



Joint Task Force National Capital Region Medical **DIRECTIVE**

NUMBER 4151.01

JUL 14 2011

Incorporating Change #2, ~~May 16~~ December 17, 2012

J-4

SUBJECT: Medical Equipment Management

References: See Enclosure

1. PURPOSE. This Directive, in accordance with the authority in References (a) through (d), establishes policy and, with the guidance in Reference (e), describes the process for requirements and maintenance of medical equipment management. *This management includes* medical acquisition, storage, handling, distribution, maintenance, and disposition of materiel, construction, maintenance and operation of facilities, servicing, repairing and disposal of equipment, medical systems integration, and acquisition of furnishing and support services among other requirements.

a. Establishes the policy to provide Joint Health Service Logistic Support (HSLS) by *within* the Joint Task Force National Capital Region Medical (JTF CapMed) ~~Joint Operations Area (JOA) over all joint organizational entities and commands within the National Capital Region (NCR)~~ in accordance with References (f) and Reference (g).

b. In accordance with the references cited above provides Joint HSLS within the *Joint* Medical Treatment Facilities (MTFs) and Centers. Joint HSLS provides the specialized products and services required to support all provisions of medical support in the *Joint* MTFs and Centers. The importance of medical logistics cannot be overstated, and Joint HSLS is an integral part of health care management that is critical to the delivery of health care across the full spectrum of military operations in the *Joint Operations Area (JOA)* by the *Joint* MTFs and Centers.

2. APPLICABILITY. This Directive applies to the JTF CapMed Headquarters, Fort Belvoir Community Hospital (FBCH), Walter Reed National Military Medical Center (WRNMMC) [hereafter, WRNMMC and FBCH are referred to as *Joint* MTFs], and the Joint Pathology Center (JPC).

3. DEFINITION

JUL 14 2011

Medical Systems. A network of medical and/or non-medical equipment or equipment system(s) integrated for delivery of patient care that are managed by a cross-functional group including clinicians, medical logisticians, facilities, and information technology specialists. Medical systems typically consist of two or more individual items (components) working in concert, and may be considered incomplete or unusable in the absence of any one of its component items.

4. POLICY. It is JTF CapMed policy that:

a. Equipment management programs for JTF CapMed equipment shall be structured and managed to achieve and maintain inherent performance, safety, and reliability levels of the materiel. In addition, programs are structured for meeting readiness and sustainability objectives (including mobilization and surge capabilities) as well as performance standards that meet requirements set by accrediting and regulatory bodies including the Joint Commission College of American Pathologists, and the Food and Drug Administration (*FDA*). Equipment Management Programs shall:

(1) Employ maintenance concepts that optimize process technologies, organizational structures and operating concepts to deliver efficient and effective performance of medical equipment.

(2) Be clearly linked to JTF CapMed strategic and contingency planning.

(3) Be designed for minimizing the total life-cycle cost of ownership.

(4) Adopt business practices and quality management processes to continuously improve maintenance operations and achieve cost efficiencies, and realize process cycle time reduction.

(5) Invest in the utilization of new technologies to improve the reliability, maintainability, and supportability of JTF CapMed equipment, including the cost, schedule effectiveness, and quality of maintenance tasks and processes.

(6) Employ the full spectrum of maintenance support structures available to sustain equipment and equipment systems, including organic or unique military capabilities, performance-based logistics arrangements, commercial sector support, or partnering with other activities within the JOA as applicable.

(7) Take steps to minimize and prevent Environmental, Safety, and Occupational Health hazards in maintenance activities and equipment use. Design of maintenance tasks and processes shall give consideration to environmental and human factors to allow for safe, efficient, and effective task accomplishment. Other steps should include, but not limited to: monitoring and reporting medical equipment hazards, recalls, and incidents resulting in injury or death to appropriate authorities in accordance with the FDA Safe Medical Devices Act (SMDA) (Reference (h)).

JUL 14 2011

(a) Each facility will assign a medical maintenance point of contact in writing to monitor the Medical Materiel Quality Control (MMQC) notifications via U.S. Army Medical Materiel Agency notification protocols as well as other recall notification vehicles.

(b) MMQC will provide guidance by manufacturer so that appropriate action can be taken, documented, and reported. Additional precautions shall be implemented and documented per guidance from clinical personnel to ensure staff exercises appropriate precautions to prevent potential issues if device remains in service (i.e. warning stickers).

(8) Structure maintenance programs to comply with standards as set forth by the Joint Commission under Environment of Care standards EC.02.04.01, EC.02.04.03 (Reference (i)) and any other applicable DoD regulations.

(9) Comply with periodic and as-required reporting requirements set by JTF CapMed J-4.

b. Initial maintenance programs shall:

(1) Be developed concurrently with equipment acceptance, beginning with an analysis of failure modes and effects. The programs shall consist of applicable and effective tasks for addressing failure modes and effects that incorporates manufacturer recommendations and addresses equipment criticality along with prior equipment experience. Maintenance tasks will be aligned to the appropriate levels of maintenance (i.e., MTF and Original Equipment Manufacturer (OEM)) based on criteria derived from customer requirements and cost-effectiveness analysis.

(2) Incorporate sustainment procedures interfacing effectively with JTF CapMed J-4 Logistics processes for equipment and equipment systems that shall be maintained by the OEM or other maintenance providers through maintenance contracts.

(3) Minimize requirements for support equipment including test, measurement, and diagnostic equipment. Maintenance programs shall provide the organic maintenance workforce with the range of tools necessary to enhance capabilities (e.g., interactive technical manuals, portable maintenance aids, and access to technical information), to properly equip the workforce, and to provide adequate technical and managerial training.

(4) Apply Life Cycle Management techniques using data available in Defense Medical Logistic Standard Support (DMLSS) and other support applications programs to effectively manage populations of select items throughout their life cycle.

c. Throughout the life cycle of medical equipment, maintenance processes shall be adjusted periodically to improve maintenance agility, increase operational availability, and reduce life-cycle total ownership costs. In addition:

(1) Equipment management programs within the JOA shall facilitate, collect, and analyze maintenance-related reliability data. The programs shall include sufficient analytic

JUL 14 2011

capability for identifying needed adjustments based on operating experience, materiel condition, and requirements for reliability, maintainability, and supportability modifications, and changes to training curriculums or delivery methods. The programs shall also establish and evaluate performance metrics that promote continuous improvement in maintenance, and ensuring responsiveness.

(2) The JTF CapMed Joint ~~Commands~~ *MTFs* and Centers shall periodically review maintenance workloads to identify opportunities for consolidation, regionalization, public-private partnerships, or other types of integrated support arrangements that may yield significant economies of operation while sustaining or improving responsiveness.

d. JTF CapMed Joint ~~Commands~~ *MTFs*' and Centers' maintenance operations shall be supported by robust, effective management information at all levels. DMLSS shall provide a basis for scheduling, production control, financial management, assessment of personnel and materiel performance, and quality assurance.

e. Equipment management functional areas within the *Joint* MTFs and Centers are required to perform an annual evaluation of their programs to identify effectiveness of processes and procedures implemented over the course of the calendar year. The processes and procedures evaluated should include but not limited to selection and acquiring of medical equipment, identification and inventory, inspection and maintenance strategies, monitoring and acting on equipment hazards, notices and recalls of medical equipment as well as SMDA monitoring and reporting. Acceptable outcome should include detailed analysis using both qualitative and quantitative data accumulated during this period. Metrics used in the evaluation process shall be based on accrediting standards such as Reference (i) and other applicable standards. Information presented as part of this annual evaluation should succinctly address successes, challenges, and recommendations for improvement of program processes where processes are required and are approved by the *Joint* MTF's or Center's Director of Logistics, and forwarded to the JTF CapMed J-4 ~~e~~Equipment ~~m~~Manager.

f. Medical maintenance will maintain a file on each diagnostic X-Ray system within the Joint MTFs and Centers as required per Reference (j), to include, but not limited to, initial acceptance package (DD Form 2164), FDA 2579, work order history, contract history, and annual radiation physicist reports.

g. All test equipment used in the calibration, verification, or safety analysis of medical/dental equipment will be calibrated by a qualified calibration lab at a frequency in accordance with the test equipment manufacturers' requirements or at a maximum interval of 12 months. Certificates of calibration should be provided from all Service organizations and retained in Medical maintenance for all equipment serviced. To ensure that all test equipment is calibrated and results documented at least annually, it is required that all test equipment is gained in DMLSS and an annual maintenance plan for inspection, preventive maintenance, and calibration are established.

JUL 14 2011

5. RESPONSIBILITIES

a. JTF CapMed J-4. The JTF CapMed J-4 shall monitor compliance with this Directive and shall:

(1) Review the adequacy of JTF CapMed Component equipment maintenance/management programs and resources.

(2) Review, approve, and consolidate reports submitted by the JTF CapMed Components as appropriate.

b. Commanders of Joint MTFs and Center Directors. Commanders of Joint MTFs and Center Directors shall:

(1) Establish and sustain effective and responsive medical maintenance programs for assigned equipment.

(2) ~~Program and budget for necessary resources to administer effective medical equipment management programs. Appoint in writing a qualified officer, civilian, or Non Commissioned Officer as the medical activity Maintenance Manager.~~

(3) ~~Provide a range of equipment management related reports as directed by JTF CapMed~~

~~J-4. Appoint and assign in writing a Contracting Officer Representative within the medical maintenance area to manage all facility medical maintenance contracts and to ensure cost analysis is performed for in-house versus contract maintenance.~~

(24) Program and budget for necessary resources to administer effective medical equipment management programs.

(35) Provide a range of equipment management related reports as directed by JTF CapMed J-4.

6. INFORMATION REQUIREMENTS. Templates for the following reports will be provided by the JTF CapMed J-4 to the Joint MTFs and Centers:

a. Monthly ~~Preventive~~ Maintenance ~~Completion Management~~ Report.

b. ~~Monthly Open Maintenance Work Orders 30, 60, and 90 days. Monthly report identifying recalls, notices received by the facility via MMQC notifications, manufacturer notifications, or any internally identified and reported equipment failures in accordance with the SMDA.~~

c. ~~Monthly X-ray Verification Report.~~

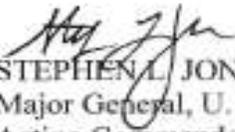
JUL 14 2011

7. RELEASABILITY. UNLIMITED. This Directive is approved for public release and is available on the ~~Internet from the~~ JTF CapMed Website at: www.capmed.mil.

8. EFFECTIVE DATE. This Directive ~~is effective immediately~~:

a. Is effective upon publishing to the JTF CapMed Website; and

b. Must be reissued, cancelled, or certified current within 5 years of its publication in accordance with JTF CapMed Instruction 5025.01 (Reference (k)). If not, it will expire effective 10 years from the publication date and be removed from the Website.


STEPHEN L. JONES
Major General, U. S. Army
Acting Commander

Enclosure
References
Glossary

JUL 14 2011

ENCLOSURE 1REFERENCES

- (a) Deputy Secretary of Defense Memorandum, “~~Establishing~~ *Authority*ies for Joint Task Force National Capital Region Medical (JTF CapMed),” ~~and JTF CapMed Transition Team (Unclassified),” September 12, 2007-February 7, 2012~~
- (b) Deputy Secretary of Defense Action Memorandum, “Civilian and Military Personnel Management Structures for the Joint Task Force National Capital Region Medical,” January 15, 2009
- I Comprehensive Master Plan for the National Capital Region Medical, April 23, 2010
- (d) Supplement to the Comprehensive Master Plan for the National Capital Region Medical, August 31, 2010
- (e) Health Affairs Policy 98-013, “Policy for Regional Tri-Service Medical Logistics Support Program,” January 23, 1998
- (f) Joint Task Force Capital Region Medical Directive-Type Memo-09-001, “Guidance for Promulgation, Development and Dissemination of Written Communication,” September 20, 2009
- (g) Deputy Secretary Defense Approved Action Memo, “Civilian and Military Personnel Management Structures for the Joint Task Force National Capital Region Medical (JTF CapMed),” January 15, 2009
- (h) The Food and Drug Administration (FDA), Safe Medical Device Act, 1990
- (i) The Joint Commission, “Hospital Accreditation Standards,” 2009
- (j) *Code of Federal Regulations Title 21, 21 CFR 1020.30*
- (k) *JTF CapMed Instruction 5025.01, “Formats and Procedures for the Development and Publication of Issuances,” March 5, 2012*

GLOSSARYACRONYMS

<i>DMLSS</i>	<i>Defense Medical Logistic Standard Support</i>
<i>FBCH</i>	<i>Fort Belvoir Community Hospital</i>
<i>FDA</i>	<i>Food and Drug Administration</i>
<i>HSLs</i>	<i>Health Service Logistic Support</i>
<i>JOA</i>	<i>Joint Operations Area</i>
<i>JPC</i>	<i>Joint Pathology Center</i>
<i>JTF CapMed</i>	<i>Joint Task Force National Capital Region Medical</i>
<i>MMQC</i>	<i>Medical Materiel Quality Control</i>
<i>MTFs</i>	<i>Medical Treatment Facilities</i>
<i>NCR</i>	<i>National Capital Region</i>
<i>OEM</i>	<i>Original Equipment Manufacturer</i>
<i>SMDA</i>	<i>Safe Medical Devices Act</i>
<i>WRNMMC</i>	<i>Walter Reed National Military Medical Center</i>