FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING (FDA MEDICINE MANUFACTURERS)

USER Facility Reporting

Issue No. 18 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Winter 1996

FDA HOLDS TRAIN-THE-TRAINER COURSE

FDA's Center for Devices and Radiological Health (CDRH) recently held a Medical Device Reporting (MDR) course to train representatives of healthcare organizations about the requirements of the MDR regulation. Attendees learned how to teach members of their respective organ-izations to comply with the MDR regulation and to file adverse event reports correctly.

FDA speakers at the 1½-day session encouraged participants to discuss any reporting problems they had encountered. Several speakers walked the students through adverse event scenarios to "fine tune" their MDR processing skills. Developing a decision tree to determine whether an adverse event is reportable was a major topic. See Issue 6 of the *Bulletin* for a sample decision tree.

In their course evaluations, students praised the "hands-on" approach. Most attendees mentioned that the practical exercises, together with the comprehensive notebook, would be very helpful as they prepared their own training sessions at their work sites. Many students indicated that they also plan to write articles about adverse event reporting for their professional journals.

Organizations represented at the course were the American Association of Homes and Services for the Aging, American Health Care Association, National Association for Home Care, American Ambulance Association, National Association of State Emergency Medical Services Directors, National Institutes of Health, and Manor Care Associates. (See article below.)

FDA REGIONS OFFER MDR TRAINING

By Brenda Lucas

FDA's Center for Devices and Radiological Health (CDRH) has designed a training course to familiarize user facilities and manufacturers with current Medical Device Reporting (MDR) requirements. The course, based on the new MDR regulation that became effective July 31, 1996, consists of three learning modules: an overview of the regulation, requirements for user facilities, and requirements for manufacturers.

CDRH has also trained the FDA field staff to present this course. They are now available to provide training at the regional level to user facilities and manufacturers on : (1) who has to report; (2) what has to be reported; (3) forms required and how to complete them; and (4) other requirements to comply with the regulation. Students who complete the course will be able to conduct training sessions at their own facilities using the materials provided in the course notebook.

The three-module structure provides a flexible education package. Each module takes approximately 90 minutes to present. If training time is limited, the overview module can be presented alone to provide general information. If more training time is available, the overview can be presented in com-bination with either the user facility module or the manufacturer module.

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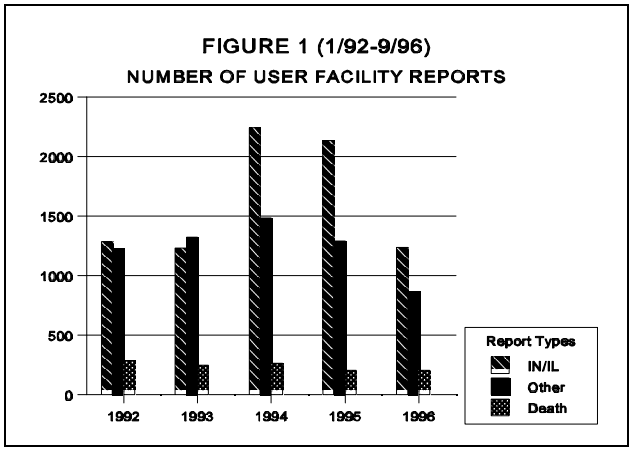
In This Issue:

SUMMARY OF USER FACILITY REPORTING: 1992-1996

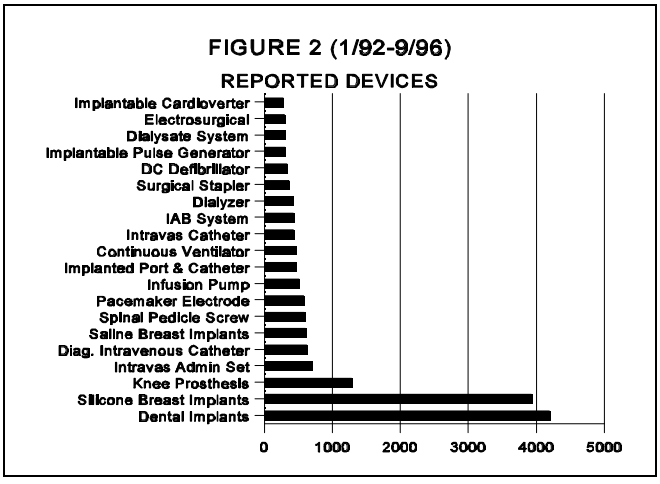
By Joyce Stanley-Harris and Arlene Underdonk

User facilities have been submitting reports for nearly five years. We thought you would be interested in some Food and Drug Administration (FDA) statistics concerning these reports. This analysis includes data from January 1992 through September 1996 (reported deaths, serious injuries, and serious illnesses). The data were analyzed for the reported devices, the type of facility that reported, and specialty areas in which adverse events occurred.

The data in Figure 1 show that reports of deaths have remained fairly constant, with an average of 243 reports yearly. User facility reports of serious injuries and serious illnesses (IN/IL) were higher during 1994 and 1995 due to increased reports involving silicone breast implants. "Other" refers to reports of use problems that do not involve injury or death or reports that contain inadequate information to classify.



In Figure 2, the largest number of reports (4,187) are for dental implants. Silicone breast implants follow closely with 3,928 reports submitted.



In Figure 3, the specialty with the highest number of reports submitted is general and plastic surgery, (7,181 reports). Cardiovascular is second with 5,256 reports

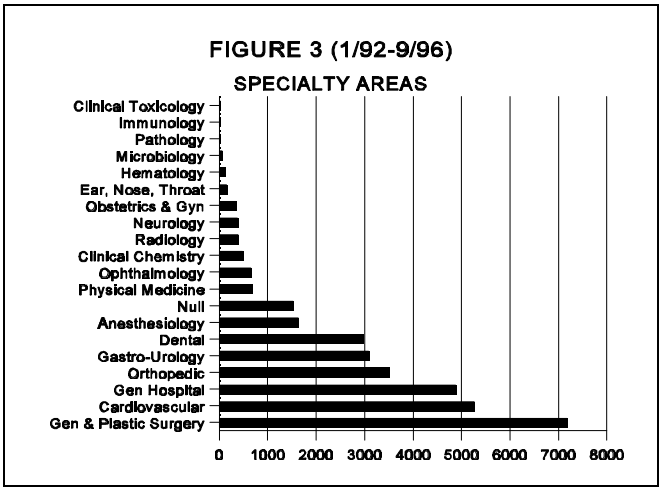
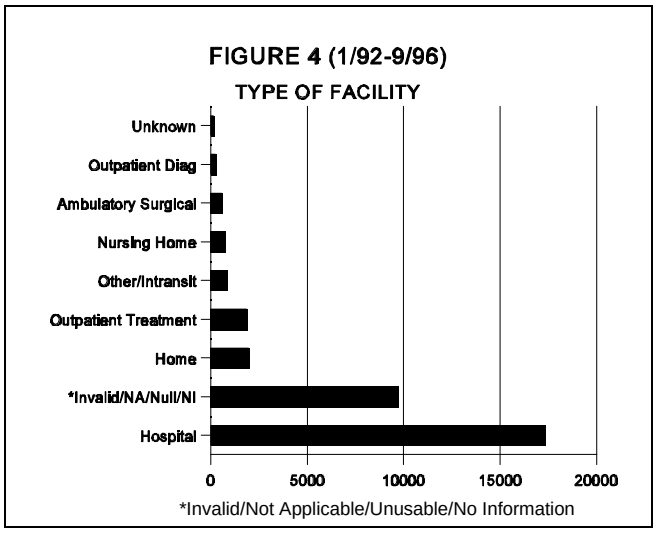


Figure 4 below shows that hospitals submit the majority of reports (17,306), followed by home healthcare facilities (1,956 reports), outpatient treatment facilities (1,844 reports), and nursing homes (733 reports). However, the type of user facility for 9,674 reports could not be determined.



The medical device reports FDA receives from user facilities provide valuable information. We use the data from these reports to alert FDA of imminent danger and to conduct trend analyses on medical devices that could present risks to the public health. FDA also uses the data to analyze reporting trends and to create a dialogue between FDA and manufacturers when problems occur with medical devices.

Joyce Stanley-Harris and Arlene Underdonk are program analysts in CDRH's Office of Surveillance and Biometrics.

THOSE CODES!

By Mary Weick-Brady, RN, MSN

The final Medical Device Reporting regulation became effective July 31, 1996. Since then, Food and Drug Administration (FDA) staff have observed numerous errors and omissions in the MDR reports submitted by user facilities to report device-related deaths and serious injuries. These errors cause major gaps in FDA's adverse event reporting database, and may also delay manufacturers' failure analyses while the manufacturers contact user facilities for additional information. FDA plans to send letters to those user facilities that have submitted incomplete mandatory forms (3500A) to request they file supplemental reports.

The following case studies are composites, based on reports filed with FDA. The names of individuals and facilities are fictitious.

Case Study 1

J.C. Mulrane, Risk Manager at the Atwood Nursing and Rehabilitation Facility, is notified that a patient has died in a special care unit. The patient, George Dunbar, is tall and heavy, with a history of organic brain syndrome (OBS), a left below-the-knee amputation (BKA) from complications of diabetes, and chronic hypertension. Since he had frequently attacked staff, his physician prescribed a vest restraint. Later, Mr. Dunbar was found dead, slumped over in his wheel-chair. It appeared that he had been strangulated by the vest restraint, which was too small for him.

At Atwood, it is the risk manager's job to report such incidents to FDA and the device manufacturer. Because it appears that the device may have caused or contributed to the death of Mr. Dunbar, J.C. realizes she must file a mandatory adverse event report with both FDA and the manufacturer. She is aware of the requirements of the new reporting regulation; however, she is unable to find the directions for filling out mandatory MedWatch Form 3500A. J.C. gets to Block F.10 on the form (the patient and device coding section) and thinks, "Now, how am I supposed to do this?" She finds the list of event terms, which was detached from the rest of the coding manual. She sees that Part 1 (Subpart A) of the coding manual is titled *Patient-Related Terms*. She muses: "Mr. Dunbar had OBS – which isn't listed in these codes; he had an amputation – which is listed; he had diabetes – which isn't listed; and he had hypertension – which is listed." J.C. promptly enters 1702 (amputation) and 1908 (hypertension) in the patient codes. She then finds the list for *Device-Related Terms*. "Now, what am I supposed to put here?" she wonders. She reviews the terms, decides there was nothing wrong with the wheelchair or the vest restraint, and leaves the device code area blank.

What Happened?

The instruction manual for the mandatory MedWatch Form 3500A requires the reporter to enter **at least one** patient code and **one** device code to describe the event most accurately. Patient codes describe what happened to the patient **as a result** of the event. Device codes describe device problems or failures that occurred during the incident. The important thing to remember is to choose the most accurate codes and to choose at least one code for the patient and one code for the device. These codes, along with the other blocks on the form, should not be left blank.

Because the instructions were detached from the coding manual, J.C. was unable to determine what to put in the coding areas. Therefore, she chose codes for Mr. Dunbar's existing diagnoses and conditions, instead of choosing the patient codes that described what had happened to him as a result of the restraint event. The most accurate code in this incident would be 1803 (death/expired). The device code area should have been completed, since a device was involved in the death. In this case, it appears that Mr. Dunbar had been wearing a vest restraint of inadequate size. The most accurate device code would thus be 1583 (size, incorrect). If it were not clear whether or not the device caused or contributed to Mr. Dunbar's death, or may have caused or contributed to his death, the user facility should still file a report within 10 days of the event. WHEN IN DOUBT, REPORT AN EVENT. If, on further investigation, the user facility determines that the device did not cause or contribute to the death of the patient, supplemental information can be filed with FDA and the manufacturer.

Case Study 2

Pat Anser, a staff member at Rolly Regional Hospital, has been assigned responsibility for reporting medical device adverse events to FDA and to manufacturers. Pat is scheduled for MDR training next month. In the meantime, he

(Continued on page 4)

THOSE CODES! - (*from page 3)*

receives a report of a patient death in the operating room. A 29-year-old patient died during ENT surgery, when an electrocautery unit ignited in the oxygen-rich environment and she sustained fatal burns. Several days have passed and Pat is being pressured to get the report out as soon as possible, since the hospital has nearly reached the 10-day deadline for re-porting. He checks the coding manual, completes the front page of the mandatory MedWatch Form 3500A, and then receives a phone call to immediately attend a meeting. Pat looks at the back of the form and quickly fills out F.1, 4, 5, and 12. Pat knows that gathering the rest of the information to properly complete Section F will take some time – time that is not available now. He quickly addresses the envelope and mails it. The patient and device codes, along with the rest of Section F, are left blank. The manufacturer subsequently had to follow up with Pat to retrieve the missing information and is thus delayed in analyzing the incident.

What Happened?

Filling in all parts of the manda-tory MedWatch Form 3500A is a legal requirement. It communicates critical patient-related information to the FDA clinicians who analyze these reports. They search the database by codes – in particular, by device and patient codes. When user facilities provide correct and complete information, it is possible to identify trends that may involve multiple devices, patient types, and manu-facturers. The results of the database analysis enable FDA to provide timely public health notifications, including safety alerts, public health advisories, and medical alerts to user facilities and patient populations.

Correct coding by user facilities enables FDA to check that the manufacturer has also reported the event when required. FDA device recalls also rely on proper coding of the MedWatch form; if codes are omitted, FDA cannot properly analyze the report and may miss a potential public health emergency. In addition, correct coding enables FDA to better respond to information requests from the public under the Freedom of Information (FOI) Act.

What Must Be Done?

Staff who are assigned responsibility for reviewing adverse events and reporting them to the manufacturer and FDA must have:

- adequate training;
- sufficient time to accurately complete the mandatory MedWatch Form 3500A within the deadline; and
- resources necessary to fill out the form, including a coding manual, copies of incident reports, and access to the device and/or patient involved, if possible.

Filling out forms completely and correctly can save:

- lives and avoid injuries;
- time and money expended on telephone calls from manufacturers to user facilities;
- FDA letters requesting missing information from manufacturers (and, in the future, from user facilities); and
- FDA inspections of manufacturing firms and user facilities to determine the facts of adverse events.

FDA field employees have been trained to become trainers of user facilities across the United States. They will train user facility staff regarding the MDR regulation, with the expectation that these individuals will use this knowledge to train staff at other facilities. For additional infor-mation about the MDR training, call 1-301-594-2735.

In the meantime, you can contribute to the joint effort of user facilities, manufacturers, and FDA by familiarizing yourself with the coding manual, including the instructions and coding for patient related and device related terms. You can receive direc-ions for obtaining a coding manual by calling 1-800-899-0381 or
1-301-827-0111 from a touch-tone telephone. Using the telephone keypad, access the SMDA Facts section of the Center for Devices and Radiological Health (CDRH) Facts-On-Demand by pressing 1 at the initial voice prompt and 2 at the second voice prompt, then entering the three-digit shelf number for the document(s) you want. To obtain a listing of available MDR documents and their sources, enter shelf number 799. Documents shorter than 20 pages are automatically sent to
the FAX number provided by the requester. Longer documents are sent by FAX after normal business hours.❂

Mary Weick-Brady, RN, MSN, is a Team Leader for the Product Evaluation Team in the Division of Postmarket Surveillance (a part of CDRH's Office of Surveillance and Biometrics).

FDA RELEASES HUMAN FACTORS GUIDANCE

In December 1996, the Food and Drug Administration re-leased a guidance document entitled *Do It By Design: An Introduction to Human Factors in Medical Devices*. The document (which is about 50 pages) emphasizes the importance of designing medical devices for safe, easy use and includes information of value to both manufacturers and healthcare practitioners. You can obtain the document from the Internet at:

http://www.fda.gov/cdrh

by selecting it from the topic index. You can also select the human factors home page from the index. To obtain a printed copy of *Do It By Design*, send a FAX to Gene Allen at 1-301-443-8818; state the document name and shelf number (995) as well as your return address.

FDA REGIONS OFFER MDR TRAINING - *(from page 1)*

FDA would like to decentralize the training as much as possible. If you are interested in receiving this training, please call the FDA contact listed for your geographical area.

Northeast Region

New York State
(zip codes 10--- & 11---)
George Walden
(718) 965-5300 ext. 5528

New York State (all other zip codes)
James M. Kewley
(716) 551-4461 ext. 3128

Massachusetts, Rhode Island, Connecticut, New Hampshire, Vermont, Maine
Joseph Raulinaitis, (508) 793-0421

Mid-Atlantic Region

Pennsylvania, Delaware
Michelle Dunaway
(215) 597-2120 ext. 4545

New Jersey
Robert Ruff
(201) 331-2970 ext. 3006

Maryland, West Virginia
Lourdes Valentin, (410) 962-3461

Virginia
Nathaniel Esaw, (804) 379-1627

Ohio, Kentucky
Guy Cartwright
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Don Aird, (612) 334-4100 ext. 129

Southwest Region

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Kansas, Iowa, Missouri, Nebraska:
Robert Wilson, (913) 752-2426

Colorado, New Mexico, Wyoming, Utah
David Glasgow, (303) 236-3086

Pacific Region

California (zip codes 935-- & above),
Nevada, Hawaii
Mark Roh, (510) 637-3980
Frank Eng, (408) 291-7548

California (zip codes 934-- & below), Arizona
Dannie Rowland, (714) 798-7649
Vickie Anderson, (714) 798-7760

Washington, Oregon, Idaho, Montana, Alaska
Sue Hutchcroft, (206) 483-4953

Indian Health Service

Mark Thomas, (301) 443-1054

Brenda Lucas is a nurse consultant in CDRH's Office of Surveillance and Biometrics.

MEDWATCH SOFTWARE AVAILABLE ON INTERNET

MedWatch software is available free through the CDRH homepage. The software can be downloaded and used to complete Forms 3500 and 3500A using a personal computer. After the indicated entries are made, the completed form can be printed and mailed to FDA and/or the manufacturer. This software does **not** permit electronic submission of MDR reports; it merely allows the form to be completed on a PC rather than a typewriter.

The software can be found at **http://www.fda.gov/cdrh/mdrforms.html** by clicking on "MedWatch Computer Forms Software." You can also access the software page directly at **http://www.fda.gov/cdrh/mdwtchgn.html** . If you have problems, please call the MedWatch Office at 800-FDA-1088 (press 0) or 301-443-0117 or send a FAX to (301) 443-5776.

FDA CONCERNED ABOUT INTERFERENCE WITH MEDICAL DEVICES

by Judith Kalson and Don Witters

Recent media reports have highlighted the possibility that cellular phones and other radio transmitters may interfere with the operation of cardiac pacemakers. FDA's Center for Devices and Radiological Health (CDRH) has been assessing this type of interference phenomenon (known as electromagnetic interference or EMI) for many years. Laboratory tests and reported incidents have shown that many different types of medical devices can be susceptible to EMI. In fact, nearly any device or product that is electrically powered can be affected by some form of EMI.

The problem occurs when EMI disrupts the normal function of a medical device. Incident reports suggest that patient safety could be compromised if a critical device (such as a cardiac pacemaker) or device function is disturbed by radio signals (e.g., from radio or TV broadcasts or two-way radios), by AC power-conducted interference (e.g., surges or "brown outs"), or by electro-static discharge (such as occurs when walking across carpet in a room with low humidity).

> "Even if devices are designed and tested for EMC, some interference problems might still occur."

With the accelerating pace of technology, especially in communications and computers, there are now many sources of radio transmission in common use. At the same time, medical devices are becoming more sophisti-cated and performing more functions. Unfortunately, when a radio transmitter – such as a cellular phone or wireless computer link – gets too close to a sensitive medi-cal device, there is a potential risk that EMI will cause serious consequences for patient safety and effective treatment.

When a device is immune to reactions with the types of signals in its use environment, it is said to be electro-magnetically compatible (EMC). Even if devices are designed and tested for EMC, some interference problems might still occur. Unfortunately, EMC can be affected by many things, such as the frequency, power output, or distance from the radio transmitter. For example, as the distance from a radio transmitter decreases, the power intensity increases, and the likelihood of EMI increases. Further, since devices are themselves sources of signals, one device may affect another.

FDA scientists have many years of experience involving EMI with medical devices. They have developed a comprehensive strategy to focus attention and devise solutions for this problem. Much of the effort is directed toward raising awareness and under-standing of the EMI phenomenon, since EMI is a complex problem that involves both the medical device and the environ-ment in which it is used. FDA's primary goal in the area of EMI is to minimize the risk of interactions by encouraging manu-facturers to design protection into the devices; by raising awareness of EMI among all concerned (including the manufacturers of radios and other EMI sources such as AC-power utilities); and by working with industry toward assuring compatibility.

Patient and clinician problems associated with EMI can be minimized by considering the following points:

- Be aware that EMI can cause steady, momentary, or intermittent disruption of the performance of medical devices.
- Follow the recommendations of device manufacturers for avoiding EMI.
- Purchase equipment that conforms to EMC standards.
- Take steps to prevent known sources of interference (e.g., cellular phones, hand-held transceivers) from coming too close to patient monitors and other sensitive electronic medical devices.
- When an EMI problem is suspected, contact the device manufacturer for assistance. Local clinical engineers may also be able to assist in identifying and correcting the problem.
- Make a note for the record if you believe a problem is linked to interference from a recognizable source of EMI in the vicinity.[1]

(Continued on page 7)

> ". . . we need your help in identifying medical devices that may have been affected by EMI, leading to serious injury or death."

FDA CONCERNED. . . (from page 6)

In recent months, FDA scientists have completed EMI testing of such devices as cardiac pacemakers, hearing aids, ventilators, and powered wheelchairs. We will continue to test medical devices and work with standards organizations and device manufacturers. However, we need your help in identifying medical devices that may have been affected by EMI, leading to serious injury or death. Under the Medical Device Reporting regulation, instances of serious injury must be reported by the user facility to the manufacturer of the device, or to FDA if the manufacturer is not known. Instances of death must be reported to the device manufacturer, if known, **and** to FDA. EMI incidents that do not involve a death or serious injury may be voluntarily reported to FDA through the MedWatch program. For more infor-mation about EMI problems, contact the Division of Small Manufacturers Assistance at 1-800-638-2041, or consult the CDRH/EMC web page at**:**

http://www.fda.gov/cdrh/emc/index.html

Reference

1. Food and Drug Administration (1994). Electromagnetic Interference May Cause Problems with Some Medical Devices. *FDA Medical Bulletin*, 24, 2. Rockville, MD: Food and Drug Administration.✪

Judith Kalson is a nurse consultant and Don Witters is a biomedical engineer. Both are in CDRH's Office of Science and Technology and are members of the CDRH EMC Work Group that Mr. Witters chairs.

COST OF PRINTING BULLETIN MAY LEAD TO AVAILABILITY ONLY ON INTERNET

Because of budget reductions, it is possible that future issues of the *User Facility Reporting Bulletin* will not be printed and will be available only through the Internet. You can access the *Bulletin* at **http://www.fda.gov/cdrh/fusenews.html**.

Remember to check quarterly for future issues of the *Bulletin*; they will be put on the Internet at the end of January, April, July, and October. All 17 past issues of the *Bulletin* are also available at the above address.

Healthcare organizations are encouraged to download the *Bulletin* from the Internet and make it available to their members. The *Bulletin*, which is not copyrighted, may be reprinted and distributed without government permission.

In order to reduce printing costs, this issue of the *Bulletin* is being mailed only to readers who returned their mailing list retention notices from the Fall 1996 issue and to readers who requested paper copies.✪

READERS' EXCHANGE

Do you sometimes feel you are out there all alone in the confusing world of Medical Device Reporting (MDR)? Well, you're not alone. In fact, FDA gets many telephone calls and letters about MDR from nurses, engineers, administrators, and risk managers. We also get tips from callers who have developed creative ways to handle MDR. In the next issue of the *Bulletin*, we'll share with you one reader's creative way of doing the semiannual report.

Now it's your turn. Perhaps you would like to share information about your facility's MDR procedures, decision tree, or in-service training. We'll pass along the best of the tips we receive. If you have a problem that other facilities might also encounter, we will answer it in this column in a subsequent issue of the *Bulletin*. We hope to hear from you by mail (address on back of *Bulletin*), FAX (301-594-0067) or E-mail (nsl@fdadr.cdrh.fda.gov). Send all correspondence to the attention of the Editor, *User Facility Reporting Bulletin*.✪

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Important information from FDA about Medical Device 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.

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

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