Defense Health Agency

ADMINISTRATIVE INSTRUCTION

NUMBER 6430.11
October 14, 2021

MEDLOG

SUBJECT: Healthcare Technology Management (HTM) Biomedical Equipment Program

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Administrative Instruction (DHA-AI) based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (w), establishes standard Defense Health Agency (DHA) processes and procedures for covering HTM functions, including Biomedical Maintenance and Quality Control for Medical Devices and Equipment (MDE) to ensure a safe, efficient, effective, and reliable healthcare environment for staff and patients.

2. APPLICABILITY. This DHA-AI applies to the DHA, the Markets, Small and Stand-Alone Medical Treatment Facility Organization, Defense Health Agency Regions, and all personnel to include: assigned or attached Active Duty, Reserve and National Guard members, members of the Commissioned Corps of the Public Health Service, federal civilians, contractors (when required by the terms of the applicable contract), other personnel assigned temporary or permanent duties at DHA and DHA Components, to include Other Lines of Business (OLB) under the authority, direction, and control of the DHA.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant References (a) through (f), that governance decision support and standard practices be communicated, ensuring all DoD Healthcare MDE in the Military Health System (MHS) are available, functional, and safe for patient centered care. Program guidance is based upon MHS strategy, risk and mission priorities, laws, regulations, and policies.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosure 3.

6. RELEASABILITY. **Cleared for public release**. This DHA-AI 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.

7. EFFECTIVE DATE. This DHA-AI:

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).

8. FORMS

a. SF 368, Product Quality Deficiency Report is available at: https://www.gsa.gov/forms-library/product-quality-deficiency-report.

b. DD Form 2163, Medical Equipment Verification/Certification is available to order from: https://forms.documentservices.dla.mil/order/.

c. DHA Form 158, Medical Equipment Repair Tag is available to order from: https://forms.documentservices.dla.mil/order/.

d. DHA Form 149 HTM Sustainment Work Order is available at: https://info.health.mil/cos/admin/DHA_Forms_Management/Lists/DHA%20Forms%20Management/AllItems.aspx.

e. FDA Form 2579, Report of Assembly of a Diagnostic X-ray System can be obtained by emailing the Forms Manager. More details at: https://www.fda.gov/about-fda/forms/requesting-forms-warehouse.

f. FDA Form 3500A, MedWatch Online Voluntary Reporting Form is an online form accessible at: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home.

/S/
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Director

Enclosures
1. References
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Glossary

ENCLOSURE 1

REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
(b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
(c) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
(d) Public Law 114-328, Section 702 "National Defense Authorization Act for Fiscal Year 2017," December 23, 2016
(e) Public Law 115–91, Section 702 "National Defense Authorization Act for Fiscal Year 2018," December 12, 2017
(f) Public Law 115–874 "John S. McCain National Defense Authorization Act for Fiscal Year 2019," July 15, 2018
(g) Public Law No: 116-92, Section 702 "National Defense Authorization Act for Fiscal Year 2020," December 19, 2019
(h) DoD Instruction 6430.02, "Defense Medical Logistics Program," August 23, 2017
(i) DHA-Procedural Instruction 6430.02, "Defense Medical Logistics (MEDLOG) Enterprise Activity (EA)," September 27, 2018
(j) DoD Instruction 5000.64, "Accountability and Management of DoD Equipment and Other Accountable Property," April 27, 2017, as amended
(k) National Fire Protection Association 70, "National Electrical Code," current edition[1]
(l) National Fire Protection Association 99, "Healthcare Facilities Code," current edition adopted[2]
(m) National Fire Protection Association 101, "Life Safety Code," current edition[3]
(n) Public Law 104-191, "Health Insurance Portability and Accountability Act (HIPAA)," August 21, 1996
(o) DoD Manual 6025.18, "Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Compliance in DoD Health Care Programs," March 13, 2019
(p) DoD Instruction 8580.02, "Security of Individually Identifiable Health Information in DoD Health Care Programs," August 12, 2015
(q) DoD Instruction 5400.11, "DoD Privacy and Civil Liberties Program," May 8, 2007
(r) Code of Federal Regulations, Title 21, Parts 1000 and 1020
(s) DoD Regulation 7000.14-R, "Department of Defense Financial Management Regulation," June 2017, as amended
(t) DoD Instruction 8500.01, "Cybersecurity," October 7, 2019, as amended
(u) Code of Federal Regulation, Title 29, Chapter XVII
(v) United States Code, Title 21, Section 201
(w) DoD Instruction 6055.08 "Occupational Ionizing Radiation Protection Program," April 9, 2021

[1] This reference can be accessed through MTF purchased copy or viewed through user account at www.nfpa.org
[2] This reference can be accessed through MTF purchased copy or viewed through user account at www.nfpa.org
[3] This reference can be accessed through MTF purchased copy or viewed through user account at www.nfpa.org

ENCLOSURE 2

RESPONSIBILITIES

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

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

b. Report MHS MDE information in accordance with Reference (g).

c. Report consolidated forecasted data for MDE Accounts for each year of the Future Years Defense Program in accordance with Reference (g).

d. Reconcile all MDE property data for all assets that the DHA owns, operates, or maintains in accordance with Reference (g).

2. DHA MARKET, SSO, AND DHAR DIRECTORS. Market, SSO, and DHAR Directors must ensure compliance with this publication.

3. DAD-MEDLOG. DAD-MEDLOG will:

a. Support strategies and programs through the responsibilities outlined in Reference (f).

b. Designate, in writing, a primary DHA MEDLOG HTM Chief Clinical Engineer.

c. Monitor and report the overall condition, utilization, and functionality of the MHS MDE portfolio.

d. Ensure all MDEs operated or maintained by an MHS organization are accurately recorded within the Accountable Property System of Record (APSR) (i.e., Defense Medical Logistics Standard Support (DMLSS), LogiCole) in accordance with established policy.

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

a. Ensure supported DHA MTF/DTF/OLBs have established site maintenance programs which will include standardized equipment management procedures.

b. Monitor and interpret Maintenance Management Report (MMR) cover letters and Key Performance Indicators (KPI) for trend analysis.

c. Support strategies and programs directed from Chief, DHA MEDLOG Division and Defense Medical Logistics Proponent Committee.

d. Serve as a subject matter expert for the Defense Medical Logistics Proponent Committee in business processes, control programs, procedures, MDE, and clinical engineering expertise. This position will not be substituted with personnel outside the DHA MEDLOG HTM Branch.

e. Establish Equipment Support Centers (ESCs) to provide supported medical activities consolidated HTM services to include, but not limited to, organizational and regional medical maintenance; biomedical engineering and technical support; technician training; consulting; and contracting services as resources.

5. DIRECTORS, MTF/DTF/OLB. The Directors, DHA MTF/DTF/OLB will:

a. Establish a local HTM program to ensure a safe environment for patients, staff, and visitors in accordance with DHA regulatory guidance and appropriate accrediting agencies.

b. Appoint, in writing, a HTM Manager who has at least 8 years of experience in the HTM service industry and at least 4 years of supervisory or managerial experience. Waivers can be submitted to DHA MEDLOG HTM and considered on a case-by-case basis.

c. Ensure resources are available for HTM to accomplish its missions in support of MDE lifecycle through a Total Cost of Ownership (TCO) concept.

d. Ensure HTM Activities are adequately resourced to remain compliant with current Occupational Safety and Health requirements in accordance with Reference (t), and are able to perform duties by containing all required space, utilities, tools, and test equipment necessary to maintain existing and new MDE introduced into the DHA MTF/DTF/OLB.

e. Ensure all assigned Biomedical Equipment Technicians (BMETs) will be used primarily for HTM Activities. BMETs will not be assigned additional duties that may adversely affect or conflict with manpower utilization.

f. Ensure Medical Unit Education and Training Director coordinates with HTM Manager to establish end-user maintenance programs to include and document completion of initial equipment orientation, periodic training, and standard operating procedures (SOPs) for operator level MDE maintenance.

g. Ensure coordination and communication is established with the Chief, DHA MEDLOG HTM, and MMR cover letters are sent on a monthly basis to the Chief, DHA MEDLOG HTM for all scheduled work orders above 30 days and all other work orders beyond 60 days.

h. Reviews the MMR cover letters included in the meeting minutes from the Environment of Care (EOC) committee or equivalent function and, as necessary, communicates concerns about key issues and regulatory compliance to the medical staff, nursing, HTM Activity Team, and other appropriate staff. Reports are reviewed and documented at a minimum quarterly.

6. DIRECTOR, DHA MTF/DTF/OLB MEDLOG. The Director, DHA MTF/DTF/OLB MEDLOG will review MMR and KPIs and, as necessary, communicates concerns about key issues and regulatory compliance to hospital leadership, medical staff and EOC committee. MMR and KPIs will be reviewed and certified on a monthly basis and routed to the DHA MTF/DTF/OLB Director.

7. DHA MTF/DTF/OLB HTM MANAGER. The DHA MTF/DTF/OLB HTM Manager will designate an HTM Sustainment Team to:

a. Ensure employment of the TCO concept and sustainment support structures available to manage DHA MTF/DTF/OLB's MDE, including organic or unique military capabilities, contracts, commercial sector support, and partnering, as required.

b. Oversee, monitor, and remediate MDE recalls, alerts, errors, incidents and report findings to the EOC Committee or equivalent function.

c. Perform an annual review and update of the DHA MTF/DTF/OLB Medical Equipment Management Plan, reporting conclusions to the MEDLOG Director and DHA MTF/DTF/OLB EOC Committee or equivalent function.

d. Advise DHA MTF/DTF/OLB staff on lifecycle management assessments for MDE requirements.

e. Program periodic in-service, formal training, and/or manufacturer training for BMETs, particularly for new equipment introduced into the activity.

f. Coordinate with DHA MTF/DTF/OLB Education and Training to establish end-user maintenance programs to include and document completion of initial equipment orientation, periodic training, and SOPs for operator level MDE maintenance.

g. Adopt business practices and quality management processes to continuously monitor and improve MDE accountability and sustainment operations using performance improvement initiatives and metrics to trend the overall effectiveness and efficiency of the Director's TCO, lifecycle, and sustainment program.

h. Analyze MMRs to create MMR cover letters. Provide MMRs and MMR cover letters to the Director, MEDLOG for routing and review prior to evaluation by the EOC Committee or equivalent functions.

i. Schedule and accomplish Preventive Maintenance Checks and Services, inspections, unscheduled services (repairs), and scheduled parts replacement on MDE, in accordance with procedures outlined in Reference (i), technical literature provided by the equipment manufacturer, and the DHA HTM Alternate Equipment Maintenance (AEM) Plan.

j. Oversee, develop, and review internal SOPs. Based on when the manager arrives and approves the SOP, the review will be done 1 year after.

k. Ensure proper utilization and training for the MDE APSR (i.e., DMLSS) by the HTM Activity Team.

8. ACCOUNTABLE PROPERTY OFFICER (APO). APO is required and appointed in writing by DHA MTF/DTF/OLB Director in accordance with Reference (g). The APO will:

a. Designate custodial areas within the DHA MTF/DTF/OLB and appoint, in writing, a Property Custodian (PC) to support property management functions for assigned MDE.

b. Initiate Financial Liability Investigation of Property Loss (FLIPL) in accordance with Reference (g) for any loss of MDE. If the items are found at a later time, adjustment documents can be changed or canceled to reflect the results of the findings.

9. PC. The PC is appointed in writing by the APO and is responsible for the accountability of designated MDE within their area of responsibility in accordance with Reference (g). The PC will:

a. Ensure all MDE is made available to HTM personnel in order to conduct scheduled and unscheduled services upon receipt of the Customer Scheduled Services Report.

b. Maintain all documents recording completion of scheduled and unscheduled services performed on MDE in PC Property Accountability File.

c. Ensure equipment is clean in compliance with infection control policies prior to HTM servicing.

d. Ensure completion of all property custodian training required by the appointment letter.

ENCLOSURE 3

PROCEDURES

1. PERFORMANCE REPORTING. Regular performance assessments are necessary to determine the extent of standard procedure adoption and to measure the ability of the Activity to achieve targeted goals. Performance reporting, achieved by completion of the MMR cover letter, is an integral step in this process by facilitating communication of the activity's performance in a reproducible format.

a. The HTM Manager will review and sign the MMR, either electronically or in pen, in the blocks labeled "Maintenance Manager." The MEDLOG Director will review and sign the MMR as the "Authenticating Officer" within 5 calendar days of the end of the month. NOTE: The completed MMR cover letter will be kept on file in the maintenance activity for at least 2 years.

b. The HTM Manager will submit the MMR cover letter monthly to the Director of MEDLOG for routing and review during the EOC Committee or equivalent function.

c. If high-risk scheduled work orders are open beyond 30 calendar days, and or all other work orders are open beyond 60 calendar days, the MMR cover letter will be endorsed by the DHA MTF/DTF/OLB Director within 10 calendar days of receipt and delivered to the Chief, DHA MEDLOG HTM for review.

d. The HTM Managers will explain any unusual entries or changes that appeared on the APSR generated MMR or the Information System Monthly Timesheet on the MMR cover letter. The MMR cover letter for record will explain the following:

(1) All scheduled services not completed.

(2) MDE with a "failed" service result.

(3) All work orders over 60 calendar days old and all scheduled work orders over 30 calendar days old.

(4) All work orders with a failure reason of "no problem found" or "operator error."

(5) Status of any prior months unable to locate (UL) scheduled work orders (including all FLIPL document numbers and status).

(6) Cancelled scheduled work orders.

(7) Utilization rate below the Enterprise performance objective.

(8) Manpower details (i.e., Permanent Change of Station, Professional Military Education, absences greater than three weeks, or other impacts to manpower).

2. WORK ORDER MANAGEMENT. The Equipment Maintenance module is used to facilitate MDE sustainment within the APSR.

a. HTM Managers will ensure a failure reason is identified utilizing the following failure reasons when completing "REPAIR" work orders: No Problem Found, Operator Error, Operator Abuse, Normal Wear and Tear, Software Error, Manufacturing Defect, Maintenance Induced, Insufficient Schedule Maintenance, Incorrect Application, Inadequate Utilities, Accidental Damage, Inappropriate Environment, and Poor User Maintenance. The failure reason will remain blank on all other work requests (i.e., Acceptance Inspections, Incident Investigations, Quality Control, and Technical Evaluations).

b. HTM Managers must track No Problem Found, Operator Error, Operator Abuse, Incorrect Application, Inappropriate Environment, and Poor User Maintenance to analyze trends of actual events and near misses occurred at their unit or activity. Trends and events are provided to the EOC Committee or equivalent function and to DHA MTF/DTF/OLB Education and Training for mitigation actions such as remedial training for MDE and practice compatibilities.

c. When completing a repair work order, ensure the failure reason is consistent based upon the technical review.

d. The HTM Manager will ensure maintenance assessments are conducted and accurately documented when completing a work order. The five approved maintenance assessments are "Excellent," "Good," "Fair," "Poor," and "No Longer Supportable."

3. SCHEDULED SERVICES. Scheduled services are routine maintenance in support of proper operation, security, increased reliability, optimized operational availability, and maximized operational life by preventive services.

a. The HTM Manager will review "Detailed Workload Request and Summary Workload Request" and ensure scheduled services are aligned appropriately by department/clinic or mission requirements in order to have MDE services performed on a predetermined interval with the department/clinic PC. Scheduling of maintenance may be adjusted when factors warrant and will follow governing policies in accordance with Reference (g) and technical literature provided by the equipment manufacturer.

b. HTM Manager will ensure the PC (or the authority having jurisdiction of the department/clinic/activity), is briefed and provided a copy of the "Customer Scheduled Services" standard inquiry report no later than the 15th calendar day of the month prior to scheduled services being due.

c. The PC must provide an updated status of location and schedule availability no later than the 25th calendar day of the month prior to scheduled services being due.

d. HTM Manager will ensure all scheduled services performed are documented using the APSR generated scheduled work order. All service items, actions and results will be selected and annotated prior to closing the work order.

e. HTM Manager will ensure work performed by contracted services will be captured as "work by other." The contractor must provide the official Field Service Report to the HTM Activity no later than 10 calendar days after services are completed in order to close the work-order.

f. HTM Manager will ensure the accuracy of all data entries (device code, manufacturer, serial number, nameplate model, common model, etc.) during scheduled maintenance and update the maintenance assessment as applicable.

g. HTM Manger will ensure at the successful completion of scheduled maintenance a DD Form 2163 "Medical Equipment Verification/Certification" is affixed to the MDE.

h. MDE clearly designated and permanently marked "TRAINING USE ONLY" by the DHA MTF/DTF/OLB. Education and Training does not require scheduled maintenance.

i. The HTM Manager will ensure an unscheduled work order is opened, with the applicable service action code within the APSR when performance of scheduled services fail and/or are outside the assigned scheduled actions. The HTM Manager will ensure the unscheduled work order number is documented in the "failed" scheduled work order with thorough notes prior to closing. The unscheduled work order will capture all corrective actions to include electrical safety inspections, if required, and scheduled maintenance actions required to place the MDE back into service.

j. The HTM Manager will ensure scheduled services for High Risk and Life Safety MDE are to be completed no later than the 15th calendar day and all other MDE will be either completed or status corrected status by the 25th calendar day of the scheduled month.

k. The HTM Manager will ensure all scheduled service data (inspection results, calibration data, Scheduled Parts Replacement (SPR) used, etc.) are documented appropriately and maintain either paper or electronic copies in the Equipment File (EF), or in the APSR, as appropriate.

4. UL. MDE that cannot be located by the HTM Activity for the performance of scheduled services presents a potential safety hazard to patients and staff. Additionally, failure to service MDE periodically could result in adverse patient safety conditions and potential negative findings by an accrediting organization.

a. The HTM Activity Team must ensure that the PC (or authority having jurisdiction of the department, clinic or activity) is provided a copy of the list of scheduled services not complete due to inability to locate or unavailability no later than the 15th calendar day of the month that

scheduled services are due. The PC must provide an updated status of location and availability no later than the 20th calendar day of the month that scheduled services are due. HTM personnel will coordinate the completion of scheduled services.

b. HTM personnel may make attempts, but are not required, to assist custodians in locating MDE. PCs are responsible to ensure equipment is made available for services.

c. If the MDE is in direct patient use or quarantined for infection control, the HTM Manager will ensure the work order is documented and the status is updated to "Awaiting Delivery From Customer."

d. If equipment is UL by the 20th calendar day of the month the work order status will be updated to UL. HTM Managers will provide an UL Report to the APO, the EOC Committee, and initiate a Patient Safety Report for all High Risk MDE. PCs will be issued a "Unable to Locate Equipment Notification" standard report and have 5 working days to locate equipment or the FLIPL will be initiated by the APO.

e. Retain the scheduled service work order(s) with the UL status until the MDE is located or until a FLIPL is initiated in accordance with Reference (g), and the item is dropped from property accountability. Upon initiation of a FLIPL, the scheduled work orders will be cancelled by the HTM Manager with an equipment location of "UL". Do not use the "Failed" status when dealing with UL scheduled services. Report all UL MDE to the EOC Committee or equivalent function.

5. UNSCHEDULED SERVICES. The following provides procedural instructions for corrective maintenance or repair of malfunctioning equipment.

a. Unscheduled services include emergency, urgent, and routine repair of MDE. These repairs may be performed either in the shop or on-site. Other forms of unscheduled services may include, but are not limited to, quality control, failed scheduled services, acceptance and technical inspections, equipment installation or assembly, and equipment incident reports. Unscheduled services must be prioritized with respect to the existing workload. The HTM Manager will determine whether an unscheduled service is prioritized as urgent or emergency. Unscheduled services should be completed by work order priority.

b. Unscheduled service requests will be created when MDE requires repair. HTM will utilize DHA Form 158 to properly tag equipment to indicate the maintenance status of the device. If the APSR is non-operational, HTM will utilize DHA Form 149, HTM Sustainment Work Order until a standard DHA form is published by DHA MEDLOG Division to properly document work-orders until the APSR is online.

c. Priorities for Unscheduled Services are categorized as one of the following: Emergency, Urgent, and Routine.

(1) Emergency. Unscheduled services result when an immediate action is required to eliminate life threatening or serious injury hazards to personnel, prevent significant loss or damage to government owned property, restore essential equipment which could jeopardize the operation of primary mission. The response time for emergency work orders is immediate not to exceed 2 hours from notification with a maximum completion time of 5 calendar days. Emergency unscheduled services exceeding 5 calendar days must have documentation to justify delays.

(2) Urgent. Unscheduled services include those which require immediate action that would become an emergency if unattended. These situations can also jeopardize the operation of patient care with respect to its primary mission. The response time for urgent work orders is 48 hours from notification with a maximum completion time of 7 calendar days. Urgent unscheduled services exceeding 7 calendar days must have documentation to justify delays.

(3) Routine. Unscheduled services cover work that, if deferred, would result in continued inconvenience in the short term with no significant impact to the ability to perform assigned operational missions, and where there is no impact to healthcare efficiency, patient access, and/or quality of care. The maximum completion time for all routine unscheduled work orders is 30 calendar days. Routine unscheduled services exceeding 30 calendar days must have documentation to justify delays.

d. HTM Managers ensure all MDE covered by service contracts or warranties are maintained and repaired within the Performance Work Statements/Statement Of Work to avoid a breach of contract or void of warranty. To avoid any unauthorized commitments, non-authorized government employees will not obligate government funds for services that are performed outside the scope of work without approval in accordance with Reference (r). All contract and warranty maintenance for MDE must be initiated by HTM Activity.

6. ACCEPTANCE INSPECTION. Acceptance inspections will be performed and documented in the APSR on all transferred and newly acquired equipment prior to use.

a. Inspect all newly procured, leased, loaned, or consigned MDE before issuing the item to a DHA MTF/DTF/OLB according to the following steps. For MDE not owned by the DHA MTF/DTF/OLB see paragraph 12 of this enclosure.

(1) Ensure item was delivered without damage, operates according to the manufacturer's specifications, and complies with applicable safety and performance standards.

(2) Document identification data, electrical safety inspection results, measurements of performance, and calibration parameters or vendor calibration documentation on the work order or an appropriate manufacturer/or equipment calibration form.

(3) Ensure that an Authorization To Operate and Authorization To Connect, if applicable, has been granted by the DHA AO under the requirements of reference (r) or as outlined in the DHA Assess and Incorporate Process, with consultation with Cyber Logistics.

(4) Review the relevant contracts and literature for warranty provisions.

(5) Complete the warranty registration data, if applicable, and forward to the manufacturer. Device tracking requirements of the Food and Drug Administration (FDA) Modernization Act may require devices to be registered as part of the warranty process.

(6) Affix an Equipment Control Number (ECN) tag to each item for identification and accountability.

(7) Verify accurate quality control data is loaded into the APSR to include network and software data.

(8) Ensure records reflect the proper normalized medical device code for the item.

(9) Establish an EF in ECN sequence. EF will be maintained through disposition.

(10) Place a copy of the warranty registration, the acceptance inspection work order, applicable contract and manufacturer's acceptance checklist in the EF.

(11) File all technical literature in the BMET technical literature library.

(12) Per manufactures' literature or environmental conditions, determine and acquire parts as appropriate.

(13) Analyze maintenance requirements and procure all required test equipment, supplies, accessories, training, or contract service required to sustain the equipment.

(14) Notify HTM Manager of manufacturer BIOMED/BMET training purchased in conjunction with equipment. Training should be completed IAW the contract language, typically found under the Delivery/Inspection/Acceptance Schedule of the contract.

b. Each HTM Activity will maintain a technical reference file on each item of medical equipment including operating and service literature.

(1) Literature will be filed so that they are traceable to the common models. If using web-based manuals, include the web address in the "Literature Location" field in the APSR.

(2) Each DHA MTF/DTF/OLB will maintain copies of its equipment operator's manuals and user maintenance procedures. These manuals and procedures will be readily available.

7. CERTIFICATION OF RADIATION EMITTING MDE. The HTM Manager will ensure all components of diagnostic medical x-ray systems (which includes dental x-ray systems), are certified by the FDA, Department of Health and Human Services, and Center for Devices and Radiological Health in accordance with References (p) and (q). For radiation surveys or acceptance inspection of devices that produce ionizing radiation, contact the appropriate

qualified health physicist. HTM Activity Teams coordinating equipment installation within the region of applicability (50 United States and its territories) will send the original (white copy or electronic copy) of FDA Form 2579, "Report of Assembly of a Diagnostic X-ray System", within 15 calendar days to Center for Devices and Radiological Health Document Mail Center– WO66-G609, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002. The state agency copy (yellow or electronic copy) will be forwarded to DHA MEDLOG HTM, within 30 calendar days of the installation. The HTM Manager will retain the pink or electronic copy in the EF for the x-ray system.

8. RADIATION SURVEYS. Radiation surveys are conducted in support of occupational and patient safety.

a. A properly qualified health physicist will conduct a complete radiation protection survey before new x-ray facilities are opened for use in accordance with Reference (p) and (u).

b. When replacing x-ray equipment with similar capabilities and workloads, the health physicist must evaluate shielding effectiveness and can approve interim use of the facility until the survey is completed.

c. The post installation radiation survey will be completed within 30 calendar days of the Notice of Readiness To Inspect date.

d. Any discrepancies in the radiation surveys that may be attributable to the manufacturer must be referred immediately to the manufacturer through the contracting agency.

e. Notify the Installation Radiation Safety Officer when replacing any major component of an x- ray system in accordance with Reference (q). The Radiation Safety Officer will make the determination whether a radiation protection survey is needed. If needed, contact the appropriate qualified health physicist.

f. File copies of the radiation protection survey and/or post installation radiation survey in the EF. The preparer furnishes additional copies of such reports to the ESC and DHA MEDLOG HTM.

g. Servicing HTM Activity documents all steps taken to resolve the discrepancies noted on radiation surveys in the APSR.

9. MDE HAZARD, ALERTS, AND RECALLS (HAR). The purpose of the MDE HAR Program is to provide message notification and guidance for the suspension, reporting, and disposition of medical and/or dental materiel found to be defective, unsafe, or otherwise unsatisfactory for use.

a. HTM Activities will use the following sources: Alerts Tracker® from ECRI Institute, Medical Materiel Quality Control, DHA MEDLOG HTM generated Quality Control, HAR messages, and direct sources such as the FDA, Prime Vendors/manufacturers, etc.

b. Upon initial assignment to a Medical Unit, the BMET will request an account profile and register for prescribed programs. The point of contact for account registration will be coordinated with the DHA MTF/DTF/OLB HAR Coordinator.

c. Medical Devices and Equipment Recall Classifications and Crosswalk can be found in the associated HAR Program.

d. HTM Activities will document recalls that affect an item within the inventory as a Quality Control or modification work order within the APSR. Documentation will include as much detail as possible after completing recall procedures.

e. Manufacturer direct notifications to an HTM Activity will respond immediately to action or implement corrective procedures. HTM Activity will submit a copy of the notification and actions taken directly to the HAR Program, and DHA MEDLOG HTM within 2 business days by email: dha.detrick.med-log.mbx.htm@mail.mil.

10. MDE DEFECT REPORTING. The MDE defect reporting process applies to product deficiencies detected on new, or newly reworked Government-owned products that do not fulfill their expected purpose. Defect reporting is used to document the discrepancy and provide as much information as is available that may help determine the root cause of the deficiency, identify corrective action to be taken, and inform others of the discovered deficiency.

a. HTM Activities will report equipment defects as a Category I or II complaint, using both SF 368, "Product Quality Deficiency Report," and FDA Form 3500A, MedWatch Online Voluntary Reporting Form. Medical staff, patient safety, risk management, and MEDLOG personnel will evaluate the credibility, validity, and potential harm of an item before submitting a materiel complaint. The DHA MTF/DTF/OLB's Healthcare Risk Manager will make the final determination if a materiel-related incident warrants processing a complaint.

(1) Download SF 368 from https://www.gsa.gov/forms-library/product-quality-deficiency-report and ensure individually identifiable health information is not included in accordance with References (k) and (l).

(2) Download the FDA Form 3500A, from the United States FDA website and follow the website instructions for Medical Device Reporting. This form requires individually identifiable health information and will be safeguarded in accordance with HIPAA privacy and security rules.

(3) Follow submission instructions for the SF 368 and FDA 3500A. In addition, email completed copies to DHA MEDLOG HTM at: dha.detrick.med-log.mbx.htm@mail.mil.

b. Medical staff, patient safety, risk management, and MEDLOG personnel will evaluate the credibility, validity, and potential harm of an item before submitting a materiel complaint. The

DHA MTF/DTF/OLB's Healthcare Risk Manager will make the final determination if a materiel-related incident warrants processing a complaint. Incident investigations will be initiated for the following events:

(1) An incident is an event in which equipment or a procedure has caused, or may have caused, undesirable outcome, death, or injury to a patient, staff member, and or visitor. For specific information about Cyber Security incidents see paragraph 11 of this enclosure.

(2) HTM Activity will properly preserve medical equipment items that may have been involved in a device-related incident. The equipment operator will ensure that no device settings are changed, and all accessories and consumables are attached or intact. The item will not be cleaned until after the investigation unless infection control procedures require the item to be cleaned. The contaminated equipment should be labeled to indicate the hazards.

(3) The HTM Manager will conduct a formal investigation in conjunction with the DHA MTF/DTF/OLB Patient Safety Officer, Risk Manager, or others as appropriate. The HTM Manager can request ESC support during formal investigations as warranted.

(4) Investigating BMET will follow the prescribed DHA process, in accordance with Reference (r), and in conjunction with the local DHA MTF/DTF/OLB processes.

(5) The investigation will be conducted by no less than two BMETs and include: impounding the equipment, noting the position of all knobs and dials on the equipment (and photographing if possible), noting missing components or parts, noting the overall condition of the equipment, interviewing involved personnel, identifying exact items of consumable supplies by lot number, date of manufacture, or other means, perhaps by getting the original packaging out of the trash, and reviewing maintenance history and test procedures. For small facilities in which two BMETs are not available to conduct the investigation, one BMET assisted by another disinterested DHA MTF/DTF/OLB staff member is acceptable.

(6) The investigating team will examine the three basic interfaces (operator-device, patient-device, and consumable-supply-device), to determine the cause of an incident.

(7) The HTM Activity will work with the Patient Safety Officer to develop local procedures that clearly delineate the responsibilities for conducting an incident investigation involving medical equipment. Outline the responsibilities for these investigations in the local Quality Control/Risk Management plan.

(8) The HTM Activity will assist the DHA MTF/DTF/OLB Patient Safety Officer and DHA MTF/DTF/OLB Education and Training to inform PCs and operators of their responsibilities in equipment-related incident investigations.

11. CYBER SECURITY INCIDENTS. Response actions are immediate steps taken as an incident is discovered. These actions are to ensure patient safety, safeguard Protected Health Information (PHI) and reduce the scope of damage to the network or other devices.

a. Continue to follow Military Service policies, including opening an unscheduled work order and capturing all the details of the event and actions taken in the work order notes field. In addition, email DHA MEDLOG HTM at: dha.detrick.med-log.mbx.htm@mail.mil and complete the DHA Incident Response Checklist at https://info.health.mil/dadio/InfoSec/csdocs/Migrated%20to%20MEDCOI%20-%20Site%20Incident%20Response%20Checklist.doc.

b. DoD Health Records containing PHI are protected by the HIPAA Privacy, Breach Notification, and Enforcement Rules in accordance with References (k) and (l). DoD Health Records maintained in digital form must be compliant with the HIPAA Security Rule in accordance with Reference (l). DoD Health Records are also protected by the Privacy Act in accordance with References (l) and (m).

12. SUPPORTING EQUIPMENT NOT OWNED BY THE DHA MTF/DTF/OLB. HTM Activities will utilize local policies for on-boarding non-government owned MDE with the inclusion of the following steps:

a. Use of MDE not owned by the DHA MTF/DTF/OLB for more than 30 calendar days will be gained on the DHA MTF/DTF/OLB s' property records following the acceptance procedures outlined in paragraph 6 of this enclosure.

b. The PC will maintain accountability of MDE not owned by the DHA MTF/DTF/OLB and assure MDE is processed back to the original owner following local procedures.

c. BMETs will ensure MDE not owned by the DHA MTF/DTF/OLB is in compliance with appropriate utilization and safety checks prior to use.

d. All DHA MTF/DTF/OLBs will conform to the requirements in Reference (i), regardless of ownership. All line powered devices in patient care vicinities are required to meet the same safety requirements as MDE. All DHA MTF/DTF/OLBs will ensure personally owned items meet safety requirements.

13. PATIENT MOVEMENT ITEMS (PMI) AND AEROMEDICAL EVACUATION (AE) PROGRAMS. PMI has specific standardized medical equipment and durable supply items which are certified Safe-to-Fly in support of patient transport.

a. All PMI Program equipment is AE Certified and Safe-to-Fly approved and is approved for use in AE Patient Movement by the Global Patient Movement Joint Advisory Board.

b. The host HTM maintenance activity of AE and Critical Care Air Transport Team units will report unserviceable PMI to the Air Mobility Command Surgeon, Medical Readiness Logistics Office.

c. The host HTM Activity will closely coordinate with Air Mobility Command Surgeon, Medical Readiness Logistics Office for tracking and PMI recovery.

d. Contact information for Air Mobility Command Surgeon, Medical Readiness Logistics Office is as follows: organizational email address at hqamcpmi@us.af.mil, or at Defense Switched Network 312-779-6952, Commercial 618-229-6952, Toll free 877-286-1931.

14. PARTS MANAGEMENT. Management of parts stock to ensure optimal availability of medical equipment.

a. BMET performing MDE maintenance actions will be responsible for researching part(s) required as well as ensuring parts information is properly cataloged and requested.

b. Once a justified need is determined for part(s), servicing BMET will submit a parts request to the HTM Manager for approval and submission to proceed with acquisition.

c. Once parts are received, they will be issued and recorded to the MDE record prior to installation.

d. Coordinate SPRs with APSR generated maintenance plans 30 calendar days ahead of scheduled month to ensure SPR are available to complete service action prior to the 15th day of the scheduled month. Annual reoccurrence SPRs should be considered for inclusion in the authorized stock list approved by HTM Manager.

15. SERVICE CONTRACTS FOR MAINTENANCE. HTM Activities use Service Contracts as an optional tool to augment the capability of services provided.

a. ESC will:

(1) Ensure HTM Activities within their geographical area are considered in developing contracts for support of MDE (i.e., time and materials, labor-hour, cost, fixed-priced contracts).

(2) Provide direction and support for activities within their geographical area whom have specialized MDE requirements to align contracts back to the geographical or centralized levels.

b. HTM Manager will:

(1) Ensure all contracts are loaded and correctly tied to the equipment to be serviced in the APSR.

(2) Ensure that all services performed under an annual or one-time service contract are captured in the APSR (i.e., DMLSS in the Work By Other tab).

(3) HTM Manager should consider the following clauses with the contracting agency for each contract:

(a) The service report must accompany the MDE being serviced within 10 calendar days. The service report will provide detailed information regarding the cause of the MDE malfunction and corrective action taken. Include, at a minimum, the time required to complete the work, price of labor (hourly rate), and a list of parts replaced with prices for each part.

(b) After performing scheduled services, the Contracting Officer's Technical Representative will affix and/or update DD Form 2163.

(c) Contractor will use only repair parts which are manufacturer new or parts that meet manufacturer specifications.

(d) Required manufacturer/or equipment forms and extracts from pertinent directives will be furnished to the contractor's service representative by the government.

(4) Coordinate with the Contracting Officer to appoint a qualified HTM Activity member to serve as a Contracting Officer's Representative/Contracting Officer's Technical Representative within the HTM Activity for all service contracts. MDE operators or supervisors of MDE operators will not contact service vendors for MDE services unless appointed as the Contracting Officer's Representative with coordination directly with the HTM Activity.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

AEM	Alternate Equipment Maintenance
APO	Accountable Property Officer
APSR	Accountable Property System of Record
BMET	Biomedical Equipment Technician
DAD	Deputy Assistant Director
DHA	Defense Health Agency
DHA-AI	Defense Health Agency Administrative Instruction
DMLSS	Defense Medical Logistics Standard Support
ECN	Equipment Control Number
EF	Equipment File
EOC	Environment of Care
ESC	Equipment Support Centers
FDA	Food and Drug Administration
FLIPL	Financial Liability Investigations of Property Loss
HAR	Hazard, Alert, and Recall
HTM	Healthcare Technology Management
KPI	Key Performance Indicators
MDE	Medical Devices and Equipment
MEDLOG	Medical Logistics
MHS	Military Health System
MMR	Maintenance Management Report
MTF	military medical treatment facility
PC	Property Custodian
PHI	Protected Health Information
PMI	Patient Movement Items
SPR	Scheduled Parts Replacement
TCO	Total Cost of Ownership
UL	Unable to Locate

PART II. DEFINITIONS

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

AEM Plan. Maintenance activities and frequencies that differ from those recommended by the manufacturer. DHA HTM may choose to employ alternate maintenance activities and/or schedules with developed, implement, and maintained central AEM program to minimize risks to patients and others in the use of medical equipment.

DHA MTF/DTF/OLB. A unit is an organization title for the subdivision of activities performing MEDLOG. Examples include a stand-alone operational MEDLOG teams, MTFs DHA MTF/DTF/OLBs, and research and development organizations, medical device manufacturing facilities, Military Entrance Processing Stations, Navy Operational Support Centers, and Veterinary Services.

EOC Committee. The committee monitoring the EOC; the EOC is made up of the following three basic elements: the building or space, including how it is arranged and special features that protect patients, visitors, and staff, and equipment used to support patient care or to safely operate the building or space.

Healthcare Technology Management. The field responsible for managing the selection, maintenance, and safe and effective use of medical equipment and systems.

HTM Manager. A manager appointed by the DHA MTF/DTF/OLB Director to manage the HTM program ensuring a safe environment for patients, staff, and visitors in accordance with DHA regulatory guidance and appropriate accrediting agencies.

MDE. Medical devices as defined in Reference (p) and other equipment identified by a centrally managed device code.

Medical Equipment Management Plan. Defines the mechanisms for interaction and oversight of the medical equipment used in the diagnosis, treatment, and monitoring of patients to ensure that equipment used in patient care is safe, available, accurate, and affordable.

Notice of Readiness to Inspect. A written notice upon the completion of installation and after contractor makes available to the using activity any training (e.g., initial application, operator and service training), required by the manufacturer to properly use the equipment, the equipment will be turned over to the government inspecting activity as fully functional, ready for inspection and acceptance procedures. Submission of the notice of readiness for inspection, and any other notice required by this provision by electronic mail is acceptable, provided that the party giving such notice obtains and preserves electronic evidence of receipt at the email address or addresses of the party or parties who have a right to notice under this clause. The Government will provide appropriate email addresses on the purchasing documentation.

protected health information. Individually identifiable health information (as defined in the HIPAA Privacy Rule) that is transmitted or maintained by electronic or any other form or medium.

TCO. A financial estimate intended to help DHA and DHA MTF/DTF/OLBs determine the direct and indirect costs of a product or system. It is a management accounting concept that can be used in full-cost accounting of ecological economics where it includes social costs. TCO includes Test, Measurement, and Diagnostic Equipment, Risk Management Framework/Authorization to Operate, Training, Maintenance, Purchase, Delivery, Install, Operation Labor, Utilities, Supplies, Health & Safety, Disposition.

x-ray system. Any manufactured or assembled electronic product which, when in operation, contains or acts as part of an electronic circuit and emits (or in absence of effective shielding or other controls would emit) electronic product radiation. Any manufactured or assembled article that is intended for use as a component, part, or accessory of any aforementioned manufactured or assembled electronic products which, when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation in accordance with Reference (p).