



# Defense Health Agency

## PROCEDURES MANUAL

NUMBER 4000.02  
October 18, 2021

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DHA MEDLOG

SUBJECT: Medical Devices and Equipment (MDE) Requirements Management

References: See Enclosure 1.

1. **PURPOSE.** This Defense Health Agency-Procedures Manual (DHA-PM), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (q), establishes the Defense Health Agency's (DHA's) process to manage MDE requirements for the Defense Health Agency Medical Logistics Enterprise across the Military Health System (MHS) to enhance readiness, enable trusted patient care and increase efficiency through world-class healthcare technology delivery.
2. **APPLICABILITY.** This DHA-PM applies to the DHA, DHA Components (activities under the authority, direction, and control of the DHA), Military Departments (MILDEPS), and all personnel including assigned or attached active duty and Reserve members, federal civilians, contractors (when required by the terms of the applicable contract), and other personnel assigned temporary or permanent duties at DHA, DHA Components, and other lines of business (OLBs).
3. **POLICY IMPLEMENTATION.** It is DHA's instruction, pursuant to and in compliance with References (d) through (q), that DHA Medical Logistics (MEDLOG) Healthcare Technology Management (HTM) will provide a disciplined and structured process for MDE requirements management and approval.
4. **CANCELLED DOCUMENTS.** This DHA-PM supersedes Defense Health Agency-Procedural Instruction 6000.02, "Healthcare Technology Management (HTM) Medical Devices and Equipment (MDE) Requirements Management for Military Medical Treatment Facilities (MTFs)", 15 June 2020.
5. **RESPONSIBILITIES.** See Enclosure 2.

6. PROCEDURES. See Enclosure 3.

7. RELEASABILITY. **Cleared for public release.** The DHA-PM is available on the Internet from the Health.mil site at: <https://health.mil/Reference-Center/Policies> and is also available to authorized users from the DHA SharePoint site at: <https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx>.

8. EFFECTIVE DATE. This DHA-PM:

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).

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

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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) 10 U.S. Code, Section 1073c—Administration of Defense Health Agency and Military Medical Treatment Facilities
- (e) Joint Chiefs of Staff Joint Doctrine Publication 4-02, “Joint Health Services,” December 11, 2017, as amended
- (f) DoD Instruction 6430.02, “Defense Medical Logistics Program,” August 23, 2017
- (g) DoD Instruction 5000.64, “Accountability and Management of DoD Equipment and other Accountable Property,” April 27, as amended
- (h) DoD Directive 5000.01, “The Defense Acquisition System,” September 9, 2020
- (i) DoD Instruction 5000.02, “Operation of the Adaptive Acquisition Framework,” January 23, 2020
- (j) DoD Instruction 8500.01, “Cybersecurity,” March 14, 2014
- (k) DoD Instruction 8510.01, “Risk Management Framework (RMF) for DoD IT,” March 12, 2014, as amended
- (l) DHA-Interim Procedures Memorandum 18-013, “Risk Management Framework (RMF),” October 10, 2018
- (m) ASD Command, Control, Communications, and Intelligence (C3I) Memorandum, “Disposition of Unclassified DoD Computer Hard Drives,” June 4, 2001
- (n) Federal Acquisition Regulation (FAR), as amended
- (o) Defense Federal Acquisition Regulation Supplement (DFARS), as amended
- (p) DoD 7000.14–R, “Financial Management Regulation,” as amended
- (q) DHA-Administrative Instruction 109, “Defense Health Agency Decision-Making Architecture (DMA),” October 15, 2019

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. Per Reference (a), and the authority, direction, and control of the ASD for Health Affairs, the Director, DHA, exercises management responsibility for the MEDLOG Enterprise Activity (EA) and develops appropriate management models for specific functions and processes.

2. ASSISTANT DIRECTOR, COMBAT SUPPORT

- a. Exercises overall responsibility for DHA MDE requirements management.
- b. Ensures MTFs implement and comply with this DHA-PM.
- c. Coordinate with Secretaries of Military Departments to ensure MTFs under their command and control comply with the procedures contained in this DHA-PM.
- d. Oversees the execution and accountability monitoring of standard processes, procedures, and appointment types by DHA, specific to MDE requirements.
- e. Supports strategies and programs through the responsibilities outlined in References (a) through (r).

3. DEPUTY ASSISTANT DIRECTOR (DAD), MEDLOG. The DAD-MEDLOG will:

- a. Exercises authority over all MDE lifecycle management (LCM) and MDE requirements management activities pursuant to references (e) through (g).
- b. Oversees MDE requirements management in all categories of MDE, including Integrated, Facilitated, and Decentralized MDE, throughout the enterprise.
- c. Ensures that the enterprise synchronizes MDE LCM processes.
- d. Provides medical logistics oversight and guidance to each DHA Customer Support Team (CST); Directors, Markets; Directors, MTFs/DTFs; and Directors, OLB.
- e. Oversees funding execution for DHA MDE as outlined within this DHA-PM.
- f. Serves as the Chairperson and a voting member of the Equipment Appeals Board (EAB) and Central Equipment Requirements for Funding (CERF) Board.

4. DIVISION CHIEF, DHA MEDLOG HEALTHCARE TECHNOLOGY MANAGEMENT (HTM)

- a. Provides enterprise policy and guidance for MDE requirements management for all Integrated, Facilitated, and Decentralized MDE.
- b. Provides LCM of all Integrated MDE within DHA.
- c. Provides LCM of Facilitated MDE or delegates to HTM Manager, MTFs/DTFs or HTM Manager, OLB, as appropriate.
- d. Delegates LCM of Decentralized MDE to HTM Manager, MTFs/DTFs or HTM Manager, OLB.
- e. Projects funding for MDE in accordance with Program Objective Memorandum requirements.
- f. Oversees the conduct of the Enterprise Requirements Assessment (ERA) team in accordance with DHA policy.
- g. Establishes and maintains MDE Baselines.
- h. Publishes and maintains MTF/DTF and OLB MDE requirements prioritization matrix input values.
- i. Publishes and maintains normalized MDE device codes and nomenclature.
- j. Publishes and maintains a DHA Enterprise equipment listing including pertinent Risk Management Framework (RMF), procurement, device code and lifecycle information.
- k. Coordinates review of MDE requirements by the appropriate enterprise clinical specialty leader, consultant, group, or designee, per clinical specialty guidance.
- l. Serves as the EAB and CERF Board Secretary and supports the DHA MEDLOG HTM Requisition and Installation Management Team (RITs).
- m. Serves as a voting member on the EAB and CERF Board.
- n. Adjudicates emergency and off-cycle MDE requirement submissions.
- o. Authorizes appeals and strategic sourcing waivers for MDE as outlined in this DHA-PM.
- p. Adjudicates MDE requirement management questions and concerns forwarded by CST or received directly from MTFs/DTFs and OLBs.

5. DIVISION CHIEF, DHA MEDLOG BUSINESS OPERATIONS (BO)

- a. Provides portfolio management services in support of the MDE requirements management, including Program Objective Memorandum submission, planning, programming, budgeting, and execution of program resources.
- b. Provides data analytics and reporting in support of MDE requirements management.
- c. Supports the Division Chief, DHA MEDLOG HTM in all EAB, CERF Board, and RIT activities.
- d. Serves as a voting member on the EAB and CERF Board.

6. DIVISION CHIEF, DHA MEDLOG SUPPLY MANAGEMENT

- a. Provides enterprise MDE Supply Management services.
- b. Coordinates supply standardization efforts with Division Chief, DHA MEDLOG HTM to ensure compatibility with MDE throughout the enterprise.
- c. Assists with ERA processes.
- d. Supports DHA MEDLOG HTM RIT activities.

7. DIVISION CHIEF, DHA MEDLOG PLANS & READINESS. The Division Chief, DHA MEDLOG Plans & Readiness will reconcile contingency program support requirements with MDE requirements management.

8. CHIEF MEDICAL OFFICER (CMO), DHA MEDLOG

- a. Acts as a clinical liaison to and supports the Division Chief, DHA MEDLOG HTM in all EAB, CERF Board, and RIT activities.
- b. Serves as a clinical liaison and voting member on the EAB and CERF Board.

9. DIRECTORS, MARKETS, SMALL MARKET AND STAND ALONE MEDICAL TREATMENT FACILITY ORGANIZATION (SSO), AND DEFENSE HEALTH AGENCY REGIONS (DHAR). Directors, Markets, SSO, and DHARs must:

- a. Ensure that the MTFs/DTFs and OLBs within their area of responsibility are appropriately resourced to execute delegated MDE LCM processes, in accordance with direction from DHA MEDLOG HTM.

- b. Assume responsibility for MDE LCM processes in their area of responsibility, where the Director, MTF/DTF or Director, OLB is insufficiently resourced to manage.
- c. Report to DAD, DHA MEDLOG on MDE LCM processes occurring in their area of responsibility.
- d. Report MDE procured without authorization to DAD, DHA MEDLOG.
- e. Assign roles and responsibilities within their area of responsibility to meet the HTM mission.

10. DIRECTORS, MTF/DTF AND OTHER LINES OF BUSINESS (OLB). Directors MTF/DTF and OLB will:

- a. Oversee MDE LCM processes within their MTF/DTF or Other Lines of Business (OLB) in accordance with guidance from DHA MEDLOG HTM.
- b. Ensure that HR assigned to the HTM Requirements Management section are fully utilized to execute the MDE Requirements Management mission in accordance with this policy.
- c. Ensure that their MTF/DTF or OLB is appropriately resourced to execute delegated MDE requirements management processes, in accordance with direction from DHA MEDLOG HTM.
- d. Oversee identification, documentation, and validation of Integrated, Facilitated, and Decentralized MDE requirements for their MTF/DTF or OLB within the designated MDE requirements management information system, Defense Medical Logistics - Enterprise Solution (DML-ES).
- e. Assign appropriate Clinical and Technical Validators to review and validate all MDE requirements submitted by their MTF/DTF or OLB.
- f. Oversee MDE requirements ranking for their MTF/DTF or OLB.
- g. Oversee submission of their MTF's or DTF's OLB's MDE requirements for approval by DHA MEDLOG HTM.
- h. Oversee confirmation of acquisition, installation, acceptance, and gain of all procured Integrated, Facilitated, and Decentralized MDE for their MTF/DTF or OLB.
- i. Report to applicable Director, Market and to DAD, DHA MEDLOG on all MDE LCM processes occurring at their MTF/DTF or OLB.
- j. Report MDE procured without authorization to Director, Market.

k. Assign roles and responsibilities within their MTF/DTF and OLB to meet the HTM mission.

11. MEDLOG OFFICER, MTF/DTF or LOGISTICS OFFICER, OLB

a. Ensures proper identification, documentation, and validation of all MDE requirements for their MTF/DTF or OLB.

b. Ensure that HR assigned to the HTM Requirements Management section are fully utilized to execute the MDE Requirements Management mission in accordance with this policy.

c. Builds, or designates a Medical Logistics Point of Contact (POC) to build, MDE requirements in the designated MDE requirements management information system, Defense Medical Logistics - Enterprise Solution (DML-ES).

d. Ensures proper submission of their MTF's/DTF's or OLB's MDE requirements for approval by DHA MEDLOG HTM, with input from end-users and stakeholders.

e. Supports the DHA MEDLOG HTM RIT for all Integrated and Facilitated MDE for their MTF/DTF or OLB.

e. Tracks MDE requirements ranking for their MTF/DTF or OLB.

f. Confirms acquisition, acceptance, and installation of all procured Integrated, Facilitated, and Decentralized MDE for their MTF/DTF or OLB.

g. Reports MDE procured without authorization to Director, MTF/DTF or Director, OLB.

h. Assigns roles and responsibilities within their Department to meet the HTM mission.

12. HTM MANAGER, MTF/DTF OR HTM MANAGER, OLB

a. Ensures proper requisition and installation of all MDE for their MTF/DTF or OLB.

b. Ensure that HR assigned to the HTM Requirements Management section are fully utilized to execute the MDE Requirements Management mission in accordance with this policy.

c. Ensures that their MTF/DTF or OLB synchronizes and executes MDE LCM processes in accordance with delegation by DHA MEDLOG HTM.

d. Supports the DHA MEDLOG HTM RIT for all Integrated and Facilitated MDE for their MTF/DTF or OLB.

- e. Serves as a Technical Validator to review all MDE requirements submitted by their MTF/DTF or OLB.
- f. Ensures proper receipt and gain process of all procured Integrated, Facilitated, and Decentralized MDE for their MTF/DTF or OLB, including assignment of normalized device code, nomenclature, manufacturer, and common model and update of network information in the Accountable Property System of Record (APSR) are accurately recorded in accordance with current DHA property accountability, management, HTM sustainment guidance and this PM.
- g. Reports all MDE LCM processes occurring at their MTF/DTF or OLB, as required.
- h. Reports MDE procured without authorization to MEDLOG Officer, MTF/DTF or Logistics Officer, OLB.
- i. Assigns roles and responsibilities within their Department to meet the HTM mission.

ENCLOSURE 3

PROCEDURES

1. OVERVIEW MDE REQUIREMENTS. The requisition of new and MDE is a key part of effective LCM of all MDE throughout DHA, enabling increased readiness, better health, and better care, at lower costs. DHA MEDLOG HTM will optimize MDE inventory through enhanced LCM by reducing variation in capability and care.

a. DHA MEDLOG HTM manages MDE, which establishes MDE as a part of the Defense Medical Logistics Enterprise across DHA, per references (e) through (g). This DHA-PM will detail the procedures, roles, and responsibilities necessary to identify, document, validate, approve, prioritize, fund, procure, confirm receipt, and confirm gain of all categories of MDE.

b. DHA MEDLOG HTM manages MDE requirements using Integrated, Facilitated, and Decentralized MDE categories as identified in this DHA-PM. MDE are categorized based on normalized device codes and nomenclatures.

(1) For all Integrated MDE. MTFs/DTFs and OLBs will identify, document, validate, prioritize, and upon central approval, coordinate with DHA MEDLOG HTM to fund, procure, confirm receipt, and confirm correct gaining of Integrated MDE in DML-ES. DHA MEDLOG HTM will occasionally identify, document, validate, prioritize, fund, procure, confirm receipt, and confirm correct gaining of Integrated MDE in DML-ES. Gains will be done in accordance with DHA MEDLOG HTM property accountability procedures.

(2) For all Facilitated MDE. MTFs/DTFs and OLBs will identify, document, validate, prioritize, and upon central approval, coordinate with DHA MEDLOG HTM to fund, procure, confirm receipt, and confirm correct gaining of Facilitated MDE in DML-ES. Gains will be done in accordance with DHA MEDLOG HTM property accountability procedures.

(3) For all Decentralized MDE. MTFs/DTFs and OLBs will identify, document, and upon local validation, prioritize, fund, procure, confirm receipt, and confirm correct gaining of Decentralized MDE in DML-ES. Gains will be done in accordance with DHA MEDLOG HTM property accountability procedures.

c. MTFs/DTFs and OLBs will submit Integrated and Facilitated MDE requirements, and decentralized MDE requirements over \$100,000, one fiscal year (FY) in advance to the DHA MEDLOG HTM, regardless of dollar value.

(1) MTFs/DTFs and OLBs must plan and manage MDE lifecycles to submit routine MDE requirements by 15<sup>th</sup> of July of each year, and in accordance with any follow-on DHA MEDLOG HTM guidance. Lack of planning is not justification to use the emergency or off-cycle processes (paragraph 8 of this enclosure).

(2) MTF/DTF and OLB Integrated and Facilitated MDE requirements, and decentralized MDE requirements over \$100,000, will be validated and locally prioritized by MTF/DTF and OLB Clinical and Technical Validators before DHA MEDLOG HTM will consider for approval and enterprise prioritization. MTF/DTF or OLB validated Integrated and Facilitated MDE requirements do not guarantee DHA MEDLOG HTM approval.

d. DHA MEDLOG HTM will review all MTF/DTF and OLB validated and locally prioritized Integrated and Validated MDE requirements, and decentralized requirements over \$100,000, for approval or disapproval throughout the FY, as submitted. DHA MEDLOG HTM coordinates appropriate planning, programming, and budgeting for approved MDE requirements.

e. DHA MEDLOG HTM will prioritize approved Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, for funding and procurement for the following FY. DHA MEDLOG HTM makes funding decisions for routine Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, through an annual CERF Board, comprised of enterprise clinical and technical DHA leaders, to establish an enterprise strategy for the following FY (strategic sourcing, MDE categorization management, and MDE LCM across the enterprise).

f. DHA MEDLOG HTM will aggregate like Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, to support enterprise standardization and equipment planning strategies for the DHA.

g. DHA MEDLOG HTM reviews appeals for disapproved Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, quarterly using an EAB. The EAB will also consider strategic source waiver requests, and make approval and funding decisions on all off-cycle MDE requirement submissions. Emergency MDE requirements will be processed according to paragraph 8 of this enclosure and thereafter reconciled at the EAB.

h. MDE requirements procedures are applicable to all MDE requirements, regardless of who identifies the requirement.

2. GENERATING MDE REQUIREMENTS. The MEDLOG Officer, MTF/DTF and Logistics Officer, OLB (for Facilitated and Decentralized), or DHA MEDLOG HTM (for Facilitated and Integrated), will submit all MDE requirements into the designated MDE requirements management information system, DML-ES LogiCole. For all Integrated MDE requirements, DHA MEDLOG HTM will establish and lead a multi-functional RIT.

a. Identifying MDE Requirements. The MTF/DTF or OLB (Decentralized), or a hybrid of both the MTF or OLB and DHA MEDLOG HTM (Integrated and Facilitated), will complete the following procedures to identify MDE requirements:

(1) Reconcile clinical capabilities of MDE inventory against existing, new, or changed missions. When existing MDE inventory is no longer clinically or technologically acceptable

and cannot meet existing, new, or changed missions, document MDE requirements in accordance with this DHA-PM. See paragraph 9 of this enclosure for guidance on rentals, leases [cost per test (CPT), cost per reportable result (CPRR)], and loans.

(2) Assess maintenance history, sustainability, supportability, and technological adequacy of MDE throughout its lifecycle. When existing MDE cannot be efficiently sustained or supported, or fails to meet minimum technological capability requirements, document MDE requirements in accordance with this DHA-PM. See paragraph 9 of this enclosure for guidance on rentals, leases (CPT or CPRR), and loans.

(3) Participate in DHA MEDLOG HTM led Enterprise Requirements Assessments (ERAs) and comply with ERA reports and guidance. MTFs/DTFs and OLBs will support ERA site visits or remote analytics by, at a minimum, providing: manpower/staffing data, clinical workload data, Standard Operating Procedures, workflows, and/or access to personnel, equipment, and facilities.

(a) In response to ERA guidance on necessary MDE inventory adjustments, document MDE requirements in compliance with ERA recommendation and in accordance with this DHA-PM.

(b) In response to ERA guidance to turn in or laterally transfer excess MDE, MTFs/DTFs and OLBs will complete the MDE transfer or turn in the MDE in compliance with the ERA and DHA property accountability, management, and sustainment guidance.

b. Documenting MDE Requirements. For identified MDE requirements, the MEDLOG Officer, MTF/DTF or Logistics Officer, OLB (Decentralized), or a hybrid of both the MTF or OLB and DHA MEDLOG HTM (Integrated and Facilitated) will document MDE requirement data within the designated MDE requirements management information system, DML-ES LogiCole, in accordance with DHA MEDLOG HTM guidance. The HTM Manager, MTF/DTF or HTM Manager, OLB will ensure correct normalized device codes and nomenclatures are used for all systems and components. The MHS device code table is available at the DHA MEDLOG HTM SharePoint. MDE requirement data must include, at least:

(1) MDE requirement importance (routine, off-cycle, or emergency). See paragraph 8 of this enclosure for more details about off-cycle and emergency requirement documentation.

(2) MDE Requirement Prioritization Factors:

(a) Criticality of need (including risk of non-action),

(b) Clinical and technological acceptability,

(c) Supportability (consider supportability costs), and

(d) Scoring of maintenance history of MDE being replaced, as applicable.

- (3) Acquisition Control Number (ACN) or Request Number.
- (4) Funding source or request for funding.
- (5) Normalized device code and nomenclature (including all necessary systems and components).
- (6) Type of inventory adjustment: new, replacement, supplement/upgrade, and transfer (including all ECNs of existing MDE to be replaced, upgraded, or transferred). MDE requested for retention requires notation in the APSR equipment record to prevent multiple replacements of the same item. See DHA MEDLOG HTM Property Accountability guidance for further clarifications.
- (7) Quantity required.
- (8) Intended use location and department (including delivery address, Continental United States or Outside of the Continental United States).
- (9) Annual workload, peak workload timeframe, and peak hours workload (estimate if no existing data).
- (10) ERA report data, as applicable.
- (11) Minimum essential characteristics (MEC).
  - (a) Clinical and technological need (must consider impact of gaps in existing Standing Operating Procedures as compared to existing, new, or changed mission).
  - (b) Accrediting body requirements.
  - (c) Utilization requirements (different from workload; estimate if no existing data).
  - (d) Adjunct consumable/supply requirements.
  - (e) Modification requirements to existing Facilities and Utilities (e.g., structural, power, emergency power, medical air/gas, heating, ventilation, air conditioning (i.e., Heating, Ventilation, Air Conditioning), steam, water, waste).
  - (f) Scope of extended installation, turn-key or incidental services requirements, if applicable.
  - (g) Existing MDE de-installation and trade-in requirements, if applicable.
  - (h) Demonstration and training requirements (clinical, technical, and biomedical).
  - (i) Network connection requirements (to the Medical Community of Interest).

- (j) Cybersecurity requirements (RMF), including DHA Medical Devices and Equipment Risk Assessment documentation for vendor(s) to complete.
  - (k) Electronic health record connectivity requirements (MHS GENESIS).
  - (l) Requirements for interoperability with any other existing MDE or systems (lab information system(s) (LIS), picture archiving and communication system(s), etc.).
  - (m) Lifecycle sustainment requirements.
  - (n) Lifecycle infection control considerations or requirements.
  - (o) Minimum of two service and operators' manuals.
- (12) Historical maintenance reports and sustainment history of existing MDE (and manufacturer end of support life notices, if applicable). Strong justification for early replacement must also be provided, including a demonstration that maintenance issues have been brought to DHA MEDLOG HTM's attention.
- (13) Total estimated initial outfitting cost.
- (14) Total estimated LCM cost.
- (15) Cost Benefit Analysis (CBA) for MDE requirements with cost estimates above \$100K (unit price of MDE) in accordance with DHA MEDLOG HTM guidance.
- (16) Rental, lease, or loan considerations, as applicable (see paragraph 9 of this enclosure).
- (17) Strategic sourcing waivers, as applicable (see paragraph 11 of this enclosure).

c. Documenting Department Level Oversight. Senior staff from requesting department will review the documented MDE requirement before proceeding to Validating, Approving and Prioritizing steps in paragraph 3 of this enclosure.

### 3. VALIDATING, APPROVING, AND PRIORITIZING MDE REQUIREMENTS.

MTFs/DTFs and OLBs will validate and establish respective local priorities for all Decentralized MDE requirements and may validate and establish respective local priorities for some Facilitated MDE requirements. DHA MEDLOG HTM will review Facilitated MDE requirements for approval, enterprise prioritization, and funding, after receiving validations and respective local priorities from MTFs/DTFs and OLBs. DHA MEDLOG HTM will review for approval, enterprise prioritization, and funding of all Integrated MDE requirements. All MDE requirement validations, local priorities, approval decisions, and enterprise priorities will be entered and

tracked in the designated MDE requirements management information system, DML-ES. Validation, approval, and prioritization of MDE requirements does not guarantee immediate funding allocation (paragraph 4 of this enclosure).

a. MTF/DTF and OLB MDE Requirement Validation. MTF/DTF and OLB requirement validations consist of both clinical and technical validations. The Director, MTF/DTF or Director, OLB oversees clinical and technical validations. If an OLB has difficulty identifying a Clinical or Technical Validator, the Logistics Officer, OLB should request assistance from the respective Director, Market. Throughout MTF/DTF and OLB technical and clinical validation, the MEDLOG Officer, MTF/DTF and Logistics Officer, OLB, or designee, will monitor all updates in the designated MDE requirements management information system, DML-ES, according to each ACN. Validation decisions do not guarantee DHA MEDLOG HTM approval.

(1) MTF/DTF and OLB Clinical Validation. MTF/DTF and OLB Clinical Validators will, at a minimum and as applicable, include: CMO, Chief of Nursing, and appropriate ancillary department(s) representatives. MTF/DTF and OLB Clinical Validators will:

(a) Confirm the following:

1. Completeness and accuracy of clinical MDE requirement data (paragraph 2.b. of this enclosure), including language addressing any clinical capability gaps.

2. Alignment with MTF/DTF or OLB clinical mission, and that it is not a duplicate MDE requirement.

3. Workload and utilization data justifies MDE requirement.

4. Clinical staffing levels, qualifications, and training appropriateness.

5. Appropriateness and validity of Non-Government MDE justification (See paragraph 9 of this enclosure), as applicable.

6. Appropriateness and validity of Strategic Sourcing Waiver justification (See paragraph 11 of this enclosure), as applicable.

7. Plausibility of CBA (for MDE requirements with unit price cost estimates above \$100K), as applicable.

8. Accuracy of Clinical MDE Requirement Prioritization Factors (criticality of need and clinical acceptability).

(b) Document each MDE requirement as clinically valid or invalid in DML-ES. An MDE requirement deemed clinically invalid must include specific written feedback, including the rationale as to why the MDE requirement is clinically invalid and what, if anything, the initial requestor may do to receive clinical validation. If an MDE requirement is documented as clinically invalid, the MDE requirement cannot proceed further to the following steps.

(2) MTF/DTF and OLB Technical Validation. MTF/DTF and OLB Technical Validators will include representation from: MEDLOG, HTM, Facilities, Health Information Technology, Cybersecurity, Risk Management/Safety, and Infection Control. MTF/DTF and OLB Technical Validators will:

- (a) Confirm the following:
1. Completeness and accuracy of technical MDE requirement data (paragraph 2.b. of this enclosure), including language addressing any technical capability gap.
  2. Alignment with MTF/DTF or OLB mission, and that it is not a duplicate MDE requirement.
  3. Appropriateness and validity of Non-Government MDE justification (See paragraph 9 of this enclosure), as applicable.
  4. Appropriateness and validity of Strategic Sourcing Waiver justification (See paragraph 11 of this enclosure), as applicable.
  5. Technical staffing requirements, including workload and utilization data to support MDE requirement.
  6. Rationale on lifecycle maintainability and supportability of requested MDE, including applicable/associated Test Measurement and Diagnostic Equipment (TMDE) requirements and repair parts.
  7. Plausibility of CBA (for MDE requirements with unit price cost estimates above \$100K), as applicable.
  8. Appropriate risk management and safety considerations.
  9. Effective and supportable infection control strategy.
  10. Completeness and accuracy of applicable/associated Facilities modifications.
  11. Appropriate cybersecurity, networking, and interconnectivity/intercompatibility considerations.
  12. Accuracy of Technical MDE Requirement Prioritization Factors (historical maintenance of MDE to be replaced, as applicable; and supportability).
- (b) Document each MDE requirement as technically valid or invalid in the DML-ES LogiCole. An MDE requirement deemed technically invalid must include specific written feedback including the rationale as to why the MDE requirement is technically invalid and what, if anything, the requestor may do receive technical validation.

b. MTF/DTF and OLB Local Prioritization and Submission. Only valid Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, will be assigned respective MTF/DTF and OLB local priorities and submitted to DHA MEDLOG HTM for approval consideration and DHA enterprise prioritization. To be valid, an Integrated and Facilitated MDE requirement, and decentralized requirements over \$100,000, must be both clinically and technically valid. MTF/DTF and OLB Technical and Clinical Validators must cohesively generate an MTF/DTF or OLB Validation Executive Summary for each Integrated and Facilitated MDE requirement, and decentralized requirements over \$100,000. Similar Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, may be included on a combined Validation Executive Summary, or aggregated local Equipment Requirements Committee Validation Executive Summary. These summaries must include, as applicable, written feedback on clinically and/or technically invalid MDE requirements. Executive summaries may include lifecycle sustainment guidance, sourcing strategies, or other mandates. Upload MTF/DTF or OLB Technical Validation Executive Summaries for each Integrated and Facilitated MDE requirement, and decentralized requirements over \$100,000, to DML-ES. Invalid Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, will be tracked internally at the MTF/DTF or OLB and either revalidated or cancelled. To establish respective MT/DTF and OLB local priorities and submit validated Integrated and Facilitated MDE requirements to DHA MEDLOG HTM for approval consideration and DHA enterprise prioritization, the MEDLOG Officer, MTF/DTF and Logistics Officer, OLB will:

(1) Establish respective MTF/DTF and OLB local priorities for all validated Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, using MDE Requirement Prioritization Factors established during MDE requirement identification and validated.

(2) Submit MTF/DTF and OLB local priorities to DHA MEDLOG HTM for approval consideration and final DHA enterprise prioritization, by documenting local priorities in DML-ES before 15 July of the FY prior to MDE requirement bona-fide need. Refer to paragraph 8 of this enclosure for guidance on how to submit Emergency and Off-Cycle MDE Requirements.

(3) Review and/or update respective MTF/DTF and OLB local priorities in DML-ES, at a minimum, according to the following schedule:

- (a) Quarterly for Medical Centers and Trauma Centers.
- (b) Semi-annually for Hospitals, Ambulatory Surgery Centers, and 24-hour Urgent Care Centers.
- (c) Annually for Clinics and OLBs.

c. DHA MEDLOG HTM MDE Requirements Approval. DHA MDE requirement approval processing is not required if the MDE requirement is authorized in accordance with the applicable DHA HTM MDE Baseline. DHA MEDLOG HTM requirements approval consists of both clinical and technical approval reviews. DHA MEDLOG HTM oversees technical and

clinical approvals. Approvals are valid for 2 FYs unless executed or otherwise cancelled. DHA MEDLOG HTM may request review of previously approved MDE requirements based upon changes in technology, DHAR or Market mission changes, MTF/DTF or OLB mission changes, or if contradictory information becomes available. Throughout DHA technical and clinical approval processes, DHA MEDLOG HTM will monitor all updates in the designated MDE requirements management information system, DML-ES, according to each ACN. DHA MEDLOG HTM approval decisions do not guarantee immediate funding allocation.

(1) DHA MEDLOG HTM Technical Approval. DHA MEDLOG HTM technical approval reviews enable efficient, cost effective solutions, while promoting standardization of MDE across DHA. The Division Chief, DHA MEDLOG HTM will oversee technical approval reviews through the designated MDE requirements management information system, DML-ES, and ultimately make technical approval decisions (approve or disapprove). DHA MEDLOG HTM technical approval reviewers will include HTM Subject Matter Experts (SMEs) in the areas of medical maintenance, property accountability, clinical/biomedical engineering, and cybersecurity, as well as other SMEs as appropriate (e.g., Facilities Management). Though reserving the right to review additional details and request additional justification, DHA MEDLOG HTM Technical approval reviewers will:

- (a) Analyze and confirm the following:
  1. Completeness and accuracy of technical MDE requirement data (paragraph 2.b. of this enclosure), including language addressing any technical capability gap.
  2. Alignment with respective MTF/DTF or OLB mission.
  3. Appropriateness and validity of Non-Government MDE justification (See paragraph 9 of this enclosure), as applicable.
  4. Appropriateness and validity of Strategic Sourcing Waiver justification (See paragraph 11 of this enclosure), as applicable.
  5. Technical staffing requirements, including workload and utilization data to support MDE requirement.
  6. Rationale on lifecycle maintainability and supportability of requested MDE, including applicable/associated TMDE requirements.
  7. Plausibility of CBA (for MDE requirements with unit price cost estimates above \$100K), as applicable.
  8. Appropriate risk management and safety considerations.
  9. Effective and supportable infection control strategy.
  10. Completeness and accuracy of applicable/associated facilities modifications.

11. Accuracy of Technical MDE Requirement Prioritization Factors (historical maintenance of MDE to be replaced, as applicable; and supportability).

- (b) Confirm accuracy of MTF/DTF or OLB Technical Validation.
- (c) Reconcile MDE requirement against applicable DHA MDE Baseline.
- (d) Reconcile historical and existing MDE requirements to prevent duplicate requests.
- (e) Confirm compliance with enterprise, DHARs, SSOs, and/or Markets initiatives, as well as with applicable integration initiatives.
- (f) Validate mission impact justification. MDE requested for retention requires notation in the APSR equipment record to prevent multiple replacements of the same item. Strong justification for early replacement must also be provided, including a demonstration that maintenance issues have been brought to DHA MEDLOG HTM's attention.
- (g) Coordinate cybersecurity risk assessment of requested MDE with Cybersecurity Logistics (CyberLOG), to include networking and interconnectivity/intercompatibility considerations.
- (h) Coordinate assessment by Facilities or other auxiliary programs.
- (i) Document each MDE requirement as technically approved or disapproved. An MDE Requirement deemed technically disapproved must include specific written feedback, including the rationale as to why the MDE requirement was technically disapproved and what, if anything, the initial requestor may do to receive a technical approval. Feedback will include procedures and timelines for appealing disapproval decision before the EAB (paragraph 10 of this enclosure).
- (j) Generate a DHA MEDLOG HTM Technical Approval Executive Summary for each MDE Requirement. Similar MDE requirements may be included on a combined DHA MEDLOG HTM Technical Approval Executive Summary. Written feedback for disapproved MDE requirements will be included, as applicable. DHA MEDLOG HTM Technical Approval Executive Summaries may include lifecycle sustainment guidance, sourcing strategies, or other mandates. DHA MEDLOG HTM Technical Approval Executive Summaries will be uploaded to DML-ES for each MDE requirement.

(2) DHA Clinical Approval. Dependent on the MDE requirement, if enterprise clinical approval review is required (e.g., Healthcare Informatics, Clinical Consultant/Specialty Leader or Board, Nursing, ancillary Clinical Consultant/Specialty Leader, or Board), DHA MEDLOG HTM will coordinate the routing of the MDE requirement to appropriate clinical approval bodies. The Division Chief, DHA MEDLOG HTM will coordinate clinical approvals through the designated MDE requirements management information system, DML-ES, and ultimately facilitate clinical approval decisions (approve or disapprove). Clinical approval reviewers will:

(a) Confirm the following:

1. Completeness and accuracy of clinical MDE requirement data (paragraph 2.b. of this enclosure), including language addressing any clinical capability gaps.

2. Completeness and accuracy of DHA MTF/DTF or OLB Clinical Validation.

3. Alignment with MTF/DTF or OLB clinical mission, and that it is not a duplicate MDE requirement.

4. Alignment of MDE requirement to DHA, DHARs, Markets, SSOs, MTF/DTF, or OLB clinical mission.

5. Appropriateness and validity of Non-Government MDE justification (See paragraph 9 of this enclosure), as applicable.

6. Appropriateness and validity of Strategic Sourcing Waiver justification (See paragraph 11 of this enclosure), as applicable.

7. Plausibility of CBA (for MDE requirements with unit price cost estimates above \$100K), as applicable.

8. Plausibility of mission impact justification. A strong justification for replacement will be required if the item being replaced is still suitable for use. Strong justification for early replacement must also be provided.

9. Workload and utilization data justifying the MDE requirement.

10. Clinical staffing levels, qualifications, and training appropriateness.

11. Accuracy of Clinical MDE Requirement Prioritization Factors (criticality of need and clinical acceptability).

(b) Document each MDE requirement as clinically approved or disapproved. An MDE requirement deemed clinically disapproved must include specific written feedback, including the rationale as to why the MDE requirement is clinically disapproved and what, if anything, the initial requestor may do to receive clinical approval. Feedback will include procedures and timelines for appealing disapproval decision before the EAB (paragraph 10 of this enclosure).

(c) Generate a DHA Clinical Approval Executive Summary for each MDE requirement. Similar MDE requirements may be included on a combined DHA Clinical Approval Executive Summary. Written feedback for disapproved MDE requirements will be included, as applicable. DHA Clinical Approval Executive Summaries may include sourcing strategies, guidance, or other mandates. DHA Clinical Approval Executive Summaries will be uploaded by DHA MEDLOG HTM to DML-ES for each MDE requirement.

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d. DHA MEDLOG HTM Enterprise Prioritization. Only approved Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, will be assigned a DHA MEDLOG HTM enterprise priority. To be approved, an Integrated and Facilitated MDE requirement, and decentralized requirements over \$100,000, must be both technically and clinically approved. Disapproved Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, will be documented in DML-ES LogiCole and may be resubmitted through the Appeal process (paragraph 10 of this enclosure) or cancelled by the MTF/DTF or OLB. The CERF Board will prioritize approved Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, annually between 15 July and 30 September of the FY prior to the MDE requirement bona-fide need. The CERF Board approach to the MDE requirement funding prioritization process will focus on enhancing, optimizing, and improving health care in support of the Quadruple Aim. The CERF Board voting members will include: the CERF Board Chairperson (DAD, DHA MEDLOG); Clinical group representation, such as Radiology, General Surgery/Perioperative Nursing, Internal Medicine, Pharmacy, Laboratory, etc.; CMO, DHA MEDLOG; Division Chief, DHA MEDLOG HTM; and Division Chief, DHA MEDLOG BO. To track all approvals, disapprovals, and the aggregated prioritization of all MDE requirements, the DHA MEDLOG HTM will:

(1) Using respective MTF/DTF and OLB local priorities as a starting reference point, the CERF Board will establish DHA enterprise priorities from 1-n for all approved Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, by respective estimated funding type (i.e., one 1-n list for Defense Health Program (DHP) Other Procurement and another for DHP Operations & Maintenance (O&M) funding, respectively). The CERF Board may adjust enterprise priorities throughout the FY based on, but not limited to, the following:

(a) If an MTF/DTF or OLB changes an MDE Requirement Prioritization Factor, local priority, or criticality of need for MDE.

(b) If an MTF/DTF or OLB cancels an MDE requirement.

(c) If an opportunity for a bulk buy or strategic purchase of MDE requirements that results in an overall cost savings becomes available.

(d) To prevent loss of funds due to procurement timelines potentially exceeding appropriation's expiration dates.

(2) The DHA MEDLOG HTM will document CERF Board established DHA enterprise priorities in DML-ES for potential funding (paragraph 4 of this enclosure).

(3) The EAB will review and/or update DHA enterprise priorities quarterly, or as necessary, in DML-ES.

4. FUNDING MDE REQUIREMENTS. MDE requirement funding decisions will be documented in DML-ES. The DHA MEDLOG BO will allocate funding to DHA MEDLOG

HTM. All DHP Other Procurement funding for MDE requirements will be allocated to DHA MEDLOG HTM, regardless of Integrated, Facilitated, or Decentralized MDE categorization. All funding for Integrated MDE requirements will be allocated to DHA MEDLOG HTM. All O&M funding for Facilitated MDE requirements will be allocated to either DHA MEDLOG HTM or distributed to the respective MTF's/DTF's or OLB's appropriate contracting partner. All O&M funding for Decentralized MDE requirements will be allocated to the MTF/DTF or OLB, or distributed to the respective MTF's/DTF's or OLB's contracting partner. MTFs/DTFs and OLBs will be able to use this funding for approved and prioritized MDE requirements above the cut-line, per the CERF Board and EAB, and for no other requirements.

a. Routine MDE Requirements. Funding for routine MDE requirements will be allocated by appropriation for MDE requirement procurement during the FY following the CERF Board determination of enterprise priorities of all routine Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, established between 15 July and 30 September of the prior FY.

b. Off-Cycle MDE Requirements. The DHA EAB funds off-cycle Integrated and Facilitated MDE requirements, and decentralized requirements over \$100,000, according to enterprise priorities up to available equipment procurement budget amounts quarterly for distribution by appropriation for MDE requirement procurement during the current FY. See paragraph 8 of this enclosure for details.

c. Emergency MDE Requirements. The Division Chief, DHA MEDLOG HTM coordinates approval and funding of emergency MDE requirements throughout the FY. See paragraph 8 of this enclosure for details.

d. Insufficient Funds. The MEDLOG Officer, MTF/DTF or Logistics Officer, OLB will request additional funding from the Division Chief, DHA MEDLOG HTM, should the actual cost of a funded Integrated and Facilitated or Decentralized MDE requirement over \$100,000 that exceeds the amount of funding allocated. The funding request will include the amount of funding required, a summary of the acquisition strategy and documentation supporting the need for additional funding. DHA MEDLOG HTM reserves the right to request additional information to rationalize the increase.

e. Local Funding Request. The MEDLOG Officer, MTF/DTF or Logistics Officer, OLB will request permission from the Division Chief, DHA MEDLOG HTM, to locally fund an unfunded, but approved Decentral MDE requirement (DHP O&M only).

f. Funding Above MTF/DTF or OLB Procurement Authority. Funds for MDE requirements at a cost that exceeds the MTF's/DTF's or OLB's procurement authority will not be distributed to the MTF/DTF or OLB. If inadvertent distribution occurs, the MTF/DTF or OLB will return the funding to DHA MEDLOG HTM. If an MDE requirement cost exceeds MTF/DTF or OLB procurement authority during the acquisition process, the MTF/DTF or OLB or contracting partner will return the funding to DHA MEDLOG HTM.

5. SOURCING MDE REQUIREMENTS. DHA MEDLOG HTM will evaluate sourcing strategies for Integrated and Facilitated MDE requirements, and decentralized requirements over

\$100,000. MDE requirement purchasers will follow sourcing strategies provided in DHA Approval Executive Summaries or this guidance. The contracting partner can specify required sourcing strategy documentation. The Tri-Service Medical Excess Distribution System should be reviewed first for all validated, approved, and prioritized MDE requirements.

a. Strategic Sourcing. Use of strategic sources is mandatory. DHA MEDLOG HTM strategic sourcing lists are available on the DHA MEDLOG SharePoint webpage at: <https://info.health.mil/sites/medlog/SitePages/Home.aspx>. The list correlates all normalized MDE device codes and nomenclatures available under each strategic sourcing vehicle. New Strategic Sources or Strategic Source Waivers may be requested in accordance with paragraph 11 of this enclosure. Strategic sourcing for medical equipment and supplies that are not readily available on DLA E-Cat, or other previously competed contract vehicles noted above should be coordinated with DAD P&C to ensure strategic sourcing decisions are compliant with the Competition in Contracting Act.

b. Non-Strategic Sourcing

(1) Review the Tri-Service Medical Excess Distribution System list for excess MDE that may meet MDE requirement need(s) before engaging in Non-Strategic Sourcing. Coordinate lateral transfer of MDE that meets your requirements with MDE losing activity.

(2) Conducting Market Research. If no strategic source is available and MDE must be procured by competition, MDE requirement market research must be conducted and documented in a manner appropriate for the complexity of the MDE requirement and sourcing research effort as well as comply with applicable FAR, DFAR, and DHA guidance on industry requests for information. Industry Requests for Information for non-strategic sourcing MDE must be coordinated through DAD P&C. In addition, appropriate technical and/or clinical representation is required for procurement of MDE. Product selection teams will include Technical and Clinical Validators as well as federal acquisition SMEs. Technical and clinical product selection criteria (including potential vendor demos or site walk-throughs) will be used for evaluating sources in competitive requirements. Such visits must be coordinated with DHA OGC and the supporting contracting activity to ensure compliance with applicable DHA and DoD guidance regarding industry engagements. The MTF/DTF and OLB Technical and Clinical Validators will advise the DHA contracting activity on Decentralized and Facilitated MDE requirements. DHA MEDLOG HTM Technical and Clinical representation will advise the contracting activity on Integrated and Facilitated MDE requirements. MTF/DTF and OLB Technical and Clinical Validators may be requested to assist with DHA MEDLOG HTM executed Integrated and Facilitated MDE procurements.

(3) Documenting Market Research. MDE requirement market research must be documented using multiple sources and include, at a minimum, the following information from each source available in the market:

(a) Ability to supply MDE meeting all clinically and technically approved MDE Requirements Data (paragraph 2.b. of this enclosure).

- (b) Clearance to market MDE, granted by the Food & Drug Administration.
- (c) MDE country of origin and other origin or zones as dictated by law.
- (d) MDE compatibility with MHS GENESIS, as applicable.
- (e) MDE sustainability and supportability, including:
  - 1. Unique TMDE.
  - 2. Unique equipment sustainment requirements.
  - 3. LCM offerings.
- (f) MDE lifecycle costs (install, purchase, and sustainment) by requesting estimates from vendors.
- (g) MDE RMF authority to operate status, including authority to operate number or source completed DHA Medical Devices and Equipment Risk Assessment documentation.
- (h) Contract vehicle availability (see paragraph 5.a of this enclosure).
- (i) For requirements that can be competed amongst multiple available sources, develop technical and clinical product selection criteria including previously documented MEC, including potential vendor demonstration or site walk-through requirements, in accordance with DHA DAD P&C guidance.
- (j) For MDE requirements that cannot be competed, or where one or more vendors are being excluded from competition, provide limited source justification as required by DAD P&C, or other contracting activity policy and guidance.
- (k) Additional documentation, as required by tasked contracting activity.

(4) Documenting Product Selections Decisions. Follow specific guidance for documenting product selection decisions from the servicing contracting activity, if a strategic source is not identified by DHA MEDLOG HTM and/or does not already exist.

6. PROCURING MDE. For the purposes of this DHA-PM, the scope of procurement and contracting refers to procurement and contract acquisition of MDE to meet the MEDLOG EA requirements for MDE, per references (e) through (g). MDE requirements documentation, MECs, and MDE sourcing strategy documentation should be used as preparation for contract execution. Technical and clinical product selection criteria (including MECs, and potential vendor demos or site walk-throughs) will be used for evaluating sources in competitive requirements. Depending on the contracting activity, additional procurement documentation may be required. MDE will only be procured in accordance with the applicable DHA Approval

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Executive Summaries, EAB, and CERF Board mandates. MDE requirements will not be submitted to a contracting activity if the MDE requirement has been invalidated, disapproved and/or if the MDE requirement has not been prioritized for funding. Technical and/or clinical SMEs are required for procurement of MDE; the technical evaluation team must include technical and clinical SMEs.

a. Suspenses. Respective MTFs/DTFs, OLBs, and/or DHA MEDLOG HTM will submit procurement documents before contracting authority suspense. All MDE requirements documentation must be submitted to contracting activity for execution of funded MDE requirements before contracting authority suspense. MTFs/DTFs or OLBs must notify DHA MEDLOG HTM if potentially unable to meet contracting activity suspenses, or in cases where a contracting activity will not process a funded MDE requirement.

b. Administrative Quality Assurance (QA). Respective MTFs/DTFs, OLBs, and/or DHA MEDLOG HTM will conduct and document procurement quality control before submitting procurement requirements to the contracting activity. Document and correct errors identified by the contracting activity, who will review and process all funded MDE requirements. The contracting activity may request additional information or documentation, as required in accordance with references (i) and (o) through (q). Additional input or documentation requested may be a draft performance work statement, statement of work, market research memorandum, Independent Government Cost Estimate, Limited Source Justification, customer Best Value Determination, and/or small business set aside determination, as applicable.

c. Technical Documentation Required for QA. To ensure purchases can be appropriately analyzed explained to the required oversight entities, all applicable technical and clinical SMEs, whether at the MTF/DTF, OLB, and/or DHA MEDLOG HTM will conduct a document quality review to ensure the required documents are in contract/purchase files before award. These documents include the following Government Acquisition Key Supporting Documents (KSDs) as shown below for all procured MDE, especially if the procurement is in bulk for multiple MTFs/DTFs and OLBs. Vendor or Contractor-provided documentation will not suffice as Acquisition KSDs. All MDE official Government contract actions, official Government Purchase Card (GPC) buys, Internal Transfers between MTFs/DTFs or OLBs, or other Non-Government-owned acquisition must include all Financial Improvement and Audit Readiness (FIAR) compliant details/language, other legally-required language, and any other contract language stipulated in the applicable DHA Approval Executive Summary. Acquisition KSDs must include, but not be limited to: requirement bona-fide need; contract award; line item configuration; item description/nomenclature; manufacturer; distributor (as applicable); common model; nameplate model; national stock number (if known); unique item identifier or DoD recognized Item Unique Identification; operating system; software or firmware version; line item cost (costs for equipment acquisition, installation, training, and trade-in credits each separated); recipient location (DoD activity address code, unit identification code, and activity name); acquisition date; warranty term; indication of Government or Non-Government (lease, loan, etc.) ownership; owner (both accountable and custodial organization); all legally required documentation; cybersecurity contract language (as provided by DHA CyberLOG; and all other documentation required to meet FIAR requirements.

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d. Execution. The requesting MTF's/DTF's or OLB's contracting partner will not procure Integrated or Facilitated MDE without the approval of DHA MEDLOG HTM. DHA MEDLOG may approve contracting for MDE by either a DHA contracting activity, or other approved contracting activity through assisted acquisition. Validated and funded Decentralized MDE requirements may be executed by a DHA contracting activity or through an approved assisted acquisition agreement.

(1) Integrated MDE requirements will be executed by either the DHA contracting activity, or other approved contracting activity through assisted acquisition. DHA MEDLOG HTM assumes responsibility for forwarding MDE requirements and providing additional procurement documentation to the contracting activity, as required. The Division Chief, DHA MEDLOG HTM will ensure execution of approved MDE procurements prior to funding expiration. DHA MEDLOG HTM will provide all required documentation to the MTF/DTF or OLB as necessary based on this DHA-PM and published HTM guidance. DHA MEDLOG HTM technical and clinical representation will technologically and clinically advise the contracting activity on Integrated MDE requirements; MTF/DTF and OLB Technical and Clinical Validators may be requested to assist.

(2) Facilitated MDE requirements will be executed in accordance with the Approval Executive Summary, which may include a combination of DHA MEDLOG HTM and MTF/OLB DTF execution activities. DHA MEDLOG HTM and MTF/DTF or OLB Technical and Clinical Validators will technologically and clinically advise the contracting activity on Facilitated MDE requirements.

(3) Decentralized MDE requirements, including decentralized requirements over \$100,000, will be executed by the MTF/DTF or OLB through the DHA contracting activity, or approved assisted acquisition, unless otherwise directed by the DHA HTM. The MTF/DTF or OLB assumes responsibility for forwarding MDE requirements and providing additional procurement documentation to the contracting activity, as required. The MTF/DTF or OLB will ensure execution of approved MDE procurements prior to funding expiration. The MTF/DTF or OLB Technical and Clinical Validators will technologically and clinically advise the contracting activity on Decentralized MDE requirements.

(4) Respective MTFs/DTFs, OLBs, and DHA MEDLOG HTM must obtain and properly file all Acquisition KSDs. The contracting activity must provide the aforementioned Acquisition KSDs, including all required details, to the respective MTF(s)/DTF(s), OLB(s), and DHA MEDLOG HTM, to meet all FIAR requirements. Respective MTFs/DTFs, OLBs will request and detail to the contracting activity the documents that must be provided in accordance with DHA property accountability, management, and sustainment guidance. Contract modifications will be required, if Government Acquisition KSDs do not include all required information for the MEDLOG EA.

7. CONFIRMING RECEIPT OF MDE. Confirmation of MDE receipt is required. Receipt of executed contract, GPC buy receipt, Internal Transfers between MTFs/DTFs or OLBs, or other Non-Government-owned acquisition will initiate MDE delivery coordination and, as applicable,

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installation management. Upon receipt of MDE, the responsible contracting officer representative, property book officer, or other accounting official will ensure that the HTM Manager, MTF/DTF or HTM Manager, OLB receives all Receipt KSDs, such as, but not limited to, shipping documentation, packing slips, and acceptance document(s), whether provided by the contracting authority or the contractor. Completed receipt and gain confirmation documents (Acquisition KSDs, Receipt KSDs, and APSR detail report) will be forwarded by the HTM Manager, MTF/DTF and HTM Manager, OLB to DHA MEDLOG HTM within 7 calendar days of MDE receipt for Facilitated and Integrated MDE. Confirmation of Facilitated and Integrated MDE installations will be forwarded by the HTM Manager, MTF/DTF and HTM Manager, OLB to DHA MEDLOG HTM within contractual timelines.

a. Onboarding MDE. For Decentralized MDE, the HTM Manager, MTF/DTF or HTM Manager, OLB will coordinate delivery and installation with the facility manager and/or vendor, as appropriate. For Facilitated MDE, the HTM Manager, MTF/DTF or HTM Manager, OLB will coordinate delivery and installation with the facility manager and/or vendor and DHA MEDLOG HTM, as applicable. For Integrated MDE, DHA MEDLOG HTM will coordinate delivery and installation with the facility manager and/or vendor and the HTM Manager, MTF/DTF or HTM Manager, OLB. MDE may require facility modification for installation requiring additional funds which must be coordinated prior to delivery and receipt.

b. Receipt and Gain. All MDE will be received and gained in accordance with DHA property accountability and management guidance and DHA MEDLOG HTM Sustainment guidance. Confirmation of acquisition [full delivery and completed install (as applicable)] of all Integrated and Facilitated MDE, and decentralized MDE over \$100,000, will be provided to DHA MEDLOG HTM. All MDE will be gained in the APSR within 7 calendar days of receipt in accordance with references (h) and (r), using the normalized device code and nomenclature assigned to the initially documented MDE requirement in DML-ES.

8. EMERGENCY AND OFF-CYCLE MDE REQUIREMENTS. Instances will occur when routine requirement approval procedures will not be feasible for emergency or off-cycle MDE requirements. Lack of planning is not justification to label an MDE requirement as emergency or off-cycle.

a. Emergency MDE Requirements. Emergency MDE requirements will not follow the same process as routine or off-cycle requirements, but procurement of MDE to meet emergency needs will follow correct acquisition procedures.

(1) Submission of Emergency MDE Requirements. The MEDLOG Officer, MTF/DTF or Logistics Officer, OLB may submit emergency MDE requirements in memorandum format to the Division Chief, DHA MEDLOG HTM at any time during the year. The memorandum will include as its subject, "Emergency MDE Requirement (FY ##)" and will address, at a minimum, the following:

(a) Justification for emergency consideration.

(b) Mission impact if delayed.

(c) Funding source (i.e., locally available or in lieu of funding another funded MDE requirement).

(2) Approval/Disapproval of Emergency MDE Requirements. The Division Chief, DHA MEDLOG HTM will approve or disapprove submitted emergency requirements within 24 business hours (target is 4 business hours). DHA MEDLOG HTM decisions will be documented on a response to the Emergency MDE Requirement memorandum. Additional information and/or guidance may be provided separately.

(3) Documentation of Emergency MDE Requirements. MTFs/DTFs and OLBs must document approved emergency MDE requirements in the designated MDE requirements management information system, DML-ES LogiCole, within 5 business days of contact with DHA MEDLOG HTM. MTFs/DTFs and OLBs must clearly indicate that the requirement is an approved emergency requirement by establishing it as an emergency new equipment request and by uploading the approved Emergency MDE Requirement (FY ##) memorandum in DML-ES.

(4) Emergency MDE Requirement Funding. The Division Chief, DHA MEDLOG HTM will assist in the coordination of funding emergency MDE requirements with the Division Chief, DHA MEDLOG BO. Unless local or enterprise level excess funding is available, approved emergency requirements may be funded by defunding other DHA approved/funded MDE requirements.

b. Off-Cycle MDE Requirements. Off-cycle Integrated and Facilitated and decentralized requirements over \$100,000 may be submitted at any time during the year and will be continuously reviewed for approval and funding by the EAB. Unless otherwise indicated, all off-cycle requirements are processed for approval in the same manner as routine MDE requirements but Integrated and Facilitated requirements, or requirements over \$100,000 will otherwise be reviewed quarterly by the DHA EAB. Off-cycle requirements will be clearly labeled as such in the designated MDE requirements management information system, DML-ES LogiCole, and should contain the FY of the current execution year. Procurement of MDE to meet off-cycle needs will follow the correct acquisition procedures.

(1) Off-Cycle MDE Requirements Documentation. Off-cycle requirements will include a justification memorandum signed by the Director, MTF/DTF or Director, OLB addressing why the requirement was not identified during planning the prior FY. The justification memorandum will be included in the off-cycle MDE requirement submission in the designated MDE requirements management information system, DML-ES LogiCole. The memorandum must address the following:

(a) Justification for requirement.

(b) Rationale why requirement was not identified earlier.

(c) Rationale for off-cycle review (consider availability of MDE in the referral network).

(d) Mission impact due to any delays.

(2) Off-Cycle Approval/Disapproval. Off-cycle Integrated and Facilitated requirements, and off-cycle requirements over \$100,000, will be considered for funding at the quarterly EAB following the off-cycle submission. Off-cycle Integrated and Facilitated requirements, and decentralized requirements over \$100,000, must be approved and funded by the EAB before they can be executed. Once approved and funded, the requirement will follow the normal acquisition method of procurement.

c. Funding Emergency and Off-Cycle Requirements. Each off-cycle or emergency requirement approved for funding may require the deferment of funding for a previously approved MDE requirement to the following FY.

9. NON-GOVERNMENT OWNED MDE. Requesting initial contract execution for Non-Government Owned MDE will be submitted like routine MDE requirements in the designated MDE requirements management information system, DML-ES LogiCole, excluding execution of existing approved option periods, MDE rentals, and short-term MDE demonstrations. Non-Government Owned MDE contract actions may be appropriate to meet immediate mission or clinical requirements where purchasing cannot be supported, in accordance with Reference (n) subpart 7.4. Requests for Non-Government Owned MDE will clearly indicate the party responsible for sustainment actions. The HTM Manager, MTF/DTF or HTM Manager, OLB processes all Non-Government MDE upon arrival on-site.

a. MDE Rentals and Leases. For MDE requirement submission purposes, MDE rentals are limited to less than 60 consecutive calendar days, whereas MDE leases are equal to or longer than 60 consecutive calendar days. CPT, CPRR, and supply/consumable contracts including MDE are considered MDE leases for MDE requirement submission purposes. Leasing MDE on the basis of possible future technology advances is not an acceptable justification for a rental, lease, CPT, CPRR, or supply/consumable contract including MDE. All forms of Non-Government Owned MDE leases will be classified as either capital leases or operating leases and will adhere to Reference (p).

(1) MDE Rentals. MDE rentals provide flexibility to meet short-term, peak demands, where leasing or purchasing similar MDE would be prohibitive. Rentals of MDE, less than 60 consecutive calendar days, do not require an MDE Lease Justification. Biannually, historical rentals over the prior 6 months will be reported by the MTF or OLB to DHA MEDLOG HTM for trend analysis. Common MDE rentals include MTF short-term needs due to:

(a) Arrival of patient(s) outside of projected demographic.

(b) Natural disaster, wartime, or other scenario requiring care for higher quantity of patients than projected.

(c) Patient(s) requiring a procedure or care only performed using MDE not owned by the MTF/DTF, where the MDE will not likely be needed past that single case (NOTE: this will not apply where the MTF has no clinical or technical providers trained on the proper use of the class/type of MDE; requirements for clinical services using contractor-provided MDE will be routed for procurement as a service).

(d) Procedures only performed using MDE that is less costly to rent by procedure rather than long-term leasing or outright purchasing the MDE.

(2) MDE Leases. If requesting a lease of MDE, excluding vehicle requests, for more than 60 calendar days (overall period of performance), the MTF/DTF or OLB must prepare written justification to lease versus purchase, in accordance with Reference (o) subpart 207.4. This MDE Lease Justification must be submitted along with the MDE requirement to DHA MEDLOG HTM for technical and clinical approval. Modifications to extend existing rentals past 60 consecutive calendar days require an MDE Lease Justification. MDE Lease Justifications are not required to exercise initially approved option periods. MDE Lease Justifications must include:

(a) Estimated use period and potential workload.

(b) Identification, availability, and advantages (financial and operating) of either acquisition option/method.

(c) Lease cost estimate for the entire life expectancy (LE) of the MDE (based on MHS Device Code Table), to include maintenance, transportation, installation, cybersecurity, and other service costs (NOTE: cybersecurity costs will include RMF fees and any fees required to retain all Hard Disk Drives or internal storage media, per Reference (m)).

(d) Net purchase cost estimate for the entire LE of the MDE (based on MHS Device Code Table), to include maintenance, transportation, installation, cybersecurity, and other service costs.

(e) Serviceability of specific MDE by HTM Sustainment (unless service is provided by vendor).

(f) Pending technological improvements, as applicable.

(g) Potential need for MDE by other MTF/DTF or OLB after use by requiring MTF/DTF or OLB, as applicable.

(h) Average trade-in value at LE and any other details required by Reference (n) subpart 7.401, as applicable.

(3) CPT and CPRR Contracts. CPT contracts, CPRR contracts, or other similar contract actions for MDE will be considered MDE Leases for MDE requirement submission purposes. CPT contracts and CPRR contracts require an MDE Lease Justification regardless of period of

performance or cost, unless qualifying as an emergency rental. Upon receipt of CPT equipment, MEDLOG will gain equipment using transaction code CPT.

(4) Supply or Consumable Contracts including MDE. Supply contracts for consumables or reagents used with MDE where the MDE is provided by a contractor, either at (a) no cost or (b) a cost built-into the cost of consumables or reagents, will be considered MDE Leases for MDE requirement submission purposes. Establishment of this type of supply contract action that includes MDE will require an MDE Lease Justification regardless of period of performance or cost, unless qualifying as an emergency rental.

(5) Emergency MDE Rentals. When failure to obtain MDE by emergency rental action would lead to loss of life or harm to a patient or personnel, the MTF or OLB should contact the CST or DHA MEDLOG HTM immediately, as needed. Emergency rental actions do not require DHA MEDLOG HTM approval, as long as the term does not exceed sixty (60) consecutive calendar days. Extensions of or follow-on actions to an emergency rental will require an MDE Lease Justification, if exceeding 60 consecutive calendar days total.

b. Vendor / MTF Agreements for MDE. All requests for external loan agreements that place Non-Government owned MDE in MTF/DTF or OLB custody will be submitted as an MDE requirement. External loan agreements for MDE longer than 60 consecutive calendar days require DHA MEDLOG HTM technical and clinical approval. Short-term independent clinical or technical staff use demonstrations of Non-Government Owned MDE (not used in direct patient care) will require an agreement between the vendor and MTF, but do not require an MDE requirement submission. It is required that vendor demonstration and external loan agreements include a clause entirely removing damage and loss liability from the Government, to be confirmed by Market, MTF/DTF, or OLB Legal Counsel.

(1) External MDE Loans. Loans of MDE included in existing sustainment contracts do not require approval by DHA MEDLOG HTM, unless DHA HTM Sustainment guidance indicates otherwise.

(2) Internal MDE Loans. Loans of Government Owned MDE between MTFs/DTFs or OLBs do not require an MDE requirement or MOU or MOA. However, loans between MTFs/DTFs and OLBs will be submitted for approval by the DHA MEDLOG HTM Property Lead in accordance with the DHA HTM Sustainment guidance. If the internal MDE loan exceeds 60 consecutive calendar days, the MTFs/DTFs and OLBs should consider transferring ownership of the MDE in accordance with DHA property accountability and management guidance.

(3) Emergency MDE Loans. Like emergency MDE rentals, when failure to obtain MDE by emergency loan would lead to loss of life or harm to a patient or personnel, the MTF/DTF or OLB should contact the CST or DHA MEDLOG HTM immediately, as needed. Emergency loans do not require DHA MEDLOG HTM approval unless exceeding 60 consecutive calendar days.

(4) Short-term Vendor Demonstrations of MDE. Vendor demonstrations that place MDE in the custody of an MTF/DTF or OLB without vendor direct supervision of clinical and technical staff will require a signed agreement between the MTF/DTF and the vendor that has been reviewed and approved by the servicing DHA OGC attorney. Vendor demonstrated MDE will not be used directly in support of patient care.

c. Demonstrations of MDE for Source Selection Purposes. Demonstrations of MDE for the purpose of source selection decisions must occur during the procurement process, under the supervision/direction of a Contracting Officer. Any demonstrations done outside the procurement process without the supervision/direction of a Contracting Officer cannot be used in source selection decisions. Prior to procurement, source selection MDE demonstrations will be coordinated in accordance with the associated request for offer or request for proposal. MTF/DTF and OLB requirements for source selection MDE demonstrations will be requested on the MTF's/DTF's and OLB's initial MDE requirement submission. Official source selection MDE demonstrations are not feasible for every MDE requirement and will be evaluated on a case by case basis.

10. APPEALING MDE REQUIREMENT DISAPPROVALS. DHA MTFs/DTFs and OLBs may appeal MDE requirement disapprovals within 10 business days of receipt of the MDE requirement Disapproval Executive Summary. The Division Chief, DHA MEDLOG HTM may extend time allowable for an MTF/DTF or OLB to submit a full and justified appeal to the EAB, not to exceed 30 calendar days. To officially appeal an MDE requirement denial, the MEDLOG Officer, MTF/DTF and Logistics Officer, OLB must submit a MFR (Appeal Memorandum) to the Division Chief, DHA MEDLOG HTM. The Division Chief, DHA MEDLOG HTM will review all appeals before submission to the EAB and may immediately approve any appeal. Incomplete MDE requirement submissions are not valid justifications for appeals.

a. Appeal Memorandum. The MEDLOG Officer, MTF/DTF and Logistics Officer, OLB must generate a complete Appeal Memorandum for each appeal. Incomplete Appeal Memorandums will not be considered by the Division Chief, DHA MEDLOG HTM or the EAB. The MEDLOG Officer, MTF/DTF and Logistics Officer, OLB will keep a local record of all Appeal Memorandums with associated MDE requirements documentation for a minimum of 5 calendar years. Appeal Memorandum must include:

- (1) ACN.
- (2) MDE Nomenclature.
- (3) Respective MTF/DTF or OLB.
- (4) Requirement POC at the MTF/DTF or OLB.
- (5) DHA MTF/DTF or OLB Technical Review Decision.
- (6) DHA MTF/DTF or OLB Clinical Review Decision.

- (7) DHA MEDLOG HTM Technical Review Decision.
  - (8) DHA MEDLOG HTM Clinical Review Decision.
  - (9) Justification for appeal.
  - (10) Signature of Appeal POC (MEDLOG Officer, MTF/DTF or Logistics Officer, OLB).
  - (11) Signature of Director, MTF/DTF or Director, OLB (not by direction).
- b. EAB. The EAB meets four times a year to centrally assess MDE requirements priorities, review appeals of disapproved requirements, review waivers to strategic sourcing contract vehicles, and prioritize funding of off-cycle requirements. Voting members of the EAB consist of the DAD, DHA MEDLOG (Chairperson); CMO, DHA MEDLOG; Division Chief, DHA MEDLOG HTM; and the Division Chief, DHA MEDLOG BO.

(1) Appeal Decision Memorandum. The EAB will format all official appeal responses as a MFR (Appeal Decision Memorandum). The Appeal Decision Memorandum includes information from the initial Appeal Memorandum and the following:

- (a) Appeal POC.
- (b) Appeals decisions (deferral, denial, approval, approval with conditions).
- (c) Justification.
- (d) Notification of next steps.

(2) EAB Decisions. Appeal deferrals will commonly require additional supporting documentation, details, and/or clarifications. Appeal deferrals should be done in a timely manner with the goal of completing the appeal process prior to the annual CERF Board. Appeal denials lead to the denial of the MDE requirement. Appeal approvals lead to the overturning of the initial MDE requirement disapproval, granting the MTF/DTF or OLB permission to procure the MDE without deviation from the MDE requirement. An appeal approval with conditions leads to the overturning of the initial MDE requirement disapproval, with specific mandates for the MTF, OLB and/or Market and/or MTF/DTF. All mandates, communication plans, and timelines will be included in the EAB Appeal Decision Memorandum under notification of next steps.

## 11. STRATEGIC SOURCE REQUESTS AND WAIVERS.

a. Requesting New Strategic Sources. Do not wait for the DHA MEDLOG HTM to establish a new strategic source before executing the purchase of a funded MDE requirement. If a strategic sourcing vehicle is not available for certain MDE, and the MTF/DTF or OLB determines that there should be enterprise consideration for a strategic source for the MDE, a

MEDLOG Officer, MTF or Logistics Officer, OLB may submit a Strategic Source request in memorandum format to the Division Chief, DHA MEDLOG HTM.

(1) New Strategic Source Justification. Requesting enterprise consideration of establishment of a new strategic source must include justification of the benefit from a strategic sourcing approach for an existing or new enterprise wide capability, such as:

(a) Requirements for MDE that are high dollar total enterprise cost, lower dollar with a high volume amongst the enterprise, or similar requirements that can be aggregated.

(b) Changes in clinical standard(s) of care, requiring re-review by enterprise clinical or technical personnel.

(2) Strategic Source Evaluation. DHA MEDLOG HTM may consider new strategic sources, for efficiency, to leverage purchasing power, and to reduce overall lifecycle costs to the enterprise. Strategic source evaluation and selection may not be used to avoid federal competition requirements and should only be used for MDE that is available on E-Cat, or other previously awarded contract vehicle. Any strategic sourcing outside of existing sources must be coordinated with DAD P&C to ensure compliance with the Competition in Contracting Act. MDE strategic source requests will be evaluated by DHA MEDLOG HTM for content on an ongoing basis and recommendations will be forwarded to the EAB and/or CERF Board for approval decisions. The DHA MEDLOG HTM will conduct evaluations in the following areas:

- (a) Throughput capacity of applicable contracting offices and authorities.
- (b) Return on investment of the contracting effort.
- (c) Clinical standard of care and stability/relevancy of technology.
- (d) Cybersecurity.
- (e) Lifecycle sustainment plan.
- (f) Existing ability or future costs for MDE integration with other MDE or enterprise systems.

(3) Strategic Source Request Decisions. The DHA MEDLOG HTM will make and communicate decisions on the strategic source requests within 60 days. The MEDLOG Officer, MTF and Logistics Officer, OLB will keep a local record of all strategic sourcing requests with associated MDE requirements documentation for a minimum of 5 years.

b. Requesting Strategic Sourcing Waivers. Do not submit a Strategic Sourcing Waiver Request for an MDE requirement for which a contract has already been awarded. If a strategic sourcing vehicle is available for required MDE, but the strategic sourcing vehicle cannot supply MDE meeting the MTF's/DTF's or OLB's unique clinical and/or technical needs, the MEDLOG Officer, MTF/DTF or Logistics Officer, OLB may submit an may submit a Strategic Sourcing

Waiver request to DHA MEDLOG HTM. DHA MEDLOG HTM tracks all waiver requests and resultant decisions made.

(1) Strategic Source Waiver Request Justification. Strategic Source Waiver Requests must include justification(s) that specify why a respective strategic source will not meet the sourcing needs of the MDE requirement. The MEDLOG Officer, MTF/DTF and Logistics Officer, OLB will only submit Strategic Sourcing Waiver Requests for unique functional capabilities and requirements.

(2) Strategic Source Waiver Request Evaluation. The DHA MEDLOG HTM will review Strategic Sourcing Waivers Requests for content and forward recommendations to the EAB and/or CERF Board for approval, approval with conditions, or denial. Incomplete Strategic Sourcing Waiver Requests will not be considered. DHA MEDLOG HTM may disapprove Strategic Sourcing Waiver Requests that are based solely on MDE make and model preferences.

(3) Strategic Source Waiver Request Decisions. All official Strategic Source Waiver Request decisions will be formatted as a MFR (Strategic Sourcing Waiver Request Decision Memorandum). Similar Strategic Sourcing Waiver Request Decisions may be formatted on a singular MFR. Strategic Sourcing Waiver Request decisions will be delivered to the MEDLOG Officer, MTF/DTF or Logistics Officer, OLB within 10 business days of decision. The MEDLOG Officer, MTF/DTF and Logistics Officer, OLB will keep a local record of all Strategic Sourcing Waivers with associated MDE requirements documentation for a minimum of the life of the procured MDE.

(a) Strategic Source Waiver Request deferrals will not exceed one (1) quarterly EAB cycle, becoming automatically disapproved without adequate, complete justification(s). Deferrals will commonly require additional supporting documentation, details, and/or clarifications.

(b) Strategic Source Waiver Request disapprovals do not lead to MDE requirement disapprovals. Instead, Strategic Source Waiver Request disapprovals require compliance with the mandatory strategic source. Strategic Source Waiver Request disapprovals may not be appealed.

(c) Strategic Source Waiver Request approvals grant the MTF/DTF or OLB the authority to procure MDE outside of the mandatory strategic sourcing vehicle.

(d) Strategic Source Waiver Request approvals that come with conditions will include specific mandates or actions that the MTF/DTF or OLB must complete in addition to being authorized to procure MDE outside of the mandatory strategic sourcing vehicle. All mandates, communication plans, and timelines will be included in the Strategic Sourcing Decision Memorandum under decision implementation guidance.

(e) Strategic Sourcing Waiver Request Decision Memorandums will includes information from the initial Strategic Sourcing Waiver Request and the following:

1. Waiver POC.
2. Waiver decisions (deferral, denial, approval, approval with conditions).
3. Decision justification.
4. Decision implementation guidance.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ACN	Acquisition Control Number
APSR	accountable property system of record
ASD	Assistant Secretary of Defense
BO	Business Operations
CBA	cost benefit analysis (also commonly called business case analysis)
CERF	Central Equipment Requirements for Funding
CMO	Chief Medical Officer
CPRR	cost per reportable result
CPT	cost per test
CST	Customer Support Team
CyberLOG	Cybersecurity Logistics
DAD	Deputy Assistant Director
DHA	Defense Health Agency
DHA-PM	Defense Health Agency-Procedures Manual
DHAR	Defense Health Agency Regions
DML-ES	Defense Medical Logistics-Enterprise Solution (also called LogiCole)
DHP	Defense Health Program
DTF	Dental Treatment Facilities
EA	Enterprise Activity
EAB	Equipment Appeals Board
ERA	Enterprise Requirements Assessment
FIAR	Financial Improvement and Audit Readiness
FY	fiscal year
HR	Human Resources
HTM	Healthcare Technology Management
KSD	Key Supporting Documents
LCM	lifecycle management
LE	life expectancy
MDE	Medical Devices and Equipment
MEC	minimum essential characteristics
MEDLOG	Medical Logistics
MFR	Memorandum for Record

MHS	Military Health System
MHS GENESIS	formal name for the Military Health System electronic health record
MILDEPS	Military Departments
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
MTF	Military Medical Treatment Facility
OLB	Other Lines of Business
O&M	Operations & Maintenance (specific to funding)
POC	Point of Contact
QA	Quality Assurance
RIT	Requisition and Installation Management Team
RMF	Risk Management Framework
SME	subject matter expert
SSO	Small Market and Stand Alone Medical Treatment Facility Organization
TMDE	Test Measurement and Diagnostic Equipment

## PART II. DEFINITIONS

Decentralized MDE. MDE having a lifecycle managed by the respective MTF/DTF or OLB, according to DHA MEDLOG policies and procedures. MDE 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.

Designated MDE requirements management information system. Enterprise system allowing a single point of access for entering and viewing MDE acquisition requests. The user will have visibility of an MDE request from creation through the review and approval process. Enterprise visibility of all new equipment requests in the designated MDE requirements management information system allows cost-saving initiatives by providing the ability to collect and analyze equipment demand and consolidate acquisitions. The current enterprise solution is DML-ES LogiCole.

DTF. Subordinate activities, elements, or organizations administered and managed by DHA at which direct patient dental care occurs.

Emergency MDE Requirement. An MDE requirement necessary for or involved in saving a life, preventing suffering, distress, or loss of faculty, limb, or eyesight. A true emergency MDE requirement situation is rare.

Enterprise Requirements Assessment. Evaluation of MDE needs, demands, and future projections across the DHA, using multi-dimensional authoritative data analytics and data modelling. These analytics will continuously refresh the MDE baseline. ERA site visits will be implemented by exception, triggered by certain criteria such as MDE capability gaps, significant mission changes, Military construction projects, site requests, and audits or inspection reports requiring action.

External MDE Loan. Borrowing of MDE by an MTF/DTF or OLB from an entity external to the DHA Enterprise (e.g., National Institutes of Health or a private company).

Facilitated MDE. MDE having a lifecycle jointly managed by both DHA MEDLOG HTM and the respective MTF/DTF or OLB. For each Facilitated MDE, DHA MEDLOG HTM will specify which aspects of the MDE lifecycle which the MTF/DTF or OLB will manage. In most cases, DHA MEDLOG HTM will manage cybersecurity and sustainment of Facilitated MDE. Defined by device code in the HTM Lifecycle Management Device codes spreadsheet at the following link: <https://community.max.gov/display/DoD/HTM+Requirements+Sub-Group>.

Integrated MDE. MDE, specific to certain device codes, for which DHA MEDLOG HTM will directly oversee complete LCM, 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 an MTF's Picture Archiving and Communication System (PACS). Defined by device code in the HTM Lifecycle Management Device codes spreadsheet at the following link: <https://community.max.gov/display/DoD/HTM+Requirements+Sub-Group>.

Internal MDE Loan. Borrowing of MDE by a DHA MTF/DTF or OLB from another DHA MTF/DTF or OLB.

MDE Baselines. MDE allowance lists for MTFs/DTFs and OLBs specific to device codes, established through comprehensive asset analysis, to include the current inventory state, identified mission requirements, risk, RMF, resource availability and sustainment for a multi-year projection. Baselines will be updated as required for mission changes, clinical needs, new technology, or as law or policy demands. For all MDE requirements that are absent from an MDE Baseline, MDE requirements may be used to develop a new MDE Baseline. The Division Chief, DHA MEDLOG HTM, in coordination with the ERA team, will publish MDE Baselines to establish benchmark quantities of MDE for MTFs/DTFs and OLBs.

MDE Lifecycle Management. The act of administering procedures and guidance for MDE requirement generation, validation, approval, strategic planning, funding, procurement, initial delivery, installation, acceptance, property accountability, management, sustainment, decommissioning, final dispositioning, and disposal.

Medical Devices and Equipment (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 manufacturer to be used for patient care.

Medical Logistics. A function of the MHS that provides the ability to organize and provide LCM of specialized medical products and logistics services required to support health readiness requirements across the range of military operations. MEDLOG functions include management of medical materiel (supplies, gases, equipment, and assemblages), medical equipment and its maintenance (including medical repair parts), blood distribution, optical fabrication, medical facilities management, MEDLOG services, and medical contracting.

Memorandum of Agreement. Used to document the specific terms and responsibilities that two or more federal entity parties agree to in writing. MOAs can be used to document a single reimbursable purchase, non-recurring reimbursable support, and non-reimbursable support. Consecutive reimbursable MOAs will not be used for similar single reimbursable purchases or non-recurring support to circumvent the use of DD Form 1144.

Memorandum of Understanding. Used to document issues of general understanding between two or more federal entity parties that do not involve reimbursement.

MTF. Subordinate activities, elements, or organizations administered and managed by DHA at which direct patient care does occur, including, but not limited to, medical centers, hospitals, ambulatory surgery centers, clinics, dental treatment facilities (DTFs).

Non-Government Owned MDE. Any accountable MDE in Government custody by means of a rental, lease, external loan, or vendor demonstration agreement. This includes MDE provided within a CPT, CPRR, supply/consumable contract or GPC buy.

Normalized data. Organized information, with eliminated redundancies and removed inconsistent dependencies within a database.

Off-cycle MDE Requirement. Unanticipated mission essential requirement that must be both approved and executed to meet the mission during the current FY. Cannot be routine MDE requirement that has not been appropriately planned or funded.

OLB. Subordinate activities, commands, elements or organizations administered and managed by DHA at which direct patient care does not occur, those with primary missions including, but not limited to, administration, optical fabrication, research, training, or regional and field (remote) activities.

Ranking Factors. A statistical pairwise comparison of these four values will generate a single rank value for each MDE requirement: criticality of need of new MDE (including risk of non-action); clinical and technological acceptability of new MDE; supportability of new MDE (consider supportability cost); and scoring of maintenance history of MDE being replaced, as applicable.

Strategic purchasing. The tactical aggregation of multiple Market, MTF/DTF or OLB MDE requirements within a specific clinical specialty or having a certain device nomenclature to

leverage consolidated purchasing power commonly using an identified strategic sourcing vehicle.

Strategic sourcing. A collaborative and structured process of analyzing an organization's spend and using the information to make business decisions about acquiring commodities and services more efficiently and effectively. Strategic Sourcing benefits include increased collaboration and communication, enhanced supplier relationships and market expertise, improved holistic views of Defense-wide requirements, increased workforce skills, standardized business processes, maintained workforce balance, reduced number of duplicative business arrangements, and reduced duplication of effort.