ISSUE NO. 4 Spring 1993

FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING (FDA, MEDICINE, MANUFACTURERS)

USER Facility Reporting

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THE FIRST YEAR OF USER FACILITY REPORTING

M. Lee Bancroft, Charles Conklin, and Chester T. Reynolds

Part I. A User Facility Perspective

Boston's Beth Israel Hospital began planning in the Summer of 1991 to implement the section of the Safe Medical Devices Act of 1990 (SMDA) that requires Medical Device Reporting (MDR) by user facilities. Although we had been following the progress of the legislation in Congress, we were surprised when SMDA was enacted in the Fall of 1990. We viewed compliance with SMDA as an elaboration of an already extensive quality assurance program. Thus, we avoided the need for significant increases in personnel.

Beth Israel's User Facility Reporting System. We decided that overall responsibility for MDR would fit best within the Quality Assurance/Risk Management (QA/RM) Department, although other departments such as clinical engineering would be involved in implementing the system. (An incident reporting system of a broader nature than required by SMDA had been in place in the Anesthesia and Critical Care Department for some time.) The decision to make the QA/RM Department responsible for MDR has been a good one. Most reports are related to non-capital devices such as indwelling catheters and prosthetics, and the QA/RM staff members generally have clinical backgrounds.

We delegated responsibility for implementing MDR to **one individual** with support from several departments. This approach has been effective since all aspects of the program are reviewed by the same person, who has a vested interest in making compliance as efficient as possible. (continued on page 2)

PUBLIC AVAILABILITY OF USER REPORTS

When a user facility sends FDA a report of an adverse experience with a medical device, the report may be released to the public in accordance with the Freedom of Information (FOI) Act, which is applicable to most documents held by U.S. government agencies. Release of reports is also subject to the Privacy Act, which governs access to an individual's U.S. government records .

In general, user reports will be available to the public in accordance with the FDA regulations in Title 21, Part 20, of the Code of Federal Regulations. FDA will **not** release trade secrets and commercial or financial information that is privileged or confidential; inter- or intra-agency memoranda or letters; **personnel, medical and similar files**, disclosure of which constitutes a clearly unwarranted invasion of personal privacy; and investigatory records compiled for law enforcement purposes.

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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*

THE FIRST YEAR OF USER FACILITY REPORTING . . . (from page 1)

We next identified individuals with expertise concerning a specific device or category of devices. These clinicians are consulted periodically as part of an informal "hazard evaluation group." The group includes the risk manager and may include a clinical engineer, a purchasing agent, and a central processing administrator. This group is responsible for deciding if an internal recall is justified, based on the severity of the reported incident(s) and the consequences for patient care of such a recall.

Our review of existing reporting mechanisms found them to be suitable for MDR with one exception—the use of written incident reports. Completion of the written report process causes an unacceptable delay in reporting to the QA/RM Department. This would make it difficult to meet the 10-day limit for reporting to the manufacturer and/or FDA. Therefore, we decided to include all types of incident reporting in the hospital's clinical computing system. This new service is now being tested on two floors of the hospital.

Educational Efforts. Educational efforts began with brief presentations before staff meetings and inclusion of announcements in the general materials circulated throughout the hospital. We used flow charts to outline the reporting mechanisms being initiated. Although detailed written procedures have since been developed, we felt that complex materials were not needed initially.

A random survey of hospital staff indicated that few were aware of SMDA. There were also serious misconceptions about what was reportable. Some misconceptions arose because of the difference between how SMDA defined "reportable" and what is commonly considered reportable in the peer-review medical literature. Many of our clinicians thought that known complications in the use of devices (such as disconnection during mechanical ventilation or failure of an orthopedic prosthesis after several years of use) would not be reportable unless they occurred under truly unusual circumstances.

Initial training emphasized the increased clinician reporting imposed by the SMDA definition of a reportable event. The response by most clinicians has been positive. To maintain this positive attitude, we have kept to a minimum the amount of additional paperwork that reporters must complete. Most of the paperwork is completed by members of the QA/RM staff, with only essential details left for the reporter to complete. We also inform the reporter of the disposition of the report. We ask each manufacturer to provide a written report of its evaluation, and we share this with the reporter.

During the first year, Beth Israel spent about 240 staff-hours to provide educational efforts directly related to MDR. This will decrease considerably in the future, but staffing changes will require a continuous educational commitment.

As with any new program, some problems were encountered. Meeting the reporting deadline—10 days from the time medical personnel become aware of an incident—has proven difficult. Our computer-based reporting system will improve this situation, but some departments such as pathology will continue to have their own special requirements.

Failed Implants. One intent of Congress in passing SMDA was to improve postmarket surveillance of medical devices. This may be difficult to achieve in the area of implants, because of the problems involved in returning failed devices to the manufacturers.

The reporting of failed implants has increased both the volume and complexity of the program. Retrieving, marking, and handling failed implants required the development of specific protocols and procedures. All retrieved implants must also be considered contaminated material, subject to the Universal Precautions procedures of the Centers for Disease Control. Most manufacturers prefer to receive a failed device in the condition in which it was removed from the patient, without any processing. This minimizes the possibility that post-explantation damage might be confused with in-use wear or damage.

Presently, an explanted device that contains up to 50 ml of infectious, or possibly infectious, material is exempt from the Department of Transportation regulation (49 CFR 173.386) governing shipment of hazardous materials. If this exemption (which is due to expire on January 1, 1994) is not extended, the return of any failed device to the manufacturer will require completion of a hazardous material manifest prior to shipment.

Identification of implants has also created difficulties, particularly when the original implantation was done at another institution. The patient must request that the previous institution release a copy of the medical record to Beth Israel

Hospital. Transfer of the record frequently takes longer than 10 days and often does not take place at all. The result may be a report with no information about the manufacturer, the implant date, or the catalog/lot/serial numbers—not worth much! Fortunately, this may improve when the device tracking section of SMDA becomes effective on August 29, 1993. Without a central database for implant information, many of the identification problems will continue.

Another issue with explanted medical devices is ownership. Hospital counsel is of the opinion that a prosthesis or implant removed from a patient is the property of the patient. Therefore, if an implanted device is removed from a patient, we give the patient first right of possession.

Recent Federal court rulings have further complicated the issue of disposition of explanted devices. A class action suit, pending before the Alabama Federal District Court, may result in more stringent requirements concerning the retention of explanted devices by a hospital. Presently, most hospitals discard explanted devices after about 30-60 days. Any new requirement to maintain failed devices could turn healthcare institutions into custodians of evidence for future lawsuits. (See page 5 for *Part II. The FDA Perspective.*)

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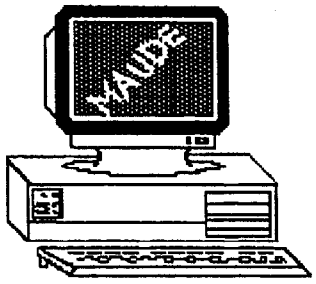


MAUDE UPDATE: SEMI-ANNUAL REPORTS

In the last issue of the *Bulletin*, I described the types of error that are occurring most commonly on the Medical Device Reporting (MDR) event Test Form. In this issue, I will do the same for semi-annual reports.

We have now received semi-annual reports for the two six-month reporting periods of 1992. As of the end of 1992, approximately 900 semi-annual reports had been entered in the MAUDE database. Once again our analysts are noticing indications of reporter confusion in some areas.

As with MDR event reports, most of the errors are related to numbering of reports. Generally, we are seeing two types of numbering error:

1. **Failure to use Health Care Financing Administration (HCFA) numbers correctly.** Some user facilities have not been including their HCFA numbers on their MDR reports, while others are using HCFA numbers on their semi-annual reports that are different from those used on their individual MDR reports. You should use one HCFA number on all MDR reports. This is the number that FDA uses to identify the facility. If your facility has multiple HCFA numbers, you should choose one HCFA number for your facility location and use it consistently on all your reports. There should also be consistency between MDR reports and semi-annual reports—the HCFA number that appears on each semi-annual report should have been used on all the MDR reports covered by that semi-annual report. (See page 5, *User Facility ID Number.*)

2. **Errors in number sequencing.** The report numbers in the second semi-annual reporting period of a year should continue the sequencing of the first reporting period. For example, if the lowest to highest report numbers on the first semi-annual report of 1992 range from 1234567890-1992-**0001** to 1234567890-1992-**0010**, then the second semi-annual report of that year should begin with 1234567890-1992-**0011**, corresponding to the MDR report sequences of that period. Instead, some facilities are beginning their second semi-annual report with **0001**.

If you provide no number, or an incorrect report number, our staff must delay the data entry process to assign a number, usually by looking up previously entered records to attempt to create a valid number. However, the user facility's official MDR contact (the person who submits reports for the facility) is in a much better position to do this accurately.

If you are not sure of your correct HCFA number, your MDR contact can obtain this information from your billing department. **Your official HCFA number is the number under which your facility bills HCFA for its Medicare payments.**

I would also like to clarify who must submit semi-annual reports. If your facility has experienced a reportable event (regardless of whether you have reported it to FDA or the manufacturer), you must submit a semi-annual report for the period

in which the event occurred. If your facility experienced no reportable event during a semi-annual reporting period, you need not file a semi-annual report for that period. Some facilities are reporting anyway—listing report numbers **0000 to 0000.** Over 200 user facilities have reported unnecessarily.

The reason we require semi-annual reports, even though individual MDR reports have been sent to manufacturers and/or FDA, is to allow us to audit manufacturers. Since facilities report only device-related deaths to FDA and report all other events to the manufacturers, FDA needs the semi-annual reports to check manufacturer compliance with the complaint investigation and reporting requirements.

We note with encouragement that many of these errors in reporting have occurred much less frequently in the second semi-annual reporting period of 1992 than in the first. This seems to indicate that user facilities have become more familiar with the reporting requirements of SMDA. In fact, many facilities that did not submit a semi-annual report for the first reporting period—but had reportable events—now seem to be "up to speed" and have submitted a semi-annual report for the second half of 1992. ∇

-Cathy Hix
Office of Information Systems

UPDATE ON USER FACILITY REPORTING STUDY

As we reported in the last *Bulletin*, FDA awarded contracts to the states of Colorado, Massachusetts, and Texas to collect data from randomly selected facilities on user facility costs and benefits associated with medical device reporting (MDR) requirements of the Safe Medical Devices Act of 1990 (SMDA), as well as reporting rates. Data will be analyzed by facility category: hospital, nursing home/residential care, outpatient treatment, outpatient diagnostic, and ambulatory surgical.

We have received monthly reports from the three states since December 1992. These reports help us understand how facilities are complying with SMDA. Final state reports to FDA are due in September 1993. By the end of January 1993, the state contractors had visited 175 facilities to collect data and give a briefing on SMDA and its requirements for facilities. The monthly reports indicate that 40 to 50 percent of facilities visited are not aware of SMDA; awareness is greatest among hospitals.

Massachusetts state contractors were accompanied on several facility visits by Gary Beard, from FDA's Office of Regional Operations, and Cindy Blandford, from the Office of Management Services in FDA's Center for Devices and Radiological Health. Gary and Cindy report that facility personnel were very cooperative and willing to discuss SMDA and its effect on their facility. The Massachusetts contractors spend a lot of time briefing facilities about SMDA and answering questions.

Bonnie Markovitz and Glasco Smith—also from the Office of Management Services—and Gary Beard recently accompanied state contractors on several facility visits in Colorado and Texas. We were impressed by the level of support from these facilities.

At this time we will not report on the data collected during the facility visits. Data collection is continuing, so we want to avoid any possibility of introducing a bias into future facility responses.

We encourage facilities in the study to ask the contractors, who have been trained by FDA, any questions they may have about reporting. ∇

-Glasco Smith
Office of Management Services

PUBLIC AVAILABILITY OF USER REPORTS

(from page 1)

Before a report is released, FDA will delete patient names and any other information that would identify patients. Generally, all names will be deleted from a medical file before it is released. Under the Privacy Act, FDA will release to a patient all information in any report that concerns the patient, except for trade secret or confidential commercial information.

FDA may not release the identity of a device user facility that makes a report, except in connection with:

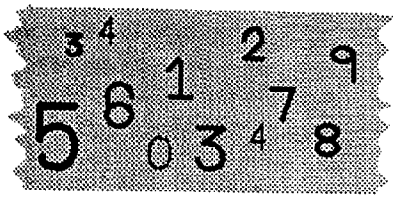
- an enforcement action brought to remedy a failure or refusal to comply with reporting requirements; or

- a communication to the manufacturer of the device that is the subject of the report.

FDA may disclose a report to an authorized employee of the Department of Health and Human Services or the Department of Justice, or to authorized committees or subcommittees of Congress.

A report may not be used in a civil action involving private parties unless the facility, an individual employee of the facility, or an attending physician was aware, at the time of filing, that the report was false. ∇

-Joseph M. Sheehan
Office of Standards & Regulations



USER FACILITY ID NUMBER

Some user facilities are submitting Medical Device Reporting (MDR) reports without a user facility identification (ID) number. When the MDR regulation is final, you will be required to use your Health Care Financing Administration (HCFA) reimbursement number or FDA-assigned ID number. If your facility does not have a HCFA number, use all zeros for the user facility ID number. We will assign a user facility ID number and notify you, in writing, of the number.

If you want us to assign you a user facility ID number before you submit an MDR report to a manufacturer or to FDA, please mail or FAX your request (including the facility name, address, and telephone number) to:

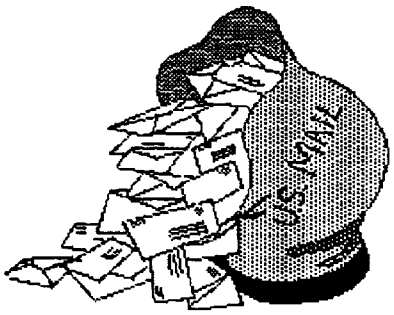
Information and Analysis Branch
Office of Compliance and Surveillance (HFZ-351)
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

FAX: 301-427-1967.

If your facility has already submitted one or more MDR reports to FDA with a missing or incorrect ID number, we will send you (or have already sent you) a letter to inform you of the user facility ID number we have assigned to you. **Your facility should always use this number for individual MDR reports and for any required semi-annual reports.**

From our experience we believe most facilities that submit MDR reports have a HCFA number. Perhaps some facilities have not been able to determine what their HCFA number is. **If your facility is reimbursed by HCFA under the Federal Medicare system, you have at least one HCFA number.** The billing office in your facility should know the HCFA number. ∇

-Susan E. Bounds
Office of Compliance and Surveillance



MAIL BAG

Changes in the Bulletin Mailing List. We have received many requests for name and/or address changes on our *Bulletin* mailing list. We recently restructured our databases to make such changes possible.

Please send us your old mailing label when you request a change, so we can identify your database. All requests should be in writing to the following address:

Editor: User Facility Bulletin
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-240)
5600 Fishers Lane
Rockville, MD 20857

FAX: 301-227-8067

Please type (or print) the new address to help us correctly enter it in the database.

If you have already submitted a name and/or address change without sending your old mailing label, please notify us again according to the above directions.

Additions to the Mailing List & Requests for Other Publications. When requesting to be added to the *Bulletin* mailing list, or requesting other publications, use the above address. State the names of the publications wanted, the quantity, and your name and complete mailing address. Please type (or print) your request. ∇

-Clifford Evans
Office of Training and Assistance

THE FIRST YEAR OF USER FACILITY REPORTING

Part II. The FDA Perspective

The problems in implementing SMDA are not all in the hospital setting. For FDA's Center for Devices and Radiological Health (CDRH) this is the first regulatory involvement with device user facilities (i.e., hospitals, nursing homes, and outpatient facilities) rather than manufacturing facilities.

The user facility Medical Device Reporting (MDR) requirements present significant challenges for both CDRH and user facilities. CDRH received no increase in resources (either staff or funding) to implement SMDA, resulting in great demands on its infrastructure. For example, a completely new data processing system had to be designed to handle the information required under SMDA. In addition, new procedures and training programs for industry and user facilities had to be developed, tested, and disseminated.

In response to the challenge, CDRH has focused on ways to

make the processing and analysis of reports more efficient. Two major components of this effort are a new reporting form and the use of computers and/or computer outputs to transfer data to CDRH.

Reporting Form. After the MDR Test Form was published in 1991, FDA proposed a new universal form to replace a variety of existing forms that relate to problems with devices, drugs, and biologics. The proposed form was published in the February 26, 1993, *Federal Register* (58 FR 11768) with a 45-day comment period. One side of the proposed form is for voluntary reporting by health professionals; the other is for mandatory reporting by user facilities, manufacturers, and distributors. Please **do not use** the new universal form until you are advised to do so. The FDA computer system cannot presently handle it.

A conference for exchanging information on the universal form will be held on June 3, 1993, at the Crowne Plaza Hotel in Rockville, Maryland.

Electronic Data Transfer. Electronic submissions are encouraged. The use of computers and computer outputs (tape, floppy disks, etc.) to submit data to CDRH is a major feature of MDR. Several companies are developing the required software to enable user facilities to use this method of reporting. CDRH cannot endorse an individual vendor but will, upon request, review a vendor's product to ensure compatibility with the FDA system. Most companies are waiting for publication of the final reporting form before they begin marketing their products. Details of electronic reporting are not yet final. CDRH will provide guidance when the final MDR regulation is published.

Both the universal form and electronic data transfer are intended to improve the quality of information submitted. Before MDR, the quality of information received from manufacturers concerning device problems was poor. One reason Congress required MDR was to increase the quality of information being submitted about device problems. User facilities are the best possible source of information about devices.

Problems with Data Received. CDRH expected that user facilities would need some time to become familiar with the new reporting requirements. However, after 16 months user facilities are still confused about what is reportable, how to complete the Test Form, and other aspects of reporting. To help facilities understand how to report, this *Bulletin* routinely features articles on data quality. Confusion about the following is common:

• Where to send individual MDR reports. Reports of device-related **deaths** should be sent to FDA and the manufacturer (if known). If there is a **serious injury** or a **serious illness** and the manufacturer is **unknown**, the MDR report should be sent to FDA. To date, FDA has received over 700 individual MDR reports of serious injury or serious illness that should have been reported only to the manufacturer.

• Malfunction reports. Malfunction reports need not be submitted to FDA or the manufacturer, unless intervention was required to prevent serious illness, serious injury, or death. Malfunction reports to manufacturers are encouraged, however, since under certain circumstances manufacturers are required to report malfunctions to FDA.

• Semi-annual reports. Semi-annual reports should be submitted **only** if an individual MDR report was submitted to either FDA or a manufacturer during the previous six months.

• Numbering of individual MDR reports and semi-annual reports. A correct number begins with a facility's HCFA number (up to 10 digits) followed by the calendar year (4 digits) and a sequence number for each individual report (up to 4 digits). For example, Beth Israel's HFCA number is 220086; this is 1993; and the first individual MDR report submitted for the year is number 1. The complete number would then be 220086-1993-0001.

USER FACILITY REPORT NUMBER

220086	1993	0001
User Facility ID No.	- Year -	Sequence No.

If 10 individual MDR reports are submitted in 1993, the complete number of the last individual report would be 220086-1993-0010. For 1994, the HCFA number will remain the same (220086), but 1994 will replace 1993, and a new series of individual sequence numbers will begin. (See pages 3 and 5 for related articles.)

Misconceptions about Penalties. There seems to be misunderstanding about the penalties for failing to report. The civil penalties—$15,000 per violation and up to $1,000,000 per legal proceeding—**are not** in effect at this time. They will not be instituted until after FDA conducts studies of user facility compliance and submits reports to Congress. These reports are due by November 1993 and August 1994. If a particular category of user facility is found not to be in compliance with

MDR, civil penalties could be applied to that type of facility. If user facilities in general are not complying with MDR, civil penalties will be applied universally in August 1994. FDA can also enforce the MDR regulation under its existing authorities. If necessary, FDA can obtain an injunction against a facility that fails to comply with MDR. Continued noncompliance could then subject the facility to a possible contempt of court citation and other penalties.

Health departments in three states are currently visiting user facilities to ascertain reporting compliance. (See page 4, *Update on User Facility Reporting Study*.) Later this year, FDA investigators will begin inspecting facilities in all 50 states to determine compliance with MDR.

Although user facility personnel have shown cooperation and a positive attitude, compliance with MDR appears to be minimal. Our mailing list of possible user facilities is about 80,000. To date, only 2,834 reports have been received and only 664 of these should have been submitted to FDA. During the same period, 47,605 reports of death and serious injury were received from device manufacturers under the 1984 MDR regulation. Since most MDR reports are sent to manufacturers by healthcare facilities, there is obviously gross underreporting or misunderstanding by user facilities.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) will check for MDR compliance beginning in 1993. If the potential civil penalties and Federal contempt charges are not sufficient to bring about compliance, the need for JCAHO accreditation may do so.

Chester T. Reynolds is the Director of the Post Market Management Staff in the Office of Compliance and Surveillance, Center for Devices and Radiological Health, U.S. Food and Drug Administration, Rockville, MD 20850.

Summary From Both Perspectives

Complying with Federal regulations and maintaining accreditation are necessary but should not be the primary motivation for MDR. Improvement in the quality of patient care is the intent of MDR. This can best be accomplished by using the reporting data to minimize risk. For example, Beth Israel was able to remove from use (prior to patient injury) several devices that were considered hazardous and to limit the implantation of one other type of device. These improvements have resulted from data collected at a single institution. This is exactly what should happen as a result of collecting and analyzing event data. The data can be a valuable tool for investigating and analyzing systems, techniques, and equipment to determine the safest approach to current use. They also provide valuable information for planning future use or acquisition of medical devices.

Data received through device tracking (effective August 29, 1993) may improve the accuracy of MDR. Improvements in automatic identification mechanisms such as bar coding to the unit level (currently being considered by the Health Industry Business Communications Council) will simplify device identification and reduce transcription errors. It may also benefit user facilities by increasing the efficiency of inventory control and charging mechanisms.

Finally, user facilities will serve their own best interests by reevaluating their compliance with MDR. Failure to do so will have the unfortunate result of unnecessarily increasing financial and regulatory burdens on the entire healthcare industry. ∇

COMING in SUMMER 1993

The next issue of the *Bulletin* is scheduled for Summer 1993. Please send your articles, questions, and comments, by June 1, to the attention of the Editor, User Facility Reporting Bulletin, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-240), Rockville, MD 20857.

Some of the articles scheduled to appear in the Summer issue are:

- MDR: Therapy and Diagnostic Devices
- MAUDE Update
- Q. & A.

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