Defense Health Agency

PROCEDURAL INSTRUCTION

NUMBER 4140.01
September 13, 2021

DAD-MEDLOG

SUBJECT: Normalization of Medical Devices and Equipment (MDE) and General Equipment

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Procedural Instruction (DHA-PI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (g), and (h) parts 801 and 380, establishes the Defense Health Agency's (DHA) procedures to prescribe normalized device codes, nomenclature, and Accountable Property System of Record (APSR) data points for DHA MDE and General Equipment (GE) in accordance with the DHA Device Code Table data normalization of MDE and GE property management. Normalization, in this context is a standardization of data elements across the DHA enterprise and will solidify knowledge of the comprehensive DHA MDE and GE baseline. This will enhance audit readiness, increase efficiencies of future procurement actions; streamline Risk Management Framework processes; unencumber product Hazards, Alerts, and Recalls identification and resolution; and prevent unnecessary data duplication and improve interoperability between Military medical treatment facilities (MTFs) and within Markets, Small Market and Stand-Alone Medical Treatment Facility Organization (SSO), and Defense Health Agency Regions (DHAR).

2. APPLICABILITY. This DHA-PI applies to the DHA, DHA Markets, SSO, DHAR, Military Departments (MILDEPS); and military medical treatment facilities (MTFs) and dental treatment facilities (DTFs), within the MHS.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to References (d) through (g), that this DHA-PI outlines procedures to ensure compliance with paragraphs 1.2. and 4.6. of Reference (j), and establishes minimum requirements for data elements of accountable MDE and GE records.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosure 3.

6. PROPONENT AND WAIVERS. The proponent of this publication is the Deputy Assistant Director (DAD), Medical Logistics (MEDLOG). When Activities are unable to comply with this publication the activity may request a waiver that must include a justification, to include an analysis of the risk associated with not granting the waiver. The activity director or senior leader will submit the waiver request through their supervisory chain to DAD-MEDLOG to determine if the waiver may be granted by the Director, DHA or their designee.

7. RELEASABILITY. Cleared for public release. This DHA-PI 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-PI:

a. Is effective upon signature.

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

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

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Glossary

ENCLOSURE 1

REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
(b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
(c) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
(d) United States Code, Title 10, Section 1073c "Administration of Defense Health Administration and military medical treatment facilities", January 6, 2017, as amended
(e) DoD Instruction 6430.02, "Defense Medical Logistics Program," August 23, 2017
(f) DHA-Procedural Instruction 6430.02, "Defense Medical Logistics (MEDLOG) Enterprise Activity (EA)," September 27, 2018
(g) DoD Instruction 5000.64, "Accountability and Management of DoD Equipment and Other Accountable Property," April 27, 2017, as amended
(h) Code of Federal Regulations, Title 21, "Food and Drugs" Chapter I, Subchapter H, April 1, 2018

ENCLOSURE 2

RESPONSIBILITIES

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

a. Ensure established property management policies, standards, and performance measures that monitor and evaluate DHA-wide performance of property accountability, management, and interoperability are followed.

b. Ensure property management goals and expectations are clearly communicated throughout the Enterprise.

c. Implement this policy by providing direction on uniformity in the identification, classification, and inventory reporting of property.

d. Promote the use of best practices for property accountability and management.

2. ASSISTANT DIRECTOR, COMBAT SUPPORT. The Assistant Director, Combat Support, must:

a. Ensure a controlled environment for property accountability and oversight, to prevent loss, damage, theft, or waste, and to ensure appropriate financial reporting.

b. Promote the use of best practices for MDE and GE accountability and management, including the normalization of MDE and GE data in the APSR.

c. Promote successful system interfaces with standardized terminology, policies, and procedures.

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

a. Establish MDE and GE property management policies, standards, and performance measures.

b. Oversee the monitoring and evaluation of DHA Component performance in their achievement and sustainment of effective property accountability and management.

4. CHIEF, DHA MEDLOG HEALTHCARE TECHNOLOGY MANAGEMENT (HTM). The Chief, DHA MEDLOG HTM, must:

a. Appoint a DHA MEDLOG HTM Device Code Manager (DCM) to ensure the enterprise assigns the appropriate normalized device code, nomenclature, manufacturer, and common model to MDE and GE in the APSR and leads the DHA Device Code Working Group.

b. Assign HTM personnel, as needed, to manage and update MDE and GE records in the APSR.

c. Oversee the process for determining the proper maintenance intervals for MDE and GE.

5. DCM, DHA MEDLOG HTM. The DCM, DHA MEDLOG HTM must:

a. Provide monthly non-compliance data quality reports to DHA Component leadership, to include all MDE and GE reflecting [L####], [99998], and [99999] device codes in the DHA APSR and MDE and GE having mismatched APSR data points in comparison to the normalized standards.

b. Update the DHA Device Code Table, as appropriate, and publish a copy on the DHA MEDLOG HTM SharePoint (located at the link provided in paragraph 1.a. of Enclosure 3).

c. Request Joint Medical Logistics Functional Development Center (JMLFDC) patch the APSR, as needed, to ensure that device codes, nomenclatures, manufacturers, and common models, are available for selection in the APSR and align with the DHA Device Code Table.

6. SECRETARIES OF THE MILDEPs. The Secretaries of the Military Departments must ensure MTFs and DTFs under their authority, direction, and control comply with this DHA-PI.

7. DIRECTORS, DHA COMPONENTS. The Directors, DHA Components, must:

a. Ensure the proper resources are allocated for proper implementation of gaining and accountability of MDE and GE at their DHA Component.

b. Ensure the proper resources are allocated for implementation of HTM at their DHA Component.

c. Receive status reports of MDE and GE records, in accordance with this DHA-PI and Reference (g).

8. MEDLOG OFFICER, DHA COMPONENT. The MEDLOG Officer, DHA Component, must:

a. Assist in implementation of the gaining and accountability of MDE and GE at their DHA Component.

b. Ensure all MDE and GE acquisition documentation is available and provided to the HTM Manager, DHA Component, allowing for the proper gaining and accountability of MDE and GE at their DHA Component.

c. Actively assess, evaluate, and report status of MDE and GE records to the Director, DHA Component, in accordance with this DHA-PI and Reference (g).

9. HTM MANAGERS, DHA COMPONENTS. The HTM Managers, DHA Components, must:

a. Ensure all MDE and GE within their DHA Component are assigned the appropriate normalized device code, nomenclature, manufacturer, and common model in the APSR for all existing and new records.

b. Assign HTM personnel, Accountable Property Officer (APO), Biomedical Equipment Technicians, and/or Property Custodians, as needed, to manage and update MDE and GE records in the APSR.

c. Ensure the proper maintenance intervals are applied to all MDE and GE.

ENCLOSURE 3

PROCEDURES

1. INTRODUCTION. Paragraph 1.2.f. of Reference (g) states, "Standard common practices, processes, and taxonomy, including Unique Identifier (UID) or comparable methods and electronic transactions, will be used to the maximum extent practicable to improve the capability to gather, organize, and assess information on accountable government property." Additionally, paragraph 4.6.a. of Reference (g) states, "the following data elements, at a minimum, are required of an accountable property record and APSR: name, part number, description (noun, nomenclature), [nameplate and/or common] model number, serial number and national stock number." This data set of the required 16 data elements in Reference (g) of an accountable property record is the data element in which requires normalization across the DHA enterprise.

a. The DHA Device Code Table normalizes APSR data fields of all accountable MDE and GE records to ensure compliance with Reference (g). The data fields include device code, device nomenclature, device class, specialty, Federal Supply Classification, risk level, life expectancy, accountability, required maintenance activities (i.e., maintenance action type), required maintenance frequency (e.g.., interval/periodicity) and device definitions of MDE and GE across the MHS. The DHA Device Code Table is located at the following Common Access Card-enabled webpage:
https://info.health.mil/bus/medlog/healthtech/Pages/Forms/AllItems.aspx.

b. The DHA Device Code Table and Device Code Working Group, led by the DHA HTM DCM, utilize Original Equipment Manufacturer operator and/or service manuals, along with ECRI Institute (formerly Emergency Care Research Institute) Universal Medical Device Nomenclature System (UMDNS) industry standards for risk based maintenance, to establish the appropriate maintenance frequencies for the associated MDE and GE.

2. INSTRUCTIONS. All DHA Component HTM Managers, whether directly or through their HTM Personnel (APOs, Biomedical Equipment Technicians [Property Custodians, or otherwise]), must perform the following steps to ensure specific accountable MDE and GE record fields become and remain normalized in the APSR, according to the DHA Device Code Table. The MDE and GE record fields will be reviewed for accuracy by DHA Components HTM Managers encompassing but not be limited to, device code, nomenclature, manufacturer, and common model.

a. Existing MDE and GE. DHA MEDLOG HTM, in conjunction with the JMLFDC, has reviewed the APSR for Equipment Records of MDE and GE identified as high risk level, as a potential connection point to the MHS Electronic Health Record (MHS GENESIS), and as

gained prior to December 31, 2017. This review yielded a proper assignment of normalized data points. The results of this data normalization review are reflected as entries in the APSR "Equipment Notes" tab of each reviewed MDE and GE. For the MDE and GE already reviewed by DHA MEDLOG HTM and JMLFDC, the following steps must be completed no later than 12 months from signature of this instruction.

(1) The DHA Component HTM Manager, APO, or designee(s) must compare the DHA Device Code Table data normalization to the respective MDE and GE record fields in the APSR. Each of the respective MDE and GE record fields in the APSR must be corrected to match the normalized data.

(2) In the review conducted by DHA Component HTM Manager, APO or designee(s), if existing entries for the MDE and GE record fields in the APSR already align with the corresponding DHA Device Code Table data normalization, no further action is required.

(3) If any MDE and GE record fields require correction in the APSR and there are no discrepancies with DHA Device Code Table data normalization, the DHA Component HTM Manager, APO, or designee(s) will update the MDE and GE record fields in the APSR with the corresponding DHA Device Code Table normalized data. Upon completion of record update, the DHA Component HTM Manager, APO, or designee(s) will enter a new note in the "Equipment Notes" tab with the following input, "Applied, Equipment Record has been updated."

(4) If any MDE and GE record fields require correction in the APSR and there are discrepancies with DHA Device Code Table data normalization, the DHA Component HTM Manager, APO, or designee(s) will review the DHA Device Code Table for appropriate alternates (located at the link provided in paragraph 1.a. of Enclosure 3). Using the provided DHA Device Code Table, the DHA Component HTM Manager, APO or designee(s) will update the MDE and GE record fields in the APSR with the selected appropriate alternate. A new note with the following input "Discrepancy, used alternate (enter device code used)" will be entered in the "Equipment Notes" tab. The DHA Component HTM Manager, APO or designee(s) will utilize the normalized DHA Device Code Table to account for the exact MDE and GE accurately.

b. New MDE. In coordination with the New Equipment Request (NER) process, on an ongoing basis, prior to purchasing new MDE, the DHA Component HTM Manager, APO, and HTM Personnel must complete the following:

(1) Select the appropriate device code from the DHA Device Code Table, located at the link provided in paragraph 1.a of Enclosure 3. This selected central device code may be included in the official NER documentation.

(2) If the appropriate device code is not found on the DHA Device Code Table, the DHA Component HTM Manager, APO or designee(s) will first review ECRI Institute's UMDNS for an appropriate device code potentially excluded from the DHA Device Code Table.

(a) With this ECRI UMDNS device code and nomenclature, the DHA Component HTM Manager, APO, or designee(s) will utilize the DHA Global Service Center (GSC), specifically the Remedy portal, to request that a new device code, nomenclature, manufacturer, and/or common model be added the DHA Device Code Table. To reach the DHA GSC visit: https://gsc.health.mil/ and make the request to the DHA HTM DCM for review and action.

(b) The DHA Component HTM Manager, APO, or designee(s) will open the Remedy ticket. If the DHA HTM DCM locates appropriate device code, nomenclature, manufacturer, and/or common model that was not initially found by the DHA Component HTM Manager, APO, or designee(s), the HTM DCM will close the Remedy ticket and provide guidance to the DHA Component HTM Manager, accordingly.

(c) Once the appropriate new device code, nomenclature, manufacturer, and common model has/have been added to the DHA Device Code Table and APSR, the DHA Component HTM Manager, APO, or designee(s) will assign it appropriately to the new equipment, following the instructions in Reference (h), currently in draft.

(3) In the event there are no matches on the Device Code table or ECRI's UMDNS. The DHA Component HTM Manager, APO or designee(s) will utilize the DHA Global Service Center (GSC), specifically the Remedy portal, to request that a new device code, nomenclature, manufacturer, and/or common model be added the DHA Device Code Table. To reach the DHA GSC visit:
https://gsc.health.mil/ and make the request to the DHA HTM DCM for review and action.

(4) Identification of potential gaps within the DHA Device Code Table will be initially identified by DHA Component HTM Managers during the NER process, rather than at the time of equipment arrival at the DHA Component. In instances where a DHA Component is in jeopardy of not meeting the accountable property gain deadlines due to lack of appropriate device code being available for selection in APSR, the DHA Component HTM Manager, APO, or designee(s) will place a 'High' priority Remedy ticket in queue to request DHA HTM DCM guidance.

(5) When reviewing Original Equipment Manufacturer operator and service manuals, and considering local environmental conditions, frequency of use, and equipment age, if alternate maintenance intervals are selected by the DHA Component HTM Manager, the maintenance frequency must always be equal to or more stringent than the DHA Device Code Table. Confirmation of any deviation must be approved in writing by the Chief, DHA MEDLOG HTM. The DHA Component HTM Manager, APO, or designee(s) will coordinate any approved reduction through the local DHA Component Environment of Care (EOC)

Committee. Furthermore, the Chief, DHA MEDLOG HTM written approval of the deviation will be documented and recorded in both the EOC committee's meeting minutes and the Medical Equipment Management Plan.

c. Legacy Device Codes: [99998] General Purpose Medical Equipment, [99999] General Purpose Non-Medical Equipment and [L#####] locally created device codes are no longer authorized.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

APO	Accountable Property Officer
APSR	Accountable Property System of Record
DAD	Deputy Assistant Director
DCM	Device Code Manager
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
DHAR	Defense Health Agency Regions
ECRI	ECRI Institute (formerly Emergency Care Research Institute)
GE	General Equipment
GSC	Global Service Center
HTM	Healthcare Technology Management
JMLFDC	Joint Medical Logistics Functional Development Center
MDE	Medical Devices and Equipment
MEDLOG	Medical Logistics
MHS	Military Health System
MILDEPS	Military Departments
MTF	Military medical treatment facility
NER	New Equipment Request
SSO	Small Market and Stand-Alone Medical Treatment Facility Organization
UMDNS	Universal Medical Device Nomenclature System

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this DHA-PI.

APO. An individual who, based on their training, knowledge, and experience in property management, accountability, and control procedures, is appointed by proper authority to establish and maintain an organization's accountable property records, systems, and/or financial records, in connection with Government property, irrespective of whether the property is in the individual's possession. Comparable terms include: Army-Supply Support Accountable Officer/Property Book Officer; Navy-Personal Property Manager; Air Force-Accountable Officer/Chief of Supply/Chief of Material Management; Marine Corps-Accountable Officer; Joint Commands-Joint Property Book Officer.

data normalization. The process of organizing information, eliminating redundancies, and removing inconsistent dependencies within a database.

general equipment. Personal property that is functionally complete for its intended purpose, durable, and nonexpendable. Equipment generally has an expected service life of two years or more; is not intended for sale; does not ordinarily lose its identity or become a component part of another article when put into use; has been acquired or constructed with the intention of being used.