FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING (FDA MEDICINE MANUFACTURERS)

USER Facility Reporting

Issue No. 16 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Summer 1996

MDR TELECONFERENCE REACHES LARGE AUDIENCE

By Chester T. Reynolds

An audience estimated at over 75,000 participated in the Food and Drug Administration's May 7 teleconference on medical device reporting (MDR). If you were at one of the more than 5,000 downlink sites, we hope the three-hour session helped you understand the importance of MDR as well as its basic requirements. For those who were unable to view the teleconference, the session is summarized below. Videotapes of the telecon-ference, and guidance documents, are available as explained on page 5. Goals of the conference included:

- providing user facilities and manufacturers an overview of their respective reporting responsibilities;
- explaining how FDA uses MDR reports to protect the public health;
- briefly discussing how to complete the MDR reporting forms;
- providing sources of detailed information about MDR; and
- providing an opportunity for interactive questions and answers.

FDA panelists discussed a list of actions recommended to help user facilities comply with MDR. (Although the final MDR regulation did not become effective until July 31, 1996, user facilities have been required to report since November 1991.) The list included:

- appoint an MDR contact person;
- obtain MDR forms and documents;
  - Form 3500A (mandatory MedWatch form), instructions, and coding manual
  - Form 3419 for semiannual reporting
  - *Medical Device Reporting for User Facilities* (guidance document)
- develop written procedures to promote consistency;
  - standardize the review process
  - use flow charts or decision trees
- establish a complaint file;
  - document any decision NOT to report;
  - keep copies of reports sent to manufacturers and to FDA;

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PUBLIC HEALTH ADVISORY ON ELECTRIC HEATING PADS PROMPTED BY MDR REPORTS

By Joan M. Rudick

After receiving the following report of serious burns to patients from electric heating pads, analysts at the Food and Drug Administration (FDA) searched its Medical Device Reporting (MDR) database for additional problems.

A medical student working in the emergency room of the Medical Center at the University of Virginia became concerned about patients admitted to the hospital with serious burns from the use of electric heating pads. These patients often had compromised or insensate skin due to congenital spinal bifida, diabetes, or paralysis.

The MDR database search revealed 47 reports of patient burns, fires, and burn holes**.** One report related to an incident in which an

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In This Issue:

A REVIEW OF MANDATORY MEDWATCH FORM 3500A AND SEMIANNUAL REPORT FORM 3419

By Joyce Stanley-Harris

User facilities that have reported to FDA generally seem to understand how to complete and submit the Medical Device Reporting (MDR) forms. The following addresses a few sections of the forms that continue to cause problems.

FDA FORM 3500A - MEDWATCH MANDATORY REPORTING FORM

User Facility ID Number - Record your User Facility ID number-Year-Sequence number in the upper right corner box on the front page. Your User Facility ID number is the Health Care Finance Administration (HCFA) - Medicare Provider number. Always use the same ID number on your MDR forms. If you do not know your HCFA number, check with your facility's billing office; if they do not know it, send your report to FDA and use 10 zeros for your ID number. We will then assign an FDA number to your facility. Be sure to include the year and sequence number of the report even if you use zeros for your ID number. For example:

0000000000-1996-0001.

Remember to change the calendar year every January 1 and start your report sequence numbers again at 0001. For example:

1234567890-1997-0001.

Section A - A patient identifier allows the user facility to locate the record of a particular event if more information is needed by FDA and/or the manufacturer. Since confidentiality prohibits use of a patient's name or social security number, use the patient's initials or the case number.

Section B - Item 1 is for reporting an ***adverse event*** or a ***product problem***, or both if appropriate. Mark the ***adverse event*** box to report a death or serious injury. If a device mal-function played a role in the event, also mark the ***product problem*** box.

If there was a device malfunction that did ***not*** involve a death or serious injury, then mark the ***product problem*** box if you believe the malfunction would be likely to cause or contribute to a death or serious injury if it were to recur. Although you are not required to file such a report, FDA encourages your facility to report it to the manufacturer. You may use FDA Form 3500A (the mandatory MedWatch form) to report to the manufacturer, since it provides more detail about the event. The user facility ID number and sequence number can also be used to identify the report.

Section B - Item 2 - Identify the appropriate outcomes attributed to the event. Check the ***disability*** box,
if the device may have caused or contributed to a permanent injury or impairment.

Section B - Item 5 - The ***event description*** is important since it presents details of the device event and what effect(s) the event had on the patient. Please be sure to include all information that will assist the manufacturer and/or FDA in evaluating the event.

Section D - Identify any ***suspect medical device*** and supply all applicable information in this section. With some devices, such as implants, it may be difficult to ascertain model numbers, serial numbers, etc. In these cases, provide all numbers relevant to the device; if more information becomes available, send a follow-up report with the additional information. Record all numbers exactly as indicat-ed on the device, in the catalog, or in other accompanying material.

If multiple devices were in use when an event occurred and you are unable to determine which device(s) contributed to the event, complete additional ***Sections D (all items) and F (items 9-14)*** for each device and attach them to the report form.

Section D - Item 4 - Identify the operator of the device: health profes-sional, lay user/patient, or other. Reporters often check "other" and write, for example, "respiratory therapist" or "emergency medical technician." In such instances, the ***health professional*** box should have been checked. Remember, the term "health professional" means not only physicians but all medical personnel including nurses, therapists, and technicians.

Section D - Item 9 asks if the device is available for evaluation, and if it was sent to the manufacturer for evaluation. The user facility is ***not*** required to send a device to the manufacturer for evaluation, but FDA believes the manufacturer is the best source for proper testing and evalua-tion. In any case, ***do not send the device to FDA***, because we do not routinely evaluate failed devices.

(Continued on page 3)

A REVIEW OF MEDWATCH FORMS - *(from page 2)*

Section E - Initial reporter. This section is to identify the person at the user facility who observed or was involved in the event. ***Do not confuse this with Section F, Item 4 (contact person).***

Section F - **For use by user facility/distributor - devices only** . Use the same report number in block 2 that was recorded in the upper right corner on the front page. In block 7, check whether the report is an initial
or follow-up report. If it is a follow-up report, record its number (e.g., 1, 2, or 3). ***Always identify a follow-up report with the same ID number as the initial report.*** Include only new and/or corrected information on the report form. Do not complete the whole report again – just fill in items that differ from the initial report. This will save you time and help FDA to readily identify new or corrected information.

FORM FDA 3419 - MEDICAL DEVICE REPORTING SEMIANNUAL USER FACILITY REPORT

Part 1 - Cover Sheet

Item 1 - Report Period - Submit semiannual reports twice a year: January 1 and July 1. Include in the semi-annual report all ***reports submitted*** Jan. 1 - June 30 or July 1 - Dec. 31, as opposed to ***events occurring*** during that period. For example, if an adverse event occurs on June 24, the facility has 10 working days to complete and submit a report. You could report the event after June 30 and include it in the semiannual report for July 1 - Dec. 31 (due on January 1).

Item 5 - Record the lowest report number and the highest report number submitted to FDA and/or manufacturer(s) during the 6-month period. For example:

123456000-1990-0001 and 123456000-1990-0009.

Part 2 - Summary of Event

Complete ***Part 2*** for each event reported during the semiannual reporting period. This is the information that was submitted to FDA and/or the manufacturer on MedWatch FDA Form 3500A (mandatory MedWatch form). Instead of preparing a separate Part 2 for each event report, you may attach a copy of each report submitted. For any voluntary malfunction report made using FDA Form 3500A, you may either include inform-ation about the report in your semiannual report or simply explain that report numbers missing from the sequence were used for voluntary reports. Remember:

- Send injury reports to the device manufacturer. Do not send injury reports to FDA, unless you do not know the manufacturer of the device.

- Send death reports to FDA and to the manufacturer, if known. Submit each report within 10 working days after becoming aware of a reportable event. Mail completed forms to:

  FDA/CDRH
  Medical Device Reporting
  P.O. Box 3002
  Rockville, MD 20847-3002

Please mark the envelope to indicate the contents (i.e., Semiannual Report or User Facility Report). This will help FDA process your report.✿

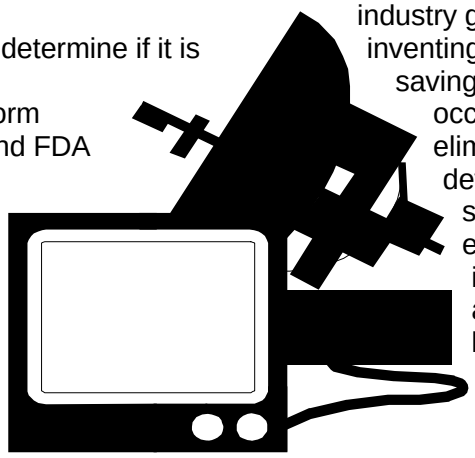
Joyce Stanley-Harris is a Program Analyst in CDRH's Office of Surveillance and Biometrics.

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; 5600 Fishers Lane (HFZ-230); Rockville, MD 20857. Back issues are also available on Internet and Facts on Demand. See Page 5.

MDR TELECONFERENCE REACHES LARGE AUDIENCE - *(from page 1)*

- establish a system that identifies device-related events;
- review each adverse event to determine if it is reportable;
- send each death report (on Form 3500A) to the manufacturer and FDA within 10 working days;
- send each serious injury report to the manufacturer within 10 days (if the manufacturer is not known, send report to FDA);
- submit semiannual reports on January 1 and July 1 ONLY if you have reported to FDA and/or a manufacturer during that 6-month period; and
- periodically audit your system to make sure it is functioning as planned.



FDA suggested establishing a team, composed of staff who are well-informed about the regulation, to determine if an adverse event is reportable under MDR. Rather than developing a completely new system for dealing with adverse events, consider modifying your present system to accommodate MDR requirements.

Perhaps the most important message from the teleconference is that FDA considers MDR to be a vital source of information about potentially hazardous devices. The agency does not consider all devices to pose a problem and recognizes that the device industry generally does an excellent job of inventing, developing, and producing life-saving technologies. However, problems do occur and FDA is responsible for eliminating or reducing public exposure to device hazards. Through the MDR system, FDA receives adverse experience information for review and initiates corrective action where appropriate. User facilities and their healthcare professionals are in the best position to recognize device problems and report them.

FDA also believes that submitting an MDR report should be viewed as an essential aspect of patient care. It is an opportunity for a user facility to further protect patients by ensuring that device-related problems are promptly identified, evaluated, and corrected. Your MDR submission is more than just a report – it is the first step in a system that investigates the adverse event, determines possible causes, and takes corrective action when necessary to protect patients.✿

Chester T. Reynolds is Associate Director for MDR Policy in the Office of Surveillance and Biometrics. He is currently working with the Office of Compliance to develop an MDR Compliance Program.

HEATING PADS - *(from page 1)*

infant had died as a result of third-degree burns from a heating pad, coupled with the infant's compromised health status. Most burns were due to user error, such as prolonged use, sleeping while using the heating pad, using an old or worn heating pad, and ignoring the warning label's caution against use on patients with insensate skin. At particular risk are infants and the elderly.

"Your MDR reports to FDA do make a difference."

Since an electric heating pad is a common consumer product, FDA contacted the Consumer Product Safety Commission (CPSC). CPSC reported that each year about eight deaths occur and over 1,600 burns are treated in hospital emergency rooms as a result of using electric heating pads. About 45% of those injured are over age 65.

After deliberations with CPSC, a joint FDA/CPSC Public Health Advisory, "Hazards Associated with the Use of Electric Heating Pads", was issued on December 12, 1995, to inform health professionals and consumers of the potential risks. The Advisory was sent to hospitals, nursing homes, hospices, healthcare professionals, home healthcare agencies, and consumer groups throughout the country. Your MDR reports to FDA do make a difference.✿

Joan Rudick is a Public Health Analyst in the Office of Surveillance and Biometrics.

WHERE TO GET MDR MATERIALS

NTIS. The National Technical Information Service (NTIS) sells all MDR materials. These include the forms; instructions and coding manual for FDA Form 3500A; guidance documents for user facilities, manufacturers, and distributors; and *Federal Register* notices (in paper copy or on microfiche). Also available are a videotape of the May 7, 1996, teleconference and two instructional videotapes about how to complete forms 3500A, 3419, 3417 and 3381. You can order any of these materials by calling 703-487-4650 or writing to NTIS at 5285 Port Royal Road, Springfield, VA 22161. For a listing of the NTIS materials and their costs, request document number 3799 from Facts on Demand (see below).

Internet. We maintain an Internet World Wide Web site for easy access to MDR information. The FDA home page can be accessed at: **http://www.fda.gov** . Click on the Medical Devices and Radiological Health icon, then on Program Areas, then on Medical Device Reporting (MDR) to reach the MDR documents and back issues of the *User Facility Reporting Bulletin*.

Facts on Demand .. Using a touch-tone telephone, you can obtain additional information through CDRH's 24-hour (7 days a week) automated FAX system called Facts on Demand (FOD) at 800-899-0381 or 301-827-0111. Specify document number 5799 to get a listing of MDR documents available through Facts on Demand (select 1 at the first voice prompt, 2 at second prompt, and then follow subsequent prompts). Request document 3799 for a listing of MDR documents available from NTIS and document number 7799 for a listing of MDR documents on Internet.✿

FREQUENTLY ASKED MDR QUESTIONS

By E. Wayne Robinson

Question: *Which MedWatch form should a facility use to voluntarily report a malfunction that did not result in a death or serious injury — the voluntary report form or the mandatory one?*

Answer: FDA requests user facilities to voluntarily submit reports of malfunctions that are likely to result in a death or serious injury if they recur. FDA suggests using the mandatory MedWatch form (FDA Form 3500A), because it provides for more information about the event.

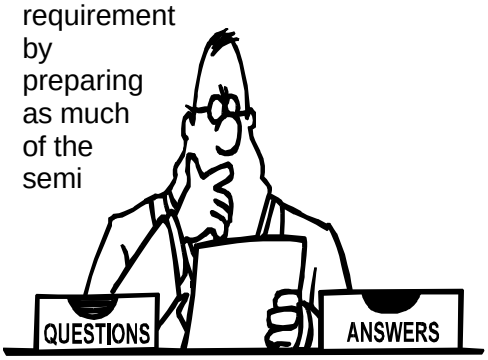
Send the report to the manufacturer rather than FDA, so the manufacturer can evaluate the event. The user facility should assign a user facility report number to each voluntarily submitted malfunction report.

Question: *Should voluntary reports of malfunctions be included in the semiannual report?*

Answer: User facilities do not have to include voluntarily submitted reports in their semiannual reports. However, omitting these reports will leave gaps in the user facility report number sequence. Therefore, the user facility should explain in the semiannual report that the missing numbers were assigned to voluntarily submitted malfunction reports.

Question: *Semiannual reports are due on January 1 and July 1 of each year to cover the 6-month periods ending December 31 and June 30, respectively. Why doesn't FDA allow more time for preparing these reports? Do you really expect user facilities to prepare semiannual reports on holidays or weekends?*

Answer: Because the Safe Medical Devices Act specified the due dates for semiannual reports, FDA did not have the flexibility to allow more time. User facilities may minimize the difficulty in complying with this requirement by preparing as much of the semi annual report as possible before the due date.



The semiannual report can be finished and mailed by the close of business on the last work day before the due date. Remember, the semiannual report must include all reports **submitted** during the report-ing period. Therefore, if an event occurs less than 10 working days prior to the semiannual report due date and an individual event report has not been submitted, that event need not be included in the semiannual report.

(Continued on page 6)

FREQUENTLY ASKED MDR QUESTIONS - *(from page 5)*

Question: *What is meant by "user error" and why does FDA require that it be reported?*

Answer: User error is any error or mistake made by someone using a medical device. It might result from: labeling that is inadequate, confusing or misleading; poor design of the device; or simple errors of judgment. User error (or "use error" as it is sometimes called) is report-able by user facilities if the error was a factor – or may have been a factor – in a reportable device-related event, i.e., a death or serious injury.

FDA wants reports of user error, because they may indicate the need for: (1) better design or labeling of the device; (2) notifying users about the problem; or (3) better education of device users. FDA is **not** concerned with the identity of the person who made the error, but we are concerned about **why** the error was made and **how** to prevent its recurrence.✿

E. Wayne Robinson is a specialist in Medical Device Reporting in the Office of Surveillance and Biometrics.

WE URGE YOU TO REPORT MEDICAL DEVICE DESIGN PROBLEMS

By Ron Kaye

FDA urges user facility personnel to report problems they feel may be caused by device design. Injuries and deaths have resulted from well-intentioned users who made errors because of design features of the medical devices they used. Errors can be made by anyone who uses a medical device, including patients, practitioners, and maintenance personnel. In addition to potentially fatal errors, poorly designed equipment causes frustration, anxiety, confusion, and delays, which can then lead to other kinds of errors. Many of these errors could be prevented. In some cases, manufacturers could do a better job designing devices to accommodate users. In other cases, the manufacturer and FDA could have been made aware of the problem earlier. As a device user, you can help prevent future errors by reporting problems with the design of medical devices. This article will help you better understand problems with device design and how to report them.

"As a device user, you can help prevent future errors by reporting problems with the design of medical

You may experience a problem with the design of a device that causes you to make an error. On another occasion, you may notice a problem but avoid making an error. Either way, reporting the problem will help others analyze the problem and correct it. You can report medical device design problems on Form 3500 (voluntary) or 3500A (mandatory). We suggest you use Form 3500A because it requests more device information about the problem. In either case, we urge you to describe how the device was being used when the problem occurred. The paragraphs that follow are intended to provide a basic understanding of the relationship between errors and device design.

"Severe design problems may actually *lead* the user to commit an error."

It is often difficult to know whether or not errors are design-related. We often blame ourselves for errors that result from inadequacies of device design. It is difficult to accept the fact that we may make an error in spite of our best efforts, but we can take comfort in knowing that we are not alone. Most of us have been "stuck" or confused when using a computer application, because the information display did not give clear guidance as to the next action to take. Too often, design problems in computer applications, medical devices, and even everyday consumer devices can cause confusion and *invite* error. Severe design problems may actually *lead* the user to commit an error.

Good device design anticipates user errors and takes steps to prevent them. This requires careful consideration of the abilities and expectations of the users, the characteristics of the environment in which the device will be used, possible

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WE URGE YOU TO REPORT MEDICAL DEVICE DESIGN PROBLEMS - *(from page 6)*

error scenarios, and errors that have occurred with similar devices. A good design will have incorporated these considerations to ensure safe and efficient use of the device. Good design will also incorporate specific measures to prevent serious errors. A mismatch between the design of a device and any of the above consider-ations will increase the likelihood of error. For example, manufacturers may overlook the special design considerations needed when devices will be used by those having restricted abilities due to age, disability, or any condition that affects movement, coordination, thought processes, or the senses. User expectations based on established operating procedures or prior use of similar devices may also be overlooked by designers.

Devices and users interact through what is called the *user interface*. A *user* is anyone who interacts with the device, including the practitioner, patient or lay user, reprocessor, or maintainer. The *user interface* is the medium through which any user interacts with a device. Obvious parts of the interface are the controls, displays, and alarms. Less obvious are the operating procedures, manuals, labels, operating instructions, maintenance procedures, and training necessary to install, operate, and maintain the device.

"As a device user, you may find that identifying and understanding inadequacies in the design of medical device user interfaces can be a challenging task."

As a device user, you may find that identifying and under-standing inadequacies in the design of medical device user interfaces can be a challenging task. There are countless examples of deficient user interfaces that have led to problems. These problems can manifest themselves in a variety of ways; three examples are provided here:

***Example 1*- Flexible GI endoscopes:** The design of some endoscopes includes small internal channels. These channels are poorly reached by the cleaning tools typically used for this task, and the design provides no means to monitor the effectiveness of the cleaning. The result is that endoscopes are sometimes insufficiently disinfected between patients. Although the user does not clean the endoscope adequately, the designer of the endoscope bears responsibility for having designed a device that invites the user to commit this error.

***Example 2* - Blood recovery devices:** Some blood recovery devices may over-pressurize clamped tubing carrying blood and cause it to burst. This happens when personnel use the device in ways that the designer did not anticipate. Operating room (OR) personnel often temporarily clamp the tubing leading from the blood recovery pump with a hemostat while changing infusion bags between automatic pumping cycles. There is no pressure sensor in the circuit to stop the pump if the hemostat has not been removed when the pump cycles on again. Thus, the tubing may rupture, spewing potentially infectious blood throughout the OR. The user error is failing to remove the clamp prior to the pump cycling on. In this example, the way the device is actually used differs from the way the designer thought it would be used because important characteristics of the user environment were not considered.

***Example 3* - Laparoscopic insufflators:** After use, these may be contaminated with patient material that has flowed backwards from the patient into the insufflator. The user may not be able to see that the device is contaminated and may introduce contamination into the next patient. The designer did not anticipate this problem when the device was designed and, therefore, bears responsibility for the design that leads to this error.

As a medical device user, you and your patients have the most to gain from devices that are well-designed. As a customer, you can exercise your influence by encouraging manufacturers to design devices that are appropriate and effective for users. Manufacturers need to understand that purchasers of their equipment are concerned about the safety and effectiveness of its design. You can exercise your influence by critically evaluating a product's user interface before deciding to purchase it. When you use a device, inform the manufacturers about design features that you believe could lead to errors. In the final analysis only you, the device user, can judge the design of a device.✿

Ron Kaye is a Human Factors Psychologist in the Office of Health and Industry Programs, CDRH .

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Food and Drug Administration
Center for Devices and Radiological Health (HFZ-230)
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Important information from FDA about Medical Device Reporting

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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.

Editor: Nancy Lowe
Assistant Editors: Herb Spark
Mary Ann Wollerton
Graphics Specialist: Edie Seligson

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
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