Issue No. 2 Fall 1992

FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING (FDA, MEDICINE, MANUFACTURERS)

# USER Facility Reporting

Please route to: ☐ ADMINISTRATOR ☐ RISK MANAGER ☐ BIOENGINEER ☐ QUALITY ASSURANCE

## MEDICAL DEVICE AMENDMENTS OF 1992

On June 16, 1992, the Medical Device Amendments of 1992 (PL 102-300) became law, to take effect one year after enactment or upon the effective date of a final regulation issued by the Food and Drug Administration (FDA), whichever comes first. The 1992 amendments made the following changes in the user facility reporting provisions of the Safe Medical Devices Act of 1990 (SMDA):

- The criteria for determining whether there is a reportable event were amended. Under SMDA, user facilities were required to report when they receive or become aware of "information that reasonably suggests that **there is a probability** that a device has caused or contributed to" a reportable event. Under the 1992 Amendments, user facilities will be required to report when they receive or become aware of "information that reasonably suggests that a device has **or may have** caused or contributed to" a reportable event.
- The 1992 Amendments added a new reportable event in addition to death, serious illness, and injury. It will require the reporting of "other significant adverse experiences as determined by the Secretary by regulation to be necessary to be reported." These events are to be defined by FDA in the final regulation.

  The legislative history indicates that Congress intended that this category include events such as concussions; fractures; burns; temporary paralysis; or temporary loss of sight, hearing or smell.
- Finally, the 1992 amendments deleted the word "immediate" from the definition of "serious illness" and "serious injury." The definition now reads "necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure."

These changes will be reflected in the final rule that FDA plans to issue at the end of 1992.

*- Joseph M. Sheehan*
*Office of Standards and Regulations*

## COMMENTS RECEIVED ON PROPOSED MEDICAL DEVICE REPORTING REGULATION

Prior to publication of the proposed medical device reporting (MDR) regulation on November 26, 1991, FDA's Center for Devices and Radiological Health (CDRH) initiated a program to encourage comments from device user facilities. Thousands of individuals were reached through speeches and exhibits at professional meetings and articles in journals and the trade press.

As a result, FDA received 305 responses totaling over 1,300 pages. Most came from the healthcare community, with almost every state represented. Healthcare professional organizations and industry trade groups were among the respondents. Thus the individuals whose interests are represented number in the millions.

The comments are very important to FDA since they contain the observations and concerns of the user

**In this issue:**



Department of Health and Human Services • Public Health Service

A Quarterly Bulletin

Center for Devices and Radiological Health
Food and Drug Administration
Rockville, Maryland 20857

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

community regarding the possible impact of the regulation. They also provide FDA with an intellectual "test" of how the proposed rules will function in the real world.

Many of the comments favor the basic objective of the proposed regulation. In fact, some respondents stated that physicians' offices should also be considered "facilities," and be subject to reporting.

Other comments, however, indicate that the proposal is too broad and needs clarification if FDA expects facilities to understand and comply with the requirements.

Major concerns involve the following areas of the proposal:

- Reporting of user error;
- The status of facility employees when they are also patients;
- FDA access to patient files;
- Potential legal liability associated with reporting; and
- Definitions, particularly the definition of a "medical device."

Some representative comments we received are:

- "Imminent hazard" is not well-defined;
- The term "adverse incident" should not be used;
- The concept of "caused or contributed to" is not clear. Reports should be submitted only when there is a clear relationship between the device and the death, serious injury or serious illness;
- The term "necessitates immediate surgical or medical intervention" is difficult to interpret;
- The term "probability" should be deleted from the definitions;
- The definition of "serious injury/illness" is too broad;
- The economic impact statement does not reflect the actual costs involved in reporting;
- The confidentiality of patient/hospital records and the potential for lawsuits should be addressed;
- Reporting forms must be simple and should not require facilities to determine the cause of the problem.

We have summarized the comments, and some will be used to modify the language of the final regulation or will be explained in its preamble. Other concerns will be addressed in educational materials and distributed to device user facilities after the final regulation is published. Overall, the comments have helped FDA understand the problems facing user facilities as they attempt to comply with the MDR regulation.

The regulation has been rewritten several times to reflect user concerns. We anticipate publishing a final regulation by the end of 1992.

*- Chester T. Reynolds*
*Office of Compliance and Surveillance*

## EVALUATION OF DEVICE USER FACILITY REPORTING

The Safe Medical Devices Act of 1990 directs the Secretary of Health and Human Services to prepare and submit to Congress two reports evaluating the User Facility Reporting Requirements (UFRR). The Office of Management Services (OMS) within CDRH will coordinate the necessary studies and prepare the two reports. Due dates and topics to be covered are as follows:

**Report 1: November 1993**

- Safety benefits of UFRR;
- Burdens of UFRR on FDA and on device user facilities;
- Cost-effectiveness of UFRR; and
- Recommendations for legislative reform.

**Report 2: August 1994**

- Assessment of the degree of compliance by user facilities.

We are now designing the evaluation methodology, but timing is a major concern. Since a final rule implementing the law will not be published until the end of 1992, there is uncertainty regarding the eventual requirements on user facilities. At present, they need only comply with the "spirit of the law," not the specifics of the tentative rule published on November 26, 1991. Even if the regulations become final by the end of 1992, it will be several months before CDRH can make the desired assessment.

CDRH has selected a sample design that includes about 475 device user facilities of several types which FDA field investigators will visit once the regulation is final. The investigators will collect much of the information to be used in the evaluation. User facilities under SMDA include hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities. In the November 1991 proposed regulation, FDA added outpatient diagnostic facilities to the definition of a user facility.

CDRH will also use other mechanisms to meet the evaluation objectives. One is to use state contract inspections to obtain baseline data on incidents reported and on burdens imposed by compliance

with the requirements. FDA recently requested proposals from the states. User facilities will be contacted first by the state investigators and later by the FDA inspectors.

A second mechanism is to use the results of a survey taken by a national healthcare association.

*- Carl F. Blozan*
*Office of Management Services*

## QUIZ: ARE THESE MEDICAL DEVICE INCIDENT REPORTS REQUIRED?

To help clarify what is required by the Safe Medical Devices Act of 1990, we present excerpts from some user facility incident reports submitted to FDA.

Read the following, then decide whether a report is required in each instance and, if so, where it should be sent.

1. No audible alarm was noted by nursing personnel for the asystole status of a patient who expired.

2. While the staff attempted to identify the reason for malfunctioning of an intra-aortic balloon console, air was injected into the arterial port instead of the balloon port during the manual inflation/deflation process. The patient experienced central nervous system complications and died a week later. The facility could not duplicate the console problem.

3. A patient was in the operating room for insertion of a jugular vena cava filter. The device deployed partially and was entrapped in the right atrium. Attempts to remove the device resulted in lacerations of the right atrium and vena cava. The patient died.

4. When a patient used the step of an examination table, the step slipped into the table and caught the patient's foot. The patient's toe was fractured and the nailbed was macerated. The reporter alleged poor product design.

5. An asymptotic patient underwent elective removal of intact gel-filled breast implants. No complications were reported.

6. A disposable resuscitation bag was used with the oxygen connection at "flush." During the procedure, the oxygen line was checked and the oxygen port (normally connected to the base of the bag) was found to be improperly welded. The patient died after receiving room air instead of oxygen.

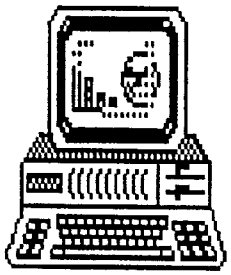
7. An autopsy revealed that a patient died as the result of complications related to the failure of an artificial heart valve.

8. Six months after a 57-year old, 168-pound patient had a fractured femur repaired with screws, the screws broke. The patient then had to undergo a second surgery to replace the broken screws.

9. A phlebotomist was drawing blood when the tube broke as he withdrew it from the needle. Since he was covered with blood, he immediately showered and changed his clothing. He was then seen by the emergency room physician. No treatment was required.

10. A nursing home patient suffered a cerebral hemorrhage when the back pulled off his shower chair and he fell to the floor.

See page 5, ANSWERS TO QUIZ, for FDA's evaluations.



## CDRH'S "MAUDE" SYSTEM

Because the 1990 law substantially broadens the requirements for reporting medical device incidents, CDRH estimates that the number of such reports sent to FDA each year could quadruple! To prepare for this, for the past year our computer staff has been developing an automated system to enter, store, and analyze the information in these reports. The system is called "MAUDE," which stands for Manufacturer and User Device Experience.

The MAUDE system is being developed in phases, some of which are already operational. The first phase, the data entry module, was completed and put into use in March of this year. This module consists of programs to capture the information from user facility/distributor event reports and user facility semi-annual reports. Eventually this module will capture data from the many other reports required under SMDA, including manufacturer event reports, manufacturer monthly reports, and manufacturer baseline reports. As of July 31, over 800 user facility event reports were entered in the system.

CDRH already has an automated reporting system to manage data required by the 1984 Medical Device Reporting (MDR) regulation. We initially considered using this system to capture SMDA reports,

but the increased requirements of SMDA make the MDR system inadequate to handle the additional reports. Also, the modifications would be difficult to make, so we are developing the new system. The new system will integrate MDR report data with other CDRH databases to provide the most complete possible profile of manufacturers and device performance.

A major goal in developing the new system is to ensure data quality, so that sound analysis can be conducted. A second goal is to automate, wherever possible, the collection and analysis of data from device experience reports. Automation of the systems will allow our staff to more effectively identify significant device problems. For example, the new system will "code," or identify, products both generically and by the manufacturer-specific model information. The generic device coding will allow for searches and analysis of the database according to type of device. Also under development is a statistically-based trend analysis capability. This system will look for trends among a type of product as well as among reports from an individual manufacturer.

Eventually the new system will provide other functions, including generation of management and workload reports; automated support of followup activities, such as computer-generated letters; and a query capability to be available CDRH-wide as well as to FDA field offices.

We will report on system progress in subsequent issues of the Bulletin.

*- Cathy Hix*
*Office of Information Systems*

## DEVICE TRACKING

FDA wishes to alert you to recent legislation that may affect members of the healthcare community. The Safe Medical Devices Act of 1990 includes a provision that requires the tracking of certain medical devices from the manufacturer through the distribution chain to the patient. This will ensure that certain devices can be traced to the appropriate patients or users if any hazards develop with the devices.

Although the **manufacturer** is responsible for the tracking of certain devices, it will be necessary for all parties involved in the distribution chain to assist and cooperate in the tracking process. The readers of this Bulletin may be participants in the distribution chain for tracked devices. Please share this information with any of your colleagues who you believe may be affected by these tracking requirements.

FDA published a proposed rule in the *Federal Register* (FR) of March 27, 1992, and asked for comments on the proposal. After modifying the proposed rule in response to the many significant comments received, FDA published a final rule in the FR of May 29, 1992. This rule will be **effective no later than August 29, 1993.**

The final rule identifies 21 devices to be tracked. The list includes devices that are permanently implanted, such as heart valves and pacemakers, as well as devices that are life-sustaining or life-supporting and are used outside a user facility, such as apnea monitors and defibrillators. Following is the list of devices to be tracked:

- 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
- 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

To obtain a copy of the May 29 *Federal Register* and/or the tracking summary tables, write to the Division of Small Manufacturers Assistance (HFZ-220), Office of Training and Assistance, Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857, FAX 301-443-8818.

FDA would appreciate any assistance that you can provide in disseminating this information to your colleagues.

*- Mary Frances Colvin*
*Office of Training and Assistance*

## ANSWERS TO QUIZ

FDA made the following evaluations:

1. The information in this report is sparse. From the limited information available, it appears to be a reportable event that should be sent to **both** the manufacturer and to FDA because the patient died.

2. This report does not provide information about the source of the malfunction in the intra-aortic balloon console. The user tried to diagnose the problem while the patient was connected to the console, and an adverse event ensued. The November 26, 1991, tentative final rule proposes that adverse events contributed to or caused by user errors be reported. SMDA, however, does not require that user errors be reported. FDA is interested in having **as much information as possible** about device problems reported. For example: What caused the user to conclude that the device was not functioning properly? What was the device doing or not doing that contributed to or caused the event? Report to **both** the manufacturer and FDA.

3. There is insufficient information in the report to determine whether the event was the result of a defective device. Because immediate surgical intervention was required to repair the lacerations, FDA considers this a reportable event. Report to **both** the manufacturer and FDA.

4. There is insufficient information in the report to determine how the device contributed to the patient's serious injury. The facility's report attributes the event to a design defect. The report should be sent to the **manufacturer** only, because it involved a serious injury. Under the 1984 medical device reporting (MDR) requirements, the manufacturer has an obligation to investigate the event.

5. The patient underwent elective surgery. Since the prostheses were not found to be defective, this is not a reportable event.

6. This is definitely a required report. The device apparently was not manufactured according to specifications. The incident should be reported to **both** the manufacturer and to FDA, because the patient died.

7. This event must be reported to **both** the manufacturer and to FDA, because the failure of the artificial heart valve ultimately caused the death of the patient.

8. Because the device broke, additional surgery was required to prevent permanent damage to a body structure. The report should be sent to the **manufacturer** only.

9. This is not a required report because the physician determined that the phlebotomist was not injured.

10. There is insufficient information to evaluate why or how the back pulled off the chair. There is no indication that the patient died, so the report should be sent only to the **manufacturer** of the chair, if known. We will review the manufacturer's report to FDA to determine the problem with the device.

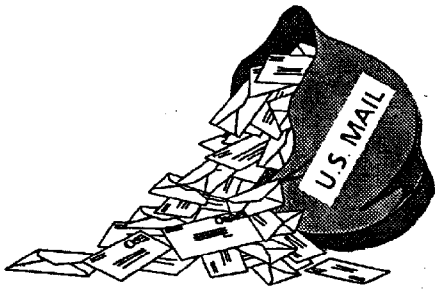
How did you do? Both FDA and manufacturers appreciate reports that have as much information as possible to facilitate evaluation and followup.

*- Lily Ng*
*Office of Science and Technology*

*- Susan Ellen Bounds*
*Office of Compliance and Surveillance*

## ROUTE SLIP

Please notice that under the masthead of this User Facility Reporting Bulletin we have provided a route slip for you. This merely indicates our suggestions for personnel we believe would be interested in reading the Bulletin. Not every facility will have all these positions on the staff, while some will have more. Please feel free to make photocopies of the Bulletin if you wish to route it to individuals.




## WE NEED TO HEAR FROM YOU!

User facilities are invited to submit articles that could help other facilities comply with SMDA. Some possibilities are: (1) how your facility trains its staff to comply with the reporting requirements; (2) how your facility decides which device-related problems should be reported; and (3) how your facility uses device incident information in quality assurance and purchasing decisions. FDA is also interested in hearing about problems encountered in reporting and how they were resolved.

We also encourage you to send suggestions for articles to be included in future Bulletins. As we receive miscellaneous information, we will pass it along in a column, perhaps entitled "Did You Know?"

# HIGHLIGHTS OF THE USER FACILITY MEDICAL DEVICE REPORTING (MDR) REQUIREMENTS

| If you are a: | But are not a: | Then you are a: |
|---|---|---|
| Hospital<br>Nursing Home<br>Ambulatory Surgical Facility<br>Outpatient Treatment Facility<br>Outpatient Diagnostic Facility | Physician's Office | User Facility |

## USER FACILITY RESPONSIBILITIES AS OF NOVEMBER 28, 1991

| If you: | Then you must: | Time frame: |
|---|---|---|
| Receive information that reasonably suggests that a device caused or contributed to a DEATH | Report to BOTH the manufacturer and FDA | Within 10 working days |
| Receive information that reasonably suggests that a medical device caused or contributed to a SERIOUS INJURY or SERIOUS ILLNESS | Report to the manufacturer ONLY (If the manufacturer is unknown, report to FDA.) | Within 10 working days |
| Submitted any reports to the manufacturer or FDA during a 6-month reporting period | Send to FDA a SEMIANNUAL SUMMARY of all reports submitted to manufacturers and/or FDA | - January 31 for the preceding July through December<br>- July 31 for the preceding January through June |

## PROPOSED PROCEDURES TO IMPLEMENT NOW
(from the "Tentative Final Rule" published in the November 26, 1991, Federal Register (56FR60024)

- Implement and maintain WRITTEN MDR PROCEDURES to train employees about their reporting responsibilities.
- Establish INTERNAL SYSTEMS for the timely, effective identification and evaluation of events.
- Establish a DOCUMENTATION and RECORDKEEPING SYSTEM for:
  - information considered prior to determining if an event is reportable,
  - all information and reports submitted to manufacturers and/or FDA,
  - information that facilitates semiannual report submissions, and
  - access and timely followup and inspection by FDA.
- Establish a DEVICE INCIDENT FILE and maintain records of any information, including any written or oral communication, received and documented that concerns any event subject to reporting.
- Maintain COPIES of any required records for 2 YEARS after submitting to the manufacturer and/or FDA.

## CIVIL PENALTIES

Failure to comply with the MDR reporting requirements is a prohibited act. Persons who violate the provisions are subject to being enjoined, imprisoned, and fined. Civil penalties will not be effective until 1994, and then only if certain types of facilities are not complying with the requirements.

## CALENDAR OF FDA EXHIBITS AND PRESENTATIONS ON SMDA

**October - December 1992**

(For additional information, please contact the sponsoring organization.)

| Date | Event Site | Sponsoring Organization | Exhibit | Presentation |
|---|---|---|---|---|
| Oct. 11-14 | Anaheim CA | Interscience Conference on Antimicrobial Agents<br>1325 Massachusetts Avenue, NW<br>Washington, DC 20005-4171<br>(202) 737-3600 | X | |
| Oct. 17-21 | San Francisco CA | American Health Care Association<br>1201 L Street, NW<br>Washington, DC 20005-4014<br>(202) 898-2807 | X | X |
| Oct. 22 | Baltimore MD | NAACOG: Organization for Obstetric, Gynecologic, and Neonatal Nurses<br>409 12th Street, SW<br>Washington, DC 20024<br>(202) 638-0026 | | X |
| Oct. 26-28 | Boston MA | American Association of Homes for the Aging<br>901 E Street, NW (Suite 500)<br>Washington, DC 20004<br>(202) 508-9473 | X | |
| Nov. 1-5 | San Diego CA | American Osteopathic Association<br>142 E. Ontario Street,<br>Chicago, IL 60611<br>(312) 280-5800 | X | |
| Nov. 4-6 | Chicago IL | Joint Commission on Accreditation of Healthcare Organizations<br>1 Renaissance Blvd.<br>Oakbrook Terrace, IL 60181<br>(708) 916-5407 | X | |
| Nov. 8-11 | Las Vegas NV | American Society for Healthcare Risk Management<br>840 N. Lakeshore Drive<br>Chicago, IL 60611<br>(312) 280-6425 | X | |
| Nov. 11-15 | San Francisco CA | American Medical Women's Association<br>801 N. Fairfax Street (Suite 400)<br>Alexandria, VA 22314<br>(703) 838-0500 | X | |
| Nov. 15-18 | Baltimore MD | American Society of Nephrology<br>1101 Connecticut Avenue, NW (Suite 700)<br>Washington, DC 20036<br>(202) 857-1190 | X | |
| Nov. 16-18 | Nashville TN | Association of Military Surgeons of the United States<br>9320 Old Georgetown Road<br>Bethesda, MD 20814<br>(301) 897-8800 | X | |
| Nov. 18-21 | Atlanta GA | National Home Health Care Exposition, SEMCO<br>1130 Hightower Trail<br>Atlanta, GA 30350<br>(404) 641-8181 | X | X |
| Dec. 5-10 | San Francisco CA | American Academy of Dermatology<br>930 North Meacham Road<br>Schaumburg, IL 60173-496<br>(708) 330-0230 | X | |

☆ U.S. GOVERNMENT PRINTING OFFICE: 1992 – 312-216 – 814/73627

## COMPLICATIONS WITH USE OF SMALL-BORE CATHETERS IN CONTINUOUS SPINAL ANESTHESIA

In May 1992, FDA sent a "Safety Alert" to anesthesia care providers, hospital administrators, hospital pharmacists, and risk managers to alert them to a serious hazard associated with continuous spinal anesthesia using small-bore catheters (27 gauge or smaller). The information in the Alert is summarized below.

Since December 1989, small-bore catheters have been used in continuous spinal anesthesia. As of May 1992, FDA received 11 medical device reports (MDR) of cauda equina syndrome in which small-bore catheters were used to deliver 5% lidocaine with 7.5% glucose to the intrathecal space. This compares with only 1 case of cauda equina syndrome associated with the use of epidural catheters since 1984. FDA has received reports that the use of small-bore catheters for continuous spinal anesthesia has recently increased. This increase may be contributing to the rise in complications.

Cauda equina syndrome is a prolonged and possibly permanent neurological deficit characterized by one or more of the following: loss of bladder and/or bowel function, loss of perineal sensation, and decreased sensation or mobility of the lower extremities.

Over the last several months, FDA has examined this problem extensively. Because of safety concerns, we are advising against the use of small-bore catheters for continous spinal anesthesia. Please note that the following are not affected by the Safety Alert: use of epidural catheters; single-dose spinal injection of 5% lidocaine with 7.5% glucose.

FDA is also taking action to remove from the market all small-bore catheters. This action affects devices from five manufacturers: Kendall Healthcare Products Company; Preferred Medical Products; Concord Laboratories, Inc.; Telflex Medical, Inc.; and Medevices, Inc.

If drug or device manufacturers, medical facilities, or physician groups wish to conduct controlled clinical studies demonstrating the safety and efficacy of small-bore catheters to deliver a specific local anesthetic for continuous spinal anesthesia, FDA will consider Investigational New Drug (IND) and Investigational Device Exemption (IDE) applications.

Send medical questions pertaining to this subject to: Suzanne Parisian, M.D.; Office of Health Affairs, CDRH (HFZ-70); 1390 Piccard Drive; Rockville, MD 20850; FAX 301-427-1968. For a copy of the Safety Alert, write to Office of Training and Assistance, CDRH (HFZ-250); 5600 Fishers Lane; Rockville, MD 20857.

*- E. Jane McCarthy CRNA, Ph.D.*
*Office of Standards and Regulations*

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

OFFICIAL BUSINESS
**PENALTY FOR PRIVATE USE, $300**

**FIRST CLASS**
POSTAGE AND FEES
PAID
PHS/FDA
PERMIT NO. G-285