Issue No. 3 Winter 1992

FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING (FDA, MEDICINE, MANUFACTURERS)

USER Facility Reporting

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TRAINING MEDICAL PERSONNEL TO COMPLY WITH SMDA

By Marvin Shepherd

Introduction. When the Safe Medical Devices Act of 1990 (SMDA) became effective in November 1991, device user facilities were concerned that training medical personnel to comply with SMDA would be a formidable task. This need not be true, if care is taken in identifying who is to be trained and what is to be taught. The following guidelines provide one approach to training.

Four groups need to be addressed, at different levels: (1) general staff, (2) device operators, (3) the incident investigating team, and (4) user facility managers.

General Staff. Compliance at this level can be achieved by providing an information sheet that outlines the responsibilities of all staff under SMDA. The 1-2 page sheet should include at least the following:

- brief description of the purpose of the law;
- effective date of the law, November 28, 1991;
- responsibilities of the user facility under the law;
- location of the printed policy and procedures that apply to device-related incidents;
- notice to employees that they should report any incident they become aware of, even if they did not observe it; and
- how to report incidents.

Since the general staff of most facilities will probably never be required to report device problems, their training will be strictly for information rather than for application.

The information sheet should be sent to all employees, then provided to new employees during their orientation. Annual employee re-training should include a review of the facility policy and procedures and an explanation of any changes in them. (continued on page 2)

CONTRACTS AWARDED FOR USER FACILITY REPORTING STUDY

On September 30, 1992, FDA awarded contracts to the Departments of Health in Colorado, Massachusetts, and Texas to collect data that will provide FDA with preliminary information about user facility costs and benefits associated with medical device reporting (MDR). The states will also provide information on the percent of facilities with MDR procedures in place and the rates of reporting by the facilities.

In October, we conducted a State Contractor Training Program in Rockville, Maryland. Two representatives from each state participated in this day-and-a-half program. Many offices within CDRH contributed to the training program, as did FDA's Office of Regulatory Affairs and the Health Care Financing Administration (HCFA).

(continued on page 5)

In this issue:

Department of Health and Human Services • Public Health Service

A Quarterly Bulletin

Center for Devices and Radiological Health
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Rockville, Maryland 20857

Nancy Lowe, *Editor*
Mary Ann Wollerton, *Asst. Editor*

TRAINING MEDICAL PERSONNEL . . . (from page 1)

Device Operators. According to a 1986 Government Accounting Office report, 82% of all device-related incidents are discovered by nurses and physicians. Other device operators, such as technologists, were not mentioned in the report. This may be an indication that technologists need more training than nurses and physicians about how to report.

Physicians with admitting privileges should also be included in the training program, as well as nurses, technologists, and physicians under contract to the facility.

Training can be an elaboration of the present training in reporting unusual occurrences. The additional training needed depends on how the user facility policy and procedures are written; frequently, incident followup begins with completion of an Unusual Occurrence Form (UOF).

The UOF should contain a question such as: "In your judgment, did a medical device cause or contribute to this incident?" The device operator training should emphasize to the operator that this question is on the UOF and requires an answer. The device operator need not determine if the incident is reportable to FDA or the manufacturer. The investigating team will make this determination and will gather all the information required to assure compliance with the requirements of SMDA.

For operators who answer "yes," the UOF should request any additional information unique to the device, such as the manufacturer's name, the model and serial number (or equipment control number), and the lot number if the device was disposable. The UOF should also request narrative information on whether environmental factors may have affected the device and any other information the operator considers pertinent to the incident.

Device operators should be made aware of the need to secure the device involved (and all its accessories) in some manner until the device is in the hands of the incident investigating team. Securing the device can present problems. In an active user facility, circumstances such as a continuing surgical procedure may prevent a device or room from being immediately secured. The securing of large medical devices (e.g., CTs, MRIs, x-ray machines) may interfere with emergency healthcare. It is important to use professional judgment and consider the seriousness of the incident.

Device operators must also be made aware that they are required to report each and every device malfunction that has the potential for serious injury. If an SMDA reportable event occurred previously and a device fails in an identical or similar manner, the succeeding instances should be reported on a UOF even if no injury occurred.

Incident Investigating Team. Ideally, the Incident Investigating Team (IIT) should include a clinical engineer, risk manager, and quality assurance manager. The IIT must receive all the training and information provided to device operators, and must also be knowledgeable in the techniques of accident investigation. The IIT must be intimately aware of the user facility policy and procedures that incorporate the requirements of SMDA and FDA regulations.

The person identified as the MDR contact for liaison with FDA will most likely be on the IIT or on the committee to which it reports. The MDR contact must know about all incidents, in order to respond to any questions from FDA.

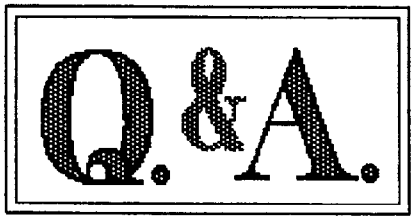
The facts gathered during the investigation should help the IIT identify the causes of the incident and determine whether the incident is reportable under SMDA. Even if the event is not reportable under SMDA, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation standards require that it be reported to the user facility safety committee. The quality of the investigation and its conclusions will greatly affect the likelihood of repeat occurrences.

User Facility Managers. Administrators and other managers are responsible for assuring compliance with the law. By implication, they are responsible for writing and implementing policy and procedures that will assure compliance. They must be sufficiently aware of SMDA and its implications to responsibly implement the policy and procedures, including providing the various kinds of training outlined above. Finally, administrators and other managers must be constantly aware of changes in the regulations under SMDA.

Conclusion. The various steps that facilities take to implement SMDA should not obscure the primary goal of reducing device-related incidents. By keeping this goal in mind, user facilities can respond effectively to questions that may arise concerning the content of a training program. ∇

Mr. Shepherd is a Professional Safety Engineer who recently retired from the

University of California Medical Center in San Francisco. He has published over 60 articles on medical device safety. He continues his educational and consulting activities concerning device safety in Walnut Creek, California. Questions relating to this article may be directed to Mr. Shepherd at (510) 945-0137, FAX 945-7384.



FREQUENTLY ASKED QUESTIONS

We at FDA are frequently asked the following questions, which you may encounter at your own facility:

Q. Must a facility designate a contact person to be responsible for MDR (medical device reporting)?

A. Yes. FDA needs to be able to communicate with someone at each facility who is knowledgeable about the MDR reports submitted to FDA and the manufacturers, in case it is necessary to follow up on a report. A facility may use a third party to submit the reports, but the institution remains responsible for the accuracy and completeness of the information and for meeting all reporting requirements.

Q. What action does a manufacturer take when a report is received?

A. Under the good manufacturing practices regulation (Part 820 of Volume 21 of the Code of Federal Regulations), a manufacturer must investigate complaints about its products. The manufacturer usually contacts the complainant to obtain as much information as possible for its investigation and the required report for FDA.

Many manufacturers, however, have informed FDA that user facilities are not permitting them access to products that have caused problems. FDA cannot require a facility to grant the manufacturer access to the device; that must be negotiated by the parties involved.

Q. What does "FDA approved" mean?

A. FDA can approve a medical device that is new or has not yet been classified, if the safety and effectiveness data submitted in a premarket approval (PMA) application are found sufficient. Before any new indication can be added to a product already on the market, a firm must also submit data to support the new claim and obtain further approval from FDA.

Most devices enter the market by the premarket notification process [often called 510(k)]. This means that FDA finds them to be substantially equivalent to devices marketed prior to May 1976 (the date of enactment of the Medical Device Amendments of 1976). These devices are not "approved" but are found to have the same indications for use and the same technology as devices previously on the market. FDA regulations prohibit marketing these devices as "FDA approved."

Q. If a patient brings his or her own medical device (e.g., a wheelchair) into a user facility for personal use and the device causes or contributes to the patient's injury or death, is the event reportable?

A. Yes. If the device is in use at the facility and an adverse event occurs, ownership of the device is not a question. The user facility is responsible for reporting any event that was (or may have been) contributed to or caused by a medical device.

Q. Is the reporting requirement still in effect or has it been delayed?

A. It has not been delayed. The requirement for user facilities to report under the Safe Medical Devices Act (SMDA) became effective November 28, 1991. Only the requirement to track certain devices has been delayed until August 29, 1993, as a result of the Medical Device Amendments of 1992. (See page 6 for a list of the devices to be tracked.)

Q. Are mental health facilities considered user facilities under SMDA?

A. Yes. Although they may not use many high-tech devices, they definitely use medical devices. Needles, syringes, patient restraints, and electroconvulsive therapy devices are just a few examples.

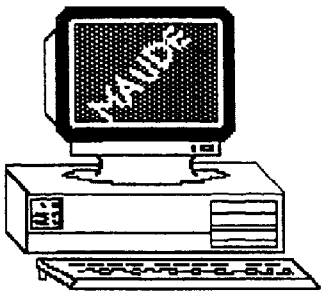
Q. Do physicians need to be aware of the reporting requirements, even though their offices are exempt from reporting?

A. Yes. If a reportable device event occurs in a user facility where a physician is employed or otherwise formally affiliated, he or she has an obligation to begin the reporting process. Also, the facility may need the physician's opinion about the device's contribution to the patient's death, serious injury, or serious illness.

FDA also encourages any physician who experiences a problem with a device to report it to the

voluntary product Problem Reporting Program (PRP) by calling 1-800-638-6725 or writing to FDA's contractor, the United States Pharmacopeia, 12601 Twinbrook Parkway, Rockville, MD 20852. Do NOT use the PRP for reports required by SMDA. ∇

- Susan E. Bounds
Office of Compliance and Surveillance



MAUDE UPDATE: ERRORS IN REPORTING

In the last issue of the *User Facility Reporting Bulletin*, I reported on the new MAUDE system developed by CDRH to capture data from user facility reports. I also promised to inform you about progress on this system.

Nearly 1,500 event reports have now been entered in the system—approximately 1,300 from user facilities and 200 from distributors. Our data analysts are noticing that the respondents appear not to fully understand the reporting requirements, as well as some of the questions on the Test Form. Of the 1,500 reports, nearly 1,400 contain at least one error. I would like to use this MAUDE Update to describe the types of error that occur most commonly in the reports and to clarify the reporting requirements to help avoid errors in future reports.

Omitted Answers

Analysts are finding errors in answers to nearly three-fourths of the 58 questions on the Test Form. The majority of these errors are omissions, rather than incorrect information or "bad values." Most frequently omitted is the answer to question 43 which asks whether a device has been destroyed or disposed of ("yes" or "no" being the choices). Respondents are failing to answer this question on over half the Test Forms.

Other answers frequently omitted include:

- "certainty of device as cause of/contributor to event" (question 40);
- "date event was reported to manufacturer" (question 30);
- "device purchase date" (question 13);
- "device labeled for single use" (question 14);
- "imminent hazard to public health" (question 27); and
- "device used as labeled/ intended" (question 31).

FDA is looking carefully at these omissions for potential noncompliance issues that may arise when the regulation implementing the medical device reporting requirements of SMDA is final.

Questions That Allow for Multiple Answers

A few questions in particular are frequently being answered in a way that indicates some confusion on the part of respondents. These are the four questions that allow for multiple coded responses:

- "method of evaluation" (question 37);
- "results of evaluation" (question 38);
- "conclusion" (question 39); and
- "corrective actions taken by facility" (question 41).

The choices for the answers are one-, two-, and three-digit codes.

The multiple blanks on the form are intended to capture more than one answer, if necessary. For example, if four different methods of evaluation were used, a respondent should include the code for each of the four methods. If only three methods were used, the last blank should remain empty. Many respondents are putting only one digit in each blank, causing the response to appear as a bad value in the database.

Inconsistent Numbering

Analysts are also finding errors relating to consistency in numbering the reports. The user facility report number should consist of a combination of:

- the user facility ID number assigned by the Health Care Financing Administration (HCFA),
- the year in which the report is being filed, and
- the four-digit sequence number.

User facilities should assign sequence numbers in the order of occurrence of reportable events within the year, beginning with "0001" for the first event of that year. Thus, the report number for a user facility's tenth report filed in the year 1992 might be 1234567890-1992-0010.

Although most facilities have a single HCFA number, some facilities have multiple HCFA numbers. In these cases, the user facility should choose one HCFA number for each facility location and use that number consistently on all SMDA reports from that location. We are finding, instead, that many user facilities use different HCFA numbers within the same facility location. This results in multiple sequencing schemes. Some facilities are not even attempting to sequence their reports, thus requiring our data entry staff to try to assign sequence numbers.

MDR Contact

User facilities should designate one person to maintain liaison with FDA for medical device reporting (MDR) purposes. This MDR contact need not necessarily be the person closest to the event, such as the operating room nurse who was present when a device failed. More appropriately, it should be someone in a position to know about, or find out about, events throughout the facility. Many facilities appoint the "risk manager" as the MDR contact.

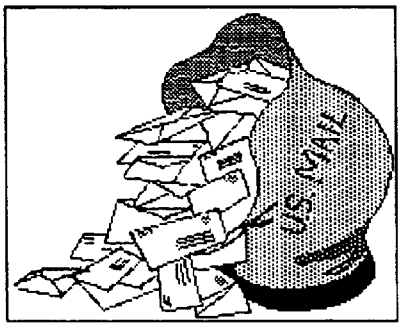
Designating a single MDR contact facilitates keeping the detailed records about reportable events, and their reporting history, in a central place. It is also helpful when sequencing the reports. When several contacts in a facility are reporting events, they are often unaware of the sequencing schemes others have used and institute their own. This results in conflicting sequencing of reports.

Data Quality

CDRH's Office of Information Systems has made data quality a major goal of its new MAUDE system. Information that is omitted or incorrect requires several additional steps in the data entry process, because the data entry staff must call up additional screens to attempt to verify the data. At best, this delays the data entry process, but there is a potential danger as well. Sound analysis requires sound data, and poor or missing data may hamper detection of dangerous trends or malfunctions in medical devices. ∇

- Cathy Hix
Office of Information Services

MAILBAG



We still need to
hear from you !!!

We are pleased to have Marvin Shepherd's article on the front page of this issue. (Mr. Shepherd recently retired as an engineer at the University of California Medical Center in San Francisco.) Perhaps some of our other readers will be motivated to submit an article for the Spring issue.

So, pick up your pencils—or more likely these days, sit down at your computer—and tell us what is going on at your facility. If you are considering this, please remember that we have publishing deadlines. We would like to have your draft by the second week in February. If this is not possible, call us and we will work out a schedule.

If you are not interested in actually writing an article, we would still like to have your suggestions for articles in future issues. We'll find an author! We would like to tailor these Bulletins to your needs, so we need to know what you want. Your feedback helps us serve you better. If you want to see more information on a topic, we urge you to call Nancy Lowe at 301-443-2436 or Mary Ann Wollerton at 301-443-4600 with your suggestions.

Please remember: your interests, as well as your problems, are our major concern. ∇

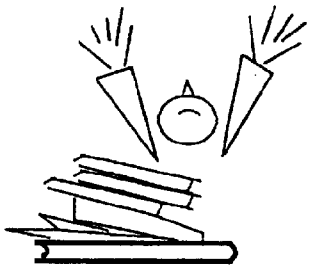
- Mary Ann Wollerton
Office of Training and Assistance

CONTRACTS . . . (from page 1)

Under the Safe Medical Devices Act of 1990, the term "user facility" includes hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities. Outpatient diagnostic facilities are included by regulation. State inspectors will be visiting user facilities between December 1992 and July 1993. The final state reports to FDA are due in September 1993.

The state information will be incorporated into two evaluation reports due to Congress in November 1993 and August 1994. The November 1993 report will contain evaluative components concerning user facility reporting, including safety benefits, burdens on FDA and device user facilities, cost-effectiveness, and recommendations for legislative reform. The August 1994 report will contain information on device user facility compliance with MDR requirements. ∇

- Cindy Blandford
Office of Management Services



OOPS !

In our Fall 1992 issue, we inadvertently omitted 2 of the 21 devices that require tracking. The 2 devices are:

- Replacement heart valve
- Infusion pumps (electromechanical only)

For your convenience we are providing the complete list of 21 devices as given in the May 29, 1992, Federal Register.

Devices To Be Tracked
as of August 29, 1993

- Vascular graft prosthesis of less than 6 millimeters diameter
- Vascular graft prosthesis of 6 millimeters and greater diameter
- Ventricular bypass (assist) device
- Implantable pacemaker pulse generator
- Cardiovascular permanent pacemaker electrode
- Annuloplasty ring
- Replacement heart valve
- Automatic implantable cardioverter/defibrillator
- Tracheal prosthesis
- Implanted cerebellar stimulator
- Implanted diaphragmatic/phrenic nerve stimulator
- Implantable infusion pump
- Breathing frequency monitors (apnea monitors) including ventilatory effort monitors
- Continuous ventilator
- DC-defibrillator and paddles
- Silicone inflatable breast prosthesis
- Silicone gel-filled breast prosthesis
- Silicone gel-filled testicular prosthesis
- Silicone gel-filled chin prosthesis
- Silicone gel-filled Angelchik reflux valve
- Infusion pumps (electromechanical only)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration (HFZ-240)
Center for Devices and Radiological Health
Rockville, Maryland 20857

ATTN: Editor, User Facility Reporting Bulletin

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