

CLINICAL ENGINEERING

Biomedical Equipment Maintenance



Safe Medical Devices Act - Updated Requirements

The Food and Drug Administration (FDA) issued its final rule on medical device reporting under the Safe Medical Devices Act (SMDA) on 11 December 1995. The rule clarifies and expands existing requirements for health care facilities. This article explains how Air Force Medical Treatment Facilities (MTFs) remain in compliance with this requirement.

The rule states that information from any source reasonably suggesting a device has, or may have "caused or contributed," to the death or serious injury of a patient or employee of the facility, must be reported directly to the FDA. Additionally, deaths must be reported directly to the FDA and the manufacturer; and serious injuries must be reported directly to the manufacturer or the FDA. Also, submit a semiannual report to the FDA outlining all reportable incidents. Fortunately, the Defense Personnel Support Center (DPSC) has made arrangements with the FDA to simplify this process for all DoD health care facilities. DoD facilities remain in compliance with all SMDA incident reporting requirements through use of the Standard Form 380, "Reporting and Processing Medical Materiel Complaint/Quality Improvement Report." AFMLL 2-96 and AFMAN 23-110, Vol. 5, Chapter 19, Attachment 1 have additional information on preparation and submission of the SF 380. This report must be completed and submitted to DPSC within ten working days of any reportable

incident. A reportable incident is defined as any event reasonably suggesting a device "has or may have caused or contributed, to the death or serious injury of a patient or employee of the facility." The Defense Personnel Support Center (DPSC) point of contact on all SMDA issues is Mr. Leo Coyle, DSN 444-2118.

Additional requirements of the final version of the SMDA include maintaining written programs and documentation of reportable incidents. Device user facilities are required to maintain and implement written medical device reporting procedures. These procedures must cover incident identification, evaluation, and transmission, as well as documentation and record-keeping requirements on reportable events. Health care facilities must also establish and maintain event files that contain information related to the adverse event, documentation of deliberations and decision-making processes, and copies of forms and other information submitted to DPSC. Health care facilities are required by the SMDA to retain this file for at least two years.

Copies of established SMDA compliance Operating Instructions (OIs)/policies are available from AFMLO/FOM upon request. The final rule becomes effective on 11 April 1996. (AFMLO/FOM, Capt William R. Wood, DSN 343-4024)

Operator Training

Can your hospital meet the equipment operator training standards of the Joint Commission or an Air Force Health Services Assessment team? This article outlines the necessary requirements for compliance, and offers insight and advice on how to meet these requirements.

The Joint Commission 1996 Comprehensive Accreditation Manual for Hospitals requires a medical equipment management plan that encompasses, among other things, processes for a medical equipment orientation and education program (Standard EC.1.8). This training must be provided to the **equipment operators** (physicians, nursing and ancillary clinical staff who use the equipment to diagnose or treat patients) and include:

- (1) capabilities, limitations, and special applications of the equipment;
- (2) basic operating and safety procedures;
- (3) emergency procedures in the event of equipment failure;
- (4) information and skills necessary to perform any necessary user maintenance; and
- (5) processes for reporting equipment management problems, failures, and user errors.

The training program will be evaluated by inspection teams through review of orientation and staff education plans and specific curricula, as well as through staff interviews. Be prepared to present training documents for clinical and ancillary clinical staff, as well as biomedical equipment technicians. When questioned, medical equipment operators must be able to describe or demonstrate the five points listed above for any patient-related equipment they are responsible for using (Standard EC.2.1). All answers from the staff should accurately reflect the organization's current policies and

procedures. The staff may be asked questions similar to the following: (*A sample answer follows the question.*)

Question: *What are the limitations of this defibrillator?*

Answer: (*CCU nurse*) *This unit is battery operated, so we can discharge it approximately twenty times before the output begins to decrease. After that, it must be recharged. As a result, we always keep the charger plugged in. Also, the ECG portion of the attached monitor is not diagnostic quality, therefore, we only use it to determine if a patient is in asystole and requires defibrillation.*

The standards indicate that a team approach is essential to create the training documents. Personnel involved should include representatives from nursing, human resources, and logistics/maintenance. AFI 41-201, paragraph 2.35. requires medical equipment maintenance personnel help train operators on patient-related equipment. Training should be offered when a new equipment system is issued and additionally when requested by the section. All training should be documented and maintained in the using section, as well as in the maintenance activity. If the training cannot be provided in-house, equipment maintenance personnel are required to arrange training with the equipment manufacturer or distributor.

If you are offering the training to the equipment custodian, keep in mind that he or she may not be an equipment operator. In order to meet the above requirements, it may be helpful to provide a letter to the custodian addressing his or her responsibilities with regard to operator training and identifying him or her as your liaison with the section. Depending on local policies and procedures, custodian responsibilities could include:

(1) ensuring all equipment operators within their section are trained in the proper operation of the equipment;

(2) notifying the maintenance activity when initial or refresher training is required; and

(3) maintaining documentation for any equipment training received.

If appropriate, the custodian could be trained in the operation of equipment and, in turn, provide training to their section.

Operator training is an important facet of the overall equipment management plan that can help prevent patient and staff injury or death resulting from improper equipment use. Care should be taken to ensure your facility is in compliance with current inspection standards. Elements of the Air Force Health Services Assessment Guide which relate to this topic are MHC.5.3.3 Equipment/Environment, HCS.1.2.4 Equipment Operator Training, and HRU.1.2.2 Individual Competence Documentation (**Attachment 1**, pages 1 through 3). (AFMLO/FOM, Capt David Zemkosky, DSN 343-4028)

Quality Assurance

Safety Alert -- Monitoring Systems, Physiologic, MDC 12636, Marquette Patient Monitoring Products

Marquette issued a safety alert via letter dated 5 December 1995. The manufacturer identified a potential dosage calculation problem in their neonatal monitoring software when used with the hand-held, remote control numeric keypad. An underdosage of the specific medication to be delivered will occur when all of the following specific circumstances are present:

(1) The patient monitor is equipped with one of the following software versions:

-Tramscope monitors equipped with all levels of Version 7 software

-Tramscope monitors equipped with all levels of Version 17 software

-SOLAR 7000 monitors equipped with all levels of Version 1 software or Version 2 software

-SOLAR 8000 monitors equipped with all levels of Version 1 software or Version 2 software

-EAGLE Series 1 monitors equipped with all levels of Version 4 software

-EAGLE Series 2 monitors equipped with all levels of Version 4 software

-EAGLE 4000 monitors equipped with all levels of Version 4 software

-EAGLE 3000/3100 monitors equipped with all levels of Version 1 software

(2) The software is selected to, and operating in, the "NEONATAL" monitoring mode.

(3) Calculation variables used to calculate a drug dose are entered using a hand-held, remote control numeric keypad.

Until the corrected software is available and has been installed in all affected monitors, ***discontinue use of the remote control and remove from service immediately.*** The Dose Calculations feature can be used in the "NEONATAL" mode by entering the data via the TRIM KNOB® control on the front panel of the monitor.

This situation does not exist in levels of software other than those mentioned. Furthermore, it

does not occur when the monitor is operating in the "ADULT" or "OPERATING" monitoring modes.

Users should ensure they have received the 5 December 1995 letter from Marquette, and completed and returned the enclosed reply card. Any questions can be addressed to the Customer Satisfaction group at (800) 243-1977 or (414) 362-3353.

Safety Alert -- Computers, Radio-Therapy Planning System, MDC 13281, Computerized Medical Systems Inc. (CMS), FOCUS Radiation Treatment Planning Systems; Software Release 1.1.2 and Below

Reference ECRI *Health Devices Alerts* number 1996-A8, 23 February 1996, Accession number A2963. Incorrect dose calculations, errant exiting by the system from planning screens to the main menu screen, and other programming anomalies may occur when using these units. CMS initiated a field correction on 15 January 1996 by releasing software version 1.2.0 to correct the problems and provide a reference guide and tutorial updates. Users should verify receipt of the 15 January 1996 letter with software release 1.2.0, reference guide, and tutorial updates from MCS. Load the software update onto all units, and update old reference guides and tutorials with the revised pages. Complete and return the reply card to CMS. If additional information is needed, CONUS customers should contact the CMS Customer Support Department at (800) 878-4267; overseas customers should contact their local CMS FOCUS representative.

Safety Alert Update -- Physiologic Monitoring Systems, Telemetric, MDC 13987, Hewlett-Packard, Model M2300A Digital Telemetry Systems

Reference ECRI *Health Devices Alerts* number 1996-A8, 23 February 1996, Accession number A2964. See also Safety Alert in AFMLL 12-95, addressing Model M2300A central station unit's not resetting to default values after a patient is discharged. Updated information from previous alert indicates the problem affects systems used with Central Stations Models M23560 and 78510. On the affected systems, the ECG high- and low-heart-rate alarm settings do not reset to the default values after a patient is discharged, and a new patient is admitted. The manufacturer plans to address this problem in the next software release for both central station monitors. Users should ensure the M23560 and 78510 central station monitors are configured to display the ECG heart rate alarm limits at all times. Additionally, label the unit until the updated software is installed. The label should read as follows: ***This system does not have heart-rate alarm-limit defaults. Verify that high- and low-heart-rate alarm limits are set appropriately for each patient.*** For further information, contact Alan Barbell, ECRI, at (610) 825-6000.

Safety Alert Update -- Radiographic Units, Mammographic, MDC 12425, Bennett X-Ray Technologies, Contour Mammography Units

Reference ECRI *Health Devices Alerts* number 1996-A8, 23 February 1996, Accession number A2970. Alert reports a patient's breast was lacerated when it was pinched between the magnification platform and belly shield on a Bennett Contour mammography unit. The patient was being prepared for a mediolateral magnified image acquisition, and accidentally

pushed against the magnification platform and shifted it towards the x-ray tube. When the technician attempted to reposition the free end of the belly shield, the patient's breast was pinched in the hinge between the magnification platform and the shield. Tests performed by the hospital indicate the magnification platform is not rigidly held in place when the C-arm is oriented for a mediolateral image acquisition. This introduces the risk of patient injury, as well as the risk of motion artifacts on mediolateral magnification images. Bennett will provide a modified platform, designed to stay more securely in place to all requesting facilities in exchange for the current platform. Users should be made aware of Bennett Contour mammography unit's potential for pinching injury. In the event the platform shifts and the belly shield is displaced, personnel should move the patient away from the unit before correcting the problem. For further information, CONUS customers should contact Bennett X-Ray technologies at (800) 922-9399 to request a modified platform in exchange for their current platform. Overseas customers should contact their local Bennett dealership or contact Bennett X-Ray Technologies at (800) 922-9399. (AFMLO/FOM, Capt William Wood, DSN 343-4024)

Food and Drug Administration (FDA) Recalls/Alert Notices

Attachment 2, paragraph 1, provides information on FDA medical equipment recalls and alerts. Personnel from clinical engineering, biomedical equipment maintenance, quality assurance, and safety should follow the guidance provided to ensure the effective maintenance and management of medical equipment. (AFMLO/FOM, Capt William Wood, DSN 343-4024)

Medical Equipment Management

Shared Procurement Equipment Items Currently Available

Attachment 1, pages 4 and 5, contains a list of all current Shared Procurement contracts and optional contracts available through DPSC. If you plan to order any of these items for your facility, use the specific ordering instructions and overall program guidance contained in AFMLL 4-96, pages CE-4 and CE-5. (AFMLO/FOM, Capt David Zemkosky, DSN 343-4028)

“Piggyback” Contracts Currently Available

AFMLL 02/03-96, Attachment 1, pages 1 and 2, contains a list of all current “piggyback” contracts currently available through DPSC. These contracts will allow facilities to “piggyback” requirements onto existing orders placed for specific quantities. Many of these contracts are designed to buy large quantities at the same price. The list in AFMLL 02/03-96 includes available quantities and “Order By” dates. To order, send your requisitions to DPSC (using the MILSTRIP process), Attn: Mr. J. Gallagher/DPSC-MQA, and reference the contract number (from the listing) in the notes section. (AFMLO/FOM, Capt David Zemkosky, DSN 343-4028)

WILLIAM H. HILL
Deputy Chief
Air Force Medical Logistics Office