Defense Health Agency

PROCEDURAL INSTRUCTION

NUMBER 6000.02
June 15, 2020

DAD-MEDLOG

SUBJECT: Healthcare Technology Management (HTM) Medical Devices and Equipment (MDE) Requirements Management for Military Medical Treatment Facilities (MTFs)

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Procedural Instruction (DHA-PI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (j), establishes the Defense Health Agency's (DHA) process to manage MDE requirements for MTFs and other lines of business (OLBs) across the Military Health System (MHS), enhances readiness, enables trusted patient care, and increases efficiency through world-class health technology delivery.

2. APPLICABILITY. This DHA-PI applies Services Secretaries, DHA, and DHA Markets, and MTFs (i.e., medical centers, clinics, dental treatment facilities), and OLBs (i.e., non-MTF training facilities, administration, research and development facilities, regional and field activities (remote locations), and subordinate organizations administered and managed by DHA) under the authority, direction, and control of the Director, DHA.

3. POLICY IMPLEMENTATION. It is DHA's instruction, in accordance with References (c) through (i), that HTM provides a disciplined and structured process for MDE requirements.

4. CANCELLED DOCUMENTS. This DHA-PI supersedes Service policy with respect to approval and authorization of MDE in support of the Medical Logistics (MEDLOG) Enterprise Activity. The Services are responsible for the cancellation of these publication. This DHA-PI does not supersede procurement procedures and funding policies.

5. RESPONSIBILITIES. See Enclosure 2.

6. PROCEDURES. See Enclosure 3.

7. PROPONENT AND WAIVERS. The proponent of this publication is the Deputy Assistant Director (DAD), MEDLOG. When Activities are unable to comply with this publication the activity may request a waiver by providing justification that includes a full analysis of the expected benefits and must include a formal review by the activities senior legal officer. The activity director or senior leader will endorse the waiver request and forward them through their chain of command to the Director, DHA to determine if the waiver may be granted.

8. RELEASABILITY. **Cleared for public release**. This DHA-AI is available on the Internet from the Health.mil site at: www.health.mil/DHAPublications and is also available to authorized users from the DHA SharePoint site on the SECURE Internet Protocol Router Network at: https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx.

9. EFFECTIVE DATE. This DHA-PI:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (c).

10. FORMS. The following NAVMED forms are available at: https://www.med.navy.mil/directives/Pages/NAVMEDForms.aspx.

a. NAVMED 6700/12, Capital Equipment Request (used for equipment items $100,000 and above).

b. NAVMED 6700/13, Expense Equipment Request (used for equipment items less than $100,000).

/S/
RONALD J. PLACE
LTG, MC, USA
Director

Enclosures
1. References
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Glossary

ENCLOSURE 1

REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
(b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
(c) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
(d) Public Law 114-328, "National Defense Authorization Act for Fiscal Year 2017"
(e) DoD Instruction 5000.02, "Operation of the Defense Acquisition System," January 7, 2014, as amended
(f) DHA-Procedural Instruction 6430.02, "Defense Medical Logistics (MEDLOG) Enterprise Activity (EA)," September 27, 2018
(g) DHA-Interim Procedures Memorandum 18-013, "Risk Management Framework (RMF)," September 20, 2019
(h) DHA-Interim Procedures Memorandum 18-015, "Cybersecurity Program Management," September 23, 2019
(i) Code of Federal Regulations, Title 48
(j) DHA-Administrative Instruction 109, "Defense Health Agency Decision-Making Architecture (DMA)," October 15, 2019

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. The Director, DHA, will:

a. Exercise overall responsibility for the DHA MDE Requirements Management Program.

b. Implement policy, guidance, and instruction consistent with References (a) through (j).

2. SERVICE SECRETARIES. Service Secretaries will ensure the Service Surgeons General, MTFs under their command and control comply with this DHA-PI.

3. DAD, MEDLOG. The DAD-MEDLOG Directorate must:

a. Exercise authority over all MDE lifecycle management activities, in accordance with Reference (j), including lifecycle management of MDE below the Simplified Acquisition Threshold.

b. Oversee MDE requirements management in all categories of MDE including integrated, facilitated, and decentralized MDE throughout the enterprise.

c. Synchronize MDE lifecycle management processes amongst DHA MEDLOG HTM, the Services, Markets, MTFs, and OLBs.

d. Provide medical logistics oversight and guidance to the Services, Markets, MTFs, and OLBs.

4. CHIEF, DHA MEDLOG HTM. The Chief, DHA MEDLOG HTM must:

a. Review integrated MDE lifecycle management funding requirements on an annual basis by the Program Objective Memorandum submission deadline, and submit out-of-cycle urgent requirements to quarterly review board.

b. Publish a single MDE requirements priority grading matrix.

c. Publish standard MDE naming conventions.

5. DIRECTORS, MTF. The Directors, MTF must provide for the lifecycle management of decentralized MDE and, as directed, aspects of the lifecycle management of facilitated MDE including proper resourcing, use, care, and property management of all MDE used at the MTF.

6. DIRECTORS, OLB. The Directors, OLB must provide for the lifecycle management of decentralized MDE and, as directed, aspects of the lifecycle management of facilitated MDE, including proper resourcing, use, care, and property management of all MDE used at the OLB.

7. LOGISTICS OFFICERS, MTF. The Logistics Officers, MTF will execute the lifecycle management of all categories of MDE including integrated, facilitated, and decentralized MDE in accordance with this DHA-PI and the continually updated MDE lifecycle category list available at: https://info.health.mil/bus/medlog/healthtech/mesc/MESC_Library/Forms/AllItems.aspx.

8. LOGISTICS OFFICERS, OLB. The Logistics Officer, OLB will execute the lifecycle management of all categories of MDE including integrated, facilitated, and decentralized MDE in accordance with this DHA-PI and the continually updated MDE lifecycle category list available at: https://info.health.mil/bus/medlog/healthtech/mesc/MESC_Library/Forms/AllItems.aspx.

ENCLOSURE 3

PROCEDURES

1. REQUIREMENTS OVERVIEW. The MEDLOG MDE requirements process is based on processes outlined in References (d), (e), and (i).

a. These procedures apply to all integrated, facilitated, and decentralized MDE as defined in this DHA-PI.

b. Requirements are managed in accordance with their lifecycle management categories of either integrated, facilitated, or decentralized.

c. DHA MEDLOG expedites and increases efficiency of all MDE lifecycle management activities from execution throughout use in enterprise patient care. DHA MEDLOG will have visibility of all MDE requirements management activities for MTFs and OLBs requiring MDE.

(1) The Services will provide DHA MEDLOG with access to all current MDE requirements management systems.

(2) DHA MEDLOG must:

(a) Leverage data available in current MDE requirements management systems to facilitate strategic sourcing and promote enterprise standardization.

(b) Assess requirements for consolidation and enterprise-level management.

(c) Reconcile all executed and pending items using the Service-provided funding documents and/or Defense Medical Logistics Standard Support (DMLSS) Due-In/Due-Out data.

d. MTFs and OLBs will continue to document all MDE requirements using the existing Service-provided MDE requirements management systems for requirement submission and for maintaining requirement packages, including a LogiCole New Equipment Request (NER) or:

(1) Army: Centralized Enterprise Requirements Program, General Fund Enterprise Business System, Web MEDCASE Requirements & Execution, and DMLSS;

(2) Air Force: DMLSS, the Integrated Global Equipment Request System;

(3) Navy: NAVMED 6700/12 Capital Equipment Request (used for equipment items $100,000 and above), or NAVMED 6700/13 Expense Equipment Request (used for equipment items less than $100,000).

e. The Services will provide DHA MEDLOG a list of all integrated and facilitated MDE requirements, as well as all decentralized MDE requirements with a system/unit cost greater than or equal to $100,000 by July 15, in the Fiscal Year (FY) preceding the year of MDE requirement execution need (e.g., requests for FY 2021 should be submitted by July 15, 2020). MTFs and OLBs will supplement their requirements management system documentation by sending missing artifacts as attachments on a formatted email to: dha.detrick.med-log.mbx.htmjointrequirement@mail.mil with Subject: Integrated (or Facilitated) Requirement Artifacts <MTF or OLB> <SERVICE> <REQUIREMENT NUMBER> <MDE requirement management system name> if existing Service provided MDE requirement management systems cannot accommodate the submission of any of the following artifacts. The listing will include:

(1) Priority (Local and/or Service)

(2) Essential characteristics or specification of equipment

(3) Local routing approval

(4) Justification for requirement

(5) Workload numbers annually

(6) Installation requirements

(7) Packaging and shipping requirements

(8) Training requirements

(9) If replacement, historical maintenance record

f. Integrated and facilitated MDE requirements and decentralized MDE requirements over $100,000 submitted after July 15 are not authorized for procurement in the following FY.

g. DHA MEDLOG HTM subject matter experts will conduct technical and clinical assessments of all submitted requirements for completeness, verify requirement validity, and determine what lifecycle management aspects, if any, DHA MEDLOG HTM must oversee.

h. DHA MEDLOG HTM will notify Services, MTFs, and OLBs of its findings annually by August 16. Communications will include detailed guidance on appeals, resourcing, acquisition strategy, cybersecurity, procurement, and delivery.

i. MTFs and OLBs may submit appeals through their respective Service to DHA annually by September 16 preceding the FY of MDE need.

j. DHA MEDLOG HTM will centrally manage all integrated MDE requirements management activities, including prioritization, resourcing, acquisition strategy development,

cybersecurity, procurement and delivery. DHA MEDLOG HTM will communicate real time statuses of integrated MDE requirements management activities using Service-provided MDE requirements management systems.

k. The MTF and OLB will coordinate with DHA MEDLOG HTM to manage facilitated MDE requirements management activities, including prioritization, resourcing, acquisition strategy development, cybersecurity, procurement, and delivery.

2. DECENTRALIZED REQUIREMENTS

a. MTFs and OLBs are authorized to locally manage all decentralized requirements in accordance with existing Service policy that meet all of the following criteria:

(1) System/Unit cost is less than $100,000.00.

(2) The requirement is not identified as an integrated or facilitated MDE requirement.

(3) DHP funding allocated to the MTF or OLB is available or can be requested at lower than the DHA headquarters level for acquisition, cybersecurity, and installation as applicable.

b. MTFs and OLBs will document MDE decentralized requirements utilizing existing MDE requirements management systems.

3. URGENT MDE REQUIREMENTS

a. DHA MEDLOG has the authority to determine if the MDE requirement is urgent, is not urgent but should be inserted onto the current FY list, or is not urgent and should be inserted onto the next FY budget.

b. Requirements with greater urgency including concerns over life, limb, or eyesight should involve a call to DHA MEDLOG HTM.

c. Approval decisions will be based on urgency of requirement, technical assessments, and clinical assessments conducted by various DHA subject matter experts. Approval communications will include acquisition strategy information. Urgent requirements initial processing by DHA MEDLOG HTM will normally take less than 2 business days.

d. Disapprovals can be appealed to the DAD-MEDLOG.

e. MTFs and OLBs are authorized to locally manage urgent decentralized requirements, as long as:

(1) Total cost for acquisition, cybersecurity, and installation is less than $100,000.

(2) DHP funding allocated to the MTF or OLB is available or can be requested (and obtained) at lower than the DHA headquarters level for acquisition, cybersecurity, and installation.

(3) Processing and execution is done in accordance with this DHA-PI and existing Service policy and requirements management systems. This includes, as necessary, processing Unfunded Requirements in accordance with the existing Resource Management policy, and the DHA portal submission requirements.

f. Urgent requirements for integrated/facilitated MDE and requirements of or over $100,000 are not authorized for local management, but will be submitted by the MTF and OLB to DHA MEDLOG HTM in the following format:

(1) Letter of Urgency, including information on availability of allocated DHP funding, signed by the MTF or OLB Director or appointed officer or designee.

(2) MTFs will supplement their requirements management system documentation by sending missing artifacts as attachments on a high priority formatted email to: dha.detrick.med-log.mbx.htmurgentrequirement@mail.mil with Subject: URGENT REQUIREMENT <MTF> <SERVICE> <REQUIREMENT NUMBER> <MDE requirement management system name> if existing Service provided MDE requirement management systems cannot accommodate the submission of any of the following artifacts:

(a) Priority (Local and/or Service)

(b) Essential characteristics or specification of equipment

(c) Local routing approval

(d) Justification for requirement

(e) Workload numbers annually

(f) Installation requirements

(g) Packaging and shipping requirements

(h) Training requirements

(i) If replacement, historical maintenance record

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

DAD	Deputy Assistant Director
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
DMLSS	Defense Medical Logistic Standard Support
FY	Fiscal Year
HTM	Healthcare Technology Management
MDE	Medical Devices and Equipment
MEDLOG	Medical Logistics
MHS	Military Health System
MTF	Military Medical Treatment Facility
OLB	Other Line of Business

PART II. DEFINITIONS

These terms and their definitions are for the purposes of this DHA-PI.

lifecycle management. The act of managing MDE from requirements management through sustainment and final disposition.

MDE. Any instrument, apparatus, implement, machine, implant, appliance, or related article, including the software or Enterprise solution necessary for its proper application, intended by the manufacture to be used for patient care. MDE lifecycle management categories include decentralized MDE, facilitated MDE, and integrated MDE.

decentralized MDE. MDE having a lifecycle managed by the MTF or OLB according to DHA MEDLOG policies and procedures. Decentralized MDE is not classified as either integrated or facilitated. MDE not explicitly designated as integrated or facilitated may still be re-categorized as such by DHA MEDLOG HTM at any time. MDE connected to MHS GENESIS or potentially needing direct connections to MHS GENESIS will not be considered decentralized MDE. DHA HTM will not oversee any aspects of lifecycle management during the duration of this DHA-PI.

facilitated MDE. MDE having a lifecycle jointly managed by both DHA MEDLOG HTM and the respective MTF or OLB. For each facilitated MDE, DHA MEDLOG HTM will specify which aspects of the MDE lifecycle which the respective MTF or OLB will manage. In most

cases, DHA MEDLOG HTM will manage cybersecurity and sustainment of facilitated MDE. Facilitated MDE is further defined by device code at: https://info.health.mil/bus/medlog/healthtech/mesc/MESC_Library/Forms/AllItems.aspx.

integrated MDE. MDE, specific to certain device codes, for which DHA MEDLOG HTM will directly oversee complete lifecycle management, including standard requirements, acquisition, delivery, sustainment, and disposition options. Cybersecurity and configuration control for integrated MDE will be managed fully by DHA MEDLOG HTM usually through a designated Product Support Management Office. For example, integrated MDE includes components associated with a Picture Archiving and Communication System. Further defined by device code at: https://info.health.mil/bus/medlog/healthtech/mesc/MESC_Library/Forms/AllItems.aspx

requirements management. Activities related to MDE requirements identification, lifecycle sustainment planning, approval, prioritization, resourcing, acquisition strategy development, cybersecurity, procurement and delivery.

strategic sourcing. The collaborative and structured process of critically analyzing an organization's spending and using this information to make business decisions about acquiring services more effectively and efficiently. Strategic sourcing is a proven best practice and reflects how the DoD acquires services and many products. For the purposes of this DHA-PI, indicates a reduction in sources of supply to a minimum viable number that allows for competition but also permits a reduction in the expenses related to sustaining too many variations of products.

urgent requirement. A requirement that, if not addressed immediately, will adversely affect patient care.