FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING

USER Facility Reporting

Issue No. 24 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Summer 1998

WHAT TO EXPECT DURING AN FDA USER FACILITY INSPECTION

by Jacqueline Eghan

The objective of an FDA inspection is to determine whether the device user facility is meeting the statutory reporting requirements of the Safe Medical Devices Act of 1990 (SMDA) and following the requirements of the Medical Device Reporting (MDR) Regulation (Chapter 21, Part 803, of the *Code of Federal Regulations*). The final implementing regulation was published on December 11, 1995, and became effective on July 31, 1996. Your facility should have a copy of the regulation available, so that your staff can become familiar with it.

An inspection is an opportunity for the user facility to show FDA that it is adhering to the regulations and to start a dialog with FDA if there are improvements that should be made. The inspection process can be a positive educational experience, for both FDA and the user facility. FDA is also a resource to help users solve problems and provide answers to questions about the MDR process.

The MDR Regulation requires device user facilities to:

- develop written MDR procedures;
- establish an MDR event file;
- report device-related deaths to FDA and the manufacturer within 10 working days using FDA form 3500A;
- report device-related serious injuries including serious illnesses to manufacturers within 10 working days using FDA form 3500A or to FDA if the identity of a manufacturer is not known; and
- submit an annual report on January 1st using FDA form 3419. (Prior to February 19, 1998, user facilities were required to submit semi-annual reports.)

The annual report contains a coversheet and either summarizes or provides copies of all MDR death and serious injury reports submitted to FDA and/or manufacturers during the previous calendar year. An annual report is not required if the facility has not submitted any MDR reports to the FDA and/or device manufacturers during the reporting period.

FDA field offices will conduct inspections of the following type of facilities:

- hospitals;
- ambulatory surgical facilities;
- nursing homes;
- outpatient diagnostic facilities; and
- outpatient treatment facilities.

In This Issue:

Inspections are not typically announced in advance, but a facility may first be contacted by telephone to ensure that the site is still in business and to ensure that appropriate staff will be available.

Upon arrival at the facility, the FDA investigator will present identification which consists of an ID card (credentials) and sometimes a badge. The investigator will issue an FDA-482, Notice of Inspection, to the person in authority at the facility. The Notice of Inspection lists the date of the inspection, the address of the district office responsible for the inspection, and the name of the investigator. It also lists the name and title of the person contacted at the facility. The form should be kept by the facility in case they need to contact the FDA district office or the investigator at a later date.

During the inspection, the investigator will talk to responsible staff, such as the risk manager, and review records to determine the facility's compliance with the MDR regulations. This will include:

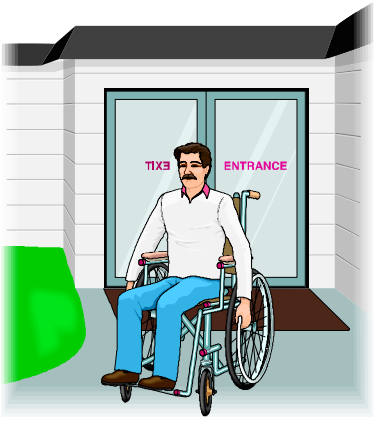
Written MDR Procedures (§ 803.17). User facilities are required to develop, maintain, and implement written MDR procedures. This includes any standard operating procedures developed to review events and submission of MDR reports.

MDR Event Files, (§ 803.18). User facilities are required to retain a copy of each device-related death or serious injury report reviewed for MDR reporting. For those not considered MDR reportable, the file should contain an explanation of why the event was not reportable and should be signed by the person responsible for the decision.

Individual Adverse Event Reports (§ 803.30). The investigator will verify that a FDA form 3500A was prepared for each reportable event and sent to FDA and/or the manufacturer as required by the regulation. FDA should receive reports of serious injury only with a User Facility's Annual Report, unless the identity of the device manufacturer is not known. If the facility conducted its own investigation, FDA is authorized access to that information during the inspection.

Wrap-up meeting. The investigator will discuss any outstanding issues with the facility and note any unresolved items on the FDA form 483.

During the inspection, FDA has authority to review MDR event files and to review pertinent medical records relative to those event files. A facility's MDR event files must contain information on the decision process used to determine if an adverse event was MDR reportable (i.e., decision process documented in record, decision tree, etc.) These MDR event files may incorporate references to relevant information in other files instead of making duplicate copies of the records for MDR event files. Other relevant information may include medical records, patient files, incident report files, engineering reports, service files, etc. References to other information must be clearly specified and the location clearly identified.



Any MDR deficiencies will usually be noted on FDA Form 483, Inspectional Observations, and provided to the facility at the conclusion of the inspection. The investigator may choose to discuss some issues that are not written on the FDA form 483 during the wrap-up meeting. The investigator will discuss the list of observations and advise the facility on how to respond to the FDA district office regarding any deficiencies noted. The investigator will note in the inspection report any discussion with the facility and the facility's response to the items listed. The facility may be required to submit a written response to the FDA district office explaining how any MDR problems noted during the inspection have been corrected or the reasons why they disagree with the investigator's observations.

After the inspection is completed, the investigator will submit the Establishment Inspection Report (EIR) to FDA management. This documents the user facility inspection and includes a section on any discussions with officials of the user facility.

If the facility is not in compliance with the MDR requirements of 21 CFR Part 803, FDA may conduct a follow-up inspection in three to six months to determine if corrections have been made.

If you have any questions or need further guidance from FDA, contact the Division of Small Manufacturers Assistance at 800-638-2041, or the Division of Surveillance Systems within the Office of Surveillance and Biometrics at 301-594-2735.

Jacqueline Eghan is a Consumer Safety Technician in the Center's Office of Compliance.

PUBLIC HEALTH MESSAGE: ELECTRODE LEAD WIRES & PATIENT CABLES

In late August 1998, the Food and Drug Administration (FDA) will be notifying user facilities about an important requirement that will help to safeguard patients from electrical hazards associated with lead wires and cables used on many medical devices. Beginning January 1, 1999, only electrode lead wires and patient cables that are protected may be used with the following devices:

- breathing frequency monitors;
- ventilatory effort monitors (apnea detectors);
- electrocardiographs (ECGs);
- radiofrequency physiological signal transmitters and receivers;
- cardiac monitors;
- electrocardiograph electrodes (including pre-wired ECG electrodes);
- patient transducer and electrode cables (including connectors);
- medical magnetic tape recorders (e.g., Holter monitors);
- arrhythmia detectors and alarms; and
- telephone electrocardiograph transmitters and receivers.

Protected cables and leads are those that cannot be inadvertently inserted into electrical outlets, posing an electrocution hazard to patients. FDA is taking this action because patients have been seriously harmed or killed when unprotected electrode lead wires and patient cables have been accidentally inserted — in some cases by young children and in other

cases by health care personnel — into live electrical outlets.

User facilities can fulfill this regulatory requirement by using inexpensive conversion adapters to the cables and leads. Adapters for most medical devices are available from many sources. In some cases, retrofitting may work. User facilities should contact their suppliers to see what kind of correction will work best. If the correction is unreasonably expensive, the facility may request a variance or exemption from FDA. The request needs to document that conversion adapters are not feasible and retrofitting is too expensive.

The request must also propose an alternate method of dealing with the problem and clearly show that it is effective in protecting patients.

The above requirement applies to devices already in use. Devices manufactured after May 1998, have to meet the new Performance Standard for Electrode Lead Wires and Patient Cables (see copy of the May 9, 1997 *Federal Register* on page 25497). Under the standard, device manufacturers must use protected electrode lead wires and patient cables.

At the present time, FDA has applied both the manufacturer performance standard and the user facility requirement to the ten devices in the above list because they pose the greatest risk. Beginning on May 9, 2000, these requirements will apply to electrode lead wires and patient cables that are used with all types of medical devices. In the interim, FDA strongly suggests that user facilities avoid mistakes by labeling all devices that use electrode lead wires and patient cables with a cautionary statement, such as "USE ONLY PROTECTED CABLES AND LEADS WITH THIS DEVICE" and by segregating protected and unprotected electrode lead wires and patient cables.

User facilities should share this information with their risk managers, biomedical engineers, nursing staff, and various departments that use electrode lead wires and patient cables to insure that they are making the required changes.

For more information see the FDA Web Site at http://www.fda.gov/cdrh (search in the Topic Index under L for Lead Wires) or contact Mr. Stewart Crumpler in the Office of Compliance at 301-594-4659 or by FAX at 301-594-4672. A copy of "Guidance on the Performance Standard for Electrode Lead Wires and Patient" can be requested by FAX at 301-443-8818.

For more information, see the FDA Web Site at http://www.fda.gov/cdrh.

From THE Editor

FUTURE OF *BULLETIN* UNCERTAIN

When the *User Facility Reporting Bulletin* was first printed in June 1992, it had a circulation of 90,000. The mailing list was refined and circulation remained at about 77,000 for several years. In the Spring 1994 issue, we included a reader survey to help determine what topics readers want in the *Bulletin* and how they would like to receive it. Overwhelmingly, readers answered that they preferred paper copy (83 percent) followed by FAX (8 percent), and electronic transmission, i.e., computer (3 percent). See Issue 10 for an analysis of the questionnaire.

Because of budget reductions, in the Fall issue of 1996, we asked readers to return a retention notice to continue receiving printed copies of the *Bulletin*. Circulation of the printed copy dropped to about 7500. At the same time, the *Bulletin* (including all back issues) was made available on the Internet (http://www.fda.gov/cdrh/fusenews.html) and by FAX on the CDRH Facts-on-Demand (F-O-D) system. By calling F-O-D at 1-800-899-0381 using a touch-tone telephone, readers can request a FAX copy of any issue of the *Bulletin* as well as other documents relating to medical devices.

By the Summer of 1997, it was clear that money would no longer be available for printing and mailing the *Bulletin*. We asked readers if they would like to automatically receive the *Bulletin* by FAX, and many readers sent us their FAX numbers. Unfortunately, money for the equipment upgrades for automatically FAXing was not available. Since then, the *Bulletin* has been available only through the Internet and F-O-D.

We are now trying to determine if there is sufficient readership of the *Bulletin* to justify its continuation. We are gathering statistics from our Internet site and the Facts-on-Demand system. Your thoughts about this decision are welcome. You can write to the Editor, User Facility Reporting Bulletin, Food and Drug Administration, Center for Devices and Radiological Health, HFZ-230, Rockville, MD 20857, by e-mail at nsl@cdrh.fda.gov, and by FAX at 301-594-0067.

FDA CAUTIONS USERS OF VACUUM ASSISTED DELIVERY DEVICES

by Sheila J. Murdock, Ph.D.

On May 21, 1998, FDA issued a Public Health Advisory to obstetricians, family practitioners, nurse mid-wives, pediatricians, radiologists, hospital risk managers, and others who use vacuum delivery devices to assist with deliveries or provide care to those neonates. The purpose of the Advisory was to alert healthcare providers to the potential for fetal vacuum extractors to produce life-threatening injuries. The Advisory notes that no intrumented delivery is risk-free; it addresses only the fetal vacuum extractor. Healthcare professionals responsible for the care of neonates who have undergone a vacuum assisted delivery are urged to monitor neonates for signs and symptoms of device-related injuries.

Although all vacuum assisted delivery neonates will have some head swelling (caput succedaneum), healthcare providers need to be aware that two major life-threatening complications following this procedure have been reported to FDA:

- **Subgaleal hematoma** occurs when emissary veins are damaged and blood accumulates between the gallea aponeurotica and the periosteum of the skull. Since the subaponeurotic space has neither containing membranes nor boundaries, the hematoma may extend from the orbital ridges to the nape of the neck. This condition is dangerous because of the large space for blood to accumulate and the possibility of a life-threatening hemorrhage.

Signs: diffuse head swelling, pallor, hypotension, tachycardia, and increased respiration rate. These signs may be present at delivery or noticeable several hours up to a few days after delivery. The swelling is diffuse and may shift when the infant's head is repositioned; it indents easily when palpated. In some cases, the swelling is difficult to distinguish from scalp edema. Sometimes, the hypotension and pallor are more noticeable than the cranial findings.

- **Intracranial hemorrhage** may include subdura, subarachnoid, intraventricular, and/or intraparenchymal hemorrhage.

Signs: indications of cerebral irritation, including convulsions, lethargy, obtundtation, apnea, bulging fontanelle, poor feeding, increased irritability, bradycardia, and/or shock. The signs and symptoms are sometimes delayed until several hours after birth.

Recommendations

Use these devices only when a specific indication is present.

- Be sure that persons who use these vacuum devices for assisted delivery are well trained in their use, and are aware of the indications, contraindications, and precautions.

- Before using a vacuum assisted delivery device, read and understand the device's instructions. Pay particular attention to the manufacturer's instructions regarding cup placement, vacuum strength, cumulative duration of applications, and number of recognized extraction attempts. Use steady traction because rocking or torque movements may be dangerous. It is important to read the instructions for each device type. Instructions for each device may vary.

- Alert those who will be responsible for the infant's care that the vacuum assisted delivery device has been used, so that they can monitor the infant for signs of complications.

- Educate the neonatal care staff about the complications of vacuum assisted delivery devices that have been reported to FDA. They should watch for signs of these complications in any infant whose delivery was vacuum device assisted.

- Report adverse events associated with vacuum assisted delivery devices to FDA as described below.

Reporting Adverse Events to FDA

The Safe Medical Devices Act of 1990 requires hospitals and other user facilities to report deaths, serious illnesses, and serious injuries to FDA and/or the manufacturer using the mandatory reporting Form 3500A. When reporting adverse events, include background information such as the patient's general condition, concurrent complications, interventions in response to the adverse event, and any other potentially relevant circumstances. This information can help FDA in its evaluation of the event(s).

Even if a report is not mandatory, FDA would appreciate your reporting it on a voluntary basis, since the report may provide important information on why these adverse events are occurring. Submit voluntary reports to FDA's voluntary reporting program, MedWatch, by telephone at 800-FDA-1088, by FAX at 800-FDA-0178, or by mail to HFA-2, 5600 Fishers Lane, Rockville, MD 20857. Use Form 3500 for voluntary reports.

Getting Additional Information

If you have questions about these devices, contact Sheila Murdock in the Office of Surveillance and Biometrics, HFZ-510, 1350 Piccard Drive, Rockville, MD, 20850. A full-text copy of this Public Health Advisory may be found on the CDRH homepage at www.fda.gov/cdrh/safety.html.

You can obtain future FDA Public Health Advisories, Safety Alerts, and other FDA postmarket safety notifications by list server subscription via e-mail. To subscribe, send an e-mail request to:

fdalist@archie.fda.gov.

In the text of the message, type:

subscribe dev-alert.

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IMPLANTED PACEMAKERS: AVOIDING ELECTROMAGNETIC INTERFERENCE*

by Diane Dwyer, R.N., B.S.N.

A person with a pacemaker implant became faint while talking on a cellular telephone. In another incident, a pacemaker user became dizzy while sitting near a person using a cellular telephone. Unfortunately, later investigations could not confirm whether or not these symptoms were related to cellular telephone use.

What may have been the cause?

Implantable pacemakers are designed to sense and pace the heart when a patient's own conduction system fails. However, electrical signals from some cellular telephones may interfere if used within 6 inches (15 cm) of the pacemaker. A sensitive pacemaker may sense electrical activity from a nearby cellular telephone, and this activity may inhibit the pacemaker.

What precautions can be taken?

Share these tips with patients who have pacemakers:

- Read the pacemaker manual.
- Hold the telephone to the ear on the opposite side of the pacemaker.
- Store the telephone on the side opposite of the implant and at least 6 inches away.
- If feeling dizzy or faint, have the pacemaker checked.

Anti-theft systems in stores may also pose problems. Give your patients these additional tips:

- Walk at an ordinary pace through anti-theft devices; do not linger near them.
- If the pacemaker changes its pacing mode in response to an anti-theft device, move away

immediately. The pacemaker should revert to its previous mode as distance increases.

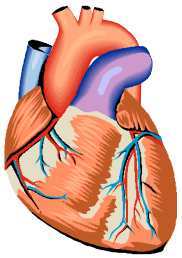
For more information about the relationship of cellular telephones to pacemaker implants, see FDA's Website at http://www.fda.gov/cdrh.

Diane Dwyer is a Nurse Consultant in the Product Evaluation Branch of CDRH's Office of Surveillance and Biometrics.

*This article was adapted from the March issue of the *Nursing 98*.

SAFEGUARDING CARDIAC GUIDE WIRES: FOLLOW THESE TIPS TO AVOID BREAKAGE*

by Cathleen Michaloski, B.S.N., M.P.H.



During a percutaneous transluminal coronary angioplasty (PTCA) procedure, a guide wire broke inside a patient's coronary artery. The patient needed surgery to remove the guide wire fragment.

Cardiac guide wires are often used to help place balloon dilatation catheters during intravascular interventional procedures, including PTCA. Among the reports that FDA receives, the most common adverse event associated with guide wires is breakage of the tip or wire. Other potential adverse events that may occur with breakage include air embolism, perforation, and infarction.

Although a physician handles the guide wire during the procedure, a nurse can follow these general guidelines to minimize the risk of breakage before the procedure:

- Read and follow carefully the product labeling instructions and precautions.
- Remove the wire slowly and carefully from the carrier tube to avoid damaging the distal tip. Check for any tiny surface bends or scrapes.
- Make sure that the wire size is compatible with the balloon dilatation catheter.
- Do not try to straighten a bent guide wire.
- To avoid shearing, wires with special coating should not be withdrawn through a metal needle cannula. Never reuse or resterilize the device.

Cathleen Michaloski is a Nurse-Epidemiologist in the Product Evaluation Branch of CDRH's Office of Surveillance and Biometrics.

*This article was adapted from the April issue of *Nursing 98*.

User Facility Reporting Bulletin

FDA produces the *User Facility Reporting Bulletin* quarterly to assist hospitals, nursing homes and other medical device user facilities in complying with their statutory reporting requirements under the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Administration Modernization Act of 1997.

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