

**Army Regulation 40–60**

**Medical Services**

# **Army Medical Materiel Acquisition Policy**

**Headquarters  
Department of the Army  
Washington, DC  
6 May 2014**

**UNCLASSIFIED**

# ***SUMMARY of CHANGE***

AR 40-60

Army Medical Materiel Acquisition Policy

This major revision, dated 6 May 2014--

- o Implements Department of Defense Directive 5000.01 and Department of Defense Instruction 5000.02 (throughout).
- o Incorporates policy from AR 70-1 which covers materiel acquisition (throughout).

Medical Services

Army Medical Materiel Acquisition Policy

By Order of the Secretary of the Army:

RAYMOND T. ODIERNO  
General, United States Army  
Chief of Staff

Official:



GERALD B. O'KEEFE  
Administrative Assistant to the  
Secretary of the Army

**History.** This publication is a major revision.

**Summary.** This regulation implements Army policies and outlines procedures for the acquisition of materiel as it pertains to The Surgeon General's responsibility for managing medical commodities.

**Applicability.** This regulation applies to the Active Army, the Army National Guard/Army National Guard of the United States, and the U.S. Army Reserve, unless otherwise stated.

**Proponent and exception authority.** The proponent of this regulation is The Surgeon General. The proponent has the authority to approve exceptions or waivers to this regulation that are consistent with

controlling law and regulations. The proponent may delegate this approval authority, in writing, to a division chief within the proponent agency or its direct reporting unit or field operating agency, in the grade of colonel or the civilian equivalent. Activities may request a waiver to this regulation by providing justification that includes a full analysis of the expected benefits and must include formal review by the activity's senior legal officer. All waiver requests will be endorsed by the commander or senior leader of the requesting activity and forwarded through their higher headquarters to the policy proponent. Refer to AR 25–30 for specific guidance.

**Army internal control process.** This regulation contains internal control provisions and provides an Internal Control Evaluation for use in evaluating key internal controls (see appendix B).

**Supplementation.** Supplementation of this regulation and establishment of command and local forms are prohibited without prior approval from The Surgeon General, 7700 Arlington Boulevard, Falls Church, VA 22042–5144.

**Suggested improvements.** Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) directly to The Surgeon General (DASG–LOZ), 7700 Arlington

Boulevard, Falls Church, VA 22042–5144.

**Committee management.** AR 15–1 requires the proponent to justify establishing/continuing committee(s), coordinate draft publications, and coordinate changes in committee status with the U.S. Army Resources and Programs Agency, Department of the Army Committee Management Office (AARP–ZA), 9301 Chapek Road, Building 1458, Fort Belvoir, VA 22060–5527. Further, if it is determined that an established "group" identified within this regulation, later takes on the characteristics of a committee, as found in the AR 15–1, then the proponent will follow all AR 15–1 requirements for establishing and continuing the group as a committee.

**Distribution.** This publication is available in electronic media only and is intended for command levels A, B, C, D and E for the Active Army, the Army National Guard/Army National Guard of the United States, and the U.S. Army Reserve

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## Chapter 1 Introduction

### 1–1. Purpose

This regulation implements Department of Defense (DOD) Directive (DODD) 5000.01, Department of Defense instruction (DODI) 5000.02, and Army Regulation (AR) 70–1, and establishes the Army’s policy for medical acquisition programs. This policy applies to those acquisition programs funded by Army resources, as well as to those assigned to the Army for execution by the Assistant Secretary of Defense for Health Affairs (ASD(HA)) and funded by Defense Health Program (DHP) resources. It does not cover the acquisition of capital investment equipment for TDA Health Care Activities, or the initial outfitting of expanded or newly constructed health care facilities, which are procured under the Army’s centrally funded medical care support equipment (MEDCASE) program, in accordance with AR 40–61. This regulation also specifies Army acquisition workforce management responsibilities within the U.S. Army Medical Department (AMEDD).

### 1–2. References

Required and related publications and prescribed and referenced forms are listed in appendix A.

### 1–3. Explanation of abbreviations and terms

Abbreviations and special terms used in this regulation are explained in the glossary.

### 1–4. Responsibilities

Responsibilities are listed in chapter 2.

### 1–5. Tenets of Army medical acquisition

*a.* The purpose of Army medical acquisition is to field required medical products efficiently, on time, and within all budgetary, ethical, and legal constraints.

*b.* Projects must be affordable, and must meet a validated military need. Project leaders at all levels should balance their responsibility as program advocate with those as a steward of taxpayer resources. Project leaders should continuously evaluate their programs to ensure that they meet a valid military requirement, and will be affordable through the planned product lifetime. Project leaders should notify decision makers as soon as they believe a program’s projected cost may exceed its benefit to the Army.

*c.* Integrated product teams (IPTs) are integral to medical acquisition. Product development efforts require significant lifecycle analysis and planning, and this is most effective with a multi-disciplinary approach.

### 1–6. General medical acquisition policy and guidance

*a.* The AMEDD will acquire only U.S. Food and Drug Administration (FDA) or Environmental Protection Agency (EPA) approved products for Soldier use, whenever such approvals would be needed for civilian-use products.

*b.* Acquisition strategies will maximize use of commercial and non-developmental products and processes. Acquiring commercial or non-developmental products to meet capability shortfalls presents a significant opportunity to Army medicine to realize capabilities with predictable and lower costs, shorter schedules to field, and reduced technical risk, while maintaining a standard of care consistent with current medical practice.

*c.* The AMEDD will integrate acquisition policy contained in DODD 5000.01, DODI 5000.02, and AR 70–1 with FDA/EPA requirements, while streamlining and tailoring procedures within statutory and program requirements. The AMEDD Process that integrates DOD acquisition and FDA/EPA regulations is referred to as the Decision Gate Process.

*d.* The AMEDD will use integrated, multidisciplinary teams to plan and execute acquisition functions. These IPTs will include key stakeholders for each program, from both within and outside of the AMEDD, as necessary. IPT chairs are responsible to ensure that necessary stakeholders are included on the IPT and identified in their IPT charter.

## Chapter 2 Army Responsibilities and Department of Defense Roles

### Section I Department of the Army

#### 2–1. The Surgeon General

*a. The Surgeon General (TSG)/Commanding General, MEDCOM will—*

(1) Oversee all aspects of the organization, administration, and staff supervision of activities that manage medical materiel.

(2) Approve medical materiel management systems, including automated and manual, and the medical materiel acquisition process, programs, and program data throughout the Army. This includes the composition and budgeting of medical assemblages and procurement appropriation-funded medical materiel equipment.

(3) Provide advice and assistance to Headquarters, Department of the Army (HQDA) agencies and Army activities on MEDLOG procedures and MEDLOG systems.

(4) Appoint one U.S. Army Medical Department (AMEDD) representative to serve as a member of the Defense Medical Materiel Program Office (DMMPO).

(5) Provide the Army's functional input to DOD Medical Logistics MEDLOG systems and serve as the functional proponent of Department of the Army MEDLOG systems.

(6) Exercise overall responsibility as the force provider for all medical materiel mobilization programs and support for deployed and deploying forces.

(7) Exercise overall responsibility as the force provider for all Army Medical Treatment Facilities.

(8) Responsible official for medical materiel in the Army repositioned stock (APS) program.

(9) Manage the MEDLOG applications of the Army Logistics Civil Augmentation Program (see AR 700-137).

(10) Manage worldwide medical materiel logistics assistance for Army activities and for non-U.S. forces as approved by the Army Security Assistance Program (see AR 700-4 and AR 1-75 /Secretary of the Navy Instruction (SECNAVINST) 4900.49/Air Force Joint Instruction (AFJI) 16-104).

(11) Ensure health hazard assessments of equipment and systems that emit radiation, contain radioactive material, or expose Soldiers to any other potential health hazard not evaluated as part of the FDA or EPA approval process, have been completed as early as practical in their development and before fielding (see AR 385-10 and AR 40-10).

(12) Provide strategic medical logistics planning for contingency and mobilization requirements.

(13) Be responsible for Planning, Programming, Budgeting, and Execution (PPB&E) in the production and lifecycle management, to include pre-planned product improvement of medical Mission Equipment Packages (MEP) used onboard Army aircraft not specifically designed, produced, and procured for aeromedical evacuation but are so designated and are assigned to aeromedical evacuation units.

(14) Be responsible for developmental costs (RDT&E) associated with post-fielding modification changes derived from TSG, to medical systems or medical subsystems of Army aircraft specifically designed, produced, and procured for aeromedical evacuation.

(15) Coordinate with Medical Evacuation Proponency Directorate (MEPD), Directorate Combat Doctrine Development (DCDD), Prepotency Directorate (PD) MEDEVAC and U.S. Army Training and Doctrine Command (TRADOC) capability manager for Lift in the Joint Requirements Oversight Council and/or Joint Capabilities Integration Development System (JCIDS) validation of AMEDD capabilities requirements for the MEDEVAC MEP.

(16) Oversee the development and execution of the AMEDD Investment Strategy (AIS), an enterprise approach to synchronize efforts and initiatives to ensure consistency with Army and DOD guidance and plans.

(17) Assign Clinical Consultants will serve as the lead specialty subject matter expert to TSG, providing expert advice on proposed materiel solutions.

*b. Commanding General, Army Medical Department Center and School.* The CG AMEDDC&S, as the principal agent to CG, MEDCOM for medical combat doctrine, training development and operational test and evaluation in support of Army field medicine, will—

(1) Be responsible for developing doctrine, organization, training, and materiel requirements within the guidelines established by CG, TRADOC, through the CG, MEDCOM, in accordance with Army health care standards as established by TSG.

(2) As the combat developer—

(a) Represent the CG, MEDCOM as the Combat Developer (CBTDEV) in the acquisition process for medical materiel.

(b) Determine items of medical materiel required to—

1. Implement force development objectives.

2. Support medical concepts of operations, organization, and doctrine.

(c) Review and coordinate medical materiel proposals, equipment improvement recommendations, and suggestions to identify and evaluate the need for the new or improved medical materiel.

(d) Schedule, review, and initiate actions to modify existing medical assemblage component configuration; develop, in coordination with USAMRMC and other participants, new medical assemblages to include sets, kits, and outfits to support AMEDD missions.

(e) Initiate, in accordance with JCIDS, Army, and TRADOC policy and procedures, Army capability documents for medical materiel. Ensure all capability documents are coordinated with the materiel developer, logistician, trainer, tester and evaluator, and IPT members prior to submission for approval.

(f) Review and validate product improvement proposals for medical materiel to insure that the proposals are compatible with stated materiel objectives.

- (g) Develop proposed priorities for research, development, and acquisition (RDA) of medical materiel and medical assemblages.
  - (h) Represent the user in studies, testing, evaluations, acquisition decisions, and priority of efforts supporting the development of medical materiel.
  - (i) Review, coordinate, and comment on materiel capability documents proposed by other combat developers.
  - (j) Manage, through the Director, MEPD, and the shared and specified requirements in the Vice Chief of Staff of the Army (VCSA) Aeromedical Evacuation Charter in coordination with the CG, U.S. Army Aviation Center of Excellence (USAACE).
- (3) As training developer—
    - (a) Represent the CG, MEDCOM as the training developer in the acquisition process for medical materiel, equipment, and systems.
    - (b) Ensure training requirements are adequately identified and documented in appropriate medical capability documents in accordance with AR 71–9.
    - (c) Ensure training requirements are adequately identified and documented in appropriate capability documents. Develop system training plans in support of program capability documents in accordance with AR 350–1.
    - (d) Develop and document requirements for medical training aids, devices, simulators and simulations categorized as a non-system in accordance with the JCIDS process (see AR 71–9).
    - (e) Determine requirement for New Equipment Training (NET) to accompany medical equipment fielding, in accordance with AR 350–1.
    - (f) Participate in the NET and displaced equipment training planning process, to include a review of the training strategy as outlined in the System Training Plan in accordance with AR 350–1.
    - (g) In support of test and evaluation, develop the training strategy, requirements, and package for individual, collective and unit training; conduct or oversee training for medical program operational testing (OT) or evaluation; and certify that the Soldier players are adequately trained (see AR 73–1).
    - (h) Determine training supportability and ensure that training equipment and personnel requirements are included in basis of issue plans and supporting documents (see AR 71–32).
    - (i) Manage, through the Director, MEPD, the shared and specified requirements in the VCSA Aeromedical Evacuation Charter in coordination with the CG, USAACE.
- (4) As tester—
    - (a) Represent the CG, MEDCOM as the independent operational tester for medical acquisition.
    - (b) Prepare test design plans and conduct OTs, and user assessments of materiel having medical implications, and medical information management/information technology (IM/IT), in accordance with AR 73–1.
    - (c) Prepare and publish reports of user assessments and tests.
    - (d) Participate as members of Integrated Concept Teams (ICTs) and IPTs in accordance with AR 70–1 and AR 71–9.
    - (e) Develop and submit documents required for resourcing, scheduling, and conducting user tests on medical materiel and medical IM/IT.
    - (f) Participate as the AMEDD test representative in planning, conducting, and reporting user tests and assessments conducted by nonmedical test organizations.
- c. Commanding General, U.S. Army Medical Research and Materiel Command will—*
- (1) Serve as the Medical Materiel Developer (MATDEV), logistician, and technical and developmental tester for TSG, and act as Milestone Decision Authority (MDA) responsible for RDA and logistical support for assigned acquisition category (ACAT) II and III medical materiel programs.
  - (2) Serve as the Deputy for Medical Systems to the ASA(ALT), and advise the Army Acquisition Executive and Army Systems Acquisition Review Council concerning medical and health hazard issues during system acquisition.
  - (3) Supervise, evaluate, and exercise program direction and control over program managers (PMs).
  - (4) Conduct developmental tests, evaluations, and assessments for medical materiel systems and support operational tests.
  - (5) Act as chief technology officer to maintain and manage the medical science and technology base.
  - (6) Support and comply with the Army HHA Program, per AR 40–10.
  - (7) Develop POMs and fund requirements in support of medical RDA and logistics programs, and manage resources in accordance with the AIS.
  - (8) In coordination with Program Executive Office, PEO Aviation, manage the medical specific materiel solutions in support of aeromedical evacuation.
  - (9) Conduct PPB&E in the production and lifecycle management, to include pre-planned product improvement of medical MEP used onboard Army aircraft not specifically designed, produced, and procured for aeromedical evacuation but are so designated and are assigned to aeromedical evacuation units.
  - (10) Program and manage developmental costs (RDT&E) associated with post-fielding modification changes derived

from TSG, to medical systems or medical subsystems of Army aircraft specifically designed, produced, and procured for aeromedical evacuation.

(11) In coordination with Director, MEPD provides direction and guidance for the development, acquisition, testing, systems integration, product improvement and fielding of aeromedical evacuation medical systems.

(12) In accordance with DHA management of RDT&E, direct the use of USAMRMC scientific peer and programmatic processes as well as acquisition process to meet the ASD(HA) requirements, for executing assigned DHP RDT&E funding, Congressional Special Interests and Oversees Contingency Operations appropriations to the DHP that is consistent with the ASD(HA)'s intent, guidance, approval and all regulations and policies.

*d. Principal Assistant for Acquisition will—*

(1) Serve as the MDA, as recommended by CG, USAMRMC and delegated by the Army Acquisition Executive. As MDA, establishes the Decision Gate Process Guide to designate mandatory procedures for assigned programs in accordance with DODI 5000.02.

(2) Serve as FDA Sponsor's Representative on behalf of TSG, in accordance with the Code of Federal Regulations (CFR) 21 CFR 312 Subpart D, and AR 40-7.

(3) Oversee advanced development of assigned medical products, procurement and fielding of new technology into the medical force structure.

(4) Serve as the AMEDD Acquisition Career Management Advocate (ACMA), responsible for monitoring compliance with the Defense Acquisition Workforce Improvement Act (DAWIA) within the AMEDD. The ACMA will report compliance to the Army's Deputy Acquisition Career Manager in accordance with AR 70-1.

(5) Interface with nonmedical Program Executive Officers to develop and field medical solutions.

(6) On behalf of TSG, serve as the type classification authority for assigned products, in accordance with AR 700-142.

*e. Principal Assistant for Research and Technology PA(R&T) will—*

(1) Serve as the Technical Director and Chief Scientist for all of the Command's assigned Science & Technology (S&T) Programs, and acts for the CG, USAMRMC in executing all responsibilities for research and technology of medical materiel.

(2) Provide executive-level oversight and management, authoritative direction and guidance, develop policies and plans, and integrate and coordinate execution of all functions, operations, and activities involved in providing support for the Command's research and technology programs.

(3) Be responsible through the DHA for developing investment plans, policies, and processes to meet DOD requirements and guidance for execution management of assigned DHP RDT&E programs. Lead the staff management support of all DHP RDT&E programs within the MRMC on behalf of the CG.

(4) Direct the JPC chairs to develop programs and provide execution guidance in accordance with DHA RDT&E management consistent with the ASD(HA)'s intent and all regulations and policies.

(5) Advise and support the Principal Assistant for Acquisition and external Program Executive Officers, Project Managers, and Milestone Decision Authorities on biomedical technology options and readiness for transition to advanced development.

(6) Advise and support the Office of Medical Systems, ASA(ALT), in activities needed to support the CG's major oversight functions as the Deputy for Medical Systems.

(7) Provide advice, guidance, and ensures support, to the Medical Technology Staff Officer in the Office of the Deputy Assistant Secretary of the Army for Research and Technology.

*f. Principal Assistant Responsible for Contracting (PARC) will serve as the Procurement and Contracting Advisor to the CG and/or Head of the Contracting Activity (HCA), MRMC. The PARC is responsible for advising the CG/HCA and other Headquarters Staff on appropriate acquisition plans and methods through Command Procurement Policy in accordance with the Federal Acquisition Regulation (FAR), the Defense and Army FAR supplements, and the DOD Grants and Assistance Regulation. The PARC is also responsible for implementing local policy when necessary as well as providing oversight, training, and appointment of the Contracting Officers and Grants Officers, who are by law the Business Agents for the Government. The PARC also serves as the Director of the U.S. Army Medical Research Acquisition Activity which provide operational support to MRMC's acquisition mission by generating and managing contracts and assistance agreements for MRMC and supported customers. Other procurement organizations (agents) external to the MRMC may be designated by the PARC in cases where contracts may already exist or where other support factors may be more effectively achieved through an alternate contracting agent. The functions of the external agents may also include representing the Government in the solicitation, award, and post award management of contracts and assistance agreements to ensure that these processes are conducted in accordance with all applicable acquisition regulations.*

*g. Program, Project, and/or Product Managers. will—*

(1) Design, plan, program, coordinate, and execute assigned acquisition programs, in coordination with the IPT, to deliver a capability that meets military requirements within the approved cost-schedule-performance baseline.

(2) Identify and request resources needed to execute the approved acquisition strategy, then manage the assets provided to efficiently achieve product delivery.

(3) Form IPTs to manage acquisition projects, as medical product development is too complex and risky for any single individual to manage alone.

(4) Provide candid program assessments to leadership, to include recommending program cancellation when the program will no longer affordably meet a valid military requirement.

(5) Participates in the Command's Decision Gate (DG) process in accordance with the DG Operating Guide.

*h. Research Area Directors will—*

(1) Be responsible for planning, coordinating, and overseeing responsive research programs and execution of RDT&E funding to develop and field new medical knowledge and materiel products and implement new biomedical technologies for Service-members.

(2) Serve as the principal advisors to the Principal Assistant for (Research & Technology) PA(R&T) and provide support to other Command offices in the areas of S&T issues, requirements, initiatives, laboratory core competencies and associated infrastructure, compliance, and program justification for assigned programs in accordance with planning guidance, validated threats, and operational requirements.

(3) Provide senior-level management oversight and integrated program guidance and direction to assigned program leaders (for example, research coordinators).

(4) Serve as the chairs of the respective Joint Technology Coordinating Groups and serve on assigned committees. Serve as the Integrating IPT chairs for Army-funded S&T programs.

(5) Also serve as the JPC chairs for those research programs funded by Army S&T and DHP RDT&E funds.

(6) Provide administrative and related support for all Research Area Directorate (RAD) and/or JPC matters related to their research program.

(7) Participate in the Command's DG process in accordance with the DG Operating Guide.

*i. Office of the Staff Judge Advocate/Office of Research and Technology Applications will—*

(1) Supervise and manage the administration, control, and coordination of all patent, copyright, trademark, and other IP activities with the AMEDD.

(2) Serve as the IP and technology transfer legal technical-channel supervisor for all attorneys at all AMEDD units.

(3) Administers all legal aspects of the AMEDD's Technology Transfer Program that include review and negotiation of CRADAs, and Patent License Agreements PLAs, and IP marketing and licensing support. Assist in the implementation and/or administration of policy in this area and coordinates collaborative agreements activities of subordinate laboratories.

## **2-2. Office of Assistant Secretary of the Army for Acquisition, Logistics and Technology (ASA(ALT)) and Program Executive Officer, Aviation**

*a. The ASA(ALT)'s staff principal for medical materiel acquisition matters is the Deputy for Medical Systems. As assigned by the ASA(ALT), The Deputy, Medical Systems will—*

(1) Provide the principal HQDA staff operational interface between the Army Medical Department; HQ, MRMC; and the ASA(ALT).

(2) Serve as a special advisor to the CG, MRMC, on Congressional and DOD actions impacting medical program responsibilities.

(3) Serve as the service component acquisition link to the Armed Services Biomedical Research Evaluation Management (ASBREM) Committee Secretariat in support of the Deputy for Medical Systems.

*b. The Program Executive Office, Aviation is—*

(1) Responsible for PPB&E in the production and lifecycle management of aircraft designed, produced, and procured specifically for aeromedical evacuation, to include pre-planned product improvement of all aviation and medical systems, subsystems, and components, through the Utility Helicopters Program Office. Also responsible for integration and lifecycle management costs associated with the Surgeon General requirements resulting in post-fielding modifications to aircraft specifically designed, produced, and procured for aeromedical evacuation.

(2) Responsible for aircraft not specifically designed, produced, or procured for the aeromedical evacuation mission, responsible for integration costs associated with the medical Mission Equipment Packages.

(3) Responsible for RDA and logistical support for assigned and approved Army Acquisition Categories (ACATs) aeromedical evacuation aircraft Programs as delegated by the Army Acquisition Executive.

(4) Serve as an advisor for aviation systems to the Army Acquisition Executive (AAE) (ALT), and advise the AAE and Army Systems Acquisition Review Council concerning aeromedical evacuation issues during system acquisition.

(5) Supervise, evaluate, and exercise program direction and control over Program Managers (PMs).

(6) In coordination with the Director, MEPD, provides direction and guidance for the development, acquisition, testing, systems integration, product improvement, and fielding of aircraft and systems designed for aeromedical evacuation.

### **2-3. Chief Information Officer /G-6**

The CIO/G-6 is the Army interoperability certification (AIC) authority. The CIO/G6 will- Be responsible for AIC policy, regulations, scope, standards, roles, and responsibilities as they pertain to interoperability. All Army Information Technology-National Security System (IT/NSS) are required to be certified for interoperability by the CIO/G-6.

### **2-4. Deputy Chief of Staff, G-3/5/7**

DCS, G-3/5/7 is the final Army approval authority for all Army capability requirements through the formal military staffing process.

## **Section II**

### **Department of Defense organizations**

Although responsibilities are not assigned to DOD organizations through this AR, Army medical acquisition is dependent upon the following organizations performing their assigned responsibilities, which are noted below.

### **2-5. Assistant Secretary of Defense for Health Affairs**

The ASD(HA) performs the following in accordance with DODD 5136.01:

*a.* Exercises authority, direction and control over Defense Health Program (DHP) Research, Development, Test and Evaluation (RDT&E) activities, and approves final allocation of funds through the Defense Health Agency(DHA) based on Army recommendations for RDT&E programs assigned to the Army for execution by ASD(HA)) and funded by Defense Health Program (DHP) resources. This may include the Defense Medical Research and Development Program (DMRDP), the Congressional Special Interest, Overseas Contingency Operations (OCO)-funded programs, and other DHP RDT&E programs.

*b.* Directs the DMRDP to discover and explore innovative approaches to protect, support, and advance the health and welfare of military personnel, families, and communities.

*c.* Develops policies and guidance in support of DHP RDT&E President's Budget for DHP, Congressional Special interest (CSI) and OCO funds.

*d.* Provides guidance to accelerate the transition of medical technologies into deployed products; and to accelerate the translation of advances in knowledge into new standards of care in multiple military-relevant areas.

*e.* Approves DHP RDT&E Program Strategy Guidance prior to Program and Budget Reviews. Provides guidance for, reviews, and approves the Program Objective Memorandum, Budget Estimate Submissions and Program Budget Review. Executes the roles of OSD-level Program Resource sponsor throughout all phases of the PPB&E process. Through the DHA and the DMRDP Office provides strategic guidance throughout the DHP RDT&E program cycle.

### **2-6. Defense Logistics Agency**

DLA, as a provider of medical materiel to the DOD, performs the following roles:

*a.* Pursuant to DODD 5101.9, DOD Executive Agent (EA) for medical materiel.

(1) Establish the strategies, relationships, and expectations for Class VIII support through Performance-based agreements.

(2) Synchronize requirements and commercial capabilities.

(3) Establish a single computation and management process, and tools for surge and sustainment requirements.

(4) Extend the Defense Working Capital Fund to Theater Lead Agents.

(5) Consolidate investment in war reserve materiel surge and sustainment materiel.

(6) Monitor, assess, and report supply chain readiness metrics.

*b.* Pursuant to DOD Manual 4140.26-M, the DOD IMM for consumable items.

(1) Execute materiel management actions for the Class VIII medical supply chain to include planning, organizing, directing, coordinating, controlling, and evaluating the application of resources to ensure the effective and economical support of military forces. This will include provisioning, cataloging, requirements determination, acquisition, distribution, maintenance, and disposal.

(2) Conduct demand and supply planning that optimizes supply chain resources to meet established support strategies and employs collaboration between support providers and their customers as they relate to IMM.

(3) Structure internal IMM procedures to provide responsive, consistent, and reliable support to the Soldier during peacetime and war.

(4) Adopt and/or adapt best commercial business practices when such practices will contribute to improved IMM performance and reduced total lifecycle systems cost.

(5) Coordinate with the Services on advanced acquisition planning efforts to ensure the seamless transition of products from the advanced development to full production stage to ensure that such medical products are available for purchase through the best value, cost effective, and efficient mechanisms possible taking into account the full lifecycle support requirements for such items (for example, training, installation, and maintenance service).

(6) In collaboration with the Services, develop plans and programs that effectively project and sustain DOD forces deployed in Theaters of Operation.

(7) Develop, support, and sustain the Defense Medical Logistics Standard Support - Wholesale portfolio of systems applications to enable integration and optimization between the DOD medical logistics, transportation, and commercial industry partners.

(8) Develop, maintain, and provide business intelligence tools that assist customers in optimizing the value they receive from DLA acquisition programs at the lowest delivered cost.

(9) Provide customer assistance in the use of DLA acquisition programs and business intelligence tools to ensure DLA customers receive best value at the lowest delivered price.

## **2-7. Armed Forces Pest Management Board**

- a. Serves as the DOD user representative for pest-related programs.
- b. Validates capability gaps and establishes requirements for DOD pest-related materiel solutions.
- c. Determines pest-related product acceptability for Service use.

## **2-8. Armed Services Blood Program Office**

a. The ASBPO supports research and development programs devoted to progress and improvement in the areas of blood product safety, purity, potency, and efficiency including related techniques, facilities, and materials according to policy guidance from the ASD(HA) and the Assistant Secretary of Defense for Research and Engineering.

b. In coordination with the Directorate of Combat Development & Doctrine (DCDD), AMEDD Center and School (AMEDDC&S) and the Army Blood Program Office (ABPO), provide recommendations on research and development requirements that ensure continued progress and improvement of blood banking techniques, procedures, equipment, and material.

c. Program funding for procurement and fielding of blood products to operational forces.

## **Chapter 3**

### **Army Medical Acquisition Process**

#### **3-1. Overview of the medical acquisition process**

a. DG is the process the AMEDD uses to implement DODD 5000.01, DODI 5000.02, and AR 70-1, tailored for the acquisition of ACAT II and III medical products. DG integrates and aligns the Defense Acquisition System, the FDA/EPA regulatory process, and best medical industry practices into a coherent process.

b. All medical product development efforts will be based on approved military medical requirements. The medical commodity is diverse and complex, including medical devices, drugs, and biologics for both Table of Organization and Equipment (TO&E) and Table of Distribution and Allowances (TDA) organizations, and is resourced with RDTE, procurement, Operations and Maintenance, and DHP appropriations. As a result, medical materiel requirements may originate from a variety of sources. Army requirements for TO&E organizations typically originate through the JCIDS, but valid medical materiel requirements may also be directed by the ASD(HA), the Department of the Army (DA), or directly from Congress.

c. Acquisition planning is continuous. IPTs are responsible to appropriately document their acquisition planning, and to keep documentation current. Program plans will be used to actively manage programs, and not be prepared merely for reviews or inspections.

d. Contracts Versus Assistance Agreements.

(1) The use of contracts is covered under Title 31, United States Code 6301 (31 USC 6301) for the purpose of acquiring property/ and/or services for the direct benefit or use of the U.S. Government; or when the agency decides in a specific instance that the use of a procurement contract is appropriate. Contracts provide a direct benefit (deliverables) to the government that need not have a wide-based public purpose, but a specific mission purpose. Since contracts are intended for acquiring established property or services, to include advanced development, contracts are funded with multiple types of funding, to include military construction (MILCON), procurement, operations and maintenance, and RDT&E (budget activities 6.1-6.7).

(2) The use of Assistance Agreements (Grants and Cooperative Agreements) is covered under 31 USC 6304 and 31 USC 6305 for the purpose of transferring property or services to State/local government or other recipient to carry out a wide-based public purpose of support or stimulation authorized by a law of the United States. Grants are used for this purpose when substantial involvement is not expected between the executive agency and the State, local government, or other recipient when carrying out the activity contemplated in the agreement. Cooperative Agreements are used when substantial involvement is expected. Substantial involvement is based on factors including collaboration, participation, or intervention in the program or activity being performed. Assistance Agreements carries a military relevance and a public purpose. Since Assistance Agreements are limited to basic and applied research efforts, the primary

funding is provided through RDT&E funds (budget activities 6.1–6.3). There are cases where an Assistance Agreement includes some advanced development efforts and limited RDT&E budget activity 6.4 funds may be added to the agreement through a modification. These considerations are addressed on a case-by-case basis. RDT&E 6.5–6.7 funds are not appropriate for primary use on Assistance Agreements.

### **3–2. Oversight of assigned medical acquisition programs**

*a. Milestone Decision Authority.* The MDA is the designated individual with overall responsibility for an acquisition program. Each acquisition program will have only one MDA. The MDA has the authority to approve entry of an acquisition program into the next phase of the acquisition process, and will be accountable for cost, schedule, and performance reporting to higher authority, including Congressional reporting. MDA for Army medical programs is delegated from the AAE by memorandum to a flag-level individual, and cannot be further delegated.

*b. The Integrated Product Team.* The AMEDD will use IPTs to conduct program management activities beginning no later than a development effort's entry into the Materiel solution analysis phase of the acquisition lifecycle. The IPT will consist of multifunctional experts chartered by the MDA to conduct research, development, and acquisition activities for a capability. The charter provides IPT members with the authority to speak for their organizations and make decisions appropriate to their level during the acquisition process. IPTs will operate on a consensus basis. Should consensus not be achieved on a major decision, the IPT chair and/or PM will raise the issue up the programmatic chain for resolution.

*c. Product Lifecycle Review Committee.* The PLRC is an intermediate level oversight committee consisting of key functional stakeholders in the research, development, acquisition, fielding, use, and lifecycle support of medical products. The PLRC provides guidance and resources to IPTs, and is the first stop to resolve issues that the IPT cannot. PLRC decisions will be made on a consensus basis. If the PLRC cannot achieve consensus on an issue, the issue will be raised to the Executive Management Committee (EMC) for resolution.

*d. The EMC.* The EMC is co-chaired by the PAA and/or PART, and consists of the senior stakeholders in the research, development, acquisition, and user communities. The EMC provides executive-level oversight and support to programs and technologies beginning at the Materiel Development Decision (MDD), and advises the MDA prior to acquisition decisions. The EMC also addresses issues that the IPTs and PLRCs cannot resolve.

*e. Reviews.* Medical acquisition programs managed under DG are subject to several types of review.

(1) *Milestone Decision reviews.* These event-based reviews are required by DODI 5000.02, and include the MDD and the Milestone A, B, and C Decision Reviews. MDA decisions made at these reviews will be documented in an acquisition decision memorandum.

(2) *In-Progress Reviews.* Periodic IPRs will be conducted for all programs managed under DG. The MDA may vary the time between individual program reviews based on the assessment of each program.

(3) *Trigger reviews.* Other events may trigger an MDA review, such as an adverse clinical event, a pending baseline breach, loss of development partner support, unanticipated decision by a development partner, or an unresolved IPT issue that is delaying progress. In the event of a lack of consensus at IPT or PLRC level, both the majority and the dissenting views will be presented to the MDA. Resulting decisions will be documented.

### **3–3. Tailoring documentation for medical programs**

*a.* Acquiring commercial or non-developmental products to meet capability needs presents a significant opportunity to Army Medicine to fill capability gaps with predictable and lower costs, shorter times to field, and reduced technical risk, while maintaining a standard of care consistent with current medical practice. Acquisition strategies will maximize use of commercial and non-developmental products and processes.

*b.* Analysis of Alternatives (AOA) and Cost Benefit Analysis (CBA) considerations. AOAs and CBAs will be robust assessments of alternatives, based upon current market research, and at a minimum will consider any potential commercial solutions, as well as the status quo. Status quo scenarios will not assume an unrealistic static situation, but instead will consider reasonable technology advances that would occur even if the AMEDD takes no action. AOAs and CBAs may be prepared by subject matter experts on the IPT, but if this is done, at a minimum it must be independently reviewed by staff external to the IPT to minimize potential for, and the perception of, bias. AOAs and CBAs are not part of the source selection process.

*c.* The AMEDD will incorporate required acquisition program information and plans into an Integrated Program Summary (IPS). The IPS will include required information identified in DODI 5000.02. The MDA will provide documentation tailoring guidance to PMs and/or IPTs early in a program's life, and again prior to milestone reviews. PMs will document plans in sufficient detail for the MDA to make sound lifecycle decisions.

*d.* The IPS will describe the program's current status, and the IPT's plan to advance a product through the acquisition process to fill the identified capability gap. The IPS is a management tool, and as such will be maintained in a current status and not merely prepared prior to milestone reviews.

*e.* Commercial and non-development item Acquisition Strategies for commercial and non-developmental items will identify appropriate operational tests and/or user assessments to verify operational effectiveness and suitability in the

intended environment. IPTs will assess existing product documentation and augment it, if necessary, to match the planned product support strategy.

*f.* Acquisition of medical end items at table of distribution and allowances medical treatment facilities. Acquisition of capital investment equipment for Health Care Activities, and the initial outfitting of expanded or newly constructed health care facilities, is accomplished under the MEDCASE program in accordance with AR 40–61. The MEDCASE program uses DHP Procurement, DHP operations O&M, or DHP MILCON funds, and does not apply to equipment procured with RDT&E, or other centrally-managed DA-level funded capital investment equipment acquisition programs. Procedural guidance for MEDCASE acquisition is contained in SB 8–75, MEDCASE.

*g.* Nonmedical health care materiel. For Soldier health-related materiel needs that will not result in a Class VIII product, the medical combat developer and the medical materiel developer will jointly coordinate with the Sustainment Division, Requirements Integration Directorate, and Army Capabilities Integration Center (ARCIC) for preparation of capability documents.

### **3–4. Medical Products with an Information Management/Information Technology Component**

*a.* AMEDD activities developing or procuring products with an IM/IT component will coordinate with the MEDCOM CIO/G–6 for DHP-funded products, or the Army CIO for Army-funded products. CIOs will provide current guidance for IM/IT and Defense Business Systems. AMEDD activities will obtain required certifications, or obtain waivers, as necessary.

*b.* AMEDD activities developing or procuring any product, including patient care devices, that will exchange data with other devices will obtain required network certifications, authorizations, and spectrum allocation before fielding.

*c.* AMEDD activities developing or acquiring business systems that exceed a total cost of \$1,000,000 over the future-years defense program, regardless of funding source, will obtain Defense Business System Management Council certification before obligating funds. Medical devices with the primary function of direct patient care, which merely collect, store, or transmit data as part of the patient care function do not meet the statutory definition of business systems in 10 USC 2222(j)(1). Decision process for medical product having IM/IT implications.

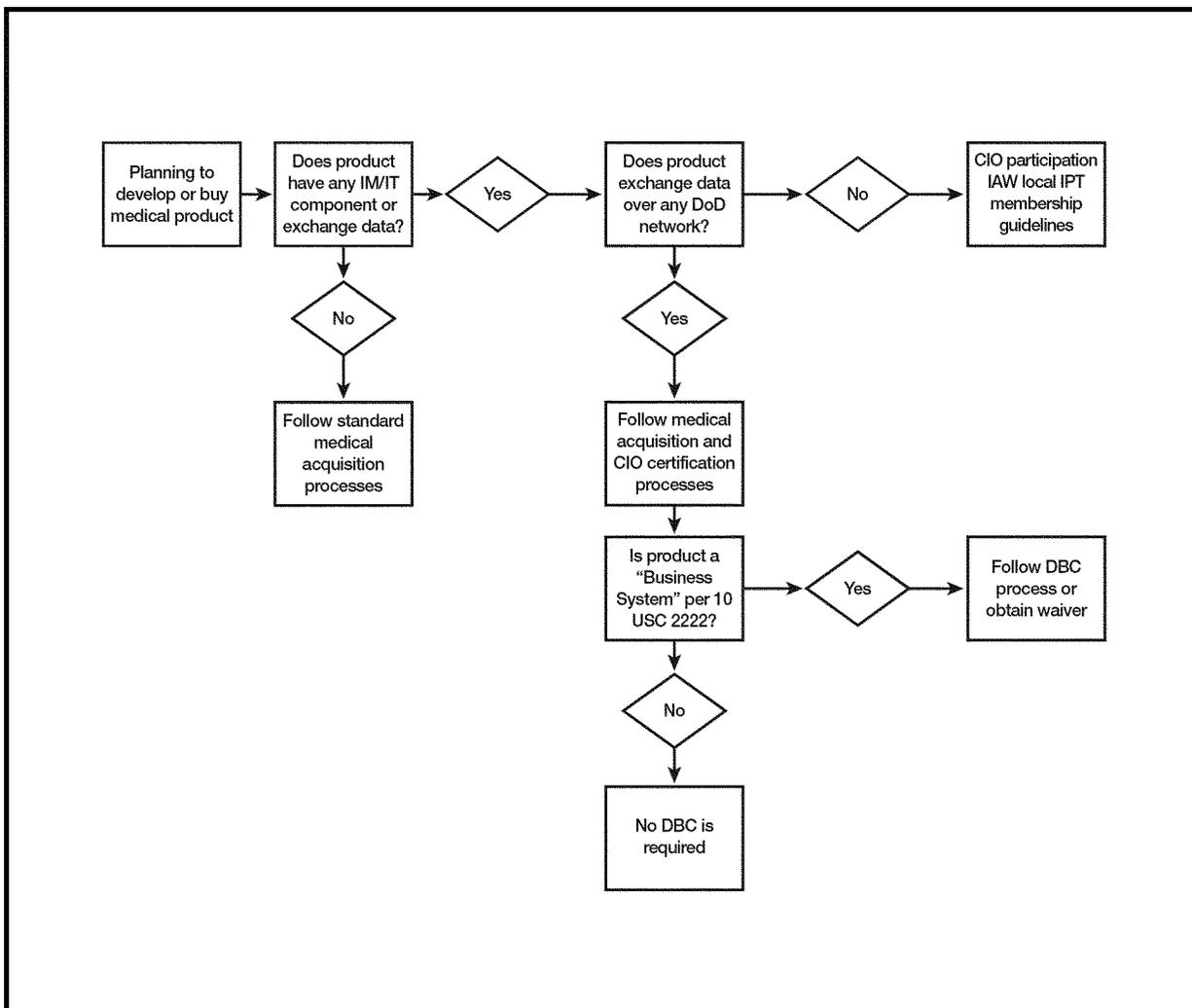


Figure 3–1. Decision process for medical having Information Management/Information Technology implications

### 3–5. Protecting Critical Program Information

Protecting critical program information (CPI) is an important consideration for all materiel developers. Medical programs do not generally possess CPI, but they may, so early identification is important. AMEDD activities will evaluate every research, development, and acquisition program for CPI, beginning at the MDD. The ARTPC, utilizing the DOD CPI Identification Survey and associated processes, identifies those programs which potentially contain CPI. All programs that are determined to possess CPI will prepare a Program Protection Plan as part of milestone decision reviews.

## Chapter 4 Funding for Medical Research, Development, and Acquisition

### 4–1. Army and/or individual Service and Defense Health Program

*a.* The acquisition process is an overlay to the calendar-driven DOD PPB&E Process. Both Army and DHP medical research and development programs are funded through the PPB&E process.

*b.* IPT chairs and product managers will provide input to the PPB&E process that reflects actual resources required to conduct their development effort.

## **4–2. External funding sources**

Because of the unusually high cost and risk associated with medical product development, most Army medical research, development and acquisition efforts are funded from a variety of sources. Resource providers may be governmental or nongovernmental, and may include:

- a.* Army, Navy, Air Force, or Marines
- b.* DOD organizations
- c.* Federal agencies
- d.* State agencies
- e.* Congressionally-directed accounts
- f.* Civilian aid agencies
- g.* Development project partners (for example, industry and academia)
- h.* A project having an external source of funds alone does not automatically obviate DG oversight. The appropriate degree of oversight will be determined by the MDA, after considering the source of the resources involved, specific program risks, urgency of the requirement, as well as opportunity cost of personnel and facilities working on the project.

## **Chapter 5 Determining and Documenting Requirements**

### **5–1. Medical materiel for table of distribution and allowances facilities**

Commanders of TDA medical activities will establish investment equipment requirements for their individual activity, which will be filled under the MEDCASE program, per AR 40–61.

### **5–2. Department of Defense, other Service, and Army medical materiel**

For medical materiel that will require research and development resources, the MDA may accept requirements documented in a number of ways, including the following:

- a.* A validated Service-specific or JCIDS capability document.
- b.* A directive memorandum from ASD(HA).
- c.* A directive memorandum from the ASA(ALT).
- d.* An approved Operational Needs Statement and/or Joint Urgent Operational Needs Statement.
- e.* When a requirements document is expressed in operational or functional terms, with insufficient technical detail, IPTs will develop and document technical requirements to meet the user need, using a target product profile or performance specification

### **5–3. Medical materiel for Table of Organization and Equipment organizations**

- a.* A medical materiel need, to include product improvements, may be identified by the following:
  - (1) DCDD, and MEPD (for aeromedical evacuation only), in support of new or changed medical materiel development efforts to—
    - (a)* Correct an operational shortcoming or inadequacy in existing materiel, as a result of new doctrine, or;
    - (b)* Take advantage of a breakthrough in technology.
  - (2) The materiel developer, users, or logistician, when technology advances sufficiently to warrant equipment upgrade or developments.
  - (3) The logistician, when chronic acquisition or maintenance problems occur with fielded items.
  - (4) The combat developer, users, materiel developer, or logistician, in response to operational concepts, materiel proposals, or external ideas and suggestions.
- b.* Determining the requirement for medical assemblages to support Army TO&E organizations is discussed in Chapter 7.

### **5–4. Adopting other Service-specific or Joint Capabilities and Integration Development System capability document as an Army requirement**

Any JCIDS capability document for medical materiel not originating from an Army combat developer is considered as being from another Service (see AR 71–9). To gain approval as an Army requirement, the AMEDD combat developer will—

- a.* Initiate an Army annex and appendix.
- b.* Coordinate, for review and comment, the basic capability document with annex/appendix with the AMEDD MATDEV, trainer, logistician, and tester.

c. Submit the basic capability document with Army or AMEDD annex or appendix to TRADOC ARCIC for formal staffing and subsequent approval by DCS, G-3/5/7 as an Army requirement.

## **5-5. Prioritizing requirements**

The combat developer will develop a list of medical materiel requirement priorities annually. The materiel developer will consider these priorities during the PPB&E process, individual project development decisions, acquisition strategies, and to manage the medical RDA portfolio.

# **Chapter 6 Test and Evaluation**

## **6-1. Overview of test and evaluation**

a. The essential elements of test and evaluation (T&E) of medical materiel, medical-related materiel, and IM/IT systems with medical applications are similar to those applied to non-medical systems acquisition. The differences in execution of T&E for medical systems are largely related to—

- (1) Specific organizations designated to provide and support testing.
  - (2) Additional considerations related to requirements for use, testing, reporting, and approval of systems by other Government agencies such as the FDA and the EPA.
  - (3) The requirement for product integration across the span of healthcare operations, from individual Soldier self-aid through long-term care in the Military Healthcare System/Veterans Administration.
  - (4) The requirement for medical systems to support the range of combat and non-combat missions.
  - (5) A recognition of the distinct skills and technical expertise resident within the medical community to conduct and support T&E of medical systems.
  - (6) Verification of clinical safety and efficacy of medical materiel, gathered under Good Clinical Practices, provided to the FDA.
- b. While essentially a risk mitigation tool, T&E within the DOD framework provides information to—
- (1) Decision-makers responsible for procuring effective, suitable, and survivable systems.
  - (2) MATDEV for identifying and resolving technical and logistical support issues.
  - (3) Managers for making the best use of limited resources.
  - (4) Operational users for refining requirements, validating system architectures, and supporting the development of doctrine, organizations, training, materiel, leadership development and education, personnel, facilities and tactics, techniques, and procedures.

## **6-2. Test and evaluation planning**

Test and evaluation planning for medical materiel encompasses both clinical and/or developmental testing (DT) necessary to achieve FDA or EPA approval for the product, as well as operational/user testing to determine military utility. Pharmaceutical products that are not Service member-carried generally do not require operational testing. FDA/EPA approval, if required, is needed before conducting operational testing with military personnel.

a. The exclusion of DHP-funded IM/IT systems from the requirements of AR 70-1 will not apply to systems being developed by Army activities, except where specific DOD or multi-service and/or multi-agency governance regulations or agreements apply.

b. All AMEDD acquisition programs will address requirements for DT and OT in appropriate acquisition documents. It is a required element for Defense Business Systems, which includes most medical IM/IT systems, and in the program IPS for other medical products.

c. Responsibility for conducting T&E falls under two separate Commands within the AMEDD:

(1) DT responsibility falls under the Commander, MRMC, organizationally, and is functionally aligned with MATDEV activities. DT and other technical testing may be performed on behalf of the MATDEV by technical activities within MRMC, United States Government DOD, Army, and/or AMEDD agencies, independent contractors, and the commercial developer.

(2) OT&E responsibility falls under the Commander, AMEDDC&S with the U.S. Army Medical Department Board (USAMEDDBD), the Service-component Operational Test and Evaluator for medical materiel systems having medical implications, and medical C4I/IT.

(3) Organizations involved in OT&E will be organized to execute all activities with careful consideration to avoid organizational conflicts of interest (OCI) and the appearance of OCI. OCI considerations shall be addressed at all points in T&E planning and execution, and may limit involvement and presence of contractor and non-government personnel, as well as Government employees with personal interest, in T&E activities.

d. Although DT and OT have functional descriptions which are generally useful for delineating the representative activities of the organizations involved, the categorization of a test event or function as DT or OT is based solely on

the organization responsible for the conduct of the test event. Recognition of the independent role and organizational separation of the OT&E is a key element the DOD T&E framework.

*e.* MATDEVs should incorporate operational assessments and user feedback of operational effectiveness, operational suitability and survivability early in the acquisition process. Integrated and combined DT/OT events are also encouraged to capture efficiencies in design and execution of the T&E strategy. Continuous evaluation of systems under development should include comprehensive review of all available data and information.

*f.* Coordination and commitment of T&E personnel and resources to support T&E of medical systems is established in any of several documents including the T&E Strategy, T&E Master Plan (TEMP), and T&E working integrated product team (WIPT) charter. Test organizations rely on external resources to provide test participant personnel and facilities for individual test events through a combination of organization, installation, MEDCOM and Army processes, each with varying capability and capacity to support T&E efforts. Some test efforts may require lead times of up to 14 months and may not be easily rescheduled to accommodate program delays.

*g.* Working within the considerations above, T&E has no time constraints of it, but will be aligned to the program and schedule requirements for the medical materiel system or item to be tested and evaluated. Conflicts and scheduling issues will be resolved through direct coordination between the MATDEV and the head of the responsible test activity (for example, Commander, MRMC and President, USAMEDDBD, for DT and OT events, respectively).

### **6–3. Test and evaluation planning and strategy**

*a.* Planning for T&E of medical material systems begins with the development of user needs and continues throughout the acquisition process. Requirements development should ensure that identified requirements are testable, measurable, and operationally relevant. Early modeling and simulation (M&S) may also inform and influence T&E planning, realizing that robust M&S and T&E are mutually supportable, working together to realize cost avoidance and risk-reduction potentials. System evaluators should be active participants in system IPTs throughout the acquisition process.

*b.* Planning the T&E strategy begins early. The T&E strategy supports the acquisition strategy and confirms system achievement, as a minimum, of threshold requirements defined in the JCIDS and Business Capability Lifecycle documents. The principal acquisition program level document describing the T&E strategy is the TEMP.

(1) The MATDEV/PM has the overall responsibility to develop the TEMP. Additional information may be found in AR 73–1, DA Pam 73–1, and the Defense Acquisition Guidebook. For TEMPs not requiring HQDA or OSD approval, tailoring is authorized. While the TEMP format is a guide, tailoring is allowed to reduce the TEMP development effort and manage its size.

(2) When required, the PM shall submit an approved TEMP that describes the approach for integrating developmental, operational, and live-fire testing evaluation and addresses test resource planning. The TEMP will include a test plan that addresses Technology development phase activity, including the identification and management of technology risk, and the evaluation of system design concepts against the preliminary capability requirements identified in the AOA. Test planning shall address T&E aspects of competitive prototyping, early demonstration of technologies in relevant environments, and the development of an integrated test approach.

(3) The TEMP is updated for each subsequent milestone decision review, in the event of a baseline breach, or upon a significant change to the capability development document (CDD), capability production document (CPD), or information support plan (ISP).

(4) Once approved by the MDA, the TEMP serves as a contract between the acquisition, requirements, and the T&E communities for executing the T&E strategy. The TEMP is the basic planning and strategy document for a system lifecycle T&E. The acquisition and T&E communities use the TEMP to generate detailed T&E plans and to ascertain schedule and resource requirements associated with the T&E of a given system. The TEMP provides the road map for integrating modeling, simulation, testing, evaluation plans, schedules, and resource requirements.

*c.* Medical products being developed for exclusive use in TDA healthcare facilities under a FDA investigational new drug (IND) or investigational device exemption (IDE) only require a TEMP if the MDA specifically requires one, or if the program is on the OSD T&E Oversight List.

*d.* Non-developmental items (NDIs) selected as direct replacements for existing components of sets, kits, and/or outfits will normally be subjected to minimal or no government testing when previous test and performance data or user market surveys are considered complete and valid for determining military suitability and logistics supportability; this determination will be made by the MATDEV. MATDEVs, Combat Developers (CBTDEVs) and system evaluators will make maximum use of prior test information (including information from commercial manufacturers, users, other services, agencies, or countries).

### **6–4. Developmental testing**

Developmental testing of medical materiel will focus primarily on where the product and/or device will be used. The device or packaging in the case of pharmaceuticals will be exposed to various environmental conditions that it will encounter when used by the military. Most commercial medical products are not designed for use outside and exposed

to nature. The developmental testing will evaluate the medical product's capability to withstand exposure to environmental conditions such as high temperature, low temperature, vibration, dust, rain, and salt fog. Other tests to determine the product's capability to withstand rough handling will be performed. FDA/EPA approval is not required at the time developmental testing is performed.

#### **6-5. Test and evaluation working integrated product team**

*a.* The MATDEV will form a T&E working-level integrated product team (WIPT). The T&E WIPT's primary objective is to develop and document the T&E strategy, the TEMP, and an integrated T&E schedule. The MATDEV and/or PM, or acquisition authority for all medical materiel systems, to include medical IM/IT, regardless of acquisition category level, will charter the T&E WIPT as soon as the materiel need is identified. The T&E WIPT will assist the MATDEV in managing system T&E throughout the system lifecycle.

(1) The T&E WIPT will optimize the use of appropriate T&E expertise, test assets, targets, instrumentation, facilities, simulations, and models to achieve test integration, thereby reducing costs to the Army and decreasing acquisition cycle time.

(2) The T&E WIPT resolves issues and assists the MATDEV/PM in developing and coordinating the TEMP.

(3) Additional information on T&E WIPTs can be found in AR 73-1. DA Pam 73-1 provides the TEMP Development and T&E WIPT.

*b.* Product IPTs, within the construct of the MRMC DG Process, will include appropriate representatives from the responsible DT and OT organizations.

#### **6-6. Developmental and/or technical test and evaluation supporting Food and Drug Administration and/or Environment Protection Agency Approval (that is, clinical and non-clinical trials)**

*a.* T&E planning to achieve FDA or EPA approval include gathering data under GCP, as delineated in the CFR. Medical products must first be determined "reasonably safe" before they may be tested on human subjects. Human testing is regulated by the Surgeon General's Human Subjects Review Board (HSRB).

*b.* Principles—

(1) T&E is conducted throughout the medical materiel development process via non-clinical studies and clinical trials to—

(*a*) Evaluate and demonstrate safety and efficacy in humans.

(*b*) Ensure protection of health and environment.

(2) Non-clinical and clinical testing is performed in accordance with all applicable regulatory requirements including the CFR Title 21.

(3) Products subject to EPA jurisdiction are governed by 40 CFR.

#### **6-7. Interoperability testing**

Interoperability testing applies to all medical IM/IT systems having interfaces or interoperability requirements with other systems. All systems with multi-service or joint system interfaces require interoperability certification by the Joint Interoperability Test Command (JITC). The program's net-ready key performance parameter is a source of interoperability requirements and should incorporate the total system architecture. Interoperability testing may consist of demonstrations using message analysis or parsing software with limited interface connectivity, or extend to full-scale scenario-driven exercises with all interfaces connected.

#### **6-8. Operational Test and Evaluation**

*a.* The USAMEDDBD is the Service component operational tester for medical materiel, systems having medical implications, and medical C4I/IT. The USAMEDDBD has primary responsibility for the conduct of operational testing within the AMEDD. The USAMEDDBD also coordinates assistance and support of the Army Operational Test Command (OTC) efforts in the testing of non-medical systems with medical implications, where the primary system test is being tested in an OT by OTC. The USAMEDDBD may also provide assistance and support to the other Service operational test activities upon request. For multi-Service test and evaluation of information systems, such as those systems developed by the TRICARE Management Activity, and where the Army is the lead Service for acquisition responsibilities will be coordinated between the Army Evaluation Center within Army Test and Evaluation Command and the USAMEDDBD. The USAMEDDBD will serve as the AMEDD proponent for OT&E issues and Service representation for multi-Service and multi-Agency medical system acquisition.

*b.* The primary objective of OT&E in support of the medical materiel acquisition process is the verification of capability against operational goals and objectives, generally defined by the critical operational issues and criteria for the system under test. The structure and execution of OT&E is directed at determining the operational effectiveness, operational suitability and survivability in meeting the users' requirements. These requirements are determined by analysis of the systems' requirements documents (for example, CDD and CPD), various acquisition program documents (for example, TEMP), user Concept of Operation (CONOPS), operational mode summary (OMS) and/or mission

profile, business processes, system architectures, and the common operational picture. OT relies on observation and measurement of system attributes and performance against testable requirements.

## **6–9. Test and evaluation budget and financial considerations**

The PM is responsible for programming and request adequate funding to execute the T&E Program. Prior to a full-rate production or full deployment decision, through initial OT&E for a given product or major system increment, funding will be from program RDT&E appropriations. A procurement appropriation and/or O&M appropriation may be used to fund testing conducted after the full rate production decision, using the same appropriation that funded the development. Medical IM/IT testing and evaluation following the full deployment decision will be funded from RDT&E or O&M appropriations, depending upon the purpose of the product effort being developmental or general purpose, respectively.

## **Chapter 7**

### **Medical Materiel, Equipment, and Assemblages for Table of Organization and Equipment Organizations**

#### **7–1. Intent**

*a.* This chapter outlines policies for determining, identifying, managing and documenting the requirement for medical materiel (that is, supplies), medical equipment and medical sets, kits, outfits and/or medical assemblages necessary to support the medical capability in Army TO&E organizations.

*b.* This chapter does not apply to—

- (1) Units organized under a TDA.
- (2) CG, U.S. Army Special Operations Command when acting as the capability developer, trainer, and user representative for Army special operations forces (see AR 70–1).

#### **7–2. Medical Sets, kits, and Outfits and/or Medical Assemblages**

*a.* A medical SKO and/or assemblage is an identified grouping of medical and nonmedical supplies and/or equipment designated to facilitate a specific medical function based on an organization's Minimum Mission Essential Wartime Requirement (MMEWR) in support of health care during 72 hours of sustained major combat operations. They may be made up of component support items included in more than one class of supply; may include separately type-classified end items; may include component and support items for which logistic responsibilities are assigned to more than one agency; and may include nonexpendable, durable, and expendable component and support items. Medical SKO and/or assemblages will be Army type-classified, controlled by a supply catalog, and identified as a single item of supply with a unit of issue of set, kit, or outfit.

*b.* Army medical SKO and/or assemblages associated with a Line Item Number (LIN) will be documented on the TO&E and authorized by the Modified TO&E (MTO&E) (see AR 71–32).

*c.* Those SKO and/or assemblages not associated with a LIN will be listed in Common Table of Allowances (CTA) 8–100.

*d.* For the purpose of the remainder of this chapter, the terms assemblage and SKO have the same meaning.

#### **7–3. Determining requirements**

*a.* The AMEDDC&S, in its capacity as the AMEDD CBTDEV, will determine the type and basis of issue of medical materiel, equipment and assemblages required to support the medical capability in TO&E organizations. DCDD, MEPD (for aeromedical evacuation only), and AMEDDC&S will exercise functional CBTDEV responsibility for determining and managing requirements.

*b.* The MRMC in its capacity as the AMEDD MATDEV will be responsible for all resourcing aspects for medical materiel in support of TO&E organizations. The U.S. Army Medical Materiel Agency (USAMMA) will exercise functional responsibility for resourcing.

#### **7–4. Medical assemblage management**

*a.* The requirement for medical, dental, optical, and veterinary assemblages documented to a TO&E will be based on the defined organization mission as stated in Section 1 of the applicable TO&E. Only those assemblages and equipment necessary to support MMEWR will be documented on the organizations TO&E in accordance with the policies stated in AR 71–32 and elsewhere in this chapter.

*b.* Assemblages required, but not qualifying for documentation on a TO&E, will be identified in CTA 8–100. These assemblages will be comprised of only materiel as classified expendable or durable. Medical equipment identified as major equipment, and associated with a valid LIN, will not be a component of these assemblages. An example of an assemblage to be listed in the CTA would be a first aid kit required for an aircraft or a vehicle.

*c.* Assemblage composition and Unit Assemblage List (UAL). All materiel comprising an assemblage, except book

sets will be identified by National Stock Number (NSN) in a UAL. The UAL may also contain additional information determined by the CBTDEV and MATDEV necessary to constitute a complete list. All UALs will be identified through an alpha/numeric numbering system.

*d.* Assemblage review.

(1) Those existing assemblages managed by the CBTDEV will be reviewed for adequacy every three years or as determined necessary to meet a changed TO&E organizational mission.

(2) Reviews will be conducted through a panel process. The CBTDEV will establish internal procedures to manage the review process.

(3) The final panel results and recommendations will be reviewed and approved by the appropriate Office of the Surgeon General consultant(s).

(4) The approved panel results will be identified and listed in the UAL. The CBTDEV will transmit the approved UAL to the MATDEV for resourcing and utilization.

(5) The assemblage review process will not be used as a mechanism for altering unit mission, organization, or personnel strength. These types of actions require an Army Force design update (see AR 71–32).

*e.* Assemblages not managed by the CBTDEV will be managed and reviewed by the Materiel Directorate.

*f.* Logisticians and managers of medical unit assemblages will review UAs and UALs frequently to ensure integration of all updates and changes, and ensure accurate unit status reporting. For assistance, the USAMMA Web site at [www.usamma.amedd.army.mil](http://www.usamma.amedd.army.mil) provides additional information.

### **7–5. New medical assemblages**

*a.* A new assemblage that is to be documented with a LIN on a TO&E, to support a new or revised medical capability of a TO&E organization, will be developed and managed by the CBTDEV. These assemblages will be documented to the TO&E as outlined elsewhere in this regulation.

*b.* A new assemblage which is to be listed in CTA 8–100 will be developed by the CBTDEV.

*c.* In both paragraphs a and b above, a panel process and clinical approval will be used to determine the components of the assemblage.

### **7–6. Major medical equipment (items)**

*a.* Medical equipment that qualifies as a major item will be associated with a LIN, as outlined elsewhere in this regulation (see AR 71–32).

*b.* Major items will not be identified in the Unit Assemblage (UA) as a consumable or durable item. The NSN of the equipment will be listed in the UA; however, it will be clearly identified as an Associated Support Item of Equipment (ASIOE).

### **7–7. Documenting medical materiel requirements**

*a.* Documenting medical assemblages and major medical equipment to Army TO&E will be in accordance with AR 71–32.

*b.* Specific policies for medical assemblages and medical equipment are as follows:

(1) Medical assemblages and stand-alone items of medical equipment, which are determined by the AMEDD CBTDEV to be significant to the successful accomplishment of an organizations medical mission, will be documented to applicable TO&E with a LIN (see AR 71–32).

(2) Medical assemblages which contain only consumable and/or durable materiel, and are widely used by both medical and non-medical organizations, may be listed in CTA 8–100. These assemblages will not be associated with a LIN. The AMEDD CD will determine which assemblages qualify for inclusion in CTA 8–100. Medical assemblage having ASIOE will not be listed in CTA 8–100.

(3) Medical equipment as an ASIOE to assemblages. Medical equipment which meets any of the following criteria will be documented as ASIOE to a medical assemblage and will require a LIN.

*(a)* Mutual determination by the CBTDEV and MATDEV that an equipment item, regardless of unit cost, should be an ASIOE to an assemblage.

*(b)* Medical equipment which requires the Biomedical Equipment Specialist, Military Occupational Specialty 68A to perform periodic preventive maintenance checks and services (PMCS), to include certification or calibration services in accordance with the manufacturers maintenance manual. Note: Before or after operation checks and services clearly identified as those which can be performed by the operator (user) are not considered PMCS.

### **7–8. Medical book sets**

*a.* The CBTDEV is responsible for cyclic review and identification of components of each Army Medical Book Set. The Book Sets are reviewed every three years to coincide with the corresponding assemblage review.

*b.* The contents of each Book Sets and acquisition information will be published in Supply Bulletin 8–75 annually.

*c.* The basis of issue for the Book Sets will be as stated in CTA 8–100.

d. The NSNs for Book Sets are published in the Universal Data Repository CD-ROM, the Federal Logistics Information System and the Medical Services Information Logistics System.

### **7–9. Medical resupply and supply sets**

a. Medical Resupply Sets contains an additional seven days of supply to replenish selected assemblages. The USAMMA will develop MRSs that are intended for a given force type such as a division, armored cavalry regiment, or brigade. Known as "Recommended Stockage Lists (RSL)," these resupply sets are used for contingency planning. Units and/or Commands may add or delete items to provide mission-specific support and to adjust the allowances for existing items in recommended stockage lists. These RSLs will not have assigned LINs and will not be required or authorized by TO&E and/or MTO&E. In addition, because these are planning SKOs and not authorizations, supply catalogs will not be published for recommended stockage lists.

b. Supply sets are found only in the Combat Support Hospital (CSH). They will contain an additional seven day complement of Class VIII supplies to support CSH. The CBTDEV will develop these sets. These sets will be documented to the CSH TO&E with a LIN.

## **Chapter 8 Acquisition, Logistics, and Technology Workforce Management**

### **8–1. U.S. Army Medical Department Acquisition, Logistics and Technology workforce management**

TSG will develop and manage the AMEDD AL&T workforce in accordance with the DAWIA and AR 70–1.

### **8–2. Career development U.S. Army Medical Department Acquisition, Logistics and Technology workforce career development policy**

a. Officers assigned to acquisition positions will be assigned the 8X skill identifier in accordance with DA Pam 611–21, and meet training and certification requirements for the assigned position in accordance DA Pam 600–3 in any of the seven acquisition career fields:

- (1) Program Management (A)
- (2) Contracting (C)
- (3) Systems Planning
- (4) Research Development
- (5) Engineering-Science and Technology Management (S/I)
- (6) Information Technology (R)
- (7) Testing and Evaluation (T)

b. Officers assigned the 8X skill identifier are part of the Army's acquisition workforce; however, they are not assigned to the Army's acquisition functional community. AMEDD Officers may apply and be accepted into the Army's Acquisition Corps and compete for Acquisition board positions.

c. Civilians assigned to acquisition positions must meet training and certification for assigned position in accordance with AR 70–1.

## **Appendix A References**

### **Section I Required Publications**

#### **AR 70-1**

Army Research, Development, and Acquisition (Cited in paras 1-5c, 2-9d(4), 3-1a, 6-2a, 7-1b(2), 8-1, and 8-2c.)

#### **AR 73-1**

Test and Evaluation Policy (Cited in para para 2-9 and terms.)

#### **DODD 5000.01**

The Defense Acquisition System (Cited in para para 1-5c.) (Available at <http://www.dtic.mil/whs/directives>.)

#### **DODI 5000.02**

Operation of the Defense Acquisition System (Cited in para para 1-5c.) (Available at <http://www.dtic.mil/whs/directives>.)

### **Section II Related Publications**

A related publication is a source of additional information. The user does not have to read it to understand this regulation. DOD publications are available at <http://www.dtic.mil/whs/directives>.

#### **AR 1-75**

Administrative and Logistical Support of Overseas Security Assistance Organizations

#### **AR 11-2**

Managers' Internal Control Program

#### **AR 11-18**

The Cost and Economic Analysis Program

#### **AR 25-1**

Army Information Technology

#### **AR 25-30**

The Army Publishing Program

#### **AR 40-5**

Preventive Medicine

#### **AR 40-7**

Use of Investigational Drugs and Devices in Humans and the Use of Scheduled Controlled Drug Substances

#### **AR 40-10**

Health Hazard Assessment Program in Support of the Army Acquisition Process

#### **AR 40-61**

Medical Logistics Policies

#### **AR 70-31**

Standards for Technical Reporting

#### **AR 70-57**

Military-Civilian Technology Transfer

#### **AR 71-9**

Warfighting Capabilities Determination

**AR 71-32**

Force Development and Documentation

**AR 350-1**

Army Training and Leader Development

**AR 350-10**

Management of Army Individual Training Requirements and Resources

**AR 350-38**

Policies and Management for Training Aids, Devices, Simulators, and Simulations

**AR 385-10**

The Army Safety Program

**AR 602-2**

Manpower and Personnel Integration (MANPRINT) in the System Acquisition Process

**AR 700-4**

Logistics Assistance

**AR 700-127**

Integrated Logistic Support (ILS)

**AR 700-137**

Logistics Civil Augmentation Program

**AR 700-142**

Type Classification, Materiel Release, Fielding and Transfer

**AR 708-1**

Logistics Management Data and Cataloging Procedures for Army Supplies and Equipment

**AR 710-1**

Centralized Inventory Management of the Army Supply System

**AR 710-2**

Supply Policy below the National Level

**AR 725-1**

Special Authorization and Procedures for Issues, Sales, and Loans

**AR 725-50**

Requisitioning, Receipt, and Issue System

**AR 750-1**

Army Materiel Maintenance Policy

**AR 750-10**

Army Modification Program

**AR 750-43**

Army Test, Measurement, and Diagnostic Equipment

**AR 750-1**

Army Materiel Maintenance Policy

**CJCSI 3170.01**

Joint Capabilities Integration and Development System (Available at <https://dap.dau.mil/policy/Pages/overview.aspx>.)

**DA Pam 25-1-1**

Army Information Technology Implementation Instructions

**DA Pam 70-3**

Army Acquisition Procedures

**DA Pam 73-1**

Test and Evaluation in Support of System Acquisition

**DA Pam 611-21**

Military Occupational Classification and Structure

**DA Pam 700-56**

Logistics Supportability Planning and Procedures in Army Acquisition

**DA Pam 700-142**

Instructions for Materiel Release, Fielding, and Transfer

**DOD 4140-26-M**

DOD Integrated Materiel Management (IMM) for Consumable Items: Operating Procedures for Item Management Coding (IMC)

**DODD 5101.9**

DOD Executive Agent for Medical Materiel

**DODD 5136.01**

Assistant Secretary of Defense for Health Affairs

**DODD 5136.13**

Defense Health Agency (DHA)

**MIL-HDBK-881**

Work Breakdown Structure (Available at <http://www.srs.gov/>.)

**MIL-HDBK-502A**

Product Support Analysis (Available at <https://acc.dau.mil/hal/>.)

**MIL-STD-1472F**

Department of Defense Design Criteria Standard (Available at [http://dcmo.defense.gov/products-and-services/business-enterprise-architecture/8.0/lrp/products/HTML\\_source/MIL-STD-1472F.htm](http://dcmo.defense.gov/products-and-services/business-enterprise-architecture/8.0/lrp/products/HTML_source/MIL-STD-1472F.htm).)

**10 USC 2222**

Service Supply and Procurement (Available at <http://uscode.house.gov/>.)

**31 USC 6301, 6304, 6305**

Using Procurement Contracts and Grant and Cooperative Agreements (Available at <http://uscode.house.gov/>.)

**Section III****Prescribed Forms**

No forms prescribed in this section.

**Section IV****Referenced Forms**

Unless otherwise indicated, DA Forms are available on the APD Web site (<http://www.apd.army.mil>).

**DA Form 11-2**

Internal Control Evaluation Certification

## **Appendix B Internal Control Evaluation**

### **B-1. Function**

The function covered by this evaluation is medical materiel acquisition.

### **B-2. Purpose**

The purpose of this evaluation is to assist medical acquisition program, project, and product managers in evaluating the key internal controls provided by the medical acquisition process. It is intended as a guide, and does not cover all controls.

### **B-3. Instructions**

Answers must be based on the actual testing of key internal controls (for example, through document analysis, direct observation, sampling, or other). Answers that indicate deficiencies must be explained, and the corrective action identified in supporting documentation. These internal controls must be evaluated at least once every 5 years. Certification that the evaluation has been conducted must be accomplished on DA Form 11-2 (Internal Control Evaluation Certification).

### **B-4. Internal control test questions**

- a.* If my acquisition program is funded with Budget Activity 6.3 or higher research and development funds, and/or the technology is assessed to be at or beyond Technical Readiness Level (TRL 3), have I scheduled and completed a MDD with the MDA?
- b.* Do I have on file an approved requirements document, as described in AR 40-60?
- c.* Do I have on file an Acquisition Decision Memorandum (ADM) approving the path forward, signed by the MDA, for the MDD and every milestone decision review the program has completed?
- d.* Am I managing the program with the current IPS and acquisition program baseline (APB) that have been approved by the MDA?
- e.* Am I maintaining all other program documentation that is required by the MDA, in accordance with DODI 5000.02 and AR 40-60?

### **B-5. Supersession**

Not applicable.

### **B-6. Comments**

Help make this a better tool for evaluating internal controls. Submit comments to the Office of The Surgeon General (DASG-LOZ), 7700 Arlington Boulevard, Falls Church, VA 22042-5144.

## **Glossary**

### **Section I Abbreviations**

#### **AAO**

Authorized Acquisition Objective

#### **ACAT**

Acquisition Category

#### **ACMA**

Acquisition Career Management Advocate

#### **AIS**

AMEDD Investment Strategy

#### **AMC**

U.S. Army Materiel Command

#### **AMEDD**

U.S. Army Medical Department

#### **AMEDDC&S**

U.S. Army Medical Department Center and School

#### **AOA**

Analysis of Alternatives

#### **APS**

Army Prepositioned Stock

#### **ARNG**

Army National Guard

#### **ARTPC**

Army Research and Technology Protection Center

#### **AS**

Acquisition Strategy

#### **ASBPO**

Armed Services Blood Program Office

#### **ASD (HA)**

Assistant Secretary of Defense for Health Affairs

#### **ASIOE**

Associated Support Items of Equipment

#### **ATEC**

U.S. Army Test and Evaluation Command

#### **BA**

Budget Activity

#### **BOIP**

Basis of Issue Plan

#### **BOIPFD**

Basis of Issue Plan Feeder data

**C4I**  
Command, Control, Communications, Computers, and Intelligence

**CARDS**  
Catalog of Approved Requirements Documents

**CBA**  
Cost-Benefit Analysis

**CBTDEV**  
Combat Developer

**CCB**  
Configuration Control Board

**CDD**  
Capability Development document

**CDR**  
Critical Design review

**CG**  
Commanding General

**CI**  
Commercial Item

**CIO**  
Chief Information Officer

**CJCSI**  
Chairman of the Joint Chiefs of Staff Instruction

**COEA**  
Cost and Operational Effectiveness Analysis

**CPD**  
Capabilities Production Document

**CPI**  
Critical Program Information

**CRADA**  
Cooperative Research and Development Agreement

**CSH**  
Combat Support Hospital

**CTA**  
Common Table of Allowances

**CTEA**  
Cost and Training Effectiveness Analysis

**CTP**  
Coordinated Test Program

**DA**  
Department of the Army

**DAWIA**

Defense Acquisition Workforce Improvement Act

**DCDD**

Directorate of Combat and Doctrine Development

**DG**

Decision Gate

**DHA**

Defense Health Agency

**DHP**

Defense Health Program

**DLA**

Defense Logistics Agency

**DMMPO**

Defense Medical Materiel Program Office

**DMRD**

Defense Medical Research and Development Program

**DOD**

Department of Defense

**DOTMLPF**

Doctrine, organizations, training, materiel, leadership, and education, personnel, and facilities

**DRPM**

Direct reporting program manager

**DPSC**

Defense Personnel Support Center

**DT**

Developmental Testing

**DTP**

Detailed Test Plan

**EAD**

Equipment Availability Date

**EIA**

Environmental Impact Assessment

**EIS**

Environmental Impact Statement

**EMC**

Executive Management Committee

**EMD**

Engineering and Manufacturing Development

**EPA**

Environmental Protection Agency

**ETM**

Extension Training Materiel

**FBOIP**

Final Basis of Issue Plan

**FDA**

US Food and Drug Administration

**FDTE**

Force Development Test and Experimentation

**FAR**

Federal Acquisition Regulation

**FEA**

Front-End Analysis

**FMOS**

Final MOS

**FOC**

Full Operational Capability

**FOE**

Follow-On Evaluation

**FQQPRI**

Final QQPRI

**FRP**

Full Rate Production

**FSC**

Federal Supply Classification

**FUE**

First Unit Equipped

**FYDP**

Five Year Defense Program

**GCP**

Good Clinical Practices

**HCA**

Head of Contracting Authority

**HHA**

Health hazard Assessment

**HQDA**

Headquarters, Department of the Army

**ICTP**

Individual and Collective Training Plan

**ICD**

Initial capabilities Document

**ICT**

Integrated Concept Team

**IE**

Independent Evaluation

**IEP**

Independent Evaluation Plan

**IER**

Independent Evaluation Report

**ILIR**

In-House Laboratory Independent Research

**ILS**

Integrated Logistic Support

**IMM**

Integrated Materiel Manager

**IND**

Investigative New Drug (application)

**INSCOM**

U.S. Army Intelligence and Security Command

**IOC**

Initial Operational Capability

**IP**

Intellectual Property

**IPR**

In-Process Review

**IPT**

Integrated Product Team

**ISD**

Instructional System Design

**ITP**

Individual Training Plan

**JCIDS**

Joint Capability Integration and Development System

**JTA**

Joint Table of Allowances

**JWG**

Joint Working Group

**LCMC**

Life Cycle Management Command

**LIN**

Line Item Number

**LRIP**

Low Rate Initial Production

**LSAR**

Logistic Support Analysis Requirement

**M&S**

Modeling and Simulation

**MATDEV**

Materiel Developer

**MDA**

Milestone Decision Authority

**MDD**

Materiel Development Decision

**MDR**

Milestone Decision Review

**MEDCASE**

Medical Care Support Equipment

**MEDCOM**

U.S. Army Medical Command

**MEDMAP**

Medical Materiel Acquisition Process

**MEP**

Mission Equipment Package

**MEPD**

Medical Evacuation Proponency Directorate

**MES**

Medical Equipment Set

**MFP**

Materiel Fielding Plan

**MILCON**

Military Construction

**MIMER**

Minor Medical Equipment Requirement

**MOS**

Military Occupational Specialty

**MRSA**

Materiel Readiness Support Activity

**MS**

Milestone (acquisition process)

**MT**

Materiel release

**MMEWR**

Minimum Mission Essential Wartime Requirements

**MRMC**

U.S. Army Medical Research and Materiel Command

**MRS**

Medical Resupply Set

**MTOE**

Modified Table of Organization and Equipment

**NATO**

North Atlantic Treaty Organization

**NET**

New Equipment Training

**NDA**

New Drug Application

**NDI**

Non-development Item

**NICP**

National Inventory Control Point

**NME**

New Molecular Entity

**NSN**

National Stock Number

**O&M**

Operations and Maintenance

**ASA(ALT)**

Assistant Secretary of the Army for Acquisition, Logistics, and Technology

**OCI**

Organizational Conflict of Interest

**OFT**

Operational Feasibility Testing

**OMA**

Operation and Maintenance, Army

**OMAR**

Operation and Maintenance, Army Reserve

**OMARNG**

Operation and Maintenance, Army National Guard

**ORTA**

Office of Research and Technology Applications

**OSD**

Office of the Secretary of Defense

**OSUT**

On-Site User Test/Testing

**OT**

Operational Test

**OT&E**

Operational Test and Evaluation

**OTC**

U.S. Army Operational Test Command

**OTP**

Outline Test Plan

**OTRS**

Operational Test Readiness Statement

**OTSG**

Office of the Surgeon General

**PAA**

Principal Assistant for Acquisition

**PARC**

Principal Assistant Responsible for Contracting

**PI**

Product Improvement

**PIP**

Product Improvement Program

**PLRC**

Product Lifecycle Review Committee

**POI**

Program of Instruction

**POM**

Program Objective Memorandum

**PM**

Program, Project, Product Manager

**PMCS**

Preventive Maintenance Checks and Services

**PPBES**

Planning, Programming, Budgeting, and Execution System

**PWRMR**

Prepositioned War Reserve Materiel Requirements

**P3I**

Pre-Planned Product Improvement

**QQPRI**

Qualitative and Quantitative Personnel Requirements Information

**R&D**

Research and Development

**RAM**

Reliability, Availability, and Maintainability

**RCM**

Reliability Centered Maintenance

**RDA**

Research, Development, and Acquisition

**RDTE**

Research, Development, Test, and Evaluation

**RSC**

Readiness Significant Component

**RSL**

Recommended Stockage Lists

**SKO**

Sets, Kits and Outfits

**TDA**

Table of Distribution and Allowances

**TO&E**

Table of Organization and Equipment

**UAL**

Unit Assemblage List

**USAMMA**

U.S. Army Medical Materiel Agency

**SPA**

Skill Performance Aid

**SPEF**

Single Program Element Funding

**SPF**

Single Project Funding

**SSI**

Special Skill Identifier

**SSN**

Standard Study Number

**SSP**

System Support Package

**STD LI**

Standard Line Item Number

**STO**

Science and Technology Objective

**S&T**

Science and Technology

**TAEDP**

The Army Equipment Distribution Plan

**TC**

Type Classification

**TDA**

Table of Distribution and Allowance

**TDP**

Technical Data Package; Test Design Plan

**TEMP**

Test and Evaluation Master Plan

**TDR**

Training Device Requirement

**TFT**

Technical Feasibility test

**TIWG**

Test Integration Working Group

**TM**

Technical Manual

**TMDE**

Test, Measurement, and Diagnostic Equipment

**TOE**

Table(s) of Organization and Equipment

**TPSP**

Training Plan Support Package

**TRADOC**

U.S. Army Training and Doctrine Command

**TRS**

Test Readiness Statement

**TSARC**

Test Schedule and Review Committee

**TSG**

The Surgeon General

**TSP**

Test support Package

**TTSP**

Training Test Support Package

**USAMEDDBD**

U.S. Army Medical Department Board

**USAMMA**

U.S. Army Medical Materiel Agency

**USAMRMC**

U.S. Army Medical Research and Materiel Command

**USAACE**

U.S. Army Aviation Center of Excellence (USAACE)

**USAR**

U.S. Army Reserve

**WIPT**

Working Integrated Product Team

**Z LIN**

Developmental Line Item Number

**Section II****Terms****Acquisition program**

A directed funded effort that provides a new, improved, or continuing materiel, weapon or information system or service capability in response to an approved need.

**U.S. Army Medical Department investment strategy**

An enterprise approach to synchronize efforts and initiatives to ensure consistency with Army and DOD guidance and plans.

**Associated support items of equipment**

An end item required to support the operation, maintenance, and/or transportation of a BOIP item. ASIOE is listed on the BOIP of the item it supports. ASIOE has its own LIN and is separately documented into TO&E/Vertical-The Army Authorization and Documents System.

**Basis of issue**

The number of items authorized for issue to an individual, a unit, or an activity. The basis of issue (BOI) is stated in authorization documents.

**Catalog of approved requirements documents**

A DA catalog of approved objectives and requirements that provides guidance to combat development activities and the research and development (R&D) program.

**Capability Development Document**

A document that captures the information necessary to develop a proposed program(s), normally using an evolutionary acquisition strategy. The CDD outlines an affordable increment of military useful, logistically supportable and technically mature capability.

**Capability Production Document**

A document that addresses the production elements specific to a single increment of an acquisition program.

**Capital investment equipment**

Medical equipment with a unit price exceeding \$100,000.00. Sets are not considered capital investment medical equipment.

**Combined development and operational testing**

A single event that produces data to answer developmental and operational system issues. A Combined DT/OT is usually conducted as a series of distinct DT and OT phases at a single location using the same test items. For the case where a single phase can be used to simultaneously meet developmental and operational issues, this testing will be referred to as Integrated DT/OT. Combined DT/OT and Integrated DT/OT are encouraged to achieve time, cost, and

resource savings, however, they should not compromise DT and OT objectives in the Defense Acquisition Guidebook (see AR 73-1).

### **Commercial Item**

A commercial item is any item, other than real property, that is of a type customarily used for nongovernmental purposes and that has been sold, leased, or licensed to the general public; or has been offered for sale, lease, or license to the general public; or any item evolved through advances in technology or performance and that is not yet available in the commercial marketplace, but will be available in the commercial marketplace in time to satisfy the delivery requirements under a government solicitation. Also included in this definition are services in support of a commercial item, of a type offered and sold competitively in substantial quantities in the commercial marketplace based on established catalog or market prices for specific tasks performed under standard commercial terms and conditions; this does not include services that are sold based on hourly rates without an established catalog or market price for a specified service performed.

### **Commercial off the shelf**

A subset of commercial item, COTS is defined as any item of supply that is—

- a.* A commercial item;
- b.* Sold in substantial quantities in the commercial marketplace; and
- c.* Offered to the Government without modification, in the same form in which it is sold in the commercial marketplace; and does not include bulk cargo, as defined in section 3 of the Shipping Act of 1984 (46 U.S.C. App. 1702), such as agricultural products and petroleum products.

### **Common table of allowances item**

An item of materiel that can be authorized by a common or specific usage criteria and that does not require documentation in TAADS-R and decentralized computation of requirements by the Structure and Composition System (see AR 71-32).

### **Cooperative research and development agreement**

A legal agreement between one or more Federal laboratories and one or more non-Federal parties under which the laboratory provides personnel, services, facilities, equipment, or other resources (but not funds), with or without reimbursement, and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts that are consistent with the missions of the Army R&D activity.

### **Cost of operational effectiveness analysis**

A documented investigation of—

- a.* Comparative effectiveness of alternative means of meeting a requirement for eliminating or reducing a force or mission deficiency.
- b.* The validity of the requirement in a scenario that has the approval of TRADOC and HQDA.
- c.* The cost of developing, producing, distributing, and sustaining each alternative for a time preceding the combat application.

### **Cost and training effectiveness analysis**

A methodology that involves documented investigation of the comparative effectiveness and costs of alternative training systems for attaining defined performance objectives. Usage patterns and training scenarios are taken into consideration. Training concepts: training equipment: training strategies: programs of instruction: and training impacts of new materiel, organization, tactics and employment techniques or families of systems may be examined in a CTEA.

### **Critical issues**

Those issues, associated with the development of an item or system, that are of primary importance to the decision-maker in reaching a decision to allow the item or system to continue into the next phase of development.

### **Defense Health Program**

Established by statute, all funds appropriated to carry out the functions of the Secretary of Defense with respect to medical and health care programs of the Department of Defense are appropriated to the DHP account. The DHP appropriation for FY 2011 exceeded \$32 billion.

### **Development tester**

An activity engaged in conducting development testing that may be any one or a combination of the materiel developer's activities, including the contractor.

**Developmental testing**

Testing of materiel systems conducted by the materiel developer. The principle of a single, integrated development test cycle is used to demonstrate that the design risks have been minimized, the engineering development process is complete, and the system will meet specifications; and to estimate the system's military utility when it is introduced. DT is conducted in factory, laboratory, and proving ground environments.

**Environmental impact assessment and/or environmental impact statement**

An analysis of ongoing activities or proposed plans and programs that include systematic analyses of the environmental impact (adverse and beneficial) on land, air, water, man, and other biota.

**First unit equipped date**

The scheduled date a system or end item and its agreed upon support elements are issued to the designated IOC unit and training specified in the NET plan has been accomplished. Support elements to be issued with system or end item will be specified in the materiel fielding plan or other gaining command developer agreement documents.

**Front-end analysis**

In training development, precisely defining performance requirements through equipment analysis and functional analysis, which yields a total task list; assessing the requirements of each task against target population skills; and determining which tasks (although covered by the related technical manual) require supplementary training. (Other) The analysis phase of Instructional System Design (ISD) in which doctrine is combined with the job and task analyses process.

**Health hazard assessment (see AR 40-10)**

The Army's formal process used to identify, control, or eliminate health hazards associated with the development and acquisition of new materiel.

**Initial capabilities document**

Documents the need for a materiel approach to a specific capability gap derived from an initial analysis of materiel approaches executed by the operational user and, as required, an independent analysis of materiel alternatives. It defines the capability gap in terms of the functional area, the relevant range of military operations, desired effects, and time. The ICD summarizes the results of the DOTMLPF analysis and describes why non-materiel changes alone have been judged inadequate in fully providing the capability.

**Initial operational capability**

The criteria and schedule when a program must attain initial operational capability is defined the program's CDD and CPD. It is the first attainment of the capability (as declared by the IOC organization) by a Modified TOE unit and supporting elements to operate and maintain a production item or system effectively provided:

- a. The item or system has been Type Classified - Standard or approved for limited production.
- b. The unit and support personnel have been trained to operate and maintain the item or system in an operational environment.
- c. The unit can be supported in an operational environmental in such areas as special tools, test equipment, repair parts, documentation, and training devices. This designation is usually applied at a point in the Defense Acquisition Model that is after the full-rate production decision review and implies that the unit is combat ready.

**Independent evaluation (user tests)**

The process by which the combat developer examines the test design and test report to extrapolate from other evidence, including experimental, historical, and analytical data; and which provides military judgment to assess or estimate the military utility and operational effectiveness of the tested system, including RAM. For user tests, it is used to concentrate on the operational aspects of the materiel system and to consider other programmed testing and comments on operational tests provided by participants in the materiel acquisition process. Each independent evaluation is used to assess the adequacy of testing and the validity of test results.

**Independent evaluation plan**

The materiel developer's or operational tester's internal master plan to evaluate a materiel system's technical or operational effectiveness.

**Independent evaluation report**

A report that provides an assessment of item or system. Technical performance and operational effectiveness versus critical issues as well as the adequacy of testing to that point in the development of the item or system.

**Individual and collective training plan**

A plan developed to reflect how training on new and improved equipment will be incorporated into CONUS schools, training centers, and units worldwide. The plan details all training support required for weapon/equipment systems. It also describes the training required. Both individual and collective for each MOS and TOE associated with the weapon/equipment system.

**Initial operational capability**

The initial operational capability is the first attainment of the capability by a TOE unit and supporting elements to operate and maintain effectively a production item or system provided:

**The item or system has been type classified as standard or approved for limited production**

The unit and support personnel have been trained to operate and maintain the item or system in an operational environment.

**The unit can be supported in an operational environment in such areas as special tools, test equipment, repair parts, documents, and training devices**

Integrated logistic support (see AR 700–127)

**A unified and iterative approach to the management and technical activities**

To influence operational and materiel requirements, system specifications, and the ultimate design or selection (in the case of NDI or commercial item).

**Define the support requirements best related to system design and to each other**

Develop and acquire the required support.

**Provide required operational phase support for best value**

Seek readiness and cost improvements in the materiel system and support systems throughout the operational lifecycle.

**Integrated product/process team**

A working level team of representatives from all appropriate functional disciplines working together to build successful and balanced programs, identify and resolve issues, and provide recommendations to facilitate sound and timely decisions.

**Lifecycle management**

A management process applied throughout the life of a system that bases all programmatic decisions on the anticipated mission-related and economic benefits derived over the life of the system.

**Line item number**

A six-character alpha numeric identification of a generic nomenclature and the line on which the generic nomenclature is listed in SB 700–20, the Army Master Data File and Army authorization documents.

**Logistician**

A command or agency other than the materiel developer, combat developer, training developer, and user representative, which is responsible for independent logistic surveillance and evaluation of materiel acquisition programs. The logistician accomplishes this by reviewing program documents for logistic support considerations and recommending changes to the proponents; by taking part in selected special task forces, special study groups, and test integration working groups; by taking part as a regular member of IPRs; and by assisting the logistic elements of combat and materiel developers, trainers, and user representatives in carrying out their respective functions in the Integrated Logistic Support Program.

**Maintainability**

A characteristic of design and installation that inherently provides for an item to be retained in or restored to a specified condition within a given time when it is maintained in accordance with prescribed procedures and resources.

**Major item**

A final combination of component parts or materials that is ready for its intended use. It is important enough to be subject to continuing, centralized, individual item authorization and management throughout all command support echelons.

**Manpower and Personnel Integration**

The process of integrating all relevant information and considerations regarding the full range of manpower, personnel,

training, human factors engineering, system safety, health hazards, and Soldier survivability into the system design, development and acquisition process to optimize total system performance and minimize ownership costs over the life of the program.

### **Market research**

A continuous process for gathering data on product characteristics, suppliers' capabilities, and the business practices that surround them, plus the analysis of that data to make acquisition decisions. Market research has two phases: market surveillance and market investigation.

### **Materiel developer**

The RDA command, agency, or office assigned responsibility for the product under development or being acquired. The term may be used generically to refer to the RDA community in the materiel acquisition process (counterpart to the generic use of CAPDEV).

### **Materiel Fielding Plan**

A document, which in final updated form, contains all the detailed plans, schedules, procedures, actions, and status necessary to successfully deploy, process, and sustain a new item in the field. The MFP is capable of being transmitted to the gaining command and, with comparable gaining command plans, serves as the basis for signed agreements and replaces the Logistic Support Plans formerly required by AR 750-1.

### **Milestone decision authority**

The person vested with the authority to make milestone decisions. This may be the Defense or Component Acquisition Executive, a PEO, or for Army medical materiel, the CG USAMRMC, or designee.

### **Modified table of organization and equipment**

An authorization document that prescribes the modification of a basic TO&E necessary to adapt it to the needs of a specific unit or type of unit.

### **New equipment training**

The initial transfer of knowledge from the developer or provider to the user and or trainer. This training is required to instruct on-site personnel in the use of equipment and establish a training base and, or unit training capability in Army Commands, Army Service component commands, direct reporting units, NG and Army Reserve units for new or modified equipment.

### **Non-development item**

A NDI is any previously developed item of supply used exclusively for government purposes by a Federal Agency, a State or local government, or a foreign government with which the United States has a mutual defense cooperation agreement; any item described above that requires only minor modifications or modifications of the type customarily available in the commercial marketplace in order to meet the requirements of the processing department or agency. (DAU Glossary of Acquisition Terms. See also FAR Part 2.101.)

### **Operational test readiness statement**

A statement of the materiel systems readiness for OT provided to the command or agency responsible for OT by the materiel developer, the combat developer, and the training developer. OTRS elements will be provided at one time before testing for separate OT following DT. Depending on the degree of time overlap between DT and OT OTRS are delivered at various times before and during DT.

### **Operational tester**

That command or agency responsible for the conduct of operational testing of items and systems. It derives program and budget information for OT, writes OT portion of the coordinated test program determines when, where, how, and by whom OT will be accomplished and prepares operational test design plans, conducts or directs the conduct of OT reports on test results and provides independent evaluations. For most Army medical programs, the designated independent operational tester is the AMEDD Test Board.

### **Operational testing**

Testing and evaluation of materiel systems accomplished with typical user operators, crews, or units in as realistic an operational environment as possible to provide data to estimate—

*a.* The military utility, operational effectiveness, and operational suitability of new systems. Suitability includes compatibility, interoperability, reliability, availability and maintainability, supportability, operational Soldier-machine interface, and training requirements.

b. From the user viewpoint, the system's desirability, considering systems already available and the operational benefits and, or burdens associated with the new system.

c. The need for modification to the system.

d. The adequacy of doctrine, organization, operating techniques, tactics, and training for employment of the system; the adequacy of maintenance support for the system; and, when appropriate, its performance in a countermeasures environment.

### **Outline test plan and/or resume sheet**

The formal document included in the FYTP that contains appropriate administrative information; the test purpose, objective, scope, and tactical context: resource requirements; and cost estimates.

### **Product Improvement Program**

A program to incorporate an engineering change and/or a modification change after production to correct design deficiencies, improve operation or maintenance, reduce costs, simplify design, achieve compatibility with other systems/equipment, or enable it to be used in a new role.

### **Program, project, product manager**

The chartered manager for an acquisition program. A PM may be subordinate to the AAE, a PEO, or another AAE-designated MDA.

### **Provisioning**

Provisioning is the management process for determining and acquiring the number and quantity of different support items required to operate and maintain an end item for an initial period of service.

### **Qualitative and quantitative personnel requirements information**

A compilation of specified organizational, doctrinal, training, and personnel information developed by the materiel developer in coordination with TRADOC for new or modified materiel items.

### **Reliability, availability, and maintainability**

The concepts, objectives, and responsibilities for RAM during system development as prescribed in AR 70-1. RAM characteristics must be specified for the design of the materiel and considered and assessed concurrently throughout the system lifecycle. RAM applies primarily to systems developed, produced, or acquired for use by the Army in the field, specifically including facilities to the extent that they are integral components of systems and modified systems.

### **Reliability centered maintenance**

An essential ingredient of thorough maintenance planning concentrating on that part of planning that requires the determination of scheduled and unscheduled maintenance tasks. Through RCM a detailed logic process is provided to segregate maintenance requirements into on-condition, hard time, and condition-monitoring categories.

### **Sets, kits, and outfits**

A collection of component items and support items designed to accomplish one general function. It is identified, cataloged, authorized, and issued as a single end item. It may be made up of components and support items included in more than one class of supplies; may include separately type-classified end items; may include components and support items for which logistic responsibilities are assigned to more than one agency; and may include nonexpendable, durable, and expendable components and support items.

### **Skill performance aids**

A systematic approach to developing technical documents and training.

a. The key features are as follows:

(1) Systematic analysis of the equipment to identify all performance tasks.

(2) Analysis of all tasks to develop step-by-step performance procedures.

(3) Development of Soldier-tested manuals with full procedures.

(4) Identification of performance tasks that require supplementary training.

(5) Development of lesson and training management materials to directly support the technical manual. After all materials are validated and verified, the technical manual becomes the primary resource of all training. The TM is the primary reference source for using training materials.

b. Includes requirement for a front-end analysis (FEA) (that is, task analysis, equipment analysis, functional analysis, behavioral task analysis).

c. A support package that enables Army units to receive, use, and maintain equipment with a minimum of outside

technical assistance and outside training support. Training is restricted to teaching equipment specific task sequences, plus use of the technical manual that is the basic reference.

**Table of distribution and allowances**

Authorization document that specifies the organizational structure and the personnel and equipment requirements and authorizations of a military unit to perform specific mission for that there is no appropriate TO&E.

**Table of organization and equipment**

The TO&E is a document that prescribes the wartime mission, capabilities, organizational structure, and mission essential personnel and equipment requirements for military units.

**Technical feasibility test**

This test is the responsibility of the materiel developer and provides test data for a technical evaluation and assessment of items and systems developed by another service, a foreign nation, or a commercial firm. The results of this type of testing may provide input for a new LR, LOA, or HOC; modification of an outline development plan, development plan, or the initiation of a PIP. TFT may be evaluated by the decision review as qualifying for DT 1.

**Technical data package**

A term used to describe the documentation that specified the form, fit, function, and manufacture requirements for an item or service. The TDP is directly associated with the production package and includes selected technical data and other related data, such as specifications, plans, engineering drawings, standards, models, objectives, performance requirements, procedures, techniques, test and verification documents to insure conformance, or production package and production equipment component part purchase descriptions.

**Test design plan**

A formal document approved by the test organization that states the circumstances under which a test is executed, the data required from the test, and the means of handling test data.

**Test support unit**

The command or agency that supports a test by providing military personnel and TOE units and a portion of the operational test directorate.

**Trainer**

The command or agency responsible for conducting the training that will provide the skills necessary to operate and logistically support materiel systems being developed or otherwise acquired.

**Training developer**

The agency responsible for developing the training program to include strategy, unit and institutional training requirements, program of instruction (P01) development, training aids requirements, and other associated training requirement functions.

**Training device**

Any three-dimensional object developed, fabricated, or acquired specifically to improve the learning process. May be either system or non-system devices. System devices are designed for use with one system or item of equipment, including subsystems and components. Non-system devices are designed to support general military training and/or for use with more than one system or item of equipment.

**Training test support package**

A package used to train user troops for testing and planning data collection on training requirements.

**Type classification**

Army process used to establish the degree of acceptability of materiel for Army use. See AR 700-142 for TC policy details.

**User testing**

A generic term encompassing OT, the Concept Evaluation Program (CEP), and Force Development Test and Experimentation.

**Unit Assemblage List**

A UAL is a listing of supplies and or equipment contained in an assemblage. This list has all the necessary item

descriptive information for identification. Components contained within this list are also identified by NSN's and or LIN's, if applicable.

### **Section III**

#### **Special Abbreviations and Terms**

This section contains no entries.

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