

**DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL DEPARTMENT ACTIVITY
Fort Carson, Colorado 80913-4604**

MEDDAC Regulation
No. 750-1

13 Feb 2008

**Maintenance of Supplies and Equipment
MAINTENANCE OF MEDICAL EQUIPMENT**
Supplementation of this publication is prohibited

History: This regulation was originally published 21 May 92. This revision is the fourth printing.

Summary: This regulation establishes policy and guidance for maintenance of medical equipment and maintenance of supplies and equipment.

Applicability: The information contained within applies to all staff of Evans Army Community Hospital (EACH), both military and civilian.

Proponent and exception authority: The proponent agency for this regulation is the Logistics Division (LOG), Equipment Management Branch (EMB), Medical Maintenance Section (MMS). The proponent has the authority to approve exceptions to this regulation that are consistent with controlling directives.

Army management control program: This regulation is not subject to the requirements of AR 11-2, as it contains no internal management control provisions.

Suggested improvements: Users are invited to send comments and improvements on DA Form 2028 (Recommended Changes to Publications) to the Commander, MEDDAC, ATTN: MCXE-LOG-EMB-MMS, Fort Carson, CO 80913-4604.

FOR THE COMMANDER:
OFFICIAL:


NOEL J. CARDENAS
LTC, MS
Deputy Commander for
Administrative Services


JOEL M. SUNDQUIST
GS12, DAC
Chief, Administrations &
Telecommunications

DISTRIBUTION:
B

*This regulation supersedes MEDDAC Reg 750-1, dated 09 OCT 07

TABLE OF CONTENTS

Purpose – Page 2

Reference – Page 2

General – Page 3

Explanation of Responsibilities – Page 3

Appendix A, Maintenance Support Procedures – Page 6

Appendix B, Receipt, Turn-In, and Disposition of Medical Equipment – Page 12

Appendix C, Medical Instrument Recycling Program (MIREP) – Page 15

Appendix D, Defibrillator Care and Performance Testing – Page 17

Appendix E, Medical Materiel Complaints, Safe Medical Devices Act – Page 19

Appendix F, The Joint Commission (TJC) – Page 23

Appendix G, Safe Medical Devices Act (SMDA), Equipment Failures/recalls, alerts – Page 24

1. **PURPOSE.** This pamphlet prescribes principles, policies, and assigns responsibilities for an integrated maintenance program which will result in safe, reliable, maintainable, and supportable medical equipment within activities of USAMEDDAC, USADENTAC, VETCOM, and TOE medical units within Evans scope of responsibility. This equipment maintenance and maintenance-related functions are provided for the ease of user reference. It provides uniform guidance and direction to standardize operating procedures.

2. REFERENCES.

- a. AR 40-61
- b. AR 735-5
- c. AR 750-1
- d. DA Pamphlet 710-2-2
- e. DA Pamphlet 750-8
- f. National Fire Prevention Association (NFPA) Manual 99.
- g. TB MED 750-1
- h. TB MED 7
- i. Joint Commission references.
- j. MEDCOM Reg 40-21

3. **GENERAL.** This publication is designed to provide uniform guidance and direction to ensure safe, reliable, maintenance and support of medical equipment within activities of USAMEDDAC, USADENTAC, VETCOM, and TOE medical units within Evans scope of responsibility.

4. **EXPLANATION OF RESPONSIBILITIES.** Identifying equipment shortages and malfunctions is the responsibility of supervisors at every level. Each activity shall have written procedures identifying how and what to do during medical equipment malfunction, i.e., evaluate patient, call Medical Maintenance, and report incident.

a. The MEDDAC Commander will:

(1) Provide, from available resources, funds essential for the Medical Maintenance Section to accomplish its missions.

(2) Ensure that clinical services and departments establish user maintenance programs that include initial orientation, periodic training, and standing operating procedures for operator level equipment maintenance.

(3) Program periodic in-service, formal Army training, and/or manufacturer training for Biomedical Equipment Specialist (BES), particularly for new equipment introduced into the activity.

(4) Program and make available tools and test equipment necessary to maintain new equipment introduced into the activity.

(5) Program sufficient travel funds so that maintenance personnel may perform required preventive maintenance services at satellite activities.

(6) Use assigned BESs for medical maintenance duties primarily and not for additional duties that may adversely affect the maintenance of medical equipment.

(7) Determine when a waiver of the Maintenance Expenditure Limit (MEL) established by the MEDCOM may be granted to allow repair of critical items of medical equipment for medical equipment over the Medical Care Support Equipment (MEDCASE) program threshold (>\$250,000).

b. The Deputy Commander for Clinical Services will:

(1) Ensure compliance with, and evaluate clinicians and clinical staff on the equipment operator support and performance programs.

c. Chief, Logistics Division will:

(1) Review maintenance policies, standards, reports, and quality assurance controls to evaluate the effectiveness of the medical equipment maintenance program.

(2) Requested tools and test equipment are given adequate priority on CEEP and MEDCASE procurement actions based on true urgency.

(3) Ensure that requested tools and test equipment be given adequate priority for Capital Expense Equipment Program (CEEP) and MEDCASE procurements.

(4) Use assigned BESs for medical maintenance duties primarily and not for additional duties that may adversely affect the maintenance of medical equipment.

(5) Authorize stockage of critical items of medical equipment in the Medical Standby Equipment Program (MEDSTEP).

(6) Authorize stockage of mission essential repair parts required to support critical items of medical equipment.

(7) Formal manufacturer's training & TDY is programmed into the budget.

(8) Medical materiel complaints are reported and/or corrected.

(9) Determine when a waiver of the Maintenance Expenditure Limit (MEL) established by the MEDCOM may be granted to allow repair of critical items of medical equipment for medical equipment under the MEDCASE program threshold (<\$250,000).

d. Chief, Equipment Management Branch will:

(1) Implement and manage the medical equipment management program.

(2) Formally monitor Army owned or supported medical equipment throughout its life cycle.

(3) Provide recommendations to the MEDDAC staff for the MEDCASE program and to the CEEP manager concerning medical equipment replacement requirements.

(4) Monitor medical equipment recalls and equipment/operator errors and report findings to the Environment of Care (EOC) committee.

(5) Conduct an annual evaluation of the medical equipment management program and report conclusions to the EOC committee.

(6) Justify formal training objectives and requirements.

e. The Chief of each department or service will:

(1) Analyze and evaluate equipment functionality, staff training and equipment availability for patient care.

(2) Ensure operator maintenance programs are included in annual performance evaluations of all supervisors.

(3) Work in conjunction with the MEDCASE / CEEP manager and the Chief, Equipment Management Branch, to implement the five-year replacement plan.

f. The OICs & NCOICs of patient care areas will:

(1) Notify the Property Management Section (PMS) and the Medical Maintenance Section before any purchase, rental, lease, cost-per-test, or borrowing agreement is made.

(2) Ensure that all medical equipment is listed on the Defense Medical Logistics Standard Support (DMLSS) hand receipt and that discrepancies are reported to the Equipment Management Branch.

(3) Notify the Medical Maintenance Section of medical equipment malfunctions as they occur.

(4) Ensure that at least one copy of operator literature or locally developed procedure is on hand for each type of medical equipment on the hand receipt.

(5) Develop standing operating procedures which outline operator-level maintenance such as performance testing, accessory replacement, operator orientation, and training.

(6) Train their subordinates in The Joint Commission (TJC) and EOC standards, utilizing the TJC guidance, manufacturers literature, clinic Standing Operating Procedures (SOPs), and any other relevant training information.

(7) Turn in medical equipment to Property Management Section that is excess to the needs of the department.

g. The Equipment Operator (EO) will:

(1) Perform daily operator preventive maintenance.

(2) Notify supervisory personnel when equipment does not function in accordance with the manufacturer's specifications.

(3) Verify that all required medical equipment accessories are available and in good working condition.

(4) Ensure that sufficient user replaceable parts necessary for proper equipment operation are available.

(5) Check equipment electrical power cords for cracks and frays and for physical displacement of cords from plug receptacles.

(6) Continually monitor Medical Equipment Verification/Certification labels, DD Form 2163, for expired dates.

(7) Operator level maintenance is a **supervisory responsibility**.

APPENDIX A MAINTENANCE SUPPORT PROCEDURES

1. **EQUIPMENT USER/OPERATOR MAINTENANCE.** The user is primarily defined as the operator of the equipment, but may also include the hand receipt holder (usually the NCOIC), the OIC, or the Chief of the department. The condition of all medical equipment directly relates to the extent of care the user exercises while operating and maintaining the equipment. To ensure the success of the equipment user/operator maintenance program, users must perform the following actions on an interval and/or as needed basis:

a. Match all medical equipment in the respective clinic/ward/department with the corresponding hand receipt. Do this monthly or as scheduled by the Property Management Section manager, whichever comes first.

b. Perform operational checks in accordance with (IAW) the manufacturer's specifications on all medical equipment in the clinic/ward/department. Emergency equipment (defibrillators, crash carts, narcotic cabinets, life support monitors, etc.) will be tested and inspected regularly IAW the latest clinical TJC standards. Daily checks should include but not be limited to cleaning exterior surfaces, air filters, removing tape, dirt, and lint. In addition, replace all light bulbs and accessories that are removable without the extensive aid of hand tools.

c. Check electrical power cords for cracks or tears.

d. Equipment in need of repair needs to be properly identified and isolated to avoid operator usage prior to repair by the Medical Maintenance Section.

(1) Pull the equipment in question off-line if it is portable.

(2) Affix a piece of masking or adhesive tape on a visible part of the defective equipment. Annotate "DO NOT USE!" on the tape to make clear that the equipment is defective.

(3) Contact the Medical Maintenance Section to open a work order.

2. **IN-SERVICE TRAINING.** The Medical Maintenance Section will provide in-service maintenance related training for the user, upon written request. Training consisting of clinical applications must be requested through Chief, Logistics. Users requesting training should include the name, manufacturer and model number of the item they are requesting training for, along with proposed date, time, and location. The Chief, Equipment Management Branch, along with the NCOIC or OIC of the requesting department will schedule the required training.

3. **USER/OPERATOR TRAINING AND MEDICAL EQUIPMENT ORIENTATION.** Clinical supervisor personnel must establish a written program for conducting annual Medical Equipment Orientation and Operator Training IAW TJC requirements. Each clinic/ward/department will tailor the written program to their equipment. The training must be documented. At a minimum, address and implement the following requirements to achieve compliance:

- a. Outline the procedures for obtaining medical equipment repair services.
- b. Teach the capabilities, limitations, and special applications of all assigned medical equipment.
- c. Teach the basic operation and safety procedures for the proper use of medical equipment.
- d. Outline emergency intervention procedures in the event of medical equipment failure.
- e. Provide the information and enhance skills necessary to perform operator maintenance responsibilities.
- f. Teach and train the procedures for reporting medical equipment problems, failures, and user errors.
- g. Address the availability and location of alternate medical equipment.
- h. Improve and maintain operator skills by ensuring that the hand receipt holder maintains one copy of manufacturer's operating literature for each type of medical equipment on hand.

4. SCHEDULED SERVICES. Both the GPRMC and MEDCOM mandate the performance of scheduled services for medical equipment in a timely and efficient manner. It minimizes costly repairs and provides optimal safety for the patient. Therefore, it is imperative that equipment is located and serviced during the scheduled month.

- a. The following four types of services may be scheduled:

(1) Preventive Maintenance Checks and Services (PMCS). PMCS covers all actions performed in an attempt to retain an item in a specified condition by providing systematic inspections, detection, and prevention of incipient failures. DMLSS code PM.

(2) Electrical Safety Testing (ST). Safety tests provide information to the repairer concerning electrical current flow characteristics of the equipment. Deteriorated power cords are the most common cause of failed electrical safety tests. The test verifies that the path of least resistance for current flow is through the power cord rather than the human body. DMLSS code INSP.

(3) Calibration/Verification/Certification (CVC) testing is the process of comparing a medical instrument of unverified accuracy with a test instrument of known and greater accuracy, which is traceable to the National Institute of Standards and Technology (NIST). The purpose of these tests are to detect any discrepancy in the accuracy of the unverified instrument. DMLSS code CAL.

(4) Scheduled Parts Replacement is performed when a manufacturer designates that certain non user replaceable parts be replaced on a scheduled recurring basis. DMLSS code SPR.

- b. The Medical Maintenance Section will formally notify you when your area is scheduled for services with a written notice accompanied with a list of the equipment to be checked. Make sure to

annotate the location of the equipment on the list prior to the BES performing the services. This will aid in providing thorough and prompt services.

c. After the Medical Maintenance Section performs scheduled services in your area, file the completed Scheduled Services Listing in your maintenance folder.

d. Unable to Locate Equipment (UL). The BES will formally notify you and the Property Book Officer (PBO) of any not located items. Make every effort to locate the identified item(s) by the suspense date. After that, the hand receipt holder must then initiate a Financial Liability Investigation. The hand receipt holder may be found financially liable and be charged for the cost of the equipment.

e. Verifying Calibration Labels:

(1) DD Form 2163, Medical Equipment Verification/Certification label. The purpose of this label is to inform equipment users as to whether or not equipment is within calibration. Users are responsible for inspecting this label prior to each use of the equipment. If a label is found to be past the date due posted on the label, the user must remove the equipment from use and notify the Medical Maintenance Section.

(2) DA Label 175, Defibrillator Energy Output Certification label. The purpose of this label is to inform the equipment user of the actual defibrillator output at a given setting. Users are responsible for inspecting this label prior to each use of the defibrillator. If a label is found to be past the expiration date posted on the label, the user must remove the equipment from use and notify the Medical Maintenance Section.

5. REQUESTING MAINTENANCE SUPPORT. The Medical Maintenance Section provides maintenance support for all medical equipment belonging to the hospital and supported activities. The maintenance of non-medical equipment should be coordinated through the Property Section. For after normal hour emergency requests see the following section covering emergency maintenance.

a. Routine Maintenance. Normal hours of operation are 0730-1530 Monday through Thursday. MMS is open for limited operations Fridays for Sergeant's Time until 1200 hours and from 1200-1530 for in-shop training, administrative functions, condition code inspections (TI/XI), and maintenance of in-shop equipment. Only emergency repair requests are accepted on Fridays. The following procedures will be followed when requesting routine maintenance services from the Medical Maintenance Section:

(1) When a piece of equipment breaks down or is suspected of malfunctioning, the user must initiate a work request to the Medical Maintenance Section, either in person or telephonically. If requesting in person, after receiving the maintenance information (ECN number), the work order clerk retrieves a work order number from DMLSS and gives it to the requester. Telephonic work orders are usually made for equipment that is serviced on-site. If the request is made telephonically, the work order clerk inputs the work order in the system, retrieves a number and then reads the number back to the requester. For telephonic work requests call (719)526-7001/2.

(2) Portable items must be brought to the Medical Maintenance Section, while equipment that cannot be transported will be serviced on-site.

(3) After the equipment is repaired, the Medical Maintenance Section notifies the user to pick up their equipment, assuming it was brought to the shop for repair. If the equipment is repaired on-site, the BES will have a representative of the area sign the work order. This does not hold the signer to any personal liability. It just acknowledges that the work is complete as stated on the work request.

(4) All equipment will be examined for cleanliness by the operator prior to submitting a work request. To preclude the possibility of contaminant transfer and to meet infection control standards, all medical equipment will be sanitized by the user before acceptance.

(5) Work order priorities for repair and services have been established IAW DMLLS. Justification is based on the use of equipment to sustain life, level of patient care for the clinic/unit/department, and importance of the equipment regarding the clinic/unit/department's mission.

b. Emergency, urgent and routine Maintenance. The following procedures will be followed when requesting emergency, urgent and routine maintenance services from the Medical Maintenance Section:

(1) Emergency repairs. **NOTE: True emergencies** are those that put patients and/or staff at risk, with no substitute equipment available to alleviate the emergency condition. Work orders for emergencies are accepted telephonically. Emergency (Immediate Priority) repairs are assigned priority Emergency, our highest priority.

(2) Urgent repairs. These repairs are assigned priority Urgent. This code is assigned to work orders when delay in returning the affected item to service will have an adverse impact on patient care and may result in a life and death (emergency) situation.

(3) Routine repairs. This work is assigned priority Routine and is completed on a first come first served basis.

6. CONTRACT MAINTENANCE. The Chief, Equipment Management Branch, will establish and maintain a system for providing annual and one-time contractual services for medical equipment. Contract services will be used IAW the mission requirements of the Medical Maintenance Section and its manpower capabilities.

a. The Chief, Equipment Management or designated representative is the only personnel authorized to contact civilian firms, manufacturers, or contractors for contract repair service(s). Any other personnel contacting outside repair services will be subject to billing for all costs incurred.

b. When contract services are performed on-site, the equipment users will ensure the integrity of the service performed, and may sign the service report indicating that service was performed to their satisfaction.

c. The Medical Maintenance Section must be provided with the service report for payment purposes. All service(s) performed will be captured on the DMLSS equipment maintenance history.

d. The Medical Maintenance Section will initiate all service contracts required on either an annual or one-time basis. Annual contracts will be identified on the DMLSS contract report.

7. **WARRANTY SERVICES.** As with contract maintenance, no one other than the Chief, Equipment Management Branch or their representative, is authorized to make warranty service calls to vendors for on-site service or to send equipment to the vendor. All warranty equipment, like other medical equipment, must be tracked in the DMLSS database, to include all services performed during the warranty period.

8. **LEASE, COST-PER-TEST/REAGENT EQUIPMENT.**

a. Equipment of this type is considered non-government owned medical equipment. As with government owned medical equipment however, this equipment must be placed on the property book for accountability.

b. Services on this type of equipment falls under the category of contract maintenance (see above) and therefore follows the same guidelines with regard to who is authorized to contact civilian firms. Lease and cost-per-test/reagent equipment may receive repairs and scheduled services from a source other than the Medical Maintenance Section. As such, it is critical that before any services are performed on any equipment, the vendor supply a written Terms of Agreement stating who is responsible for the repairs and scheduled services of the equipment, and at what intervals.

c. Anyone contacting a vendor with the intent of requesting or arranging contractual services, regardless who is paying for it, obligates government funds and is liable for all costs incurred.

9. **LOANED MEDICAL EQUIPMENT.** Loaned medical equipment falls under two categories, equipment loaned to the USA MEDDAC, and equipment that the USA MEDDAC loans to other agencies.

a. **Medical Equipment Loaned to the USA MEDDAC.** All loaned equipment must be reported to the Equipment Management and Services Branch. It is the responsibility of the clinic/ward/department to ensure that this action is accomplished prior to the equipment being used in patient areas. All loaned medical equipment must be inspected by the Medical Maintenance Section to verify that it is safe for use.

b. **Medical Equipment Loaned to Other Agencies.** It is the policy of USA MEDDAC not to loan government medical equipment to civilian institutions except for declared emergency situations and upon written approval of the MEDDAC/DENTAC Commander.

10. **PERSONAL EQUIPMENT.** Any personally owned electronic based devices such as CD recorders, tape recorders, must be inspected for electrical safety hazards by the Safety Officer.

11. **MEDICAL STANDBY EQUIPMENT PROGRAM (MEDSTEP).** A MEDSTEP asset will be authorized only if the end item is not already supported by the United States Army Medical Materiel Agency (USAMMA) MEDSTEP program and the item is determined to be critical to the health care mission. All MEDSTEP assets will be approved by the MTF Commander and maintained by the Medical Maintenance Section. Contact the Medical Maintenance Section for current inventory of MEDSTEP items.

12. MEDICAL MAINTENANCE SECTION COMPUTER SUPPORT. The Medical Maintenance Section is responsible for maintenance support of computer equipment under the following conditions:

- a. The computer serves as the output device for medical equipment, but not solely for information storage.
- b. The computer controls or influences the operation or function of medical equipment.
- c. Without the computer, the medical equipment cannot perform its primary function.
- d. The computer was purchased as an integral component of the overall system.

APPENDIX B
RECEIPT, TURN-IN AND DISPOSITION OF MEDICAL EQUIPMENT

1. RECEIVING NEW MEDICAL EQUIPMENT.

a. New medical equipment will be accepted via the Logistics Division. There are no exceptions. The Equipment Management Branch (EMB) will notify the hand receipt holder of the requesting clinic/ward/department that the equipment has arrived and is ready for pick-up. This will occur after the equipment has been received, catalogued, and given a technical evaluation for issue by the Medical Maintenance Section.

b. No equipment should be delivered directly to the end user without processing through the Logistics Division. Should such delivery occur, the hand receipt holder must contact EMB immediately. EMB will coordinate the proper receipt and inspection procedures with the Medical Maintenance Section.

c. Lease, Cost-Per-Test/Reagent, Loaned Equipment.

(1) This is the most difficult category of medical equipment to track. Equipment falling under this category is usually non-Army owned. The user, without exception, must ensure that the equipment is on the hand receipt. If in question, remove equipment from patient use immediately! Report all suspect equipment, to include equipment provided under reagent purchase agreements, to the Medical Maintenance Section. This must occur before operating any equipment. Failure to this opens the strong possibility of the government incurring liability due to association with use of the equipment. Any equipment not meeting these conditions may constitute a TJC finding.

(2) Vendors/manufacturers tend to bring their equipment onto the premises without understanding what the procedures are for equipment receipt. Do not accept any new medical equipment directly from a vendor/manufacture. Only accept equipment from the Equipment Management Branch.

(3) To insure there is no unreported equipment, perform a physical reconciliation of medical equipment against the hand receipt on a monthly basis. Report any equipment not on the hand receipt to the Equipment Management and Services Section.

2. TURNING IN EQUIPMENT.

a. Department Chiefs, OIC's, and NCOIC's should contact the Medical Maintenance Section when a decision is desired to turn in medical equipment as excess. The number one goal for CEEP/MEDCASE funds in fiscal year 2008 is procurement of equipment within or past 1 year replacement. Consider the other following factors when making such a decision:

(1) Mission Requirements. What are the clinical requirements in relation to patient enrollment over a given period of time, both present and future?

(2) Health Affairs Policies. How will the push for medical equipment standardization affect the process of deciding which equipment needs to be turned in?

(3) Budget Constraints. How will monetary policies affect purchasing capabilities over time?

(4) The Five Year Replacement Plan. The CEEP/MEDCASE manager sends a DMLSS generated report to each hand receipt holder on an annual basis. This report gives detailed information regarding a clinic/ward/department's equipment assets. Departments will arrange to meet with the Chief, Equipment Management Branch, to identify the current and future status of equipment assets. Departments will route CEEP/MEDCASE requests to replace equipment identified by the Department and the Chief Equipment Management Branch.

(5) Uneconomically Repairable Equipment. The Medical Maintenance Section (MMS) is responsible for coding medical equipment and notifying the clinic/ward/department when the item is uneconomical to repair. MMS also weighs the pros and cons of turning in the equipment versus requesting a waiver (command authorization to continue supporting the equipment to satisfy clinical requirements).

b. Once a decision is made to turn in equipment, contact the hand receipt manager at the Property Section to initiate the process.

3. WAIVER POLICY.

a. The basic philosophy of the waiver policy is to provide for controls to preclude the routine use of repair funds on equipment that should be replaced rather than repaired.

b. The excessive use of waivers indicates poor equipment replacement planning and forecasting.

c. The Maintenance Expenditure Limit (MEL) is the factor used to determine the repair eligibility of medical equipment. The MEL for medical equipment is a percentage of the current acquisition price, based on life expectancy remaining.

d. When the estimated cost to repair a piece of equipment exceeds the MEL, further maintenance is not authorized except when a waiver of the MEL is approved by the local approval authority.

e. The Hospital Commander is the only approving authority for waivers on medical equipment with the unit price above the MEDCASE threshold (\$250,000).

f. The Chief, Logistics Division, is the waiver approving authority for equipment with a unit price below the MEDCASE threshold.

g. The NCOIC, Medical Maintenance will notify the hand receipt holder when a piece of equipment is determined to be uneconomically repairable. An explanation of the condition code will be provided as well.

(1) The hand receipt holder will make the determination whether or not to repair the equipment.

(2) If it is determined that a repair will be made that will exceed the MEL complete the memorandum endorsing the action. The memorandum will be staffed through Chief, Equipment Management Branch; to Chief, Logistics Division.

h. The Chief, Equipment Management Branch will file the memorandum and initiate the approved action, either repairing or condition coding the equipment.

APPENDIX C
MEDICAL INSTRUMENT RECYCLING PROGRAM (MIREP)

1. DEFINITIONS.

a. Medical instrument recycling is a program initiated to extend the useful life of durable medical instruments through reconditioning.

b. Durable instruments are listed with Accounting Requirement Code (ARC) of "D". Similar nonstandard items are also accepted for recycling. All hand-held stainless steel surgical instruments at Evans Army Community Hospital.

c. Recycling process is the restoring of instruments to a like-new condition, when repaired, adjusted, redefined hatches, sharpened, cleaned, and/or polished. Coverage includes all parts, all labor, and all container repairs.

2. ESTABLISHING SERVICE SUPPORT.

a. Established a service contract with Mobile Instrument Service (GPRCO Contract # W81K00-07-F-0417) to perform on-site recycling. This service is managed and controlled by the COR, EMB Technician Contracts of the Medical Maintenance Section.

b. The contractor will provide all required parts and labor to maintain the instruments in a serviceable condition in accordance with the manufacturer's specifications, phone support and continuous product information updates and bulletins. Contractor will provide technical assistance, replacement parts and repair required by the manufacturer. Contractor service will ensure medical instruments are 100% operational, repair necessary to return the medical instruments and containers from an inoperable instrument to a totally functional state of operation. Contractor will complete on-site service and will not take any medical instruments off site unless authorized by the COR.

c. OR/Central Material Supply (CMS) will be responsible to collect the instruments on hand to recycle. Mobile Instrument Service comes on-site every other Wednesday, not to exceed 30 on-site visits per year, to include 6 plus sets per day including container repair.

3. ACCOUNTABILITY OF SERVICED INSTRUMENTS.

a. OR/CMS & Medical Maintenance Section COR will receive, upon completion of any services, a written service report with detailed information regarding the instrument malfunction and corrective action taken. This report will include part/catalog numbers, price per part (if needed), description of instrument (model number), quantity of instruments, unit price and total price.

b. Central Material Services Supervisor or appointed technician will verify the service and report any discrepancies to the Medical Maintenance Section COR. The COR will ensure payment is made only for the service performed.

c. At the beginning of the month, the COR will open a work order for the on-site Mobile Instrument Service to be performed. Once service has been completed for the month, the COR will annotate on the work order the dates of service, cost of each visit, Bio-Medical Technician man-hours and any other pertinent information for the on-site service. This information is for accountability/ tracking of the contract and all services performed for Evans Army Community Hospital.

4. UNSERVICEABLE INSTRUMENTS.

a. Central Material Services and Medical Maintenance Branch will receive a written service report with detailed information regarding instrument malfunction/ or unserviceable cause. The written service report can be used by OR/CMS as justification to order new instruments of similar type.

b. The unserviceable equipment will then be turned in to the Logistics Material Section scrap metal container located on the Logistics loading dock.

APPENDIX D
OPERATOR DEFIBRILLATOR CARE AND PERFORMANCE TEST

1. REQUIREMENTS.

a. Orientation shall be part of in-processing to a new job. It is the responsibility of staff management to provide continued education to verify levels of competency on equipment.

b. An SOP to provide initial orientation, periodic training plan, user checks and services shall be developed in each section.

c. Operator's manuals along with the SOP and training documentation files, shall be maintained in every area a defibrillator is located.

d. Daily performance verification test shall be performed IAW operator's manual and documented on DD Form 314 or Crash Cart inspection log with the training and testing . Daily verification consists of a physical inspection, battery, and functional tests **in accordance with manufacturer's specifications** to insure operational readiness. Deficiencies or discrepancies will be reported to the Medical Maintenance Section for corrections. Medical Maintenance Section will perform required scheduled services to include appropriate documentation semi-annually. This PMCS doesn't replace the user's daily performance test.

2. PROCEDURE FOR DAILY TEST: Operator's manual provides procedures on daily performance verification on each specific model defibrillator. Properly trained operators should be assigned or tasked to test or operate the specific model defibrillator. Supervisors will train and documentation the training on all required personnel. The Medical Maintenance Section may be contacted to assist in all levels of operator training.

a. PHYSICAL INSPECTION. Perform a complete physical inspection to the defibrillator and its accessories for loose or missing hardware, cracks, dents, damaged plugs, frayed cords and contamination from foreign substances, cracked or pitted paddles.

**WARNING: CRACKED PLASTIC HANDLES OR PITTED PADDLES COULD
RESULT IN A SHOCK TO THE USER OR BURNS TO THE PATIENT.**

b. AC/DC OPERATION.

(1) Connect the defibrillator to appropriate AC power (110v, 60Hz). Verify that the battery charge light is illuminated. Depress the POWER button. Verify that the POWER light is illuminated. Unplug and plug in the power cord several times to confirm defibrillator operation in both AC and DC modes. Verify that the battery charge light is only on when AC power is applied and that the defibrillator remains on during the AC/DC operation.

(2) Batteries will perform best if they are used regularly but not continuously overcharged for long periods of time. Long term over-charging can occur if the instrument is continually operated from AC line power. To minimize this condition, allow the unit to operate on battery power for 45 minutes once each week and document in the operators equipment file. This

performance test will effectively work the battery to satisfy this requirement. Routine medical equipment preventive maintenance service provides for deep discharge, semiannually.

- c. BATTERY LEVEL METER. Verify that the battery meter is within the green zone.
- d. ENERGY DUMP/PERFORMANCE TEST - refer to Operator's Manual..

APPENDIX E

MEDICAL MATERIEL COMPLAINTS

1. **COMPLAINT POLICY.** According to the Safe Medical Device Act (SMDA) of 1990, medical device user facilities must begin reporting incidents that reasonably suggest there is a probability that a medical device has caused or contributed to the death, serious injury, or serious illness of a patient, effective 28 November 1991. Materiel found to be injurious or unsatisfactory will be reported on Medical /Dental Product Quality Deficiency Report (M/DPQDR) The items will be thoroughly evaluated before submitting the complaint. Medical materiel complaint procedures are contained in SB 8-75-11 and AR 40-61 (Section V, Medical Materiel Complaints).

2. TYPES OF MATERIAL COMPLAINTS.

a. Type I.

(1) Type I complaints are submitted for materiel, including equipment, determined by use or test to be harmful or defective to the extent that using the materiel has or may cause death, injury, or illness. Immediate action must be taken to report such materiel and suspend its issue and use.

(2) Type I complaints can be initially classified only by medical or dental officers familiar with the details of the complaints. Professional personnel will carefully ascertain and evaluate all pertinent facts to preclude unnecessary delay or undue alarm because of the immediate worldwide notification required for Type I complaints.

b. **Type II.** Type II complaints are used to report materiel, other than equipment, that is suspected of being harmful, defective, deteriorated, or otherwise unsuitable for use. Personnel must take expeditious action to report such materiel and to suspend its issue and use.

c. **Type III.** Type III complaints are used to report equipment that is determined to be unsatisfactory because of malfunction, design, defects (attributable to faulty materiel, workmanship, or quality inspection), or performance. Such complaints do not necessarily require suspension of the items.

3. DEFINITIONS.

a. A medical device is an article that is:

(1) Recognized in the official national formulary, or the U.S. Pharmacopedia, or any supplements.

(2) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals.

(3) Intended to affect the structure or any function of the body of man/animal, and which does not achieve its principal intended purposes through chemical action within or on the body of man/animal and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(4) Examples include: Anesthesia machines, defibrillators, pacemakers, catheters, thermometers, patient restraints, hearing aids, blood glucose monitors, x-ray machines, etc.

b. Serious injury or serious illness:

(1) Is life threatening.

(2) Results in permanent impairment of a body function or permanent damage to a body structure.

(3) Necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

4. SUBMITTING MATERIEL COMPLAINTS.

a. All medical materiel complaints, regardless of procurement source, will be submitted on a Complaint Form to DSCP via online at:

https://dmmonline.dscp.dla.mil/forms/mpqdr_entry_new.asp

b. Complaint Forms completed on nonstandard items procured through DSCP must cite the purchase order number and document number.

c. Report the circumstances of Type I complaints immediately to DSCP, through the quickest means, that is, by telephone or immediate message.

(1) During normal duty hours (0700 - 1700 hours Eastern Time), call the DSCP ESOC at DSN 444-2111/2112, or commercial 215 737-2112. A fax may also be sent to: Commercial 215 737-2081/7109 or DSN 444-2081/7109.

(2) After duty hours, the numbers called above will automatically transfer to the Staff Duty Officer. If the transfer does not occur or the call is not answered, call the following numbers: DSN 444-2341 or commercial 215 737-2341.

d. The HCA submitting Type I complaints will document the call immediately and send written confirmation within 12 hours via facsimile or submit a Complaint Form online. For Type I complaints only, the identity and contact information for the authorizing Medical Officer is required. When a Type II or III complaint is determined appropriate, the medical unit will submit the Complaint Form within 48 hours either by mail to the DSCP address shown below, facsimile to DSN 444-3120/Commerical 215-737-3120, telephonically to DSN 444-2891/Commerical 215-737-2891 or online.

Director, DSCP
ATTN: DSCP-MRCM

700 Robbins Ave
Philadelphia PA 19111-5092

e. Follow-up by mail or electronically with photographs and drawings of equipment with Type III complaints to help describe or substantiate the complaint.

f. Include a specific statement on the storage conditions of the materiel on the Type II complain. An example of the statement would be: "Controlled temperature warehouse or unheated warehouse."

g. Forward copies of the Complaint Form as directed below:

(1) If not submitted online, forward one copy of complaints regardless of procurement source to:

Director, DSCP
ATTN: DSCP-MRCM
700 Robbins Avenue
Philadelphia PA 19111-5092

(2) One copy of complaints on standard and nonstandard materiel purchased locally to the appropriate local contracting activity.

(3) One copy of complaints for GSA catalog materiel to the GSA regional office.

(4) Information copies of all complaints will be sent to the following addressees

(a) Defense Medical Standardization Board
ATTN: Staff Director
1423 Sultan Drive
Fort Detrick MD 21702-5013

(b) Commander, USAMMA
ATTN: MCMR-MMO-SO
1423 Sultan Drive, Suite 100
Fort Detrick MD 21702-5001

h. The preferred method for the submission of a complaint is electronic filing of a Complaint Form. This method provides simultaneous copies going to DSCP, the DMSB, and the USAMMA, through the INTERNET at https://dmmonline.dscp.dla.mil/forms/mpqdr_entry_new.asp . Upon submission of the complaint, DSCP acknowledges receipt of the complaint via email or other method.

i. Medical materiel complaints submitted on a Complaint Form are exempted from information requirements control under *AR 335-15*.

j. The 21 CFR prescribes reporting certain materiel/equipment conditions to the FDA under the Safe Medical Devices Act (SMDA). Logistics personnel will coordinate and provide a copy of the Complaint Form to the Risk Manager as part of the Risk Management Program.

The Risk Manager is required under The Joint Commission (TJC) to review the SMDA information on the Complaint Form and assess the potential risk.

k. Additional reports may be required under *AR 385-40*

APPENDIX F
The Joint Commission (TJC)

1. RESPONSIBILITIES, MEDDAC/DENTAC Commander is responsible for:

- a. Assuring an adequate operator/user maintenance program is established.
- b. Providing necessary training for Equipment Management Branch personnel IAW TJC.
- c. Ensuring test equipment and repair parts are made available.

2. Chiefs/Departments/Divisions/Services/Activities are responsible for:

a. Ensuring that each piece or type of equipment has written equipment operation and user maintenance procedures. (These procedures are usually outlined in the manufacturer's literature which each activity is required to maintain on all medical equipment IAW MEDCOM Reg. 750-1) TJC and HR.1 through HR.4 also requires a user training program be established to manage the clinical and physical risks associated with medical equipment.

b. Ensuring that there is orientation and at least annual continuing education of individuals who use and/or maintain the equipment and that required training is documented IAW TJC paragraphs listed in paragraph a. above.

c. Ensuring hand receipt holders attend initial and annual logistics training. This training ensures all activities are current on Medical Supply, Property Management, and Medical Maintenance procedures and able to properly train operators in maintaining their assigned equipment.

d. Maintaining an adequate stockage of operator replaceable parts and accessories.

3. Operators are responsible for:

a. Attending orientation and annual continuing education on the operation, care and maintenance of all equipment operated IAW TJC para. EC.1.3.6 and HR.1 through HR.4.

b. Ensuring that before, during and after operational tests, cleaning and operators maintenance is performed.

c. Reporting all defective equipment to their Chief/NCOIC for preparation of necessary paperwork and coordination with Equipment Management Branch for repairs.

APPENDIX G
SAFE MEDICAL DEVICE ACT PROCEDURES
EQUIPMENT FAILURES/RECALLS/ALERTS/USER ERRORS

1. REFERENCES.

- a. Food and Drug Administration (FDA), Safe Medical Devices Act (SMDA)
- b. TB MED 750-1, Operating Guide for Medical Equipment Maintenance

2. PURPOSE.

a. To provide guidance and assign responsibility to all MEDDAC personnel to monitor and identify significant adverse events involving medical devices.

b. The SMDA provides a mechanism for the FDA and manufacturers to identify and monitor significant adverse events involving medical devices, so that problems may be detected and corrected in a timely manner.

3. APPLICABILITY.

a. This SOP applies to all personnel assigned or attached to the Fort Carson MEDDAC with duty in Building 7500 or any outlying MEDDAC building.

b. The SMDA requires device user facilities (hospitals) to report to the device manufacturer when the facility determines that a device has or may have caused or contributed to a patient death or serious injury. In the case of death, the facility must also send a report to the FDA. The FDA Form 3500A will be used and submitted within ten work days from the time that any medical personnel employed by or affiliated with the facility becomes aware that the device may have caused or contributed to a death or injury.

c. The following procedures apply to any MEDDAC medical equipment and/or device adverse occurrence(s) as defined by the FDA in the SMDA.

4. RESPONSIBILITIES. When/if a piece of medical equipment and/or device is suspect in contributing to an adverse affect on a patient:

a. Employee will:

(1) Notify the Safety Office immediately (within the first hour) verbally at 6.7371/4.5586/6.7710.

(2) Turn in the equipment/device and all consumables and disposables (any item used in

conjunction with the equipment) to the Safety Manager for lockup and further testing within the first hour.

The equipment will be turned in as it was used. DO NOT change or adjust any settings/dials/etc on the equipment prior to turning in. Bring it as used during procedure in which incident occurred.

(3) If the Safety Manager cannot be contacted, secure the equipment and contact the NCOIC/Chief of Logistics.

(4) If after duty hours, weekend, etc., contact the AOD to call the Safety Manager via cell phone.

(5) If the AOD or the Safety Manager cannot be contacted, secure the equipment and contact the NCOIC/Chief of Logistics.

b. Upon notification, the Safety Manager will:

(1) Obtain a list of personnel involved.

(2) Contact Chief Medical Maintenance.

(3) Contact the Risk Management Office.

(4) Contact the Patient Safety Office.

(5) At the request of the Risk Manager, set up interview times with each individual who was in the room at the time the equipment was used.

(6) At the request of the Risk Manager and the Patient Safety Representative, attend the interviews of each individual to obtain their views on the events leading to and the actual occurrence.

(7) Complete the FDA Form 3500A and determine who must be notified (manufacturer and/or FDA).

c. Chief, Medical Maintenance will:

(1) Make a decision with the Safety Officer if the in-house Medical Maintenance Section will inspect the equipment, or an outside agency.

(2) Complete the medical equipment section of FDA Form 3500A.

(3) Testing and further procedures are outlined in the Medical Maintenance internal SOP.

d. Risk Management Officer will:

(1) Schedule and conduct the personnel interviews.

(2) Complete the clinical section of FDA Form 3500A.

e. Patient Safety Representative will:

- (1) Attend the personnel interviews.
- (2) Assist in completing the clinical section of FDA Form 3500A.

f. Other Actions Taken by the Safety Manager:

- (1) Maintain all records in the MEDDAC Safety Office for a period of two years.
- (2) Submit a semi-annual report on FDA Form 3419 on 1 January and 1 July of each year. If no incidents have occurred, no report is necessary.
- (3) The semi-annual report will include:
 - (a) The FDA assigned reporting number;
 - (b) Reporting year;
 - (c) Reporting period;
 - (d) Report date;
 - (e) Complete name and address of the user facility;
 - (f) Name, title, and address of the contact person;
 - (g) Lowest and highest report numbers of the reports submitted to the FDA and/or manufacturer during the reporting period.
 - (h) Total number of reports attached or summarized; and
 - (i) Basic information about each reported event or a copy of the FDA Form 3500A that was submitted for each event.

5. If the adverse event is determined to not meet the FDA mandatory reporting requirements, the MEDDAC Command (Commander, DCA, DCCS, DCHS, or CSM) will decide if voluntary reporting will occur.

6. DEFINITIONS.

a. Malfunction: The failure of a device to meet its performance specifications or to perform as intended. A malfunction is reportable when it is likely to cause or contribute to a death or serious injury if it were to recur. This SOP assumes that a malfunction will recur. A malfunction is reportable if any one of the following is true:

- (1) The chance of it causing such event is not remote or minute;
- (2) It affects the device in a catastrophic manner that may lead to a death or serious injury;
- (3) It causes the device to fail to perform its essential function and compromises the device's therapeutic, monitoring, or diagnostic effectiveness, which could cause or contribute to a death or serious injury;
- (4) The device involves a long-term implant or a device that is considered to be life-supporting, or life-sustaining;
- (5) The manufacturer takes or would be required to take action to reduce a risk to health as a result of the malfunction; or

(6) A malfunction of the same type has actually caused or contributed to a death or serious injury in the past.

b. Medical Personnel: any individual who:

(1) Is licensed, registered, or certified by a state, territory, or other governing body to administer health care;

(2) Has received a diploma or a degree in a professional or scientific discipline;

(3) Is an employee responsible for receiving medical complaints or adverse event reports;

or

(4) Is a supervisor of such persons.

c. Permanent: permanent damage or impairment is irreversible damage or impairment that is not trivial.

d. Reportable Event: The adverse events or problems that the medical device regulation requires to be reported. These include patient deaths and serious injuries that medical devices have or may have caused or contributed to (i.e. the device may have directly caused the events or played a role in the events).

e. Serious Injury: Three possible types:

(1) Life threatening injuries;

(2) Injuries that result in permanent damage or impairment; and

(3) Injuries that require medical intervention to preclude permanent damage or impairment.

f. User Facility Reporting Number: The number that uniquely identifies each report submitted by a user facility to manufacturers and FDA. The number consists of three parts:

(1) The user facility's ten-digit Health Care Financing Administration (HCFA) number. If the HCFA number is less than ten digits, fill the remaining spaces with zeros;

(2) The four digit calendar year in which the report is submitted; and

(3) The four-digit sequence number of the reports submitted for the year, starting with 0001. For example: 1234567890-1996-0001.

7. OPERATOR/USER RELATED EQUIPMENT ERRORS. The Medical Maintenance Section is responsible for conducting monthly reviews of all completed work orders. If evidence of possible operator/user related equipment error is found to have contributed to the cause of the equipment malfunction, a notice is sent to the hand receipt holder (HRH). The HRH is expected to follow suggested corrective action(s).

8. MEDICAL DEVICE RECALLS/ALERTS.

a. The Medical Maintenance Section must report all recalls/alerts that affect Evans medical equipment to the EOC committee on a quarterly basis.

b. The Medical Maintenance Section will also notify hand receipt holders of any Medical Device.

9. POINT OF CONTACT. Questions in reference to SMDA should be directed to the MEDDAC Safety Manager, Logistics Division, ext 6.7371/4.5586/7710.