MEDDAC/DENTAC/VS Regulation 750-1

Maintenance of Supplies and Equipment

Maintenance of Medical Equipment

Headquarters
U.S. Army Medical Department Activity
Fort George G. Meade
2480 Llewellyn Avenue
Fort George G. Meade, MD 20755-5800
10 September 2002

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SUMMARY of CHANGE

MEDDAC REG 750-1
Maintenance of Supplies and Equipment

Specifically, this revision—

- Has been published in a new format that includes a cover and this “Summary of Change” page.

- Reformats the title page. The Contents section now includes the page numbers that the various chapters and paragraphs begin on.

- Throughout the regulation, “Fort Meade Dental Clinic Command” and “DCC” have been changed to “U.S. Army Dental Activity, Fort George G. Meade” and “DENTAC”.

Department of the Army
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History. This is the fourth revision of the publication. It was originally published on 31 July 1995.

Summary. This regulation prescribes procedures for procuring new medical equipment, for inspection and accountability of medical equipment, for orientation and education of staff personnel to use medical equipment, and for maintenance management.

Applicability. This regulation applies to the U.S. Army Medical Department Activity, Fort George G. Meade (MEDDAC) headquarters, all outlying clinics of the MEDDAC, the U.S. Army Dental Activity, Fort George G. Meade (DENTAC), and the Fort Meade Branch Veterinary Services (VS).

Proponent. The proponent of this regulation is the Chief, Logistics Division (LOG).

Supplementation. Supplementation of this regulation is prohibited.

Suggested improvements. Users of this publication are invited to send comments and suggested improvements, by memorandum, directly to the Commander, U.S. Army Medical Department Activity, ATTN: MCXR-LOG-MM, Fort George G. Meade, MD 20755-5800, or to the MEDDAC's Command Editor by fax to (301) 677-8088 or e-mail to john.schneider@na.amedd.army.mil.

Distribution. Distribution of this publication is by electronic medium only.

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* This publication supersedes MEDDAC/DCC/VS Reg 750-1, dated 14 November 2000

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Glossary

Chapter 1
Introduction

1-1. Purpose
This regulation prescribes policies, and procedures, and responsibilities governing the maintenance of medical equipment within this command. This regulation provides specific guidance to assist chiefs, supervisors, and equipment operators to achieve and maintain high maintenance standards for medical equipment.

1-2. References
Required publications, related publications and referenced forms are listed at appendix A.

1-3. Explanation of abbreviations and terms
Abbreviations and special terms used in this regulation are explained in the glossary.

Chapter 2
Responsibilities

2-1. The MEDDAC Commander
Materiel maintenance is a command responsibility. The MEDDAC commander will—

a. Place maximum emphasis on operator preventive maintenance of all medical equipment used for patient care.

b. Allocate adequate time for equipment operators' (EOs) preventive maintenance services on a scheduled basis.

c. Establish periodic in-service and/or informal training in maintenance programs for EOs.

d. Program periodic in-service, formal Army training and/or manufacturer training for equipment maintainers, particularly for new equipment introduced into the command.

e. Ensure that abuse of equipment under user control is prevented. Evidence of abuse will be investigated and corrective action will be taken.

f. Ensure that the medical maintenance activity is centrally located, accessible, and has ample storage space for repair parts, supplies, tools, and test equipment.

2-2. The Chief, LOG
The Chief, LOG will—

a. Exercise staff supervision of the medical maintenance program within the MEDDAC.

b. Ensure that the medical maintenance repair facilities are operated in accordance with (IAW) applicable regulations.

c. Ensure that medical equipment technicians are not assigned additional duties that may adversely affect maintenance of medical equipment.

2-3. Maintenance managers
Maintenance managers will ensure that—

a. The concepts, objectives, and policies established by The Surgeon General and Headquarters, U.S. Army Medical Command are met for the maintenance of medical equipment.

b. The maintenance of all Army owned medical equipment is effectively performed throughout its life cycle. A system will be developed to ensure that manufacturer warranties are utilized to the fullest extent possible.

c. The maintenance programs for repair, calibration, verification, certification, preventive maintenance, and safety testing and inspection services are performed consistently with available resources.

d. They provide planning, guidance and assistance to the Chief, Plans, Training, Mobilization and Security Division in the development of educational and training programs in maintenance for EOs and maintenance personnel.

e. The MEDDAC commander and staff, through the Chief, LOG, are routinely updated on the status of medical equipment maintenance and associated programs.

f. A library of service manuals is maintained in each medical maintenance activity for all medical equipment in use.

g. Scheduled and unscheduled workloads are assigned to repair technicians commensurate with their technical training.

h. They maintain liaison with department, division and section officers in charge and noncommissioned officers in charge in order to provide timely and informative communications concerning maintenance services.

i. Interpretation and application of maintenance service procedures are IAW military and/or manufacturer's instructions.

j. Repairers are knowledgeable of regulatory requirements that are applicable to assigned tasks, such as radiological health, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and National Fire Protection Association (NFPA) Standard 99.

k. Maintenance personnel are knowledgeable of hazard communications, lockout/tagout, and other applicable Occupational Safety and Health Administration, Department of the Army, U.S. Army major commands, and local safety program requirements.

2-4. The Property Book Officer (PBO)

The PBO will account for all Class VIII non-expendable equipment (medical equipment valued at $2,500 or more that retain their original identity and are not consumed in use). Property accountability will be IAW AR 40-61 and AR 710-2.

2-5. Section supervisors and medical equipment operators

The range and complexity of medical equipment used to provide health care requires that equipment operators and their supervisors be responsible for their portion of the activity maintenance program. Section supervisors and equipment operators will ensure that—

a. Adequate time is allotted to equipment operators on a daily basis for the care and cleaning of their equipment. Supervisors must ensure that before, during, and after operation, maintenance tasks are performed IAW manufacturer's instructions and TM 8-6500-001-10-PMCS.

b. Malfunctioning equipment is promptly reported to, or taken to, Medical Maintenance.

c. Equipment operators ensure that equipment meets infection control standards and is labeled with a Biohazard Label, noting which parts of the machine could not be disinfected, and that operator maintenance is performed IAW manufacturers' instructions. Equipment submitted for repair which is found to be unclean will be returned to the user for cleaning prior to being serviced

by maintenance personnel. Maintenance personnel shall wear personal protection equipment to repair or access areas that the user is unable to disinfect.

d. A work request is initiated in a timely manner for maintenance services beyond those normally considered to be operator maintenance.

e. Equipment publications are obtained and maintained for all technical items of equipment within their area of responsibility. Equipment publications will accompany the equipment at turn-in.

f. Equipment operators order and replace accessories and parts that do not require tools, extensive disassembly, critical alignment or adjustment after their installation. User replacement parts and accessories include but are not limited to such items as hand pieces, transducers, batteries, filters and lamps.

g. Equipment operators will request TI of medical and dental equipment when such equipment is excess to their needs prior to turn-in to the property book office.

h. Section supervisors are responsible for training their subordinates in the JCAHO Environment of Care standards pertaining to the Medical Equipment Management Plan. Clinic standing operating procedures, emergency preparedness plans, and training shall include these issues.

Chapter 3
Procurement of New Equipment, Inspection and Accountability, and Orientation and Training

3-1. General

Equipment used by medical personnel is most critical to the mission since its purpose is to save lives and prevent suffering of the sick and wounded. Therefore, the highest standards of maintenance for medical equipment are mandatory. Maintenance functions vary from simple preventive maintenance procedures performed by the operator to complex repairs performed by the medical maintenance activity. Maintenance operations will be primarily based upon the policies contained in AR 40-61, AR 750-1, and AR 750-2.

3-2. Procurement of new equipment

a. Medical materiel acquisition policies and procedures will be employed to minimize logistics support requirements. (See AR 40-60.)

b. The following policy is established to achieve maximum coordination between medical equipment managers and users:

(1) *Procurement*. Equipment users are advised that Medical Maintenance is part of the equipment procurement approval process. The procurement packet will be reviewed by the maintenance manager.

(2) *Inclusion in the Medical Maintenance Program*. The maintenance manager will determine what equipment should be included in the Medical Maintenance Program. The decision will be based on the equipment's function. Evaluation criteria is contingent on the intended use of the equipment. Equipment used for diagnosis, treatment, and monitoring will be included. Evaluation of physical risks associated with the equipment will be considered. Maintenance requirements and equipment incident history are also considered.

c. The Army Medical Department Property Accounting System (AMEDDPAS) is the automated maintenance management system for retail table of distribution and allowances (TDA)

activities. (See HSC Reg 750-1.)

d. Personally owned equipment. The use of personally owned equipment is discouraged; however, if such equipment is permitted, the nursing staff safety representative should visibly inspect the item(s) for obvious defects.

3-3. Inspection and accountability

All patient care equipment entering the health care facility for use must be processed through property management and medical maintenance. This includes all newly purchased, leased, borrowed, used for demonstration or evaluation, and cost per test equipment.

a. *New equipment*. Newly purchased medical equipment will undergo a complete safety and acceptance inspection by medical maintenance before it is accepted and issued into the patient care facility. This inspection will ensure that the item meets contract specifications, is operational, and is safe for use. Any equipment found defective during the inspection will not be accepted until the identified problem has been resolved.

b. *Leased, rented and personally owned equipment*. All leased, rented or personally owned medical equipment brought into the patient treatment facility will undergo a safety inspection similar to that described in para a above before it us used. This will significantly reduce the potential of serious injury or death to patients and staff.

c. *Equipment that fails inspection*. Medical equipment that fails the safety inspection will be identified and the manufacturer will be notified of the hazard. A copy of the item deficiency report will be provided to the MEDDAC Safety/Environment of Care Committee.

3-4. Orientation and training

JCAHO requires this organization to orient and educate all staff personnel who interact with medical equipment. This organization will establish, maintain and document an effective medical equipment orientation and education program for patient care providers and equipment operators. Patient care providers include physicians, nursing staff, and ancillary clinical staff who use medical devices. Sections that use medical equipment will establish, document and maintain a training program that will provide—

a. Training to orient personnel on the capabilities, limitations, special applications and problem indicators of medical equipment. This training will include basic operating instructions, user-level preventive maintenance, and section-specific safety procedures.

b. Training on specific emergency procedures to be followed when equipment fails. This training will include availability of backup equipment, and routine, emergency and incident reporting procedures.

Chapter 4
Maintenance Management Procedures

Section I
Maintenance Support

4-1. Reporting abuse or misuse

Anyone who suspects that medical equipment is being abused or misused must report such to the

maintenance manager.

4-2. Types of repairs

a. *Routine repairs*. Routine repairs will be handled during the normal duty hours of 0730 to 1630, Monday through Friday. (All other periods are non-duty hours.) Priority for repair will be established IAW mission requirements.

b. *Emergency repairs*. Emergency repairs will take priority over all other maintenance services. A medical equipment repairer will be on-call during all non-duty periods (see paragraph *a* above) to handle all emergency repairs.

4-3. Submitting repair requests

a. Whenever equipment malfunctions, the section supervisor will ensure that all user maintenance, as prescribed by the equipment's user manual, has been performed. If the malfunction persists, a maintenance request will be submitted to Medical Maintenance. The request may be submitted in person or telephonically and will include the—

(1) Name and phone number of the requester.
(2) Clinic or activity where the equipment is located.
(3) Nomenclature of the equipment.
(4) Material Management Control Number (MMCN) of the equipment, when applicable.
(5) Complete description of the malfunction.

b. Work orders for equipment that has not been accounted for on the property book will not be accepted until the equipment is picked up on the property book. In an emergency, the work order may be processed using the group managed MMCN for the requesting hand receipt or activity.

4-4. Repair procedures

a. Initiation of a maintenance request. Upon receiving a request for equipment repair, Medical Maintenance will—

(1) Confirm whether the repair is routine or emergency.
(2) Initiate MEDCOM Form 643. (A separate form will be initiated for each repair.)
(3) Prioritize routine repairs IAW priorities for repair.
(4) Determine the site for the repair.
(a) All repairs will be conducted on site, if possible.
(b) When on site repairs are not possible, the green copy of the MEDCOM Form 643 will be given to the representative of the using activity at the time Medical Maintenance takes possession of the equipment. This form serves as a temporary hand receipt until the equipment is returned to the using activity. The user must return this copy of the form to Medical Maintenance in order to reclaim the repaired equipment.

(5) At no time will repairs be made to equipment when it is being utilized to diagnose a pa-tient or when a patient is connected to it, nor will maintenance personnel repair or service equipment which does not meet infection control standards for cleanliness.

(6) Ensure that repair costs do not exceed the 1-time Maintenance Expenditure Limit specified by TB MED 7. If an item of equipment is identified as being uneconomically repairable, a "Waiver for Repair" memorandum will be prepared and sent to the hand receipt holder for endorsement. The MEDDAC commander, or his designee, is the approving authority and may

approve those that impact on the MEDDAC's ability to provide adequate patient care. If the commander approves a waiver, the item will be repaired. The approved waiver will be maintained on file in Medical Maintenance until the item is disposed of.

(7) Forward medical equipment that is beyond the MEDDAC's repair capabilities to the appropriate Army Depot or to a civilian contractor. This determination will be made by the maintenance manager. Reliance on contract repair will be kept to an absolute minimum.

(8) Notify the using activity when unusual delays in accomplishing work are anticipated.

(9) Inform the section supervisors of requesting activities when items are ready for pickup from Medical Maintenance, and take appropriate measures to ensure the equipment is picked up in a timely manner.

(10) During non-duty hours/periods, emergency requests will be made through the administrative officer of the day (AOD) or staff duty (SD). The AOD/SD is the only individual authorized to contact the maintenance technician on-call. Procedures for requesting emergency work orders are contained in the AOD/SD instructions.

Section II
Scheduled Preventive Maintenance Program

4-5. General

Medical Maintenance will pursue a comprehensive and effective preventive maintenance program IAW AR 40-61, chapter 6, manufacturers' literature, and other applicable directives. Scheduled PMCS will take precedence over all but emergency repair requirements. (See AR 40-61, paragraph 6-4.)

4-6. Coordination with manufacturers

All coordination for repairs to medical equipment will be accomplished by Medical Maintenance. Using activities are not authorized to contact civilian firms, manufacturers or contractors for installations, warranty services, or repairs. (Any other personnel contacting outside repair services will be subject to billing for all costs incurred.)

4-7. Contract maintenance

a. The objective of medical maintenance operations is to support the health care mission. To support this objective, an MEDDAC capability for the performance of maintenance operations will be established and maintained. This will include a capability for individual and unit training and a rotation base to assure readiness for mobilization or peacetime.

b. The overall policies and procedures for the Army Warranty Program are contained in AR 40-61 and AR 700-139. Contract maintenance support criteria is specified in AR 40-61, para 6-15. Annual contract maintenance will be utilized only when it is clearly more practical or cost effective for unique, highly complex, low-density items.

4-8. Warranty and contract records

Medical maintenance will maintain all warranty and contract records for medical equipment. This will ensure verification of services and establishment of maintenance histories.

Section III
Disposal and Replacement

4-9. Disposal

Property Management will manage the turn-in of medical materiel to the DRMO. Medical equipment in condition code H may be turned in directly from the property management officer to the DRMO. The PBO will report material to the DRMO IAW AR 40-61, AR 725-50, and this regulation.

4-10. Replacement

a. *Coordination responsibilities*.

(1) *Medical Maintenance coordination responsibilities*. Medical materiel acquisition policies and procedures are stated in AR 40-60 and SB 8-75-MEDCASE. All requisitions for medical equipment will be reviewed by Medical Maintenance for determination and coordination of—

(a) Removal of existing equipment (if any).

(b) Installation, calibration and safety testing of new equipment.

(c) Maintenance support requirements for new equipment.

(d) Training requirements for users and repairers. (Two copies of operator and service manuals are normally included in the purchase of the equipment.)

(2) *Facilities Engineer coordination responsibilities*. Requisitions that may require site preparation will be reviewed by the facility engineer, who will determine whether there are any requirements for site preparation. Of particular importance are the availability of normal operating and emergency power sources, water, drainage, steam, exhaust, and potential building modifications.

b. *Life expectancy as criteria for replacement*. The fact that an item is approaching or has aged beyond its life expectancy is not sufficient cause for replacement. (See TB MED 7.) Life expectancy is merely a guideline when planning and managing a medical equipment program. Full consideration will be given to the actual needs for the item in terms of improvements in health care and technology, effects on operational costs, equipment dependability, and workload.

c. *MEDCASE*.

(1) The MEDCASE Program is the Army Medical Department (AMEDD) program for the acquisition of capital investment equipment for TDA health care facilities and the initial outfitting of expanded or newly constructed health care facilities. MEDCASE Program procedures are prescribed in SB 8-75-MEDCASE.

(2) The AMEDDPAS is used to manage MEDCASE Program development at the activity level.

(3) The data and narratives in MEDCASE requests will clearly demonstrate why an item is no longer acceptable for use, what item is needed to replace it, what cost benefits may be relevant, and the impact on mission accomplishment if the replacement item is not acquired. (See SB 8-75-MEDCASE.)

Section IV
Electrical Safety

4-11. General

The fundamental element of the electrical safety program is safe equipment operation. The medical treatment facility (MTF) is a unique environment that requires special procedures to ensure patient and staff safety. The MEDDAC commander, DENTAC commander, and VS chief will enforce require-ments within their respective commands to ensure that all patient care electrical equipment is safe for use.

4-12. Designation of critical care and other areas

The safety manager or officer will designate in writing those areas in the MTF that are considered to be critical care, wet locations, and anesthetizing locations as defined in NFPA Standard 99. This designation will be made annually and submitted to the safety committee for review and to the MTF commander or director for approval.

4-13. Testing and evaluating electrical equipment

Medical Maintenance will ensure that all electrical medical equipment is tested and evaluated for compliance with safety standards. This will be accomplished upon initial receipt of the equipment (before it is used in patient care), and annually thereafter.

4-14. Use of plug adapters, extension cords, and power strips

Electrical plug adapters and extension cords are permitted for use within the MTF provided they are manufactured to the requirements of NFPA Standard 99, and are approved by the safety manager or authority having jurisdiction.

4-15. Equipment recalls and alerts

a. Medical Maintenance is responsible for informing hand receipt holders of any medical device recalls and alerts pertaining to equipment on their hand receipt.

b. All medical equipment recalls and alerts will be investigated and corrected, if applicable. A copy of all reports will be furnished to the MEDDAC Safety Manager and the Safety and Environment of Care Committee, to be documented on the Information Collection and Evaluation System.

Section V
Reports

4-16. General

a. According to the Safe Medical Devices Act of 1990, and the Medical Device Amendments of 1992, all patient care facilities are required to report incidents that reasonably suggest that a medi-cal device has caused or contributed to a serious injury, illness or death to a patient.

b. Equipment Failure/Serious Incident. Any time a piece of medical equipment fails to operate while in support of a patient and may have or did contribute to the improper care, injury or death of a patient, the user is required to submit a DA Form 4106 (Quality Assurance/Risk Management Document) to the Risk Management Office.

c. If possible, leave all equipment as they were (with controls unchanged). Do not unplug of disconnect the equipment. Save all disposables and packages. Document the incident. Identify all personnel present and list their telephone extensions.

d. Risk Management must investigate the cause and report findings IAW the Safe Medical Devices Act.

4-17. Medical Device Reporting (MDR) report

a. *Incident report*. The Risk Manager is responsible for submitting a MDR incident report to the Food and Drug Administration (FDA) not later than 10 working days after the facility becomes aware of an incident.

b. *Obtaining assistance to complete MDR reports*. Questions concerning reporting procedures for the MDR incident report should be directed to the local U.S. Department of Health and Human Services in the Washington DC area. Call 1-800-638-2041 or 301-443-6597.

4-18. Potential equipment hazard reports

a. Equipment operators will report all potential equipment hazard to their section supervisors. Section supervisors will in turn notify Medical Maintenance.

b. Operator/user-related equipment errors (O/UREE). Medical Maintenance is responsible for conducting monthly reviews of all completed work orders. When evidence of possible O/UREE is found to have contributed to the cause of the equipment malfunction, a notice will be sent to the hand receipt holder owning the equipment. Each instance of possible O/UREE affects the safety of the patient and operator and must be documented to determine the cause. Corrective action must be taken to preclude a recurrence. Each O/UREE will be reported to the Safety/Environment of Care Committee.

Appendix A
References

Section I
Required Publications

AR 40-60
Policies and Procedures for the Acquisition of Medical Material. (Cited in paras 3-2 and 4-10.)

AR 700-139
Army Warranty Program Concepts and Policies. (Cited in para 4-7.)

AR 710-2
Supply Policy Below the Wholesale Level. (Cited in para 2-4.)

AR 725-50
Requisitioning, Receipt, and Issue System. (Cited in para 4-9.)

AR 750-1
Army Materiel Maintenance Policy and Retail Maintenance Operations. (Cited in para 3-1.)

AR 750-2
Army Materiel Maintenance, Wholesale Operations. (Cited in para 3-1.)

HSC Reg 750-1
Maintenance of Medical Equipment. (Cited in para 3-2.)

NFPA Standard 99
Standard for Health Care Facilities. (Cited in paras 4-12 and 4-14.)

SB 8-75-MEDCASE
Army Medical Department Supply Information. (Cited in para 4-10.)

TB MED 7
Maintenance Expenditure Limits for Medical Material. (Cited in paras 4-4 and 4-10.)

Section II
Related Publications

A related publication is merely a source of additional information. The user does not have to read it to understand this regulation.

AR 40-61
Medical Logistics Policies and Procedures.

AR 310-25
Dictionary of United States Army Terms

AR 325-50
Authorized Abbreviations, Brevity Codes, and Acronyms

DA Pam 738-750
Functional Users Manual for The Army Maintenance Management System (TAMMS)

JCAHO Manual
Joint Commission on Accreditation of Healthcare Organizations Comprehensive Accreditation Manual for Ambulatory Care.

Medical Device Amendment of 1992

Safe Medical Device Act of 1990

TB 38-750-2
Maintenance Management Procedures for Medical Equipment

TM 8-6500-001-10-PMCS
Operator's Preventive Maintenance Checks and Services for Reportable Medical Equipment (Consolidated)

Section III
Prescribed Forms

This section contains no entries.

Section IV
Referenced Forms

DA Form 4106
Quality Assurance/Risk Management Document

MEDCOM Form 643
Automated Maintenance

Glossary

Section I
Abbreviations

AMEDD
Army Medical Department

AMEDDPAS
AMEDD Property Accounting System

AOD
administrative officer of the day

DENTAC
Fort Meade Dental Clinic Command

DRMO
Defense Reutilization Management Office

EO
equipment operator

HSC
United States Army Health Services Command (Former identity of MEDCOM.)

IAW
in accordance with

JCAHO
Joint Commission on Accreditation of Healthcare Organizations

LOG
Logistics Division

MEDCASE
medical care support equipment

MEDCOM
U.S. Army Medical Command

MEDDAC
U.S. Army Medical Department Activity, Fort George G. Meade

MDR
medical device reporting

MMCN
material maintenance control number

MTF
medical treatment facility

NFPA
National Fire Protection Association

O/UREE
operator/user-related equipment errors

PMCS
preventive maintenance checks and services

SD
staff duty

TDA
table of distribution and allowances

TI
technical inspection

VS
Fort Meade Branch Veterinary Services

Section II
Terms

Emergency repair
A repair to support the health-care mission in a life or death situation, or other urgent medically-related mission requirement.