FOOD AND DRUG ADMINISTRATION

USER Facility Reporting

MEDICAL DEVICE REPORTING

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Guest Article

MEDICAL DEVICE REPORTING FROM AN INSURANCE COMPANY PERSPECTIVE

By Randall S. Hunsberger, PE, ARM

Before the user facility reporting requirements of the Safe Medical Devices Act (SMDA) became effective in late 1991, Healthcare Underwriters Mutual Insurance Company (HUM) started a series of in-service programs to inform its members of the reporting requirements. Several regional training programs were presented for administrative, risk management, and engineering personnel. Information about medical device reporting (MDR), as well as sample policies and procedures, was given to each of the attendees. In addition, a telephone consultation service was made available to each of the members for answering specific MDR questions. In 1993, the in-service training program was expanded to include the medical device tracking requirements.

HUM also provides each of its 165 insured facilities (hospitals, nursing homes, diagnostic and treatment centers, and health maintenance organizations) with extensive risk management engineering and other technical services. These include on-site surveys and training programs to inform the insured facilities about current regulations governing the facility, its equipment, and safety.

Most of the insured facilities are small to medium (75 to 200 beds) and are located in the state of New York. While there has been some divergence from the mean, a sample indicates that facilities averaged approximately one mandatory MDR incident reported to the manufacturer and/or the Food and Drug Administration during 1994. Some facilities submitted several mandatory reports.

Member hospitals have attributed their success in complying with SMDA to the training program and consultation services provided by HUM and the information provided by FDA through its quarterly *User Facility Reporting Bulletin.* ✣

Editor's Note: Readers are invited to write us about their MDR experiences for possible publication in a future issue.

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MAUDE UPDATE

By Cathy Hix

There are now over 18,000 user facility, distributor, and voluntary reports in the MAUDE database. ("MAUDE," which stands for Manufacturer and User Device Experience, is an automated system developed in response to the broadened reporting requirements of the Safe Medical Devices Act.) Of course, manufacturer reports are not yet in MAUDE, because they are still being entered into the existing medical device reporting(MDR) database pending promulgation of the final MDR regulation. Once this happens the MAUDE database will increase dramatically, not just in quantity but in quality, because manufacturer reports will verify device and model information and contain their analyses of the events. So, we do not yet

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HOW TO REQUEST MDR RECORDS UNDER THE FREEDOM OF INFORMATION ACT

By Les Weinstein, Esq.

If you want a copy of an MDR (Medical Device Reporting) report that has been submitted to the Food and Drug Administration (FDA) by a manufacturer or importer, you can submit a request to FDA, citing the Freedom of Information (FOI) Act. It is very important to know what to include in your request and where to send it, so that FDA can respond quickly. All FOI requests must be in writing, addressed to:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Your letter should include: your name, address, telephone number, and a description of the desired records (identified as specifically as possible). A request for specific information that is releasable to the public can be processed much more quickly than a request for "all information" on a particular subject. Also, a more specific and limited request will cost less for search, review, and duplication. FOI searches cover only existing records; they will not compile information that is not readily identifiable and available.

Since FOI requesters may have to pay fees covering some or all of the cost of processing a request, you may want to mention the maximum dollar amount you are willing to pay. If the fees exceed this amount, FDA will contact you before filling the request. Do not send payment with your request; you will be billed later.

The 1984 MDR regulation requires device manufacturers and importers to report to FDA when a device may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction recurs. The MDR regulation [21 CFR 803.9] states that any MDR report, including any FDA record of a telephone report, is available for public disclosure under FOI. Examples of some requests are: copies of all adverse event reports associated with a specific device or manufacturer; a copy of a report previously filed by the requester; and statistical counts of the number of device incident reports received by FDA.

Before releasing a record, FDA will delete any trade secret or confidential commercial information and any information that would constitute an invasion of personal privacy, such as patient names or other identifiers. Typically, we release the name of the manufacturer and the device, the model number, and a description of the reported adverse event.

If you wish to receive MDR reports on a routine basis, you can get them by subscription from the National Technical Information Service (NTIS), Springfield, VA 22161. NTIS reports are sorted only by device panel code (e.g., Panel Code 73 - Anesthesiology; Panel Code 87 - Orthopedics) — not by device or manufacturer. ✣

Editor's note: See issues 4 and 9 for previous articles on FOI and Medical Device Reporting.

Les Weinstein served as Acting Director of the CDRH Freedom of Information Staff. He is presently a regulatory counsel in the International Standards Program of the Office of Health and Industry Programs.

HOW TO AVOID PROBLEMS WITH MDR REPORTS

By Susan E. Bounds

In the following interview, Arlene Underdonk (Acting Chief of the Information and Analysis Branch in the Office of Surveillance and Biometrics) explains how to avoid problems when submitting Medical Device Reporting (MDR) reports.

Q. Are user facilities required to report device-related adverse events caused by user error?

A. **Ms Underdonk**: FDA is interested in learning about device injuries attributed to user error, because such events may indicate that the labeling for a device does not provide adequate directions for use or adequate warnings. In such cases, MDR reports may alert FDA of the need for improved labeling to prevent future injures.

At this time, reporting of user errors with medical devices is not explicitly required. The proposed implementing regulation for MDR (published in the November 26, 1991, *Federal Register*) requires the reporting of device-related user error that results in death, serious injury, or serious illness. We expect that the final MDR regulation will also include this requirement.

Q. Which form should a facility use to report adverse device events?

A. **Ms Underdonk**: While not yet required by regulation, user facilities should use the mandatory MedWatch form (3500A) to report device-related deaths, serious injuries, and serious illnesses. When the MDR final rule is effective,

the mandatory MedWatch form will be required.

Although a user facility has no legal obligation to report a device malfunction that does not result in a death, serious injury, or serious illness, FDA encourages the facility to report the malfunction to the manufacturer (who is required by law to report it to FDA). Malfunction reports provide important information to manufacturers and FDA concerning potential safety problems.

FDA would like user facilities to use the mandatory MedWatch form (3500A) when reporting malfunctions to the manufacturer. This will ensure that the manufacturer receives all information needed to report to FDA.

If a user facility wants to notify FDA of other device-related events or problems (e.g., problems with labeling or packaging), the voluntary MedWatch form (3500) should be used. This form is also used to report to FDA serious adverse events and important product problems relating to all products used in medical therapy (i.e., drugs, biologics, medical devices, special nutritional products) when such reporting is not required by federal law or regulation. FDA does NOT require user facilities to report adverse drug or biologic reactions. Therefore, if a user facility chooses to report these events to FDA, the voluntary form should be used. Adverse drug and biologic reactions are usually reported by the pharmacy department within the user facility.

The voluntary form should not be used to report device-related deaths, serious injuries, or serious illnesses. It does not meet the mandatory reporting requirements for a user facility.

Q. How can a facility find its HCFA number to use in the User Facility Report Number?

A. **Ms Underdonk**: A facility's billing office uses its HCFA (Health Care Finance Administration) "provider number" for Medicare reimbursement. If a facility has more than one HCFA number, the reporter should choose one number and use it on all subsequent MDR reports.

If a facility is unable to determine its HCFA number or does not receive Medicare funds, it may report using all zeros in the first part of the User Facility Report Number. FDA will assign an identification number and notify the facility. The assigned number should then be used on all subsequent MDR reports to FDA and manufacturers.

A facility with multiple sites may elect to have one contact person report from a central site. The contact person must then attach a list of names of

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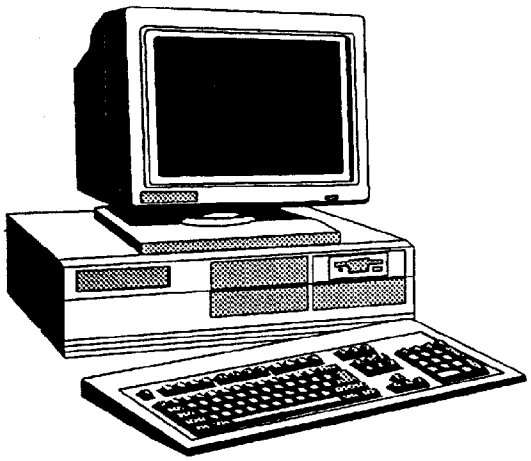
MAUDE UPDATE *(Continued from page 1)*



have a statistically significant volume of data on which to base trend analysis. We do, however, have a substantial amount of event data, and I'd like to describe how it is used in the Center for Devices and Radiological Health.

Because MAUDE allows the aggregation of data in many configurations (such as by product, specific model, and/or family of devices), it enables Center analysts to see the information in a variety of ways. They can examine all events related to specific devices, groups of devices, or a particular manufacturer. They can also look for problems that cut across product lines or entire industries. While not a true statistical approach, MAUDE does allow the Center to identify areas where problems exist, as well as the types of problems. The Center can then determine an appropriate course of action. Based on review of certain events, the Center may want to propose specific products or those in a particular region for corrective actions, such as recalls and injunctions. Or, it may become aware of an imminent hazard with a particular product, which can be addressed by issuing an FDA Safety Alert, a Public Health Advisory, or another form of risk communication. If the potential for risk is less serious, the Center may use a "Dear Doctor" letter to advise physicians of misuse or malfunctions.

One of the most important issues is how well users understand the intended use of the device. This is particularly true of home-use devices, which are used by a high percentage of lay caregivers. Because many device problems can be attributed to user error, analysts look at the data for just such information. Analysis of MAUDE data can lead to such solutions as improved user education (e.g., in the form of better guidelines for a target user group); labeling changes across entire product lines; and even product redesign.

In the future, MAUDE data will be used for epidemiological analysis and in the development of medical device standards. MAUDE will also include a trend and statistical analysis function. This will allow analysts to compute statistical trends, such as an increase in frequency or severity of reported events for a particular model, family, or type of device. In addition, the system will match all related reports, so all information submitted to the Center pertaining to a specific device event will be cross-referenced. This will allow Center analysts to see a complete picture of a particular event.

As the development of MAUDE continues and manufacturers' reports are entered into the system, the database will allow the Center to be more proactive in its efforts to keep pace with the performance and use of medical devices.

In a future issue, I plan to discuss how MAUDE data are used outside the Center. ✣

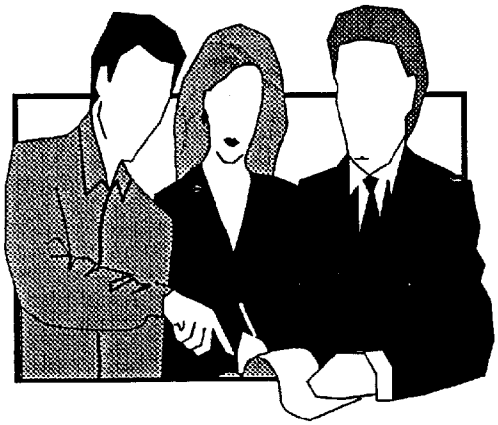
Cathy Hix is Chief of the Training and User Support Branch in the Office of Information Systems.

BACK ISSUES AVAILABLE

Back issues of this Bulletin are available. If your collection is incomplete, just let us know which issues you need. Our mailing address is: Food and Drug Administration, Center for Devices and Radiological Health (HFZ-230), 5600 Fishers Lane, Rockville, MD 20857.

AAMI/FDA CONFERENCE WILL ADDRESS HUMAN FACTORS IN MEDICAL DEVICE DESIGN, REGULATION, AND SAFETY

The Association for the Advancement of Medical Instrumentation (AAMI) and the Food and Drug Administration (FDA) will cosponsor a two-day conference on human factors issues concerning medical devices. The conference will be held September 12-13, 1995, at the Washington Hilton Hotel and Towers in Washington, D.C.



FDA has identified human error as a major source of patient injuries. In an effort to reduce human error in the operation and maintenance of medical devices, FDA is developing a program to address the role human error plays in the design and use of medical devices. The conference will provide a forum for introducing FDA's new human factors program and will encourage discussion of human factors issues among manufacturers, device users, and regulatory personnel.

Conference topics include:

- FDA's Human Factors Program Plan
- Human factors and FDA premarket and postmarket activities
- The role of human factors in GMPs and quality systems
- Human factors in device incident reporting
- Medical device industry perspectives
- Device user perspectives
- The process of human factors engineering including usability testing
- Case studies/models of successful human factors design
- The user/computer interface
- Design of labeling and user instructions
- Liability issues
- Interpretation and use of human engineering standards
- Resources for human factors design

HUMAN FACTORS COLUMN COMING SOON!

A new column dedicated to human factors will debut in the Summer issue of the *Bulletin*.

Human factors:
a systematic approach to reducing errors associated with injuries and deaths by designing equipment around the characteristics of the user and work environment

Through presentations and interactive breakout sessions, device manufacturers will receive the critical information they need to ensure that their design practices and procedures are consistent with the latest regulatory requirements. From the clinical standpoint, the design program intends to help assure that those responsible for purchasing devices are adequately informed to make suitable purchase decisions, and that users and service or maintenance technicians are provided adequate instructional material and training in the proper use and care of devices.

For additional informational or to register for the conference, contact Laura Duffy at AAMI, 800-332-2264; 703-525-4890, extension 260; or Fax number 703-276-0793. ✣

HOW TO AVOID PROBLEMS WITH MDR REPORTS - *(Continued from page 3)*

all facilities and their respective HCFA numbers and addresses (sections F-2 and F-3 of form 3500A) to the first MDR report submitted. The address on the form should coincide with the central reporting site.

Q. How should semi-annual reports be submitted and when are they due?

A. Ms. Underdonk: We expect that the final MDR regulation will require use of a specific form for the semi-annual report. Currently, a semi-annual submission must include a summary of each report submitted to FDA and/or the manufacturer during the previous 6-month period. **Semi-annual reports are due on January 31 and July 31.**

Each summary should include:

- the user facility name and identification number;
- sequence numbers used;
- name and address of the manufacturer;
- name of the device;
- model, catalog, serial, and lot numbers;
- a brief description of the event; and
- the recipient(s) of the report, i.e., FDA and/or the manufacturer.

In lieu of submitting a summary of each report, a facility may submit a copy of each report previously submitted to FDA and/or the manufacturer.

Each semi-annual report should be submitted in an envelope clearly marked "Semi-Annual Report." We also request that all cover letters and attachments, including copies of individual reports sent with the semi-annual report, be clearly marked or stamped "Semi-Annual Report." Individual reports enclosed with the semi-annual report often become separated from both the cover letter and the envelope. This makes it difficult to determine whether the individual report is an initial submission or part of a semi-annual report.

Q. Must reports be typewritten?

A. Ms Underdonk: We request that all MDR reports be typewritten. Handwritten reports are often illegible, requiring followup telephone calls that are time consuming for both the reporter and the FDA analyst. We also ask reporters:

- to use additional sheets of paper if any blocks are too small to record the requested information;
- not to continue information appropriate for one block into another block; and
- not to write information outside of blocks.

Some facilities have developed computer software facsimiles which greatly aid in completing the form. Currently, FDA's MedWatch office is developing electronic data entry software.

Q. How should a facility report an event when more than one device was being used simultaneously with the patient?

A. Ms Underdonk: If the user facility cannot determine which device caused or contributed to the event, separate additional sections of Block D (Suspect Medical Device) and parts of Block F (For use by user facility/distributor-devices only) that pertain to the subject device should be completed for each device and attached to the report. The user facility report number should contain the same sequence number for the event, regardless of the number of medical devices reported.

If other medical products were in use when the event occurred but are not suspected of causing or contributing to it, they may be reported in Block 10 (Concomitant medical products).

Q. Where should reports be submitted?

A. Ms. Underdonk: Each mandatory report and its envelope should be specifically identified, i.e., "User Facility Report" or "Semi-Annual Report."

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HOW TO AVOID PROBLEMS WITH MDR REPORTS - *(Continued from page 6)*

Send an initial **mandatory** MedWatch form (3500A) for a device-related **death** (and any supplements), as well as semi-annual reports, to:

Medical Device Reporting
Food and Drug Administration
Center for Devices and Radiological Health
P.O. Box 3002
Rockville, MD 20847-3002

Send a **mandatory** MedWatch form (3500A) for a **serious injury or serious illness** to the manufacturer of the device. If the manufacturer cannot be identified, send the form to FDA at the above address.

For additional information or clarification about the mandatory MedWatch form, send inquires to FAX number 301-594-3781.

Send a **voluntary** MedWatch form (3500) to:

MedWatch
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

To voluntarily report by telephone or to obtain voluntary MedWatch forms, call 800-FDA-1088; to report by FAX, call 800-FDA-0178; and to report by modem, call 800-FDA-7737 (voluntary reports only). ✣

Susan E. Bounds, a Consumer Safety Officer in the Office of Surveillance and Biometrics, is a specialist in user facility reporting.

User Facility Reporting
A Quarterly Bulletin

The *User Facility Reporting Bulletin* is an FDA publication 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 and the Medical Device Amendments of 1992.

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REMINDER

Semi-Annual Reports

are due

July 31, 1995