

# CLINICAL ENGINEERING

## Biomedical Equipment Maintenance



### Aeromedical Certification Label for Aeromedical Evacuation (AE) Equipment

Equipment used in the air evacuation system must be certified and labeled accordingly. Uncertified equipment must not be used in flight. AFMLO, in coordination with Armstrong Laboratory/CFTS and HQ AMC, has designed and purchased labels for identification of certified AE equipment. The labels will be attached to all equipment identified and certified for AE use. A letter addressing this program was forwarded to all medical equipment maintenance activities, major commands (MAJCOMs), and AE Squadrons on 4 Jun 96. The letter addresses identification and labeling aspects of the program and provides overall program guidance. The objective of the program is to ensure all equipment used in the AE system is certified and labeled. Highlights of the implementation process are as follows:

Medical equipment maintenance activities will carry out the base-level implementation. Medical equipment maintenance personnel must coordinate implementation of this initiative with War Reserve Materiel (WRM) and AE customer accounts. Biomedical equipment technicians (BMETs) at every medical maintenance activity must take the following actions:

- Label all air-certified equipment newly issued to aeromedical squadrons
- Determine certification status of in-use equipment at aeromedical squadrons and label accordingly

- Inspect in-use equipment held by other activities for use in the aeromedical evacuation system and ensure it is certified and labeled
- Determine the certification status of WRM equipment designated for use in the air evacuation system and label accordingly

AFMLO will request Medical Equipment Repair Centers (MERCs) verify the status of this program during manning assistance or annual site visits, and will follow-up with all bases who are identified as having AE missions. Required changes to AFI 41-201 resulting from this program will be provided at a later date. If you have not received the referenced letter yet, please contact our office. (AFMLO/FOM-M, TSgt Benjamin Allen, DSN 343-4039)

### ECRI Recommends Steps To Prevent Electromagnetic Interference Of Medical Devices

ECRI has revised its recommendations on the use of cellular phones and radio-frequency (RF) transmitting devices in healthcare facilities. The recommendations call for hospitals to concentrate on reducing the electromagnetic interference (EMI) risks in the areas of greatest concern.

ECRI has relaxed its previous position calling for the prohibition of the use of transmitting devices by patients and visitors throughout the hospital. ECRI now suggests restricting unnecessary use of cellular phones, handheld receivers, and other RF-transmitting devices of similar or higher output power in patient care and diagnostic areas where there is a high density of instrumentation. Such restrictions would be warranted, for example, in intensive care areas; operating rooms; and emergency, labor and delivery, and therapeutic radiology departments.

Hospitals should also instruct all staff to be attentive to unexpected performance of medical equipment; incorporate purchase specifications that require manufacturers to provide evidence of devices' EMI immunity; and inform patients, visitors, and staff of the hospital's policy through appropriate signage and distribution of information.

The complete report from ECRI appears in the February - March 1996 issue of ECRI's journal *Health Devices*. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

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## Career Advisor's Corner

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### Do You Need X-Ray Training?

If your answer is yes, pay attention. The Clinical Engineering instructors from Sheppard AFB, Texas will provide training on x-ray procurement/acceptance inspection procedures **at your base**. This two-week (10 academic days) course provides the necessary skills and knowledge required to perform preprocurement surveys, acceptance inspections and post calibration radiation inspection (PCRI) surveys on radiographic and fluoroscopic x-ray systems.

The first week of the course includes training on preprocurement aspects as regulatory guidance, responsibilities, formatting, power supply determinations, blueprint orientation, room drawings, and accomplishing an actual preprocurement survey. The second week of training covers acceptance responsibilities, cost reimbursement and administrative procedures, and step-by-step instruction on each acceptance and PCRI test according to Air Force and 21 CFR standards. In addition, students will receive training on various invasive and non-invasive test equipment, National Electrical Code (NEC) standards, and quality assurance testing. Upon graduation, the graduate will be capable of

completing the DPSC Acceptance Inspection Package and offering technical advice during the procurement and installation phases of the x-ray preprocurement process. This knowledge and skill can also be applied to other investment procurement and installation projects such as sterilizer, dental operator and x-ray systems, and dental lab systems.

The host facility must provide the funds to cover the cost of travel and per diem for each instructor. The average total cost per instructor is \$1,000.00. Class size is limited to six students per instructor; however, more than one instructor can be requested per class in order to accommodate more students.

This course has been taught in CONUS and overseas locations, as well as for Army and Navy counterparts. Feedback from graduates on the course has been outstanding. This mobile training opportunity can be beneficial for all assigned BMETs at your facility and within your region, saving your facility thousands of dollars in training costs.

If you have questions or need more details, contact TSgt McNeill, Advanced Courses Instructor Supervisor. (384th Training Squadron, TSgt McNeill, DSN 736-3659)

### List of Biomedical Equipment Repair Personnel

**Attachment 1**, pages 1 through 12 contain a list of all biomedical equipment repair personnel by duty location. The list was produced from the April - May database so there may be some changes due to PCS duty assignments. (AFMLO/FOM-E, DSN 343-4040)

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## Quality Assurance

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### **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-P, Capt David Zemkosky, DSN 343-4028)

### **Safety Alert -- Defibrillator Analyzers, MDC 11127, R2 Medical 188LM Defibrillator Testers, Cardiotronics**

Reference ECRI *Health Devices Alerts* Number 1996-A23, 7 June 1996, Accession No. A3048. ECRI reports that visible sparking occurred within the unit during a routine 300 J discharge test of a defibrillator cable. Further inspection revealed burn marks on the inside and the outside of the tester. No injuries were reported, but the tester no longer functioned. Cardiotronics states that the sparking is associated with failure of the load resistor located within the fully enclosed case of the tester and that there is no chance of injury to the operator. Approximately 1.6% of the distributed testers are affected with this problem. ECRI concurs that the incidence of this failure of the tester is low and does not pose any serious risk to the operator. All facilities should contact Cardiotronics Technical Services for a replacement tester free of charge if (a) you observe sparking in any of the above listed units during a defibrillator test discharge or (b) an open circuit exists when you measure the resistance between the two terminals on the tester with an ohmmeter. For

further information, contact Cardiotronics at (800) 441-9466 or (619) 431-9446.

### **Safety Alert -- Coagulator, Radionics Model 440 Series Bipolar Coagulator, Radionics, Inc.**

Reference safety notice dated January 16, 1996, from Radionics, Inc. Radionics advised that all facilities should advise personnel using a Model 440 coagulator of the following warning:

The Model 440 Series Bipolar Coagulator is designed to be durable medical equipment. Physical impact, however, such as dropping the unit, may result in damage to the coagulator and subsequent injury to the patient or operator. If the 440 coagulator is or has been subjected to impact, discontinue use and immediately return it to Radionics.

For further information or to receive the revised Model 440 Operator Manual that includes this warning, contact Radionics, Inc. at (617) 272-1233.

### **Safety Alert -- Monitors, Apnea, MDC 12575, Model 9200 Apnea Monitors, Aequitron Medical, Inc.**

Reference ECRI *Health Devices Alerts* Number 1996-A25, 21 June 1996, Accession No. A3061. ECRI reports that Aequitron will no longer recertify or provide replacement parts for Aequitron Model 9200 (nonmemory) apnea monitors after July 31, 1996. All Model 9200 field repairs and recertification programs will also be discontinued on July 31, 1996. The firm advises that by the July 31, 1997, End-of-Service date, all Model 9200 units should be permanently removed from service. Customers were provided this

information by letter dated May 15, 1996. All facilities that have a Model 9200 apnea monitor should verify the receipt of the May 15, 1996, letter from Aequitron, and inform all appropriate departments that parts and recertification will no longer be available for these units after July 31, 1996. Do not use uncertified or improperly maintained monitors. For further information, contact Aequitron at (800) 497-3787 in the U.S.; customers outside the U.S. should contact Aequitron by phone at (612) 557-9200 or by fax at (612) 557-8200. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

### **Type II Materiel Complaints - Information Exchange**

A summary of the most recent medical materiel complaints involving medical equipment is listed below. This summary is provided for information only. Please note the complaints *are not validated*. They do not constitute a recall, nor do they require you to perform the sort of inspection and reporting associated with equipment hazards. If you have experienced a similar problem locally, please submit an SF 380 in accordance with AFMAN 23-110, Vol. 5, Chapter 19. It is important that we receive documentation of equipment problems since severity and impact of a materiel defect is frequently judged by the number of separate complaints received.

Camera, Gamma Scintillation Biad 24", Trionix Medical Corp. **Complaint:** An activity reports that a Trionix Gamma Camera Head shifted downward striking a patient in the abdomen. In this model, a radial drive motor gear box assembly turns a ball screw shaft to raise the gamma camera head assembly. After further inspection, the problem was determined to be a broken ball screw shaft in the gamma camera head assembly. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

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## **Medical Equipment Management**

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### **Shared Procurement Equipment Items Currently Available**

AFMLL 13-96, Attachment 1, pages 13 and 14, contains a list of all current Shared Procurement contracts and optional contracts available through the Defense Personnel Support Center (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 04-96, pages CE-4 and CE-5. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

### **"Piggyback" Contracts Currently Available**

AFMLL 13-96, Attachment 1, pages 15 and 16, 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 reduced prices, and are written with the option of buying additional quantities at the same price. The list includes available quantities and "Order By" dates. To order, send your MILSTRIP requisitions to DPSC, and reference the contract number (from the listing) in the notes section. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

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