibility risk assessments should be completed. Production cost estimates meet DTC goals.	SDD leading to a Milestone C decision.
9	System, component, or item previously produced or in production, *or* the system, component, or item is in LRIP. Ready for Full Rate Production (FRP).	During LRIP, all systems engineering/design requirements should be met, and there should only be minimal system engineering/design changes. Technologies must have matured to at least TRL 9. Materials are in production and available to meet planned production schedules. Manufacturing processes and procedures are established and controlled in production to three-sigma or some other appropriate quality level. Machines, tooling, and inspection and test equipment deliver three-sigma or some other appropriate quality level in production. Production risk monitoring is ongoing. LRIP actual costs meet estimates.	Production and deployment leading to an FRP decision.

Table I-3. Current Iteration of Proposed DoD MRLs (Continued)

MRL	Definition	Description	Acquisition Phase
10	System, component, or item previously produced or in production, *or* the system, component, or item is in FRP.	The highest level of production readiness. Minimal engineering/design changes. System, component, or item is in production or has been produced and meets all engineering, performance, quality, and reliability requirements. All materials, manufacturing processes and procedures, and inspection and test equipment are controlled in production to six-sigma or some other appropriate quality level in production. A proven, affordable product is able to meet the required schedule. Production actual costs meet estimates.	FRP/ sustainment

MRLs present a way to operationally define, measure, and manage manufacturing maturity (i.e., through a structured approach and using proven tools and techniques to identify and quantify). Once identified, these MRLs provide visibility into manufacturing and program risk areas and can be used as a part of a comprehensive risk identification and mitigation program. As such, they must address the basic elements of a manufacturing process.

When DoD teams address MRL accomplishments at each acquisition Milestone decision, they need a common set of manufacturing risk categories for each phase of development. These categories should build from lower to higher levels, be tied to the acquisition program's knowledge maturation, and incorporate standard phraseology and terms and approved metrics.

MRL content, focus, and depth of knowledge change as a technology proceeds from discovery, through system development, onto the factory floor, and into the hands of the warfighter. Some MRLs (i.e., 1–4) are Pre-Milestone A. Other MRLs (i.e., 5–8) are designed to support Milestones B and C and also LRIP and FRP decisions. MRL 9 is designed to support risk management needs for DoD production and reprocurement (i.e., spares and maintenance) activities. MRL 10 is designed to support FRP.

I.4.2 MRL Exit Criteria

Table I-4 provides suggested exit criteria and ties to TRLs and acquisition phase requirements against manufacturing doctrinal key elements, core activities, and critical processes. The ultimate goal is to provide knowledge of manufacturing risks to a given program (at various stages of development) to enable decision-makers (at all levels) to make informed decisions on risk mitigation strategies and plans. MRLs must be defined

Table I-4. Suggested MRL Exit Criteria

DoD MRLs									
Acquisition Phase		**Pre CR**	**CR – MS A**	**TD – MS B**	**SDD – DRR**	**Post DRR**	**MS C**	**LRIP – FRP**	**FRP**
Criteria	**Metric**	**MRL 1–3**	**MRL 4**	**MRL 5**	**MRL 6**	**MRL 7**	**MRL 8**	**MRL 9**	**MRL 10**
Technical	Technical	TRLs 1–3	Must be assessed at minimum of TRL 4.	Must be assessed at minimum of TRL 5.	Must be assessed at minimum of TRL 6.	Must be assessed at minimum of TRL 7.	Must be assessed at minimum of TRL 8.	Must be assessed at minimum of TRL 9.	Essentially no design changes.
Technology and Industrial Base	Technology and Industrial Base	Identify technology leadership (foreign/ domestic); (commercial/government.	Dual-use vs. spin on/off, commercial or government, DoD or other government.	Industrial base analysis accomplished to identify potential sources.	Industrial base (IB) exists for similar components or plan developed for developing facilities.	Sole/single/foreign sources stability is assessed/monitored.	Sources available, multi-sourcing where possible. Delivery schedules demonstrated to support LRIP build.	Prime source is on contract. Labor agreements have been established.	Monitor capacity utilization and labor issues.
Design	Producibility Program		Initial producibility evaluation on design initiated.	Producibility Engineering and Planning (PEP) activities (including DFMA) programmed.	Producibility is part of design process. Initial trade studies conducted—performance vs. producibility.	Producibility enhancements have begun.	Producibility analysis and DFMA activities complete. Process and design producibility improvements implemented.	Design producibility improvements demonstrated in LRIP. Process producibility improvements ongoing.	Design producibility improvements demonstrated in FRP. Process producibility improvements ongoing.
	Form, Fit, and Function		Form, fit, and function packaging constraints identified.	Packaging constraints are monitored and tentative plans established.	Packaging plan to meet requirements completed. Repackaging plans require no new technology and no adverse effects on producibility.	Verified that HW meets packaging plan requirements on pilot line.	Packaging changes pose no adverse effect on schedule or producibility.	Verified that HW meets packaging plan requirements in LRIP. Packaging changes pose no adverse affect on schedule or producibility.	Verified that HW meets packaging plan requirements in FRP. No packaging changes required.
	Custom Components		Custom components identified.	Custom component issues identified.	Plans completed to address custom component issues.	Custom component plan implemented.	Custom component fabrication/assembly is stable and proven on pilot line. Plan established to address any fabrication/assembly issues.	Custom components have no fabrication/ assembly rate issues adversely affecting production.	Program is in FRP, with no custom components required.
	Key Characteristics (KC)		KCs identified.	Tolerances established for KCs.		KCs evaluated against industry standards.	Pilot line build verifies that KCs can be met with manufacturing processes. No manufacturing issues associated with meeting KCs.	All KCs are controlled in production to 3-sigma or other appropriate quality level.	All KCs are controlled in production to 6-sigma or other appropriate quality level.
Materials	Maturity	Characterize basic materials for manufacturability.	Completed survey to determine if materials have been used before.		Maturity has been assessed on similar materials in production. Specific programs identified.		Materials proven and validated on pilot line.	Material is proven and controlled in LRIP.	Material is proven and controlled in FRP.
	Availability	Including scale-up challenges.	ID use of exotic/critical/ hazardous materials, and associated lead times.		ID availability issues. Complete a plan to address availability issues. ID long-lead items.		Availability issues addressed. Long-lead procurement initiated for LRIP. No availability issues pose significant effect on LRIP.	Availability issues addressed. Long-Lead procurement initiated for FRP. No availability issues pose significant effect on FRP.	Program is in FRP, with no availability issues.

Table I-4. Suggested MRL Exit Criteria (Continued)

DoD MRLs									
Acquisition Phase		**Pre CR**	**CR – MS A**	**TD – MS B**	**SDD – DRR**	**Post DRR**	**MS C**	**LRIP – FRP**	**FRP**
Criteria	**Metric**	**MRL 1–3**	**MRL 4**	**MRL 5**	**MRL 6**	**MRL 7**	**MRL 8**	**MRL 9**	**MRL 10**
Materials (Continued)	Sources		ID sole source/single source/foreign source vendors.		Complete a plan that minimizes sole/single/ foreign sources. Need for sole/single/ foreign source justified ID potential alternative sources.		Sole/single/foreign sources stability is assessed/monitored and sufficient to meet LRIP. Potential alternate sources being developed as necessary.	Sole/single/foreign sources stability is assessed/monitored. Sources available, multi-sourcing where possible. Delivery schedules demonstrated to support LRIP build.	Sole/single/foreign sources stability is assessed/monitored. Sources available for all items. Delivery schedules demonstrated to support FRP builds.
	Materials Planning		Parts lists available with associated lead times.		Make/buy evaluations initiated. Bill of Materials (BOM) initiated.		Make/buy decisions and BOM complete to support LRIP.	Make/buy decisions and BOM complete to support FRP.	Program is in FRP, with no make/buy or BOM changes.
	Special Handling		ID special-handling requirements (i.e., shelf life, HMMP, HAZMAT, storage environment, and so forth).		Special-handling issues identified. Complete a plan to address special-handling issues.		Special-handling procedures implemented on pilot line build. No special-handling issues to effect LRIP.	Special-handling procedures demonstrated in LRIP. No special-handling issues to effect FRP.	Special-handling procedures demonstrated in FRP.
Cost and Funding	Cost – Weapon System Level		Manufacturing cost drivers Identified.	System-level DTC goals established. Manufacturing cost considerations affect technology choices and development. Manufacturing cost drivers/goals analyzed.	Subsystem- and major-component-level DTC goals established. Evaluation performed on subsystem DTC goals to show that these goals are achievable. Production cost goals set. Components/trade studies identified for potential cost reduction. A Production Cost Reduction plan developed.	DTC estimates are < 125% of cost goals. System and subsystem DTC estimates are monitored. Detailed production cost estimates established. Cost reduction efforts underway. Incentives are in place.	DTC estimates meet cost goals Production cost estimates meet cost goals.	LRIP actual costs meet goals.	Rate production actual costs meet goals.
	Cost – Technology Level		Manufacturing cost drivers Identified and goals established.	Production costs estimated and tracked against goals. Cost risk mitigation efforts active.	Production cost estimates meet DTC goals.	Production cost estimates validated.	Prototype production demonstrated at cost.		
	Funding	Identify alternative approaches and costs.	Available funding sufficient to reach MRL 5. Estimate funding needed to reach MRL 6.	Available funding sufficient to reach MRL 6. Estimate funding needed to reach MRL 7.	Available funding sufficient to reach MRL 7. Estimate funding needed to reach MRL 8.	Available funding sufficient to reach MRL 8. Estimate funding needed to reach MRL 9.	Available funding sufficient to reach MRL 9.	Available funding sufficient to reach MRL 10.	Production budgets sufficient for production at required rates and schedule.

Table I-4 Suggested MRL Exit Criteria (Continued)

DoD MRLs									
Acquisition Phase		**Pre CR**	**CR – MS A**	**TD – MS B**	**SDD – DRR**	**Post DRR**	**MS C**	**LRIP – FRP**	**FRP**
Criteria	**Metric**	**MRL 1–3**	**MRL 4**	**MRL 5**	**MRL 6**	**MRL 7**	**MRL 8**	**MRL 9**	**MRL 10**
Process Capability and Control	M&S (Production Line)	ID current manufacturing concepts or producibility needs based on laboratory studies.	Production M&S approaches are considered.	Production lines to be modeled are identified.	Production simulation software identified.	Initial production line simulation models developed.	Simulation models used to determine bottlenecks and improve process.	Simulation model validated by LRIP build. Production simulation models used as tool to assist in managing LRIP.	Simulation model validated by FRP build. Production simulation models used as tool to assist in managing FRP.
	Assembly Methods		ID assembly requirements.	Plan to develop processes complete.	Process development initiated. Specific automation requirements considered.	Analysis of assembly methods in relevant manufacturing environment.	All assembly methods developed, documented, and verified on pilot line.	Work instructions complete and verified. Assembly methods complete and demonstrated in LRIP.	Assembly methods demonstrated in FRP.
	Maturity	Define Manufacturing state of the art	Identify process requirements. Complete survey to determine if process has been used before.		Maturity has been assessed on similar processes in production. Specific programs identified.	Process requirements proven and validated in relevant manufacturing environment.	Process requirements proven and validated on pilot line.	Manufacturing processes and procedures are established and controlled in production to 3-sigma or other appropriate quality level.	Manufacturing processes and procedures are established and controlled in production to 6-sigma or other appropriate quality level.
	Manufacturing Technology Initiatives	Manufacturing science and advanced manufacturing technology initiatives identified.		Manufacturing technology initiatives Identified.	Required manufacturing technology initiatives efforts initiated.	Required manufacturing technology initiatives developed.	Required manufacturing technology initiatives developed/ demonstrated.	Manufacturing technology developments implemented.	All manufacturing technology requirements achieved.
	Yields		Yield assessment on similar processes complete.	Yield issues identified. Start plans for yield improvements.	Yield goals established and are realistic and achievable. Complete plans for yield improvements	Yield improvements initiated as necessary.	Yield data gathered on pilot line build.	Demonstrated LRIP yield goals are met. Yield rates acceptable for FRP.	High-rate production yield rates have been demonstrated. Yield improvement process ongoing.
	Tooling		Tooling requirements are considered.		ID tooling requirements and provide supporting rationale to denote the need for special tooling.	Complete a plan to implement tooling.	Pilot line developed and proven out using hard tooling.	Tooling demonstrated in LRIP. Multiple tooling requirements identified and procurement initiated.	Tooling demonstrated to support maximum FRP.
	Special Test Equipment (STE)		STE requirements are considered.		ID STE requirements and provide supporting rationale to denote the need for STE.	Complete a plan to implement automated STE.	Pilot line developed and proven out with STE.	STE demonstrated in LRIP. Multiple STE requirements identified and procurement initiated.	STE demonstrated to support maximum FRP.
Quality Management			Develop quality strategy. Begin quality planning	Contractor quality model analyzed. DCMA resources identified.	Contractor quality model understood. DCMA resources integrated.	Key product realization process structures identified, with special emphasis on supply chain quality management.	Key product realization processes established and integrated throughout the supply chain.	Contractor and supply chain quality is at an acceptable level	Continuous quality improvement.

Table I-4 Suggested MRL Exit Criteria (Continued)

DoD MRLs									
Acquisition Phase		**Pre CR**	**CR – MS A**	**TD – MS B**	**SDD – DRR**	**Post DRR**	**MS C**	**LRIP – FRP**	**FRP**
Criteria	**Metric**	**MRL 1–3**	**MRL 4**	**MRL 5**	**MRL 6**	**MRL 7**	**MRL 8**	**MRL 9**	**MRL 10**
Manufacturing Personnel	Special skills	Manufacturing functional representation on IPTs.	Special skills required are identified.	Complete a plan to minimize special skills required.	Complete a plan to implement special skills required.	Training/certification initiated for special skills required.	Special skills verified on pilot line build.	Training/certification complete. All special skills requirements are met and demonstrated in LRIP.	All special skills requirements are met and demonstrated in FRP.
Facilities	Facilities		Facility require-ments/needs identified. Survey IB.		New or existing lines. Dedicated or shared facilities.		Specific facilities in place and validated. Production flow defined.	Rate projections refined and estimated capaci-ties meet FRP require-ments. Any facility line changes are validated.	Production facilities in place and capacity demonstrated to meet maximum FRP rate requirements.
Manufacturing Planning	Manufacturing Planning, Scheduling, and Control	Coordinate with Technology Area Plan (TAP).	Develop manufacturing strategy. Integrate with acquisition strategy.	Develop initial manu-facturing plan. Inte-grate with risk management plan.	Update manufacturing plan.	Update manufacturing plan.	Update manufacturing plan.	Implement manufac-turing plan.	Update manufacturing plan.

for each technology. In addition, they must progress within the context of a system-level (i.e., material, piece part, component, subassembly, and system) perspective. They should be an integral part of a program's acquisition and risk management plans and strategies. Finally, MRLs should address program risks using standard information obtained as part of the IPPD process by IPTs.

I.4.3 MRL Risk Roll-Up Assessments for Systems and Programs

The DoD MRL process is envisioned as a two-phased effort. The first phase consists of a discrete (i.e., bottoms-up) assessment of the relative maturity of a technology (from a manufacturing and quality perspective) against DoD program goals and objectives. The second phase is designed to compile the findings of individual MRL assessments into a concise format for analysis and decision-making at subsequent levels of the program, including program risks and recommended risk mitigation actions.

At each stage of development, a technology should be assessed and evaluated for relative risk in meeting established program goals. Each MRL should be identified at the appropriate risk level (i.e., low, medium, or high). Figure I-2 provides a format.

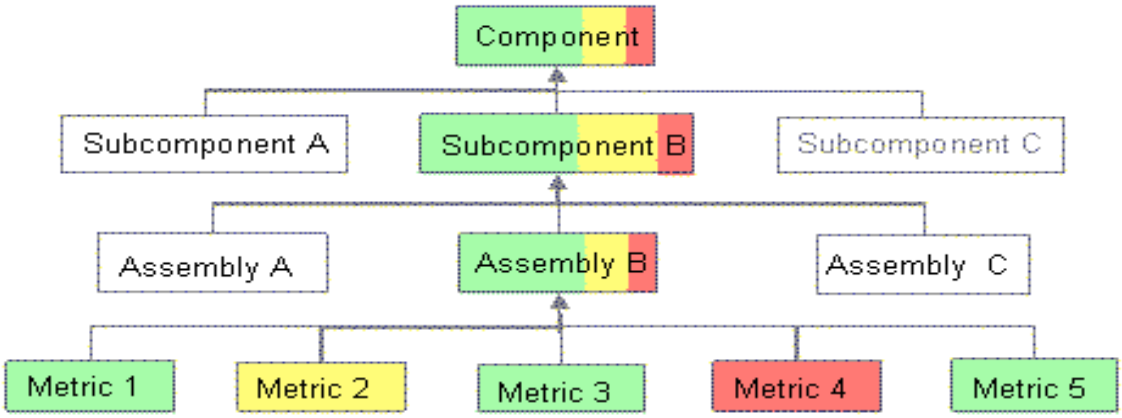

Figure I-2. Metric Roll-up Chart
[Source: MDA *Engineering and Manufacturing Readiness Level (EMRL) Draft Implementation Guide*]

Note for Figure 1-2:

Green: *Complete.*
Yellow: *Not complete; no effect on cost or schedule.*
Red: *Not complete; significant effect on cost or schedule.*

During the second phase of MRL assessments, program management should assess the risks of lower-tier MRLs (i.e., components and parts) for subsequent (i.e., higher-order) risk mitigation efforts (see Figure I-3). No magic formula exists for rolling up the effects of components, assemblies, or subsystems into one system-level metric. One of the options that make the most sense is to establish weighted guidelines that take into account the criticality of an emerging high-risk technology. It is critically important to understand that a single high-risk technology could be a program showstopper.

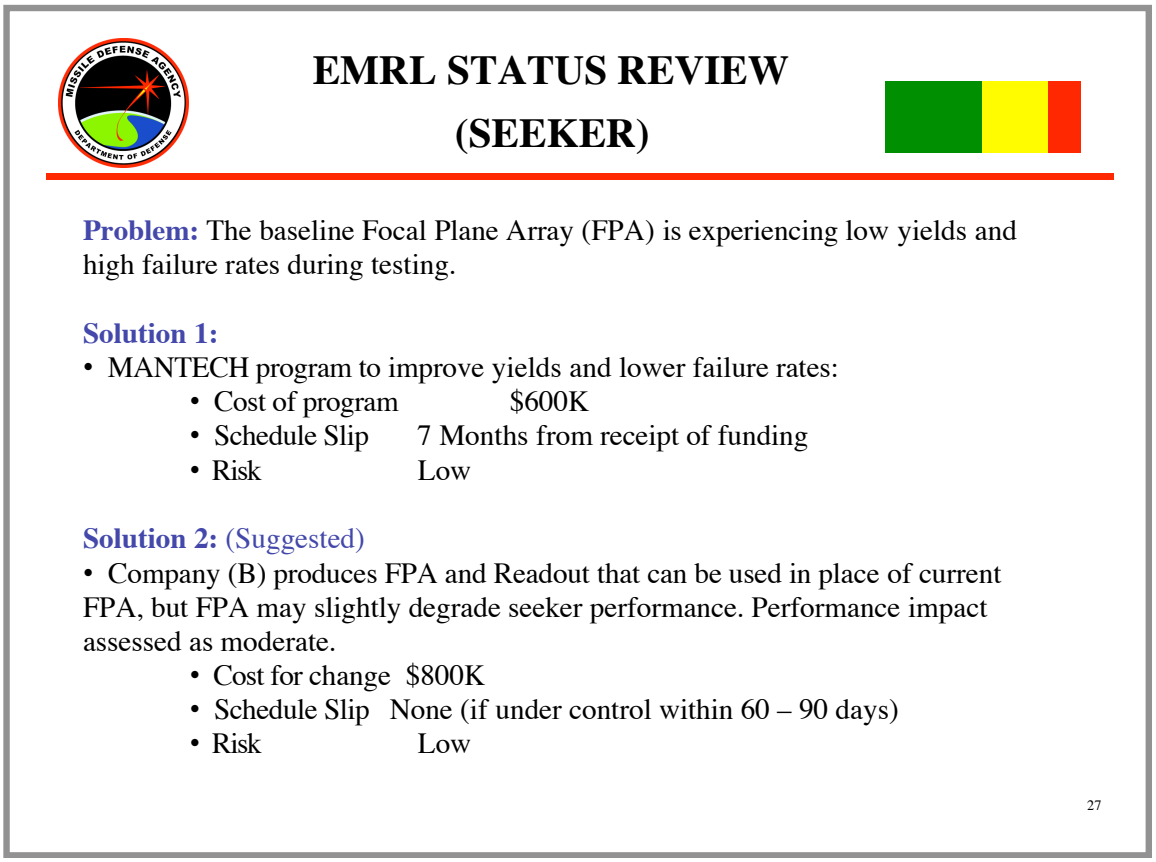

Figure I-3. Sample EMRL Status Review (Seeker)
(Source: MDA *EMRL Draft Implementation Guide*)

The status of MRLs that do not meet phase goals should be reviewed, and program management must make a decision among alternatives (see Figure I-3):

- System element (i.e., component)
- Problem (i.e., baseline component yields and failure rates during testing)
- Program effects (i.e., cost, schedule, and technical risks)
- Alternative solutions (i.e., technical, cost, schedule, and/or business).

I.4.4 Acquisition Risk Mitigation Actions

As with all acquisition program risks, those associated with industrial capabilities, manufacturing, production, and quality will require an integrated risk management strategy and plans for the program. Risk handling strategies and mitigation efforts will address two areas: technical and business. MRLs provide the IPTs with a focus on major program functional risks, a doctrinal body of knowledge of key risk areas, and core competencies for risk identification and mitigation activities.

Additional information is provided on suggested manufacturing management risk identification and management activities, tools, and techniques (see Subsection I.5). Also provided is a list of manufacturing management-related Web sites as a resource for obtaining detailed information on this body of knowledge (see Subsection I.6).

I.5 RECOMMENDED TOOLS FOR MANUFACTURING RISK IDENTIFICATION AND MITIGATION

Note: *These are only some of the tools that are available to manufacturing managers. The inclusion of these tools in this Deskbook does not constitute an endorsement of any individual or company. The tools are listed in alphabetical order.*

I.5.1 Advanced Quality Systems (AQSs)

AQSs are designed to provide suppliers the tools and the training needed so that the supplier or vendor can deliver quality products and services on time. AQSs involve the systematic reduction of variation in key characteristics. AQS process steps include

- Identifying key characteristics.
- Determining where key characteristics will be measured and setting up control charts.
- Collecting data and determining if the key characteristic is "in control." If not in control, determining the source of variation and remove the special causes of variation.
- Establishing controls for key process parameters and document in the AQS control plan.

I.5.2 Design for Manufacturing and Assembly (DFMA)™

DFMA™ is a systematic analysis of an assembly to simplify its design, assembly, and manufacturing capabilities without effecting performance. The analysis supports the

determination of the theoretical minimum number of parts that must be in the design for the product to function as required. Manufacturing costs are reduced as unnecessary parts are identified and eliminated.

I.5.3 Design of Experiments (DOE)

DOE is a structured, organized method for determining the relationship between factors and the output of a process. This knowledge allows engineers to optimize the design (robust) and improve quality, reliability, and performance while reducing costs. The goal is to achieve a "robust design" (i.e., a design that performs as intended regardless of variation in a product's manufacturing process). Off-line quality is a tool used by design and production engineering to maximize functional quality by designing and building quality in.

I.5.4 International Organization for Standardization (ISO) 9001:2000

ISO 9001:2000 is a series of international quality standards used by companies and organizations to provide a basis for ensuring customers that processes and procedures that will help to ensure quality products and services are in place. The intent of the ISO 9001:2000 series is to provide consistent customer satisfaction and improved competitiveness. ISO 9001:2000 quality standard consists of five sections; Quality Management System, Management Responsibility, Resource Management, Product Realization and Measurement, Analysis and Improvement.

I.5.5 Lean-*Pathways*®

Lean-*Pathways*® applies lean manufacturing practices on key suppliers based on their strategic importance to the program. Suppliers complete a series of diagnostic tools, training, data collection, and process mapping exercises designed to teach them how to identify improvement opportunities. The teams identify and implement solutions during Accelerated Improvement Workshops (Kaizen events) to reduce cycle times and improve work processes. The Lean-*Pathway*s process includes conducting internal operations review and mapping value streams, developing a future state analysis and identifying gaps and setting priorities, conducting in-plant opportunity reviews, developing a roadmap, hosting improvement workshops, and implementing solutions.

I.5.6 Malcolm Baldrige National Quality Award Criteria[95]

The Malcolm Baldrige National Quality Award criteria are used to improve performance and competitiveness and ensure delivery of value to the customer. The award promotes quality awareness and publicizes how businesses and organizations can use quality improvement programs to improve performance and achieve excellence. Baldrige criteria have been developed for seven key business areas: (1) leadership, (2) strategic planning, (3) customer and market focus, (4) measurement, analysis, and knowledge management, (5) human resource focus, (6) process management, and (7) business results. Improvement is based on the establishment of a documented approach, the deployment of that approach, and the results attained.

I.5.7 Manufacturing Technology (ManTech) Programs

DoD, Army, Navy, Air Force, and DLA ManTech programs contribute to the ability of the U.S. industrial base to develop, mature, and produce military equipment that is affordable and presents a low-risk production environment. The ManTech program addresses production issues early—from system development through transition to production and sustainment—by identifying and funding manufacturing risk areas and technologies. The JDMTP is organized to identify and integrate requirements, conduct Joint program planning, develop Joint strategies, and oversee the execution of ManTech programs.

I.5.8 Quality Function Deployment (QFD)

QFD is a structured methodology used to capture requirements (the voice of the customer), which then drive the design. QFD is a matrix that provides visibility into the customer requirements and design process. This matrix gives the engineers a structure for examining all of the requirements to ensure that they have developed design solutions that will meet those needs. The matrix is made up of what's, how's, customer perceptions, and other factors that will eventually be used to drive design solutions and ultimately customer satisfaction.

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95 Malcolm Baldrige was Secretary of Commerce from 1981 until his death in a rodeo accident in July 1987. Baldrige was a proponent of quality management as a key to this country's prosperity and long-term strength. He took a personal interest in the quality improvement act that was eventually named after him and helped draft one of the early versions. In recognition of his contributions, Congress named the award in his honor.

I.5.9 Six Sigma

Six Sigma provides organizations a tool for focusing on continuous improvement activities to achieve near perfection without dramatically increasing costs. Sigma is a term denoting one standard deviation. Six Sigma will encompass 99.9997 percent of the sample. In quality terms, this is approaching near perfection. Three sigma or 99.73 percent perfection, will result in 54,000 incorrect drug prescriptions a year or five missed landings at Dulles International Airport each day. Six Sigma will only lead to one incorrect drug prescription every 25 years or one missed landing in 10 years at all the U.S. airports combined. Six Sigma process steps include defining, measuring, analyzing, improving, and controlling processes.

I.5.10 Technical Risk Identification and Mitigation System (TRIMS)

TRIMS is a knowledge-based, process-oriented technical risk identification and management tool developed by the Navy's Best Manufacturing Practices Center of Excellence (BMPCOE). Based on the DoD 4245.7-M *(Transition From Development to Production)* templates and NAVSO P-6071 *(Best Practices: How to Avoid Surprises in the World's Most Complicated Technical Process)*, it provides early and continuous insight into technical risks and mitigation efforts. TRIMS is highly tailorable, flexible, and scalable for specific program needs. It is an element of the BMPCOE Program Manager's Work Station (PMWS) toolkit and provides insight into technical process risks before they become downstream cost and schedule problems.

I.5.11 Theory of Constraints (TOC)

TOC identifies constraints in a process to minimize their effect by improving throughput, productivity, and closely control resources (inventory and other expenses). A constraint is a factor that limits an organization's ability to achieve its goal. The output of a plant (or process) is dictated by the bottleneck. In TOC terms, the bottleneck is called the "drum," and it paces the plant. "Buffer" is the inventory in front of the bottleneck that is there to ensure that the bottleneck is never idle. The "rope" is the communication system used to communicate the inventory needs of the bottleneck back to the material release point. Control the bottleneck to control production. TOC process steps are

- **Step 1:** Identify the constraint.
- **Step 2:** Get more production at that constraint with the existing capacity limitations.

- **Step 3:** Keep materials from sitting idle in a queue at a nonconstrained resource.
- **Step 4:** Find other ways to increase capacity if needed (e.g., second shift).
- **Step 5:** Go back to step 1.

I.6 WEB SITES RELATED TO MANUFACTURING MANAGEMENT

Table I-5 lists some Web sites related to manufacturing management. **Note:** *Some sites may be restricted to a .mil addressee. Also, the government does not endorse any of the commercial sites.*

Table I-5. Manufacturing Management-Related Web Sites

Best Practices	Best Manufacturing Practices: http://www.bmpcoe.org Industry Week's Census of Best Manufacturing Practices: http://www.industryweek.com/
Diminishing Manufacturing Sources and Material Shortages (DMSMS)	Defense Microelectronics Activity (DMEA): http://www.dmea.osd.mil/ DMSMS GIDEP Site: http://www.dmsms.org/ and http://www.gidep.org/
Environmental	EPA's Laws and Regulations: http://www.epa.gov/epahome/lawreg.htm The Defense Environmental Network and Information eXchange (DENIX): http://sa.kevric.com/eq/eqdenix.htm Joint Group on Pollution Prevention (JG-PP): http://www.jgpp.com/
Industrial Base	DCMA's Industrial Analysis Center: http://www.dcma.mil/communicator/archives/spring%20summer%202003/industrial.htm Defense Manufacturing in 2010 and Beyond: http://books.nap.edu/html/defman/ Industrial Base Information Center: http://www.ml.afrl.af.mil/ibic/
Lean	Lean Enterprise Institute: http://www.lean.org Lean Aerospace Initiative (LAI): http://web.mit.edu/lean/index.html
ManTech	DoD: http://www.dodmantech.com Army: http://www.armymantech.com/ Navy: https://www.navymantech.com/home.html Air Force: http://www.ml.afrl.af.mil/mlm/
Process Improvement Tools	SixSigma: http://www.isixsigma.com/ ASC/EN Manufacturing Development Guide: http://www.wpafb.af.mil/alpha-index.html PMWS can be accessed from the Navy's BMPCOE Web site www.bmpcoe.org. Statistical Process Control Links [National Aeronautics and Space Administration (NASA)]: http://www.hq.nasa.gov/office/hqlibrary/ppm/ppm31.htm
Quality	Baldrige National Quality Program (BNQP): http://www.quality.nist.gov/ Quality Digest: http://www.qualitydigest.com/ Quality Online: http://qualitymag.com
Supply Chain Management	Supply Chain Council: http://www.supply-chain.org/ Supply Chain Today: http://supplychaintoday.com/

ACRONYMS AND ABBREVIATIONS FOR APPENDIX I

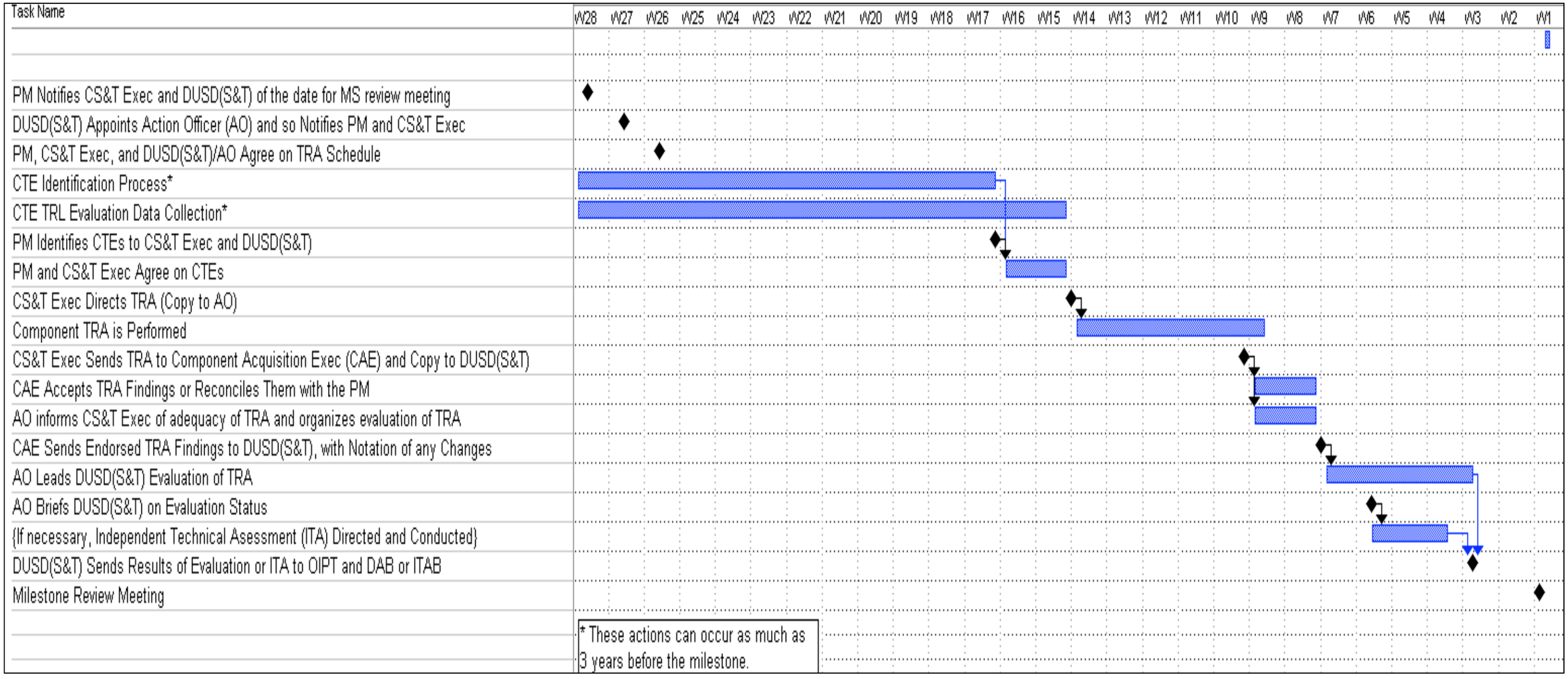
ACTD	Advanced Concept Technology Demonstration
AFRL	Air Force Research Laboratory
AKSS	AT&L Knowledge Sharing System
AQS	Advanced Quality System
ASC/EN	Aerospace Engineering Directorate (WPAFB)
AT&L	Acquisition, Technology, and Logistics
ATD	Advanced Technology Demonstration
BMPCOE	Best Manufacturing Practices Center of Excellence
BNQP	Baldrige National Quality Program
BOM	Bill of Materials
CDR	Critical Design Review
CPD	Capability Production Document
CPI	Critical Program Information
CR	Concept Refinement
DAD	Defense Acquisition Deskbook
DAU	Defense Acquisition University
DTC	design-to-cost
DCMA	Defense Contract Management Agency
DENIX	Defense Environmental Network and Information eXchange
DFARS	Defense Federal Acquisition Regulations Supplement
DFMA	Design for Manufacturing and Assembly
DFX	Design for Excellence
DLA	Defense Logistics Agency
DMEA	Defense Microelectronics Activity
DMSMS	Diminishing Manufacturing Sources and Material Shortages
DoD	Department of Defense

DoDD	Department of Defense Directive
DoDI	Department of Defense Instruction
DOE	Design of Experiments
DRR	Design Readiness Review
DT&E	developmental test and evaluation
DTC	design-to-cost
EMRL	Engineering and Manufacturing Readiness Level
EPA	Environmental Protection Agency
FRP	Full Rate Production
GIDEP	Government-Industry Data Exchange Program
HAZMAT	hazardous material
HMMP	Hazardous Material Management Program
HW	hardware
IB	industrial base
ICA	Industrial Capability Assessment
ID	identify
IOT&E	Initial Operational Test and Evaluation
IPPD	Integrated Product and Process Development
IPT	Integrated Process Team
ISO	International Organization for Standardization
JDMPT	Joint Defense Manufacturing Technology Panel
JG-PP	Joint Group on Pollution Prevention
KC	Key Characteristics
LAI	Lean Aerospace Initiative
LCL	Life-Cycle Logistics
LRIP	Low Rate Initial Production
M&S	modeling and simulation
ManTech	Manufacturing Technology
MDA	Missile Defense Agency
MRL	Manufacturing Readiness Level
MS	Milestone
NASA	National Aeronautics and Space Administration

NAVSO	Navy Staff Office
NIST	National Institute of Standards and Technology
PCA	Physical Configuration Audit
PEP	Producibility Engineering and Planning
PMWS	Program Manager's Work Station
PR	Program Element
PRR	Production Readiness Review
QFD	Quality Function Deployment
QM	quality management
R&D	research and development
RAM	Reliability, Availability, and Maintainability
S&T	science and technology
SBA	Simulation-Based Acquisition
SDD	System Development and Demonstration
STE	Special Test Equipment
SVR	System Verification Review
T&E	test and evaluation
TAP	Technology Area Plan
TD	Technology Development
TOC	Theory of Constraints
TRIMS	Technical Risk Identification and Mitigation System
TRL	Technology Readiness Level
WPAFB	Wright Patterson Air Force Base

APPENDIX J.
EASY-REFERENCE DISPLAYS OF THE TRA ACTIVITIES TIME LINE AND THE HARDWARE/SOFTWARE TRLs

Suggested Time Line for TRA Activities for ACAT ID and IAM Programs



Hardware and Software Technology Readiness Levels (TRLs)

[Sources: *Defense Acquisition Guidebook* (October 2004) *and IT TRL Working Group Minutes* (November 2004)]

Hardware TRL Definitions, Descriptions, and Supporting Information			Software TRL Definitions, Descriptions, and Supporting Information		
TRL Definition	**Description**	**Supporting Information**	**TRL Definition**	**Description**	**Supporting Information**
1 *Basic principles observed and reported.*	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development (R&D). Examples might include paper studies of a technology's basic properties.	Published research that identifies the principles that underlie this technology. References to who, where, when.	**1** *Basic principles observed and reported.*	Lowest level of software technology readiness. A new software domain is being investigated by the basic research community. This level extends to the development of basic use, basic properties of software architecture, mathematical formulations, and general algorithms.	Basic research activities, research articles, peer-reviewed white papers, point papers, early lab model of basic concept may be useful for substantiating the TRL level.
2 *Technology concept and/or application formulated.*	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.	Publications or other references that outline the application being considered and that provide analysis to support the concept.	**2** *Technology concept and/or application formulated.*	Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies using synthetic data.	Algorithms run on a surrogate processor in a laboratory environment, instrumented components operating in laboratory environment, laboratory results showing validation of critical properties.
3 *Analytical and experimental critical function and/or characteristic proof of concept.*	Active R&D is initiated. This includes analytical studies and laboratory studies to validate physically the analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.	Results of laboratory tests performed to measure parameters of interest and comparison to analytical predictions for critical subsystems. References to who, where, and when these tests and comparisons were performed.	**3** *Analytical and experimental critical function and/or characteristic proof of concept.*	Active R&D is initiated. The level at which scientific feasibility is demonstrated through analytical and laboratory studies. This level extends to the development of limited functionality environments to validate critical properties and analytical predictions using nonintegrated software components and partially representative data.	Algorithms run on a surrogate processor in a laboratory environment, instrumented components operating in laboratory environment, laboratory results showing validation of critical properties.
4 *Component and/or breadboard validation in a laboratory environment.*	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared with the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.	System concepts that have been considered and results from testing laboratory-scale breadboard(s). References to who did this work and when. Provide an estimate of how breadboard hardware and test results differ from the expected system goals.	**4** *Module and/or subsystem validation in a laboratory environment (i.e., software prototype development environment).*	Basic software components are integrated to establish that they will work together. They are relatively primitive with regard to efficiency and robustness compared with the eventual system. Architecture development initiated to include interoperability, reliability, maintainability, extensibility, scalability, and security issues. Emulation with current/legacy elements as appropriate. Prototypes developed to demonstrate different aspects of eventual system.	Advanced technology development, stand-alone prototype solving a synthetic full-scale problem, or standalone prototype processing fully representative data sets.
5 *Component and/or breadboard validation in a relevant environment.*	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment. Examples include "high-fidelity" laboratory integration of components.	Results from testing a laboratory breadboard system are integrated with other supporting elements in a simulated operational environment. How does the "relevant environment" differ from the expected operational environment? How do the test results compare with expectations? What problems, if any, were encountered? Was the breadboard system refined to more nearly match the expected system goals?	**5** *Module and/or subsystem validation in a relevant environment.*	Level at which software technology is ready to start integration with existing systems. The prototype implementations conform to target environment/interfaces. Experiments with realistic problems. Simulated interfaces to existing systems. System software architecture established. Algorithms run on a processor(s) with characteristics expected in the operational environment.	System architecture diagram around technology element with critical performance requirements defined. Processor selection analysis, Simulation/Stimulation (Sim/Stim) Laboratory buildup plan. Software placed under configuration management. COTS/GOTS in the system software architecture are identified.
6 *System/subsystem model or prototype demonstration in a relevant environment.*	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in a simulated operational environment.	Results from laboratory testing of a prototype system that is near the desired configuration in terms of performance, weight, and volume. How did the test environment differ from the operational environment? Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level?	**6** *Module and/or subsystem validation in a relevant end-to-end environment.*	Level at which the engineering feasibility of a software technology is demonstrated. This level extends to laboratory prototype implementations on full-scale realistic problems in which the software technology is partially integrated with existing hardware/software systems.	Results from laboratory testing of a prototype package that is near the desired configuration in terms of performance, including physical, logical, data, and security interfaces. Comparisons between tested environment and operational environment analytically understood. Analysis and test measurements quantifying contribution to system-wide requirements such as throughput, scalability, and reliability. Analysis of human-computer (user environment) begun.
7 *System prototype demonstration in an operational environment.*	Prototype near or at planned operational system. Represents a major step up from TRL 6 by requiring demonstration of an actual system prototype in an operational environment (e.g., in an aircraft, in a vehicle, or in space). Examples include testing the prototype in a test bed aircraft.	Results from testing a prototype system in an operational environment. Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level?	**7** *System prototype demonstration in an operational high-fidelity environment.*	Level at which the program feasibility of a software technology is demonstrated. This level extends to operational environment prototype implementations where critical technical risk functionality is available for demonstration and a test in which the software technology is well integrated with operational hardware/software systems.	Critical technological properties are measured against requirements in a simulated operational environment.
8 *Actual system completed and qualified through test and demonstration.*	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.	Results of testing the system in its final configuration under the expected range of environmental conditions in which it will be expected to operate. Assessment of whether it will meet its operational requirements. What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before finalizing the design?	**8** *Actual system completed and mission qualified through test and demonstration in an operational environment.*	Level at which a software technology is fully integrated with operational hardware and software systems. Software development documentation is complete. All functionality tested in simulated and operational scenarios.	Published documentation and product technology refresh build schedule. Software resource reserve measured and tracked.
9 *Actual system proven through successful mission operations.*	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation (OT&E). Examples include using the system under operational mission conditions.	OT&E reports.	**9** *Actual system proven through successful mission-proven operational capabilities.*	Level at which a software technology is readily repeatable and reusable. The software based on the technology is fully integrated with operational hardware/software systems. All software documentation verified. Successful operational experience. Sustaining software engineering support in place. Actual system.	Production configuration management reports. Technology integrated into a reuse "wizard"; out-year funding established for support activity