Defense Health Agency

PROCEDURAL INSTRUCTION

DHA EHR FUNCTIONAL CHAMPION

SUBJECT: Military Health System (MHS) GENESIS Medical Device Guidance to Military
Medical Treatment Facilities (MTFs)

References: See Enclosure 1.

1. <u>PURPOSE</u>. 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 (f), establishes Defense Health Agency's (DHA) procedures to:

   a. Provide key stakeholders' responsibilities for connecting medical devices to MHS
GENESIS.

   b. Establish clinical expectations for connecting medical devices to MHS GENESIS.

   c. Provide references for MTFs to use in procuring medical devices that will be connected to
MHS GENESIS.

   d. Provide process for MTFs to elevate medical device connection issues related to MHS
GENESIS.

2. <u>APPLICABILITY</u>. This DHA-PI applies to the DHA, Military Services, Markets, and MTFs.

3. <u>POLICY IMPLEMENTATION</u>: It is DHA's instruction, pursuant to References (a) through
(f), that a medical device governance structure, direction, and processes be established for
connecting and interfacing medical devices to MHS GENESIS.

4. <u>RESPONSIBILITIES</u>. See Enclosure 2.

5. <u>PROCEDURES</u>. See Enclosure 3.

6. <u>RELEASABILITY</u>. **Cleared for public release**. This DHA-PI is available on the Internet from the Health.mil site at: <u>www.health.mil/DHAPublications</u>.

7. <u>EFFECTIVE DATE</u>. 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).

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Director

Enclosures:
   1. References
   2. Responsibilities
   3. Procedures
   4. References for MTFs to Use When Procuring Medical Devices
   5. Process for MTFs to Use When Elevating Device Issues
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) DoDI 5400.16, "DoD Privacy Impact Assessment (PIA) Guidance," July 14, 2015
(e) Assistant Secretary of Defense for Health Affairs Memorandum, "Interim Guidance for Medical Devices," November 1, 2017[1]
(f) Memorandum of Agreement Between the DHA, PEO DHMS, U.S. Army Medical Command, U.S. Navy Bureau of Medicine and Surgery, and U.S. Air Force Medical Service for Military Health System GENESIS Implementation, September 12, 2018[2]

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[1] This reference can be found at: https://info.health.mil/sites/stratp/mditf/SitePages/Home.aspx
[2] This reference can be found at: https://info.health.mil/sites/stratp/mditf/SitePages/Home.aspx

ENCLOSURE 2

RESPONSIBILITIES

1. <u>DHA FUNCTIONAL CHAMPION (FC)</u>. Under the authority, direction, and control of the Assistant Secretary of Defense for Health Affairs, the DHA FC must:

a. Facilitate oversight of implementation and operational management of this DHA-PI.

b. Provide functional (clinical) governance for connecting medical devices to MHS GENESIS and make decisions, in collaboration with Service Chief Medical Information Officers (CMIOs) and MTFs, for what is connected during MHS GENESIS Go-live events and Post MHS GENESIS Go-live events across the MHS.

c. Collaborate with MTF points of contact (POCs); Defense Healthcare Management System Modernization (DHMSM) Program Management Office (PMO); DHA/Service Health Technology Management (HTM) functions; Medical Device Integration (MDI) Community; Deputy Assistant Director (DAD), Information Operations (IOs) staff; DHA/Service Cybersecurity Logistics; and others for medical device issues and assist in identifying requirements for new medical devices and clinical capability.

d. Govern the MDI Solution Owner and MDI Task Force (TF) in the processes and policies to connect medical devices to MHS GENESIS.

e. Collaborate with Service CMIOs, MTFs, DHA/Military Services, and DHMSM PMO to identify and validate devices that will be connected to MHS GENESIS in current and future states.

f. Pre-MHS GENESIS Deployment State. Advise and assist Medical-Community of Interest (Med-COI) personnel on zone architecture and internet protocol plans as they impact clinical operations and capabilities.

g. Share medical device authority to operate (ATO) status information with MTFs during pre-MHS GENESIS Go-live events.

h. Collect and share functional and technical data on connecting medical devices to MHS GENESIS to include, but not limited to, device nomenclatures, manufacturer's information, versions, equipment numbers, connection methods, MHS GENESIS compatibility, and ATO status. Communicate data to various stakeholders such as DHA/Service HTM functions, DHMSM PMO, MDI Community, Med-COI personnel, etc.

i. Provide DHMSM PMO, DHMSM contractors, DHA/Service HTM functions, and Med-COI personnel with medical device inventory data (for devices that will connected to MHS GENESIS), for each MTF prior to Current State Assessment in accordance with timeline established in Reference (f).

j. For existing medical devices, assist DHMSM PMO, DHMSM contractors, and DHA/ Service HTM functions with manufacturer relationships concerning manufacturer support in the pre-MHS GENESIS deployment state and with site engagements related to any medical device training and implementation issues.

k. Ensure documented lessons learned are communicated to MTFs, DHA/Service HTM functions, DHMSM PMO, and any others that will benefit.

l. Complete the medical device final, site-specific, MHS GENESIS medical device Go-live list, and coordinate with MTFs, DHMSM PMO, DHMSM contractors, and DHA/Service HTM functions to identify the required work for connecting medical devices to MHS GENESIS.

2. <u>SERVICE CMIOS</u>. The Service CMIOs must:

a. Offer clinical advice to all actors for medical device clinical capability requirements.

b. Validate clinical capability and medical device connection and interface requirements, as required.

3. <u>DHA AND SERVICE HTM FUNCTIONS (i.e., CLINICAL ENGINEERING)</u>. The DHA and Service HTM Functions (i.e., Clinical Engineering) must:

a. Provide direction to MTFs, Military Services, DHMSM PMO, DHA FC, MDI TF, and others on what medical devices to procure based on numerous planning factors, such as meeting required clinical capability, MHS GENESIS compatibility, technical obsolescence, clinical relevance, ATO status, lifecycle costs, lifecycle management, and acquisition strategies.

b. Advise the DHA FC and CMIOs on medical device and equipment (MDE) capabilities.

c. Provide updates and recommendations to the MDI TF, DHA FC, and CMIOs on procurement strategies.

d. Coordinate and execute cybersecurity work for medical devices. Collaborate with stakeholders (i.e., MTFs, DAD-IO, DHA FC, DHMSM PMO), and others in support of ATO and Risk Management Framework (RMF) efforts.

e. Post-MHS GENESIS Deployment State. Advise and assist Med-COI personnel on zone architecture and Internet Protocol plans as it impacts clinical operations and capabilities.

f. Be the source of medical device ATO status across the MHS. Communicate status as required to various stakeholders.

g. Assist MTFs with migrating devices for Med-COI, updating contracts or establishing agreements for Med-COI and integration with MHS GENESIS, and gathering required information.

4. <u>MARKET AND MTF DIRECTORS</u>. The Market and MTF Directors must:

a. Support MHS GENESIS MDI and connectivity during deployment and subsequent sustainment activities.

b. Coordinate with the DHMSM PMO, Service CMIOs, and DHA FC during MHS GENESIS pre-deployment activities to validate the initial list of medical devices that will connect to MHS GENESIS and correct any changes in accordance with the timeline established in Reference (f).

c. Develop, coordinate, and maintain Interconnection Security Agreements covering all interfaces between MTF systems and DHA systems. The DHA FC will assist the MTFs in coordinating these Interconnection Security Agreements for signature by the appropriate DHA officials.

d. Communicate within their own Market/MTF to ensure all medical devices are correctly identified for connection in a timely manner and ensure the Market/MTF personnel understand the timeline in Reference (f).

e. Participate in the migration activities and provide documentation for the Ports, Protocol, and Services for medical devices and infrastructure in accordance with Reference (f). This includes information from existing medical device manufacturers to support the RMF and ATO process. Failure to have information readily available may have a negative impact on the device's ability to communicate and may result in a loss of clinical functional capabilities as they relate to integration with MHS GENESIS or optimal zone architecture for cybersecurity compliance under Med-COI. If MTFs need help with or cannot perform this task, the MTFs can reach out to the DHA/Service HTM headquarter functions to coordinate how this task gets accomplished.

f. Participate in testing MHS GENESIS connection of medical devices as well as connectivity of computers, printers, and other equipment or peripherals such as barcode readers or scanners and assisting with cutoffs and/or decommissioning as required.

g. Assist with testing and troubleshooting to eliminate and diagnose medical device errors pre-MHS GENESIS deployment and post-MHS GENESIS migration. This includes serving, as needed, as a liaison between DAD-IO, manufacturers, Med-COI personnel, DHMSM PMO, and DHMSM contractors to fulfill information and data exchange requirements.

h. For existing medical devices and manufacturers, update contracts or establish agreements with manufacturers to cover onsite or remote support for migration of systems and medical devices to both the Med-COI enclave and integration with MHS GENESIS. For existing medical devices, collaborate with manufacturers to ensure connection preparation is accomplished, where needed, and ensure the manufacturer is available during MHS GENESIS site deployment, when needed. If MTFs need help with or cannot perform this task, the MTFs can reach out to the DHA/Service HTM headquarter functions to coordinate how this task gets accomplished.

i. In collaboration with MTF Biomedical Technicians, and/or MTF Clinical Engineering, and/or MTF Information Technology, gather all network connectivity requirements and design documents (Interface Control Documents (ICDs) and Interconnection Security Agreements, clinical or administrative documentation, and image conformance statements (e.g., Digital Imaging and Communications in Medicine), and associated interface communication protocol documentation (e.g., Health Level Seven). Make this information available for MHS GENESIS support. If MTFs need help with or cannot perform this task, the MTFs can reach out to the DHA/Service HTM headquarter functions to coordinate how this task gets accomplished.

j. Ensure all medical devices and system support software is up to date with all required operating system and application updates.

k. Ensure medical device information is properly updated or entered into property accountability records to include network, software, and cybersecurity information for each device connected to MHS GENESIS.

l. Ensure the connected medical devices have an approved ATO. If the medical devices do not have a current, approved ATO, the MTF will need to coordinate with their DHA/Service medical device cybersecurity specialists to ensure an ATO package is prepared and submitted, to include a Privacy Impact Assessment.

m. Assist in identifying MHS GENESIS pre-deployment connected medical devices as well as interfaces to both internal and external Electronic Health Records (EHRs) and business systems.

n. Verify network information is accurate and up to date for transitioning devices and systems pertaining to activities and workflow communication requirements from legacy network to Med-COI.

o. Ensure Business to Business and data exchange information is accurate as required.

p. Ensure site personnel are trained on all medical devices and associated systems for both maintenance and administration, as required, for ongoing clinical utilization, network connection, and MHS GENESIS interface requirements, processes, methods, and testing. Additionally, annually review personnel training and certification (or as deemed necessary), to ensure personnel meet necessary qualifications.

q. Ensure medical device service manuals are readily available and up to date prior to MHS GENESIS deployment.

r. Provide facility infrastructure support, planning, and coordination for necessary infrastructure additions and alterations for medical device or system implementation in accordance with Reference (f). Coordinate with DHA Health Information Technology, as necessary, for this task.

s. For new medical devices and systems acquisitions, budget for and allocate funding to cover the total cost of the device/system including MHS GENESIS connection/interfacing costs, cybersecurity (RMF, ATO, continuous monitoring, patching), costs, re-internet protocol costs, system upgrades, training costs, and lifecycle sustainment costs. MTFs may need to coordinate with Resource Managers, DHA Health Information Technology, DHA/Service HTM functions, and others to obtain cost information in order to budget accordingly.

t. Track the time spent on MHS GENESIS medical device tasks.

u. Ensure privacy impact assessments are conducted for any new and existing medical devices used to collect, maintain, use, or disseminate personally identifiable information (PII) in accordance with Reference (d).

ENCLOSURE 3

PROCEDURES

1. <u>MHS GENESIS GO-LIVE EVENT AT EACH MARKET/MTF</u>. All decisions to connect medical devices to MHS GENESIS begin with a validated, clinical need to exchange data with MHS GENESIS. Medical devices to be connected to MHS GENESIS will initially be identified and validated during a pre-implementation site assessment (in accordance with timeline in Reference (f)), performed by the MDI TF in collaboration and coordination with MTF staff and DHMSM PMO. The MDI TF develops the list of devices to be connected at each MTF in consensus with local staff and leadership and sends it to DHA FC and DHMSM PMO for consideration and action. Other groups, such as DHA/Service HTM functions, are coordinated with for final list validation. A final site assessment (in accordance with timeline in Reference (f)), performed by DHMSM PMO and DHMSM contractors, called a Current State Assessment, will ensure the devices are identified and validated before the MHS GENESIS Go-live event at each MTF. MTFs can request DHA/Service HTM functions to augment site assessments as they need.

2. <u>POST MHS GENESIS GO-LIVE EVENT FOR EACH MARKET/MTF</u>

   a. All medical devices which are not connected during each MTF MHS GENESIS Go-live Event will fall into what's called a "sustainment" function. This means these medical devices will require additional planning and evaluation to determine how and when they will be connected. In many instances, these devices will require some level of governance approval and will have to be worked into a prioritization backlog. Governance approval means devices have to be approved through the DHA FC staff and DHMSM PMO.

   b. If a MTF, Military Service, or DHA organization purchases new MDEs prior to deployment of MHS GENESIS, they should not automatically assume the device(s) will be connected, as all devices have to be approved and prioritized. The respective MTF or Military Service has the responsibility to coordinate the RMF effort for each device and fund the MHS GENESIS connection and/or interface work. The actual connection activity and schedule must be coordinated with the DHMSM PMO and DHA FC. If a newly purchased MDE replaces previously connected MHS GENESIS MDE, there is a reasonable expectation the new MDE will also be connected. The work to connect or interface the MDE will have to be projected and placed in a work queue.

3. <u>DEVICE PRIORITIES</u>. The DHA FC has developed a prioritization approach to determine which medical devices will be connected to MHS GENESIS.

   a. The general approach to connect medical devices at each MTF is:

(1) Where the lack of an EHR/device connection or interface directly impacts patient safety. MTFs must identify this as their first priority.

(2) Currently connected devices to Composite Healthcare System (CHCS)/Armed Forces Health Longitudinal Technology Application (AHLTA)/Essentris.

(3) Currently connected devices which feed data to other clinical systems, pending a validated, clinical need.

(4) Devices not currently connected to CHCS/AHLTA/Essentris, but a clinical requirement for connection exists. These devices may not be connected at an MHS GENESIS Go-live event; rather, these devices can be connected post-deployment and are site specific.

   b. The following clinical areas and device types have been identified for connection and/or interface to MHS GENESIS and are the most common for patient care:

(1) Laboratory (Lab)

(a) Lab Information Management Systems;

(b) Lab Analyzers; and

(c) All currently connected and interfaced lab devices to CHCS/AHLTA/Essentris, with a valid ICD.

(2) Automated Device Systems and Imaging Management Systems

(a) Imaging Management Systems will be connected regardless of modality. (Note: Imaging Management Systems are referred to as Picture Archive and Communication Systems (PACSs)).

(b) All currently connected and interfaced radiology devices and systems to CHCS/ AHLTA/Essentris, with a valid ICD.

(c) Examples of clinical areas having Imaging Management Systems are:

(1) Radiology

(2) Cardiology

(3) Nuclear Medicine

(4) Ophthalmology and Optometry

(5) Gastrointestinal, Endoscopy, and Urology

(6) Ear, Nose, and Throat

(7) Dermatology

(8) Dental Radiology

(9) Obstetric Ultrasound

(10) Point of Care Ultrasound

(11) Radiation Oncology

(12) and Sleep Study

(3) Pharmacy

(a) Pharmacy Management Systems when independent of the dispensing systems.

(b) Automation systems, workflow software, dispensing cabinets, and robotics.

(c) "Will Call" systems when independent of other systems.

(d) Point of use systems.

(e) All currently connected and interfaced pharmacy devices and systems to CHCS/AHLTA/Essentris, with a valid ICD.

(4) Point of Care devices (e.g., blood analyzers).

(5) Surgical and Critical Care Services:

(a) Anesthesia machines.

(b) Patient monitoring systems: physiological and fetal monitors.

(c) Ventilators.

4. OTHER CONNECTED DEVICES

a. The following direct patient care devices may connect to MHS GENESIS, but require further analysis (accomplished by the MTF) to determine if current connectivity to CHCS/AHLTA/Essentris exists, and if there is an MTF-specific, clinically-validated need to connect the specific device to MHS GENESIS:

(1) Infusion pumps

(2) Patient monitoring devices and systems (other)

(3) Ventilators (other)

(4) Hemodialysis

(5) Audiology to include analyzers and audiometers

(6) Ophthalmology and optometry specific devices (where devices are not connected through PACS or do not have an approved ICD)

(7) Electrocardiogram (Carts)

(8) Beds

(9) Apheresis units

(10) Extracorporeal membrane oxygenators

(11) Non-Digital Imaging and Communications in Medicine Standard and intermittent imaging devices (without a current PACS connection). Includes: dermatology, endoscopy (ear, nose, and throat), gastrointestinal, and intermittent devices.

b. Analysis is accomplished by the MTF on a case-by-case basis for each clinical area and device. Specific medical device (make and model), connection, and interface decisions are based on these factors, to include, but not limited to: patient safety, charting delays and/or errors, current connection status, utilization, enterprise procurement strategies, cybersecurity considerations, and point in device lifecycle. MTFs can request DHA/Service HTM functions to augment site assessments as they need.

ENCLOSURE 4

REFERENCES FOR MTFS TO USE WHEN PROCURING MEDICAL DEVICES

1. Medical and dental device procurement and acquisition decisions must be made in consultation with the DHA/Service HTM functions (i.e., Clinical Engineers). Acquisitions decisions must consider:

a. The clinical requirement and essential characteristics of the medical and dental device, to include the device-specific, industry-established data standard with MHS GENESIS.

b. Information about already approved, ongoing or planned medical/dental device standardization efforts.

c. Current or in-process ATO or ATO with Conditions under RMF.

d. If a previous or current ATO has not been accomplished on a required device, planning must carefully consider the following:

(1) Local capability to accomplish ATO authorization (to include a Privacy Impact Assessment approval process).

(2) Respective DHA/Services cybersecurity capability/capacity to accomplish ATO authorization.

(3) Use of other Military Service/National Capital Region capability/capacity to accomplish ATO authorization. Inter-Service and inter-agency reciprocity are to be used to the maximum extent possible by sharing assessment and authorization packages.

e. Cost of maintaining cybersecurity compliance throughout the device's lifecycle.

f. Other acquisition costs such as site preparation, training, test measurement and diagnostic equipment, contract overhead, interfaces, maintenance and sustainment.

g. Requirements of the medical and dental device Original Equipment Manufacturer (OEM) to comply with DoD and Service cybersecurity requirements to include continued ATO accreditation, OEM baseline continuous monitoring and updates, and business-to-business gateways (if required), at the time of award and throughout the device's OEM supported lifecycle.

2. Information to help MTFs with MHS GENESIS medical device questions or issues is posted at: https://info.health.mil/sites/stratp/mditf/SitePages/Home.aspx. The types of information posted on this website are:

    a. Device lists for currently connected MHS GENESIS devices.

    b. POCs (DHA FC, CMIO, MDI, HTM, cybersecurity, etc.).

    c. Frequently Asked Questions and Lessons Learned for MDI implementation.

3. Information to help MTFs with ATO and medical device acquisition questions or issues is posted at: https://info.health.mil/bus/medlog/healthtech/SitePages/Home.aspx. The types of information posted on this website are:

    a. Medical devices with ATOs.

    b. Medical device cybersecurity and acquisition guidance.

ENCLOSURE 5

PROCESS FOR MTFs TO USE WHEN ELEVATING DEVICE ISSUES

1. MTFs and Services will normally work with DHA FC staff and DHMSM PMO to identify and validate which medical devices will connect to MHS GENESIS upon initial deployment, to include capturing all relevant device connectivity data. This is the standard method.

2. Outside of the standard method, and to communicate an MHS GENESIS medical device connection or interface issue, users will enter a Global Support Center Remedy ticket, selecting the "OCHIO-MDI" drop down. This will identify the Remedy ticket appropriately and ensure proper routing.

3. A copy of the remedy ticket must also be sent to the following inbox: dha.ncr.j-3.mbx.mdi-task-force@mail.mil.

4. DHA FC staff, working with stakeholders (DHMSM PMO, DAD-IO, DHA/Service HTM functions and others) will recommend actions to take on the remedy ticket. DHA FC staff are responsible for providing feedback on the remedy ticket status.

5. Entry points for MTFs:

    a. For MHS GENESIS medical device connection or interface questions and issues contact the DHA FC at: dha.ncr.j-3.mbx.mdi-task-force@mail.mil.

    b. For medical device RMF or ATO questions, issues, or status, contact the DHA HTM Community. DHA/Service HTM POC contact information is located at: https://info.health.mil/sites/stratp/mditf/SitePages/Home.aspx.

    c. For medical device procurement and acquisition direction or advice, contact the DHA/Service HTM Community. DHA/Service POC contact information is located at: https://info.health.mil/sites/stratp/mditf/SitePages/Home.aspx.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

AHLTA	Armed Forces Health Longitudinal Technology Application
ATO	Authority to Operate
CHCS	Composite Healthcare System
CMIO	Chief Medical Information Officer
DAD	Deputy Assistant Director
DHA	Defense Health Agency
DHMSM	Defense Healthcare Management System Modernization
EHR	Electronic Health Record
FC	Functional Champion
FDA	U.S. Food and Drug Administration
HTM	Health Technology Management
ICD	Interface Control Document
IO	Information Operation
Lab	Laboratory
MDE	Medical Device and Equipment
MDI	Medical Device Integration
Med-COI	Medical-Community of Interest
MHS	Military Health System
MTF	Military Medical Treatment Facility
OEM	Original Equipment Manufacturer
PACS	Picture Archive and Communication System
PMO	Program Management Office
POC	Point of Contact
RMF	Risk Management Framework
TF	Task Force

PART II. DEFINITIONS

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

Accessory. An article that is not a device and is intended specifically by its manufacturer to be used with a device to enable the device to be used in accordance with the manufacturer's intended use of the device.

Medical Device Classification. The U.S. Food and Drug Administration (FDA) has established regulatory classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classifications based on the level of control necessary to assure the safety and effectiveness of the device. The three classifications and the requirements which apply to them are:

   Device Regulatory Class and Controls are as follows:

      Class I General Controls

         With Exemptions

         Without Exemptions

      Class II General Controls and Special Controls

         With Exemptions

         Without Exemptions

      Class III General Controls and Premarket Approval

Medical Device/Systems. Any instrument, apparatus, implement, machine, implant, appliance, or related article, including the software or enterprise solution necessary for its proper application, intended by the manufacture to be used for patients for one or more of the specific purposes of:

   Diagnosis, prevention, monitoring, treatment, in the cure, or alleviation of disease, or alleviation of or compensation for an injury or handicap. Supporting or sustaining life, and control of conception.

   Investigation, replacement, modification, or support of the anatomy or of a physiological process, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Including FDA medical devices/systems or applications, and other non-FDA regulated medical devices or applications that perform a single and/or dedicated medical function, either directly or in support of another medical device, clinical service or application that directly impact a patient's health care, (i.e., Biological Refrigeration (Blood Banks, etc.), Optical Fabrication, Pharmacy packaging equipment, Radio-Frequency Identification/ real-time location system and Temperature Sensitive Monitoring Program, and Medical Device Data System).

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

> Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them.

> Pharmaceuticals, blood products, and allografts. Examples: Medical devices include infusion pumps, pharmacy automation systems, lab analyzers, and electrosurgical units. Certain electronic radiation emitting products with medical application and claims that meet the definition of medical device to include diagnostic ultrasound products, x-ray machines, and medical lasers.

If a product is labeled, promoted, or used in a manner that meets the following definition in Section 201 of Reference (g), it will be regulated by the FDA as a medical device and is subject regulatory controls.

Note: Medical Device definition does not apply to mobile applications that function as a health record (EHR) system or personal health record system.

MHS GENESIS Deployment. This term refers to a specific event, in which the new EHR, MHS GENESIS, is installed at an MTF or site. For the purposes of this DHA-PI, the term "deployment" is the single event, and is distinguished from all follow-on work for medical devices.

MHS GENESIS Sustainment. This term refers to the time period after MHS GENESIS deployment at an MTF or site and is used in this DHA-PI to reflect that other medical devices can and will be connected in this time period known as "sustainment" versus the initial "deployment."