



# UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES



## SUBJECT: Medical Devices and Equipment Sustainment Program

### Instruction 4144

DEC 03 2019

(LOG)

#### ABSTRACT

This Instruction formalizes and brings awareness and structure to the Uniformed Services University of the Health Sciences (USU) Medical Devices and Equipment (MDE) Sustainment Program.

**A. Purpose.** This Instruction establishes policy, assigns responsibility, and prescribes principles and procedures for supporting an integrated medical device/medical device systems (equipment) sustainment program, within Uniformed Services University (USU), Armed Forces Radiobiology Research Institute (AFRRI), and all satellite activities.

**B. References.** *See Enclosure 1.*

**C. Applicability.** This Instruction applies to all supported activities that request and receive Medical Device/Medical Device Systems support from Technical Services Branch, Logistics Division, USU, Bethesda, Maryland.

**D. Definition of Terms.** *See Enclosure 2.*

**E. Procedures.** *See Enclosure 3.*

**F. Responsibility.**

1. The Vice President for Finance and Administration, USU will:

a. Provide, from available resources, funds essential for the Logistics Division, Technical Services Branch to accomplish its mission in support of lifecycle through a Total Cost of Ownership concept (TCO).

b. Bring the applicable provisions of this instruction to the attention of all concerned and make them readily available to the University.

2. Director, Logistics Division will:

a. Appoint in writing a primary Activity Sustainment Manager.

- b. Review MDE sustainment policies, standards, reports, and quality assurance controls to evaluate the effectiveness of the equipment sustainment program.
- c. Ensure that all MDEs that are operated, or maintained by a USU element is accurately recorded within the approved authoritative Information System (IS) of record (i.e. Defense Medical Logistics Standard Support [DMLSS]) in accordance with policy established in *Reference a*.
- d. Ensure that clinical research services and departments establish operator level sustainment programs that include initial orientation, periodic training, and standard operating procedures (SOPs) for operator level equipment sustainment.
- e. Evaluate the performance of equipment operators and organizational sustainment through sustainment inspections; ensure deficiencies found during inspections are documented and corrected.
- f. Ensure all assigned Biomedical Equipment Technicians (BMETs) will be used primarily for Technical Services Branch (TSB) duties, in accordance with *Reference (b)*.
- g. Provide sustainment services to activities on a scheduled basis.
- h. Allocate sufficient training and travel funds so that sustainment personnel may receive on-site and off-site training on equipment as required.
- i. Ensure TSB is adequately resourced to remain compliant with current Occupational Safety and Health requirements in accordance with *Reference (c)*.
- j. Program and procure tools and test equipment necessary to maintain new equipment gained by the activity.
- k. Authorize stock of mission essential repair parts required to support critical equipment.

3. Chief, Technical Services Branch will:

- a. Oversee, develop, and review internal SOPs annually.
- b. Formally monitor government owned or supported equipment throughout its life cycle.
- c. Advise and provide recommendations to USU staff for the procurement program concerning equipment replacement requirements and lifecycle management assessments for MDE.
- d. Oversee, monitor, and remediate MDE recalls, alerts, errors, incidents and report findings to appropriate personnel. *See Enclosure 4.*

- e. Program periodic in-service training, and/or manufacturer training for BMETs, particularly for new equipment gained by the facility.
- f. Establish periodic in-service training, and/or formal training for equipment operators as required or requested.
- g. Ensure that training objectives are established for equipment sustainment personnel and that tuition and temporary duty (TDY) estimates are included in the annual TSB budget.
- h. Comply with and ensure that 100% of equipment not serviced within the scheduled sustainment period, are removed from use if there is potential for unsafe use or damage to the equipment. *See Enclosure 5.*
- i. Determine when a waiver of the Maintenance Expenditure Limit (MEL) established by applicable regulation may be granted to allow repair of critical items.

4. Chief, Property Management Office Branch will:

- a. Implement and manage the equipment management program.
- b. Provide guidance and assistance to other organizational elements that do not have database tracking capabilities for equipment.
- c. Designate custodial areas within USU and appoint, in writing, a Departmental Property Custodian (DPC) to support property management functions for assigned MDE.
- d. Initiate a Financial Liability Investigation of Property Loss (FLIPL) and document on a DD Form 200 in accordance with *Reference d* for any MDE lost, damaged, destroyed, or stolen. If the item(s) are found at a later time, adjustment documents can be changed or canceled to reflect the results of the findings.
- e. Conduct an annual evaluation of the equipment management program and report conclusion to appropriate personnel.

5. Chief, Clinical Activities/Departments will:

- a. Analyze their respective MDE program with emphasis on equipment availability to meet required mission.
- b. Work in conjunction with their Department Property Custodian/Equipment Manager and the Chief, Technical Services Branch, to implement the five-year replacement plan.
- c. Ensure personnel within their department actively support and participate in the USU MDE sustainment program.

d. Ensure operator level sustainment programs are included in the annual performance evaluation of all supervisors.

e. Prevent the abuse of material under operator control; investigate and report to Logistics instances of abuse and take appropriate action.

6. Officers in Charge (OICs), Non-commissioned Officers in Charge (NCOICs), Senior Enlisted Advisors (SEA) and Departmental Property Custodians will:

a. Notify Logistics Division, Property Management Office and the Technical Services Branch before any purchase, rental, lease, cost-per-test, or any borrowing agreement is made per *Reference (n)*.

b. Ensure that all equipment is listed on the Defense Medical Logistics Standard Support (DMLSS) Custodian Receipt/Location (CRL) list and that discrepancies are reported to the TSB and Property Management Branch.

c. Notify TSB, Logistics Division of all equipment malfunctions as they occur and remove the equipment from service immediately. Do not allow anyone access to the equipment until proper investigative procedures are initiated.

d. Ensure written procedures are established and followed when equipment fails including the use of interventions and backup equipment.

e. Ensure that at least one copy of operator's literature or locally developed operator procedure is on-hand for each piece of equipment on the CRL.

f. Train their department in The Joint Commission (TJC) standards by utilizing TJC accreditation manual for hospitals, manufacturers' literature, department SOPs, Emergency Preparedness Plans (EPPs), and any other relevant training information.

g. Ensure that property is accounted for and cared for IAW manufacturer, local, and regulatory guidance.

h. Investigate all incidents of equipment misuse/abuse.

i. Turn-in any equipment to the Logistics Division, Property Management Branch that is deemed excess.

j. Ensure that equipment orientation and operator training is conducted.

k. Ensure that operator training is documented.

l. Implement operator level preventive sustainment programs that ensures equipment operator monitoring and sustainment before, during, and after use of each piece of equipment.

m. Report any confirmed Unable to Locate (UL) equipment immediately to the Property Management Branch. The Departmental Property Custodian will ensure that the equipment has been searched for prior to initiating a Financial Liability Investigation of Property Loss (FLIPL) IAW *Reference (d)*.

n. Ensure that all equipment is made available for sustainment/maintenance.

7. The Equipment Operator will:

a. Perform daily operator level sustainment, to include cleaning the exterior surfaces of the equipment, all components, and all accessories in the area.

b. Check equipment power cords for cracks, frays, and/or physical displacement of cords from plug receptacles.

c. Notify supervisory personnel and TSB when equipment does not function in accordance with manufacturer's specifications.

d. Verify that all required equipment accessories are available and in good working condition.

e. Ensure that sufficient operator replaceable parts necessary for proper equipment operation are available.

f. Continually monitor DA Label 175, Defibrillator Energy Output Certification, and DD Form 2163, Equipment Verification/Certification labels for expired dates. Immediately notify the NCOIC and/or TSB of expired/illegible labels and suspend use of the equipment until corrected.

**G. Effective Date.** This Instruction is effective immediately.



Richard W. Thomas, MD, DDS, FACS  
President

Enclosure:

1. References
2. Definition Of Terms
3. Sustainment Support Procedures
4. Safe Medical Devices Act Equipment Failures/Recalls/Alerts/Operator Errors
5. Receipt, Turn-In And Disposition Of Equipment

**REFERENCES**

- (a) DHA-Interim Procedural Manual 19-XXX, "Use of Defense Medical Logistics Standard Support (DMLSS) as the System of Record for Medical Logistics (MEDLOG) Enterprise Activity (EA),
- (b) SB 8-75-11, "Army Medical Department Supply Information," dated November 20, 2016.
- (c) Title 29, Code of Federal Regulations, "Labor."
- (d) USU Instruction 7201, "Reporting of Government Property Lost, Damaged, Destroyed or Stolen," dated September 13, 2006.
- (e) AR 40-61, "Medical Logistics Policies," dated January 28, 2005.
- (f) AR 735-5, "Property Accountability Policies," dated November 9, 2016.
- (g) AR 750-1, "Army Material Maintenance Policy," dated August 3, 2017.
- (h) DA Pam 710-2-2, "Supply Support Activity Supply System: Manual Procedures," dated September 30, 1998.
- (i) TB MED 7, "Maintenance Expenditure Limits for Medical Material," dated October 8, 1993.
- (j) TB MED 750-1, "Operating Guide for Medical Equipment Maintenance," dated April 13, 1998.
- (k) National Fire Prevention Association (NFPA) 99, Health Care Facilities.
- (l) The Joint Commission (TJC) on the Accreditation of Healthcare Organizations Comprehensive Accreditation Manual for Hospitals (CAMH).
- (m) NAVMED P-5132, "BUMED Equipment Management Manual," dated April 7, 2014.
- (n) USU Instruction 4100, "Loan, Transfer, and Removal of Property from the USU Campus and all Satellite Locations," dated February 29, 2016.

## DEFINITION OF TERMS

1. **Accessories:** Items which enhance or provide additional capabilities to an end item. An accessory may be expendable, durable, or non-expendable; whereas a component is a functional element of a set or system, an accessory is considered to be a supplementary item. A transducer for an ultrasound scanner is a component of that end item. Additional transducers, which provide additional capabilities, are considered to be accessories to the end item.
2. **Automated External Defibrillator (AED):** Commercially available automatic defibrillators that analyze cardiac rhythm and advise the operator/user to check pulse, perform CPR or defibrillate when appropriate. Some models automatically defibrillate after a warning to providers, while other models provide recommendation and require a rescuer to initiate the defibrillation.
3. **Biomedical Equipment Specialist (BES)/Equipment Maintainer:** Personnel trained in the repair of equipment. Assigned Army personnel are in MOS 670A, 68A, and appropriate civilian medical repairer series.
4. **Calibration/Verification/Certification (CVC):** The comparison of a medical device of unverified accuracy to a measurement device of known accuracy to detect and correct, if necessary, any deviation from required performance specifications. The verification of the calibration of an item of equipment compared to the original manufacturer's specification using calibrated Test Measurement Diagnostic Equipment (TMDE). Physical calibration is not accomplished unless the verification step indicates the system is within tolerances. The final step to every verification and/or calibration is to certify compliance by affixing a completed DD Form 2163, equipment Verification/Certification.
5. **Equipment Control Number (ECN):** A sequential control number assigned to each equipment item.
6. **Equipment Operator (EO):** The person responsible for operation an item of equipment and providing before, during and after operator sustainment. These services may consist of dusting, washing, cleaning, checking for loose or missing hardware, checking for frayed cables and replacing operator replacement items and accessories.
7. **Inspection (INSP):** Electrical safety testing verifies that the path of least resistance for electrical current flow is through the equipment power cord instead of the human body. Testing will be performed by Technical Services Branch personnel in accordance with NFPA 99, Chapter 7.
8. **Maintenance Expenditure Limit (MEL):** The maximum repair cost that can be expended to repair an item one time. The MEL for equipment is a percentage of the current acquisition price based on life expectancy remaining.

9. **Sustainment Significant Equipment:** Equipment which has manufacturer developed scheduled service procedures and sustainment literature, will be considered sustainment significant and included in the equipment management program.

10. **Equipment:** Generic term used when referring to all patient care/electrically operated medical, dental, or diagnostic equipment included in the equipment management program.

11. **Operator Replacement Item:** Those items and accessories that do not require installation or repair by an equipment maintainer. Items and accessories (hand pieces, transducers, and so forth) that can be replaced by operators are not classified as repair parts, but operator replacement items. Operator replacement items do not require extensive disassembly of the item, critical alignment or adjustment after replacement, or tools. Operators should not attempt repairs beyond those authorized as part of operating technique.

12. **Preventive Maintenance (PM):** Preventive maintenance consists of periodic equipment inspections to ensure normal operation in accordance with manufacturer literature or other defined standards. Minor adjustments, internal cleaning, lubrication and proactive replacement of critical parts are accomplished during these services.

13. **Scheduled Parts Replacement (SPR):** Parts identified to be replaced on a routinely scheduled basis by the manufacturer, institutional knowledge, or experience.

14. **Scheduled Services (SS):** Scheduled services consist of preventive sustainment, calibration/verification/certification, and electrical safety testing services performed by TSB personnel. Scheduled services are generally scheduled in DMLSS by using the customer base dates for the department. These base dates are usually semi-annually or in accordance with manufacturer requirements, whichever is more stringent.

15. **Unscheduled Sustainment:** The remedial repairs performed by qualified Biomedical Equipment Specialists to return malfunctioning equipment to a fully serviceable condition.

16. **Work Order:** Written request for the performance of unscheduled sustainment services is submitted by an equipment operator. A work order may be submitted in person or telephonically.

17. **Total Cost of Ownership:** A financial estimate intended to help USU and subordinate elements determine the direct and indirect costs of a product or system. It is a management accounting concept that can be used in full-cost accounting of ecological economics where it includes social costs. (TMDE, RMF/ATO, Training, Maintenance, Purchase, Delivery, Install, Operation Labor, Utilities, Supplies, Health & Safety, Disposition).



## SUSTAINMENT SUPPORT PROCEDURES

1. EQUIPMENT OPERATOR/USER SUSTAINMENT. The operator is primarily defined as the user of the equipment, but may also include the equipment custodian, usually the NCOIC, the OIC, or the chief of the department. The condition of all equipment directly relates to the extent of care the user exercises while operating and maintaining the equipment. To ensure success, the equipment user must perform the following actions on an interval and/or as needed basis:

a. Reconcile all equipment in the respective department with the corresponding custodian receipt/location list (CRL). This reconciliation must be conducted monthly or as scheduled by the Property Management Office (PMO), Inventory Account Manager, whichever comes first.

b. Perform operational checks IAW manufacturer's specifications on all equipment in the department. Emergency equipment (defibrillators, crash carts, narcotic cabinets, life support monitors, and so forth) will be tested and inspected regularly IAW the latest 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 tools.

c. Check electrical power cords for damage.

d. Equipment that requires repair must be identified and removed from the work areas.

1) Immediately affix a piece of masking or adhesive tape on a visible part of the defective equipment. And annotate "DO NOT USE!" on the tape to make clear that the equipment is defective. This would be considered tagging out the piece of equipment until repairs are completed.

2) Contact Technical Services Branch (TSB) to open a work order. TSB WILL RESPOND AND FORMALLY TAG OUT THE EQUIPMENT DO NOT CONTACT A VENDOR OR MANUFACTURER DIRECTLY!

a) TSB's authority to work with vendors comes via a contractual arrangement established by a USU Contracting Officer.

b) Only a Contracting Officer can obligate the Government.

c) If a vendor performs work in advance of OFFICIAL direction from a Contracting Officer, the Government is not obligated to pay the contractor.

d) This results in an Unauthorized Procurement Action (UPA) and the financial liability for contractor payment is with the individual who directed the action.

2. IN-SERVICE TRAINING. The Logistics Division and TSB will provide in-service sustainment related training for the operator, upon written request. Training consisting of clinical applications must be requested through Director, Logistics Division. Operators

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, TSB, along with the NCOIC/SEA or OIC of the requesting department will schedule the required training. The operator can obtain a training outline from TSB which satisfies reporting requirements.

3. OPERATOR TRAINING AND EQUIPMENT ORIENTATION. Clinical supervisory personnel must establish a written program for conducting annual equipment orientation and operator training. Each department will tailor the written training 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 requesting equipment repair services.
- b. Teach the capabilities, limitations, and special applications of all equipment.
- c. Teach the basic operations and safety procedures for the proper use of equipment.
- d. Outline emergency procedures in the event of equipment failure.
- e. Provide the information and enhance skills necessary to perform operator sustainment responsibilities.
- f. Teach and train the procedures for reporting equipment problems, failures, and operator errors.
- g. Address the availability and location of alternate equipment.
- h. Improve and maintain operator skills by ensuring that the equipment custodian maintains one copy of manufacturer's operating literature for each type of equipment on hand.

4. LIFECYCLE MANAGEMENT (SCHEDULED EQUIPMENT REPLACEMENT).

a. Life Expectancy is determined by using the correct Item Device Code in the DMLSS automation system. This code is generated by a data base contained in the Emergency Care Research Institute (ECRI). Every piece of equipment loaded into DMLSS will receive a proper device code when it is accepted into DMLSS. This code generates the scheduled service intervals and life expectancy of each piece of equipment.

b. It is the customer's ultimate responsibility to identify equipment on the CRL from the DMLSS automation system provided by the Logistics Division's PMO.

- 1) On this report customers will identify their requested actions that include: keep in service, replace, or turn in as excess.

- a) If the option is to keep a piece of equipment past lifecycle in service, a justification will have to be turned into the TSB and be approved before final action is taken.
- b) If the customer wishes to replace the piece of equipment, they are responsible for market research.
- c) If the customer wishes to turn the piece of equipment in as excess, they must follow the procedures from PMO for proper turn in of devices.
- d) Logistics TSB will publish an Equipment Replacement Report each year, the customer will then have 45 days to review and return the report back to TSB. During this time the customer will do one of the above mentioned course of action for each piece of equipment on the report. Once all reports are collected and analyzed by Logistics, priorities for replacement will be determined based on:

- (1) Frequency of use
- (2) Nature of use
- (3) Environment of use
- (4) Experience and knowledge of the user
- (5) Care and attention paid to use and operator maintenance
- (6) Existence, capability and cost of maintenance support
- (7) Stage in product life cycle
- (8) Management of scheduled and unscheduled maintenance
- (9) Availability and cost of consumables and spare parts
- (10) Availability and cost of replacement devices
- (11) Relative efficacy and effectiveness of the alternative methods and devices
- (12) Business and safety risks associated with continued or discontinued use
- (13) Strategic and political risks associated with continued or discontinued use
- (14) Compliance with current codes and standards
- (15) Technological or clinical redundancy
- (16) Funding availability
- (17) Other unforeseen factors

- 2) Customers will be notified when to submit their Purchase Requests.

5. SCHEDULED SERVICES. Defense Health Agency (DHA), DoD regulations and service specific regulations mandate the performance of scheduled services for equipment in a timely and efficient manner. Scheduled services minimize costly repairs and optimizes safety; therefore, it is imperative that equipment is located and serviced during the scheduled sustainment month.

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

- 1) Preventive Maintenance (PM) is the care, servicing, inspection, detection, and correction of minor faults before these faults cause serious damage. This includes all actions performed in an attempt to retain an item in a specified condition (such as internal

and external lubrication, tightening nuts and bolts, replacing frayed electric cords and plugs, spot painting, rust removal, and so forth). DMLSS code PM.

2) Inspection (INSP) encompasses both electrical safety and performance inspection actions as follows. Inspecting equipment to ensure that patients, visitors and staff members are not subject to injury resulting from an unsafe physical or electrical environment created by the equipment. Operating equipment to ensure that it performs within the designed specifications stated by the manufacturer. 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, to detect and correct, if necessary, any deviations from required performance specifications of the unverified equipment. Ensure output is within acceptable tolerance limitations and adjustments within those limitations. Diagnostic and therapeutic output is critical. Test equipment used must be traceable to the National Institute of Standards and Technology (NIST). DMLSS code CAL.

4) Scheduled Parts Replacement (SPR) is a scheduled event used for situations where the criticality of the equipment dictates that a part(s) with a predictable useful life be replaced before that life expires as recommended by the manufacturer's literature or from knowledge and experience (this may include batteries, filters, rubber goods, desiccant, O-rings, etc.). DMLSS code SPR.

b. TSB will formally notify the property custodian of equipment that requires service. The custodian must annotate the list with the location of the equipment and return it to TSB prior to the Biomedical Equipment Specialist (BES) performing the services. This will aid in providing thorough and prompt services.

c. After TSB performs scheduled services in your area, ensure that you print a copy of the scheduled services listing provided by TSB.

d. Unable to Locate equipment (UL). The BES will formally notify the equipment custodian and PMO of UL items. The equipment custodian will make every effort to locate the identified item(s) within five calendar days of notification and take the item(s) to the TSB for the required scheduled services. After the suspense, the list of items will be forwarded to the PBO and the equipment custodian must initiate a FLIPL. The equipment custodian may be found financially liable and charged for the cost of the equipment.

e. Verifying Calibration Labels:

1) DD Form 2163, equipment Verification/Certification label (see Figure 1). The purpose of this label is to provide equipment operators with a visual indicator of the completion of equipment calibration services. Operators are responsible for inspecting this label prior to using the equipment. If the date due posted on the label is delinquent or illegible, the operator must remove the equipment from the patient or area of operation and notify TSB immediately for resolution.

Equipment Control Number (ECN) assigned to your equipment item

Frequency of calibration; in this case, a calibration is required every six months (semi-annually).

MEDICAL EQUIPMENT VERIFICATION/CERTIFICATION							
1. I.D. NUMBER G2924		2. MODEL NO. LP 9P		3. SERIAL NO. 0105957			
4. AUTHORITY AR 40-61		5. LEVEL 1		6. FREQUENCY S			
UIC	CERTIFIED BY	DATE COMPL	DATE DUE	UIC	CERTIFIED BY	DATE COMPL	DATE DUE
W2P0AA	MC	OCT 13	APR 14				
W2P0AA	BC	APR 14	OCT 14				

DD FORM 2163, 1 NOV 78

Date (MMYY) calibration was last completed

Date (MMYY) next calibration is due



Figure 1 – DD Form 2163, Equipment Verification/Calibration

2) DA Label 175, Defibrillator Energy Output Certification label (see Figure 2). The purpose of this label is to provide the equipment operator with a visible indicator of the actual defibrillator output at a given setting. Operators are responsible for inspecting this label prior to using the defibrillator. If the expiration date posted on the label is delinquent or illegible, the operator must remove the equipment from use and notify TSB immediately for resolution.

3.5 (TB 38-750-2) 40 MAX

INDICATED ENERGY OR CONTROL SETTING (WATT-SECONDS)	ENERGY DELIVERED TO A 50 OHM LOAD (WATT-SECOND)
10	9.6
20	19.2
30	28.8
50	47.9
75	71.7
100	95.5
150	141.9
200	203.5

DATES

CERTIFICATION MAR 2010	EXPIRATION SEP 2010
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INSPECTOR  
L. Young

DA LABEL 175 REPLACES DD FORM 1942 1  
JAN 67 JUN 74, WHICH WILL BE USED

**Figure 2 – DA Label 175, Defibrillator Energy Output Certification**

6. REQUESTING SUSTAINMENT SUPPORT. The TSB provides sustainment for all equipment belonging to the USU and supported activities. For after normal duty hours emergency requests, see the following section covering emergency sustainment.

a. Routine Sustainment. Normal hours of operation are 0630-1500 hours, Monday through Friday. The following procedures will be executed when requesting routine sustainment services from TSB:

- 1) When equipment fails or is suspected of malfunctioning, the operator must initiate a work request to TSB, either in person, telephonically or via web portal. If requesting in person, after receiving the sustainment information, TSB generates a work order number from DMLSS for the requester for the equipment. If the request is made telephonically, the work order clerk inputs the work order in the system, and provides it to the requester. For telephonic work requests, contact TSB at 301-295-0681.
- 2) Portable items must be brought to TSB. Non-portable equipment will be serviced on-site. Other large portable equipment may be done on-site depending on the degree of repair needed.
- 3) After the equipment is repaired, TSB notifies the operator to pick up their equipment, assuming it was brought to the shop for repair. Whoever arrives to retrieve the equipment must be listed on an authorization documentation. If the equipment is repaired on site, the BES will have a department representative sign the work order. This signature serves as validation that the work is complete as stated on the work order.



4) All equipment are examined for cleanliness by the operator prior to submitting a work request to ensure it is cleaned and sanitized. To meet infection control standards, all equipment will be properly disinfected according to manufacturer's recommendations by the operator prior to acceptance.

5) Work order priorities are defined in *Reference (b)*.

b. Emergency, urgent and routine sustainment. The following procedures will be followed when requesting emergency, urgent and routine sustainment services from TSB:

1) Emergency Repairs. Without this equipment, the activity is unable to perform assigned mission(s). Loss of equipment functionality prevents patients' access to health care resulting in cancellation, deferment, and/or rescheduling of all medical appointments and/or procedures (for example, CT becomes Non-Mission Capable (NMC) and patients are diverted to another facility outside the network). Work orders for emergencies are accepted telephonically.

2) Urgent Repairs. Without this equipment, the activity's ability to perform assigned operational mission(s) is impaired resulting in decreased healthcare efficiency, patient access, and/or quality of care. For instance, a sterilizer becomes NMC; however, they have more than one sterilizer, but procedures become delayed in the due to extended processing time of items.

3) Routine Repairs. Work requests required for all other equipment at the first opportunity. Loss of equipment does not significantly affect the primary function and service of the activity, but is required to support mission.

7. CONTRACT SUSTAINMENT. Chief, TSB, in coordination with the Acquisition Division, will establish and maintain a system for providing annual and one-time service contracts for equipment. Contract services will be used IAW TSB mission requirements and manpower capabilities. The Chief, TSB or his/her designated representative(s) are the only personnel authorized to contact civilian firms, manufacturers, or contractors for contract repair service(s).

a. Equipment operators or supervisors of equipment operators **shall not** contact service vendors for equipment services. It is important that manufacturer/vendor service representatives coordinate directly with TSB activity to provide service on equipment. All contract activity needs to be captured in DMLSS by TSB or designated personnel. Any unauthorized personnel contacting outside repair services could be personally liable and subject to billing for all costs incurred.

b. When contract services are performed on-site, equipment operators will ensure the integrity of the service performed, and may sign the service report indicating that service was performed to their satisfaction IAW service contract requirements (Performance Work Statement). If operator is provided a copy of the service report a copy must be presented to TSB for annotation in DMLSS and the equipment record.

c. TSB must be provided with the service report for payment purposes. All service(s) performed will be captured on the DMLSS equipment sustainment history.

d. TSB will initiate all service contracts required on either an annual or one-time basis. When establishing a service contract record for equipment in DMLSS, all activities will use the service contract (SC) record in DMLSS to reflect the contract information from a specific contract managed by the activity.

8. WARRANTY SERVICES. As with contract sustainment, no one other than the Chief of TSB, or his/her designated representative(s), 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 equipment, must be tracked in the DMLSS database, to include all services performed during the warranty period. Any other personnel contacting outside repair services will be subject to billing for all costs incurred.

9. LEASE, COST-PER-TEST/REAGENT EQUIPMENT.

a. Equipment of this type is considered non-Government owned equipment. As with Government owned equipment, this equipment must be placed on the property book for accountability and safety purposes.

b. Services on this type of equipment falls under the category of contract sustainment (see above) and therefore follows the same guidelines with regard to who is authorized to contact civilian vendors. Lease and cost-per-test/reagent equipment may receive repairs and scheduled services from a source other than the TSB. As such, it is critical that before any services are performed on any equipment, the vendor must supply a written Terms of Agreement to the Chief of TSB, stating who is responsible for the repairs and scheduled services of the equipment, and at what intervals. *Any supply items and repair parts purchased under the Terms of Agreement must be captured in DMLSS by the Contracting Officer's Representative (COR).*

c. Any unauthorized personnel contacting outside repair services could be held personally liable and subject to billing for all costs incurred.

10. LOANED EQUIPMENT. Loaned equipment falls under two categories; equipment loaned to USU and equipment USU loaned to other agencies.

a. Equipment Loaned to USU. All loaned equipment must be reported to the PBO. It is the responsibility of the department to ensure that this action is accomplished prior to the equipment being used. All loaned equipment must be inspected by TSB to verify that it is safe for use.

b. Equipment Loaned to Other Agencies. It is the policy of USU not to routinely loan Government equipment to civilian institutions. For exceptions see USU Instruction 4100.

11. EQUIPMENT EXAMINATIONS, EVALUATIONS, DEMONSTRATIONS AND EQUIPMENT TRIALS.



a. It is wise to test a new technology, a new model or to a purchase from a new manufacturer of equipment before investing large sums of money. The staff is encouraged to request possible vendors to demonstrate their products in the facility. However, the staff must request permission to do so by completing the Material Examination/ Evaluation/ Demonstration Agreement as outlined in AR 40-61. The contract agreement will also meet the criteria of AR 40-61.

b. TSB will inspect all equipment intended for use on or by patients or staff before such use.

c. TSB will not perform scheduled or unscheduled services on equipment included in this program.

## 12. PERSONAL EQUIPMENT.

a. USU does not authorize the use of privately owned equipment within USU or its satellite activities.

b. Any personally owned electronic based devices must be inspected for electrical safety hazards by the Safety Officer.

13. MEDICAL STANDBY EQUIPMENT PROGRAM (MEDSTEP). USU does not have a MEDSTEP.

14. MEDICAL MATERIEL BENEFITS PROGRAM (MMBP). USU does not have a MMBP.

15. MEDICAL SUSTAINMENT RESPONSIBILITY FOR COMPUTER/SERVER SUSTAINMENT.

a. Supply Bulletin (SB) 8-75-MEDCASE defines categories of Information Mission Area equipment (IMAE).

b. TSB is responsible for the sustainment of the computer if all of the conditions below apply:

- 1) The computer serves as the output device for equipment, but not solely for information storage.
- 2) The computer controls or influences the operation or function of equipment.
- 3) Without the computer, the equipment cannot perform its primary function.
- 4) The computer was purchased as an integral component of the overall system.

c. This guidance above is to assist in determining if the sustainment of a computer is the responsibility of TSB. Do not use these guidelines as the sole criteria for a decision. Consider local conditions, the actual application of the computer, and the normal commercial source of sustainment, such as equipment vendor or computer equipment vendor.

**16. THE JOINT COMMISSION (TJC).**

- a. TJC surveyors use Environment of Care standards from the Accreditation Manual for Hospitals to evaluate the operation of the USU equipment management program.
- b. The Chief, TSB will maintain the Equipment Management Program documents and ensure TJC compliance.

**17. COLLEGE OF AMERICAN PATHOLOGISTS (CAP).**

- a. TSB managers will establish procedures to provide a legible copy of each completed sustainment transaction (scheduled or unscheduled) for laboratory equipment to a designated laboratory representative.
- b. Laboratory personnel will provide sustainment reports to TSB when contract vendors leave their reports with laboratory employees.

**SAFE MEDICAL DEVICES ACT  
EQUIPMENT FAILURES/RECALLS/ALERTS/OPERATOR ERRORS**

1. EQUIPMENT FAILURE/SERIOUS INCIDENT. Under the Safe Medical Device Act, anytime the operation of a piece of equipment is deemed to have contributed to the death, injury, or illness of a patient or staff, the operator/user must take these steps:

- a. Impound the equipment. DO NOT allow anyone access until proper investigative procedures are initiated with all appropriate personnel present. DO NOT change any control settings on the equipment. Ensure that all accessories and consumables remain with the equipment.
- b. If possible, take photos of the scene. Emphasize the control settings of the equipment.
- c. Contact the Safety Officer immediately.
- d. The Safety Officer assumes control of the impounded equipment and all disposable supplies and packing materials until they can be inspected. The Safety Officer then establishes an investigative team, which in turn reviews the occurrence to determine a course of action. If the team determines the occurrence to be reportable under the Safe Medical Devices Act, the Safety Officer will forward all relevant information to Defense Logistics Agency – Troop Support (DLA-TS) using the automated SF 380 on their web site, or the Patient Safety Reporting Link, <https://patientsafety.csd.disa.mil>, within 10 working days of the incident.

2. OPERATOR/USER RELATED EQUIPMENT ERRORS. TSB 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 equipment custodian. The equipment custodian is expected to follow suggested corrective action(s).

3. MEDICAL DEVICE RECALLS/ALERTS.

- a. TSB must report all recalls/alerts that affect equipment to the priority level of USU leadership on a monthly basis.
- b. TSB will also notify equipment custodians of any medical device recalls/alerts pertaining to equipment on their custodian action/location list.

## RECEIPT, TURN-IN AND DISPOSITION OF EQUIPMENT

### 1. RECEIVING NEW EQUIPMENT.

a. New equipment is accepted into USU via the Property Management Branch (PMO); there are no exceptions. The PMO will notify the equipment custodian of the requesting department when the equipment is ready for pick-up. This will occur after the equipment is placed on the property book and given a technical evaluation for issue by TSB.

b. No equipment is delivered directly to the operator/division/department/lab without first processing through PMO. If such a delivery occurs, the equipment custodian must contact the PMO immediately. The PMO will coordinate the proper receipt, tagging, and inspection procedures with TSB.

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

1) This is the most difficult category of equipment to track. Equipment falling under this category is usually non-Government owned. The operator, without exception, must ensure the equipment is on the CRL. If in question, report all suspect equipment, to include equipment provided under reagent purchase agreements, to the PMO and the TSB. This must occur before operating any equipment. Failure to follow this guideline opens the strong possibility of the Government incurring a liability. Any equipment not meeting these conditions may constitute a finding by TJC.

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 equipment directly from a vendor/manufacturer. Only accept equipment from your Inventory Account Manager, Department Property Custodian, or TSB.

3) To ensure there is no unreported equipment, perform a physical reconciliation/inventory of equipment against the CRL on a monthly basis. Report any equipment not on the CRL to the PMO.

### 2. TURNING IN EQUIPMENT.

a. The department property custodian, with the collaboration of respective OICs, NCOICs, and input from the TSB, determines when to turn in equipment as excess to department needs. Consider the following factors when making such a decision:

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

2) Health Affairs Policies. How will the push for 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 PMO sends a DMLSS generated CRL to each Departmental Property Custodian on an annual basis. This report provides detailed information regarding a department's equipment assets. If you have any questions call and arrange to meet with PMO to help determine the current and future status of equipment assets.

5) Uneconomically Repairable Equipment. TSB is responsible for coding equipment and notifying the department when the item is uneconomical to repair. Weigh the pros and cons of turning in the equipment versus requesting a waiver, that is, command authorization to continue supporting the equipment to satisfy clinical requirements.

b. Once a decision is made to turn in equipment, contact PMO to initiate the process IAW *Reference (n)*.

### 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 may indicate poor equipment replacement planning and forecasting.

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

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

e. The President of the University is the only approving authority for waivers on equipment with the unit price above the investment threshold (\$250,000).

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

g. The NCOIC/SEA, TSB will notify the department property custodian when a piece of equipment is determined uneconomically repairable and supply the sustainment history and the work request explaining the condition code.

1) The Departmental Property Custodian will make a 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 the Chief, TSB to the Director, Logistics Division. (See Figure 3)

h. The NCOIC/SEA, TSB files the memorandum in the equipment record and initiates the approved action, either repairing or applying a condition code to the equipment.



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES  
4301 JONES BRIDGE ROAD  
BETHESDA, MD, 20814

MEMORANDUM FOR [REDACTED], ATTN: Hand Receipt Holder

SUBJECT: Unserviceable/Uneconomically Repairable Medical Device/Medical Device System,  
ECN: [REDACTED]

1. The Medical Device/Medical Device System (MD/MDS) identified on the enclosed maintenance work order and active equipment detail report is not economically repairable and should be disposed of for the reason(s) indicated below:

☐ Repair exceeds the Maintenance Expenditure Limit (MEL).

MEL = [REDACTED]

Estimated cost of repair = [REDACTED]

☐ MD/MDS is no longer supported by the manufacturer.

☐ MD/MDS is considered hazardous for safe use.

2. If repair is not desired, endorse and return all correspondence to Technical Services Branch (TSB) and schedule an appointment with property management to turn in the MD/MDS.
3. If repair is desired, prepare a detailed letter of justification and endorse all correspondence to the Director, Logistics Division.
4. Before a decision is made to request a waiver, please consult the property book officer, the equipment manager, and TSB. As a purchase packet will need to be started before this waiver is approved.
5. Point of contact for this memorandum is [REDACTED] at 301-319-4588 or via e-mail [REDACTED]

2 Encls  
Maintenance Work Order  
Active Equipment Detail Report

[REDACTED]  
Branch Chief, Technical  
Services Branch

SUBJECT: Unserviceable/Uneconomically Repairable Medical Device/Medical Device System,  
ECN: [REDACTED]

1. ☐ Repair not required. Dispose of item through property management.
2. ☐ Repair required. Endorsement to the Chief, Logistics Division.

Justification:

[REDACTED]

3. Point of contact for this action is [REDACTED]

[REDACTED]

Hand Receipt Holder

Recommend ☐ Approval ☐ Disapproval for this waiver

[REDACTED]

Signature,  
Director, Logistics Division

Figure 3 – Waiver Memorandum for Unserviceable/Uneconomically equipment