NUMBER 6430.05 July 8, 2021

DAD-MEDLOG

SUBJECT: Medical Image Management Systems Support Office (MIMSO)

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 (q) establishes the Defense Health Agency (DHA) MIMSO within the DHA Medical Logistics (MEDLOG) Division, Healthcare Technology Management (HTM) Branch. The DHA MIMSO is responsible for coordination, execution, and establishment of medical image management procedures across the functional elements of the DHA. The creation of this DHA-PI ensures the DHA MIMSO is effectively managed, and commercial off the shelf (COTS) Picture Archive and Communication System (PACS) requirements are appropriately defined against the clinical need and supporting business case.
- 2. <u>APPLICABILITY</u>. This DHA-PI applies to the DHA, DHA Components (activities under the authority, direction, and control of DHA), and the Military Departments and the military medical treatment facilities (MTFs)/dental treatment facilities (DTFs) under their authority, direction, and control).
- 3. <u>POLICY IMPLEMENTATION</u>. It is DHA's instruction, pursuant to References (d) through (q), that the DHA will:
- a. Transition the Service PACS Offices into a single DHA MIMSO. Service PACS Offices will follow current Service requirements for acquisition, system lifecycle management, and sustainment of PACS until the DHA MIMSO is adequately staffed and fully funded to manage medical image management systems for the enterprise.
- b. Develop and maintain an enterprise-wide medical image management strategy that considers all aspects of diagnostic imaging, regardless of type, from image acquisition to storage.

- c. Develop image management governance models for all medical images and associated metadata elements, ensuring models are applied uniformly to assure the highest clinical value.
- d. Develop a medical image lifecycle management (ILM) strategy and standardize medical imaging technical workflows.
- 4. RESPONSIBILITIES. See Enclosure 2.
- 5. PROCEDURES. See Enclosure 3.
- 6. <u>PROPONENT AND WAIVERS</u>. The proponent of this publication is Deputy Assistant Director (DAD)-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 the DAD-MEDLOG to determine if the waiver may be granted by the Director, DHA or their designee.
- 7. <u>RELEASABILITY</u>. **Cleared for public release**. This DHA-PI 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 <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).

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

Enclosures

- 1. References
- 2. Responsibilities
- 3. Procedures

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) National Defense Authorization Act for Fiscal Year 2017, Section 702
- (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) DHA-Administrative Instruction 109, "Decision-Making Architecture (DMA)," October 15, 2019
- (h) DHA-Procedural Instruction 6000.02, "Healthcare Technology Management (HTM) Medical Devices and Equipment (MDE) Requirements Management for Military Medical Treatment Facilities (MTFs)," June 15, 2020
- (i) Code of Federal Regulations, Title 21, Chapter 1, Section 892.2050, "Picture Archiving and Communications System," April 29, 1998, as amended
- (j) DHA-Procedural Instruction 8400.01, "Cybersecurity Logistics (CyberLOG) Medical Devices and Equipment (MDE) Risk Management Framework," March 2, 2020
- (k) DHA Health Information Technology Catalog of Services, June 14, 2016¹
- (l) DHA-Interim Procedures Memorandum 18-013, "Risk Management Framework (RMF)," September 20, 2019
- (m) DoD Directive 8140.01, "Cyberspace Workforce Management," October 5, 2020
- (n) DoD 8570.01-M, "Information Assurance Workforce Improvement Program," December 19, 2005, as amended
- (o) Mammography Quality Standards Act (MQSA) Regulations, Subpart B: Quality Standards and Certification, Section 900.12(c)(4)(i), "Medical Records and Mammography Reports"
- (p) DoD Instruction 8580.02, "Security of Individually Identifiable Health Information in DoD Health Care Programs," August 12, 2015
- (q) DoD Manual 6025.18, "Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs," March 13, 2019

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¹This reference may be found at: https://info.health.mil/hit/id/km/intranet/Guides/HIT_Catalog_of_Services.pdf.

ENCLOSURE 2

RESPONSIBILITIES

- 1. <u>DIRECTOR, DHA</u>. The Director, DHA, will:
 - a. Exercise overall responsibility for the DHA MIMSO.
- b. Support the development of an enterprise-wide image management strategy for all medical images.
- 2. <u>DAD-MEDLOG</u>. The DAD-MEDLOG must:
- a. Exercise authority over the MIMSO pursuant to Reference (g), and in accordance with References (e) and (f).
- b. Ensure the MIMSO establishes policies and administration of medical image management systems for DHA.
- 3. CHIEF, DHA HTM BRANCH. The Chief, DHA HTM Branch must:
 - a. Ensure the MIMSO is adequately staffed and funded to support the DHA mission.
- b. Submit out-of-cycle, urgent requirements to the quarterly review board utilizing procedures outlined in Reference (h).
- 4. <u>CHIEF, DHA CYBERSECURITY LOGISTICS (CYBERLOG)</u>. The Chief, DHA CyberLOG must:
- a. Direct all Medical Devices and Equipment cybersecurity activities across the Military Health System (MHS) in accordance with Reference (j).
 - b. Coordinate PACS Risk Management Framework activities with MIMSO.

5. MIMSO OFFICE MANAGER. The MIMSO Office Manager must:

- a. Reside in DHA MEDLOG, HTM Branch, and is responsible for COTS medical image management system acquisitions, operation, and sustainment.
 - b. Assist with coordinating the transition of the Service PACS Offices to the DHA MIMSO.
- c. Solicit advice and support from the appropriate DHA Clinical Consultants/Subject Matter Experts and provide guidance and oversight pertaining to the DHA MIMSO.
- d. Develop and implement a comprehensive medical image management system product support strategy.
- e. Coordinate medical image management system lifecycle management activities for DHA components.
- f. Coordinate and maintain medical image management system connections for MHS GENESIS implementation.
- g. Coordinate and maintain medical image management system teleradiology connections between DHA Components and/or Markets.
- h. Advise the appropriate DHA clinical boards/specialty groups on the technical implementation of medical image management and image sharing across the enterprise.
- i. Continuously assess the status of medical image management systems deployed across the MHS to identify improvement opportunities in support of DHA medical image management initiatives.
- j. Ensure medical image management systems are in compliance with cybersecurity requirements defined by CyberLOG as outlined in Reference (j).
 - k. Identify and communicate budgetary requirements for COTS PACS' and the MIMSO.
- 1. Consolidate and/or create centralized service maintenance agreements for currently installed and newly acquired medical image management systems.
- m. Develop a strategy to combine existing regional medical image archive solutions into a single unified platform.
- n. Ensure PACS are in compliance with the requirements for safeguarding protected health information outlined in References (p) and (q).

- 6. <u>SECRETARIES, MILITARY DEPARTMENTS</u>. The Secretaries of the Military Departments will ensure MTFs and DTFs under their command and control comply with the guidance in this publication.
- 7. MARKET, SMALL MARKET AND STAND-ALONE MEDICAL TREATMENT FACILITY ORGANIZATION (SSO), AND DEFENSE HEALTH AGENCY REGIONS (DHAR) DIRECTORS. The DHA Market, SSO, and DHARs Directors must:
- a. Assist the MIMSO in ensuring PACS deployed within their DHA Component(s) are installed consistent with DHA policies.
- b. Assign a Picture Archive and Communication System-System Administrator (PACS-SA) to manage all PACS associated administrative tasks.
- 8. MARKET, SSO, DHAR, MTF, AND DTF PACS-SA. The Market, MTF, and DTF PACS-SA is assigned by the Market, SSO, DHAR, MTF, and DTF Director to ensure the system(s) are properly maintained and the medical image management system are continuously ready and clinically safe for use. The Market, SSO, DHAR, MTF, and DTF PACS-SA must:
 - a. Maintain day-to-day PACS operations, management, and troubleshooting.
- b. Maintain cybersecurity training and certifications, as required in the applicable position descriptions and contracts, in accordance with References (m) and (n).
- c. Ensure vendor service tickets and medical maintenance work orders have been properly coordinated with sustainment.
 - d. Escalate vendor service tickets to MIMSO if not resolved within 5 business days.
 - e. Notify MIMSO via e-mail at: dha.detrick.med-log.mbx,pacs@mail.mil of:
 - (1) Any unscheduled downtime;
 - (2) Receipt of new equipment (e.g., trade outs, new systems, monitors); and
- (3) Local Storage concerns (e.g., image cache, advanced notice of new modalities, new requirements).
 - (4) Lost or broken external connections that cannot be resolved locally.
- f. Follow the breach response procedures outlined in Reference (q), upon discovery of a breach of protected health information (should images within the PACS be compromised).

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9. MTF DIRECTORS. The MTF Directors must:

- a. Assist the MIMSO in ensuring PACS deployed within their MTF are installed consistent with DHA policies.
 - b. Assign a PACS-SA to manage all PACS associated administrative tasks.

10. <u>DTF DIRECTORS</u>. The DTF Directors must:

- a. Assist the MIMSO in ensuring PACS deployed within their MTF are installed consistent with DHA policies.
 - b. Assign a PACS-SA to manage all PACS associated administrative tasks.

ENCLOSURE 3

PROCEDURES

- 1. <u>ESTABLISHMENT OF THE DHA MIMSO</u>. DHA MEDLOG, HTM Branch, will coordinate the transition of activities from the current Service PACS Offices into the MIMSO.
- a. The Service PACS Offices will follow current Service specific process for procurement, system lifecycle management, and sustainment of PACS until the MIMSO is adequately staffed and fully funded to assume management of medical image management systems for the enterprise.

b. The MIMSO will:

- (1) Identify medical image management requirements for the following clinical areas at all DHA Components within each Market, SSO and DHAR to include, but not limited to radiology, cardiology, dental, endoscopy, nuclear medicine, radiotherapy, obstetrics, gynecology, ophthalmology, optometry, dermatology, pathology, veterinary medicine, and medical photography.
- (2) Coordinate technical connections with operational PACS to ensure images are properly stored in a central archive.
- (3) Define an organizational structure to support future medical image management system acquisition, system lifecycle management and sustainment.
- 2. <u>ENTERPRISE-WIDE MEDICAL IMAGE MANAGEMENT STRATEGY</u>. The MIMSO will ensure medical image management requirements are continually assessed and updated as necessary. Integration with other MHS medical information systems will be built into system requirements prior to procurement. The MIMSO is responsible for establishing procedures, including coordination with appropriate organizations to execute medical image management for DHA and will:
- a. Solicit advice and support from the appropriate DHA Clinical Consultants/Subject Matter Experts and provide guidance and oversight pertaining to the MIMSO. Representatives from DoD components, and other Government agencies not mentioned within this DHA-PI may be invited to participate on an as-needed basis.
- b. Under the guidance and support of the various clinical communities, establish a configuration control panel to ensure successful integration and interoperability across the enterprise so that patient care will not be impacted when a patient moves between MTFs and DTF for care.

c. Coordinate within DHA MEDLOG for requirements generation, lifecycle management, analysis and assessments, and disposition of systems.

3. MEDICAL IMAGE MANAGEMENT GOVERNANCE MODEL

- a. The MIMSO will establish procedures for normalizing medical image data. The process of normalizing data ensures all patient imaging records are captured with accurate patient demographics and minimal redundancy.
- b. Normalization is accomplished by utilizing systems that originate source of truth data. Within the DoD these systems include, but are not limited to, Defense Enrollment Eligibility Reporting System, Composite Health Care System, Armed Forces Health Longitudinal Technology Application, and MHS GENESIS®. Information received from these systems are transferred via Health Level Seven messaging based off of scheduling and/or orders to the associated medical image management system for the creation of modality and diagnostic reading worklists.
- c. The process for ensuring all images are accessible involves the MIMSO verifying that the PACS vendor's unique and propriety formats are not being utilized, and their system is able to export to an industry standardized format. These formats include, but are not limited to, Digital Imagine and Communications in Medicine (DICOM), Health Level Seven (HL7), Joint Photographic Experts Group (JPEG) 2000, Moving Picture Experts Group (MPEG), and Portable Document Format (PDF). Compression algorithms are to be set to lossless to ensure data integrity of medical imaging.
- d. Third-party imaging studies are required to be imported back into the DoD's Enterprise Clinical Imaging Archive solution. With input from the clinical community, MIMSO will establish procedures for managing third-party studies at both the local and enterprise levels.
- e. The MIMSO will work with the DHA Health Informatics, Telehealth or Virtual Health Offices, and appropriate clinical consultants to coordinate system to system connections for the purpose of medical image sharing to include teleradiology.
- 4. <u>ILM STRATEGY</u>. MIMSO will establish a medical ILM strategy and technical image workflow processes for all medical image management systems deployed throughout the MHS. ILM is a holistic enterprise imaging strategy that manages images from acquisition at the imaging modality and initial storage through final disposition. At a minimum, ILM will consider:
- a. Developing an image retention policy for all medical images stored in DHA medical image management systems, or central archives to include mammography as required by Reference (o).

b. Defining where studies are stored, replicated, how they are compressed, the tier of storage on which they are stored, purging rules, and keeping studies up-to-date (e.g., patient name and demographic changes).

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

COTS commercial off the shelf CYBERLOG Cybersecurity Logistics

DAD Deputy Assistant Director DHA Defense Health Agency

DHA-PI Defense Health Agency-Procedural Instruction

DHAR Defense Health Agency Region

DTF dental treatment facility

HTM Healthcare Technology Management

ILM image lifecycle management

MEDLOG Medical Logistics
MHS Military Health System

MIMSO Medical Image Management Systems Support Office

MTF military medical treatment facility

PACS Picture Archive and Communication System

PACS-SA Picture Archive and Communication System-System Administrator

SSO Small Market and Stand-Alone Medical Treatment Facility

Organization

PART II. DEFINITIONS

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

lossless compression. Compression of an image that reduces the file size with no loss of quality.

medical imaging. The technique and process of creating a visual representation of the interior or exterior of a body for clinical analysis and medical intervention.

medical image management system. Is a generic term used for COTS PACS. A PACS, as described in Reference (i), is a Class II medical device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. The hardware components may include workstations, digitizers, communications devices, computers, medical grade monitors, and digital data storage devices. The software components

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may provide functions for performing operations related to image manipulation, enhancement, compression, or quantification. The terms medical image management system and PACS may be used interchangeably.

<u>normalizing data</u>. Process of ensuring all patient records are captured with accurate patient demographics and images are stored in industry standardize formats.

<u>source of truth</u>. In information systems design and theory, single source of truth is the practice of structuring information models and associated data schema such that every data element is stored exactly once. For PACS, this applies to patient demographic data which uses Defense Enrollment Eligibility Reporting System as the source of truth for DoD.

third-party services. Services performed outside of a MTF such as a commercial reading service.

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