FOOD AND DRUG ADMINISTRATION

USER Facility Reporting

Issue No. 8 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Spring 1994

A Note From James L. Morrison, Acting Director Office of Health and Industry Programs

Help! Only you, our readers, can help us answer these questions: Should we continue issuing this bulletin and if so, should we modify its content? Please take a few minutes to answer the questions on pages 4 and 5 and mail us your responses by August 1. Your answers will affect our plans.

We began issuing the *User Facility Reporting Bulletin* in the Summer of 1992 as part of our mandate under the Safe Medical Devices Act of 1990 (SMDA). The Act requires the Food and Drug Administration (FDA) to educate all U.S. device user facilities concerning their reporting responsibility under SMDA. Device user facilities include hospitals, nursing homes, outpatient diagnostic and treatment facilities, and ambulatory surgical facilities.

Government efforts sometimes seem to be self-perpetuating. We do not want this bulletin to be such an effort. We want to know if the *User Facility Reporting Bulletin* has helped you understand your responsibilities to report serious medical device problems to manufacturers and FDA. Should we consider discontinuing it? Do you need additional information about reporting? If so, what information do you need and how would you prefer to get it? We will publish the results of your responses in an upcoming issue. Thank you for your comments.

James L. Morrison

FDA SENDS SAFETY ALERTS AND PUBLIC HEALTH ADVISORIES TO WARN OF MEDICAL DEVICE RISKS

by Joan M. Rudick

The healthcare community can look to FDA safety alerts and public health advisories for information about risks or potential risks associated with the use of medical devices.

The CDRH Office of Surveillance and Biometrics issues alerts and advisories directly to users of medical devices — doctors, nurses, hospital administrators, risk managers, biomedical and clinical engineers — whenever an event takes place that warrants special attention.

Safety alerts differ from public health advisories in the degree and certainty of the risk. Generally, safety alerts discuss an occurrence that has actually caused or contributed to a death or serious injury, while public health advisories describe potential risk. Both

In This Issue:

recommend actions to prevent or minimize risk to patients and health professionals; both affect a widespread and diverse user population and usually pertain to more than one make of a device.

Safety alerts issued by manufacturers differ from those issued by FDA. A manufacturer's safety alert is generally limited to a specific make and model of device. It often concerns faulty design or operation and is usually part of a firm's recall process.

FDA has issued several safety alerts during the past year. Three are especially important to user facilities Laerdal Defibrillators (January 26, 1994), Unsafe Patient Lead Wires and Cables (September 3, 1993), and Hazards of Heated-Wire Breathing Circuits (July 14, 1993).

The ***Laerdal defibrillator*** safety alert describes several problems with Laerdal's HeartStart (HS) Automatic and SemiAutomatic External Defibrillators, models HS 1000, HS 1000S, and HS 3000. Through its medical device reporting (MDR) system, FDA received reports of malfunctions that could result in patient death or serious injury. FDA has instructed Laerdal to further investigate the cause and magnitude of these problems.

In the meantime, the safety alert recommends that users take the following precautions:

- Test the defibrillator at the beginning of each shift (an Operator Shift Checklist is provided);
- Perform all periodic maintenance recommended by the manufacturer; and
- In Model HS 1000S, check the patient for evidence of pulse and breathing before allowing the machine to deliver a second or repeated shock, which may be unnecessary.

The ***Unsafe Patient Lead Wires and Cables*** safety alert discusses the potential for electrocution of infants on apnea monitors when inappropriate, unsafe lead wires and cables are used with this device. An incident of an infant who was electrocuted while on a hospital apnea monitor is cited. Recommendations are:

- Purchase and use only protected lead wires and cables with apnea monitors to prevent lead wire and cable connection to a power source; remove unprotected lead wires and cables from hospital areas that use apnea monitors;
- Alert staff to the potential problem; and
- Consider replacing all unprotected lead wires and cables for medical devices that use patient electrodes.

Until all unprotected lead wires and cables are replaced, the following **precautions** are advised:

- Label all power cords "120 volts" at the female end;
- Disconnect patients from monitors only at the monitor or the patient electrodes; and
- Hardwire or clamp the power cable to the monitor.

A December 28, 1993, public health advisory extends the warning against using unsafe electrode lead wires and patient cables with apnea monitors to include all other devices that may use electrode lead wires with unprotected pins. An illustration of both safe and unsafe lead wires is included in the advisory.

The ***Hazards of Heated-Wire Breathing Circuits*** safety alert warns health professionals of the possibility that heated-wire circuits used with humidifiers for ventilator patients may overheat, soften, and collapse if they are used improperly. Factors contributing to this problem are:

- Electrical incompatibility between heated-wire breathing circuit and humidifier; and
- Operation of the device outside the accepted range of specified flow or minute volumes.

You are encouraged to copy and distribute the alerts and advisories when you receive them. For additional information or copies, contact the Office of Surveillance and Biometrics, FAX 301-594-2968.❖

Joan M. Rudick is a public health analyst in CRDH's Office of Surveillance and Biometrics.

FDA WILL CO-SPONSOR CONFERENCE ON UNPROTECTED PATIENT CABLES & ELECTRODE LEAD WIRES

The Food and Drug Administration's Center for Devices and Radiological Health, the American Hospital Association, and the Health Industry Manufacturers Association will co-sponsor a conference on July 15, 1994. The conference will provide a forum for comment on both the problem of unprotected patient cables and electrode lead wires and FDA's proposed rulemaking (May 19, 1994, ***Federal Register***) to resolve the problem. All interested parties — manufacturers, device users, device user facilities, health professionals, and regulators — are invited to attend.

The conference will be held at the Sheraton Washington Hotel in Washington, D.C., from 8:30 a.m. to 5:00 p.m. Advance registration is required. To register or to receive additional information about the conference, contact Kathy Pointer, Sociometrics, Inc., 8300 Colesville Road, Suite 550, Silver Spring, MD 20910; telephone 1-800-729-0890 or 301-608-2151; FAX 301-608-3542.

Reminder

Semiannual reports are due by July 31

PLEASE ANSWER . . .

We need to hear from you so that we can evaluate the effectiveness of the *User Facility Reporting Bulletin* and identify what additional information our readers need. Please take a few minutes to answer the questions below and return the form by **August 1.** We will publish the results in a future issue.

Thank you for your assistance.

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1. Should we continue publishing the *User Facility Reporting Bulletin?*
   ____ yes ____ no

2. How useful is the *User Facility Reporting Bulletin* in promoting your understanding of user facility reporting requirements under the Safe Medical Devices Act (SMDA)?
   ____ The *Bulletin* provides a lot of new information about user facility reporting.
   ____ The *Bulletin* corroborates what I already know about user facility reporting.
   ____ The *Bulletin* provides no new information about user facility reporting.

3. How would you prefer to receive the Bulletin?
   ____ electronically (using a computer and modem)
   ____ FAX
   ____ printed copy (presently used)

4. Please check the topics about which you need additional information.
   ____ Establishing internal processes/procedures to ensure facility compliance with SMDA medical device reporting (MDR) requirements
   ____ Details of filing an MDR submission
   ____ Feedback by FDA on medical device reporting
   ____ Summaries of FDA safety alerts
   ____ Medical device tracking
   ____ Other (please specify)

5. How do you receive information about medical device reporting other than from the *User Facility Reporting Bulletin*?

6. Where is the *Bulletin* circulated within your facility?
   ____ Administration
   ____ Biomedical/Clinical Engineering
   ____ Nursing Administration
   ____ Quality Assurance Management
   ____ Risk Management
   ____ Not being circulated
   ____ Other (please specify)

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7. If only one person in your facility were to receive the *Bulletin,* who should it be?
   - ___ Facility Administrator
   - ___ Biomedical/Clinical Engineer
   - ___ Nurse Administrator/Manager
   - ___ Quality Assurance Manager
   - ___ Risk Manager
   - ___ Other (please specify)

8. This is the eighth issue of the *Bulletin.* Which other issues have you seen?
   - ___ Issue 1 (Summer 1992)
   - ___ Issue 2 (Fall 1992)
   - ___ Issue 3 (Winter 1992)
   - ___ Issue 4 (Spring 1993)
   - ___ Issue 5 (Summer 1993)
   - ___ Issue 6 (Fall 1993)
   - ___ Issue 7 (Winter 1993)

9. Do you retain copies for future reference?
   ___ yes ___ no

10. What is your title?
   - ___ Facility Administrator
   - ___ Biomedical/Clinical Engineer
   - ___ Nurse Administrator/Manager
   - ___ Quality Assurance Manager
   - ___ Risk Manager
   - ___ Other (please specify)

11. Please check the type of your facility.
   - ___ ambulatory surgical facility
   - ___ hospital
   - ___ nursing home
   - ___ outpatient diagnostic facility
   - ___ outpatient treatment facility
   - ___ other (please specify)

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