FOOD AND DRUG ADMINISTRATION

USER Facility Reporting

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MEDICAL DEVICE REPORTING: A PUBLIC HEALTH PARTNERSHIP

By Chester T. Reynolds

The final Medical Device Reporting (MDR) regulation was published in the December 11, 1995, *Federal Register*. This new regulation facilitates the implementation of the user facility reporting requirements of the Safe Medical Devices Act (SMDA) and adds new requirements. It also makes significant changes in the existing reporting requirements for device manufacturers to make their reporting requirements consistent with those for user facilities. The effective date for MDR was extended from the original date of April 11, 1996 to July 31, 1996, to give additional time for user facilities and manufacturers to prepare for the new requirements.

Publication of a final MDR regulation culminates years of effort to develop a device reporting partnership among the Federal, manufacturing, and medical communities. The new MDR system is designed to ensure that the most serious problems with medical devices will be identified at the user level and reported to, then investigated by, the manufacturer and FDA. The agency will work within the device community to determine if safety problems exist; explore the most effective strategies for resolving problems; and provide feedback to users, manufacturers, and the public.

All three partners are necessary for MDR to be successful, but the most important partner is the user facility. Only the user facility has direct access to the patient and the device, as well as the clinical skills necessary to detect any adverse effects. Once a device-related event is identified, the user facility is in the best position to obtain information that manufacturers and FDA need to determine whether the event presents a public health risk.

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HUMAN FACTORS AND MEDICAL DEVICES: LACK OF DEVICE FEEDBACK

By Marilyn Sue Bogner, Ph.D.

Medical device design should be user-driven, i.e., designed with the user in mind. Human factors problems occur when medical devices are not designed to accommodate the characteristics of the users and the environments in which the devices are operated. If a device is not designed for the user, problems in use can result in spite of the user's training and caution.

Although human factors problems may occur in the use of simple devices, they are much more likely to arise in the use of technologically advanced devices, e.g., programmable devices such as infusion pumps. When problems occur in the use of devices, users tend to blame themselves, thinking they should have known better. Remedial efforts often focus on the users, such as providing additional training or creating special teams to handle the equipment. These activities may not substantially reduce the problem when it stems from faulty design of the medical device. Devices that are not designed for ease of operation can be difficult to operate safely and effectively, leading to errors.

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In This Issue:

FDA WILL PRESENT LIVE SATELLITE TELECONFERENCE ON FINAL MDR REGULATION

On May 7, 1996, from 1:00 to 4:00 p.m., e.s.t., the Food and Drug Administration will present a **live** satellite teleconference on the final Medical Device Reporting (MDR) regulation which contains some **new requirements** that device user facilities need to know.

Which user facilities must comply with provisions of the final MDR?

Hospitals – providers of diagnostic, therapeutic, surgical, and other patient services which include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities

Ambulatory Surgical Facilities – providers of same-day outpatient surgical services

Nursing Homes – providers of skilled nursing care, hospice care, or rehabilitation services

Outpatient Diagnostic Facilities – providers of diagnostic testing on an outpatient basis, for example, diagnostic radiography, mammography, ultra-sonography, electrocardiography, magnetic resonance imaging, computerized axial tomography, and in-vitro testing services (Note: does not include physicians' offices.)

Outpatient Treatment Facilities – providers of nonsurgical therapeutic care on an outpatient basis; includes ambulance providers, rescue services, and home healthcare services (Note: does not include physicians' offices.)

What will the broadcast cover?

The broadcast will cover the following:

- Purpose of the MDR regulation
- How the regulation will affect user facilities
- How to report adverse events to FDA and manufacturers
- Required reporting forms
- Information required in reports
- Requirements for semi-annual reports
- How FDA uses the data received
- Regulatory sanctions

Who should watch this teleconference?

- Patient care providers
- Nurse administrators
- Facility administrators
- Risk managers
- Quality assurance managers
- Providers of ambulance or rescue services
- Providers of home healthcare services
- Biomedical/clinical engineers or technicians
- Anyone who becomes aware of a device-related death or injury in a user facility

How much will it cost to receive the broadcast?

There is **no charge** to receive this broadcast. You must have access to a Ku-band or C-band satellite dish in order to receive the signal. Unfortunately, FDA cannot arrange individual downlink sites. Places you might contact for assistance in locating a dish include:

- Hospitals
- State/local health offices
- Fire/rescue stations
- Professional associations
- Colleges/universities
- Cable TV stations
- Hotels

The site for the broadcast may charge a service fee. If you find there is a fee, consider forming a partnership with other facilities in your area to share the costs of the viewing station.

How can I participate?

To receive the satellite coordinates, you **must register** for this event; call 1-800-305-0748* and give your FAX number. You will receive back ***by FAX*** the satellite coordinates and important telephone numbers to call on the day of the broadcast.

*The 800 number will not give you specifics about the MDR regulation. Information that will be helpful for the teleconference can be obtained from the Internet at **http://www.fda.gov** (see article on page 5 of this Bulletin for instructions on how to get to the MDR home page on the Internet). *Mary Ann Wollerton, Reporter.*

MEDICAL DEVICE REPORTING: A PUBLIC HEALTH PARTNERSHIP - *(from page 1)*

FDA wants to be sure that user facilities understand the important role they play in this partnership. Reporting is required by law, but public safety information has always been an important concern of the entire device community. MDR should be viewed as part of total patient care and professional responsibility, not just another reporting requirement. The only way FDA and manufacturers can obtain quality information about actual and suspected device problems is for well-informed users to take an active and determined part in MDR reporting. MDR will increase our knowledge about device safety problems and provide better information for all concerned.

Although user facilities have been required to report deaths and serious injuries since 1991, the final MDR regulation also contains some new requirements. The following is an overview of the major requirements of the final MDR regulation, but it is important to review the entire regulation.

What, When, & Where to Report

• **Deaths** - to FDA **and** the manufacturer within 10 working days.

• **Serious injuries** - to the **manufacturer only** (if the manufacturer's name is unknown, then to FDA) within 10 working days.

• **Summary of reported deaths and serious injuries -** to FDA on January 1 and July 1. This report sum-marizes all death and serious injury reports submitted to FDA **and** manufacturers for the previous six-month period.

• **Malfunctions** - Although user facilities are not required to report malfunctions that do not result in death or serious injury, FDA encourages user facilities to report

such events directly to manufac-turers using Form 3500A. Unlike user facilities, device manufacturers and distributors must report malfunctions to FDA and they need your input.

Highlights of the New Regulation

• **Definitions** - The MDR regulation contains 30 definitions that clarify terms and concepts contained in the regulation. For example, the MDR regulation defines who is considered a "patient" for purposes of reporting and when a device actually "causes or contributes to a reportable event." Understanding the definitions is necessary in order to comply with the regulation.

• **Forms** - User facilities will use two reporting forms– Mandatory MedWatch Form 3500A for reporting deaths and serious injuries and FDA Form 3419 for semi-annual reports. In addition to several other reporting forms, manufacturers and distributors are required to complete their sections of Mandatory MedWatch Form 3500A.

– **Individual Reports** - Each MDR report must be submitted on Mandatory MedWatch Form 3500A.

– **Semi-Annual Reports** - All semi-annual reports must be submitted using FDA Form 3419. In lieu of submitting a summary of each reported event, a user facility may complete only Part 1 of Form 3419 and attach a copy of each mandatory report (Form 3500A) filed during the reporting period. If no MDR reports were submitted during the reporting period, a semi-annual report is **not** required.

• **Requests for Additional Information** - FDA staff may contact a user facility by phone or in writing for additional information concerning an event. These requests will have a specified time limit for response and will require prompt attention.

• **Written MDR Procedures** - User facilities, as well as manufacturers, must have written guidance explaining how they intend to comply with MDR requirements.

• **Files** - User facilities must establish and maintain files that contain a copy of every report and all information sent to FDA and/or the manufacturer,**as well as information about events that were evaluated but not reported.** The file on an unreported event must explain why the user facility did not file a report.

• **Reporting Codes** - Form 3500A requires user facilities to provide patient and device codes from the MedWatch coding manual. It is important not to leave **any** fields blank on the MDR form, since a blank field will result in FDA followup. This information is needed by both the manufacturer and FDA to evaluate the event and analyze the MDR data.

• **Inspections** - User facilities will be visited by FDA investigators to determine whether they are in compliance with MDR. At the conclusion of each inspection, the facility will be given a written report; any observed MDR violations will be listed. To avoid sanctions, violations must be re-solved promptly. *(Continued on p.4)*

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• **Sanctions** - FDA can issue various types of written notification to inform a user facility of its failure to comply with MDR. An inadequate response could result in civil monetary penalties or warning letters.

When FDA receives an MDR report, our healthcare professionals evaluate it and compare it to other data. A decision is then made regarding its actual or potential risk. Depending on the nature and severity of the risk, appropriate corrective action is initiated. In addition, FDA maintains MDR data in an automated information system that is used by FDA staff to assess device safety and identify trends.

Last year, FDA received over 95,000 MDR reports; many of these were submitted by user facilities. During this same period, FDA classified over 500 device recalls that involved thousands of devices in user facilities and other locations.

User facility participation in MDR should increase the number of reports about medical device problems and improve the quality of the information they contain. This will increase our ability to resolve safety problems.

In order to effectively participate in the MDR partnership, it is important for your facility to obtain a copy of the MDR regulation; the reporting forms, instructions, and codes; and FDA guidance on how to implement your MDR program. (See page 5 of this Bulletin for instructions on how to obtain MDR information.) FDA will continue to provide guidance and plans to hold a teleconference on May 7, 1996, to discuss MDR in detail and give you an opportunity to ask questions. Details about the teleconference appear on page 2 of this Bulletin; additional information will appear in the Spring issue. If you have questions after reading the MDR materials, please FAX them to 1-301-594-2235.

MDR PROGRAM STARTER KIT

THINGS TO DO

[ ] Obtain MDR Documentation
- Regulation
- Reporting forms
- Instructions/coding manual
- Guidance manual**:** *Medical Device Reporting for User Facilities*

[ ] Designate MDR Contact Person

[ ] Develop Written Procedures

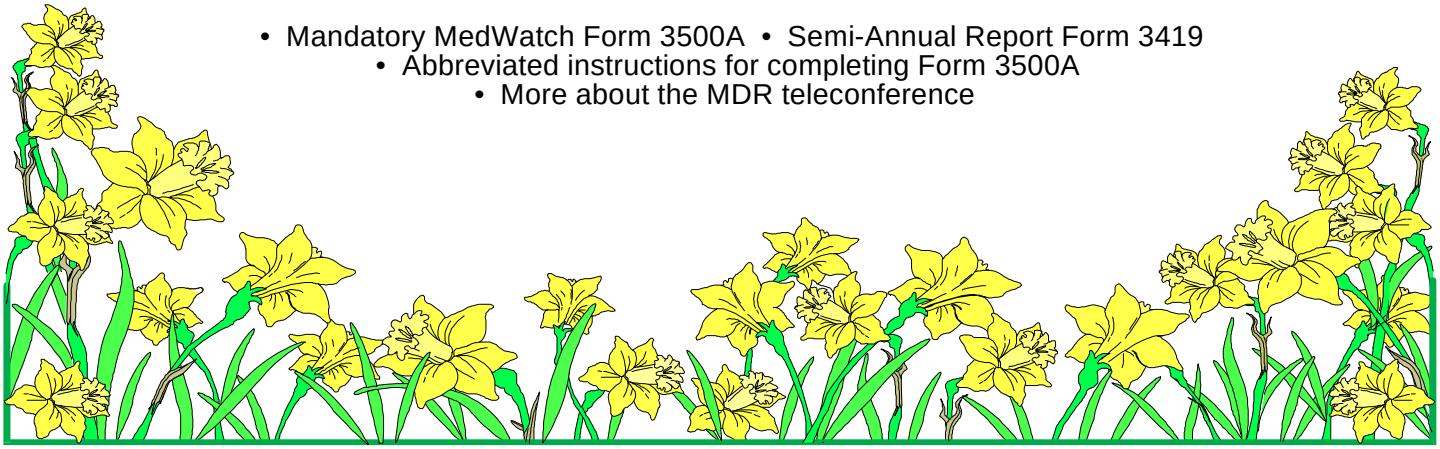
[ ] Establish MDR event file

[ ] Develop internal systems to**:**
- Identify device-related events
- Determine whether events must be reported
- Provide documentation of decisions
- Ensure that forms are properly completed and submitted

Chester T. Reynolds is Associate Director for MDR Policy in CDRH's Office of Surveillance and Biometrics. He is currently working with the Office of Compliance to help develop its MDR Compliance Program.

Coming in the Spring Issue of the Bulletin

• Mandatory MedWatch Form 3500A • Semi-Annual Report Form 3419
• Abbreviated instructions for completing Form 3500A
• More about the MDR teleconference



USER FACILITY REPORTING BULLETIN AND MDR INFORMATION ARE NOW ON INTERNET

by Kevin O'Reilly

FDA now has a homepage on the Internet, with links to various programs. FDA's address (or URL) is:

http://www.fda.gov

To access the medical device reporting (MDR) information, click on the following menu items in sequence (after each selection a new screen will appear; wait until the screen is completed before clicking on the next item):

1. Medical Devices and Radiological Health
2. Program Areas
3. Medical Device Reporting (MDR)

The MDR homepage contains links that enable you to access issues of the User Facility Reporting Bulletin, Mandatory MedWatch Form 3500A, instructions and codes for completing 3500A, and the final MDR regulation from the Federal Register of December 11, 1995. All documents are in **Portable Document Format** (PDF). To view them, you must have a program that reads PDF.

We have provided a link to the Adobe homepage so you can download a **free** PDF reader, called **Acroread**. Follow these steps in sequence (they will only work if you have Windows 3.1 and the Netscape web browser).

Creating An Acroread Directory

1. If you're in Netscape, exit.

2. Double click on the **File Manager** icon. It looks like a filing cabinet.

3. Click on **C:** at the top of the next screen to get into the root directory.

4. Click on **File,** then click on **Create Directory**. Name the directory **Acroread** and click on **OK**.

5. Click on **File,** then click on **Exit**.

Downloading the Acroread Program to the Acroread Directory

6. Return to Netscape, then return to the MDR homepage. Click on **Free Readers for PDF files**.

7. Once the Adobe webpage loads, click on **Free Acrobat Reader**.

8. Click on **Adobe (R) Acrobat (R) Reader 2.1 for Windows (R)**.

9. As you scroll down, you'll see a **DOWNLOAD** list. Click on **US English DOWNLOAD 1528560 bytes**.

10. At the next screen, click on **Save to Disk**.

11. In the small box, under **Directories**, double click on **C:**.

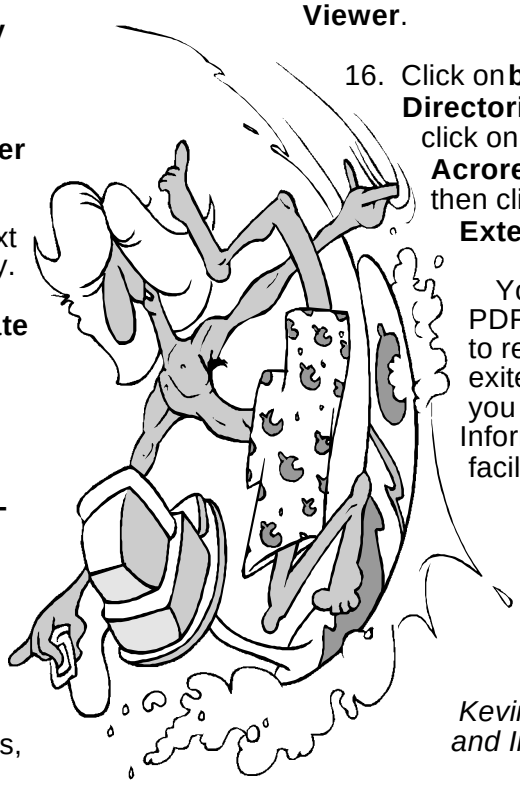
12. In the same box, double click on **Acroread**, then click on **OK**. Acroread will take a while to download; when it has finished, exit Netscape.

Setting Up Acroread

13. Return to **File Manager** and click on **Acroread**.

14. On the right side of screen, double click on **Acroread.exe**. This will set up Acroread. Click on the following, in sequence: **Accept**, **Install**, **OK**. Minimize Adobe Acrobat after the installation is complete.

15. Return to Netscape, then return to the MDR homepage. Click on the PDF document you wish to read. This will create another window asking what you want to do with this document. Click on **Configure a Viewer**.



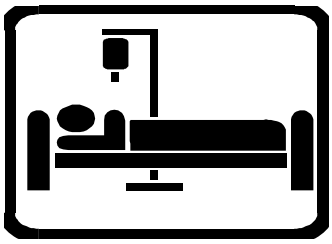
16. Click on **browse.** In the small box, under **Directories**, double click on **C:**, then double click on **Acroread**. In the left box, click on **Acroread.exe**, then click on **OK**. Wait, then click on **OK** at the **Configure External Viewer** window.

You should now be able to view all PDF files on the Internet. You may have to repeat steps 15 and 16 when you have exited Netscape and want to re-enter. If you have questions, please consult the Information Systems Specialist in your facility.

Happy Surfing!

Kevin O'Reilly, in the Office of Health and Industry Programs, specializes in information systems.

HUMAN FACTORS AND MEDICAL DEVICES: LACK OF DEVICE FEEDBACK - *(from page 1)*



Problems in the use of technologically advanced medical devices reflect experience with technology throughout society. Donald Norman, a well-known writer and applied researcher, points to a common source of use error in his book, *Turn Signals are the Facial Expression of Automobiles* (1992, Reading, MA: Addison-Wesley Publishing Company, Inc.). He states:

> Much of modern technology seems to exist solely for its own sake, oblivious to the needs and concerns of the people around it, people who, after all, are supposed to be the reason for its existence. (p. *ix*)

Many aspects of technology invite error. This article addresses one type of use problem in complex, technologically sophisticated medical devices– the lack of feedback to indicate the state of the device.

Feedback in Medical Devices

Feedback is the indication of a device's reaction to the user's action. It is information that acknowledges the action, providing a basis for the next action. Lack of feedback occurs when users receive no useful information about a device's response to their actions. In some cases, the lack of informative feedback may not be a problem. For example, in dialing a telephone number, the feedback a person typically receives is the sound that indicates entry of each number and the ringing when dialing has been completed. This level of feedback is sufficient unless the user is distracted while dialing and loses track of how many numbers have been dialed. However, when an incorrect number is dialed, it is a simple matter to hang up and redial.

Another type of error in telephone dialing occurs when a person begins dialing a number that is similar to a familiar number and– instead of completing the intended number– the person dials the more familiar number. The less familiar activity is taken over and transformed into a similar, more familiar activity. This is referred to as "capture." Feedback about actions can reduce the likelihood of capture by providing the user with reminders. An example of such feedback is seen in telephones that display the numbers that have been dialed. When a user experiences distraction or capture, the display provides a record of activity.

Many medical devices are technologically sophisticated and involve programming that is similar to dialing a telephone, with the same possibilities for distraction and capture but with far more serious consequences. Most programmable medical devices provide negligible feedback– not even the feedback of sound to acknowledge an action by the user.

An infusion pump provides an example of the importance of feedback in medical devices. Regardless of the setting in which an infusion pump is used– hospital, clinic, or home– the person programming the pump may be distracted. Stress, which is commonplace in the healthcare setting, also can reduce a person's level of cognitive functioning, including the ability to remember. Without feedback about which steps have been executed, persons programming infusion pumps may not recall where they are in the process. When resuming programming after a distraction, they may continue from where they believe they are in the task, or return to the beginning. Feedback in the form of an ongoing record of the programming would reduce the likelihood of error resulting from inaccurate recall of the executed steps.

Opportunities for capture also exist in programming infusion pumps. A person who works in a particular unit of a facility may become accustomed to programming infusion pumps to deliver medication in a specific way because of the type of patient on the unit. The person may then be assigned to work in another unit in the facility where pumps are programmed differently. When an initial segment of the new programming is the same as, or similar to, familiar programming, the person's intention to execute the new programming may be captured by the familiar and result in a distortion of the desired programming. Again, feedback in the form of an easily accessed record of programming activity would allow the user to confirm programming of the intended steps.

"The human factors approach considers not what users should do, but what typical users actually do."

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Mode of Operation Feedback

The following example is based on a Medical Device Report (MDR) of an adverse event filed with FDA. This example points to the importance of having information readily available about the mode of operation of infusion pumps.

> An RN programmed an infusion pump to give two initial doses of pain medication. She thought the concentration mode was set at 1.0 mg, but it had actually been set at 10.0 mg by the previous user. After initial setup, the pump does not indicate the concentration mode. The patient was given two initial doses at ten times the intended dose. The patient arrested but was revived.

This adverse event resulted from a human factors problem: the user did not have a clear indication of the state of the pump on which to base subsequent actions. It might be expected that the user would program an initial setup with each use, but that often is an unrealistic expectation given the user's workload. The human factors approach considers not what users should do, but what typical users actually do. In the above example, user-driven design would provide a clear indication of the concentration mode currently programmed into the device. Alternatively, the concentration could default to zero any time the pump is disconnected, making it necessary to enter the drug concentration with each use. When a medical device design is developed using such human factors considerations, the final device can be more safely and effectively operated by typical users in typical use environments. FDA needs your help to know about use problems so that human factors issues can be addressed.

"Remember: If you have a problem, report it!"

Accessory Attachment Feedback

Lack of feedback about how an accessory of a device is attached can lead to adverse events. Infusion pump tubing is such an accessory attachment. Most users have experience with the typical procedure in which the tubing is threaded from the top to the bottom. When they are faced with a pump in which the tubing must be loaded differently, i.e., from the bottom to the top, the less familiar procedure may be captured by the familiar. This results in the user attaching the tubing from the top to the bottom. The following example, based on an adverse event report submitted to FDA, illustrates the phenomenon of capture.

> The infusion pump design required the tubing to be attached by threading it from the bottom up. After correctly performing the initial steps, the nurse then threaded the tubing from the top down – in spite of receiving training by the company representative. The medicine over-infused, and the patient's health status was compromised.

This event would not have occurred if the pump had been designed to provide feedback to alert the user to incorrect attachment of the tubing or if the design had prevented the device from functioning when the accessory tubing was attached improperly. Another human factors approach would be to design the tubing pathway to prevent incorrect threading. These human factors approaches reflect knowledge of the characteristics of the users, their work environments, and the problems they experience. FDA wants to learn about problems with device attachments.

Single Flashed Message Feedback

Some medical devices provide feedback, but display the message so briefly that users only see it if they are looking directly at the display at the moment it appears. When users are not aware of the message, they continue to use the device without taking into account what could be important information. In some instances users notice that there is a display, but the message appears so briefly it cannot be comprehended. Typically, such messages cannot be retrieved – even if the information can be retrieved, users must first be aware that a message has been flashed in order to realize they need to retrieve it. Human factors based design would provide a message that stays on the screen until acknowledged by the user pressing a button. Additionally, an audible signal could alert the user to the presence of the message.

Importance of Reporting Use Problems

Undoubtedly you know of other cases where useful feedback is needed, as well as other problems in using medical devices. Not only might these problems contribute to an event that harms a patient, they also may cause you to spend a lot of energy developing "work-arounds" – energy that could be better spent in other tasks. This knowledge is

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HUMAN FACTORS AND MEDICAL DEVICES: LACK OF DEVICE FEEDBACK - *(from page 7)*

important to FDA and the manufacturer – even when death or serious injury has not occurred. **Remember: If you have a problem, report it!** Others may have the same problem. Lack of feedback, and other problems in the use of medical devices, represent errors waiting to happen. Most adverse events actually result not from a single error, but from a cascade of errors. Information you provide about use problems can lead to changes that reduce the likelihood of adverse events.

FDA has two systems for reporting problems with the use of medical devices. If the problem results in serious injury or death, you are required to report, using Mandatory MedWatch Form 3500A. If a malfunction or other product problem does not involve a serious injury or death, FDA encourages you to report it to the manufacturer. Although this reporting is voluntary, we suggest using MedWatch Form 3500A because it provides more information to the manufacturer.

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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.

The publication's contents may be freely reproduced. Comments should be sent to the Editor.

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