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MEDICAL MATERIEL ACQUISITION MANAGEMENT

HANDBOOK

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This handbook has been prepared for Army Medical Department personnel involved in all aspects of materiel acquisition. It describes the Medical Materiel Life Cycle System Management process and serves as an instruction manual for new personnel and as a "roadmap" for product development action officers to follow. The handbook reflects the latest acquisition initiatives, particularly as they relate to non-major systems. The handbook addresses, and is limited to, responsibilities of the materiel developer, combat developer, logistician, trainer and tester of medical materiel. The Surgeon General's responsibilities associated with the acquisition of non-medical materiel are not included.

There are two volumes. Volume One, Chapters 1 through 8, provides an overview of the Army Life Cycle System Management Model, the participants in the medical materiel acquisition process, pre-milestone I activities, and a summary of medical materiel programs -- development, nondevelopment, modified nondevelopment, and product improvement. Volume Two

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Block 19 - consists of eighteen acquisition process chapters (such as Integrated Logistics Support, Test and Evaluation, and Training) each with accompanying flow charts that show the sequence of events and document flow by time and agency/office responsibility. Narrative descriptions are provided to assist action officers involved in the specific process.

The handbook also discusses the regulatory interfaces required for medical materiel development and production including biological and pharmaceutical product developments.

PREFACE

The Medical Materiel Acquisition Management (MEDMAM) Handbook describes the policies, procedures, documentation and responsibilities necessary for implementing the materiel acquisition concept contained in AR 1000-1, Basic Policies for Systems Acquisition; AR 70-1, Systems Acquisition Policy and Procedures; AR 71-9, Materiel Requirements; and AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel (currently under revision).

A Joint Working Group of representatives from key Army Medical Department (AMEDD) organizations in the acquisition process, with assistance provided by the Defense Systems Management College (DSMC), was convened to develop this Handbook. The Handbook was primarily prepared for AMEDD personnel involved in all aspects of materiel acquisition. It describes the Medical Materiel Life Cycle System Management Model (LCSMM), and integrates the myriad of processes, decisions, and key players involved in medical materiel acquisition management.

This Handbook is a major achievement in documenting the medical materiel acquisition process. It reflects the latest acquisition initiatives as they relate to non-major systems and medical materiel. The Handbook will be kept current through periodic reviews by the Joint Working Group. Accordingly, recommendations for clarification, changes, additions, deletions or other improvements to make this a more useful document should be forwarded to the U.S. Army Medical Materiel Development Activity.

I strongly recommend the use of this Handbook for the Army Medical Department. This documentation and clarification of the complex process for development and acquisition of medical materiel is a significant and major step in our capability to improve and enhance readiness.

Quinn H. Becker
Lieutenant General
The Surgeon General

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FOREWORD

This handbook has been prepared for Army Medical Department personnel involved in all aspects of materiel acquisition. It describes the medical materiel life cycle management process and serves as an instruction manual for new personnel and as a "roadmap" for product development action officers to follow. The handbook reflects the latest acquisition initiatives, particularly as they relate to non-major systems. It has also incorporated the changes in the recently released Army Regulations 70-1, System Acquisition Policy and Procedure and 71-9, Materiel Requirements, as well as the expected to be released AR 70-10, Test and Evaluation. These 1986 revisions have significant impact on the AMEDD materiel acquisition process. Changes range from terminology through procedural to conceptual and include:

TERMINOLOGY

- MANPRINT versus Soldier Machine Interface;
- Technical Tests to encompass development and other engineering tests;
- User Tests to encompass operational and CBTDEV tests;
- Market Analysis to encompass market surveillance and market investigation;
- Abbreviated Analysis for IPR programs in lieu of the Cost and Operational Effectiveness Analysis.

PROCEDURAL

- Eliminate DA IPR and simplify IPR procedures;
- Add Master Evaluation Plan as an annex to the TEMP;
- Delete MARDIS requirements
- Add performance characteristics to the O&O Plan and uses O&O Plan as a requirements document to Milestone II;
- Delete the LOA, TDLOA, LR, TDLR;
- JMRB replaces DSARC.

- Add Non-System Training Device Requirement;
- Make the ROC the standard requirements document after Milestone II;
- Add Expedited Essential ROC for urgent requirements;
- Introduces BDP and MAMP as links between mission need assessment and program initiation.

CONCEPTUAL

- Requires continuous evaluation;
- Provides "license" for tailoring - The Army Streamlined Acquisition Process (ASAP).

The Surgeon General (TSG) has Army Staff responsibility for medical materiel Research, Development, Test and Evaluation (RDT&E). Specifically, TSG will monitor the life cycle management of Army medical materiel from research and exploratory development through production and deployment. The Surgeon General is also charged with developing policies, responsibilities and general procedures for the acquisition of medical materiel; assessing health hazards; providing advice and consultation to Army materiel and combat developers in investigation of attendant problems related to medical aspects of non-medical RDT&E programs; and maintaining coordination and liaison with the Department of the Army Deputy Chief of Staff for Personnel for system safety and the Commanding General, U.S. Army Materiel Command for human factors engineering of developmental materiel. This handbook addresses, and is limited to, responsibilities of the materiel developer, combat developer, logistician, trainer and tester of medical materiel. The Surgeon General's responsibilities associated with the acquisition of non-medical materiel are not included.

This handbook consists of two volumes. Volume One, Chapters 1 through 8, provides an overview of the Army life cycle system management model, the participants in the medical materiel acquisition process, pre-milestone I activities, and a summary of medical materiel programs -- development, non-development, modified nondevelopment, and product improvement.

Volume Two consists of eighteen acquisition process chapters (such as Integrated Logistics Support, Test and Evaluation, and Training each with accompanying flow char that show the sequence of events and document flow by time and agency/office responsibility. Narrative descriptions are provided to assist action officers involved in the specific process.

A Glossary of Terms, List of References, and List of Acronyms and Abbreviations are provided at the end of the Handbook. Specific references are provided with each chapter and, when appropriate, appendices provide additional information.

Whenever, in this publication, "man", "men", or their related pronouns appear, either as words or parts of words (other than with obvious reference to named male individuals), they have been used for literary purposes and are meant in their generic sense.

Additional copies of this handbook may be obtained through a written request to the U.S. Army Medical Materiel Development Activity, Attn: SGRD-UMS, Fort Detrick, Frederick, MD 21701. Comments and/or recommendations regarding the handbook should be submitted on DA Form 2028 to the above address.

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MEDICAL MATERIEL ACQUISITION HANDBOOK

VOL I

CHAPTER 1

THE U.S. ARMY MATERIEL ACQUISITION PROCESS

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1.1 BACKGROUND

This chapter is an overview of The U.S. Army Materiel Acquisition Policies, Procedures, Processes and Participants. It is a summary, which, through the Life Cycle System Management Model (LCSMM), describes the Army's "cradle to grave" concept of system acquisition and management. This chapter emphasizes non-major systems acquisition policies and procedures as these constitute the vast majority of Medical Materiel Acquisition Programs. The Medical Materiel Acquisition Programs are described in Chapter 2. Department of Defense Directive 5000.1, Acquisition of Major Defense Systems and Department of Defense Instruction 5000.2, Major Systems Acquisition are implemented by Army Regulations 1000-1, Basic Policies for Systems Acquisition, and 70-1, System Acquisition Policy and Procedures, as well as AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel. In addition, AMC/TRADOC Pamphlet 70-2, Materiel Acquisition Handbook describes the AMC/TRADOC system acquisition procedures.

1.2 THE CONCEPT-BASED REQUIREMENTS SYSTEM

The Army has developed a comprehensive approach to attain its goal of balance between readiness, modernization, sustainability and force structure. This approach, called the Concept-Based Requirement System (CBRS), is the basis from which all requirements evolve, and provides the focus for development of doctrine, force design, training programs, and programs for new and improved Army materiel.

The CBRS process begins with a visualization of how the Army intends to fight. This visualization or operational concept, is refined and applied to thirteen TRADOC mission areas (see Chapter 3, Pre-Program Initiation Activities). These mission areas serve as the basis for evaluating the Army's capability to address the projected threat.

Mission Area Analysis (MAA) is the tool used by the combat developers (CBTDEV) to analyze operational concepts and identify specific deficiencies in doctrine, training, organizations (force structure) and materiel. The Battlefield Development Plan (BDP) is a prioritized list of primary deficiencies.

In response to this ongoing MAA/BDP process, the Materiel Developer (MATDEV) targets emerging technologies with the potential to remedy identified materiel deficiencies. The Department of the Army Long Range RD&A Plan (LRRDAP) documents this focus by correlating the requirements identified in the MAA/BDP to research and development efforts within the Army. The Mission Area Materiel Plan (MAMP) then identifies candidate technologies and prioritizes specific projects and their development plans against the Army identified deficiencies.

Before the Army initiates a materiel acquisition program to correct an identified deficiency, the Combat Developer (CBTDEV) must first consider the relative effectiveness of changing doctrine, organization, and/or training. When training, doctrine or organizational changes are not a viable solution to a deficiency, a number of materiel acquisition alternatives are available. AR 70-1, System Acquisition Policy and Procedures, and AR 1000-1, Basic Policies for System Acquisition are the primary documents guiding materiel acquisition activities. The objective of system acquisition is to "accomplish timely and effective research, development, testing and acquisition of ... materiel systems... at the lowest life cycle cost while responding to approved operational requirements..." (AR 70-1). AR 70-1 also directs that the following materiel options be evaluated in the order listed before initiating a new development program:

- Product Improvement - Improving an existing item to take advantage of the latest technology and training and logistics investments;
- Nondevelopment Item - Buying existing domestic or foreign commercial or military equipment;
- Modified Nondevelopment Item - Modifying existing domestic or foreign commercial or foreign equipment.

A new development program should be initiated only after a determination is made that these alternatives are not feasible, practical and/or viable.

1.3 ACQUISITION PROGRAM CATEGORIES AND PARTICIPANTS

1.3.1 Acquisition Program Categories. There are three categories of acquisition programs. Program designation occurs at program initiation, e.g., approval of the Operational and Organizational (O&O) Plan.

1. DOD Major Program. A DOD Major Program is so designated by the Secretary of Defense (SECDEF) based on risk, urgency of need, Congressional interest, joint Service involvement, or resource requirement. A major program is initiated by a Justification for Major System New Start (JMSNS). The JMSNS is prepared when estimated funding exceeds $200 million RDTE or $1 billion procurement (FY80 dollars). DOD major programs are required to be reviewed by the Joint Requirements and Management Board (JRMB) and approved by the SECDEF at each milestone. The JRMB review process replaced the DSARC in 1986.

2. Designated Acquisition Program. A Designated Acquisition Program (DAP) is so designated by the Army Acquisition Executive (AAE), who is the Assistant Secretary of the Army for Research, Development and Acquisition, based on review of an approved O&O Plan, and an assessment of importance, complexity, and resource requirements. At each milestone, DAPs are reviewed by the Army Systems Acquisition Review Council (ASARC) and require AAE approval of key milestones.

3. In-Process Review. An In-Process Review (IPR) Program describes all other programs. At each milestone, IPR programs are reviewed by a materiel developer conducted IPR. No higher review is required if the IPR participants agree. If there is disagreement, resolution will be accomplished through the MATDEV chain of command up to the DCSRDA. If there is disagreement in the medical materiel acquisition process, review and approval is the responsibility of HQDA (OTSG).

The three program types are summarized in Appendix A.

1.3.2 Acquisition Program Participants. Many organizations are involved in the Army materiel acquisition process. Appendix B summarizes the functions of the primary participants. Organizations serve to represent the key functional entities directly required to execute a coordinated materiel acquisition program. These functional entities include the Combat Developer, Materiel Developer, Tester, Logistician and Trainer.

1.3.2.1 Office of the Secretary of the Army. The Office of the Secretary of the Army (OSA) is responsible for providing policy guidance and directing the ASARC. The Assistant Secretary of the Army (Research, Development and Acquisition) serves as the Army Acquisition Executive (AAE). He is the principal advisor and staff assistant to the Secretary of the Army for acquisition of Army systems. In addition, OSA reviews all O&O plans to determine whether to designate the program as a Designated Acquisition Program (DAP), in which case it is subject to ASARC review and subsequent Secretary of the Army approval.

1.3.2.2 Headquarters, Department of the Army. The Headquarters, Department of the Army (HQDA) exercises general staff responsibilities for all Army acquisition activities. Specifically, the Deputy Chief of Staff for Research, Development and Acquisition (DCSRDA) has responsibility for the formulation and execution of DA RDA activity. The DCSRDA appoints a member of his staff as the Department of the Army System Coordinator (DASC) to serve as a focal point for all aspects of development and acquisition for a specific system or group of systems.

1.3.2.3 Deputy Chief of Staff for Operations and Plans. The Deputy Chief of Staff for Operations and Plans (DCSOPS) develops strategic concepts, plans and broad force requirements. He also directs the monitoring and issuance of guidance for CBTDEV programs. The DCSOPS appoints members of his staff as Force Integration Staff Officers (FISO) to provide user representation on the DA staff and serve as a coordinator between the user and materiel development communities. Organizational Integrators (OI) are assigned to the ODCSOPS staff to act as the Army staff coordinators on force integration issues from an organizational standpoint.

1.3.2.4 Deputy Chief of Staff for Logistics. The Deputy Chief of Staff for Logistics (DCSLOG) has responsibility for ensuring that proper logistic policy is inserted in R&D, force development and procurement regulations. He also establishes the HQDA position as to the supportability and acceptability for DOD major programs and DAPs. The DCSLOG designates individuals on his staff as DA Logistics Support Officers (DALSO). The DALSO represents the Integrated Logistics Support (ILS) interests of the materiel and combat developers on the DA staff.

1.3.2.5 The Deputy Chief of Staff for Personnel. The Deputy Chief of Staff for Personnel (DCSPER) is responsible for preparing the HQDA position on health hazards, and system safety; analyzing materiel systems' qualitative and quantitative personnel requirements; the operation of Army-wide human factors engineering, personnel, and training RDT&E programs; and management of the Manpower and Personnel Integration (MANPRINT) requirements. The DCSPER appoints members of his staff as DA Personnel System Staff Officers (PERSSO). The PERSSO acts as the HQDA focal point for manpower, personnel, and training issues for one or more systems.

1.3.2.6 Comptroller of the Army. The Comptroller of the Army (COA) directs financial management matters. He schedules and coordinates DAP and selected IPR program materiel system cost estimates, reviews program life cycle cost estimates, and recommends the Army cost position to the ASARC.

1.3.2.7 The Surgeon General. The Surgeon General (TSG) monitors the life cycle management of Army medical materiel, as well as assessing the health hazards of materiel, and investigating the medical aspects of non-medical Research, Development, Test and Evaluation (RDTE) programs. He also develops policy, responsibilities and general procedures for acquisition of medical materiel.

1.3.2.8 Combat Developer. The U.S. Army Training and Doctrine Command (TRADOC) is the Army's principal CBTDEV, and is responsible for the formulation of doctrine, concepts, organization, materiel requirements, and objectives. The CBTDEV also represents the user's requirements in the materiel

acquisition process. Other organizations that have CBTDEV responsibilities include the CG U.S. Army Health Services Command (USAHSC) through the Academy of Health Sciences (AHS) for medical materiel. A Memorandum of Understanding (MOU) defines the relationships of HSC with TRADOC, and provides AHS with a status similar to that of a TRADOC school.

Three positions in TRADOC serve as focal points for acquisition programs. The TRADOC System Staff Officer (TRASSO) and the TRADOC Integration Staff Officer (TISO) are the system (materiel) and organizational coordinators respectively at HQ TRADOC. The TRADOC System Manager (TSM) is appointed by the CG TRADOC to serve at the proponent school as the manager of all facets of user input and user actions throughout development, production, and deployment of assigned systems. For systems without a TSM, the school's Director of Combat Development serves as the focal point.

1.3.2.9 Materiel Developer. The U.S Army Materiel Command (AMC) is the Army's principal MATDEV. Four other organizations have been designated as MATDEVs: Chief of Engineers, The Surgeon General (TSG), the U.S. Army Information Systems Command and the Strategic Defense Command. The MATDEVs are responsible for research, development, and production of a system in response to approved requirements. The MADTEVs also conduct technical testing. Program/Project/Product Managers (PM) provide centralized management of acquisition programs. Formal charters, approved at an appropriate level, define the PMs responsibilities and required coordination.

Two positions at HQ AMC serve as focal points for acquisition programs. The Weapon System Staff Manager (WSSM) is responsible for the system management functions during the entire acquisition cycle, and acts for the Deputy Chief of Staff for Development, Engineering and Acquisition until the system transitions, and the Deputy Chief of Staff for Supply, Maintenance, and Transportation thereafter. The Weapon System Support Officer (WSSO) is responsible for providing functional support to the WSSM. The WSSO is the single expert at HQ AMC knowledgeable in the details of the weapon system(s) from the standpoint of his functional area, e.g., contracting and testing.

1.3.2.10 User Testers. These testers conduct comprehensive user testing and perform independent evaluations. Operational Testing (OT) of major systems is primarily the responsibility of the U.S. Army Operational Test and Evaluation Agency (OTEA). Non-major system user testing is usually conducted by TRADOC for Army systems. The AMEDD user tester is the AMEDD Board, AHS.

1.3.2.11 Logistician. The Logistician is the command or agency responsible for logistic supportability issues of materiel acquisition programs. For most equipment, the U.S. Army Logistics Evaluation Agency fills this role. The U.S. Army Medical Materiel Agency serves this function for the AMEDD.

1.3.2.12 Trainer. The trainer is normally the same organization as the CBTDEV. Consequently, TRADOC, AHS, and the U.S. Army Information Systems Command have training responsibilities.

1.3.2.13 Readiness Proponent. The Readiness Proponent is the activity responsible for logistic support of materiel systems after transition of responsibility from the materiel developer, and extending through the life of the system. Transition occurs after Milestone III for developmental systems and modified NDI, and at Milestone I for NDI programs. Logistic support includes materiel fielding, new equipment training, readiness analyses, and analyses and corrections of design and production deficiencies.

Representatives from the organizations described in the preceding paragraphs direct the acquisition process. Collectively, they are referred to as the Army Materiel Acquisition Team along with other representatives from HQDA, Army Major Commands and Program Management Offices (see Appendix B).

1.4 THE LIFE CYCLE SYSTEM MANAGEMENT MODEL

1.4.1 General. The purpose of the Army's materiel acquisition process is to provide a sequence of events and phases of program activities and decisions which will ensure efficient and effective fielding of fully supportable systems that respond to validated Army requirements. This process is best described by using a Life Cycle Systems Management Model (LCSMM) which depicts

graphically and by narrative description, the "standard" or "model" process for developing, acquiring, fielding and supporting new items of equipment. Existing LCSMMs range from simple charts (AR 70-1) to highly detailed representations (DA PAM 11-25). The LCSMM portrayed in Chart 1-1 (fold out at end of chapter) is tailored to present a simplified version of non-major system acquisition procedures, in consonance with the goals of this handbook.

The primary objectives of the LCSMM for Army systems are to:

- Outline general procedures for the development and acquisition of Army systems from materiel concept investigation through ultimate disposal of obsolete systems (cradle to grave concept).
- Provide a convenient outline for checking completeness of coordination and correlation of combat development; research and development; production and logistic support; training; personnel requirements and Headquarters, Department of the Army actions relating to the development, acquisition, and maintenance of Army systems.
- Provide information to personnel involved in the development and acquisition of Army materiel systems regarding the correlation of activities of their commands or agencies with related activities of other commands and agencies.

The LCSMM concept pertains to both major and non-major systems. There are, however, significant differences in the intensity of management of major and non-major systems, including the management documentation requirements and the level at which program Milestone Decisions are made.

The LCSMM guides all Army materiel acquisition activities. It is divided into phases of activity, each separated by a decision review, in which the status of the program is assessed relative to its cost, schedule, support and performance objectives. Chart 1-1 illustrates the process decision points, funding and documentation requirements for Army non-major systems.

There are three categories of acquisition documents: requirements, program management, and program decision.

1. Requirements documents state an Army need against which the program is conducted. They are generated by the combat developer, with the assistance of the materiel developer, and approved by the decision authority. Examples of existing requirements documents are O&O Plans, JMSNS, Letters of Agreement (LOA), Letter Requirement (LR) or Required Operational Capability (ROC), and Joint Service Operational Requirement (JSOR) for multi-Service programs. If appropriate, Training Device Requirements documents (TDLR or TDLOA) were also prepared. Based on the 1986 revision of AR 71-9, the LOA, LR, TDLOA, and TDLR will no longer be used. However, existing approved documents will remain in effect until the program is completed. The O&O Plan or JMSNS and ROC or JSOR are the standard requirements documents for all new programs.

2. Program Management documents provide individual plans for implementing the Acquisition Strategy (AS). Program management documents include: the Acquisition Plan, the Individual and Collective Training Plan, the Configuration Management Plan, the Test and Evaluation Master Plan and the System MANPRINT Management Plan.

3. Program decision documents are normally generated by the MATDEV with CBTDEV assistance. They are reviewed by the review body and approved by the Decision Authority. These documents include the System Concept Paper (SCP), the Decision Coordinating Paper (DCP), and the Integrated Program Summary (IPS).

1.4.2 Pre-Program Initiation Activities. A need for a materiel acquisition program is supported by an ongoing Mission Area Analysis (MAA) conducted by the CBTDEV which constantly assesses the capability of a force to perform within a particular battlefield scenario and functional area. MATDEVs are responsible for maintaining a strong technology base in anticipation of correcting deficiencies and to increase capabilities. MAA and the technology base are mutually supportive. Research and development is guided by the Long Range Research, Development and Acquisition Plan (LRRDAP) (see Chapter 9, The LRRDAP).

The Army's Long Range Research, Development, and Acquisition Plan, TRADOC's Mission Area Analysis process, and the Materiel Developer's Mission Area Materiel Plans combine to provide a roadmap of how to meet the future threat. They provide a means to consider future implications of current decisions and ways to couple these actions with the Planning, Programing, Budgeting, and Execution System for resource allocation (see Chapter 10, The PPBES Process).

Mission Area Analysis synthesizes information gained from many individual studies and analyses into a single, internally consistent framework. To facilitate the detailed analyses of the Army's ability to execute its wartime missions, the overall battlefield concept has been divided into 13 mission areas, e.g., Air Defense, Close Combat (light), and Fire Support, (see Chapter 3, Pre-Program Initiation Activities, for a complete listing).

These mission areas serve as the basis for measuring the capabilities of the force programmed in the current Program Objectives Memorandum (POM). Each mission area is assigned to a TRADOC center/school for analyses and the prioritization of resulting deficiencies. When specific mission deficiencies are identified which appear to warrant development of new or improved materiel, an Operational and Organizational (O&O) Plan is prepared by the CBTDEV in coordination with MATDEV, the trainer, and the logistician.

If, during staffing of the O&O Plan, MATDEV estimates that the proposed program will require in excess of $200 million RDTE or $1 billion in procurement (FY80 dollars), then a Justification for Major System New Start (JMSNS) must be prepared and submitted to HQDA (see AR 70-1, System Acquisition Policy and Procedures, and AR 71-9, Materiel Objectives and Requirements).

1.4.3 Program Initiation Decision (Milestone 0). All O&O Plans are approved by HQ TRADOC, which constitutes program initiation. Approved O&O Plans are forwarded to HQDA. The ODCSOPS circulates the O&O Plans to allow the AAE the opportunity to designate programs as DAPs. Unless so designated by the AAE, the programs are managed by IPRs at the MATDEV level.

1.4.4 Concept Exploration Phase. The MATDEV and CBTDEV are primarily responsible for the conduct of the Concept Exploration (CE) Phase based on the approved O&O Plan. This phase of the acquisition process identifies and explores alternatives and acquires information necessary to select the best options for system concepts and hardware/computer software development. Consideration of threat is particularly critical during this phase. Technical and resource requirements for proposed systems are established through studies and the development and evaluation of experimental concepts. Critical technical, training, logistic, operational, health, human factors engineering, safety, reliability, producibility, cost, and manpower issues are identified for resolution in order to minimize future development risks. Investigations must also analyze support and readiness characteristics of current systems, develop alternative operational and support concepts, and evaluate the manpower and logistic support resource implications of each alternative.

The Concept Exploration Phase may draw heavily on ongoing efforts conducted in the Technology Base (6.1, 6.2, 6.3A). However, all new RDT&E funding to support Concept Exploration will be 6.3B.

In exploring alternatives, Product Improvement (PI) (Chapter 8), Nondevelopment Item (NDI) (Chapter 6), and Modified NDI (Chapter 7) programs must be considered.

1.4.5 Milestone I Decision - Concept Approval. The first major milestone decision involves concept selection and approval to enter the next phase, normally the Demonstration and Validation (D&V) Phase. The Decision Authority validates the requirement and approves the AS (an Annex to the SCP) proposed by the materiel developer to satisfy the requirement.

The documents required for the Milestone I decision review include the SCP, the TEMP, the Integrated Logistic Support Plan (ILSP), and the Concept Formulation Package (CFP). These documents are used in the Milestone Decision Review Process (MDRP) (see Chapter 12, The MDRP).

The decision review for IPR programs is conducted by the MATDEV. The IPR reviews the program, and if concurrence is reached, the IPR recommendation is forwarded to the Decision Authority who documents his decision in a System Acquisition Decision Memorandum (SADM) based on the IPR recommendation. If the IPR cannot reach agreement, and intervening command levels cannot resolve the issue, the minutes are forwarded to HQDA (DCSRDA) for resolution and issuance of a SADM.

For DAPs, decision review is accomplished by the ASARC. Based on the ASARC's recommendations, the AAE issues a SADM. Once the SADM has been issued, constituting approval to enter the next phase, it is distributed by ODCSRDA.

1.4.6 Demonstration and Validation Phase. The MATDEV, in coordination with the CBTDEV, trainer, and logistician, conducts the Demonstration and Validation Phase effort based on direction provided by the SADM. This phase consists of steps necessary to verify preliminary design and engineering; accomplish necessary planning; analyze trade-off proposals; resolve or minimize logistic and reliability problems and health, safety, and human factors engineering issues identified during the Concept Exploration Phase; prepare a detailed requirements document; and validate the concept for entry into the Full Scale Development (FSD) Phase.

The Demonstration and Validation Phase is supported by the 6.3B, advanced development (system) RDT&E funding category. Much of the documentation generated during this phase is an update of that developed during the Concept Exploration Phase. The CBTDEV also prepares a Cost and Effectiveness Analysis (CEA) (Chapter 13, The Concept Formulation Package Process).

In addition, during this phase and before Milestone II, the CBTDEV, in coordination with the MATDEV, prepares a requirements document. In the past the document could be either a Required Operational Capability (ROC) or a Letter Requirement (LR) for low value items. Currently, the ROC is the standard requirements document. In the case of System training devices, the Trainer, in coordination with the MATDEV, will prepare an annex to the ROC.

At the same time, the MATDEV is responsible for coordinating input in the preparation of the Basis of Issue Plan (BOIP) and Qualitative and Quantitative Personnel Requirements Information (QQPRI) (see Chapter 11, The Requirements Document Process, and Chapter 16, The Training and Training Device Process).

The ROC, BOIP and QQPRI for Designated Acquisition Programs are forwarded to HQDA for review and approval by DCSOPS. The CBTDEV and MATDEV jointly approve documents for IPR programs. After approval of these documents, the Decision Coordinating Paper (DCP) and, if required by the decision authority, the Integrated Program Summary (IPS), are also prepared.

1.4.7 Milestone II - Program Go-Ahead. The second milestone decision point involves deliberations for the program go-ahead decision and approval to proceed to the next phase, normally the Full Scale Development (FSD) Phase. Documentation for all programs to support the Milestone II decision consists of the requirements document, DCP, IPS (if requested by the Decision Authority), TEMP, and CEA. IPRs or ASARCs, are conducted the same as at Milestone I. The Milestone II decision is documented in a SADM which authorizes the program to enter the next phase.

1.4.8 Full Scale Development Phase. The FSD phase is conducted, based on direction provided by the SADM. During this phase, the system, with all items necessary for its support, including training devices and computer resources, is fully developed, engineered, fabricated, tested/evaluated, and a decision made on its acceptability for entering the Army inventory. Non-materiel aspects required to field an integrated system are developed, refined, and finalized. The FSD Phase is supported by the 6.4, Engineering Development, category of RDT&E funding.

Documentation during this phase is similar to that prepared during the Demonstration and Validation Phase. The ILSP, TEMP, AS, AP, and other applicable program management documents are updated. Technical and User Tests (Chapter 17) are conducted. In addition, the BOIP and QQPRI are amended. During this phase, the MATDEV (in coordination with the CBTDEV) prepares the

Type Classification (TC) documentation. The MATDEV, in conjunction with the gaining command and logistician, prepares the initial Materiel Fielding Plan (MFP). The MATDEV also prepares the Milestone III decision documentation, i.e., a DCP and, if required by the Decision Authority, an IPS.

1.4.9 Milestone III - Production Go-Ahead. The third major decision point is the production decision. This includes approval for subsequent deployment. Normally, the Decision Authority delegates the Milestone III decision to the lowest level in the organization where there is a comprehensive view of the program.

Documentation to support Milestone III consists of the DCP, IPS (if requested by the decision authority), TEMP, CEA, and TC documentation. DCSRDA distribution of the approved SADM and a formal TC decision allows the program to enter the Production and Deployment Phase.

1.4.10 Production and Deployment Phase. During this phase, operational units are trained, equipment is procured and distributed, and logistic support provided. Also, production testing and evaluation are accomplished. Product improvements that have been preplanned are applied to the equipment as required. This phase is managed by the readiness proponent and is supported primarily by procurement and Operations and Maintenance (O&M) funds. The materiel release authority assures that materiel released to the field is suitable in terms of safety, quality, performance, reliability, maintainability, and environmental factors.

1.4.11 Operation and Support. During this period in the systems life cycle, the effective and efficient support of the fielded system is the Army's primary concern. The readiness of the system is continually assessed relative to program objectives. The previous planning by the acquisition personnel drives the process. The scope of the program/project/product manager responsibility is decreased as the management activities associated with the program decrease.

1.4.12 Disposal. During ongoing MAA activities, the ability of deployed systems to meet emerging threats is assessed. At some point, further performance enhancement is no longer cost effective or desirable in light of development opportunities and operational requirements. System disposal is normally then implemented, completing the system life cycle.

1.5 ARMY STREAMLINED ACQUISITION PROCESS

As stated in AR 70-1: "tailoring an acquisition program provides the MATDEV with the flexibility to not only modify the standard acquisition process as a reactive necessity but also to make proactive planning decisions to significantly alter, combine or eliminate phases in the process." Basic approaches that can be used to simplify or eliminate phases in the acquisition process are Nondevelopment Items (NDI) (Chapter 6), Modified NDI (Chapter 7), and the Army Streamlined Acquisition Process (ASAP) discussed below.

The regulatory basis for ASAP and an overall description of the program are provided in Chapter 7 of AR 70-1, Systems Acquisition Policy and Procedure. The objective of ASAP is to reduce substantially the total time required to develop, produce, and deploy systems. An initial focus on mature technology and a reorientation of formal milestones and acquisition phases are two key features of this alternative to the traditional acquisition process.

Under ASAP, requirements are structured for companion "now" and "later" capabilities. The "now" capability evolves from the employment of mature technology particularly at the component level. Army laboratories and Army contractors continue to focus their technology base activities on mission area needs. Thereby, capability growth proceeds in parallel with the acquisition cycle for the initial capability. The follow-on capability or capabilities may be implemented via a Pre-Planned Product Improvement (P^3I) program. Figure 1-1 compares ASAP to the standard DoD acquisition process. ASAP combines appropriate elements of Concept Exploration and Demonstration and Validation into a scaled down Proof of Principle approach. Entry into Proof of Principle is governed by a determination by a Technology Integration Steering Committee that the technology and/or components required for system development are essentially at hand.

Upon completion of the demonstrations and experimentation conducted during the Proof of Principle Phase, a final determination is made as to which aspects of the requirement are appropriate for Full Scale Development versus deferred development in a P^3I approach. The collapsed Milestone I/II decision review then constitutes a go-no-go commitment to development and production. The Development and Production Prove Out Phase encompasses Full Scale Development and, whenever possible, production prove out on production representative items. The ability to achieve production proveout during this phase and Type Classification Standard at the end of it (Milestone III) are enhanced by the initial focus on mature technology and/or components.

1.6 REFERENCES

DODD 5000.1, Major System Acquisitions, 1986

DODI 5000.2, Major System Acquisition Procedures, 1986

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

AR 70-1, System Acquisition Policy and Procedures, 1986

AR 70-10, Test and Evaluation, 1986

AR 70-16, Department of the Army System Coordinator (DASC) System, 1975

AR 70-17, System/Program/Project/Product Management, 1976

AR 71-9, Materiel Requirements, 1986

AR 71-10, Department of the Army Force Integration Staff Officer (FISO) System, 1979

AR 71-12, The Department of the Army Logistics Support Officer, 1979

AR 602-2, MANPRINT in the Materiel Acquisition Process, 1986

AR 1000-1, Basic Policies for System Acquisition, 1983

DA Pamphlet 11-25, Life Cycle System Management Model for Army Systems, 1975

AMC/TRADOC Pamphlet 70-2, Materiel Acquisition Handbook, 1984

TRADOC Reg 11-7, Operational Concepts and Army Doctrine, 1985

APPENDIX A

APPENDIX A

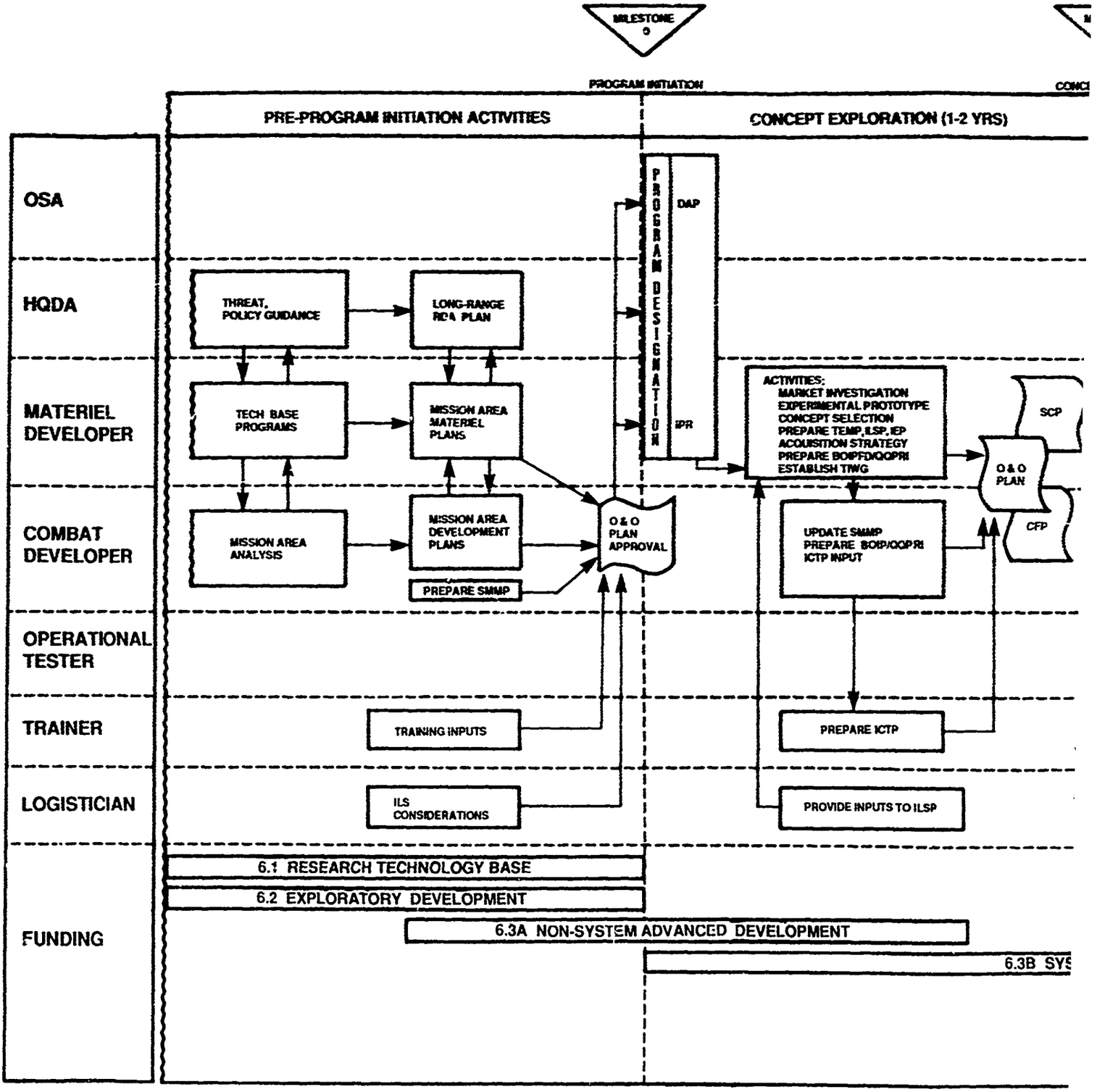
ACQUISITION PROGRAM CATEGORIES

PROGRAM CATEGORIES	CRITERIA	PROGRAM INITIATION	MANAGEMENT	MILESTONE REVIEW INPUT DOCUMENTS	HIGHEST MILESTONE REVIEW	HIGHEST APPROVAL AUTHORITY	MILESTONE REVIEW APPROVAL DOCUMENT
DOD MAJOR	- High risk - Urgency of need - Congressional interest - Joint Service involvement - Resource requirements ($200 million for R&D or $1 billion for production)	JMSNS and O&O Plan	System, Program, or Project Manager	SCP/DCP IPS TEMP	JRMB	SECDEF	SDDM
NON-MAJOR							
DAP	- Importance - Complexity - Resource requirements	O&O Plan	Program or Project Manager	SCP/DCP IPS TEMP	ASARC	AAE	SADM
IPR	- All other programs	O&O Plan	Project or Product Manager or Project Officer	SCP/DCP TEMP	IPR	MATDEV or DCSRDA or OTSG	SADM

ABBREVIATIONS:

AAE - Army Acquisition Executive
ASARC - Army Systems Acquisition Review Council
DAP - Designated Acquisition Program
DCSRDA - Deputy Chief of Staff for Research, Development and Acquisition
DOD - Department of Defense
IPR - In-Process Review
IPS - Integrated Program Summary
JMSNS - Justification for Major System New Start
JRMB - Joint Requirements and Management Board
MATDEV - Materiel Developer
O&O Plan - Operational and Organizational Plan
SADM - System Acquisition Decision Memorandum
SDDM - Secretary of Defense Decision Memorandum
SCP/DCP - System Concept Paper or Decision Coordinating Paper
SECDEF - Secretary of Defense
TEMP - Test and Evaluation Master Plan

APPENDIX B


MILESTONE 0
PROGRAM INITIATION
PRE-PROGRAM INITIATION ACTIVITIES
CONCEPT EXPLORATION (1-2 YRS)
OSA
HQDA
MATERIEL DEVELOPER
COMBAT DEVELOPER
OPERATIONAL TESTER
TRAINER
LOGISTICIAN
FUNDING
PROGRAM DESIGNATION
DAP
IPR
THREAT, POLICY GUIDANCE
LONG-RANGE RD&A PLAN
TECH BASE PROGRAMS
MISSION AREA MATERIEL PLANS
MISSION AREA ANALYSIS
MISSION AREA DEVELOPMENT PLANS
PREPARE SMMP
O&O PLAN APPROVAL
ACTIVITIES:
MARKET INVESTIGATION
EXPERIMENTAL PROTOTYPE
CONCEPT SELECTION
PREPARE TEMP, ILSP, IEP
ACQUISITION STRATEGY
PREPARE BOIP/FD/OOPRI
ESTABLISH TIWG
SCP
O&O PLAN
CFP
UPDATE SMMP
PREPARE BOIP/OOPRI
ICTP INPUT
TRAINING INPUTS
PREPARE ICTP
ILS CONSIDERATIONS
PROVIDE INPUTS TO ILSP
6.1 RESEARCH TECHNOLOGY BASE
6.2 EXPLORATORY DEVELOPMENT
6.3A NON-SYSTEM ADVANCED DEVELOPMENT
6.3B SYS

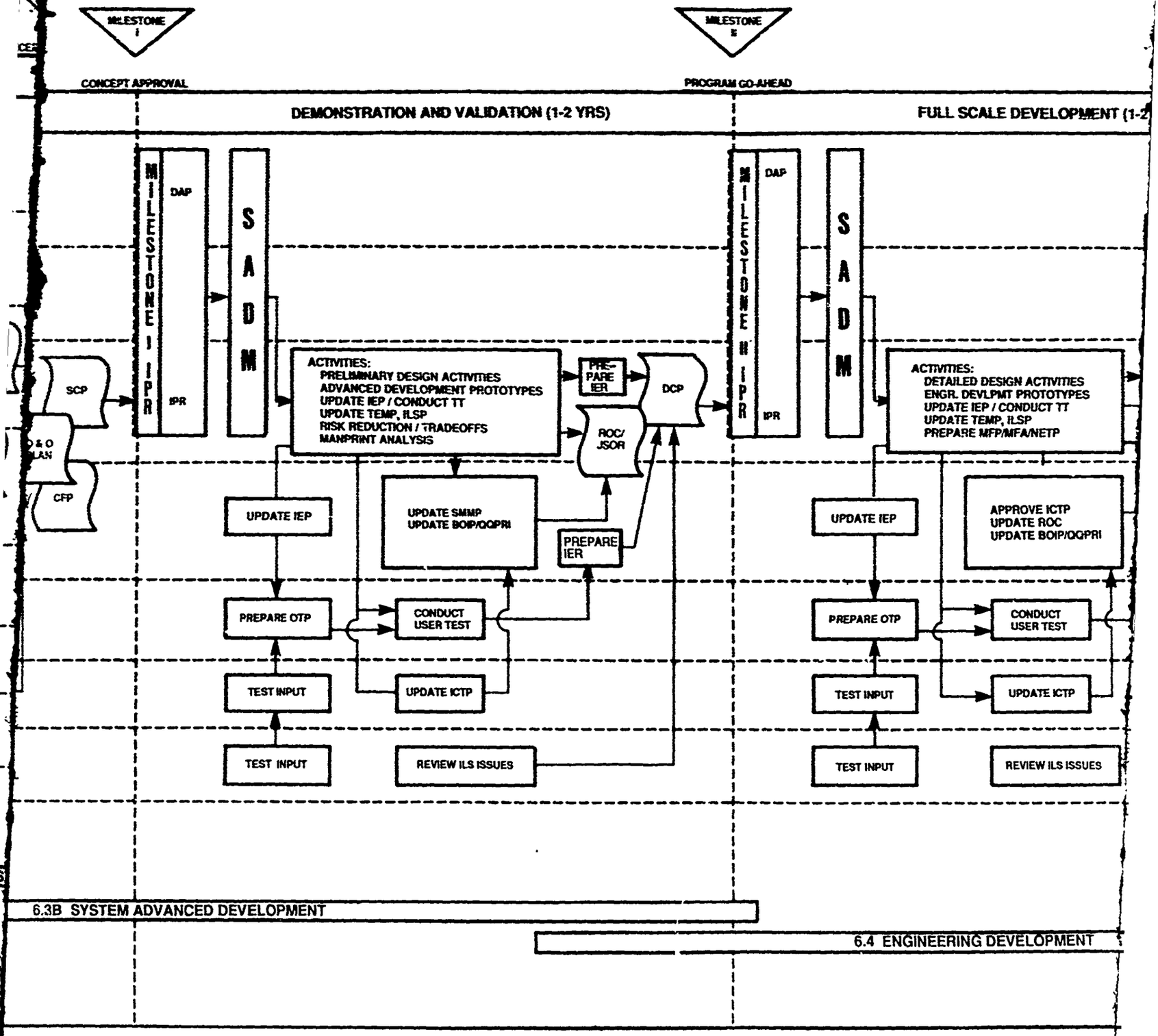
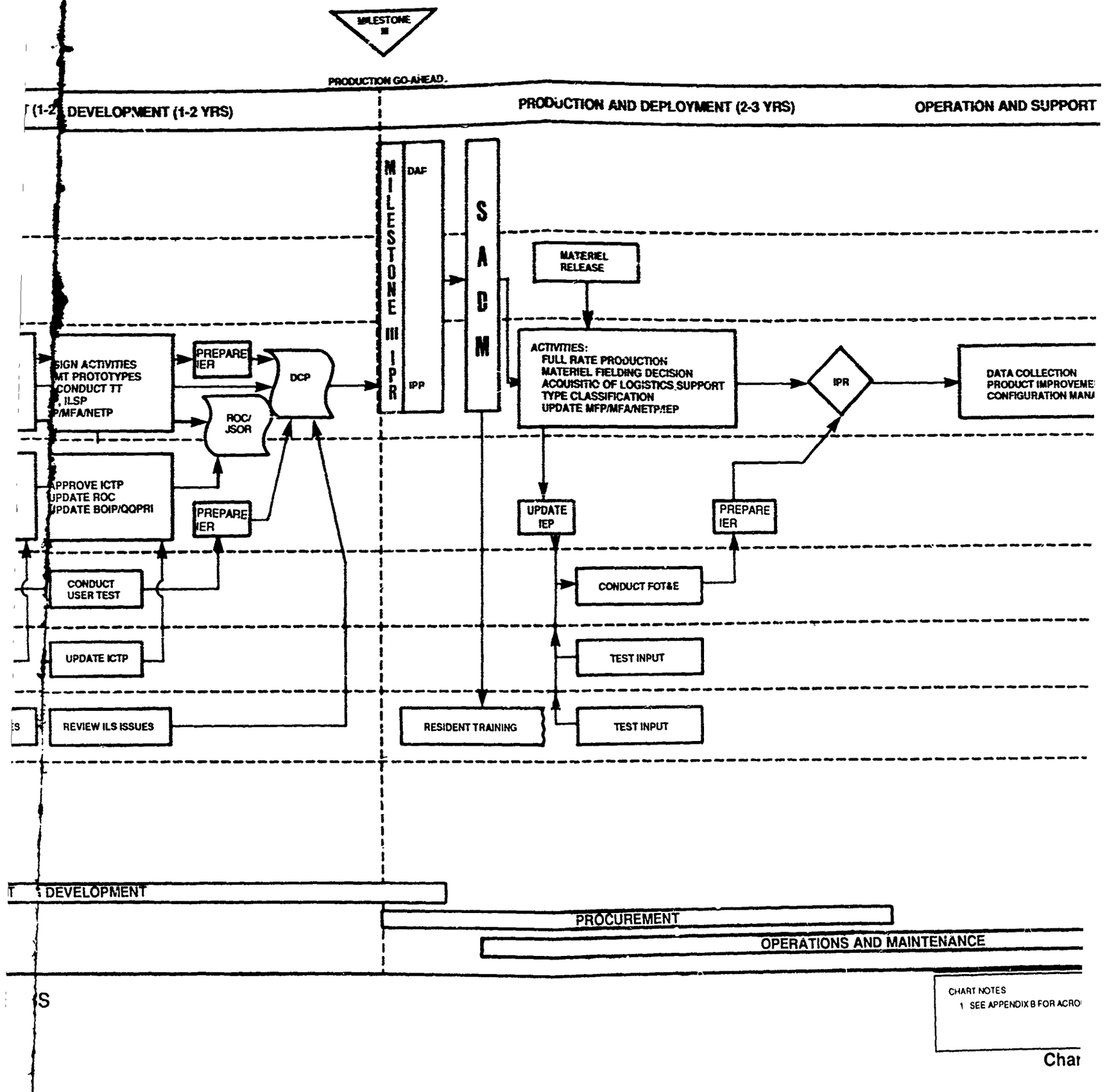


Chart 1-1. U.S. ARMY NON-MAJOR SYSTEM ACQUISITION PROCESS

2


MILESTONE III
PRODUCTION GO-AHEAD
DEVELOPMENT (1-2 YRS)
PRODUCTION AND DEPLOYMENT (2-3 YRS)
OPERATION AND SUPPORT
MILESTONE III IPR
DAF
IPP
SACM
MATERIEL RELEASE
ACTIVITIES:
FULL RATE PRODUCTION
MATERIEL FIELDING DECISION
ACQUISITIC OF LOGISTICS SUPPORT
TYPE CLASSIFICATION
UPDATE MFP/MFA/NETP/IEP
IPR
DATA COLLECTION
PRODUCT IMPROVEME
CONFIGURATION MANA
SIGN ACTIVITIES
MT PROTOTYPES
CONDUCT TT
, ILSP
P/MFA/NETP
PREPARE IER
DCP
ROC/ JSOR
APPROVE ICTP
UPDATE ROC
UPDATE BOIP/QQPRI
PREPARE IER
UPDATE IEP
PREPARE IER
CONDUCT USER TEST
CONDUCT FOT&E
UPDATE ICTP
TEST INPUT
REVIEW ILS ISSUES
RESIDENT TRAINING
TEST INPUT
DEVELOPMENT
PROCUREMENT
OPERATIONS AND MAINTENANCE
CHART NOTES
1 SEE APPENDIX B FOR ACRO

3

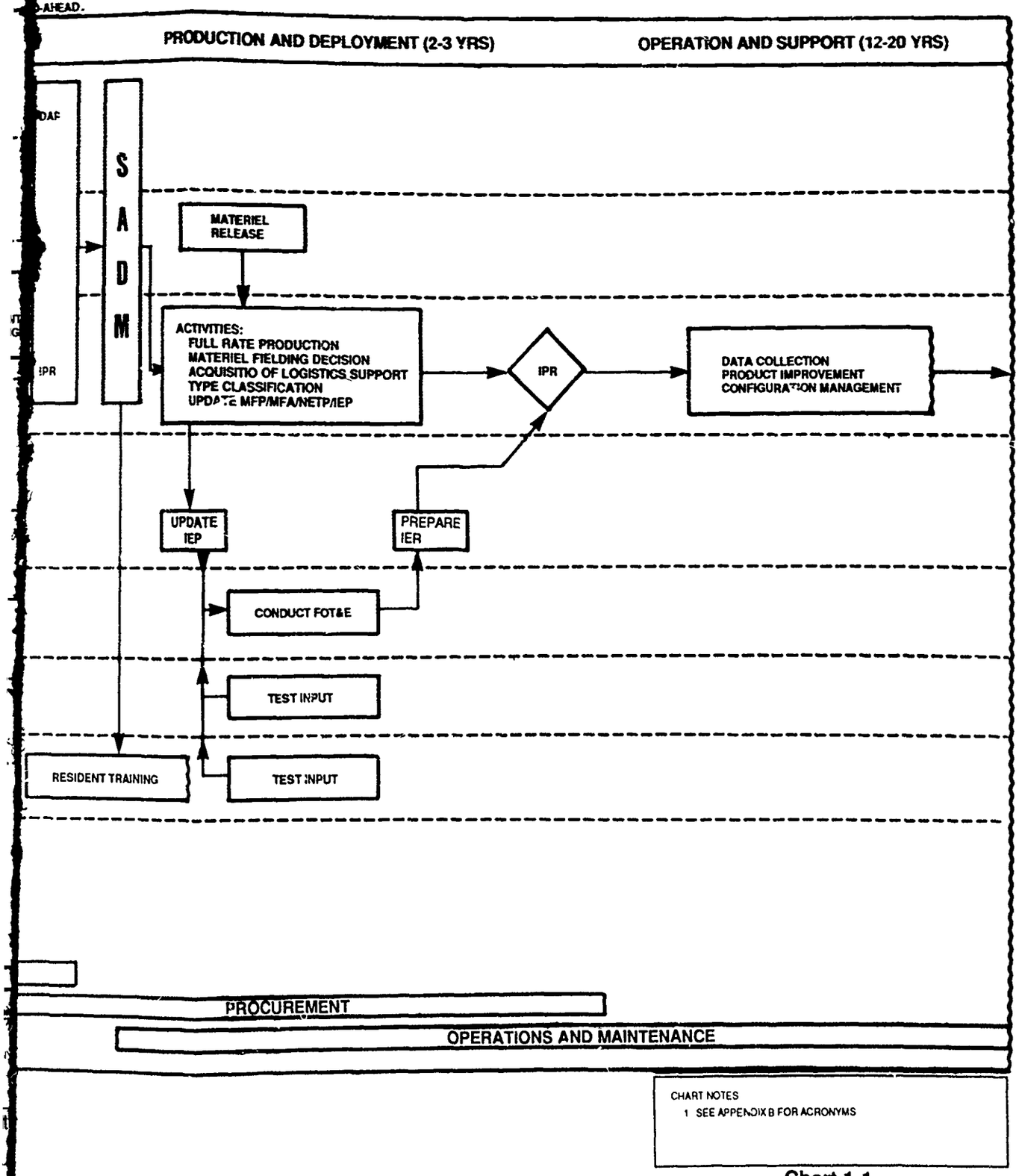


CHART NOTES
1 SEE APPENDIX B FOR ACRONYMS

Chart 1-1

APPENDIX B
U. S. ARMY MATERIEL ACQUISITION PROCESS PARTICIPANTS

FUNCTION	ORGANIZATION/TITLE
Army Acquisition Executive	Assistant Secretary of the Army (Research, Development and Acquisition)
ASARC Chairman	Vice Chief of Staff
ASARC Members	Under Secretary of the Army; DUSA (OR); ASA (RDA); ASA (IL); ASA (FM); ASA (MRA); General Counsel; CG AMC; CG TRADOC; DCSRDA; DCSOPS; DCSPER; DCSLOG; Comptroller of the Army; ACSI; ACSIM; Director PA&E; CG OTEA; CG MTMC; Chief Army Reserve; Chief National Guard. [Chief of Engineers and Chief of Office of Congressional Legislative Liaison may attend if involved with significant issues]
Materiel Acquisition Team Members	Department of the Army System Coordinator (DASC) - DCSRDA Department of the Army Force Integration Staff Officer (FISO) - DCSOPS or OTSG Department of the Army Organizational Integrator (OI) - DCSOPS Department of the Army Logistic Support Officer (DALSO) - DCSLOG Department of the Army Personnel System Staff Officer (PERSSO) - DCSPER TRADOC System Manager (TSM) or Director of Combat Developments (DCD)-Proponent School, TRADOC or AHS TRADOC System Staff Officer (TRASSO) - HQ TRADOC Program/Project/Product Manager (PM) - MATDEV
Organizations/Commands	
Combat Developers	TRADOC, USACC, AHS, INSCOM
Materiel Developers	AMC, COE OTSG, USAISC
User Testers	OTEA, TRADOC, AHS
Technical Testers	AMC/USAMRDC
Logisticians	LEA, USAMMA
Trainers	TRADOC, AHS

CHAPTER 2

MEDICAL MATERIEL ACQUISITION PROCESS PARTICIPANTS

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2.1 DESCRIPTION

This chapter describes the agencies and players involved in the medical materiel acquisition process. It includes those within the Army Medical Department (AMEDD) as well as those in other Army agencies, the Office of the Secretary of Defense, and other agencies of the federal government. The involvement of the agencies and players described herein range from pre-program initiation activities, such as technology base management and mission area analysis, to the acquisition, operation, support, and ultimate displacement and/or disposal of acquired systems and equipment. Figure 2-1 shows those AMEDD staffs and organizations and Army Major Commands involved in the medical materiel acquisition process.

2.2 THE SURGEON GENERAL

Army Regulation (AR) 1000-1, Basic Policies for Systems Acquisition, and AR 70-1, Systems Acquisition Policy and Procedures, specify that The Surgeon General (TSG) has Army Staff responsibility for medical research, development, test, and evaluation (RDT&E). Specifically, TSG monitors life cycle management of Army medical materiel from research and exploratory development through production and deployment; and develops policy, responsibilities, and general procedures for acquisition of medical materiel. AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, supplements AR 1000-1 and AR 70-1, and establishes basic AMEDD policies for research and development in the area of acquisition and fielding of medical systems/products.

The Office of The Surgeon General has been designated as the lead agency for research and development in the areas of infectious diseases and combat dentristy with appropriate budgetary and management authority over the other Services. The Office of The Surgeon General has also been designated as the executive agent for the medical aspects of chemical and biological warfare defense. However, as an executive agent, TSG can only observe and recommend to the other Services.

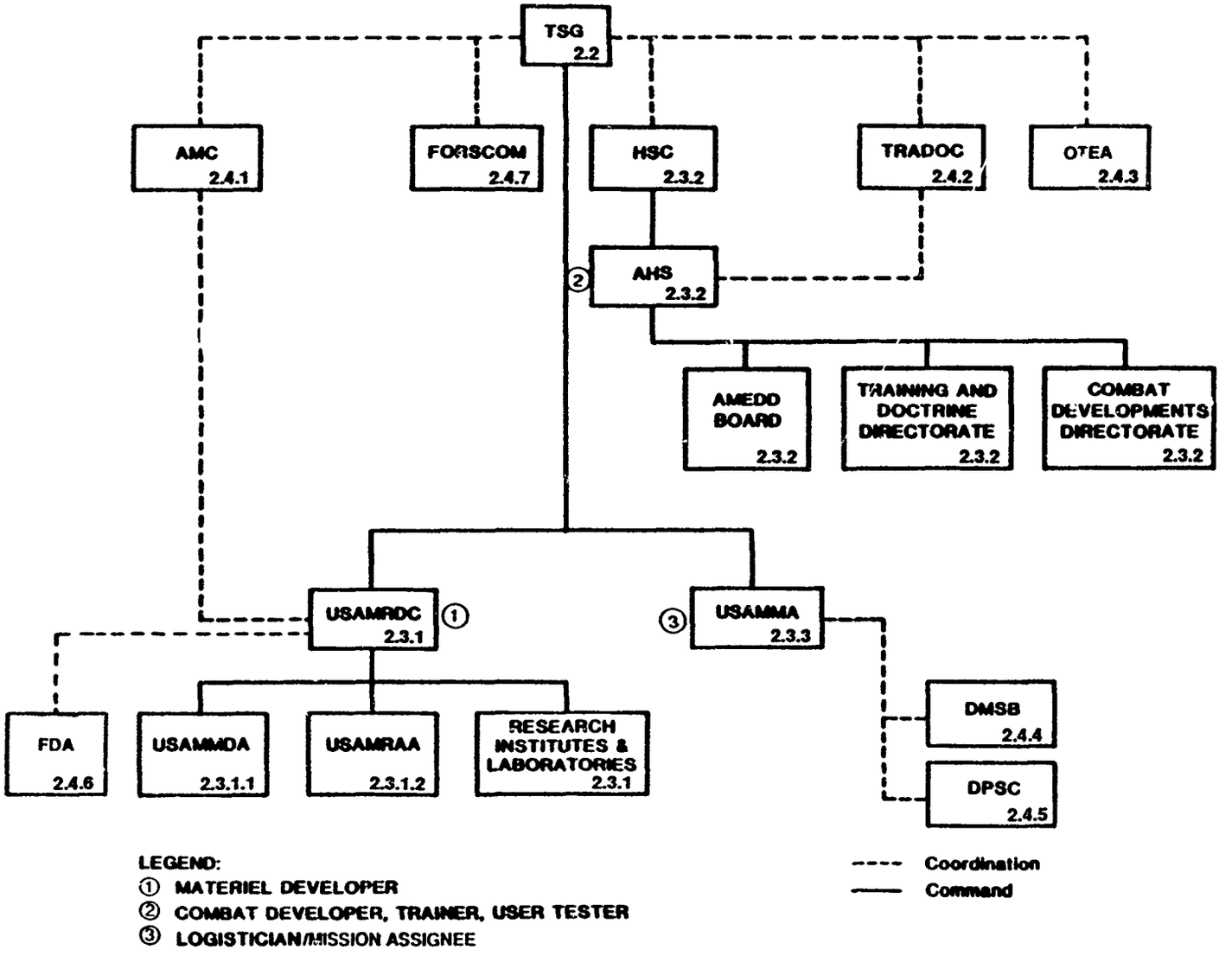


Figure 2-1. MEDICAL MATERIEL ACQUISITION PROCESS PARTICIPANTS

The staff elements in the Office of The Surgeon General (OTSG) which participate in the medical materiel acquisition process include the Assistant Surgeon General for R&D, the Assistant Surgeon General for Dental Services, and the Health Care Operations and Professional Services Directorates. OTSG Regulation 15-16 establishes the Army Medical Department Technical Committee (AMDTC) which operates as a permanent advisory board to TSG. Its mission includes acting as the principal staff interface between the Combat Developer (CBTDEV) and the Materiel Developer (MATDEV), ensuring the orderly integration of development and operational testing of new medical materiel, and coordinating the procurement and issue of newly standardized items.

The Surgeon General also has responsibilities related to non-medical research and development programs in the areas of human factors engineering, safety, health hazards, and other medical aspects of combat and materiel development. These non-medical program responsibilities are beyond the scope of this handbook.

2.3 AMEDD AGENCIES

2.3.1 The U.S. Army Medical Research and Development Command. The U.S. Army Medical Research and Development Command (USAMRDC) is the MATDEV for the Surgeon General and is tasked to plan, coordinate, direct, execute, supervise and review the AMEDD RDT&E Program (See USAMRDC Memorandum 10-1, 1 March 1983). The Commander, USAMRDC also serves on the staff of TSG as the Assistant Surgeon General for Research and Development. Within the Headquarters, five Research Area Directors (RADs) are responsible for program planning for each of the five programmatic areas shown in Figure 2-2.

RESEARCH AREA	PROGRAMMATIC RESPONSIBILITY
I	Military Disease Hazards
II	Combat Casualty Care
III	Army Systems Hazards
IV	Combat Dentistry
V	Medical Chemical Defense

Figure 2-2 USAMRDC Research Areas

There are also nine research institutes and laboratories which are responsible for research programs, or research and development program execution. They are:

- Letterman Army Institute of Research
- Walter Reed Army Institute of Research
- U.S. Army Aeromedical Research Laboratory
- U.S. Army Institute of Dental Research
- U.S. Army Institute of Surgical Research
- U.S. Army Medical Research Institute of Chemical Defense
- U.S. Army Medical Bioengineering Research and Development Laboratory
- U.S. Army Medical Research Institute for Infectious Diseases
- U.S. Army Research Institute for Environmental Medicine

2.3.1.1 The U.S. Army Medical Materiel Development Activity. The U.S. Army Medical Materiel Development Activity (USAMMDA) is a subordinate command of the USAMRDC. It has full line authority in centrally managing all phases of development and initial production of assigned systems and products. Three Project Management Offices (PMO): Biological Systems, Pharmaceutical Systems,

and Applied Medical Systems, and a Project Management Support Office (PMSO) carry out the responsibilities as specified in USAMMDA Memorandum 10-1, 24 November 1984. Figure 2-3 shows the RDT&E program relationships among the RADs, the Laboratories, and the USAMMDA PMOs.

2.3.1.2 The U.S. Army Medical Research Acquisition Activity. The U.S. Army Medical Research Acquisition Activity (USAMRAA) is a subordinate activity of USAMRDC, and performs all extramural R&D contracting and contract administration services. The Activity obtains contractual support for the medical R&D program in the areas of production engineering measures, quality assurance, international logistics requirements, contract administration, small business and legal services, and contract labor relations. In addition, the USAMRAA Research and Development Contract Division provides R&D contract training to Contracting Officer's Representatives (COR) at the laboratories, USAMMDA, and other activities.

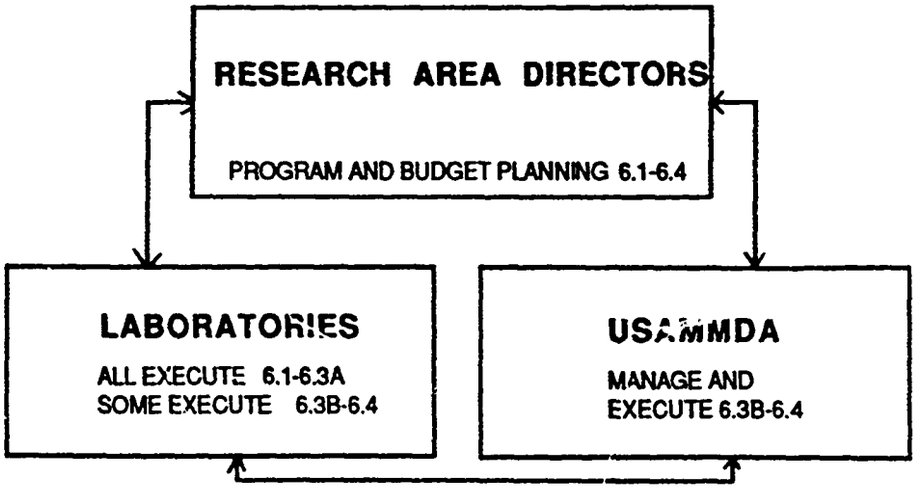


Figure 2-3. RADS/Laboratories/USAMMDA Relationships

2.3.2 The Academy of Health Sciences. The Academy of Health Sciences (AHS) as delegated by the Health Services Command, is the combat developer, trainer, user tester and user representative for most medical materiel. However, there are exceptions such as the U.S. Army Chemical School which is the CBTDEV for some medical products. These functions are carried out primarily by the Directorate of Combat Developments, the Directorate of Training and Doctrine, and the U.S. Army Medical Department Board. AHS is the Military Occupational Specialty (MOS) and Area of Concentration (AOC) developer for medical personnel. Army Regulation 10-43 prescribes the organization and functions of the U.S. Army Health Services Command, and AHS Regulation 10-1 describes the specific missions and functions of the AHS.

2.3.3 The U.S. Army Medical Materiel Agency. The U.S. Army Medical Materiel Agency (USAMMA) is the designated mission assignee and medical logistician in the medical materiel acquisition process. As the logistician, USAMMA provides ILS support and evaluates and manages the materiel readiness aspects of medical materiel acquisition programs. As the mission assignee for Non-Development Items (NDI), USAMMA is responsible for the Acquisition and Deployment Phase activities following the IPR decision to pursue the NDI process. USAMMA also manages the transition of Medical Sets, Kits, and Outfits (MSKO) through the Production and Deployment Phase. Organization and functions of USAMMA are prescribed in AR 10-71.

2.4 NON-AMEDD AGENCIES

2.4.1 The U.S. Army Materiel Command. The U.S. Army Materiel Command (AMC) is the Army's principal materiel developer. Medical materiel acquisition projects may interface with AMC in several areas including type classification (accepted for Service use) of medical materiel, and support of medical materiel training device requirements through AMC's Project Manager for Training Devices (PM-TRADE).

2.4.2 The U.S. Army Training and Doctrine Command. The U.S. Army Training and Doctrine Command (TRADOC) is the Army's principal combat developer and directs all other combat development activities including those performed by AHS. TRADOC has final approval authority over all Operational and Organizational Plans and Individual and Collective Training Plans (ICTP). TRADOC also

provides guidance in the preparation of Basis of Issue Plans (BOIP) and reviews, updates, coordinates, and publishes BOIPs, Quantitative and Qualitative Personnel Requirements Information (QQPRI), and decisions for non-medical Military Occupational Specialties (see Chapter 18, The BOIP/QQPRI Process).

2.4.3 The U.S. Army Operational Test and Evaluation Agency. The U.S. Army Operational Test and Evaluation Agency (OTEA), is the independent operational tester reporting to the Vice Chief of Staff of the Army. OTEAs mission includes a continuous and extensive review of test activities throughout the Army. The Army Medical Department Board test plans and test reports are subject to OTEA review. In addition, in the case of major or special interest programs, OTEA may conduct operational tests for the AMEDD.

2.4.4 The Defense Medical Standardization Board. The Defense Medical Standardization Board (DMSB), as established by Department of Defense Directive (DODD) 6430.2, is the single point of entry for standardized items. The DMSB provides logistics inputs to the initial screening process when standardized or tri-Service items are involved. The DMSB also investigates and standardizes items for use by other Services, when feasible and with tri-Service concurrence. The DMSB prepares or reviews essential characteristics of all items that will enter production, and directs the standardization and acquisition of materiel for all Deployable Medical Systems (DEPMEDS).

2.4.5 The Defense Personnel Support Center. The Defense Personnel Support Center (DPSC) participates in each of the LCSMM milestone review processes as an observer. DPSC also participates in the development of project acquisition strategy and serves as the tri-Service National Inventory Control Point (NICP) for medical materiel. Finally, following Army Type Classification (TC) and based on data provided by USAMMA, DPSC prepares contract specifications from which contractors manufacture medical materiel items. DPSC also procures and distributes medical materiel throughout its life cycle.

2.4.6 The Food and Drug Administration. The Food and Drug Administration (FDA) has oversight responsibilities throughout the life cycle of pharmaceutical and biological systems and applied medical devices. The FDA reviews and approves Investigational New Drug (IND) documents and Investigational Device Exemptions (IDE) submitted by USAMMDA after Milestone I. After Milestone III, USAMMDA submits the New Drug Application (NDA) licensure application, or Pre-Market Approval (PMA) documents for approval. The FDA requirements are superimposed on the materiel acquisition process commencing with the Concept Exploration Phase and continue through production and deployment.

2.4.7 Other Participants. Other activities that participate in the medical materiel acquisition process include the U.S. Army Forces Command (FORSCOM), industry, academic institutions, other Services, other Federal government agencies such as the Environmental Protection Agency and the Department of Agriculture and other nations. Their participation ranges from contributions to the medical technology base, and the imposition of regulatory requirements on the process, to development and production of medical materiel and products.

2.4.8 Memorandums of Agreement/Understanding. In order to achieve an agreed-upon basis for coordination among Army commands, between AMEDD and DOD agencies, and between AMEDD and Federal agencies, several Memorandums of Agreement/Understanding have been executed. These are described in Appendix A.

2.5 PERSONNEL

2.5.1 General. Action officers at the various agencies are designated as focal points for all matters relating to one or more specific systems/products. These personnel are found in the OTSG, USAMMDA, USAMMA, and AHS. The AMEDD assigns personnel to HQ TRADOC, ODCSPER-DA, ODCSOPS-DA, other Services, and other commands and staffs where medical materiel acquisition coordination is necessary. In turn, several non-AMEDD commands and staffs and other Services assign representatives to AMEDD agencies. Points of contact for medical materiel acquisition are listed in Appendix B.

2.5.2 The Department of the Army System Coordinator. The Department of the Army System Coordinator (DASC) is an individual or team designated by the DCSRDA-HQDA under the provisions of AR 70-16, DASC System, to function as the HQDA focal point representing the materiel developer for acquisition matters. The DASC coordinates the status of all events in the LCSMM for a major system, a designated non-major system requiring HQDA in-process review approval, or one or more similar or related non-major systems selected for DASC management.

The DASC's responsibilities are to ensure that HQDA is aware of all significant events in the system development process, and that the Program/Project/Product Manager (PM) is aware of all budget, policy, requirement, and doctrinal actions affecting his program. In order to do this, he continually interacts with all concerned Army Staff agencies. The DASC plays a major role in providing support for program and budget development, preparation, and defense of his system's resource requirements for submission to the Congressional appropriation cycle, and has a key role in responding to Congressional inquiries. He is the HQDA POC, coordinator and expediter for all briefings and documentation in preparation for system ASARCs and Joint Requirements and Management Boards (JRMB). The JRMB replaced the DSARC, effective 3 June, 1986. The Director of Planning, Programming and Budgeting of the Medical R&D Command serves as the Executive Assistant to the Assistant Surgeon General for Research and Development, and fulfills the function of the DASC for all AMEDD materiel development programs.

2.5.3 The Department of the Army Force Integration Staff Officer System. Army Regulation 71-10, establishes the Force Integration Staff Officer (FISO) System. The FISO is a person (or team) named by the DCSOPS-HQDA to act as the HQDA requirements coordinator and to represent the interests of the combat developer on all aspects of materiel needs, acquisition, and deployment for a specific new or product-improved system. His concern is integration of new systems into the Army force structure. He has a primary DA role in the requirements process. Once a requirement is approved, he monitors actions to develop the Basis of Issue Plan (BOIP), manpower requirements, training considerations, strategy and doctrine implications, and assignment of resources.

He serves as coordinator between the user community and the DASC (materiel developer). The AMEDD implements the FISO concept by assigning FISOs to the Health Care Operations Directorate (DASG-HCZ), OTSG.

2.5.4 The Department of the Army Organizational Integrator. The Organizational Integrator (OI) acts as the Army Staff coordinator on force integration issues from an organizational perspective. The OI manages the changes to organizations caused by the introduction of new and product improved materiel, as well as structural or doctrinal change. The OI coordinates and integrates the materiel development efforts of the DASC, DALSO, PERSSO and FISO from the perspective of the organization or unit commander. Three Army Medical Department officers will be assigned to the Office of the Deputy Chief of Staff for Operations and (DAMO-FDL) or to OTSG to serve as OIs and staff medical organizational ges.

2.5.5 The Department of the Army Personnel System Staff Officer. The Personnel System Staff Officer (PERSSO), appointed by the DCSPER, is the HQDA focal point for all manpower, personnel, and training issues associated with new systems development and fielding for specific projects or groups of projects. An AMEDD officer currently serves in the ODCSPER (DAPE-MPA) as the PERSSO for medical materiel.

2.5.6 The Department of the Army Logistics Support Officer. The DA Logistics Support Officer (DALSO) is an individual in the Office of the Deputy Chief of Staff for Logistics representing the ILS interests of the materiel developer and combat developer on the DA staff. The DALSO monitors new or product improved materiel acquisitions to ensure that all elements of ILS, as outlined in AR 700-127 are satisfactorily scheduled and completed. The DALSO is also responsible for all phases of logistic support for existing materiel systems in the force structure. The Health Care Logistics Division (DASG-HCL) performs these functions for the OTSG.

2.5.7 The TRADOC System Staff Officer. The TRADOC System Staff Officer (TRASSO) is designated to function as the principal HQ TRADOC point of contact for assigned materiel systems, projects, or programs. TRASSOs are normally selected from the staff assigned to one of the Mission Area Directorates within the Office of the Deputy Chief of Staff for Combat Developments (ODCSCD). The TRASSO monitors all aspects of the development program for assigned systems to ensure that all events are progressing properly. He coordinates development and approval of the HQ TRADOC position for milestone decision reviews and other issues for his systems. He expedites procAssing of all systems-related actions through the HQ TRADOC staff, either to HQDA, HQ AMC, HQ USAMRDC or to the proponent school. An AMEDD officer serves in HQ TRADOC (ATCD-SE) as the TRASSO for medical materiel programs.

2.5.8 The TRADOC System Manager/Director of Combat Developments is appointed and chartered by the CG TRADOC to function as a focal point for coordination of the combat developer, user and trainer efforts in the development and acquisition of assigned system(s). TRADOC System Managers (TSMs) are appointed for selected and DAP programs. TSMs are appointed early in the development cycle, normally at the same time as the PM. He is the TRADOC counterpart of the PM and is usually located at the proponent school. For systems without an assigned TSM, the Director of Combat Developments (DCD) at the proponent school, including the AHS, serves as the focal point.

2.5.9 The Program/Project Manager is appointed by the Secretary of the Army to manage the acquisition process for a specific program or group of programs. AR 70-17, System/Program/Project/Product Management, establishes procedures and assigns responsibilities governing the use and application of centralized management of the materiel acquisition process. Project Management Offices (PMO) for biological and pharmaceutical systems and applied medical systems have been established by USAMMDA. The USAMMDA concept of project management provides for considerable individual variation in the PMO organizations designed to meet specific mission requirements while effectively employing scarce resources. The PMs manage development and modified non-development programs through the Milestone III decision review at which time

the programs are transitioned to USAMMA for management during the Production and Deployment Phase. USAMMA Product Managers also manage non-development items and medical sets, kits and outfits from Milestone I through the Production and Deployment phase. USAMMA Product Managers are appointed by the Commander, USAMMA and are not chartered by the Secretary of the Army. Product Management is an internal management and control device for programs that do not require program/project management.

Project and Product Managers are responsible for all aspects of their programs and may be called on to present and defend their programs before milestone decision reviews. They are responsible for developing and coordinating the program's Acquisition Strategy, program management documents and the decision documentation submitted at each milestone review.

2.6 REFERENCES

DoDD 5000.1, Major System Acquisitions, 1986

DoDI 5000.2, Major System Acquisition Process, 1986

DoDD 6430.2, DoD Medical Standardization Board, 1984

AR 40-10, Health Hazards Assessment in Support of the Materiel Acquisition Decision Process, 1983

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

AR 70-1, Systems Acquisition Policy and Procedures, 1986

AR 70-10, Test and Evaluation, 1986

AR 70-16, The Department of the Army System Coordinator (DASC), 1975

AR 70-17, System/Program/Project/Product Management, 1976

AR 71-9, Materiel Requirements, 1986

AR 71-10, The Department of the Army Force Integration Staff Officer (FISO) System, 1979

AR 71-12, The Department of the Army Logistics Staff Officer (DALSO), 1979

AR 1000-1, Basic Policies for Systems Acquisition, 1983

OTSG Regulation, Army Medical Department Technical Committee (AMDTC), 1981

APPENDIX A

MEMORANDUMS OF AGREEMENT
AND
MEMORANDUMS OF UNDERSTANDING

1. MOA Between the Health Services Command (HSC) and HQ TRADOC. This MOA provides an agreed-upon basis for coordination between the Commander, U.S. Army Training and Doctrine Command (TRADOC) and the Commander, U.S. Army Health Services Command (HSC) in the execution of their interrelated responsibilities for combat and doctrine developments, training and training developments, and user testing in the U.S. Army. The Commandant, Academy of Health Sciences, serves as the principal agent of the Commander, HSC for the functions listed above.

The Commander, TRADOC has designated the U.S. Army Logistics Center as the principal agent for the integration of all the actions pertaining to health service support operations for the U.S. Army. Other agents designated by the TRADOC Commander are:

- The U.S. Army Combined Arms Center is the principal agent for management of the Doctrinal Literature Program.
- The U.S. Army Soldier Support Center is the Executive Agent for TRADOC on all matters pertaining to concepts and doctrine in human resource development, to include personnel considerations in the materiel acquisition process, and other personnel-related programs.
- The U.S. Army Training Support Center is responsible for centrally managing the production, procurement, warehousing, and delivery of training support products including training devices.

2. MOA between USAMRDC/USAMMA/AHS and the AMC Project Manager for Training Devices. This MOA defines responsibilities and establishes procedures of the Project Manager for Training Devices (PM-TRADE) in support of the development and/or procurement of non-system medical training devices for AHS and for system specific medical training devices for the USAMRDC or USAMMA. The agreement covers the concept formulation, validation, full scale development and initial procurement of training devices.

3. MOA between the USAMRDC and the U.S. Army Troop Support Command (TROSCOM). This MOA clarifies/amplifies the interfaces between the respective support roles in the fielding process for Insect and Rodent Control Equipment and other systems identified for transition to TROSCOM.

4. An MOA between the USAMRDC and the DPSC. This MOA was established to promote liaison and direct communication between the USAMRDC and DPSC and their subordinate elements for the development and procurement of medical materiel, and to ensure that a minimum time lag occurs between Army type - classification and DPSC production contracting.

5. MOU between the USAMRDC and the FDA. This MOU formalizes the relationships and defines the responsibilities of the USAMRDC and the FDA to each other during the research, development, and pre-marketing acquisition of medical materiel for military application. The MOU is limited to quality assurance support by the FDA for USAMRDC Advanced Development (6.3B) and Engineering Development (6.4). Medical materiel, for the purpose of this MOU, includes drugs, biological products, protective cosmetics, and medical devices.

6. MOU between the USAMRDC and the Aerospace Medical Division, USAF Systems Command. This MOA establishes the concept, policy and process for joint Army/Air Force planning, programming, coordinating, and executing of advanced development (6.3B) and engineering development (6.4) programs for medical defense against chemical warfare. The MOA provides for each Service to review its assigned missions for their applicability for integration into a joint development program and provides the basis for resolving programmatic issues at the execution level.

7. MOU Between the FDA and the DOD. This MOU establishes procedures for approval to conduct clinical investigations under three circumstances: standard studies, studies with unique requirements, and studies requiring classified information. The DOD is solely responsible for determining the security classification. Classified clinical investigations do not require the filing of formal "Notice of Claimed Investigation Exemption for a New Drug". Approval by the Service's Investigational Drug Review Board and Surgeon General automatically provides the exemption required to conduct clinical investigations. When testing has established the safety and efficacy of such drugs with reasonable certainty, approval for their extensive use in military personnel may be obtained by joint action of representatives of the DOD and the FDA.

APPENDIX B

POINTS OF CONTACT FOR MEDICAL MATERIEL ACQUISITION

APPENDIX B

POINTS OF CONTACT FOR MEDICAL MATERIEL ACQUISITION

COMMAND STAFF	DIRECTORATE/DIVISION/BRANCH
Headquarters, Department of Army, Washington, D.C. 20310	
Office of the Surgeon General	Health Care Operations Directorate (DASG-HCZ) Doctrine, Policy & Organization Div. (DASG-HCD) Health Care Logistics Div. (DASG-HCL)
Office of the Deputy Chief of Staff for Operations and Plans	Force Requirements Directorate (DAMO-FDR)
Office of the Deputy Chief of Staff for Personnel	Personnel Plans and Systems Directorate (DAPE-PS) Military Personnel Management Directorate (DAPE-MP) Force Management Division (DAPE-MPM)
Office of the Deputy Chief of Staff for Research, Development and Acquisition	Combat Support Systems Directorate (DAMA-CSZ) Support Systems Division (DAMA-CSS) Executive Secy ASARC (DAMA-RAX) Materiel Plans and Programs Directorate (DAMA-PPZ) Primary Standardization Office (DAMA-INP)
Program Analysis and Evaluation Directorate	(DACS-DPZ)

U.S. Army Operational Test and Evaluation Agency, 5600 Columbia Pike Falls Church, VA 22041	Combat Support and Non-Major System Division (CSTE-CSS) Test Division (CSTE-TD)
Headquarters, U.S. Army Materiel Command, 5001 Eisenhower Ave Alexandria, VA 22333	Deputy Chief of Staff for Development, Engineering, and Acquisition (AM CDE) Program Integration Division (AMCDE-PI) Office of the Surgeon (AMCSG)
Program Manager-Training Devices (PM-TRADE) Orlando, FL 32813	
U.S Army Human Engineering Laboratory, Aberdeen Proving Ground, MD 21005	(SLCHE-DA)
Equipment Authorizations Review Activity (EARA) 5001 Eisenhower Ave Alexandria, VA 22333-0001	Authorization Document Analysis Division (AMXEA-AD)
U.S. Army Troop Support Command, St. Louis, MO 63120	Deputy for Logistics Support (AMSTR-Z)
Headquarters, U.S. Army Training and Doctrine Command Fort Monroe, VA 23651	Office of the Deputy Chief of Staff for Combat Developments (ATCD) Studies and Analysis Directorate (ATCD-AC) Force Integration Directorate (ATCD-D)

HQ TRADOC (continued)	Systems Management Directorate (ATCD-E) Combat Service Support Directorate (ATCD-S) Test and Evaluation Directorate (ATCD-T)
	Office of the Deputy Chief of Staff for Training (ATTG) Unit Training Directorate (ATTG-U) System Training Directorate(ATTG-Y)
	Office of The Deputy Chief of Staff For Doctrine (ATDO) Support Directorate (ATDO-S) Surgeon (ATMD)
U.S. Army Combined Arms Center Fort Leavenworth, KS 66027	Force Design Directorate (ATZL) Materiel Integration Directorate (ATZL-CAM)
U.S. Army Logistics Center, Fort Lee, VA 23801	Materiel Systems Directorate (ATCL) Unit Training Directorate (ATCL)
Soldier Support Center, National Capital Region 200 Stovall St. Alexandria, VA 22332	Force Structure Design and Personnel Requirements Directorate (ATZI-NPT)
U.S. Army TRADOC Combined Arms Test Activity, Fort Hood, TX 76544	
U.S. Army Training Support Center, Fort Eustis, VA 23604	

U.S. Army Development and Employment Agency, Fort Lewis, WA 98433	Force Development Division Combat Service Support Branch (MODE-CSSB)
U.S. Army Combat Developments Experimentation Center Fort Lewis, WA 98433	
Chemical School Fort McClellen, AL 36205	Combat Developments Directorate (ATZN-CM-CS)
Headquarters, U.S. Army Health Services Command, Fort Sam Houston, TX 78234	Plans, Operations, and Training Directorate (HSOP-SP)
Academy of Health Sciences Fort Sam Houston, TX 78234	Combat Developments Directorate (HSHA-CDM) Training and Doctrine Directorate (HSHA-TTC) AMEDD Board (HSHA-UBD)
Headquarters, U.S. Army Medical Research and Development Command Fort Detrick, MD 21701	Resource Management Directorate (SGRD-RM) Research Program Directorate (SGRD-PL)
U.S. Army Medical Materiel Development Activity Fort Detrick, MD 21701	Project Management Offices (SGRD-UMB) (SGRD-UMA) (SGRD-UMP) Project Management Support Office (SGRD-UMS)
U.S. Army Medical Research Acquisition Activity Fort Detrick, MD 21701	Research and Development Contract Division (SGRD-RMA)

U.S. Army Medical Materiel Agency
Fort Detrick, MD 21701

Readiness Directorate (SGMMA-RM)
Maintenance Directorate (SGMMA-M)

Defense Personnel Support Center
2800 S. 20th St.
Philadelphia, PA 19101

Defense Medical Standardization
Board, Fort Detrick, MD 21701

CHAPTER 3

PRE-PROGRAM INITIATION ACTIVITIES

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3.1 PURPOSE

The purpose of the activities conducted during Pre-Program Initiation is to establish and obtain approval of Program Initiation (Milestone 0) documents. DOD major programs are approved through submission of a Justification for Major System New Start (JMSNS) to the Office of Secretary of Defense (OSD). The JMSNS must be approved by OSD prior to entry into the Concept Exploration (CE) Phase. For all DOD non-major programs, approval to enter the Concept Exploration Phase is accomplished by Operational and Organizational (O&O) Plan approval. Less than major programs are categorized as either Designated Acquisition Programs (DAP) or In-Process Review (IPR) programs. The characteristics of these programs are described in Chapter 1.

3.2 GENERAL

Medical materiel acquisition procedures follow those established in AR 70-1, Systems Acquisition Policies and Procedures, AR 71-9, Materiel Objectives and Requirements Documents, and AR 700-86, Life Cycle Management of Clothing and Individual Equipment, and as further implemented by the Surgeon General in AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel. This chapter describes the activities and procedures necessary to initiate a program and start the CE Phase. Chapter 4, Concept Exploration Phase Activities covers the activities and procedures essential to carry the program to Milestone I.

The Army has established a comprehensive approach to the requirements development process that enables it to attain its goal of balance among readiness, modernization, sustainability and force structure. The Concept Based Requirements System (CBRS) is the basis from which all requirements evolve and provides the focus for development of doctrine, force design, training programs, and programs for new or improved Army materiel.

The Army CBRS is shown schematically in Figure 3-1. It is based on an umbrella concept -- a broad generic operational concept that generally describes how the U.S. Army will operate for the near or far term. From this umbrella concept come specific operational concepts which describe related

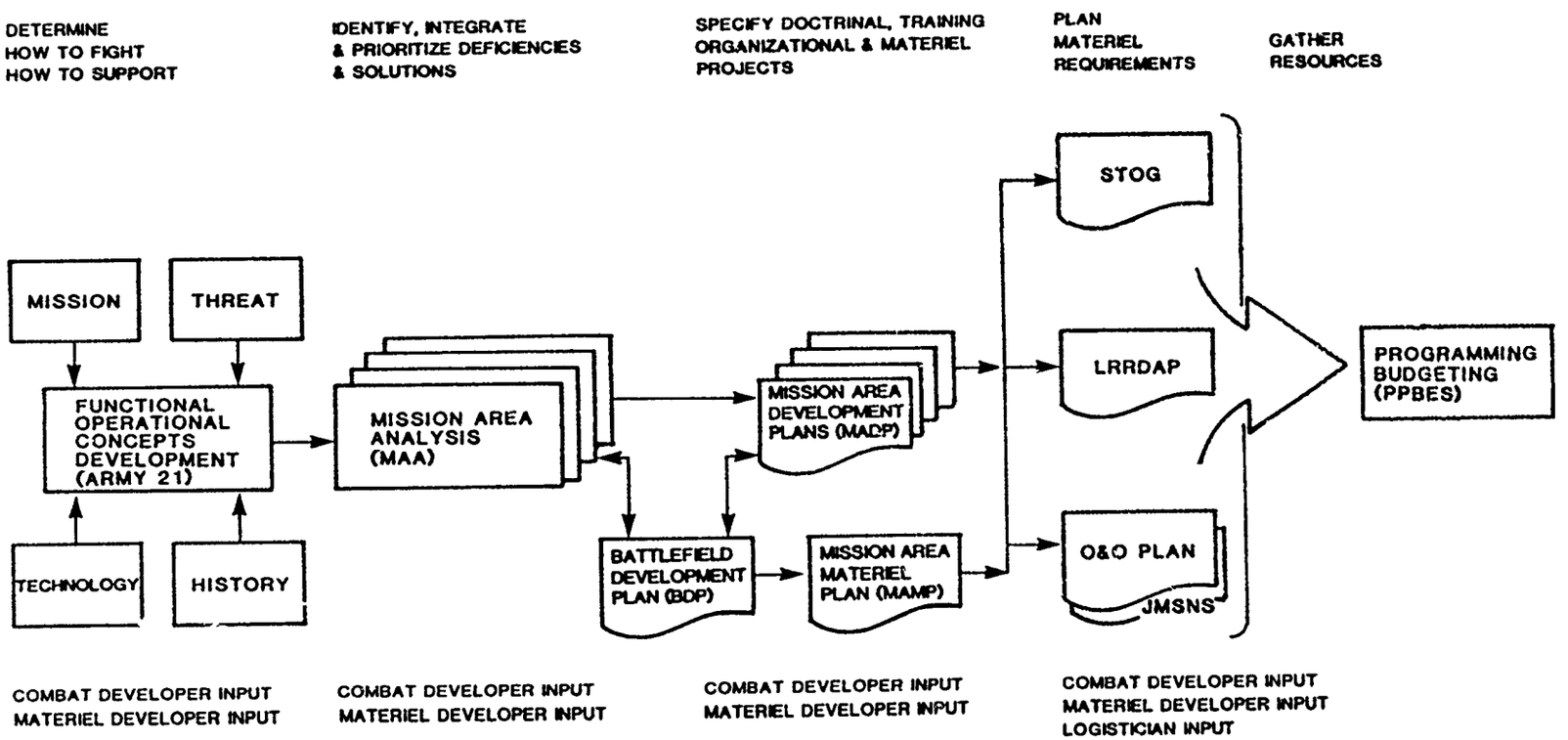


Figure 3-1. THE ARMY CONCEPTS BASED REQUIREMENTS SYSTEM

battlefield functions and mission areas. TRADOC Regulation 11-7, Operational Concepts and Army Doctrine, provides a discussion of CBRS.

Medical materiel requirements must be developed through the CBRS. The AMEDD's program to comply with overall Army acquisition policy is the AMEDD Medical Materiel Acquisition Process shown in Figure 3-2, which emphasizes Pre-Program Initiation activities.

Unique to the acquisition process for developing medical materiel is the need to comply with the Food and Drug Administration (FDA) regulations. The responsibility for the regulation of drugs, protective cosmetics, biologics and medical devices resides with the Food and Drug Administration of the Department of Health and Human Services. The main objective of this regulatory process is the control, development, testing, and production of safe, pure and effective products. While historically these efforts are accomplished by commercial concerns, such as pharmaceutical companies, the Army, as a sponsor, assumes responsibility for compliance with applicable provisions of FDA regulations. See Chapter 2, Appendix A, for MOU between USAMRDC and FDA.

3.3 PRE-PROGRAM INITIATION ACTIVITIES

Pre-Program Initiation Activities stem from the identification of deficiencies and their potential materiel solutions during the CBRS process.

3.3.1 Development of the Operational Concept. Under the CBRS all planning is based on an overall operational concept. As described in TRADOC Regulation 11-7 this is a notional idea that describes the performance of one or more combat, combat support, or combat service support functions. It defines in basic terms how the Army plans to fight and provide support. The concept is formulated by the Combat Developer giving consideration to:

- Current and future Army missions (DA Guidance);
- Historical perspectives (Combat Developer);

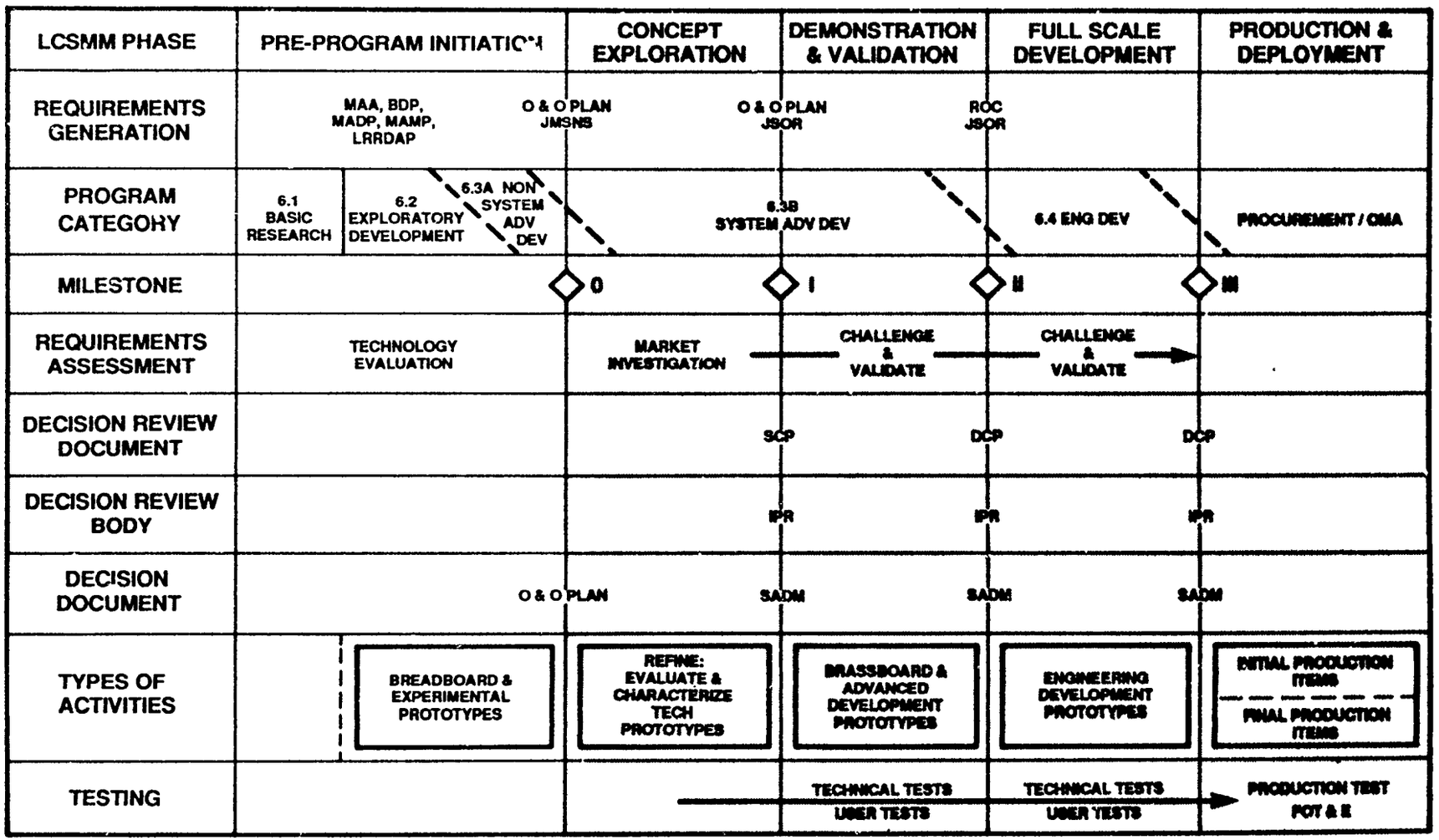


Figure 3-2. Medical Materiel Acquisition Process

- Threat implications (Intelligence Community);
- Technological capabilities and projections of both the Soviets and the the U.S. (Materiel Developer).

The AHS, as the Combat Developer for medical materiel, provides the AMEDD's input to the CBRS, and is responsible for developing the Operational Concept of medical support for the combat soldier.

3.3.2 Technology Base. Early investigations involve close coordination among the combat developer, training developer, and materiel developer to ensure that the technology base can be applied effectively to solving identified deficiencies. USAMRDC, which is responsible for medical materiel development, works closely with its laboratories, industry, academia, other Services, other federal agencies, and foreign sources to ensure that a strong science and technology base is maintained. The science and technology base program must be consistent with the CBRS and ensure that the thrust of technology is oriented to the CBRS and can support it by identifying and stimulating the relevant emerging technologies

3.3.3 Mission Area Analyses. Following the establishment of an overall operational "umbrella" concept, an analysis is made of various functional area operational concepts to determine tasks and identify deficiencies in areas of doctrine, training, organization and materiel. This activity consists of several parallel efforts called Mission Area Analyses (MAA) which are directed to long range planning as they relate to:

- Materiel Acquisition;
- Identification of critical technical, operational, standardization and interoperability deficiencies;
- Logistics support problems for resolution subsequent to approval of a mission need.

The TRADOC and AMEDD interfaces for the mission areas are shown on Figure 3-3. Although there is some medical application to all mission areas, medical materiel development is most applicable to: Combat Service Support; Battlefield Theater Nuclear Warfare; Combat Support, Engineering and Mine Warfare; Nuclear, Biological, Chemical; and Aviation areas. AMEDD's mission area analysis inputs are to Combat Service Support and Nuclear, Biological, and Chemical MAAs.

MAA's are performed under the direction of the TRADOC Deputy Chief of Staff for Combat Developments (DCSCD) by the proponent TRADOC centers and schools as well as the Academy of Health Science (AHS). The AHS for example, using the Army's programmed force, projected threat, and Air Land Battle doctrine, will employ operations research and system analysis techniques to examine medical related battlefield tasks to be accomplished; will assess its capability to accomplish them; and will develop a list of deficiencies in the areas of doctrine, training, organization and materiel. From this analysis a corresponding series of solutions are recommended. AHS, as the combat developer for medical materiel provides major inputs to the Combat Service Support (CSS) MAA. The Logistics Center integrates these requirements with other inputs into the CSS Mission Area Development Plan.

3.3.4 Mission Area Development Plan. The deficiencies and their solutions, identified in the MAA, are general in nature and it is necessary to translate them into specific projects. The Mission Area Development Plan (MADP), developed and published annually by each mission area proponent, makes this transition from general corrective actions to specific projects, and provides milestone schedules for feeding programming and budgeting documents. The MADP drives the R&D procurement efforts and provides a materiel development section which targets the materiel deficiencies and corrective actions identified in the MAA. The Logistics Center (the CSS Mission Area proponent) develops the CSS MADP with inputs from AHS. Other proponents shown on Figure 3-3, develop their own MADPs which include AMEDD related inputs.

MISSION AREA	MEDICAL MATERIEL DEVELOPMENT	MEDICAL IMPLICATIONS	TRADOC PROPONENT
CLOSE COMBAT, LIGHT		X	INFANTRY CENTER, FT BENNING, GA
CLOSE COMBAT, HEAVY		X	ARMOR CENTER, FT KNOX, KY
COMBAT SERVICE SUPPORT (MEDICAL)	X	X	LOGISTIC CENTER, FT LEE, VA
FIRE SUPPORT		X	FIELD ARTILLERY CENTER, FT SILL, OK
COMMUNICATIONS		X	SIGNAL CENTER, FORT GORDON, GA
INTELLIGENCE & ELECTRONIC WARFARE		X	INTELLIGENCE CENTER, FT HUACHUCA, AZ
AIR DEFENSE		X	AIR DEFENSE CENTER, FT BLISS, TX
COMMAND AND CONTROL		X	COMBINED ARMS CENTER, FT LEAVENWORTH, KS
BATTLEFIELD THEATER NUCLEAR WARFARE	X	X	COMBINED ARMS CENTER, FT LEAVENWORTH, KS
COMBAT SUPPORT, ENGINEERING & MINE WARFARE	X	X	ENGINEER CENTER, FT BELVOIR, VA
NUCLEAR, BIOLOGICAL, CHEMICAL	X	X	CHEMICAL SCHOOL, FT MCCLELLAN, AL
AVIATION	X	X	AVIATION CENTER, FT RUCKER, AL
SPECIAL OPERATING FORCES		X	INSTITUTE OF MILITARY ASSISTANCE, FT BRAGG, NC

Figure 3-3. AMEDD Role in the MAA Process

3.3.5 Battlefield Development Plan. The Battlefield Development Plan (BDP) is generated by TRADOC to consolidate results of individual mission area analyses. It describes the battlefield environment forecast for the Army of the future, highlights the doctrine used as the foundation for analysis, and assesses the Army's capability to survive and win on that battlefield. The BDP provides an assessment which cuts across mission area lines as well as the overall TRADOC list of prioritized deficiencies. The BDP provides the relative priority of all deficiencies and identifies non-materiel problems and communicates critical materiel deficiencies to the development community. The BDP is an annual planning document that serves as a guide for the technology base prioritization processes performed jointly by HQDA, each MATDEV, and each CBTDEV. This process supports the development of the Army Long Range RDA Plan (LRRDAP) and guides the materiel developers in preparing the Mission Area Materiel Plans. The AHS, as the CBTDEV for AMEDD, ensures that AMEDD's requirements receive their full consideration in the prioritization process.

3.3.6 Mission Area Materiel Plan. The Medical Research, Development, and Acquisition (RDA) Mission Area Materiel Plan (MAMP) presents a comprehensive description of medical R&D projects and the supported combat requirements. It is prepared by USAMMDA under the direction of the USAMRDC Director of Research Plans. Close coordination with AHS facilitates evaluation of medical materiel development activities conducted to meet identified Battlefield Development Plan deficiencies. The primary purpose of the MAMP is to enhance communication and cooperation between the user and developer communities and to establish a consolidated program review document. It provides The Surgeon General with a formal mechanism for setting AMEDD priorities to develop and field medical materiel in support of the BDP. It contains a wide variety of essential data and its use is not limited by time or a single organization. It is a living document, in that periodic updates will result in adjustments to plans by the AHS and USAMMDA on a continuing and iterative basis. The Medical RDA MAMP provides the framework for essential programmatic efforts: e.g., Long Range RDA Plans; Planning, Programming, Budgeting, and Execution System (PPBES) activities; and cohesive RDA strategies to overcome Mission Area Analyses deficiencies.

3.3.7 Long Range Research, Development and Acquisition Plan. Because of the long lead times required for materiel development, it is essential that coordination between requirements is kept in focus by the development activities, and particularly the laboratories, to ensure that their efforts are directed to user needs. The LRRDAP provides an overall plan that displays R&D programs and individual systems in support of requirements which were initially identified and prioritized in the CBRS. The LRRDAP provides a roadmap for the R&D community, stabilizes the RDA process, couples planning with the PPBES through the POM process, and provides an audit trail of approved actions. The LRRDAP establishes the strategy for focusing technology on identified problems following the priorities established during the MAA process. The Plan is translated into funding programs at an intensive management review which allocates resources against the established investment strategy. This review is led by a core team of senior representatives from MATDEV, CBTDEV and the DA Staff. Following publication of the LRRDAP, AHS establishes the Army Medical Department Priority Program (AMEDD PRIPROG) which provides TSG with a formal mechanism for setting AMEDD priorities to develop and field medical materiel in support of the BDP.

3.3.8 Operational and Organizational Plan. The Operational and Organizational (O&O) Plan represents the culmination of the pre-concept activities and is the primary program initiation document for AMEDD materiel acquisitions. The O&O Plan describes how and where a product or system will be integrated into the force structure, deployed, operated and supported in peace and wartime. It represents an agreement between the combat and materiel developers that a mission deficiency exists which requires a materiel solution. It establishes readiness objectives and forms the basis for ILS planning. The O&O Plan provides decision-makers with essential information to initiate the Concept Exploration Phase and provides specific guidance for follow-on actions. The O&O Plan addresses the system as an integral part of an organization, rather than as an isolated system. The initial O&O Plan contains as much information as is available including performance characteristics, and is reviewed prior to the Milestone I decision to reflect significant changes in threat, technology or doctrine.

The O&O Plan is prepared in accordance with AR 71-9, Materiel Requirements. As shown in Figure 3-4, the development of the O&O Plan starts at AHS, based on the MAA and BDP, with USAMMA and USAMMDA providing inputs along with inputs from other Army activities and other services. After a series of reviews, the O&O Plan is sent to the OTSG for validation prior to forwarding to HQ TRADOC for Army approval, which signifies program initiation. The TRADOC approved O&O Plan is then sent to HQDA for information and designation as a DAP if appropriate.

3.3.9 MANPRINT. Manpower and Personnel Integration (MANPRINT) is an Army effort to integrate into materiel development and acquisition all relevant information concerning human factors engineering, manpower, personnel, training, system safety, and health hazards. It is an iterative and interdependent process designed to improve performance and reduce manpower and personnel requirements through trade-off analyses during design. The CBTDEV is responsible for the integration of MANPRINT considerations in the O&O Plan and for the initiation of a Systems MANPRINT Management Plan in the pre-program initiation phase. The Materiel Developer must ensure that the system under development is designed with these considerations in mind.

3.3.10 Planning, Programming, Budgeting & Execution System Funding Profile. The Planning, Programming, Budgeting and Execution System (PPBES) funding profile translates subject specific cost estimates into year-by-year funding requirements for R&D, Investment, and Operation and Support categories, and is included in various program management documents. The PPBES funding profile is prepared by the RAD with inputs from the USAMMDA and USAMMA. The PPBES process is addressed in detail in Chapter 10.

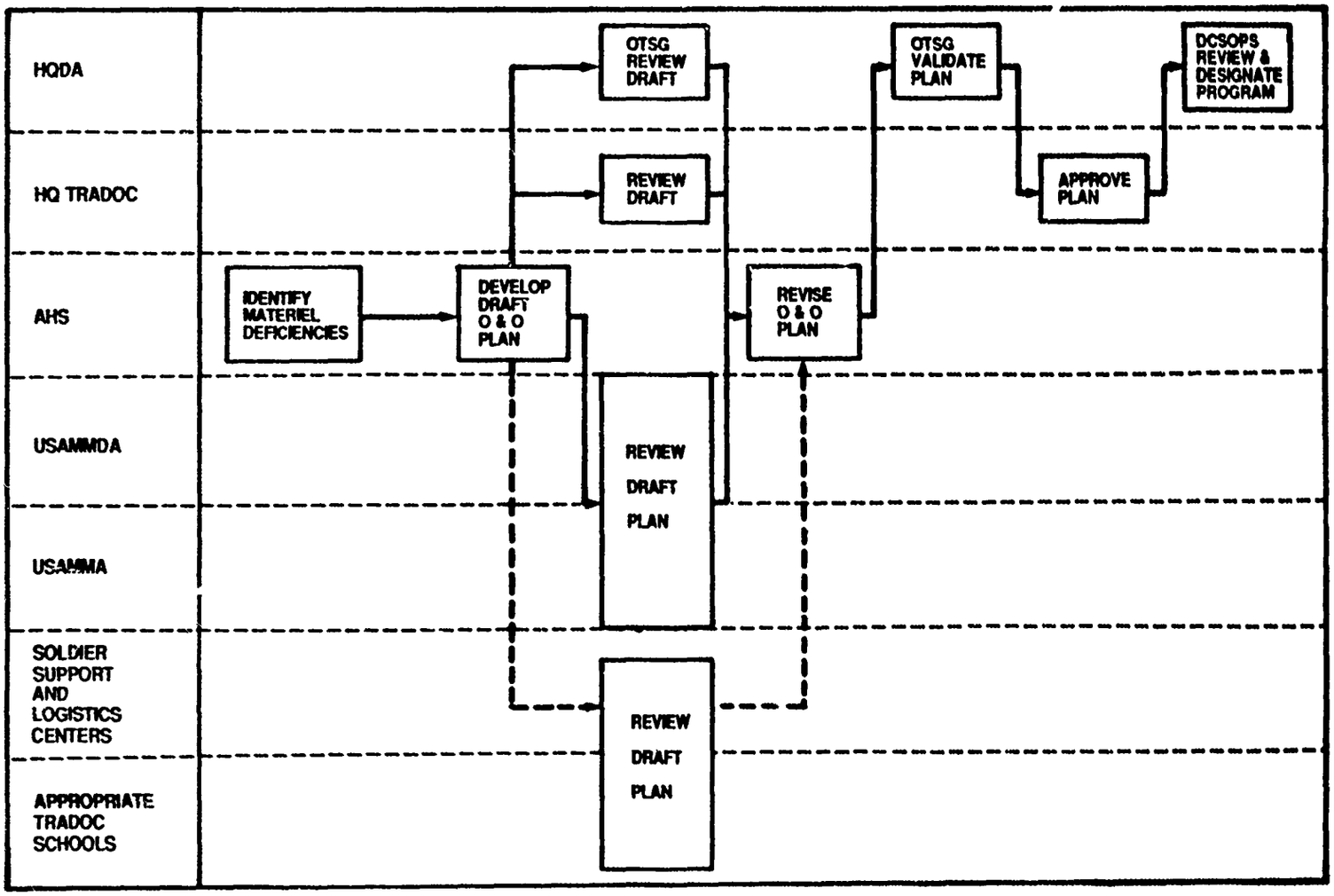


Figure 3-4. DEVELOPMENT OF THE OPERATIONAL AND ORGANIZATIONAL PLAN

3.4 REFERENCES

AR 40-10, Health Hazards Assessment in Support of the Materiel Acquisition Decision Process, 1983

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

AR 70-1, Systems Acquisition Policy and Procedures, 1986

AR 71-9, Materiel Requirements, 1986

AR 602-2, MANPRINT in the System Acquisition Process, 1986

AR 700-86, Life Cycle Management of Clothing and Individual Equipment, 1983

AR 1000-1, Basic Policies for System Acquisition, 1983

TRADOC Regulation 11-7, Operational Concepts and Army Doctrine, 1985

TRADOC Circular 602-XXX, Manpower and Personnel Integration (MANPRINT), Draft

CHAPTER 4

CONCEPT EXPLORATION PHASE ACTIVITIES

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4.1 PURPOSE

This chapter provides a brief overview of the activities to be conducted and documentation to be developed and staffed during the Concept Exploration (CE) Phase. The activities that take place during the Concept Exploration Phase of the acquisition process are designed to:

- Identify and Explore alternatives (including Nondevelopment Items (NDI) or Modified Nondevelopment Item (MOD-NDI) alternatives);
- Acquire information necessary to select the best alternatives for system concepts and hardware or computer software development;
- Develop an acquisition strategy to guide the conduct of the program.

Concept Exploration establishes the justification and the groundwork presented at Milestone I for initiating a developmental, NDI, MOD-NDI or product improvement program. Figure 4-1 shows the relationships of the Concept Exploration Phase to the other phases of the Medical Materiel Acquisition Process.

4.2 GENERAL

Pre-Program Initiation activities are conducted to identify deficiencies and develop alternative solutions. Upon approval of the Operational and Organizational (O&O) Plan, or in the case of a major program, the Justification for Major System New Starts (JMSNS) authorization is granted to proceed to the Concept Exploration Phase. The Concept Exploration Phase explores in-depth various alternative materiel solutions which can satisfy an identified deficiency. Analyses are conducted during Concept Exploration to obtain the most practical path to correcting deficiencies identified during Pre-Program Initiation. These analyses consider all the various means of satisfying a medical deficiency.

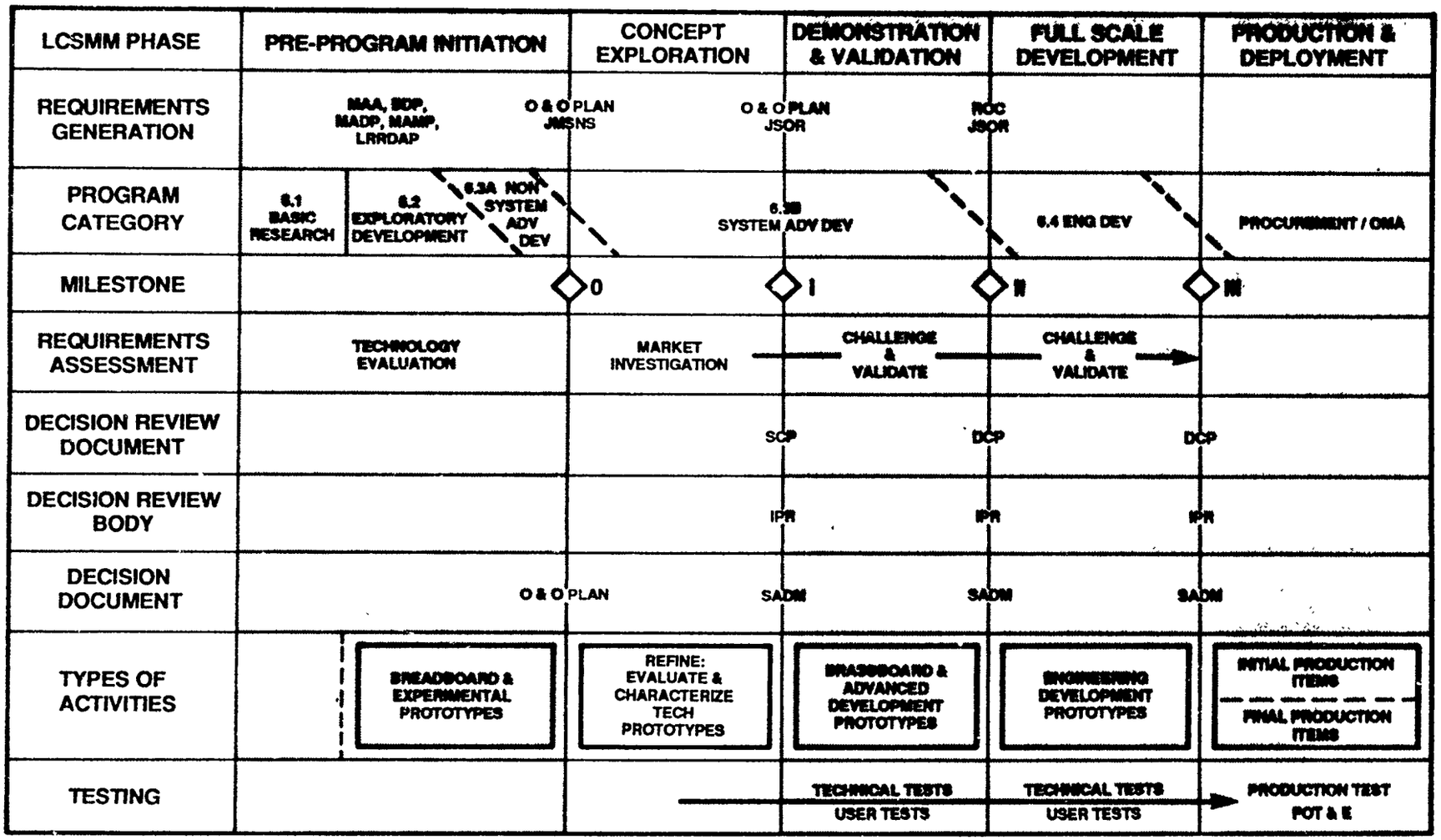


Figure 4-1. Medical Materiel Acquisition Process

4.2.1 Alternative Solutions. Before initiating a new materiel development program, the following alternatives must be considered.

- Improving an Existing Item to take advantage of training and logistics investments, (e.g. a product improvement program);
- Buying Existing domestic or foreign commercial or military equipment, (e.g. a nondevelopment item);
- Modifying Existing "off the shelf" equipment, (e.g. a modified non-development program).

Only after it is determined that these alternatives are not feasible should a costly and time-consuming development program be initiated.

4.2.2 Medical Materiel Areas. Medical acquisition programs are divided into three distinct areas;

- Pharmaceutical Systems which may include such items as skin decontaminants, antimalarial drugs, and wound healing agents and dressings;
- Biological Systems which may include such items as vaccines and antitoxins;
- Applied Medical Systems which may include such items as X-rays, resuscitators, sterilizers and oxygen generating systems.

Project Management Offices (PMOs) within USAMMDA have been established for each of these areas. In addition, a Project Management Support Office provides administrative, business/financial, and logistics management support to the PMOs. As programs are initiated, they are transitioned from the laboratory to the appropriate PMO for management of the Concept Exploration and subsequent acquisition phases. This transfer is accomplished through the Medical Systems Review Committee where issues such as technical progress, the status of the requirement, and market analysis results are discussed and recommendations for program initiation made.

4.3. CONCEPT EXPLORATION PHASE

4.3.1 General Objectives. The many tasks which are required during Concept Exploration require the coordination with, and/or inputs from, several major Army commands and laboratories, within and outside the medical community, and extend beyond the Army to other Services and the Food and Drug Administration (FDA). During Concept Exploration, an established sequence of events provides a systematic path to Milestone I approval with authorization to enter the Demonstration and Validation Phase of the acquisition process. A simplified schematic of this process is shown on Chart 4-1, which is provided as a fold-out at the end of the chapter and has blocks keyed to corresponding paragraphs of this chapter.

4.3.2 Specific Activities.

SEE CHART 4-1

1. Independent Evaluation Plan. Based on the O&O Plan developed during Pre-Program Initiation, it is first necessary to develop an evaluation plan upon which to measure how the capabilities of a proposed system can satisfy the materiel deficiency. This plan, called an Independent Evaluation Plan (IEP), is prepared by the AHS, in coordination with USAMMDA and USAMMA prior to the market investigation. The IEP normally includes issues and criteria for testing, and identifies data sources and requirements. The IEP states the approach for independent evaluation and reporting, develops site descriptions and schedules, specifies the analytical plan, and identifies program constraints. The IEP guides the Market Investigation to assess the applicability of items being evaluated.

2. Market Investigation. The market analysis is the process of gathering information about available products to determine if any can meet a documented need. Market analysis includes ongoing market surveillance and specific market investigations. Market investigations are conducted following program initiation in accordance with Army guidance to ensure that a decision to begin a new product development can be justified, because acquisition of an NDI, Modified NDI or PI is always preferable to new development. The results of the investigation assist the MATDEV in preparing the Acquisition Strategy; when an NDI or Modified NDI approach is selected, a Technical Data Package will be prepared.

A market investigation under the direction of USAMMDA is conducted by the appropriate PMO, either in-house or by a contractor, to determine whether the stated need can be met by any item currently available from military or civilian sources, foreign or domestic. Failure to identify a suitable item will result in a new product development program. If, during a pre-IPR Market Investigation, an item is identified which will satisfy the need for a product in development, further development of that product could be stopped at any time. Information about relevant impending industrial development activities will also be gathered in the course of a market investigation and should be utilized in tailoring an acquisition strategy for developmental programs. If, at the conclusion of a market investigation, a decision is made to enter a developmental or MOD-NDI program, USAMMDA will assume responsibility; if the decision is made to proceed with an NDI program, USAMMA will have responsibility. In development of the market investigation six separate actions are required:

a. Develop Information Base. USAMMDA, in conjunction with AHS and USAMMA, obtains and reviews all pertinent documents in order to adequately define the product's use scenario, physical characteristics, logistical concerns and procurement issues. As part of this effort, criteria will be established to determine feasibility and suitability. The following documents should provide this essential information:

- Mission Area Analysis;
- Battlefield Development Plan;
- Mission Area Materiel Plan;
- Operational and Organizational Plan.

b. Develop Questionnaire. USAMMDA formulates the approach and the questions to be used in screening companies to identify NDIs and modified NDIs. The questionnaire is usually developed in four parts, the first three directed to the manufacturer, the fourth to the customer. Manufacturer directed questions address operational and technical requirements, modification of available products, and logistical requirements; customer directed questions address typical customer experience with product safety, deficiencies, and overall usefulness.

c. Identification of Manufacturers. USAMMDA should contact the following sources to identify manufacturers of potential interest:

- Embassies and Trade Associations;
- Computerized data bases;
- Reference directories.

In many cases, the investigator will be knowledgeable of all sources of biologicals and pharmaceutical products and medical equipment. These investigations will be simple, probably accomplished by several phone calls. Other investigations may be considerably more extensive.

d. Survey of Manufacturers. USAMMDA obtains answers to the questionnaire from each viable manufacturer.

e. Survey of Product Customers. USAMMDA identifies product customers and obtains answers to questionnaire. Customer can be identified by product manufacturer, local distributor, other Government agencies, and other sources.

f. Market Investigation Report. Upon completion of the five steps described above, the data is analyzed and a report is prepared documenting the advantages and disadvantages of each product and the results of any suitability or feasibility tests. It provides the conclusions and recommendations for pursuing an NDI, PI, MOD-NDI, or new development effort. Of major importance is the assurance that whatever the type of effort, it must satisfy user requirements and be supportable in the field. The acquisition procedures for the life cycle of Developmental Programs is summarized in Chapter 5. NDI, Modified NDI, and Product Improvement Programs are summarized in Chapters 6 through 8.

3. Independent Evaluation Report. Following the market investigation, AHS reviews the Market Investigation Report and develops an Independent Evaluation Report (IER) in coordination with USAMRDC, USAMMDA and USAMMA to determine how the materiel item under consideration can meet the requirements of the IEP. The IER provides an assessment of item or system technical performance and operational effectiveness as well as the adequacy of testing to that point of development. The IER provides a valuable input to the Acquisition Strategy by establishing a basis for determining if a Nondevelopment Item is adequate, whether a Modified NDI is required, whether to improve an already available inventory item under a Product Improvement Program initiative, or whether it is necessary to develop a new item to meet the requirement.

4. Baseline Cost Estimate. Based on the information provided from the Pre-Program Initiation activities and additional information from the market investigation and other analyses, a detailed breakout of cost, specifically the source/derivation of costs is prepared: the Baseline Cost Estimate. This life cycle cost estimate covers the major cost categories of research and development, investment, and operating and support for all viable alternatives. The BCE is developed by USAMMDA with support from the HQ USAMRDC, the research institutes, laboratories and contractors. The BCE is maintained current with the latest information and cost estimates and becomes the source document for all cost estimate requirements such as the PPBES, O&O Plan, Acquisition Plan, Trade-off Studies, etc. The BCE is further discussed in Chapter 22, Program Cost and Schedule Controls.

5. Update Planning Programming, Budgeting, and Execution System Funding Profile. The BCE is the basis for updating the Planning, Programming, Budgeting, and Execution System (PPBES) funding profile which was developed during Pre-Program Initiation. It is updated to show the potential impact of the maturing product on the POM. The updated PPBES considers the POM and budget lead times, and includes both development and production and deployment estimates. USAMMDA prepares the update with inputs from the laboratories, contractors, USAMMA and the RAD. The PPBES process is discussed further in Chapter 10, The PPBES Process.

6. Prepare Acquisition Strategy. Based on the IER results, the Acquisition Strategy (AS) is developed. The AS is the key document prepared after approval of the O&O Plan, and it should be developed as early as possible in the Concept Exploration Phase. The AS discusses general strategy for the total program and details strategy for progressing to Milestone I. It emphasizes program structure, and specifically addresses competition and contracting planning for all phases. The AS, in addition to addressing program structure and contracting, also addresses, as appropriate: tailoring, supportability, manufacturing, testing, cost growth, technical risk, health, safety, human factors engineering, endurance, and any issues for resolution. It serves as a conceptual basis for developing detailed strategies and functional plans (e.g., Integrated Logistics Support Plan, Acquisition Plan, Test and Evaluation Master Plan) and is tailored to the unique requirements of the particular program. For medical items the AS must also address any requirements to obtain FDA approval for any new drug or pharmaceutical or medical device, and an overview of the plan to achieve the necessary approval.

The Acquisition Strategy is prepared by USAMMDA and is provided as an annex to the System Concept Paper (SCP) for ASARCs or IPRs prior to Milestone I. Formal approva of the SCP constitutes approval of the AS, and authority for USAMRDC to enter the next acquisition phase. However, if an NDI program is approved, management of the item transfers to USAMMA.

7. Prepare Acquisition Plan. The Acquisition Plan (AP) evolves directly from the Acquisition Strategy and documents the means by which the PM plans to accomplish that strategy. The Acquisition Plan establishes the acquisition planning process and provides a comprehensive approach for achieving the goals, such as reliability and maintainability data, as defined in the materiel requirements. Acquisition Plans are prepared by the MATDEV for all systems and major items of hardware and software which are to be developed or produced.

8. Update Manpower and Personnel Integration. A relatively new initiative called Manpower and Personnel Integration (MANPRINT) emphasizes the early and continuous consideration of manpower, personnel, and training, as well as health, safety and human factors engineering issues which must be addressed in force modernization. MANPRINT activities during the Concept Exploration phase include:

- Transition MANPRINT responsibility to the PM;
- Update the System MANPRINT Management Plan;
- Integrate MANPRINT into program management plans;
- Develop MANPRINT data to support the organizational and operational concepts, determine probable requirements, and support planning for support and training programs;
- Identify training research requirements;
- Conduct Human Factors Engineering Analysis;
- Conduct Health Hazard and System Safety Assessments.

The Commanding General (CG), TRADOC, assures that MANPRINT is considered and applied in MAAs, JMSNS, and O&O Plans; the Commander, Soldier Support Center-National Capital Region, is the Executive Agent for the CG TRADOC for integrating MANPRINT. The AHS ensures that MANPRINT considerations are fully addressed throughout the materiel acquisition process for medical related systems and families of systems. MANPRINT is addressed in more detail in Chapters 14.

9. Develop Test and Evaluation Master Plan/Establish Test Integration Working Group. Testing is conducted as early as practicable and throughout an acquisition program in order to demonstrate how well a materiel system/item meets its technical and operational requirements and to resolve any problems, either technical, operational, or logistical. To ensure that this testing will be conducted as smoothly as possible, the Test Integration Working Group coordinates the preparation of the Test and Evaluation Master Plan (TEMP).

The TEMP identifies and integrates the efforts and schedules of all T&E to be accomplished prior to key decision points. The TEMP also identifies resources which will be needed to support the test program, relates test objectives to required system characteristics and critical issues, and establishes integration objectives and responsibilities.

Results of any previous studies, such as a Market Investigation Report, an IEP or IER, are primary considerations in developing a TEMP. The TEMP contributes to other plans such as the ILSP, S&I Plan, and CMP. The TEMP must consider the testing requirements of these individual plans and at the same time consider its impact on these plans and their execution. This integration should be addressed in the Acquisition Strategy.

The TEMP establishes testing requirements anticipated throughout the development of the proposed materiel system/item and should address both Technical Testing and User Testing requirements. It addresses not only the test effort but also the requirements for personnel and materiel.

The TEMP for medical products also describes all proposed clinical studies that are necessary for the particular project and its test cycle. For most medical products the TEMP is embodied in the clinical study protocols required for regulatory purposes. Additional user tests may be needed for specific military issues; these additional tests will be described in the TEMP. The TEMP is considered approved with the approval of the Acquisition Strategy (see Chapter 17, The Test and Evaluation Process).

A Test Integration Working Group (TIWG) provides a forum for face-to-face communication in preparing the Test and Evaluation Master Plan (TEMP). The TIWG is established at the direction of USAMMDA and assists the PM in coordinating test requirements, techniques, procedures, scoring criteria, data collection, and evaluation; it also helps eliminate redundancy in testing and in reducing the cost and time for testing. If, due to the nature of the project, a TIWG is not considered necessary, justification for not using the TIWG must be clearly established in the Acquisition Strategy. The principal AMEDD members are USAMMDA (MATDEV), USAMMA (Logistician), and AHS (CBTDEV, Trainer, User Tester, and Independent Evaluator). TRADOC, FORSCOM, and contractors participate if required. Additional information on the action and responsibilities of the TIWG is included in Chapter 17.

10. Prepare Individual and Collective Training Plan. The AHS-Trainer, with coordination from USAMMDA, USAMMA, other AHS organizations, and TRADOC is responsible for the preparation and coordination of the Individual and Collective Training Plan (ICTP) during the Concept Exploration Phase. The ICTP presents a concept for training which, because of the lack of specific information, will be general in nature. It provides inputs to other analyses and plans and identifies the constraints that training requirements and resources may impose on the design of materiel.

11. Threat Needs Assessment. To ensure that a program is still required and that its development is properly directed, the Threat Needs Assessment, a major input to the MAA and the BDP, is updated. The Threat Needs Assessment characterizes enemy capabilities including what, where, when, and how enemy deployment is possible; and/or characterizes the natural disease and biological threats which may require development of a new product. The AHS, jointly with USAMMDA and the Armed Forces Medical Intelligence Center (AFMIC), updates the Threat Needs Assessment.

12. Review Operational and Organizational Plan. During Concept Exploration the Operational and Organizational (O&O) Plan is reviewed and updated if necessary to ensure that it continues to reflect the current needs of the Army, and that its objectives can be achieved by the planned program established in the Preprogram Initiation phase.

13. Prepare ILS, CM, and S&I Plans.

a. Integrated Logistics Support Plan. The Integrated Logistics Support (ILS) process is established by AR 700-127. It is a phased approach to ILS that extends through the materiel acquisition phases and is designed to integrate logistic support into the development process. AR 700-127 sets forth the policy and responsibilities, and states the actions and activities required to achieve the objectives of the Army Integrated Logistic Support Program:

- The reduction of operating and support costs, and simplification of equipment operation and maintenance, through design requirements and influence on early design efforts;
- The design, development, test, and acquisition of support to assure satisfactory operation and readiness of the system or item in the field.

The ILS process begins during the Concept Exploration Phase and requires collaboration with the Combat and Training Developer in preparing the initial need statement and the Operational and Organizational Plan. The Logistic Support Analysis will begin at the time during which, among other considerations, criteria will be set for both reliability and logistic support considerations which will affect the design and configuration of a new item. Logistic involvement at this stage of development provides the opportunity for establishing supportability as a primary design consideration. U.S. Army Medical Department policy requires that ILS be tailored to suit the type of product.

To ensure that the ILS program will be effectively executed, ILS planning for the twelve elements of the ILS process starts in Concept Exploration and is formally documented in the Integrated Logistic Support Plan (ILSP) which describes the total ILS program for a materiel acquisition. The Army's twelve ILS elements (AR 700-127) are:

1. Maintenance Planning
2. Manpower and Personnel
3. Supply Support
4. Support Equipment and Test, Measurement and Diagnostic Equipment
5. Technical Data
6. Training and Training Devices
7. Computer Resources Support
8. Facilities
9. Packaging, Handling and Storage
10. Design influence to include logistic-related Reliability, Availability and Maintainability
11. Standardization and Interoperability
12. Transportat on and Transportability

The Integrated Logistic Support Plan is made up of a series of subordinate plars. It is used as an operating document for the ILS process, and becomes part of the system engineering, materiel development, and acquisition processes by being made a part of Program Management Documents such as the Acquisition Plan. The ILSP establishes the planning required for the overall program throughout the life cycle. It anticipates support requirements for technical and user testing and as such provides an input to, and must be coordinated with, the Test and Evaluation Master Plan. The ILSP is a living document which must be under continual revision and is reviewed in detail at each acquisition milestone. Preparation of the ILSP will be accomplished by USAMMDA in coordination with AHS and USAMMA. Normally, an ILS Management Team (ILSMT) will be established to facilitate the coordination and to ensure consideration of all ILS elements. The ILSP and other ILS requirements and procedures will be discussed in detail in Chapter 15, The ILS Process.

b. Configuration Management Plan. The Configuration Management Plan (CMP) defines and describes the Government's schedule and procedures for configuration management. The CMP covers drawings, specifications, Technical Data Package, configuration reviews and audits, quality assurance and reliability, and other products with which the developing product may interface. This configuration management process should be carefully tailored to the quantity, size, scope, stage of life cycle, nature and complexity of the item involved, whether it is developed at Government expense or with private funds, and whether the item is new, in current development production or operational inventory.

USAMMDA is responsible for preparing the CMP; however, because of FDA requirements, the contractors ordinarily develop the CMP. Close coordination with USAMMA and AHS is essential. Chapter 19, The Configuration Management Process, provides more information on Configuration Management.

c. Standardization and Interoperability Plan. Standardization and Interoperability (S&I) considerations are important for most medical products, which by their nature can be used by other Services, NATO, and other allies. For this reason S&I considerations will be incorporated into materiel and support system design and selection. S&I is a significant element of the Market Investigation because S&I requires the use of proven (off-the-shelf) and emerging systems when program objectives will not be compromised. The S&I plan for medical products and equipment describes the interactions and coordination required to ensure that S&I is addressed for the product in question.

Measuring the effectiveness of the S&I plan may be part of the TEMP, depending on the system. Coordination with other Services and allies will begin early in development and continue throughout the acquisition process. Standardization is the process by which system managers achieve maximum subsystem commonality with materiel systems within DA, other Services, and NATO allies to reduce support requirements and to obtain interoperability objectives. Interoperability is the ability of systems, units, or forces to provide services to, and accept services from, other systems, units, or forces. The S&I Plan is prepared by USAMMDA with inputs from the OTSG, and Air Force and Navy points of contact.

14. Execute Advance Procurement Plan. In anticipation of the numerous procurement actions which are required during the life cycle, USAMMDA develops an advance procurement plan to identify these actions so that none will be overlooked. Execution of the plan in the CE phase includes:

- Preparation of a notice of forthcoming solicitation for publication in the Commerce Business Daily;
- Preparation and issuance of a Request for Proposal (RFP) detailing the development work to be done by the contractor;
- Conducting a Source Selection Board (SSB) to evaluate responses;
- Awarding a contract.

USAMMDA ordinarily prepares the Commerce Business Daily announcement and the RFP, and conducts the Source Selection Board. The U.S. Army Medical Research Acquisition Activity (USAMRAA) issues the announcement and the RFP, and makes the contract award. The R&D laboratories and institutes play a key role in providing the technical input to the RFP and participating in the SSB process.

15. Prepare Concept Formulation Package. The Concept Formulation Package (CFP) summarizes the results of the Concept Exploration Phase and establishes the technical and economic specifications for a product. It comprises a Trade-Off Determination (TOD), Trade-Off Analysis (TOA), Best Technical Approach (BTA) and a Cost Effectiveness Analysis (COEA) or an Abbreviated Analysis (AA). Overall responsibility for the CFP lies with AHS; specific responsibility for, and purpose of, each of the components are indicated below:

- Trade-Off Determination (USAMMDA)
  - establishes feasibility
  - includes technical risk
  - estimates life cycle cost and acquisition schedules
  - describes technical approach

- Trade-Off Analysis (USAMMDA and AHS)
  - establishes mission and performance envelopes
  - analyzes system trade-offs of risks, capabilities, costs, schedule, manpower and support
  - selects best technical approach
- Best Technical Approach (USAMMDA and AHS)
  - compares description of the Best Technical Approach and ILS concept
  - substantiates engineering aspect
  - identifies resources requirements
  - provides environmental documentation
- Cost and Operational Effectiveness Analysis or Abreviated Analysis (AHS)
  - compares means of solving deficiencies
  - confirms requirements
  - estimates LCC of each alternative
  - estimates benefits relative to cost of a product

The detailed format for the CFP is given in Appendix E of AR 71-9. The CFP process is discussed in detail in Chapter 13 of this Handbook.

16. Update Independent Evaluation Plan. USAMMDA and AHS-CD, as the independent evaluators for technical and user tests respectively, update the Independent Evaluation Plans (IEPs) for technical and user tests. The IEPs address all aspects of evaluation responsibilities relative to the system. They are based on activities conducted and plans developed during Concept Exploration, such as the Market Investigation, the TEMP, and any test reports which may be available. The IEP details the independent evaluator's actions for evaluating the system, and is updated periodically throughout the acquisition process to reflect materiel and program changes. The objectives of the IEP are to: (1) address the issues; (2) describe the evaluation of issues

which require data from sources other than tests; (3) state the technical or user test issues; (4) state criteria; (5) identify data sources; (6) state the approach to the independent evaluation; (7) specify the analytic plan; and (8) identify program constraints. Close cooperation is maintained with TIWG members to ensure that the intent of the requirements are reflected in the IEP.

17. Prepare Requirements Document. A Joint Services Operational Requirement (JSOR) is necessary for Joint Service programs and may be prepared prior to Milestone I. The requirements document process is described in detail in Chapter 11.

18. Prepare Documentation for the FDA. USAMMDA, in coordination with USAMRDC (laboratory), is responsible for the preparation of the Investigational Device Exemption (IDE) and the Notice of Claimed Investigational Exemption for a New Drug (IND). These documents are required for devices and for drugs and vaccines respectively, and should be submitted to the FDA prior to Milestone I (see Chapter 24, Regulatory Interfaces).

19. Prepare System Concept Paper. A System Concept Paper (SCP) is the decision management document which is prepared by USAMMDA in coordination with AHS and USAMMA. The SCP supports the Milestone I decision by summarizing the results of the Concept Exploration Phase. The SCP provides a brief description of the system or item under development and summarizes any previous guidance and decision. The SCP identifies the applicable broad mission area and describes the validated threat and inadequacies of existing systems. It includes the identification of the concepts which will carry into the next acquisition phase, and provides the rationale for eliminating other concepts. The Acquisition Strategy is provided as an Annex to the SCP. Chapter 12, The Milestone Decision Review Process, provides further information.

4.4 IN-PROCESS REVIEW

An In-Process Review (IPR) is held before proceeding to the next phase. The IPR reviews and approves the SCP in which the project status is discussed and a course of action recommended. The IPR is a review body which evaluates the status of a product and makes recommendations to the decision authority.

It provides recommendations on system concepts, system development, type classification, and production decisions. The IPR is a forum at which agencies responsible for taking part in the materiel acquisition process can present their views and ensure their consideration before proceeding with the Milestone I decision.

The IPR is scheduled, coordinated and chaired by the Commander, USAMMDA. Meeting participants will vary according to the product being considered. Voting members are the Materiel Developer (Commander, USAMMDA), the Combat Developer and Trainer (Commandant, AHS) and the Logistician (usually Commander, USAMMA) or their representatives. Upon completion of the IPR, the approval authorities (Commander, USAMRDC, and Commandant, AHS) review and approve the minutes and sign the System Acquisition Decision Memorandum (SADM). A dissenting vote at the IPR requires that the decision and dissenting comments be reviewed by TSG for final approval. The IPR process is further addressed in Chapter 12.

4.4.1 IPR Member Preparation. The IPR members are prepared for the review by their respective organizations. Position Papers are prepared by USAMMDA staff, AHS staff and USAMMA staff for their respective members.

4.4.1.1 USAMMDA Position Paper. USAMMDA consolidates the inputs of the research institutes and laboratories and the Research Area Directors. The PM reviews his technical progress and the status of the product with respect to the CE Phase requirements. USAMMDA also prepares a Business and Financial Summary which highlights funding requirements in order to complete development, characterize risks, and provide LCC projections and other financial data. The minutes of the Medical System Review Committee (MSRC) may also be included. A position paper, developed from these sources, is prepared for the USAMMDA IPR member. The paper provides the MATDEV's position and recommendations on the technical, programmatic, and business issues.

4.4.1.2 AHS Position Paper. AHS provides a Position Paper to the AHS IPR members. This paper documents those issues of training, testing, mission accomplishment, threat analysis and operational performance which fall under the Combat Developers purview.

4.4.1.3 USAMMA Position Paper. The USAMMA staff prepares a Position Paper for the USAMMA IPR voting members. This paper identifies all pertinent issues concerning logistics, such as spare parts, configuration management, transportation, storage, or any other consideration which may affect supportability. The issue paper addresses not only current issues but those which may affect production and deployment.

4.5 REFERENCES

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

AR 70-1, System Acquisition Policy and Procedures, 1986

AR 71-9, Materiel Requirements, 1986

AR 602-2, MANPRINT in the Material Acquisition Process, 1986

AR 700-127, Integrated Logistic Support, 1983

AR 1000-1, Basic Policies for Systems Acquisition, 1983

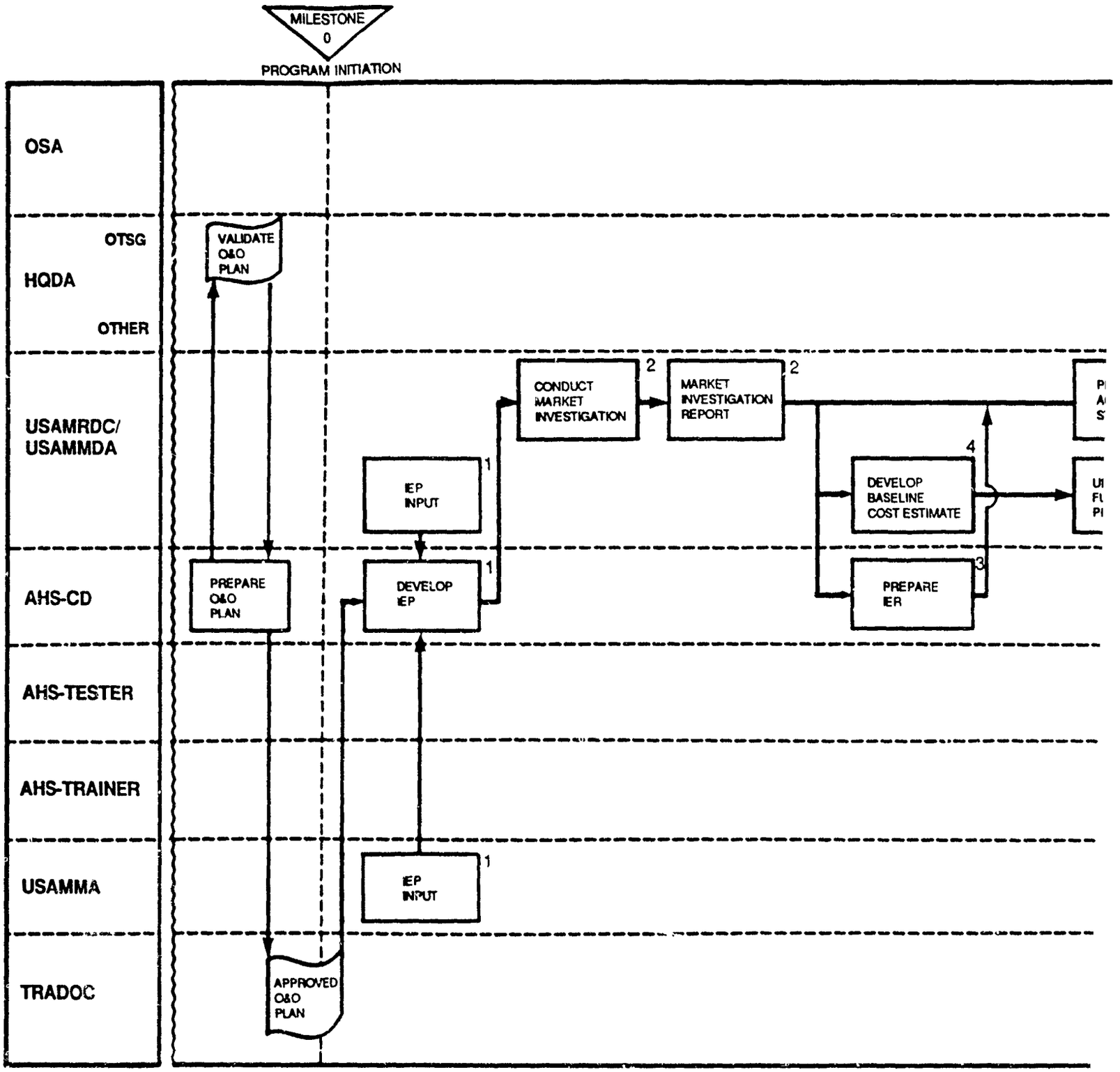
USAMMDA Memo 70-15, Medical System Review Committee, 1985

USAMMDA Memo 70-20, In-Process Reviews, 1985

USAMMDA Memo 70-30, Market Investigations, 1985

USAMMDA Memo 70-37, Configuration Management, 1985

USAMMDA Memo 700-127, Integrated Logistics Support (ILS), 1985


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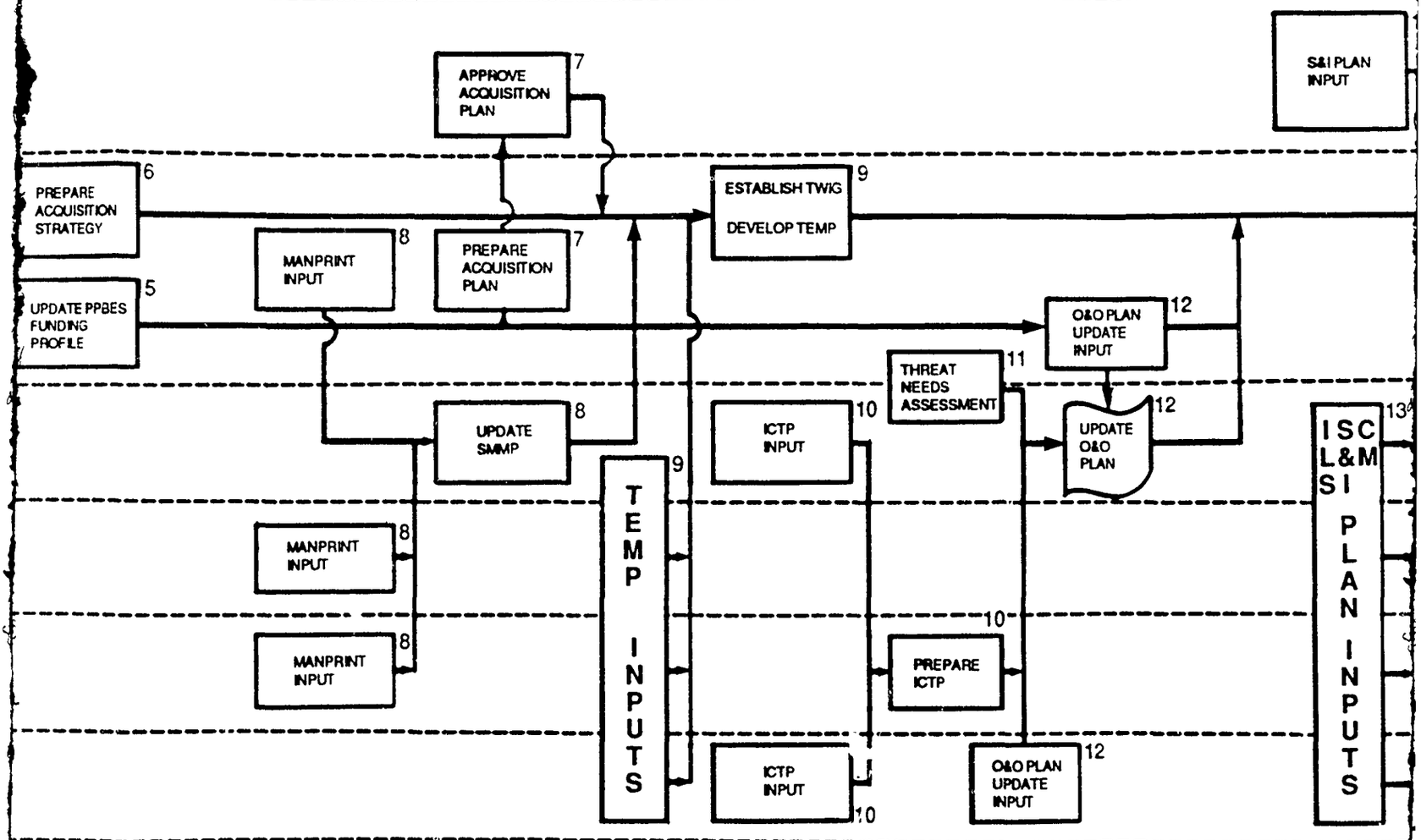
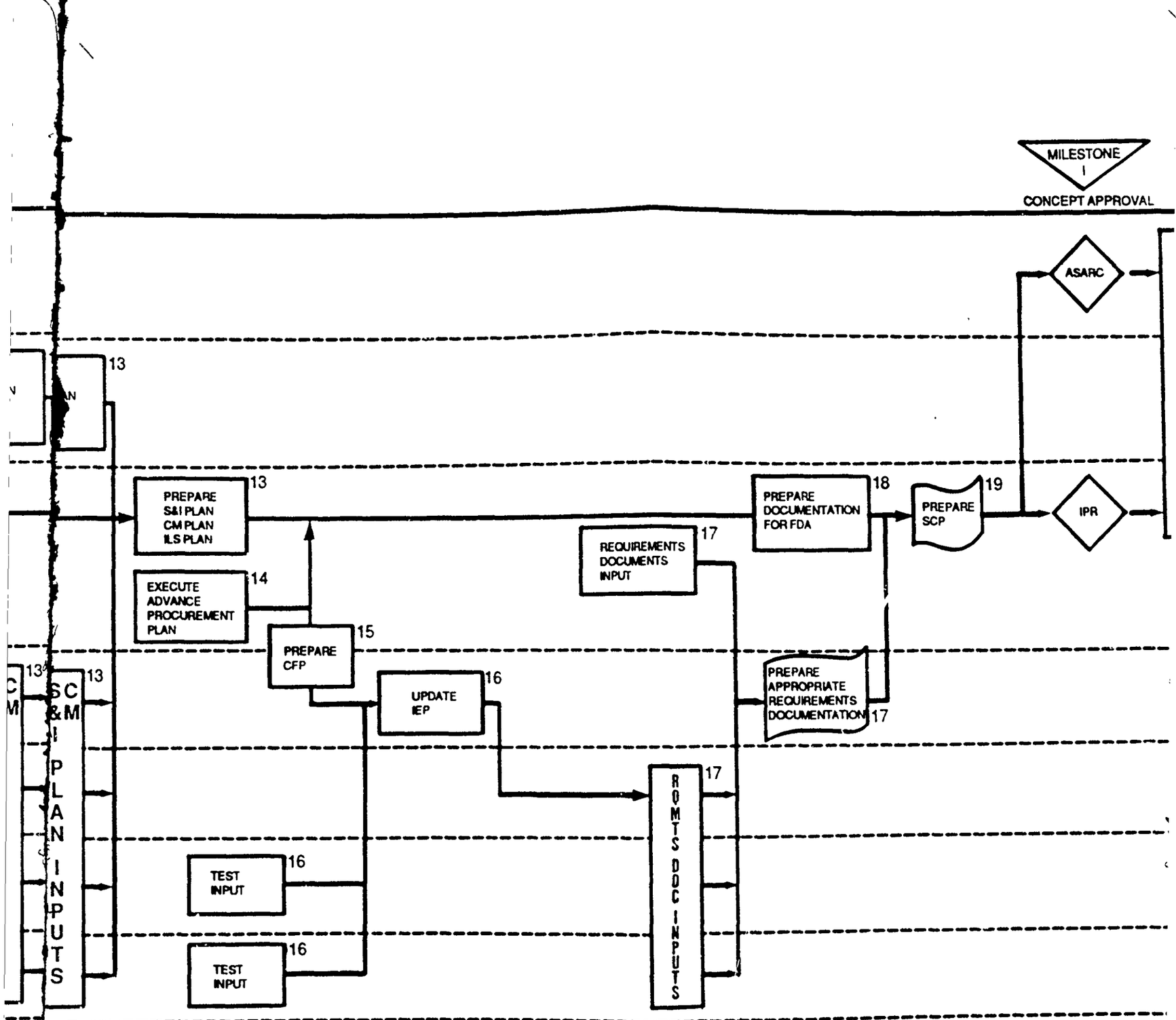


Chart 4-1. MEDICAL MATERIEL CONCEPT EXPLORATIO

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TIOATION PHASE

CHART NOTES

1. SEE APPENDIX B FOR
2. BLOCK N. BERS CO THAT DISCUSS THE A

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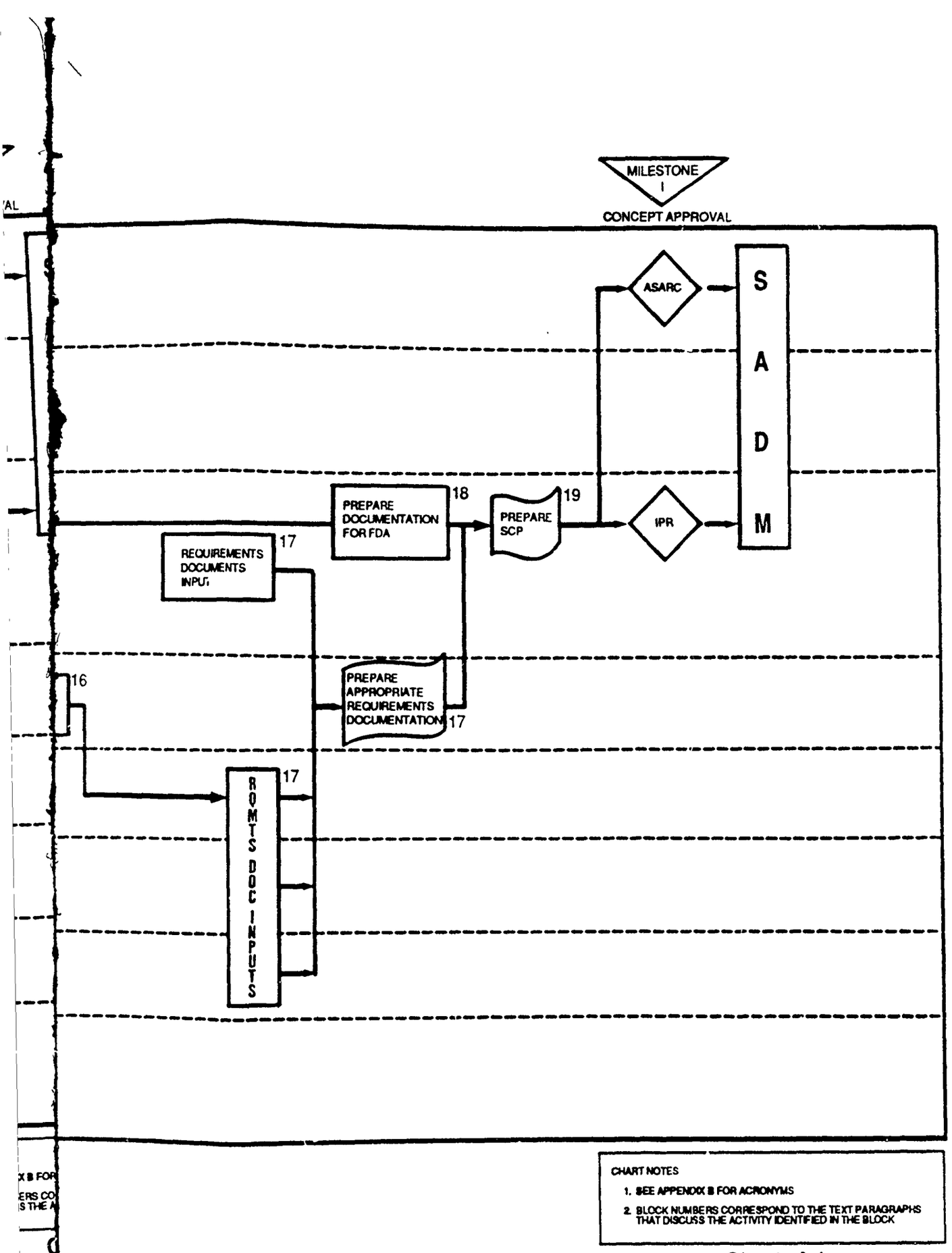


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 4-1

CHAPTER 5

DEVELOPMENT PROGRAM

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5.1 PURPOSE

This chapter describes the typical activities that are necessary to acquire medical materiel items using a development approach. The period addressed starts with the Milestone I decision at the end of the Concept Exploration Phase and ends with the attainment of the Initial Operational Capability (IOC). This is a summary chapter, one of eight such chapters in the overview section of this handbook. More detailed discussions of each acquisition function are provided in Chapters 9-26.

> **NOTE:**
>
> Portions of the activity descriptions in this chapter are applicable to all medical materiel development programs. However, the total content is primarily representative of extensive non-major development programs for hardware/software systems. In all instances, an acquisition strategy must be developed that is tailored to the specific needs of the individual systems.

5.2 GENERAL

Authorization to implement a development program is provided by the Milestone I System Acquisition Decision Memorandum (SADM) (refer to Chart 5-1 at the end of this chapter). The SADM confirms or modifies guidance to attain the selected system concept as defined in the System Concept Paper. The medical materiel development process is guided by the Army Life Cycle System Management Model discussed in Chapter 1 and displayed in Chart 1-1. The responsibilities and procedures applicable to medical materiel are described in this chapter and Chart 5-1. The U.S. Army Medical Research and Development Command (USAMRDC) is the Surgeon General's Medical Materiel Developer. USAMRDC has delegated authority to USAMMDA for the central management of all assigned systems and products to accomplish the materiel developer's objectives. The development program process applies to biological, pharmaceutical

and applied medical systems, and is managed through Milestone III by the respective Project Managers at USAMMDA and then transitioned to USAMMA. A glossary of terms, a list of abbreviations and acronyms, and a compilation of references are presented at the end of Volume II.

5.3 INTRODUCTION

Chart 5-1 summarizes the events, activities, documentation, and decisions required to complete a development program. The number within each block on the flow chart relates to the text paragraph that discusses the activity identified in the block. The chart is designed to present, in relative order within each phase, the primary responsibilities of each participating organization. The text discusses the activities in each of three phases: demonstration and validation, full scale development, and production and deployment. (Concept Exploration Phase is discussed in Chapter 4).

5.4 DEMONSTRATION AND VALIDATION (D&V) PHASE

5.4.1 General Objectives. This phase is initiated by the Milestone I decision. Its length will vary among programs; normal lengths will be in the one-to-two year range. The objectives of the D&V Phase include:

- Verify the selected system concept as expressed in the Concept Formulation Package (CFP) and the initial performance parameters described in the Operational and Organizational (O&O) Plan, or Joint Services Operational Requirement (JSOR);
- Analyze trade-off proposals;
- Resolve or minimize problems identified in the Concept Exploration Phase, and;
- Update the requirements document.

5.4.2 Specific Activities

SEE CHART 5-1

1. In-Process Review. Development program recommendation approved by decision authority.

2. Update the Acquisition Strategy and Acquisition Plan. USAMMDA updates the Acquisition Strategy (AS) and Acquisition Plan (AP) (prepared during the Concept Exploration Phase) based on changes delineated in the SADM. The AP is the responsibility of the PM but is prepared by the contracting officer. Approval procedures for the AP are contained in the Army Federal Acquisition Regulation (FAR) Supplement, Part 7, (see Chapter 4, Event 7).

3. Update the System MANPRINT Management Plan. Lead responsibility for MANPRINT transitions from AHS-CD to USAMMDA after Milestone I. The USAMMDA is responsible for updating the System MANPRINT Management Plan (SMMP). Inputs are provided by the AHS (CD, Trainer, and Tester) and USAMMA. The SMMP addresses the MANPRINT strategy to be employed during the acquisition process, data sources, program concerns, a milestone schedule, and task descriptions. The SMMP is approved by the Commander, USAMMDA (see Chapter 14, MANPRINT).

4. Update Integrated Logistic Support Plan. USAMMDA, in coordination with AHS and USAMMA, updates the Integrated Logistic Support Plan (ILSP). The focus at this stage should be on logistic design and resource issues to be included in trade-off analyses, (see Chapter 4, Event 13a, and Chapter 15, The ILS Process).

5. Submissions to the Food and Drug Administration.

a. Devices. For Class III medical devices, the USAMRDC laboratory or the USAMMDA-PMO submits an Investigational Device Exemption (IDE) request through the USAMRDC Human Use Review Office (HURO) to the FDA prior to the start of clinical investigations. The investigational exemption allows for limited production and distribution of a device. The FDA has thirty days to deny or clinical investigations may proceed. Refer to Chapter 24, Regulatory Interfaces, for additional information.

b. Drugs and Vaccines. The USAMRDC laboratory or USAMMDA-PMO submits a "Notice of Claimed Investigational Exemption for a New Drug" through HURO and the OTSG Human Subjects Research Review Board to the FDA. The subject drug is called an Investigational New Drug (IND). The notice to the FDA provides the complete composition of the drug or vaccine, its source, and how it is made. Results of all animal studies and a plan for testing are also provided. The FDA has thirty days to approve or deny the IND. Refer to Chapter 24.

6. Request Z-LIN. USAMMA requests/obtains a development line item number (Z-LIN) from the Army Materiel Command (AMC). The Z-LIN is a means of tracking the item through the logistics community during the acquisition process.

7. Preliminary Design and Test. Based on input from USAMMDA, the U.S. Army Medical Research Acquisition Activity (USAMRAA) prepares and awards a contract to perform preliminary design activities, fabricate advanced development prototypes, and conduct Technical Tests (TT).

8. Update the Test and Evaluation Master Plan. USAMMDA updates the Test and Evaluation Master Plan (TEMP) in coordination with the Test Integration Working Group (TIWG) members (refer to Chapter 4, Event 9).

9. Prepare BOIPFD/QQPRI. The USAMMDA prepares Basis of Issue Plan Feeder Data (BOIPFD) and initiates the Qualitative and Quantitative Personnel Requirements Information (QQPRI). The O&O Plan and SMMP provide input to these documents. The BOIPFD/QQPRI are processed together as a package through the Office of The Surgeon General to Equipment Authorizations Review Activity, who forwards the BOIPFD/QQPRI to HQ TRADOC for further processing.

10. Update Independent Evaluation Plan. AHS-CD and USAMMDA prepare the Independent Evaluation Plans (IEPs) for user testing and Technical Testing (TT) respectively for each product/system in the materiel acquisition process. These plans, although closely coordinated for maximum efficiency of test resources and to ensure complete testing of the product/ system, are prepared separately for user testing and TT. The IEPs provide vital guidance for TT and user test activities. They describe the item/system to be tested; provide test objectives, issues, and criteria; and prescribe evaluation procedures and types of analyses to be conducted.

11. Update Individual and Collective Training Plan. AHS-Trainer, in coordination with USAMMDA, other AHS activities, and TRADOC, updates the Individual and Collective Training Plan (ICTP) (refer to Chapter 4, Event 10).

12. Prepare New Equipment Training Plan. Based on inputs from the Basis of Issue Plan Feeder Data and Qualitative and Quantitative Personnel Requirements Information (BOIPFD/QQPRI), ICTP, and SMMP, and in coordination with AHS, USAMMA prepares the New Equipment Training Plan (NETP). The NETP provides, in part, the initial transfer of knowledge on the operation and maintenance of new equipment from the materiel developer to the tester, trainer, and user. The NETP is approved by HQDA, Office of the Deputy Chief of Staff for Operations and Plans. New equipment training is part of the fielding process (see Chapter 20, The Materiel Fielding and New Equipment Training Process).

13. Conduct Technical Tests. Based on the IEP prepared by the designated independent evaluator, and in accordance with the contractual requirements, the contractor prepares the Technical Test (TT) plans which are coordinated among the TIWG members. The USAMMDA (PMO) manages the TT and prepares, with contractor assistance, the test report.

14. Conduct User Test.

a. Prepare Outline Test Plan. The Outline Test Plan (OTP) contains administrative information, test purpose, issues, scope, tactical context, and resources requirements in support of the test. The AMEDD Board prepares the OTP based on the IEP and other inputs; and coordinates the document with the TIWG members and U.S. Army Operational Test and Evaluation Agency (OTEA). The OTP is submitted to the Test Schedule and Review Committee (TSARC); when it is approved the OTP is a formal tasking document that is placed in the five year test program. The OTPs are updated semiannually.

b. Prepare Test Design Plan. The Test Design Plan (TDP) is prepared by the AMEDD Board for user tests. The TDP includes a method by which the item/system is to be tested, restates the test objectives, issues and associated criteria, and plans for data collection and analysis. It is coordinated among the TIWG members and a copy is provided to OTEA for review.

c. Provide Test Support Package. The AHS-Trainer provides input to AHS- Tester in the form of a training test support package. The package includes training requirements for the user test personnel and data collection in the area of training requirements.

d. Prepare Test Report. The tester prepares a test report upon completion of the user test. The report presents data obtained during the test and describes the conditions under which the test was conducted. The Final Test Report contains a comparison of test criteria with test results. The test report is provided to AHS-CD for their evaluation.

15. Prepare Independent Evaluation Report. USAMMDA and AHS-CD prepare the Independent Evaluation Reports (IERs) for technical and user tests respectively. The IERs are based on the TEMP, IEP, and the test reports. They provide an assessment of the materiel systems operational and technical effectiveness versus the issues contained in the IEPs and other issues, as appropriate. They present the evaluators' conclusions and positions on the future capability of the system and identify issues to be addressed in subsequent tests. The reports are provided to the milestone review body by USAMMDA. The independent evaluators may brief their evaluation results directly to the review body.

16. Prepare and Staff BOIP/QQPRI. HQ TRADOC forwards the BOIPFD/QQPRI package to the Academy of Health Sciences which is responsible for preparing the BOIP and Training Impact Statement from the BOIPFD/QQPRI, and for staffing with the involved TRADOC schools and integrating centers. After development of the BOIP and QQPRI data, AHS forwards the package through the integrating center (Logistics Center) to HQ TRADOC for further coordination and submission to HQDA (DCSOPS) for approval. Several iterations of the total staffing process may be required. A BOIP is used to determine the number of new or improved items of equipment and personnel to be included in Tables of Organization and Equipment (TOE) Level 1. A QQPRI is used to determine the need for the establishment or revision of Military Occupational Specialties (MOS) and other skill identifiers and to update plans for training (see Chapter 18, The BOIP/QQPRI Process).

17. Prepare Requirements Document. A Required Operational Capability (ROC) or Joint Services Operational Requirement (JSOR) is required at Milestone II. See Chapter 11, Requirements Documents, and Chapter 23, Joint Service Coordination.

18. Prepare the Decision Coordinating Paper. After approval of the requirements document and the BOIP/QQPRI, USAMMDA, in coordination with AHS and USAMMA, prepares a Decision Coordinating Paper (DCP) and other milestone supporting documents. The DCP summarizes the acquisition planning for the

system life cycle and provides a management overview of the program. It is a top-level summary document, limited to eighteen pages, that identifies alternatives, goals, and thresholds. The DCP is required for all levels of program reviews. At the request of the decision authority, an Integrated Program Summary (IPS) may also be required. The IPS summarizes, in greater detail than the DCP, the plan for a system acquisition. The PMO is responsible for the preparation, coordination, and staffing of the DCP and IPS (see Chapter 12, Milestone Decision Review Process, for more details). Other documentation to support this milestone decision includes:

- Cost Effectiveness Analysis (CEA): AHS-CD, in coordination with USAMMDA, updates the CEA (Chapter 13, The Concept Formulation Process);
- TEMP and AS: USAMMDA updates, in coordination with AHS and USAMMA;
- Human Factors Engineering Analysis (HFEA) of all MANPRINT issues: USAMMDA, in coordination with AHS, USAMMA, and AMC (Human Engineering Laboratory), performs a formal HFEA (Chapter 14, The MANPRINT Process);
- Transportability Engineering Analysis: When required, the Military Traffic Management Agency prepares an updated Transportability Engineering Analysis of potential transportability problems (Chapter 15, The Integrated Logistic Support Process).

19. Conduct Milestone II In-Process Review. USAMMDA convenes a Milestone II IPR and may recommend a tentative decision to continue into Full Scale Development. The review is held at HQDA for DAP programs. The decision authority issues a SADM that directs and guides the Full Scale Development Phase effort.

5.5 FULL SCALE DEVELOPMENT PHASE

5.5.1 General Objectives. The Milestone II decision is documented in a SADM which approves the DCP and supporting documents, and authorizes entry into Full Scale Development. The length of this phase will vary among programs; normal length will be in the one-to-two year range. The objectives of FSD include:

- Develop/design the system and all items necessary for its support;
- Manufacture engineering development prototypes, and;
- Evaluate the capability, producibility, operational suitability, and logistic supportability of the completed design.

5.5.2 Specific Activities.

SEE CHART 5-1

20. Review/Update Requirements Documents. AHS, in coordination with USAMMDA, updates, if necessary, the ROC/JSOR.

21. Update Program Management Documents. USAMMDA, in coordination with AHS and USAMMA, updates the AS, AP, SMMP, ILSP, and TEMP.

22. Detailed Design Activities/Engineering Development Prototype. Based on input from USAMMDA, USAMMRA prepares and awards a contract to perform detailed design activities, manufacture engineering development prototypes, and conduct development tests.

23. Establish the Transition Planning and Tracking Group. The USAMMDA and USAMMA establish the Transition Planning and Tracking Group (TPTG) no later than ninety days after Milestone II. The appropriate USAMMDA PM is the TPTG Chairperson. The members of the TPTG normally are the USAMMA Readiness Project Officer and representatives of laboratories supporting the development. Other TPTG members may include the USAMMDA PMSO, other PMO representatives, and other USAMMA representatives.

One of the early TPTG activities is preparation of a Transition Plan. The basic structure of a plan should be accomplished within 120 days after the TPTG is formed. A plan is required for all developmental programs, although

the size, scope, and level of detail involved depend on the complexities of the transition process. The plan should be coordinated with the Defense Medical Standardization Board. The basic purpose of the Transition Plan is:

- Provide a management tool for achieving transition;
- Provide a transition planning vehicle;
- Identify tasks, establish responsibilities and milestones for successful transition;
- Establish a realistic and achievable transition date;
- Document the transition process.

The Transition Plan is approved by the Commander, USAMRDC and becomes part of the Milestone III production decision.

> **NOTE:**
>
> Products undergoing improvement programs and subsystems that will transition as a component of a larger system do not need a Transition Plan. Example: power supply for a refrigerator.

24. Update IEPs, Conduct and Evaluate Tests, and Prepare IERs. User and technical testers prepare OTPs and/or Test Design Plans, conduct tests, and prepare test reports. The AHS-CD and USAMMDA prepare IEPs prior to the tests and IERs of the test results (see events 10 through 13 of D&V Activities).

25. Update BOIP/QQPRI. The AHS-CD, in coordination with USAMMDA, prepares and staffs the amended BOIP/QQPRI.

NOTE:

DA approved BOIP/QQPRI are required for a Milestone III production decision unless a waiver is obtained from HQDA (DCSOPS).

26. Update ICTP. The AHS-Trainer updates the ICTP.

27. Update NETP. USAMMA, in coordination with the AHS (Trainer), updates the NETP. The AHS, in coordination with USAMMA, provides training to operators and maintainers who participate in user tests.

28. Prepare Initial Materiel Fielding Plans and Materiel Fielding Agreements. USAMMDA, in coordination with the AHS (CD and Trainer), USAMMA, and the gaining commands, prepares initial Materiel Fielding Plans (MFPs) and Materiel Fielding Agreements (MFAs). This planning is completed during the Production and Deployment phase (refer to Chapter 20, The Materiel Fielding and New Equipment Training Process).

29. Production Proveout. Prior to a Milestone III full rate production decision, USAMMDA, in coordination with AHS-CD and AHS-Tester, ensures that the operational effectiveness and suitability of the developmental item have been established by T&E on items "sufficiently representative of the expected production system", (refer to DOD Directive 5000.3, March 12, 1986). When there is significant risk that the engineering development prototypes previously tested are not sufficiently representative of the production line models, USAMMDA procures a limited quantity of hard-tool manufactured production models. USAMMDA, in coordination with AHS-CD and AHS-Tester conducts the additional evaluations required to ensure readiness for full-rate production.

30. Approve TDP. Under guidance of USAMMDA, the developing contractor or in-house laboratory develops the Technical Data Package (TDP) describing the production configuration of the developed system/item. USAMMDA approves the TDP in a Critical Design Review (or series of incremental reviews) and formal Functional Configuration Audit prior to the Milestone III decision.

31. Prepare FDA Submissions.

a. Devices. FDA regulations require that an application for Premarket Approval (PMA) be submitted for Class III devices. USAMRDC (Laboratory) and the contractors assemble the required data for submission by USAMMDA (PMO). The PMA provides all information concerning investigations which have been made as to whether or not the device is safe and effective. In addition, data is provided regarding its composition and principles of operation; manufacturing methods and controls, and such other information as may be required by the FDA. Approval of the PMA application is required prior to production and distribution of the device. Refer to Chapter 24, Regulatory Interfaces.

b. Drugs and Vaccines. Upon the completion of human tests and determination by the sponsor that the drug or vaccine is safe and effective under specified conditions, a New Drug Application (NDA) or Licensure Application is submitted to the FDA. Approval of the NDA or License is required prior to production of the drug. In addition, the manufacturer must report to the FDA frequently (quarterly initially) on the production, safety, and effectiveness of the new drug. Refer to Chapter 24, Regulatory Interfaces.

32. Review Preparations for Transition. The Transition Planning and Tracking Group (TPTG) reviews the preparations for the transfer of management responsibility to USAMMA. This review occurs approximately ninety days prior to the transition date. The results of the review are presented by the TPTG chairperson to the IPR for appropriate action.

33. Request NSN. Not less than ninety days prior to the IPR, USAMMA requests/obtains assignment of an NSN for the item through DMSB and DPSC. The NSN assignment is a prerequisite to assignment of a standard LIN and type classification.

34. Request Standard LIN. Not less than thirty days prior to the IPR, USAMMA requests a standard LIN from the Army Materiel Command. The standard LIN replaces the Z-LIN and is required for type classification.

35. Prepare DCP and Supporting Documentation. In preparation for a Milestone III IPR:

- USAMMDA updates the AS and AP;
- USAMMA and DPSC confirm the establishment of production readiness (e.g., facilities, logistic support resources, correction or planned correction of design deficiencies);
- AHS-CD updates the COEA/AA, if required;
- USAMMDA, in coordination with AHS-CD and AHS-Trainer, USAMMA and AMC (Human Engineering Laboratory), perform a formal HFEA of all MANPRINT issues (see Chapter 14);
- USAMMDA obtains a transportability approval from the Military Traffic Management Command for identified transportability problems (Chapter 14), and;
- USAMMDA prepares the DCP, and IPS if required by the decision authority.

36. Conduct Milestone III In-Process Review. USAMMDA conducts a Milestone III IPR to recommend the final decision to produce and deploy. The review is held at HQDA for DAP programs. The decision authority issues a SADM that directs and guides the Production and Deployment Phase effort.

5.6 PRODUCTION AND DEPLOYMENT PHASE

5.6.1 General Objectives. The Milestone III decision is documented in a SADM which approves the decision documents and authorizes entry into the Production and Deployment Phase. During this phase, management of the program is transitioned from USAMMDA to USAMMA, equipment is acquired and distributed, personnel and units are trained, and logistic support is provided. In addition, the Defense Personnel Support Center (DPSC) becomes responsible for soliciting and awarding production contracts.

5.6.2 Specific Activities.

SEE CHART 5-1

37. Validate Type Classification. Prior to the program's transition to USAMMA, the item must also be approved for type-classification standard (accepted for Service use) by the IPR Decision Authority and validated by OTSG. Documentation required for TC includes the BOIP, QQPRI, and Military Occupational Specialty decisions.

38. Transition to USAMMA. USAMMA's management role commences with the Milestone III IPR approval to transition the program from USAMMDA. Transition is aided by the fact that the USAMMA staff and the USAMMA Product Manager were involved in the program from the start. For example, USAMMA is a member of the TPTG, and is involved in ILS planning, materiel fielding, and new equipment training planning to include coordination with AHS-Trainer for the ICTP. USAMMA already has in hand the IPR Minutes and SADM, the requirements document, an acceptable TDP, a production model that meets all technical and performance requirements, and residual tasks identified; all of which are required for subsequent activities.

39. Transfer Technical Data Package to the DMSB. USAMMA prepares documentation for standardization of the item and forwards the Technical Data Package (TDP) to DMSB. The DMSB reviews or prepares the appropriate documentation, completes the standardization process, and forwards the package to the Defense Personnel Support Center (DPSC).

40. DPSC Responsibilities. The DPSC is responsible for the preparation of the solicitation package, awarding the contract, and continuing production. DPSC also conducts Production Acceptance Test and Evaluation (PAT&E)

which is intended to ensure that the contractor can furnish a product that meets established technical criteria. Upon successful completion of the PAT&E, production continues and deployment commences.

> NOTE:
>
> Both USAMMDA and USAMMA interface with DPSC throughout the medical materiel acquisition process. The technical interface continues during the contracting, production and procurement activities to include monitoring the PAT&E. In addition, the FDA may also monitor the PAT&E. See MOA between USAMRDC and DPSC.

41. The Individual and Collective Training Plan. Based on the results of the Milestone III IPR and BOIP and QQPRI input, the AHS-Trainer prepares the final Individual and Collective Training Plan (ICTP). This plan includes the full range of training from initial qualification, sustainment and follow-on for all MOS and all levels. The ICTP provides input to the Materiel Fielding Plan, the Materiel Fielding Agreement prepared by USAMMDA, and the New Equipment Training Plan prepared by USAMMA, in coordination with AHS and the gaining commands.

42. Materiel Release. At the request of USAMMA, the OTSG (Health Care Operations Directorate) authorizes the release of medical materiel. The release of the first system is a control mechanism to verify that all materiel and logistics deficiencies identified in operational testing have been corrected; that all logistics resources required to support the initial deployment are available concurrent with the release of the system; and that the materiel is suitable in terms of safety and health, human factors engineering, and environmental factors.

43. Resident Training. The AHS-Trainer is responsible for institutional training and preparation and issuance of Exportable Training Materiels. Resident training starts in sufficient time to begin graduating students approximately six months prior to the First Unit Equipped (FUE) date.

44. Deployment/FUE. USAMMA, in coordination with the Organizational Integrator at OTSG, is responsible for the deployment of the new equipment in accordance with the Materiel Fielding Plan and Materiel Fielding Agreements made with the gaining units. Provisions are also made to identify, report, and correct deployment problems (see Chapter 20).

45. Follow-on Test and Evaluation. Although performance and supportability of a system are demonstrated before deployment, there may be Follow-On Test and Evaluation (FOT&E) requirements. If an FOT&E is required, AHS-CD, in coordination with USAMMA and AHS-Trainer, inputs requirements to the AMEDD Board, which conducts the FOT&E. The FOT&E provides data to answer operational issues that were not resolved by earlier testing. The AHS-CD monitors the FOT&E, prepares the evaluation, and initiates corrective action as required (see Chapter 17, The Test and Evaluation Process).

46. Initial Operational Capability. The Initial Operational Capability (IOC) is the first attainment of the capability by a unit and its support elements to effectively operate and maintain a production item or system.

5.7 REFERENCES

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

AR 70-1, Systems Acquisition Policy and Procedures, 1986

AR 70-10, Test and Evaluation, 1986

AR 70-61, Type Classification of Army Materiel, 1985

AR 71-2, Basis of Issue Plans and Qualitative and Quantitative Personnel Requirements Information, 1982

AR 71-3, User Testing, 1986

AR 71-9, Materiel Requirements, 1986

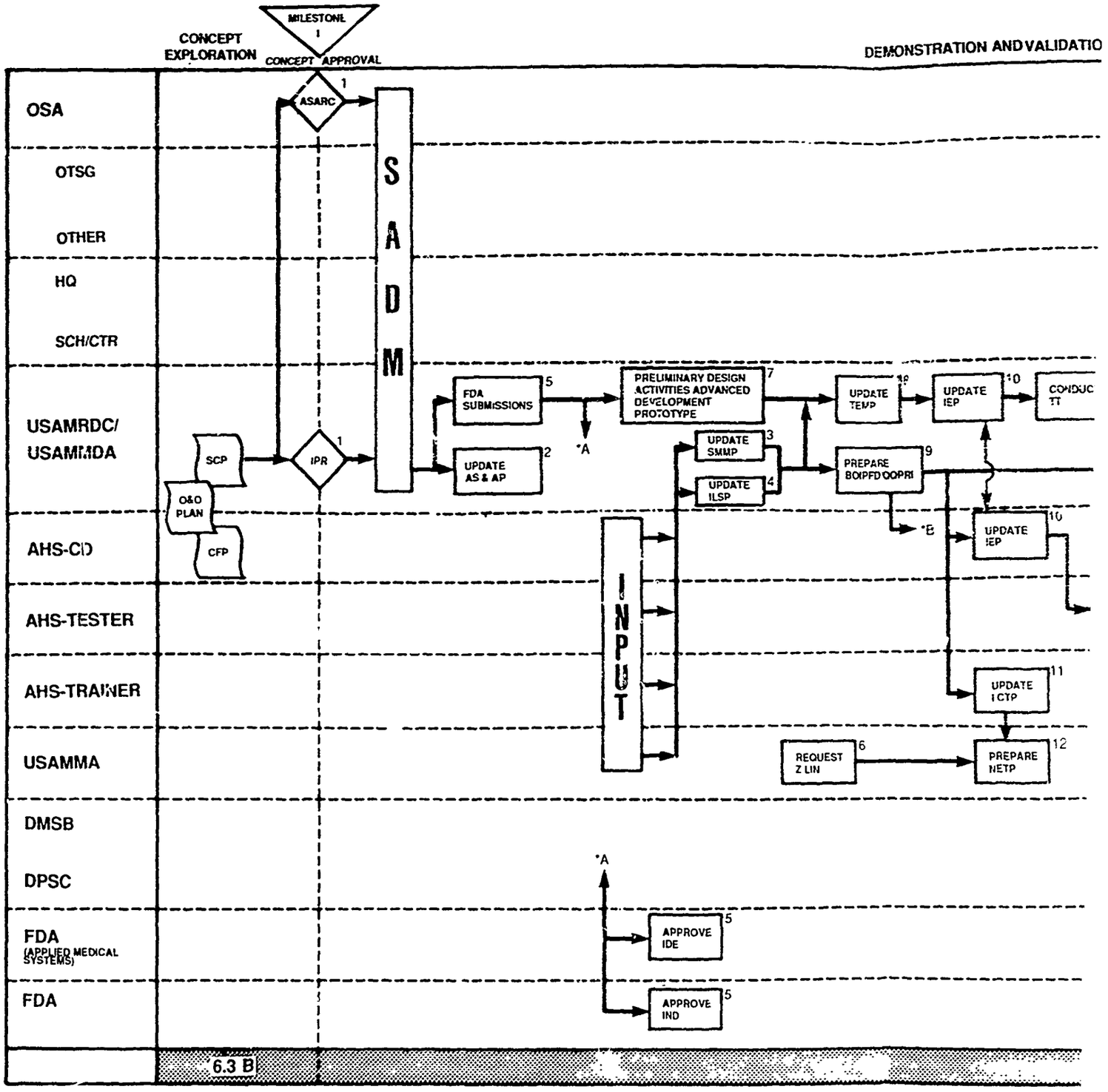
AR 350-35, Army Modernization Training, 1984

AR 602-2, MANPRINT in the Materiel Acquisition Process, 1986

AR 700-127, Integrated Logistic Support, 1983

AR 1000-1, Basic Policies for System Acquisition, 1983

TRADOC R 351-9, Individual and Collective Training Plan for Developing Systems, 1982


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CONCEPT APPROVAL
CONCEPT EXPLORATION
DEMONSTRATION AND VALIDATIO
OSA
OTSG
OTHER
HQ
SCH/CTR
USAMRDC/ USAMMDA
AHS-CD
AHS-TESTER
AHS-TRAINER
USAMMA
DMSB
DPSC
FDA (APPLIED MEDICAL SYSTEMS)
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ASARC
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S A D M
IPR
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UPDATE AS & AP
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PRELIMINARY DESIGN ACTIVITIES ADVANCED DEVELOPMENT PROTOTYPE
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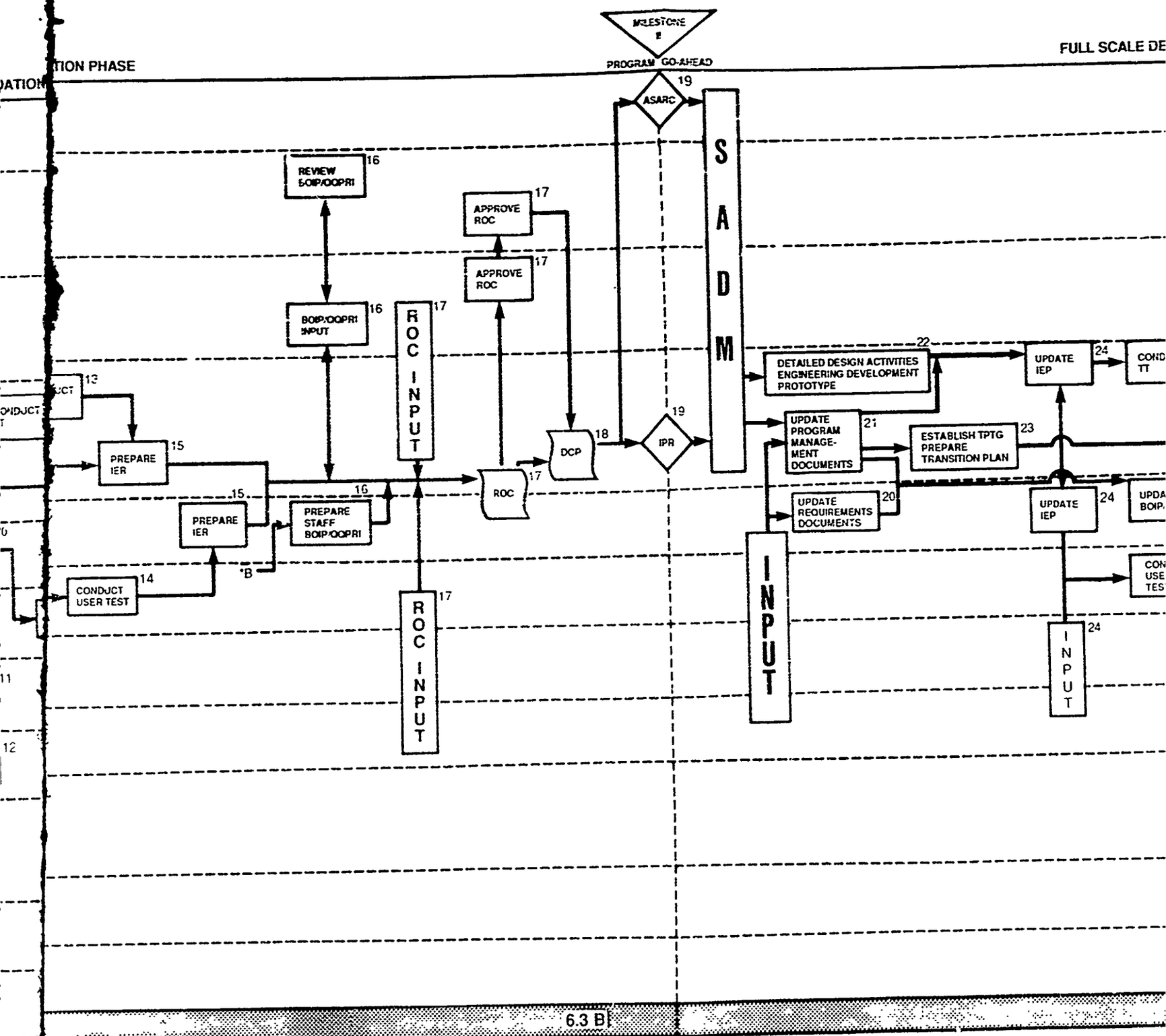
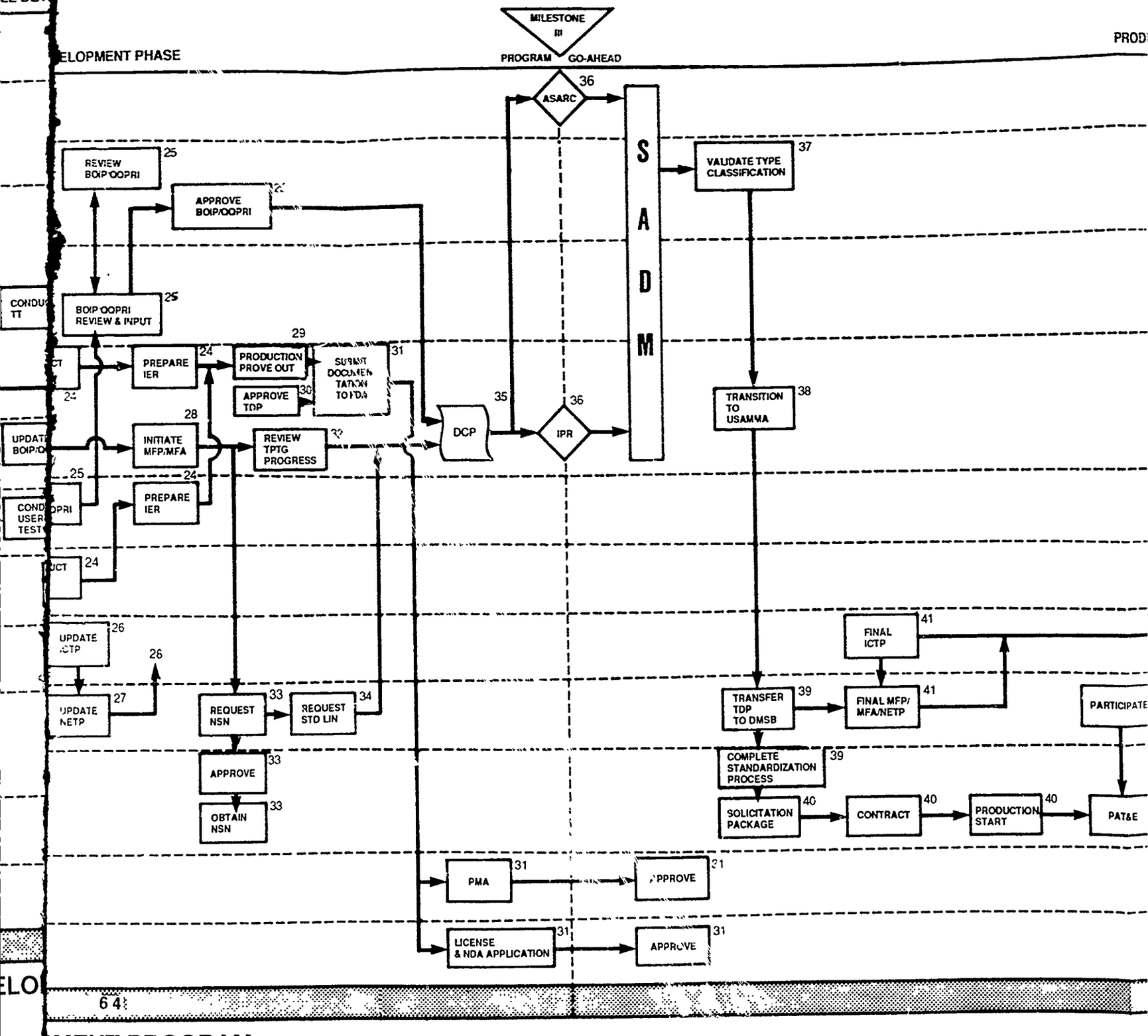


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3

PRODUCTION AND DEPLOYMENT PHASE

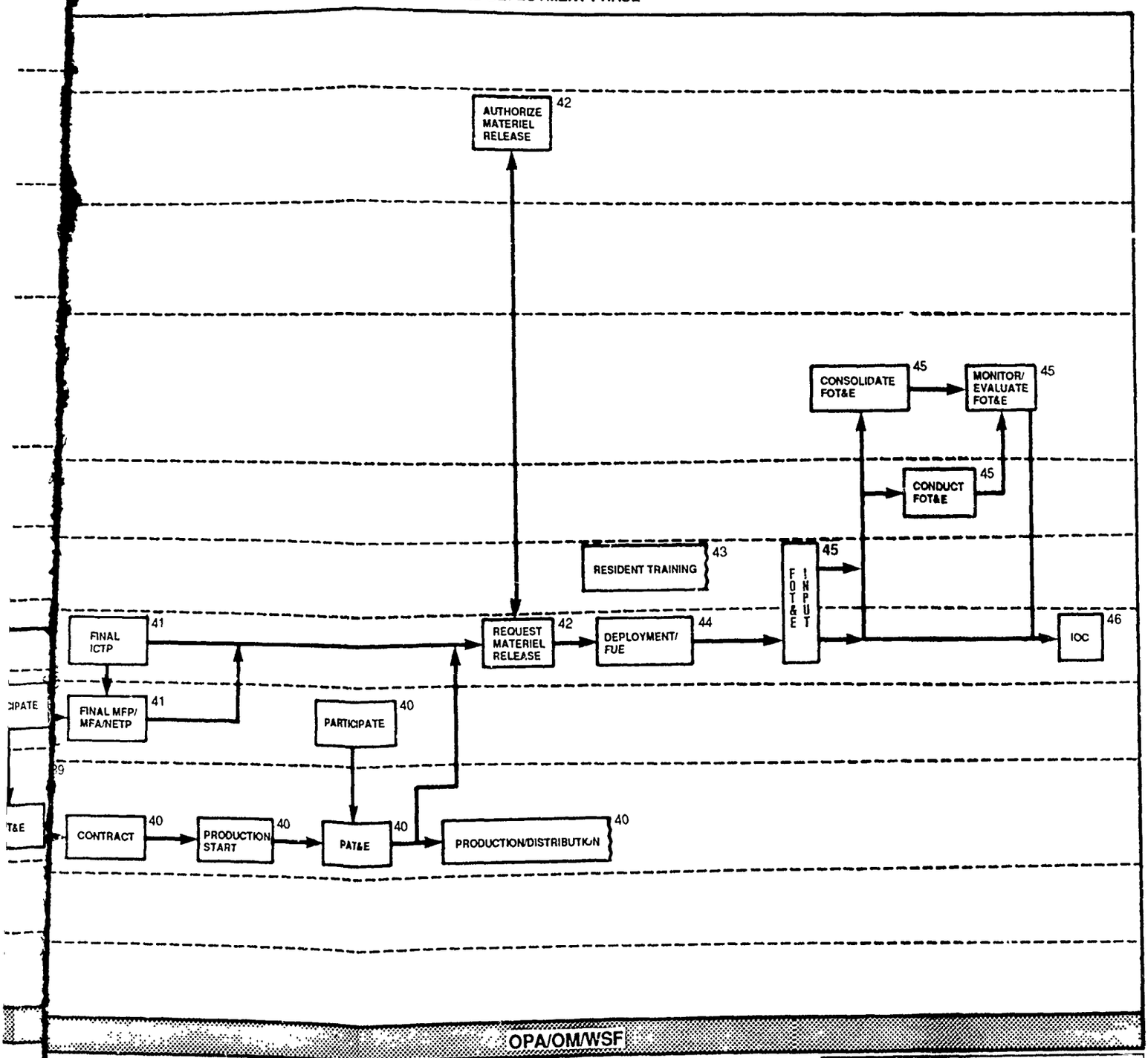


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 5-1

CHAPTER 6

NONDEVELOPMENT ITEM PROGRAM

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6.1 PURPOSE

The purpose of this chapter is to provide an overview of Nondevelopment Item (NDI) program activities performed subsequent to the formal NDI decision (normally the Milestone I decision). The acquisition process for the NDI program is tailored to combine the development program D&V and FSD Phases into an NDI Acquisition Documentation Phase that is managed by USAMMA from the Milestone I decision on. Development and NDI programs have similar Production and Deployment Phases following the Milestone III decision. Chart 6-1 portrays the NDI program activities. More detailed descriptions of the acquisition functions involved in the NDI process are in Chapters 9 through 26.

6.2 GENERAL

An NDI approach becomes the selected solution to a materiel need when a market investigation performed during the Concept Exploration Phase results in a determination that an existing item is available to satisfy the stated need in its existing configuration (See Chapter 4, para 4.2.2, Event 2). The need as further defined in a requirements document includes operational, technical, logistics supportability, and MANPRINT factors. In some instances, in order to ensure suitability and feasibility of the NDI in the anticipated combat environment, confirmatory tests (technical and user) may be necessary. More detailed descriptions of the test and evaluation process for NDI are in Chapter 17.

6.2.1 Sources. NDI may be selected from:

- Commercial sources (U.S. or foreign);
- Materiel developed and in use by other U.S. military services or government agencies, or;
- Materiel developed and in use by foreign military services.

6.2.2 Advantages. Selection of NDI from these sources offers three major benefits:

- Time to fielding is greatly reduced;
- RDTE costs are eliminated or reduced to that required to confirm suitability in a military environment;
- Currently available state-of-the-art technology is obtained to satisfy the materiel need.

6.2.3 Challenges. NDI also presents challenges such as:

a. Essential ILS activities normally accomplished in preproduction phases must be accelerated to support initial fielding. Reliance upon contractor support during an initial deployment period is often required.

b. The design of the selected item must satisfy the requirements of logistics supportability and MANPRINT (e.g., human factors engineering and operator and maintainer skill capabilities). Design influence cannot be imposed in the same manner as for developmental items; it must be accomplished in the selection process. For other Service and other nation military items, selection is accomplished by the market investigation process. In the case of commercial items, the solicitation and source selection evaluation must be employed to select a design that is compatible with the military mission and its environment.

c. Reprocurement of commercial items can lead to proliferation of different configurations of hardware and software and, in turn, logistic support, training, and configuration management problems. Consideration should be given to:

- Initial (one time) procurement of the total authorized requirement including long term support items (i.e., repair parts) and/or;
- Pre-negotiated multi-year procurement of add-on requirements and replacements from the initial source.

6.3 INTRODUCTION

Chart 6-1, a flow chart at the end of this chapter, summarizes the events, activities, documents and decisions required to complete an NDI program. Numbers within the blocks on the flow chart relate to the text paragraph that discusses the activity identified in the block. The chart is organized to present, in their relative order, the primary responsibilities of each participating organization. The text discussion summarizes, by acquisition phase, the NDI program activities.

6.4 ACQUISITION DOCUMENTATION PHASE

6.4.1 General Objectives. This phase encompasses the procurement, logistics, and MANPRINT planning activities required in preparation for a Milestone III production decision.

> **NOTE:**
>
> If a program can be clearly demonstrated as low risk with minimum logistics requirements, it may be possible to prepare a solicitation package as part of the Market Investigation. In that case, Milestone I approves the NDI Acquisition Strategy and authorizes competitive procurement thus eliminating the requirement for a Milestone III.

6.4.2 Specific Activities.

SEE CHART 6-1

1. Program Transition to USAMMA. If the Decision Authority approves the NDI Acquisition Strategy as recommended by the Milestone I review, a System Acquisition Decision Memorandum (SADM) is issued that is the authority for initiating the NDI program. Program management responsibilities are then transferred from USAMMDA to USAMMA.

2. Z-LIN. USAMMA requests/obtains a developmental line item number (Z-LIN) from the U.S. Army Materiel Command. The Z-LIN provides a means of tracking the item through the logistics community during this phase.

3. Request Joint Services Approved Requirements Change. If the non-developmental item is part of a Joint Service Approved Requirement, the OTSG provides the updated appropriate documents to the Defense Medical Standardization Board (DMSB) for concurrence (see Chapter 23, Joint Service Coordination).

4. Update the System MANPRINT Management Plan (SMMP). Lead responsibility for MANPRINT transitions from AHS-CD to USAMMA after Milestone I. The USAMMA is responsible for updating the System MANPRINT Management Plan (SMMP). Inputs are provided by AHS (CD, Trainer, Tester) and USAMMDA. The SMMP addresses the MANPRINT strategy to be employed during the acquisition process, data sources, program concerns, a milestone schedule, and task descriptions. The SMMP is approved by the Commander, USAMMA (see Chapter 14, The MANPRINT Process).

5. Prepare BOIPFD/QQPRI. The USAMMA prepares the Basis of Issue Plan Feeder Data (BOIPFD) and initiates the Qualitative and Quantitative Personnel Requirements Information (QQPRI). The O&O Plan and SMMP provide input to these documents. The BOIPFD/QQPRI are processed together as a package through the Office of the Surgeon General to the Equipment Authorizations Review Activity who forwards the BOIPFD/QQPRI to HQ TRADOC for further processing, (See Chapter 18, The BOIP/QQPRI Process).

6. Update Integrated Logistics Support Plan (ILSP). USAMMA updates the ILSP with a focus on the identification and development of logistic support resources (see Chapter 15, The Integrated Logistics Support Process).

7. Prepare New Equipment Training Plan (NETP). Based on inputs from the Basis of Issue Plan Feeder Data and Qualitative and Quantitative Personnel Requirements Information (BOIPFD/QQPRI), and coordination with AHS, USAMMA prepares the NETP. The NETP provides, in part, the initial transfer of knowledge on the operation and maintenance of new equipment from the materiel

developer to the tester, trainer, and user. The NETP is approved by HQDA, Office of the Deputy Chief of Staff for Operations and Plans. New equipment training is part of the fielding process (see Chapter 20, The Materiel Fielding and New Equipment Training Process, for more details).

8. Prepare and Staff BOIP/QQPRI. HQ TRADOC forwards the package to the Academy of Health Sciences who is responsible for preparing the BOIP and Training Impact from the BOIPFD/QQPRI, and for staffing with the involved TRADOC schools and integrating centers. After development of the BOIP and QQPRI data, AHS forwards the package through the integrating center (Logistics Center) to HQ TRADOC for further coordination and submission to HQDA (DCSOPS) for approval. Several iterations of the staffing process may be required. A BOIP is used to determine the number of new or improved items of equipment and personnel to be included in Tables of Organization and Equipment (TOE) Level 1. A QQPRI is used to determine the need for the establishment or revision of Military Occupational Specialties (MOS) and other skill identifiers, and to update plans for training (see Chapter 18, The BOIP/QQPRI Process).

9. National Stock Number (NSN). Not less than ninety (90) days prior to the IPR, USAMMA requests/obtains assignment of an NSN for the item through DMSB and DPSC. The NSN assignment is a prerequisite to assignment of a Standard LIN and type classification.

10. Standard Line Item Number. Not less than thirty (30) days prior to the IPR, USAMMA requests a standard LIN from the Army Materiel Command. The standard LIN replaces the Z-LIN and is required for type classification.

11. Update Individual and Collective Training Plan (ICTP). The AHS-Trainer, in coordination with USAMMA, other AHS activities, and TRADOC schools and centers, updates the ICTP (See Chapter 16, The Training and Training Device Process).

12. Prepare Materiel Fielding Plans (MFP)/Materiel Fielding Agreements (MFA). USAMMA, in coordination with the AHS (CD and Trainer), Defense Personnel Support Center, and the gaining commands, prepares MFPs and MFAs (See Chapter 20, The Materiel Fielding and New Equipment Training Process).

13. Prepare Technical Data Package (TDP). USAMMA compiles the technical data package, in coordination with USAMMDA and AHS (CD and Trainer). The objective is to satisfy performance and logistics supportability requirements and MANPRINT-related design constraints and to do so in a competitive manner. The TDP takes the form of a specification or functional purchase description and is derived primarily from the essential characteristics and the logistics assessments and constraints stated in the Required Operational Capability or other requirements document approved prior to Milestone I.

14. Prepare Decision Coordinating Paper (DCP). In preparation for a Milestone III IPR:

- AHS (CD) updates the COEA/AA;
- USAMMA updates the AS and AP;
- USAMMA prepares the Type Classification Package,
- USAMMA and DPSC confirm the establishment of production readiness (e.g., facilities, logistic support resources, correction or planned correction of design deficiencies);
- USAMMA and AHS, in coordination with AMC (Human Engineering Laboratory), perform a Human Factors Engineering Analysis (HFEA) if required;
- USAMMA obtains a transportability approval from the Military Traffic Management Command for identified transportability problems (Chapter 15, The Integrated Logistics Support Process).

15. Conduct Milestone III In-Process Review. USAMMA conducts a Milestone III IPR to recommend the final decision to produce and deploy. The review is held at HQDA for Designated Acquisition Programs. The Decision Authority (AAE for DAP and Director HCO, OTSG for IPR programs) issues a SADM that directs and guides the Production and Deployment Phase effort.

6.5 PRODUCTION AND DEPLOYMENT PHASE

6.5.1 General Objectives. The Milestone III decision is documented in a SADM which approves the decision documents and authorizes entry into the Production and Deployment Phase. During this phase, equipment is acquired and distributed, personnel and units are trained, and logistic support is provided. In addition, the DPSC becomes responsible for soliciting and awarding contracts and for procurement and distribution of the item.

6.5.2 Specific Activities.

SEE CHART 6-1

16. Validate Type Classification (TC). Prior to transfer of solicitation and procurement responsibility to DPSC, the item must be validated as type classified standard (accepted for Service use) by OTSG. Documentation required for TC includes the BOIP, QQPRI, and Military Occupational Specialty decisions (refer to Chapter 12, The Milestone Decision Review Process).

17. Transfer TDP to DMSB. USAMMA prepares documentation for standardization of the item and forwards the TDP to the Defense Medical Standardization Board (DMSB). The Board reviews or prepares the essential characteristics of the product, completes the standardization process, and forwards the package to the DPSC.

18. DPSC Responsibilities. The DPSC, in coordination with USAMMA, is responsible for the preparation of the solicitation package and awarding the contract. The solicitation should elicit sufficient information from competitive bidders to enable selection of an item that is supportable in its intended combat environment and for which there is adequate assurance of required contractor support over its expected life span.

DPSC also conducts, and USAMMA participates in, the Production Acceptance Test and Evaluation (PAT&E) which is intended to ensure that the contractor can furnish a product that meets established technical criteria. Upon successful completion of the PAT&E, production continues and deployment commences.

19. Resident Training. The AHS-Trainer is responsible for institutional training and preparation of Exportable Training Materials. Resident training starts in sufficient time to begin graduating students approximately six (6) months prior to the First Unit Equipped (FUE) date.

20. Materiel Release. At the request of USAMMA, the OTSG (HCD) authorizes the release of medical materiel. The release of the first system is a control mechanism to verify that all materiel and logistics deficiencies identified in user testing have been corrected; that all logistics resources required to support the initial deployment are available concurrent with the release of the system; and that the materiel is suitable in terms of safety and health, human factors engineering, and environmental factors.

21. Deployment/FUE. USAMMA, in coordination with the OTSG (Organizational Integrator) is responsible for the deployment of the new equipment in accordance with the Materiel Fielding Plan and Materiel Fielding Agreements made with the gaining units. Provisions are also made to identify, report, and correct deployment problems.

22. Follow-on Test and Evaluation. Although performance and supportability of a system are demonstrated before deployment, there may be Follow-on Test and Evaluation (FOT&E) requirements. If an FOT&E is required, USAMMA and AHS-Trainer provide input to the AHS-CD for consolidation of their requirements to the AMEDD Board, who conducts the FOT&E. The FOT&E provides data to answer user issues. (see Chapter 17, The Test and Evaluation Process).

23. Initial Operational Capability (IOC). The Initial Operational Capability (IOC) is the first attainment of the capability by a unit and its support elements to operate and maintain effectively a production item or system.

6.6 REFERENCES

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

AR 70-1, System Acquisition Policy and Procedures, 1986

AR 70-10, Test and Evaluation, 1986

AR 70-61, Type Classification of Army Materiel, 1985

AR 71-2, Basis of Issue Plans and Qualitative and Quantitative Personnel Requirements Information, 1983

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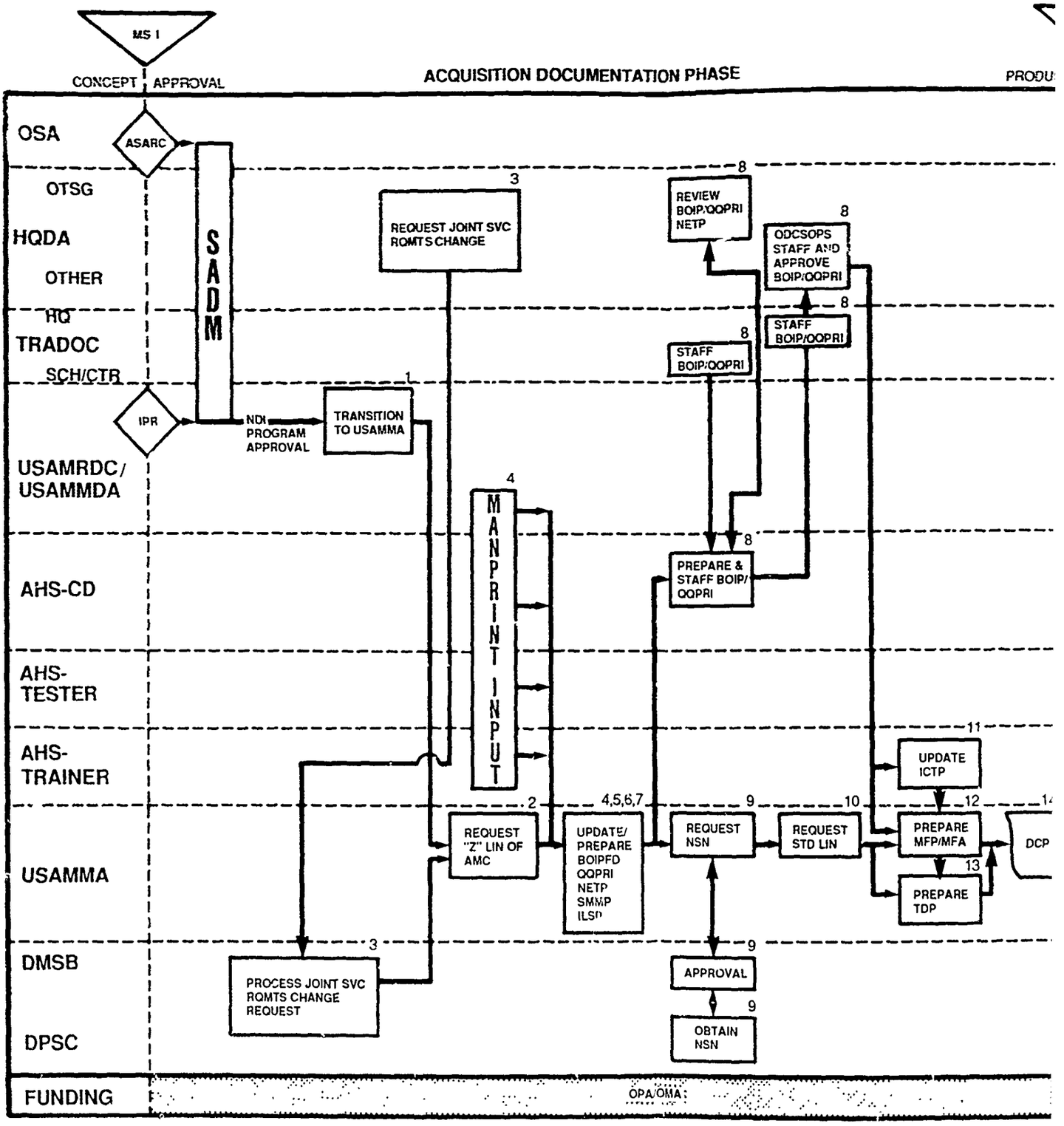
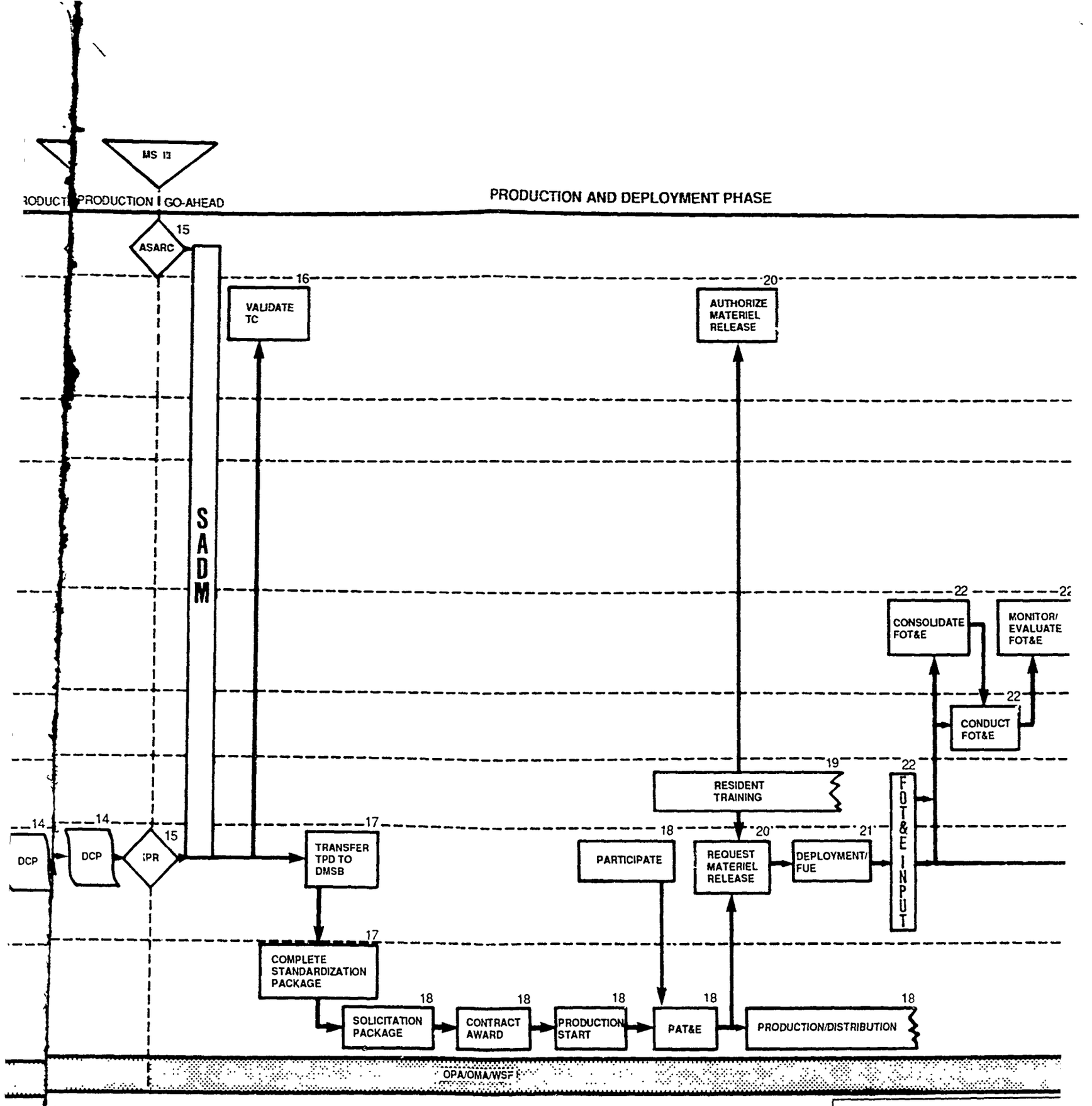

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USAMRDC/ USAMMDA
AHS-CD
AHS-TESTER
AHS-TRAINER
USAMMA
DMSB
DPSC
FUNDING
OPA/OMA
REQUEST JOINT SVC RQMTS CHANGE
MANPRINT INPUT
REVIEW BOIP/OOPRI NETP
ODCSOPS STAFF AND APPROVE BOIP/OOPRI
STAFF BOIP/OOPRI
STAFF BOIP/OOPRI
PREPARE & STAFF BOIP/ OOPRI
REQUEST "Z" LIN OF AMC
UPDATE/ PREPARE BOIPFD OOPRI NETP SMMP ILSP
REQUEST NSN
REQUEST STD LIN
UPDATE ICTP
PREPARE MFP/MFA
PREPARE TDP
DCP
PROCESS JOINT SVC RQMTS CHANGE REQUEST
APPROVAL
OBTAIN NSN

Chart (



art 6 Chart 6-1. NDI PROGRAM

CHART NOTES

1 SEE APPENDIX B FOR ACRONYMS

2 BLOCK NUMBERS CORRESPOND TO THE TEX THAT DISCUSS THE ACTIVITY IDENTIFIED IN T

Chart 6-1

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PRODUCTION AND DEPLOYMENT PHASE

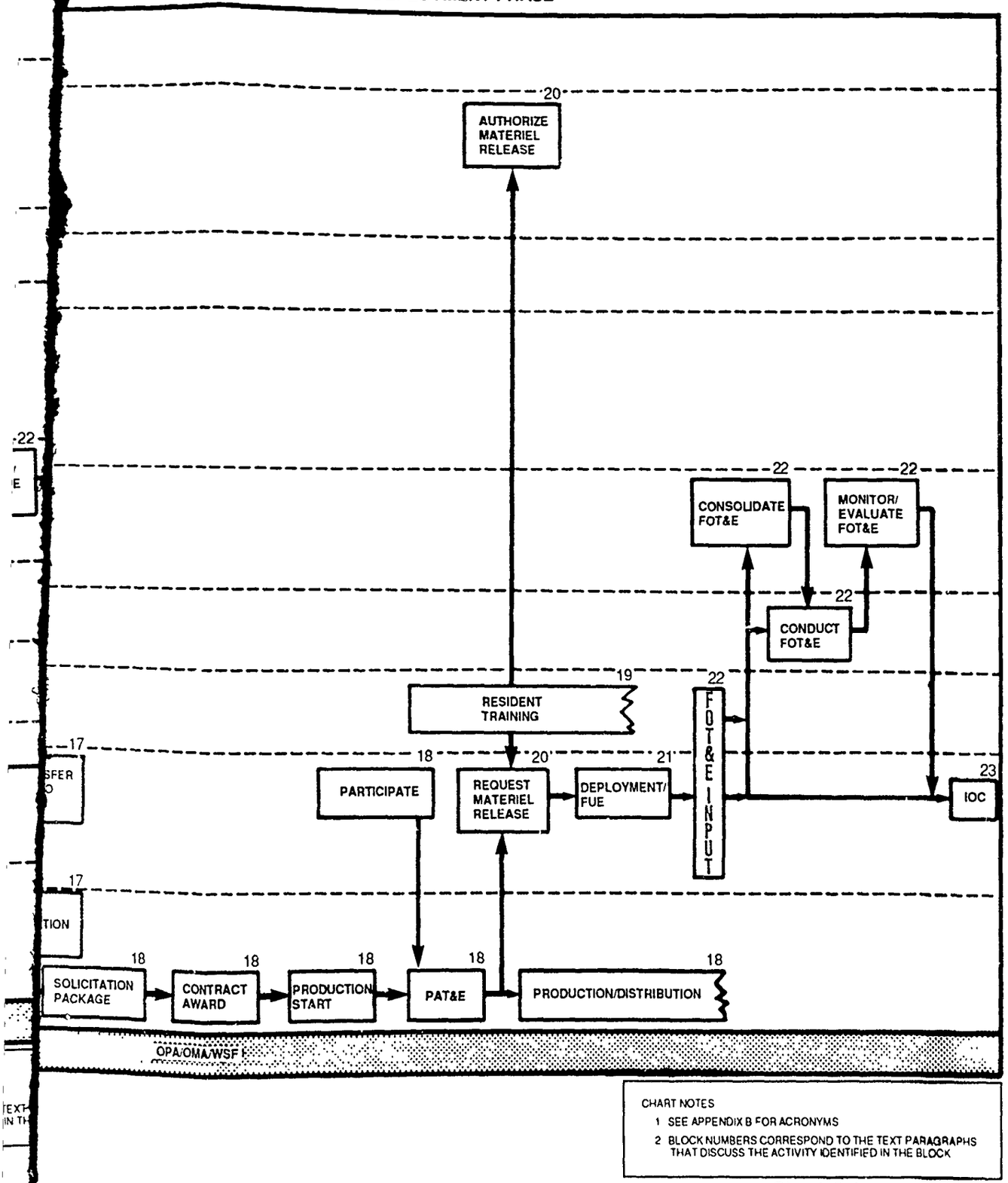


CHART NOTES

1 SEE APPENDIX B FOR ACRONYMS

2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 6-1

CHAPTER 7

MODIFIED NONDEVELOPMENT ITEM PROGRAM

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7.1 PURPOSE

This chapter describes the typical activities necessary to acquire medical materiel using a Modified Nondevelopment Item (MOD-NDI) process approach. The period addressed starts with the Milestone I decision at the end of the Concept Exploration Phase and ends with the attainment of IOC. This is a summary chapter, one of eight such chapters in the overview section of the Medical Materiel Acquisition Handbook. More detailed descriptions of the various acquisition functions involved in the MOD-NDI process are provided in Chapters 9-26.

7.2 GENERAL

The need to modify equipment to satisfy an Army requirement is normally determined during the Concept Exploration Phase. This determination is made when the results of a market investigation indicate a standard commercial product must be modified, or it is evident that items developed by another service or country must be modified. It is also possible that the need to modify equipment may be indicated by tests or analyses conducted during Demonstration and Validation or Full Scale Development Phases. The Acquisition Strategy supporting the Modified Nondevelopment program and the approved requirements document authorize the start of the MOD-NDI program.

The MOD-NDI program has the same advantages and disadvantages as the NDI program, however, in contrast to the "pure" NDI program discussed in Chapter 6, the MOD-NDI program has a development phase prior to the production and deployment phase. The development phase is necessary because the item requires modification for one or more reasons. Either it will be used in a military environment that differs substantially from its intended use in the commercial environment or it will be used as a component of a system that requires hardware and/or software development and integration. Even with an established requirement, the extent of the modification will vary and there will be some degree of risk in meeting the user's needs, some engineering effort and testing required, and the expenditure of RDT&E funds. Therefore, the program will be managed by a USAMMDA project management office for applied medical systems.

The MOD-NDI program imposes a challenge on the acquisition community to meet the requirements of MANPRINT, ILS, and the other acquisition functions within the shortened acquisition period. The MOD-NDI acquisition strategy must be tailored to the unique characteristics of each program. Although the majority of the MOD-NDI programs will be IPR programs, some may qualify as DAP programs, be so designated by the Army Acquisition Executive (ASA [RDA]), and be reviewed at HQDA.

7.3 INTRODUCTION

Chart 7-1, a flow chart at the end of this chapter, summarizes the events, activities, documents and decisions required to complete a MOD-NDI program. Numbers within the blocks on the flow chart relate to the text paragraph that discuss the activity identified in the block. The chart is organized to present, in their relative order, the primary responsibilities of each participating organization. The text discussion summarizes, by phase, the MODNDI program activities.

7.4 REQUIREMENTS DEFINITION AND PLANNING PHASE

7.4.1 General Objectives. This phase is initiated by the Decision Authority's approval of the Milestone I recommendations for a MOD-NDI acquisition strategy. The System Acquisition Decision Memorandum (SADM) provides the authority and guidance for the program. The phase will average about 12 months in length but will vary considerably according to the nature and extent of the required modification. The objectives of this phase are to complete the engineering efforts, test the modifications, and prepare or update the necessary documents such as the acquisition plan, the integrated logistics support plan, and the materiel fielding plan. The phase ends at MS III with the production decision.

7.4.2 Specific Activities.

SEE CHART 7-1

1. Update the Acquisition Strategy and Acquisition Plan. The Acquisition Strategy (AS) and Acquisition Plan (AP) prepared during the Concept Exploration Phase will be updated based on changes delineated in the SADM. The AP is the responsibility of the PM but is prepared by the contracting officer. Approval procedures for the AP are contained in the Army Federal Acquisition Regulation (FAR) Supplement, Part 7. (see Chapter 4, Concept Exploration Phase Activities and Chapter 12, The Milestone Decision Review Process).

2. Review the Operational and Organizational Plan. The AHS (CD, Trainer and Tester) USAMMDA, and USAMMA, review the Operational and Organizational (O&O) Plan and the requirements document for Milestone III and update them as required.

3. Update SMMP. The USAMMDA is responsible for updating the System MANPRINT Management Plan (SMMP). Inputs are provided by the AHS (CD, Trainer, and Tester) and USAMMA. The SMMP addresses the MANPRINT strategy to be employed during the acquisition process, data sources, program concerns, a milestone schedule, and task descriptions. The SMMP is approved by the Commander, USAMMDA (see Chapter 14, The MANPRINT Process).

4. Prepare BOIPFD/OQPRI. The USAMMDA prepares Basis of Issue Plan Feeder Data (BOIPFD) and initiates the Qualitative and Quantitative Personnel Requirements Information (QQPRI). The O&O Plan and SMMP provide input to these documents. The BOIPFD/QQPRI are processed together as a package through the Office of the Surgeon General to the Equipment Authorizations Review Activity who forwards the BOIPFD/OQPRI to HQ TRADOC for further processing.

5. Establish the Transition Planning and Tracking Group (TPTG). The USAMMDA and USAMMA establish the TPTG no later than 90 days after Milestone I. The appropriate USAMMDA Project Manager is the TPTG Chairperson. The members of the TPTG normally are the USAMMA Product Manager and representatives of laboratories supporting the development. Other TPTG members may include the USAMMDA PMSO, other PMO representatives, and other USAMMA representatives. One of the early TPTG activities is preparation of a Transition Plan. The basic structure of a plan should be accomplished within 120 days after the TPTG is formed. A plan is required for all MOD-NDI programs, although the size, scope, and level of detail involved depends on the complexities of the transition process. The plan is coordinated with the Defense Medical Standardization Board. The basic purpose of the Transition Plan is to:

- Provide a management tool for achieving transition;
- Provide a transition planning vehicle;
- Identify tasks, establish responsibilities and milestones for successful transition;
- Establish a realistic and achievable transition date, and;
- Document the transition process.

The commanders, USAMMDA and USAMMA approve the Transition Plan as part of the Milestone III production decision.

> NOTE:
>
> Products undergoing Product Improvement Programs (PIP) and sub-systems that will transition as a component of a larger system do not need a Transition Plan. Example: power supply for a refrigerator.

6. Modification of Joint-Service Items. If the item to be modified will be used by two or more Services, a modification request must be forwarded by USAMMA to DMSB for its concurrence. In addition, the OTSG (HCO) determines other Service and/or nation interest in the item.

7. Request Z-LIN from AMC. USAMMA requests/obtains a development line item number (Z-LIN) from the Army Materiel Command (AMC). The Z-LIN provides a means of tracking the item through the logistics community during the acquisition process.

8. Update Individual and Collective Training Plan. The AHS-Trainer, in coordination with USAMMDA, other AHS organizations, and TRADOC is responsible for updating the Individual and Collective Training Plan (ICTP). The ICTP presents a concept for training, provides inputs to other analyses and plans (such as the NETP), and identifies the constraints that training requirements and resources may impose on the design of materiel.

9. Prepare New Equipment Training Plan. Based on inputs from the BOIP/QQPRI, requirements documents and the ICTP, USAMMA prepares a New Equipment Training Plan (NETP). The NETP provides, in part, the initial transfer of knowledge on the operation and maintenance of new equipment from the materiel developer to the tester, trainer, and user. The first NETP is developed within 30 days of forwarding the first QQPRI to AHS-CD. New equipment training is part of the fielding process (see Chapter 20 for more details).

10. Update TEMP and ILSP. These two documents are updated by USAMMDA with inputs from the BOIP/QQPRI package, the SMMP, the O&O Plan, and the Acquisition Strategy and Acquisition Plan. The TEMP and ILSP in turn provide input to the Transition Plan, training plans, test plans, and the Materiel Fielding Plan (MFP).

11. Prepare Specifications and Procurement Data. USAMMDA prepares the specifications for the Modified NDI. With USAMMDA input, the USA Medical Research Acquisition Activity (USAMRAA) contracts for prototype design, development, and testing. The contractor develops a Technical Data Package that is structured to permit competitive solicitations among qualified contractors during the Production and Deployment Phase.

12. Prepare and Staff BOIP/QQPRI. HQ TRADOC forwards the package to the Academy of Health Sciences which is responsible for preparing the BOIP and Training Impact Statement from the BOIPFD/QQPRI, and for staffing with the involved TRADOC schools and integrating centers. After development of the BOIP and QQPRI data, AHS forwards the package through the integrating center (Logistics Center) to HQ TRADOC for further coordination and submission to HQDA (DCSOPS) for approval. Several iterations of the total staffing process may be required. A BOIP is used to determine the number of new or improved items of equipment and personnel to be included in Tables of Organization and Equipment (TOE) Level 1. A QQPRI is used to determine the need for the establishment or revision of Military Occupational Specialties (MOS), or Additional Skill Identifiers (ASI) and to update plans for training (see Chapter 15, BOIP/QQPRI).

13. Update Independent Evaluation Plan. The AHS-CD and USAMMDA update the independent evaluation plans (IEP) for user testing and technical testing respectively. For each item/system in the materiel acquisition process, these plans, although closely coordinated for maximum efficiency of test resources, and to ensure complete testing of the item/system, are prepared separately for user testing and TT. These plans provide the critical issues which are included in the TEMP. The IEP provides vital guidance for TT and user testing activity. It describes the item/system to be tested; provides test objectives, issues, and criteria; and prescribes evaluation procedures and types of analyses to be conducted.

14. Conduct Technical Tests. Based on the IEP prepared by the designated independent evaluator and in accordance with the contractual requirements, the contractor prepares the appropriate test plans which are coordinated among the TIWG members. The USAMMDA (PMO) manages the technical tests and, with contractor assistance, prepares the test report.

15. Conduct User Tests.

a. Prepare Test Requirements Documentation. The AMEDD Board (AHS-Tester) prepares an abbreviated Requirement Letter/Disposition Form containing all resource and administrative information required to support innovative

testing. The test requirements document is based on the IEP and coordinated with AHS (CD and Trainer) and USAMMDA. Innovative testing (Concept Evaluation Program) can address most of the user's unresolved issues in a MOD-NDI program. The innovative test is accomplished with Health Services Command assets. The AHS-Tester prepares a Test Design Plan (TDP) which is coordinated with the TIWG members. The TDP includes a method by which the item/system is to be tested; restates the test objectives, issues, and associated criteria; and plans for data collection and analysis. It is coordinated among the TIWG members and a copy is provided to OTEA for review.

b. Test Support Packages. The AHS-Trainer and USAMMA provide input to AHS-Tester in the form of test support packages. These packages include training requirements for the user test personnel and data collection instructions in the area of training requirements and logistics issues.

c. Prepare Test Report. The AMEDD Board prepares a test report upon completion of the user test. The report presents data obtained during the test and describes the conditions under which the test was conducted. The Final Test Report contains a comparison of test criteria with test results. The test report is provided to the AHS-CD for their independent evaluation.

16. Prepare Independent Evaluation Report. The AHS-CD and USAMMDA prepare the Independent Evaluation Report (IER) for user and technical tests respectively. The IERs are based on the TEMP, IEP, and the test reports. They provide an assessment of the materiel system's operational and technical effectiveness versus the issues contained in the IEPs and other issues, as appropriate. They present the evaluators conclusions and positions on the future capability of the system, and identify issues to be addressed in subsequent tests. The reports are provided to the milestone review body by USAMMDA. The independent evaluator may brief his evaluation results directly to the review body.

17. Initiate Materiel Fielding Plans and Materiel Fielding Agreements. USAMMDA, in coordination with the AHS-CD and Trainer, and the gaining commands, prepares initial MFPs and MFAs. This planning is completed during the Production and Deployment Phase (refer to Chapter 20, Materiel Fielding and New Equipment Training).

18. National Stock Number. Not less than ninety days prior to the IPR, USAMMA requests/obtains assignment of a National Stock Number (NSN) for the item through DMSB and DPSC. The NSN assignment is a prerequisite to assignment of a Standard LIN and type classification.

19. Request Standard LIN. Not less than thirty days prior to the IPR, USAMMA requests a standard LIN from the Army Materiel Command. The standard LIN replaces the Z-LIN and is required for type classification approval at Milestone III.

20. Review TPTG Progress. The Transition Planning and Tracking Group (TPTG) reviews the preparations for the transfer of management responsibility to USAMMA. This review occurs approximately ninety days prior to the transition date. The results of the review are presented by the TPTG chairperson to the IPR for appropriate action.

21. Prepare the Decision Coordinating Paper. The DCP summarizes the acquisition planning for a system's life cycle and provides a management overview of the program. It is a summary document, limited to eighteen pages, that identifies alternatives, goals, and thresholds. The DCP is required for all levels of programs. At the request of the decision authority, an Integrated Program Summary (IPS) may also be required. The IPS summarizes, in greater detail than the DCP, the plan for a system acquisition. The PMO is responsible for the preparation, coordination, and staffing of the DCP and IPS (see Chapter 12, The Milestone Decision Review Process).

22. Conduct Milestone III IPR. USAMMDA conducts a Milestone III IPR recommending the final decision for type classification of the item and production and deployment. The review is held at HQDA for Designated Acquisition Programs. If the Milestone III review recommendations are approved, the Decision Authority issues a SADM that directs and guides the Production and Deployment Phase effort.

7.5 PRODUCTION AND DEPLOYMENT PHASE

7.5.1 General Objectives. This phase is initiated by the Milestone III decision. During this phase, management of the program is transitioned from USAMMDA to USAMMA, equipment is acquired and distributed, personnel and units are trained, and logistic support is provided. In addition, the DPSC becomes responsible for soliciting and awarding contracts, and for production and distribution of the equipment.

7.5.2 Specific Activities.

SEE CHART 7-1

23. Validate Type Classification. The Type Classification (TC) recommendation is approved by CG USAMRDC and validated by OTSG for IPR programs if the IPR members unconditionally concur. If the IPR members do not agree, the issue will be resolved at OTSG. The ASARC has TC approval authority for Designated Acquisition Programs.

24. Transition to USAMMA. USAMMA's management role commences with the Milestone III IPR approval to transition the program from USAMMDA. Transition is aided by the involvement, from the start, of the USAMMA staff and the USAMMA Product Manager. USAMMA is also a member of the TPTG, is involved in

ILS, materiel fielding, and new equipment training planning to include coordination with AHS-Trainer for the ICTP. USAMMA already has in hand the IPR Minutes and SADM, the requirements document, an acceptable TDP, a production model that meets all technical and performance requirements, and residual tasks identified; all of which are required for subsequent activities (see Chapter 19, The Configuration Management Process).

25. Transfer Technical Data Package (TDP) to the DMSB. USAMMA prepares documentation for standardization of the item and forwards the TDP to DMSB. The DMSB reviews or prepares the appropriate documentation, completes the standardization process, and forwards the package to the Defense Personnel Support Center (DPSC).

26. Defense Personnel Support Center (DPSC) Responsibilities. The DPSC is responsible for the preparation of the solicitation package, awarding the contract, and continuing production. DPSC also conducts the Production Acceptance Test and Evaluation (PAT&E) which is intended to ensure that the contractor can furnish a product that meets established technical criteria. Upon successful completion of the PAT&E, production continues and deployment commences.

> NOTE:
>
> Both USAMMDA and USAMMA interface with DPSC throughout the medical materiel acquisition process. This interface continues during the contracting, production and procurement activities to include monitoring the PAT&E activities. In addition, the FDA may also monitor the test (see MOA between USAMRDC and DPSC).

27. The Individual and Collective Training Plan. Based on the results of the Milestone III IPR, and with BOIP and QQPRI input, the AHS-Trainer prepares the final Individual and Collective Training Plan (ICTP). This plan includes the full range of training from initial qualification, sustainment and follow-on for all MOS and all levels. The ICTP provides input to the Materiel Fielding Plan, the Materiel Fielding Agreement and the New Equipment Training Plan.

28. Final MFP/MFA/NETP. USAMMA is responsible for updating and coordinating the MFP, MFA, and NETP in preparation for fielding.

29. Materiel Release. At the request of USAMMA the OTSG (HCD) authorizes the release of medical materiel. The release of the first system is a control mechanism to verify that all materiel and logistics deficiencies identified in operational testing have been corrected; that all logistics resources required to support the initial deployment are available concurrent with the release of the system; and that the materiel is suitable in terms of safety and health, human factors engineering, and environmental factors.

30. Resident Training. The AHS-Trainer is responsible for institutional training and preparation of Exportable Training Materials. Resident training produces graduate students approximately six months prior to the First Unit Equipped (FUE) date.

31. Deployment/FUE. USAMMA, in coordination with OTSG (Organization Integrator), is responsible for the deployment of the new equipment in accordance with the Materiel Fielding Plan and Materiel Fielding Agreements made with the gaining units. Provisions are also made to identify, report, and correct deployment problems (see Chapter 20).

32. Follow-on Test and Evaluation. Although performance and supportability of a system are demonstrated before deployment, there may be Follow-on Test and Evaluation (FOT&E) requirements. If an FOT&E is required, USAMMA and AHS-Trainer provide input to the AHS-CD who consolidates their requirements to the AHS-Tester, which conducts the FOT&E. The FOT&E provides data to answer user issues that were not resolved by earlier testing. The AHS-CD monitors the FOT&E and prepares an independent evaluation report which is provided to USAMMA for action (see Chapter 17, The Test and Evaluation Process).

33. Initial Operational Capability. The Initial Operational Capability (IOC) is the first attainment of the capability by a unit and its support elements to effectively operate and maintain a production item or system.

7.6 REFERENCES

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

AR 70-1, System Acquisition Policy and Procedures, 1986

AR 70-10, Test and Evaluation, 1986

AR 70-61, Type Classification of Army Materiel, 1985

AR 71-2, Basis of Issue Plans and Qualitative and Quantitative Personnel Requirements Information, 1983

AR 71-3, User Testing, 1986

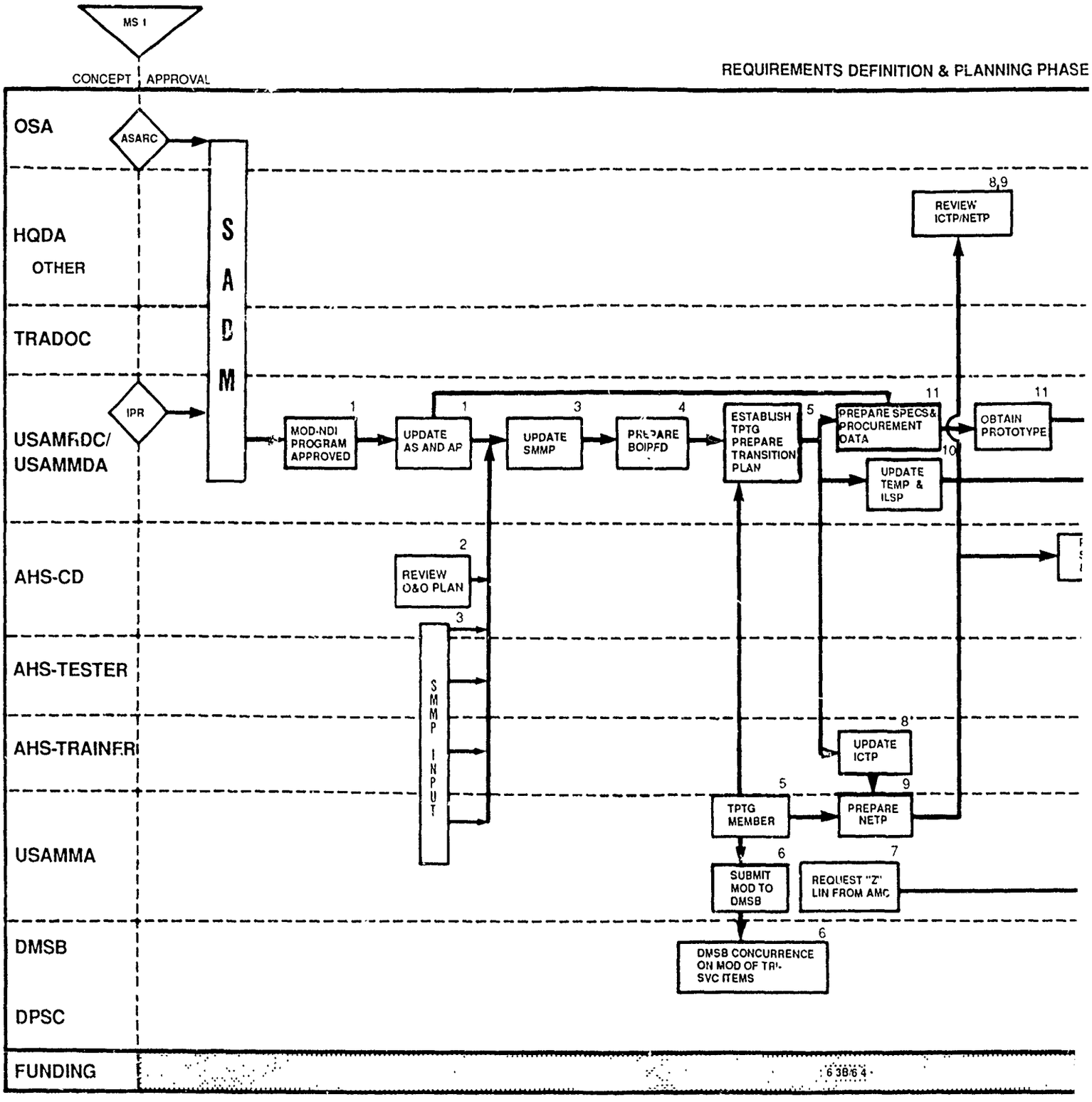
AR 350-35, Army Modernization Training, 1984

AR 602-2, MANPRINT in the Materiel Acquisition Process, 1986

AR 700-127, Integrated Logistic Support, 1983

AR 1000-1, Basic Policies for System Acquisition, 1983

TRADOC Regulation 351-9, Individual and Collective Training Plan for Developing Systems, 1982


MS I
CONCEPT APPROVAL
REQUIREMENTS DEFINITION & PLANNING PHASE
OSA
ASARC
HQDA
OTHER
TRADOC
USAMRDC/
USAMMDA
IPR
S A D M
MOD-NDI PROGRAM APPROVED
UPDATE AS AND AP
UPDATE SMMP
PREPARE BOIPFD
ESTABLISH TPTG PREPARE TRANSITION PLAN
PREPARE SPECS& PROCUREMENT DATA
OBTAIN PROTOTYPE
REVIEW ICTP/NETP
UPDATE TEMP & ILSP
AHS-CD
REVIEW O&O PLAN
AHS-TESTER
SMMP INPUT
AHS-TRAINER
UPDATE ICTP
USAMMA
TPTG MEMBER
PREPARE NETP
SUBMIT MOD TO DMSB
REQUEST "Z" LIN FROM AMC
DMSB
DMSB CONCURRENCE ON MOD OF TRI- SVC ITEMS
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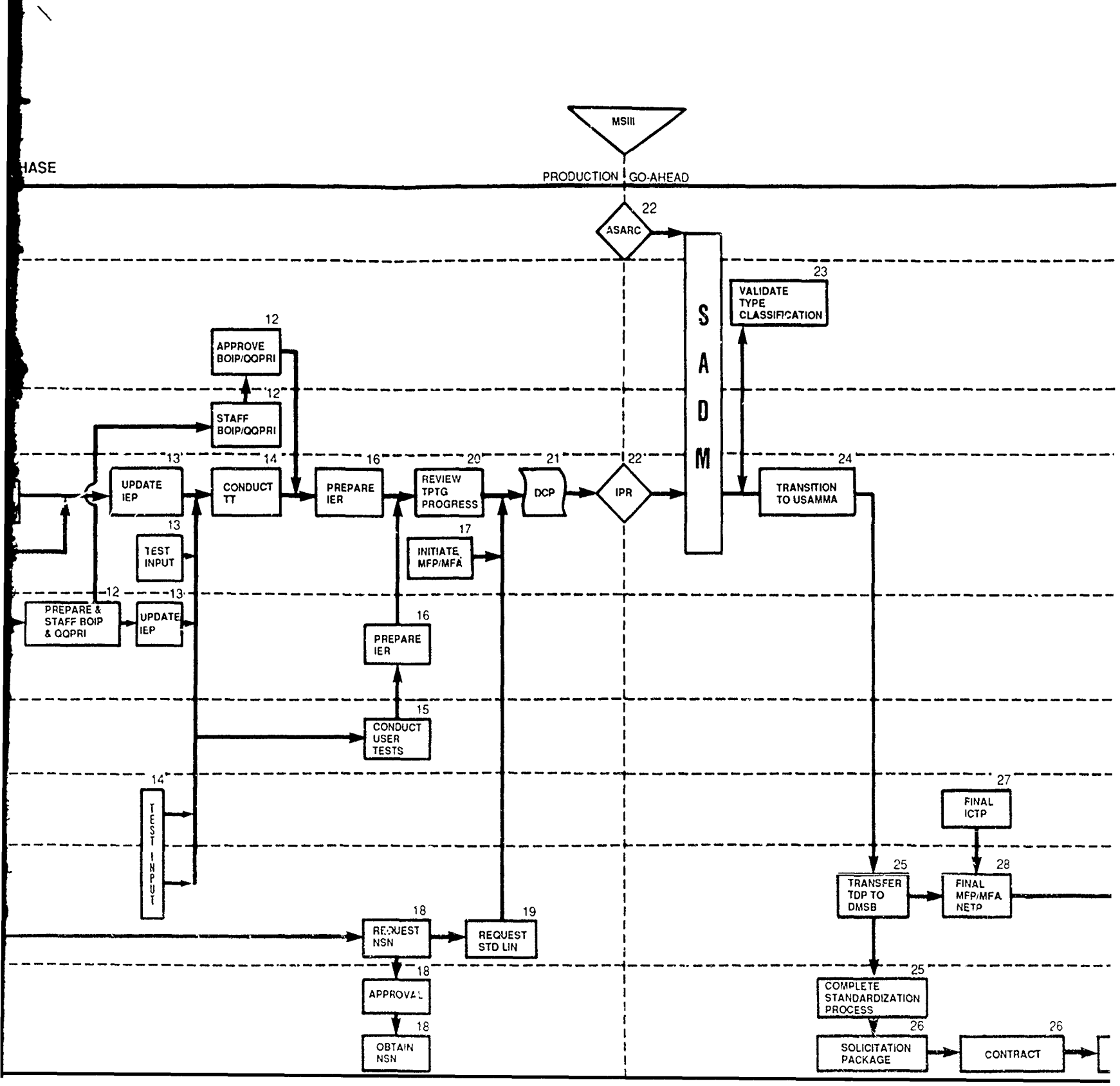

HASE
MSIII
PRODUCTION GO-AHEAD
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ASARC
S A D M
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VALIDATE TYPE CLASSIFICATION
12
APPROVE BOIP/QQPRI
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STAFF BOIP/QQPRI
13
UPDATE IEP
14
CONDUCT TT
16
PREPARE IER
20
REVIEW TPTG PROGRESS
21
DCP
22
IPR
24
TRANSITION TO USAMMA
13
TEST INPUT
17
INITIATE MFP/MFA
12
PREPARE & STAFF BOIP & QQPRI
13
UPDATE IEP
16
PREPARE IER
15
CONDUCT USER TESTS
14
TEST INPUT
27
FINAL ICTP
25
TRANSFER TDP TO DMSB
28
FINAL MFP/MFA NETP
18
REQUEST NSN
19
REQUEST STD LIN
18
APPROVAL
18
OBTAIN NSN
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COMPLETE STANDARDIZATION PROCESS
26
SOLICITATION PACKAGE
26
CONTRACT

CHART 7-1. MODIFIED NDI PROGRAM

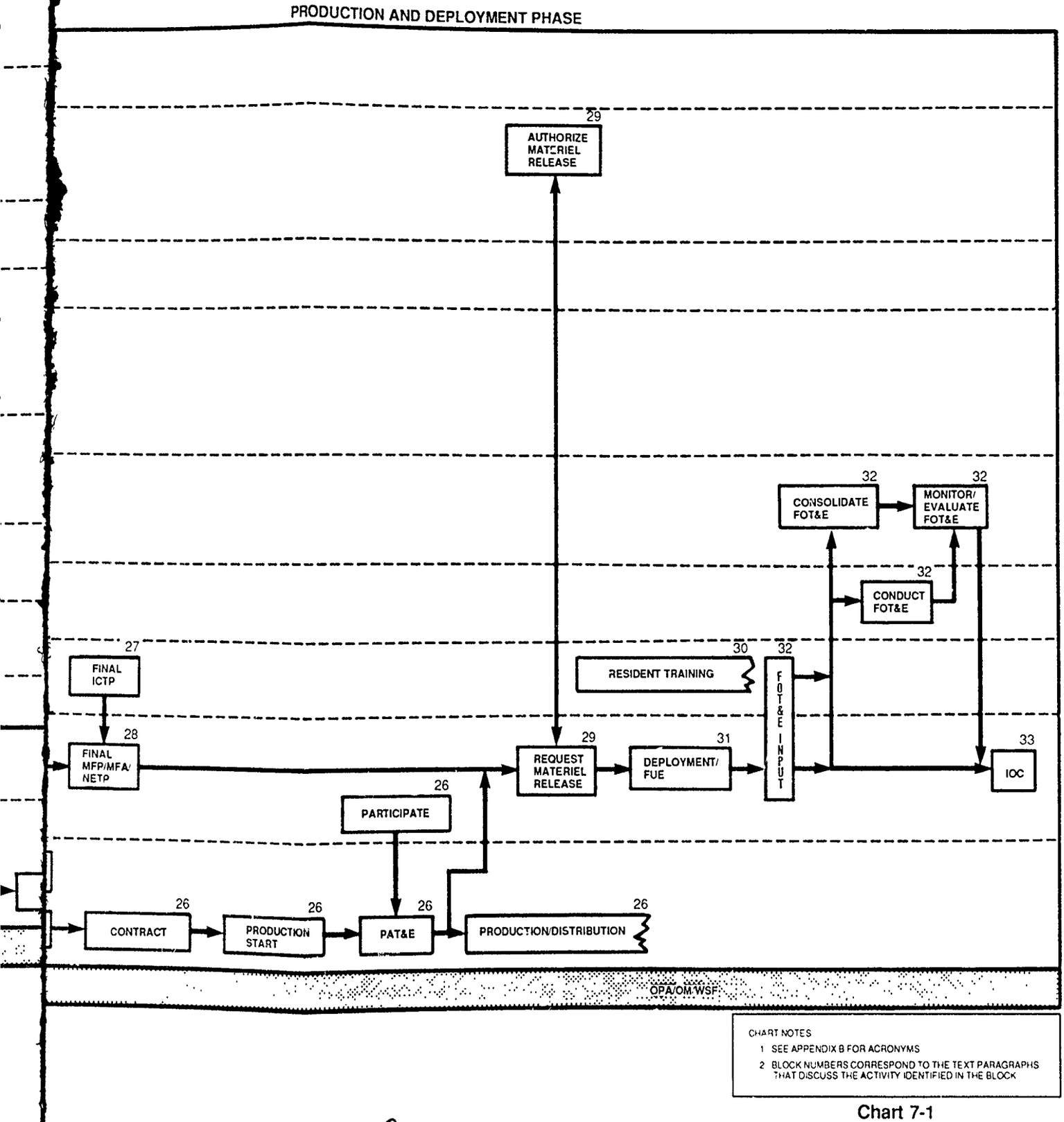


CHART NOTES

1 SEE APPENDIX B FOR ACRONYMS

2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 7-1

CHAPTER 8

PRODUCT IMPROVEMENT PROGRAM

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8.1 PURPOSE

This chapter describes the typical activities necessary to solve a materiel deficiency or respond to user complaints/recommendations using a product improvement process approach. This is a summary chapter, one of eight such chapters in the overview section of the Medical Materiel Acquisition Handbook. More detailed descriptions of the various acquisition functions are provided in Chapters 9-26.

8.2 GENERAL

A Product Improvement (PI) is a configuration change to an existing piece of equipment in response to a user validated need. Product improvement may be determined to be the solution to a materiel deficiency identified during preprogram initiation or during Concept Exploration Phase activities. Product improvements require testing to assure that they accomplish what is intended without jeopardy to any interfacing system. Improvements are accomplished by application of a modification kit in the field, by conversion in an Army depot or contractor facility, or by engineering change during production if the equipment is still in production. Since PI is a preferred method for satisfying materiel requirements, the desirability of making improvements to existing equipment rather than initiating new developments must be carefully weighed.

The objectives of Product Improvement Programs include:

- Increase personnel safety and/or reduce damage to equipment;
- Improve operational capability in response to user needs;
- Reduce the cost of production and/or operational support;
- Improve reliability, availability, and maintainability;
- Correct performance deficiencies;
- Improve standardization and interoperability;

- Comply with legislative requirements;
- Increase the life of an item in the field, or;
- Conserve energy.

Army Regulation 70-15, Product Improvement of Materiel, sets policies and procedures for the management of product improvements. Other regulations and guidance documents pertaining to PI are listed in paragraph 8.5.

A proposed equipment change will be considered as a PI only if it meets the following two basic criteria:

- The change involves an engineering effort to: design the change; determine the effect of the change on form, fit, and function; produce and test a prototype kit or reconfigured item; and prepare or update technical documentation and software.
- The change involves a retrofit to an operational inventory item. That is, the item to be changed is type classified standard and some or all of the items in the first manufactured quantity have been fielded.

Types of improvement efforts that are excluded from the PI program are listed in paragraph 1-6, AR 70-15.

The Product Improvement Proposal (PIP) and supporting documentation provide a visible audit trail, substantiate the need for the improvement, identify all of the resources required and provide the plan, including schedules and milestones, for developing and applying the modification or conversion or making changes during production. These documents constitute a viable management plan to accomplish timely fielding of the improved item or system.

Although the majority of the PIPs will be IPR programs, some may qualify as DAP programs and would be so designated by the Army Acquisition Executive (ASA[RDA]) and reviewed at HQDA. This chapter emphasizes the process as it applies to IPR Programs.

NOTE:

The Pre-Planned Product Improvement (P3I) is one form of a Product Improvement Program. P3I is a systematic and orderly process identified as an element of a development program acquisition strategy wherein, during the design phase of a new system, specific steps are funded and taken to help accommodate evolutionary and cost effective upgrading of the system sometime in the future.

The PIP process may be divided into three phases -- an Engineering Phase, a Procurement/Production Phase and an Application Phase. The Engineering Phase Activities are similar to the Demonstration and Validation and Full Scale Development Phases as described in Chapter 5, Development Program. In the following discussion of the PIP Engineering Phase, only the exceptions to the procedures described in Chapter 5 are discussed. Figure 8-1 illustrates the initial Engineering Phase Activities which have been singled out for discussion because they differ from initial development program activities, shown in Chart 5-1 of Chapter 5.

At the end of the engineering phase, all PIPs will undergo a decision review (AR 70-1) before any TDP changes can be made and before procuring or producing kits or other materiel for equipment modifications.

The PIP Procurement/Production and Application Phases are comparable to the Production and Deployment Phase of a development program as described in Chapter 5 and shown in Chart 5-1. Figure 8-3 presents the activities required to complete and field a product improvement. These activities, shown in Figure 8-3, are described in Section 8.4.

8.3 ENGINEERING PHASE ACTIVITIES

8.3.1 General Objectives. The initial engineering phase activities are designed to ensure that the product improvement is needed, prepare the PIP package, present the package to the Configuration Control Board, and obtain product improvement program approval. The objectives of the PI Engineering

Phase also include designing and manufacturing a prototype; conducting and evaluating technical and user tests; reviewing the technical data package and determining the scope of the changes; preparing life cycle cost estimates; and preparation of program management and decision review documents. The Engineering Phase ends with a production decision at the Milestone III review.

8.3.2 Specific Activities. Figure 8-1 illustrates the initial engineering phase activities which are described in the following paragraphs.

1. Prepare PIPs. The USAMMDA manages and coordinates preparation of the Product Improvement Proposal and conducts the review process.

- USAMMDA responsibilities include:
  - Determining the need for the PIP in coordination with AHS and USAMMA;
  - Ensuring that only essential and cost effective improvements are approved;
  - Coordinating the PIP with other Services (through the OTSG), and;
  - Coordinating the PIP with the Defense Medical Standardization Board.

2. Validate PIP Need. AHS-CD reviews and validates the need for the PIP (ensures that the PIP agrees with materiel, training, logistics support, and operational objectives).

- AHS-CD also:
  - Prepares or changes whatever requirements documents are needed;
  - Prepares a Cost and Operational Effectiveness Analysis (COEA) or Abbreviated Analysis (AA) if required;
  - Gives a priority to the PIP.
- AHS-Trainer reviews the PIP for training impacts.

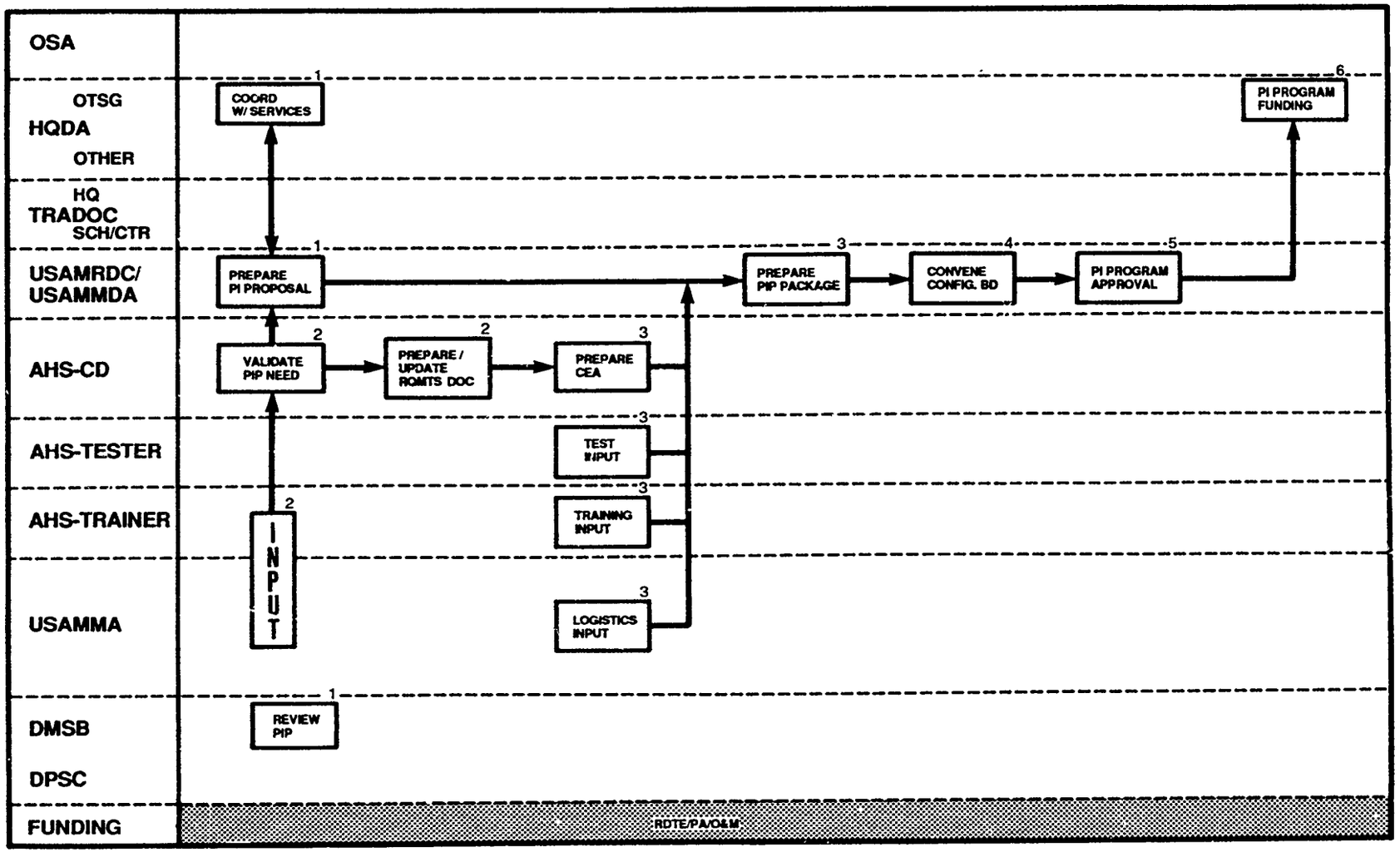


Figure 8-1. INITIAL ENGINEERING PHASE ACTIVITIES

- USAMMA or the AMC Readiness Proponent reviews the PIP for logistical impacts by:
  - Determining the issue status of affected items;
  - Assessing the impact of the improvement on existing Army inventory and logistics resources, and;
  - Developing an agency position on the advisability of the product improvement.
- Defense Medical Standardization Board reviews the PIP and provides input to the initial screening process when standardization of a multi-Service item is involved.

3. Prepare the PIP Package. USAMMDA, in coordination with AHS (CD, Trainer, Tester) and USAMMA, prepares the PIP package and determines when to enter the PIP processing cycle. The PIP package consists of a group of documents that clearly describe and fully justify all aspects of the proposed improvements. At a minimum, the following documents are included in the package (responsible agency shown in parentheses).

- Product Improvement Management Information Report (PRIMIR) DA Form 3701-R (USAMMDA);
- The COEA or AA (AHS-CD);
- A life cycle cost analysis (USAMMDA);
- A technical description of the improvement and its engineering approach (USAMMDA);
- An assessment of the improvement's impact on RAM, logistics support resources, and readiness (USAMMA);
- A proposed TEMP (USAMMDA);
- The Materiel or Modification Work Order (MWO) Fielding Plan (USAMMDA and USAMMA);
- A Milestone Plan (USAMMDA);
- An environmental assessment (USAMMDA), and;
- A statement of user representative concurrence (AHS-CD).

4. Convene Configuration Control Board. USAMMDA convenes the Configuration Control Board (CCB). The CCB chairperson and representatives from USAMMDA, USAMMA, USAMRDC, AHS, and others such as Army Materiel Command readiness proponents constitute the CCB. The CCB evaluates the PIP, considers alternatives, trade-off analyses, and resource availability. The CCB recommendations are provided to the PM.

5. PIP Program Approval. For PIPs with total cost (Research Development Test and Evaluation [RDT&E], Procurement Appropriation [PA], and Operation and Maintenance [O&M]) less than $50M, approval authority rests with USAMRDC. For PIPs that exceed the $50M threshold, approval authority is retained at HQDA (ODCSRDA).

> **NOTE:**
>
> PIP approval does not guarantee resource allocation. It merely allows the PIP to compete with all other candidates for AMEDD funding each year. USAMMDA must ensure that funds are programmed and budgeted through established channels during the budget cycle.

6. PI Program Funding. There is no single category of funds for PIPs. The appropriations used are RDT&E, PA, O&M, and Stock Fund (SF). The authority and procedures for funding PIPs are the ones that govern these appropriations. To determine the proper funding for each phase of a PI Program, the following factors must be considered:

- The justification for the PIP, i.e., does it result in an expanded performance envelope (operational capability);
- The production status of the item being improved, i.e., in or out of production;
- The type of item to be improved, i.e., whether it is an investment or expense item.

Figure 8-2 summarizes the appropriations that are applicable in each PIP Phase for each of the factors described above. AR 37-100-XX should be consulted for specific funds to cite in all cases shown in the figure. Questions regarding whether a PIP or portions of a PIP should be charged to RDT&E, PA, OM, or SF should be referred to the USAMRDC (Comptroller Division) for resolution.

8.3.3 Continuing Engineering Phase Activities. The events and documents required for completion of the Engineering Phase are tailored versions of the Demonstration and Validation and Full Scale Development phases described in Chapter 5 and displayed in Chart 5-1. Requirements for these activities will vary across a broad spectrum. At the high end are RDT&E-funded programs selected prior to Program Initiation or during Concept Exploration as the preferred method to develop enhanced performance capabilities. At the other end are O&M-funded engineering and verification activities required to correct specific deficiencies in fielded equipment. The discussions in the following paragraphs provide guidelines to the tailoring process.

1. Basis of Issue Plan Feeder Data/Qualitative and Quantitative Personnel Requirements Information. USAMMDA prepares the feeder data for an amended BOIP (or for a new BOIP if there is not an existing BOIP for the product being improved). USAMMDA also initiates a QQPRI unless the PIP:

- as no training impact;
- Produces no changes to performance characteristics and capabilities;
- Requires no personnel changes required to support the PIP item;
- Requires no additional items of equipment required to support the PIP item.

See Chapter 18, The BOIP/QQPRI Process.

2. Test and Evaluation. The Test and Evaluation Master Plan (TEMP), initially prepared for the Configuration Control Board Review, is updated during the Engineering Phase. The Test Integration Working Group (TIWG) coordinates the TEMP preparation process.

PIP PHASE	ACTION	TYPE OF ITEM	PRODUCTION STATUS	APPROPRIATION
ENGINEERING	Engineering that results in no change in performance envelope	Investment (PA Procured)	In production	PA
			Out of production	O&M
		Expense (SF Procured)	Not applicable (N/A)	O&M
	Engineering that results in a change in performance envelope	Investment or Expense	N/A	RDT&E
PROCUREMENT/ PRODUCTION	Procurement of kits or reconfigured material	Investment	In production	PA
		Expense		SF or O&M
		Investment	Out of production	PA
		Expense		SF or O&M
APPLICATION	Application of kit or reconfigured material	Investment	N/A	O&M
		Expense	N/A	SF or O&M
	Data collection and follow-up PIP evaluation	Investment	In production	PA
			Out of production	O&M
		Expense	N/A	O&M

Figure 8-2 Funding for Most Common PIPs - Active Army

AHS-CD determines whether the product improvement requires user testing in coordination with USAMMDA and USAMMA, or higher level authority; a PIP will be judged "user test significant" if it has one or more of the following characteristics:

- It changes the safety characteristics;
- It greatly improves an item's RAM;
- It markedly changes logistics support needs.

If AHS-CD determines that user testing is not required, justification is presented at the Milestone III review. USAMMDA, however, will determine the type and scope of verification in coordination with USAMMA and AHS-CD. Verification tests will be conducted as prescribed in Chapter 5, AR 70-15, Product Improvement of Materiel.

> **NOTE:**
>
> PIs funded from the RDT&E appropriation will have both Technical and User Testing as prescribed in AR 70-10 and AR 71-3. Verification tests will be conducted on PIs funded from other than RDT&E appropriations.

3. Training. USAMMA, in coordination with USAMMDA, updates/prepares the New Equipment Training Plan (NETP) and AHS-Trainer updates/prepares the Individual and Collective Training Plan (ICTP) if required by the nature of the product improvement. The NETP addresses any changes in operation and maintenance due to the product improvement and the application of the modification kit, if appropriate. The ICTP addresses any changes in resident and unit training due to the product improvement.

4. Materiel Fielding Plan/MWO Fielding Plan. USAMMA prepares the Materiel Fielding Plan or MWO Fielding Plan (MWOFP). This plan establishes how, and if, the users will implement the modification work order, how product improvement performance data will be collected, and the funding provisions.

The resulting Materiel Fielding Agreements (MFA) will establish agreement on responsibilities for implementing the MFP/MWOFP. Test significant product improvements require MFA/MFPs (See Chapter 20, The Materiel Fielding and New Equipment Training Process). Non-test significant product improvements use MWOFPs.

5. Integrated Logistics Support and System MANPRINT Management Plans. USAMMDA updates the SMMP and ILSP (see Chapters 14 and 15). These plans address the logistics, manpower, personnel, training, human factors engineering and safety impacts due to the product improvement.

6. Review Technical Data Package (TDP). Under the guidance of USAMMDA, the contractor develops the Technical Data Package (TDP) describing the production configuration of the modified system/item and components of the modification kit. USAMMDA approves the TDP prior to the Milestone III decision, (refer to Chapter 19, The Configuration Management Process).

7. Type Classification Approval. Prior to the program transition to the Readiness Proponent, the item may require type-classification/retype-classification as standard (accepted for Service use) by the Decision Authority and validation by OTSG. Documentation required for TC includes the requirements document, BOIP, QQPRI, and Military Occupational Specialty decisions. If necessary, a new National Stock Number and a new standard LIN are also obtained (see AR 70-61, Type Classification of Army Materiel, for additional requirements for product improvement programs).

8. Prepare Decision Coordinating Paper. In preparation for a Milestone III decision:

- AHS updates the COEA or AA, if required;
- USAMMDA updates the AS and AP;
- USAMMDA confirms the establishment of production readiness (e.g., facilities and logistic support resources), and;
- USAMMDA prepares a DCP, and, if required, an IPS.

8.4 PROCUREMENT/PRODUCTION AND APPLICATION PHASES

8.4.1 General Objectives. The Procurement/Production Phase is initiated by the Milestone III decision. During this phase, management of the program is transitioned from USAMMDA to the Readiness Proponent, and modification kits are produced. In addition, the DPSC becomes responsible for soliciting and awarding contracts, and for production and distribution of the modification kits. The Application Phase begins with the materiel release authorization. During this phase, modification kits are applied, personnel and units are trained, and logistic support is provided.

8.4.2 Specific Activities.

SEE FIGURE 8-3

NOTE:

This discussion starts with the transfer of the technical data package from the Readiness Proponent to the Defense Medical Standardization Board (DMSB) and the subsequent functions of the Defense Personnel Support Center (DPSC). Product improvement program activities following the Milestone III decision and up to the transfer to DMSB are the same as discussed in Chapter 5 and shown in Chart 5-1. They are not repeated here.

1. Transfer TDP to DMSB. USAMMA prepares documentation for standardization of the item and forwards the TDP to DMSB. The Board reviews or prepares the Essential Characteristics (EC) of the product, completes the standardization process, and forwards the package to the DPSC.

2. DPSC Responsibilities. The DPSC is responsible for the preparation of the solicitation package, awarding the contract, and getting production started. DPSC in coordination with USAMMA, may also conduct Production Acceptance

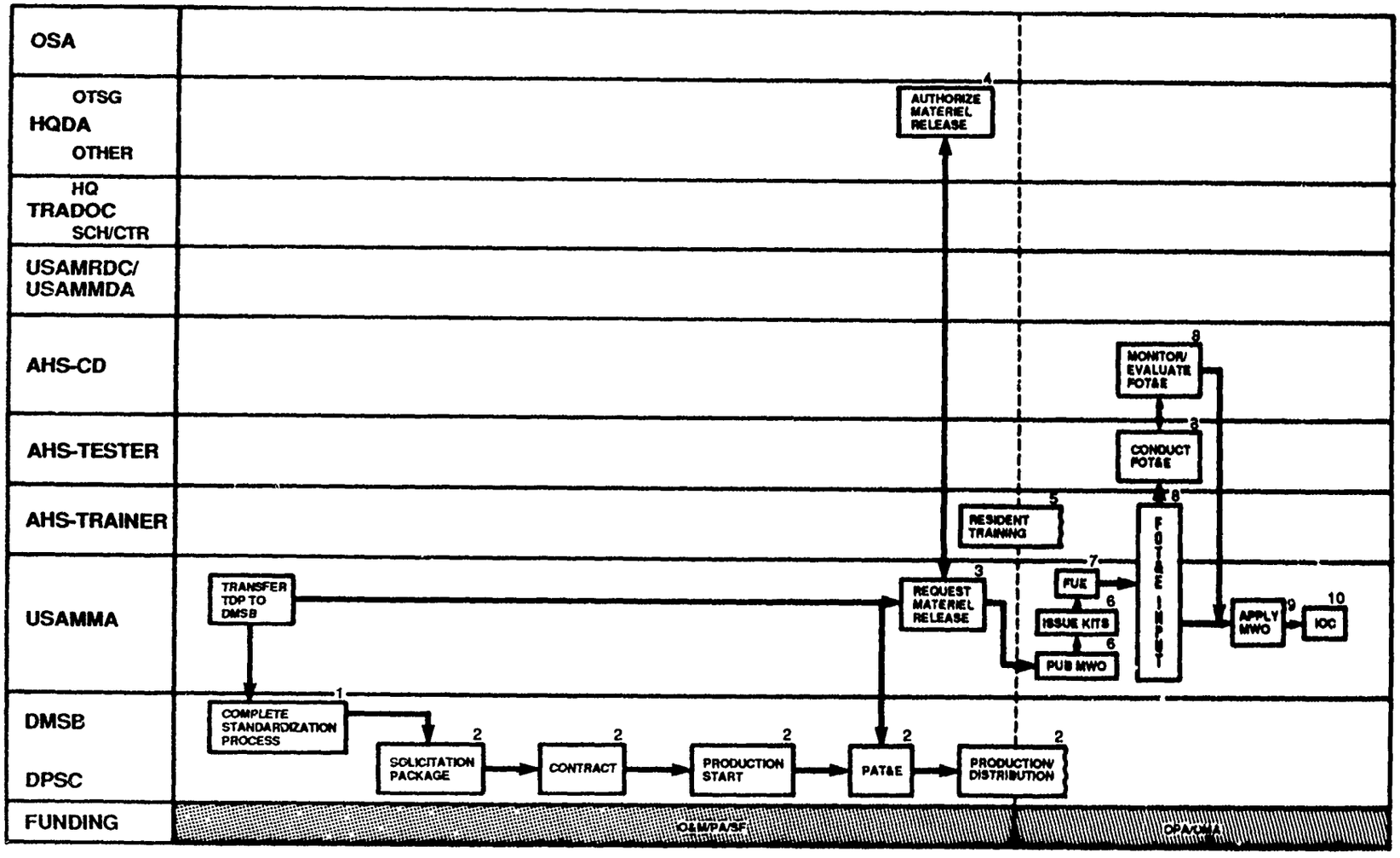


Figure 8-3. PROCUREMENT/PRODUCTION AND APPLICATION PHASES

Test and Evaluation (PAT&E). Upon successful completion of PAT&E, production of the modification kits and, if applicable, modified production systems continues and application commences. The USAMMA provides the Army funded requirements to DPSC.

> **NOTE:**
>
> Both USAMMDA and USAMMA interface with DPSC throughout the medical materiel acquisition process. The interface continues during the production and procurement activities to include monitoring the Production Acceptance Test and Evaluation. In addition, the FDA may also monitor the test. See MOA between USAMRDC and DPSC.

3. Publish MWO. USAMMA provides for the publication of the approved MWOs.

4. Materiel Release. At the request of USAMMA, the OTSG (HCZ) authorizes the publication of the MWO and release of the modification kit and/or modified production system. The release of the first kit/system is a control mechanism to verify that all materiel and logistics deficiencies identified in operational testing have been corrected; that all logistics resources required to support the initial deployment are available concurrent with the release of the system; and that the materiel is suitable in terms of safety and health, human factors engineering, and environmental factors, (see DA Circular 700-85-1, Materiel Release for Issue).

5. Resident Training. Changes to resident training, as prescribed in the ICTP are implemented so that graduates are provided approximately six months prior to the First Unit Equipped (FUE) date.

6. Issue Kits. DPSC issues the modification kits and the first unit is equipped based on the MFP/MWOFP and the MOUs negotiated by the Readiness Proponent with the gaining commands.

7. Deployment/FUE. The Readiness Proponent is responsible for application of the modification kit in accordance with the procedures and schedules negotiated with the gaining commands.

8. Follow-on Test and Evaluation. Although performance and supportability of the product is demonstrated prior to issuance of the kits, there may be a requirement for a Follow-on Test and Evaluation (FOT&E). It is conducted by the AHS-Tester based on inputs from the Readiness Proponent and AHS-CD and Trainer. AHS-CD monitors and evaluates the FOT&E and prepares the IER.

9. Implement MWO/Collect Data. The Readiness Proponent has the responsibility to ensure the satisfactory installation of the modification kits to the Army's medical materiel inventory including equipment in the hands of the troops. Kits can be applied by a Government contractor, by a depot team at the depot or in the field, or by the gaining unit.

> NOTE:
>
> Units cannot be required to apply modification kits unless so agreed in an MOU between the Readiness Proponent and the gaining command.

Following installation of the kits, if required, the Readiness Proponent ensures that data on the performance of the improvement is collected. This is done to verify that the improvement is working properly. If needed, follow-up corrections will be made. The costs involved in collecting and analyzing data for follow-up evaluations will be included as part of the cost of the PIP.

10. Initial Operational Capability. The Initial Operational Capability (IOC) is the first attainment of the capability by a unit and its support elements to effectively operate and maintain the modified system.

8.5 REFERENCES

AR 37-100-XX, The Army Management Structure

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

AR 70-1, System Acquisition Policy and Procedures, 1986

AR 70-15, Product Improvement of Materiel, 1980

AR 70-37, Configuration Management, 1984

AR 70-61, Type Classification of Army Materiel, 1985

AR 71-2, BOIP/QQPRI, 1982

AR 71-3, User Testing, 1986

AR 750-10, Modification of Materiel, 1984

DA Circular, 700-85-1, Materiel Release for Issue, 1985

MEDICAL MATERIEL ACQUISITION HANDBOOK

VOL II

CHAPTER 9

THE LONG RANGE RDA PLANNING PROCESS

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9.1 PURPOSE

This chapter describes the documents and events that constitute the Long Range RDA Planning Process, from the long range look of the Mission Area Analysis (MAA) through the Long Range Research, Development, and Acquisition Plan (LRRDAP) interface with the PPBES. While some of the material was discussed in summary form in Chapter 3, this chapter provides more detailed information on the interaction of the individual AMEDD commands and agencies in the preparation and staffing of the planning documents. Furthermore, the chapter will present: 1) the sequential steps that must be followed to get a new R&D effort initiated, and; 2) the cyclical nature of the system as new projects are integrated with ongoing efforts in the annual budgeting cycle.

> **NOTE:**
>
> This chapter does not provide formats for these documents. They are all relatively new requirements and in most instances the formats are changing year by year as the Army seeks to find the most effective way of communicating the necessary information.

Chart 9-1 (a fold-out chart at the end of the chapter) shows the overall Long Range RDA Planning Process, with the events portraying the sequence required to bring a new project into existence. The chart carries no time sequence because the intervals are not predetermined. While the MAA and the Medical Systems Program Review (MSPR) are not annual requirements, the Mission Area Development Plan (MADP), the Mission Area Materiel Plan (MAMP), and the LRRDAP are. Thus, one of the sources for the preparation of this year's Mission Area Materiel Plan is the previous year's MAMP.

The text discusses the activities and the participants at each step of the process. The LRRDAP process must be approached with a sense of applying the principles of the outlined procedures with the flexibility to adjust to modifications generated by a rapidly changing materiel acquisition and budget environment.

9.2 GENERAL

The process, which ensures that research and development activities are responsive to the needs of the Army, begins with the Mission Area Analysis and culminates in the Army Long Range Research Development and Acquisition Plan. The Process establishes a procedure that attempts to channel the Army's research and development to those efforts which are directed at resolving the identified materiel deficiencies in the Army's concept of current and future battlefield operations. The benefits of the MAMP and the LRRDAP are derived from: 1) the total cognizance of all materiel solutions to deficiencies both medical and nonmedical, and; 2) the integration of needs, solutions, priorities and funding.

9.3 LONG RANGE RDA PLANNING

9.3.1 General Objectives. The purpose of the Long Range RDA Planning process is to formulate a medical materiel RDA program that balances the needs of the Army with available funds and capabilities. Thus, the materiel and combat developers must work closely together. The CBTDEV identifies deficiencies from his MAA and Battlefield Development Plan (BDP), and the MAMP is the MATDEV's plan to solve the deficiencies. The CBTDEV has the ultimate responsibility for determining when deficiencies have been solved. See Chapter 3, Pre-Program Initiation, Figure 3-3.

9.3.2 Specific Activities.

SEE CHART 9-1

1. Medical Mission Area Analysis (MAA). As discussed in Chapter 3, the Army conducts MAA for 13 separate Mission Areas, one of which, Combat Service Support (CSS), is of primary concern for the AMEDD. The Academy of Health

Sciences (AHS), provides the medical portion of the MAA for CSS to the U.S. Army Logistics Center (ALC or Log Center), the TRADOC proponent. The CSS MAA addresses those efforts directly related to capabilities which provide tactical commanders with supplies, maintenance services, energy, medical support and personnel administration support. The AMEDD input shows how TSG intends to provide battlefield medical support to the Army, the perceived difficulties, and deficiencies.

To provide this information, the AHS studies, in-depth, those policies which define the Army's perceptions of the battlefield of the future. The current doctrinal approaches must be reviewed and fully understood in order to project the most effective means of providing medical support. AHS identifies the functional requirements that the AMEDD must respond to, seeks input from the Surgeons of the various MACOMS, and also receives guidance from OTSG.

The AMEDD functional definition comes from the Medical Systems Program Review and Mission Area Analysis. While the two are complementary, they are by no means duplicative. The MSPR outlines functional concepts, new directions, and philosophical approaches to the battlefield of the future. The MAA assesses the AMEDD's ability to meet the requirements generated and identifies the deficiencies perceived with respect to doctrine, training, organization and materiel. Thus the MSPR defines the goal, while the MAA identifies all of the circumstances which preclude the AMEDD from currently meeting the MSPR goals.

2. Prepare CSS Mission Area Analysis. The Log Center integrates the AMEDD input (generally without modification) into the CSS MAA.

3. Prepare The Medical Mission Area Development Plan. The MAA defines the problems and deficiencies; the Mission Area Development Plan (MADP) is the follow-on document in which solutions to those problems are proposed. The solutions may range from the creation of new TOEs or command structures to the design and development of major end items of military medical equipment. The MADP is actually a non-prioritized list of the problems (deficiencies) and

proposed solutions. Thus, the MADP should be responsive to every deficiency included in the MAA, and the solutions proposed must be well considered and provided in detail. Tentative schedules from program initiation to fielding should be provided to include any testing requirements. Funding requirements should be estimated and funding sources identified, where possible. Primary and secondary responsibility for each effort should be identified.

The MADP is prepared by AHS-CD in coordination with other agencies. The AHS Training and Doctrine Directorate must be an active participant, because of the potential impact on the AHS training mission.

USAMRDC is also a major contributor to the MADP. A promising R&D effort may be incorporated into the MADP as the proposed solution to an existing deficiency. In fact, that R&D effort was probably initiated in response to an earlier MADP. USAMMDA should be able to provide AHS with assessments on the feasibility, schedules and resource requirements of any materiel solutions proposed in the MADP.

The MADP does not commit funds or task activities; however, it does define the range of future activity in all areas of "enhancing the AMEDD". A research project, a TOE change, or a training policy which is not included in the MADP as a proposed solution to an identified MAA deficiency, will have a difficult time getting any priority for resources or funding.

4. CSS Mission Area Development Plan. Medical input to the CSS MADP is not forwarded to the Log Center by AHS until it has the support of OTSG, HSC, and USAMRDC, as well as AHS. This is not shown as a formal staffing procedure in Chart 9-1, but must be recognized as an internal AMEDD requirement. The Log Center forwards the deficiency descriptions to HQ TRADOC using Mission Area Deficiency Fact Sheets.

5. Prepare The Battlefield Development Plan. The Battlefield Development Plan (BDP) is prepared by HQ TRADOC based on input from the Army's 13 mission area proponents. TRADOC reviews the MAA for each of the 13 mission areas, correlates them to the supporting MADP, and begins the process of integrating and prioritizing the tasks to be pursued. The BDP therefore summarizes the perceived functional deficiencies in meeting the Army's future operational concepts. It represents a consensus of future battlefield doctrine, training, organization, and materiel deficiencies. The Mission Area proponent identifies as many doctrine, organization and training solutions as practicable before suggesting, in consonance with the appropriate MATDEV, materiel fixes.

The process of integrating the thirteen MAAs into a single prioritized list goes through three phases.

Phase I	The Mission Area Proponents identify and prioritize deficiencies within each Mission Area.
Phase II	MACOM General Officers integrate the Phase I lists into the BDP.
Phase III	General Officers at HQDA level make the final adjustments to the BDP.

The AMEDD is a key participant in this process. As a member of the team developing the CSS MADP for the Log Center, the AHS provides representatives to the prioritization meetings. In this capacity, AHS justifies the medical deficiencies and ensures that they receive appropriate prioritization.

The BDP serves as the final product in the MAA process. It aggregates recommended solutions into three resource priority groupings, characterized as "minimum risk", "at risk", and "high risk". HQ TRADOC assigns final priorities and publishes the BDP. The BDP is the principal basis for the development of the MAMP and the LRRDAP which align materiel solutions and funding profiles. It is also the basis for the requirements documents to develop or acquire materiel.

6. Mission Area Materiel Plan. The MAMP Process is geared to respond to the BDP deficiencies. It is a collation of materiel solutions to deficiencies identified in the BDP and provides a systematic, prioritized long range research, development and acquisition strategy for materiel acquisitions. USAMRDC is responsible for the annual preparation of the Medical Research, Development and Acquisition (RDA) MAMP. This is usually delegated to USAMMDA since the emphasis of the MAMP is on medical materiel development programs that satisfy BDP deficiencies. However, extensive coordination across all AMEDD organizations is essential because of the scope of the effort required to develop and field medical materiel. USAMMA becomes involved because of its eventual responsibility for the procurement, fielding, and other elements of Integrated Logistics Support (ILS). AHS-CD assesses whether the materiel being developed adequately resolves the materiel deficiencies identified in the BDP, and also ensures that all deficiencies which were identified as having a materiel solution are included in the Medical RDA MAMP.

Thus, the MAMP is a highly integrated process resulting in a comprehensive document. Every medical R&D effort is individually described, assessed, and prioritized, whether it is newly conceived or a multi-year effort approaching culmination. Included are the status of funding, the schedule and milestones, the functional area managers for each project, and the contribution value of the projected solution to the identified BDP deficiency. Thus, each project is assessed not only for its technical and programmatic adequacy but also for its relationship to the BDP.

The MAMP is also a working document. New information on resource availability, schedule adjustments, breakthroughs, complications, ILS factors, etc., are added to the MAMP so that it will always provide an up-to-date picture of the medical materiel development program.

7. Prioritization Review Committee. The BDP is the prioritized list of all of the Army's battlefield deficiencies. An AMEDD Review Committee, consisting of materiel developer representatives and chaired by USAMMDA, reviews the list as well as the Medical RDA MAMP and establishes a medical program prioritization. This Review Committee develops a total prioritization in order to support the USAMRDC budgeting and resources allocation requirements. The Commander, USAMRDC is the decision authority.

8. MAMP Validation. The Medical RDA MAMP is reviewed and validated at OTSG.

9. Update, Publish, and Distribute the Medical RDA MAMP. After the MAMP is validated by OTSG, it is published and transmitted by USAMRDC, through the appropriate AMC Mission Area Manager, to HQ AMC. Distribution is also made to all of the participants in the Medical RDA MAMP development process.

10. Prepare CSS MAMP. AMC is responsible for the preparation of the CSS MAMP, where together with the other mission areas, it provides commanders and staff with a total array of materiel solutions to identified BDP deficiencies. The Medical RDA MAMP is an adjunct to the CSS MAMP because it outlines the specific medical materiel program supporting Army Combat Service Support requirements.

11. Logistics R&D Plan. The purpose of this plan is to establish a coordinated research and development program that ties together combat and materiel development with appropriate logistics support. Products being developed by the AMEDD frequently generate critical supply needs outside the AMEDD. Requirements for transport vehicles, fuel, oxygen, and standard tentage incorporated into the MAMP must be provided to the agency responsible for meeting those needs. Therefore, a copy of the Medical RDA MAMP is provided to the Army Logistics Center for its review, to ensure proper funding consideration for Logistics R&D Programs.

12. Convert Programs to PDIP Format. Program Development Increment Package (PDIP) codes are used to identify total funding resources for each R&D project, and are the mechanism that enables the Army to initiate or continue work on these efforts. Project initiatives identified in the MAMP must be resourced in the PDIP format for consideration in the LRRDAP. The PDIP format is a fixed standard format, designed to suport the Planning, Programming, Budgeting and Execution System (PPBES), which specifically outlines the total resources required for a given level of effort. It may be further divided into smaller executable levels of effort for funding and/or prioritization purposes.

The aggregation of MAMP data to accommodate the PDIP format requirements facilitates development of the LRRDAP which feeds into PPBES. (See Chapter 10). In addition to the PDIP funding data, the LRRDAP contains the description of the PDIP, the specific BDP deficiencies that this system/effort supports and its contribution value, and the LRRDAP priority by year by each category. The LRRDAP consists of four categories or increments of funding into which portions of each program fall. From the programs which are guaranteed funding to those whose probability of funding is extremely low, the four funding categories are minimum (protected), risk, high risk, and unfunded. The relative prioritization of funding accorded each effort in the LRRDAP should generally correspond directly to the priority assigned in the MAMP, as modified by DA Guidance.

The development of the AMEDD LRRDAP is a joint effort. HQ, USAMRDC is responsible for developing an AMEDD LRRDAP with the full participation and concurrence of representatives from OTSG and AHS. The interface of the LRRDAP with the PPBES is discussed in greater detail in Chapter 10 as part of the budget process since it is the basis of funding for all proposed AMEDD R&D.

13. USAMRDC Input to DA LRRDAP. Utilizing the MAMP assessments, the Command Priorities, and DA Guidance, USAMRDC assigns Program Element/Project Lines and their corresponding funding levels to appropriate PDIP and increments. Each increment or category represents a portion of the total resource

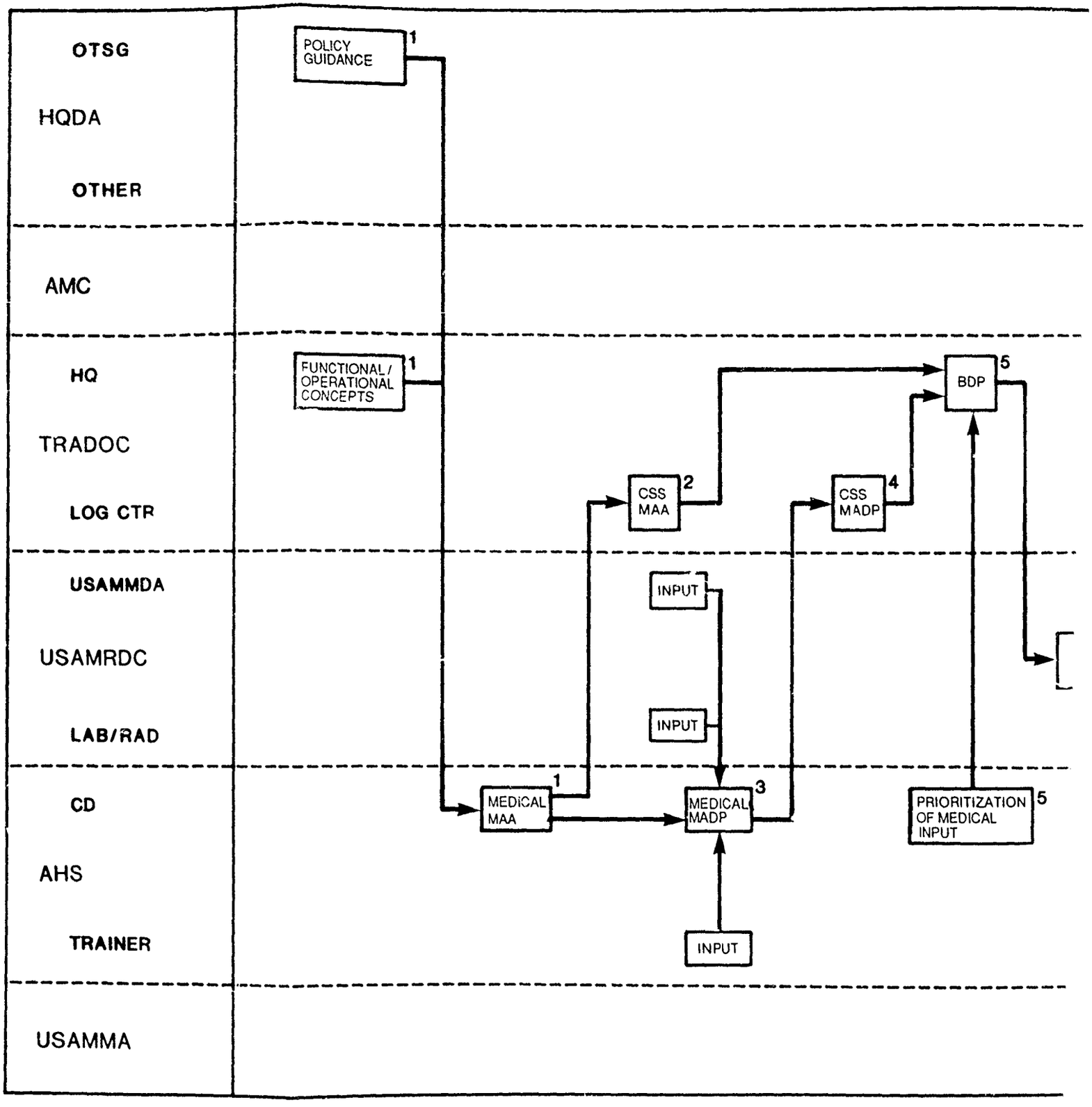
requirement. There can be multiple increments within a PDIP. This data is submitted through OTSG, the Office of the Assistant Surgeon General for Research and Development (DASG-RDZ) to the ODCSRDA, where it is considered for formal integration in the DA LRRDAP. This information is also provided to AHS for review.

14. AHS Input to TRADOC. AHS is responsible for reviewing the USAMRDC data and ensuring that all PDIP increments are correctly included in the TRADOC priorities listing for the TRADOC submission to the DA LRRDAP. Thus, concurrent with the USAMRDC submission to OTSG, the AHS submits the same LRRDAP information to the Army Logistics Center as the CSS Integrating Center into the TRADOC LRRDAP, which is also referred to as the TRADOC Priorities Program. That document is then reviewed by HQ TRADOC before transmittal to DA for incorporation into the DA LRRDAP.

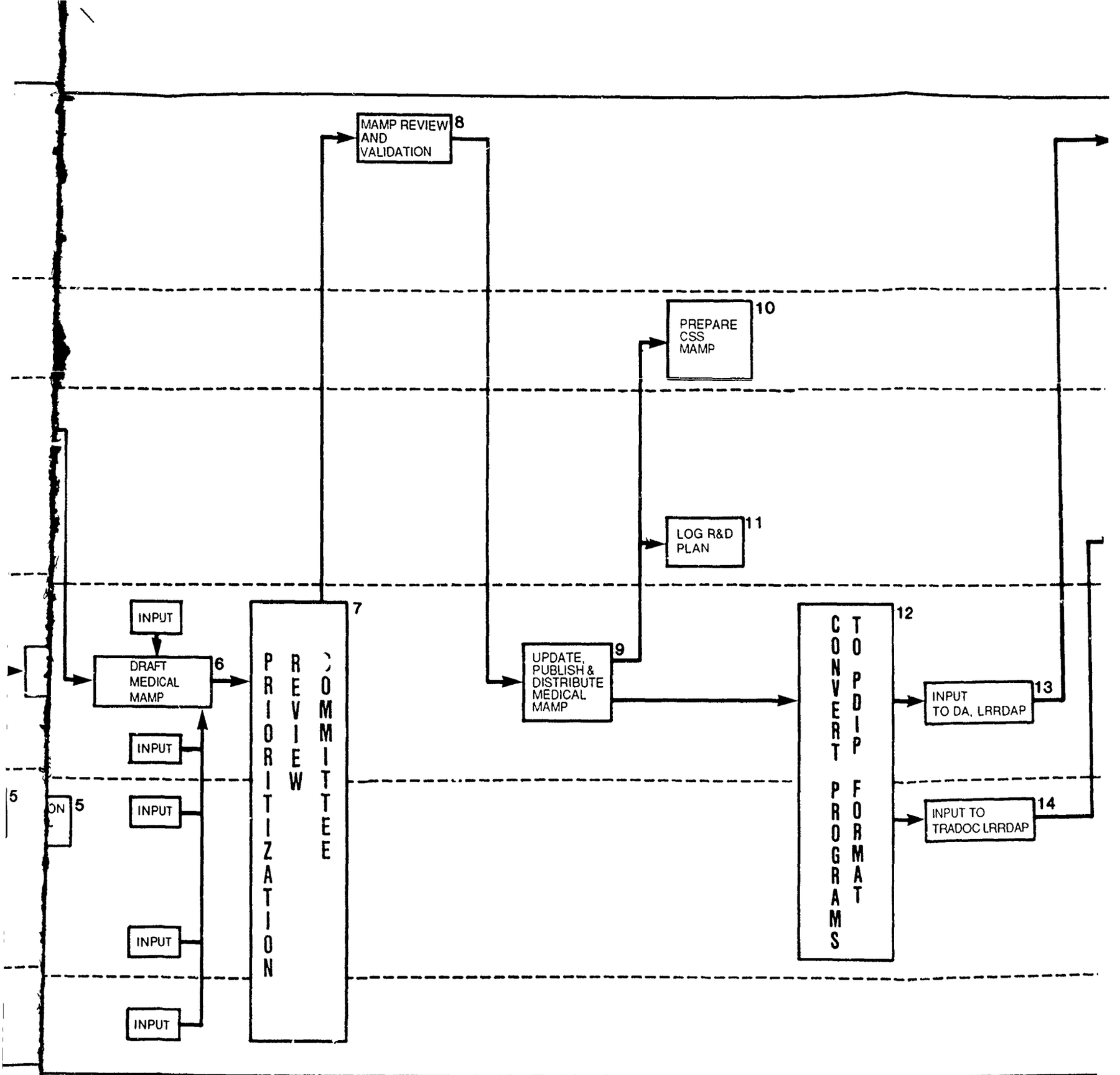
15. Preparation of the DA LRRDAP. Although DCSOPS provides the final LRRDAP prioritization, DCSRDA reviews all RDTE funding submitted in the LRRDAP. The AMEDD has an additional opportunity for ensuring that the DA LRRDAP reflects the AMEDD requirements. If the input data was modified at TRADOC or changes occurred since the original submission from OTSG, the difference will be resolved at HQDA where TSG is a member of the DA Staff.

9.4 REFERENCES

Chief of Staff Regulation 1-15, Army Long Range Planning System, 1981
AR 1-1, Planning, Programming, Budgeting, and Execution System, 1986
AR 70-1, System Acquisition Policy and Procedures, 1986
AR 71-9, Materiel Requirements, 1986
TRADOC Regulation 11-7, 1984
MOU, TRADOC and HSC, 1985
Medical RDA MAMP, current year


OTSG
HQDA
OTHER
AMC
HQ
TRADOC
LOG CTR
USAMMDA
USAMRDC
LAB/RAD
CD
AHS
TRAINER
USAMMA
POLICY GUIDANCE
1
FUNCTIONAL / OPERATIONAL CONCEPTS
1
CSS MAA
2
CSS MADP
4
BDP
5
INPUT
INPUT
INPUT
MEDICAL MAA
1
MEDICAL MADP
3
PRIORITIZATION OF MEDICAL INPUT
5

CHART



ART 9-1. THE LONG RANGE RDA PLANNING PROCESS

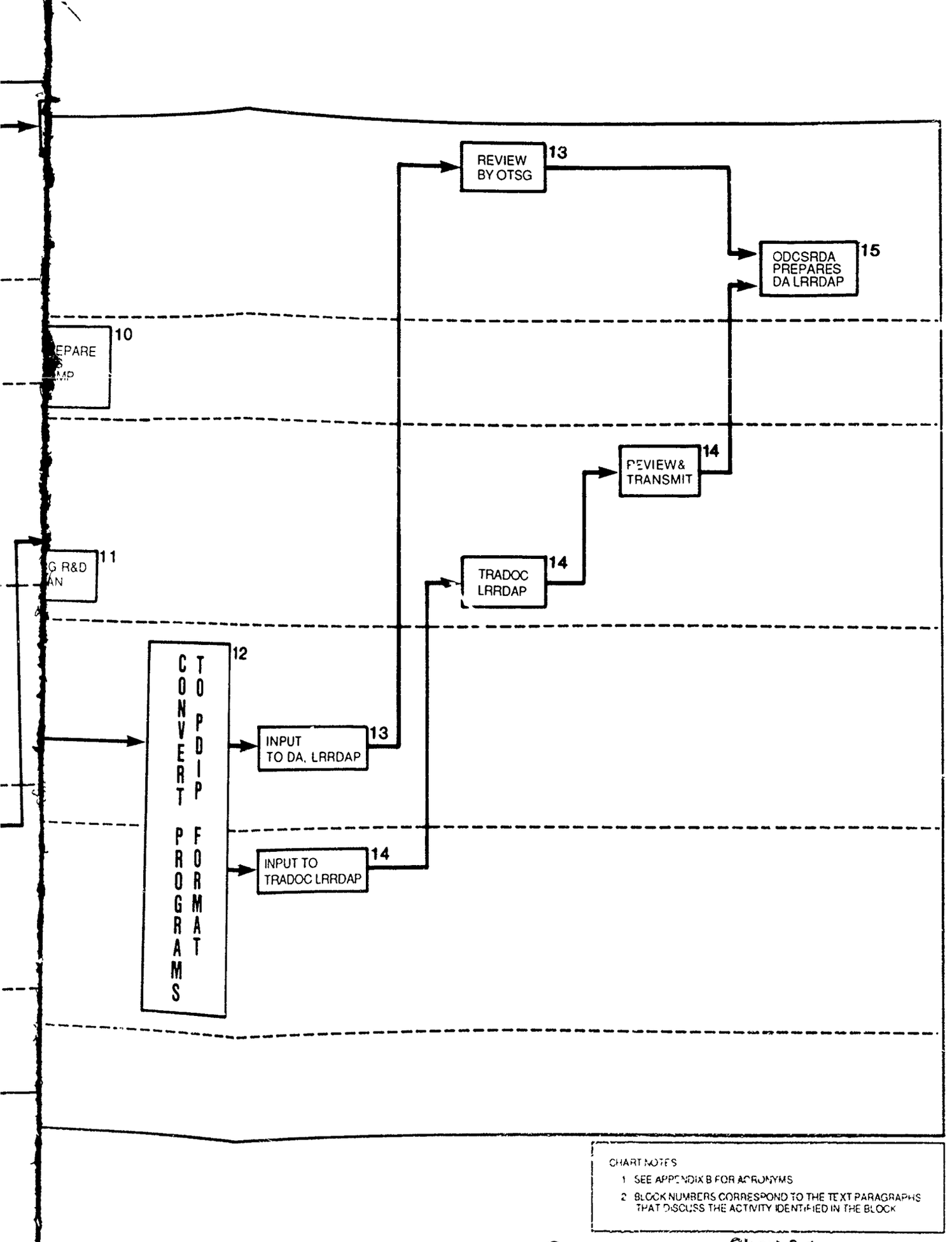


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 9-1

CHAPTER 10

THE PPBES PROCESS

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10.1 PURPOSE

This chapter provides a summary description of the Planning, Programming, Budgeting and Execution System (PPBES) process and addresses in detail the financial management functions that must be accomplished by the medical materiel R&D community.

Emphasis is provided on those PPBES actions involving USAMRDC, USAMMDA, and specific HQDA offices. Many PPBES activities within the Office of the Secretary of Defense, Secretary of the Army, Office of Management and Budget, the Joint Staff, HQDA, plus Congressional activities will be mentioned only briefly. The references at the end of the chapter provide a listing of documents that fully explain the PPBES process within the noted organizations and the functions of Congress. However, in the interest of completeness, a short overview of the PPBES is necessary.

Chart 10-1, a two page flow chart at the end of this chapter, summarizes the PPBES activities relating to a single fiscal year. Numbers near the blocks on the flow chart relate to the text paragraph that discusses the activity identified in the block. The flow chart and text should be used together in order to track the timing of events for the single fiscal year presented in this chapter. The chart is organized to present primarily USAMRDC, USAMMDA, OTSG, and certain other HQDA actions as they apply to the management of medical materiel RDT&E funds. Figure 10-1 displays the overlapping PPBES cycles. Figure 10-2 is a summary of one fiscal year's activities from the end of the planning phase, through the programming and budgeting phases, which represents the majority of the activities addressed in this chapter.

10.2 GENERAL

The Surgeon General and his subordinate activities must skillfully manage the numerous PPBES responsibilities linked to the successful achievement of medical materiel research and development. Achievement of the highest standards in medical materiel RDTE must be balanced with adequate funds and military/civilian personnel levels to ensure the continued movement of prograr

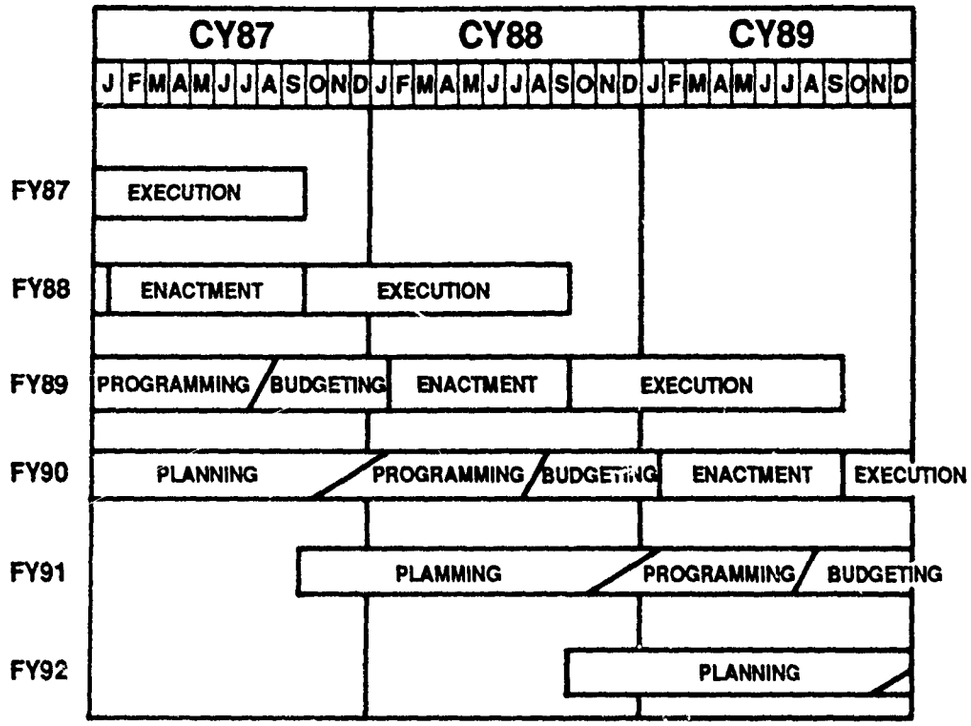


Figure 10-1 Cycle Overlap for Single Year Funds

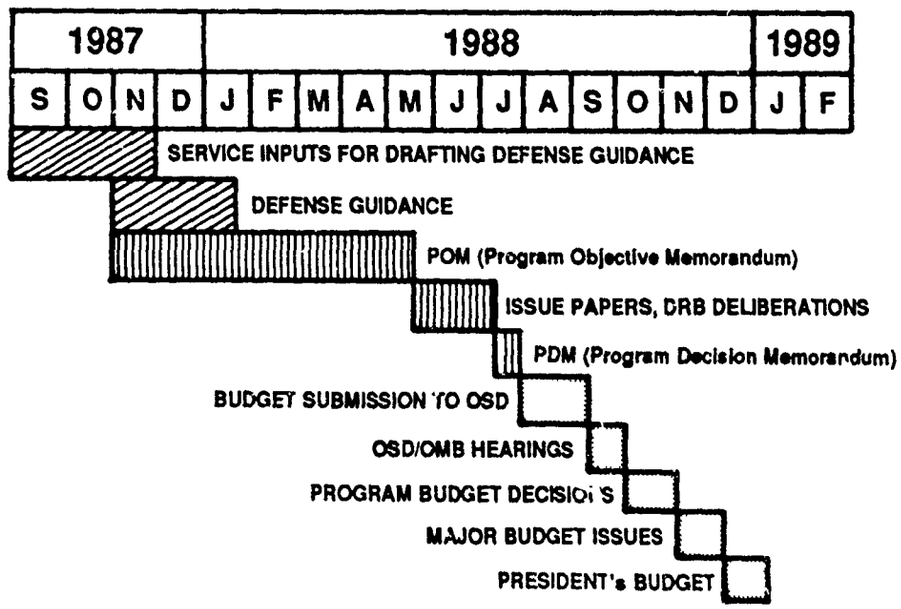


Figure 10-2 Planning, Programming, and Budgeting

through the entire RDTE process and to sustain supporting activities. The competition for resources within the entire DoD and the Army is intense. Only those programs with solid justification and quality PPBES management will achieve levels of stability or even survive funding and manpower environment review panels.

The Defense Reorganization Act of 1958 gave the Secretary of Defense (SECDEF) two distinct lines of authority under the policy guidance and direction of the President and the National Security Council. A direct line of command was established through the Joint Chiefs of Staff (JCS) to the Unified and Specified Commands. A line for administrative control of the military departments and for the management of the support of military forces was established through the Secretaries of the Military Departments. Through the command line of authority, the SECDEF issues decisions regarding threat appraisal, strategy, and forces. Through the administrative or management line of authority, he issues decisions regarding program goals to support the forces, and budgeting of annual funds to support the programs. The process through which these decisions and resultant actions are integrated is the DOD Planning, Programming and Budgeting System (PPBS).

The planning, programming and budgeting process can be summarized as:

1. Collect intelligence;
2. Appraise the threat;
3. Based on national policy, develop strategy to meet the threat;
4. Determine force levels to support the strategy;
5 Program materiel systems, manpower and support over a period of time to attain fiscally constrained force levels;
6. Budget annual allocations of funds to procure men and materiels required to carry out programs;
7. Obligate and disburse appropriated funds within the law.

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7. Obligate and disburse appropriated funds within the law.

countries of significance to the United States. Based on the above guidance, and inputs from the Defense Resource Board (DRB), the SECDEF issues the Defense Guidance (DG) in late January, constituting an authoritative statement on centralized direction for defense planning and programming.

The Army's Planning Phase is initiated with the publication of the Army Strategic Appraisal (ASA) in mid-November. Published by the Strategic Studies Institute of the Army War College, it portrays mid-range trends and addresses strategic and force planning issues three to ten years in the future. This document is prepared for the Army Staff but is developed outside the Joint Strategic Planning System and, therefore, presents an independent, unconstrained view of the future. The Army examines intermediate objectives, policy, and strategy to determine force objectives attainable within expected availability of dollars and manpower.

This process, called Macro Analysis, identifies force alternatives for presentation to, and decision by, the Chief of Staff Army (CSA) and Secretary of the Army (SA). The selected alternative establishes an objective force that becomes the subject of the Army Guidance (AG) which is the Army's counterpart to the DG. It consists of four volumes which are timed to precede specific events addressed in each volume's text. Volume I, which pertains to the Army's Planning Phase, is distributed in draft in August and referred to as The Army Plan (TAP). TAP lays out what the Army wants to do in support of the Army mission and describes how the Army will build the objective force. TAP is refined in early fall, reviewed as a major topic of interest at the October Commanders' Conference, and disseminated to MACOMs/agencies in December.

The Army also publishes the Long-Range Research, Development and Acquisition Plan (LRRDAP) which translates the goals and objectives contained in TAP into specific research, development, and acquisition programs. The Army uses the LRRDAP to validate priorities and to provide guidance to the Army Staff, MACOMs and subordinate activities in developing the Program Objectives Memorandum (POM) and Extended Planning Annex (EPA).

Within the Army's planning framework, USAMRDC interfaces with DA planning. This interface includes the DA LRRDAP, and the Extended Planning Annex to the Program Objectives Memorandum (POM). The USAMRDC planning phase entails coordination within the command (Research Area Directors), the institutes and laboratories noted in Chapter 2; and coordination with AHS, TRADOC, and AMC in establishing the structure and operational needs which drive the requirements for medical research and development. USAMRDC translates generic capability and needs into specific materiel plans, including technology or R&D planning, implementation plans, and resource needs.

10.3.2 Specific Planning Activities.

SEE CHART 10-1

1. Army Long Range Research, Development and Acquisition Plan. The LRRDAP is a multi-volume set containing descriptions and priorities of RDTE programs/projects underway and programs to be undertaken in future years (5-20 years). Volume I is a summary, Volume II shows prioritization, and Volume III contains detailed LRRDAP worksheets grouped by mission area. Each detailed LRRDAP worksheet describes a program/project/ system and shows program objectives, need, 15-year resource profile (dollars) and priority (by year). ODCSRDA distributes a draft to RDTE components in July for review and update. After updates are submitted, ODCSOPS/TRADOC prioritizes programs/projects and distributes worksheets to DASCs and FISOs for comment in October.

A critical element in this review is attainment of priority consistency between development and procurement components of programs. ODCSOPS resolves priorities and provides them to ODCSRDA which publishes the LRRDAP in final form in December. Detailed LRRDAP worksheets showing proposed changes are submitted to DCSRDA in July. "Corrected" worksheets and comments on the prioritization process are submitted in October. Correction of narrative for

final DA copy is accomplished in early December, and no changes to resource profiles or priorities are permitted at this time. Each RAD is responsible for preparing the Detailed LRRDAP worksheets for his respective research area. PMs may be requested by the RADs to provide updates for existing programs and program narrative and resource estimates for new programs. See Chapter 9 for a complete discussion of the LRRDAP process.

10.4 PROGRAMMING PHASE

10.4.1 General Objectives. Programming translates planning outcomes into more specific requirements for the scheduled, balanced allocation of resources, and identifies how they are to be distributed and applied during the five year period (POM) following the budget year. Programming links planning for goals with budgeting for resources to achieve the goals. At the same time, it records in the Army five-year programs how these resources are to be distributed to component activities and undertakings. Prepared in consonance with centralized direction formalized in Defense Guidance (DG), the proposed program is published each May as the Program Objective Memorandum. The POM is submitted to the Office of the Secretary of Defense, which examines program major issues in terms of overall defense need. Changes are issued as a Program Decision Memorandum (PDM). As approved by the Secretary of Defense, the document forms the basis for preparing the annual budget.

Program Functional Reviews are carried out in mid-March when each functional proponent briefs the Program Budget Committee (PBC) on the content of its program. A primary purpose of the review is to identify issues that have yet to be resolved. An attempt is made to resolve these issues, with unresolved issues passed to the Select Committee (SELCOM). The Functional Review/ SELCOM addresses all unresolved issues and develops a balanced program. Similarly, the USAMRDC RDTE Program Review covers the status of R&D Programs. It is held prior to POM build, with its purpose being to familiarize DA staff, the user community, and other materiel developers with the priority and status of R&D programs.

10.4.2 Specific Programming Activities.

SEE CHART 10-1

2. Army Guidance and Program Budget Guidance. The Army's Programming Phase is coordinated by the Army's Program Analysis and Evaluation Directorate (PAED), and is initiated with the issuance of AG, Volume II, in November. This volume, which describes program development, precedes the issuance of program instructions in AG, Volume III, and specific instructions for POM submission in AG, Volume IV. PAED also has responsibility for preparing the Extended Planning Annex. The EPA is an annex to the POM and it extends the five year program of the POM ten additional years. The EPA facilitates the transition from planning to programming by identifying long-term objectives and assessing the resources needed to achieve them.

The Director of the Army Budget (DAB) in the Comptroller's office prepares a Program and Budget Guidance (PBG) document that transmits to the commands and operating agencies instructions and staff data regarding available dollar and manpower resources. It is the single authoritative source of command resource guidance and is issued three times annually in two volumes. Volume I contains general instructions and expresses the views of Headquarters, Department of the Army, on various programs common to all commands and agencies. Volume II contains resource data applicable to a particular command and is published individually for each command and agency. The October/November PBG reflects appropriations levels for the new current year.

3. USAMRDC Program Review. The entire USAMRDC program (6.1-6.4 funding) is briefed to the Director of Army Research and Technology (ODCSRDA) to familiarize the HQDA staff, user community and other materiel developers with

the status and priority of medical R&D programs in preparation for POM build. Emphasis is on demonstrating adherence to programs to meet Army needs/deficiencies as identified in various Mission Area Analyses and the draft Army Guidance. Contents of the briefing include program elements, objectives, funding, major milestones, accomplishments, opportunities, planned products, and joint Service relationships and issues. Approximately an hour is scheduled for each research area and the medical materiel development program. The one-day review is conducted at a USAMRDC facility, with the Commander, USAMRDC chairing the review. Each RAD briefs on his research area and the Commander, USAMMDA briefs on the medical materiel development program. The PMs provide inputs for their respective product areas and USAMMDA-PMSO consolidates the inputs and prepares overall USAMMDA materiel. Briefing format is specified in the tasking letter from the USAMRDC Planning, Programming and Budgeting Directorate.

4. POM Development Increment Preparation and Prioritization. Each program/project is broken into increments representing discrete identifiable tasks with separate funding and manpower increments. A maximum of four increments (numbered 1 through 4) are permitted for each program/project. Increments for the various research areas are consolidated into two packages -- one for technology base programs (6.1-6.2 funding), and one for materiel development programs (6.3-6.4 funding), and ranked by the HQ USAMRDC. The two ranked packages are forwarded to ODCSRDA as a markup of the existing packages.

Manpower changes evolving from the analysis are forwarded to OTSG in an annually-specified format. OTSG resolves medical manpower requests with other requirements and works with ODCSRDA to update the manpower sections of the increments previously submitted by USAMRDC. Functional Review Panels then rank them against other Army Program PDIP fund increments and manpower requests to meet the Total Obligation Authority (TO_A) provided by Defense Guidance. All of the POM program/project increment Program Development Increment Package (PDIP) activities are accomplished during January, February, and March. Each USAMMDA PM is responsible for preparing increment sets for assigned programs/projects and forwarding them to the appropriate RAD(s) through

USAMMDA-PMSO. PMs may also be tasked by the RADs to prepare inputs to increment sets on programs/projects for products that will enter the development phase in future years. The RADs are responsible for submitting assembled program/project increment sets to the USAMRDC Planning, Programming and Budgeting Directorate which forwards them through the Assistant Surgeon General for R&D (DASG-RDZ) to ODCSRDA. The Other Procurement, Army (OPA) appropriation, and the Operation and Maintenance, Army (OMA) appropriation are not administered by USAMRDC. However, the RADs and PMs are responsible for coordinating requirements for these funds with other commands when formulating Program Decision Increment Packages. OPA appropriation provides for the procurement of investment (over $3,000/unit) products/ end items/sets, kits and outfits. OMA appropriation provides for the procurement (less than $3,000/ unit), operation and maintenance of all Army organizational equipment and facilities including depots, fixed and field medical activities, and training activities. Therefore, the PMs should obtain the funding estimate for OPA from USAMMA, and for OMA from USAMMA or AHS, as appropriate, and coordinate requirements with DASG-HCL to ensure proper timing of funds with the planned fielding date in the acquisition strategy.

The program/project increment prioritization package consists of a summary of programs/projects and associated funding requirements for five years. The format is illustrated in a USAMMDA Memo 11-1.

5. Development of Program Development Increment Packages. When new RDTE initiatives are identified the action officer prepares a justification for expanding a current PDIP or creating a new PDIP, and forwards it to the Deputy Chief of Staff for Research Programs, USAMRDC. The set of up to four increments is identified as a Program Development Increment Package. Each PDIP represents a discrete, identifiable program with separate funding and manpower increments. The minimum (core) increment represents the minimum resource level that will produce a completed, useful capability to meet the identified need. Each of the other increments will result in an enhanced capability to meet that need. New increments are categorized as "unfunded" until they have been evaluated against existing PDIPs by one of the Functional Review Panels and assigned a priority. There are currently nine panels:

- Structuring;
- Manning;
- Training;
- Mobilizing and Deploying;
- Providing Facilities;
- Managing Information;
- Equipping;
- Sustaining;
- Managing.

Funding increments of the medical PDIPs will normally be assigned to the Equipping (EQUIP) panel chaired by DCSRDA for review. PDIPs may be developed and coordinated at any time. However, new PDIPs are entered into the system in January for the Functional Review which occurs in late February. Currently, USAMRDC operates under two primary PDIPs - one for technology base programs (6.1-6.2 funding) and one for materiel development (6.3-6.4). Within these PDIPs USAMRDC submits detailed increments grouping them by protected, at-risk and unfunded levels. The RADs will normally prepare draft PDIPs in conjunction with various combat developers. The USAMMDA PMs may be called upon to assist in developing the materiel development phases of the programs/projects. All PDIP increments are processed through, and submitted by, the USAMRDC Planning, Programming and Budgeting Directorate. PDIP forms are shown in USAMMDA Memo 11-1.

6. POM Submission to OSD. Each PDIP is assigned to a "functional" point of contact on the Army Staff, and a contact point in PAED. The PDIP submission contains the names of these POCs. At the end of February, PAED distributes all PDIPs to functional area panels for ranking, based on Army functions. They produce eight lists of PDIPs that are merged by DCSOPS into a single list (the Adjusted Program) for review by the Ranking Committee (a subcommittee of the Program and Budget Committee (PBC)). A final prioritized list is negotiated between the Ranking Committee and DCSOPS, who sends the list to PAED.

During late March and early April, PAED prepares a draft POM, and program directors discuss and defend their proposed programs in that draft before the PBC. This results in a refined draft POM, which is presented to the Select Committee (SELCOM) for further review and modification. The PBC and SELCOM explore issues, risks, and trade-offs, and evaluate the overall program in terms of program balance and ability, within given resources, to carry out the Army missions. The SELCOM then presents its recommendations to the Chief of Staff and the Secretary of the Army for final review and approval. Once approved, the staff and PAED develop the final Army POM, which goes to the SECDEF in mid-May. OSD reviews the POM from May to August.

10.5 BUDGETING PHASE

10.5.1 General Objectives. The budgeting phase expresses the program need for dollars and manpower as requests for congressional appropriations. During budgeting, detailed funding estimates are developed to support approved plans and programs, then justified and defended throughout DA/DOD budget reviews and hearings. The budgeting phase proceeds in two separate stages. The first stage is budget formulation which comprises the development of Army budget estimates, their review, and eventual approval as part of the President's Budget. The second stage is budget justification, which relates to the process of Congressional review and approval. Preparation of documentation to support the USAMRDC budget development process includes:

- POM to Budget Actions;
- Command Operating Budget (COB);
- Congressional Descriptive Summaries (CDSs);
- RD-5 Descriptive Summaries (RD-5).

These activities are described individually in the following paragraphs.

General support for the budget development process to higher management levels (HQDA, OSD and OMB) and in Congress is provided by cognizant program, budget and technical officers. This support includes preparation of formal briefings and issue/information papers, as well as telephonic responses, to provide clarification and additional justification, and to reclama decisions having major impact on Army capability. Program Budget Decisions (PBDs) and the markups by the House and Senate Armed Services Committees (HASC/SASC) and the House and Senate Appropriations Committees (HAC/SAC) have formal reclama procedures.

Submission Schedule

(1) USAMMDA budget due to the USAMRDC Comptroller 1 June.

(2) HQDA budget construction begins in July and continues into September.

(3) OSD/OMB hearings start in late September and continue through October. The hearings schedule is published in early September and issues are identified even earlier.

(4) Program Budget Decisions are issued from October through December with reclamas due shortly after a PBD is issued.

(5) The President's Budget is submitted to Congress in late January or early February.

(6) The HASC/SASC markup begins in March and the HAC/SAC markup begins in July.

Most responses are required in a matter of days, and sometimes hours, and the flow of information is usually by the most direct and expedient manner possible. Generally, the RADs will work with the USAMMDA PMs and the USAMRDC Planning, Programming and Budgeting Directorate on narrative and justification. The USAMRDC Comptroller Division will work with USAMMDA-PMSO and the RADs on correction and revision of budget data. Written submissions are normally provided as issue/information papers or briefing charts. In some cases, individuals may be called upon to testify in OSD/OMB or Congressional hearings. A formal reclama system is used to appeal budget decisions.

10.5.2 Specific Budgeting Activities.

SEE CHART 10-1

7. RDTE POM to Budget Actions. At the end of the POM review cycle, commands/agencies are provided an opportunity to make budgetary adjustments to programs/project increments submitted as PDIPs. These actions are to fine tune program funding, adjusting programs for improved executability, making adjustments based on Congressional actions and other adjustments based on more current information. They are not to be used to re-open programmatic issues for which decisions have been made during the POM review. Once these accounting changes are entered into the POM data base, it is converted to budget format by copying the program year data from the POM into the budget year for the budget and adjusting the columns for subsequent years. The resulting file becomes the baseline budget which is published as guidance for the budget development process. Actions are due to ODCSRDA in July. The USAMRDC Planning, Programming and Budgeting Directorate, supported by the USAMMDA PMO input to USAMRDC RAD is responsible for preparing the documentation required to affect program/project change action.

8. Command Operating Budget (COB) and Obligation Plan. The COB costs resource decisions are made during the program cycle and are updated where justified to reflect command requirements. The COB provides information on budget and workload data and on operating requirements for the upcoming fiscal year. COB instructions are issued to the commands/agencies in March with the USAMMDA COB due June 1st to the USAMRDC Comptroller. Commands submit the COB to HQDA in July. USAMMDA-PMSO is responsible for preparing the COB and submitting it to the USAMRDC Comptroller. USAMMDA PMs are responsible for the review of operating and extramural budgets for assigned projects/products and for providing their input to the USAMRDC RADs through the PMSO.

The RDTE Obligation Plan for PM Operations is prepared by USAMMDA and submitted to USAMRDC with the COB. This document will be revised some fifteen months later at the start of budget execution. USAMRDC (SGRD-RM) then consolidates all inputs and submits a budget schedule along with the COB to the Comptroller of the Army. The obligation plan/budget schedule, at appropriation level detail, presents a monthly profile of planned obligations.

9. RD-5 Data. This document provides concise and formatted program descriptions and cost displays in support of the Army RDTE budget. The RD-5s are also used in preparation of the Congressional Descriptive Summaries (CDS). Prior to their preparation in early August by USAMRDC, inputs are coordinated with the RADS and USAMMDA PMOs and the PMSO.

10. The Army Budget and Reclama Process. Headquarters, Department of Army consolidates COB submissions into the Army Budget and submits it to the Office of the Secretary of Defense. After joint review by OSD and the Office of Management and Budget (OMB), it is merged into the President's Budget (PB) for submission to Congress. During the joint review in October, changes are issued as Program Budget Decisions. The Army may file a formal reclama to request reconsideration of a PBD to change the level of resources in a portion of the Army's budget. Actions in this phase are identified as budget year actions.

11. Congressional Descriptive Summaries (CDSs). CDSs are generalized descriptions provided to Congress to describe each program element, with detail for each project. These worksheets, published as DA PAM 5-6, accompany the President's Budget submitted in January. A CDS consists of a brief description of the program element and the mission need. It includes a comparison between actual expenditures and the figures submitted with the previous year's CDS, along with an accompanying explanation. CDSs highlight program accomplishments, future efforts, and other program elements needed for support activities or funding research and technology efforts in the program area. The CDS is the single most important document associated with Army appropriations. CDSs are forwarded to HQDA during the October to December period preceding the January submission of the President's Budget. The USAMRDC RADs and

the USAMMDA PMSO receive specific guidance from USAMRDC Planning, Programming and Budgeting Directorate regarding their input. USAMMDA PMs prepare CDSs for each medical materiel development program element (6.3B/6.4 funding). These will be forwarded to the RADs through the USAMMDA PMSO. The RADs, together with the USAMMDA-PMSO, provides past year budgeting information and budget estimates for each program element. The PMSO audits financial sections to assure consistency with the overall program and evolving budget and program decisions and forwards them to the RADs.

12. Congressional Activities. Three major committees in each house act upon the Defense budget: the Budget Committees, the Armed Services Committees, and the Appropriations Committees. The Budget Committees deal with aggregate budget levels as a whole. The Armed Services Committees deal with total dollars for mission areas and are responsible for legislation that authorizes programs and permits appropriations to be made. The Appropriations Committees are responsible for appropriating specific funds.

The authorization process conducted by the Armed Services Committees begins the Congressional action on the DoD budget and normally extends from January to May. Detailed review begins early in February, based upon the President's budget and justification materials provided by the service budget offices. Overview statements and testimony are routinely delivered by the SECDEF, Chairman of the JCS. Similarly, Service secretaries, Chiefs of Staff, and senior officers provide overview statements and testimony, with additional testimony and/or back-up materials from service program offices. When committee and subcommittee hearings are complete, the committees mark-up legislation and issue an accompanying report. The process occurs in parallel in the House and Senate, with differences reconciled by a conference committee. The final authorization bill is passed and forwarded to the President for signature.

The Appropriations Committees perform very similar activities, with the additional input of the authorization bill provisions as it moves through the committee process. The final, agreed-upon appropriations bill is intended to be passed and signed by the President by September 30 so that it can take effect on October 1, the beginning of the new fiscal year.

10.6 BUDGET EXECUTION PHASE

10.6.1 General Objective. The recently added Execution Phase brings new focus to work for carrying out the program and budget. Budget execution, as the final stage in the PPBES process, concerns administrative control of funds, apportionment requests, commitments, obligations, and disbursements with regard to the effectiveness of results for feedback into preparation of future budgets. Actions in this stage are identified with the current year and prior years.

The Execution Phase begins with the issuance of a Funding Letter in late September and a more extensive Funds Authorization Document (FAD) in mid-October or as funds are apportioned and allocated. Transfer of funds between program elements ("reprogramming") is authorized at various levels subject to Congressional and higher headquarter's limitations. When Congress is unable to pass the budget by the beginning of a particular fiscal year and provides Continuing Resolution Authority (CRA), operating agencies must assess the impacts of any restrictions imposed. A CRA is authorization to expend funds at some limited level short of full budget authority. These assessments are passed to higher levels so that necessary action can be taken to minimize serious short-term impacts.

Commands and agencies are required to provide input for high-level execution reviews for evaluating and reporting on how well resources are being applied to accomplish Army goals. Similar reviews are held at all levels.

10.6.2 Specific Budget Execution Activities.

SEE CHART 10-1

13. RDTE, Army Obligation Plan. RDTE, Army Obligation Plan is prepared during the first quarter of each fiscal year to show obligations expected to be incurred in each month of the current year. Total planned obligations are typically expected to exceed some threshold as a percent of authorized funds as shown in the Funds Authorization Document. The plan includes separate sections for funds from the current and previous fiscal years respectively. Actual obligations are tracked monthly against the plan and explanations prepared when variances exceed plus or minus 5% or $1 million, whichever is less. The USAMMDA PMs provide project extramural obligation plans to USAMMDAPMSO and monitor actual obligations against these plans. They notify USAMMDAPMSO when project plans will impact planned obligations and provide explanations on these changes and any excessive variances.

14. Availability of Funds. Appropriations make funds available for disbursing, but do not authorize incurring obligations. Funds must first be apportioned by the Office of Management and Budget (OMB). OMB approves apportionment requests submitted through the SECDEF, authorizing the obligation of funds in specified amounts and for specified periods, activities, functions, or projects.

The schedule of events will differ depending on the Congressional timing for approving the appropriations bills. In principle, all of these activities should be completed by the beginning of the new fiscal year. However, if the appropriations are not passed until the last moment or if continuing resolutions are passed instead of appropriations bills, execution of plans will also be delayed.

USAMRDC in turn, makes funds available by allotment. The recommended obligation of funds as individual orders are placed and contracts awarded. Appropriate organizations make disbursements as materiel is delivered and services performed, accounting for funds and submitting data on these obligations and disbursements. The U.S. Army Finance and Accounting Center consolidates the data and prepares monthly accounting reports.

During the execution year, ongoing obligation, expenditure, and disbursement of funds are reported and reviewed in a variety of formats to meet a wide array of management and fiscal control needs. Monthly obligation and outlay data are reported to USAFAC where they are consolidated and compared with plans for monthly obligations and outlays. Deviations between plans and actuals are reported to Appropriation Directors and to the COA. The COA reports on the financial status of all appropriations at monthly execution briefings to top Army staff members. Monthly reports on obligations and outlays are also sent to the Assistant Secretary of Defense (Comptroller) and to the Treasury Department. Reports are used to adjust current and budget year funding allocations.

15. Reprogramming of Funds. As the budget is executed, the funding requirements for individual programs and projects may change. Some programs may be delayed while others may require acceleration. Congress has authorized limited transfers ("reprogramming") of funding to meet these contingencies. Authority to reprogram funds between program elements varies with the organizational level and program elements involved. The main steps in reprogramming are identification of need, identification of source for funds, request and approval of reprogramming action, revision of funding documents, and notification. The USAMMDA PM, in conjunction with the appropriate RAD, is responsible for identifying funding deficits and excesses on specific development projects and notifying USAMMDA-PMSO of changes required in the FAD. The PM notifies the PMSO of intra-project or intra-program element reprogramming actions and requirements for which sources have not been identified. The PMSO identifies sources for these latter cases and prepares a reprogramming request through the appropriate RAD for the USAMRDC Comptroller. The PMSO forwards a request for additional funding if it is unable to identify a source of excess funds within the USAMMDA purview. After the USAMRDC Comptroller adjusts the FAD, USAMMDA-PMSO notifies the affected RADs and PMs.

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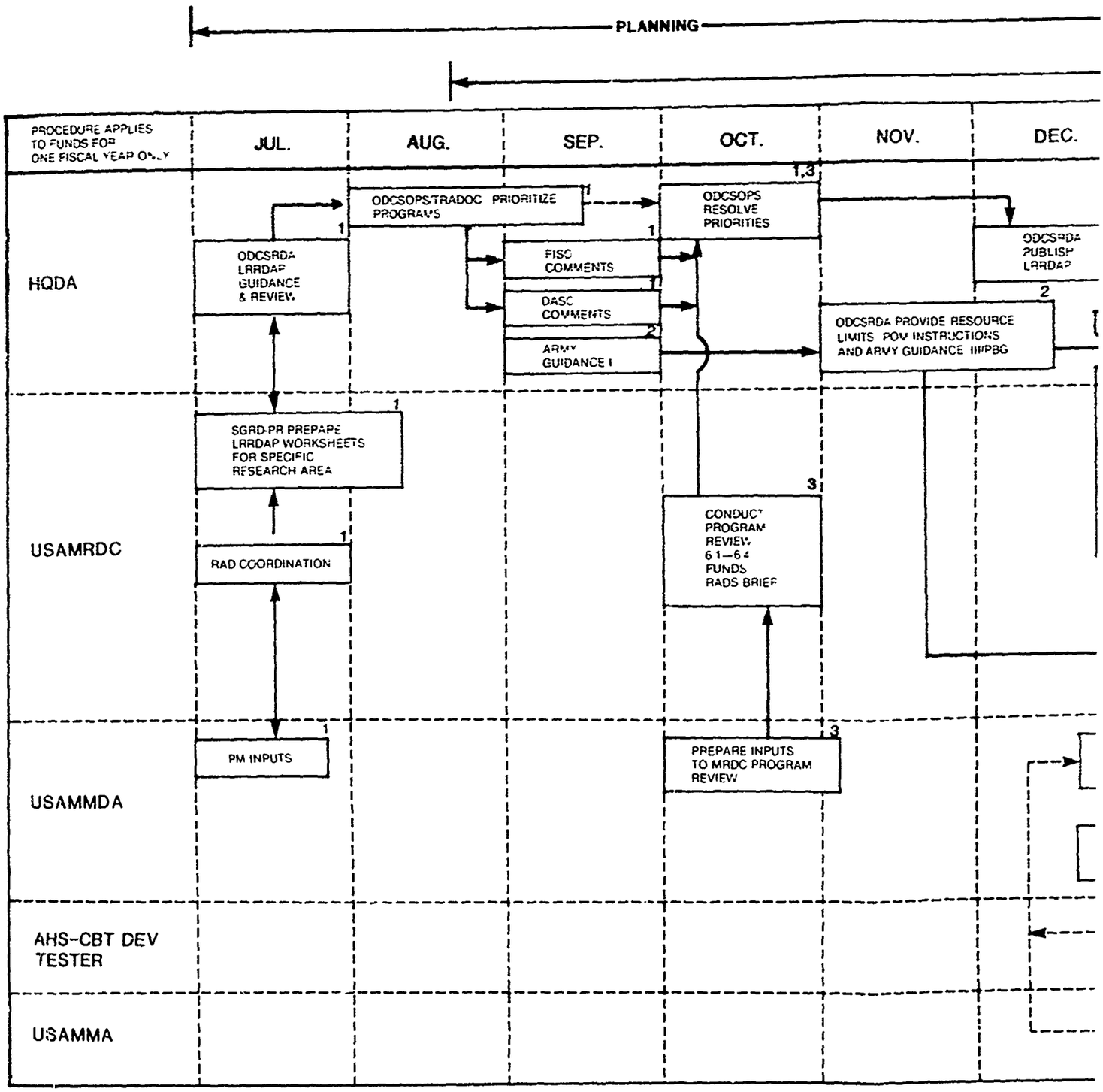
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PLANNING
PROCEDURE APPLIES TO FUNDS FOR ONE FISCAL YEAR ONLY
JUL.
AUG.
SEP.
OCT.
NOV.
DEC.
HQDA
USAMRDC
USAMMDA
AHS-CBT DEV TESTER
USAMMA
ODCSOPS/TRADOC PRIORITIZE PROGRAMS
ODCSOPS RESOLVE PRIORITIES
ODCSRDA LRRDAP GUIDANCE & REVIEW
FISC COMMENTS
DASC COMMENTS
ARMY GUIDANCE I
ODCSRDA PUBLISH LRRDAP
ODCSRDA PROVIDE RESOURCE LIMITS POM INSTRUCTIONS AND ARMY GUIDANCE III/PBG
SGRD-PR PREPARE LRRDAP WORKSHEETS FOR SPECIFIC RESEARCH AREA
RAD COORDINATION
CONDUCT PROGRAM REVIEW 61–64 FUNDS RADS BRIEF
PM INPUTS
PREPARE INPUTS TO MRDC PROGRAM REVIEW

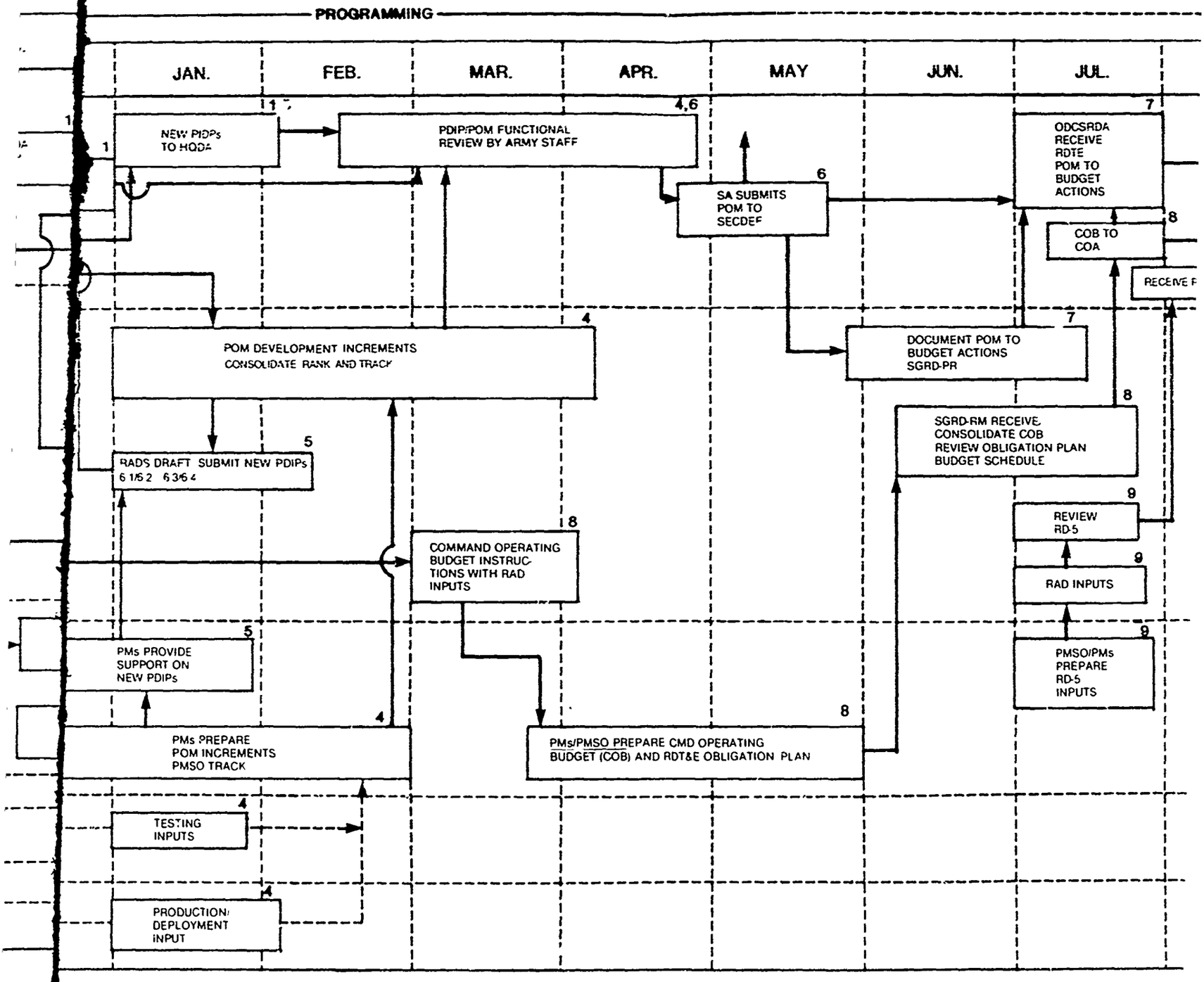


Chart 10-1, THE PPBES PROCESS

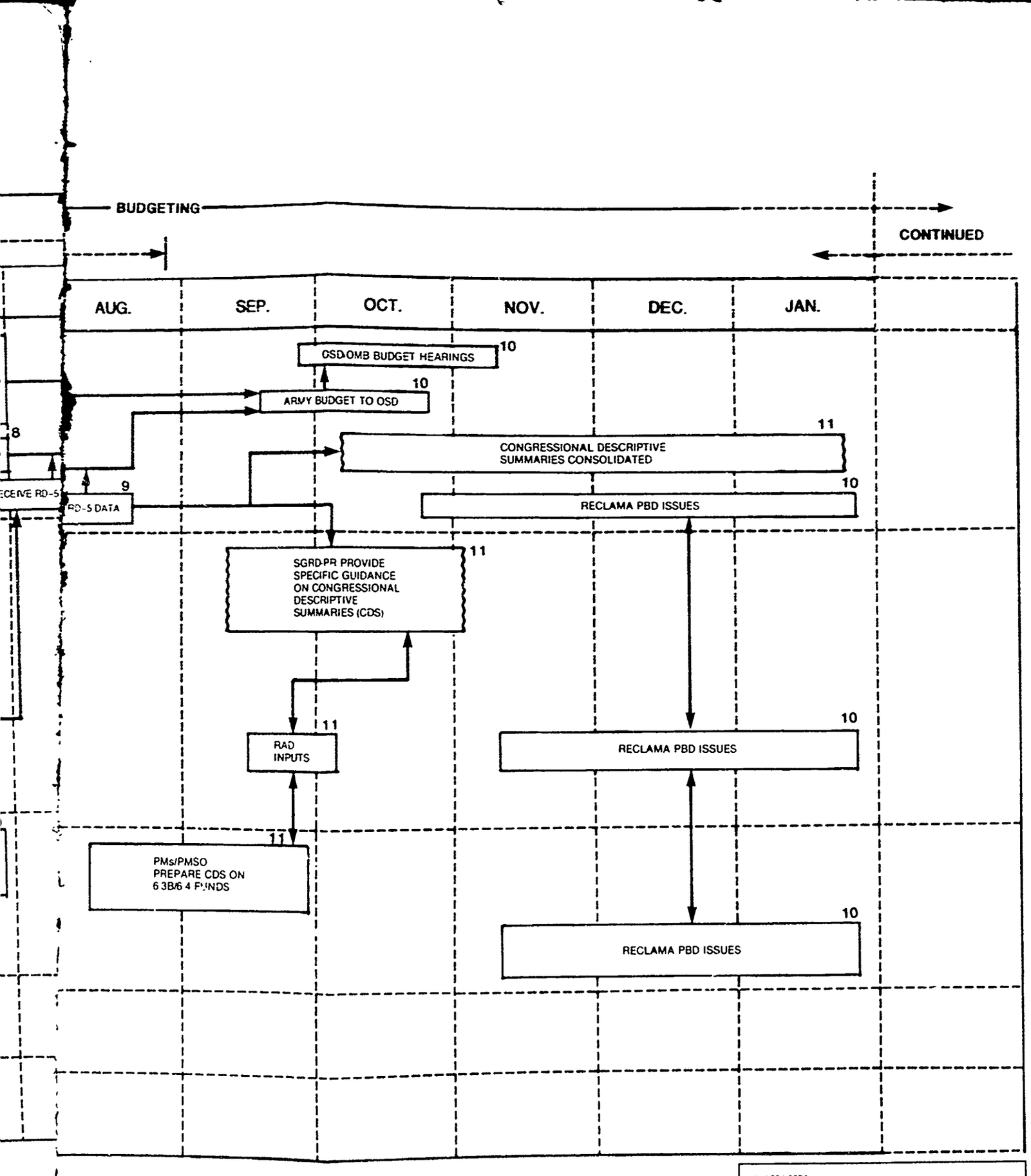


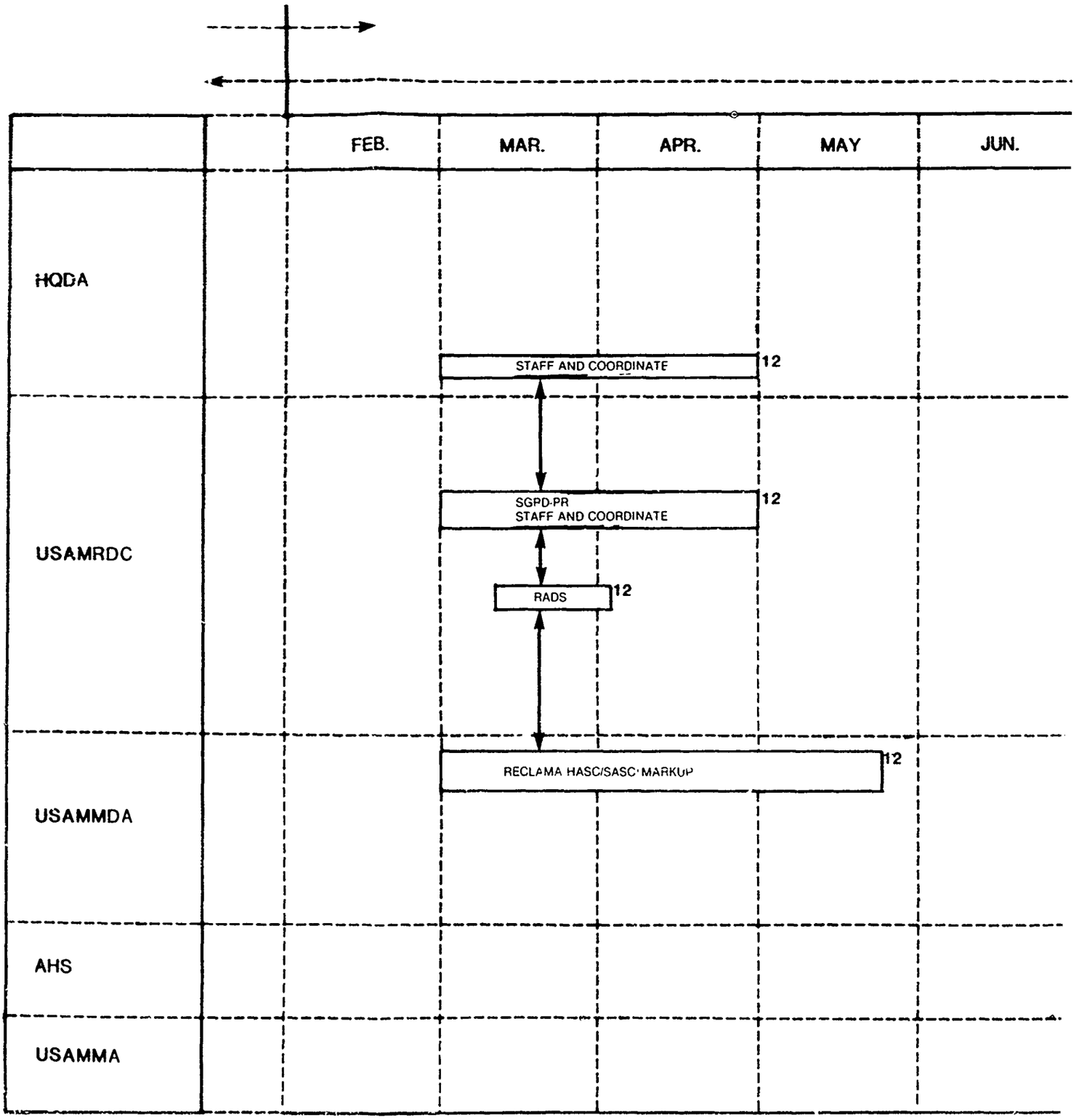
CHART NOTES

1 SEE APPENDIX B FOR ACRONYMS

2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 10-1

3


FEB.
MAR.
APR.
MAY
JUN.
HQDA
STAFF AND COORDINATE
12
USAMRDC
SGPD-PR
STAFF AND COORDINATE
12
RADS
12
USAMMDA
RECLAMA HASC/SASC MARKUP
12
AHS
USAMMA

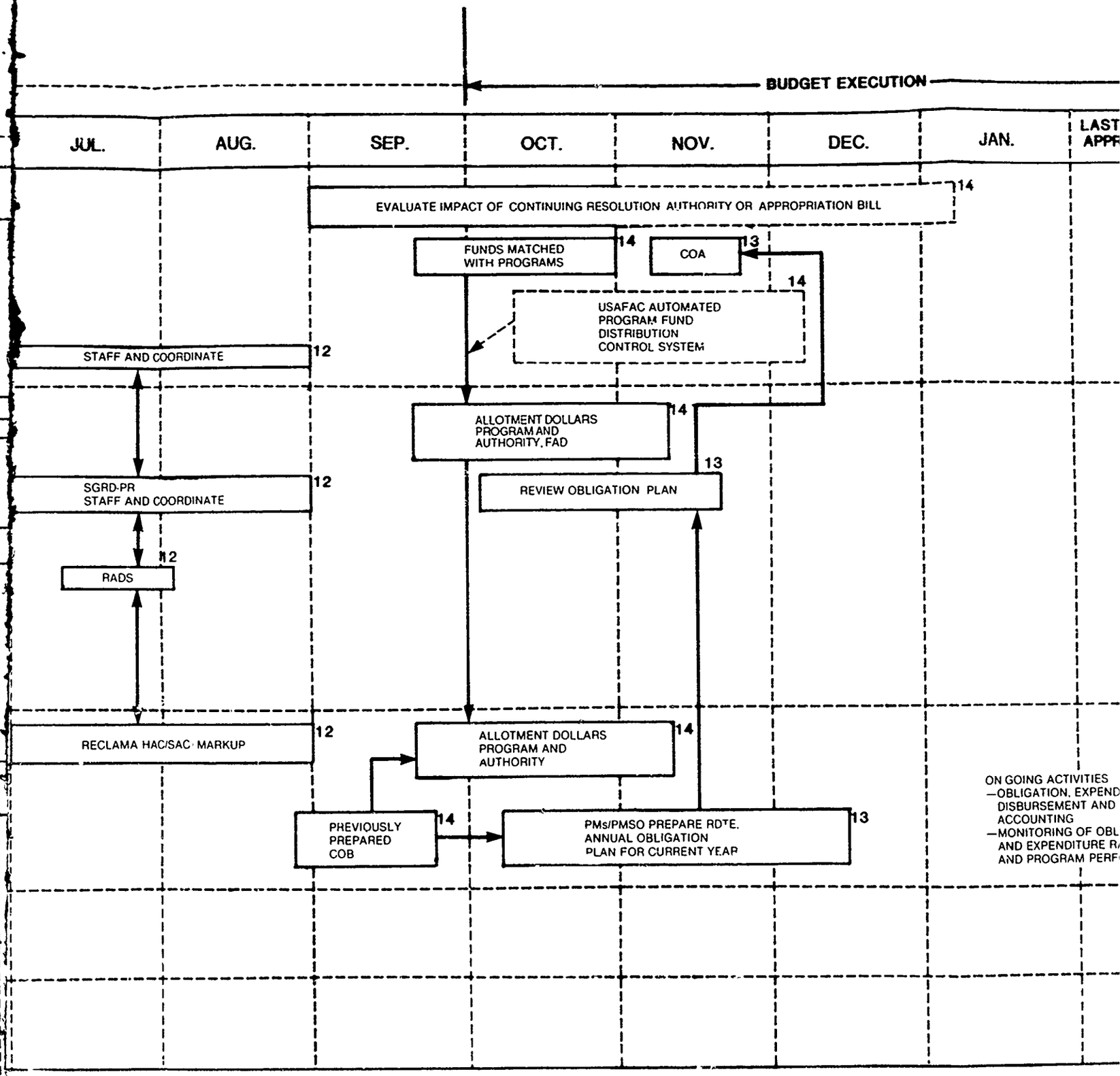


Chart 10-1, THE PPBES PROCESS (Continued)

2

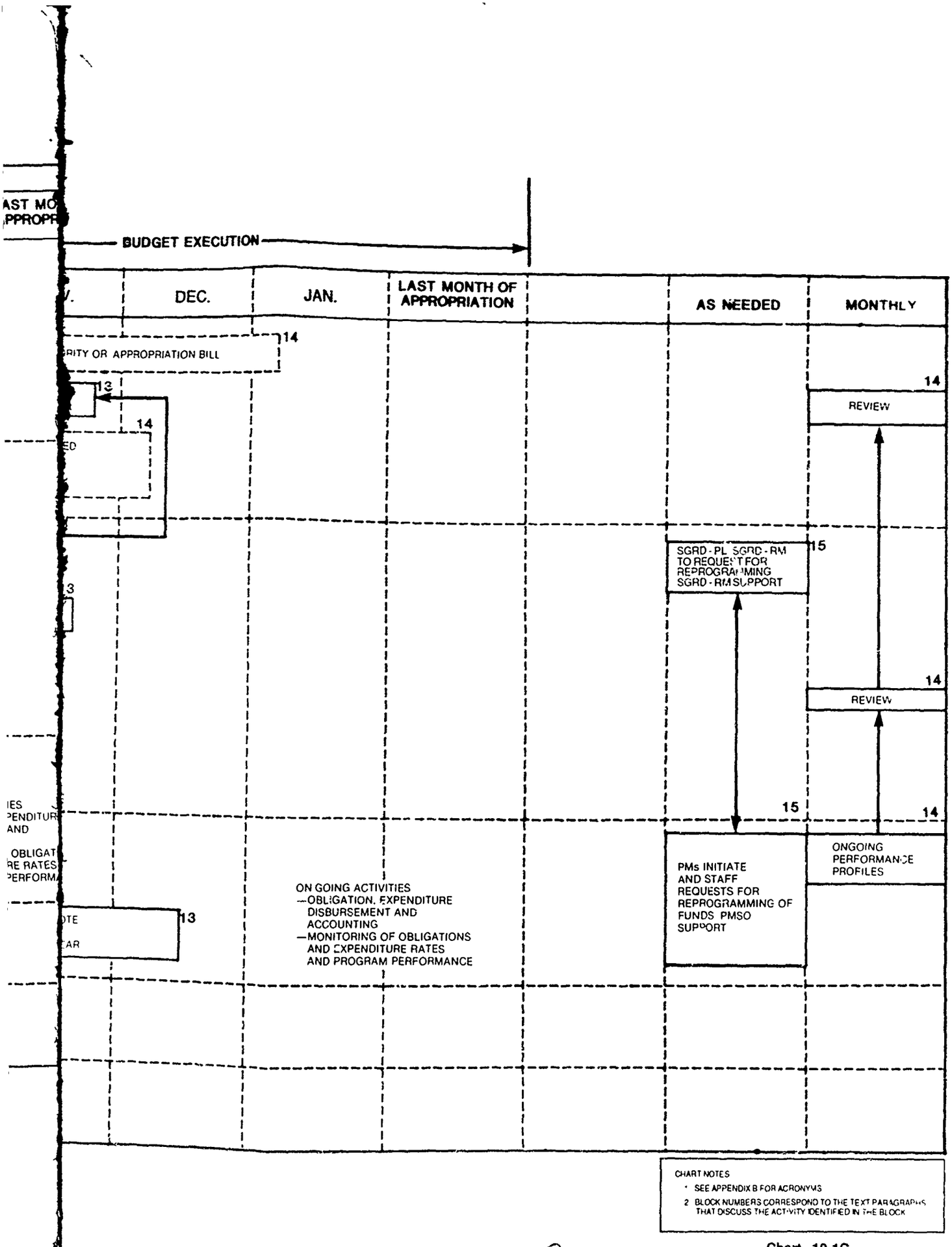

BUDGET EXECUTION
DEC.
JAN.
LAST MONTH OF APPROPRIATION
AS NEEDED
MONTHLY
14
REVIEW
SGRD - PL SGRD - RM TO REQUEST FOR REPROGRAMMING SGRD - RM SUPPORT
15
14
REVIEW
15
14
PMs INITIATE AND STAFF REQUESTS FOR REPROGRAMMING OF FUNDS PMSO SUPPORT
ONGOING PERFORMANCE PROFILES
ON GOING ACTIVITIES
—OBLIGATION, EXPENDITURE DISBURSEMENT AND ACCOUNTING
—MONITORING OF OBLIGATIONS AND EXPENDITURE RATES AND PROGRAM PERFORMANCE
13
CHART NOTES
* SEE APPENDIX B FOR ACRONYMS
2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 10-1C

CHAPTER 11

THE REQUIREMENTS DOCUMENT PROCESS

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11.1 PURPOSE

This chapter describes the normal requirements documents preparation and staffing procedures for development and nondevelopment programs. The description is time phased, beginning with pre-program initiation procedures, and ending with the Full Scale Development (FSD) activities leading to a production decision.

Chart 11-1, a flow chart at the end of this chapter, highlights selected events, activities, documents and decisions required to complete and approve requirements documents in support of non-major medical materiel development programs. The number on each block in the flow chart relates to the corresponding numbered text paragraph that discusses the activity identified in the block. The chart is designed to present, in relative order within each phase, the primary responsibilities of each participating organization.

11.2 GENERAL

The Concept-Based Requirements System (CBRS) is the process by which doctrine, training, organizational, and materiel deficiencies are identified and corrected. Deficiencies identified in Mission Area Analyses are translated into solutions in the form of new doctrine, training, organizations, or materiel. The development of materiel requirements documents is one possible outcome of CBRS. Refer to AR 71-9, Materiel Requirements, and to Chapter 3, Pre-Program Initiation Activities, and Chapter 9, The Long Range Research, Development, and Acquisition Plan.

> NOTE:
>
> The process described in this chapter is based upon the 1980 edition of AR 71-9. This edition eliminates requirements for new Letters of Agreement (LOA) and makes the Required Operational Capability (ROC) the standard requirements document for entry into Full Scale Development. However, previously approved LOAs and Letter Requirements (LRs) remain in effect until they come under a milestone review.

11.2.1 Operational and Organizational Plan. The Operational and Organizational (O&O) Plan, is the program initiation document in the medical materiel acquisition process. It provides a front-end agreement to conduct the medical materiel acquisition process to meet a concept based requirement. The O&O Plan is a mandatory element of the medical materiel acquisition process and provides the minimum essential information necessary to conduct Concept Exploration and Demonstration and Validation Phase activities. It addresses the materiel item as an integral part of an organization, rather than as an isolated item. The O&O Plan is limited to ten pages. An approved O&O Plan constitutes a valid requirement to program and expend funds in order to conduct concept exploration. The O&O Plan also serves as the basis for determining if a Justification for a Major System New Start (JMSNS) is required.

11.2.2 Required Operational Capability. The Required Operational Capability (ROC) concisely states the minimum essential operational; technical; MANPRINT (personnel, manpower, safety, health, human factors engineering, training); logistics; and cost information necessary to start full scale development or acquisition of a materiel system.

The ROC is a formal requirements document with implicit commitment to an eventual production decision. The ROC is submitted when AHS and USAMMDA agree that the need has been validated, the operational and technical feasibilities of the proposed system have been established, the system is determined to be cost and operationally effective, and the system is ready for entry into the engineering development category of the RDTE program. In the case of NDI programs, a ROC is prepared to support the combined Milestone I/Milestone III decision review. The approved O&O Plan is attached as Annex B to the ROC.

The Expedited Essential Required Operational Capability (EEROC) is an abbreviated requirements document that concisely states a user's urgent operational need that if not satisfied will severely inhibit the unit from accomplishing a primary mission. The EEROC is based on an approved O&O Plan and is for use when equipment alternatives are NDI requiring minimal or no modifications. It should capitalize on "in-production technology" and provide for a limited procurement of an initial lot of equipment for issue to a unit for operational use and testing.

Approval of an EEROC is a two phase process consisting of: 1) validation of the urgent operational need, and 2) approval of the EEROC. Validation and approval authority rests with HQDA (ODCSOPS). The formats for the EEROC validation request and for the EEROC are described in AR 71-9, Appendix D.

11.2.3 Joint Service Operational Requirement. The requirements document, when the same end item is to be used by more than one military Service, is a Joint Service Operational Requirement (JSOR). A JSOR replaces the ROC. Except for requiring joint Service coordination, the JSOR is processed in a manner similar to the ROC. The format for an Army initiated JSOR is the same as that for a ROC. When another Service has the lead, the JSOR will be prepared in that Service's format. Within the Army, a JSOR is always approved at ODCSOPS. After ODCSOPS approval, the JSOR is formally coordinated with other Services and Government agencies and then published by TRADOC.

11.2.4 Training Device Requirements. Training devices are either: (1) system devices - those acquired to support a specific system/item; or (2) non-system devices - those acquired to support general military training or training on more than one system/item. A system oriented training device requirement is included as an annex to the ROC or JSOR of the system. Non-system training devices are acquired as separate acquisition programs. The Training Device Need Statement (TDNS) is the initial document that identifies a need for a nonsystem training device in response to a training deficiency. It is similar to the O&O Plan in that it also provides front-end agreement on the requirement to initiate the Concept Exploration Phase. A Nonsystem Training Device Requirement (NSTDR) is initiated upon approval of the TDNS and presents operational, technical, MANPRINT, logistics, and cost information necessary for development, testing, and procurement of the nonsystem training device. A Commercial Training Device Requirement (CTDR) is prepared for a training device not requiring the expenditure of RDT&E funds. Figure 11-1, summarizes the characteristics of the requirements documents described in paragraphs 11.2.1 through 11.2.4.

Primary Requirement Documents	Prepared By	Approval Authority	Phase In Which Prepared	Purpose
Operational and Organization (O&O) Plan*	AHS-CD	HQ TRADOC	Pre-program Initiation	Identifies need for new or improved mission capability.
Required Operational Capability (ROC)	AHS-CD	HQDA** (DCSOPS)	Demonstration and Validation	States the minimum operational, technical, MANPRINT, logistics, and cost information necessary to enter FSD or Production. System training device requirements are attached as an annex to the ROC.
Joint Service Operational Requirement (JSOR)	AHS-CD	HQDA** (DCSOPS)	Concept Exploration/Updated in Demonstration and Validation	See ROC Purpose. JSOR takes the place of a ROC when the AMEDD is tasked to develop a joint Service system.
Training Device Need Statement (TDNS)	AHS-Trainer	HQ TRADOC	Pre-program Initiation	Identifies need for new or improved training capability. Only used for non-system TDs. Similar to O&O plan for system.
Non-System Training Device Requirement (NSTDR)	AHS-Trainer	HQDA** (DCSOPS)	Concept Exploration	States the need, essential characteristics, MANPRINT, and cost information necessary to enter FSD or Production.
Commercial Training Device Requirement (CTDR)	AHS-Trainer	HQDA** (DCSOPS)	Concept Exploration	Describes characteristics of a TD which does not require RDTE expenditures.

* Must be staffed and validated by OTSG before approval.

** HQDA (DCSOPS) approves ROCs, CTDRs, and NSTDRs for DAP systems and all JSORs. AHS and USAMRDC approve ROCs, CTDRs, and NSTDRs for IPR systems.

Figure 11-1 Requirements Documents Summary

11.3 PRE-PROGRAM INITIATION

11.3.1 General Objectives. One of the results of the pre-program initiation activities is the preparation of the Operational and Organizational Plan. The O&O Plan is the program initiation document in the medical materiel acquisition process.

11.3.2 Specific Activities.

SEE CHART 11-1

1. Develop Draft O&O Plan. AHS, as a result of the Mission Area Analysis/Mission Area Development Plan process, determines that a particular deficiency can only be met by a materiel solution. At that point, a draft O&O Plan is initiated by AHS-CD and prepared in coordination with USAMMDA, with input from AHS-Tester, AHS-Trainer, and USAMMA.

2. Staff Draft O&O Plan. The draft O&O Plan is then forwarded to OTSG, HQ TRADOC, interested TRADOC schools and centers, USAMMDA, USAMMA, MACOMS, allies and the other Services. In addition, a copy is forwarded to the Defense Medical Standardization Board (DMSB) for comment on standardization implications. These activities are invited to comment on the draft O&O plan and to attend a scheduled Joint Working Group (JWG) meeting.

3. Convene JWG. A JWG is then convened. Depending on the significance of the system (issues, fiscal, political, etc.) there may be a meeting or there may be only an oral or written consultation. AHS-CD serves as the chairman of the JWG, with USAMMDA serving as the co-chairman. The JWG output is a final draft O&O Plan, which is forwarded to OTSG for validation.

4. Validate/Approve O&O Plan. After OTSG validation, the final draft O&O Plan is forwarded to HQ TRADOC (DCSCD) for approval and distribution. The approved plan is forwarded to HQDA. ODCSOPs circulates it within the Army Staff and Secretariat to determine if the program will be selected to be a Designated Acquisition Program (DAP). Unless specifically designated as a DAP, it becomes an IPR program. Once approved, the O&O Plan constitutes program initiation and supports the Concept Exploration Phase and Demonstration and Validation Phase activities.

The O&O Plan also provides the basis for determining whether a Justification for Major System New Start (JMSNS) is required. The JMSNS is a requirements document that identifies and supports the need for a new or improved mission capability when it may cost more than $200 million in RDTE or $1 billion in procurement, FY 80 dollars. JMSNS must be forwarded from HQDA to the Office of the Secretary of Defense for approval as Major System New Starts. (Refer to AR 71-9).

11.4 CONCEPT EXPLORATION PHASE ACTIVITIES

11.4.1 General Objectives. The O&O Plan provides requirements documentation for the performance of Concept Exploration and Demonstration and Validation activities. However, it is appropriate to ensure that current threat data, operational characteristics, etc., are incorporated in the O&O Plan prior to entry into Demonstration and Validation.

11.4.2 Specific Activities.

SEE CHART 11-1

5. The Concept Exploration Phase Activities are described in Chapter 4.

6. Review/Update O&O Plan. AHS-CD, in coordination with USAMMDA, with input from AHS-Tester, AHS-Trainer and USAMMA, reviews and, if necessary, updates the O&O Plan. Changes which alter the operational characteristics must be approved by HQDA ODCSOPS. AHS and USAMRDC approve all other changes. In the case of a joint program, the JSOR will be prepared for Milestone I. In the case of an NDI or MOD-NDI program, a ROC should be prepared.

7. System Concept Paper (SCP). USAMMDA combines the O&O Plan, updated if necessary, with other program documentation (including an SCP) for use in the Milestone I review. Milestone I approval by the decision authority is considered Concept Approval and authorizes entry into the Demonstration and Validation Phase.

11.5 DEMONSTRATION AND VALIDATION PHASE

11.5.1 General Objectives. During the D&V phase, USAMMDA and AHS prepare the ROC. Approval of the ROC at Milestone II supports the Full Scale Development phase efforts. In the case of a joint program, the JSOR is prepared prior to Milestone II.

11.5.2 Specific Activities.

SEE CHART 11-1

8. Demonstration and Validation Phase. These activities, or their equivalent, for the various acquisition programs are discussed in Chapters 5 through 8.

9. Develop Draft ROC or JSOR. AHS-CD, in coordination with USAMMDA and with input from AHS-Trainer, AHS-Tester, and USAMMA prepares the draft ROC or JSOR.

10. Review Draft ROC or JSOR. The draft ROC or JSOR is then staffed with OTSG, HQ TRADOC, interested TRADOC schools and integrating centers, AHS-Trainer, AHS-Tester, USAMMDA, USAMMA, MACOMS, allies and the other Services. In addition, a copy is forwarded to DMSB for comments on logistics and standardization implications. These activities are invited to comment on the draft and to participate in a JWG.

11. Convene JWG. A JWG is convened to review the results of the staffing of the ROC or JSOR. AHS-CD provides the chairman and USAMMDA provides the co-chairman. Depending on the significance of the program, the JWG may assemble for a meeting or conduct their business by written or oral consultation. The JWG output is a final draft ROC or JSOR.

12. Validate ROC/JSOR Package. The final draft ROC/JSOR is forwarded to OTSG for validation.

13. DCSOPS Approve ROC/JSOR. After OTSG validation, ROCs for DAP systems and all JSORs are forwarded through TRADOC, to ODCSOPS for review and approval. TRADOC includes the ROC/JSOR in the BOIP/QQPRI package and forwards the package to ODCSOPS. AHS and USAMRDC jointly approve ROCs for IPR systems.

14. Publish and Distribute ROC/JSOR. HQ TRADOC (DCSCD) is responsible for publishing and distributing ROCs for IPR systems after OTSG validation, and ROCs for DAP systems and all JSORs after ODCSOPS approval.

15. Decision Coordinating Paper. The approval requirements document is included with other program documentation, such as the Decision Coordinating Paper (DCP), prepared for the Milestone II review. Approval of the program at Milestone II authorizes entry to the Full Scale Development (FSD) phase.

11.6 FULL SCALE DEVELOPMENT PHASE

11.6.1 General Objectives. During the FSD phase, USAMMDA and AHS prepare for the production decision (Milestone III). If necessary, the ROC or JSOR is updated to reflect changes since Milestone II.

11.6.2 Specific Activities.

SEE CHART 11-1

16. Full Scale Development Activities. FSD activities, if appropriate, for each type of acquisition program are discussed in Chapters 5 through 8.

17. Review/Update ROC/JSOR. If there are significant threat, mission deficiency, or technology changes during FSD, the ROC or JSOR is updated. Changes which alter the operational characteristics must be approved by the original approval authority. AHS and USAMRDC approve all other changes.

18. Decision Coordinating Paper. The approval requirements documents are included with other program documentation, such as the Decision Coordinating Paper (DCP), for review at Milestone III. Approval of the program at Milestone III authorizes entry to the Production and Deployment (P&D) Phase.

11.7 REFERENCES

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983
AR 70-1, System Acquisition Policy and Procedures, 1986
AR 71-9, Materiel Requirements, 1986
AR 1000-1, Basic Policies for Systems Acquisition, 1983

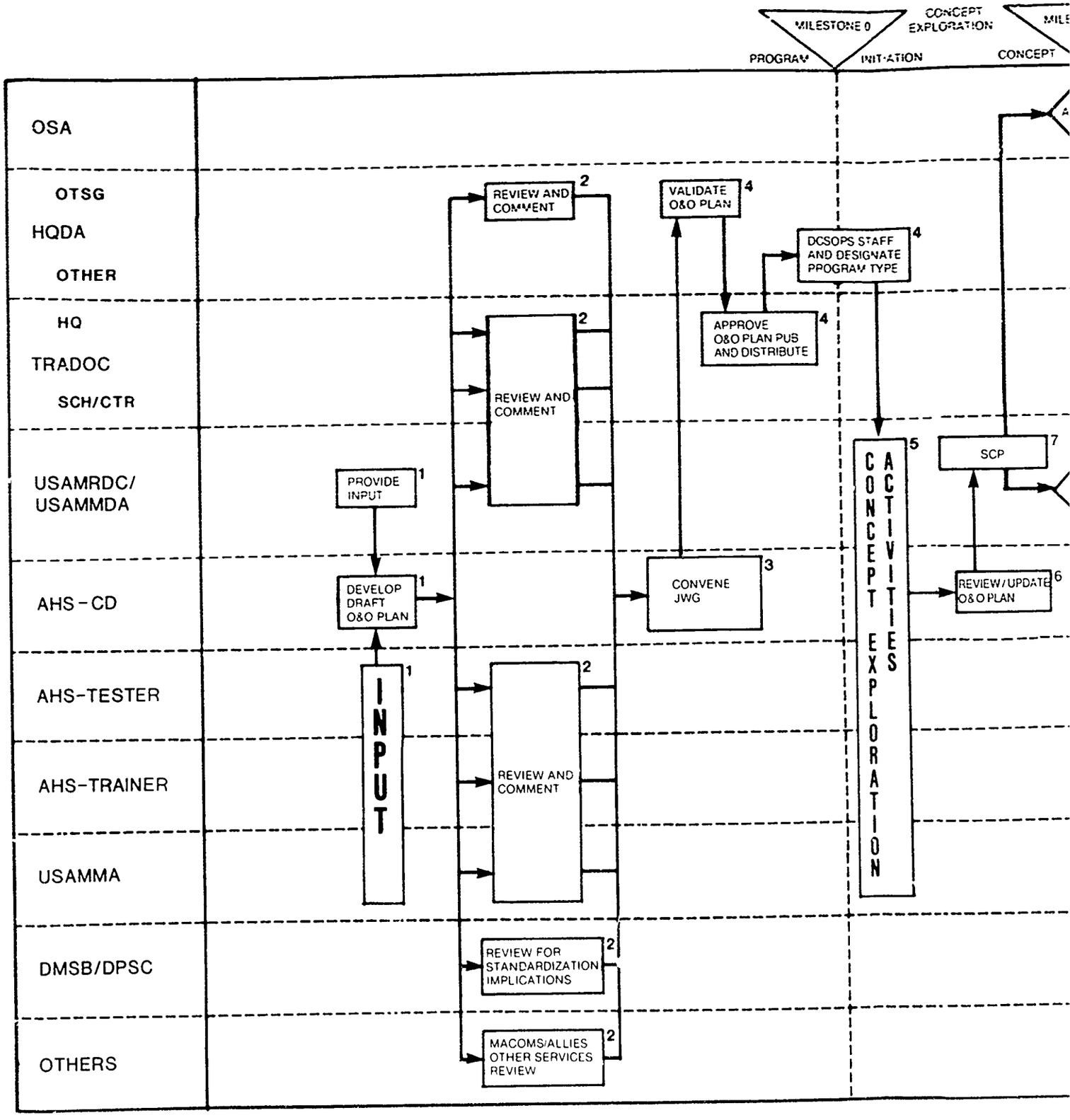
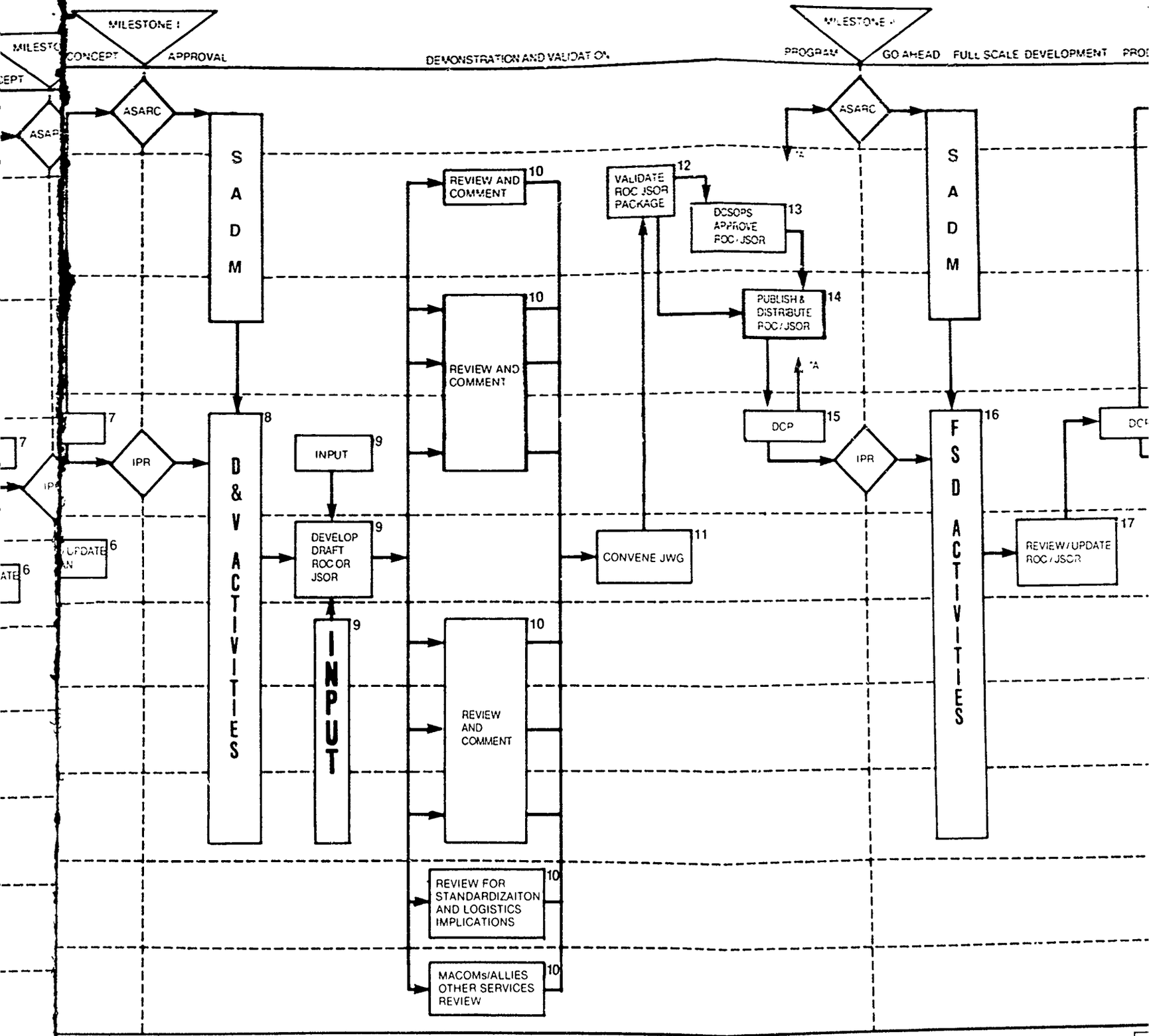


Chart 11-1, THE REQUIREMENTS



NTS DOCUMENT PROCESS

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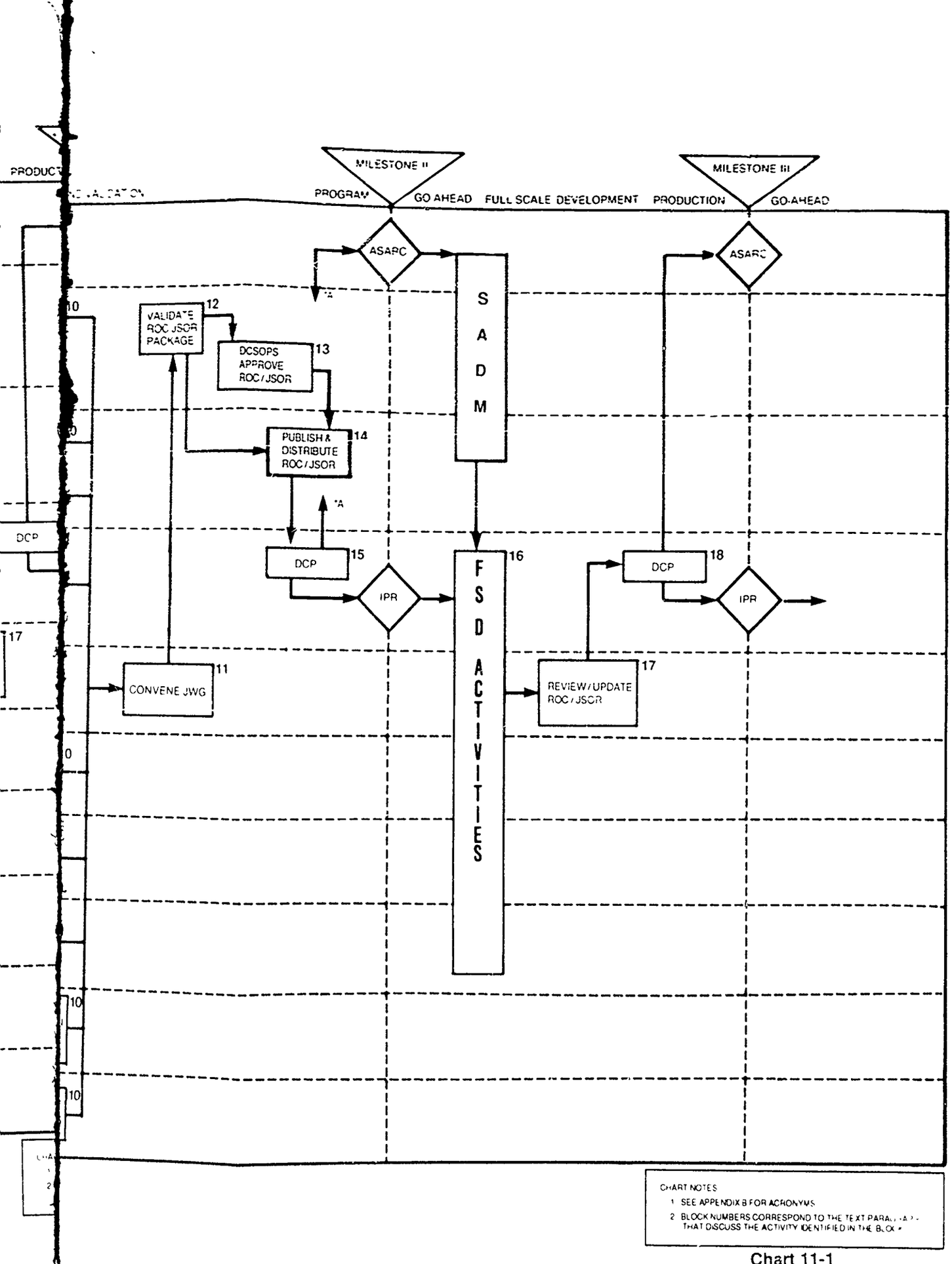


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 11-1

CHAPTER 12

THE MILESTONE DECISION REVIEW PROCESS

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12.1 PURPOSE

This chapter describes the Milestone Decision Review Process (MDRP) and the events, documents, and responsibilities as they apply to medical materiel acquisition programs. Two process flow charts (Charts 12-1 and 12-2) show the events sequence and document flow horizontally by time and vertically by the agency/office responsible for accomplishing the event or processing the document. Chart 12-1 describes the MDRP for IPR programs. Chart 12-2 describes the process for DAP. The two charts are discussed in paragraphs 12.2 and 12.3 respectively.

The MDRP for nondevelopment programs varies from that shown in Charts 12-1 and 12-2. These variations are discussed in Section 12.4. IPRs and ASARCs for Joint Service Programs are discussed in Chapter 23.

12.2 GENERAL

The Medical Materiel Milestone Decision Review Process provides for program reviews at key milestones for all materiel acquisition programs. Each of these milestones is based on the accomplishment of critical events in the acquisition process and is scheduled so that the decisions made can have maximum impact on resources to be expended in subsequent phases.

All medical materiel programs use the milestone management process as well as the normal Planning, Programming, Budgeting, and Execution System (see Chapter 10). The decision milestones that require specific management action before acquisition of the system can continue are:

- Milestone 0, Program Initiation and entry into Concept Exploration;
- Milestone I, Concept Selection and entry into Demonstration and Validation;
- Milestone II, Program Go-Ahead and entry into Full Scale Development;
- Milestone III, Production Go-Ahead and entry into Production and Deployment.

MILESTONE 0, the first decision point, initiates the medical materiel acquisition program and authorizes entry into the Concept Exploration Phase. Preprogram initiation activities culminate in TRADOC's approval of the Operational and Organizational Plan which was prepared by AHS with USAMMDA, USAMMA, TRADOC, and OTSG inputs.

MILESTONE I, the next major decision point, evaluates the System Concept Paper (SCP) and the proposed Acquisition Strategy (AS) and prepares recommendations to the decision authority for entry into the next phase, normally the Demonstration and Validation (D&V) Phase. It provides the authority to develop the system sufficiently to support the next milestone decision. Milestone I decisions establish thresholds and objectives to be met and reviewed at the next milestone, approve the AS and the Test and Evaluation Master Plan (TEMP) for the recommended concept, and set a dollar threshold that cannot be exceeded to carry the program through the next milestone.

MILESTONE II, the next major decision point, is flexible and depends upon the tailored AS approved by the decision authority at Milestone I. This review will be held on completion of the Demonstration and Validation Phase and after the requirements document has been approved. At the minimum, the review will evaluate the Decision Concept Paper (DCP), the AS, and the TEMP. The purpose of this review is to evaluate information obtained during the preceding phases, and to prepare recommendations for the decision authority concerning entry into the next phase, normally the Full Scale Development (FSD) Phase.

MILESTONE III, is the next major decision point. The result should be a production decision and authorization for entry into the Production and Deployment Phase. Type Classification (TC) approval is normally part of the Milestone III decision. The Milestone III decision may be delegated by the decision authority to the lowest level in the organization at which a comprehensive view of the program rests. The review normally follows completion of technical and user tests. Its purpose is to: determine effectiveness; supportability (at all levels, including depot); producibility and production readiness; system safety; and suitability of the system as a result of FSD activities; and to recommend initiation of the Production and Deployment Phase.

NOTE:

AR 70-1 provides examples of the SCP, DCP, and IPS and their annexes.

The MDRP serves as the forum to evaluate the status of the program and to surface critical issues that must be resolved before decisions can be made and appropriate actions recommended to the decision authority. Views of participating agencies are presented and considered. A full interchange of information and freedom to consider and accept other courses of action are essential. Review participants are expected to have sufficient authority to allow evaluation of information presented and to modify their agencies' positions when appropriate. Army Regulations 70-1, System Acquisition Policy and Procedures and 15-14, System Acquisition Review Council Procedures provide primary guidance for the conduct of the MADP.

There are three levels of decision reviews:

- The Joint Requirements and Management Board (JRMB) provides information and recommendations to the Secretary of Defense (SECDEF) when decisions are necessary on Department of Defense (DOD) Major Programs. The Secretary of the Army is a member of the JRMB. The JRMB process is not discussed in this handbook.

- The Army Systems Acquisition Review Council (ASARC) develops the Army's course of action on DOD major programs in preparation for the JRMB review, or develops the basis for decision for the Army Acquisition Executive (AAE) on Designated Acquisition Programs (DAPs). The ASARC is chaired by the Vice Chief of Staff, U.S. Army. This handbook discusses only the latter function of the ASARC.

- The In-Process Review (IPR) makes recommendations to the appropriate decision authority when milestone decisions are required for systems that are In-Process Review (IPR) programs. The IPR is chaired by the Commander, USAMMDA (or the Commander USAMMA for NDI programs).

Decision authorities for medical materiel acquisition programs are:

- The Army Acquisition Executive (AAE) is the decision authority for DAPs.

- The Commander, U.S. Army Medical Research and Development Command and the Commandant, Academy of Health Sciences comprise the joint decision authority for IPR programs.

After a milestone review, the decision authority issues a System Acquisition Decision Memorandum (SADM). The SADM provides the decision authority's approval of goals and thresholds for cost, schedule, performance, and supportability; approval of exceptions to the normal acquisition process; and other directions as appropriate.

12.3 IN-PROCESS REVIEW PROGRAMS

12.3.1 General Objectives. The IPR is a review body convened to evaluate the status of medical materiel acquisition projects and make milestone recommendations to the decision authority. There are three types of IPRs -- formal, special, and informal. All three types of IPRs may be conducted: the formal review when a milestone decision is required; a special review when a major decision is required other than Milestone I, II, and III decisions; and an informal review to review program status and determine an appropriate course of action when a formal decision is not required. The latter two IPRs are tailored to meet the purpose and urgency of the review. Program documentation and participation in special IPRs will follow the general structure for formal IPRs. Program documentation for special reviews will be dictated by the purpose of the IPR. Supporting documentation and invitations to take part will be provided to the same members and observers designated for formal IPRs. This section addresses only the formal milestone decision IPRs.

The IPR is scheduled, coordinated, and chaired by the Commander USAMMDA. Voting members of the IPR are normally USAMMDA, AHS, and USAMMA, but could be the Logistics Evaluation Agency (LEA). When a Joint Service Requirement has been established and formalized by a Joint Service Operational Requirement (JSOR), described in Chapter 23, Joint Service Coordination, participating Services will be invited to participate in the IPR. Non-voting participants are included at the Chairman's discretion and can include representatives from any of the following organizations:

- o OTSG and other HQDA staffs (at their discretion);
- o USAMMDA PM responsible for the product;
- o USAMMDA PMSO;
- o USAMRDC;
- o TRADOC (including schools and integrating centers);
- o USACTA for Test Measurement and Diagnostic Equipment Issues;
- o DA Metric Office;
- o Military Traffic Management Command for Transportability Problems;
- o Human Engineering Laboratory for MANPRINT Issues;
- o AMC (including subordinate commands);
- o PM-TRADE;
- o Defense Medical Standardization Board;
- o Defense Personnel Support Center; and
- o Food and Drug Administration.

The preparation for and conduct of the review requires the examination of the status of all of the acquisition functions. These include: validated requirements; product cost, schedule, and performance; tests conducted and planned; resources and priorities; supportability; and market investigation results.

The review board's recommendations in the form of minutes and a draft System Acquisition Decision Memorandum (SADM) are provided to the decision authorities -- Commander, USAMRDC and Commandant, AHS. The Decision Authority's approval and issuance of the SADM authorizes entry into the next phase of the acquisition process.

12.3.2 Specific Activities

SEE CHART 12-1

1. PM Confirms IPR Date and Proposes Agenda. Each August, the USAMMDA Project Management Support Office (PMSO) prepares a schedule of IPRs for the next fiscal year. Approximately ninety (90) days prior to the date scheduled for his product's IPR, the proponent PM will confirm to the IPR chairman that he will be prepared to meet the IPR requirement. In some cases a USAMMDA Ad Hoc Working Group may be formed to determine the project's status and readiness for an IPR. The PM will also propose an agenda for the IPR, e.g., project status, issues, and alternatives to be presented and discussed at the IPR.

2. Schedule IPR and Notify Participants. The IPR chairman will schedule the IPR and provide written notification not later than seventy-five (75) days prior to the IPR to the members and any non-voting participants (observers) desired. The chairman also approves participation of representatives of organizations and agencies external to USAMMDA as observers or members for a particular agenda.

3. Appoint Members/Identify Participants. USAMMA and AHS appoint the IPR member to represent their command and notify the IPR chairman. Other organizations also identify the personnel who will attend the IPR as observers.

4. PMO Prepare IPR Package. The PMO develops an IPR package for inclusion in a read-ahead package for each IPR member. The IPR package will include the following documents:

- o System Concept Paper (SCP) for Milestone I;
- o Decision Coordinating Paper (DCP) for Milestone II or III;

- o Acquisition Strategy;
- o Updated O&O Plan (if required);
- o Test and Evaluation Master Plan;
- o Approved Requirements Document; and
- o System MANPRINT Management Plan (SMMP).

The IPR package should also provide management summaries and issue papers. The management summaries may cover such subjects as Need and Threat Status, Business and Financial Status, Logistics Status, and Technical Status. Issue papers, one page in length, identify problems, facts pertaining to the problem, issues, and recommendations to the IPR members. Identification of all issues early-on facilitates both the members preparation for the IPR and the conduct of the IPR. In addition, documents related to the unresolved issues should be included in the IPR package. For instance, the Materiel Fielding Plan should be provided if there is an unresolved fielding issue.

> NOTE:
>
> USAMMDA Memo 70-20, In-Process Reviews, contains examples of IPR Package documents.

5. Distribute the IPR Package and Tentative Agenda. The IPR package is distributed to the IPR members not later than forty-five (45) days prior to the scheduled IPR. According to the Milestone being reviewed, the nature of the product, and based on the anticipated issues, a tentative agenda is prepared, approved by the chairman, and distributed with the IPR package to the IPR members and observers.

6. Provide Position Statement. Upon receipt of the IPR read-ahead package and the tentative agenda, USAMMA and AHS prepare command position papers for the Chairman. The IPR members are encouraged to initiate contact with the PMO in order to resolve problems and clear up uncertainties. Command positions should be provided to the chairman not later than two weeks prior to the IPR.

7. PM Prepare Draft SADM. The PM prepares a draft SADM for the IPR chairman. Within two weeks of the IPR, the PM will also provide the chairman with any major change in product status or issues not previously identified in the IPR package.

8. Consolidate Issues, Publish Agenda, and Arrange Conference. USAMMDA has approximately one week to consolidate the IPR issues, prepare the agenda, notify all participants, and make all of the conference administrative arrangements.

9. Chairman Approves Agenda and SADM and Conducts IPR. The agenda and the draft SADM, together with the members position papers, are provided to the chairman. If it is apparent that there are unresolved issues and/or the PM or others have provided major changes in product status or identified new issues, the chairman will conduct the review as scheduled. The PM briefs the IPR in accordance with the approved agenda. At the chairman's discretion, and based on the issues, others may also be required to brief the IPR, e.g., combat developer, trainer, logistician, and tester.

> NOTE:
>
> The DA Handbook, Briefing the ASARC, contains useful guidance for user, developer, and tester briefings as well as briefing guidelines.

10. IPR Cancelled. If the members have provided concurrence statements and there are no issues to be resolved, the chairman may cancel the IPR (or delete the product from the agenda if there are other products being reviewed

by the IPR). The members unconditional concurrences with the PM recommendations are forwarded by letter of transmittal to the Commander, USAMRDC. Information copies are forwarded to all participants.

11. Prepare Minutes. The official minutes of the IPR are prepared by USAMMDA, signed by the IPR members and the Commander, distributed to the IPR members, and forwarded with the draft SADM, SCP/DCP/IPS, and requirements document, to the Commander, USAMRDC within two days after the IPR.

12. Approve IPR Minutes and SADM. The Commander, USAMRDC and the Commandant, AHS approve the IPR minutes and the SADM and return both documents to USAMMDA. This action should be accomplished within 12 days of their receipt at USAMRDC and HSC in order that there is minimum delay in executing the decision authority's guidance. In the case of the Milestone III review, Type Classification (TC) will also be specifically approved by USAMRDC and HSC then forwarded to OTSG for validation. For NDI programs TC recommendations are forwarded by USAMMA to OTSG for approval.

13. Reconcile IPR Issues. If the IPR members fail to reach a unanimous agreement, the decision authority forwards the minutes and draft SADM to OTSG for resolution. USAMMDA, AHS, and USAMMA should anticipate the requirement to brief OTSG on the disputed issues. Following resolution of the issues, TSG will provide an addendum to the IPR minutes and revise (if necessary) and sign the SADM. These documents will be returned to USAMMDA for distribution and subsequent action. In the case of a Milestone III review, OTSG also validates the TC action.

14. Distribute Minutes to Participants. USAMMDA distributes the minutes and the SADM to the IPR participants. A copy of the SADM is also sent to HQDA (ODCSRDA) for information.

15. Continue the Program and Coordinate Follow-Up Actions. Upon receipt of the approved minutes, the PMO has the authority to continue the program as directed. PMOs are responsible for recording the IPR results in the Materiel

Status Record and tracking and ensuring completion of follow-on actions required by the decision authority. Follow-on action requirements will be coordinated with the other materiel acquisition participants as necessary.

12.4 MILESTONE DECISION REVIEWS FOR OTHER PROGRAMS

12.4.1 Nondevelopment Programs. These programs normally require only two reviews -- Milestone I and Milestone III (see Chapter 6). The preparation for and conduct of these reviews is similar to those activities described in Sections 12.2 and 12.3 for the development program. However, at Milestone III, the Commander, USAMMA chairs the IPR.

12.4.2 Modified Nondevelopment Programs. These programs may require only two reviews -- Milestone I, Program Go-Ahead and Milestone III, Production Go-Ahead (see Chapter 7). The preparation for and conduct of these reviews is similar to those activities described in Sections 12.2 and 12.3 for the development program. The Commander, USAMMDA is responsible for both the Milestone I and the Milestone III reviews.

12.4.3 Product Improvement Programs. These programs require a Milestone III review and production/procurement decision at the end of the Engineering Phase. The review is the responsibility of the Commander, USAMMDA (see Chapter 8, Product Improvement Program).

12.5 DESIGNATED ACQUISITION PROGRAMS

12.5.1 General Objectives. The Designated Acquisition Program (DAP) is reviewed by the Army Systems Acquisition Review Council (ASARC). The ASARC is chaired by the Vice Chief of Staff, U.S. Army (VCSA). The members of the ASARC are designated officials of the Army Staff, Army Secretariat, major commands and agencies. A complete listing of ASARC members is provided in AR 15-14, Systems Acquisition Review Council Procedures.

The three types of ASARC meetings are:

- o Milestone Decision Review (MDR) - a decision meeting to arrive at a recommendation to the Army Acquisition Executive to proceed to the next phase in the materiel acquisition cycle.
- o DA Program Review - a decision meeting of the ASARC for a reason other than a MDR.
- o Functional Area Information Briefing - an information briefing on generic or a family of related systems, e.g., night vision devices.

The ASARC reviews and recommends appropriate action to the AAE, the approval authority for decision. At the ASARC, emphasis is placed on face-to-face discussions of critical program issues leading to an Army position. Decisions/guidance provided will be reflected in revisions to the SCP or DCP to form the Program Directive Document (PDD) which is the authorized program baseline.

The Deputy Chief of Staff for Research, Development, and Acquisition (DCSRDA) exercises general staff responsibility for coordinating preparation for all ASARC reviews. The DCSRDA has appointed a permanent Executive Secretary of the ASARC from the Systems Review and Analysis Office (SRAO). The Executive Secretary is responsible to the VCSA and the ASA (RDA) for ASARC administrative matters. His other responsibilities include (See AR 15-14 for a complete listing):

- o Prepare and publish an ASARC guidance directive containing a coordinated plan of action before each scheduled ASARC meeting. The plan will detail the responsibilities and tasks necessary to prepare for the MDR;
- o Review those staff and field actions required before the ASARC MDR and coordinate with the Ad Hoc Working Group;
- o Coordinate all presentations to the ASARC;
- o Prepare the minutes for each meeting for VCSA approval;
- o Based on the decisions of the ASARC, revise and staff the SCP/DCP/IPS to form the PDD.

12.5.2 Specific Activities

SEE CHART 12-2

1. Notify OTSG of ASARC Requirement. Approximately twelve (12) months prior to the scheduled ASARC date, USAMRDC will inform OTSG that a program will be prepared for the review as scheduled. A USAMMDA Ad Hoc Working Group may be formed to evaluate the status of the program and its readiness for the ASARC and direct the PM to resolve problems as appropriate. The OTSG (SGRD-RDZ) will be requested to initiate coordination with the ASARC Executive Secretary.

2. Conduct Milestone Planning Meeting and Establish the Ad Hoc Working Group. The ASARC Ad Hoc Working Group (AHWG) will be established by the Systems Review and Analysis Office, ODCSRDA in coordination with the DASC at the OTSG. The AHWG normally consists of representatives from the Army and Secretariat Staffs, USAMMDA, AHS, OTEA, MTMC, HQ TRADOC and others as appropriate. The AHWG will meet as required over a period of eight (8) to twelve (12) months. One of its first actions is to prepare a plan of action leading to the ASARC date. The AHWG develops a comprehensive plan and schedule of events to prepare the program for the ASARC review; determine if all DA requirements for the ASARC MDR are met; generally review documents and activities within the members functional areas; resolve minor issues; assist in the drafting and revision of SCP/DCP/IPS; and assist in administrative requirements in preparing for the ASARC.

3. ASARC Executive Secretary Publish Guidance. The ASARC Executive Secretary publishes an ASARC guidance directive which includes the coordinated plan of action for the ASARC meeting prepared by the AHWG. The plan details the responsibilities and tasks necessary to prepare for the ASARC MDR. It assigns briefing responsibilities, topics for consideration, required documentation and issues for resolution that may be required in the briefing.

4. Conduct Program Review. USAMMDA, AHS, USAMMA, and others, as necessary, conduct a review of the program much like the IPR discussed earlier in this chapter. The review should follow the ASARC guidance, the ASARC AHWG plan and schedule, and the requirements for the specific milestone review and entry into the next acquisition phase. This in-house review normally takes place seven (7) to ten (10) months prior to the ASARC.

5. Recommended AMEDD Position. Based on the results of the program review, the Commander, USAMMDA forwards a recommended position on the program status and issues through the Commander, USAMRDC to OTSG.

6. Brief OTSG. The PM, PMSO, AHS, USAMMA and others as required can expect to be required to brief the program to OTSG.

7. Establish AMEDD Position. The Surgeon General establishes the AMEDD position which then serves to guide all participants in their preparations for the Preliminary Review and the ASARC.

8. AHWG Meetings. The AHWG will meet as dictated by the complexity of the program, the number of issues and controversies, and the program's position in the acquisition cycle. The PM and other program principals can expect to be involved in a requirement for almost continuous coordination with the OSA and DA staffs in addition to the AHWG meetings. Beginning approximately three months prior to the scheduled ASARC, program documentation must be provided to HQDA for review. Figure 12-i lists the minimum documentation requirements and their schedules.

Other documents may be required according to the issues, the nature of the product, and the milestone being reviewed. Documents are provided and briefings are scheduled and coordinated by the OTSG (DASC) with the ASARC Executive Secretary.

Document/Event	Schedule (Before ASARC)
Draft SCP/DCP/IPS to HQDA	3 Months
Draft TEMP to HQDA	3 Months
Draft SI Plan to HQDA	3 Months
Risk Analysis to HQDA	2 Months
HFEA to HQDA	2 Months
Safety Risk Assessment to HQDA	2 Months
COEA to HQDA	2 Months
Production Readiness Report	2 Months
Preliminary Cost Analysis Brief	6 Weeks
DT/OT Test Reports and IERs to HQDA	1 Month
ILS Review at HQDA	1 Month
Final Cost Analysis Brief	12 Work Days

Figure 12-1 Pre-ASARC Requirements

9. Preliminary Review. A Preliminary Review (PR) is normally held two (2) to four (4) weeks before an ASARC meeting. The purpose of the PR is to: a) ensure that there has been adequate preparation for the ASARC; b) review and identify all outstanding program issues; c) resolve minor issues; d) select and clearly define major issues to be presented to the ASARC; and e) determine the ASARC agenda.

NOTE:

Briefers will prebrief their positions to OTSG before the PR.

The PR is a two-star level system review chaired by the Assistant DCSRDA, or in his absence, the Director, Systems Review and Analysis Office. The attendees are representatives of the designated members of the ASARC. The Executive Secretary will provide each attendee copies of all available relevant information prior to the PR.

The PR agenda is prepared by the ASARC Executive Secretary. Normally it will be structured to allow the Army Staff and other activities/agencies, as required, to present studies, analyses, or positions on issues in their areas of interest. Transportability, MANPRINT, ILS, testing, cost effectiveness/affordability and system safety will be specifically addressed at a PR. The PM and AHS briefer will tailor their briefings to ensure that the critical issues are clearly presented. Additional briefers may be designated by the chairman.

The ASARC agenda is determined at the PR. Agenda items for each review will vary with the milestone being addressed, the system being presented, and the issues involved. Figure 12-2 presents a typical ASARC MDR agenda.

The AHS briefing will focus on the critical issues related to the system requirement. It must clearly demonstrate the requirement for the system and clarify the role of the system in relation to other existing or developing systems that compete for funds. User issues, including training and user testing, will be presented if they are determined to be critical at the PR.

The PM briefing is primarily a description of the issues related to alternatives for the future of the program. Acquisition strategy, schedule, and costs must be addressed. The briefing should demonstrate, as applicable, consideration of competition; preplanned product improvement; producibility; design to cost; power requirements; front end funding; or whatever the areas that may be required by the ASARC guidance. Developer issues determined by the PR to be critical will also be presented.

NOTE:

Refer to DA Handbook, Briefing the ASARC, for useful guidance and tips.

Agenda Item	Responsible Agency	Time (Minutes)
Introduction	ODCSRDA	5
User Brief Requirement (Key User Issues)	AHS	20
Developer Brief Update Accomplishments Acquisition Strategy Schedule Costs System Safety (Key Issues)	PM	20
Tester Brief (If Critical Issues)	OTEA	15
Others	As Designated	5 - 12 each brief
Discussion	Chairman	40

Figure 12-2. ASARC Agenda

10. Chair ASARC. The VCSA chairs the ASARC. The Executive Secretary prepares the minutes, recording the recommendations of the ASARC and any dissenting views. The minutes are coordinated with the OTSG DASC and then forwarded to the VCSA for approval. On approval, the decision/guidance of the ASARC will be incorporated in the Program Directive Document to provide the authorized program baseline for implementation. The approved minutes and a draft SADM are forwarded to the Secretary of the Army through the decision authority. The Secretary of the Army signs and issues the SADM.

11. Continue Approved Program and Coordinate Follow-On Actions. Receipt of the signed SADM provides the PM with authority to enter the next acquisition phase. In some cases conditions may have to be met prior to proceeding to the next phase. If follow-on actions are required, they are coordinated by the PM.

Figure 12-3 summaries the MDRP for medical materiel acquisition programs.

	DEVELOPMENT PROGRAMS AND MOD NDI PROGRAMS	NDI PROGRAMS
IN-PROCESS REVIEW		
Chairman:	Cdr, USAMMDA	Cdr, USAMMA
Decision Authority:	Cdrs, USAMRDC and AHS	Director, Health Care Operations, OTSG
Voting Members:	AHS USAMMA USAMMDA	AHS USAMMA USAMMDA
Conflict Resolution:	TSG	TSG
DESIGNATED ACQUISITION PROGRAM		
Chairman:	VCSA	VCSA
Decision Authority:	AAE	AAE
Voting Members:	ASARC	ASARC

Figure 12-3. Summary of the Medical Materiel MDRP

12.6 REFERENCES

AR 15-14, Systems Acquisition Review Council Procedures, 1986

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

AR 70-1, Systems Acquisition Policy and Procedures, 1986

AR 70-6, Type Classification of Army Materiel, 1985

AR 70-17, System/Program/Project/Product Management, 1976

AR 71-9, Materiel Requirements, 1986

AR 1000-1, Basic Policies for System Acquisition, 1983

DA Circular 700-85-1, Materiel Release for Issue, 1985

DA Guide for PM, TSM and Other Briefers, Briefing the ASARC, 1985

USAMMDA Memo 70-20, In Process Reviews, 1985

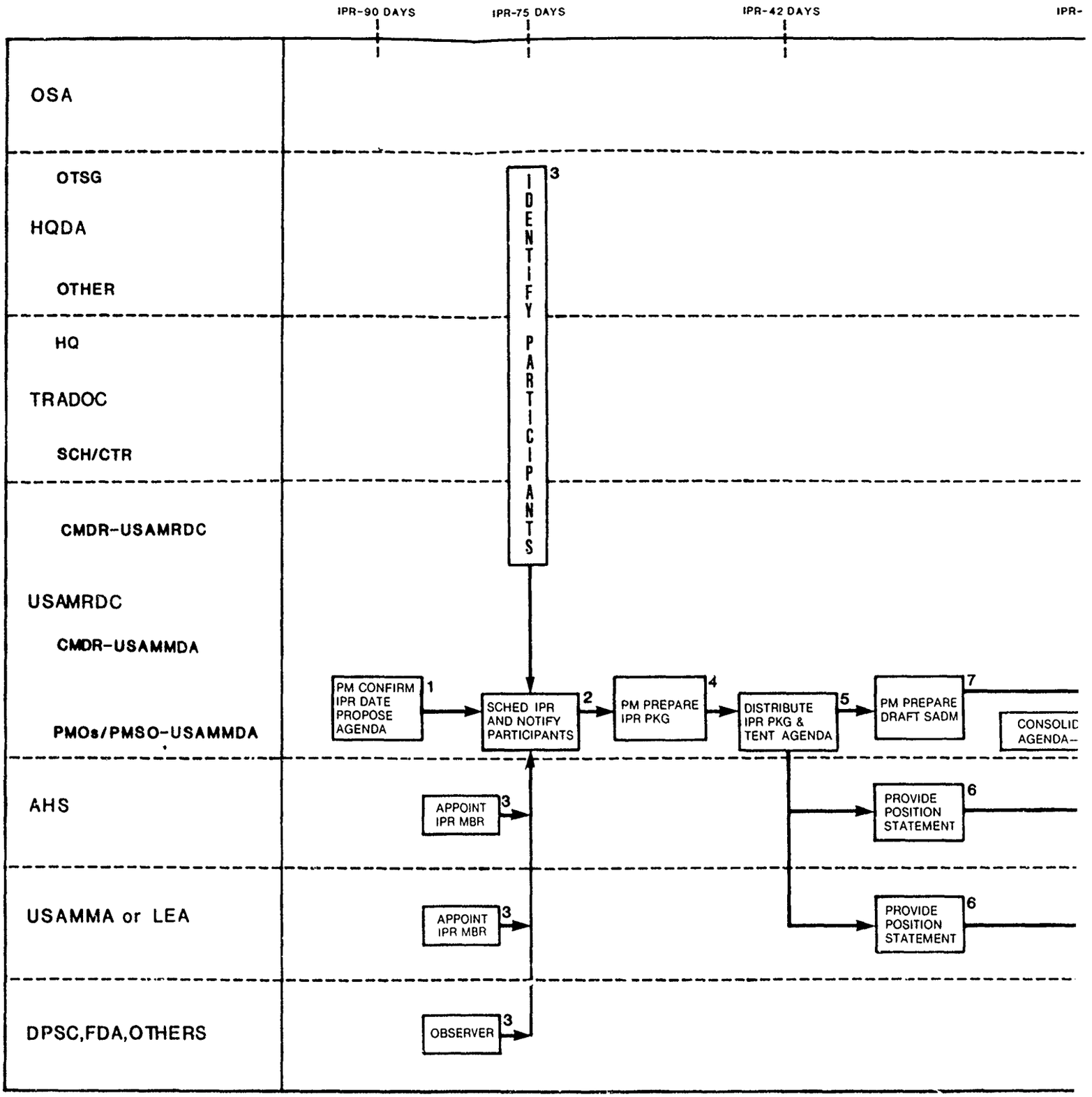


Chart 12-1, THE MILESTONE DECISION REVIEW

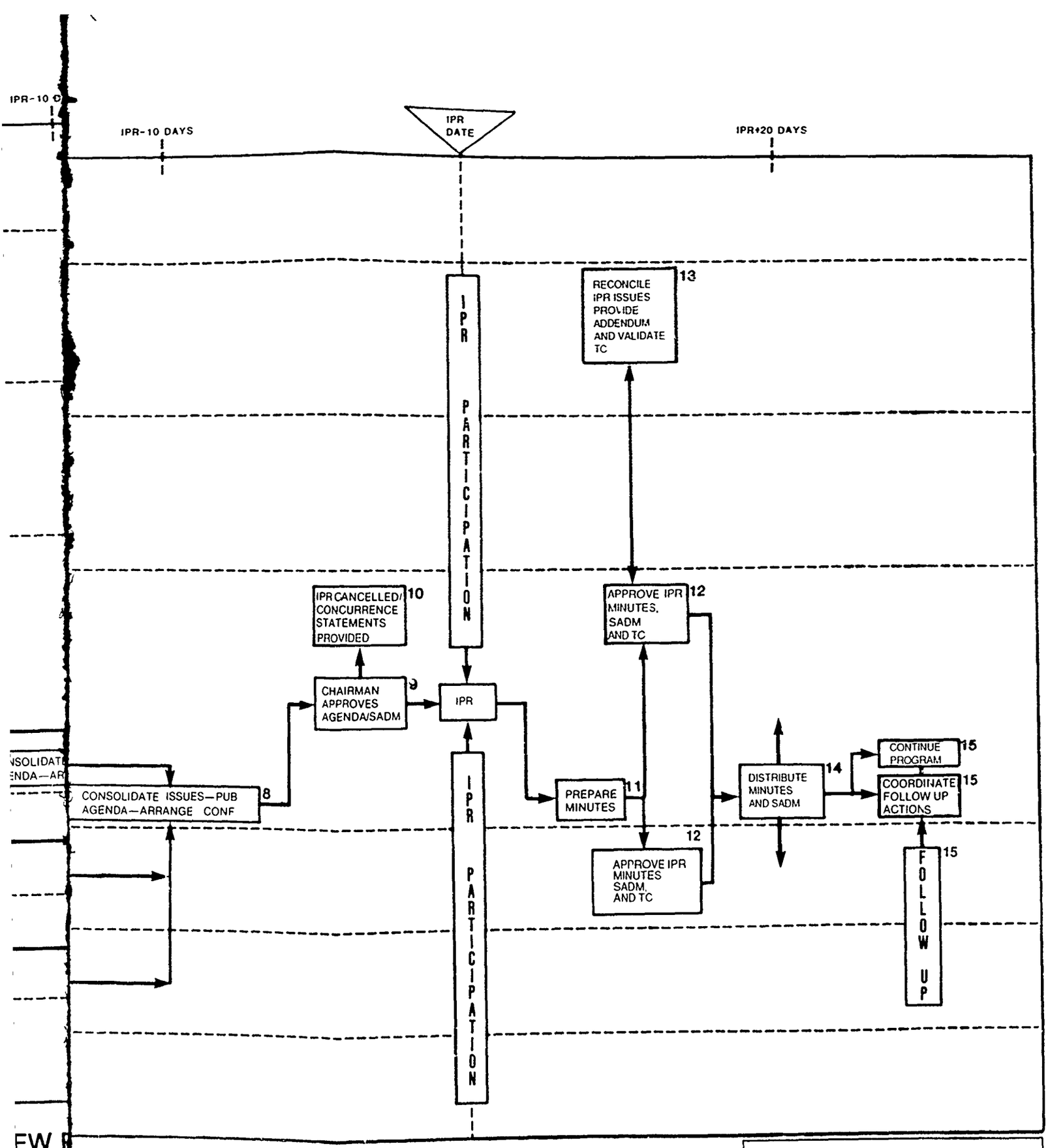


CHART NOTES

1 SEE APPENDIX B FOR ACRONYMS

2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

VIEW PROCESS – IPR PROGRAMS

Chart 12-1

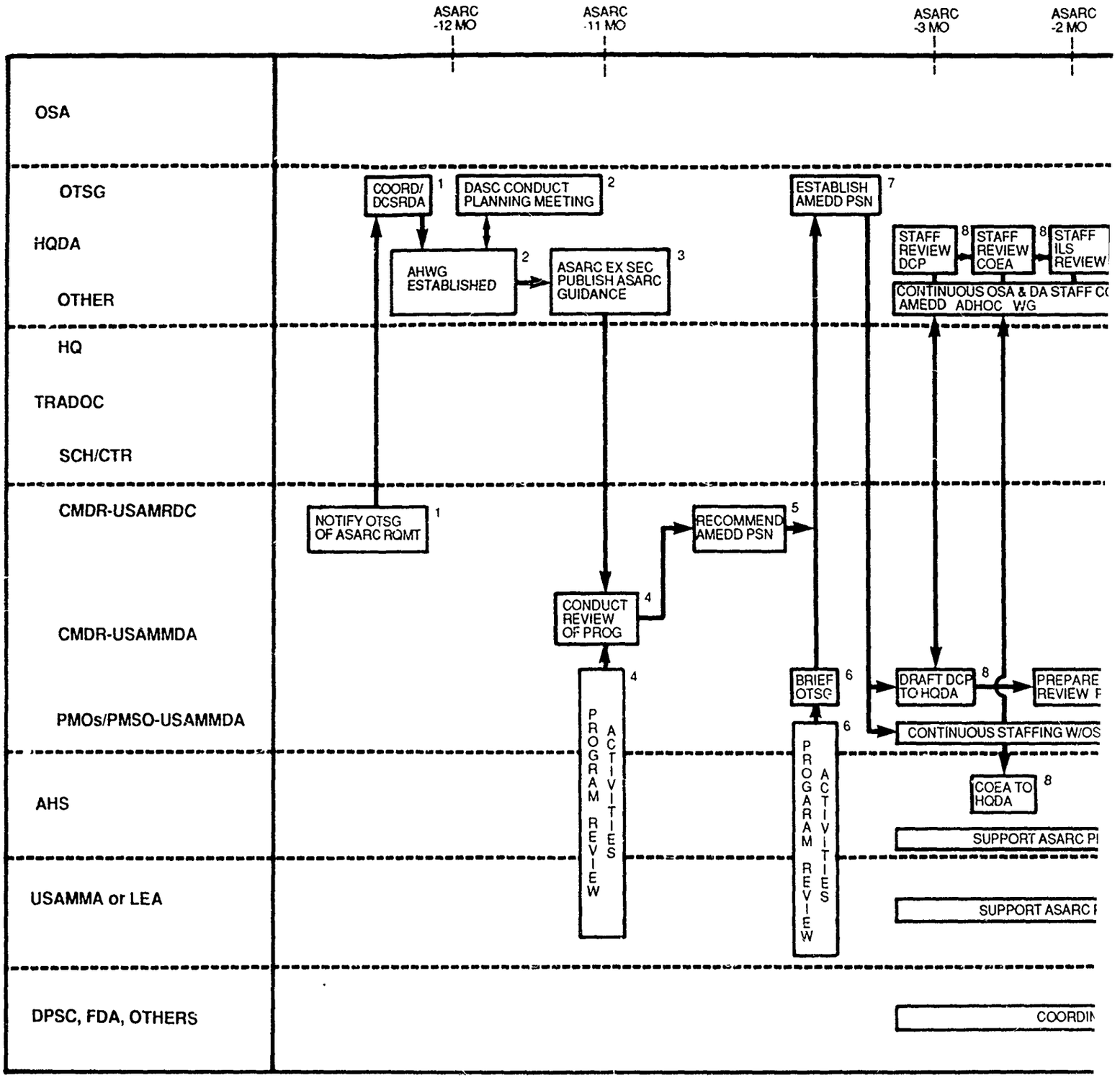
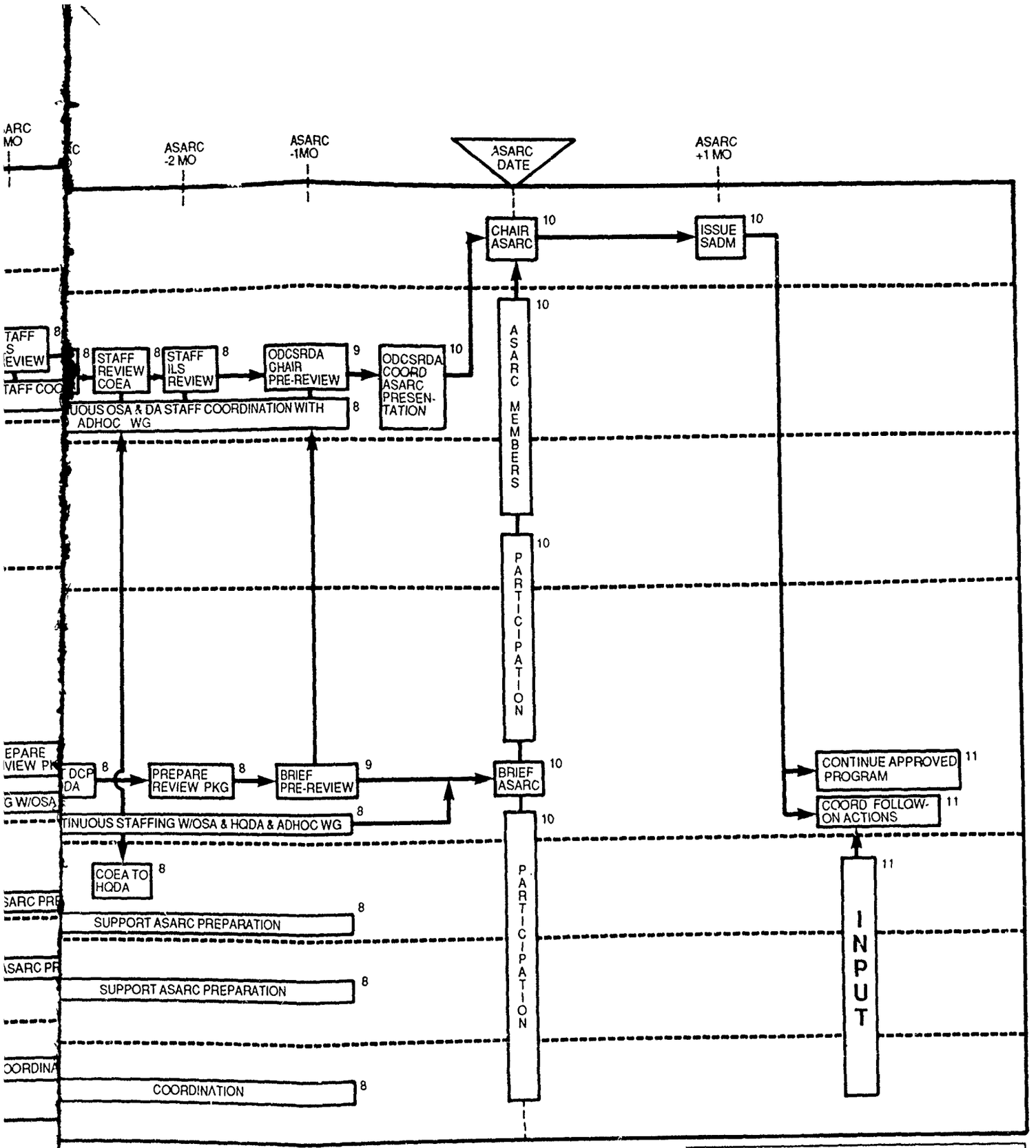


Chart 12-2, THE MILESTONE DECISIO



NE DECISION REVIEW PROCESS - DAP

CHART NOTES

1 SEE APPENDIX B FOR ACRONYMS

2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 12-2

CHAPTER 13

THE CONCEPT FORMULATION PACKAGE

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13.1 PURPOSE

This chapter describes the activities associated with developing the Concept Formulation Package (CFP) for an In-Process Review (IPR) program in preparation for a Milestone I decision. A Designated Acquisition Program (DAP), requiring an ASARC, demands a more extensive process. For example, it is not anticipated that a Special Study Group (SSG) or a Special Task Force (STF) will normally be required in developing a CFP for an IPR program, but either one may be required for a DAP.

13.2 GENERAL

The Concept Formulation Package is completed prior to Milestone I. It summarizes the results of efforts conducted during Concept Exploration, establishes the technical and economic specifications for a product, and provides input for developing the System Concept Paper (SCP). The CFP consists of four documents: a Trade-Off Determination (TOD), a Trade-off Analysis (TOA), a Best Technical Approach (BTA), and a Cost Effectiveness Analyses (CEA). The CEA is the most critical of the four documents, and requires inputs from the other three. Overall responsibility for initiating and assembling the CFP lies with the Academy of Health Sciences, Directorate of Combat Developments (AHS-CD). In certain instances, such as large, high interest programs, a Special Study Group (SSG) or Special Task Force (STF), may be formed to plan, coordinate, and conduct some or all of the CFP activities. The format for the CFP is given in full in Appendix H of AR 71-9. Each of the components of the CFP will be discussed in the order shown on Chart 13-1, a fold-out chart at the end of this chapter.

13.3 SPECIFIC ACTIVITIES

SEE CHART 13-1

1. Initiation of the CFP. Following approval of the O&O Plan by TRADOC, the AHS-CD takes the lead in developing the CFP, and provides guidance to USAMMDA for preparation of the first three documents (TOD, TOA, and BTA).

2. Prepare Trade Off Determination. The Trade Off Determination (TOD) is prepared by USAMMDA based on guidance from AHS-CD with input from USAMMA. The TOD identifies the feasible approaches, including the results of a market investigation conducted by USAMMDA. It also provides a Life Cycle Cost (LCC) estimate for each approach to determine whether the approaches fall within an affordable funding profile. The TOD addresses only technical and funding considerations, it does not address the operational aspects of the system. It provides the following information based on results of activities conducted during Concept Exploration:

- Individual technical approaches considering product improvement and procurement of nondevelopment items as alternatives to new development;
- Evidence that the proposed technical approach is an engineering one rather than an experimental one, e.g., the technology is in hand;
- Identification of the technical risks associated with the proposed approach;
- Trade-offs for the suggested technical approach;
- LCC and schedule estimates of each approach as related to acquisition of the item;
- The recommended technical approach (included in the technical approach are technical analysis of risks); trade-offs; capabilities needed; costs; schedules; ILS requirements; estimated total manpower requirements; health hazard assessment; safety, and human factors engineering requirements; and environmental and ecological factors).

3. Prepare Trade Off Analysis. The Trade-Off Analysis (TOA) is prepared jointly by USAMMDA and AHS-CD with logistics related inputs provided by USAMMA. The TOA looks at the approaches identified in the TOD in light of the mission and performance envelopes in which they will be required to operate. This scrutiny is necessary in order to identify the best approach in filling

the operational requirement. The TOA provides the following information based on other documents such as the Threat Assessment and the System MANPRINT Management Plan (SMMP), conducted during Concept Exploration:

- Mission and performance envelopes with justification and rationale;
- Analysis of system trade offs, risks, capabilities, estimated total costs, schedules and logistic support;
- Selection of the best approach from an operational and ILS aspect;
- Establishment of environmental and ecological factors, health hazard assessment, safety and human factors engineering requirements that the Army must address in fielding the system.

4. Prepare Best Technical Approach. The Best Technical Approach (BTA), like the TOA, is prepared jointly by USAMMDA and AHS-CD with logistic related inputs provided by USAMMA. The BTA looks at the recommendation of the TOD and TOA, and the results of other Concept Exploration Activities and describes the recommended BTA and ILS concept. It provides a more detailed breakdown of funding estimates by category, e.g., Research, Development, Test and Evaluation (RDTE); Operations and Maintenance Army (OMA); Procurement Army (PA); and Military Construction (MILCON). It gives the following information derived from activities conducted during Concept Exploration:

- Description of the BTA and ILS concept based on the results of the TOD and TOA;
- Evidence that the proposed BTA is engineering rather than experimental;
- Estimated cost (RDTE, OMA, and Military Construction Appropriation), total Army manpower requirements, procurement, and scheduling estimates;
- Appropriate supporting environmental documentation.

Following finalization of the BTA, AHS-CD updates the initial O&O Plan, AHS-Trainer prepares the Individual and Collective Training Plan (ICTP), and USAMMDA prepares the Integrated Logistic Support Plan. The BTA provides information for developing other related plans and studies.

5. Prepare Cost and Training Effectiveness Analysis. A Cost and Training Effectiveness Analysis (CTEA) is the responsibility of AHS-Trainer, and may be required in support of the Cost and Effectiveness Analysis (CEA) to compare alternative training programs for a developing system. The CTEA will address: the type of training, whether organic or contractor; the location of training; the requirement for training devices; training publications; and the need, composition, and deployment schedule of a New Equipment Training Team. The CTEA will be an input to the initial CEA and each update. CTEA studies in support of the CEA provide the basis for:

- Comparing the cost effectiveness levels of various training subsystem alternatives;
- Selecting the training subsystem alternative which best supports and minimizes the costs associated with the Army's training mission;
- Providing training subsystem data inputs for consideration at required decision points during the acquisition cycle.

6. Prepare Cost Effectiveness Analysis. A Cost Effectiveness Analysis is a documented investigation of the comparative effectiveness of alternative means of meeting a requirement by eliminating or reducing a force or mission deficiency against a defined threat, and by optimizing the cost of developing, producing, distributing, and sustaining each alternative system in a military environment for a time preceding the combat application. A CEA may be either a Cost and Operational Effectiveness Analysis (COEA), for DOD major programs and DAPs, or an Abbreviated Analysis (AA) for IPR programs.

The COEA/AA is conducted by AHS-CD and is an evaluation of the combat effectiveness of a system as part of a force. As shown on Chart 13-1 the COEA, or the AA in the case of an IPR program, is the final step in the CFP

process. The Milestone I COEA/AA is performed to narrow the list of alternatives to those most preferred. The COEA/AA looks at the overall information available to determine whether or not the cost of the program justifies the anticipated benefits. USAMMA provides the logistic cost estimates and supporting documentation; USAMMDA provides and/or arranges for RDTE and production cost estimates, as well as any MILCON requirements. It is important that each section of the CFP be as thoroughly executed as possible in the sequence described. The omission of any element in the development sequence transfers the burden for that part of the overall evaluation to the following portion of the CFP. In addition to the TOD, TOA and BTA, inputs for preparation of the COEA/AA include the various plans prepared during Concept Exploration.

The COEA/AA determines the contribution of the candidate system to improving the unit's ability to discharge its mission; it assesses the cost of the system to accomplish this improvement; and it provides decision makers with information to evaluate the benefits anticipated from its use in the operational scenario. For medical systems, benefits are usually expressed in terms of reduction in lives lost, number of man days saved, or reduction in time hospitalized. During preparation of the COEA/AA, it may appear that the cost, schedule, manpower requirement, or some other issue puts the continued development of the proposed system in question. If this occurs, a special IPR will be called by the Commander, USAMMDA, to determine whether to proceed with, modify, or cancel, the approach being taken.

The AA, which is used for IPR programs, is much simpler than the COEA. It will frequently consist of cost performance relationships for only the most important system parameters performed in-house by the proponent agency using limited manpower and resources. The AA will normally not exceed five pages.

As a rule, the Milestone I COEA/AA will be updated at Milestone II or III if significant changes have occurred in the mission, threat, technology, or alternatives. Costs will be updated for each milestone. AHS-CD will review

previous COEA/AAs and other studies and make recommendations to TSG. TSG will make the final decision based on the AHS-CD's recommendation and other available information.

7. Assemble Concept Formulation Package. The AHS-CD assembles the TOD, TOA, BTA and COEA/AA into the proper CFP format required by AR 71-9, and forwards it to USAMMDA for incorporation into the System Concept Paper (SCP). A cover letter is prepared which includes:

- An introduction that describes the purpose of the package, how it is organized, the objectives of concept formulation, and the effort needed to meet objectives;
- A description of the system setting forth the logistic support concept, LCC and manpower requirement estimates, and the reliability availability, and maintainability requirements;
- Need and limitations that affect results and conclusions provided in the appendices;
- Brief summaries of conclusions, key unresolved problems, and prospects of solution.

8. Prepare System Concept Paper. The CFP provides information which is needed to develop the System Concept Paper for the Milestone I decision review. A similar input would be provided to the Decision Coordinating Paper which is required for a Milestone II or III decision review.

13.4 REFERENCES

DODD 5000.1, Major Systems Acquisition, 1986
DODI 5000.2, Major System Acquisition Procedures, 1986
AR 1000-1, Basic Policies for Systems Acquisitions, 1983
AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983
AR 70-1, System Acquisition Policy and Procedures, 1986
AR 71-9, Materiel Requirements, 1986
AR 11-28, Economic Analysis, 1975
AR 11-18, Cost Analysis Program, 1976

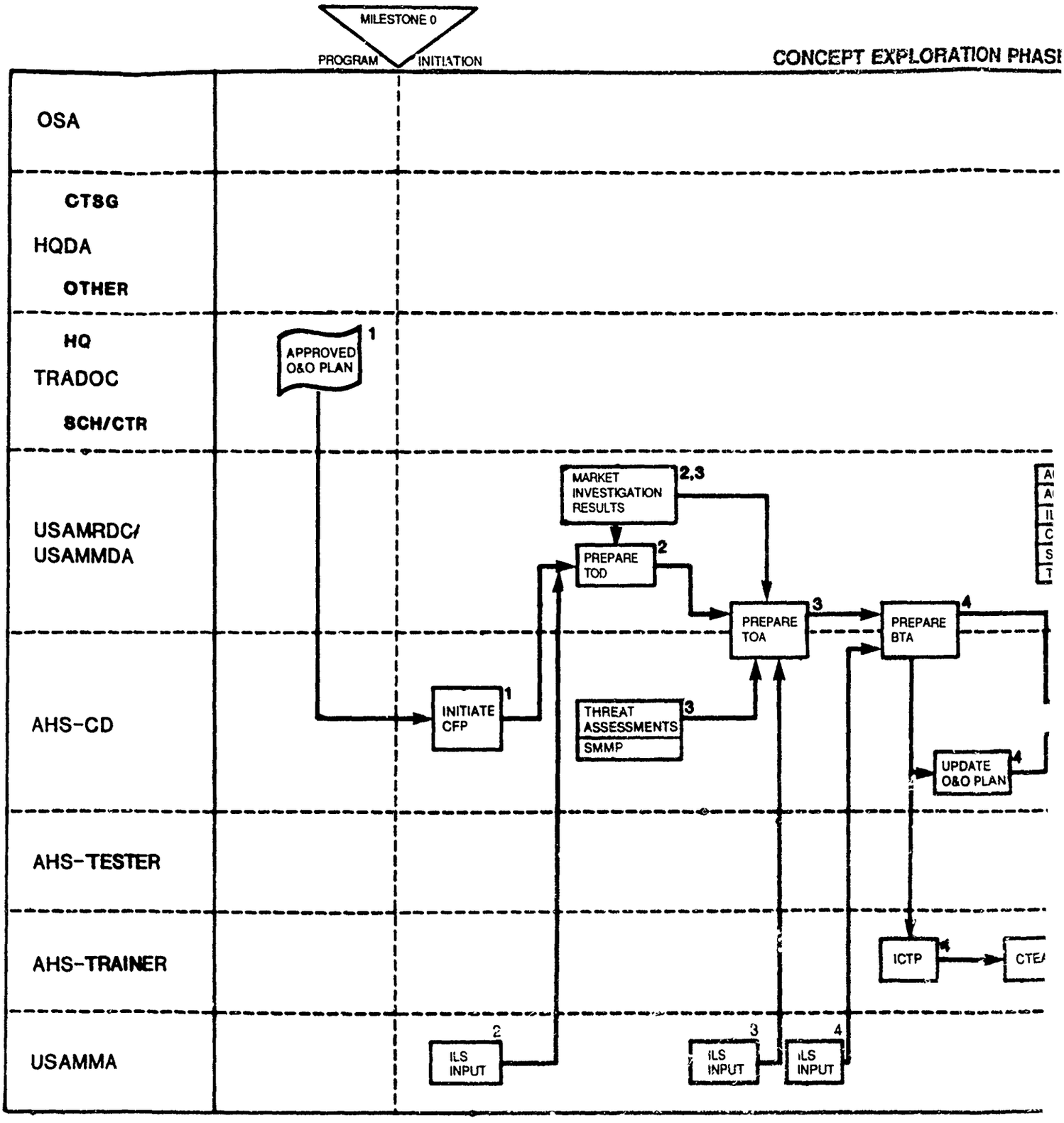
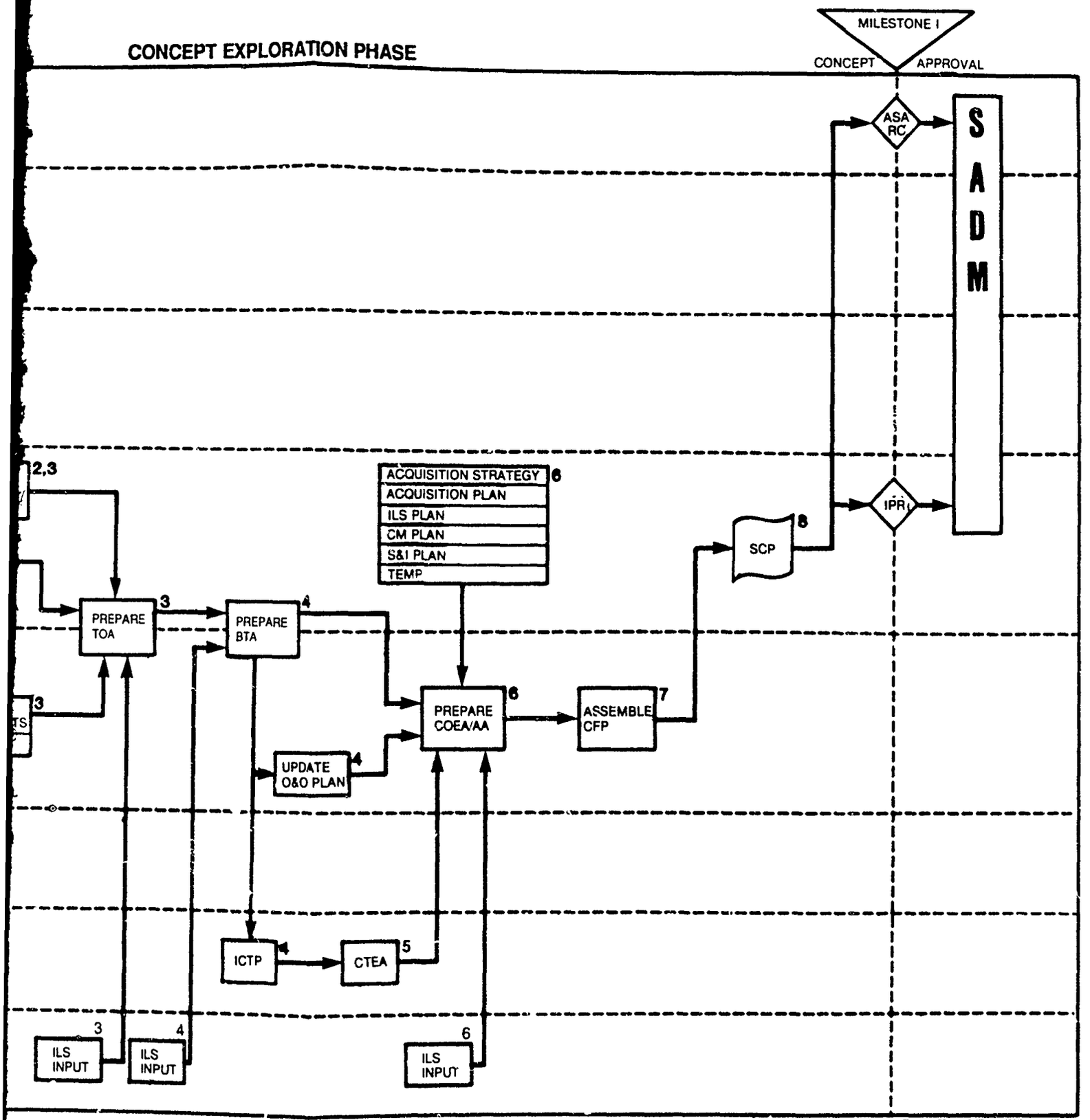


Chart 13-1, THE CONCEPT FORMULAT



THE CONCEPT FORMULATION PROCESS

CHART NOTES

1 SEE APPENDIX B FOR ACRONYMS

2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 13-1

CHAPTER 14

THE MANPRINT PROCESS

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14.1 PURPOSE

This chapter outlines the scope, objectives, organizational responsibilities, and activities of the MANPRINT process in the acquisition of medical materiel. It also describes the roles of Integrated Logistic Support (ILS) and Human Factors Engineering Analysis (HFEA) in the MANPRINT process.

> **NOTE:**
>
> Portions of the activity descriptions in this chapter are applicable to all medical materiel acquisition programs. However, the total content is primarily representative of extensive nonmajor development programs for applied medical systems (See Chart 14-1). In all instances a System MANPRINT Management Plan (SMMP) must be developed that is tailored to the specific needs of the individual systems.

14.2 GENERAL

MANPRINT refers to the comprehensive management and technical effort to optimize total system effectiveness by continuous integration into materiel development and acquisition all relevant information concerning the following:

- Human Factors Engineering
- Manpower
- Personnel
- Training
- System Safety
- Health Hazards

14.2.1 Objectives. The primary goal of MANPRINT is to assure the early and continuous consideration of the above MANPRINT elements in pre-program initiation activities and in each phase of the materiel acquisition process. Specific objectives of the MANPRINT program are to:

a. Influence soldier-materiel system design for optimum total system performance by considering Human Factors Engineering (HFE); Manpower; Personnel; Training (MPT); System Safety (SS); and Health Hazard Assessments (HHA) before making a functional allocation of tasks among people, hardware and software.

b. Assure that Army medical materiel and concepts for their employment conform to the capabilities and limitations of the fully equipped soldier to operate; maintain, supply, and transport the materiel in the operational environment consistent with tactical requirements and logistic capabilities.

c. Integrate combat development and technology base management information systems with personnel long-range planning.

d. Assist the trainer in determining, designing, developing, and conducting sufficient, necessary, and integrated Army training.

e. Improve control of total life cycle costs of soldier-machine systems by assuring consideration of the costs of personnel resources and training for alternative systems during the conceptual stages and for the selected system during subsequent stages of acquisition.

f. Assure, through basic and applied studies, research, and exploratory development in human factors engineering; soldier-materiel system analysis; and experimental, physiological, and psycho-physical psychology, that equipment designs and operational concepts are compatible with the capabilities and limitations of operators and maintainers.

g. Develop a unified, integrated data base to define ranges of human performance, compare them against system performance requirements, and provide for the timely development of trained operators and maintainers.

h. Assure that systems engineering is consistent with safety and health standards.

i. Provide MANPRINT data for the development of technical manuals, field circulars, field manuals, and other training media and technical publications. Assure that the use of these publications does not require aptitudes, education, or training beyond the requirements set to perform the tasks they describe.

j. Apply MANPRINT concepts and current educational technology to analysis, design, and development of training devices and skill performance aids.

k. Influence the Manpower, Personnel and Training related objectives of the ILS process.

14.2.2 Responsibilities.

AHS

- Apply MANPRINT in the Mission Area Analysis (MAA) process.
- Manage MANPRINT efforts prior to the program initiation and during the Concept Exploration phase of system development and provide MANPRINT support to USAMMDA after Milestone I.
- Apply MANPRINT in doctrinal, combat, and training developments and incorporate MANPRINT specifications and requirements in system requirements documents.
- Prepare assessments of manpower, personnel, and training (MPT) implications for inclusion in the Concept Formulation Packages (CFP).
- Approve system safety risk assessments.

- Prior to Milestone I, initiate Human Factors Engineering Analyses (HFEA) on Army medical materiel, in coordination with other commands, and support the development of HFEAs by USAMMDA subsequent to Milestone I.

- Assure that MANPRINT issues are identified, tested, and evaluated in user tests.

USAMRDC/ USAMMDA -
- Provide MANPRINT support to AHS prior to program initiation and during the Concept Exploration Phase of the materiel acquisition process, and manage MANPRINT efforts after Milestone I with AHS support.

- Integrate MANPRINT into the materiel research, development, and acquisition cycle.

- Perform appropriate human factors and system safety RDT&E.

- Develop, coordinate, and implement Human Factors Engineering design and performance specifications, standards, and procedures.

- Employ the Logistic Support Analysis (LSA) process to analyze, generate, and document MPT, safety, and human factors constraints and requirements for materiel systems being acquired.

- Prepare Health Hazard Assessment Reports for, and as assigned by, OTSG, generally for systems with potential health hazards that are not fully defined and for which additional research is required.

- Prior to Milestone I, support AHS in the development of HFEA on Army Medical Materiel and initiate the development of HFEA, in coordination with other commands, after Milestone I.

- Include MANPRINT as a mandatory factor during source selection evaluations.

- Assure the inclusion of MANPRINT in technical tests and product improvement programs.

EHA - Prepare Health Hazard Assessment Reports for, and as assigned by, OTSG, generally for systems with potential hazards for which criteria are well defined.

USAMMA - Manage MANPRINT efforts subsequent to Milestone I for nondevelopment items (NDI) and subsequent to Milestone III (and transition of responsibility) for development items.

- Initiate development of HFEA for NDI, in coordination with other commands, prior to Milestone III.

- Assess medical system MANPRINT performance/deficiencies during post-deployment supportability assessments.

TSG - Manage the preparation of Health Hazard Assessments for inclusion in HFEAs. Monitor the application of biomedical and health standards throughout the materiel development and acquisition cycle.

- Provide interface between AMEDD activities and other DA staff elements on MANPRINT issues.

AMC - The Army Materiel Command's Human Engineering Laboratory (HEL) assists the USAMMDA PMO developer, as required, in the development of an HFE input to the HFEA.

DA DCSPER - Exercise primary DA staff responsibility for the MANPRINT program.

- Develop, coordinate, and disseminate MANPRINT program policy and guidance to all Army commands and agencies.

DA DCSLOG - Assure interface of MANPRINT in the Army ILS program. For medical materiel, the Directorate of Health Care Operations, Logistics Division (OTSG) provides interface between USAMMA and DCSLOG on MANPRINT-related ILS issues.

DA DCSRDA - Assure proper and systematic application of MANPRINT within the research and development community. For medical materiel, the Assistant Surgeon General for Research and Development (OTSG) provides interface between USAMRDC and DCSRDA on MANPRINT research and development issues.

DA DCSOPS - Assure application of MANPRINT methodologies in system requirements documents and acquisition objectives. For medical materiel, the Directorate of Health Care Operations Doctrine, Policy, and Organization Division (OTSG) provides interface between AMEDD activities (AHS and USAMRDC) on MANPRINT issues relating to operations and doctrine.

TRADOC - Ensure that MANPRINT is considered and reported in Mission Area Analysis (MAA), doctrinal, combat, and training developments.

- Conduct MANPRINT training for Army staff, agencies, and major commands.

- Ensure that requirements documents produced under AR 71-9, include adequate specification of MANPRINT requirements.

- Analyze personnel requirements and propose an operator and maintainer MOS decision to DCSPER as part of BOIP/QQPRI process.

14.3 THE SYSTEM MANPRINT MANAGEMENT PLAN (SMMP)

The SMMP serves as a planning and management guide and an audit trail to identify the sources, tasks, analyses, trade-offs, and decisions that must be made to address MANPRINT issues during the materiel acquisition process. The SMMP is also a source document for the Integrated Logistic Support Plan (ILSP)

and identifies the Logistic Support Analysis tasks required to support the MANPRINT process. It is initiated by AHS-CD prior to program initiation and updated as required. After Milestone I, the AHS transitions SMMP responsibilities to USAMMDA for developmental items, modified NDI, and PIP; and to USAMMA for NDI. The SMMP contains five sections:

- Summary - overview of MANPRINT strategy to be employed and the highlights of the SMMP.
- Description - Description of the proposed materiel system, summary of acquisition strategy, participating activities and their roles, and MANPRINT related guidance provided by higher authority.
- MANPRINT Strategy - Description of MANPRINT objectives, available data sources, and MANPRINT analysis effort.
- Concerns - Discuss issues/areas of concern that have been identified and require special attention during the materiel acquisition process.
- Tabs - Identify data sources, the MANPRINT milestone schedule, descriptions of MANPRINT tasks and MANPRINT-related LSA tasks, questions to be resolved, and SMMP coordinating commands. Refer to AR-602-2, MANPRINT in the Materiel Acquisition Process, and TRADOC-CIR 602-XXX (draft) MANPRINT, for details.

14.4 MANPRINT AND INTEGRATED LOGISTIC SUPPORT

ILS documentation will consider MANPRINT as specified in AR 700-127, Integrated Logistics Support. Logistics Support Analysis tasks may be used to determine MANPRINT requirements as described in Appendix B. Hardware vs. Manpower (HARDMAN) and Early Comparability Analysis (ECA) are two MANPRINT techniques currently available for MANPRINT analysis and as inputs to the BOIP/QQPRI process.

MANPRINT reviews may be conducted as part of the ILS reviews and will assess the status and adequacy of MANPRINT planning for a materiel system.

14.5 MANPRINT AND HUMAN FACTORS ENGINEERING ANALYSIS

NOTE:

Three key roles in the HFEA process are those of the initiator, integrator, and approver. The initiator establishes the requirement for the HFEA; identifies the elements to be included, the data needs, and sources; and initiates the process by requesting data and analyses for each MANPRINT element selected for the HFEA. AHS-CD is the initiator prior to Milestone I. After Milestone I, this role is performed by USAMMDA for developmental items, modified NDI, and PIPs, and by USAMMA for NDI. The initiator for each HFEA is also the integrator, and in this capacity develops a total HFEA from the input provided. Formal approval of the HFEA is performed by Commandant AHS prior to Milestone I and CG, USAMRDC (Assistant Surgeon General for R&D) after Milestone I.

HFEA reflects the results of an assessment of each of the six MANPRINT elements to establish whether issues exist which would preclude the scheduled transition of an acquisition program to the next phase of the materiel acquisition life cycle. The HFEA also identifies MANPRINT concerns which, while not critical in terms of program decisions, are resolvable, and must be addressed during the subsequent phase of the acquisition cycle.

The HFEA depends on the acquisition of MANPRINT data from a wide variety of sources involved in the system acquisition process. The HFEA process (paragraph 14.5.2 below) depicts the data collection and analysis activities and responsibilities in support of HFEA. However, each system, depending on maturity, complexity, etc., has a requirement for different types of data and different sources of data. A prime responsibility of the MANPRINT initiator is to ascertain the data needs and sources and to assure that the requisite data is made available in support of the analysis.

An HFEA is required on all Designated Acquisition Programs and In Process Review (IPR) programs having soldier-materiel system interface. Waiver of the HFEA requires DA DCSPER approval for Designated Acquisition Programs. Waiver for IPR programs requires joint USAMMDA-AHS approval for developmental, modified NDI, and PIPs, and joint USAMMA-AHS approval for NDI systems.

14.5.1 MANPRINT Issue Categories.

a. Critical Issue. A critical issue identifies MANPRINT aspects of a medical system which are highly likely to result in either a serious health, safety or human performance problem that could cause extensive system damage, operational failure, serious injury, occupational illness; or place an intolerable burden on the manpower, personnel and training resources of the Army. The severity of these problems is such that their continued existence may preclude the scheduled transition of the program to the next phase of the materiel life cycle.

b. Major Issue. A major issue identifies MANPRINT aspects of a medical system which are moderately likely to result in either a serious health, safety, or human performance problem which could cause extensive system damage, operational failure, serious injury, or occupational illness; or place a serious burden on the manpower, personnel and training resources of the Army.

c. Other Issues. Other issues identify health, safety, manpower, personnel, training, or human performance problems of lower priority than those described as critical or major, but which over time or under stressful conditions, could cause system damage or degrade performance. A significant number of these issues, assessed together for cumulative effect, may be considered a critical or major issue.

14.5.2 The HFEA Process.

SEE FIGURE 14-1

1. The HFEA is initiated by AHS-CD prior to Milestone I and by USAMMDA or USAMMA thereafter (See Note above). The initiator identifies data needs tailored to particular programs under consideration and requests data and analyses inputs for each MANPRINT element covered by the HFEA as follows:

- Manpower/Personnel/Training - Input is provided by AHS-CD and AHS-Trainer. USAMMDA supports MPT input through ILS and LSA activities.
- Human Factors Engineering - Input is provided by USAMMDA-PMO. HEL and the supporting USAMRDC laboratory and/or contractor provide support.
- System Safety - Input in the form of a System Safety Risk Assessment (see Figure 1, AR 385-16) is developed by USAMMDA-PMO. The AHS Safety Office assists as required and approves the assessment.
- Health Hazard Assessment - Input in the form of a Health Hazard Assessment Report (HHAR) is provided by the Office of The Surgeon General (OTSG). The OTSG assigns the HHAR development to either USAMRDC (SGRD-PLC) or the Army Environmental Health Agency (HSHB-QA) depending upon the nature of the developmental effort, whether safety standards are in place, or whether unexplored health aspects are involved.

2. The initiator prepares a draft HFEA in the format shown in Appendix A.

3. The initiator convenes an HFEA Review Board comprised of representatives from all HFEA participating activities.

4. The initiator prepares a revised draft HFEA, based upon Review Board comments, for approval by Commandant, AHS (prior to Milestone I) or CG, USAMRDC thereafter.

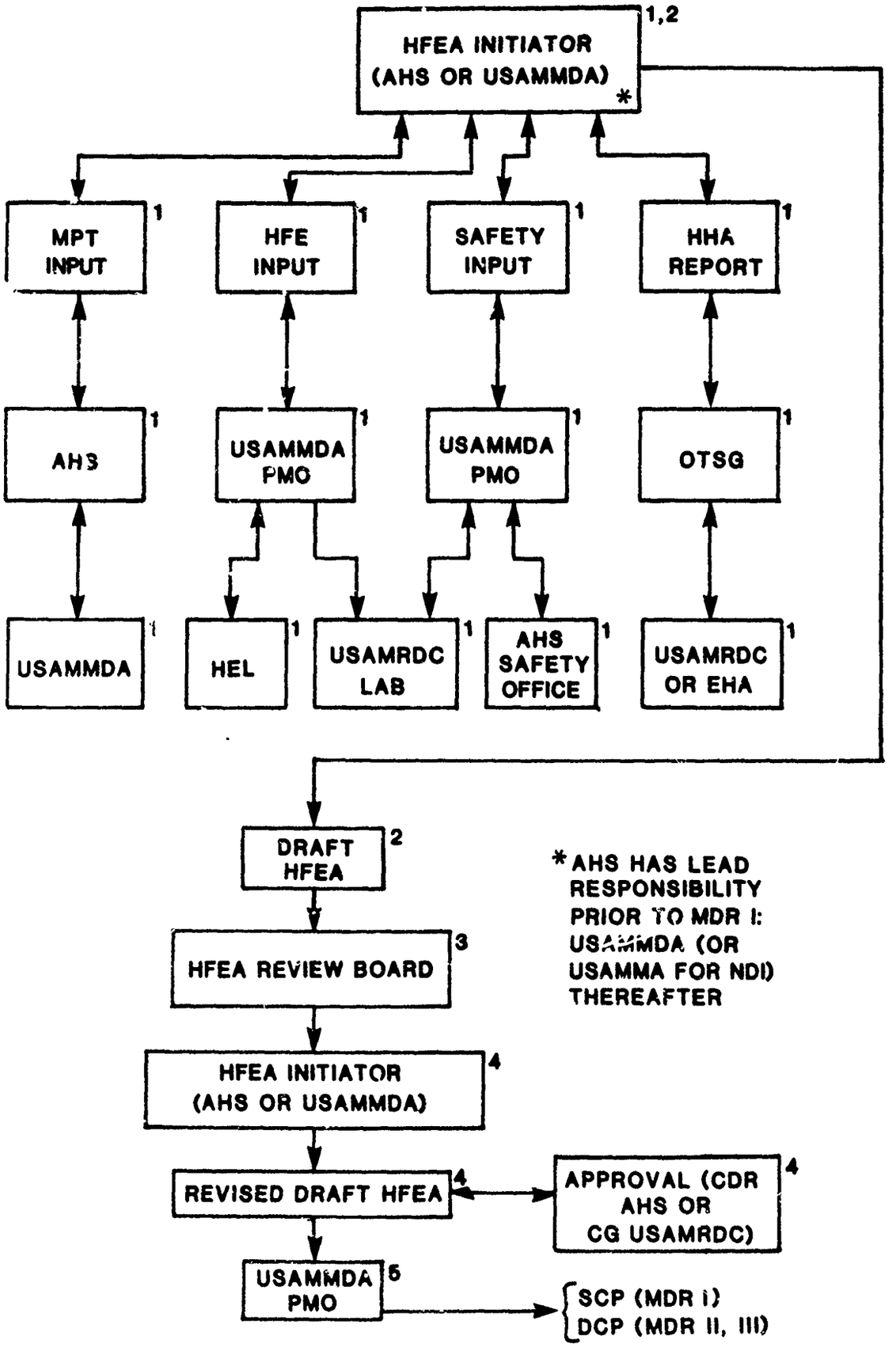


Figure 14-1 The HFEA Process

5. The HFEA initiator furnishes the approved HFEA to USAMMDA-PMO for inclusion with the System Concept Paper (SCP) or Decision Coordinating Paper (DCP) as milestone decision review supporting documentation.

14.6 PRE-PROGRAM INITIATION

14.6.1 MANPRINT Objectives. MANPRINT objectives prior to program initiation include:

- Initiation of MANPRINT planning;
- Identification of MANPRINT-related deficiencies in the mission area;
- Forecasts of manpower capabilities and skills in the target time frame;
- Development of target audience descriptions;
- Early design influence in the initial requirement document.

14.6.2 Specific Activities.

SEE CHART 14-1

NOTE:

MANPRINT activities may be divided into two categories: (1) direct activities performed and completed by MANPRINT personnel such as updating a SMMP; (2) contributory activities in which MANPRINT personnel provide input or comment to broader acquisition activities such as providing input to a CFP. Chart 14-1 and the narrative text employ a verb statement (e.g, "UPDATE SMMP") to identify direct MANPRINT activities, and a noun statement (e.g., "CFP") to identify contributory MANPRINT activities.

1. Prepare Initial System MANPRINT Management Plan. The MANPRINT program is initiated when the decision is made to meet a battlefield deficiency by improving or procuring equipment. The initial SMMP, prepared by AHS-CD in coordination with AHS-Trainer and USAMMDA, addresses the MANPRINT strategy to be employed during the acquisition process, data sources, program concerns, milestone schedule, and task descriptions (refer to paragraph 14.3).

2. Collect Data. At this stage AHS-CD collects data primarily to develop MANPRINT design influence parameters. This may include current and projected military force levels and quality measures.

3. Perform Use Study. Through participation in Mission Area Analyses, AHS-CD identifies specific human capabilities and limitations related to the intended use of the new medical system (refer to Appendix B, paragraph 1).

4. Perform Early Comparability Analysis (ECA) and Comparative Analysis. AHS-CD performs an ECA on a predecessor system, if one exists. A primary use of ECA at this stage is the identification of manpower, personnel, and training (MPT) "high driver" tasks that can be eliminated or limited in the design of the new or improved medical system. It is a "lessons learned" approach to design development (Refer to Appendix D of TRADOC Circular 602-XXX). AHS-CD also performs a Comparative Analysis (LSA Task 203) on a Baseline Comparison System (BCS) to project MPT requirements including target audience descriptions (refer to Appendix B, paragraph 2). This LSA task and the ECA are performed in a consolidated effort.

5. Operational and Organizational Plan (O&O Plan). AHS incorporates MANPRINT issues and design requirements into the O&O Plan. Requirements are stated in general terms and address, as appropriate, manpower needs and constraints, personnel selection, human factors engineering, system safety, training needs and constraints, and health hazards.

14.7 CONCEPT EXPLORATION (CE) PHASE

14.7.1 MANPRINT Objectives. MANPRINT objectives of this phase include:

- Formulation of a system concept that meets MANPRINT requirements and constraints;
- Development of manpower, personnel, and training requirements for the selected system concept;
- Incorporation of MANPRINT requirements and constraints in solicitation documents.

14.7.2 Specific Activities.

SEE CHART 14-1

NOTE:

Lead MANPRINT responsibility during this phase is retained by AHS-CD. USAMMDA, AHS-Trainer, and USAMMA provide support and input, as required, for all direct and contributory activities.

6. Market Investigation. The Market Investigation, which is the responsibility of USAMMDA, assesses the capabilities of existing products and their suppliers to satisfy MANPRINT requirements and constraints. AHS-CD participates in planning and evaluating the results of the market investigation.

7. Acquisition Strategy (AS). AHS-CD, supported by USAMMDA, develops MANPRINT planning data for inclusion in the AS.

8. Update SMMP. AHS-CD updates the SMMP to reflect the AS.

9. Integrated Logistic Support Plan (ILSP). As discussed in section 14.4, the LSA process of the ILS Program is a vehicle for the detailed development of MANPRINT requirements. USAMMDA, supported by AHS-CD, and AHS-Trainer, incorporates MANPRINT tasks and schedules into the ILSP and plans derived from the ILSP (e.g., Logistics Support Analysis Plan, Integrated Support Plan). The SMMP is the source document that provides MANPRINT information to the ILS Plan.

10. Test and Evaluation (T&E) Activities. T&E planning and programs are developed and executed by the Test Integration Working Group (TIWG) and the activities that comprise the TIWG (i.e., USAMMDA, AHS, USAMMA, and the supporting laboratory or contractor) (Refer to paragraphs 4.3.13 and 4.3.14 and Chapter 17, The Test and Evaluation Process). AHS-CD, supported by USAMMDA and AHS-Trainer, provides input to, and ensures that MANPRINT requirements and issues are addressed in, T&E documents. These documents include the Test and Evaluation Master Plan (TEMP), Issues and Criteria, Detailed Test Plans, Independent Evaluation Plans and Reports, Test Reports, etc. The basic question that must be addressed is "Can this soldier with this training perform these tasks to these standards under these conditions?" While testing intensifies in later phases, planning for all tests, particularly user tests, must respond to this basic MANPRINT question by identifying the issues to be resolved, the test environment (troop selection, troop training, and operating conditions), the tasks, the standards, and the methods of evaluation required to examine the issues.

11. Analyze Manpower, Personnel, and Training (MPT) Requirements. AHS-CD, supported by USAMMDA, employs analytic techniques to estimate MPT requirements for alternative system concepts. A Comparative Analysis (LSA Task 203) (refer to Appendix B, paragraph 2) is again performed. Composites of the BCS and the characteristics of the alternative system concepts are employed to project MPT requirements for the new system alternatives based upon comparisons to existing requirements for the BCS.

12. Prepare Individual and Collective Training Plan (ICTP). AHS-Trainer develops the ICTP, (refer to Chapter 16, The Training and Training Device Process).

13. Concept Formulation Package (CFP). AHS-CD, supported by USAMMDA and AHS-Trainer, ensures that MANPRINT issues receive full consideration in Trade-Off Determinations and Trade-Off Analyses and that the Best Technical Approach (selected alternative) satisfies critical MANPRINT requirements and constraints. Refer to Chapter 13, The Concept Formulation Process.

14. Request for Proposal (RFP). USAMMDA, supported by AHS-Trainer and AHS-CD, develops and provides MANPRINT requirements for inclusion in the RFP(s) to U.S. Army Medical Research Acquisition Activity (USAMRAA) in order to initiate contractor effort during the D&V Phase. These include, for example, quantitative and qualitative MPT constraints; citation of military standards and specifications for human factors engineering, safety, and health hazards; and MANPRINT design verification procedures. Suggested MANPRINT material for RFPs is provided in HQ AMC letter, AMCPP-S, 14 June 1985, subject: Manpower and Personnel Integration (MANPRINT).

15. Perform Human Factors Engineering Analysis (HFEA). AHS-CD integrates and Commandant, AHS approves, an HFEA (refer to section 14.5) to identify critical or major MANPRINT issues that preclude entry into the D&V Phase and other issues that require correction or further review during that phase. USAMMDA-PMO appends the HFEA to the SCP as supporting documentation for the Milestone I decision review.

16. System Concept Paper (SCP). USAMMDA-PMO incorporates in Annex F (Acquisition Strategy) a summary of plans to ensure that soldier-machine interface considerations will be addressed during system design.

14.8 DEMONSTRATION AND VALIDATION (D&V) PHASE

14.8.1 MANPRINT Objectives. MANPRINT objectives of this phase include:

- Incorporation of MANPRINT requirements in conceptual design;
- Evaluation of MANPRINT issues in technical and user tests;

- Development of a training strategy and identification of training devices and requirements;
- Incorporation of detailed MANPRINT requirements in the requirements document (ROC, JSOR, NSTDR) leading to Full Scale Development.

14.8.2 Specific Activities.

SEE CHART 14-1

NOTE:

Lead MANPRINT responsibility is transferred to USAMMDA. AHS-CD, AHS-Trainer, and USAMMA provide support and input, as required, to all direct and contributory activities.

17. AS Update. USAMMDA, supported by AHS-CD, updates MANPRINT planning data for inclusion in the AS.

18. Update SMMP. USAMMDA updates the SMMP to reflect the AS.

19. ILSP Update/LSA. USAMMDA, supported by AHS-CD and AHS-Trainer, incorporates updated MANPRINT tasks and schedules into the ILSP and associated plans (e.g., LSA Plan) (refer to section 14.4). The pace of LSA and its documentation increases during this phase. USAMMDA, AHS-CD, and AHS-Trainer participate in the performance of trade-off studies (LSA Task 303) seeking the best balance among hardware characteristics, support concepts (including MPT), and support resource requirements. This is a continuing process as the preliminary design evolves during this phase. LSA Task 401 is also performed selectively to determine training requirements (refer to Appendix B).

20. Preliminary Design Activities. USAMMDA MANPRINT personnel participate in the System Requirements Review and the System Design Review to ensure that essential MANPRINT requirements and constraints are incorporated in system and development specifications. Refer to Chapter 19, The Configuration Management Process.

21. T&E Activities. USAMMDA, supported by AHS-CD and AHS-Trainer, provides input to, and ensures that MANPRINT requirements and issues are addressed in, T&E documents (Refer to Activity 10 and Chapter 17). MANPRINT personnel of these activities also ensure that technical and user independent evaluation reports address MANPRINT issues and that corrective actions are established for issues identified.

22. Basis of Issue Plan (BOIP)/Qualitative and Quantitative Personnel Requirements Information (QQPRI). USAMMDA and AHS-CD employ LSA and MANPRINT test evaluations in the development of BOIP and QQPRI (refer to Chapter 18, The BOIP/QQPRI Process).

23. Update ICTP. AHS-Trainer updates the ICTP.

24. Prepare New Equipment Training (NET) Plan. USAMMA prepares the initial NETP (Refer to Chapter 20, The Materiel Fielding and New Equipment Training Process).

25. Requirements Document. AHS-CD, AHS-Trainer and USAMMDA MANPRINT personnel provide input to the MANPRINT assessment paragraph of the ROC or TDR and ensure that the operational characteristics specified are compatible with MANPRINT-related logistic support analyses and test results. These will include special human engineering characteristics and soldier performance specifications (aptitudes and skills).

26. Request for Proposal (RFP). USAMMDA, supported by AHS-CD, AHS-Trainer, and USAMMA, develops and provides MANPRINT requirements for inclusion in RFP(s) to USAMRAA in order to initiate contractor effort during the FSD phase. These include, for example, development of unique training devices (if

required), determination of detailed MPT requirements by task analysis (LSA Task 401), citation of appropriate military standards and specifications, and technical test and evaluation of MANPRINT-related design issues. Also refer to Activity 14.

27. Perform HFEA. USAMMDA integrates and CG, USAMRDC approves, an HFEA (refer to section 14.5) to identify critical or major MANPRINT issues that preclude entry into the FSD phase and other issues that require correction or further review during that phase. USAMMDA-PMO appends the HFEA to the DCP as supporting documentation for the Milestone II decision review.

28. Decision Coordinating Paper (DCP). USAMMDA-PMO incorporates in Annex F (Acquisition Strategy) a summary of plans to ensure that soldier-machine interface considerations will be considered during design.

14.9 FULL SCALE DEVELOPMENT (FSD) PHASE

14.9.1 MANPRINT Objectives. MANPRINT objectives of this phase include:

- Evaluation of MANPRINT issues in technical and user tests;
- Detailed determinations of MPT requirements based upon task analyses.

14.9.2 Specific Activities.

SEE CHART 14-1

29. AS Update. USAMMDA, supported by AHS-CD, updates MANPRINT planning data for inclusion in the AS.

30. Update SMMP. USAMMDA, supported by AHS-CD and USAMMA, updates the SMMP to reflect the AS.

31. ILSP Update/LSA. USAMMDA, supported by AHS-CD, AHS-Trainer, and USAMMA, incorporates updated MANPRINT tasks and schedules into the ILSP and associated plans (e.g., Post-Deployment Supportability Assessment Plan) (refer to section 14.4). Detailed task analyses (LSA task 401) and an Early Fielding Analysis (LSA task 402) are performed. Determinations are made of detailed training and training device requirements, maintenance manhour requirements by MOS and level of maintenance, and sources of manpower and personnel skills. Also, refer to Chapter 15, The Integrated Logistic Support Process.

32. Detailed Design Activities. USAMMDA MANPRINT personnel participate in Preliminary and Critical Design Reviews to ensure that design and product specifications accommodate MANPRINT requirements and constraints.

33. T&E Activities. Refer to Activities 10 and 21.

34. Amended BOIP/QQPRI. USAMMDA AND AHS-CD employ LSA and MANPRINT test and evaluations to develop amended BOIP/QQPRI (refer to Chapter 18).

35. Update ICTP. AHS-Trainer updates the ICTP (refer to Chapter 16).

36. Update NETP. USAMMA updates the NETP (refer to Chapter 20).

37. RFP. USAMMDA, supported by AHS-CD, AHS-Trainer, and USAMMA, develops and provides MANPRINT requirements for inclusion in RFP(s) to USAMRAA in order to initiate contractor effort during the Production and Deployment (P&D) Phase. These requirements may include procurement requirements for training devices, the conduct of NET during the deployment phase, and MANPRINT evaluations during supportability assessments.

38. Perform HFEA. USAMMDA integrates and CG, USAMRDC approves, an HFEA (refer to Section 14.5) to identify critical or major MANPRINT issues that preclude entry into the P&D phase and other issues that require correction or further review during that phase. USAMMDA-PMO appends the HFEA to the DCP as supporting documentation for the Milestone III decision review.

14.10 PRODUCTION AND DEPLOYMENT (P&D) PHASE

14.10.1 MANPRINT Objectives. MANPRINT objectives of this phase include:

- Completion of all MANPRINT actions prior to or concurrent with initial deployment; that is, soldiers are available and prepared to operate, maintain, and support the first unit equipped with the new medical materiel and;
- Post-deployment assessment of MANPRINT capabilities and/or deficiencies and their correction.

14.10.2 Specific Activities.

SEE CHART 14-1

NOTE:

Lead MANPRINT responsibility is transferred to USAMMA. AHS-CD, AHS-Trainer, and USAMMDA provide support as required.

39. Update Supportability Assessment Plan. USAMMA updates the Post-Deployment Supportability Assessment Plan (LSA Task 501.2.5) to include MANPRINT issues (refer to Appendix B, paragraph 13).

40. Materiel Release Request. USAMMA, supported by AHS-CD, AHS-Trainer, and AHS-Tester jointly determine and advise the Materiel Release Review Board at OTSG as to whether:

- All MANPRINT issues identified in the HFEA prior to Milestone III have been successfully resolved, and;
- Adequate MPT capabilities (required manpower in appropriate MOS categories and properly trained) are available to support the first unit equipped and continuing deployment.

41. New Equipment Training (NET). If required, USAMMA provides NET to initially deployed units (refer to Chapter 16).

42. Supportability Assessment. USAMMA assesses the effectiveness of the soldier-machine interface and other MANPRINT issues in operational support of the medical materiel. Any MANPRINT element deficiencies are identified for corrective action as required.

14.11 TAILORING THE MANPRINT PROCESS

The foregoing material in this chapter is based upon extensive non-major development programs. The degree of MANPRINT activity required for development programs will depend primarily upon the extent and complexity of soldier-machine interface required for their operation and support. USAMMDA and AHS jointly tailor the MANPRINT process during preparation and updating of the SMMP. MANPRINT application to other programs is discussed below.

14.11.1 Nondevelopment Items (NDI). Acquisition of NDI deviates from the developmental process. Responsibility for NDI program management transfers to USAMMA after the NDI decision at Milestone I. The MANPRINT requirements are basically unchanged. Potential human factors engineering, manpower, personnel, training, system safety, and health hazard problems are identified and resolved. In the market investigation, AHS and USAMMDA evaluate the extent to which available medical materiel satisfies MANPRINT requirements and constraints stated in the O&O Plan and determines testing required to confirm the choice of NDI. In the solicitation process, USAMMA and Defense Personnel Support Center (DPSC) elicit sufficient MANPRINT-related data from bidders to screen out alternatives with critical and major deficiencies and to rank alternatives with full consideration of MANPRINT issues.

14.11.2 Product Improvements. Product improvement programs, including preplanned product improvements, offer opportunities to correct MANPRINT-related materiel deficiencies exhibited during operation and support of the deployed medical system. AHS and USAMMA provide input to USAMMDA's Product Improvement Proposal based upon the post-deployment supportability assessment of MANPRINT performance.

14.11.3 Pharmaceuticals and Biologicals System. Safety is the primary MANPRINT concern for these commodities. In general, FDA approval of the "Notice of Claimed Investigational Exemption for a New Drug" and the "New Drug Application" satisfies the requirement for a System Safety Risk Assessment.

14.12 REFERENCES

AR 40-10, Health Hazard Assessment in Support of the Army Materiel Acquisition Decision Process, 1983

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1984

AR 70-1, Systems Acquisition Policy and Procedures, 1986

AR 70-25, Use of Volunteers as Subjects of Research, 1974

AR 385-16, Systems Safety Engineering and Management, 1985

AR 602-1, Human Factors Engineering Program, 1983

AR 602-2, MANPRINT in the Materiel Acquisition Process, 1986

AR 700-127, Integrated Logistic Support, 1983

MIL-HDBK-743, Anthropometry of U.S. Military Personnel

MIL-HDBK-759, Human Factors Engineering for Army Materiel

MIL-HDBK-46855, Human Engineering Requirements for Military Systems, Equipment and Facilities

MIL-STD-759, Human Factors Engineering for Army Materiel

MIL-STD-882B, System Safety Program Requirements

MIL-STD-1472, Human Engineering Design Criteria for Military Systems, Equipment and Facilities

MIL-STD-1474, Noise Limits for Army Materiel

TRADOC Cir, 602-XXX, Manpower and Personnel Integration (MANPRINT) (Draft)

Human Engineering Laboratories (HEL) Memorandum Number 70-9 (Draft)

APPENDIX A

HFEA FORMAT

HFEA FORMAT

The following is an HFEA format adapted from HEL draft Memorandum 70-9.

I. PREFACE

A standard statement is inserted which describes the purpose of the HFEA and its coverage. It identifies the HFEA initiator and other participants.

II. EXECUTIVE SUMMARY

Identifies Milestone for which HFEA was written, describes data base and significant data voids and lists critical and major issues. Finally, makes recommendation for transition to next phase of life cycle or not to transition until specified problems are overcome.

III. INTRODUCTION

A. System Description. Describes medical system to degree required to orient the reader toward MANPRINT aspects of the system.

B. System Integration and Interactions. This subsection is included only when the medical system under consideration requires that other systems be employed to achieve its forecasted effectiveness. When included, this section answers the questions "Does the system interface effectively with the other systems on which it depends or which depend on it"; and "Are the human performance requirements for the integrated operation and maintenance of the system feasible, given the design of the hardware and the personnel selection criteria and training envisioned?" Human factor implications of any problems in multi-system performance are explained.

C. Principal Human Performance Requirements. System operation and maintenance requirements which depend on human performance are summarized (e.g., reaction time, accuracy, time and repair, etc.). Critical MANPRINT related tasks are identified along with human performance requirements, equipment, environment and the mission variables likely to affect human performance.

IV. SYSTEM HFEA ANALYSIS

The HFEA initiator includes coverage of the following topics:

A. Human Performance Requirements for Operations and Maintenance. Addresses problems related to the ability of the planned personnel with the projected training to accomplish all critical tasks to an acceptable standard on the equipment as designed. The HFEA initiator estimates system performance consequences of not correcting the problems and offers recommendations for corrective action including alternative approaches.

B. Equipment Design. Deals not only with the design of the equipment as it applies to the user-system interface, but with the effects of the natural and induced environment.

C. Personnel Selection and Manpower. Addresses the issue of whether the military personnel proposed to operate and maintain the system have adequate aptitude and skills for their assigned tasks. Relevant manpower issues are identified.

D. Training. Discusses the validity of the concepts underlying the system training program. Where there is reason to believe that inadequate training contributed to reported or observed human performance problems, an assessment is provided of the proposed training

as related to the problems. Problems of negative transfer of training caused by design discrepancies between the current and previous systems are identified, their impact assessed, and the necessary corrections proposed.

E. Health Hazard Assessment (HHA). Summarizes the contents, conclusions, and recommendations of the formal Health Hazard Assessment Report (HHAR), which is prepared in accordance with AR 40-10. The full HHAR is appended to the HFEA.

F. Safety Assessment. Summarizes the System Safety Risk Assessment, including conclusions and recommendations, which is prepared in accordance with AR 385-16. The full System Safety Risk Assessment is appended to the HFEA.

G. Conclusions. Restates all principal conclusions made in the preceding subsections.

H. Recommendations. A specific recommendation is made as to whether the system should or should not enter the next phase of the acquisition cycle. The recommendation to proceed may be made without qualification. One qualification is the addition of a notation that priority attention be directed to issues discussed in this section of the HFEA, with required testing included in the recommendation. A second qualification is a notation that the system can proceed to the next phase, contingent on an agreement to take certain actions during the next phase. For this qualification, the specific problems to be corrected will be detailed. If a problem must be corrected immediately the corrective action will be stated.

APPENDIX B

MANPRINT-RELATED LSA TASKS

MANPRINT-RELATED LSA TASKS

The following LSA tasks (listed in order of initial application in the acquisition life cycle) are vehicles for the integrated application of MANPRINT and ILS processes. Lead responsibility for these tasks is exercised by AHS-CD up to Milestone I, by USAMMDA-PMO through program transition, and by the Readiness Proponent (USAMMA or an AMC major subordinate command) thereafter. Refer to Chapter 15, The Integrated Logistic Support Process.

1. LSA Task 201, Use Study. The Use Study identifies and documents the pertinent supportability factors related to the intended use of the new system to include specific human capabilities and limitations. Factors developed may include, for example, projected daily usage of the new system, repair turn-around times, and personnel skill and knowledge requirements. Results of the study are included in the O&O Plan and other requirements documents. The Use Study is performed initially prior to program initiation and updated through the Full Scale Development (FSD) phase.

2. LSA Task 203, Comparative Analysis. This task requires the development of a Baseline Comparison System (BCS) or composite system which represents the characteristics of the new system. The BCS is used to project supportability parameters (to include manpower, personnel, and training requirements) and to determine the supportability, cost, and readiness drivers of the new system. Human factors engineering, safety, and health hazard specialists provide input to this task concerning problems in comparative systems which will be prevented in the case of the new system. The Early Comparability Analysis (see paragraph 14.6.2 activity 3) also provides input to this task. The comparative analysis is performed prior to program initiation and updated through FSD.

3. LSA Task 101, Development of an Early LSA Strategy. The early LSA strategy identifies those MPT-related LSA tasks which influence design and meet ILS and MANPRINT program objectives. MPT resource constraints and objectives and available MPT data are considered during LSA strategy development.

This task is performed just prior to program initiation and prior to Milestone I.

4. LSA Task 102, LSA Plan. The LSA plan describes the task performance schedule. It also describes how the LSA effort will interface with other systems engineering disciplines and with programs related to individual ILS elements (e.g. training programs). This task is performed during the Concept Exploration (CE) phase and updated through FSD.

5. LSA Task 103, Program and Design Reviews. Design reviews include assessment of the MPT impacts of proposed design features and assessment of the status of corrective actions. These reviews also track compliance with contractual human factors and safety requirements. This task is performed during the CE phase and updated through the Production and Deployment (P&D) phase.

6. LSA Task 202, Mission Hardware, Software and Support System Standardization. Task 202 defines, in quantitative and qualitative terms, manpower and personnel standardization constraints that affect the system design. Risks and impacts associated with using existing manpower and personnel are also identified as part of this task. Results are included in requirement documents.

7. LSA Task 205, Supportability and Supportability Related Design Factors. This task establishes the quantitative supportability characteristics (such as maintenance manhours per operating hour), objectives, goals, thresholds and constraints for the new system. These goals, thresholds and constraints are included in appropriate requirements documents and in the contract request for proposal (RFP). MPT, human factors, and system safety constraints/requirements are identified as part of this task. This task is performed during CE and updated through FSD.

8. LSA Task 301, Functional Requirements Identification. This task identifies the tasks required to operate and maintain the system and is performed during CE and updated through FSD.

9. LSA Task 302, Support System Alternatives. This task defines viable support system alternatives for the new system. The MPT requirements of support alternatives are identified. The task is performed during CE and updated through FSD.

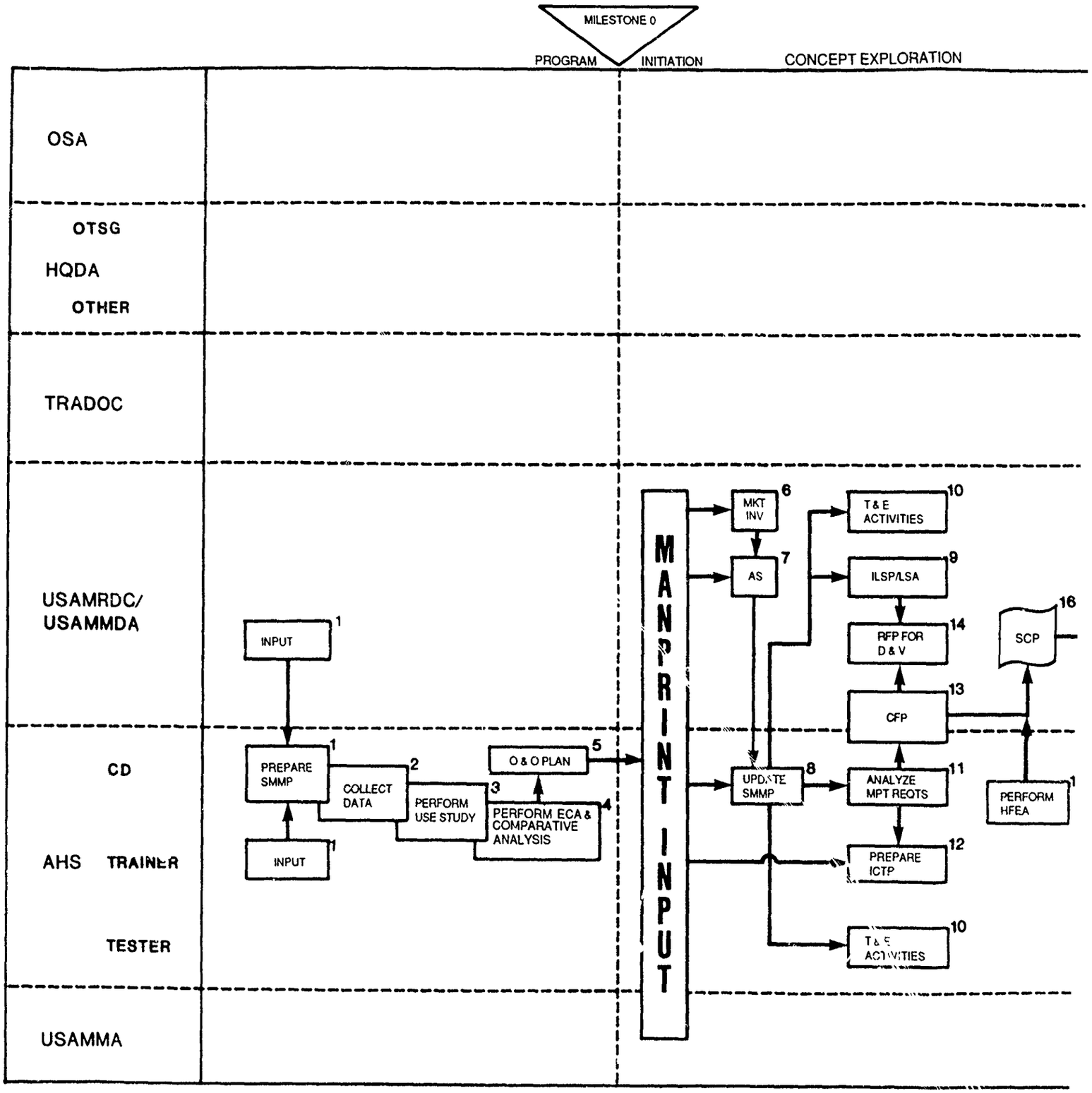
10. LSA Task 303, Evaluation of Alternatives and Tradeoff Analysis. This task estimates and evaluates manpower and personnel implications of the support alternatives identified by task 302 in terms of total numbers of personnel required, job classifications, skill levels and experience required, and training requirements. This task also includes evaluations and tradeoffs among design, operations, training, and personnel job design to determine the optimum solution for attaining and maintaining proficiency of operating and support personnel. These evaluations consider shifting of job duties among job classifications, alternative technical publications concepts, and alternative mixes of formal training, on-the-job training, unit training and use of training simulators. The task is performed during CE and updated through FSD.

11. LSA Task 401, Task Analysis. This task includes identification of all support resources associated with each operation and maintenance task. Resources include manpower requirements, new or restructured personnel skills, training devices, and training requirements. Tasks which exceed established MPT constraints are flagged so that design solutions can be formulated. The Task Analysis provides source data for preparing training documentation and technical manuals. It is performed selectively during Demonstration and Validation (D&V) and extensively during FSD.

12. LSA Task 402, Early Fielding Analysis. This task assesses the impact of the new materiel system on existing medical materiel, supply, maintenance, and transportation systems. This analysis is performed during FSD and identifies existing sources for obtaining the manpower and personnel required for the

new medical system and the impact on existing operational systems which results from using these sources.

13. Task 501, Supportability Test, Evaluation and Verification. This task involves planning and conducting tests that assess the achievement of specified supportability requirements. Testing for achievement of MPT, safety, and human factors requirements/constraints is an integral part of this task. MANPRINT testing issues are included in supportability test and evaluation plans, objectives and criteria. This task also identifies corrective actions for any requirements that are not met. Planning activities for this task are performed during CE and all following phases. Post-deployment assessments are performed during the P&D phase.


MILESTONE 0
PROGRAM INITIATION
CONCEPT EXPLORATION
OSA
OTSG
HQDA
OTHER
TRADOC
USAMRDC/
USAMMDA
CD
AHS TRAINER
TESTER
USAMMA
INPUT
1
PREPARE SMMP
1
COLLECT DATA
2
PERFORM USE STUDY
3
PERFORM ECA & COMPARATIVE ANALYSIS
4
O & O PLAN
5
INPUT
1
MANPRINT INPUT
MKT INV
6
AS
7
UPDATE SMMP
8
T & E ACTIVITIES
10
ILSP/LSA
9
RFP FOR D & V
14
CFP
13
ANALYZE MPT REQTS
11
PREPARE ICTP
12
T & E ACTIVITIES
10
SCP
16
PERFORM HFEA
1

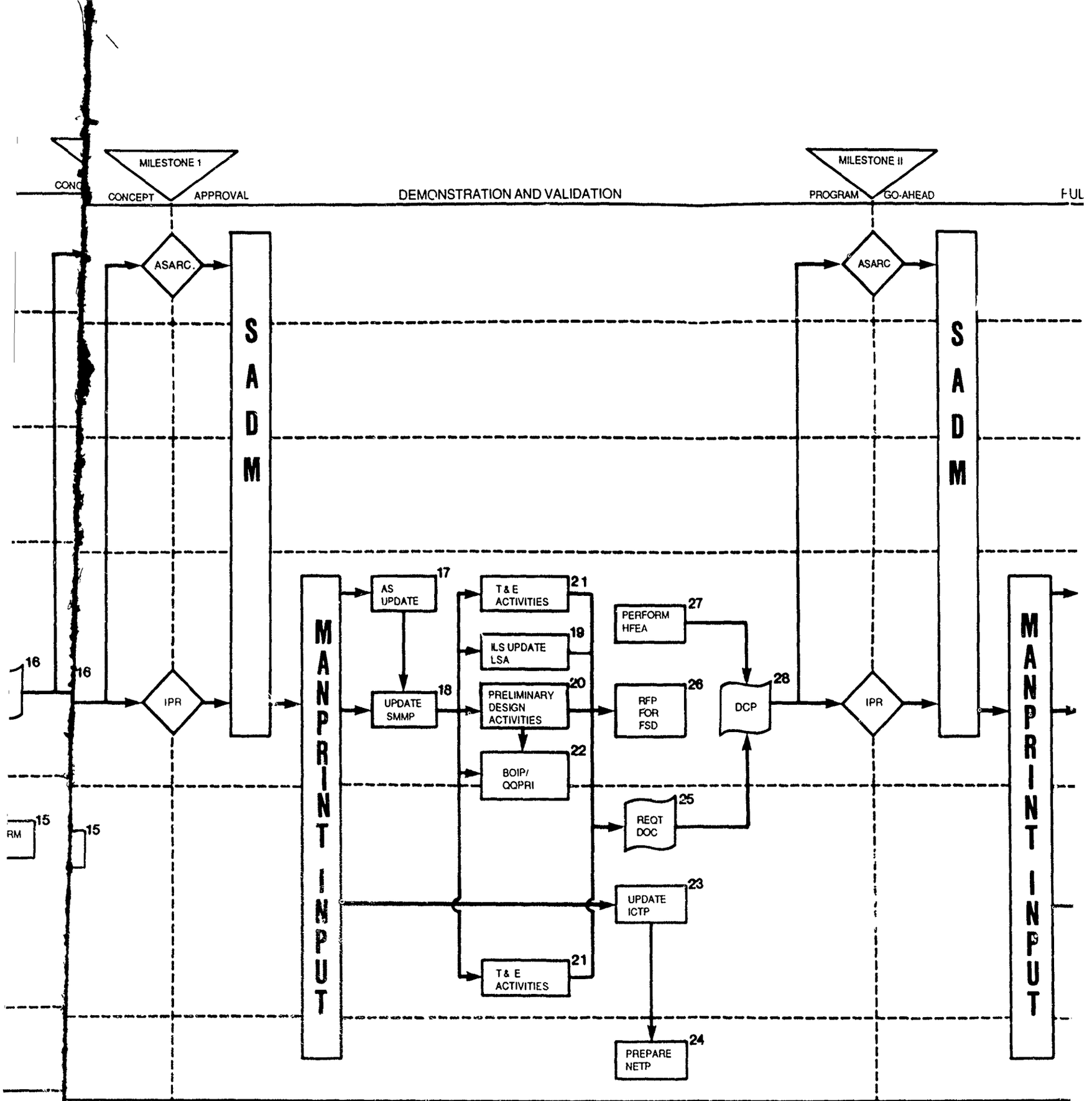


Chart 14-1 The MANPRINT Process

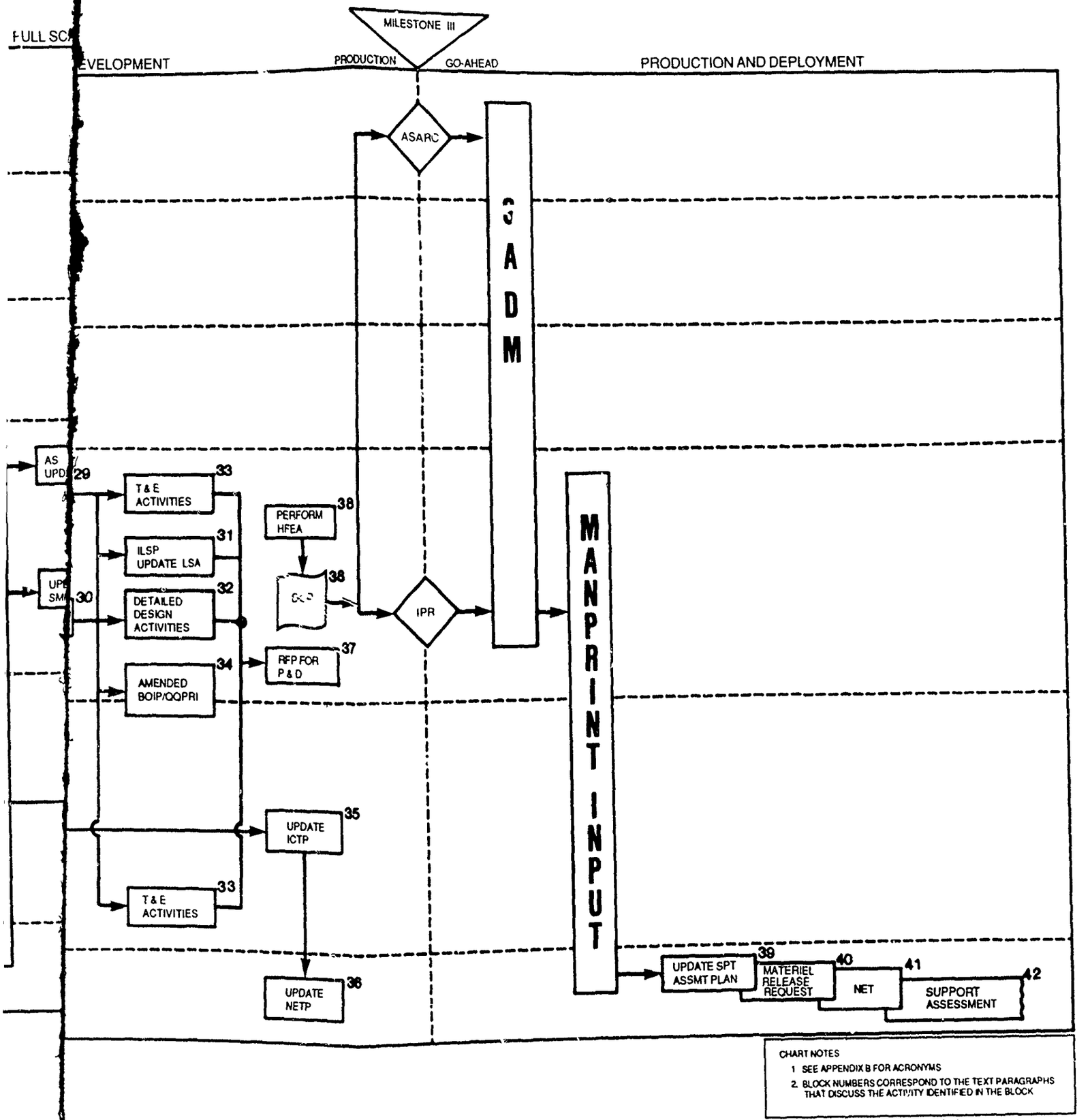


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 14-1

CHAPTER 15

THE INTEGRATED LOGISTIC SUPPORT PROCESS

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15.1 PURPOSE

This Chapter outlines Integrated Logistic Support (ILS) requirements and procedures to apply throughout the acquisition life cycle of medical materiel.

15.2 GENERAL

ILS is employed to:

- Influence the supportability design of new materiel acquisitions;
- Plan, program, develop, acquire, test, and deploy all necessary support resources to ensure the supportability and readiness of the item when fielded.

> **NOTE:**
>
> Portions of the activity descriptions in this chapter are applicable to all medical materiel acquisition programs. However, the total content is primarily representative of extensive nonmajor developmental programs for applied medical systems (see Chart 15-1). An ILS Plan and ILS/ Logistic Support Analysis (LSA) Strategies must be developed in all instances that are tailored to the specific needs of the individual systems.

15.2.1 Elements of ILS. The twelve ILS elements listed below comprise the total ILS resources that contribute to attainment of system readiness objectives.

ILS ELEMENTS

- Design influence to include logistic-related reliability, availability, and maintainability (RAM)
- Maintenance Planning
- Manpower and Personnel
- Supply Support

- Support Equipment and Test, Measurement, and Diagnostic Equipment
- Training and Training Devices
- Technical Data
- Computer Resources Support
- Packaging, Handling, and Storage
- Transportation and Transportability
- Facilities
- Standardization and Interoperability

15.2.2 Objectives. The objectives of ILS management (as stated in AR 700-127) are to:

- Influence materiel system requirements and design to achieve and sustain established levels of operational readiness while minimizing support requirements.
- Ensure that all elements of manpower, training, and logistics are planned, developed, tested, evaluated, procured, and deployed concurrently with materiel systems.
- Prepare the actual user and the personnel, training, and logistics systems to operate and support materiel systems when fielded.
- Provide procedures to integrate and acquire the ILS elements effectively.
- Improve logistics standardization and interoperability of materiel within DA, other Services, and allied nations.

15.2.3 Responsibilities. Responsibilities for principal ILS activities are summarized in the matrix in Figure 15-1.

15.3 DESIGNING FOR SUPPORT

Readiness and Supportability (R&S) threshold and supportability related design factors must be established prior to Milestone II (transition to Full Scale Development). These are required to meet the design influence and

ILS ACTIVITY	DEVELOPMENT ITEM OR MODIFIED NDI FOR WHICH USAMMA IS THE READINESS PROPONENT AND LOGISTICIAN	DEVELOPMENT ITEM OR MODIFIED NDI FOR WHICH AMC IS THE READINESS PROPONENT AND USALEA IS THE LOGISTICIAN	NDI AND SKO FOR WHICH USAMMA IS THE READINESS PROPONENT AND LOGISTICIAN
CONDUCT ILS PLANNING AND TASKS	USAMMDA	USAMMDA	USAMMA
SUPPORT ILS PLANNING AND TASKS	USAMMA AHS-TRAINING -USER TESTING	AMC AHS-TRAINING -USER TESTING	AHS-TRAINING AHS-USER TESTING
POST-DEPLOYMENT LOGISTICS SUPPORT	USAMMA-ILS LEAD AHS-TRAINING DPSC-SUPPLY & SUPPORT	AMC-ILS LEAD -SUPPLY & SUPPORT	USAMMA-ILS LEAD AHS-TRAINING DPSC-SUPPLY & SUPPORT

Figure 15-1. ILS Responsibilities

standardization and interoperability objectives stated in paragraph 15.2.2, above. Figure 15-2 identifies design influence requirements in AR 700-127, Integrated Logistic Support and corresponding LSA tasks documented in MIL-STD-1388-1A, Logistic Support Analysis.

15.4 DEFINING THE SUPPORT

The ILS resource requirements (ILS elements) are developed to implement the baseline support and maintenance concepts and to achieve the stated system readiness objectives (peacetime and wartime). Figure 15-3 displays the linkages of source data, analyses, records, and computation that determine the choice and quantity of the ILS resources needed to support user tests and operational deployment.

PRE-PROGRAM INITIATION	• Identify manpower, training, and logistics constraints (mission area analysis)	• Perform mission area analyses • Analyze intended use; identify supportability factors Use Study (LSA Task 201)
CONCEPT EXPLORATION	• Define baseline operational scenarios for both peacetime and wartime for recommended system alternatives • Identify manpower, training, and logistics cost drivers of current systems and targets for improvement on the new system • Establish support and RAM parameters to assess the effect on system readiness and support costs. Estimate achievable values of these parameters • Establish tentative system readiness objectives (SRO)	• Identify peacetime and wartime employment Use Study (LSA Task 201) • Develop a baseline comparison system; determine supportability, cost and readiness drivers Comparative Analysis (LSA Task 203) • Identify design opportunities for improved supportability Technological Opportunities (LSA Task 204) • Define supportability related design constraints Mission Hardware, Software, and Support System Standardization (LSA Task 202) • Updated Manpower, Personnel, and Training (MPT) constraints (Comparative Analysis (LSA Task 203) • Establish R&S objectives (LSA Task 205.2.2)
DEMONSTRATION AND VALIDATION	• Establish consistent set of readiness goals and thresholds for RAM including built-in test equipment and other support parameters • Perform tradeoffs to determine the best balance among hardware characteristics, support concepts, and support resource requirements	• Establish supportability characteristics and supportability related design factors (LSA Task 205) • Perform evaluations of alternatives and tradeoff analyses (LSA Task 303)

Figure 15-2 Development of Readiness and Supportability Objectives and Design Factors

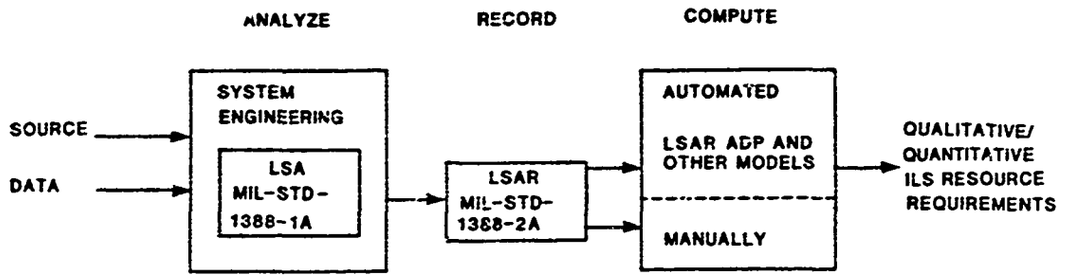


FIGURE 15-3
Overview of LSA/LSAR Process

a. Analysis. Logistic Support Analysis (LSA), is performed as a subset of, and is fully integrated with, the system engineering processes employed to develop and document the system acquisition. LSA techniques applicable to each acquisition phase are described in MIL-STD-1388-1A.

b. Record. LSA data, generated by the system developer's performance of LSA, may be documented in fifteen (15) data records that comprise the Logistic Support Analysis Record (LSAR)(MIL-STD-1388-2A, DOD Requirements for a Logistic Support Analysis Record).

c. Computation. Manual computation of manhour summaries, provisioning input data, support equipment utilization, and other ILS resource summaries is appropriate for small and relatively uncomplex medical systems. However, for large, relatively complex systems it may be preferable to document the LSAR in an automated media (e.g., cards, tape) and employ automated compilation. The Joint Service LSAR/ADP system is a standard ADP system developed by the Services for use by contractors, if they do not have a validated system of their own. The U.S. Army Materiel Readiness Support Activity (MRSA) in Lexington, Kentucky is the lead activity in the application of the standard system. MRSA

will provide the software and instructions on request and is available to assist in setting it up at a contractor's facility. MRSA will also validate a contractor-developed system for use on DOD contracts. This support is normally provided during early FSD and is furnished without charge to DOD contractors.

15.4.1 Maintenance Planning. Maintenance planning is the lead analytic activity that provides input to development of ILS resource requirements. Figure 15-4 identifies the LSA/LSAR/computation processes employed to determine the requirements.

Alternate operational and support concepts are developed during Concept Exploration (CE). A baseline support concept and a maintenance concept and supporting analyses are established during Demonstration and Validation (D&V). Detailed operation and maintenance tasks are identified during D&V and Full Scale Development (FSD). Maintenance planning identifies: the level of maintenance at which each task (e.g., remove, disassemble, fault locate) is performed, tools and test equipment required, task times, and task frequencies. Post-Production Support Analyses (LSA Task 403) are also performed and a Post Production Support Plan prepared during FSD.

As indicated in Figure 15-4, source data includes the current maintenance system employed for similar medical systems, organizational and operational concepts, and the evolving design of the new medical system. Logistic support analyses are employed as required to identify tasks, task distributions, and task frequencies. For example, repair level analysis determines task distribution by level of maintenance. Failure Modes Effects and Criticality Analysis (FMECA) determines corrective maintenance tasks and Reliability Centered Maintenance (RCM) determines scheduled maintenance tasks. Results of the analyses are documented on the LSA records identified in Figure 15-4. When employed, LSA ADP reports provide a convenient display of maintenance planning as a guide for the development of other ILS resource requirements. For example, LSA-004, "Maintenance Allocation Summary", documents maintenance task allocations (test, service, replace, etc.) for components of the medical system.

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ILS ELEMENT	BASIC SOURCES	LSA	LSAR	LSA ADP REPORTS	OTHER STUDIES	COMPUTATIONAL MODEL
Maintenance Planning	o Service maintenance system o Organizational and operational concepts o Test Field and historical data o R&M Predictions	o Repair level analyses o FMECA o RCM o Task analyses o Survivability analyses o Analysis of existing manpower sources	A B B1 B2 C D	LSA-003 Maintenance Summary LSA-004 Maintenance Allocation Summary LSA-016 Preliminary Maintenance Allocation Chart LSA-024 Maintenance Plan		Maintenance simulation models
Manpower and Personnel	o R&M predictions and modeling o Test data o Field data o Historical data	o Task analyses o Survivability analyses	A C D G	LSA-001 Direct Annual Maintenance Man-Hours LSA-002 Personnel and Skill Summary	o Available manhours o Indirect productive time o Battle damage simulations o COEA	Manpower models
Supply Support	o Reliability predictions and modeling o Test data o Field data o Historical data	o FMECA o RLA o Task analyses o Survivability analyses	B C D H	LSA-036 Provisioning Requirements	o Battle damage simulations o Cannibalization policy	"Spare to availability" models Sortie generation models
Support Equipment and Test, Measurement and Diagnostic Equipment	o Lists of standard support and test equipment o GSA/DLA tool specifications	o Task analyses	B C D	LSA ADP REPORTS LSA-005 Support Equipment Utilization Summary LSA-007 Support Equipment Requirements LSA-020 Tools and Test Equipment Requirements		

Training and Training Devices	o Existing personnel skills capabilities, and programs of instruction o Training devices available	o Task analyses	C D E G	LSA-01 Requirements for Special Training Device LSA-014 Training Tasks List
Technical Data	o System functional requirements o Production documentation o Technical Manual standards and specifications o Descriptions of personnel capabilities (Target Audience)	o FMECA o RCM o RLA o Task analyses o Survivability analyses	B C D H E1	LSA-015 Sequential Task Description LSA-020 Tool and Test Equipment Requirements LSA-029 Repair Parts List LSA-030 Special Tool List LSA-040 Components of End Item List LSA-041 Basic Issue Items List LSA-042 Additional Authorization List LSA-043 Expendable/Durable Supplies & Materials List LSA-050 Reliability Centered Maintenance Summary LSA-055 Failure Mode Detection Summary
Computer Resources Support	o System functional requirements o Test reports o Field reports	o Post production support analyses		
Packaging, Handling, and Storage	o Design requirements and existing capabilities	o Task analyses	H	LSA-025 Packaging Requirements Data LSA-026 Packaging Developmental Data
Transportation and Transportability	o Existing transportation system and capabilities	o Task analyses	J	
Facilities	o Facilities available o Funding Constraints o Organizational and operational maintenance concept	o Task analyses	F	LSA-012 Requirements for Facility

Figure 15-4 Development of ILS Resource Requirements

15.4.2 Manpower and Personnel. This element encompasses the identification and acquisition of military and civilian personnel with the skills and grades required to operate and support the medical system at peacetime and wartime rates. Manpower constraints are identified prior to program initiation. Manpower drivers of a similar existing system (baseline comparison system) are identified, and projected manpower requirements for the new system are developed by comparative analysis during the CE phase. Consideration of Manpower, personnel, and training are written into the ILS Plan (Section 15.6) to ensure that the effects of human factors engineering, personnel, training, and availability constraints, and potential force structure changes, and other MANPRINT considerations, are included in ILS and LSA activities (refer to Chapter 14, The MANPRINT Process).

As system design is performed during the FSD phase, data becomes available to enable the development of more precise estimates based upon detailed task analyses. Source data identified in Figure 15-4 are used to identify task durations and frequencies that are recorded on the data records listed. The LSA ADP system displays data in formats convenient for manpower computation. LSA-001, "Direct Annual Maintenance Manhours", lists the direct annual manhours of each required maintenance occupational specialty at each level of maintenance. LSA-002, "Personnel and Skill Summary", identifies maintenance manhours, time, and the required number of personnel by task, work unit code, or technical manual functional group code. Maintenance manhour requirements developed by USAMMDA are converted to manpower requirements by AHS-CD for incorporation in Qualitative and Quantitative Personnel Requirements Information (QQPRI) and Tables of Organization and Equipment (TOE). AHS-CD also determines requirements for operating and staff personnel.

15.4.3 Supply Support. Supply Support encompasses all actions required to identify and obtain the spares and repair parts needed to attain peacetime and wartime readiness objectives. The source data and LSA techniques listed in Figure 15-4 are used to estimate mean intervals (i.e., in operating hours) between parts replacements. The LSA records identified can support all required provisioning actions. MIL-STD-1388-2A has superseded MIL-STD-1552A,

Uniform DOD Requirements for Provisioning Technical Documentation. LSA ADP report LSA-036 can provide all provisioning list deliverables cited in MIL-STD-1561, Uniform DOD Provisioning Requirements. "Sparing to Availability" is the term generally applied to models that compute stockage levels (items and quantities) required to support system readiness objectives. The Selected Essential Items Stockage for Availability Method (SESAME) has been developed by the U.S. Army System Analysis Activity for this purpose.

Selected supply support LSA studies are performed starting in D&V. All required studies and documentation should be completed during FSD. Computations of total provisioning requirements should be completed prior to the production decision (Milestone III).

15.4.4 Support Equipment and Test, Measurement, and Diagnostic Equipment. This element encompasses actions to identify and acquire all equipment required to support the operation and maintenance of the medical system. This includes associated multi-use end items; ground handling and maintenance equipment; tools; metrology and calibration equipment; manual and automatic test, measurement, and diagnostic equipment; and the acquisition of logistic support for this equipment.

Support equipment and Test, Measurement and Diagnostic Equipment (TMDE) standardization studies and the determination of developmental requirements for new support equipment and TMDE are performed during CE. Requirements for new (developmental) and standard equipment are further identified in trade-off studies performed during D&V. Detailed task analyses and documentation are performed during FSD to identify specific equipment requirements for each operating and maintenance task. The LSA ADP reports identified in Figure 15-4 support the determination of quantitative requirements for the selected items.

15.4.5 Training and Training Devices. This element encompasses all of the processes, procedures, techniques, training devices and equipment used to train personnel to operate and support medical systems. Examples include individual and crew training; new equipment training; initial, formal, and on-the-job training; and logistic support planning for training devices.

Training constraints are identified by MANPRINT analyses (refer to Chapter 14) prior to program interaction. Key training issues of similar medical systems are analyzed, targets for improvement are identified, and projected training requirements for the operational phase are identified during CE. The LSA process, through task analysis, serves to identify training and training device requirements at the task level during D&V and FSD. The output of the LSA ADP system (Figure 15-4), if used, summarizes requirements for special training devices and training tasks. Also refer to Chapter 16, The Training and Training Device Process.

15.4.6 Technical Data. This element encompasses all recorded information of a scientific or technical nature related to a program. Technical data are written instructions such as drawings; operating and maintenance manuals; specifications; inspection, test, and calibration procedures; and documentation of computer programs.

Sources, LSA techniques, and LSA records applicable to technical data are identified in Figure 15-4. MRSA is responsible for the development of Technical Manual Standards and Specifications. AHS-Trainer identifies target audiences (e.g., skill and reading comprehension levels) for medical system technical manuals.

The LSA ADP system is capable of displaying extensive data to support preparation of technical manuals. Some output reports (LSA-029 "Repair Parts List," for example) are produced directly in military standard format for technical manuals.

Draft equipment manuals must be available by late D&V to support user tests and troop training for these tests. Final technical manuals must be available to support the first unit equipped.

15.4.7 Computer Resources Support. This element is defined to include computer equipment, software, associated documentation, contractual services, personnel, and supplies needed to operate and support a computer embedded in a

medical system. Areas of special concern for ILS personnel are: 1) fault detection and fault isolation capabilities; 2) ability of maintenance personnel to differentiate between hardware and software deficiencies; and 3) management of software modification during the operational phase. Support of embedded computers and their software should be addressed in the Post-Production Support Plan prepared during FSD.

15.4.8 Packaging, Handling, and Storage. This element includes the characteristics, action, and requirements necessary to preserve, package, and handle all equipment and support items. Inputs (Figure 15-4) include existing packaging standards and containers and the capability of current handling and storage facilities and equipment.

In the CE phase, packaging and handling standards are specified, and design constraints are established to obtain compatibility with the projected support system. Component design is reviewed during D&V and FSD to assure compatibility with existing packaging assets and to determine unique protection and handling requirements. Dimensional, special handling, storage, and shelf life data are recorded on the LSAR record. The LSA ADP system is capable of producing two package summary reports (Figure 15-4).

15.4.9 Transportation and Transportability. This element encompasses the characteristics, actions, and requirements necessary to ensure the capability to transport medical materiel. Initial system transportability constraints are specified in CE. Transportability trade-offs (LSA task 303.2.12) are performed during CE and D&V to optimize the transportability concept under the identified constraints. USAMMDA submits Transportability Reports describing the transportability characteristics of the developing design to the Military Traffic Management Command-Transportability Engineering Agency (MTMC-TEA) no later than 90 days prior to the decision reviews for Milestones I, II, and III. (A completed LSAR J record satisfies the report requirement). MTMC-TEA submits a Transportability Engineering Analysis (TEA) prior to the Milestone I, II, and III decision reviews and a Transportability Approval (TA) prior to the Milestone II and III decision reviews. The Transportability report and analyses are required on all medical systems with transportability requirements stated in requirements documents. Refer to AR 70-47.

15.4.10 Facilities. This element encompasses those real property assets required to support the medical system and the studies which define types of facilities or facility improvements, locations, space needs, environmental requirements and equipment. The objective of ILS facilities planning is to assure that required facilities are available to test activities, operating forces, and support units when needed.

Preliminary facility requirements are identified by USAMMDA during CE and coordinated with potential gaining MACOMS. LSA data record F is used to document the description and justification for new facilities. These may be summarized in the LSA-012 report "Requirements for Facility".

15.5 THE INTEGRATED LOGISTIC SUPPORT MANAGEMENT TEAM (ILSMT)

An ILSMT is formed whenever relationships with organizations outside of USAMMDA are especially important to the success of a product development program. The ILSMT serves as the vehicle for coordinating, executing, updating, and assessing the ILS Plan and the development contractor's progress in meeting the contractual ILS requirements. A subteam of the ILSMT reviews the LSA process and use of the LSAR in the development of ILS resource requirements.

The ILS manager chairs the ILSMT. The composition of the ILSMT includes representatives from USAMMDA-PMO, USAMMDA-PMSO, USAMRDC, AHS-CD, AHS-Trainer, Readiness Proponent (USAMMA or AMC), the development contractor, other Services (as appropriate), and Human Engineering Laboratory (for Human Factors Engineering Analysis).

15.6 THE INTEGRATED LOGISTIC SUPPORT PLAN

USAMMDA, in coordination with the ILSMT, prepares the initial Integrated Logistic Support Plan (ILSP) during CE and updates the plan during D&V and FSD. The ILSP describes the overall ILS program and all ILS program requirements, tasks, and milestones for the current acquisition phase. It also

projects ILS program planning for succeeding phases. The ILSP is divided into three major sections: I, General; II, Plans, Goals, and Strategy; and III, ILS Milestone Schedules. The System MANPRINT Management Plan (SMMP) provides MANPRINT source data to the ILSP (refer to Chapter 14). Also refer to DA Pamphlet 700-55, Instruction for Preparing the Integrated Logistic Support Plan.

15.7 ARMY MANAGEMENT MILESTONE SYSTEM

The Army Management Milestone System (AMMS) is the Department of the Army standard, integrated life cycle management milestone reporting system and central data repository for recording system status in the acquisition cycle through fielding. (Refer to draft AR 7XX-XX, Army Management Milestone System). Milestone reporting is mandatory for all developmental and nondevelopment systems, reprocurement items, and product improvement programs that lead to type classification, materiel release, first unit equipped, or initial operational capability.

USAMMDA (for developmental, MOD-NDI, and product improvements programs) and USAMMA (for NDI programs) are responsible for developing AMMS milestones. MRSA maintains the central data base for AMMS status, provides regular and tailored reports, conducts reviews on individual systems, and provides detailed procedural guidance to AMMS milestone proponents and users.

MRSA also operates a Computer Aided Milestone Scheduling (CAMS) system to assist proponents in their initial development of ILS milestones (Section III of the ILSP). AMMS milestone proponents have direct computer terminal telephone access to the system. The proponent identifies five key program dates: 1) O&O Plan approval; 2) Milestone I approval; 3) Milestone II approval; 4) Milestone III approval; and 5) one or more first unit equipped dates. CAMS then provides a proposed detailed schedule of intervening milestones as an input aid to the AMMS proponent.

15.8 PREPROGRAM INITIATION

15.8.1 ILS Objectives. ILS objectives prior to program initiation are to identify supportability design and logistic support deficiencies in existing medical systems and constraints and technology opportunities for a proposed new system. These efforts are performed as part of the Concept Based Requirements System by AHS-CD logistics personnel supported by USAMMDA and USAMMA.

15.8.2 Specific Activities.

SEE FIGURE 15-5

1. Mission Area Analysis. The logistician's assessment of current systems should focus on deficiencies in their supportability performance (e.g., failure rates, maintenance time, fault detection and isolation capability) and on the adequacy of logistic support provided the system. In addition, the logistician should establish realistic bounds on the support resources that can be provided to a proposed new medical system. The Use Study (LSA task 201) and Comparative Analysis (LSA task 203) are conducted as part of the mission area analysis.

2. Mission Area Development Plans, Battlefield Development Plan, Mission Area Materiel Plan. Logisticians within AHS, USAMMA, and USAMMDA support development of the doctrinal, training, organizational, and materiel projects that respond to the recognized deficiencies, and provide input to the appropriate Mission Area Development Plan (MADP), Battlefield Development Plan (BDP), and Mission Area Materiel Plan (MAMP) (refer to Chapter 9, The Long-Range RDA Planning Process).

3. Programming and Budgeting. AHS, USAMMDA, and USAMMA logistics personnel ensure that adequate estimates of funding required for ILS planning and ILS resources are included in the initial POM submission for the new medical system (refer to Chapter 10, The PPBES Process).

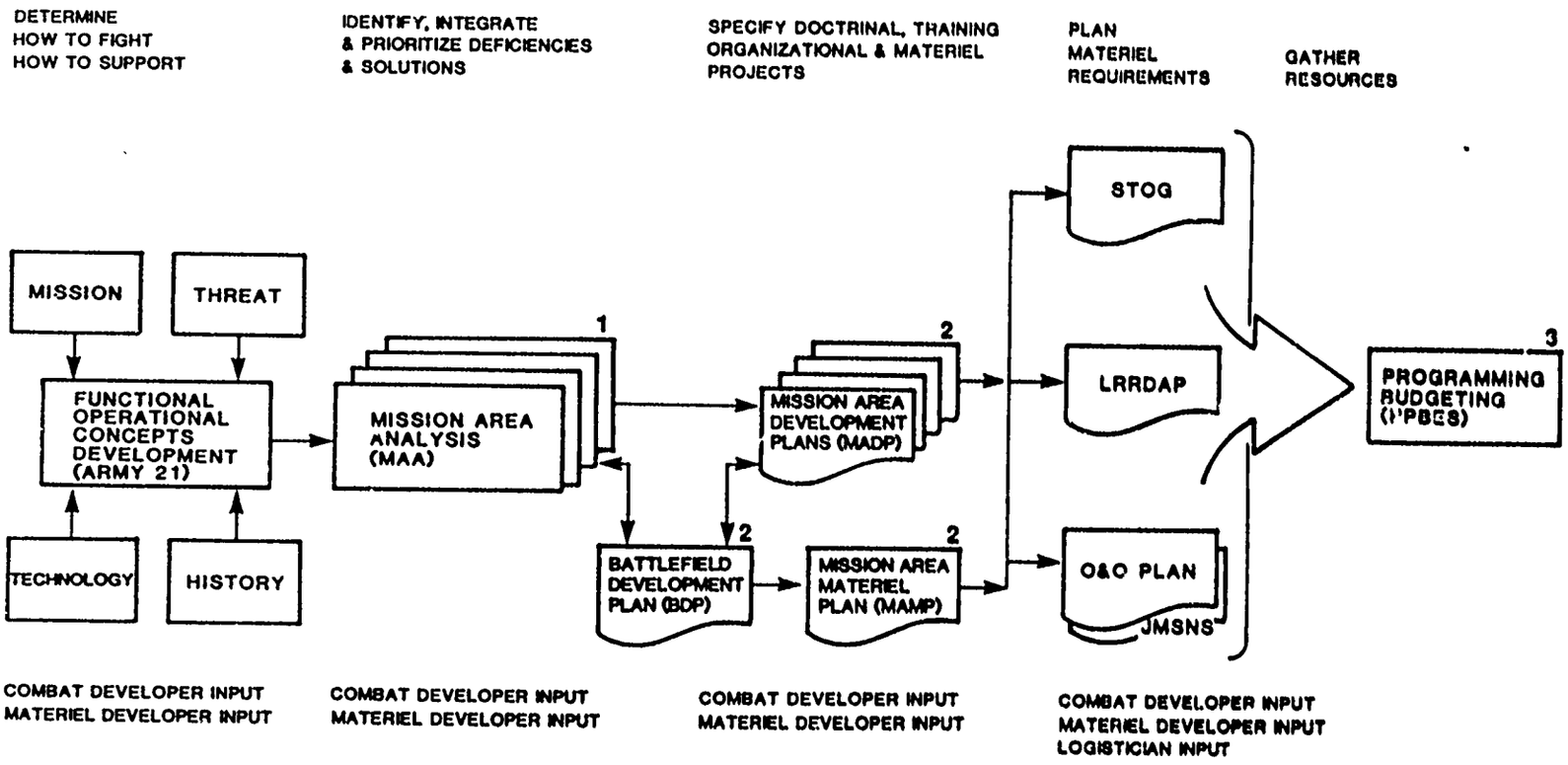


Figure 15-5. THE ARMY CONCEPTS BASED REQUIREMENTS SYSTEM

15.9 CONCEPT EXPLORATION PHASE

15.9.1 ILS Objectives. The ILS objectives of this phase include:

- o Development of a comprehensive ILS program tailored to the acquisition strategy;
- o Selection of a best technical approach capable of attaining tentative system readiness objectives within established manpower, training, and logistic constraints;
- o Development of MANPRINT requirements.

15.9.2 Specific Activities.

SEE CHART 15-1

NOTE:

ILS activities may be divided into two categories: (1) direct activities performed and completed by logistics personnel such as updating an ILS Plan; (2) contributory activities in which logistics personnel provide input or comment to broader acquisition activities such as updating an Acquisition Strategy. Chart 15-1 and the narrative text employ a verb statement (e.g., "UPDATE ILSP") to identify direct ILS activities, and a noun statement (e.g., "AS UPDATE") to identify contributory ILS activities.

1. Operational and Organizational (O&O) Plan Approval. Approval of the O&O Plan initiates CE.

2. Designate ILS Manager. The USAMMDA Project Manager designates an ILS Manager for the medical system from his office in coordination with the Project Management Support Office (PMSO).

3. Establish Integrated Logistic Support Management Team. The ILS Manager establishes the Integrated Logistic Support Management Team (ILSMT) (refer to paragraph 15.5).

4. Market Investigation. The ILS Manager, with the support of the ILSMT or its participating activities, provides input to the Market Investigation Independent Evaluation Plan (IEP) prepared by AHS-CD. The objective is to ensure that the investigation performed by USAMMDA-PMO addresses supportability design and logistic support issues of potential NDI sources (refer to paragraph 4.2.1).

5. Acquisition Strategy and Acquisition Plan. The ILS Manager provides input to, or prepares the supportability portion of, the Acquisition Strategy (AS) and the logistics considerations portion of the Acquisition Plan (AP).

6. Prepare Integrated Logistic Support Plan. USAMMDA-PMSO prepares the Integrated Logistic Support Plan (ILSP) under direction of the ILS Manager and with the support of the ILSMT or its participating activities. The ILSP is maintained compatible with the tailoring of acquisition processes established in the AS (refer to paragraph 15.6).

7. Prepare Supportability Assessment Plan. The ILS Manager prepares or directs contractor preparation of the Supportability Assessment Plan (LSA Task 500) with the support of the ILSMT or its participating activities. The plan identifies the approach, criteria, and physical resources required to evaluate supportability design of the system and the adequacy of the ILS resources developed for the system. It addresses all life cycle evaluations, including post-deployment assessments, and evaluations integrated with technical and user tests and those performed separately (e.g., logistic demonstrations). The plan is also used to develop input to the Test and Evaluation Master Plan (TEMP).

8. Test and Evaluation Master Plan. The ILS Manager provides input to, and participates in, the Test Integration Working Group's (TIWG) preparation of the TEMP. The ILS input is derived from the Supportability Assessment Plan (Activity 7).

9. Prepare Logistic Support Analysis Plan, Approve Integrated Support Plan. The ILS Manager directs preparation of the Logistic Support Analysis Plan (LSAP) (Task 102). The LSAP identifies and integrates all LSA tasks, identifies management responsibilities and activities, and outlines the approach to accomplish analysis tasks. The ILS Manager also directs preparation of, and approves, the Integrated Support Plan (ISP) which sets forth the contractor's plan to accomplish his projected ILS efforts.

10. Develop ILS Resource Requirements. The ILS Manager, with the support of the ILSMT or its participating activities, initiates the development of ILS resources required to support operational testing and deployment. Refer to paragraph 15.4 for those activities to be performed during CE.

11. Develop Army Management Milestone System Milestones. USAMMDA-PMSO selects ILS milestones from the ILSP to be included in the Army Management Milestone System (AMMS) (refer to paragraph 15.7).

12. Prepare Individual and Collective Training Plan. The AHS Trainer develops the Individual and Collective Training Plan (ICTP) (refer to Chapter 16).

13. PPBES Update. The ILS Manager, supported by USAMMDA-PMSO updates estimates of the resources required for life cycle ILS planning and logistics support of technical and user tests, supportability assessments, and field deployment. This input is incorporated into the project PPBES update furnished to HQ USAMRDC.

14. Establish System Readiness Objectives and Support Concepts. The ILS Manager, with the support of the ILSMT or its participating activities, defines peacetime and wartime baseline operational scenarios for recommended system alternatives and establishes tentative system readiness objectives (refer to paragraph 15.3).

15. Prepare Transportability Report. When required, the ILS Manager will prepare or direct contractor preparation of a Transportability Report. The report will be provided to MTMC no later than 90 days prior to the Milestone I decision review (refer to paragraph 15.4).

16. MTMC Transportability Engineering Analysis. MTMC performs the analysis of the Transportability Report and transmits it to USAMMDA-PMO prior to the Milestone I decision review. The Transportability Engineering Analysis (TEA) is one of the Milestone review documents that accompanies the System Concept Paper (SCP).

17. Preparation of Integrated Logistic Support Review Documentation. USAMMDA performs an indepth analysis of logistic support activities and prepares the Integrated Logistic Support Review (ILSR) documentation 60 to 90 days prior to the Milestone I decision review.

18. DCSLOG ILSR. AR 700-127 requires the presentation of an ILSR before major decision Milestones (I, II, III) or as otherwise required by DA ODCSLOG. The ILSR will normally be conducted for Designated Acquisition Program (DAP) medical systems and may also be requested selectively by ODCSLOG for IPR systems. The review will be chaired by a DCSLOG general officer with high level participants from the Army Secretariat (ASA-IL) and the Army Staff, including OTSG. OTSG may require a pre-briefing. ILSR assessment considerations are identified in Appendix E of AR 700-127.

19. Requirements Documents and Concept Formulation Package. The ILS Manager, with input from the ILSMT participating activities, provides ILS input to Concept Formulation Package (CFP) studies (Trade-Off Determination, Trade-Off Analysis, Best Technical Approach, and Cost and Operational Effectiveness Analysis) and assures that the selected concept meets the objectives stated in paragraph 15.9.1. The ILS Manager provides requirements documents input to USAMMDA-PMO (refer to Chapter 11, The Requirements Documents Process and Chapter 13, The Concept Formulation Package Process).

20. Request for Proposal. USAMMDA-PMSO develops and provides contractor logistics requirements to USAMRAA for inclusion in the Request for Proposal (RFP) for contractor support during D&V. This will include ILS planning activities, such as LSA/LSAR activities, supportability assessment, and the development of a system support package and new equipment training package for user tests. The LSA/LSAR requirements will be specifically tailored to the requirements of the medical system during the D&V phase. Other ILSMT participating activities provide support as required. The ILS Manager approves the ILS input prior to forwarding to USAMRAA.

21. System Concept Paper. The ILS Manager provides input to the System Concept Paper (SCP) as required. ILS issues are included in Section VII, Description of Selected Alternative, and Annex F, Acquisition Strategy of the SCP.

15.10 DEMONSTRATION AND VALIDATION PHASE

15.10.1 ILS Objectives. The ILS objectives of this phase include:

- Establishment of system supportability design requirements that achieve the best balance among hardware characteristics, support concepts, and support resource requirements;
- Verification, in user tests and logistics demonstrations, that advanced development prototypes achieve supportability design requirements;
- Validation of ILS resources developed for the system (personnel selection, training, support equipment, etc.) in realistic user testing.

15.10.2 Specific Activities

SEE CHART 15-1

22. AS/AP Update. The ILS Manager provides input to, or updates the supportability portion of, the AS and the logistics considerations portion of the AP.

23. Trade-Off Studies. The ILS Manager and the ILSMT participating activities support the USAMMDA-PMO in the performance of trade-off studies seeking the best balance among hardware characteristics, support concepts, and support resource requirements. This is a continuing process, as the preliminary design evolves during this phase.

24. Update Supportability Assessment Plan and TEMP Update. The ILS Manager updates or directs contractor update of the Supportability Assessment Plan and supports the TEMP update. Refer to Activities 7 and 8.

25. Update ILSP, LSAP, AMMS, Approve ISP Revision. USAMMDA-PMSO updates the ILSP (Activity 6), maintaining compatibility with the revised AS, and updates the AMMS Milestones (Activity 11). The ILS Manager directs the update of the LSAP and approves contractor update of the ISP (Activity 9).

26. Develop Maintenance Concept and Key System Parameters. Following completion of initial trade-off studies, the ILS Manager, supported by the ILSMT or its participating activities, develops the maintenance concept for the medical system. In addition, peacetime and wartime system readiness objectives are established and supportability design requirements (reliability, maintainability, testability, etc.) are developed as guidelines for preliminary design.

27. Preliminary Design. The ILS Manager or logistics management personnel in USAMMDA-PMSO provide input to, and participate in, the approval of System Specifications (Type A) and Development Specifications (Type B). These specifications govern the contractor's preliminary design activities and manufacture of advanced development prototypes.

28. Perform Logistic Demonstrations. USAMMDA-PMSO manages the preliminary Logistic Demonstration and Physical Tear-Down of an advanced development prototype. This is performed to validate the maintenance concept and the preliminary system support package. This activity is performed prior to the formal user test (Activity 29).

29. Independent Evaluation Plan, Technical Test, and Independent Evaluation Report. The ILS Manager and supporting logistics management personnel provide test issues to USAMMDA-PMO for inclusion in the Technical Test Independent Evaluation Plan (IEP) and support the technical tests as required (refer to Chapter 17, The Test and Evaluation Process).

30. Independent Evaluation Plan, User Test, and Independent Evaluation Report. The ILS Manager and supporting logistics management personnel play two important roles in user tests; namely that they provide test issues to AHS-CD for inclusion in the user test IEP, and they support the tests. ILS objectives are to validate the supportability design and to verify the effectiveness of the planned support capability. A major concern of the ILS Manager and the ILSMT activities is to ensure that the testing is conducted under conditions as representative as possible of post-deployment usage. The ILS Manager and the ILSMT activities are responsible for development of the preliminary system support package (supply support, support equipment, and TMDE, etc.) and the test training support package.

31. Update ILS Resource Requirements. Contractor ILS personnel update the ILS resource requirements. The preliminary design, Logistic Demonstration, and technical and user test reports provide input to the LSA/LSAR process that defines the resource requirements (refer to Activity 10 and Paragraph 15.4).

32. PPBES Update. The ILS Manager, supported by USAMMDA-PMSO updates ILS funding requirements for inclusion in the project PPBES Update (refer to Activity 13).

33. Prepare Basis of Issue Plan/Qualitative and Quantitative Personnel Requirements Information. USAMMDA-PMSO provides Basis of Issue Plan (BOIP) feeder data and Qualitative and Quantitative Personnel Requirements Information (QQPRI) input to AHS-CD for completion of the BOIP/QQPRI. Updated manpower and personnel data developed in activity 30 provide input to the process (refer to Chapter 18, The BOIP/QQPRI Process).

34. Update ICTP. AHS-Trainer updates the ICTP (refer to Chapter 16, The Training and Training Device Process).

35. Develop New Equipment Training Plan. USAMMA plans development of initial training for the new medical system (refer to Chapter 20, The Materiel Fielding and New Equipment Training Process).

36. Update Transportability Report, Obtain Transportability Engineering Analysis and Transportability Approval. When required, the ILS Manager provides an updated Transportability Report to MTMC-TEA no later than 90 days prior to the Milestone II decision review. MTMC provides a TEA and Transportability Approval (TA) to the USAMMDA-PMO prior to the decision review for inclusion in the DCP package. Refer to Activities 15 and 16 and paragraph 15.4.9.

37. Conduct Command Logistics Status Review. USAMMDA-PMSO provides a status review of the ILSR documentation 60-90 days prior to the Milestone II decision review.

38. DCSLOG ILSR. When required, the USAMMDA-Project Manager conducts the DCSLOG ILSR prior to the Milestone II decision review (refer to Activity 18).

39. Requirements Documents/Cost Effectiveness Analysis. The ILS Manager, with support from the ILSMT activities, provides logistics input to AHS-CD for inclusion in requirements documents and the updated cost effectiveness analysis (COEA or AA).

40. Request for Proposal. USAMMDA-PMSO develops and provides contractor logistics support requirements to USAMRAA for inclusion in RFP(s) for contractor support during the Full Scale Development (FSD) phase. This will include ILS planning activities such as LSA/LSAR activities, supportability assessment, development of a system support package and new equipment training package for user tests, and if required, long lead time provisioning items to support initial deployment. The LSA/LSAR requirements should be specifically tailored to the requirements of the medical system during FSD. Other ILSMT participating activities provide support as required. The ILS Manager approves the input prior to forwarding to USAMMRA.

41. Decision Coordinating Paper. The ILS Manager provides input to the Decision Coordinating Paper (DCP) as required. ILS issues are included in Section VII, Description of Selected Alternative, and Annex F, Acquisition Strategy of the DCP.

15.11 FULL SCALE DEVELOPMENT PHASE

15.11.1 ILS Objectives. The ILS objectives of this phase include:

- o Completion of the definition of ILS resources required to obtain peacetime and wartime system readiness objectives;
- o Verification of the supportability performance of engineering development prototypes and hard-tooled preproduction models by user testing programs;
- o Verification of the adequacy of the total system support package (ILS resources) by user testing programs;
- o Preparation of contractual requirements for all ILS resources required at the First Unit Equipped (FUE) date.

15.11.2 Specific Activities

SEE CHART 15-1

42. AS/AP Update. The ILS Manager provides input to, or updates the supportability portion of, the AS and the logistics considerations portion of the AP.

43. Update Supportability Assessment Plan and TEMP Update. The ILS Manager updates or directs contractor update of the Supportability Assessment Plan and supports the TEMP Update. Refer to Activities 7 and 8.

44. Update ILSP, LSAP, AMMS, Approve ISP Revision. USAMMDA-PMSO updates the ILSP (activity 6), maintaining compatibility with the revised AS and updates the AMMS milestones (activity 11). The ILS Manager directs update of the LSAP and approves contractor update of the ISP (activity 9).

45. Transition Planning and Tracking Group and Transition Plan. The ILS Manager and PMSO participate in Transition Planning and Tracking Group (TPTG) activities in order to assure an effective transfer of ILS responsibilities to USAMMA in the Production and Deployment Phase (refer to Chapter 5, Development Program).

46. Detailed Design Activities. The USAMMDA ILS Manager participates in the preliminary design reviews that govern the contractor's detailed design activities and manufacture of engineering development prototypes (refer to Chapter 19 The Configuration Management Process). ILS concerns primarily relate to the supportability design of the medical system and design of system unique support equipment and training devices.

47. Perform Logistics Demonstration. USAMMDA-PMSO manages the final Logistics Demonstration and Physical Tear Down of the engineering development prototype, if required. These are performed to revalidate the maintenance concept and validate the final system support package. This activity is performed prior to the technical and user tests.

48. IEP, TT, and IER. The ILS Manager provides test issues to USAMMDA PMO for inclusion in the technical test evaluation plan and supports the test as required (refer to Chapter 17).

49. IEP, User Test, and IER. The ILS Manager provides test issues (supportability design and support adequacy) to AHS-CD for inclusion in the user test IEP. The ILS Manager also ensures that a complete (or adequate) final system support package and a training support package are available to support the user test.

50. Update ILS Resource Requirements. ILS resource requirements are updated through the detailed design activities, Logistic Demonstration, and technical and user test reports that provide input to the LSA/LSAR process (refer to Activity 10 and paragraph 15.4).

51. PPBES Update. The ILS Manager, supported by USAMMDA-PMSO, updates ILS funding requirements for inclusion in the PPBES Update (refer to Activity 13).

52. Amend BOIP/QQPRI. USAMMDA-PMSO provides amended BOIP feeder data and QQPRI input to AHS-CD for completion of the BOIP/QQPRI. Updated manpower and personnel data developed in activity 50, provide input to this process (refer to Chapter 18).

53. Obtain National Stock Number and Standard Line Item Number. USAMMDA requests USAMMA to obtain a National Stock Number (NSN) for the item (through DMSB and DPSC) and a Standard Line Item Number (STD LIN) (through AMC) (refer to Chapter 5).

54. Update ICTP. AHS-Trainer updates the ICTP (refer to Chapter 16).

55. Update NETP. USAMMA updates the NETP (refer to Activity 34 and Chapter 16).

56. Prepare Draft Materiel Fielding Plan/Materiel Fielding Agreement. USAMMDA prepares a draft Materiel Fielding Plan (MFP) and Materiel Fielding Agreement (MFA) (refer to Chapter 20).

57. Update Transportability Report, Obtain TEA and TA. Refer to Activities 15, 16, and 35 and paragraph 15.4.9.

58. Update ILSR Documentation. USAMMDA-PMSO provides a status update of the ILSR documentation 60-90 days prior to the Milestone III decision review.

59. DCSLOG ILSR. When required, the Project Manager conducts the DCSLOG ILSR prior to the Milestone III decision review (refer to Activity 18).

60. TPTG Progress Review. The ILS Manager presents the status of ILS activities to the TPTG.

61. RFP. USAMMDA-PMSO develops and provides contractor logistic support requirements to USAMMRAA for inclusion in RFP(s) for contractor support during the Production and Deployment phase. This will include continuing ILS planning, such as LSA/LSAR activities, and procurement and delivery of ILS resources (supply support, support equipment and TMDE, contractor field technicians (where appropriate), final draft technical manuals, etc., required to support the first unit equipped and continuing deployment and operation.

62. DCP. The ILS Manager provides input to the DCP as required.

15.12 PRODUCTION AND DEPLOYMENT PHASE

15.12.1 ILS Objectives. The ILS objectives of this phase include:

- o Validation and delivery of ILS resources to meet First Unit Equipped (FUE) and continuing deployment;
- o Assurance that supportability deficiencies are corrected and that corrections are validated in a follow-on test and evaluation (FOT&E);
- o Assurance, through post-deployment supportability assessment, that system performance and logistic support are adequate to achieve the system readiness objective within projected manpower and operation and support (O&S) cost target levels and implementation of corrective actions as required.

15.12.2 Specific Activities.

SEE CHART 15-1

63. Transition to USAMMA. USAMMA's program management role, including ILS management, begins at this point. USAMMDA retains an engineering support role to assist USAMMA and DPSC as required on production and readiness issues during the entirety of the Production and Deployment Phase.

64. Transfer TDP. USAMMA transfers the TDP through DMSB to DPSC.

65. Solicitation Package. DPSC prepares a solicitation package, awards the production contract and conducts the Production Acceptance Test and Evaluation (PAT&E). USAMMA personnel participate.

66. Update Supportability Assessment Plan. USAMMA updates the Supportability Assessment Plan prepared by USAMMDA (refer to Activity 7), with a focus on Post-Deployment Supportability Assessment (LSA Task 501.2.5). If sample data collection is required, USAMMA prepares a Concept Paper (AR 750-37) and submits it to the MRSA 120 days prior to the planned start of field data collection.

67. Start Resident Training. AHS-Trainer initiates resident training in sufficient time to begin graduating students approximately six months prior to the First Unit Equipped (FUE) date (refer to Chapter 16).

68. Request Materiel Release. USAMMA monitors the status of logistic support resources required to support FUE and provide advice as to whether the availability of logistic support resources meets Full Release requirements. If there are logistic support shortfalls, USAMMA will assess the impact of the

shortfall and the availability of interim support capabilities and/or effective work-arounds and provide a recommendation as to whether Conditional Release approval should be sought (refer to Chapter 20).

69. Follow-On Test and Evaluation. USAMMA logistic management personnel participate in the evaluation of Follow-on Test and Evaluation (FOT&E) results to ensure that any previously identified supportability deficiencies have been corrected.

70. Assess Performance and Support. USAMMA initiates assessment of the performance (i.e., readiness) of the system and the effectiveness of logistic support.

15.13 TAILORING ILS ACTIVITIES

The foregoing material in this chapter is based upon development of applied medical systems. All deliverable AMEDD items will require ILS considerations ranging from storage, packaging, and inventory control for commercial pharmaceuticals, to extensive ILS planning, LSA/LSAR, technical manuals, etc., for large-scale development medical systems. In all instances, the selection and degree of sophistication of ILS requirements must be tailored to:

- The acquisition method, i.e., development, modified NDI, NDI, product improvement;
- The acquisition phase i.e., CE, D&V, FSD, P&D;
- The extent of maintenance required (applied medical systems versus pharmaceuticals versus biologicals);
- The degree of organic support required versus contractor support;
- The amount of funds available for investment in tasks;
- Schedule constraints;
- Data and analyses available.

Appendix A to MIL-STD-1388-1A provides guidance on LSA tailoring. Appendix E to MIL-STD-1388-2A provides guidance on LSAR tailoring.

15.14 REFERENCES

MIL-STD-1388-1A, Logistic Support Analyses, 1983

MIL-STD-1388-2A, DOD Requirements for a Logistic Support Analysis Record, 1984

AR 70-1, System Acquisition Policy and Procedures, 1986

AR 70-47, Engineering for Transportability, 1985

AR 700-127, Integrated Logistic Support, 1983

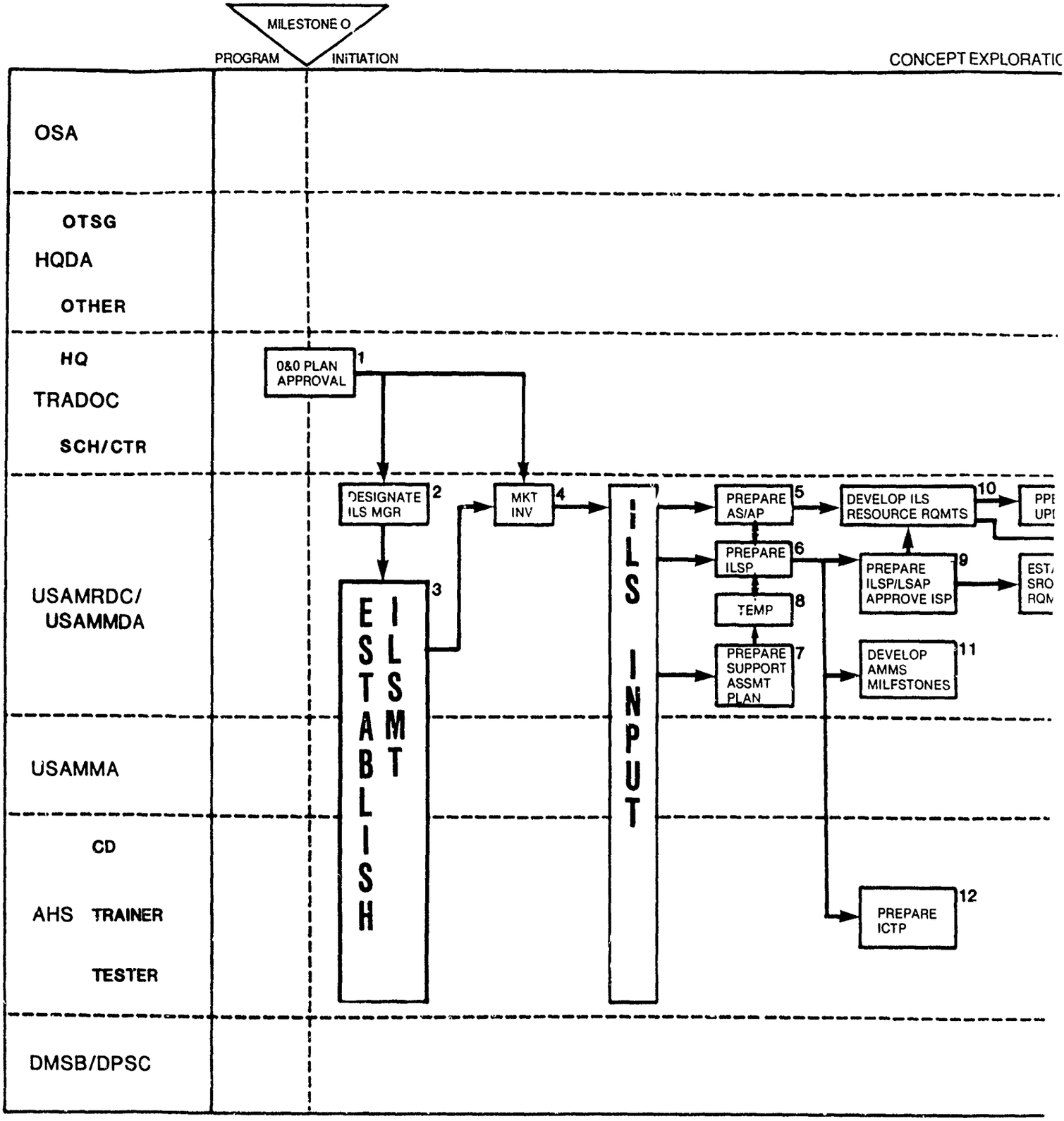
AR 750-37, Sample Data Collection: The Army Maintenance Management System, 1986

A7XX-XX (Draft), Army Management Milestone System

DA PAM 700-55, Instruction for Preparing the Integrated Logistic Support Plan, 1985

USAMMDA Memo 700-127, Integrated Logistic Support, 1985

Memorandum of Agreement between U.S. Army Medical Research and Development Command (MRDC) and U.S. Army Troop Support Command (TROSCOM), 1985


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PREPARE ILSP 6
TEMP 8
PREPARE SUPPORT ASSMT PLAN 7
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PREPARE ILSP/LSAP APPROVE ISP 9
DEVELOP AMMS MILFSTONES 11
PREPARE ICTP 12

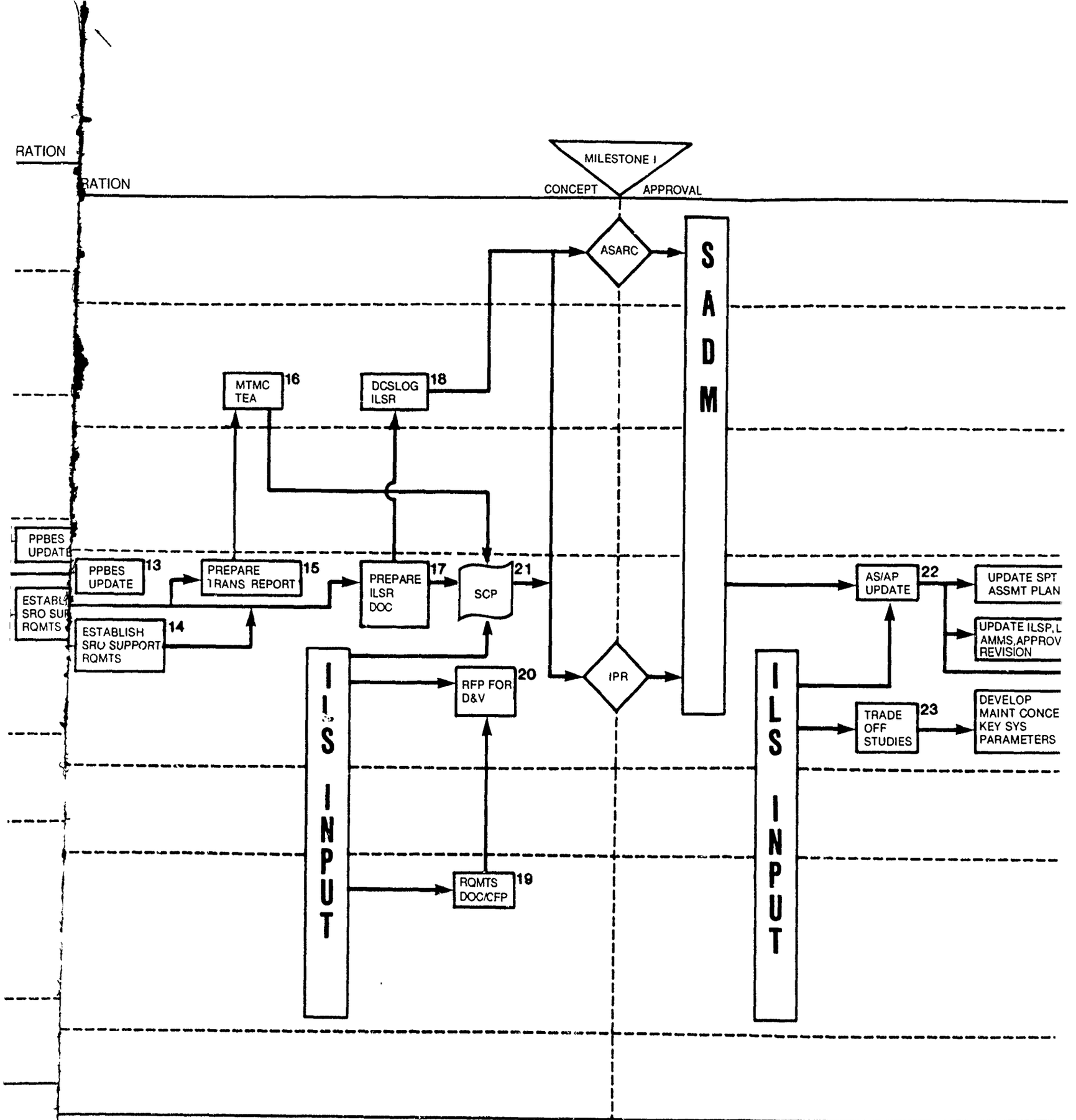


Chart 15-1, THE INTEGRATED LOGISTICS SUPPORT PROCE

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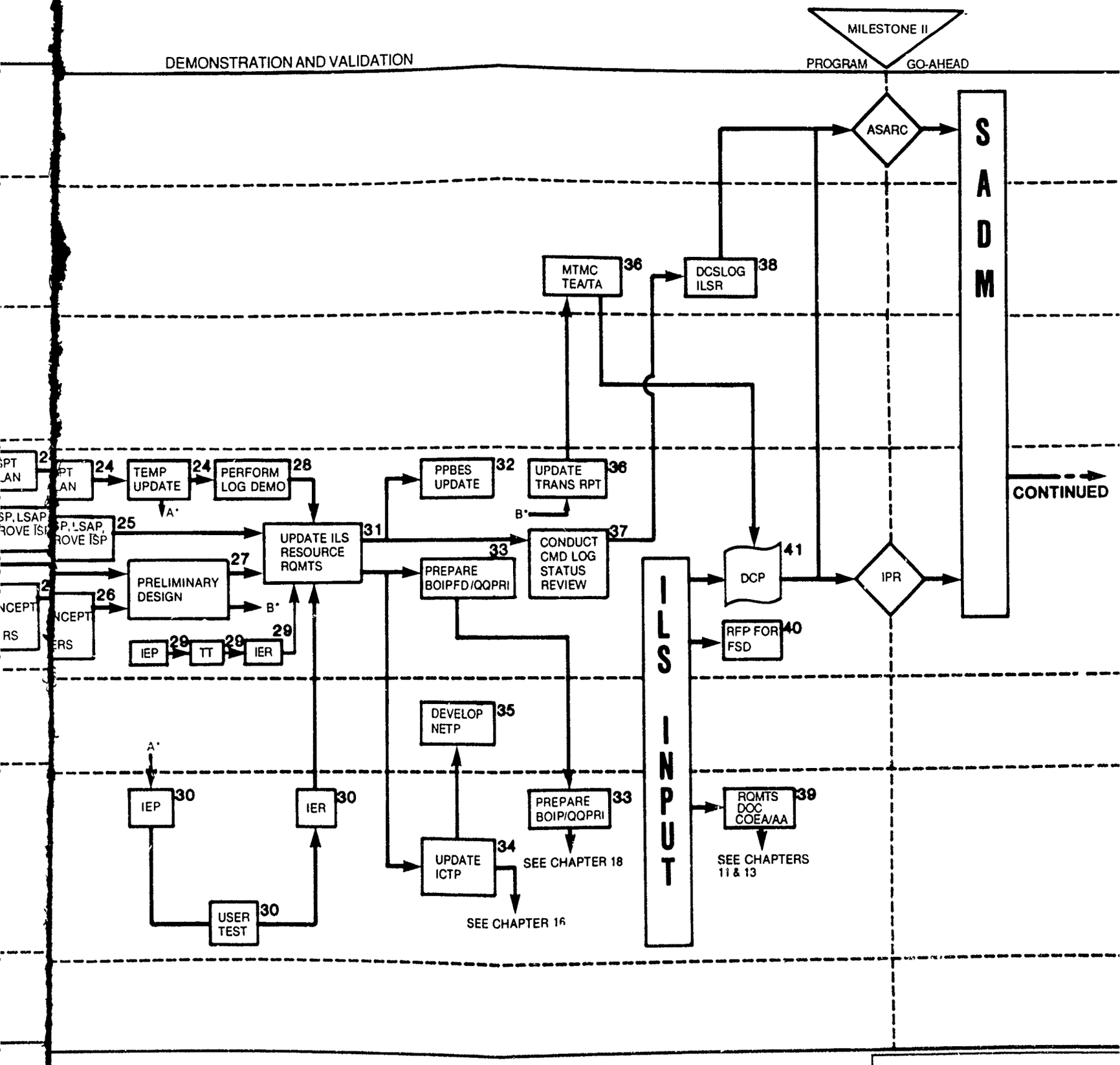


CHART NOTES

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2. BLOCK NUMBERS CORRESPOND TO THE TEXT P THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE

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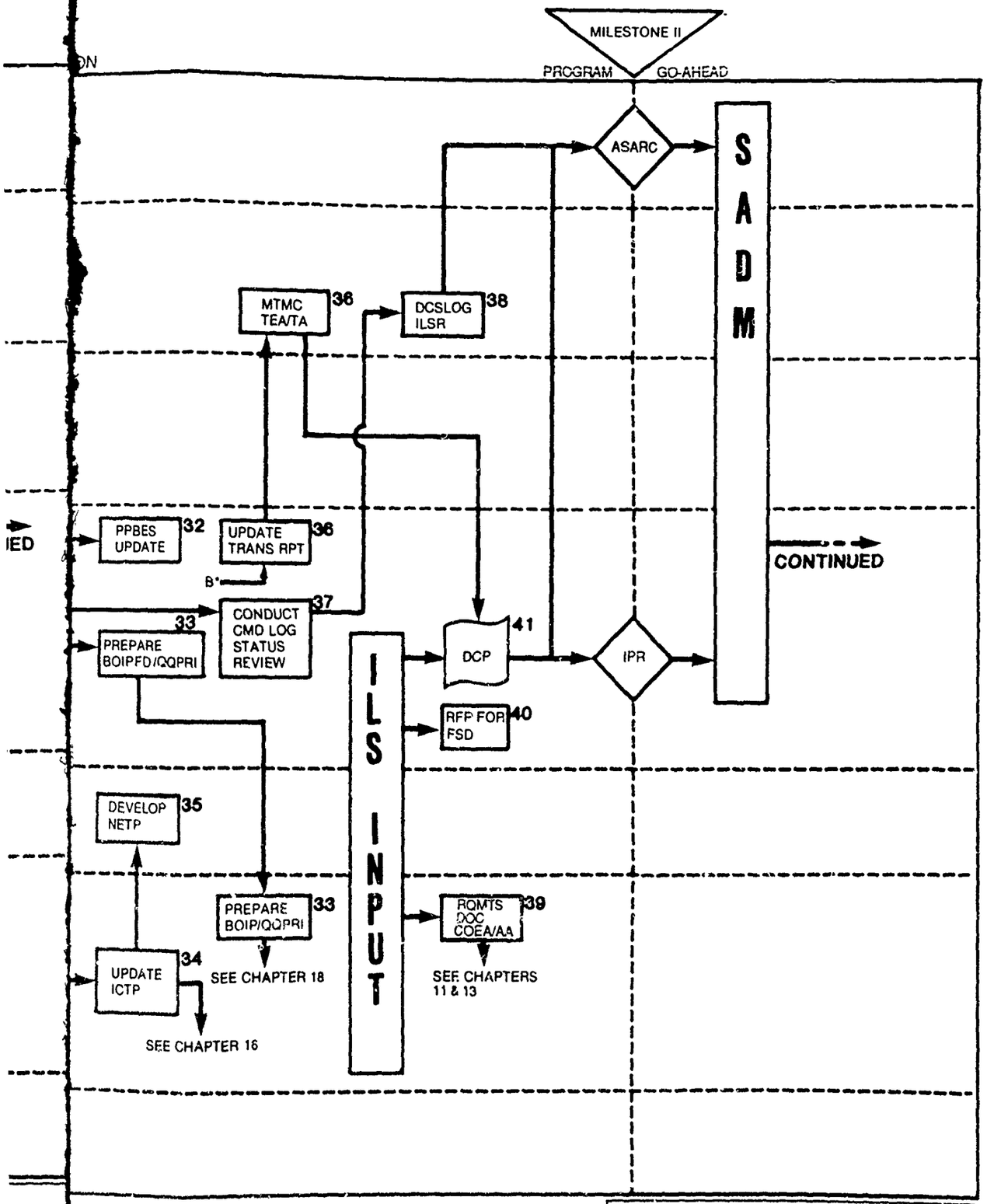


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

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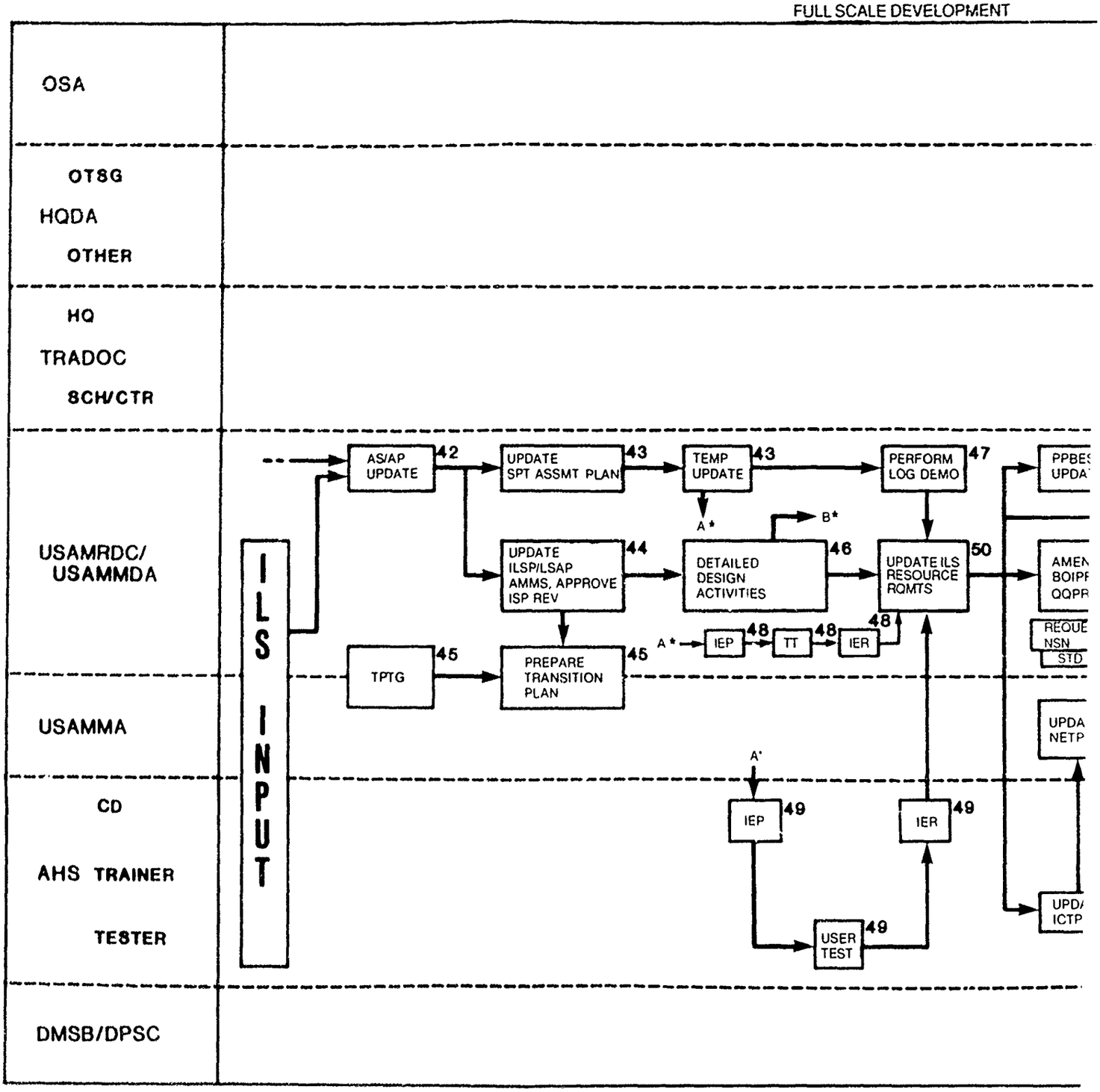
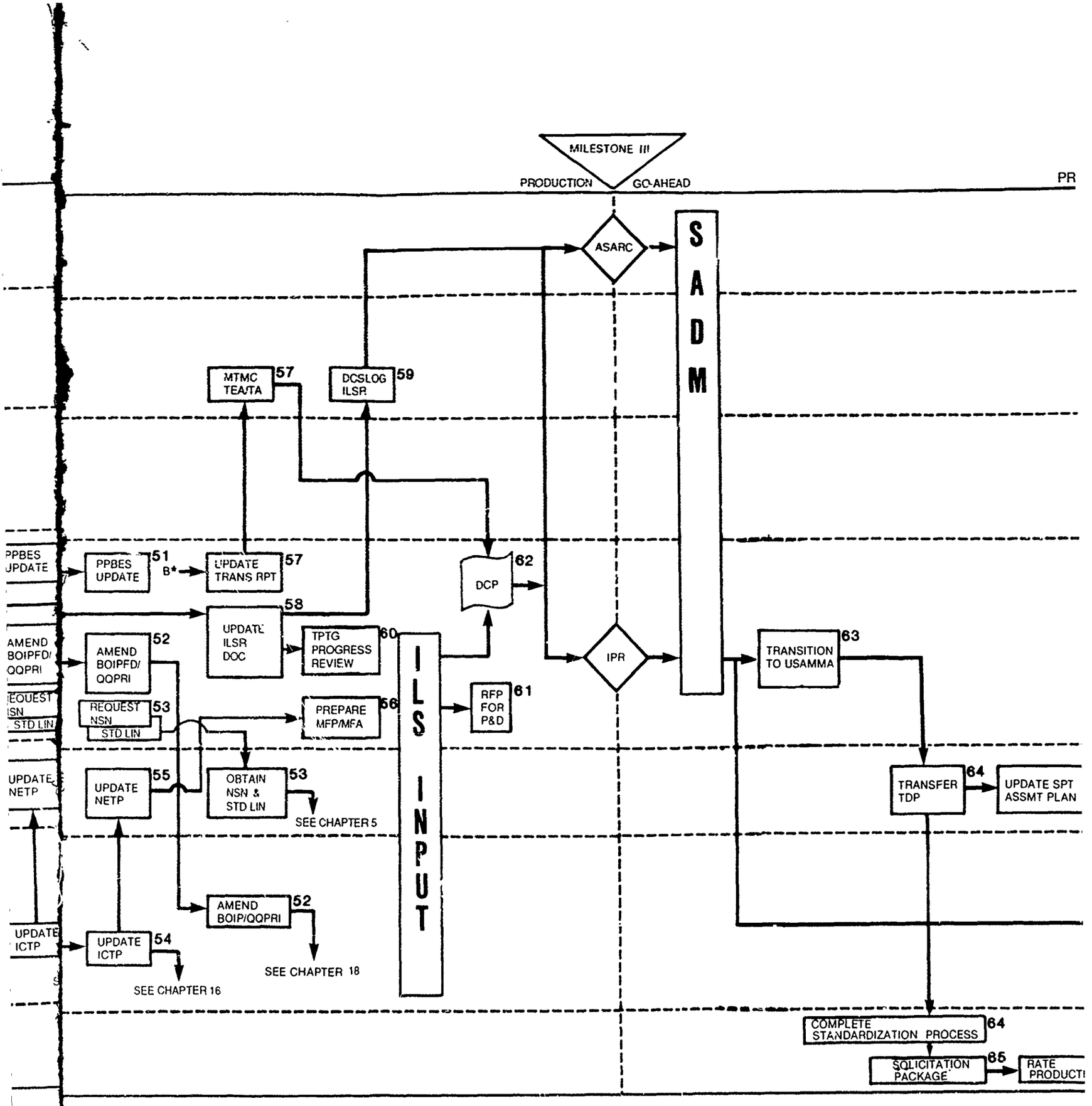

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ILS INPUT
AS/AP UPDATE
42
UPDATE SPT ASSMT PLAN
43
TEMP UPDATE
43
PERFORM LOG DEMO
47
A*
B*
UPDATE ILSP/LSAP AMMS, APPROVE ISP REV
44
DETAILED DESIGN ACTIVITIES
46
UPDATE ILS RESOURCE RQMTS
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TPTG
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PREPARE TRANSITION PLAN
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A*
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IER
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IEP
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IER
49
USER TEST
49

Chart 15-1,



1, THE INTEGRATED LOGISTICS SUPPORT PROCESS (Continued)

PROD

PRODUCTION AND DEPLOYMENT

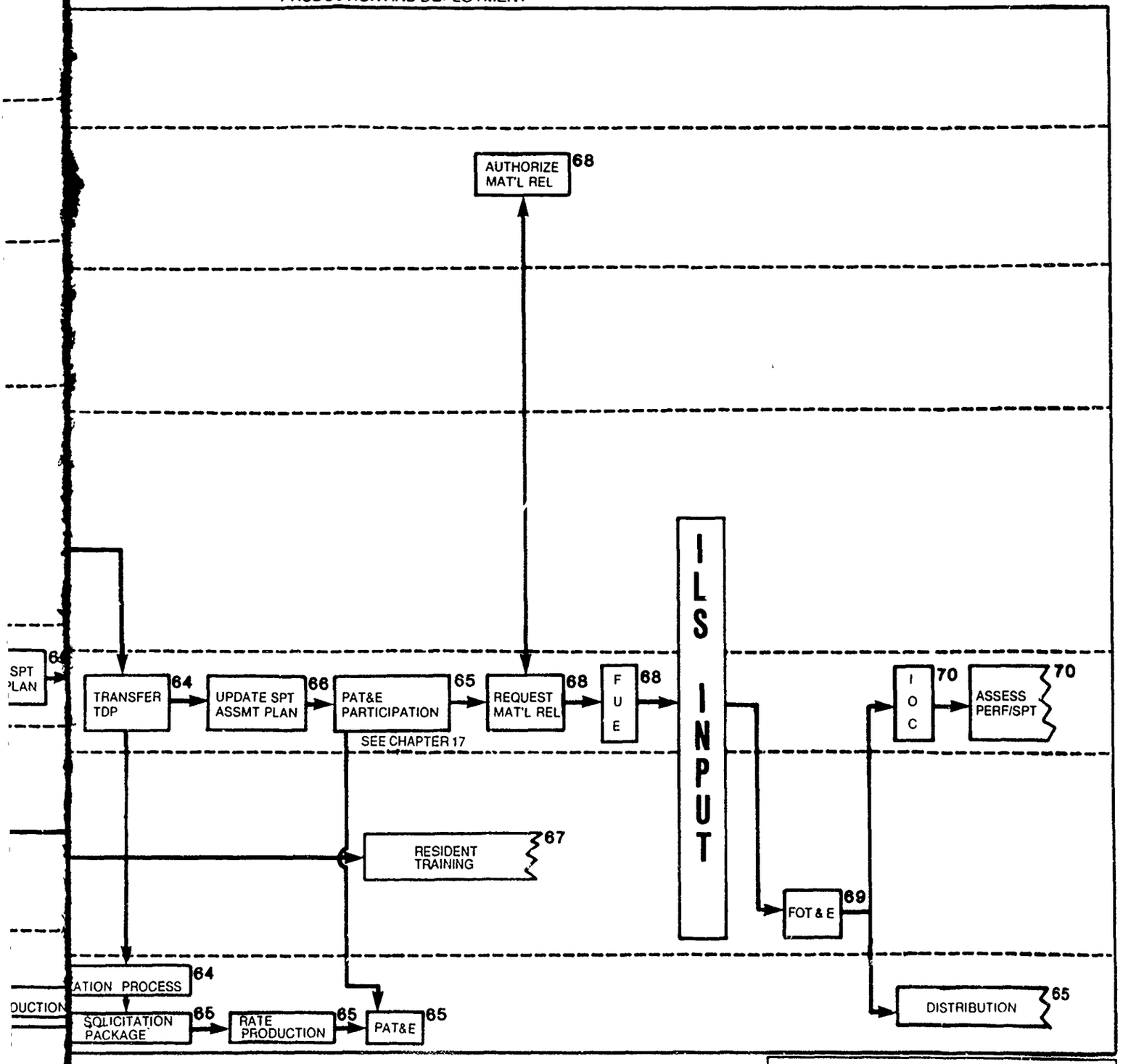


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 15-1C

CHAPTER 16

THE TRAINING AND TRAINING DEVICE PROCESS

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16.1 PURPOSE

This chapter describes the Training and Training Device Process and the events, documents and responsibilities as they apply to medical materiel acquisition programs to include the system training devices. The process flow chart (Chart 16-1 at the end of the chapter) shows the events sequence and the document flow horizontally by time and vertically by agency/office responsible for accomplishing the event or processing the document. The process described is applicable to IPR and Designated Acquisition Programs (DAP). Where there are significant differences, they are explained in the text. The training process for nondevelopment programs is discussed in Section 16.7.

16.2 GENERAL

16.2.1 Training. Army Modernization Training (AMT) is the training required to support the Army modernization process. AMT includes New Equipment Training (NET), Displaced Equipment Training (DET), Doctrine and Tactics Training (DTT), Sustainment Training (ST) and proponent training. These training tasks are discussed in AR 350-35, Army Modernization Training. Briefly, they are defined as follows:

- NET - The identification of personnel, training, and training aids and devices and the transfer of knowledge gained during development from the material developer/provider to the trainer, user, and supporter.
- DET - Training provided to users and supporters on how to operate, maintain, and employ equipment or systems currently in Army inventory that are to be redistributed within a Major Command (MACOM), or between MACOMs, as a result of the Army modernization process. Training for DET must be planned and executed as carefully as it is for NET.
- DTT - Training that provides guidance to commanders, staffs, and operators on how to employ the capabilities of new systems or organizations.
- ST - Individual and collective training conducted in the unit or resident schools, units, and organizations to ensure continued expertise on operation, maintenance, and employment of fielded systems or equipment.

In the case of medical materiel acquisition, the AHS-Trainer is responsible for identifying, planning and conducting the training required to provide the skills necessary to operate and logistically support materiel systems being developed or otherwise acquired. The trainer performs these tasks in coordination with the materiel developer (USAMMDA); the mission assignee (USAMMA) for NDI programs; the logistician (USAMMA); the AHS-Tester; and the AHS-CD and other Army staffs and commands, particularly HQ TRADOC and the TRADOC schools and integrating centers.

The training development process utilizes the Individual and Collective Training Plan (ICTP) for developing systems. The plan sets forth the sequence that describes the functional relationships between the training development tasks and the Acquisition Strategy (AS). AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, provides a guide for the accomplishment of the training development responsibilities. As is the case with most other acquisition functions, the process is tailored to accommodate the specific characteristics of the program.

16.2.2 Training Devices. Training devices are divided into two categories - system and nonsystem. The system device is developed in support of a specific system and is designed for use only with that system. It is the responsibility of the system project manager to develop, fund, and process the training device concurrent with the parent system. The requirements documents for the training devices are included as an appendix to the requirements documents for the system itself.

In contrast, a nonsystem device is one developed to support general military training or training on more than one item or system. This type of device can be developed, funded, and procured by USAMMDA, TRADOC, or PM-TRADE for the AMEDD. Separate requirements documents are required for the nonsystem training devices. These requirements are processed similar to the process described in Chapter 12. In fact, the nonsystem training device acquisition process parallels the process for a materiel system. Guidance for the training device requirements process is contained in AR 71-9, Materiel

Objectives and Requirements, AR 350-38, Training Devices: Policies and Procedures, and TRADOC Circular 70-83, Training Device Development. The remainder of this chapter addresses only the systems training devices.

16.3 CONCEPT EXPLORATION PHASE

16.3.1 General Objectives. Chapter 4 of this handbook provides an overview of the Concept Exploration Phase showing the events, documents and responsibilities and interrelationships for all acquisition functions and process participants. Training activities during the Concept Exploration Phase focus on determining the impact of a new system on training requirements. These activities include supporting the market investigation; developing training concepts/strategies; contributing to the test and evaluation planning effort, the Concept Formulation Package, the request for proposal, and the requirements document; and preparing the initial Individual and Collective Training Plan.

16.3.2 Specific Activities.

SEE CHART 16-1

1. Approve O&O Plan. The HQ TRADOC approved O&O Plan is the requirements document. It should include known or anticipated training device requirements.

2. Develop Training Concept/Strategy and MOS Recommendation. Based on the O&O Plan and early Concept Exploration Phase activities, the AHS-Trainer forms a proposed training concept that, in general terms, identifies who is to be trained; what skills are to be trained; and when, where, and how the training will be accomplished. The concept is formed with only minimal information available, however, it provides a framework for future planning and serves to identify the constraints that training may impose on the design of the materiel. The training developer also makes an initial MOS recommendation.

3. Market Investigation. The AHS-CD prepares the IEP for the market investigation. The trainer provides training issues (questions) and criteria input to the combat developer for inclusion in the IEP. These may include such questions as the availability of training materials and operator, and maintainer skill level requirements. The USAMMDA is responsible for the conduct of the market investigation and for preparation of the report. The market investigation is discussed in more detail in Chapter 4, and IEPs are discussed in Chapter 17, The Test and Evaluation Process.

The AHS-Trainer reviews the Market Investigation Report for its training implications. The trainer provides input to the System MANPRINT Management Plan (SMMP) which is updated by the AHS-CD (refer to AR 602-2).

4. Establish Test Integration Working Group and Prepare the Test and Evaluation Master Plan. USAMMDA is responsible for establishing the Test Integration Working Group (TIWG) (see Chapter 17). One of the first tasks of the TIWG is preparation of the Test and Evaluation Master Plan (TEMP). The AHS-Trainer is a member of the TIWG and participates in the preparation of the TEMP. Typical Trainer input to the TEMP may include:

- Training issues;
- Integration of training with the other MANPRINT considerations (manpower, personnel, training, health hazards, safety, and human factors engineering);
- Verify/validate accuracy and completeness of training materials;
- Identify high-risk operator and maintainer tasks.

5. Conduct Cost and Training Effectiveness Analysis. Preparation of the Concept Formulation Packages (CFP) is the responsibility of AHS-CD in coordination with USAMMDA. One step in the CFP is the preparation of the Cost and Operational Effectiveness Analysis or Abbreviated Analysis (AA). The trainer prepares the Cost and Training Effectiveness Analysis (CTEA) as an input to the COEA/AA. The entire CFP process is discussed in Chapter 13.

The CTEA is a detailed analysis of the comparative effectiveness and costs of training alternatives. These training alternatives (or strategies) are developed with respect to system alternatives. The analysis should ensure that all feasible training alternatives are considered. The analysis must result in the recommendation of a preferred training alternative.

AHS-Trainer is responsible for the CTEA development. Assistance may be requested through the TRADOC Systems Analysis Agency (TRASANA) and from the Army Training Support Center (ATSC). Information on CTEA is also available in the TRADOC Training Effectiveness Analysis Handbook and TRADOC Regulation 350-4.

6. Prepare Individual and Collective Training Plan (ICTP) and Doctrine and Tactics Training Plan. The training developer is responsible for preparing both of these plans.

- ICTP - The results of the concept exploration phase for a developing materiel system should provide sufficient information on system characteristics, support concepts, and human functions to enable AHS to formalize a proposed training concept in the ICTP. The ICTP should incorporate all known training requirements (introduction, operator, maintenance, resident, unit, and extension). A great amount of detail will not normally be available at this stage, however, as a minimum the ICTP should include a training concept, an initial resource estimate, and as much other detail as is available. The ICTP format is provided in TRADOC Regulation 351-9, ICTP for Developing Systems, Policy and Procedures.

- DTTP - The Doctrine & Tactics Training Plan is prepared by the AHS-Trainer based on Doctrine and Tactics Training (DTT) requirements provided by the AHS-CD from review of the New Equipment Training Plan. DTT provides guidance to commanders, staffs, and operators on how to employ the combat Service support capabilities of medical systems or organizations. USAMMDA ensures that DTT, as developed by AHS, is implemented as part of the NETP.

- DTT - planning for a new or improved system or organization is taught to commanders and staffs and selected cadre in order to increase combat effectiveness and to provide a capability within each MACOM to train other personnel. DTT may be conducted by training teams, use of an exportable training package or by early establishment of the training base. When DTT is not required, the NETP should be so annotated.

7. Staff/Revise/Approve ICTP. The ICTP is staffed with USAMMDA, USAMMA, TRADOC Schools and Centers, National Guard Bureau, OCAR Joining Office and all major Army areas. Following this staffing, the ICTP is revised by AHS-Trainer and forwarded to HQ TRADOC for approval. HQ TRADOC will review and staff the ICTP with all MACOMs for their review and comment. Once MACOM comments are received by HQ TRADOC, the approved ICTP and comments are returned to AHS-Trainer for update and distribution.

8. Prepare Solicitation. Although USAMRDC is responsible for preparing the solicitation for the Demonstration and Validation Phase, the AHS-Trainer should ensure that his training requirements are properly addressed. Training considerations include:

- Training goals and constraints;
- Testing requirements (also in TEMP);
- Target audience for training materials;
- Contractor's training materials requirements;
- Contractor's training responsibilities.

9. Requirements Documents. The AHS-Trainer provides the Training Assessment section to the AHS-CD. If the training assessment identifies training device requirements, these requirements should only come about after a comprehensive front end analysis has shown that a device would be a vital factor in meeting training needs. If training devices are going to be available for operational testing in the FSD phase, the AHS-Trainer must become involved at this time and the device requirement must be included with the system requirement document. The U.S. Army Training Support Center is responsible for the staffing of training device requirements and subsequently forwarding them to HQDA for review as well as to USAMMDA for submission to the Milestone Review.

10. System Concept Paper. The System Concept Paper (SCP) with the training annex and other documents is prepared by USAMMDA for submission to the Milestone I Decision Review.

16.4 DEMONSTRATION AND VALIDATION (D&V) PHASE

16.4.1 General Objectives. The objective of the trainers activities in this phase are to evaluate the trainability of the developing system, evaluate and influence alternative designs, ensure that training issues are incorporated in program management documents, and update the training development plans.

16.4.2 Specific Activities.

SEE CHART 16-1

11. Input to Program Management Plans. USAMMDA updates the Acquisition Strategy, System MANPRINT Management Plan, the Integrated Logistics Support Plan, and the Test and Evaluation Master Plan. The AHS-CD, in coordination with USAMMDA, updates the O&O Plan. The AHS-Trainer has responsibility to provide training inputs to each of these documents:

- Acquisition Strategy - The Acquisition Strategy (AS) provides input to AHS-Trainer's ICTP. The trainer should be concerned with plans for contractor's training materials and training responsibilities, training device requirements, and testing strategies related to training system development.
- System MANPRINT Management Plan - The trainer's ICTP is derived from the System MANPRINT Management Plan (SMMP). The trainer is concerned with such issues as the elimination of training tasks which are costly in manpower, personnel, and training resources. The objective is to make design changes that will reduce or completely eliminate these tasks. (See Chapter 14, MANPRINT).

- Integrated Logistics Support Plan - Training and Training Support is one of the twelve Army ILS elements. The trainer is concerned with influencing the system design to minimize the systems training impact. AHS-Trainer is a member of the ILSMT that prepares the Integrated Logistic Support Plan (ILSP).

- Test and Evaluation Master Plan - The Test and Evaluation Master Plan (TEMP), which is prepared by the USAMMDA in close coordination with the TIWG should include the trainer's requirements for testing the system training plan and specify the trainers' responsibilities for training test participants. As a member of the TIWG, AHS-Trainer ensures that its requirements and responsibilities are included (see Chapter 17).

12. Prepare Training Impact Worksheet/BOIPFD/QQPRI. USAMMDA prepares the BOIPFD/QQPRI and AHS-Trainer provides an assessment of the training impact. The Training Impact Worksheet describes the training impact of the developing system as it pertains to facilities, instructors, students, training devices, resident and non-resident course requirements and other training factors. It shows the impact in terms of additional requirements to the training base.

13. Logistics Support Analysis. The Logistic Support Analysis (LSA) effort is carried out by USAMMDA and the contractor(s). The AHS-Trainer is concerned with the early identification of critical tasks - those hard to perform tasks that will impact on the training program. The ICTP serves as one input to the contractor for determining training requirements.

14. Prepare/Review Contractor Training Material. As the contractor prepares the training materials and plans in accordance with his contractual responsibilities (see Activity 8) they should be provided to AHS-Trainer for review and input to the Training Test Support Package to be provided to AHS-Tester.

15. Independent Evaluation Plans. The AHS-CD and USAMMDA update the Independent Evaluation Plans (IEPs) for User Testing and Technical Testing respectively. USAMMDA and the contractors also prepare and conduct training for instructors and key personnel (IKPT) in preparation for testing.

AHS-Trainer is concerned with both technical and user tests, but his primary concern is the user test for evaluation of his training program. AHS-Trainer is responsible for providing the critical training test issues and test criteria (to include measures of effectiveness) to AHS-CD for inclusion in the IEP. AHS-Trainer is also responsible for providing personnel for the IKPT conducted by the contractor and developing the training portion of the Operational Test Readiness Statement (OTRS) which is prepared by AHS-CD.

16. Training Test Support Package, Tests, and Test Reports. AHS-Trainer is responsible for providing a Training Test Support Package to AHS-Tester (AMEDD Board). Because the training test support package supports the test design, it is needed six months prior to the test start date. It contains the ICTP, training data requirements, lesson plans, personnel selection criteria and training aids. The package is used to train user troops for the test, and plan data collection in the area of training requirements. In the D&V phase, contractor provided material will be utilized as well as contractor conducted training.

The user tests should validate the ICTP or indicate where revisions are necessary. AHS-Trainer provides training development personnel to the test director.

Test Reports are prepared by each test director. AHS-Trainer reviews these reports for training implications and provides input to the Independent Evaluation Reports.

17. Independent Evaluation Reports. An Independent Evaluation Report (IER) is prepared for each test by an independent evaluator (USAMMDA and AHS-CD). AHS-Trainer assists the combat developer in the preparation of the training portions of the user test IER.

18. Update/Staff Individual and Collective Training Plan. As system development progresses, tests are conducted, LSA activities expand, and other activities are initiated/completed, the AHS-Trainer will review their training

impacts and revise the ICTP as required. The revised ICTP is staffed with concerned TRADOC schools and integrating centers and submitted to HQ TRADOC for approval.

19. Revise Training Impact Worksheet/BOIP/QQPRI. A revised worksheet is provided to AHS-CD for inclusion with the BOIP/QQPRI (see Activity 12 this chapter and Chapter 18, The BOIP/QQPRI Process).

20. New Equipment Training Plan/Doctrine, Tactics and Training Plan. USAMMA is responsible for the preparation of the New Equipment Training Plan (NETP). AHS-Trainer prepares the Doctrine, Tactics and Training Plan (DTTP). OTSG reviews both plans. AHS-Trainer provides inputs to the NETP in the following areas:

- Section II - Proponent School Information;
- Section V - Training Information;
- Section IX - Training (includes training strategies and doctrine and tactics training). The NETP includes training issues and skills requiring NET identified by LSA.

21. Requirements Document. AHS-CD prepares the appropriate requirements document (see Chapter 11, The Requirements Document Process). AHS-Trainer provides input to paragraph 8, Training. A sample requirements document, paragraph 8, is at Appendix C. If a system training device is required, it is attached as an annex to the system requirements document.

> **NOTE:**
>
> If the training device requirement is trailing the system development program, the training device may have to be developed similar to a non-system training device, i.e., a separate program.

22. Decision Coordination Paper and Milestone Decision Review. The AHS-Trainer assists in the preparations for the review. If there are training issues to be briefed, he may be called upon to do so (see Chapter 12, The Materiel Acquisition Decision Process).

16.5 FULL SCALE DEVELOPMENT (FSD) PHASE

16.5.1 General Objectives. Training tasks during this phase generally parallel those of the previous phase. However, the level of detail increases as system development progresses and the training program is confirmed.

SEE CHART 16-1

16.5.2 Specific Activities.

23. Update AS, SMMP, ILSP. See Activity 11.

24. LSA Identify Training Tasks. See Activity 13.

25. Update/Review and Approve Contractor's Training Materials. See Activity 14. The contractor's training materials should have advanced to the stage where they can be implemented by the AHS-Trainer to prepare for the FSD phase tests.

26. Independent Evaluation Plan. See Activity 15. The IEP for the FSD phase has undergone continuing revision and now reflects the inputs from the tests, review decisions, and the revised program management documents.

27. Training Test Support Package, Tests, and Test Reports. See Activity 16. The emphasis transitions from contractor provided materials and instructions to AHS-Trainer responsibilities for training and training materials.

28. Independent Evaluation Reports. See Activity 16.

29. Update Individual and Collective Training Plan. See Activity 18. The ICTP continues to serve as the primary training document. It is staffed, reviewed, and approved as it was in the D&V phase.

30. Revise Training Impact Assessment. See Activity 19.

31. New Equipment Training Plan. See Activity 20.

32. Decision Coordinating Paper and Milestone Decision Review. See Activity 22.

16.6 PRODUCTION AND DEPLOYMENT (P&D) PHASE

16.6.1 General Objectives. The trainer's objective in this phase is to meet the training requirements for the First Unit Equipped Date (FUED) and achievement of the Initial Operational Capability (IOC).

16.6.2 Specific Activities.

SEE CHART 16-1

33. Prepare Final Individual and Collective Training Plan and Update Individual Training Plan. The AHS-Trainer prepares the final Individual and Collective Training Plan (ICTP) another space and updates the Individual Training Plan (ITP). The ICTP is staffed, reviewed, and approved as described in Activity 18.

The ITP consists of a set of documents which collectively constitute the plan for analyzing, designing, developing, implementing, and evaluating an individual training program. It provides for the development of resident

training, extension training products, and soldier training products. It does not pertain to collective training. The ITP is related to the ICTP; however, the ICTP relates to a specific development system and addresses several MOS, while the ITP addresses only one MOS, area of concentration, or functional training program, and looks at all systems which that specialty or program supports. The ICTP process begins in the Concept Exploration Phase, the ITP process normally begins late in the Full Scale Development Phase (after user tests and thirty months prior to the start of resident training) and continues as long as the specialty or functional program remains active. The ITP is approved by OTSG.

34. Update/Review New Equipment Training Plan. USAMMA updates the NETP with AHS-Trainer input. The ICTP and these plans must be compatible.

35. Update Training Material. The contractor's training materials are updated based on test results, milestone decision review decisions, design, changes, and training guidance. The ICTP is conducted using the updated training materials.

36. Issue Training Base Equipment. In response to AHS-Trainer's requirements which were provided earlier and are in the BOIP, USAMMA ensures that equipment for the training base is issued on schedule to support the system training programs. Equipment may be issued to AHS, TRADOC schools as required, and other training points according to previously approved plans (ICTP and the materiel fielding plan).

37. Conduct NET and DTT. USAMMA conducts NET, if required. Feedback from NET should be provided to AHS-Trainer in order that the necessary adjustments can be made to the training program. AHS-Trainer conducts DTT, if required (see Chapter 20, The Materiel Fielding Process).

38. Resident Training. Resident training should start in time to support the First Unit Equipped. Training will normally precede the FUED by a period of time at least equal to the course length (preferably earlier). Resident

training sites are AHS and TRADOC schools which are proponents of MOS for associated items of equipment. The HQDA - DCSPER operator and maintainer MOS decision is a prerequisite to resident training.

39. Training Materials Fielded. During or after the FUED, and before IOC, all training materials should be fielded. This includes:

- Soldier's Training Publications;
- ARTEP;
- Training Literature;
- Extension Training Materials;
- Training Aids/Devices;
- Technical Manuals;
- Situational Training Exercises;
- Correspondence Courses.

40. Follow On Test and Evaluation. The Follow-on Test and Evaluation (FOT&E), if required, is conducted by AHS-Tester and evaluated by AHS-CD. AHS-Trainer provides input and assists in the preparation of the IER. Adjustments to the training program are made as indicated by the test results.

41. Sustainment Training Established. This is individual and collective training conducted in the unit or resident schools, units, and organizations to ensure continued expertise on operation, maintenance, and employment of the fielded system.

16.7 NONDEVELOPMENT ITEM, MODIFIED NONDEVELOPMENT ITEM, AND PRODUCT IMPROVEMENT PROGRAMS

16.7.1 Nondevelopment Item. It is critical that training implications be thoroughly evaluated during market investigations conducted during the Concept Exploration phase. It should be kept in mind that normal technical and operational testing will not apply during most Nondevelopment Item (NDI) acquisitions. Consequently, it is necessary that a training requirements evaluation be incorporated into the Market Investigation. First, training issues and criteria must be included in the Independent Evaluation Plan which governs the conduct of the Market Investigation and which plays a major role in determining whether an NDI acquisition is feasible. If the potential NDI would replace an existing item, an assessment should be made of the training experience to arrive at lessons learned, high driver training tasks, and training goals and constraints for inclusion in the IEP and later in the requirements document. These actions will assist in setting the training parameters to be addressed in the Market Investigation based on the training goals and constraints, and the Market Investigation team should develop the data needs and information to be gathered to permit the independent evaluation of training for the MADP. The Market Investigation team should consider such issues as:

- Can the NDI be accommodated within the current training structure?
- If new training resources are required can they be supported?
- Do the training resources required for the NDI breach the training goals and constraints?
- Will the NDI call for contractor training because of the shortened acquisition schedule?
- How will New Equipment Training be handled?
- Will Doctrine and Tactics Training be required?
- Are any new MOSs required that will impact on training?
- Are new training devices required?

The Independent Evaluation Report will assess the training impact of the potential NDI acquisition. In this way, training will be an important determinant in the NDI decision process. In some cases a decision may be made to pursue NDI, with the recognition that certain training shortfalls need to be overcome before materiel fielding. In this case the plan for overcoming the training short falls should be reflected in the update of the ICTP during the Acquisition Documentation phase of the NDI acquisition. The adequacy of these planned actions will be assessed at the Milestone Decision Review to authorize Production and Deployment.

It should be kept in mind that NDI acquisitions cover a wide variety of items ranging from simple off-the-shelf to highly complex items, that nonetheless are found in the commercial marketplace. Consequently, it will be necessary to tailor the training evaluation accordingly. Also, since NDI can encompass already developed items of other Services or other Governments, the training requirements may represent a considerable burden in terms of training resources and training capabilities. However, it is also possible that existing training facilities and programs could be used by the AMEDD. If a training device is required, consideration should be given to calling for contractor support as the life cycle method of choice.

Training considerations of NDI are characterized by early attention to training issues prior to the Market Investigation and by consideration of training as a critical element in the MDRP. Thereafter, the training process is essentially the same as the normal developmental process except that special procedures may be required because of the much shorter time for production and deployment.

16.7.2 Modified Nondevelopment Item. The training activities for Modified Nondevelopment Item (MOD-NDI) are essentially as stated above for NDI, insofar as the nondevelopment aspects of the item are concerned. However, the training plan must also cover the fact that a developmental phase is required before production and deployment. The ICTP should therefore cover plans for training to meet both the commercial requirements and the added development

requirements in a single, integrated effort. The training activities are as described for development items, except that, because the schedule for development, production, and deployment are compressed, the special procedures and "work arounds" discussed for NDI may be required.

16.7.3 Product Improvement. In this case the training activities must be tailored to reflect the specific nature of each individual Product Improvement (PI). No single approach is possible because PIs run the gamut of complexity. For example, many PIs are directly responsive to reported field deficiencies that reveal the need to upgrade reliability or to correct performance deficiencies. In these cases the PI effort will normally impact only minimally on the training structure already developed and in place for the fielded system. The training effort will generally consist of an analysis to quantify the difference between the existing training requirements and resources and any additional ones imposed by the PI. Based on the analysis, the training structure is adjusted accordingly. On the other hand a PI may be instituted to improve the operational capability. A PI of this type will generally require a new requirements document because the upgraded capabilities exceed the performance envelope of the original requirements document. In these cases the training activities may be much more extensive and may even approach that of the original development effort. However, even in these instances the effort remains a PI, meaning that a training baseline is already established. It is this baseline that is built on and revised in order to accommodate the system modifications.

16.8 REFERENCES

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983
AR 70-1, System Acquisition Policy and Procedures, 1986
AR 70-10, Test and Evaluation, 1986
AR 70-15, Product Improvement of Materiel, 1980
AR 70-37, Configuration Management, 1974

AR 71-3, User Testing, 1986

AR 71-2, Basis of Issue Plans, Quantitative and Qualitative Personnel Requirements Information, 1982

AR 71-9, Materiel Requirements, 1984

AR 350-35, Army Modernization Training, 1984

AR 350-38, Training Device: Policies and Procedures, 1984

AR 602-2, MANPRINT in the Material Acquisition Process, 1986

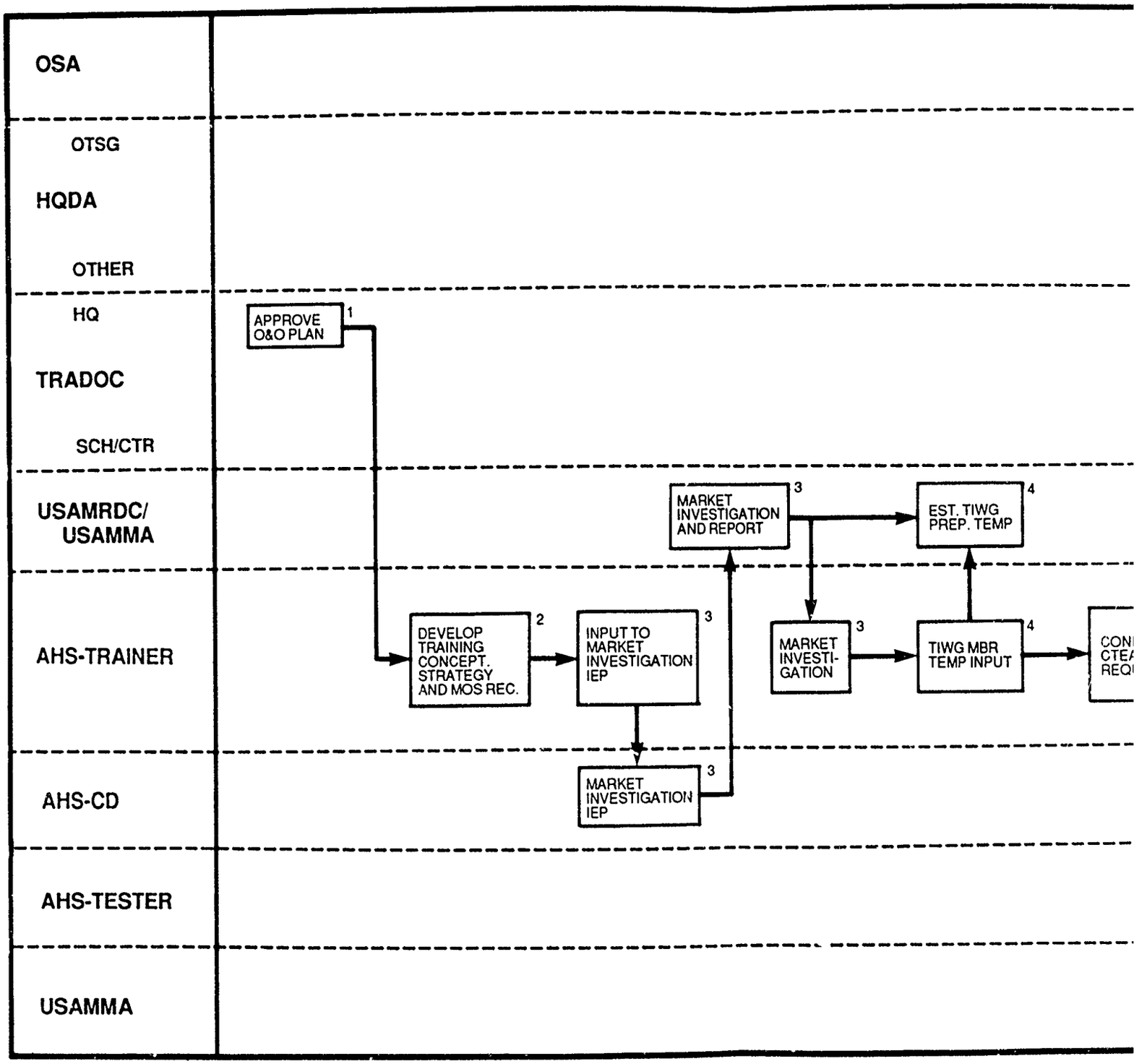
AR 700-127, Integrated Logistic Support, 1983

TRADOC Regulation 351-9, Individual and Collective Training Plan for Developing Systems, 1982

TRADOC Circular 70-83-1, Training Device Development, 1983

TRADOC Circular 602-XXX, MANPRINT in the Materiel Acquisition Process, 1985 Draft

Memorandum of Agreement, PM-TRADE/USAMMA/AHS/USAMRDC


OSA
OTSG
HQDA
OTHER
HQ
TRADOC
SCH/CTR
USAMRDC/ USAMMA
AHS-TRAINER
AHS-CD
AHS-TESTER
USAMMA
APPROVE O&O PLAN
1
DEVELOP TRAINING CONCEPT, STRATEGY AND MOS REC.
2
INPUT TO MARKET INVESTIGATION IEP
3
MARKET INVESTIGATION AND REPORT
3
EST. TIWG PREP. TEMP
4
MARKET INVESTI-GATION
3
TIWG MBR TEMP INPUT
4
MARKET INVESTIGATION IEP
3

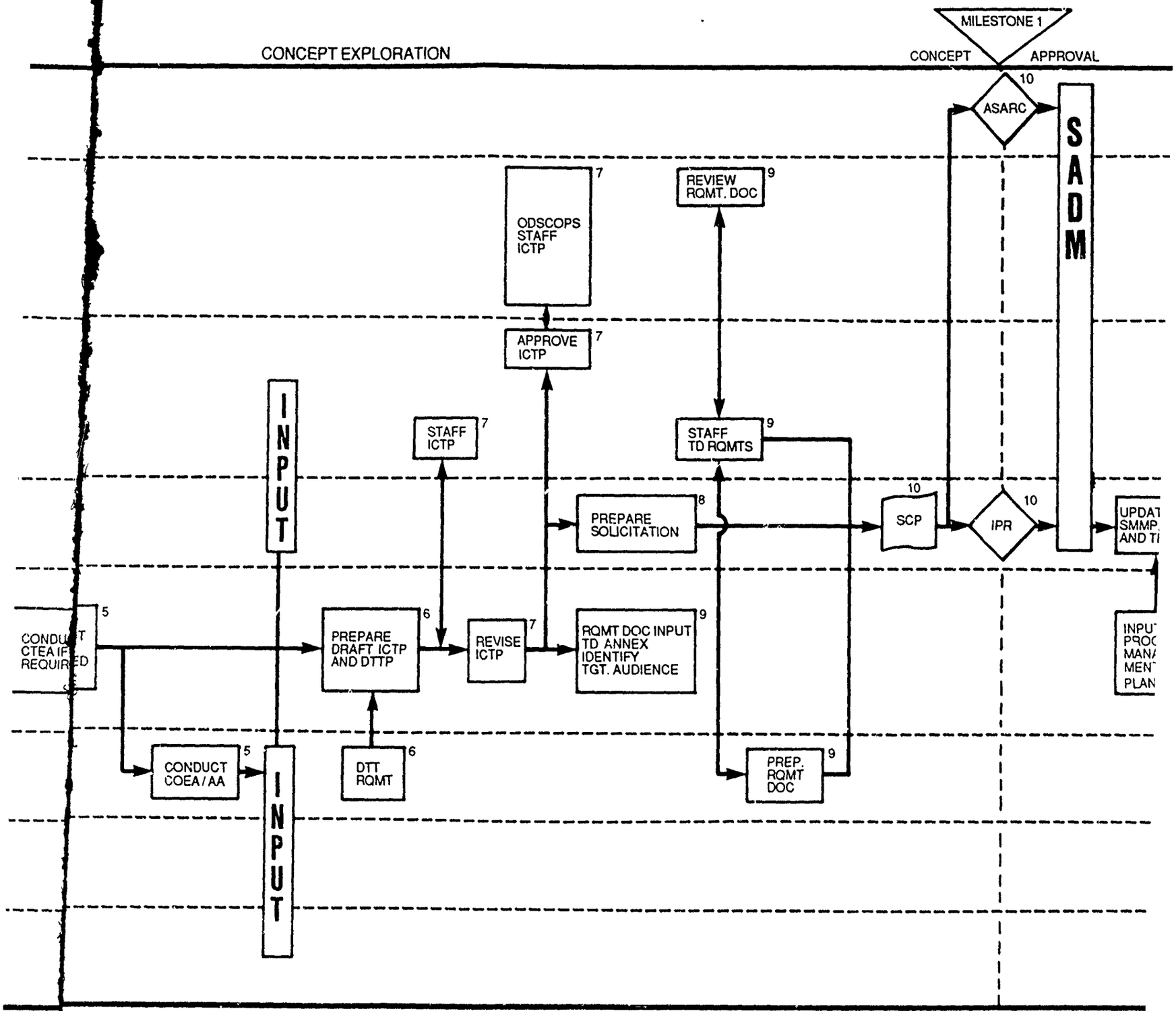
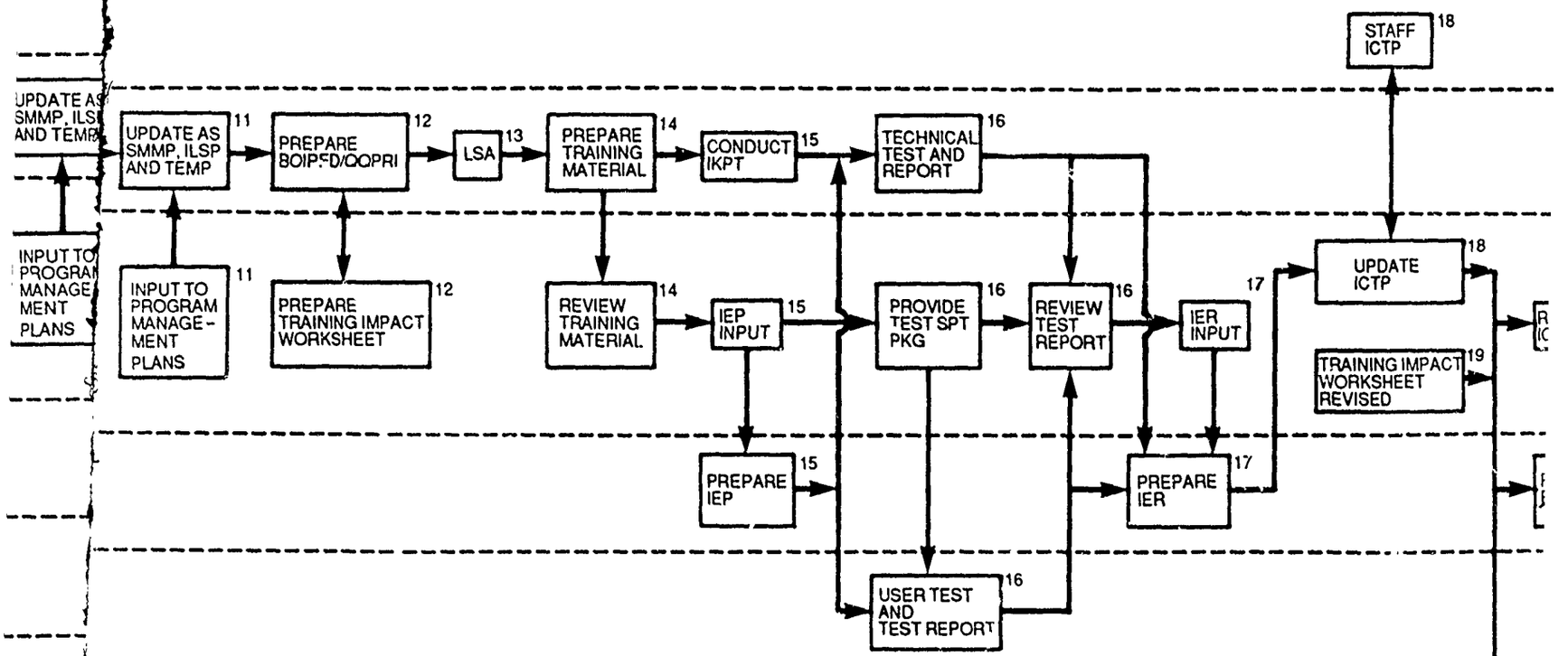


Chart 16-1, THE TRAINING AND TRAINING DEVICE

7



CE P
VICE PROCESS

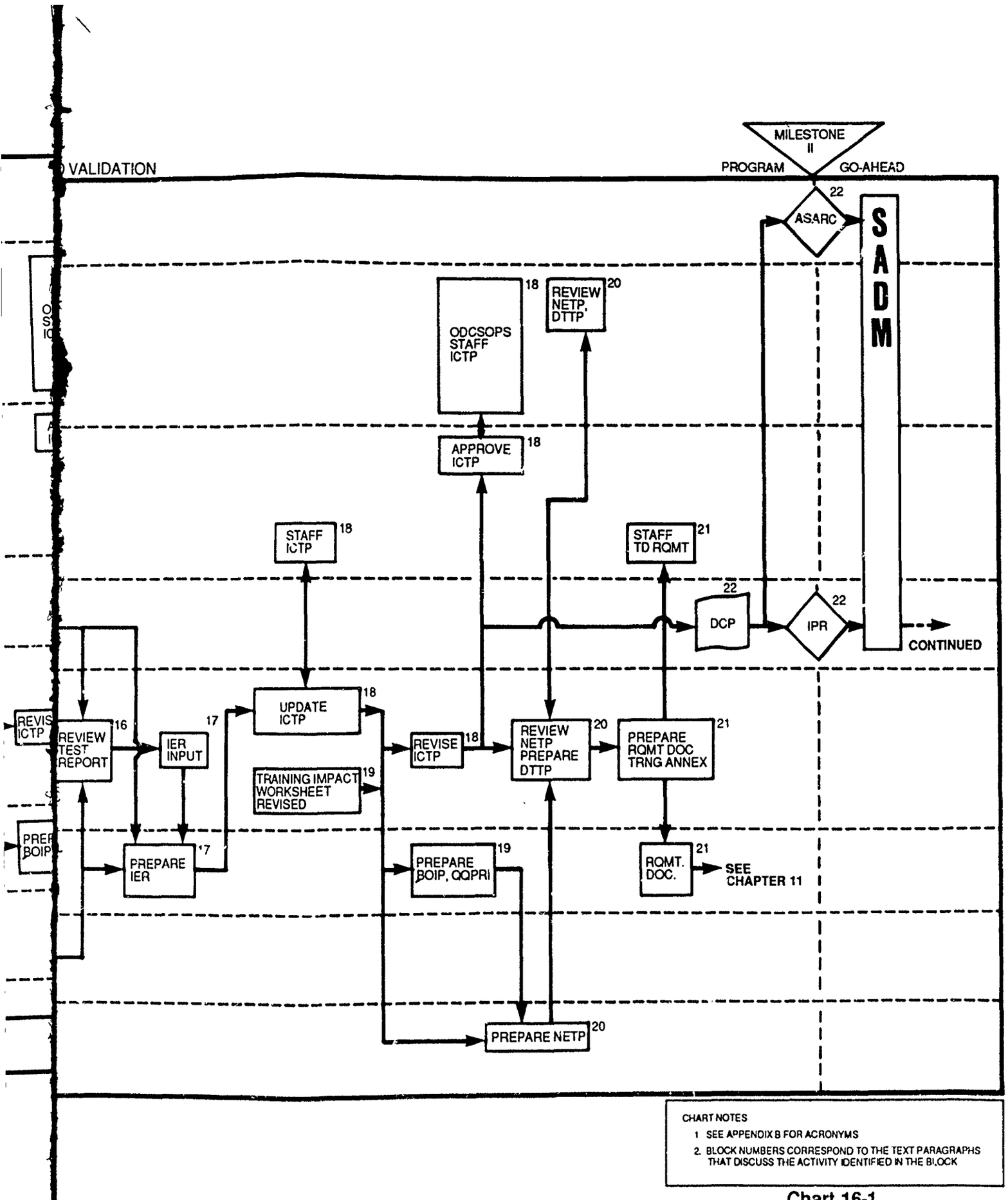
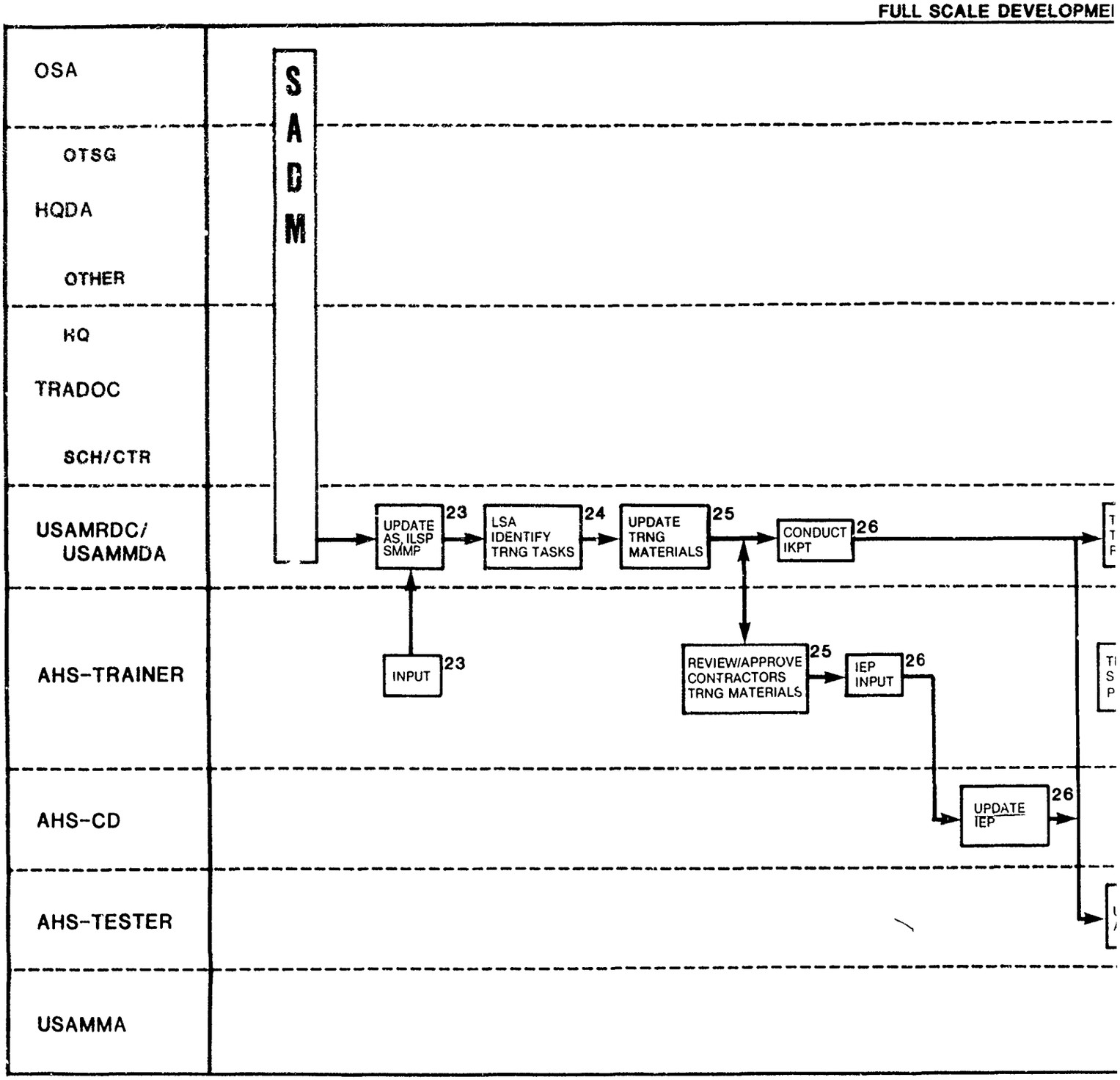


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 16-1


OSA
OTSG
HQDA
OTHER
HQ
TRADOC
SCH/CTR
USAMRDC/
USAMMDA
AHS-TRAINER
AHS-CD
AHS-TESTER
USAMMA
S
A
D
M
UPDATE AS, ILSP SMMP
23
LSA IDENTIFY TRNG TASKS
24
UPDATE TRNG MATERIALS
25
CONDUCT IKPT
26
INPUT
23
REVIEW/APPROVE CONTRACTORS TRNG MATERIALS
25
IEP INPUT
26
UPDATE IEP
26

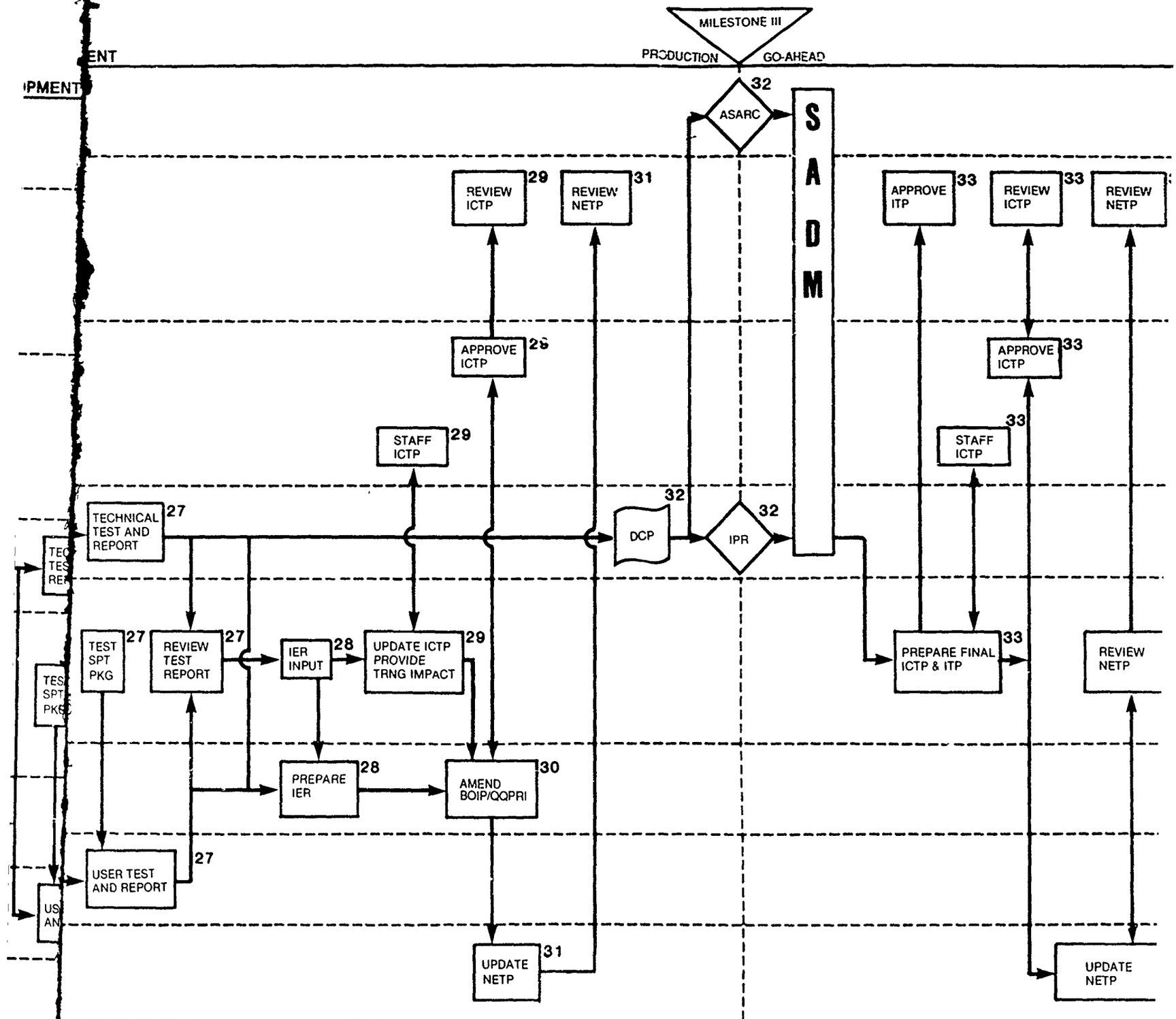


Chart 16-1, THE TRAINING AND TRAINING DEVICE PROCESS (Continued)

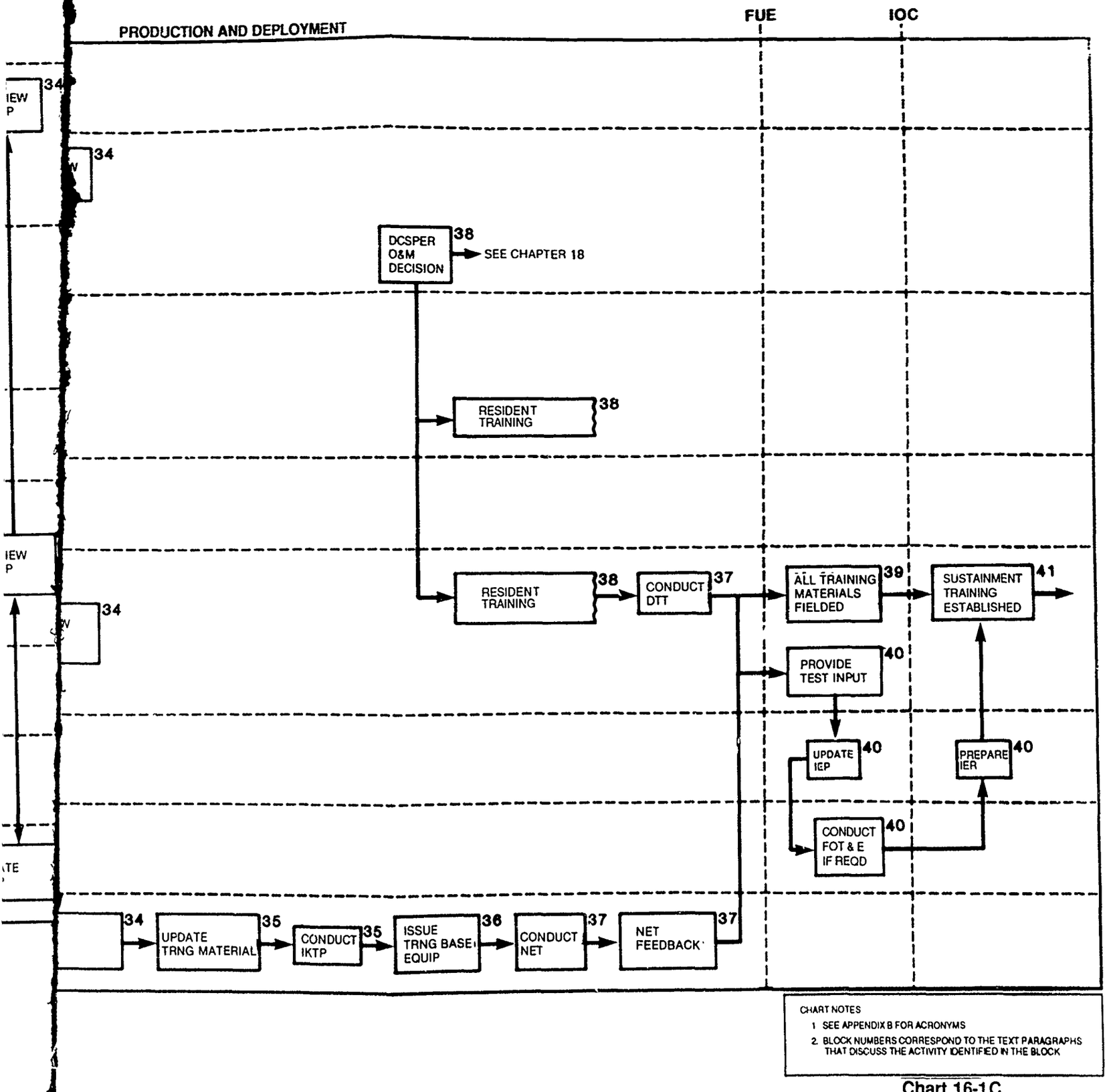


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 16-1C

3

CHAPTER 17

THE TEST AND EVALUATION PROCESS

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17.1 PURPOSE

This chapter outlines policies, procedures, and responsibilities for the acquisition test and evaluation process. It provides guidance to the AMEDD and other activities involved in medical materiel acquisition. Chart 17-1, two fold-out pages at the end of the chapter, summarizes the events, activities, documents, and decisions required. Numbers within the blocks on the flow chart relate to the text paragraph that discusses the activity identified in the block. The chart is arranged to present, in their relative order, the primary responsibilities of each participant. The chart depicts activities for development programs. The differences among Nondevelopment Item, Modified Nondevelopment Item, and Product Improvement Programs activities are discussed in Section 17.7.

17.2 GENERAL

17.2.1 Policy. Test and evaluation is conducted to assist the acquisition process; assess acquisition risks; evaluate military technical and operational effectiveness, suitability, and logistic supportability; determine compatibility and interoperability among Army systems and with other Services and nations as appropriate; and verify materiel defects correction.

Test and evaluation strategy, although flexible, is structured to implement the system Acquisition Strategy (AS). Planning, programming, and budgeting for test and evaluation begins early in the materiel acquisition cycle, i.e., immediately after program initiation.

Sufficient test and evaluation must be done before each major decision point to ensure that the major objectives of one phase have been met and that the issues are addressed before the next phase is begun. Subsequent testing should be tailored to take advantage of previous evaluations and data from other data sources.

Test policies are established in AR 70-1, System Acquisition Policy and Procedures; AR 70-10, Test and Evaluation; AR 71-3, User Testing; and AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel. Other reference documents are listed in Section 17.9.

17.2.2 Responsibilities. The participants and their function in the medical materiel test and evaluation process include the following:

- HQDA - policy and staff management
- OTEA - independent operational tester
  - TSARC
- TSG - policy and procedures
  - user test funding (start FY88)
- USAMMDA - materiel developer
  - technical tester
  - independent evaluation of technical tests
- USAMMA - logistician
  - mission assignee agency for NDI and MSKO
- AMEDD BOARD - user test organization
- HSC - TSARC Working Group
  - user test funding
- AHS-CD - user representative
  - independent evaluation for user tests
- AHS-TRAINER - user trainer
- AMC - support as requested
- TRADOC - support as requested

A Test Integration Working Group (TIWG) is established by USAMMDA after program initiation. The TIWG is comprised of members of the Acquisition Team and serves as a principal action working group throughout the materiel acquisition process. The TIWG members assist in all program actions involving test and evaluation to include:

- Test and Evaluation Master Plan;
- Request for proposals;
- Acquisition strategy;
- Evaluation of contractor's proposal;
- Continuous evaluation.

TIWGs are not intended to usurp the responsibilities or authority of any command or staff. Therefore, in the event of disagreements, issues will be resolved through normal command/staff channels.

17.2.3 Issues and Criteria. Issues are questions regarding a system which require answers during the acquisition process to support definition of strategy, refinement of requirements and designs, and milestone decision events. Criteria are the standards of effectiveness or suitability by which the issues are assessed.

a. Issues. Issues are key questions (e.g., cost, schedule, performance, quality, supportability) that must be addressed during the system's development and are of primary importance to the decision authority in reaching a decision to proceed to the next acquisition phase. Issues are nominated by the combat developer, coordinated with the materiel developer and other Acquisition Team members, and approved by the appropriate decision authority. However, issues may change during the course of the materiel acquisition process. Rationale for change or elimination of an issue will be documented to provide an audit trail. Changes to Issues are approved at each milestone for the next acquisition phase by the appropriate milestone review body, (see Chapter 12). Issues are normally identified in the System Concept Paper (SCP), Decision Coordinating Paper (DCP), and requirements document.

b. Evaluation Issues. Evaluation issues are those issues which need to be addressed by the technical or operational evaluator during their evaluation efforts. Evaluation issues are derived or extrapolated from the System Program Issues by the evaluators and coordinated with other Test Integration Working group (TIWG) members. Evaluation issues are separated into technical and operational issues for inclusion in the Independent Evaluation Plan (IEP) and to identify by whom the issue will be evaluated. Some issues are addressed by both evaluators. Evaluation issues will be addressed by whatever means necessary (analysis, observation/survey, simulation, modeling, or testing) to answer the issue. Evaluation issues which require test data are further referred to as test issues.

c. Test Issues. Test issues are those issues which require test data to adequately answer the issue. Test issues are derived from the evaluation issues by the evaluators, in coordination with other TIWG members. Test issues are separated into technical and operational issues. Test issues are documented in the appropriate IEP's and become part of the Test and Evaluation Master Plan (TEMP).

d. Critical and Non-Critical Issues for Test.

(1) Issues are partitioned into critical and non-critical categories. Each issue must include supporting rationale as to the reason for its criticality. Critical evaluation issues are important to the decision authority in addressing key questions. They must be clearly stated, measurable, and of such importance to the program that they have to be addressed prior to the next milestone decision. Test design and conduct of the test should focus on obtaining information to resolve critical test issues early in testing. Critical issues are documented in the IEP and the TEMP. Non-critical issues are issues required to be addressed by either regulatory guidance or as desired by the evaluator for completeness. Non-critical issues may become critical as the system evolves. Non-critical issues are documented in the appropriate IEPs and in the TEMP.

(2) Critical T&E issues, objectives, methodologies, and evaluation criteria shall be defined during the initial establishment of an acquisition program.

e. Criteria. Criteria are statements of the system's required operational effectiveness and suitability, technical performance, and supportability (i.e., what is required of the system). There may be one or several criteria applied to any given issue. They are developed by the combat and material developers, in an interactive process with the testers, evaluators, and other TWIG members. Criteria may be based upon program management documents, studies, regulations, military standards, and specifications. Criteria express quantitative parameters which the system should satisfy. Test criteria are documented in the IEP, TEMP, test design plan (TDP), detailed test plan (DTP), and test reports. All criteria will be supported by a clear rationale statement. Criteria are measures of the program's progress through the development and acquisition process rather than strict measures of "pass" or "fail".

17.2.4 Types of Testing.

17.2.4.1 Technical Testing (TT).

a. Development Test (DT) - the engineering test to provide data on safety, the achievability of critical system technical characteristics, refinement and ruggedization of hardware configurations, and determination of technical risks. This testing is performed on components, subsystems, materiel improvement, nondevelopment items (NDI), hardware-software integration and related software. DT includes the testing of compatibility and interoperability with existing or planned equipment and systems, and the system effects caused by natural and induced environmental conditions during the development phases of the materiel acquisition process.

b. Technical Feasibility Test (TFT) - the technical testing conducted prior to MS I or MSI/II to assist in determining safety and establishing system performance specifications and feasibility.

c. Qualification Test (QT) - the testing which verifies the design and the manufacturing process and provides a baseline for subsequent acceptance tests. The completion of Preproduction Qualification Test and Evaluation before MS III decisions is essential and will be a critical factor in assessing the system's readiness for production. Production Qualification T&E shall be conducted on production items. This accomplishes two separate functions:

(1) Preproduction Qualification Test (PPQT) - the formal contractual tests that ensure design integrity over the specified operational and environmental range. These tests usually use prototype or production hardware fabricated to the proposed production design specifications and drawings. Such tests include contractual reliability and maintainability demonstration tests required prior to production release.

(2) Production Qualification Test (PQT) - the tests which ensure the effectiveness of the manufacturing process, equipment, and procedures. These tests are conducted and a number of samples taken at random from the first production lot, and are repeated if the process or design is changed significantly, and when a second or alternate source is brought on-line. These tests are also conducted against contractual requirements.

d. Joint Development Test (JDT) - tests which provide information on each Service's system or equipment requirements, performance, or interoperability; on technical concepts, requirements, or improvements; and on the improvement or development of testing methodologies or resources.

e. Contractor/Foreign Tests - non-Government testing agreed-to and integrated into the TEMP to provide data for technical evaluation of contractor/foreign material.

17.2.4.2 User Testing.

a. Force Development Test and Experimentation (FDTE) - the testing conducted early on to support the force development and materiel development processes by examining the effectiveness of existing or proposed concepts of training, logistics, doctrine. organization and materiel. FDTE is conducted

early and can be scheduled as needed during any phase of the materiel acquisition process. They may be related to, combined with, or used to supplement Operational Tests (OT). During the requirement formulation effort, FDTE may be used to determine essential and desirable capabilities or characteristics of proposed systems. Prior to MS II, FDTE will be used to assist in refining concepts of employment, logistics, training, organization and personnel, and in lieu of OT when operational issues are adequately addressed. FDTE also includes field experiments designed to gather data through instrumentation to address a training development problem or to support simulations, models, war-games and other analytical studies. Requirements for FDTE may also be generated by the results of combat developments, training developments, or training effectiveness analysis testing and studies (AR 71-3).

b. Concept Evaluation Program (CEP) Tests - a HSC resources testing program. CEP tests provide the combat developer with a quick reaction and simplified process to resolve combat development, doctrinal, and training issues in addition to solidfying combat development requirements and supporting early milestone decisions. Also, the CEP tests are used to provide an experimental data base for requirements documents and to expedite the materiel acquisition; however CEP tests are not to be used as the primary tests to support production decisions. CEP tests may be conducted at any time.

c. Operational Tests (OT) - the field test, under realistic combat conditions, of the system for use in combat by representative military users. OT provides data to assess operating instructions, training programs, materiel, publications, and handbooks. It uses personnel with the same military occupational specialty as those who will operate, maintain, and support the system when deployed.

d. Follow-On Operational Test and Evaluation (FOT&E) - that OT&E conducted as necessary after the full production decision during production and deployment of a system. FOT&E is conducted to assess system training and logistics, and to verify correction of deficiencies, if required, and to ensure that initial production items meet operational effectiveness and suitability thresholds. FOT&E will be scheduled and programmed as a normal part

of an acquisition program. The operational independent evaluation will make maximum use of both production and preproduction qualification tests and other data sources (e.g., sample data collection, field user surveys) to assess FOT&E issues minimizing the requirement for follow-on operational testing.

e. Onsite User Test (OSUT) - tests conducted to assess the operational effectiveness and suitability of a low density materiel system being acquired by the Army that is not intended for use in a field environment. The objective and characteristics of OSUT are similar to OT&E except the test is conducted at the operational site. Testing is accomplished to verify that the organization, logistic support, and training are adequate, and that the equipment performs acceptably in an operational environment. In the AMEDD, OSUTs are limited to equipment for TDA application.

f. Joint Operation Tests (JOT) - tests using actual fielded equipment, simulators, or surrogate equipment in an exercise or operational environment to obtain data pertinent to inter-service operational doctrine, tactics, and procedures.

Figure 17-1 relates user tests and innovative testing with the materiel acquisition process.

Although TT and user tests are significantly different, they complement each other in their contribution to the acquisition process. User tests generally follow or parallel TT. The precise user test required will depend on the acquisition strategy adopted and approved. Note that FDTE and/or innovative testing can occur anywhere, as needed, to help the combat developer satisfy his responsibilities.

17.2.5 Test and Evaluation Documentation. These documents are developed to support the acquisition strategy. They describe how the test and evaluation requirements will be satisfied throughout the acquisition process. Each is subject to review and approval, some require periodic updating, and some are part of the milestone decision review process.

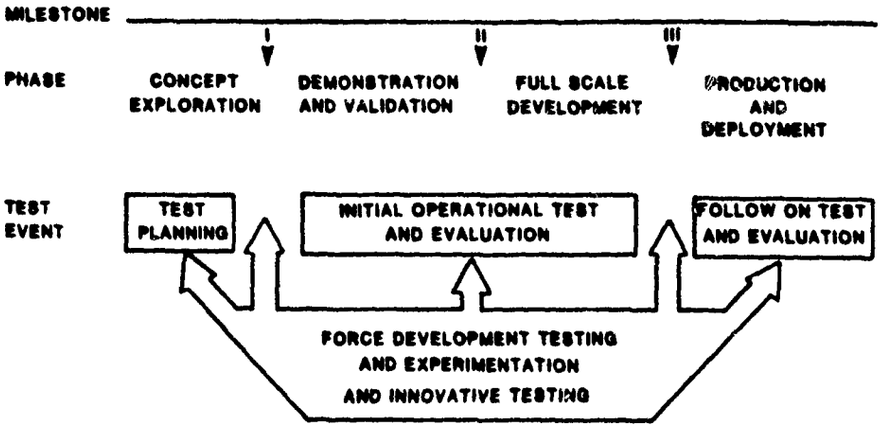


Figure 17-1
Test & Evaluation During The Materiel Acquisition Process

a. Independent Evaluation Plan. The technical independent evaluator and user independent evaluator each prepare an Independent Evaluation Plan (IEP) for all aspects of evaluation responsibilities relative to the system, to include the market investigation conducted during the Concept Exploration Phase. The IEP details the independent evaluator's actions for the evaluation of the system. The IEP is periodically updated, reflecting materiel and program changes.

The objective of the IEP is to address the issues; describe the evaluation of issues which require data from sources other than test; state the technical or user test issues; state criteria; identify data sources; state the approach to the independent evaluation; specify the analytical plan; and identify program constraints. IEPs are prepared in close cooperation with the TIWG members to ensure that the intent of the requirements is reflected in the planning.

b. Test and Evaluation Master Plan. The Test and Evaluation Master Plan (TEMP) is the basic planning document for all test and evaluation related to a particular system acquisition and is used in planning, reviewing, and approving test and evaluation. The TEMP provides the basis and authority for all other test planning documents and must be of sufficient scope and detail to explain a system's entire test and evaluation structure. Establishment of the Test Integration Working Group (TIWG) facilitates development of the TEMP.

The TEMP is a dynamic, broad plan which identifies and integrates objectives, responsibilities, resources, and schedules for all test and evaluation which either has been or will be accomplished prior to each milestone decision. An updated TEMP will be submitted with the Acquisition Strategy, SCP and DCP (AR 70-1), and provide input to the Acquisition Plan (Federal Acquisition Regulation 7.1). It is a prerequisite for all milestone decisions. All acquisition programs, including production improvements, will have an approved TEMP. The composition of the TEMP is contained in DODD 5000.3. A sample format is included in Appendix A.

c. Outline Test Plan. The Outline Test Plan (OTP) is a resource document which is prepared for the Test Schedule and Review Committee (TSARC). It contains a listing of the necessary resources and administrative information required for support of a test. The OTP will also contain the critical test issues, test conditions, and scope. OTPs are prepared by the user and technical testers (for user and technical tests respectively) for submission to the TSARC. The TSARC is governed by the provisions of AR 15-38. The CG, OTEA, chairs the TSARC and his staff (CSTE-RMD-M) administers the committee activities. The Surgeon General provides a general officer member to the TSARC. The Health Services Command represents TSG on the TSARC/WG.

d. Five Year Test Plan. The Five Year Test Plan (FYTP) is a compendium of OTPs approved by HQDA (DCSOPS) for the Chief of Staff, Army. The FYTP is published and disseminated by OTEA. The FYTP identifies validated requirements to support the Army's user test program. It is a tasking document for test execution and resource allocation for the current and budget years contingent upon fund allocation, and a planning document for the out years. OTPs for TT which require user troops are also included in the FYTP.

e. Test Design Plan. The Test Design Plans (TDPs) are formal documents which implement the TEMP and may be provided as annexes to the TEMP. The TDPs are prepared separately for the technical and user issues developed by each independent evaluator. They include a complete test design, describing required tests, the conditions under which the system is to be tested, a statement of test criteria, and measures and plans for data collection and analysis, and specifying data requirements.

f. Test Report. The Test Report (TR) is a formal document of record which reports the data and information obtained from the conduct of a test and describes the conditions which actually prevailed during test execution and data collection. Included in the TR is an audit trail of deviations from the TDP. TRs are prepared, approved, and published by USAMMDA for technical tests and AHS-Tester for user tests. The TR is a source of data used in the development of the independent evaluations and in the updating of the COEA by AHS-CD for the decision review. Test reports will be provided to the MADP review body.

g. Independent Evaluation Report. The Independent Evaluation Report (IER) is an independent evaluation of the system based on test data, test reports, studies, and other appropriate sources. IERs are prepared, approved, and published by USAMMDA for technical tests and AHS-CD for user tests at key milestone events. Under the continuous evaluation concept, the independent evaluators will periodically update their evaluation of the system.

The IER, a formal document of record, contains an assessment of the issues contained in the technical and user IEPs and other issues, as appropriate; the independent evaluator's conclusions; evaluation of test issues; the evaluator's position on the future capability of the system to fulfill the approved requirements; and identifies program constraints and their impact on the evaluation. The IERs are provided to the MADP review body (see Chapter 12).

Figure 17-2 illustrates the cyclic nature of test and evaluation documentation.

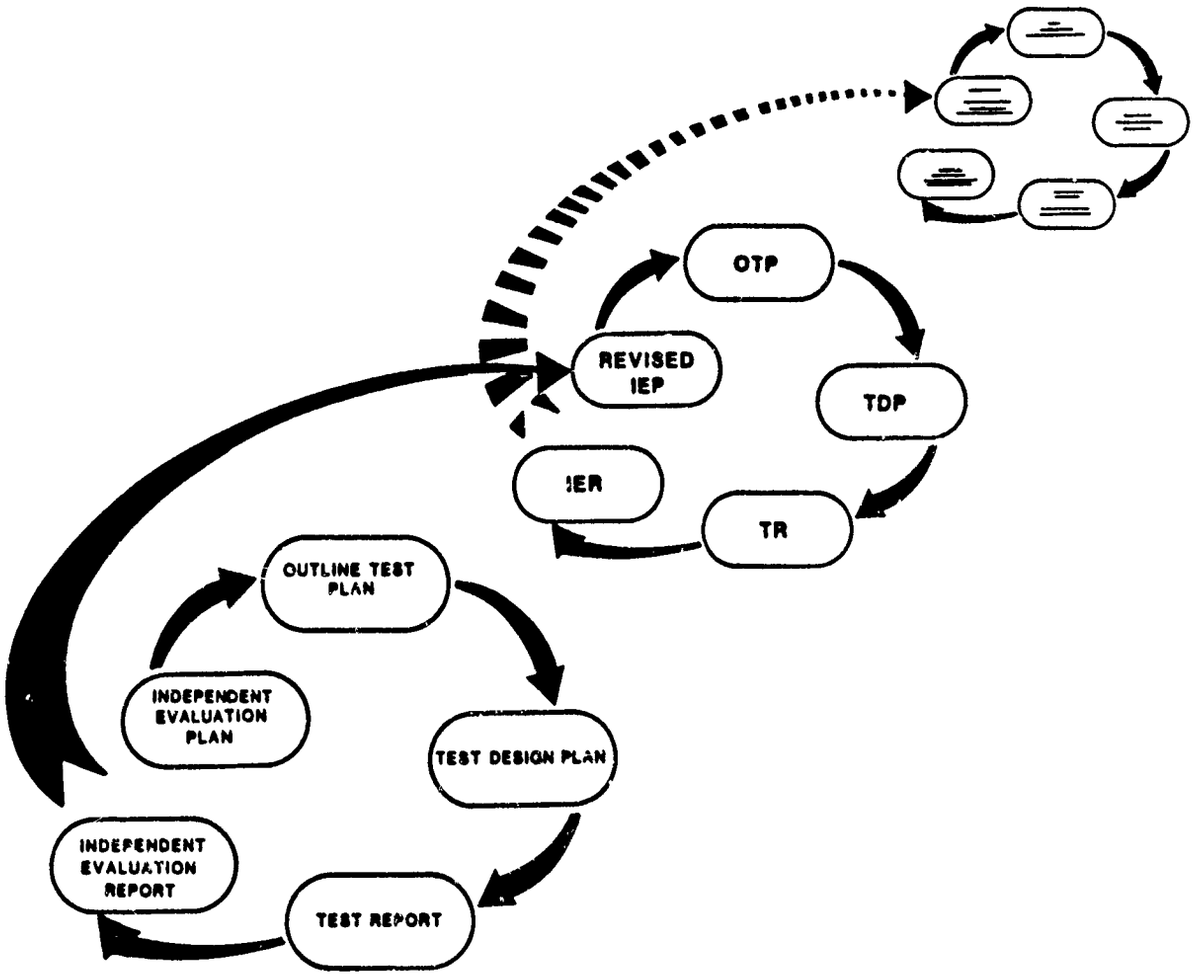


Figure 17-2 Test and Evaluation Documentation Cycles

17.2.6 Test Support Packages.

a. Test and evaluation of medical materiel includes a provision for test support packages to be provided by USAMMDA, AHS-CD, and AHS-Trainer. The test designer utilizes the support packages to ensure that planning and conduct of the test is consistent with the current user conditions. The requirements for test support packages are identified and their suspense dates set in the OTP. Their degree of development progresses parallel with the system development. Army Pamphlet 71-3, Force Development Operational Testing and Evaluation Methodology and Procedures Guide, provides guidance for the preparation of test support packages and their relationship to the test design process. Figure 17-3, summarizes the AMEDD test support package responsibilities.

b. Test Readiness Statements, Safety Releases, and Environmental Impact Assessments (EIA)/Environmental Impact Statements (EIS).

1) Test Readiness Statements (TRS) are prepared prior to start of User Testing, and certify readiness for testing. TRSs are prepared by the materiel developer for development systems and USAMMA for NDI. The Combat and Training Developer prepare TRS for Development and NDI (AR and DA PAM 71-3 and AR 40-60).

2) Safety Release (SRs) describe the specific hazards of an item or system and include technical and operational limitations and precautions. They are prepared by the materiel developer for development items and by USAMMA for NDI. The AHS Safety Manager issues SRs for tests, utilizing data from the MAT DEV/USAMMA safety release (AR 40-60 and AR 71-3).

3) EIA/EIS serve to ensure that environmental considerations are incorporated into test planning. The MAT DEV prepares EIA/EIS for development items and USAMMA prepares them for NDI.

RESPONSIBLE ACTIVITY	TEST SUPPORT PACKAGE	PURPOSE
USAMMDA (Development Items)	System Support Package	To validate training and Logistic Support Requirements and Support Capabilities
	New Equipment Training (See also Chapters 16 and 20)	To train test participants and to assist trainer with system training program
AHS-CD	Doctrine and Organization (See also Chapter 11)	To ensure test design planning is consistent with doctrine, tactics, techniques and means of employment
	Threat (See also Chapter 11)	To guide development of test conditions
AHS-Trainer	Training (See also Chapter 20)	To provide for training of user troops and to plan data collection for training requirements

Figure 17-3 Test Support Packages

17.2.7 Continuous Evaluation and Common Data Base. Continuous Evaluation represents a new thrust to assure the continuous flow of information regarding system status including planning, testing, data compilation, analysis, evaluation, conclusions and reporting to all members of the Acquisition Team from the Operational and Organizational Plan (O&O) through deployment and assessment of field performance. Continuous Evaluation will be performed by all members of the Acquisition Team. A major object is for the members to be active in surfacing critical problems at the earliest opportunity so that they may be addressed and resolved before they impact important decisions. Continuous Evaluation essentially ensures that:

- Testers and independent evaluators become system-knowledgeable early so that realistic test and evaluation requirements may be developed;
- Requirements and specifications that drive test and evaluation considerations are made known to the testers and evaluators to stabilize the test program;
- Valid contractor and Government test data as well as data from other sources (e.g., front end analysis, literature searches, modeling, simulations, MANPRINT HFEAs, LSA) are made available through a common data base and are used in the evaluation process;
- Optimum testing is performed to preclude duplication in the interests of reducing redundant and necessary testing;
- There is a basis for continuing evaluation beyond development through production and fielding so as to develop information on the current system status for use in future system developments.

17.3 CONCEPT EXPLORATION PHASE

17.3.1 General Objectives. The Concept Exploration Phase is initiated by the receipt of the Program Decision Memorandum (PDM) or approval of the Operational and Organizational Plan which constitutes Program Initiation.

- Test and evaluation is conducted on breadboard, brassboard, and prototype (to include foreign equipment and commercial items), hardware/software to assess high risk, critical components, and subsystems; to establish safety for user testing; to provide data for concept evaluation of a potential requirement, tactics, doctrine, organization training, and logistic support for the overall system; to assist in selecting preferred alternative system concepts; and to assess the user impact of candidate technical approaches. Testing may be conducted by USAMMDA test agencies, USAMRDC laboratories, contractors, and the user testers.

- The technical and user testers and independent evaluators will be formally involved in providing assistance in the structuring of program efforts, to include development of the testing portion of the Request for Proposal. Changes occurring during the contract negotiations which affect testing will be promptly communicated to the TIWG. The testers and evaluators will be involved in the Continuous Evaluation of all programs.

17.3.2 Specific Activities.

SEE CHART 17-1

1. Coordinate Issues and Criteria/Prepare IEP. AHS-CD, with input from and in coordination with, USAMMDA, USAMMA, and AHS-Trainer, prepares the IEP to guide the conduct of the Market Investigation. The Market Investigation is discussed in Chapter 4, Section 4.3.

2. Conduct Market Investigation. USAMMDA conducts the Market Investigation.

3. Conduct Technical and User Tests. In the event requisite data is not available as a consequence of the Market Investigation, it may be necessary for USAMMDA to conduct TT to determine if marketplace equipment can, in fact, meet Army requirements. Likewise, AHS-CD may require user testing to arrive at a similar decision.

4. Market Investigation Report. USAMMDA prepares this report upon completion of the five steps pertinent to the conduct of a Market Investigation. The report includes the results of any TT and user testing conducted to establish the feasibility of an NDI approach.

5. Prepare Independent Evaluation Report. AHS, in its role as independent user evaluator, prepares the Independent Evaluation Report (IER), with input from USAMRDC, USAMMDA and USAMMA. See Chapter 4, Activity 3 for further details concerning the IER in the CE phase.

6. Develop Acquisition Strategy. USAMMDA develops the Acquisition Strategy (see Chapter 4, Activity 6). If an NDI program is indicated, approval is sought at Milestone I (see Chapter 6), with program management transferring to USAMMA. If a development program is approved, USAMMDA continues management and proceeds to Activity 7.

7. Establish Test Integration Working Group. Unless the Acquisition Strategy provides justification for not establishing one, USAMMDA, as the program manager, takes the lead in establishing a Test Integration Working Group (TIWG) (see Chapter 4, Activity 9 and Chapter 17).

8. Develop Test and Evaluation Master Plan. The TIWG develops the Test and Evaluation Master Plan (TEMP) as described in Chapter 4, Activity 9 and Chapter 17.

9. Review O&O Plan. The TEMP may influence the review and update of the O&O plan by AHS-CD. The TIWG members review and provide comments (see Chapters 3 and 11).

10. Prepare D&V Request for Proposal. USAMMDA prepares the Request for Proposal with input from the TIWG.

11. System Concept Paper. The TEMP is submitted for approval with the System Concept Paper (SCP) at the milestone review and is a prerequisite for the milestone decisions (see Chapter 4, Activity 19).

17.4 DEMONSTRATION AND VALIDATION PHASE

17.4.1 General Objectives. The Demonstration and Validation (D&V) Phase is initiated by a positive Milestone I decision. Test and evaluation is conducted on brassboard and prototype hardware/software. Test and evaluation conducted during this phase supports the hardware/software design through a test-analyze-and-fix approach which will be performed at the component, subsystem, and system level; identifies the preferred technical approach, including the identification of technical risks and feasible solutions; examines the user aspects of the selected alternative technical approaches; estimates the potential user effectiveness and suitability of candidate systems; reduces design risks; establishes contractual compliance including component qualification; and evaluates technical and user Issues.

17.4.2 Specific Activities.

SEE CHART 17-1

12. Award D&V Contract. The testing section of the contract provides requirements for specific testing and testing support to be conducted by, and/or provided by, the contractor. Changes from the RFP because of contract negotiations must be identified to the TIWG.

13. Update TEMP. Based on the contractual test requirements, and the Milestone I decision authority's guidance and program changes, the TEMP is updated by USAMMDA in close coordination with the TIWG, and requires concurrence by all TIWG member agencies. The TEMP will guide the planning for TT and user tests during the D&V phase, and provide planning guidance for test and evaluation during the remainder of the program.

NOTE:

The Government's test requirements must be supported by the contractual terms.

14. Update Independent Evaluation Plans. USAMMDA and AHS-CD prepare the technical and user test IEPs respectively. The evaluation plans take into account the issues and criteria that have been identified, and available data (including contractor data) to preclude unnecessary testing. Each issue for evaluation will be identified and the methodology to be used described. Each IEP should provide procedures for the exchange of evaluation information with the other. The IEPs are staffed for concurrence by the member agencies of the TIWG. The IEPs must always be a separate document from other test planning documents. For operational tests, the IEP must be submitted twenty two - twenty seven months prior to test start date.

15. The Test Schedule and Review Committee. The USA Operational Test and Evaluation Agency (OTEA) has been tasked to manage most Army FDTE and all Joint Testing, and has responsibility for all Army operational tests. The Test Schedule and Review Committee (TSARC), which is managed by OTEA, has been tasked to control resource requirements in support of user testing. Therefore, if the AMEDD Board or other tester requires resources from outside of the Health Services Command, the requirement must be identified to the TSARC so that resourcing can be identified early for all tests scheduled in support of a system's acquisition. The Health Services Command provides a representative to the TSARC Working Group. The AMEDD Board (or other user tester) develops an estimate of test resource requirements and prepares an Outline Test Plan (OTP) from the IEP. The OTP provides a detailed description of each resource, the time and place it is to be provided, and the organizations to provide the resources.

Normally the OTPs are initially submitted to HQ OTEA in September or March five years before the test start date (T-Date). The format for the OTP is provided in DA Handbook, Test Schedule and Review Committee (TSARC), which is available from HQ OTEA. Once submitted, OTPs may be updated and resubmitted

semi-annually as "Revised OTPs". Because it is unlikely that all test requirements will be known five years in advance, a minimum time submission requirement has been established by the TSARC whereby the completed OTP must be approved by the TSARC at least one year before the first resource requirement date (R-date).

Urgent and/or unforeseen tests can be accommodated by an Out-of-Cycle OTP Submission. These submissions require general officer involvement. The TSARC Handbook outlines the specific procedures.

Upon approval, OTPs are added to the Five Year Test Program (FYTP) which is managed by OTEA. The FYTP is a compendium of TSARC-reviewed and HQDA-approved OTPs. These are resource tasking documents for tests scheduled during the current and budget years, and planning documents for tests scheduled for the out years.

16. Test Design Plans. The technical and the user testers each prepare test design plans in response to guidance from the TEMP, the respective IEPs, and the data requirements of the Cost and Operational Effectiveness Analysis or Abbreviated Analyses (COEA or AA). TDPs are formal documents that support and become an annex to, the TEMP. They are coordinated among the TIWG members, and approved by the Commander, USAMMDA or the President, AMEDD Board. Each TDP should include a complete test design, describe required tests, the conditions under which the system is to be tested, a statement of test criteria, and measures and plans for data collection and analysis. A TDP format and distribution suggestion is provided in Appendix H, AR 71-3.

17. Test Support. The AMEDD Board Test Project Manager requires information and materials from the USAMMDA, AHS-CD, and AHS-Trainer. These requirements, and the time they are needed, are included in the OTP. In addition, USAMMDA is responsible for training test personnel and trainers. This training will normally be conducted by the contractor in the D&V phase and by Government or contractor personnel in the FSD phase.

a. System Support Package. This is composite package of support elements in initial issue quantities planned for a materiel system in an operational environment. In its preliminary form it is provided before, and evaluated during, technical and operational testing and evaluation to validate the organizational, direct support, and general support maintenance capability. For Logistic supportability testing, it normally includes all draft equipment publications (operator through general support maintenance); repair parts and accessories; special and common tools; test, support, calibration and maintenance/calibration shop facilities; personnel with proper training skills; and transportation and handling equipment. USAMMDA is responsible for providing the system support package for development items and USAMMA, as the logistician, reviews the SSP. For NDI, USAMMA is responsible for providing the SSP.

b. New Equipment Training Test Support Package. This package, prepared by USAMMDA and USAMMA (for NDI), combines the documents, training aids, POI, and identification of personnel requirements to provide training to test participants and to assist AHS-Trainer in developing the system training program. The contractor may provide the training in the D&V phase using contractor provided POI, but in the FSD phase training is provided by USAMMDA to military instructor personnel who administer training to test participants using trial training materials.

c. Doctrine and Organizational. This package is provided by AHS-CD. It provides means of employment, organizational information, logistics concepts, test setting, and mission profiles to guide the test planner.

d. Threat. AHS-CD is responsible for providing the Threat Support Package. It guides the development of test conditions in test design planning. The package is a statement, based on the DA approved threat, as it pertains to the tested system.

e. Training. AHS-Trainer is responsible for providing the Training Test Support Package. It contains the training materials necessary to train user troops and to plan data collection in the area of training requirements. For example, the packages may include POI, training data collection requirements, lesson plans, personnel selection criteria, and training aids and devices.

18. Conduct Technical and User Tests. Tests are conducted in accordance with the test plans. The test organization has full authority for the conduct of the test. Interested organizations may monitor the testing. Test suspensions are discussed in Section 17-8.

19. Prepare Test Reports. The technical test and the user test project manager prepare Test Reports (TR) immediately after completion of their respective tests. The purpose of the TR is to present the conditions under which the test was conducted and report the findings resulting from the test. It is a stand alone document that is approved by the test command/agency. Approval is limited to how well the report is presented -- the reported facts cannot be changed. The TR is among the primary sources used to develop the IER and to update the COEA/AA for the next decision review.

20. Prepare Independent Evaluation Reports. The Independent Evaluation Report (IER) is an independent evaluation of the system based on test data, test reports, studies, and other sources. The IER is a separate document, prepared, approved, and published by the technical (USAMMDA) and user (AHS-CD) independent evaluators for a specific milestone decision point. Under the continuous evaluation concept, independent evaluators will periodically update their evaluations in coordination with the TIWG.

The IER is a formal document of record that contains:

- An assessment of the IEP issues;
- Independent evaluator's conclusion;
- Evaluation of the test issues;
- Evaluator's position on the future capability of the system to fulfill the approved requirements;
- Identification program constraints and their impact.

IERs are normally briefed by USAMMDA/AHS-CD directly to the pre-ASARC or the IPR. The AHS-CD, the user test independent evaluator, normally briefs the IPR. The technical independent evaluation report is briefed by the technical independent evaluator at the IPR. Frequently, only the IER Executive Summary will be available at the Milestone Review. DA Pamphlet 71-3 contains guidance for the preparation of the user test IER.

21. Update COEA or AA. The system tests were designed to meet the data requirements of the COEA/AA (see Activity 17). Upon completion of the tests and preparation of the test report and the independent evaluation report, the COEA is updated by AHS-CD in preparation for the next milestone decision review. Also, each independent evaluator, USAMMDA and AHS-CD, update their respective IEPs to reflect the test results and the updated COEA.

22. Update TEMP for MS II. USAMMDA, in close coordination with the TIWG, updates the TEMP prior to the next milestone decision review when it will be submitted with the Decision Coordinating Document and the Acquisition Strategy for approval. The updated TEMP incorporates the testing requirements from the technical tester, user tester, independent evaluators, and other Government and contractor activities. The TIWG member agencies must concur with the updated TEMP.

23. Prepare for Milestone II Review. Test and Evaluation documents and the test and evaluation inputs to other documents play a large role in the milestone review decision process.

- The TEMP is approved by the decision authority and establishes testing requirements for the next phase;
- The test independent evaluation reports are briefed at the review.

17.5 FULL SCALE DEVELOPMENT PHASE

17.5.1 General Objectives. The Full Scale Development (FSD) Phase test and evaluation is conducted on prototype systems. Sufficient funds will be programmed early by USAMMDA to ensure that ancillary equipment/components (e.g.,

training devices, ground support equipment, field maintenance test sets) are available and adequately tested. During this phase, the system design must be frozen in time to provide an adequate system support package for testing and to ensure that the system tested will be representative of the production hardware/software so that a valid assessment can be made of the system expected to be produced. Test and evaluation conducted during this phase:

- Matures engineering development prototype hardware/software including component qualification;
- Provides a valid estimate of the system's user effectiveness, suitability, and supportability;
- Ascertains whether engineering is complete;
- Identifies design problems and ascertains that solutions to these problems are in hand;
- Reduces design risks;
- Establishes contractual compliance;
- Validates general and detailed specifications, standards, and drawings for use to procure units of products;
- Evaluates technical and operational issues.

17.5.2 Specific Activities.

SEE CHART 17-1

24. Award FSD Contract.

25. Update TEMP. Based on the contractual test requirements, the Milestone II decision authority's guidance and program changes, the TEMP is updated by USAMMDA, in close coordination with the TIWG, and the concurrence of all TIWG member agencies. The TEMP will guide the execution of technical and user tests during FSD and the planning for test and evaluation during the remainder of the program.

26-33. Events 26 through 33. These events are repeats of the Demonstration and Validation Phase events 14 through 21 respectively which are discussed on pages 17-19 through 17-23.

34. Update TEMP for MS III. USAMMDA, in close coordination with the TIWG, updates the TEMP in preparation for the Milestone III review. The updated TEMP incorporates the Production and Deployment Phase testing requirements and requires the concurrence of the TIWG member agencies.

35. Prepare for Milestone III Review. Test and Evaluation documents and the test and evaluation inputs to other documents play a large role in the milestone review decision process.

- The TEMP is approved by the decision authority and establishes testing requirements for the next phase;
- The test independent evaluation reports are briefed at the review.

17.6 PRODUCTION AND DEPLOYMENT PHASE

17.6.1 General Objectives. The Production and Deployment (P&D) Phase is initiated upon approval of the decision authority. Test and evaluation is conducted on initial production items (first articles) and provides input to support the fielding decision; determines the producer's performance in producing items/systems that meet prescribed technical data package requirements, and ascertains that the products continue to meet prescribed requirements; verifies that fixes to problems found in earlier testing have been made; and provides data for evaluation of product improvements. Test and evaluation is an integral part of the design, acceptance, and introduction of system changes to improve the system; react to new threats; and reduce life cycle costs. In addition, it ensures that the initial production items meet user effectiveness and stability thresholds and evaluates system, manpower, and logistic changes to meet mature system readiness and performance goals.

17.6.2 Specific Activities.

SEE CHART 17-1

36. Transition to USAMMA. USAMMA's management role commences with the Milestone III IPR and the decision authorities' approval to transition the program from USAMMDA.

37. Transfer TDP to DPSC. USAMMA prepares documentation for standardization of the item and forwards the Technical Data Package (TDP) to DMSB.

38. Initial Production. The DPSC is responsible for the preparation of the solicitation package, awarding the contract and production. DPSC conducts Production Acceptance Test and Evaluation (PAT&E) which is intended to ensure that the contractor can furnish a product that meets established technical criteria.

39. First-Article Testing. The materiel developer or DPSC prescribes performance of the First Article Testing (FAT). USAMMA participates with USAMMDA and other Acquisition Team members, as required. If specific evaluation issues were raised in the last TEMP update, the data for the evaluation will be obtained through the FAT. The FAT results are critical in support of obtaining a full scale production decision.

40. Request Materiel Release. As part of the materiel fielding process (Chapter 20), USAMMA requests a Materiel Release from OTSG. Successful completion of FAT, including evidence that any deficiencies will be corrected prior to fielding, is included in the request for release. OTSG must approve release, either full or conditional, prior to entering full scale production. Approval by OTSG authorizes USAMMA to proceed with the execution of the Materiel Fielding Plan (MFP) and the New Equipment Training Plan (NETP), including Doctrine and Tactics Training (DTT).

41. Update Independent Evaluation Plan. If a Follow-On Test and Evaluation (FOT&E) is planned for in the last updated TEMP, AHS, in its role as independent user test evaluator, updates an IEP based on the updated evaluation and test issues derived from the TEMP Issues.

42. Conduct Follow-On Test and Evaluation. The AMEDD Board conducts the FOT&E after developing the Test Design Plan (TDP). It is critical that troops required for testing be included in the Outline Test Plan (OTP) for TSARC consideration. Subsequent to FOT&E, a TR is prepared by the AMEDD Board. The TR is provided to AHS-CD and the other TIWG members.

43. Prepare IER/Verify Corrective Action. AHS, in its independent evaluation role prepares the IER. AHS-CD initiates corrective action required to overcome deficiencies revealed in the FOT&E and verifies that the corrections have been made.

44. Full Production and Distribution. Upon acceptance of the FAT, the contractor enters full production and conducts quality conformance inspections as prescribed in the contract specifications. The Defense Contract Administration Service (DCAS), a Defense Logistics Agency activity, conducts quality assurance on behalf of the DOD. Upon acceptance by DCAS, the system is distributed as prescribed-for in the contract and materiel fielding plans.

17.7 TEST AND EVALUATION OF NDI, MOD-NDI, AND PI PROGRAMS

17.7.1 General. The test and evaluation process is tailored to the type of acquisition program, to the program acquisition strategy, and to the unique characteristics of individual programs. Regardless of the program type, the requirements for a TIWG, TEMP, IEP, TDP, TR, IER, etc., remain.

17.7.2 Nondevelopment Item Programs. NDI are considered a "no difference item" with respect to the test and evaluation process. USAMMDA is responsible for establishing the TIWG and developing the TEMP and provides input to AHS for IEP preparation. The Milestone I IPR members can be requested to recommend that the test events be waived if they are not required based on an analysis of the test issues.

Testing prior to Milestone I should be limited to that absolutely necessary to support the NDI decision. In some cases it may be necessary for the Market Investigation to enter an evaluation phase and conduct short user evaluation tests (including logistics support).

Post Milestone I testing is described in the TEMP and specifically approved by the Milestone Decision Authority. The goal is "no testing"; therefore, technical testing will not be conducted unless specific information needs are identified that cannot be satisfied by contractor or other test data sources. User tests may be waived when it can be demonstrated that the Market Investigation satisfies the users' requirements. This determination should be made at Milestone I.

Testing for NDI programs is divided into two categories:

- Category A - Off-the-shelf items to be used in the same environment for which the items were designed. Normally testing is not required prior to the production qualification test except in those cases wherein a contract possibly may be awarded to a contractor who has not previously produced an acceptable finished product and the item is assessed as high risk. In that case, preproduction qualification testing is required and included in the RFP. (AR 70-10).

- Category B - Off-the-shelf items to be used in an environment different than that for which designed. OT is required in an operational environment, unless waived or satisfied by other user testing. Preproduction qualification testing is required if previous testing has resulted in items design. Also, a production qualification test is required. (AR 70-10).

17.7.3 Modified Nondevelopment Item Programs. Test and evaluation for MOD-NDI programs is a mix of the NDI and development program processes. The test requirements are established prior to the Milestone I Review, recommended to the decision authority and, if approved, implemented in the Requirements Definition and Planning and P&D Phases. Technical tests are scoped to the degree and significance of engineering changes and logistical support implications. User tests are guided by the performance, operational, and supportability changes due to the modification of the NDI and by unsatisfied need for information on the NDI.

17.7.4 Product Improvement Programs. Test and evaluation of product improvements are also conducted in accordance with ARs 70-10, AR 71-3, and 71-15 Product Improvement of Materiel. In addition, the scope and type of testing needed for PIPs will vary. The Milestone I decision specifically approves the TEMP which establishes the test and evaluation responsibilities during the Engineering and Production and Deployment phases.

17.8 WAIVERS AND SUSPENSIONS OF TESTS

17.8.1 Waivers of Planned Testing. Requests for waivers of TT or user tests will be reviewed by the TIWG and provided, through OTSG, to OTEA for review of user tests, and to the Milestone Decision Review Decision Authority for TT and user tests approval.

Waivers of tests will be based on the availability of relevant data from other sources. The requirement for an operational evaluation will not be deleted.

Written approval/disapproval of test waivers will be provided to all TIWG members. The TIWG should consider expanding production tests or Follow-On Test and Evaluation to include those elements not previously tested.

17.8.2 Suspension of Tests. Upon identification, during testing, of a major problem, testing will be suspended by the tester.

Testing will be suspended by the tester when it is apparent that the system has little chance of meeting major requirements, poses hazards to personnel or equipment, or it becomes evident to the independent evaluator that test data and information being obtained is not valid and will not support critical test issues. In all cases, test suspension authority rests with the tester.

Upon suspension, USAMMDA will convene a program review to consider future actions. The TIWG will then be convened to prepare recommendations to the materiel developer and assist in developing work-around solutions. The recommendations will be documented in the TIWG minutes. Once the USAMMDA has a solution to the problem, the TIWG will be reconvened to determine necessary additional tests to validate the fixes. Before restart of testing, appropriate test readiness reviews will be conducted by the appropriate TIWG working groups.

The USAMMDA will notify the Milestone Decision Authority when there are cost and schedule implications because of test suspensions/changes.

17.9 REFERENCES

DODD 5000.3, Test and Evaluation, 1986

DODD 5141.2, Directorate of Test and Evaluation, 1984

AR 15-14, Systems Acquisition Review Council Procedures, 1986

AR 15-38, Test Schedule and Review Committee, 1985

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

AR 70-1, Systems Acquisition Policy and Procedures, 1986

AR 70-10, Test and Evaluation, 1986

AR 70-15, Product Improvement of Materiel, 1980

AR 71-3, User Testing, 1986

AR 71-9, Materiel Requirements, 1986

AR 602-2, MANPRINT in the Material Acquisition Process, 1986

AR 700-127, Integrated Logistics Support, 1983

AR 702-3, Army Materiel Systems RAM, 1982

AR 702-9, Production Testing of Army Materiel, 1980

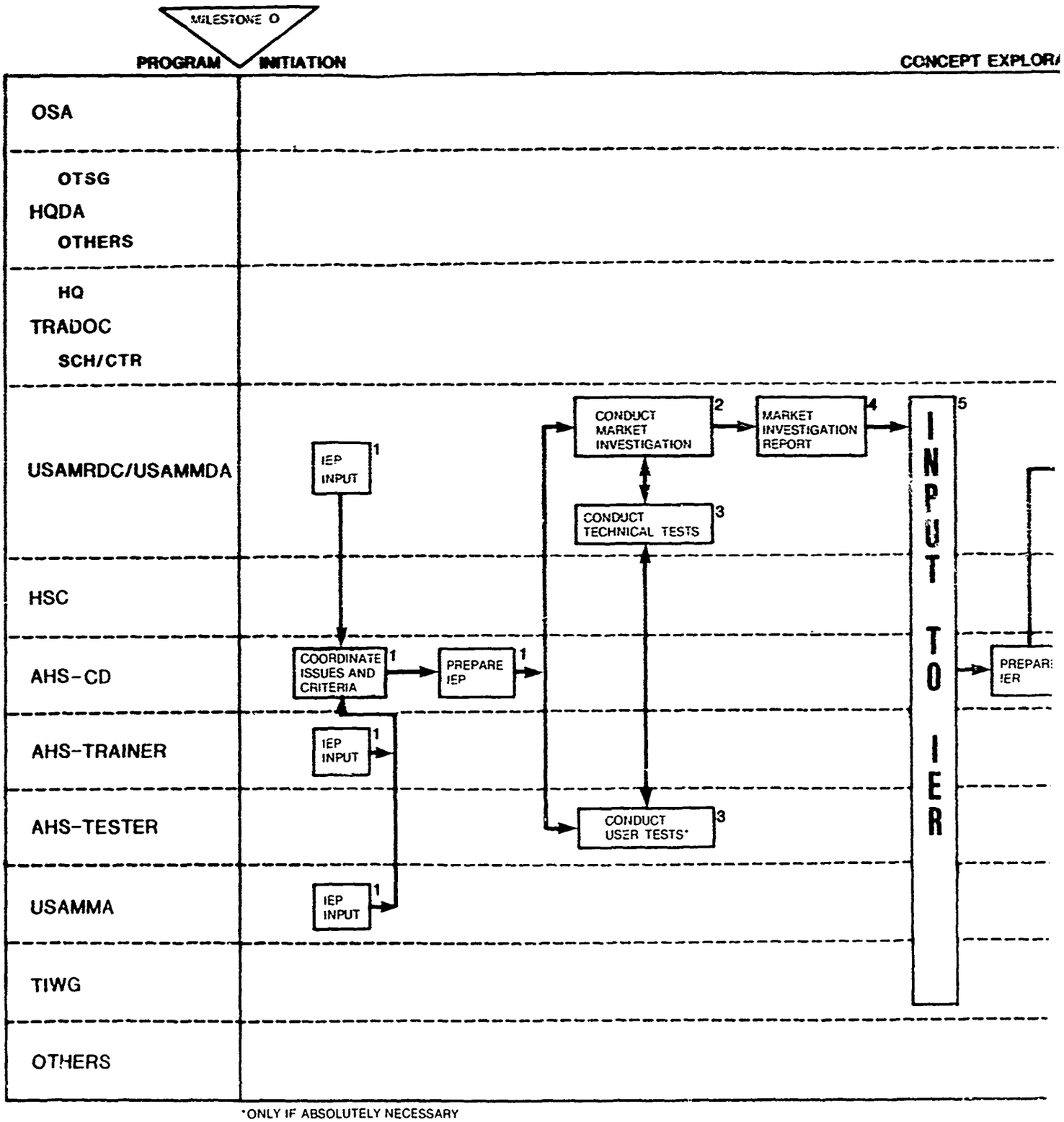
AR 1000-1, Basic Policies for System Acquisition, 1983

DA PAM, 70-21 Test Integration Working Group, 1982

DA PAM, 71-3, Force Development OT&E Methodology and Procedures Guide, 1979

DA PAM, 700-50 Supportability Test and Evaluation Guide, 1984

DA HANDBOOK, Test Schedule and Review Committee, 1986



*ONLY IF ABSOLUTELY NECESSARY

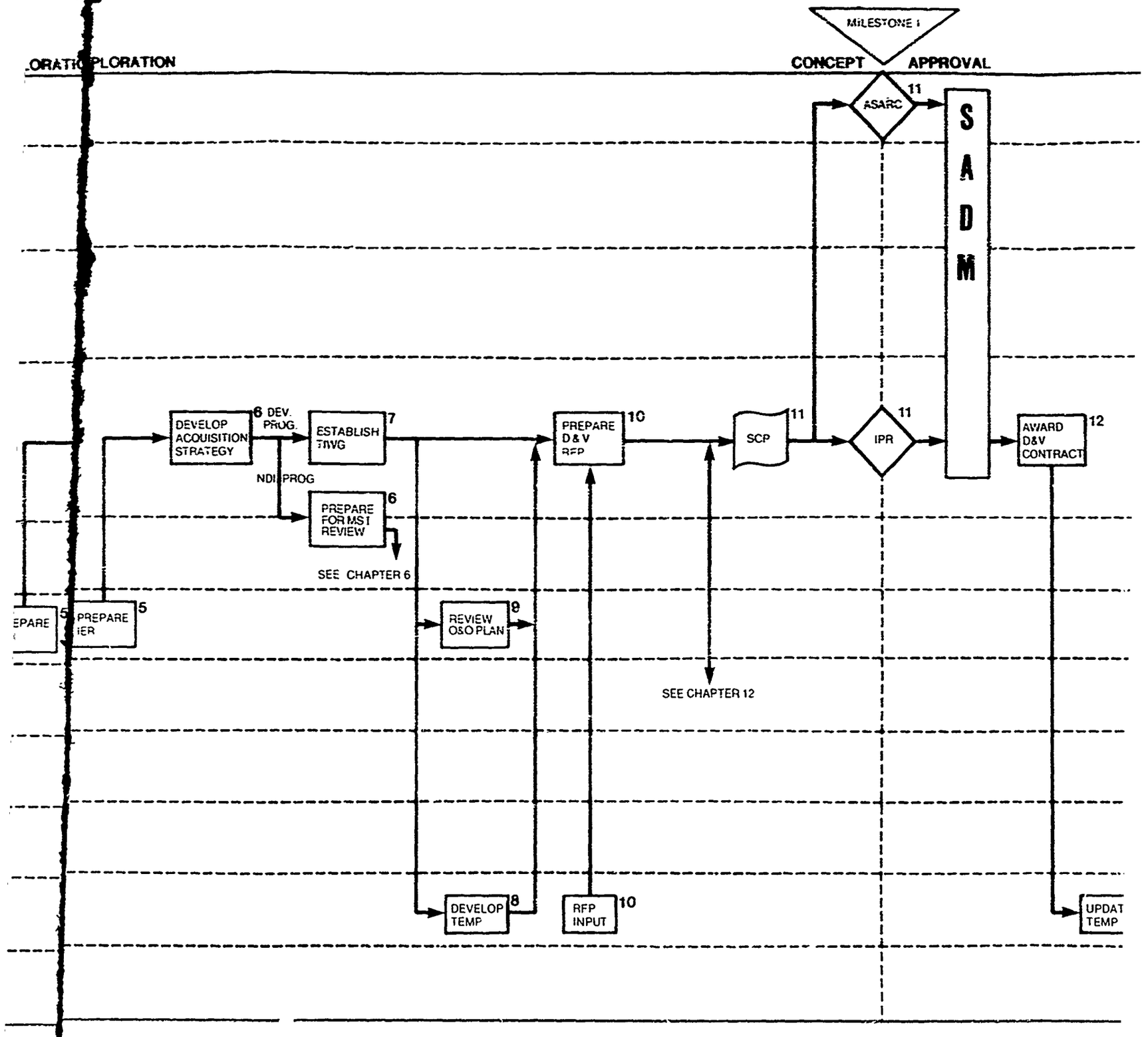
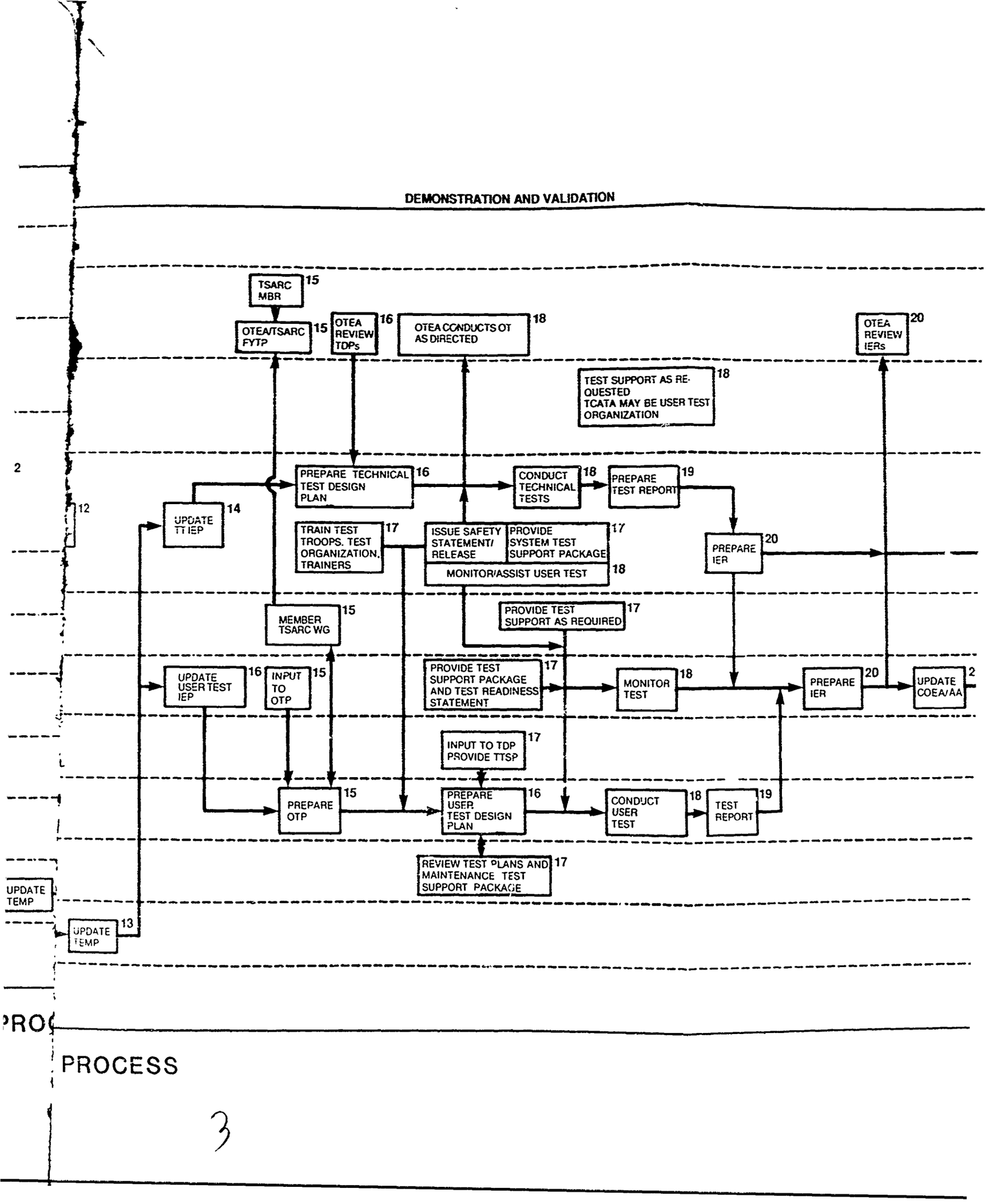


Chart 17-1, THE TEST AND EVALUATION PRC

2-


DEMONSTRATION AND VALIDATION
TSARC MBR 15
OTEA/TSARC FYTP 15
OTEA REVIEW TDPs 16
OTEA CONDUCTS OT AS DIRECTED 18
OTEA REVIEW IERs 20
TEST SUPPORT AS REQUESTED TCATA MAY BE USER TEST ORGANIZATION 18
PREPARE TECHNICAL TEST DESIGN PLAN 16
CONDUCT TECHNICAL TESTS 18
PREPARE TEST REPORT 19
UPDATE TT IEP 14
TRAIN TEST TROOPS, TEST ORGANIZATION, TRAINERS 17
ISSUE SAFETY STATEMENT/ RELEASE
PROVIDE SYSTEM TEST SUPPORT PACKAGE 17
MONITOR/ASSIST USER TEST 18
PREPARE IER 20
MEMBER TSARC WG 15
PROVIDE TEST SUPPORT AS REQUIRED 17
UPDATE USER TEST IEP 16
INPUT TO OTP 15
PROVIDE TEST SUPPORT PACKAGE AND TEST READINESS STATEMENT 17
MONITOR TEST 18
PREPARE IER 20
UPDATE COEA/AA
INPUT TO TDP PROVIDE TTSP 17
PREPARE OTP 15
PREPARE USER TEST DESIGN PLAN 16
CONDUCT USER TEST 18
TEST REPORT 19
REVIEW TEST PLANS AND MAINTENANCE TEST SUPPORT PACKAGE 17
UPDATE TEMP
UPDATE TEMP 13
12
2

PROCESS

3

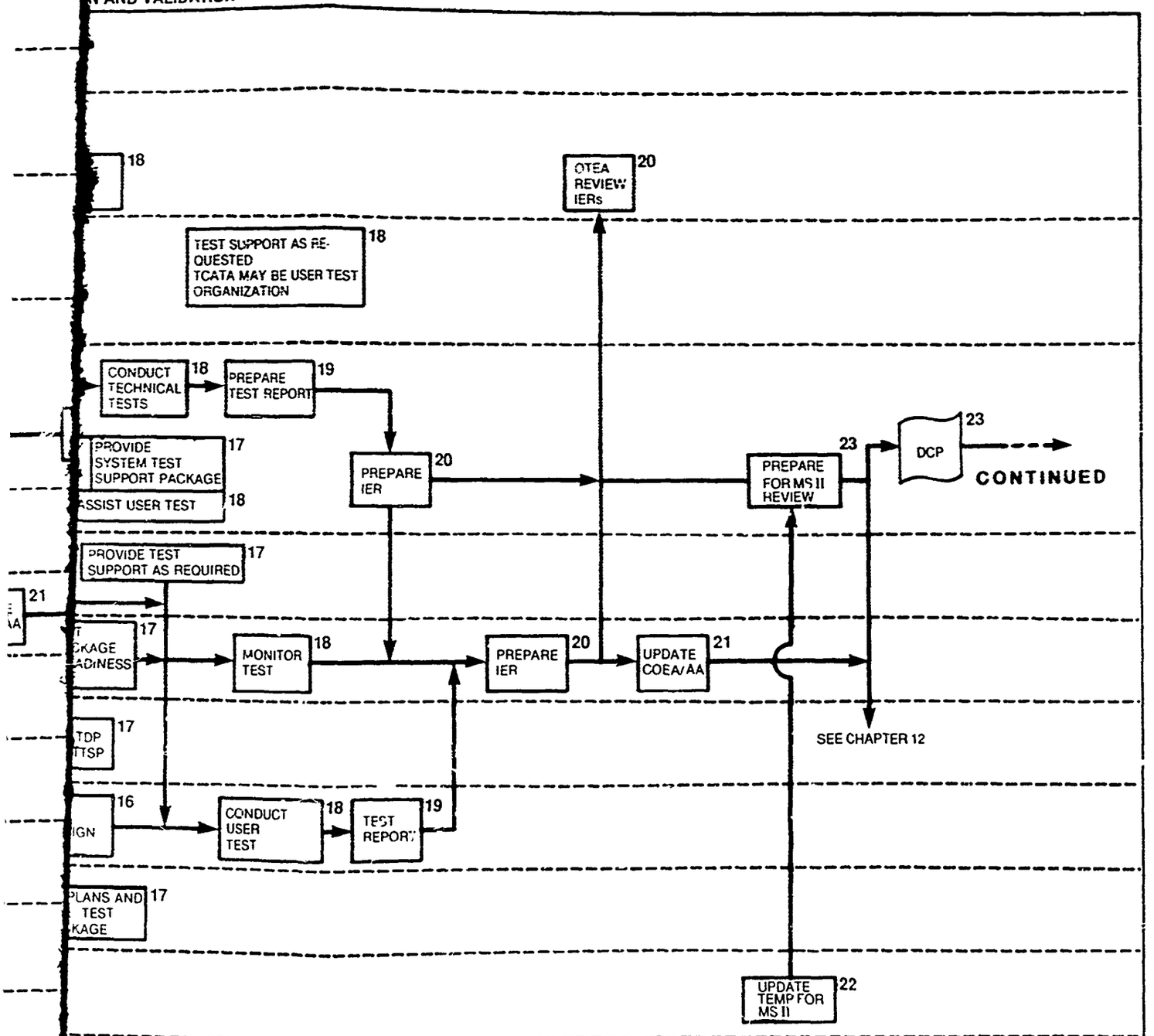
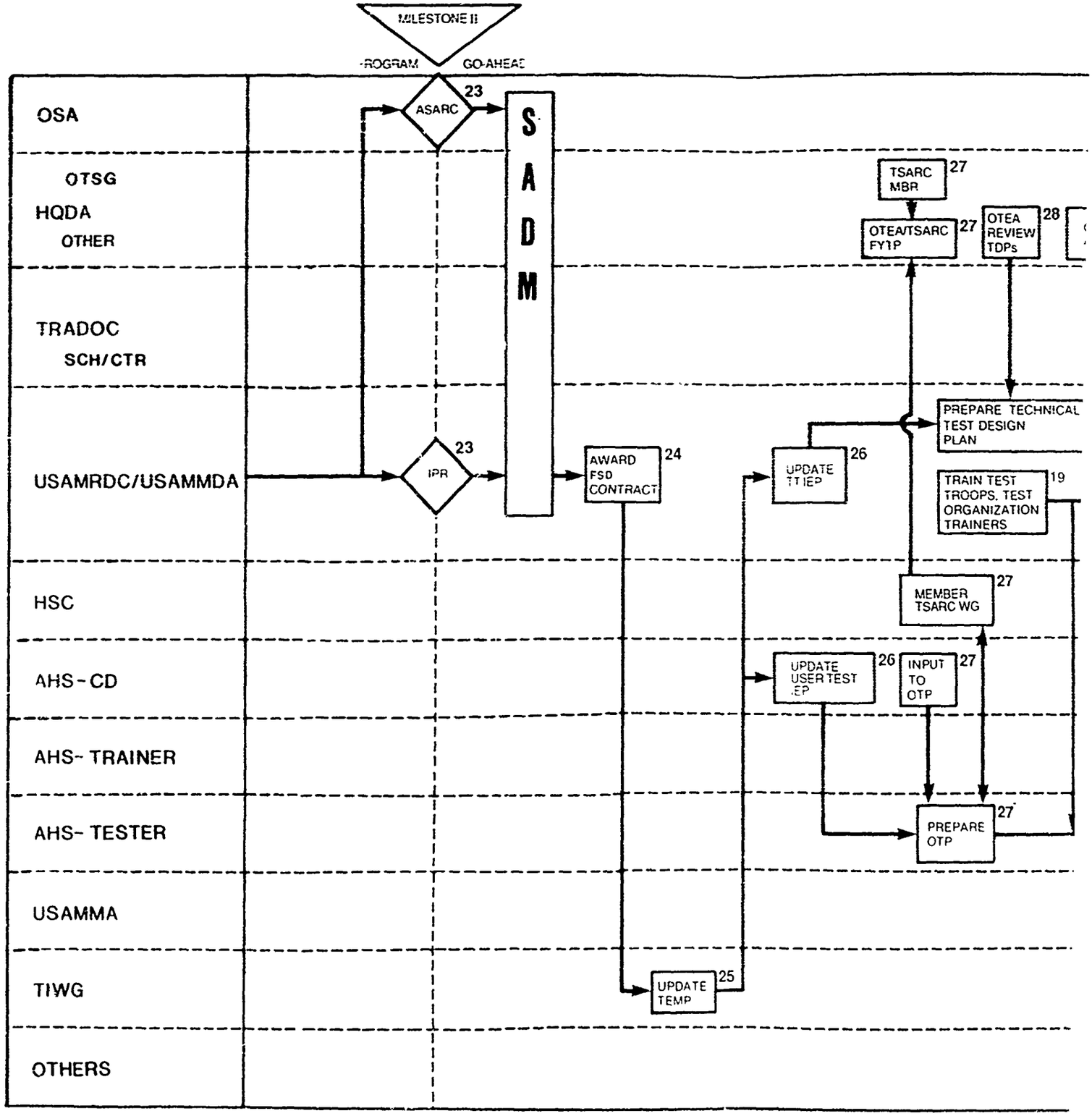


CHART NOTES

1 SEE APPENDIX B FOR ACRONYMS

2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 17-1


MILESTONE II
PROGRAM GO-AHEAD
OSA
OTSG
HQDA
OTHER
TRADOC
SCH/CTR
USAMRDC/USAMMDA
HSC
AHS-CD
AHS-TRAINER
AHS-TESTER
USAMMA
TIWG
OTHERS
ASARC
23
IPR
23
S
A
D
M
AWARD FSD CONTRACT
24
UPDATE TEMP
25
UPDATE TTIEP
26
UPDATE USER TEST EP
26
TSARC MBR
27
OTEA/TSARC FY1P
27
OTEA REVIEW TDPs
28
PREPARE TECHNICAL TEST DESIGN PLAN
TRAIN TEST TROOPS, TEST ORGANIZATION TRAINERS
19
MEMBER TSARC WG
27
INPUT TO OTP
27
PREPARE OTP
27

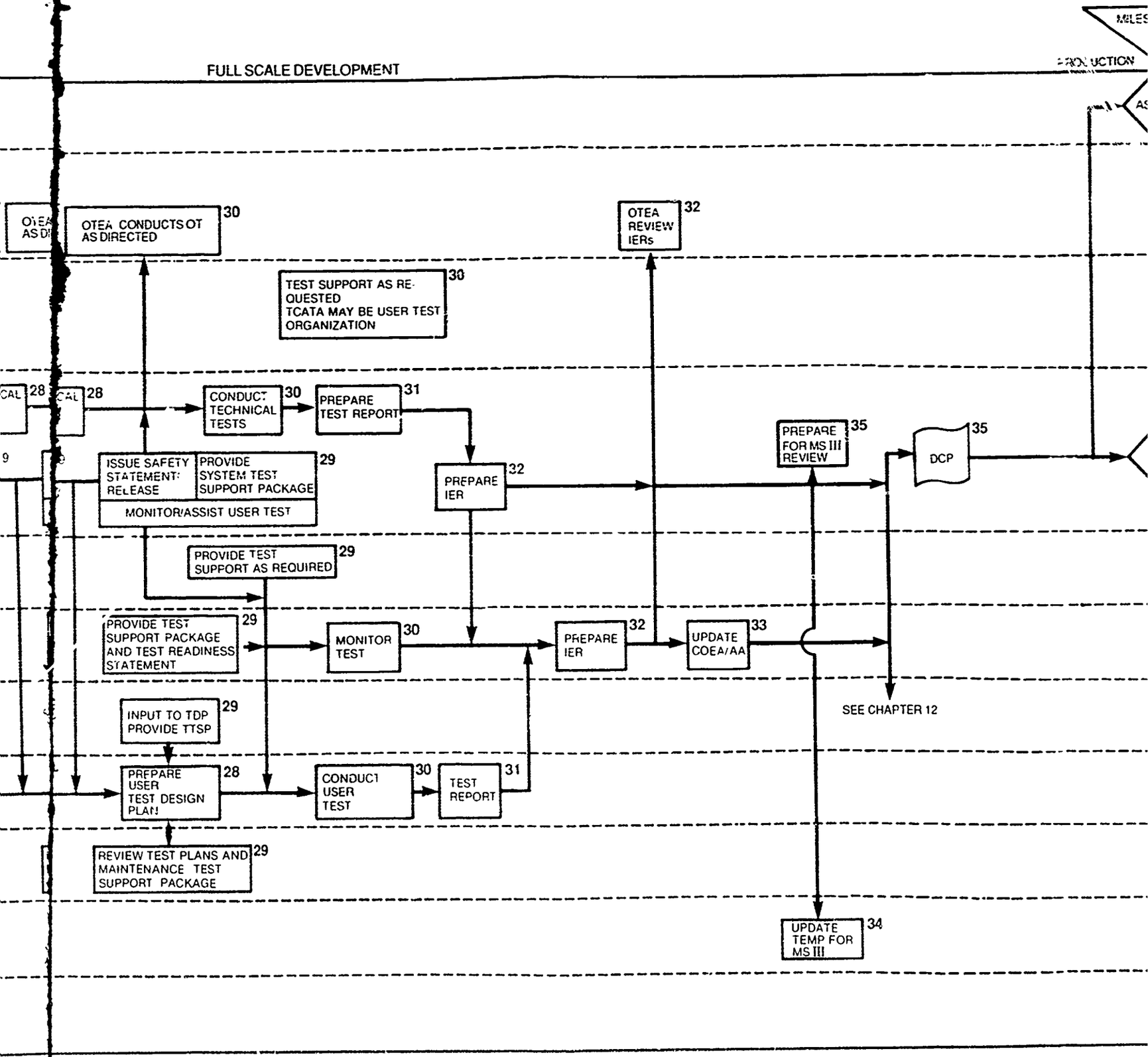


Chart 17-1, THE TEST AND EVALUATION PROCESS

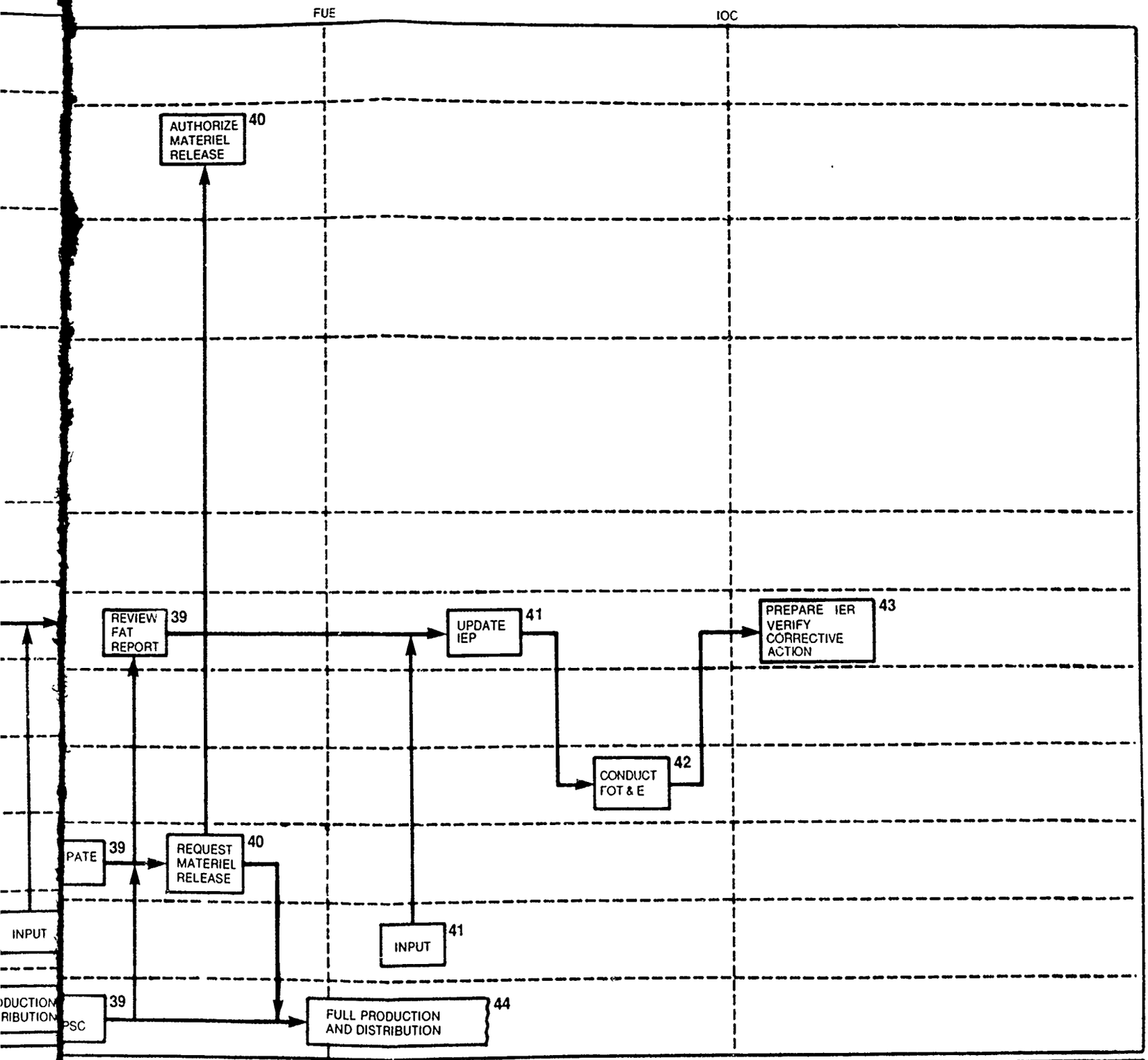


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 17-1 C

CHAPTER 18

THE BOIP/QQPRI PROCESS

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18.1 PURPOSE

This chapter addresses policies, responsibilities, and procedures for preparing, processing, approving, and amending Basis of Issue Plans (BOIP) and Qualitative and Quantitative Personnel Requirements Information (QQPRI) for new medical materiel development and nondevelopment items. Activities necessary to acquire an approved BOIP/QQPRI are described in the chronological sequence depicted in Chart 18-1.

18.2 GENERAL

The Basis of Issue Plan and the Qualitative and Quantitative Personnel Requirements Information are prepared to determine the total required quantity of a new development or Nondevelopment Item (NDI); its Associated Support Items of Equipment (ASIOE); and the number of personnel and skills required to operate, maintain, and transport the item. Both documents are developed as a cooperative effort between the materiel developer, e.g., U.S. Army Medical Materiel Development Activity (USAMMDA) and the combat developer, e.g., Academy of Health Sciences (AHS).

The BOIP is a planning document that lists specific levels at which a new or modified item may be placed in a unit or organization; the quantity of the item proposed for each organizational element; and other equipment and personnel changes required as a result of the introduction of the new item. The BOIP is neither an authorization document, a fielding or distribution plan, nor a redistribution plan for replaced items.

The QQPRI is a compilation of specified organizational, doctrinal, training and personnel information on new or modified materiel items. This information is used to determine the need for the establishment or revision of Military Occupational Specialities (MOSs), or other skill identifiers, and to prepare plans to provide the number of trained personnel required for operating and supporting a new or modified materiel item. The QQPRI is based in part on human factors studies, Logistics Support Analysis (LSA), training

strategy research, behavioral research, and, during early development stages, Manpower and Personnel Integration (MANPRINT) methodologies. It provides the most current information concerning numbers and qualifications of personnel involved in the use, maintenance, and transport of the proposed item. Where appropriate and feasible, the QQPRI describes personnel duties and tasks to include work units, performance standards and/or manpower authorization factors, recommended MOS(s), skill levels and organizations. It also includes implications for personnel selection and training, including major items for training support.

18.3 THE BOIP/QQPRI PROCESS

18.3.1 Demonstration and Validation Phase. The BOIP and QQPRI are initially developed during the Demonstration and Validation Phase, in accordance with the processing schedule depicted in Figure 18-1 and procedures described in paragraph 18-4. Both are important inputs to the Milestone II decision process. It is important that the coordination and lines of communication established in this phase are maintained throughout the life cycle of the equipment.

18.3.2 Full Scale Development Phase. During the Full Scale Development phase, a formal review of the BOIP and QQPRI will be made thirty-nine months and again thirty months before the First Unit Equipped Date (FUED). If those reviews reveal that changes to either the BOIP or QQPRI are required, the staffing and approval procedures for amended documents are the same as for the original input. However, the combat developers (TRADOC and AHS) have four rather than six months to process the amended package. This reduced time is necessary to ensure that the ABOIP initiated thirty months prior to FUED can be applied to Tables of Organization and Equipment (TOE) twenty-four months prior to FUED.

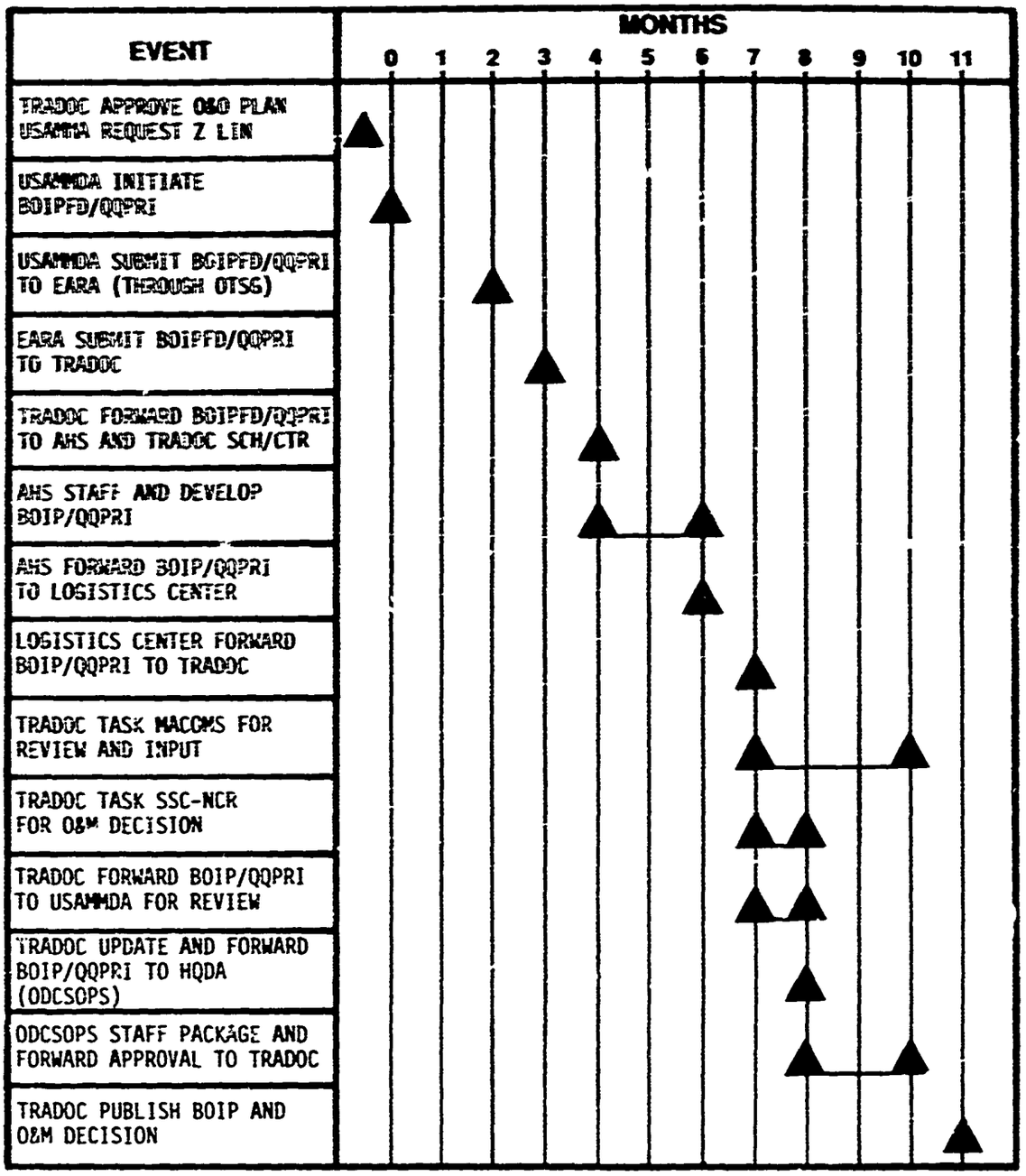


Figure 18-1. The Initial BOIP/QQPRI Processing Schedule

A HQDA-approved ABOIP and HQDA final Operator and Maintainer (O&M) decision, derived from the AQQPRI for each item of a new system, to include all special test sets and tool kits that qualify for production, are required prior to Milestone III and Type Classification Standard (TC STD). All development items of equipment required to support a system (TMDE, tool sets, test sets) must be identified during the BOIP process. This allows user MACOMs and HQDA to program people, funds, and facilities to support new equipment when it arrives at using units.

18.3.3 Amendments. Amendments to the BOIP and/or QQPRI may be submitted as the result of the formal reviews or at any other time that changes to either equipment, personnel, or ASIOE are identified. Amendments are numbered chronologically, (e.g., A1QQPRI, A2QQPRI) and follow the same staffing flow as the original submission.

18.4 DEVELOPMENT ITEM PROCESSING PROCEDURES

18.4.1 General Objectives. Chart 18-1 summarizes the detailed procedures for preparing, coordinating, reviewing, and approving the BOIP and QQPRI prior to Milestone II. The number within each block on the flow chart relates to the text paragraph below that discusses the activity identified in the block. The chart is designed to present the primary responsibilities of each participating organization in relative order.

18.4.2 Specific Activities.

SEE CHART 18-1

1. HQ TRADOC Distribute O&O Plan. Following a favorable Milestone I decision, HQ TRADOC will distribute the approved O&O plan previously developed by AHS.

2. USAMMA Request Z-LIN. As the medical logistician, USAMMA requests a development line item number (Z-LIN) from AMC. The Z-LIN is a means of tracking the item under development through the logistics community during the acquisition process until it is Type Classified Standard (TC STD).

3. AMC Assign Z-LIN. On request, AMC will assign a Z-LIN to each development item to be TC STD and provides it to USAMMA.

4. Update Manpower, Personnel, and Training Estimates. Estimates of Manpower, Personnel, and Training (MPT) requirements provide essential input to development of BOIP and QQPRI. USAMMDA, supported by AHS-CD and AHSTrainer, employs MANPRINT and Logistic Support Analysis (LSA) methodologies to update earlier estimates of MPT requirements. Estimates may be derived using the Hardware versus Manpower (HARDMAN) model and/or Comparative Analysis (LSA Task 203). Initial Logistic Support Analysis Records (LSAR) documentation may also be useful during this phase. Refer to Chapter 14, The Manprint Process, and Chapter 15, The ILS Process.

5. USAMMDA Prepare and Submit BOIP Feeder Data and Data Interchange Sheets, and Initiate QQPRI. Using the O&O plan, SMMP, and other source data, such as described above, USAMMDA prepares BOIP Feeder Data (BOIPFD) and initiates the QQPRI in accordance with guidance provided in AR 71-2. USAMMDA will also develop Data Interchange (DI) sheets in accordance with Section VI, Chapter 3, AMC Regulation 700-5. The BOIPFD/QQPRI/DI is submitted as a package through OTSG to The U.S. Army Equipment Authorization Review Activity (EARA) within sixty days after assignment of the Z-LIN. USAMMDA coordinates the documentation as follows:

a. USAMMDA ensures that all Test, Measurement, and Diagnostic Equipment (TMDE) items are reviewed by the U.S. Army Central TMDE Activity (USACTA).

b. The package is informally coordinated with AHS to ensure there are no major disagreements between the medical combat and materiel developers.

c. USAMMDA coordinates the package with OTSG in advance to ensure that processing of a BOIP/QQPRI package for a development item can be quickly forwarded to EARA.

6. EARA Review and Distribute BOIPFD/QQPRI/DI. EARA reviews the BOIPFD, QQPRI, and DI for validity, completeness, accuracy, and compatibility. The BOIPFD and QQPRI are forwarded together to HQ TRADOC. Copies of the DI are provided to the U.S. Army Depot Systems Command (DESCOM) and to the activities responsible for acquiring the items identified (i.e., - USAMMDA and AMC Major Subordinate Commands).

7. HQ TRADOC Prepare and Distribute BOIPFD/QQPRI Tasking Letter. HQ TRADOC assigns a BOIP number and initiates the BOIP automated data base header sheet. HQ-TRADOC prepares a tasking letter and forwards the BOIPFD/QQPRI package to AHS-CD with information copies to TRADOC schools and integration centers. AHS-CD is responsible for preparing the BOIP from the BOIPFD, completing the QQPRI, and staffing both with AHS-Trainer and the involved TRADOC schools and integration centers (ninety days).

8. TRADOC Schools/Integrating Centers Prepare and Submit Inputs to the BOIP/QQPRI. Involved TRADOC schools and integrating centers and AHS-Trainer develop inputs to the BOIP and QQPRI and forward them to the AHS-CD for incorporation and coordination.

9. AHS Prepare, Coordinate, and Submit BOIP/QQPRI. AHS-CD, using inputs from involved TRADOC schools/integrating centers and a training impact assessment prepared by AHS-Trainer, refines the BOIP and QQPRI. The BOIP and QQPRI are then submitted, through the Logistics Center, to HQ TRADOC with information copies provided to OTSG, USAMMDA, and HSC.

10. LOGC Review and Forward BOIP/QQPRI Package. LOGC, as the TRADOC integrating center for combat service support, reviews and forwards the BOIP/QQPRI package to HQ TRADOC.

11. HQ TRADOC Reviews and Coordinates the BOIP/QQPRI Package and Requests a Proposed Operator and Maintainer (O&M) Decision. Upon receipt of the BOIP/QQPRI package from LOGC, HQ TRADOC then takes the following actions:

a. Prepares a tasking letter to user MACOMs requesting comments and inputs to the Table of Distribution and Allowances (TDA); Joint Table of Allowances (JTA); and Additive Operational Projects (AOP) (ninety days);

b. Forwards a copy of the package to USAMMDA through EARA for review of TRADOC inputs (thirty days);

c. Provides a complete BOIP/QQPRI package to the Soldier Support Center - National Capitol Region (SSC-NCR) for a proposed O&M decision and personnel analysis (thirty days), and;

d. Internally staffs the BOIP/QQPRI package (thirty days).

12. USAMMDA/EARA Review BOIP/QQPRI Package. USAMMDA reviews TRADOC inputs to the BOIP/QQPRI package, and submits comments and recommendations back to HQ TRADOC through EARA within thirty days with information copies to AHS-CD, AHS-Trainer, OTSG, HSC and USAMMA.

13. SSC-NCR Prepare and Submit Proposed O&M Decision. SSC-NCR reviews the BOIP/QQPRI package, performs a personnel analysis, and proposes an O&M decision to HQ TRADOC within thirty days.

14. HQ TRADOC Conducts a Review Board and Forwards Package to ODCSOPS. HQ TRADOC convenes a board to review the BOIP/QQPRI package, which now includes the proposed O&M decision and review comments of USAMMDA. However, the package probably will not yet include input from the user MACOMs, which were given ninety days to provide comments. The board-reviewed package, to include the requirements document (if not previously approved by HQDA), is forwarded to ODCSOPS (DAMO FDR) for HQDA staffing and approval.

15. Staff BOIP/QQPRI Package Within HQDA. ODCSOPS staffs the BOIP/QQPRI package within HQDA, including ODCSRDA, ODCSLOG, ODCSPER, and OTSG. ODCSPER reviews the proposed O&M decision and provides final decision to DAMO FDR. ODCSOPS consolidates HQDA comments, approves the BOIP, and returns the approved package to HQ TRADOC within sixty days.

16. HQ TRADOC Transmits Approved BOIP and O&M Decision. HQ TRADOC incorporates changes directed by HQDA and recommended by MACOMs. Any MACOM inputs that result in major changes to the BOIP/QQPRI package will be restaffed with HQDA. After incorporation of all changes, HQ TRADOC prepares a transmittal letter with the approved BOIP and O&M decision as enclosures. This package is then forwarded to the MACOMs, AHS, and through EARA to USAMMDA for preliminary planning and information. This approved package must be completed before Milestone II and will be used to support the Milestone II decision.

17. Formal Reviews and Updates of BOIP/QQPRI Prior to Milestone III. At forty-two months and again at thirty-three months prior to the First Unit Equipped Date (FUED), USAMMDA, in coordination with AHS, initiates a formal review of the existent BOIP and QQPRI to determine any required changes to previous submissions that could impact on the principal item, Associated Support Items of Equipment (ASIOE), personnel, and/or training. If changes are necessary, the process just described is repeated, beginning at Block 6. The USAMMDA will prepare an ABOIP and AQQPRI, and submit both as a package thirty-nine months and again thirty months prior to FUED. During the later portion of Full Scale Development, LSAR documentation may be employed as an additional source of MPT estimates.

18. Assign Standard LIN. At the request of USAMMDA, AMC assigns a standard LIN, to replace the Z LIN issued earlier.

19. Enter BOIP/QQPRI Into CTU System. HQ TRADOC enters the BOIP/QQPRI data into the Consolidated TOE Update (CTU) system.

18.5 NONDEVELOPMENT ITEM (NDI) BOIP/QQPRI PROCESSING PROCEDURES

BOIPs and QQPRIs developed in support of NDI will follow an expedited process to facilitate fielding within twenty-four months from acknowledgement of a draft or approved requirements document. Depending on the acquisition strategy, a BOIPFD developed in support of NDI systems will be submitted by USAMMA to HQ TRADOC twelve to thirty-nine months prior to FUED. Although the processing route and actions are similar to a standard BOIP and QQPRI, the schedule of the process will be accelerated as follows:

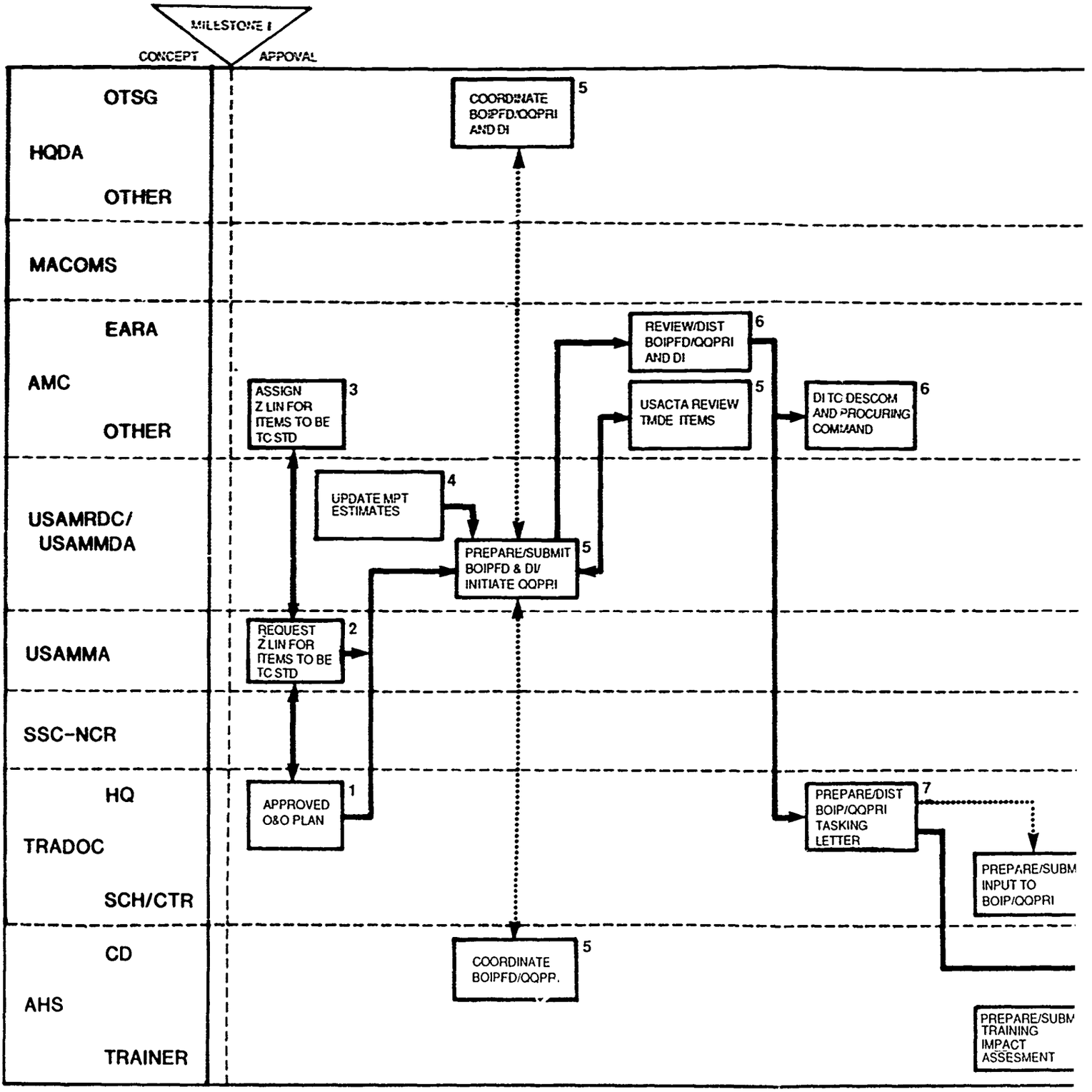
a. USAMMA processing, i.e., completion of BOIPFD, DI, QQPRI entries, and forwarding to EARA through OTSG will not exceed sixty days;

b. EARA processing and forwarding to HQ TRADOC will not exceed ten days;

c. TRADOC processing prior to forwarding to HQDA, including AHS and SSC-NCR efforts, will not exceed 180 days;

18.6 REFERENCES

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983
AR 71-2, BOIP and QQPRI, 1982
AR 71-9, Materiel Requirements, 1986
AR 570-2, Organization and Equipment Authorization Tables: Personnel, 1969
AR 611-101, Commissioned Officer Specialty Classification System, 1985
AR 611-112, Manual of Warrant Officer MOS, 1985
AR 611-201, Enlisted Career Management Fields and MOS, 1985
AR 1000-1, Basic Policies for System Acquisition, 1983
MOU between TRADOC and HSC, Draft 1985
MOA between USAMRDC and USATROSCOM, 1985
MOA between USAMRDC, USAMMA, AHS, and PM TRADE, 1984


MILESTONE I
CONCEPT
APPROVAL
OTSG
HQDA
OTHER
MACOMS
EARA
AMC
OTHER
USAMRDC/
USAMMDA
USAMMA
SSC-NCR
HQ
TRADOC
SCH/CTR
CD
AHS
TRAINER
COORDINATE BOIPFD/OQPRI AND DI
5
REVIEW/DIST BOIPFD/OQPRI AND DI
6
ASSIGN Z LIN FOR ITEMS TO BE TC STD
3
USACTA REVIEW TMDE ITEMS
5
DI TC DESCOM AND PROCURING COMMAND
6
UPDATE MPT ESTIMATES
4
PREPARE/SUBMIT BOIPFD & DI/ INITIATE OQPRI
5
REQUEST Z LIN FOR ITEMS TO BE TC STD
2
APPROVED O&O PLAN
1
PREPARE/DIST BOIP/OQPRI TASKING LETTER
7
PREPARE/SUBM INPUT TO BOIP/OQPRI
COORDINATE BOIPFD/OQPP.
5
PREPARE/SUBM TRAINING IMPACT ASSESMENT

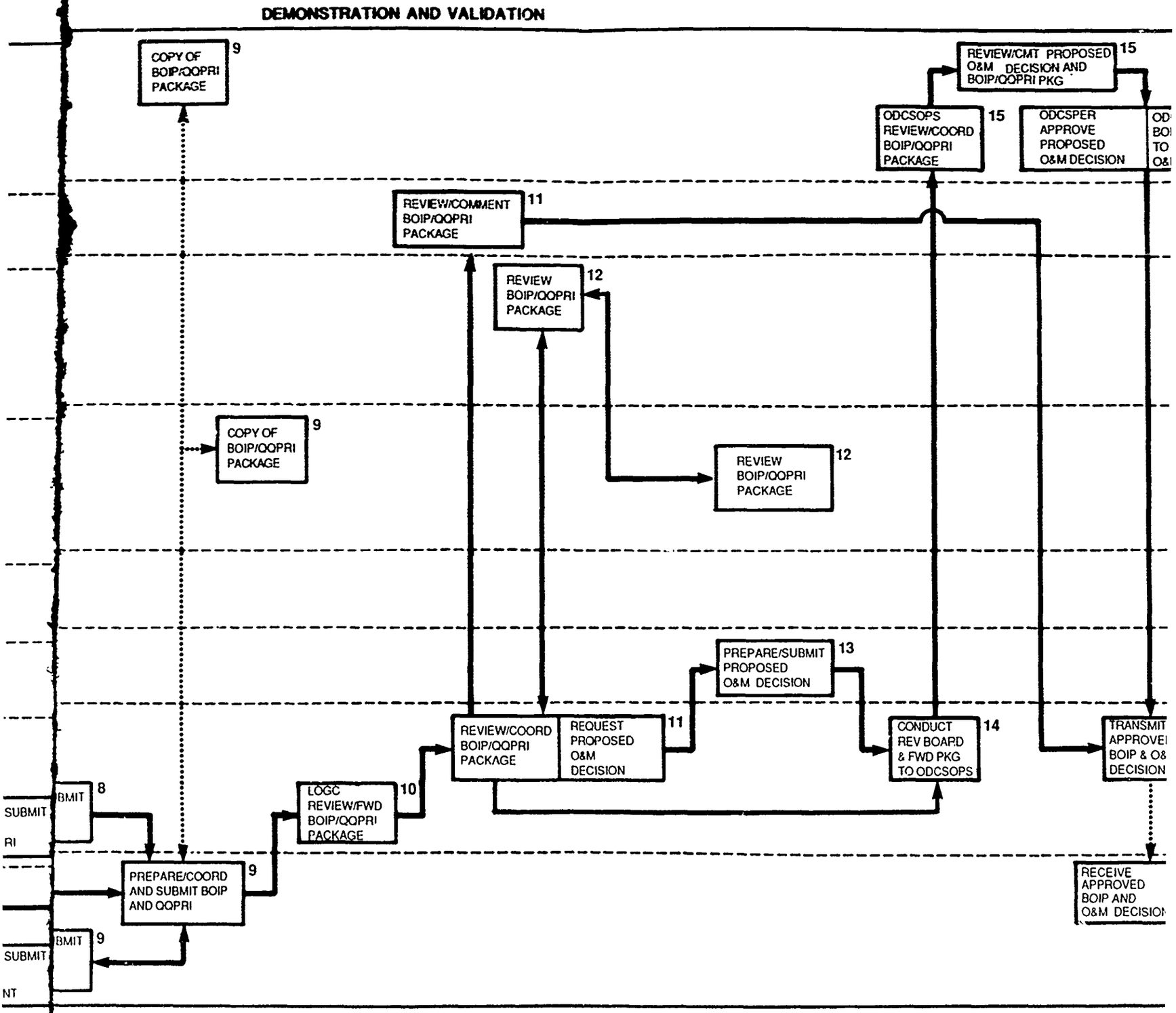


Chart 18-1, THE BOIP/QQPRI PROCESS

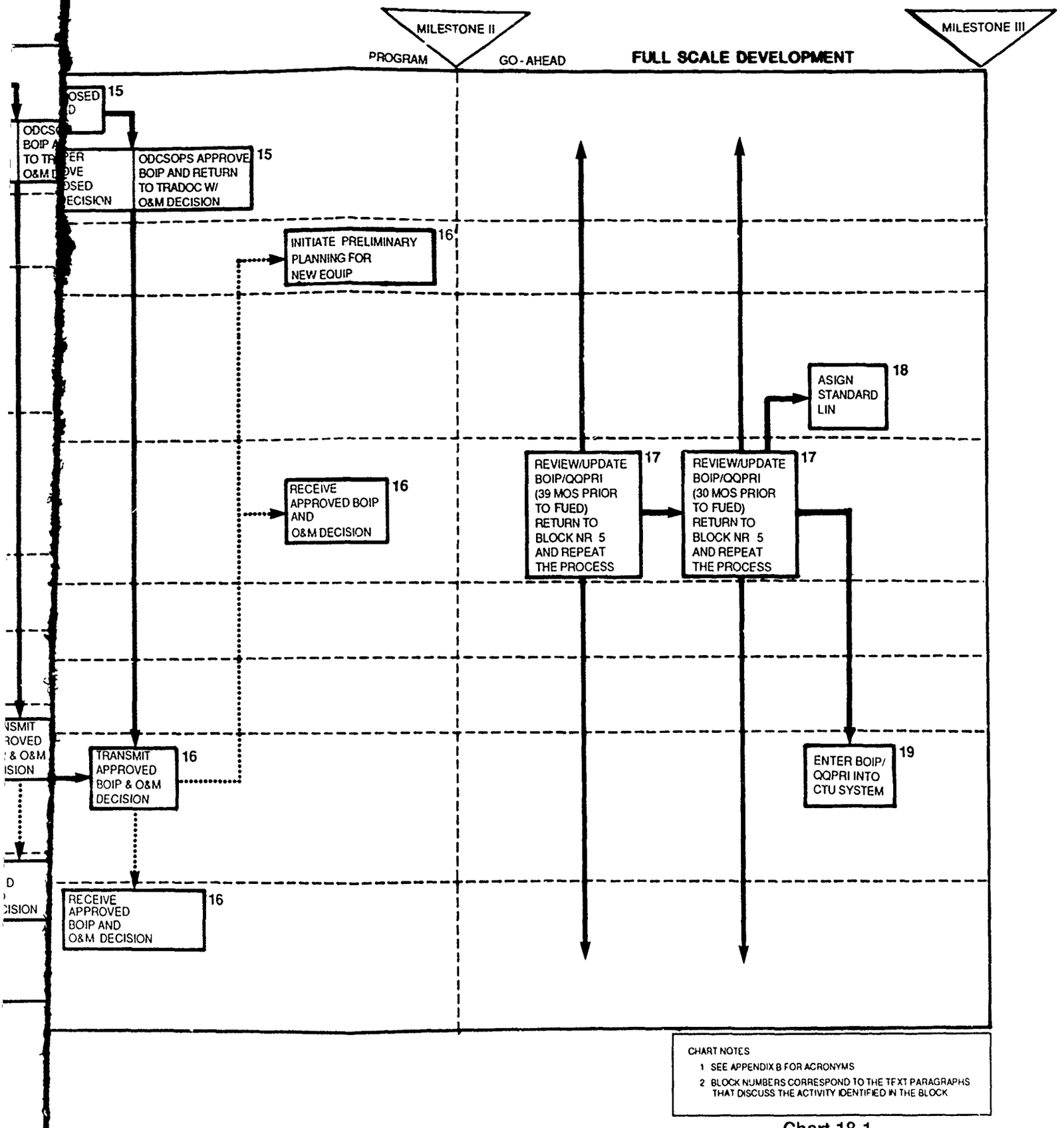

MILESTONE II
PROGRAM
GO - AHEAD
FULL SCALE DEVELOPMENT
MILESTONE III
OSED
D
15
ODCSOPS APPROVE BOIP AND RETURN TO TRADOC W/ O&M DECISION
15
INITIATE PRELIMINARY PLANNING FOR NEW EQUIP
16
ASIGN STANDARD LIN
18
REVIEW/UPDATE BOIP/QQPRI (39 MOS PRIOR TO FUED) RETURN TO BLOCK NR 5 AND REPEAT THE PROCESS
17
REVIEW/UPDATE BOIP/QQPRI (30 MOS PRIOR TO FUED) RETURN TO BLOCK NR 5 AND REPEAT THE PROCESS
17
RECEIVE APPROVED BOIP AND O&M DECISION
16
TRANSMIT APPROVED BOIP & O&M DECISION
16
ENTER BOIP/ QQPRI INTO CTU SYSTEM
19
RECEIVE APPROVED BOIP AND O&M DECISION
16
CHART NOTES
1 SEE APPENDIX B FOR ACRONYMS
2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 18-1

CHAPTER 19

THE CONFIGURATION MANAGEMENT PROCESS

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19.1 PURPOSE

This chapter outlines requirements and procedures to develop, document, and control the configuration of medical materiel.

> **NOTE:**
>
> Portions of the activity descriptions in this chapter are applicable to all medical materiel acquisition programs. However, the total content is primarily representative of extensive nonmajor developmental programs for applied medical systems. A configuration management plan must be developed in all instances that is tailored to the specific needs of the configuration item.

19.2 GENERAL

Configuration Management comprises the procedures to:

- Identify and document functional and physical characteristics of a configuration item;
- Control changes to those characteristics;
- Record and report change processing and implementation status.

19.2.1 Configuration Baselines. Baselines are established for developmental items as follows:

a. Functional Configuration Identification/Functional Baseline. This baseline prescribes for the Configuration Item (CI) (e.g., applied medical system): 1) all necessary functional characteristics; 2) tests required to demonstrate achievement of these characteristics; 3) interface characteristics with associated CIs; 4) lower level CIs, if any, and; 5) design constraints, such as envelope dimensions. This baseline is documented in type A (system) specifications and is normally completed during the Concept Exploration (CE) phase or the early portion of the Demonstration and Validation (D&V) phase.

b. Allocated Configuration Identification/Allocated Baseline. This baseline, when required (generally required for large, complex systems), prescribes for lower level CIs: 1) the functional characteristics that are allocated from those of the higher level CI; 2) tests required to demonstrate achievement of these characteristics; 3) interface characteristics with other, lower level CIs, and; 4) design constraints. The allocated baseline is documented in type B (development) specifications and is normally completed during the D&V phase.

c. Product Configuration Identification/Product Baseline. This baseline prescribes: 1) all necessary physical form, fit, and function characteristics; 2) functional characteristics selected for production acceptance testing; and 3) the production acceptance tests. This baseline provides sufficient design disclosure and detail to meet requirements for procurement, overhaul, etc. It is documented by type C (product), type D (process), and type E (material) specifications and is normally developed during the Full Scale Development (FSD) phase and completed during the Production and Deployment (P&D) phase (after completion of First Article Test).

19.2.2 Changes, Deviations, and Waivers.

a. Changes. Engineering changes to a functional, allocated, or product baseline are proposed as a Class I Engineering Change Proposal (ECP) or a Class II ECP. Class I ECPs are those that modify the functional or allocated baseline or affect the product baseline in areas such as reliability, maintainability, safety, cost, delivered manuals or other ILS resources, etc. Class II ECPs do not fall within the definition of Class I ECPs and may, for example, change only the product baseline documentation to correct errors or change material (refer to MIL-STD-480).

b. Deviations. Prior to manufacture, a contractor may request authority to deviate temporarily from documentation requirements. Deviations are designated as critical, major, or minor. A critical deviation involves a critical departure such as one affecting safety. A major deviation may affect health,

performance, interchangeability of parts, effective use, etc. A minor deviation does not affect any characteristic in the critical or major category. Refer to MIL-STD-480 and MIL-STD-109.

c. Waivers. A contractor may request approval of a waiver to a documentation requirement when, through error, the item was not manufactured in compliance with the documentation requirement. Waivers are classified as critical, major, and minor based upon the same definitions used for deviations.

19.2.3 The Configuration Manager. The USAMMDA Project Manager serves as the Configuration Manager (CM) for each project assigned and, based upon recommendations provided by a Configuration Control Board (CCB), approves or disapproves all:

- Class I ECPs;
- Critical and major requests for deviation, and;
- Critical and major waiver requests.

19.2.4 The Configuration Control Board. The CCB reviews all Class I ECPs, requests for critical and major deviation, and critical and major waiver requests, and recommends approval or disapproval to the Configuration Manager (Project Manager). The CCB chairman is nominated by the Project Manager and is normally the chief of the project Technical Operations Division. The CCB Chairman establishes the CCB by requesting participation from all functional areas that would be impacted by the approval (see paragraph 19.2.8).

19.2.5 The Configuration Change Approval Process. The essential feature of this process is that the recommendation and approval decisions must be based upon full knowledge of the intended benefits (safety, compatibility with associated items, deficiency correction, cost reduction, relief of production stoppage, improvement in operation or logistics); the impact on associated equipment and existing logistic support; and the total cost to implement. Each member of the CCB provides the Chairman of the CCB with an in-depth

evaluation of the benefits and impacts of the proposed Class I ECP, request for critical or major deviation, and critical or major waivers request.

Processing of Class I ECPs, requests for critical and major deviations, and critical and major waiver requests will be in accordance with the following procedures:

- The document will be prepared in-house (USAMMDA or laboratory) or by a contractor. The originator obtains a control number from the configuration management control point (USAMMDA-PMSO) and forwards the completed package to the control point. The contractor forwards the package through Defense Contract Administration Service (DCAS) and the Contracting Officer to the control point.
- The control point forwards copies of the document to all CCB members and, in coordination with the CCB chairman, schedules the CCB.
- All CCB members review the document and prepare their evaluations.
- The CCB chairman convenes the CCB, develops and documents a CCB position, and forwards the CCB recommendation to the Configuration Manager.
- The Configuration Manager approves or disapproves the proposal/request and forwards it to the control point.
- The control point distributes copies to the configuration status data bank, the in-house originator, or through the contracting officer to the contractor, and all CCB members. The contracting officer notifies the contractor through DCAS and, if required, initiates contract modification.
- The originator prepares an implementation plan (production cut-in point, retrofit procedures and schedule, procedures for modifying logistic support resources, etc.) and forwards it to the control point for coordination with CCB members and approval by the Project Manager.

19.2.6 Approval of Class II ECPs and Minor Deviations and Waivers. Approval of these requests is delegated by the Configuration Manager. Class II ECPs may be approved by a USAMMDA plant representative, a DCAS representative at the plant, or the contractor. Minor deviations and waivers may be approved by

a materiel review board established at the contractors plant or within USAMMDA. The Configuration Manager establishes approval authorities for these requests and documents the approval procedure in the Configuration Management Plan.

19.2.7 The Configuration Management Plan. The Configuration Manager prepares the Configuration Management Plan (CMP) in the initial portion of the CE phase. The CMP will:

- Describe the configuration item;
- Describe organizational relationships and responsibilities of each participant and activity;
- List applicable policy directions;
- Describe the baselines to be developed, timeframes for development, and the degree and phase-in of Government control;
- Describe plans for configuration management audits and design reviews;
- Outline the procedures for preparation, processing, and approval of ECPs, requests for deviation, and requests for waiver;
- Outline the procedures and responsibilities for collecting, storing, handling, verifying and presenting configuration status information to management;
- Describe requirements for the preparation of contractor CMPs.

19.2.8 Responsibilities.

• Development Manager	CDR USAMMDA
• Configuration Manager	Project Manager
• CCB Chairperson	Chief USAMMDA-PMO Technical Operations Division (or as designated by the PM)
• Configuration Management Control Point	USAMMDA-PMSO
• Configuration Status Accounting System	USAMMDA-PMSO
• CCB Participants	USAMMDA (PMO, PMSO) USAMRAA, DPSC, AHSCD, AHS-Trainer, Readiness Proponent (USAMMA or AMC major subordinate command), DMSB, Contractor

19.3 CONFIGURATION MANAGEMENT PROCEDURES

Specific Activities.

SEE CHART 19-1

1. Operational and Organizational Plan Approved. The development program is initiated. The developer begins building the functional baseline.

2. Designate CCB Chairperson. The USAMMDA Project Manager designates the CCB Chairperson, normally the Chief of his Technical Operations Division.

3. Establish the Project Configuration Control Board. The Configuration Control Board (CCB) Chairman establishes the CCB (refer to paragraph 19.2.4).

4. Prepare Configuration Management Plan. The CCB Chairman, supported by CCB members as appropriate, prepares the Configuration Management Plan (CMP). The CCB Chairman forwards the plan to the Configuration Manager for approval (refer to paragraph 19.2.7).

5. Develop Functional Configuration Identification (FCI)/Functional Baseline. The developer completes the Functional Configuration Identification (FCI)/functional baseline (refer to paragraph 19.2.1).

6. Perform System Requirements Review. When the FCI/functional baseline is complete, a USAMMDA-PMO project officer or project engineer conducts the System Requirements Review (SRR) (for the Project Manager) in order to ensure that system requirements have been completely and properly identified, and that there is a mutual understanding between the Government and the contractor on system requirements. The contractor modifies the functional baseline as required by the SRR.

7. Investigational Device Exemption/Investigational New Drug. For Class III medical devices, the USAMRDC laboratory or USAMMDA Project Manager submits an Investigational Device Exemption (IDE) application through the USAMRDC Human Use Review Office (HURO) to the Food and Drug Administration (FDA) prior to the start of clinical investigations. For an Investigational New Drug (IND), the USAMRDC laboratory or USAMMDA - PMO submits a "Notice of Claimed Investigational Exemption for a New Drug" through HURO and the OTSG Human Subjects Research Review Board (HSRRB) to the FDA. The notice provides the complete composition of the drug, its source, how it is made, the results of all animal studies, and a plan for testing on humans. (See Chapter 24, Regulatory Interfaces, for additional information).

8. Engineering Change Proposals. The functional baseline is now under configuration control - either contractor or Government. The CMP establishes when Government control will be initiated. When required (by contractor determination or Government request), the contractor prepares an ECP. When Government control is in effect, the contractor will forward the ECP to the Configuration Management Control point (USAMMDA PMSO) for CCB review and recommendation and Configuration Manager approval or disapproval (refer to paragraph 19.2.5).

9. Develop Allocated Configuration Identification/Allocated Baseline. The developer completes the allocated configuration identification/allocated baseline, when required (refer to paragraph 19.2.1).

10. Perform System Design Review. When the ACI/allocated baseline is complete, a USAMMDA-PMO project officer or project engineer conducts the System Design Review (SDR) in order to ensure that the conceptual design of the system satisfies system requirements. The developer modifies the allocated baseline as required. The allocated baselire now comes under configuration control (refer to activity 8).

11. Preliminary Design. Following Milestone II, the developer performs preliminary design (for example, this may include the development of basic design approaches and concepts and software functional flow charts).

12. Perform Preliminary Design Review. A USAMMDA-PMO project officer or project engineer conducts the Preliminary Design Review (PDR) to ensure that the preliminary design satisfies the development specifications (allocated baseline). Approval of the preliminary design authorizes the developer to proceed with detailed design.

13. Detail Design, Develop Product Configuration Identification/Product Baseline. The developer completes detail design and documentation of the product configuration identification/product baseline (refer to paragraph 19.2.1).

14. Perform Critical Design Review. A USAMMDA-PMO project officer or project engineer conducts a Critical Design Review (CDR) when detailed design is essentially complete and before release of the design for production. In large, complex configuration items, CDRs may be conducted incrementally culminating in a system-level CDR to review the completeness of preceding CDRs and ensure adequate interfaces. The CDR process ensures that the detailed design satisfies developmental specifications.

15. Pre-Production Model. The contractor manufactures hard-tooled pre-production models in accordance with the PCI/product baseline.

16. Review Transition Planning and Tracking Group Progress. The Transition Planning and Tracking Group (TPTG) reviews preparation for the transfer of management responsibility to the Readiness Proponent (USAMMA or AMC major subordinate command) approximately ninety days prior to the planned transition date. The CCB chairman reviews and presents the status of actions leading to a complete, validated, and Government-controlled product baseline.

17. Technical Tests, User Tests, Test Reports, and Independent Evaluation Reports. Technical and user tests are performed on a pre-production model(s) and test reports and Independent Evaluation Reports (IERs) are prepared (refer to Chapter 17, The Test and Evaluation Process).

18. Perform Functional Configuration Audit, Formal Qualification Review, Physical Configuration Audit.

a. Functional Configuration Audit. A USAMMDA-PMO project officer or project engineer conducts the Functional Configuration Audit (FCA) to ensure that development of the configuration item has been successfully completed. It is conducted during FSD prior to the Milestone III IPR and compares the "as tested" configuration item (based upon the TRs and IERs prepared in activity 17) to the requirements stated in the functional and allocated baselines.

b. Formal Qualification Review. When required, the configuration manager (USAMMDA Project Manager) reviews results of the FCA by way of a Formal Qualification Review (FQR) to ensure that qualification testing of the integrated system fully demonstrated the performance requirements stated in the functional and allocated baselines.

c. Physical Configuration Audit. A USAMMDA-PMO project engineer conducts the Physical Configuration Audit (PCA) to ensure that the "as built" configuration item conforms to the product configuration identification/product baseline. The term technical data package (TDP) is often used synonymously with product baseline. Thus, this process certifies the adequacy of the TDP for competitive procurement of full rate production prior to its release and transfer to DPSC and use in solicitations. The PCA consists of comparisons of the hardware produced to the TDP and determination that documents employed in the production process (manufacturing instructions, flow charts, layout diagrams, listings, etc.) were accurately derived from the TDP. When all differences have been resolved, the PCA provides reasonable assurance that the TDP is complete; matches the configuration item; is suitable for use in competitive, full rate production; and is appropriate for operational and logistical support purposes.

19. Premarket Approval/New Drug Application. FDA approval of the Premarket Approval (PMA)(for Class III medical devices) and the New Drug Approval (NDA) or license application (for drugs) are required prior to the production (Milestone III) decision. USAMMDA-PMO prepares the appropriate request (refer to Chapter 24 for additional information).

20. Transition to Readiness Proponent. Management responsibility transitions from USAMMDA to the Readiness Proponent (USAMMA or AMC major subordinate command) after the full-rate production decision (Milestone III) and the item is type classified standard. The following configuration management criteria are met prior to transfer:

- The product baseline (TDP) is complete;
- The product baseline (TDP) has been validated in a PCA (activity 18); that is, all issues have been effectively resolved;
- Configuration control of the TDP has transitioned to the Government.

> NOTE:
>
> USAMMDA maintains configuration control of developmental systems throughout their operational life and chairs the project CCB.

21. Transfer TDP. The Readiness Proponent transfers the TDP through DMSB (for standardization) to DPSC.

22. Solicitation/Contract Award. DPSC prepares the solicitation package and awards the full-rate production contract.

23. Production and Distribution. DPSC produces and distributes the product.

24. Configuration Status Accounting. USAMMDA-PMSO is responsible for establishing and maintaining (in house or on contract) configuration status accounting records that identify the initial configuration item, the status of change-proposal and change-implementation actions, and the current as-manufactured or as-modified configuration of all items (serial numbers) manufactured. The configuration status accounting system is prepared in accordance with the approved Configuration Management Plan (paragraph 19.2.7), AR 70-37, and MILSTD-482A.

25. Perform Configuration Item Verification Review. A Configuration Item Verification Review (CIVR) is required when the contractor awarded the full-rate production contract is not the same as the contractor whose pre-production model was validated in the PCA. It is also required for subsequent second sources. A USAMMDA-PMO project engineer conducts the CIVR on an early full-rate production configuration item to ensure that production items match the approved TDP and that acceptance requirements of the TDP are being met. The CIVR is complete when identified discrepancies have been resolved by modifying the production process or by modifying the TDP (by ECP action).

26. AMEDD CCB. Product improvement proposals (PIPs) developed by the USAMMDA-PMO are submitted to the AMEDD CCB for approval and submission to OTSG (refer to Chapter 8, Product Improvement Program). Specific proposed engineering changes derived from approved and funded PIPs, are processed as ECPs to the project CCB. Proposed production changes that are not to be applied to fielded systems (no PIP required) are also processed as ECPs to the project CCB (refer to activity 8 and paragraph 19.2.5).

19.4 TAILORING CONFIGURATION MANAGEMENT

The foregoing materiel in this chapter is based primarily upon developmental applied medical systems. The AMEDD community exercises configuration control of developmental items and product improvements to developmental items. This applies to all items manufactured in accordance with product, process, and materiel specifications (MIL-STD-83490) that are controlled by USAMMDA, and extends from large complex medical systems to wraps and litters.

A Configuration Management Plan is prepared for each applied medical system or family of medical systems. An abbreviated plan is used for drugs, biologicals, protective cosmetics, and simple materiel such as wraps and litters. A Configuration Control Board is established for each developmental project and product other than drugs, biologicals, protective cosmetics, and simple materiel.

Configuration management of NDI and modified NDI is limited to control of the performance specifications listed in solicitations. However, USAMMDA, USAMMA and DPSC employ the solicitation process to select acceptable commercial items whose internal configuration meets logistic supportability and soldier-machine interface (MANPRINT) requirements, as well as performance requirements.

19.5 REFERENCES

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MIL-STD-83490, Specifications, Types and Forms, 1968

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

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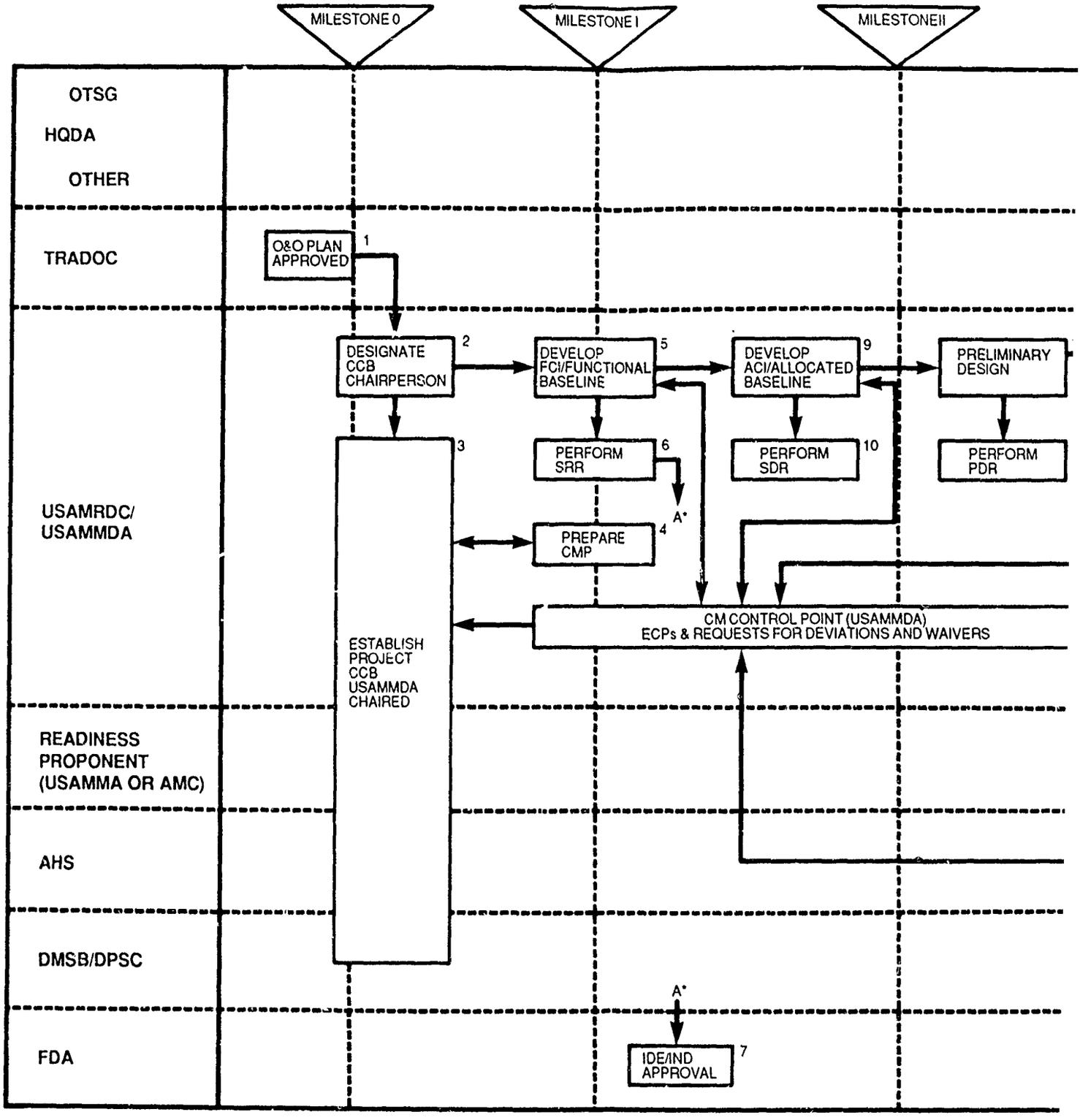
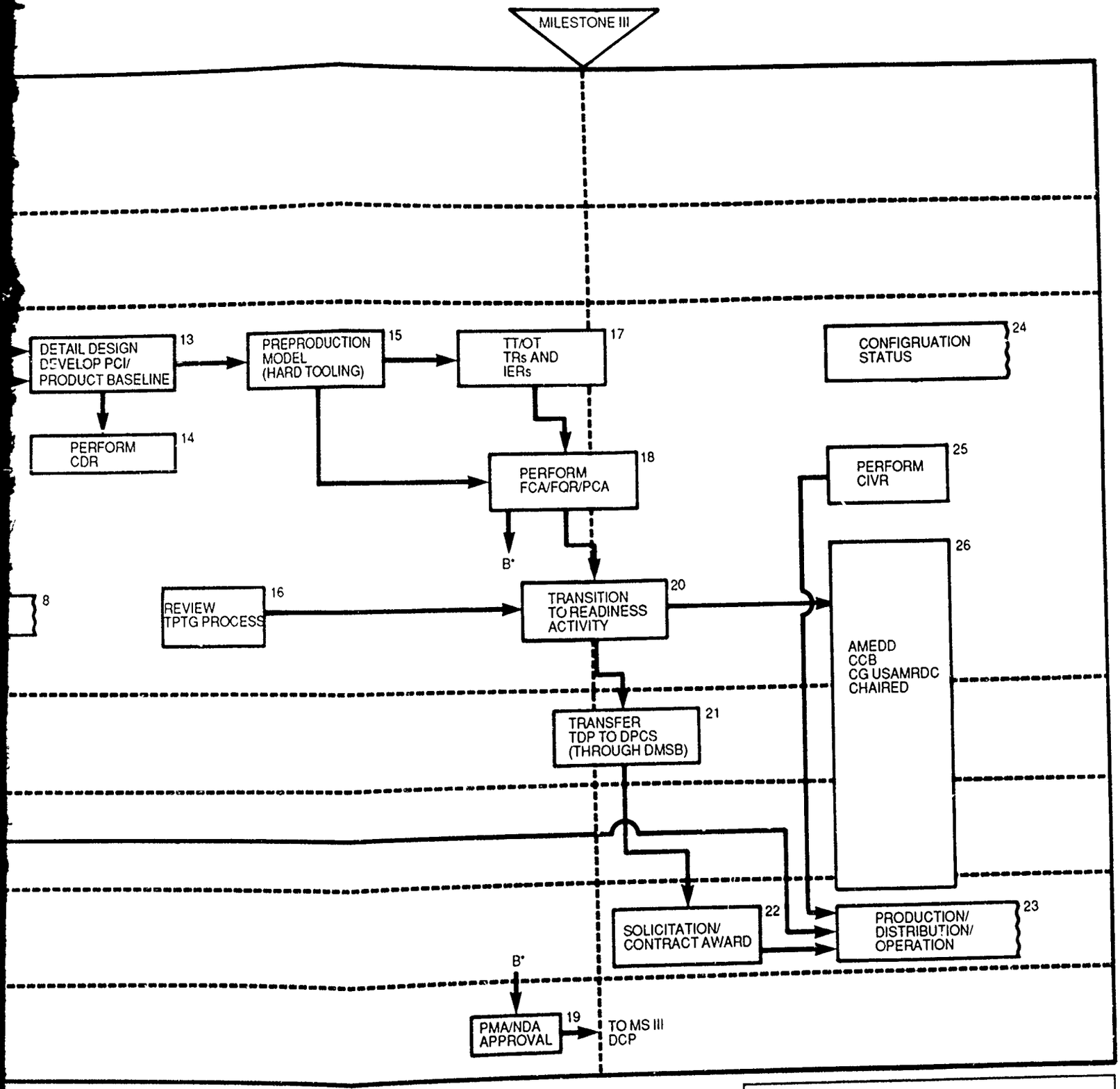


Chart 19-1, THE CONFIG



ATION MANAGEMENT PROCESS

CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 19-1

CHAPTER 20

THE MATERIEL FIELDING AND NEW EQUIPMENT TRAINING PROCESS

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20.1 PURPOSE

This chapter will describe the sequence of actions and events required to plan, manage and execute the satisfactory fielding of new systems. A description is also provided of the sequence of actions and events required to mesh New Equipment Training (NET) and associated Doctrine and Tactics Training (DTT) with the fielding process to successfully achieve the First Unit Equipped Date (FUED). Chart 20-1, at the end of this chapter, summarizes the events, activities, and documents described above. Numbers within the blocks on the flow chart relate to the text paragraph that discusses the activity identified in the block. The chart is organized to present, in their relative order, the primary responsibilities of each participating organization.

20.2 GENERAL

Proper planning, management and execution of Materiel Fielding and New Equipment Training for the initial deployment of new systems is critical in easing the heavy force modernization burden experienced by gaining MACOMs. An excellent materiel fielding operation creates a positive relationship between the materiel fielder and the gaining MACOM(s).

The Materiel Fielding and NET processes are characterized by advance planning, negotiation, and agreement between USAMMDA, USAMMA, AHS, the other acquisition team members and gaining MACOM(s). Important aspects of each of these processes are described below:

Materiel Fielding Process - The process for fielding new systems is designed to achieve an orderly and satisfactory deployment leading to First Unit Equipped (FUE). Materiel fielding is an integral part of Integrated Logistics Support (ILS) planning through the start of the Logistics Support Analysis (LSA) process and program initiation. Beginning with an early recognition of fielding requirements, constraints, and resource impacts, it evolves into

detailed planning, coordination and negotiation during the Full Scale Development (FSD) and Production and Deployment (P&D) phases. While the process is time sequenced it may be expedited to keep pace with accelerated acquisitions and nondevelopment and product improvement programs.

New Equipment Training. - Involves the initial transfer of knowledge from the materiel developer to trainers, users, testers and support personnel during development, production and fielding of new systems. Numbers and types of personnel, units to be trained and NET training strategies are determined on a system-by-system basis during NET planning. NET strategies must be flexible and reactive to the challenges of each new system. NET strategies may involve cadre training, key personnel training, exportable training materials and ideally, the establishment of a viable training base. More extended and costly organizational or total unit training may be called-for on occasion (requires HQDA (DAMO-TR) approval). The NET planning process includes the identification of the need for Doctrine and Tactics Training (DTT). Chapter 18 provides coverage of the Training and Training Devices process.

Doctrine and Tactics Training. - DTT is planned and executed by the training developer based on doctrine and tactics input from the combat developer. It provides guidance to commanders, staffs, and operators on how to employ combat capabilities of systems or organizations. DTT is always identified in the New Equipment Training Plan (NETP). Where DTT is indicated, the DTT package will be distributed through the New Equipment Introductory Briefing Team (NMIBT), New Equipment Training Team (NETT), and the DTT team separately or as an exportable training package.

Materiel Transfer and Displaced Equipment Training. - In the course of fielding new systems it may be necessary to redeploy selected systems and their support elements that have been displaced. The process for managing and executing such redeployments is the Materiel Transfer Process. It is for a system being transferred to a MACOM to which it has not been previously deployed, and which is included in the displaced system section of the Army

Modernization Information Memorandum (AMIM). The Materiel Transfer Process is similar to the Materiel Fielding Process. It involves the development of a comprehensive Materiel Transfer Plan (MTP) and a formal, time sequenced planning and execution process. As a consequence of AMIM selection criteria only a small number of medical materiel are anticipated to be included in the AMIM. The preponderance of displaced medical materiel will be transferred using a Memorandum of Agreement (MOA) between the losing and gaining MACOMs. As a general rule MOAs are used for all transfers between MACOMs that result in an increase of gaining MACOM system density but are not first-time fieldings.

In the Materiel Transfer Process, whether a system is transferred using a Materiel Transfer Plan or an MOA, a requirement may exist for Displaced Equipment Training (DET). Displaced equipment, while not new to the Army, is often viewed as new equipment by the receiving unit and therefore can generate a training requirement. The DET planning process is similar to, but less detailed than, NET planning. Doctrine and Tactics Training (DTT) may be required for DET on the same basis as for NET. Displaced equipment, however, has an established knowledge base and in many cases training is available in institutional and exportable courses. In some circumstances a need may exist to form a Displaced Equipment Training Team (DETT) to be deployed to the gaining unit.

DA Pamphlet 700-XX, Instruction for Materiel Fielding/Transfer, and AR 350-35, Army Modernization Training, provide detailed guidance governing Materiel Transfer of AMIM selected systems and DET planning and execution, respectively.

20.3 CONCEPT EXPLORATION PHASE

SEE CHART 20-1

1. Prepare Individual and Collective Training Plan. - AHS-Trainer prepares the Individual and Collective Training Plan (ICTP) as described in Chapter 16. While the information may be fragmentary at this stage, the plan identifies the potential requirement for NET.

20.4 DEMONSTRATION AND VALIDATION (D&V) PHASE

20.4.1 General Objectives. During this phase the initial planning for NET is completed. NET is conducted for test players in user tests.

20.4.2 Specific Activities.

SEE CHART 20-1

2. Prepare Draft New Equipment Training Plan. Thirty days after the forwarding of the Qualitative and Quantitative Personnel Requirements Information (QQPRI) to the U.S. Army Equipment Authorizations Review Activity (EARA), an initial draft NETP will be prepared. For medical items, the NETP will be prepared by the assigned readiness proponent (generally USAMMA but may also be AMC). Detailed instructions for the preparation of New Equipment Training Plans (DA Form 5316-R) are contained in DA Pam 350-XX. A key point is that the NETP preparation is dependent upon specific input from other than the preparing activity, as follows:

> Section I - Developer Data. The preparing activity completes this section with information received from the materiel developer/provider. This section is used to provide milestone date reporting for specific actions required in the acquisition and training cycle.

Section II - Trainer Data. The preparing activity will enter data in this section based upon information received from AHS-CD and Training. Included in this section are milestone dates for:

- Forwarding of BOIP/QQPRI documentation to HQDA for approval;
- HQDA approval of BOIP/QQPRI documentation;
- Application of requirements to TOE/TDA/CTA documentation;
- Doctrine and Tactics Training (DTT) development;
- Training/Doctrinal Documentation development and distribution;
- Technical and user testing dates;
- Equipment issue to the training base.

Section III - MOS Decision. Information for entry is received from the Office of the Deputy Chief of Staff for Personnel (ODCSPER). Point of contact (U.S. Army Soldier Support Center - National Capital Region).

Section IV - Point of Contact Data. The preparing activity enters the point of contact information as supplied by the designated commands.

Section V - Trainer Information. This section will be used by the trainer (proponent schools) to reflect the various trainer input and all information concerning the MOS shown in the QQPRI for the prime item. This section is not completed on the initial draft NETP.

Section VI - Materiel Developer Input. This section will be completed by the materiel developer to identify the training normally conducted by a contractor during the development and production phase.

Section VII - Materiel Developer. This section will be completed by the preparing activity from information received from the materiel developer/provider. This section will reflect information concerning team deployment for the accomplishment of New Equipment Training.

Section VIII - Gaining Command. This section will be completed from information received from the materiel developer/provider to reflect gaining command information for the following categories:

- Location of training;
- Number of classes;
- Total number of students;
- Student per diem/travel funds which will be paid by the gaining commands;
- Gaining command points of contact.

Section IX - Training. This section will be completed from information received from TRADOC or from AHS, and describes the total training strategy.

Section X - Resources. This section will be completed by the preparing activity from information received from the materiel developer/provider to reflect those resources, both on-hand or to be provided, which are necessary to support the NETP. This section will be used to list those resources which will be provided by the materiel developer/provider or those necessary resources which will have to be supplied by the gaining commands.

Section XI - Narrative Information. This section will be completed with narrative information from the materiel developer/provider for those items identified:

- Nomenclature;
- Brief description, to include purpose, capabilities, and major components;
- Procurement data;
- Maintenance data, to include maintenance concepts, special test equipment required, designated repair depot identification, and contractor support to be rendered;
- MOS data, as reflected in the QQPRI;
- Power requirements;
- Power source identification;
- Air conditioning requirements;
- Historical data.

In addition to those activities identified in paragraph 2-7b of AR 350-35, the initial draft NETP is distributed to USAMMDA, HQDA (OTSG), and AHS for comment and/or input.

> NOTE:
>
> In some cases new systems may not require a NETP. It is necessary to obtain an NETP waiver from HQDA (DAMO-TR) on a case-by-case basis. Justification must be based on the fact that the system has no MOS or training impact. A condensed QQPRI serves the same purpose as having obtained a waiver.

3. Complete New Equipment Training Plan. Within forty-five working days of receipt of the initial draft NETP, the activities listed in paragraph 2-7b of AR 350-35 and those activities identified above will provide data to the preparing activity to complete the NETP.

Within thirty working days of receiving data for the NETP, the preparing activity will update, publish, and distribute the updated draft NETP to those activities listed in paragraph 2-7d of AR 350-35 and USAMMDA, HQDA (OTSG), and AHS-CD and Trainer.

New Equipment Training Plans are formally presented semiannually at HQDA Consolidated Training Support Work Groups. If approved at these meetings, they are published on 31 May or 30 November in the DA Circular 350 Series publications.

4. Update Transportability Report. USAMMDA updates the Transportability Report (TR) prepared prior to Milestone I and submits it to MTMC for preparation of a Transportability Engineering Analysis and a Transportability Approval. (See Chapter 15, The Integrated Logistic Support Process).

5. Conduct NET for User Tests. The new equipment training, as depicted in the NETP covering this phase is arranged for by USAMMDA. Generally, for the D&V phase when the user test is not as extensive as for FSD and when the number of test systems is limited, the NET is arranged for contractually and conducted predominantly by the development contractor.

20.5 FULL SCALE DEVELOPMENT (FSD) PHASE

20.5.1 General Objectives. Intensive Planning for materiel fielding commences early in this phase accompanied by the establishment of a dialogue with the gaining Command(s) that will eventually lead to a Materiel Fielding Agreement in the next phase. The NETP distributed in the D&V phase is updated and inserted in the Consolidated NETP (CNETP) and is reviewed at periodic Training Support Working Group (TSWG) meetings.

20.5.2 Specific Activities.

SEE CHART 20-1

6. Uses AMIM for Fielding Planning. The Army Modernization Information Memorandum is an important document for fielding planning for any system that has been selected for inclusion therein. The AMIM is a planning document, published annually by HQDA (ODCSOPS) to provide MACOMs with key materiel force modernization information. It provides gaining MACOMs with major system distribution plans and cost factors needed to develop resource estimates to support the fielding of new systems. As noted earlier, few medical materiel systems are anticipated to be selected for AMIM. Documentation for materiel fielding is done through the AMIM; when applicable, the materiel fielding advance Letter of Notification (LON), the Mission Support Plan (MSP), and the Materiel Fielding Plan (See AR 700-127).

7. Early Fielding Analysis. USAMMDA conducts an Early Fielding Analysis as part of the Logistics Support Analysis (LSA) process (LSA Task 402) of Integrated Logistics Support (ILS). This task assesses the impact of new system introduction (to include a quantification of the risk level which surrounds system performance and supportability); identifies sources of manpower and personnel skills for the new system; determines the impact of failure to obtain the necessary logistic support resources, and determines combat essential support resource requirements. USAMMDA interfaces with AHS-CD in this analysis.

8. Prepare Letter of Notification and Draft Materiel Fielding Plan.

- Letter of Notification (LON) - The LON is prepared by USAMMDA. It is used to establish the initial fielding contact with the gaining MACOM(s) and initiates the formal negotiation and coordination of the MFP. It is forwarded to gaining MACOM's 780 days prior to FUED. When the materiel fielder determines that a system is not logistically significant to a gaining MACOM(s) and an MFP is not necessary, the LON is used to obtain gaining MACOM concurrence. The draft MFP is attached to the LON.

- Materiel Fielding Plan (MFP) - the initial draft MFP is prepared by USAMMDA, working closely with USAMMA. The MFP serves as the single, stand-alone document which consolidates all materiel fielder and gaining MACOM actions and schedules to successfully

process, deploy and sustain a system. The MFP is required for all first time fieldings of logistically significant new or product improved systems. It may be tailored either as a separate MFP for each gaining MACOM, or as a single MFP covering multiple gaining MACOMs. The MFP will be negotiated, coordinated, and finalized for each gaining MACOM. MFPs must be finalized before a materiel release can be obtained. DA Pamphlet 700-XX provides guidance for completion of the MFP. The entire materiel fielding process is keyed to the First Unit Equipped Date and is rigidly time sequenced to obtain early planning for MFP development, followed by specific time-sequenced actions to execute the actions called for in the MFP. The MFP process is initiated at least 780 days (twenty-six months) prior to FUED or 240 days prior to award of a production contract whichever is earlier. The procedures and schedules in processing, negotiating and executing the MFP are traced in the paragraphs that follow.

NOTE:

Draft MFP is also staffed for input and coordination with National Guard Bureau (NGB), AHS - CD and Trainer, and USAMMA. Instead of individual staffing it will be useful to work with the Integrated Logistics Support Management Team (ILSMT) to obtain input and coordination. The draft MFP is also provided to the Defense Personnel Support Center for information in that agencies role as the future procurement activity.

9. Provide POC/Comments on Milestones. The gaining MACOM(s) replies to the LON, provides point of contact and comments on the proposed milestones. Action occurs at least 730 days prior to FUED.

10. Comment on Draft MFP/Provide Mission Support Plan. The gaining MACOM(s) provide initial MFP comments and furnish the Mission Support Plan (MSP), if required. The requirement for an MSP is left to the discretion of the materiel fielder based on the need to support provisioning, etc. The MSP advises the materiel fielder of the using and support organizations (both Active Component (AC) and Reserve Component (RC), stockage points and preferred method of shipment. It is used by the materiel fielder to compute procurement quantities of support material and by the trainer to quantify AC, NG

and RC training requirements. Appendix D, AR 700-120, Materiel Distribution Management for Major Items, provides guidance for MSP preparation. This action occurs twenty-two months before FUED.

11. Revise MFP. USAMMDA revises the MFP after integrating comments and resolving coordination issues.

12. Updates Transportability Report. USAMMDA submits an updated Transportability Report to MTMC for preparation of a Transportability Engineering Analysis and a Transportability Approval (see Chapter 15).

13. Update NETP and ICTP. USAMMA updates the NETP based on design changes, MFP considerations, Integrated Logistics Support (ILS) activity, etc. The updated NETP is included in the CNETP and provided to AHS-Trainer for updating the ICTP, if required.

14. Review NETP at Training Support Working Group (TSWG). TSWGs are convened as necessary to develop a NETP or to coordinate specific portions of a NETP. The meetings are hosted by USAMMA. As NETPs are updated they are reviewed at the next TSWG meeting.

15. Conduct NET for User Test. The new equipment training, as depicted in the NETP, is arranged for by USAMMDA. Training requirements may involve contractor training, Individual Instructor and Key Personnel Training (IKPT), unit training, exportable training materials, etc., depending on the training strategy and considering the magnitude of user testing required.

20.6 PRODUCTION AND DEPLOYMENT (P&D) PHASE

20.6.1 General Objectives. USAMMA assumes responsibility for all fielding activities subsequent to system transition from USAMMDA. Negotiations relative to materiel fielding are completed with all gaining MACOM(s) within prescribed time constraints. The activities planned for in the MFP/MSL and

the NETP are executed. The materiel fielding and new equipment training activities mesh; the materiel arrives at the planned-for locations; NET and DTT are provided, and FUE is achieved. Lessons-learned data is fed back to USAMMA to improve future fielding, materiel shipment continues on schedule, and finally IOC is achieved.

20.6.2 Specific Activities.

SEE CHART 20-1

16. Transition to USAMMA. Following Milestone III, program management responsibilities transfer from USAMMDA to USAMMA.

17. Award Production Contract. The production contract is awarded by the Defense Personnel Support Center (DPSC).

18. Update MFP. USAMMDA updates the MFP to include:

- The gaining MACOM(s) proposed MSP;
- The gaining MACOM(s) and coordinating activities staffing comments on the initial draft MFP;
- Updated system information;
- Draft MFA.

19. Negotiate MFP/MFA. The updated MFP is provided to the gaining MACOM(s) and USAMMA by USAMMDA to begin the MFP/MFA negotiation process. USAMMA takes the lead in negotiating the final MFP/MFA with the gaining MACOM(s). The negotiations for more complex systems will normally involve

face-to-face discussions. For less complex systems, negotiations by correspondence and by telephone communication may suffice. The new draft MFP/MFA is also distributed for input and coordination as described in Activity 8, above. This action occurs seventeen months before FUED.

20. Revise MFP. USAMMA revises the draft MFP to reflect gaining MACOM(s) and staffing comments, resolves conflicts and prepares for MFA negotiations.

21. Prepare MFP and MFA for Signature. Upon completion of negotiations, USAMMA forwards a copy of the final draft MFP including the signed MFA to the gaining MACOM(s) for signature. This action occurs ten months prior to FUED.

22. MACOM Sign MFA and Return it With MFP. The gaining MACOM(s) signs the Materiel Fielding Agreement (MFA) and returns it with the final MSP (if required), to USAMMA. This action occurs eight months before FUED.

23. Distribute Final MFP/MFA. USAMMA distributes the final MFP/MFA to DA activities, the gaining MACOMs, OTSG and the other activities that participated in the input and coordination process. This action occurs seven months before FUED.

24. Deploy New Materiel Introductory Briefing Team. The NETP may plan for the use of a New Materiel Introductory Briefing Team (NMIBT) to introduce the new system to gaining MACOM commanders, staff officers and users. Programming, budgeting, coordinating, selecting team members, and scheduling is the responsibility of USAMMA. The briefing of staff officers and users provides detailed administrative and technical information to include:

- Update of MFP, expanding on the information as required;
- Limitations of the equipment which affect operation, mobility, transportability, human factors, etc.;
- Illustrations to portray the equipment;

- Summary of advantages over existing equipment;
- Deployment plans, receiving organization, delivery dates;
- Problems and their impacts, e.g., non-availability of support, proposed substitutes, etc.;
- TOE/TDA relative to personnel quantity and equipment;
- Training courses available in service schools, to include course titles, MOS to be trained, dates training is available and whether a NETT is scheduled to provide training in the command;
- Repair parts availability;
- Required requisitioning procedures;
- Data on technical and supply publications, to include publication numbers, titles, dates available and problems;
- If equipment is available, a demonstration should be arranged.

The inclusion of AHS-Trainer personnel to discuss doctrine and tactics is desirable if this would aid the introductory process. The NMIBT action should occur approximately six months before FUED.

25. Coordinate Release Date. USAMMA and the gaining MACOMs negotiate a precise system release date. This action is preceded by a joint supportability determination and system call forward. This action occurs two months before FUED.

26. Initiate Requisitions for PLL/ASL, ASIOE. The gaining MACOM(s) initiates requisitions for PLL/ASL/ASIOE, in accordance with ARs 700-120 and 725-50, Requisitioning Receipt and Issue System. It is DA policy for fielding new support systems that these standard Army requisitioning procedures be used. This action normally occurs five months before FUED.

27. Request Materiel Release. A procedure is in place for USAMMA to obtain approval from OTSG before production systems can be released to the field. In its request for release approval USAMMA demonstrates that the system is suitable for release in terms of safety and health hazards, human

factors engineering, manpower, personnel and training (MANPRINT), performance, reliability, quality, environmental factors, and availability, and adequacy of logistics support (in accordance with AR 700-127) including test, measurement and diagnostic equipment. There are three types of materiel releases:

- Full Release - Issued when the system has been tested, evaluated and meets all established requirements (specified in DA Circular 700-85-1) and the gaining MACOM(s) concur with the final MFP.
- Conditional Release - Issued when one or more of the criteria have not been met, an urgent need exists for the system and interim means of support, controls, or hardware modifications are available and acceptable to the gaining MACOM(s). Conditional releases are restricted to specific quality, location and application.
- Training Release - Request to release system for training only. System released may include prototypes or test items, items manufactured under conditions other than normal production, and systems which are incomplete and/or have not met one or more of the conditions for full release. Critical items which limit the use of the system must be identified to the gaining MACOM.

28. Approve Materiel Release. After an assessment of the details of the request for Materiel Release, OTSG advises USAMMA of its approval or disapproval. For disapprovals USAMMA must comply with OTSG requirements to obtain full release and again request approval. In the interim, materiel cannot be issued to the field.

29. Advise of Materiel Release Approval. USAMMA advises DPSC of the Materiel Release approval which initiates the process for initial shipment to FUE organizations.

30. Coordinate on Shipping Dates Based on DA Master Priority List. USAMMA and DPSC work together in assuring that shipping dates coincide with DA Master Priority List (DAMPL) priorities.

31. Deploy Equipment to FUE. DPSC ships systems from contractor's plant to FUE organizations.

32. New Equipment Received from DPSC. The systems arrive at FUE location(s), USAMMA assures proper meshing of dates for systems receipt and deployment of NETT/DTTT.

33. Deploy Materiel Fielding Team and New Equipment Training Team. For more complex system fielding, and if planned for in the MFP/NETP, USAMMA may assemble a Materiel Fielding Team (MFT) to support fielding operations. The composition is dictated by system complexity, logistic impact of the fielded system on the gaining MACOM(s), and the specific initial training needed to bridge the gap between gaining MACOM(s) existing capabilities with respect to operation, maintenance, doctrine and tactics, and the capabilities required for the new systems. The MFT could encompass the following categories of experienced personnel:

- Team leader (USAMMA or AHS - Trainer);
- Design/development personnel (USAMMDA/design contractor);
- Quality assurance personnel (USAMMDA/design contractor);
- Logistics technicians (USAMMA);
- Production contractor personnel;
- User representatives (AHS).

If stipulated in the MFP, Doctrine and Tactics Training may be provided by the AHS-Trainer concurrent with, or after, the NET has been accomplished. The NETP may require that DTT be provided as an exportable training package or through a Doctrine and Tactics Training Team (DTTT). The ideal situation is to have a training base established and producing enough graduates to support the Army, thereby negating any NET or DTT requirement.

34. NETT Conducts Training. The training prescribed in the NETP is conducted by the NETT (includes DTT).

35. First Unit Equipped Achieved. Upon receipt of the scheduled systems and its agreed upon support element by the designated initial operational capability unit, and after the training specified in the NETP has been accomplished, FUE is achieved.

36. Fielding Lessons Learned. Since the materiel fielding process is success oriented, the success and problems of each fielding operation will be documented and serve as the information base for developing improvements for future materiel fieldings. For each fielding of a significant system, USAMMA will prepare a narrative lessons learned summary. This summary will be based on lessons learned obtained from the NETT/DTT and the fielding assessment provided by the gaining MACOM(s).

37. Initial Operational Capability Achieved.

38. Continue Feedback/Lessons Learned. With the achievement of IOC, the normal Army procedures are used to report system deficiencies. At times a Sample Data Collection (SDC) program maybe required (AR 750-37).

20.7 NONDEVELOPMENT ITEMS (NDI), MODIFIED NONDEVELOPMENT ITEMS (MOD NDI), AND PRODUCT IMPROVEMENTS (PI)

20.7.1 Nondevelopment Items. The procedures and schedule for preparing, negotiating and coordinating MFPs for NDI must be compatible with the specific acquisition schedule. The time frames for MFP events for development items generally apply to NDI as well. However, when the time between production contract award and FUED is less than eighteen months, the NDI fielding schedule must be adjusted accordingly. A general description of the materiel fielding process follows:

a. USAMMA, as the materiel fielder, provides a LON and initial draft MFP to each gaining command identified in the latest AMIM distribution plan or other recognized source of distribution data such as the BOIP. The action should occur as soon as the "NDI buy decision" is made, but not later than three months prior to production contract award.

b. The final MFP should be distributed by USAMMA no later than seven months before FUED. If the "final" MFP is not completed by this time, the MFA will contain a time-phased schedule for MFP addendums to complete it. The final MFP addendum should be distributed as early as possible, but in no case later than one month before FUED. The coordination process for the LON/MFP is as described for development items.

c. The initial support package of ASL/PLL items is identified by gaining MACOMs and included in the MFP.

d. The process for NET, including DTT, for new NDI is essentially the same as for development items. NET planning considerations will take into account the special challenges of NDI acquisition. For less complex NDI considerable tailoring of the NETP is expected.

20.7.2 Modified Nondevelopment Items. The materiel fielding process for MOD-NDI is identical to that for a development item except that the time schedule is adjusted to reflect the production contract award date. See Chapter 7 for depiction of MFP events in relation to MOD-NDI life cycle events. The process for NET, including DTT, for MOD-NDI is essentially the same as for development items.

20.7.3 Product Improvement Programs. The materiel fielding process for PI is essentially identical to that for a development item, except that the time schedule will be adjusted to reflect the production contract award date and FUED. Normally, the events will occur closer to that described for developmental items than for NDI. NET, including DTT, for PI is essentially the same as for the development items as shown in Chapter 8.

20.8 REFERENCES

AR 350-35, Army Modernization Training, 1984
AR 700-120, Materiel Distribution Management for Major Items, 1980
AR-700-127, Integrated Logistics Support, 1983

AR 725-50, Requisitioning, Receipt, and Issue System, 1981

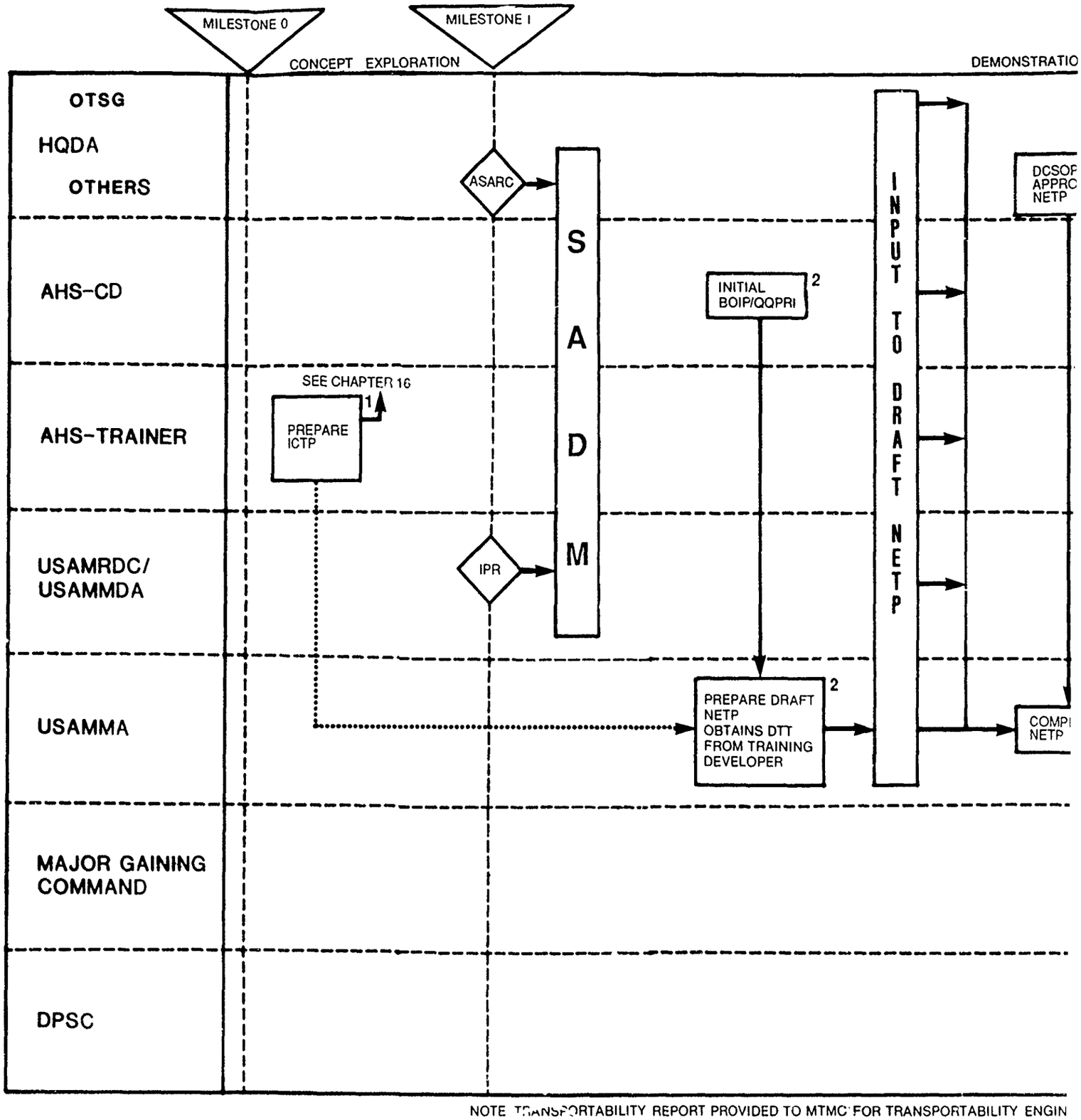
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DA Circular 700-85-1, Materiel Release for Issue, 1985

TRADOC Regulation 351-9, Individual and Collective Training for Developing System, 1982

DARCOM (AMC) Regulation 700-34, Release of Materiel for Issue, 1985



NOTE TRANSPORTABILITY REPORT PROVIDED TO MTMC FOR TRANSPORTABILITY ENGIN

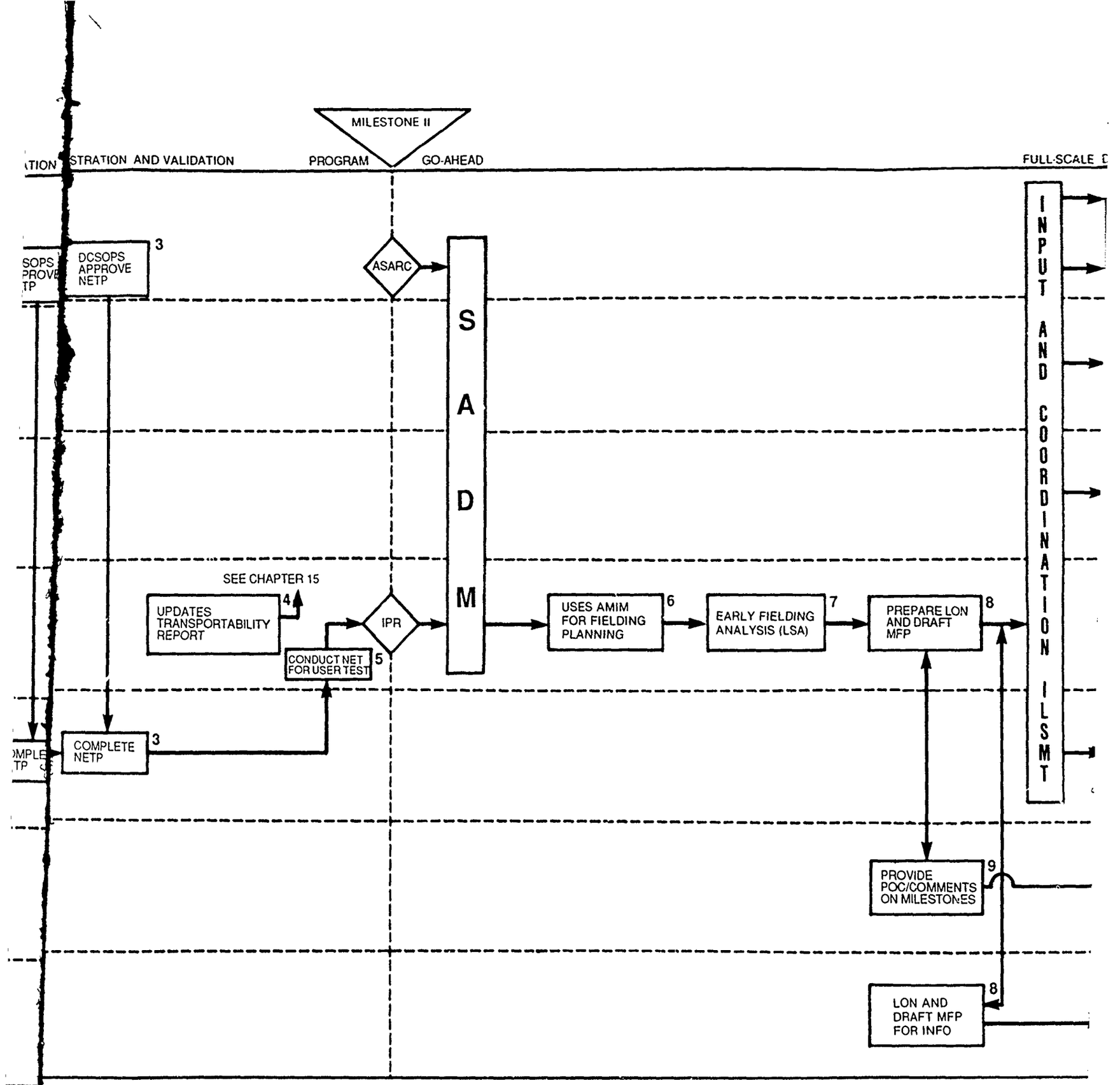


Chart 20-1, THE MATERIEL FIELDING PRO

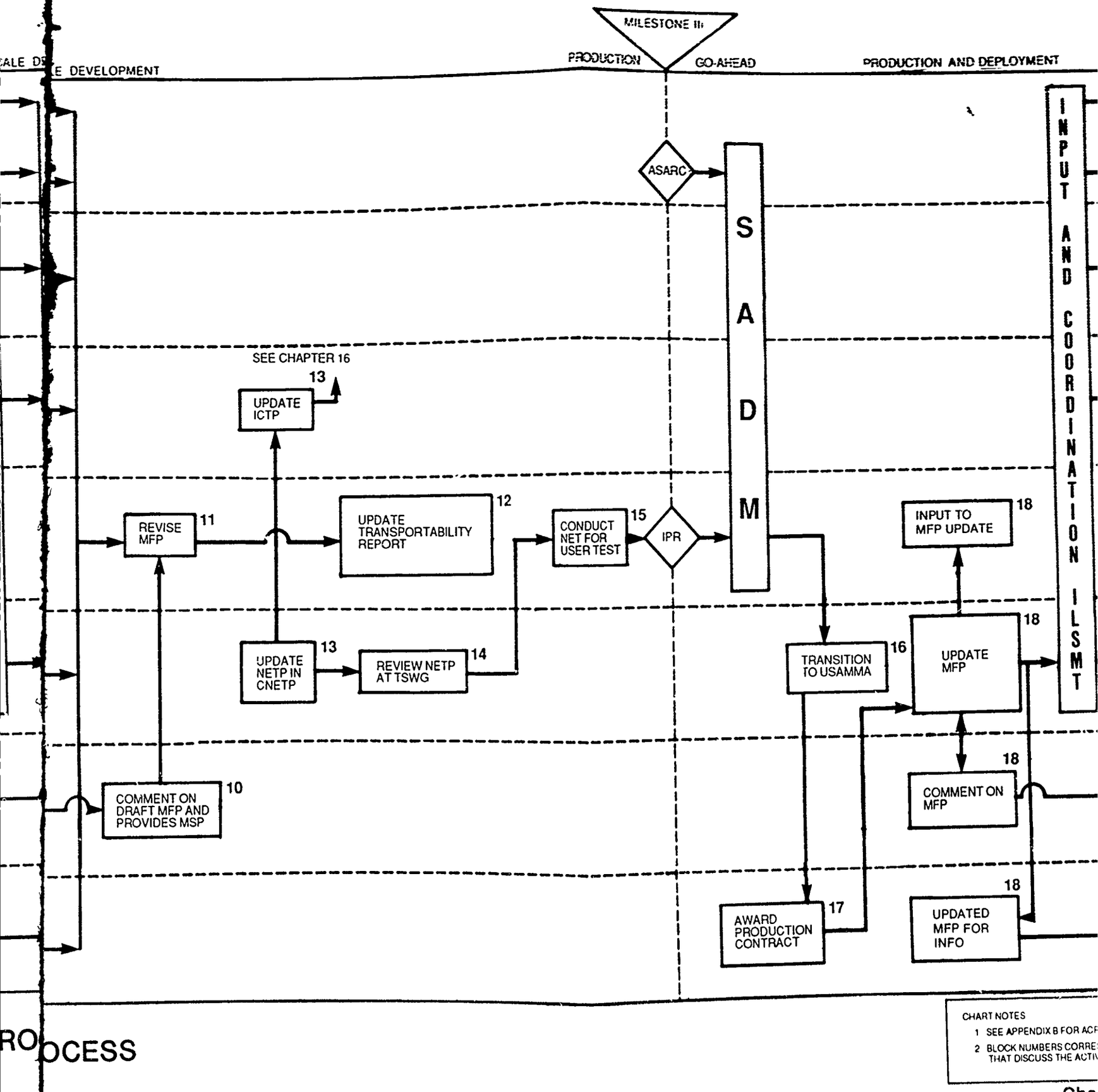


CHART NOTES

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2 BLOCK NUMBERS CORRE
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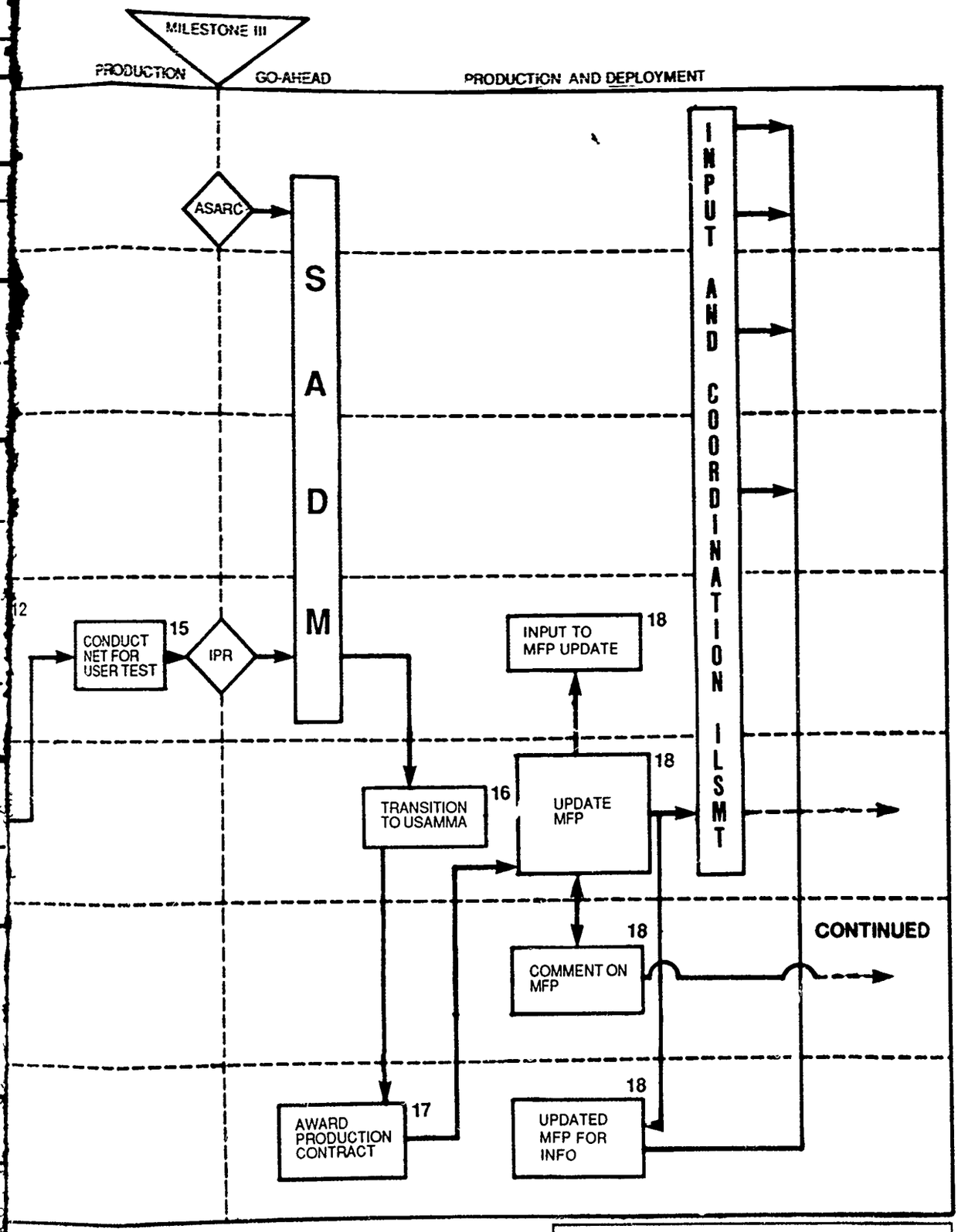
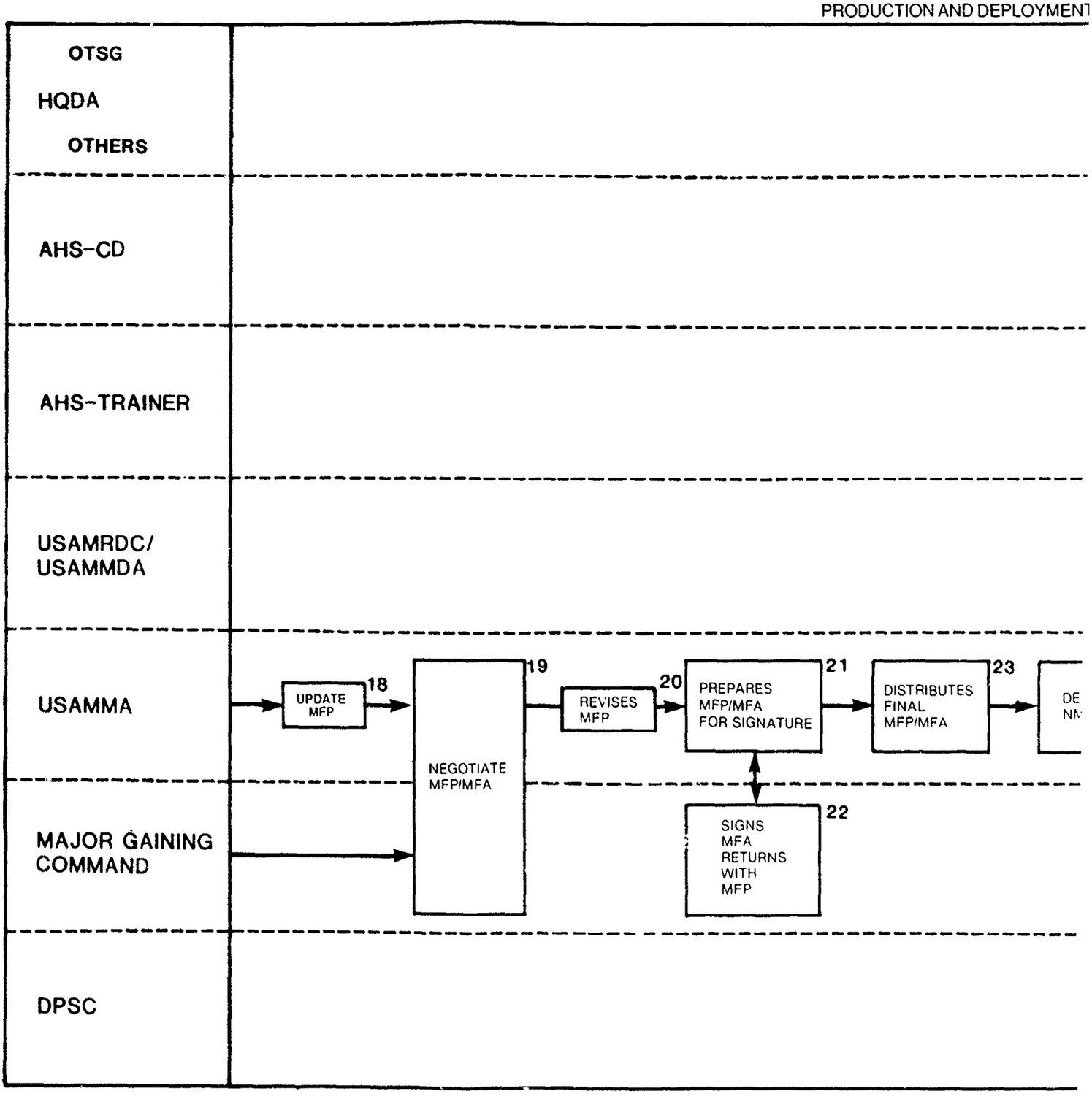


CHART NOTES

1 SEE APPENDIX B FOR ACRONYMS

2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 20-1


OTSG
HQDA
OTHERS
AHS-CD
AHS-TRAINER
USAMRDC/
USAMMDA
USAMMA
MAJOR GAINING
COMMAND
DPSC
UPDATE
MFP
18
NEGOTIATE
MFP/MFA
19
REVISES
MFP
20
PREPARES
MFP/MFA
FOR SIGNATURE
21
DISTRIBUTES
FINAL
MFP/MFA
23
SIGNS
MFA
RETURNS
WITH
MFP
22

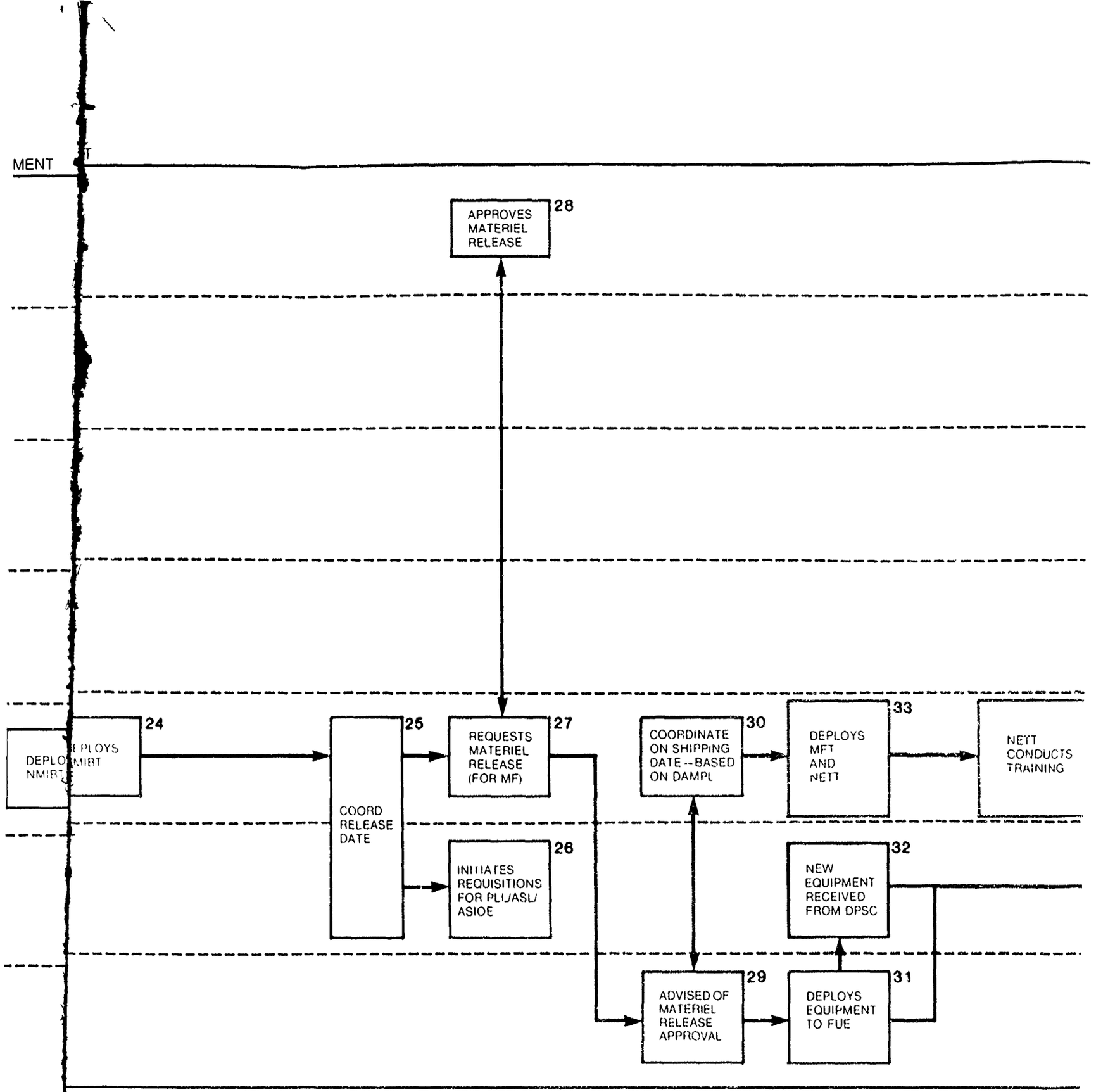
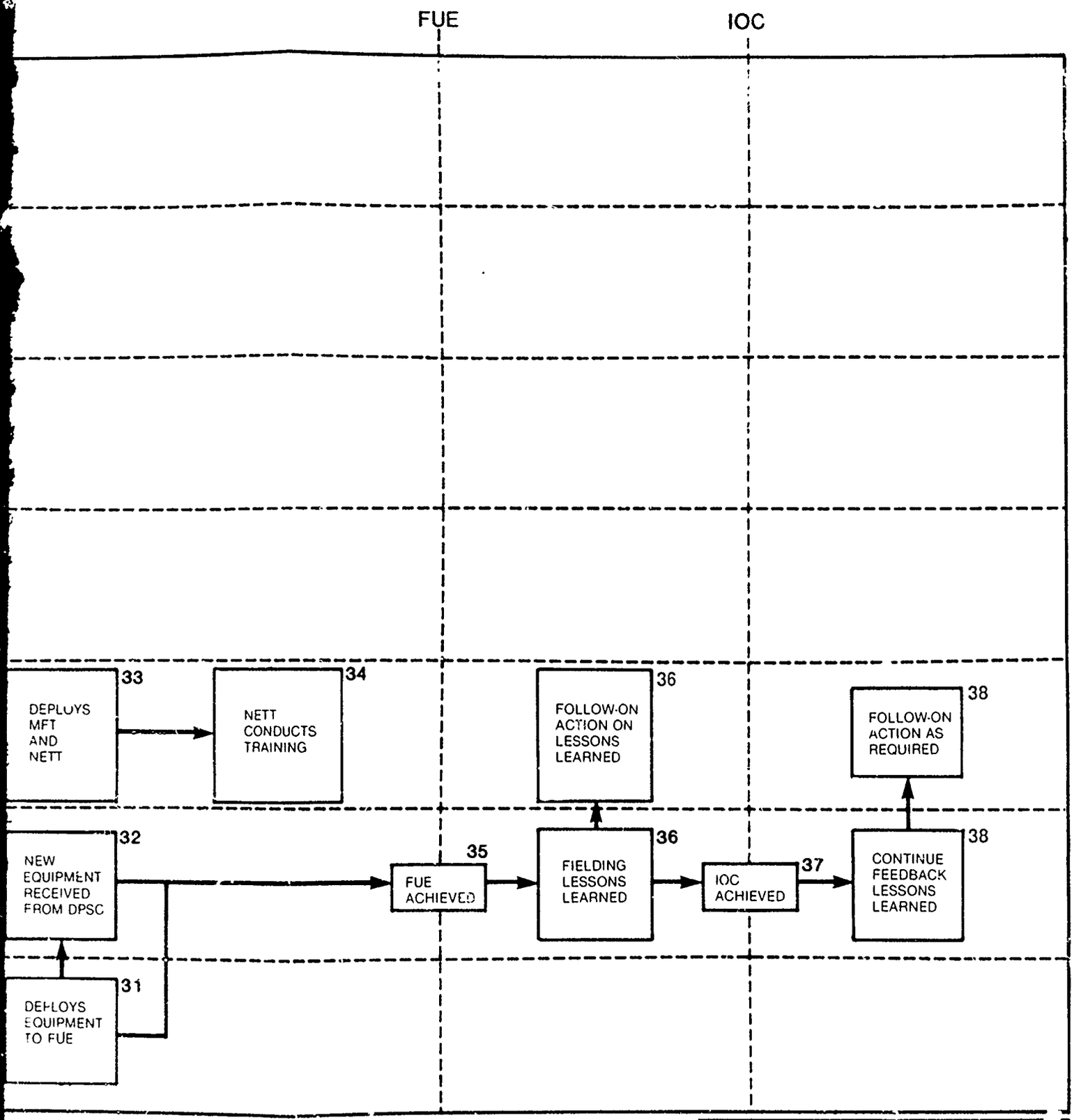


Chart 20-1, THE MATERIEL FIELDING PROCESS (Continued)

2



(Continued)

CHART NOTES

1 SEE APPENDIX B FOR ACRONYMS

2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 20-1C

CHAPTER 21

MEDICAL SETS, KITS, AND OUTFITS

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21.1 PURPOSE

This chapter is limited to the discussion of Medical Sets, Kits, and Outfits (SKO) managed by the AMEDD for medical field treatment facilities. It describes the procedures and responsibilities for developing new SKOs and for the review and update of existing SKOs. Charts 21-1 and 21-2 show the events sequence and document flow by time and by agency/office responsible for accomplishing the event or processing the document for developing and reviewing SKOs respectively.

21.2 GENERAL

21.2.1 Definitions.

a. Medical SKOs. For the purposes of this chapter, the term Medical SKO includes medical, dental, and veterinary sets. Medical SKOs also encompass the terms Medical Equipment Set (MES) and Unit Assemblage (UA) which may be referenced in other publications. There are two levels of management for SKOs: Defense Medical Standardization Board (DMSB) managed and Service managed. Those managed by DMSB are for multi-Service use and sometimes are referred to as "minor" SKOs. Service-managed SKOs for the Army are designed by AHS-CD. These are sometimes referred to as "major" SKOs. USAMMA coordinates requirements with DPSC and performs logistic staff management action as directed by OTSG. Each medical SKO is assigned a separate NSN.

> NOTE:
>
> Medical SKOs consist of medical and nonmedical items including expendable (consumable) supplies, durables, and nonexpendable equipment costing less than $3000. SKO components that have been determined by OTSG to be readiness significant or cost more $3000 are type classified, have separate TOE Line Item Numbers (LIN), and are identified as Associated Support Items of Equipment (ASIOE) in the SKO component list.

b. Nonmedical Equipment Sets. These are managed by other commands (such as the Army Materiel Command). These sets could include some medical components. There are also nonmedical sets managed by other commands and used by medical personnel (i.e., maintenance sets). Both types of sets must be coordinated with AHS-CD and USAMMA during their development.

c. New Medical SKO Development. The requirements for new SKOs are identified during the Concepts Based Requirements System process as a materiel solution to an identified deficiency. AHS-CD is responsible for the development of prototype sets. USAMMA, as mission assignee, is responsible for maintaining the SKO logistical data base, acquiring SKOs, and ensuring their logistic supportability when fielded. The development of new medical SKOs must incorporate the BOIP/QQPRI process (see Chapter 18).

d. Medical SKO Reviews. Existing SKOs are updated either on a cyclic schedule or as required by concepts, doctrine, or materiel changes. AHS-CD is responsible for reviewing and revising SKOs as required. USAMMA is responsible for updating the SKO logistical data base, ensuring the logistics supportability of SKOs, acquiring new components, managing the fielding requirements, and coordinating training, testing, and non-AMEDD component requirements.

e. Patient Workload Model. This model, managed by AHS-CD, utilizes an extensive medical data base, and generates an expected patient workload for a given scenario based on incidence of disease, injury and wounds. The data base consists of treatment profiles, which vary by level of care, for over 300 types of wounds, fractures, burns, acute medical conditions and routine sick calls.

f. Medical SKO Data Base. This is a data base managed by AHS-CD for developing prototype SKOs and accumulating changes to existing SKOs. Existing SKOs are transferred annually to the USAMMA logistical data base. Prototype assemblages are transferred as required to USAMMA.

g. Medical SKO Logistical Data Base File. This is a logistical data base that is managed by USAMMA. New SKOs and changes to existing SKOs are published annually in a supply bulletin based on data from the logistical data base.

h. Medical SKO Decision Document. This document is prepared by AHS-CD and USAMMA for the SKO development and review program. It contains LSA data, readiness significance information, testing and training requirements/assessments, draft BOIP, and cost information.

i. Readiness Significant. The criteria for the identification and listing of Readiness Significant (reportable) items is an OTSG responsibility. Readiness Significant items require separate LIN and type classification. They are ASIOE for the SKO with which they will be used.

j. High Cost Items. SKO components costing more than $3000 each as determined by USAMMA from the GSA Schedule or by USAMMDA from vendors, require a separate LIN and type classification and are ASIOE for the SKO with which they will be used.

21.2.2 Responsibilities.

a. OTSG

- Validate requirements documents for SKOs
- Review component lists for SKOs
- Reconcile IPR issues
- Assist AHS in the procurement of panel members

b. AHS-CD

- Maintain review schedule for SKOs
- Conduct reviews of existing SKOs
- Maintain the patient workload model
- Maintain the medical SKO data base

- Prepare requirements documents
- Prepare and staff BOIP/QQPRI for SKOs
- Prepare operational mode summary/mission profile
- Prepare decision documents for SKOs
- Conduct SKO in-process reviews (Director, Combat Developments chairs)
- Conduct SKO development and/or review panels and AHWGs as required
- Staff prototype SKOs
- Prepare IEPs and IERs

c. AHS-Trainer

- Prepare training assessment for SKOs
- Provide training assistance for testing and fielding as appropriate
- Prepare ICTP

d. AHS-Tester

- Build prototype SKOs
- Prepare SKO test assessment/input to IEP
- Prepare test plan
- Conduct tests of SKOs
- Prepare test report

e. USAMMA

- Provide UAs, MCNs, NSNs, and LINs as required
- Maintain the SKO logistics data base
- Act as the AMEDD POC with DMSB and DPSC
- Provide SKO status changes to AHS-CD as they occur
- Authenticate requirements documents for SI)s (w/AHS)

- Prepare and staff BOIPFD/QQPRI
- Conduct LSA
- Participate as a voting member at SKO reviews
- Obtain type classification
- Manage acquisition of SKOs
- Field SKOs
- Publish SKO changes in Supply Bulletin

f. HSC

- Provide panel members for the SKO development and review panel
- Review component listings for prototype SKOs

g. MACOMs

- Provide panel members for SKO development and review panels
- Review component listings for prototype SKOs
- Participate in the materiel fielding process

h. DMSB/DPSC

- Standardize SKOs and components as applicable (DMSB)
- Provide NSNs to USAMMA (DPSC)
- Contract for SKOs for AMEDD (DPSC)

21.3 DEVELOPMENT OF NEW MEDICAL SKOs

21.3.1 General Objectives. The process for development of new SKOs differs only slightly from the process for developing a single item of equipment. Each requires that the medical materiel acquisition process procedures be followed. If one or more components of the set are readiness significant or high cost items, they must be processed individually because they require a specific Standard LIN and Type Classification, and must also meet the medical materiel acquisition process requirements.

The X-Ray set is an example of a set that contains components that must have a separate TOE LIN. The set has a LIN and the X-Ray equipment also has a LIN. The X-Ray equipment is listed in the set as an Associated Item of Equipment (ASIOE) of the set. The prototype set is developed by AHS-CD, acquired by USAMMA, and components such as the X-Ray are developed as a separate program by USAMMDA.

21.3.2 Specific Activities.

SEE CHART 21-1

1. New SKO Requirement Identified. Requirements for new SKOs are derived from the Concept Based Requirements System process. A new SKO may be determined to be the solution to a change in mission, organization, medical treatment concept or technological advances. The new equipment development process may also be applied to an existing SKO that requires a major change as defined in paragraph 21.4.1.

2. Prepare Operational Mode Summary/Mission Profile. AHS-CD is responsible for the preparation of the Operational Mode Summary/Mission Profile (OMS/MP). It provides a description of the medical care (tasks) required, the expected patient workload by medical condition or injury, dispositions of patients, etc. For example, the frequency of actions such as patients requiring evacuation and routine sick call patients for a Battalion Aid Station SKO would be described. The mission profile also specifies the days of supply required, such as five days for a heavy division and two days for a light division. The mission profile guides both the SKO Development Panel in the set development effort, and reviewers, during the staffing of the proposed SKO components listing.

3. DCD Review. AHS-CD establishes an Ad Hoc Working Group to determine if a new SKO development requirement exists or if the deficiency can be satisfied by revising an existing SKO. The AHWG's recommendations are provided to the Director, Combat Development (DCD) for a decision.

- If the decision is to revise an existing SKO - proceed to Section 21.4, Activity 1.
- If the decision is to develop a new SKO - proceed to Activity 4, below.

4. Prepare Operational and Organizational Plan. AHS-CD is responsible for the preparation of the Operational and Organizational (O&O) Plan for the new SKO. The O&O Plan is discussed in Chapter 3.

5. Established SKO Development Panel. AHS-CD is responsible for the establishment of the SKO Development Panel. The panel consists of designated Subject Matter Experts (SME) provided with the assistance of OTSG and major commands, and may also include personnel from other Services. SMEs are personnel who have had extensive "hands on" experience in the using units and with the equipment found in the SKO. The number of panel members and the panel composition is tailored to the nature of the new SKO. AHS-CD briefs the panel members and provides guidance such as the OMS/MP and the O&O Plan prepared in Activities 2 and 4.

6. Prepare SKO Requirements Document. AHS-CD is responsible, in coordination with USAMMA, for the preparation of the Required Operational Capability (ROC). This document is initiated upon receipt of the approved O&O Plan from HQ TRADOC.

- If any of the SKO components have been identified as "high cost" or "readiness significant" items, individual O&O Plans and ROCs must be prepared. Non-medical items require coordination with the AMC proponent command. Medical items are coordinated with USAMRDC, or USAMMA as required.

- If a joint program is initiated, a Joint Services Operational Requirement (JSOR) is prepared in lieu of the ROC.

7. Initiate BOIPFD/QQPRI. USAMMA initiates the BOIPFD/QQPRI (refer to Chapter 18).

8. Develop Proposed SKO Listing. The panel members develop a proposed SKO listing that, in their professional judgement, meets the requirements and conditions of the O&O Plan. The anticipated patient workload is reviewed and each patient type is evaluated to determine the supplies and equipment used by medical personnel to provide the required care. After identifying the items required, the recommended quantities are determined by AHS-CD based on usage factors, the projected workload, and the prescribed days of supply.

9. Provide Unit Assemblage Number and SKO Component Management Control Number. AHS-CD is responsible for the development of a prototype set. The Unit Assemblage number, requested from USAMMA, provides an AHS-CD data base prototype number on which the SKO components can be loaded and maintained until the new SKO receives an NSN. AHS-CD also requests that USAMMA provide a Management Control Number (MCN) for each component not already having an NSN assigned. If a catalog search for items meeting the component requirements does not produce an alternative, USAMMA provides the MCN and obtains a Z-LIN.

10. Staff Proposed SKO Listing. AHS-CD is responsible for the staffing of the component listing for the prototype SKO. The OMS/MP, prepared in Activity 2, is revised to include the results of the panel's actions and is provided to each reviewing organization for guidance. MACOMs, AHS, using units and staffs are given ninety to one hundred twenty days to provide their comments directly to AHS-CD without staffing through channels.

11. Reconvene SKO Development Panel. The SKO Development Panel is reconvened by AHS-CD. The goal is to have the same personnel attend the second panel meeting which requires the assistance of the OTSG and the use of the Surgeon General's channels throughout the Army. The panel revises, if appropriate, their proposed SKO listing based on the comments received from the users.

12. Revise Medical SKO Data Base. AHS-CD revises the Medical SKO prototype data base and determines if any of the prototype SKO components are readiness significant or high cost items. AHS-CD transfers the file to the medical SKO logistical data base at USAMMA.

13. Initiate Logistics Support Analysis. USAMMA is responsible for conducting a Logistics Support Analysis (LSA) tailored to the SKO component list. Of particular interest are weight and cube measurements; logistical packaging; power requirements; transportability; facilities, storage, and security requirements. LSA problems with the proposed listing are communicated to AHS-CD for coordination and reconciliation.

14. In-Process Review. AHS-CD, with input from the AHS-Trainer, AHS-Tester and USAMMA, prepares the SKO Decision Document and convenes an In-Process Review (IPR) (AHS and USAMMA) to review the SKO and make recommendations to the Commandant, AHS, who is the decision authority. The decision authority issues a System Acquisition Decision Memorandum (SADM) that directs and guides the development effort.

- If the development of the SKO is approved - go on to Activity 14;
- If the development of the SKO is disapproved - reconvene the IPR and act on the decision authority's question/guidance.

15. Update SKO Data Base. AHS-CD updates the file in the medical SKO data base and transmits the file to USAMMA. USAMMA provides AHS-CD with the SKO MCN.

16. Initiate DMSB Standardization Action/Obtain NSN. For new SKO and components without an NSN, USAMMA forwards the component requirements with necessary new item information and requests that the Defense Medical Standardization Board (DMSB) initiate standardization actions, investigate Joint Service applications, and obtain an NSN for each component not already having one.

a. Initiate Standardization Action. DMSB reviews the requirement, completes the standardization actions, investigates Joint Service applications, and forwards the documentation to the Defense Personnel Support Center (DPSC).

b. Provide NSN. DPSC is responsible for the preparation of the solicitation package, and contract and procurement of the item. DPSC provides the official NSN to USAMMA through the DMSB.

c. Provide NSN to AHS-CD. USAMMA provides the NSN to AHS-CD.

17. Initiate Materiel Fielding Plan. USAMMA initiates the Materiel Fielding Plan (MFP) for the SKO. See Chapter 20, The Materiel Fielding Process.

18. Prepare Independent Evaluation Plan. AHS-CD is responsible for the preparation and continuous updating of the Independent Evaluation Plan (IEP) for user tests of the SKO. USAMMA, AHS-Trainer, and AHS-Tester provide input to AHS-CD.

19. Build Prototype SKO. AHS-CD requests AHS-Tester to assemble the prototype SKO as part of the user test program. The SKO components are either purchased directly by AHS, or USAMMA is requested to purchase them for AHS.

20. Conduct User Test and Prepare Test Report. Based on the IEP, the O&O Plan, and the requirements document, and using one or more prototype SKOs, AHS-Tester prepares a test plan and conducts the user tests. User tests such as Concept Evaluation Programs (CEP) or Force Development Test and Experimentation (FDTE) are conducted with HSC (AHS) controlled funds, personnel, and or equipment to provide information on the operational feasibility of the SKO.

Typical issues addressed in SKO testing include:

- Electrical item power requirements;
- Self contained or vehicle power source availability during evacuation;
- Special tools and equipment requirements met;
- Functional suitability of the set;
- Health and/or safety hazards;
- Adequacy of training materials;
- Sufficiency of consumable supplies for specified number of days;
- Ease of loading and unloading;
- Transportability of set by using unit;
- Functional packaging (arrangement and loading) of the set.

At the completion of the test, AHS-Tester prepares a test report which is provided to AHS-CD.

21. Independent Evaluation Report. AHS-CD, as the independent evaluator of user tests, prepares the Independent Evaluation Report (IER).

22. IPR Preparations. AHS-CD and USAMMA schedule an IPR to make type classification and production recommendations.

- AHS-CD revises, as necessary, the prototype SKO;
- USAMMA updates the LSA;
- USAMMA requests the assignment of an NSN for the SKO from DPSC, as early as possible, but not later than ninety days before the IPR;
- USAMMA requests a Standard LIN for the SKO from AMC upon receipt of the type classification approval;
- AHS-CD and USAMMA jointly prepare the SKO Decision Document, with AHS-Trainer and AHS-Tester input.

23. In-Process Review. An in-process review, chaired by AHS-CD with USAMMA as a voting member, is convened to review the SKO development and recommend its type classification and production. The IPR must also consider the status of medical and nonmedical ASIOE that are necessary for the operation of the SKO. The recommendations of the IPR are forwarded to the decision authority - the Commandant, AHS. The decision authority issues a SADM that directs and guides the fielding effort.

- If the decision authority does not approve TC and production and deployment of the SKO, the program participants return to the appropriate Activity and take the necessary actions to obtain TC and production approval.
- If the decision authority approves TC and production and deployment -- go to Activity 23.

24. Validate Type Classification. Prior to the program's transition to fielding, the item's type classification approval must be validated by OTSG.

25. Fielding. USAMMA is responsible for providing the first issue of a set to the using units from centrally controlled funds. Units order and fund replacement items. USAMMA orders the components and chests by NSN. The Defense Personnel Support Center (DPSC), as the purchasing agent, contracts for the set components and directs shipment to the DLA depots. The depots supply the requesting units on demand.

26. SKO Reviews. Every five years, or as otherwise required, AHS-CD is responsible for reviewing existing SKOs. See Section 21.4 for SKO review responsibilities and procedures.

27. Implement Training. The AHS-Trainer implements the training in conjunction with the fielding of the SKO. Training requirements are presented in the Individual and Collective Training and the Materiel Fielding Plans.

21.4 MEDICAL SKO REVIEWS

21.4.1 General Objectives. Medical SKO Reviews may be either Scheduled or Unscheduled. The Scheduled Review (cyclic) is based on a five year cycle that starts from the Initial Operational Capability. Unscheduled Reviews (out of cycle) are triggered by any one of the following actions:

- User comments/problems with the set or one or more of its components;
- OTSG and HSC consultant comments/recommendations;
- Doctrine changes;
- Organization (TOE) changes;
- FDA or other Government agency recalls or safety defect notices;
- DMSB notice that a component has been replaced or terminated.

Review requirements for SKOs vary. If the change is considered to be routine, it will be provided to USAMMA during the next scheduled annual transfer of data. However, in the event that the change will significantly enhance the unit mission, overcome significant known problems, or if the component to be replaced is defective or considered dangerous, that information will be provided to USAMMA immediately.

Changes recommended by the SKO review are considered major if they have a significant impact on the unit mission/capability or the collective/individual training requirements. Major changes are processed under new SKO development procedures beginning with Event 8 (See Section 21.3). A SKO change may be considered a major one if:

- There is a 10% or more weight increase;
- There is a 10% or more increase in cube (ft^3);
- There is a plus up in personnel -- qualitative and/or quantitative;

- There is a plus up in resident training requirements;
- There is a plus up in maintenance requirements;
- There is an additional safety requirement;
- There are changes in nonmedical ASIOE, or;
- There is a change in the type of funding.

21.4.2 Specific Activities.

SEE CHART 21-2

1. SKO Review Required. An existing SKO is either scheduled for its five year cycle review or requires an out of cycle review for one or more of the reasons described in paragraph 21.4.1.

2. Update Operational Mode Summary/Mission Profile. AHS-CD updates an operational mode summary/mission profile statement outlining the mission and characteristics of the SKO. It provides a description of the medical care (tasks) required and the expected patient workload based on selected scenarios and the mission of the set. The tasks and workloads are developed/revised from the AHS-CD developed patient/workload model. As appropriate, AHS-CD also provides information on comments received since the last review of the SKO.

3. Establish SKO Review Panel or Ad Hoc Working Group.

a. Medical SKO Review Panel. AHS-CD advises OTSG and HSC on which Subject Matter Experts (SME) are needed to conduct the review. OTSG and HSC identify available SMEs and assist AHS-CD in obtaining their release to participate in the panel review. The panel members are drawn from Army-wide resources including OCONUS units, FORSCOM, HSC, and OTSG. The Surgeon General channels are used to obtain non-AMEDD command personnel. The panel should contain sufficient personnel with the area specialties, military occupational specialties, and experience required to make decisions at the panel meeting. The SKO Review Panel conducts the formal (cyclic) reviews.

b. Ad Hoc Working Group (AHWG). The procedures described in (a) above are also used to establish an AHWG. However, the group is tailored to the type of action required. Very routine changes can be processed within AHS-CD (e.g., packaging changes which require only an NSN change) and coordinated with USAMMA.

4. Panel/AHWG Develops SKO Listing. AHS-CD convenes and chairs the meeting. The required changes are incorporated into a new SKO listing that is agreed to during the meeting. The panel/AHWG recommended SKO listing is reviewed by USAMMA.

5. DCD Decision Review. The decision to process a SKO change as Major or Minor is the responsibility of the Director, Combat Developments. The indicators in paragraph 21.4.1c are used to support the decision. The supporting documentation will identify high cost components (over $3000) and the readiness significant components as identified by OTSG Directive. The decision is reviewed by the Commandant, AHS. Minor changes are processed as described in Activities 6 through 12 of this section. Major changes are processed under New SKO Development procedures beginning with Activity 8 (see Section 21.3).

High cost components or readiness significant components require separate acquisition programs, LINs and type classification. AHS-CD prepares the O&O Plan for each of these items.

6. Obtain Component MCNs. Following the AHS decision review, AHS-CD requests a Management Control Number (MCN) from USAMMA for each new component, whether it is a readiness significant or high cost component. The MCN is a place holder that provides visibility until the National Stock Number (NSN) is obtained. USAMMA conducts a catalog survey in order to determine that no alternative items are available and issues the MCNs.

7. USAMMA Conduct LSA. USAMMA conducts a tailored Logistics Support Analysis (LSA). The LSA is directed toward weight and cube measurements, logistical packaging, power requirements, transportability, facilities, storage

requirements, and security requirements. Logistics problems with the proposed listing are quickly provided by letter to AHS-CD for reconciliation before continuing the process.

8. Request DMSB Standardization Action. For components without an NSN, USAMMA forwards the component requirements and requests that the Defense Medical Standardization Board initiate standardization actions and obtain an NSN. DMSB reviews the requirement, establishes the essential characteristics, completes the standardization actions, and forwards the documentation to the Defense Personnel Support Center (DPSC).

9. Provide NSN. DPSC provides the NSN to USAMMA. DPSC is also responsible for the preparation of the solicitation package, awarding the contract, and procuring the item.

10. SKO Decision Document. AHS-CD and USAMMA, with inputs from AHS-Trainer, AHS-Tester (if there were any tests conducted or planned) and USAMMDA, prepare the SKO Decision Document for review/approval by the Director, Combat Developments (DCD).

11. DCD Review. Approval of the SKO changes by the DCD constitutes authority to USAMMA to publish the change to the field in the supply bulletin.

12. Published Change to Field. USAMMA is responsible for the maintenance of the logistical data base. SKO component changes are published annually to be filed in the SB 8-75 Series supply bulletins which provide such information as NSN, nomenclature, unit of issue, quantity authorized and unit cost.

13. Contract for SKO. DPSC is responsible for the preparation of the solicitation package, contract and procurement of the item.

21.5 REFERENCES

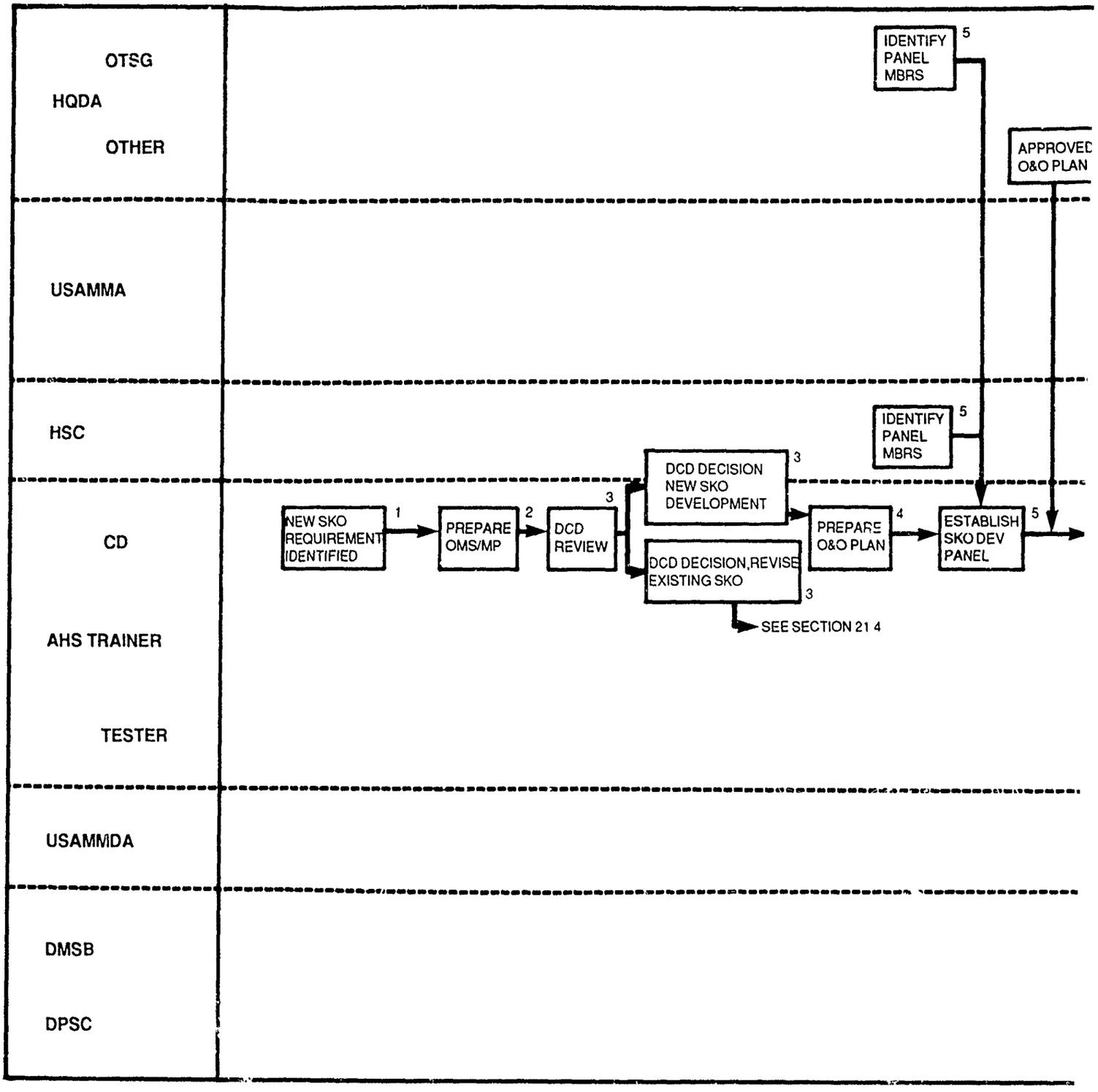
AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

AR 40-61, Medical Logistics Policies and Procedures, 1981

AR 70-1, System Acquisition Policy and Procedures, 1986

AR 71-3, User Testing, 1986

TM 8-6500-001-10, Operator Manual, Preventative Maintenance Checks and Services for Reportable Medical Items, due in 1986.


OTSG
HQDA
OTHER
USAMMA
HSC
CD
AHS TRAINER
TESTER
USAMMDA
DMSB
DPSC
IDENTIFY PANEL MBRS
5
APPROVED O&O PLAN
IDENTIFY PANEL MBRS
5
DCD DECISION NEW SKO DEVELOPMENT
3
NEW SKO REQUIREMENT IDENTIFIED
1
PREPARE OMS/MP
2
DCD REVIEW
3
PREPARE O&O PLAN
4
ESTABLISH SKO DEV PANEL
5
DCD DECISION,REVISE EXISTING SKO
3
SEE SECTION 21 4

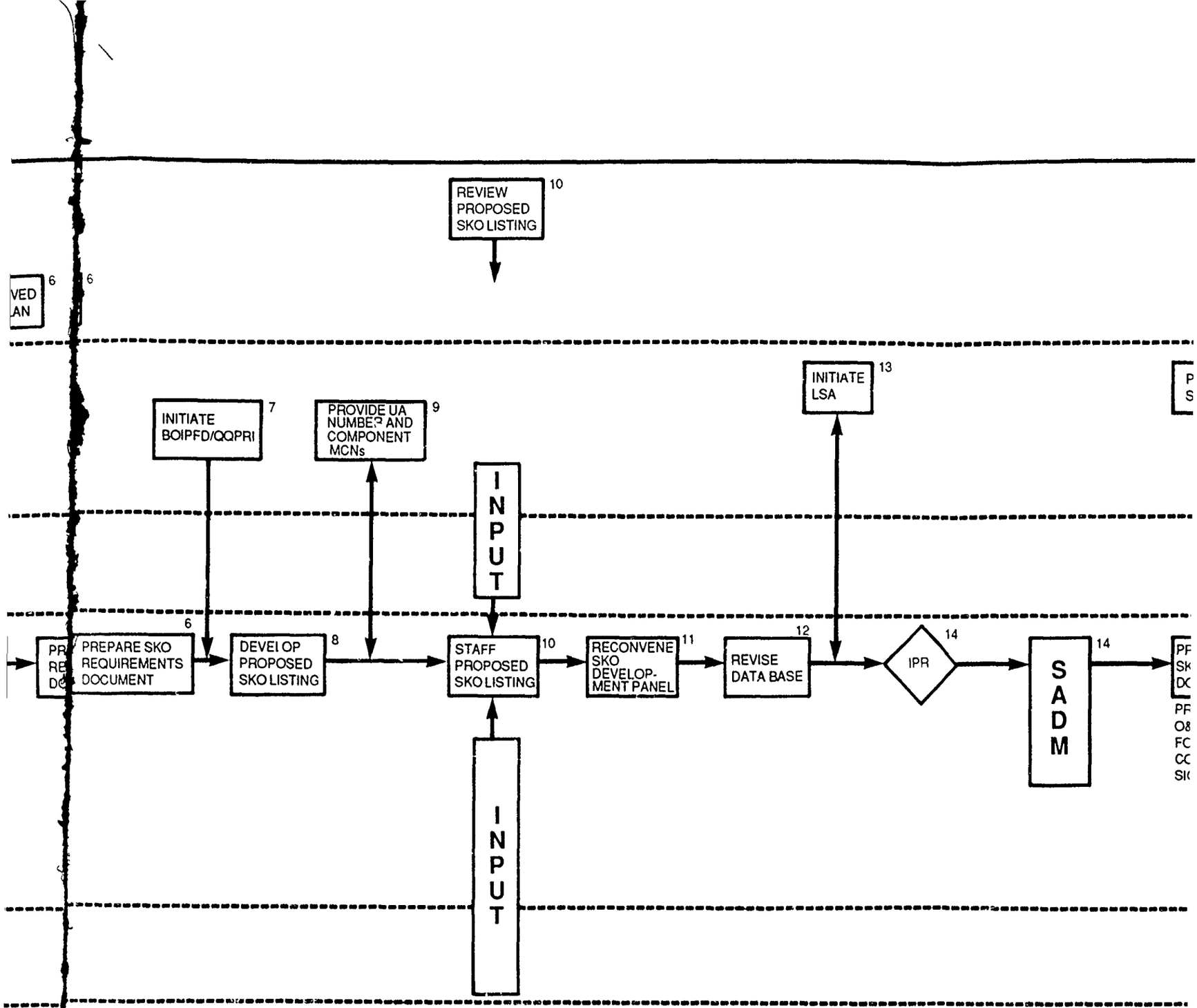
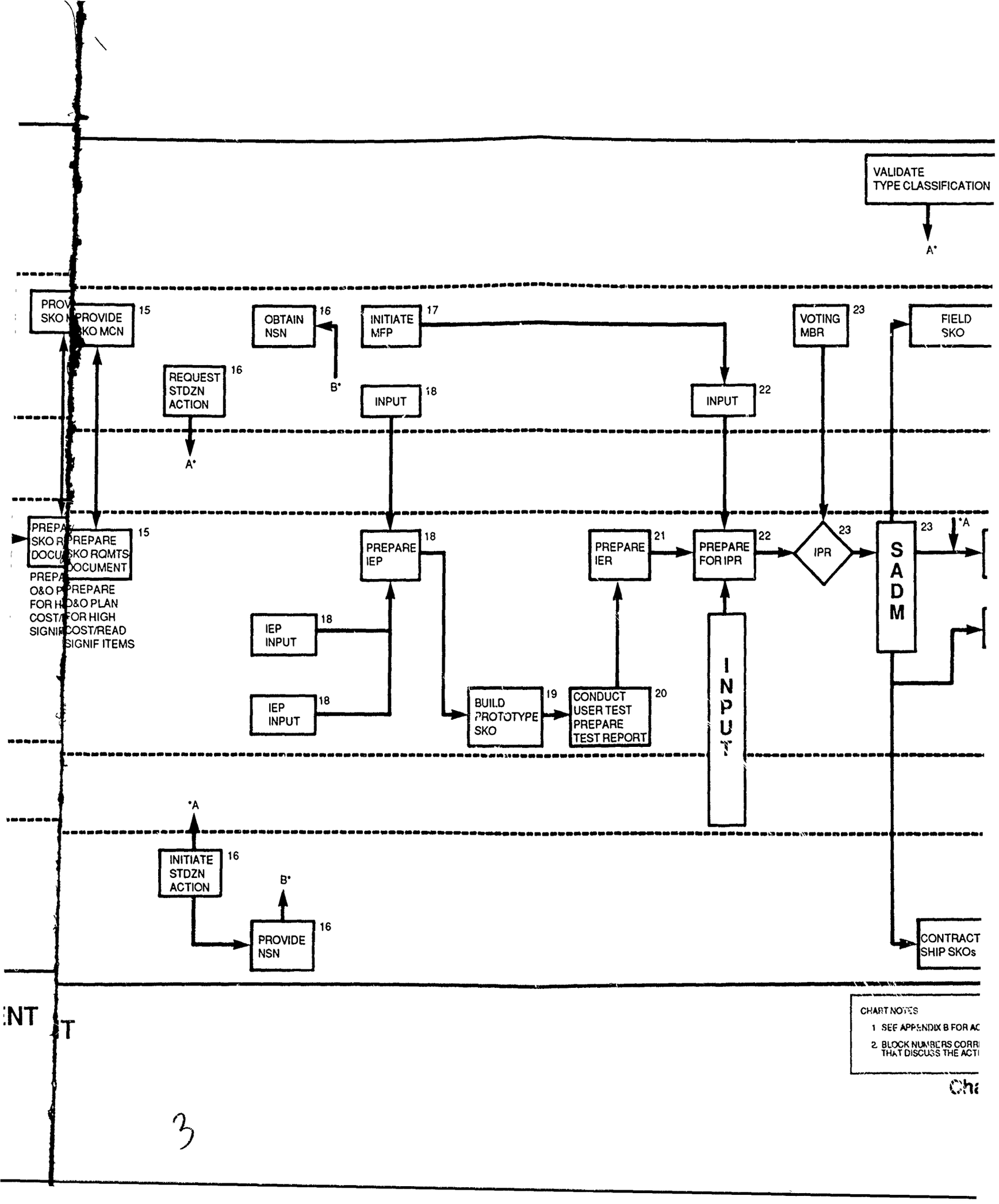


Chart 21-1, NEW MEDICAL SKO DEVELOPMENT

2


VALIDATE TYPE CLASSIFICATION
A*
PROVIDE SKO MCN
15
OBTAIN NSN
16
B*
INITIATE MFP
17
VOTING MBR
23
FIELD SKO
REQUEST STDZN ACTION
16
A*
INPUT
18
INPUT
22
PREPARE SKO RQMTS DOCUMENT
15
PREPARE O&O PLAN FOR HIGH COST/READ SIGNIF ITEMS
PREPARE IEP
18
IEP INPUT
18
IEP INPUT
18
BUILD PROTOTYPE SKO
19
CONDUCT USER TEST PREPARE TEST REPORT
20
PREPARE IER
21
PREPARE FOR IPR
22
IPR
23
S A D M
23
*A
INPUT
*A
INITIATE STDZN ACTION
16
B*
PROVIDE NSN
16
CONTRACT SHIP SKOs
CHART NOTES
1 SEE APPENDIX B FOR AC
2 BLOCK NUMBERS CORR
THAT DISCUSS THE ACTI

3

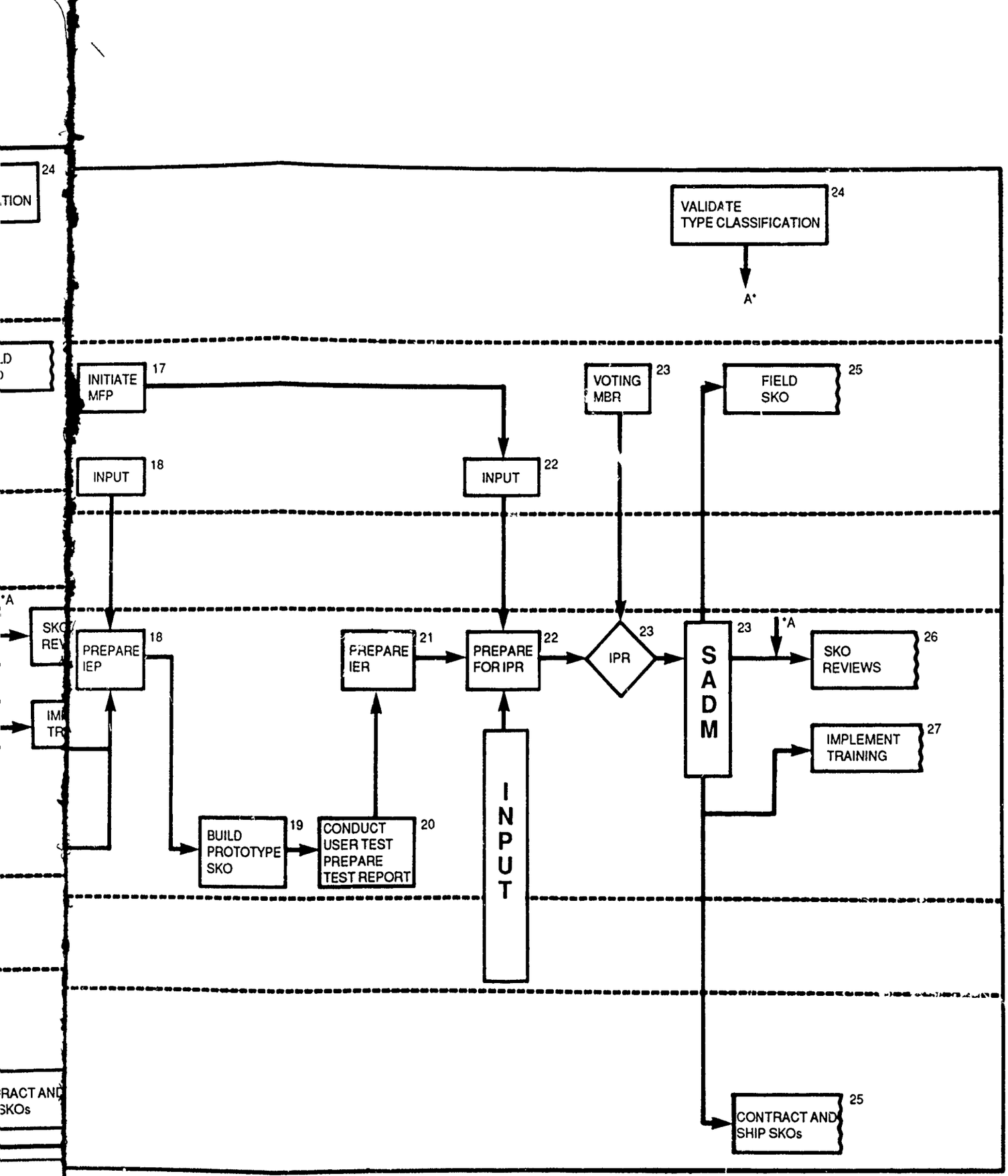


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 21-1

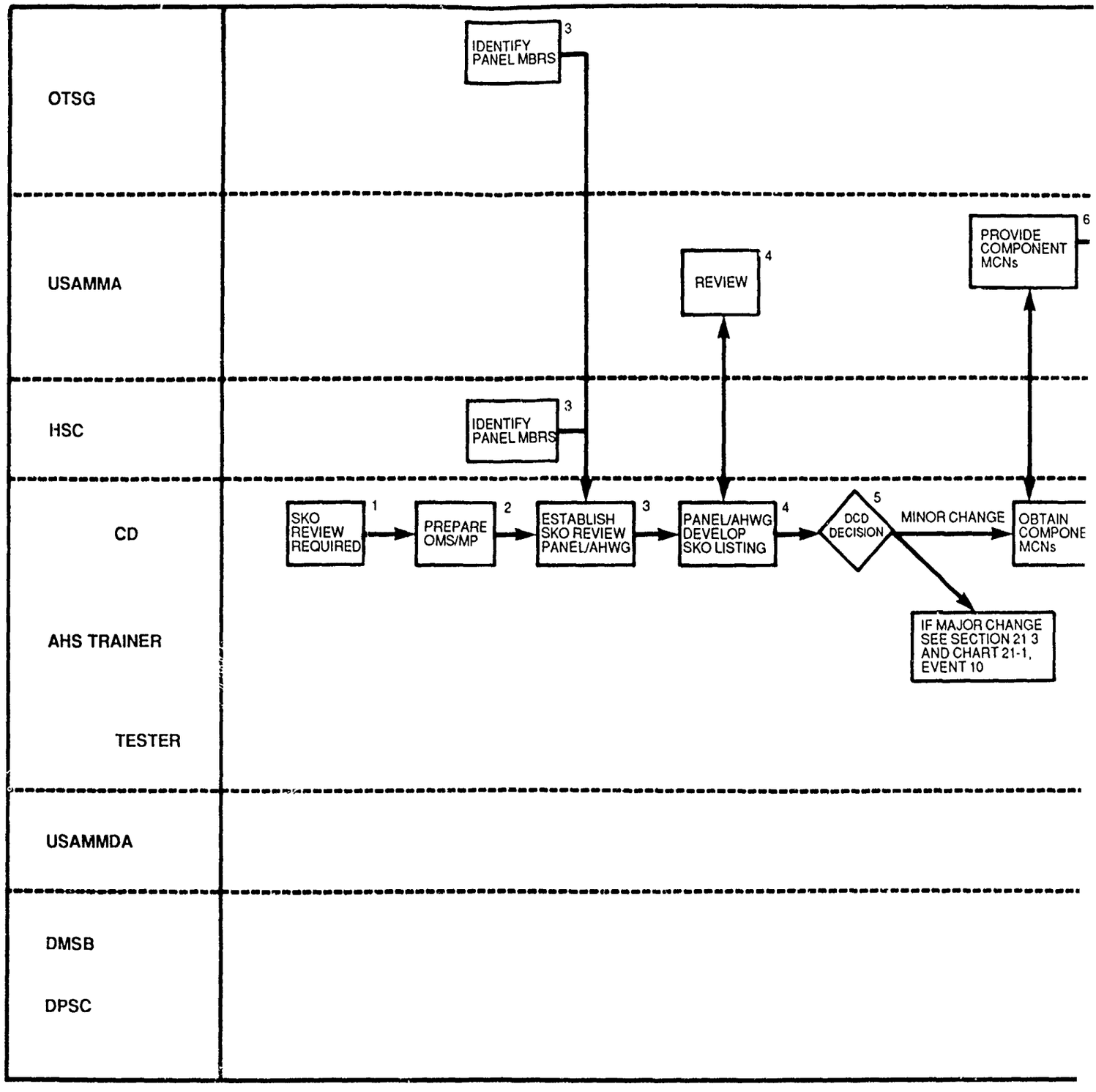
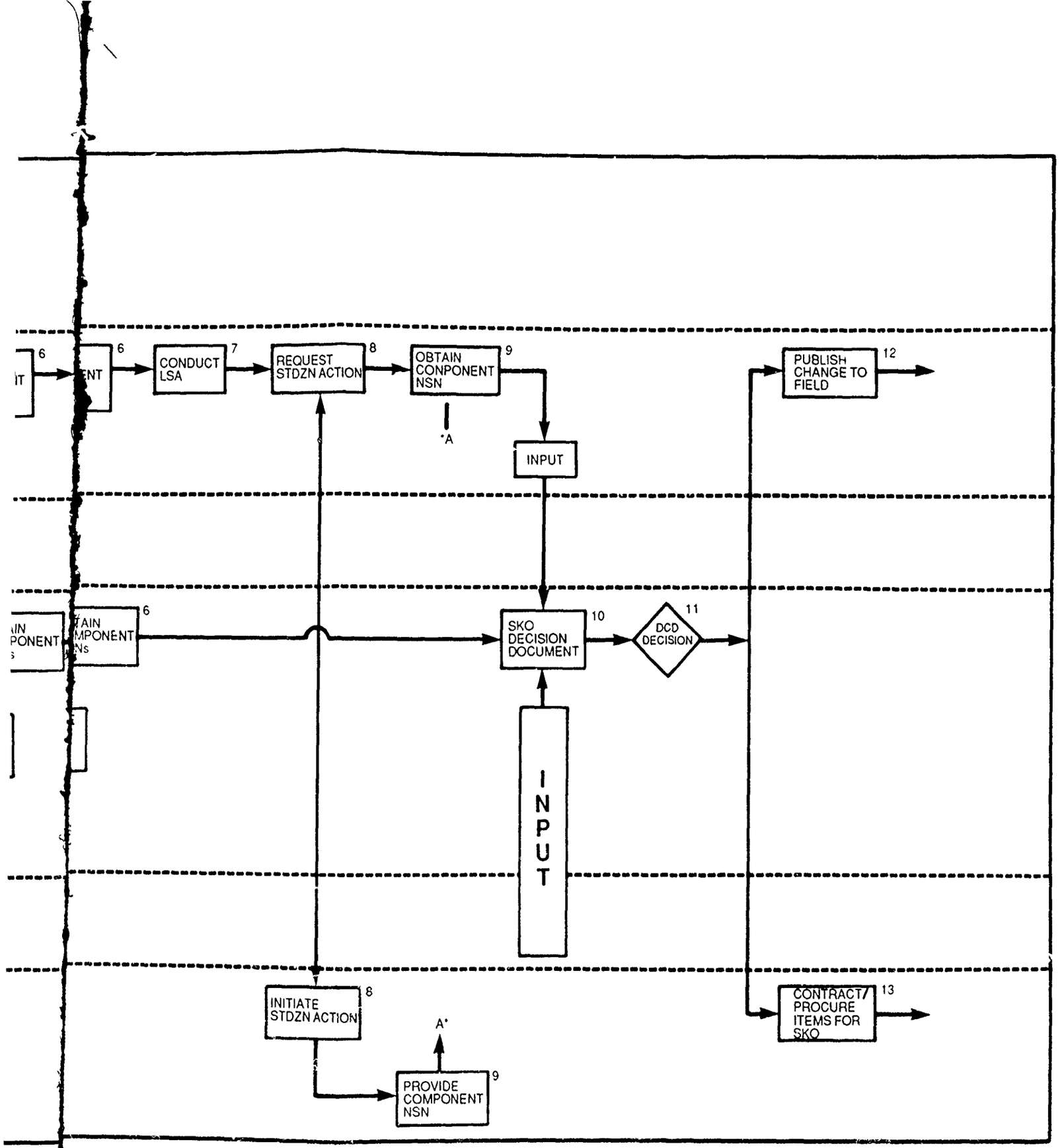


Chart 21-2, MEDICA



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CHART NOTES

1 SEE APPENDIX B FOR ACRONYMS

2 BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 21-2

2

CHAPTER 22

PROGRAM COST AND SCHEDULE CONTROLS

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22.1 PURPOSE

This chapter defines the Baseline Cost Estimate (BCE), as well as the main conventions to be used in it's development and use. It also describes the Program Data Management System (PDMS) used to control the flow of information and the Contractors Performance Measurement (CPM) process and how it is used to identify problems and control costs and schedules.

Chart 22-1 depicts this iterative process where the data output from one function contributes to the following function and at the same time provides feedback through the Program Management Control System (PMCS) to refine the output of preceeding functions. This constant interaction between functions within the funding and contracting areas enhances the control of a project and ensures a coordinated effort.

22.2 GENERAL

The functions of planning, organizing, directing, and controlling are essential to every project regardless of the type, purpose, or scope. Cost, Schedule, and Performance are the elements that define the parameters against which the success of a project is measured. Therefore the control of these elements is essential to favorable project results. Early identification of problems in any of these related areas is crucial to identifying alternatives which correct the problem and ensure project success.

Key to the effectiveness of this process is establishing a standard with which to measure, acquiring the data that relate to this standard, and establishing the information flow that facilitates the comparative analysis of performance against the standard. In this way management can identify problems and take corrective action. The Baseline Cost Estimate provides the standard upon which to measure and, therefore, must include the latest updated cost estimates at all times. The Contractor Cost Data Reports (CCDR) provide the data on contractor performance, and the Program Management Control System provides for the information flow between the various functions within project management. With this the project officer can exercise control over costs and schedules.

22.3 BASELINE COST ESTIMATE

SEE CHART 22-1

The Project Manager has the basic responsibility for developing and updating the Baseline Cost Estimate (BCE). The BCE, which covers all phases of a system's/project's life, defines the Life Cycle Costs and identifies the methodologies applied in deriving the Life Cycle Cost Estimate (LCCE). The BCE is the source for documenting funding requirements which are identified in the Operational and Organizational (O&O) Plan and the Planning, Programming, Budgeting and Execution System (PPBES). As such, the BCE is computed in both current and constant dollars.

22.3.1 Procedures. Overall guidance in preparing the BCE is included in the DA PAM 11 series pamphlets. In addition to this guidance certain conventions and considerations are applied when developing the Baseline Cost Estimate.

22.3.1.1 Cost Estimating Data Base. Within the Program Management Control System there is a cost data base consisting of quantitative historical and current activity cost data, descriptive data that documents the source and meaning of the activity cost data, and codes that permit aggregation of cost data for analytic and reporting purposes. This data base can provide the basis for developing the project's cost estimate using parametric, engineering or bottoms-up, and analogous methods. When using this data base care must be taken to ensure that the proposed project is somewhat analogous to the system within the cost data base or that the differences can be factored out.

22.3.1.2 Analysis Ground Rules. In order for all users of the BCE to be able to correctly interpret the estimates contained in the BCE, the most complete explanation possible of how the project will be developed, produced, operated, maintained, and supported is essential. The BCE includes descriptions of missions/applications, characteristics, manning, maintenance, support, and logistics policies. These documented ground rules and assumptions provide the information needed to allow proper interpretation of the cost estimates and to

ensure that changes in the BCE are considered when changing these ground rules. It also ensures that the underlying assumptions used in the cost estimates are consistent throughout the BCE.

22.3.1.3 Relevant Costs. A Cost Element Structure (CES) establishes a standard vocabulary for identifying and classifying the different costs associated with a system. It should be designed to assess all costs reasonably expected within the system's/project's life cycle. However, as system definition and research continue, additional costs may become relevant. The CES should be flexible enough to allow the addition of unforeseen cost elements as they arise.

22.3.1.4 Consistency. The basic cost structure should not change as the program progresses through the acquisition process. However, cost elements and their sub-elements should progress to greater levels of detail as development allows a greater level of definition, and experience in the project is gained. For this reason, CES should be hierarchical, that is, the sum of each set of lower elements should equal the next higher element. In this manner the CES provides flexibility in selecting the level of detail and the method by which each cost element is estimated.

In addition to ensuring consistency over time, the CES should be consistent between the proposed system/project and all alternatives. This allows systems to be directly compared and provides a measurement for decision making.

22.3.1.5 Estimating Techniques. As a system/project progresses from Concept Exploration through Production and Deployment, the tools available to the cost analyst change. Where initially, the best method for estimating costs may be a parametric cost estimating relationship, as information on the project is gained, more finite methods, such as learning curves, project officers' projections, and actual costs can be applied. The objective is to provide the greatest accuracy possible with the data available at the time the estimate is made.

22.3.1.6 Simplicity. Complexity in the derivation of a cost estimate is not desirable. If a cost estimate is to be valuable to the decision process it must be understandable. That is not to say that complex approaches to cost estimating, such as regression analysis or application of learning curves, must not be used. When these approaches to cost estimating are used the results must be explained in terms understandable by users of the BCE.

22.3.1.7 Treating Uncertainty. Although the BCE is treated as a series of point estimates, actually, each point represents a range of future possible costs. The degree of uncertainty and its impact varies with each project, complexity of development, and the information known on the cost element being estimated. When the degree of uncertainty and its impact on the cost estimate is considered significant by the project manager, a separate sensitivity analysis should be included in the BCE. When quantification of uncertainty proves impractical, a qualitative assessment of ranges should be made.

22.3.1.8 Coverage. The BCE should array the life cycle cost of the project with an annual breakout in constant and current dollars. In deriving the sustainment costs, the scenario that best reflects the use and support of the project and generates the most likely resource requirements should be used.

22.3.1.9 Significant Cost Elements. Not all cost elements require or deserve the same attention. The greatest analytic effort should be devoted to those elements accounting for a substantial part of the life cycle costs, that can be affected by the acquisition program decisions, or those that are significant in distinguishing between alternatives.

22.3.2 Uses of the BCE. The BCE provides the cost input to the O&O Plan, other requirements documents, and the PPBES, and is used as a source document for cost comparison data throughout a project's acquisition cycle. The key to control of cost is proper identification of what these costs should be. Therefore, it is important that the BCE be maintained with the latest cost estimate changes available. The BCE should be revised at least annually, incorporating all changes, and subsequently reissued. The BCE, as well as all development project cost estimates, should be validated by the USAMMDA Business and Financial Management Division.

22.4 PROGRAM MANAGEMENT CONTROL SYSTEM

SEE CHART 22-1

The Program Management Control System is a management information system developed to provide managers at all echelons with the data needed on systems/projects under development or in the Production and Deployment phase. It can provide periodic or on-demand products tailored to each user, application, and requirement. The system consists of five major functional modules: Query/Retrieval and Report Generation; Network Analysis; Cost Estimation; Financial Management; and the Base Line Project List. Additional modules can be added as required.

22.4.1 Data Input. All data entry is strictly controlled, requiring that the data flow through the PMO prior to entry into the system. This is not to restrict the type of data, or the quantity, but to ensure that the quality of the PMCS data base is maintained and that the system maintains its focus on the development and production process. After systems/products are fielded, the Operating and Support costs in the field can be invaluable to the developers of follow-on systems/products. High operating cost drivers can be identified from the data, and development efforts can be focused on reducing these to produce a system/product of the lowest life cycle cost. Therefore, it is important that this valuable operational data be collected from the user commands and entered into the PMCS data base. This data is also needed when deriving sustainment cost estimates as part of the BCE development.

22.4.2 Cost Estimation Module. As identified in paragraph 22.3.1.1, the Cost Estimation Module consists of three types of data: (1) quantitative, historical, and current activity cost data; (2) descriptive data that documents the source and meaning of the activity cost data; and (3) codes that permit aggregation of the cost data. The activity cost data base is organized to parallel generic and/or product specific management activity. The cost data contains two values; USAMMDA's internal budget and external budget.

The internal budget includes the following data relative to each development project:

- Labor, materials, travel and services;
- Extramural R&D contracts;
- USAMRDC laboratory activities;
- Project orders to other organizations.

The external budget represents budgets of other organizations, such as AHS, USAMMA, and other Services that support the development projects.

Instructions for use of the Cost Estimating Module are included in the Product/Project Cost Estimating Subsystem User's Manual.

22.4.3 Data Uses. Not only do these processes provide input to the PMCS data bases, but the PMCS also provides data to support these processes. In this way, the BCE is disseminated through the PMCS to provide input to the Work Breakdown Structure (WBS) during Request for Proposal (RFP) development. Once contracts are finalized they provide data through the PMCS to update the BCE. Acquisition strategy drives source selection, which, in turn, drives the acquisition strategy update. These interrelationships of the data, functions, and processes within the development and acquisition phases are enhanced by the common data base management system, i.e., the PMCS.

22.5 CONTRACTOR PERFORMANCE MEASUREMENT

SEE CHART 22-1

DARCOM PAM 715-13, Cost/Schedule Management of Non-Major Contracts, 1978, provides detailed guidance on establishing management controls for contracts. The Contractor Performance Measurement system established during RFP development and contract negotiation is the official source of information from which the project officer determines problems in the development or production of his system or project. It is vital, therefore, that this information cover

all aspects of the projects, have sufficient detail to be meaningful to the project manager, and be structured to provide maximum visibility of problems and deviations within the program schedule.

22.5.1 Work Breakdown Structure. Key to both sufficient coverage and detail within the information feedback is the Work Breakdown Structure established during the RFP development. This WBS should be broken into meaningful, measurable work units, that is, units that can be readily identified during contractor performance. Military Standard 881A provides basic guidance in establishing an adequate WBS. Items such as training, peculiar support equipment, system test and evaluation, initial spares, and data need to be included in the WBS. The WBS need not be restricted to tangible, deliverable items. It can also cover items such as hours of research performed in a level of effort type R&D project. All reporting requirements for the contractor must be consistent with the WBS, in as much as data on contractor performance, schedule, and costs are provided within the framework established by the WBS. Therefore, extra time spent in adequately developing a comprehensive WBS will significantly enhance the management of the project.

22.5.2. Work Packages. In order to provide a standard against which to measure contract performance (and thereby initiate corrective action), the contractors tasks must be subdivided into units of work, i.e., work packages. Work packages must: (1) be clearly distinguishable from all other work packages; (2) be assignable to a single organizational element; (3) have a scheduled start and completion date; (4) have a budgeted or assigned value expressed in terms of dollars, man-hours, or other measurable unit; (5) be limited to a relatively short time or subdivided by discrete milestones; and (6) be integrated with the schedule of performance.

22.5.3 Reporting. Periodically (monthly or quarterly) the contractor reports on the actual and planned costs of the project and the actual work accomplished and the work scheduled. Cost Performance Reports (CPR) and Cost/Schedule Status Reports (C/SSR) are used to monitor contractor performance and to provide feedback through the PMCS data network to maintain currency of the Baseline Cost Estimate, and thereby update the various requirements documents feeding the PPBS.

While formal CPRs are normally used for major system contracts, and C/SSR is normally used for systems costing more than $2 million or lasting more than one year, the reports may be applied to non-major projects at the PMs discretion. The reports to be provided by the contractor are included in the Data Item Descriptions (DIDs) as part of the contract. The DIDs recommended for contractor performance measurement for the majority of medical materiel development contracts are one or more of the following: (1) DI-A-1004, Work Breakdown Structure (WBS); (2) DI-A1021, Program Plan; (3) DI-F-1208A, Performance and Cost Report; (4) DI-A5003F, Funds Expenditure Report; (5) DI-A-5008A, Project Status Report (Management); (6) DI-F-6004B, Contract Funds Status Report (CSFR); and (7) DI-F6010A, Cost/Schedule Status Report (C/SSR). Not all of these DIDs would be used on every contract. Selection of DIDs or establishment of new DIDs may be coordinated with the PMSO. The information feedback requirements from the contractor can be costly to the government and, therefore, should be tailored to the needs of the project.

22.5.4 Measurement Parameters. In order to exercise control over costs and schedules, the Project Officer must understand: (1) what was planned for accomplishment during a specified time period on a specific work package; 2) the budgeted cost for that work; (3) what was actually accomplished and; (4) the actual cost of the work accomplished. With these four figures the Project Officer can determine if the project is on time, ahead, or can expect project slippages. The PM can also determine if the cost is on target, over budget or under budget. By establishing threshold values for each of these figures he can establish "by exception" management and require the contractor to report reasons and explanations only on those items exceeding this threshold value.

22.5.4.1 Cost Measurement. Budgeted Cost for Work Performed (BCWP) is one of the values included in the Cost/Schedule Status Report provided by the Contractor. It specifies the funds which were estimated to be required for the amount of work actually accomplished. The Actual Cost of Work Performed (ACWP) figure provided in the C/SSR is used to provide a direct comparison of budgeted to actual. Dividing the BCWP by the ACWP provides the Cost Performance Index (CPI). A CPI value of 1.00 would mean that the contract is on cost target. Less than 1.00 would mean that the contractor is over budget and more than 1.00 would mean that he is under budget.

22.5.4.2 Schedule Measurement. Schedule measurement is done very similarly to cost measurement. Comparing the Budgeted Cost of Work Scheduled (BCWS) to BCWP, the Project manager can determine if the amount of work accomplished is more or less than the amount planned for that period. Dividing the BCWP by the BCWS provides the Schedule Performance Index (SPI). An SPI of 1.00 would indicate a program on schedule. Less than 1.00 would mean behind schedule and more than 1.00 would mean ahead of schedule.

22.6 REFERENCES

DoD Instruction 7000.2, Performance Measurement for Selected Acquisitions, 1977

DoD Instruction 7000.10 Contractor Cost Performance, Funds Status, and Cost/Schedule Status Reports, 1979

DoD Instruction 7000.11, Contractor Cost Data Reporting (CCDR), 1984

DA PAM 11-2, Research and Development Cost Guides For Army Materiel Systems, 1976

DA PAM 11-3, Investment Cost Guide For Army Materiel Systems, 1976

DA PAM 11-4, Operating and Support Cost Guide for Army Materiel Systems, 1976

DA PAM 11-5, Standards for Presentation and Documentation of Life Cycle Cost Estimates for Army Materiel Systems, 1976

AMC PAM 715-8, Contractor Cost Data Reporting (CCDR) System, 1973

DARCOM-P 715-13, Cost/Schedule Management of Non-Major Contracts (C/SSR Joint Guide), 1978

MIL STD 881A, Work Breakdown Structure for Defense Materiel Items, 1975

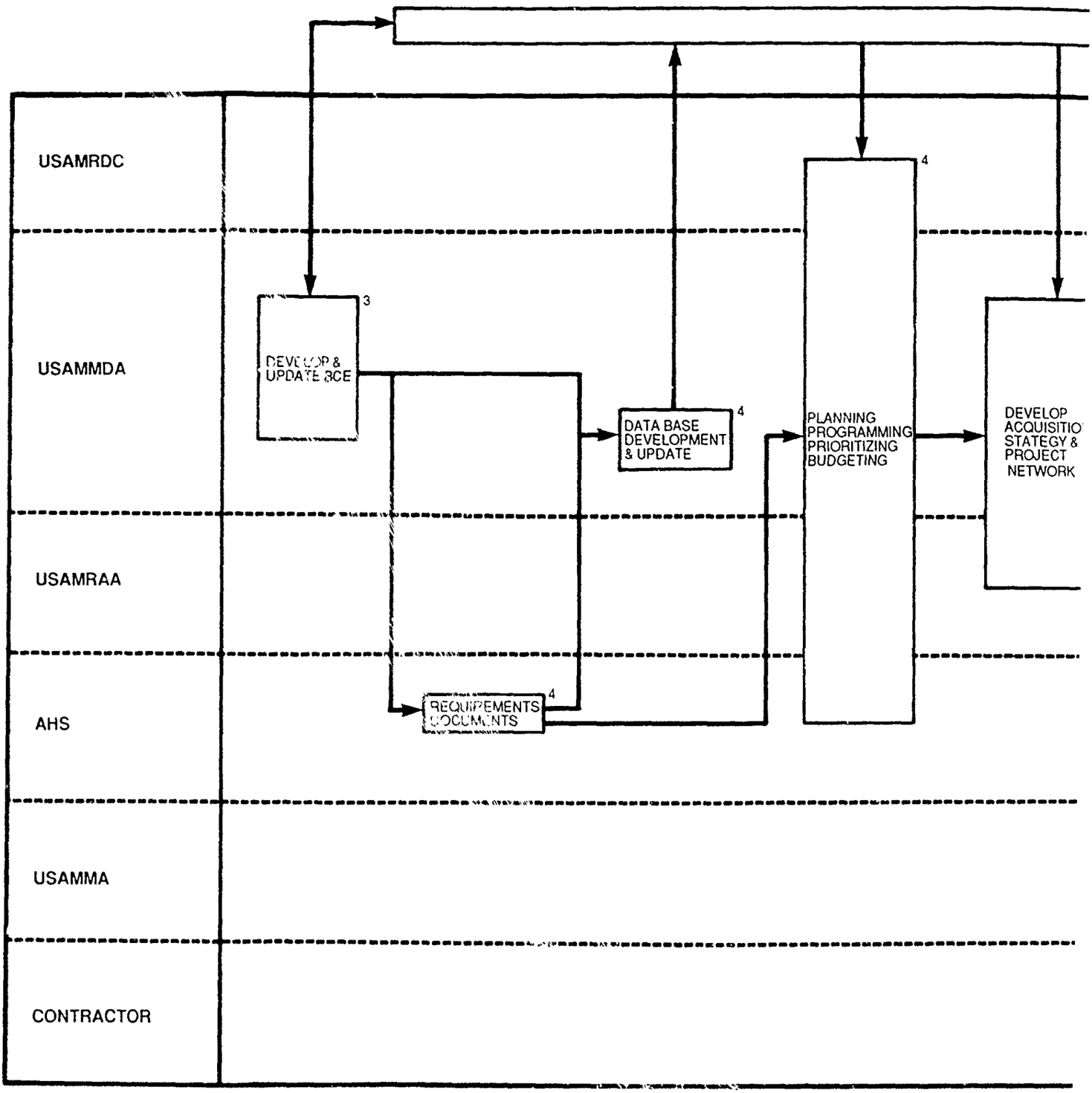
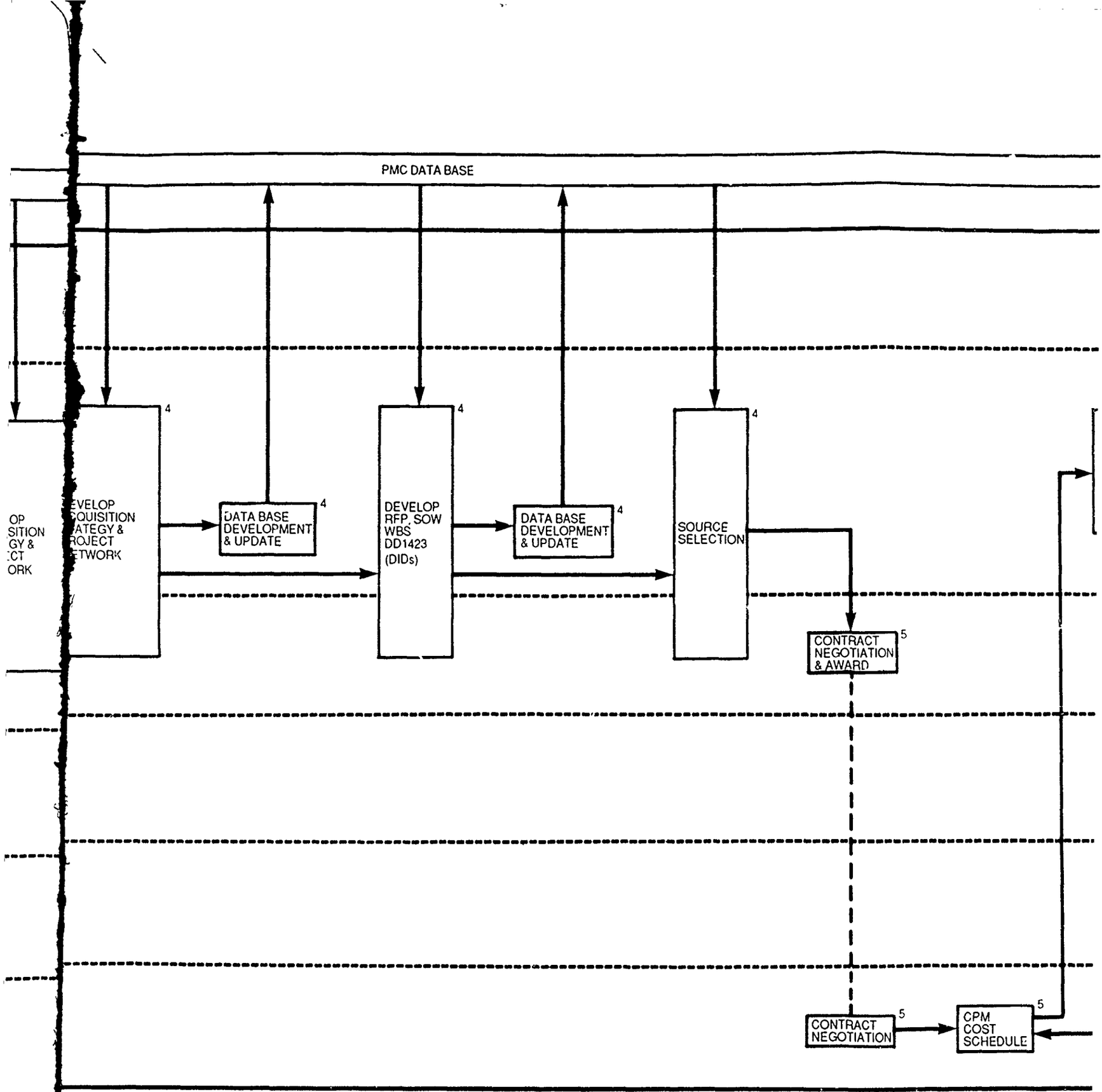
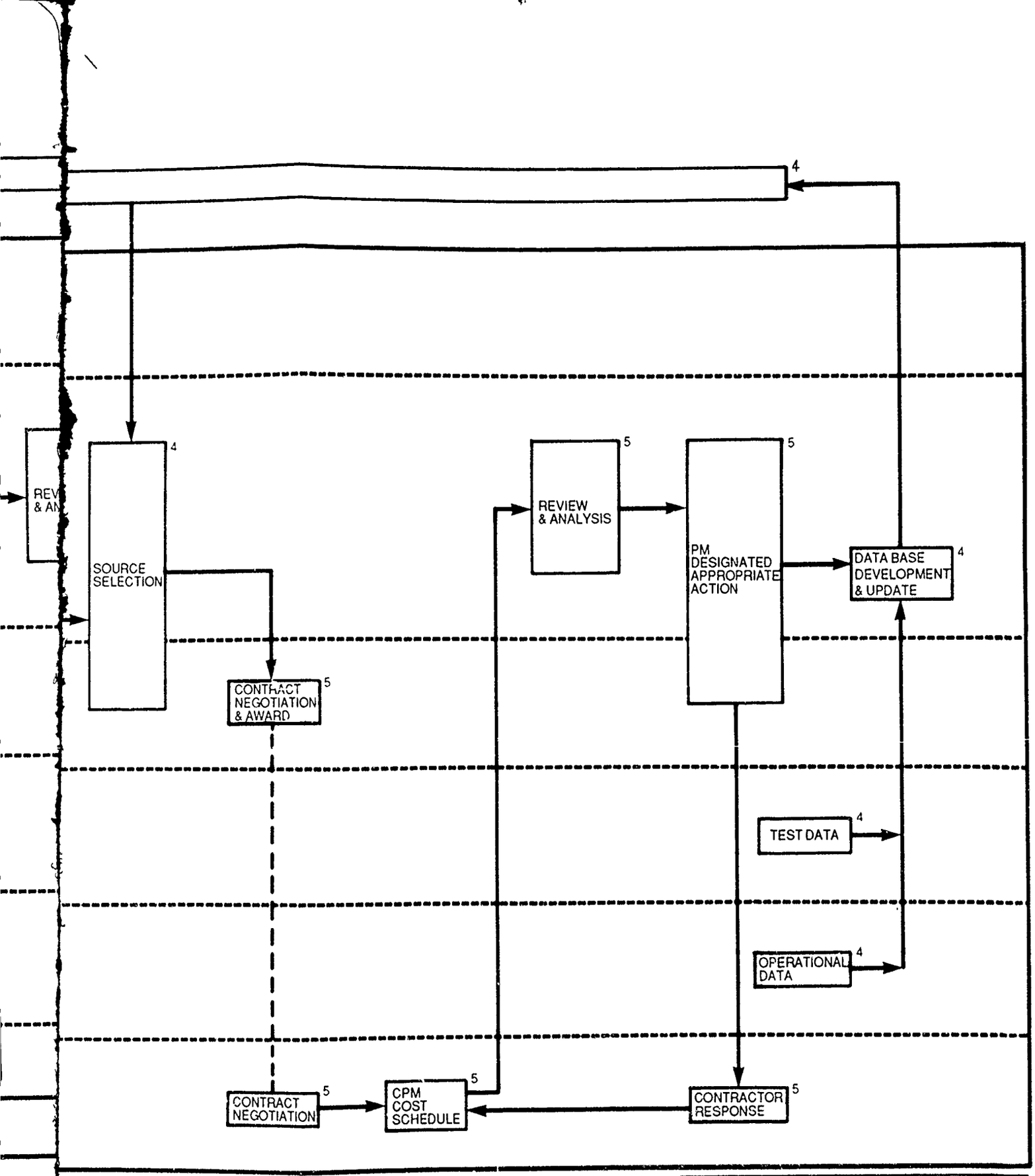


Chart 22-1, THE I



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CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 22-1

CHAPTER 23

JOINT SERVICE COORDINATION

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23.1 PURPOSE

This chapter describes the activities required by the AMEDD to comply with the need for Joint Service Coordination. It identifies the various Inter-Service structures and provides an overview of Army management responsibilities as the Executive Agent, lead or participating Service for joint programs.

23.2 GENERAL

There is a continuous need for Interservice coordination in medical materiel acquisition. Although there may be differences in operation among the Army, Navy, Air Force, and Marines, mutual cooperation in the exploitation of medical technology should be a paramount concern to all Services. The need for equipment, drugs, biologicals, and pharmaceuticals is substantially the same among the Services. All Services recognize the requirement for developing items as soon as possible through the use of tailoring, and streamlining in all types of materiel acquisition programs, i.e., Development, Nondevelopment Item (NDI) and Modified NDI.

Joint acquisition programs are endorsed by the Office of the Secretary of Defense (OSD), Congress, and the Department of Defense (DOD). They provide opportunities to reduce acquisition and logistic support costs and to improve interoperability in joint operations. Management objectives of joint programs should be directed toward: realizing the economies of joint performance of planning, analysis, and documentation; satisfying the essential peculiar needs of each Service; and meeting readiness objectives. Management of joint programs is similar to that of single Service programs, with one major exception-joint program management requires the accommodation of each participating Service's unique requirements resulting from differences in deployment, mode of employment, and logistics support concepts.

AMEDD Interservice coordination takes place with the Air Force, the Navy, and, through the Navy, with the Marines, as early as possible in the acquisition process. Building Joint Service requirements can only be accomplished through close cooperation of the Combat Developers and Logisticians of each of the participating Services.

Joint Research, Development and Acquisition (RDA) efforts, which by definition include those efforts involving the cooperation of two or more Services, can be either formal or informal. Formal efforts are established through an agreement, memorandum of understanding, or charter, and include joint funding and multi-Service staffing of the Project/Program Office. Informal coordination involves a sharing of information among the Services through exchange of data on ongoing programs but with no formal report or funding requirements involved. As used in this Handbook, Joint Services Coordination considers all of those possibilities.

23.3 DEFINITIONS

The following definitions apply to Joint Service relationships as used in this chapter.

The Executive Agent: The Service which has been designated by OSD as the lead in coordinating the requirements of a specific medical area, such as CW/CBD, and the related RDA programs of the Services. The Executive Agent has the authority to manage the program/project under the policies and procedures of its Service. It plans, programs, budgets, funds, and executes the appropriate research, exploratory development, advanced development, and engineering development for its own requirements and for joint requirements in all related areas for military purposes. Planning, programming, budgeting, and executing Service-unique requirements are the responsibilities of the individual Services.

Materiel Developer, Lead Service: The Service which has been directed agreed to formulate and execute an RDA program addressing a specific requirement which has applicability to more than one Service. In this case, the materiel developer, lead Service, will plan, program, budget, and execute the appropriate research, development and acquisition efforts.

Requirements Developer, Lead Service: The Service which has been directed: 1) to formulate and obtain approval of the requirements document(s) addressing a specific requirement which has applicability to more than one Service; and 2) to develop training programs needed to support fielding.

Participating Service: A Service which has formally expressed its intent to participate in a Joint RDA program, has signed the requirements document and, where appropriate, has planned and programmed for testing and procurement of materiel. As a general rule, the functional elements of each participating Service will operate under the policies, procedures, data, standards, specifications, criteria and financial accounting of the Lead Service.

23.4 ORGANIZATION

There is no overall single structure prescribed for the management of joint programs for medical materiel. Basic policies and required management relationships may be documented in a Joint Service Agreement, a Memorandum of Agreement (MOA) or some other documentation for managing a specific Multi-Service requirement. The lead Service Program Manager and each participating Service must establish an organizational structure which is capable of rapid response to decisions of the Program Manager and which provides a direct information path conveying the requirements of each military Service to the Program Manager. Typical staffing of a joint program office would designate key positions for the senior representative of each participating Service. The participating Service may assign a liaison officer or representative to the program office, or it may simply identify a POC to monitor the program. Normally, the interests of the Executive Agent or Lead Service dominate the program.

23.4.1 Responsibilities. DOD Directive 5136.1, Assistant Secretary of Defense (Health Affairs), designates the Assistant Secretary of Defense (Health Affairs) (ASD [HA]) as the principal staff assistant and advisor to the Secretary of Defense for all DoD health policies, programs, and activities. As part of this charter he is to "Promote coordination, cooperation, and mutual understanding within the Department of Defense and between the Department of Defense and other federal agencies and the civilian community". Although DODD 5136.1 lists in detail the several functions of the ASD(HA), one specific function which identifies his relationship with USAMRDC is in carrying out his many responsibilities in that portion of medical research and development associated with clinical technology, such as research involving the prevention of infectious diseases and care of combat casualties.

23.4.1.1 Funding. The funding arrangements are normally defined in a MOA among the Services. The formula for sharing funding responsibility varies from program to program.

- Research, Development, Test and Evaluation Funds. Requirements peculiar to one Service are normally funded by the sponsoring Service. Funding of requirements common to all participants is either provided entirely by the Executive Agent or Lead Service or split among participants according to an agreed formula (e.g., proration according to planned procurement).

- Procurement Funds. Each Service provides funds to meet its own requirements. Funding of common items, such as data and software, is prorated among participants.

- Operation and Maintenance Funds. Although Operation and Maintenance (O&M) funded activities, such as repair, rework, and modification of the deployed system, may not occur until after the disestablishment of the joint program office, the joint program funding plan must make provision for such O&M expenditures. Each Service provides separate funds for operation and maintenance requirements to support its deployed systems.

- Military Personnel Funds. Each Service bears all costs of its military personnel assigned to the joint program office.

- Military Construction (MC) Funds. A problem common to many complex Interservice programs is the lack of adequate planning for MC funds for R&D and operational deployment facilities. Generally, Services share costs required for development; funds for post deployment requirements are the responsibility of each Service. All construction in excess of $100K per facility must be funded from MC funds. The normal lead time for programming of these funds is three years before the facility is needed; some facilities may require up to seven years. Adequate advance planning, especially for unique facilities, can eliminate potential program schedule impacts during full-scale development.

Other joint funding problems may arise because of differences among the Services in their uses of various categories of funds or in funding responsibilities within a Service. There are a number of ways these differences might arise and it is important to list, early in the program, all items to be developed and procured and to review the list in detail with the comptrollers or other knowledgeable financial managers in each participating Service.

23.4.1.2 Logistics. Because missions, operating concepts, and operating environments differ from Service to Service, the area of logistics in a joint program demands a great deal of attention. There are differences in practically every aspect of support and close coordination with other Service representatives is required. Unlike many other Interservice issues, logistics issues cannot normally be solved by escalation to a higher decision authority. Logistics problems normally concern details that must be worked out by functional specialists. Although all logistic areas are important, data requirements and technical manuals deserve special attention. It helps to anticipate different Service requirements in these areas and to plan additional time for solving those problems.

23.4.2 Service Unique Characteristics.

The Army has a structured approach to medical Research, Development and Acquisition (RDA). It is based on the Concept Based Requirements System (CBRS). The requirements are identified by the combat developer (usually AHS) and the research and development is conducted under the auspices of the USAMRDC and its labs. (See Chapter 2, Medical Materiel Acquisition Process Participants). Development is the responsibility of USAMMDA, and readiness is the responsibility of USAMMA.

The Air Force's philosophy for R&D employs a more centralized approach from that of the Army, and relies less on a Service position. The Air Force operates through the Aerospace Medical Division, Brooks AFB, Texas and uses more civilian organizations under contract for the conduct of research rather than using in-house laboratories, as does the Army. The Air Force capitalizes on applying outside research to practical use. The Air Force concentrates much of its R&D efforts in the area of aeromedical evacuation and crash victim prevention and assistance.

Navy and Marine Corps R&D programs are managed by the Navy Medical R&D Command, which is part of the Navy Medical Command. The Navy Medical R&D Command has purview over the Navy's major Medical R&D facilities which are:

- Naval Medical Research Institute, Bethesda, Maryland;
- The Naval Aerospace Research Laboratory, Penscola Florida;
- The Naval Submarine Medical Research Laboratory, Groton, Connecticut;
- The Naval Health Research Center, San Diego, California;
- The Naval Biodynamics Research Laboratory, New Orleans, Louisiana;
- The Naval Blood Research Laboratory, Boston Massachusetts (a contractor operation in conjunction with the Boston University School of Medicine).

The Navy does much of its own basic research. The Navy's sea-borne mission differs from the Army's ground troop support mission; subsequently, the Navy concentrates much of its R&D efforts in such areas as the medical aspects of submarine duty (sensory deprivation), ship motion, and aerospace medicine. The majority of Navy funding, however, is programmed for combat casualty care, most of which is in support of Marine Corps requirements dealing with land/water interface and cold weather operations.

23.4.3 Coordinating Groups, Committees, Panels, and Boards. To assist in the overall management of RDA efforts related to medical and biological materiels, several formal coordinating groups and committees have been established. In addition there is much information which is relatively informal that passes back and forth among the Services, much as a result of information received at a scheduled meeting of Service representatives.

23.4.3.1 Armed Services Biomedical Research and Evaluation Management Committee. The Armed Services Biomedical Research and Evaluation Management (ASBREM) Committee is the major group for coordinating medical related RDA efforts of the three Services. The ASBREM is a joint committee, formed as a result of the House Appropriation Committee (HAC) request to study the technical, financial and organizational impacts of consolidating medical research and development activities under a single organization administered at the OSD level.

The ASBREM is a General/Flag Officer level board, composed of the Commander of the Army Medical R&D Command, the Commander of the Air Force Aerospace Medical Division, and the Special Assistant to the Surgeon General of the Navy for Research and Development. The ASBREM deals with non-system research programs (6.1-6.3A) and meets at least annually. A joint secretariate composed of O-6 grade levels from each Service ensures that appropriate action is taken on ASBREM decisions. The Deputy Commander, USAMRDC, represents the Army on the ASBREM. The four objectives of the ASBREM are:

- To increase the cost effectiveness of resource utilization through efficient use of personnel, intelligence, facilities, equipment, supplies, and services;
- To provide a mechanism to address organizational roles, conduct management studies, and resolve Service organizational/functional alignment issues;
- To ensure program relevance and obviate duplication of Services' and other agencies' programs through timely review of requirements and program plans;
- To define Service issues which require resolution/coordination with other Federal agencies.

23.4.3.2 Joint Technical Coordinating Groups. In order to implement the objectives of the ASBREM, a Joint Technical Coordinating Group (JTCG) has been established for each of the seven major biomedical R&D areas.

JTCG-1	Military Dentistry
JTCG-2	Infectious Diseases of Military Relevance
JTCG-3	Medical Chemical Warfare (CW) Defense
JTCG-4	Medical Biological Warfare (BW) Defense
JTCG-5	Systems Biotechnology
JTCG-6	Combat Casualty Care
JTCG-7	Ionizing Radiation Bioeffects

The JTCGs are composed of biomedical research managers and laboratory personnel from each of the Services. The USAMRDC Research Area Directors represent the Army on the JTCGs in their areas of responsibility. The JTCGs concentrate on research and development planning and programming and do not get involved with scientific or technical reviews. The JTCGs:

- Conduct an annual review and coordination meeting keyed to the planning, programming, and budgeting cycle of the Services;
- Make recommendations to the ASBREM Committee on inter-Service distribution of responsibility for program execution, changes in program direction or emphasis, new initiatives, and other matters dealing with program requirements and relevance.

23.4.3.3 Defense Medical Standardization Board. In order to standardize medical equipment, a Defense Medical Standardization Board (DMSB) was established by DOD Directive 6430.2, DOD Medical Standardization Board as a Joint DoD activity that reports to the Assistant Secretary of Defense for Health Affairs (ASD-HA). The DMSB ensures that in the development of medical equipment and deployable medical systems, maximum use of standardized, medical materiel shall be used.

The Secretary of the Army is responsible for administrative support for the internal administration of the DMSB and also programs, budgets and finances all operational costs of the DMSB and its staff. The DMSB membership consists of at least one medical department officer at the O-7 grade level or above from each of the military Services. In addition, the ASD (HA) and the Director, Defense Logistics Agency, each designate a representative to participate as an observer.

A major initiative of the DMSB is the Deployable Medical Systems (DEPMEDS) which is supported by the Army as Lead Service. DEPMEDS is a quad-Service standardized modular hospital equipment system capable of being located in an area of operation during a contingency, war, or national emergency. DEPMEDS

includes all deployable combat zone and communication zone Army TOE hospitals. The system also includes all medical supplies and equipment, and selected nonmedical equipment such as electrical generators, environmental control equipment, dolly sets, rigid and fabric shelters, and power distribution systems.

23.4.3.4 Joint Service Review Group. In order to ensure proper coordination of Joint Service programs in the Chemical Warfare/Chemical Biological Defense (CW/CBD) RDA area, a Joint Service Review Group (JSRG) reviews the entire program on an as-required basis and makes appropriate recommendations to the Military Department. The JSRG is chaired by the Army as DOD Executive Agent and consists of a Chairman; representatives from each Service's Headquarters Operations, Materiel Development, and Surgeon General Staff Sections; and a representative from OJCS. All JSRG recommendations for a Service to assume responsibility as a lead Service for a requirement, or to fund an RDTE program must have the concurrence of that Service.

The JSRG will formulate and recommend to the Services a Joint Plan which:

- Identifies and recommends priorities for the requirements of all the Services;
- Recommends the requirement and materiel developer lead Service(s) for each requirement;
- Indicates which Services will participate in each requirement and the key milestones for the requirement;
- Considers fiscal and programming guidance to ensure that, within the constraints of resources available, the highest priority needs of all the Services are met.

23.4.3.5 Tri-Service Aeromedical Research Panel. The Tri-Service Aeromedical Research Panel (TARP) was chartered on 5 February 1976 by the Surgeon General of each of the Services. It meets twice a year and is responsible for reviewing the overall joint programs on Aviation Medical Research. In addition, it submits recommendations to the respective Service headquarters annually.

The membership consists of twelve representatives, one of whom is selected as chairman for a term of two years. The twelve members represent the Surgeon General, the Research and Development Activities of each of the Services, and the laboratories.

23.4.3.6 Joint In-Process Review. The Joint In-Process Review (JIPR) is the decision body for technical and management issues and recommends resource utilization to the Army and Air Force. It is established under an MOA between USAMRDC and the Air Force Aerospace Medical Division. The JIPR is composed of representatives of the materiel developer, and the logisticians from the Air Force and the Army. The JIPR conducts an annual review and forecast of Army and Air Force joint programs for the respective AMD and USAMRDC Commanders.

23.4.3.7 Joint Working Group. A Joint Working Group (JWG) is established whenever a Joint Service Operational Requirement is needed to initiate the development and acquisition of a new materiel system. The JWG consists of a representative from each of the Services having an interest in the materiel system under development or procurement. The JWG will be chaired by a representative of the AHS with a representative of USAMMDA as vice-chairman. The proponent for Army medical systems (AHS) initiates action to establish the JWG with an invitation to the Services for representation on the JWG. The JWG reviews the AHS-CD first draft JSOR and prepares the second draft of the JSOR based on comments received from all Services.

23.4.3.8 Other Tri-Service Health Services Activities. In addition to activities integral to its Service, each military department participates in Tri-Service activities which support the military health care system. Those activities are jointly staffed and are utilized by more than one Service. Examples of such activities include: The Armed Forces Institute of Pathology, the Military Blood Program Office, the Armed Services Medical Regulating Office, the Defense Medical Standardization Board, Tri-Service Medical Information System, and the Armed Forces Medical Intelligence Center. A complete list of these activities is provided as Appendix B.

In general, documentation and decision requirements for joint Service programs are the same as for single Service programs except that they are coordinated and staffed jointly. An exception is the preparation of a Joint Services Operational Requirement (JSOR), which requires the participation of all potential participating Services in its preparation. The JSOR is discussed in paragraph 23.5.1.2.

Unless it is a major DoD program with a DoD program office, a single Service will be the lead Service and the requirements and formats used by that Service will be those followed by the program. It is necessary, however, for the manager of the joint project to be familiar with the organization, approving authorities, and funding authorities of the participating Service. The program schedule should accommodate the review, approval, and funding requirements of the participating Services, as far as possible.

23.5 DOCUMENTATION OF JOINT PROGRAMS

23.5.1 Joint Service Agreement. A Joint Service Agreement (JSA) specifies the responsibilities of the materiel developer lead Service, requirements developer lead Service, and one or more participating Services. A Joint Service Agreement (JSA) prescribes procedures for coordinating the Services requirements in specific materiel areas. A JSA also assures that the Services conduct coordinated programs which can be achieved within available resources, which can meet the highest priority requirements of all the Services, and which can attain the goals of the Defense Guidance. Although a JSA identifies the Executive Agent and describes overall procedures and policies, each Service is still responsible for establishing its own requirements. Establishing a Service requirement normally involves the development of materiel, technologies, and/or information.

The Joint Service Agreement for Chemical Warfare/Chemical Biological Defense is an example of a JSA. Because of the magnitude of the effort needed in the area of Chemical Warfare/Chemical Biological Defense (CW/CBD), and the high potential for common requirements, a Joint Service Agreement (JSA) was

developed and Army implementation instructions prepared specifically for this area. Thus the CW/CBD program has a detailed procedure to integrate all Service projects which fall under the CW/CBD umbrella. This JSA is dated July 5, 1984.

Although the JSA identifies the Army as the Executive Agent for CW/CBD and describes overall procedures and policies, each Service is still responsible for establishing its own requirements. For CW/CBD the documentation of the Service requirements involved the development of materiel, and technologies, and/or information documents which were classified as a Materiel Requirement, Science and Technological Objective, or a Chemical Data Need, respectively.

- A Materiel Requirement (MAR) is a requirement for a capability which will involve fielding an item of materiel where the necessary technologies are already available. MARs are addressed by system advanced development (6.3B) and full scale development (6.4) programs.
- A Science and Technology Objective (STO) is a requirement for a capability which will involve developing and/or demonstrating the technology needed to develop a specific item or family of materiel. STOs are addressed by basic research (6.1), exploratory development (6.2), and non-system advanced development (6.3A) programs.
- A Chemical Data Need (CDN) is a requirement for data on the properties and effects of a particular chemical, biological or medical system. Data obtained in response to a CDN are required to support the development of doctrine, tactics, training, and materiel. CDNs are addressed by basic research, exploratory development, nonsystem advanced development, studies, and force development tests and experimentation.

Formats and processing procedures of MARs, STOs and CDNs should be delineated in the JSA.

23.5.2 Joint Service Operational Requirement. The Joint Service Operational Requirement (JSOR) is the requirements document used when the same end item is to be used by more than one military service. The JSOR replaces the ROC for joint Service programs, and except for the Service coordination, is processed similarly to the other requirement documents. The format for an Army prepared JSOR is the same as a ROC.

The JSOR may be used to support both the Demonstration and Validation and Full Scale Development Phases. It is always approved at HQDA-Office, Deputy Chief of Staff for Operations and Plans (ODCSOPS) regardless of the dollar amount involved, when the Army is the lead Service. After ODCSOPS approval, the JSOR is coordinated formally with other interested Services and Government agencies and then published by HQ TRADOC. The characteristics and parameters of the materiel system are refined in the JSOR as development evolves. The approved JSOR is listed in the HQDA Catalog of Approved Reference Documents (CARDS). Examples of current JSORs are:

- Deployable Medical Systems;
- Chemical Warfare Agent Battle Dressing;
- Insect Arthropod Repellent System;
- Aerosolized Nerve Agent Antidote.

Detailed procedures for preparation, review, coordination, validation, authentication, and approval of the JSOR are described on the following pages in the form of descriptive paragraphs which relate to the fold out Chart 23-1.

1. During the Concept Exploration Phase, AHS coordinates informally with the other Services to determine the extent of their interest. If AHS determines that there may be a joint requirement for the development of medical materiel, it notifies USAMMDA to investigate the alternatives available to meet the requirement and the feasibility of Joint Service involvement.

2. USAMRDC-USAMMDA explore alternatives to satisfy the requirement and assist AHS in determining the interest of other Services. Established forums where these alternatives can be explored are the scheduled multi-Service reviews. Some examples are: an annual review between USAMRDC and the Air Force Systems Command, Aerospace Medical Division; periodic RDA reviews under the Joint Service Agreement on CW/CBD; and meetings of the Joint Technical Coordination Groups of the Armed Services Biomedical Research and Evaluation Management Committee.

3. If sufficient interest is expressed by the other Services, AHS-CD prepares a first draft using the ROC format shown in Chapter 11, The Requirements Documentation Process.

4. Along with the first draft JSOR, the proponent (AHS) prepares a forwarding letter to the other Services that contains an invitation to comment on the first draft JSOR and an invitation to provide representatives to the Joint Working Group (JWG) meeting. The forwarding letter establishes the location where the JWG will meet, who will chair the JWG (a representative of AHS with a representative of USAMMDA as vice-chairman) and the date (thirty days after the date of the forwarding letter).

5. The recipients of the draft JSOR determine whether to participate in the JWG or comment on the draft JSOR.

6. The JWG task is to prepare a second draft JSOR according to the comments received. Included are the costs, schedule, and milestones provided by the AHS proponent, as well as events that are unique to the system. The JWG must ensure the validity of the need based on the O&O plan.

7. AHS then coordinates the revised (second) draft JSOR with the same agencies that received the first draft plus any others that may have been identified.

> NOTE:
>
> Suspense for this coordination is thirty days from the time the second draft JSOR is provided to the recipients.

8. Based on this coordination, the action officer at AHS prepares a third draft JSOR.

9. Within seven days after the suspense date for receiving comments, the AHS action officer initiates its routing through TRADOC and the three TRADOC integrating centers (Combined Arms Center, Soldier Support Center, and Logistics Center). During staffing, the associated TRADOC integrating center (1) provides comments within its area of responsibility; (2) ensures that internal and external coordination is sufficient, and conducts such other coordination as may be considered necessary; and (3) resolves differences within the TRADOC community.

10. Simultaneously with step 9, the third draft JSOR is sent to USAMMDA for coordination to include: (1) reviewing the draft proposed JSOR; and (2) updating the cost data. A copy is also sent to USAMMA and interested Services for staffing.

11. Concurrently with steps 9 and 10, the AHS action officer sends the third draft to Major Army Commands (MACOMs) and to HQ TRADOC (ATCD-SE). TRADOC action offices staff the document with Britain, Canada and Australia (ABCA). Responses from these countries are provided to AHS for review and comment.

> **NOTE:**
>
> Steps 9, 10, and 11 should be completed within sixty days after distribution of the third draft.

12. After completion of steps 9 through 11, the AHS action officer incorporates all appropriate comments and prepares the final draft JSOR. The JWG chairman assists the proponent directorate as necessary throughout the approval process.

13. The AHS action officer submits the final JSOR to USAMMDA for formal Army coordination. USAMMDA staffs it and responds in forty-five days.

14. Based on the coordination, the AHS action officer prepares the finalized JSOR.

15. The JSOR is sent from OTSG through TRADOC to ODCSOPS for approval.

16. After approval it is coordinated formally with other interested Services and Government agencies.

17. The JSOR is then sent to HQ TRADOC for publication and distribution.

23.6 REFERENCES

DODD 5136.1, Assistant Secretary of Defense (Health Affairs), 1984

DODD 5160.5, Responsibilities for Research, Development, Test and Evaluation (RDTE) on Chemical Weapons and Chemical Biological Defense, 1976

DODD 6430.2, DOD Medical Standardization Board, 1984

Joint Logistics Commanders Guide for the Management of Joint Service Programs DSMC, April 1982

Joint Service Agreement on Chemical Warfare/Chemical Biological Defense, July 1984

AR 40-60 Policy and Procedures for the Acquisition of Medical Materiel, 1983

AR 70-1, System Acquisition Policy and Procedures, 1986

AR 71-9, Materiel Requirements, 1986

APPENDIX A

U.S. ARMY FOCAL POINTS

Wartime Requirements

Academy of Health Sciences Directorate of Combat Developments Concepts Division	AHS, HSHA-CDC Fort Sam Houston, TX 78234-6100

Doctrine

Academy of Health Sciences Medical Field Service School	AHS, MFS Fort Sam Houston, TX 78234-6100

Concept of Operations

Academy of Health Sciences Directorate of Combat Developments Materiel Division	AHS, HSHA-CDM Fort Sam Houston, TX 78234-6100

Product Development/Production

Commander U.S. Army Medical Materiel Development Activity	USAMMDA SGRD-UMZ Fort Detrick, MD 21701-5009
Applied Medical Systems	USAMMDA SGRD-UMA Fort Detrick, MD 21701-5009

Biological Systems	USMMDA SGRD-UMB Fort Detrick, MD 21701-5009
Pharmaceutical Systems	USMMDA SGRD-UMP Fort Detrick, MD 21701-5009

U.S. NAVY/MARINE CORPS FOCAL POINTS

Navy

Office of the Chief of Naval Operations Office of the Surgeon General Contingency Planning Board	CNO OP-932 Washington, D.C. 20350
Naval Medical Command	NAVMEDCOM Code 02C Washington, D.C. 20332
Naval Medical Research & Development Command	NMRDC Code 407 Bethesda, MD 20814

Marine Corps

Commandant Marine Corps	HQ Marine Corps Code-MED Washington, D.C. 20380

U.S. AIR FORCE POINTS OF CONTACT

Wartime Requirements

Medical Readiness Division Office of the Surgeon General	HQ USAF/SGHR Bolling AFB, D.C. 20332

Doctrine/Concepts

Medical Wartime Hospital Integration Office Office of the Surgeon General	HQ USAF/SGH (MWHIO) Fort Detrick, MD 21701

Development

Medical Research and Clinical Investigations Division Office of the Surgeon General	HQ USAF/SGPT Bolling AFB, D.C. 20332
Air Force Liaison Officer U.S. Army Medical Research and Development Command	USAMRDC SGRD-PL Fort Detrick, MD 21701-5012
Director of Biotechnology Air Force Systems Command	HQ AFSC/SGB Andrews AFB, MD 20334
Director of Engineering and Advanced Development Aerospace Medical Division	HQ AMD/RDC Brooks AFB, TX 78235
Engineering Development (6.3) Advanced Development (6.4)	HQ AMD/RDSX HQ AMD/RDSM

Production

Medical Logistics Division Office of Medical Support	HQ AFOMS/SGSL Brooks AFB, TX 78235
War Readiness Materiel Manager Office of the Surgeon General	HQ USAF/SGHR Bolling AFB, D.C. 20332

APPENDIX B

Tri-Service Medical Related Activities

- Advisory Group for Aerospace Research and Engineering
- American Burn Association
- American Society for Testing and Materials
- Armed Forces Epidemiological Board
- Armed Forces Institute of Pathology
- Armed Forces Medical Regulating Office
- Armed Forces Pest Management Board
- Armed Forces Radiological Research Institute
- Armed Services Biomedical Research Evaluation and Management Committee
- Armed Services Whole Blood Processing Laboratory
- Biological and Chemical Defense Research
- Biotechnology on Chemical Warfare Defense
- Consolidated Training for Certain Specialties
    - -- Behavioral Science Specialist
    - -- Bio Medical Equipment Repair (Basic and Advanced)
    - -- Combat Casualty Care Course
    - -- Health Care Administration
    - -- Medical Lab Specialist
    - -- Occupational Therapy Specialist
    - -- Psychiatric Specialist
    - -- Physical Therapist
    - -- Uniformed Services University of Health Sciences
    - -- Veterinary Specialist
- Consolidated Veterinary Services
- Defense Enrollment Eligibility Reporting System
- Defense Health Board
- Defense Health Council

- Defense Medical Standardization Board
- Defense Reserve Component Medical Council
- DOD Medical Facilities Acquisition and Maintenance
- DOD Dental Chiefs Council
- Drug Testing Laboratories
- EUCOM Blood Bank
- Helicopter Research Coordinating Panel
- Inter Service Training Review Organization
- JCS Ad Hoc Medical Steering Committee
- The Joint Committee on Medical and Dental Equipment
- Joint Fellowship in Training Aerospace Medicine
- Joint Inter Agency Propulsion Committee
- Joint Nutrition Research Planning Board
- Joint Services Medical Logistics Advisory Group
- Medical Mobilization and Deployment Steering Committee
- Military Blood Program Office
- Military Medical Regionalization Program
- National Research Council (NRC) Committee on Vision
- NRC Committee on Hearing and Bioaccoustics
- NRC Committee on Military Nutrition Research
- The Military Field Medical Systems Standardization Steering Group
- Tri-Service Advisory Panel R&D on Effects of Impact Acceleration on Man
- Tri-Service Aeromedical Research Panel
- Tri-Service Biometrics Committee
- Tri-Service Committee on Medical Equipment Planning and Management
- Tri-Service Electromagnetic Board
- Tri-Service Electromagnetic Radiation Panel
- Tri-Service Graduate Medical Education Courses
- Tri-Service Medical Board
- Tri-Service Medical Information System

- Tri-Service Prosthetic Laboratory Utilization Committee
- Tri-Service Toxicology Working Group
- WHO Expert Advisory Panel on Malaria
- Working Group on Radioprotective and Radiosensitizers

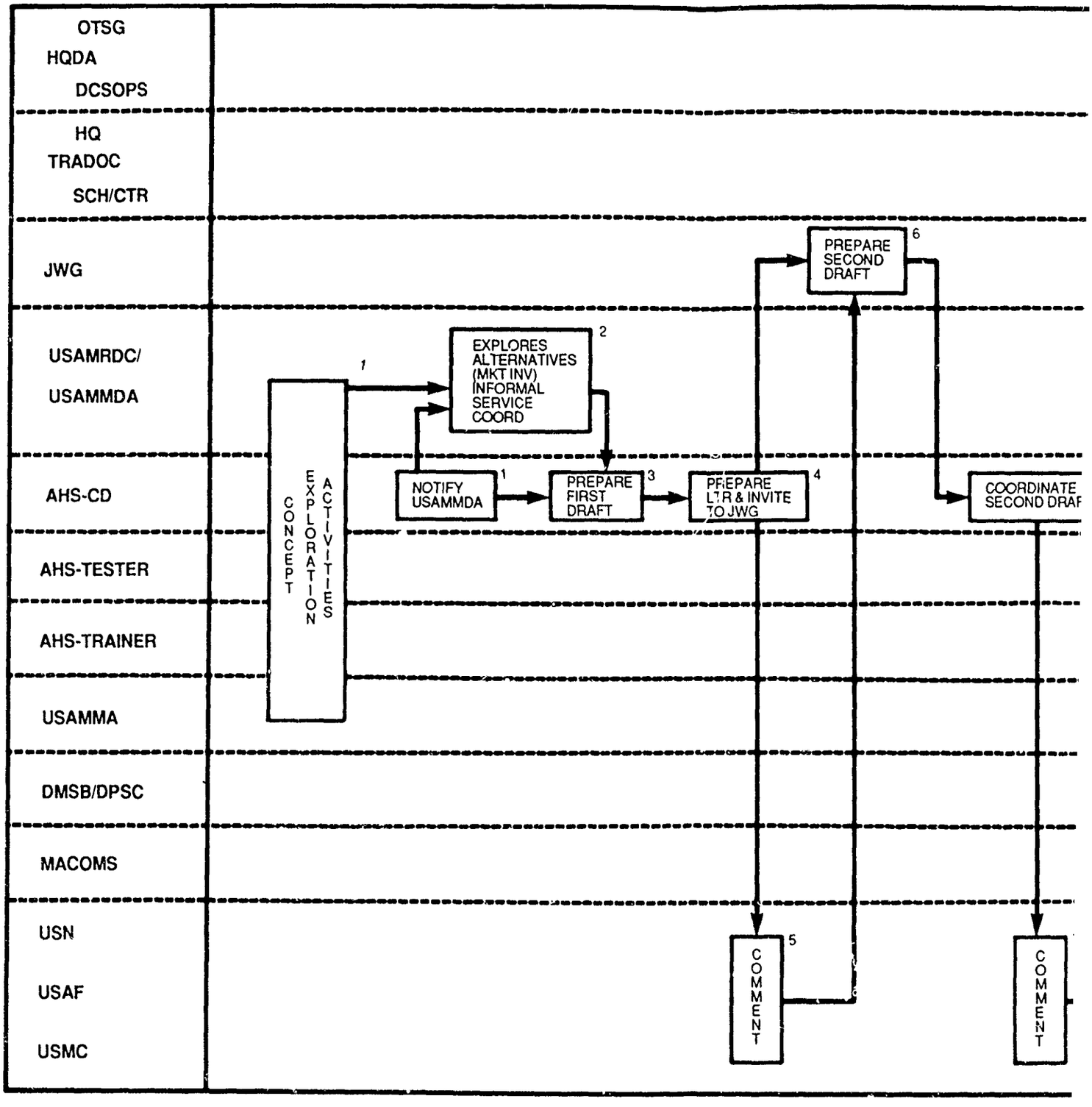
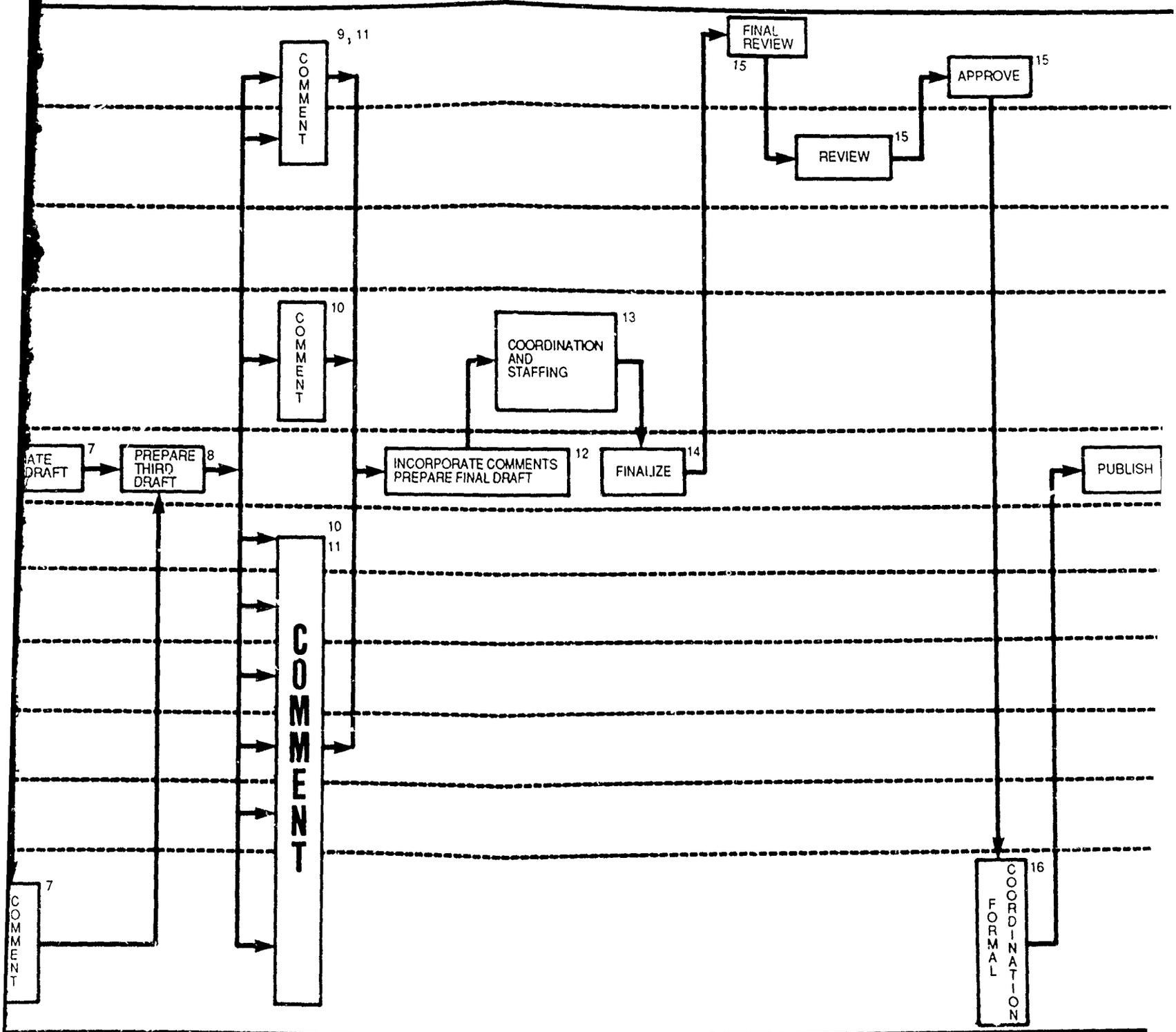


Chart 23-1, PREPARING THE JO



JOINT SERVICE OPERATIONAL REQUIREMENT

CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT THAT DISCUSS THE ACTIVITY IDENTIFIED IN THI

Chart 23-1

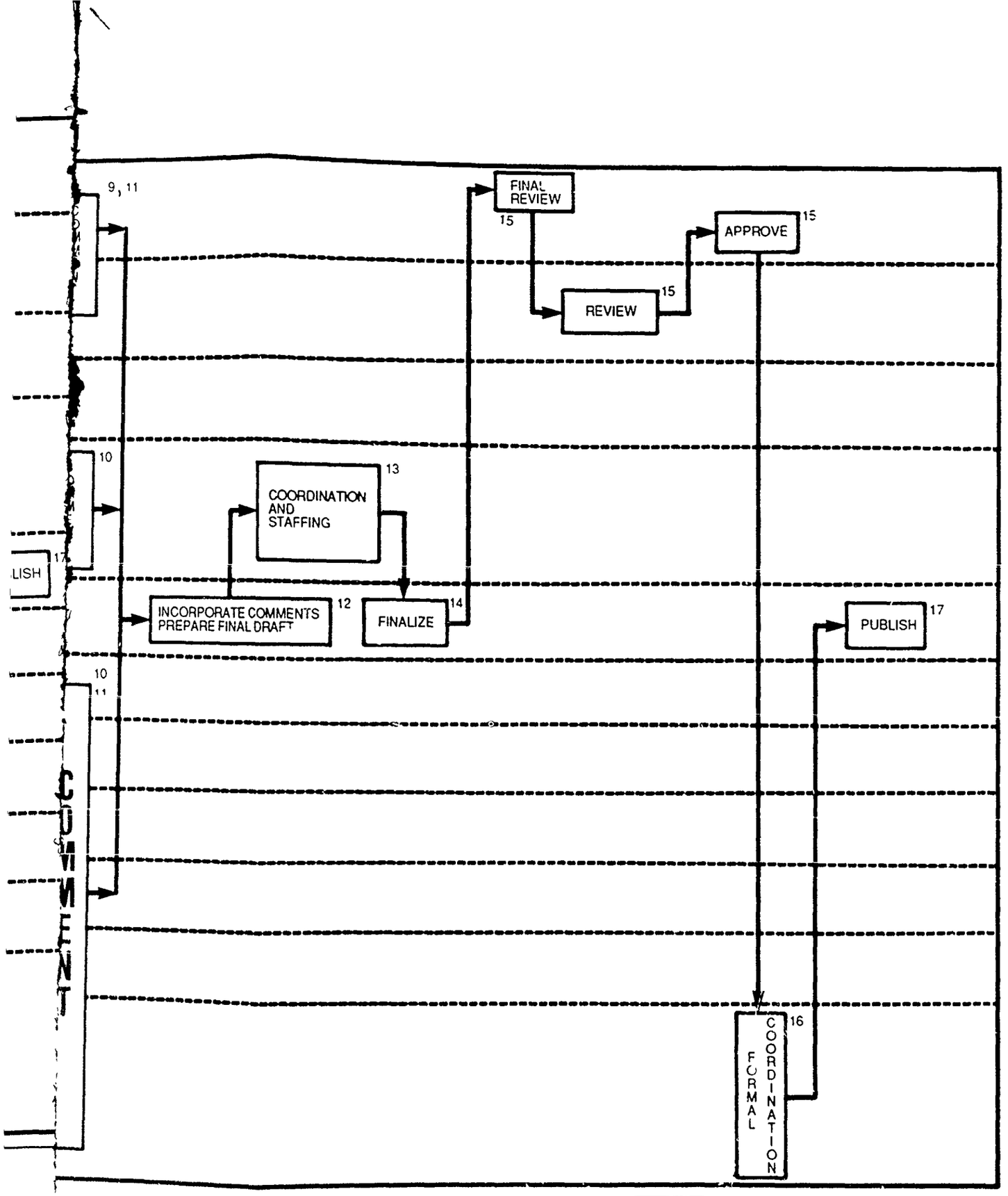


CHART NOTES

1. SEE APPENDIX B FOR ACRONYMS
2. BLOCK NUMBERS CORRESPOND TO THE TEXT PARAGRAPHS THAT DISCUSS THE ACTIVITY IDENTIFIED IN THE BLOCK

Chart 23-1

RATIONAL REQUIREMENT

CHAPTER 24

REGULATORY INTERFACES

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24.1 PURPOSE

The purpose of this chapter is to identify the requirements for interface between the U.S. Army Medical Department and the federal regulatory agencies outside the Department of Defense. These agencies have responsibilities for safeguarding the environment, protecting the health of the public, and overseeing the development of new medical products. Compliance with the reporting requirements set forth in this chapter should ensure that no product development is delayed or halted because of failure to comply with applicable federal legislation.

24.2 GENERAL

The regulatory agency most involved in the AMEDD's activity is the Food and Drug Administration (FDA), a component of the Department of Health and Human Services. The FDA is responsible for the regulation of all drugs, biologics, and medical devices used in the USA, regardless of origin. They monitor these products from the pre-clinical investigations through the production, distribution, and long-term performance of the drug/device. They are concerned not only with the safety of the product but also its effectiveness.

There are two points in the medical materiel development and acquisition process where the FDA must, by statute, be consulted before the process may continue: 1) before the initiation of testing in human subjects; and 2) before release of the product from investigational status. Nevertheless, the entire spectrum of product development is subject to their oversight, and they may intervene at any time deemed appropriate to request additional information; to personally inspect facilities, data, products or activities; or to direct change or modification in procedures being followed. Because the process differs for pharmaceuticals, biologics, and medical devices, the details of the USAMRDC/FDA interactions are discussed separately for each category.

The important role played by the FDA has been recognized in a formal Memorandum of Understanding (MOU) between the FDA and USAMRDC. The agreement, dated 11 May 1984, is of six years duration, with review of the terms scheduled at two year intervals. Primarily, the MOU requires the USAMRDC to provide the FDA with an annual five-year projected milestone schedule of developmental activity, and to seek their advice in preparing statements of work and product specifications, and also in assessing the suitability of contractors competing for USAMRDC development and production contracts. The FDA obligation is to be responsive to USAMRDC requests for guidance, and to assist the USAMRDC in ensuring that its activities are in compliance with applicable requirements of FDA code and regulations.

A 1974 Memorandum of Understanding between the FDA and the DOD establishes procedures for the conduct of clinical investigations that are classified for reasons of national security. Classified clinical investigations will not require the filing of a formal "Notice of Claimed Investigational Exemption for a New Drug" with the FDA. The Service's Review Board and Surgeon General will have the authority to approve the conduct of the necessary investigations. However, these investigations will be discussed on a frequent basis with the appropriate FDA personnel.

The U.S. Department of Agriculture presents another requirement for regulatory interface. In order to develop preventive measures or treatments for zoonotic diseases which are not native to the United States, it is frequently necessary to import live cultures of microorganisms into this country for study, a requirement that is in direct conflict with the USDA's primary mission of preventing the importation of exotic animal pathogens. The USDA publishes a list of microorganisms which are forbidden introduction into the United States. It must be reviewed by USAMRDC before any importation can be planned. If the required microorganism is on the proscribed list, a formal request for exception must be provided to the USDA, and their approval must be received before any other action can be initiated. The USDA has attached stringent safeguards to the process to ensure against introduction of the disease into the U.S. ecology. These safeguards must be incorporated into the research protocol where appropriate. If USDA approval cannot be obtained, the research may be conducted in an overseas area where the disease is endemic.

There are other federal agencies which have the potential to become involved in USAMRDC research and development activities. The Environmental Protection Agency (EPA) has varying levels of involvement in the development of biologics, but no direct role in pharmaceuticals or medical devices. Its role will be discussed in Section 24.4. It does, however, prescribe tolerance levels for any substance released into the air. In addition, environmental statements may have to be submitted with INDs.

Two terms which have general applicability across all subject areas are Good Laboratory Practice (GLP) and Current Good Manufacturing Practice (CGMP). These terms refer to a set of standards for testing and manufacturing facilities, personnel qualifications and training, project organization, quality control, and overall management. GLP is applicable to nonclinical studies, and is intended to ensure the appropriate conduct and documentation of those studies. CGMP is concerned with production and manufacturing procedures, establishing standards for product consistency and quality control. All applications to the FDA require certification that GLP and/or CGMP is being followed, as appropriate. It is the responsibility of the USAMRDC to know of these standards, to ensure that their activities (and their support contractors) are in compliance, and to affirm this compliance to the cognizant federal agency when appropriate.

Subsequent sections of this chapter are divided into three categories; pharmaceuticals, biologics, and medical devices. Each category has different requirements for submitting applications, and in some cases different agencies requiring notification and coordination. The structure requires that any proposed product that might overlap two or more areas be expressly categorized in only one; to do otherwise would greatly add to the administrative approval requirements to no useful end. The FDA is the authority for determining the proper category for medical developments, but the final determination of how the development of an item will be managed within the AMEDD rests with the USAMRDC.

24.3 DEVELOPMENT OF PHARMACEUTICALS

The Memorandum of Understanding between USAMRDC and the FDA requires that USAMRDC "involve the FDA at the earliest practicable stages of materiel development." This involvement could begin at a number of different times, depending on the course of action selected. If the research is to be conducted by a contractor, the FDA is available to provide advice on the structuring of the Request for Proposal (RFP), including the appropriate regulatory terminology that may be appropriate in the Statement of Work (SOW). They will also assist the AMEDD Source Selection Board in evaluating the professional capabilities and past conduct of the bidding firms (through the FDA Medical Products Quality Assurance Staff), and in preparing a contract for the successful bidder that will ensure that all of the FDA requirements are incorporated into the development. If the research is to be conducted "in-house", using USAMRDC personnel, laboratories, and equipment, then there is no formal requirement for FDA submission until the research advances to the stage when testing with human subjects is indicated. However, this is subject to the exceptions described in paragraphs 24.3.1 through 24.3.3.

24.3.1 Investigational New Drug Application. Prior to clinical testing, the sponsoring agency must develop a "Notice of Claimed Investigational Exemption for a New Drug", which is an application to the FDA to begin human testing. The drug is now called an Investigational New Drug (IND), hence the term "IND Application". This application is the documented history of the development effort to date, an outline of the planned clinical investigation, and a description of how the Institutional Review Board will monitor the clinical studies. Following the format of FDA Form 1571, the application contains a total of 16 distinct sections, which include the exact chemical nature of the proposed drug, the results of all animal and laboratory testing, a summary of the protocol for human testing, certification of the past and future use of GLP, the identity and qualifications of the investigators, and any known history of the previous use of the drug. The IND application must convince the FDA that it is reasonably safe to initiate the clinical investigation.

The USAMRDC Human Use Review Office (HURO) serves as the administrator for all Institutional Review Boards (IRBs) for USAMRDC. IRBs are established in each laboratory that utilizes humans in research. HURO is also the administrator and executive secretary for the Human Subjects Research Review Board (HSRRB). The HSRRB is the principal body of the Office of The Surgeon General (OTSG) for the assessment of practices and procedures by which DA employs human subjects in medical research, development, testing and evaluation activities including, but not limited to, clinical investigations and investigational drug studies. The Board will consider and recommend policy to TSG to maintain the quality of practices consistent with contemporary moral, ethical, and legal standards. It will consider protocols submitted to TSG for approval and will make written recommendations for approval or disapproval or deferral to TSG. The Surgeon General is the final approving authority for all research using human volunteers except:

- Research related to nuclear, biological or chemical threat agents. The Surgeon General will forward the protocol, together with the Board's recommendations, through the Secretary of the Army to the Under Secretary of Defense for Research and Engineering.
- Research related to alcohol and drug abuse programs. The Surgeon General will forward the protocol, together with the Board's recommendations, to the Deputy Chief of Staff for Personnel, HQDA.
- Research activities for which approval authority has been delegated to the Commander, U.S. Army Health Services Command (HSC). See AR 40-38.

The only portions of an IND application which are submitted to the HSRRB for approval are the clinical protocol, the local IRB approval and, if appropriate, the investigator's qualifications. If the human testing is being performed under contract and the IND is not sponsored by OTSG, HURO will not forward the above information to FDA. Only if the clinical trials are under an IND sponsored by OTSG will the information be forwarded to FDA by HURO.

The FDA acknowledges receipt of a submitted IND application with a letter to HSRRB. At that point, the FDA has 30 days to request that the drug be

withheld from clinical trials, or delayed until further review can be accomplished; otherwise, the research may commence. However, all revisions required by the HSRRB must be provided by the investigator and approved by HURO before the initiation of clinical trials whether or not the FDA's 30 days have elapsed. This no-action-required approval by the FDA is the normal mode of operation for IND submissions, and should be anticipated in scheduling the subsequent research.

An approved IND application has no fixed expiration date, and remains in effect until either: 1) the sponsor gains an approved New Drug Application (NDA) signifying that the research is completed; 2) the sponsor terminates the project and withdraws his IND, or; 3) the FDA withdraws its approval of the IND and directs that work be halted. To maintain its awareness of research activity being conducted, the FDA requires that an annual report of activity on each IND be submitted for review. These annual reports are also submitted through the Human Use Review Office, which monitors compliance with this requirement. Failure to comply could result in the HSRRB withdrawing its approval of the research or in the FDA withdrawing its IND approval, or both.

The FDA also requires immediate notification of any adverse medical reactions traceable to the research during the human use testing. This is not limited to human reaction; animal testing conducted subsequent to the IND submission may also result in adverse reactions not reported in the IND application that should be brought to the attention of the FDA. The legal penalties for failure to report known reactions are severe, with potential legal action in both criminal and civil courts. As a consequence, researchers should be careful to ensure that their chain of command, the IRB, HURO, and the HSRRB are fully aware of any adverse reactions that occur.

24.3.2 Institutional Review Board. The role of the Institutional Review Board (IRB) should be understood because its existence and its conduct is of extreme importance in the protection of human subjects and consequently is of substantial interest to the FDA. The IRB reviews and approves investigatory protocols. It conducts a continuing review of all human testing, ensuring that risks to the test subjects are minimized and reasonable and that privacy

and confidentiality are maintained. It ensures that the approved protocols are followed, and that all personnel conducting the study are properly trained and licensed. The proceedings of the IRB are subject to FDA review at any time. Because of the continuing nature of its responsibilities, the IRB should be geographically proximate to the investigating clinic.

24.3.3 New Drug Application. When the clinical testing has confirmed that the product is pure, safe, effective, and has appropriate dosage levels identified, USAMMDA will ensure that a New Drug Application is prepared. This application, prepared in accordance with FDA Form 356H, is a much more detailed presentation than the IND application. It summarizes all data generated under the IND, and gives extensive reports on all clinical testing and all manufacturing plans. It certifies that GLP and CGMP were followed throughout the effort. All of the packaging, the label information, the operating instructions, etc., must be provided for approval as well. In short, the NDA must provide the FDA with every item of information that might be useful to them in determining whether or not to approve the new drug for its requested use. Frequently, an NDA goes through several requests for revision or additional information before it is approved. The FDA has one-hundred eighty days to review the NDA, which is almost always extended.

OTSG-sponsored NDAs will be routed to HURO who will relay requests for additional information, and apprise The Surgeon General of the status of NDAs in the same fashion that they monitor IND applications. Two additional opportunities for regulatory interaction remain. First, the FDA requires that post-market surveillance be maintained on every drug approved for manufacturing. This requires a report every three months during the first year, every six months in the second year, and annually thereafter, a schedule which the AMEDD must monitor. This requirement also demands the immediate reporting of any known instances of unexpected or adverse reactions, quality control problems, or any other factors that reflect adversely on the safety or effectiveness of the drug.

Secondly, the FDA requires that a supplemental NDA be submitted any time that the AMEDD wants to change the packaging, labeling, dosages, uses, manufacturing process, or any part of the procedure involved in producing the drug. A supplemental NDA is not required to repeat any of the information contained in the original NDA, but it must provide justification for the change at the same level of detail that was originally provided to assess the drug itself.

24.4 DEVELOPMENT OF BIOLOGICS

The procedures followed in the development of a new biologic are similar to those followed in the preceeding section on pharmaceuticals. Indeed, the Food, Drug, and Cosmetic Act includes biologics in its definition of drugs, exempting only those products which are already governed by the Virus-Serum-Toxin Act. The coordination with the FDA prior to letting a contract is the same as the procedure discussed in Section 24.3. The requirements for an IND application (24.3.1) and an IRB (24.3.2) are also essentially identical, since all of the biologics being developed by the USAMRDC are for use by humans. The principal distinctions arise in the additional federal agencies which require coordination, and in the procedures for licensing the manufacture and production of an approved product. Accordingly, this section will concentrate on identifying the requirements that are unique to the field of biologics.

24.4.1 Biologic-Related Federal Interfaces. Much of the research being conducted in the field of biologics is involved with the application of recombinant DNA techniques, a field which has shown great potential for medical breakthroughs. To alleviate public concern for the safety of these studies, NIH has established a Recombinant DNA Advisory Committee (RAC) to define national policy on what areas of research are precluded, and what procedures will be followed in DNA investigation. Although the RAC has no force of law behind it, as its classification as an "advisory" committee would indicate, it is the expressed intention of The Army Surgeon General that the RAC guidelines will be rigorously adhered to. The RAC draws its membership from the full range of experts in biological sciences, including the AMEDD, and publishes "Guidelines for Research Involving Recombinant DNA Molecules" that are made available to all interested parties.

The Environmental Protection Agency (EPA) would be expected to closely monitor any biologic material, but only rarely becomes involved with the AMEDD. Because virtually all of the biologic products being developed by the AMEDD are vaccines and serums being prepared for human administration rather than release into the environment, it is unlikely that any of these might be an environmental threat. The EPA is heavily involved in monitoring the military's development of pesticides, but these activities are normally not pursued by the AMEDD. Only in those rare instances when the AMEDD is developing a new pesticide for use on humans do the EPA and the USAMRDC interact.

24.4.2 Application for Licensure. The FDA approval process for licensure of biological products is considerably more involved than the NDA submission required for pharmaceuticals. The licensure of vaccines requires the FDA to approve both the product and the site at which it will be manufactured. The FDA will not certify a vaccine unless a site for its manufacture has been approved, nor will they approve a site for an unapproved vaccine. As a consequence, it is mandatory that both applications be submitted concurrently. After the initial approval of a site and vaccine combination, applications to approve additional sites for production of that vaccine will be considered as stand-alone requests.

The required form for site approval is the "Application for Establishment License for Manufacture of Biological Products" (FDA Form 3210), a 9-page form that provides complete detail as to the structure of each room that will be involved in the manufacture, packaging or storing (floor plans, personnel flow, ventilation, pest control, equipment, surfaces, floors, outside areas, etc.) and the procedure that will be followed in all phases of manufacture. Records of the historical performance of the site and the corporation are required as well, including, for example, quality control, accident history, and records maintenance.

To gain approval for licensure of the biologic, an FDA Form 3212 must be completed. This 6-page form, "Application for License for the Manufacture of Bacterial Vaccines and Antigens," provides all of the detailed technical information on the characteristics of the product, the steps in its development, and the complete testing history, which requires at least as much detail as the NDA required for pharmaceuticals.

When licenses are to be issued to an Army facility applications are forwarded to the Human Use Review Office at OTSG for formal transmittal to the FDA. Once again, the FDA has one-hundred eighty days for approval, but may unilaterally extend the evaluation period indefinitely until they are satisfied with the purity, safety, and efficacy of the product.

The FDA also requires that a supplemental application be submitted any time there is a change in the labeling, packaging, marketing, or manufacturing procedure. A new licensure application is required if there is a change in the physical plant producing the biologic. The mandatory requirement for immediate reporting of any untoward or life-threatening incident caused by an investigatory or approved biological product is of paramount importance as well, and must be rigorously adhered to.

24.5 DEVELOPMENT OF MEDICAL DEVICES

Regulatory policies with respect to medical devices are considerably different than for drugs and biologics. The FDA is concerned with any potential safety hazard that a device might cause, and does not approve the manufacture of a device which does not have a demonstrable positive effect on a medical problem. Consequently, all medical devices being developed by the AMEDD must be cleared through the FDA.

Medical devices are divided into three separate classes. Class III devices are the most closely regulated, and include those devices which are primarily life-supporting or life-sustaining (ICU equipment, artificial organs, pacemakers, etc.). Class II devices are closely connected to the human

body, but are not life-essential (catheters, syringes, splints, lenses, etc.). Class I devices are associated with the body only in a peripheral way (litters, aid bags, dental chairs, etc.). The Class III devices are monitored very closely by the FDA, while the others require less attention. This section will discuss regulatory procedures for each of the three classes of medical device.

24.5.1 Class III Medical Devices. The FDA requires that any proponent of a medical device which requires clinical testing to demonstrate its safety and effectiveness must submit an application for an Investigational Device Exemption (IDE). This application has the same thirty day presumption of approval that the IND for pharmaceuticals and biologics has. An approved IDE allows limited production and limited distribution of the device in accordance with the testing protocol included in the application. Because human testing is an integral part of any Class III device development, all of the considerations of informed consent, results of an Institutional Review Board review, and statements of privacy and confidentiality must be provided. If the IDE is sponsored by OTSG, the application is submitted to the HURO for presentation to the HSRRB for approval of applicable sections and subsequent forwarding to FDA. Revisions required by the HSRRB must be received by HURO and found to be satisfactory before human testing may be initiated whether or not the FDA thirty day delay requirement has been met.

After the testing is completed and the device is judged to be both safe and effective by the USAMRDC, the preparation of a Premarket Approval (PMA) application can begin. This application provides lengthy detailed descriptions and drawings of the device (to include working samples), details of all test results, manufacturing techniques, quality control procedures, and all of the labeling, packaging, marketing, and storage considerations that had to be shown in the comparable NDA and biologic licensure applications. Here too, the FDA allows itself one-hundred eighty days to render a decision on the PMA, but reserves the right to extend the period indefinitely and request any additional information or testing it requires to demonstrate a reasonable assurance of safety and effectiveness.

Submitted concurrently with the PMA is an Initial Establishment Registration from the proposed manufacturer. While the pairing of the two applications is not as tightly bound as it is in the biologics field (a device may be approved without a suitable manufacturer having been identified), it is still required that both the device and the manufacturer be approved before production can begin.

As an alternative to the IDE/PMA sequence, a Class III device product manager may consider working directly with the FDA through a Product Development Protocol (PDP). In this process, the AMEDD consults the FDA at the beginning of the development process and the protocol for testing and development are worked out jointly. If the FDA accepts the PDP as an appropriate approach and the AMEDD follows the protocol as agreed, the FDA may declare the completed PDP to be equivalent to an approved PMA. This option is only applicable to Class III devices, and can only be pursued with the express consent and cooperation of the FDA.

24.5.2 Class I and II Medical Devices. The regulatory supervision of medical devices which are not life-sustaining or life-supporting, and which require no human testing, is limited. At present, there are two potential requirements which should be noted.

The manufacturer of a medical device which is coming on the market must submit a 510K Premarket Device and Notification to the FDA, who will evaluate the description of the device to determine whether or not it is substantially equivalent to other devices already on the market. Although the AMEDD does not intend to market its products commercially, the regulation controlling manufacture is applicable. As a consequence, the AMEDD should work with the FDA in preparing Requests for Proposal for the manufacture of Class I and II items to ensure that the successful bidder is obligated to meet the FDA reporting requirements. Any products which are manufactured by DOD facilities for use only within the DOD community would be subject to this requirement.

The second potential requirement is a set of regulations called Performance Standards Requirements, which are applicable to all classes of Medical Devices. Congress legislated that all medical devices would be required to meet certain standards before they could be marketed. However, the standards themselves have not yet been written, so the requirement is without force at this time. If and when performance standards are established, the AMEDD should incorporate manufacturer compliance with these standards into all of its medical materiel acquisition activities.

24.6 REFERENCES

Title 21, Code of Federal Regulations Food and Drug Administration

Memorandum of Understanding Between the DoD and the Food and Drug Administration, Subject: Investigational Use of Drugs by the Department of Defense, 1974

Memorandum of Understanding Between the USAMRDC and the Food and Drug Administration, Subject: Quality Assurance Support for Medical Materiel Having Military Application, 1984

AR 40-7, Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances, 1975 w/Ch 1 1980

AR 40-38, Clinical Investigation Program, 1984

OTSG Regulation 15-2, Boards, Commissions and Committees: HSRRB, 1986

USAMRDC Memo 10-1, Organization and Functions, 1985

CHAPTER 25

THE PHARMACEUTICAL PRODUCT DEVELOPMENT PROCESS

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25.1 PURPOSE

This chapter provides a summary description of the pharmaceutical product acquisition process and the functions that are carried out by the Army Medical Department (AMEDD) materiel acquisition community.

The focus of the chapter is on those events and documents that are unique to the pharmaceutical product acquisition programs. This focus is designed to ensure that all AMEDD materiel acquisition personnel will understand the nature of the pharmaceutical product acquisition process and how it relates to the materiel acquisition processes. Additional information concerning pharmaceutical products is presented in Chapter 2, Medical Materiel Acquisition Program Participants; Chapter 5, Development Program; Chapter 19, The Configuration Management Process; Chapter 23, Joint Service Coordination; and Chapter 24, Regulatory Interfaces.

25.2 GENERAL

25.2.1 Pharmaceutical Products. These are non-biological products that include:

- Drugs and antidotes;
- Drug related delivery systems such as the autoinjectors, medicated wound dressing, and transdermal patches;
- Decontamination products such as resins, barrier creams, and antipenetrants that are fielded as preventative, protective, or therapeutic modalities for certain diseases, combat casualties, and chemical warfare agents.

25.2.2 Management of Pharmaceutical Products. Initial efficacy and safety screening in support of pharmaceutical product development is conducted by one of the U.S. Army Medical Research and Development Command (USAMRDC) laboratories. The research may be accomplished in-house or by a contractor. At program initiation (Milestone 0), program management responsibility is transitioned to the U.S. Army Medical Materiel Development Activity (USAMMDA). The

project manager may establish an Ad Hoc Working Group to review the results of pre-clinical and clinical studies and to present a summary of those studies with recommendations to the IPRs.

The USAMMDA Project Manager (PM) for Pharmaceutical Systems is responsible for the development and initial production of pharmaceutical products. Following the Milestone III production decision and receipt of the Food and Drug Administration (FDA) approval of the New Drug Application (NDA); product management transitions to the U.S. Army Medical Materiel Agency, and eventually to the DPSC, for procurement, stockage and distribution of the product.

The pharmaceutical product development process requires the same documentation as materiel systems acquisition programs. Although there may be some variations due to tailoring, it is required that all three types of documentation be prepared for each pharmaceutical product, e.g., requirements documents, program management documents, and decision documents.

25.2.3 Characteristics of Pharmaceutical Programs. Most pharmaceutical projects are non-major In-Process Review (IPR) programs. In addition, many of the projects are also Joint Service programs. This is the result of The Surgeon General (TSG) being charged by DoD with the responsibility as the lead agency for research and development in the area of defense against infectious diseases and combat dental research, and as the executive agent for chemical and biological warfare defense. Figure 25-1 summarizes the pharmaceutical product development process activities.

25.3 MILESTONES

25.3.1 Milestone 0 (Program Initiation). At this point an Operational and Organizational Plan has been prepared and approved. The Medical Systems Review Committee has determined that the technical effort has progressed to the point where the project can be transferred to USAMMDA for 6.3B (system advanced development) funding.

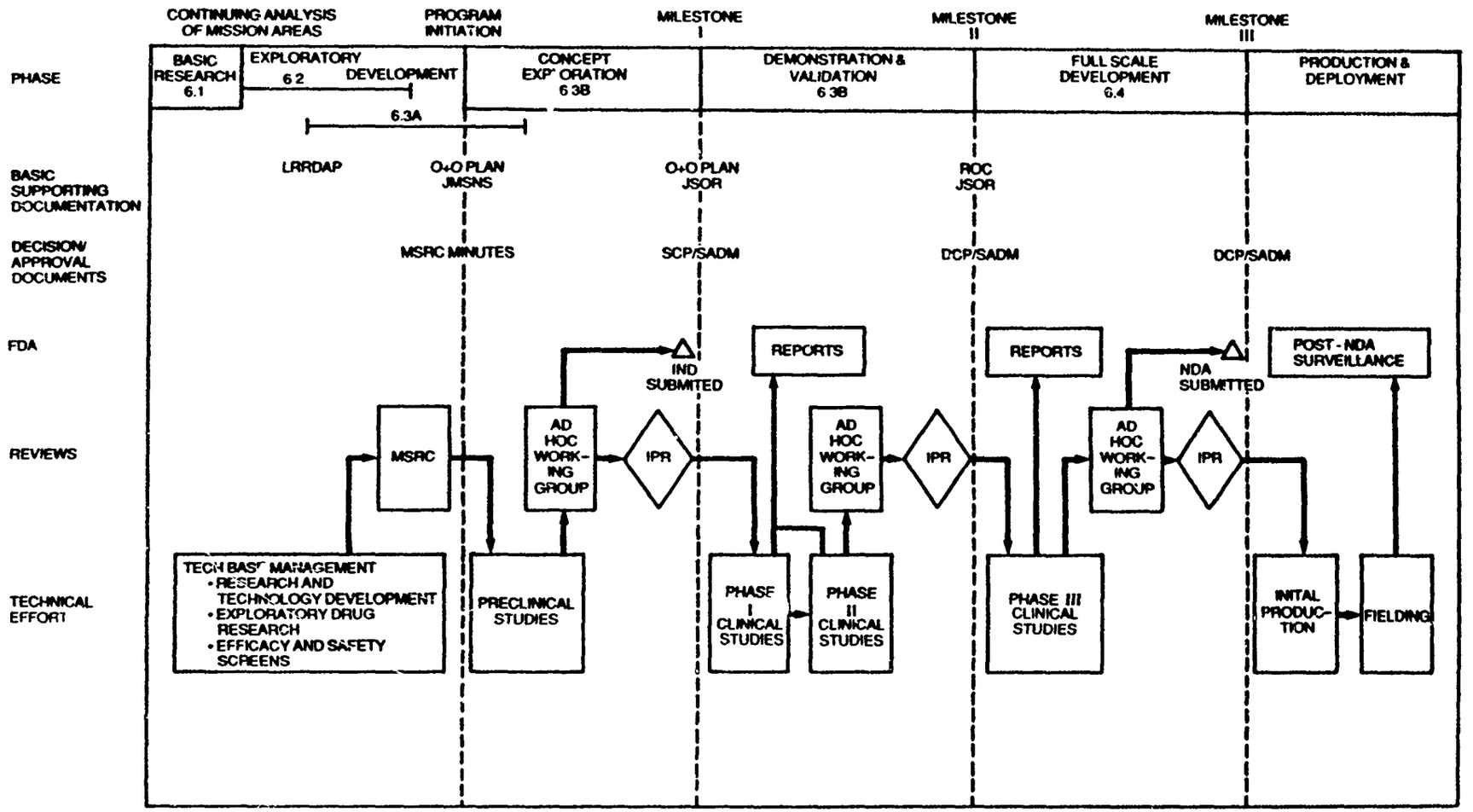


Figure 25-1 The Pharmaceutical Development Process

25.3.2 Milestone I (Concept Approval). This is a management review of the program. It is preceeded with a review by a technical Ad Hoc Working Group (USAMRDC, USAMMDA, Laboratory, Contractor, etc.) to prepare for the Milestone I review. The Milestone I review confirms that a requirement still exists, that the product is safe and effective in animals, that preparations for clinical studies have been initiated, and that the Investigational New Drug (IND) application has been prepared and submitted to the FDA.

25.3.3 Milestone II (Program Go-Ahead). This is the transition point for funding -- from 6.3B (System Level Advanced Development) to 6.4 (Engineering Development). The AHWG meets to prepare for the Milestone II review. The review of subsequent animal and initial human data confirms that the product is safe and effective and that the program warrants the expenditure of additional funds.

25.3.4 Milestone III (Production Go-Ahead). This review is the production decision point and is also preceeded by an AHWG meeting. It confirms that the New Drug Application has been prepared for submission to the FDA. If, because of costs or other reasons, the decision is not to produce the product, it may be kept as an IND program pending further investigations.

25.4 REQUIREMENTS DOCUMENTS

25.4.1 Initial Operational and Organizational Plan. Although procedures prescribed for the preparation and staffing of pharmaceutical product Operational and Organization (O&O) Plans are as described in Chapter 3, an exception is that the initial plan may not address a specific pharmaceutical product requirement. Rather, the O&O Plan may address a broad requirement, such as a program for defense against infectious diseases. In this case, the plan identifies a range of infectious diseases of military medical importance. The solutions may be pharmaceutical or biological products or hardware. They may also be prophylactic or therapeutic solutions. Prioritization of the threat (diseases) provides program direction for 6.1 and 6.2 funding.

25.4.2. Review and Update O&O Plan. The generic O&O Plan described above discusses the requirement for a program to defeat the threat of infectious diseases of military importance. One of these diseases is malaria. If the project focuses on malaria, the O&O Plan is updated to confirm that safer and more effective drugs are required for the prevention and/or treatment of soldiers operating in malaria endemic areas. Based on the updated O&O Plan, USAMMDA plans to synthesize, or otherwise obtain, new compounds, test the compounds, perform preclinical studies on the most promising compounds emerging from tests, and prepare the Notice of Claimed Investigational Exemption for a New Drug (IND) for the FDA.

25.4.3. Joint Services Operational Requirement. If one or more of the other Services have expressed an interest in the project, as is generally the case, a Joint Services Operational Requirement (JSOR) will be prepared at Milestone I instead of updating the O&O Plan.

25.4.4. Required Operational Capability. The Required Operational Capability (ROC) is prepared for the Milestone II and/or III decision reviews (the JSOR is updated in the case of joint programs). These documents identify the specific product under development. For example, in the treatment of malaria, the ROC/JSOR identifies the selected drug "mefloquine" as the therapeutic and prophylactic agent to replace chloroquine and to be used by U.S. military forces deployed in areas where the chloroquine - resistant strains are endemic.

See Chapter 11, The Requirements Document Process for details.

25.5 TEST AND EVALUATION

The Test Integration Working Group (TIWG) is established and chaired by USAMMDA. The TIWG normally assists in the preparation of the Test and Evaluation Master Plan (TEMP). The Investigation New Drug (IND) (prepared for the FDA) describes all past testing for product safety, purity and efficacy as well as all future test and evaluation plans. Test results and test plans as stated in the IND are of sufficient detail to support most of the requirements

of the TEMP. However, if there are user test or other Army test requirements, these will have to be included in the TEMP. For example, products that must be worn and/or applied by the individual soldier, may require user testing. Plans for these tests are described in the TEMP and will be reviewed at each Milestone. However, they are not generally concerns of the FDA.

Chapter 24, Regulatory Interfaces discusses the IND requirements, and the clinical investigations review and monitoring roles of USAMRDC, OTSG, and the FDA. Chapter 24 also discusses the New Drug Application (NDA) submission required at the time of Milestone III for production approval. The NDA provides a full report on the clinical investigations.

25.6 INTEGRATED LOGISTICS SUPPORT

Of the Army's eleven Integrated Logistics Support (ILS) elements; one, Supply Support, and Packaging, Handling and Storage, is generally the most applicable to pharmaceutical products. Of concern are shelf life and stability of deteriorative items, storage requirements, storage locations, and packaging requirements. The pharmaceutical product ILS plan addresses these factors, as well as any others that are relevant to the particular product. It also shows how the product will be supported with currently available techniques, staffing, and logistics. Other ILS elements that may be applicable to pharmaceutical products and included in the ILSP are Training and Training Support and Manpower and Personnel.

25.7 TRAINING

Pharmaceutical products may be administered by medical personnel; as such there is generally no soldier/product interface and no special training is required for non-medical U.S. troops. The exceptions are self administered products and products that are carried and maintained by the troops or are part of sets, kits, and outfits that are carried and used by non-medical personnel. In these cases, training requirements may be Army-wide, involving basic Army training, branch training, and/or unit training. The Individual and Collective Training Plan (ICTP) is extensively coordinated with HQ TRADOC and the TRADOC schools, as well as with FORSCOM and the Army MACOMs.

25.8 PRODUCTION

The Decision Authority's production approval at the Milestone Review and the FDA acceptance of the NDA are both required before the item can be produced. The Defense Personnel Support Center (DPSC) receives the essential characteristics of the product from USAMMA, through the Defense Medical Standardization Board (DMSB). DPSC then solicits for manufacturing the quantities required by the Army and any other interested Services. Production quantities are a function of shelf life and storage requirements. Therefore, it is unlikely that a manufacturer would produce more than what a Service requires for its immediate needs and wartime reserve.

25.9 POST-PRODUCTION MONITORING

The FDA requires the NDA holder to monitor the use of the product in order to determine if any adverse reactions have occurred with its use. USAMMA is the central reporting agency for adverse drug reactions in the Army and forwards these reports to appropriate organizations (FDA, NDA Holder, etc.).

25.10 REFERENCES

AR 40-7, Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances, 1975

AR 40-38, Clinical Investigation program, 1984

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

Title 21, Code of Federal Regulation, U.S. Dept. of Health and Human Services, Food and Drug Administration

Memorandum of Understanding between USAMRDC and FDA, 1984.

CHAPTER 26

THE BIOLOGICAL PRODUCT DEVELOPMENT PROCESS

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26.1 PURPOSE

This chapter provides a summary description of the biological product acquisition process and the functions that are carried out by the Army Medical Department (AMEDD) materiel acquisition community.

The focus of this chapter is on those events and documents that are unique to the biological product acquisition programs. This is intended to ensure that all personnel involved in the AMEDD materiel acquisition process will understand the nature of the biological product acquisition process and how it relates to the materiel acquisition process.

Additional information concerning the acquisition of biological products is presented in the following chapters of this handbook:

- Chapter 2, Medical Materiel Acquisition Program Participants
- Chapter 5, Development Program
- Chapter 19, The Configuration Management Process
- Chapter 22, Joint Service Coordination
- Chapter 24, Regulatory Interfaces

26.2 GENERAL

26.2.1 Biological Products. "Biology" is defined as the science of living organisms and life processes including the study of structure, functioning, growth, origin, evolution, and distribution of living organisms.[1] "Biological" is of or pertaining to biology. "Biological products" means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.[2]

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1. The American Heritage Dictionary, Second College Edition,
2. Public Health Service Act, Section 351

26.2.2 Management of Biological Product Development Programs. Biological product research is managed by one of the U.S. Army Medical Research and Development Command (USAMRDC) laboratories. The research may be accomplished in-house or by a contractor. At program initiation (Milestone 0), program management responsibility is transferred to the U.S. Army Medical Materiel Development Activity (USAMMDA). The project manager may establish an Ad Hoc Working Group to review the results of pre-clinical and clinical studies and to present a summary of those studies with recommendations to the IPRs.

The USAMMDA Project Manager (PM) for Biological Systems is responsible for the development and initial production of biological products. Following the Milestone III production decision and receipt of the Food and Drug Administration (FDA) approval of the Licensure Application, the U.S. Army Medical Materiel Agency assumes product management responsibilities for procurement, storage and distribution of the product.

The biological product development process requires the same documentation as materiel systems acquisition programs. Although there will be variations due to the nature of the product and the required regulatory interfaces, it is necessary that all three types of documentation be prepared for each biological product, e.g. requirements documents, program management documents, and decision documents.

26.2.3 Characteristics of Biological Project Programs. Most biological project programs are non-major In-Process Review (IPR) programs. In addition, all are Joint Service programs because The Surgeon General is charged by DOD with the responsibility (lead agency) for research and development in the areas of defense against infections diseases and combat dentistry, and as the executive agent for chemical and biological warfare defense.

26.3 BIOLOGICAL PRODUCT PROGRAM MILESTONES

SEE FIGURE 26-1

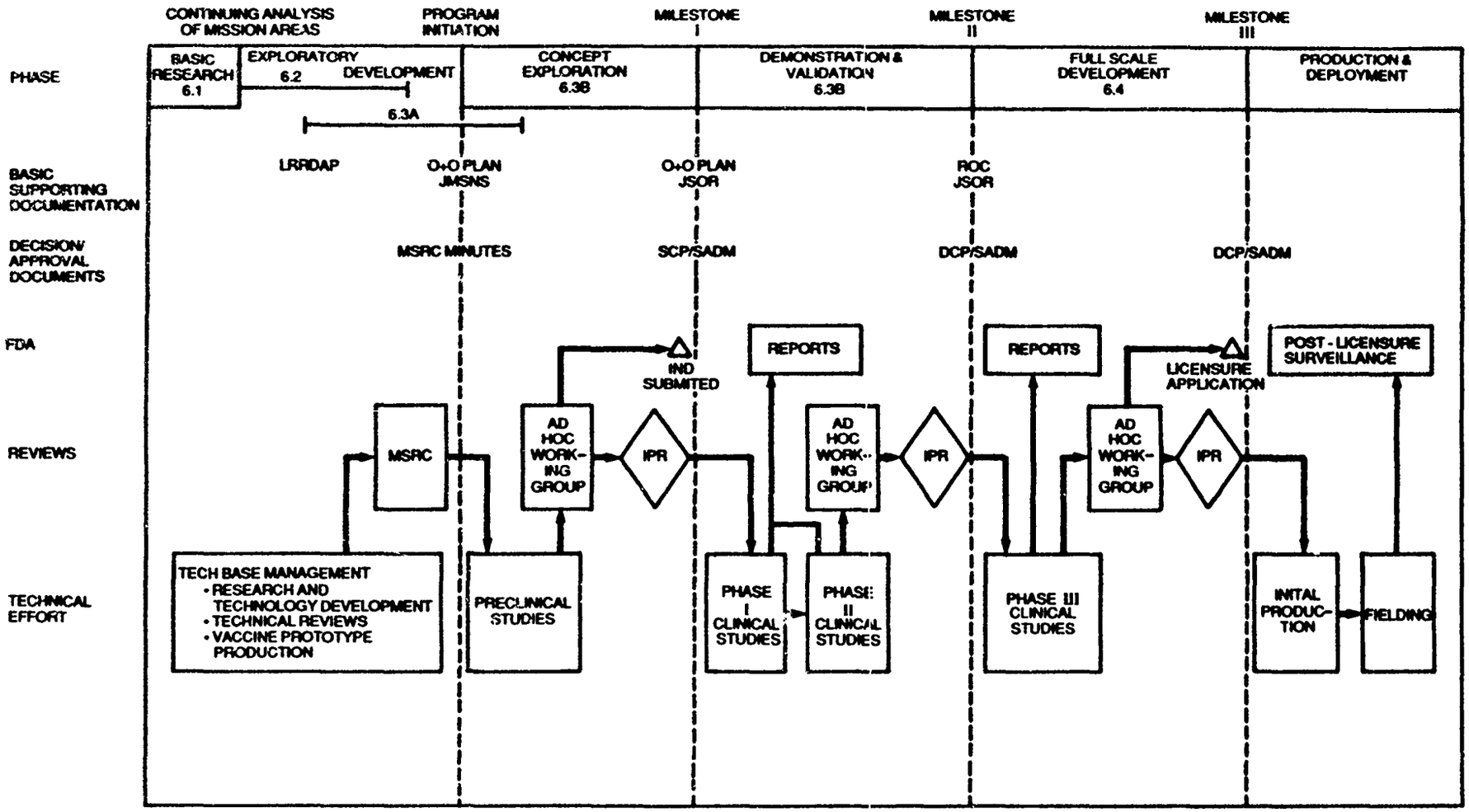


Figure 26-1 The Biological Product Development Process

26.3.1 Milestone 0 (Program Initiation). This is the point at which the Operational and Organizational Plan is approved, the project transitions to USAMMDA, and system advanced development funding (6.3B) commences.

26.3.2 Milestone I (Concept Approval). This is a management review of the program to confirm that a requirement still exists; that a market investigation has been conducted; that the product is safe and effective in animal models; that preparations for clinical studies have been initiated; and that the Investigational New Drug (IND) application to the FDA has been prepared.

26.3.3 Milestone II (Program Go-Ahead). This is the transition point for funding -- from 6.3B (System Advanced Development) to 6.4 (Engineering Development). The review should confirm that the product is safe and effective; that Phase I and II clinical investigations have been completed; and that the program warrants the expenditure of additional funds. A licensure or non-licensure decision is made at this point contingent on the establishment of the proof of efficacy during Phase III clinical testing.

26.3.4 Milestone III (Production Go-Ahead). This review is the decision point for production or the decision not to produce (because of cost or other factors), but keep it active as an IND program. The review also confirms that the Licensure Application, when required, has been prepared for submission to the FDA. The FDA must approve both the product and the site for its manufacture before production can be initiated.

> NOTE:
>
> The production contract cannot be competed -- the product can only be manufactured by the licensed producer and at the licensed facility.

26.4 REQUIREMENTS DOCUMENTS

26.4.1 The Initial Operational and Organizational Plan. The Initial Operational and Organizational (O&O) Plan is prepared by AHS and USAMMDA and approved by HQ TRADOC prior to program initiation. The procedures for the preparation and staffing of the O&O Plan are the same as those described in Chapter 3, Pre-Program Initiation. However, the O&O Plan for biological products may address a broad program rather than a specific product. In fact, the results of the research and development tasks initiated by the O&O Plan may be a biological and/or a pharmaceutical product. (See Chapter 25. The Pharmaceutical Product Acquisition Process.)

26.4.2 Review and Update O&O Plan. During the Concept Exploration (CE) Phase, USAMMDA and AHS review and update the O&O Plan which, for example, may confirm the need for safer and more effective prevention and treatment of a specific disease or injury. For Nondevelopment Item programs, AHS prepares a Required Operational Capability and the program transfers to USAMMA.

26.4.3 Milestone II (Program Go-Ahead). This is the transition point for funding -- from 6.3B (System Level Advanced Development) to 6.4 (Engineering Development). The AHWG meets to prepare for the Milestone II review. The review of subsequent animal and initial human data confirms that the product is safe and effective and that the program warrants the expenditure of additional funds.

26.4.4 Required Operational Capability. The Required Operational Capability (ROC) is prepared and approved by USAMMDA and AHS for IPR Programs and by HQDA for Designated Acquisition Programs. For more information, see Chapter 11, The Requirements Document Process.

26.5 TEST AND EVALUATION

The Test Integration Working Group (TIWG) may be established during the CE Phase. It is chaired by USAMMDA. The TIWG normally assists in the preparation of the Test and Evaluation Master Plan (TEMP). The IND (prepared for the FDA) describes all past testing for product safety, purity and efficacy

and summarizes the plans for future tests and evaluation. Test reports and test plans are so detailed that the TEMP may only need to be a cover letter to the approved human use protocol. In the unlikely event that user or other Army tests are required, they must also be described in the TEMP.

Preclinical or nonclinical tests (non-human subjects) are initiated during the Concept Exploration Phase and may continue during D&V and FSD phases. Clinical (human) tests can be initiated 30 days after FDA acknowledgement of receipt of the IND and human use approval has been granted. Phase I and Phase II clinical studies (where possible) are conducted during the Demonstration and Validation Phase. They test for safety and for laboratory efficacy, respectively. Following the Milestone II program go-ahead decision, the Class III Field Trials are conducted. The three phases of clinical tests are reported on in the licensure application.

Chapter 24, Regulatory Interfaces discusses the IND requirements, and the clinical investigations review and monitoring roles of USAMRDC, OTSG, and the FDA. Chapter 24 also discusses the License Application required at the time of Milestone III for production approval. The application provides a full report on the clinical investigations.

26.6 INTEGRATED LOGISTICS SUPPORT

Of the Army's eleven Integrated Logistics Support (ILS) elements, Supply Support, and Packaging, Handling and Storage are generally the most applicable to biological products. Of concern are shelf life and stability of deteriorative items, storage requirements, storage locations and responsibilities, and packaging requirements. The biological product ILS plan addresses these factors, as well as any others that are relevant to the particular product. It also shows how the product will be supported with currently available techniques, staffing, and logistics.

26.7 TRAINING

Generally, biological products are administered by medical personnel; therefore, there is no soldier/product interface, and no special training is required for U.S. troops.

26.8 PRODUCTION

The Decision Authority's (generally the Commander, USAMRDC) production approval and the FDA approval of the licensure are both required before the item can be produced. The Defense Personnel Support Center (DPSC) receives the essential characteristics of the product from USAMMA, through the Defense Medical Standardization Board (DMSB). DPSC then solicits the approved firm for manufacturing the quantities required by the Army and any other interested Services. Production quantities are a function of shelf life and storage requirements. It is possible that the manufacturer may produce a large quantity of the item with the intent to deliver the Service's immediate needs and store the remainder in a controlled environment at one or more sites for later issue and emergency requirements. This course of action can have four benefits: 1) lower unit costs; 2) availability of a large supply in case of mobilization or other emergency; 3) solution of the production leadtime problem; and; 4) substantially increase the acceptable shelf life, thereby decreasing maintenance costs.

Generally, biological products are produced under contract to U.S. or foreign companies, although the Army has the capability to produce small quantities at the Walter Reed Army Institute of Research, Forest Glen Section.

The FDA also requires that a supplemental application be submitted any time there is a change in the labeling, packaging, marketing, manufacturing procedure. A change in the physical plant producing the biologic requires a complete new license. The mandatory requirement for immediate reporting of any untoward or life-threatening incident caused by an investigatory or approved biological product is of paramount importance as well, and must be rigorously adhered to.

26.9 POST-PRODUCTION MONTIORING

The FDA requires the license holder to monitor the use of the product in order to determine if any adverse reactions have occurred relative to its use. USAMMA is the central reporting agency for adverse biological product reactions in the Army and forwards these reports to appropriate organizations (FDA, License Holder, etc.).

26.10 REFERENCES

AR 40-38, Clinical Investigation Program, 1984

AR 40-60, Policies and Procedures for the Acquisition of Medical Materiel, 1983

Title 21, Code of Federal Regulations, U.S. Dept. of Health and Human Services, Food and Drug Administration

Memorandum of Understanding between USAMRDC and the FDA, 1984

ABCA COUNTRIES - America, Britain, Canada, and Australia and, associated through Australia, New Zealand.

ABBREVIATED ANALYSIS - a documented investigation of the comparative effectiveness of alternative means of meeting a requirement. Prepared for In-Process Review programs.

ACQUISITION - the process consisting of planning, designing, producing and distributing system/equipment.

ACQUISITION PLAN - is derived from the Acquisition Strategy and summarizes acquisition background and need, objectives, conditions, strategy, and related functional planning (with emphasis on contractual aspects). It provides detailed planning for contracts and milestone charting.

ACQUISITION PLANNING - is the formulation of methods to bring together disciplines necessary to determine, develop, or otherwise obtain and sustain systems/equipment of requisite quality in support of requirements on time and at a fair price.

ACQUISITION PROGRAM - a defined effort funded by RDT&E and/or procurement appropriations with the express objective of providing a new or improved capability in response to a stated mission need or deficiency.

ACQUISITION STRATEGY - the conceptual framework for conducting materiel acquisition, encompassing the broad concepts and objectives which direct and control the overall development, production, and deployment of a materiel system. It evolves in parallel with the system's maturation. Acquisition strategy must be stable enough to provide continuity, but dynamic enough to accommodate change. It is documented as an annex to the DCP at Milestone I.

ACQUISITION TEAM - the Acquisition Team encompasses all functional organizations involved in the acquisition process (materiel developer, combat developer, independent evaluators, testers, logistician, doctrinaire, trainer, user, and contractor. The Acquisition Team is established early in the acquisition program, during development of the O&O Plan, to assist the materiel developer in planning the Acquisition Strategy. The Acquisition Team continues to function throughout the acquisition process and culminates after materiel fielding.

AD-HOC WORKING GROUP - a technical body established by the PM to review the results of pre-clinical and clinical studies and to present a summary of those studies along with recommendations to the IPR.

ADVANCED DEVELOPMENT (6.3) - a funding category including all projects which have moved into the development of hardware for development or operational test.

AFFORDABILITY - function of cost, priority, and availability of fiscal and manpower resources.

ANNUAL APPROPRIATION - an appropriation which is available for incurring obligations only during one fiscal year.

APPORTIONMENT - a determination as to the amount of obligations which may be incurred during a specific period.

APPROPRIATION - an authorization to incur obligation for specified purposes and to make payments out of the treasury.

APPROVAL AUTHORITY - the level of guidance and decision authority designated for approval of IPR actions (appointment of IPR chairman, approval of the AMEDD position prior to an IPR, and approval of the IPR results).

ARMY ACQUISITION EXECUTIVE - the principal adviser and staff assistant to the Secretary of the Army for acquisition of Army systems; responsible for overall management of research, development, and acquisition programs; the Assistant Secretary of the Army (Research, Development, and Acquisition) responsible for overall management of RDA programs.

ARMY ACQUISITION OBJECTIVE - quantity of an item authorized for peace time acquisition to equip the US Army approved force and specified allies in peacetime and sustain these forces in wartime from D-Day through the period, and at the level of, support prescribed by the latest OSD materiel support planning guidance.

ARMY MANAGEMENT MILESTONE SYSTEM - is the Department of the Army standard integrated life cycle management milestone reporting system and central data repository for recording system status in the acquisition cycle through fielding.

ARMY SYSTEM ACQUISITION REVIEW COUNCIL - top level DA corporate body for systems acquisition that provides advice and assistance to the Secretary of the Army. Covers DOD major programs and DAPs. (AR 15-14)

AUTHORIZATION - legislation enacted by the Congress which approves a program but does not usually provide budget authority.

AVAILABILITY - measure of the degree to which an item is in operable and committable state at the start of the mission, when the mission is called for at an unknown (random) point in time.

BANDS OF PERFORMANCE - a costing ceiling and performance floor that describes a performance characteristic of a system. The cost ceiling is the most cost and operationally effective capability that the materiel developer can achieve without going over the highest acceptable cost. The performance floor is the least operational capability that the user will accept.

BASELINE COST ESTIMATE - a life cycle cost document prepared by the materiel developer; detailed estimate of acquisition and ownership normally required for high level decisions; provides the basis for subsequent tracking and auditing.

COMMONALITY - materiel or systems that are interchangeable. Each can be used or operated and maintained by personnel trained on the other system without more specialized training. Also, repair parts and components can be interchanged and applied to consumable items without adjustment.

COMMUNICATIONS SECURITY - protection resulting from measures taken to do either of the following: deny unauthorized persons information related to national security that might be derived from telecommunications, or insure the authenticity of such telecommunications.

COMPUTER RESOURCE MANAGEMENT PLAN - the primary program management document that describes the development, acquisition, test, and support plans for computer resources integral to, or used in, direct support of Army materiel systems.

CONCEPT EVALUATION PROGRAM - innovative tests are tests conducted with command controlled funds, personnel and equipment to provide information on the operational feasibility of a concept or system.

CONCEPT FORMULATION PACKAGE - the documentary evidence that the concept formulation effort has satisfied the objectives. Normally consists of the TOD, TOA, BTA, and CEA.

CONFIGURATION MANAGEMENT PLAN - defines Government and bidder or contractor interaction and schedules procedures for conducting the configuration management program.

CONTINUING APPROPRIATION - appropriate funds which remain available for obligation and expenditure until the projects are completed and/or the funds are expended.

CONTINUING RESOLUTION - an authorization by the Congress establishing rates of expenditure, on a short-term basis, when passage of an appropriation is delayed past the beginning of the fiscal year.

CONTINUOUS EVALUATION - defined as that process which provides the continuous flow of information regarding system status to include planning, testing, data compilation, analysis, evaluation, conclusions, and reporting to all members of the Acquisition Team from the drafting of the initial Operational and Organizational (O&O) Plan through deployment reviews and assessment. CE will be performed by all members of the Acquisition Team.

COST AND OPERATIONAL EFFECTIVENESS ANALYSIS - a documented investigation of comparative effectiveness of alternative means of eliminating or reducing a force or mission deficiency against the defined threat and the cost of developing, producing, distributing, and sustaining each alternative system in a military environment for a time preceding the combat application. Also, a documented investigation of a valid requirement that HQ TRADOC and HQDA have approved. See Abbreviated Analysis.

COST AND TRAINING EFFECTIVENESS ANALYSIS - a methodology which involves documented investigation of the comparative effectiveness and costs of alternative training systems for attaining defined performance objectives, taking into

BASIS OF ISSUE PLAN - a planning document that lists certain TOE (level), TDA, CTA, JTA, and AOP in which a new item will be placed, the number of items to be included in each organizational element, and other equipment and personnel changes needed because of the new item. BOIP is not an authorization document.

BATTLEFIELD DEVELOPMENT PLAN - the summary of the various Mission Area Analysis. It integrates deficiencies identified by specific requirements and presents them to HQDA.

BATTLEFIELD INTEGRATION - the act or process of harmonizing separate materiel systems and personnel resources into a cohesive battlefield system, configured to maximize total system capabilities.

BEST TECHNICAL APPROACH - an element of the Concept Formulation Package which identifies the best technical approach(es).

BRASSBOARD - an experimental device used to determine feasibility and to develop technical and operational data, sufficiently hardened for use outside the laboratory for use in demonstrating the technical and operational principles of immediate interest.

BREADBOARD - an experimental device used to determine feasibility and to develop technical data, normally only configured for laboratory use to demonstrate the technical principles of immediate interest.

BREAK-EVEN ANALYSIS - analysis of proposed procurement and facilitization to compare potential cost of establishing a second source (facilities, educational buy, TDP, and rights cost) with potential savings due to competitive pressure from the second source.

BUDGET - a planned program for a fiscal period in terms of estimated costs, obligations, expenditures, source of funds for financing, reimbursements anticipated and other resources to be applied.

CATALOG OF APPROVED REQUIREMENTS DOCUMENTS - a DA catalog of approved requirements which provides current information on approved requirements documents to combat developers and the research and development communities.

CLINICAL STUDIES - successive phases of human testing of a particular lot(s) of a biological or pharmaceutical product subsequent to the IND approval and prior to the NDA submission.

COMBAT DEVELOPER - command or agency that formulates doctrine, concepts, organization, materiel requirements, and objectives. Represents the user community in the materiel acquisition process.

COMMERCIAL PRODUCTS OR ITEMS - products or items in regular production sold in substantial quantities to the general public and industry at established market or catalog prices.

COMMERCIAL TRAINING DEVICE REQUIREMENT - initiates acquisition or modification of training devices that are commercially available without expenditure of RDT&E funds.

consideration usage pattern and training scenarios. A CTEA can examine training concepts, training equipment, training strategies, programs of instruction, training implications of new materiel, organizations, tactics, employment techniques, or families of systems. CTEA is used in conjunction with the COEA or AA.

COST BASELINE - a validated and formally approved listing of aggregate program costs that reflects all Program Directive Document (PDD) delineated efforts. The cost baseline is a part of the Program Management Control System (PMCS) documentation.

COST EFFECTIVENESS ANALYSIS - may be a Cost and Operational Effectiveness Analysis for a DAP, or an AA for an IPR program.

COST ESTIMATE CONTROL DATA CENTER - the official point of registration and control for cost submissions, which is located within the cost analysis activity at each major subordinate command, established to review and validate cost estimates and data before release to higher headquarters.

COST PERFORMANCE REPORT - a monthly contractor report on major acquisition contracts providing status and projections of contract costs, along with explanations of significant variances and problems.

COST/SCHEDULE CONTROL SYSTEMS CRITERIA - the set of standards (criteria) used to determine the adequacy of a contractor's cost/schedule control system and the manner which it is used.

DATA EXCHANGE AGREEMENT - provides for cooperative research and development with exchange of technical and scientific information of mutual interest to the participating nations.

DATA PROCESSING INSTALLATION - facility, room, or building housing ADP equipment or storage media. Does not include areas associated with auxiliary power or output processing unless they are co-located with the DPI.

DECISION AUTHORITY - organizational level approval authority following Milestone reviews.

DECISION COORDINATING PAPER - a decision paper that gives the reason for starting, continuing, reorienting, or stopping a development program at each critical decision point during the acquisition process.

DEFENSE ACQUISITION EXECUTIVE - the principal adviser and staff assistant to the SECDEF and the focal point in OSD for system acquisitions.

DEFENSE GUIDANCE - provides Secretary of Defense guidance to the DOD Components for the preparation of their Program Objectives Memorandum.

DEFENSE MISSION - the mission of the DOD as specified by the legislative authority.

DEFENSE RESOURCES BOARD - established to supervise the OSD review of the DOD Components' POM and budget submissions and manage the program and budget review process.

DEFENSE SYSTEMS ACQUISITION REVIEW COUNCIL - an advisory group established by, and functioning for, the SECDEF, to apprise the SECDEF of the program status and readiness of each DOD major defense system to proceed to the next phase in the acquisition process. The DSARC consists of members from Office of the Secretary of Defense (OSD) and other Services. It reviews major programs at milestone decision points. [Replaced by the Joint Requirements and Management Board, June 1986].

DEPARTMENT OF DEFENSE MAJOR PROGRAM - a program which the Secretary of Defense designates as requiring his review and approval at decision points. Selection is based on resource requirements, complexity, interservice requirements, and Congressional interest.

DEPARTMENT OF THE ARMY LOGISTICS SUPPOkT OFFICER - the DA Logistics Support Officer (DALSO) is an individual in the Office of the Deputy Chief of Staff for Logistics who represents the ILS interests of the materiel and combat developers. The DALSO also monitors programs to ensure that all elements of ILS are scheduled and completed.

DEPARTMENT OF THE ARMY MODIFICATION WORK ORDER - the authorization and instruction document controlling installation of a modification to fielded equipment.

DEPARTMENT OF THE ARMY PERSONNEL SYSTEM STAFF OFFICER - the Personnel System Officer (PERSSO) is the HQDA focal point for all manpower, personnel, and training issues associated with new system development and fielding.

DEPARTMENT OF THE ARMY SYSTEM COORDINATOR - the individual designated by the DCSRDA to function as the HQDA point of contact for all aspects of system development and acquisition. Coordinates the status of all events in the acquisition process for DOD Major Systems, DAPs, IPR programs or one or more similar or related IPR programs selected for DASC management.

DESIGN-TO-COST - a management concept wherein rigorous cost goals are set during development. The control of system costs (acquisition, operations and support) to these goals is achieved by practical trade-offs between operational capability, performance, costs, and schedules. Addressed on a continual basis as part of a system's development and production process.

DESIGN-TO-COST GOAL - a specific cost established as a goal for a specific configuration, established performance characteristics, and a specific number of systems at a defined production rate.

DESIGN-TO-UNIT PRODUCTION COST - contractual provision which is the anticipated unit production price to be paid by the Government for recurring production costs, based on a stated production quantity, rate, and time frame.

DESIGNATED ACQUISITION PROGRAM - a program designated by the AAE for ASARC milestone review. Selection is based on resource requirements, complexity and Congressional interest.

DETAILED TEST PLAN - a set of explicit instructions for affecting every phase of the test, particularly test control, data collection, and analysis.

DOCTRINE - the fundamental principles by which the military force, or elements, guide their actions to support national objectives. It is authoritative but requires judgement in application.

DOD COMPONENTS - the Military Departments, the Defense agencies, the organization of the JCS, and the OSD, and activities administratively supported by OSD.

ENGINEERING CHANGE PROPOSAL - proposal to change design or engineering features of materiel under development or production. Includes proposed engineering change and documentation by which the change is described and suggested.

ENGINEERING DEVELOPMENT (6.4) - an RDTE funding category including those development programs being engineered for service use, but which have not yet been approved for procurement or operations.

ENVIRONMENTAL ASSESSMENT/ENVIRONMENTAL IMPACT STATEMENT - EA contains an estimate of whether or not a proposed system will adversely affect the environment or be environmentally controversial in which case an EIS is prepared.

EXPLORATORY DEVELOPMENT (6.2) - an RDTE funding category including effort toward the solution of specific military problems, from fundamental research to prototype study.

EXTENDED PLANNING ANNEX - a document providing program guidance for an additional ten years beyond the PPG.

FAILURE MODE EFFECTS AND CRITICALITY ANALYSIS - narrative description of probable effects of failure for each failure mode. Included is criticality of the failure; for example, completely inoperable in some modes, or operable at a degraded level of performance.

FIRST ARTICLE - INITIAL PRODUCTION TESTS - a test of the first or one of the first produced items or groups of items being procured, conducted to verify the adequacy and quality of the materiel when produced according to production drawings and the mass production process.

FIRST UNIT EQUIPPED DATE - the scheduled date a system or end item and its agreed upon support elements are issued to the designated initial operational capability unit and training specified in the new equipment training plan has been accomplished.

FISCAL GUIDANCE - the annual guidance issued by the SECDEF which provides the fiscal constraints that must be observed by the DOD Components in the formulation of force structures and FYDP and by the OSD in reviewing proposed programs.

FIVE-YEAR DEFENSE PROGRAM - the publication that records, summarizes, and displays the decisions that have been approved by the SECDEF as constituting the DOD program.

FOLLOW-ON TEST AND EVALUATION - test and evaluation conducted subsequent to the full production decision to obtain information lacking from earlier initial operational test and evaluation.

FORCE - units with their inherent doctrine, organization, personnel, materiel, and structure to carry out a specific mission, area of operation, scenario, or strategy. A force can be conceptual, planned, programed, or actual.

FORCE ANALYSIS - the determination, within projected resource constraints, of the most effective mix of units (including weapons) to carry out Army missions and functions. It involves a total Army force structure of Army components and major force categories (such as division forces). It addresses the full spectrum of time considered by the Defense Planning, Programing, and Budgeting System. Therefore, both programed and conceptual forces are considered.

FORCE DEVELOPMENT - the integration of allocated and projected Army resources into a time phased program to develop a force that is properly organized, equipped, trained, and supported to carry out the Army missions and functions worldwide. This includes force planning, programing, analysis, structuring, combat, and training developments.

FORCE DEVELOPMENT TEST AND EXPERIMENTATION - user tests that range from a small, highly instrumented and high resolution field experiment to a large, less instrumented, low resolution, controlled scenario field test. Test data are evaluated largely by using subjective rather than analytical techniques. Tests are conducted to evaluate new concepts of tactics, doctrine, organization, and new forms of materiel.

FORCE INTEGRATION STAFF OFFICER - an individual assigned to ODCSOPS to serve as the HQDA user representative for a specific system. The FISO provides continuous coordination necessary for integration of a new system into the Army force structure.

FORCE MANAGEMENT - the control of resources employed by the Army for force development. It includes force planning and programing.

FORCE PLANNING - the development of defense policies and military strategy to attain national security objectives and to determine the force objectives, capabilities, and resources to carry out the Army roles and missions. Force planning is generally related to the development of the Army Mobilization and Operations Planning System.

FORCE PROGRAMING - the translation of OSD planning and programing guidance into a comprehensive and detailed allocation of forces, manpower, and fiscal resources for a 5-year period. Program developments are published each year in the POM. It presents to OSD the Army's proposal for a balanced allocation of its resources within certain constraints.

FORCE STRUCTURING - the composition of a force, by number and types of TOE units and organizations, within given guidance. The unit and organizations prescribed by competent authority are used.

FORMAL IPR - a review convened when a formal life cycle or other major decision is required for nonmajor systems/items.

FUNCTIONAL PURCHASE DESCRIPTION - describes the minimum essential physical, functional, and other characteristics necessary to meet the stated requirement; what, if any, production testing must be performed; quality assurance, delivery schedule, logistic and maintenance support provisions, training support, technical manual and training materiel needs, and special conditions as appropriate.

GOOD LABORATORY PRACTICE - a set of standards applicable to nonclinical studies. They are concerned with ensuring the safety and accuracy of those studies. Applications to the FDA require certification that GLP are being followed.

GOOD MANUFACTURING PRACTICE - a set of standards concerned with production and manufacturing procedures. They establish criteria for product consistency and quality control. Applications to the FDA must certify that GMP are being followed.

HEALTH HAZARD ASSESSMENT - is the application of biomedical knowledge and principles to identify, evaluate, and control the risks to the health and effectiveness of personnel who test, use, or service Army systems.

HUMAN FACTOR ENGINEERING ANALYSIS - an analysis, performed in support of acquisition milestone reviews, to identify any problems in MANPRINT (human factors engineering, manpower, personnel, training, system safety, and health hazards) which may be sufficiently critical to preclude the system's preceeding into the next phase of the acquisition process. A secondary objective is to identify MANPRINT concerns which, while not critical in terms of program decisions, are resolvable, and must be addressed during the subsequent phase of the acquisition cycle.

IN-PROCESS REVIEW PROGRAM - Army acquisition programs other than DOD major or Designated Acquisition Programs.

INDEPENDENT COST ANALYSIS - an analysis of program cost estimates conducted by an impartial body disassociated from the management of the program.

INDEPENDENT COST ESTIMATES - any cost estimate developed in organizational channels separate and independent from program proponency channels and having the express purpose of serving as an analytical tool to validate or cross-check cost estimates developed in proponency channels.

INDEPENDENT EVALUATION - a continuing process used by the technical and user independent evaluators to independently determine if the system satisfies the approved requirements. It will render an assessment of data from all sources, simulation and modeling; and an engineering or operational analysis to evaluate the adequacy and capability of the system.

INDEPENDENT EVALUATION REPORT - provides a written report on the independent evaluation.

INDEPENDENT PARAMETRIC COST ESTIMATES - a highly aggregated, output related (physical and/or performance parameter), system life-cycle cost estimate accomplished outside of the functional control of the program proponents

INDEPENDENT RESEARCH AND DEVELOPMENT - a contractor's cost that is not sponsored by DOD/DA, or required in the performance of a DOD contract or grant, IR&D consists of projects in basic research, applied research, development and other concept formulation studies.

INDIVIDUAL AND COLLECTIVE TRAINING PLAN - the plan that identifies the training concept, strategy, and requirements for the system from initial qualification through sustainment and follow-on training for all MOS and at all levels.

INFORMAL IPR - an informal review which may be convened by the materiel developer at his discretion or when requested by a member, to review project status and determine an appropriate course of action when a formal decision is not required.

INITIAL PRODUCTION FACILITIES - type of provision of industrial facilities that provide production facilities necessary to support low-rate initial production of systems, end items or components.

INSTITUTIONAL REVIEW BOARD - a local board that approves clinical protocols by an institution or investigate affiliated with an institution. Must meet FDA requirements and must review ongoing clinical investigations at least annually.

INTEGRATED LOGISTICS SUPPORT - a composite of all support considerations necessary to assure the effective and economical support of a system at all levels of maintenance for its programed life cycle.

INTEGRATED LOGISTIC SUPPORT PLAN - provides a composite of all support considerations necessary to assure the effective and economical support of a system for its life cycle and serves as the source document for summary and consolidated information required in other documents of the program management documentation.

INTEGRATED PROGRAM SUMMARY - summarizes, in greater detail than the DCP, various facets of the implementation plan for a system acquisition as required by the decision authority.

INTEGRATED SYSTEM SUPPORT - considerations of logistics support aspects for a system in the context of that system's role in the force structure. Emphasizes interactive relationships such as standardization, interoperability, and resource implications (such as manpower, POL, storage, and training sites of fielding the new system.

INTERNATIONAL STANDARDIZATION AND INTEROPERABILITY PLAN - insures that equipment, procedures and documentation to be used by forces overseas are standardized or at least interoperable with equipment, procedures, and documentation of our allies.

INTEROPERABILITY - the ability of systems, units, or forces to provide services to, and accept services from, other systems, units, or forces and to use these services to enable them to operate effectively together.

INVESTIGATIONAL DEVICE EXEMPTION - these applications to FDA required to conduct clinical studies for medical devices which may pose a health risk to patients.

INVESTIGATIONAL NEW DRUG - term applied to a drug for which a "Notice of Claimed Investigational Exemption for a New Drug" has been submitted. FDA approval permits the start of clinical tests.

ISSUE PAPERS - OSD documents defining issues raised as a result of the analysis of the annual POM submittal prepared to assist the SECDEF in making his program decisions.

JOINT REQUIREMENTS AND MANAGEMENT BOARD - see DSARC

JOINT SERVICE OPERATIONAL REQUIREMENT - a statement of need for the same end item for use by the Army and at least one other military service. Army proposed JSORs usually are directed by higher authority and are prepared and processed following ROC procedures and format as much as possible.

JOINT WORKING GROUP - the JWG is composed of representatives for the combat and materiel developers and appropriate subject matter experts. The primary purpose of the JWG is to provide a forum for direct communication facilitating the coordination of requirements documents. The JWG is initiated and chaired by the combat developer in coordination with the materiel developer.

JUSTIFICATION FOR MAJOR SYSTEM NEW START - the requirements document required for all acquisitions that meet the criteria established in DODD 5000.1 (200M in RDT&E funds, $1B in procurement funds). The JMSNS is the program initiation document for DOD major systems.

LEAD SERVICE - the DOD service designated by the SECDEF to be responsible for management of a system acquisition involving two or more DOD services in a joint program.

LICENSURE - FDA's approval for the manufacture of biological products is required. The facility to be licensed must pass an inspection prior to licensure.

LIFE CYCLE COST - approach to costing that considers all costs incurred during the projected life of the system, subsystem, or component being evaluated. Includes cost to develop, procure, operate, and maintain and dispose the system.

LIFE CYCLE COST ACTIVITIES - there are five activities: development, production, military construction, fielding and sustainment. The first four are limited to the appropriations of RDTEA, Procurement, MILCON and OMA. The last (sustainment) contains procurement, MPA and OMA appropriations.

LIFE CYCLE COST CATEGORIES - there are three categories: research and development, investment, and operating and support.

LIMITED PRODUCTION - the initial, low rate production of a system in limited quantity to be used in operational test and evaluation for verification of production engineering and design maturity and to establish a production base prior to a decision to proceed with production.

LINE ITEM NUMBER - six character alpha numeric identification of the generic nomenclature assigned to identify nonexpendable and Type Classified expendable and durable items of equipment during their life cycle authorization and supply management.

LOGISTIC SUPPORT ANALYSIS RECORD - file of logistic support information in standardized format, on acquisition programs for specific new or modified systems and equipments. Serves acquisition process using logistic data derived during all phases of the process to support logistic support analysis processes. (See MIL-STD 1388-2A).

LOGISTICIAN - a command/agency other than the materiel developer, combat developer, trainer, or user representative responsible for independent logistic surveillance and evaluation of materiel acquisition programs.

LOGISTICS ANNEX - a brief description of the logistics considerations essential to program planning and decisions at Milestone reviews.

LOGISTICS SUPPORT ANALYSIS - an analytical technique used by integrated logistic support management to provide a continuous dialogue between designers and logisticians. LSA provides a system to identify, define, analyze, quantify, and process logistics support requirements for materiel acquisition programs. (See MIL-STD 1388-1A).

LONG RANGE PERIOD - usually eleven to twenty years into the future.

LONG RANGE RESEARCH, DEVELOPMENT AND ACQUISITION PLAN (LRRDAP) - the DA Long-Range RDA Plan (LRRDAP) displays R&D programs in support of requirements identified by MAAs and summarized in the Battlefield Development Plan. It portrays programs over a fifteen-year period, displays RDT&E programs that support procurement, is fully compatible with the PPBES, reflects a six-year prioritization, and is the starting point for RDA program building.

LOW COST PROGRAM - an acquisition program with an estimated RDT&E cost of less than $6 million and a production cost of less than $12 million in any one year or $50 million total RDT&E and procurement over any five-year period.

LOW RATE INITIAL PRODUCTION - a term describing a low rate of output at the beginning of production to reduce the Government's exposure to large retrofit programs and costs while still providing adequate numbers of hard tooled production items for final development and operational test prior to full production decisions.

MAINTAINABILITY - ability of an item to be retained in or restored to specified condition when maintenance is performed by personnel having specified skill levels, using prescribed procedures and resources, at each prescribed level of maintenance and repair.

MAJOR MILESTONES - a point in time at which a recommendation is made and approval sought from higher authority regarding initiation/continuation of a program.

MAJOR SYSTEM ACQUISITION - a system acquisition program designated by the SECDEF to be of such importance and priority as to require special management attention.

MANPOWER - the personnel strength as expressed in terms of the number of men and women available to, or required by, the Army.

MANPOWER AND PERSONNEL INTEGRATION (MANPRINT) - a comprehensive technical effort to support system effectiveness by integrating into the materiel development and acquisition process all relevant information concerning human factors engineering, manpower, personnel, training, system safety, and health hazards.

MANUFACTURING METHODS AND TECHNOLOGY - serves to develop and improve, or expand manufacturing technology by improving manufacturing processes, techniques, and equipment to provide for timely, reliable, economic, and high quality production of required materiel.

MARKET ANALYSIS - a broad term that includes the market surveillance and market investigation process.

MARKET INVESTIGATION - process of gathering specific product information to support NDI, MOD-NDI, development decisions generally done during CE Phase.

MARKET SURVEILLANCE - continuous process of gathering information and keeping abreast of technological progress in military and civilian communities, in U.S. and overseas.

MATERIEL DEVELOPER - the command or agency responsible for research, development, and production validation of a system (including the system for its wholesale level logistics support) which responds to HQDA-approved materiel requirements.

MATERIEL FIELDING AGREEMENT - that the PM will deliver the system and its support and that the user will be prepared for its receipt may be part of the Materiel Fielding Plan.

MATERIEL FIELDING PLAN - a document containing detailed information to allow a field unit to order supplies including authorized stockage list (ASL), prescribed load lost (PLL) repair parts, basic ordering agreement (BOA) parts, routing identifier code (RIC), project code, warranty provisions, equipment publication (EP), basic issue items, weapon system code, and special tool data.

MATERIEL RELEASE - the authority to issue materiel to the user.

MATERIEL REQUIREMENTS DOCUMENT - states concisely the minimum essential operational, technical, logistical, and cost information necessary to initiate development or procurement of a materiel system.

MATERIEL REQUIREMENTS LIST - a line-by-line list of all materiel (end item/system, associated support items of equipment, etc.) that will be supplied as a total package by the fielding command to the gaining MACOM under the Total Package/Unit Materiel Fielding (TP/UMF) concept.

MATERIEL SYSTEM - an item, system, or all systems or materiel. This includes all required system support elements.

MATERIEL TRANSFER PLAN - central document used for support and fielding planning for designated displaced systems.

MEDICAL SYSTEMS REVIEW COMMITTEE - a technical body convened at least semi-annually to make early identification, assessment, and prioritization of timing for transitioning technology base items to development (Program Initiation - Milestone 0). It provides the basis of integrating, structuring and defining workloads and actions required to support timely Program Initiation decisions.

MEMORANDUM OF UNDERSTANDING - a formal agreement on terms and schedules.

MID-RANGE PERIOD - normally the eight years after the budget year.

MILITARY ADAPTATION OF COMMERCIAL ITEMS - a funding category used to procure, modify, and test commercial items in order to develop requirements and/or satisfy approved requirements.

MILITARY OCCUPATIONAL SPECIALTY - a term used to identify a grouping of duty positions possessing such close occupational or functional relationships that an optimal degree of interchangeability among persons so classified exists at any given skill level.

MISSION AREA - a segment of the defense mission such as Combat Service Support, Fire Support, and Air Defense.

MISSION AREA ANALYSIS - an assessment of the capability of a force to perform within a particular battlefield or functional area. The analysis is designed to discover deficiencies in doctrine, organizations, training, and materiel,

and to identify means of correcting these deficiencies; stressing first doctrinal solutions, then training solutions, then organizational solutions, and finally, materiel solutions. MAA also provides a basis for applying advanced technology to future Army operations.

MISSION AREA DEVELOPMENT PLAN - transitions the MAA corrective actions to specific projects with milestone schedules so that resources can be applied to the elimination of the MAA deficiency. Each mission area proponent (TRADOC school) publishes a MADP annually. MADP contains sections on materiel, doctrinal, organizational, and training corrective actions.

MISSON AREA MATERIEL PLAN - a systematic, prioritized, long-range research, development, and acquisition strategy for materiel acquisitions identifying solutions to the deficiencies identified in the Battlefield Development Plan. Prepared annually by the materiel developer.

MISSION ASSIGNEE - an agency responsible for materiel management of items within specific Federal Supply Classification classes.

MISSION SUPPORT PLAN - a statement by the gaining MACOM that identifies how they plan to logistically support a new item/system.

NONCOMBAT DEVELOPMENT ITEM - a new item, developed or procured, in response to a DA approved materiel requirement document. It is not intended to be used in a theater of operations or to control civil disturbances.

NEW DRUG APPLICATION - the NDA is submitted to the FDA. It contains all of the information the sponsor knows about the drug. The FDA review determines whether the benefits, when used properly, outweigh the risks. The FDA review also considers packaging and labeling. Approval of the NDA authorizes production and distribution of the drug.

NEW EQUIPMENT TRAINING TEAM - a team of experts organized to conduct training of designated units or personnel on the operation and maintenance of new equipment. The NETT provides for the transfer of knowledge gained during development from the MATDEV to the trainer, user, and supporter.

NONDEVELOPMENT ITEM - a generic term describing either a commercial product or an item which has been developed and used by another Service, country, or Government agency.

OPERATION AND MAINTENANCE, ARMY - an annual appropriation that includes operation and maintenance of all Army organizational equipment and facilities and operation of medical activities. See AR 37-1200-XX for detailed descriptions and instructions.

OPERATIONAL AND ORGANIZATIONAL PLAN OR O&O PLAN - the program initiation document in the materiel acquisition process; prepared prior to the ROC or JSOR to support acquisition of new materiel systems until Milestone II.

OPERATIONAL SYSTEM DEVELOPMENT (6.7) - a funding category for R&D effort directed towards development, engineering and test of systems, support programs, vehicles and weapons that have been approved for production and deployment.

OPERATIONAL TEST AND EVALUATION AGENCY - the independent agency responsible to the VCSA for all OT&E.

OPERATIONS SECURITY - protection of military operations and activities resulting from identification and subsequent elimination or control of indicators susceptible to hostile exploitation.

ORGANIZATIONAL INTEGRATOR - the Organizational Integrator (OI) is the Army Staff coordinator for force integration issues. The OI manages the changes to organizations resulting from the introduction of new and improved materiel.

OTHER PROCUREMENT, ARMY - an annual appropriation that provides for

OUTLINE TEST PLAN - the formal document containing administrative information; the test purpose, objective, scope, tactical context, resource requirements, and cost estimates. Once approved by DA, the OTP becomes a tasking document.

PERSONNEL - a term used to describe the characteristics of an individual soldier (as opposed to a manpower space). Personnel includes consideration of MOS, specialty code, and grade.

PHASE I CLINICAL STUDIES - the first phase of human testing. It is directed at determining the safe dose range, how it is absorbed into the body and possible levels of toxicity. Test usually involve twenty to eighty healthy volunteers.

PHASE II CLINICAL STUDIES - the second phase of human testing is performed on closely monitored patients to learn about the safety and effectiveness of the product. Seldom use more than 200 patients.

PHASE III CLINICAL STUDIES - this is the most extensive testing of humans. Phase III studies are intended to ascertain with precision the products safety, effectiveness, and most desirable dosage for treatment or prevention of a specific disease.

PHYSICAL CONFIGURATION AUDIT - formal examination of the "as-built" configuration of a unit of a configuration item against its technical documentation in order to establish the item's initial product configuration identification.

PILOT PRODUCTION - the controlled manufacture of limited numbers of an item for service T&E purposes, using manufacturing drawings and specifications which have been developed for quantity production and with tooling that is representative of that to be used in unlimited production.

PLANNING, PROGRAMING, BUDGETING, AND EXECUTION SYSTEM - an integrated system for the establishment, maintenance and revision of the FYDP and the DOD budget.

PRECLINICAL STUDIES - non-human testing of a particular lot of a biological or pharmaceutical product, eventually intended for human administration.

PREMARKET APPROVAL - submitted to the FDA to obtain the license to produce a given Glass III medical device by a specific manufacturer.

PREPLANNED PRODUCT IMPROVEMENTS - planned future evolutionary improvement of developmental systems for which design considerations are effected during development to enhance future application of projected technology. Include improvements planned for ongoing systems that go beyond the current performance envelope to achieve a needed operational capability.

PREPRODUCTION PROTOTYPES - those engineering development prototypes manufactured for TT&E and OT&E prior to full production.

PRODUCT ASSURANCE PLAN - implements a product assurance program including reliability, availability and maintainability (RAM), quality hardware and software and system assessment to ensure user satisfaction, mission and operational effectiveness and performance to specified requirements.

PRODUCT BASELINE - initial approved or conditionally approved product configuration identification.

PRODUCT IMPROVEMENT - effort to incorporate a configuration change involving engineering and testing effort on end items and depot repairable components, or changes on other than developmental items to increase system or combat effectiveness or extend the useful military life.

PRODUCT IMPROVEMENT PROPOSAL - a reconfiguration of an end item of Army or multiservice materiel type-classified standard that is funded, managed, and completed as a single project. The term "PIP" is applied to the project from its start as a proposal through its completion. A PIP is initially constituted in the form of a PIP package and its status is periodically reported on Product Improvement Information Reports (PRIMIRs).

PRODUCIBILITY ENGINEERING AND PLANNING - applies to those RDT&E funded planning and system production engineering tasks undertaken by the materiel developer on major or nonmajor end items or components to insure a smooth transition from development into production. PEP, a System Engineering approach, assures that an item can be produced in the required quantities and in the specified time frame, efficiently and economically, and will meet necessary performance objectives within its design and specification constraints. As an essential part of all engineering design, it is intended to identify potential manufacturing problems and suggest design and production changes or schedule trade-offs which would facilitate the production process.

PRODUCT MANAGER - individual designated and chartered by a MATDEV, delegated authority and assigned responsibility for centralizing the management of an acquisition program that does not qualify for system, program, or project management.

PRODUCTION READINESS PLAN - addresses availability of critical materials, Government investment in production facilities, ways to increase competition in production, industrial preparedness planning, production risks and action necessary to reduce such risks, production readiness review milestones, engineering support to overcome problems and reduce costs, and minimum sustaining rate.

PRODUCTION READINESS REVIEW - a formal, documented, systematic examination of a program to determine if the system design is ready for production, production engineering problems have been identified and solutions are in progress, quality assurance and acceptance test procedures are adequate, and the Army and producer have accomplished adequate planning for the production phase.

PROGRAM AND BUDGET GUIDANCE - a HQDA document to major Army commands providing resource data.

PROGRAM BUDGET DECISION - provides the SECDEF's decisions on the budgets submitted by the DOD Components.

PROGRAM DECISION MEMORANDUM - a document which provides decisions of the SECDEF on POMs and the JPAM.

PROGRAM DIRECTIVE - provides a clear definition of the DA-approved program which is consistent with the approved acquisition strategy, funded program requirements and the Army's budget. The PD is a document of the Program Management Control System (PMCS).

PROGRAM DEVELOPMENT INCREMENT PACKAGE - covers the five program years and helps build the Army program. The PDIP helps the decision making process accommodate either decreases or increases to the TDA and manpower levels. It also provides discrete, executable levels that can be readily extrapolated to unit equipping.

PROGRAM ELEMENT - the basic building block of the FYDP, which is a description of the mission to be undertaken and a collection of the organizational entities to perform the mission.

PROGRAM ELEMENT DESCRIPTIVE SUMMARY - a backup document for an RDT&E program element as submitted to the Congress in the annual budget submittal.

PROGRAM MANAGEMENT CONTROL SYSTEM - consists of a single integrated automated data management system to control selected programs and their costs.

PROGRAM MANAGEMENT DOCUMENT - a document that contains records of program decisions and requirements. It provides analyses of technical options and the life cycle plans for developing, producing, training, and supporting materiel items.

PROGRAM OBJECTIVES MEMORANDUM - a document submitted to the SECDEF by the heads of the DOD Components which recommends the total resource requirements within the parameters of the SECDEF fiscal guidance.

PROGRAM/PROJECT/PRODUCT MANAGER - an individual chartered to conduct business of behalf of the Army who reports to the Materiel Developer or to the commander of a subordinate organization as designated by the Materiel Developer, and is assigned the responsibility and delegated the full-line authority of the Materiel Developer for the centralized management of a specified acquisition program.

PROGRAM/PROJECT/PRODUCT MANAGER CHARTER - a document stating the PM's responsibility, authority, and accountability in the management of a major system acquisition program.

PROPONENT - an organization or staff which has been assigned primary responsibility for materiel or subject matter in its area of interest.

PROVISIONS OF INDUSTRIAL FACILITIES - part of the Production Base Support Program that provides for initial production facilities, modernization, expansions, and support of production facilities.

QUALITATIVE AND QUANTITATIVE PERSONNEL REQUIREMENTS INFORMATION - a compilation of specified organizational, doctrinal, training, and personnel information developed by the materiel developer and combat developer for new or modified materiel items.

QUALITY ASSURANCE - function of management that assures that newly procured materiel conforms to the stated quality, performance, safety, and reliability standards of the TDP and contract performance specifications.

RATIONALIZATION, STANDARDIZATION, AND INTEROPERABILITY - action that increases effectiveness of alliance forces through more efficient or effective use of committed Defense resources.

RDT&E ACTIVITIES - consists of all efforts funded from the RDT&E appropriation regardless of program category or PE.

RECLAMA - a formal restatement and presentation of budget requirements in further justification of that portion of the requirements that the reviewing authorities have reduced or deleted.

RECOUPMENT - estimated cost savings from prior year programs used to finance current programs.

RELIABILITY, AVAILABILITY, AND MAINTAINABILITY - RAM requirements are those imposed on materiel systems to insure that they are operationally ready for use when needed, will successfully perform assigned functions, and can be economically operated and maintained within the scope of logistics concepts and policies. RAM programs are applicable to materiel systems, test measurement and diagnostic equipment (TMDE), training devices and facilities developed, produced, maintained, procured or modified for Army use. Reliability is the duration or probability of failure free performance under stated conditions. Availability is a measure of the degree to which an item is in operable and committable state at the start of the mission. Maintainability is

the ability of an item to be retained in or restored to specified condition when maintenance is performed by personnel having specified skill levels, using prescribed procedures and resources, at each prescribed level of maintenance and repair.

REPROGRAMMING - the transfer of funds between programs of an appropriation.

REQUIRED OPERATIONAL CAPABILITY - the primary requirements document which concisely states the minimum essential operational, technical, logistic, and cost information necessary to initiate Full Scale Development or Procurement of a materiel system. Normally prepared for Milestone II.

RESEARCH (6.1) - scientific study and experimentation directed toward increasing knowledge and understanding in those fields directly related to explicitly stated long-term national security needs.

RESEARCH AND DEVELOPMENT PLANNING SUMMARY (DD FORM 1634) - a document to provide information to the USDRE for R&D program planning review.

RESEARCH AND TECHNOLOGY WORK UNIT SUMMARY (DD FORM 1498) - a document to provide technical and management data for ongoing research and technology.

SAFETY RELEASE - documents the safety precautions to be taken by the operational tester to avoid system damage and personal injury based on developmental testing and/or a Safety Assessment report.

SECRETARY OF DEFENSE DECISION MEMORANDUM - documents each SECDEF decision, establishes program goals and thresholds, reaffirms established needs and program objectives, authorizes exceptions to acquisition policy and provides direction and guidance for the next phase of the acquisition cycle.

SELECTED ACQUISITION REPORT - a document prepared for the SECDEF by a DOD component which summarizes current estimates of technical, schedule, and cost performance in comparison with the original plans and current program.

SHORT RANGE TIME PERIOD - normally covers the current and budget years.

SOLDIER-MACHINE INTERFACE - consideration through system analysis and psychophysiology of equipment design and operational concepts to insure they are compatible with the capabilities and limitations of operators and maintenance personnel. Also referred to as soldier-materiel interface and soldier-machine interaction. See MANPRINT.

SOURCE SELECTION - the process wherein the requirements, facts, recommendations and Government policy relevant to an award decision in a competitive procurement of a system/project are examined and the decision made.

SPECIAL IPR - a formal IPR directed by HQDA or the appropriate approval authority to consider issues needing resolution or decision and not necessarily related to a particular development milestone. Special IPRs are normally used for making recommendations pertaining to such things as type classification of nondevelopment items (NDIs).

SPECIAL STUDY GROUP - group chartered by the CBTDEV and normally composed of representatives of HQDA, CBTDEV, operational tester, MATDEV, logistician trainer and PM designee, convened during Requirements/Technology Base Activity phase to conduct analysis, insure inclusion of all alternatives within an analysis, monitor experimentation, or undertake other such tasks that may require concentration of special expertise for a short duration. Normally chaired by a CBTDEV representative. MATDEV representative on the SSG develops the AS.

SPECIFIED COMMAND - a command which has a broad continuing mission and which is established and so designated by the President through the SECDEF with the advice and assistance of the JCS. It is normally composed of forces from one service.

STANDARDIZATION - the process by which various defense forces achieve the closest practicable cooperation and the most efficient use of research, development, and production resources.

STANDARDIZATION PLAN - assures that standardization will be applied in design during the development, as appropriate, to reduce cost of production and operational support.

STATEMENT OF NEED CLOTHING AND INDIVIDUAL EQUIPMENT - prepared specifically to support development, planning, programing, budgeting and fielding of all clothing (personal, optional, organizational), associated heraldics and individual equipment.

STATUS REPORT - an annual report from the SECDEF to the President highlighting the POMs and issues identified along with status of the resolution of the issues.

STUDY ADVISORY GROUP - an advisory group convened by a study sponsor and composed of representatives of various HQDA organizations, Army Staff agencies, and major army commands having a clear functional interest in the study topic or use of study results.

SYSTEM ACQUISITION DECISION MEMORANDUM - provides the Army decision authority's decision including: approval of goals and thresholds for cost, schedule, performance and supportability; approval of exceptions to the normal acquisition process; and other direction as appropriate.

SYSTEM CONCEPT PAPER - supports the DOD Milestone I decision, documents the results of the Concept Exploration Phase, and provides Acquisition Strategy for the program.

SYSTEM DESIGN CONCEPT - an idea expressed in terms of general performance, capabilities, and characteristics of hardware and software oriented either to operate or to be operated as an integral whole in meeting a mission need.

SYSTEM MANAGER - individual chartered by the Secretary of the Army, assigned responsibility and delegated full-line authority for centralized management of a specified acquisition project.

SYSTEM READINESS OBJECTIVE - measures relating to the effectiveness of an operational unit to meet peacetime and wartime mission requirements considering the unit set of equipage and the potential logistic support assets and resources available to influence the unit's operational readiness and sustainability. Peacetime and wartime SRO will differ due to usage rate, operational modes, and mission profiles and operational environments. Examples of SRO include: operational availability at peacetime usage rates, operational availability at wartime usage rates, sortie generations per given time frame (aircraft), and maximum administrative/logistic downtime (intermittent missions). SRO must relate quantitatively to system design parameters (for example, RAM) and to support resource requirements.

SYSTEM SAFETY PROGRAM PLAN - implements system safety engineering program that will assess the safety of the system and assure that the system meets the user's safety requirements and regulatory standards.

TECHNICAL DATA PACKAGE - a generic term applicable to types of technical data when used for procurement purposes. It is a composite of specifications, plans, drawings, standards, and such other data as may be necessary to describe existing materiel so they may be procured by the method contemplated.

TECHNICAL FEASIBILITY TESTING - testing by the materiel developer to provide test data for a technical evaluation and assessment of items and/or systems developed by another service, a foreign nation or a commercial firm.

TECHNICAL INDEPENDENT EVALUATOR - a command or agency independent of the PM or developing major subordinate command that conducts technical independent evaluations of Army systems.

TECHNICAL TEST(ING) - testing of materiel systems conducted by the materiel developer using the principle of a single, integrated development test cycle to demonstrate that the design risks have been minimized, that the engineering development process is complete, and that the system will meet specifications; and to estimate the system's military utility when it is introduced.

TECHNOLOGY BASE - the Army's science and technology base consisting of Research (6.1), and Exploratory Development (6.2).

TEST AND EVALUATION - the performance of test and the evaluation of test results.

TEST AND EVALUATION MASTER PLAN - a document used in the Army review and decision process to assess the adequacy of the planned testing and evaluation. It is prepared for all defense system acquisition programs. The TEMP is a broad plan that relates test objectives to required system characteristics and critical issues and integrates objectives, responsibilities, resources, and schedules for all T&E to be accomplished.

TEST DESIGN PLAN - a formal document developed by the test organization which states the circumstances under which a test and/or evaluation will be executed, the data required from the test, and the methodology for analyzing test results.

TEST INTEGRATION WORKING GROUP - a formally chartered organization chaired by the materiel developer and having as a minimum membership representatives (with authority to act for their respective commands/ activities) from the combat developer, the logistician, the operational tester, the materiel developer and, when appropriate, the contractor. The primary purpose of the TIWG is to provide a forum for direct communication to facilitate the integration of test requirements and speed up the TEMP coordination process. The objective of the TIWG is to reduce costs by integrating testing to the maximum extent, eliminate redundant testing and facilitate the coordination of test planning, interchange of test data and use of test resources to achieve cost-effective testing.

TEST REPORT - contains the data obtained from executing the test and describes the conditions which prevailed during the test execution and data collection.

TEST SUPPORT PACKAGE - test support packages are provided by the proponent materiel developer and the combat developer/trainer. The proponent materiel developer provides packages consisting of the maintenance support for the item/system and a new equipment training package. The combat developer/trainer provides the following: statement of doctrine and techniques for employment, statement of organization and basis of issue and training plan, statement of logistic support concepts, mission profiles, statement of suitable threat for test and a description of test setting, including terrain and friendly forces situations.

TEST, MEASUREMENT, AND DIAGNOSTIC EQUIPMENT - any system or device used to evaluate the operational condition of a system or equipment to identify or isolate any actual or potential malfunction.

TESTER - the agency responsible for the technical testing (TT) or user testing of materiel. TT is planned, conducted and monitored by the materiel developer. User testing is the responsibility of and is managed by OTEA and/or AHS.

THREAT - as a broad term, the ability of a potential enemy to limit or prevent mission accomplishment or to neutralize or reduce the effectiveness of a current or projected organization or item. The threat to a given U.S. system is a statement of that capability. It is prepared in detail about a specific problem or project to provide support for Army planning and development of concepts, doctrine, and materiel.

TOTAL RISK ASSESSING COST ESTIMATE - expected cost over a specified period of a materiel development program computed on the basis of cost of accomplishing work elements of work breakdown structure, including specific provisions for statistical estimation of probable costs otherwise indeterminate.

TOTAL RISK ASSESSING COST ESTIMATE FOR PRODUCTION - provides the same function for production programs as TRACE (see above) does for RDT&E programs.

TRADE-OFF ANALYSIS - a document prepared by an STF or SSG, or jointly by the combat and materiel developers, to determine which technical approach offered in the TOD is best.

TRADE-OFF DETERMINATION - the document prepared by the materiel developer. It is sent to the combat developer or to an STF or SSG to convey the feasibility of a potential system. Included are technical risks related to each approach, estimated RDTE and procurement costs and schedules.

TRADOC MATERIEL EVALUATION COMMITTEE - established to review all IPR/ ASARC milestone decision review positions or test waivers and OT test issues and criteria.

TRADOC SYSTEM STAFF OFFICER - HQ TRADOC point of contact for assigned materiel systems/projects/programs.

TRADOC SYSTEMS MANAGER - managers appointed by the CG, TRADOC for selected major and nonmajor materiel acquisition programs. They are appointed shortly after the beginning of a program or at about the same time as the AMC Project Manager. The TSM manages all facets of user input and user actions throughout the development, production, and deployment of an assigned system.

TRAINER - the agency that trains personnel to operate and maintain development items or systems.

TRAINING DEVELOPER - the agency that develops the training strategy and requirements for both institutional and unit training.

TRAINING DEVICE - items which simulate or demonstrate the function of equipment or systems such as three dimensional models, mock-ups or exhibits. They are designed, developed, or procured only for training support.

TRAINING DEVICE NEEDS STATEMENT - a document which provides the minimum essential information concerning the role of the proposed training device in an individual or collective training program, and where and how the device will be used.

TRAINING DEVICE REQUIREMENT - system training device requirements are on annex to the ROC. A Non System Training Device Requirement is used for equipments that are not part of a development system.

TRANSPORTABILITY - capability of efficiently and effectively transporting an end item of military equipment, or component, over railways, highways, waterways, ocean, and airways, either by carrier, towed, or by self propulsion.

TRANSPORTABILITY APPROVAL - a statement by the MTMC (the Army transportability agent), that an item of materiel, in its shipping configurations, is transportable by the required mode(s) of transportation.

TRANSPORTABILITY ENGINEERING ANALYSIS - an evaluation of the transportability of a materiel system/item and its components, auxiliary and ancillary equipment. An analysis will summarize its ability to be transported by the required modes of transportation.

TRANSPORTABILITY REPORT - a report submitted by the materiel developer or field unit on transportability problem items. All information necessary for a comprehensive transportability engineering analysis will be included.

TYPE CLASSIFICATION - identifies the life cycle status of a materiel system after a production decision by the assignment of a type classification designation, and records and status of a materiel system in relation to its overall life history as a guide to procurement, authorization, logistic support, and asset and readiness reporting. It is the Army implementation of the OSD designation "accepted for service use."

UNIFIED COMMAND - a command with a broad continuing mission under a single commander and composed of significant assigned components of two or more services, and which is established and so designated by the President, through the SECDEF with the advice and assistance of the JCS.

USER - that command, unit or element which will be the recipient of the production item for use in accomplishing a designated mission.

USER REPRESENTATIVE - the combat developer that acts as the user in the development of materiel.

USER TEST - a generic term which encompasses operation test, force development test and experimentation, and joint tests.

VALUE ENGINEERING - projects and studies designed to seek lowest costs for items and systems consistent with requirements performance and RAM.

WEAPON SYSTEM STAFF MANAGER - acting for the Deputy Chief of Staff of Development, Engineering, and Acquisition and for the Deputy Chief of Staff of Supply, Maintenance, and Transportation after transition, is responsible for the system management functions during the entire acquisition cycle at HQ AMC.

WEAPON SYSTEM SUPPORT OFFICER - responsible for providing functional support to the Weapon System Manager. The WSSO is the single expert at HQ AMC knowledgeable in the details of the assigned weapon system(s) from the standpoint of his functional area.

WORK UNIT - the smallest segment into which research and technology efforts are normally divided for purposes of local administration.

APPENDIX B

ABBREVIATIONS AND ACRONYMS

AA	Abbreviated Analysis
AAE	Army Acquisition Executive
ABOIP	Amended BOIP
AC	Active Component
ACI	Allocated Configuration Identification
ACWP	Actual Cost of Work Performed
ADCSRDA	Assistant Deputy Chief of Staff for Research, Development and Acquisition
ADP	Automatic Data Processing
AG	Army Guidance
AHS	Academy of Health Sciences
AHS-CD	AHS-Combat Developments Directorate
AHWG	Ad Hoc Working Group
ALC	Army Logistics Center
AMC	Army Materiel Command
AMEDD	Army Medical Department
AMIM	Army Modernization Information Memorandum
AMMS	Army Management Milestone System
AMT	Army Modernization Training
AOC	Area of Concentration
AOP	Additive Operational Projects
AP	Acquisition Plan
AQQPRI	Amended QQPRI
ARTEP	Army Training and Evaluation Plan
AS	Acquisition Strategy
ASA	Army Strategic Appraisal/Assistant Secretary of the Army
ASA (RDA)	Assistant Secretary of the Army, Research, Development, and Acquisition
ASARC	Army Systems Acquisition Review Council
ASBREM	Armed Services Biomedical Research and Evaluation Management
ASD (HA)	Assistant Secretary of Defense (Health Affairs)
ASIOE	Associated Support Items of Equipment

ASL	Authorized Stockage List
ATSC	Army Training Support Center
BCE	Baseline Cost Estimate
BCS	Baseline Comparison System
BCWP	Budgeted Cost of Work Performed
BCWS	Budgeted Cost for Work Scheduled
BDP	Battlefield Development Plan
BOIP	Basis of Issue Plan
BOIPFD	Basis of Issue Plan Feeder Data
BTA	Best Technical Approach
BW	Biological Warfare
CAMS	Computer Aided Milestone Scheduling
CARDS	Catalog of Approved Requirements Documents
CBRS	Concepts Based Requirements System
CBTDEV	Combat Developer
CCB	Configuration Control Board
CCDR	Contractor Cost Data Report
CDDP	Consolidated Decision Document Package
CDN	Chemical Data Need
CDR	Critical Design Review
CDS	Congressional Description Summary
CE	Concept Exploration
CEA	Cost Effectiveness Analysis
CEP	Concept Evaluation Program
CES	Cost Estimate Structure
CFP	Concept Formulation Package
CFSR	Contract Funds Status Report
CG	Commanding General
CGMP	Current Good Manufacturing Practice
CI	Configuration Item
CIVR	Configuration Item Verification Review
CM	Configuration Manager
CMP	Configuration Management Plan
CNETP	Consolidated NETP

COA	Comptroller of the Army
COB	Command Operating Budget
COEA	Cost and Operational Effectiveness Analysis
CPI	Cost Performance Index
CPM	Contractor Performance Measurement
CRA	Continuing Resolution Authority
CSA	Chief of Staff Army
CSS	Combat Service Support
CTDR	Commercial Training Device Requirement
CTEA	Cost and Training Effectiveness Analysis
CTU	Consolidated TOE Update
CW	Chemical Warfare
CW/CBD	Chemical Warfare/Chemical Biological Defense
D&V	Demonstration and Validation Phase
DA	Department of the Army
DALSO	Department of the Army Logistic Support Officer
DAMWO	DA Modification Work Order
DAP	Designated Acquisition Program
DAPML	DA Master Priority List
DASC	Department of the Army System Coordinator
DCAS	Defense Contract Administration Service
DCD	Director Combat Development
DCP	Development Concept Paper
DCSCD	Deputy Chief of Staff for Combat Developments
DCSLOG	Deputy Chief of Staff for Logistics
DCSOPS	Deputy Chief of Staff for Operations
DCSPER	Deputy Chief of Staff for Personnel
DCSRDA	Deputy Chief of Staff for Research, Development and Acquisition
DEPMEDS	Deployable Medical Systems
DESCOM	U.S. Army Depot Systems Command
DET	Displaced Equipment Training
DETP	Displaced Equipment Training Plan
DETT	Displaced Equipment Training Team

DG	Defense Guidance
DI	Data Interchange
DIA	Defense Intelligence Agency
DID	Data Item Description
DLA	Defense Logistics Agency
DMSB	Defense Medical Standardization Board
DOD	Department of Defense
DPSC	Defense Personnel Support Center
DRB	Defense Resources Board
DTT	Doctrine and Tactics Training
DTTP	Doctrine and Tactics Training Plan
DTTT	Doctrine and Tactics Training Team
EARA	U.S. Army Equipment Authorizations Review Activity
EC	Essential Characteristics
ECA	Early Comparability Analysis
ECP	Engineering Change Proposal
EHA	U.S. Army Environmental Health Agency
EPA	Extended Planning Annex
EPA	Environmental Protection Agency
FAD	Funding Authorization Document
FAT	First Article Test
FCA	Functional Configuration Audit
FCI	Functional Configuration Item
FDA	Food and Drug Administration
FDT&E	Force Development Test and Experimentation
FISO	Force Integration Staff Officer
FMECA	Failure Modes Effects and Criticality Analysis
FORSCOM	U.S. Army Forces Command
FOT&E	Follow-On Test and Evaluation
FQR	Formal Qualification Review
FSD	Full Scale Development
FUE	First Unit Equipped
FUED	First Unit Equipped Date

FY	Fiscal Year
FYTP	Five Year Test Plan
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practices
GSA	General Services Administration
HAC	House Appropriations Committee
HARDMAN	Hardware vs Manpower
HASC	House Armed Service Committee
HEL	Human Engineering Laboratory
HFE	Human Factors Engineering
HFEA	Human Factors Engineering Analysis
HHA	Health Hazard Assessment
HHAR	Health Hazard Assessment Report
HQ AMC	Headquarters, U.S. Army Materiel Command
HQDA	Headquarters, Department of the Army
HQ TRADOC	Headquarters, U.S. Army Training and Doctrine Command
HQ USAMRDC	Headquarters, U.S. Army Medical Research and Development Command
HSC	U.S. Army Health Services Command
HSRRB	Human Subjects Research Review Board
HURO	Human Use Review Office
ICTP	Individual and Collective Training Plan
ICU	Intensive Care Unit
IDE	Investigational Device Exemptions
IEP	Independent Evaluation Plan
IER	Independent Evaluation Report
IKPT	Instructors and Key Personnel Training
ILS	Integrated Logistic Support
ILSMT	Integrated Logistic Support Management Team
ILSP	Integrated Logistic Support Plan
ILSR	Integrated Logistics Support Review
IND	Investigational New Drug
IOC	Initial Operational Capability
IPR	In-Process Review

IPS	Integrated Program Summary
IRB	Institutional Review Board
IR&D	Independent Research and Development
ISP	Integrated Support Plan
ITP	Individual Training Plan
JCS	Joint Chiefs of Staff
JIEP	Joint Intelligence Estimate for Planning
JIPR	Joint In-Process Review
JMSNS	Justification for Major System New Start
JRMB	Joint Requirements and Management Board
JSA	Joint Service Agreement
JSOR	Joint Services Operational Requirement
JSPD	Joint Strategic Planning Document
JSRG	Joint Service Review Group
JTA	Joint Table of Allowances
JTCG	Joint Technical Coordinating Group
JWG	Joint Working Group
LCC	Life Cycle Cost
LCCE	Life Cycle Cost Estimate
LCSMM	Life Cycle System Management Model
LEA	Logistics Evaluation Agency
LIN	Line Item Number
LOA	Letter of Agreement
LOGC	U.S. Army Logistics Center
LON	Letter of Notification
LR	Letter Requirement
LRIP	Low Rate Initial Production
LRRDAP	Long Range Research, Development and Acquisition Plan
LSA	Logistics Support Analysis
LSAP	Logistic Support Analysis Plan
LSAR	Logistics Support Analysis Record
MAA	Mission Area Analysis
MACOM	Major Army Command
MADP	Mission Area Development Plan
MAMP	Mission Area Materiel Plan

MANPRINT	Manpower and Personnel Integration
MAR	Materiel Requirement
MATDEV	Materiel Developer
MC	Military Construction
MCN	Management Control Number
MDR	Milestone Decision Review
MDRP	Milestone Decision Review Process
MFA	Materiel Fielding Agreement
MFP	Materiel Fielding Plan
MFT	Materiel Fielding Team
MILCON	Military Construction
MOA	Memorandum of Agreement
MOD-NDI	Modified Nondevelopment Item
MOS	Military Occupational Specialty
MOU	Memorandum of Understanding
MP	Mission Profile
MPM	Milestone Planning Meeting
MPT	Manpower, Personnel and Training
MRDC	U.S. Army Medical Research and Development Command
MRSA	U.S. Army Materiel Readiness Support Activity
MS	Milestone
MSKO	Medical Sets, Kits, and Outfits
MSP	Mission Support Plan
MSPR	Medical Systems Program Review
MSRC	Medical System Review Committee
MTMC	Military Traffic Management Command
MTP	Materiel Transfer Plan
MWO	Modification Work Order
MWOFP	MWO Fielding Plan
NDA	New Drug Application
NDI	Nondevelopment Item
NET	New Equipment Training
NETP	New Equipment Training Plan
NETT	New Equipment Training Team

NGB	National Guard Bureau
NIH	National Institutes of Health
NMIBT	New Materiel Introductory Briefing Team
NRC	National Research Council
NSN	National Stock Number
O&M	Operation and Maintenance
O&O Plan	Operational and Organizational Plan
OCONUS	Outside Continental United States
ODCSRDA	Office of Deputy Chief of Staff, Research, Development and Acquisition
ODCSLOG	Office of Deputy Chief of Staff, Logistics
ODCSOPS	Office of Deputy Chief of Staff, Operations
ODCSPER	Office of Deputy Chief of Staff, Personnel
OI	Organizational Integrator
OJCS	Office of the Joint Chiefs of Staff
OMA	Operation and Maintenance Army
OMB	Office of Management and Budget
OMS	Operational Mode Summary
OPA	Other Procurement Army
OSA	Office of the Secretary of the Army
OSD	Office of the Secretary of Defense
OT	Operational Test
OTEA	U.S. Army Operational Test and Evaluation Agency
OTP	Outline Test Plan
OTRS	Operational Test Readiness Statement
OTSG	Office of the Surgeon General
P^3I	Preplanned Product Improvement
P&D	Production and Deployment Phase
PA	Procurement Army
PAED	Program Analysis and Evaluation Directorate
PAT&E	Production Acceptance Test and Evaluation
PBD	Program Budget Decision
PBG	Program and Budget Guidance
PCA	Physical Configuration Audit

PCI	Product Configuration Identification
PDD	Program Directive Document
POI	Program of Instruction
PDIP	Program Decision Increment Package
PBC	Program Budget Committee
PDP	Product Development Protocol
PDR	Preliminary Design Review
PERSSO	Personnel System Staff Officer
PI	Product Improvement
PIP	Product Improvement Proposal
PLL	Prescribed Load List
PM	Program, Project, or Product Manager
PMA	Premarket Approval
PMCS	Program Management Control System
PMD	Program Management Documents
PMO	Program, Project, or Product Management Offices
PMSO	Project Management Support Office (USAMMDA)
PM TRADE	Program Manager, Training Devices
POC	Point of Contact
POM	Program Objectives Memorandum
PPBES	Planning, Programming, Budgeting, and Execution System
PPBS	Planning, Programming and Budgeting System
PR	Preliminary Review
PRIMIR	Product Improvement Management Information Report
QQPRI	Quantitative and Qualitative Personnel Requirements Information
R&D	Research and Development
RAC	Recombinant DNA Advisory Committee
RAD	Research Area Director
RAM	Reliability, Availability, and Maintainability
RC	Reserve Component
RDA	Research, Development, and Acquisition
RDT&E	Research, Development, Test and Evaluation

RFP	Request for Proposal
RLA	Repair Level Analysis
ROC	Required Operational Capability
S&I	Standardization and Interoperability Plan
SA	Secretary of the Army
SAC	Senate Appropriations Committee
SADM	System Acquisition Decision Memorandum
SASC	Senate Armed Services Committee
SCP	System Concept Paper
SDC	Sample Data Collection
SDDM	Secretary of Defense Decision Memorandum
SDR	System Design Review
SELCOM	Select Committee
SESAME	Selected Essential Items Stockage for Availability Method
SI	Standardization and Interoperability
SKO	Sets, Kits and Outfits
SME	Subject Matter Expert
SMMP	System MANPRINT Management Plan
SOW	Statement of Work
SPI	Schedule Performance Index
SRAO	Systems Review and Analysis Office (ODCSRDA)
SRO	System Readiness Objectives
SRR	System Requirements Review
SS	System Safety
SSB	Source Selection Board
SSC-NCR	U.S. Army Soldier Support Center - National Capital Region
SSG	Special Study Group
SSP	System Support Package
ST	Sustained Training
STD-LIN	Standard Line Item Number
STF	Special Task Force
STO	Science and Technology Objective

STOG	Science and Technology Objectives Guide
T&E	Test and Evaluation
TA	Transportability Approval
TAP	The Army Plan
TARP	Tri-Service Aeromedical Research Panel
TC	Type Classification
TC STD	Type Classification Standard
TD	Training Device
TDA	Table of Distribution and Allowances
TDLOA	Training Device Letter of Agreement
TDLR	Training Device Letter Requirement
TDNS	Training Device Need Statement
TDP	Test Design Plan
TDP	Technical Data Package
TDR	Training Device Requirement
TEA	Transportability Engineering Analysis
TEMP	Test and Evaluation Master Plan
TIWG	Test and Integration Working Group
TMDE	Test, Measurement and Diagnostic Equipment
TOA	Trade-off Analysis
TOA	Total Obligation Authority
TOD	Trade-off Determination
TOE	Table of Organization and Equipment
TPTG	Transition Planning and Tracking Group
TR	Test Report
TRADOC	U.S. Army Training and Doctrine Command
TRASANA	TRADOC System Analysis Agency
TRASSO	TRADOC System Staff Officer
TROSCOM	U.S. Army Troop Support Command
TSARC	Test Schedule and Review Committee
TSG	The Surgeon General
TSM	TRADOC System Manager
TSWG	Training Support Working Group
TT	Technical Test

UA	Unit Assemblage
USACTA	U.S. Army Central TMDE Activity
USAFAC	U.S. Army Finance and Accounting Center
USAHSC	U.S. Army Health Services Command
USAMMA	U.S. Army Medical Materiel Agency
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USATRADOC	U.S. Army Training and Doctrine Command
VCSA	Vice Chief of Staff Army
WBS	Work Breakdown Structure
Z-LIN	Development Line Item Number

APPENDIX C

MASTER LIST OF REFERENCES

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