FOOD AND DRUG ADMINISTRATION

USER Facility Reporting

Issue No. 20 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Summer 1997

REVIEW OF MDR REPORTS REINFORCES CONCERN ABOUT EMI

by Nancy Pressly, B.S. Engr.

Because of concern about adverse events related to electromagnetic interference (EMI) with medical devices, a committee in the Center for Devices and Radiological Health (CDRH) has been reviewing the Medical Device Reporting (MDR) database. The initial work focused on the cardiovascular device area (e.g., pacemakers, defibrillators). Manufacturers of electrically powered cardiovascular devices are well aware of the potential for EMI. They have been designing and testing devices for immunity to EMI and educating users about this potential problem for many years. However, the MDR database contains a number of reports suspected to be related to EMI.

There were approximately 150,000 MDR reports entered in the cardiovascular area of the MDR database between 1984 and 1995. Determining whether or not the adverse event reported was related to EMI was difficult because EMI information was not routinely entered into the database during this period. In-depth reviews were done on 1,749 of these reports that contained text related to EMI. The committee review revealed that 576 (33%) of the reports were categorized by the group as being either highly probable, probable, or possible that the adverse event resulted from EMI. For most of the reports, the source of EMI could be identified; however, in 109 (19%) of the reports categorized for EMI, the source was unknown.

Of the 576 reports that were categorized as EMI related, 456 (79%) involved pacemakers or implantable cardiac defibrillators (ICDs). In 255 (56%) of 456 reports, the most frequent source of interference with the pacemakers and ICDs was the use of an electrosurgical unit in the vicinity of the pacemaker or ICD. In a large portion of these

(Continued on page 2)

LAST PRINTING OF USER FACILITY REPORTING BULLETIN

by Mary Ann Wollerton, M.P.A.

Starting with Issue 21, this *Bulletin* will be available to health-care facilities and other readers through an automated FAX system. Due to budget constraints and funding shortages, it is no longer possible to print and mail the *Bulletin*. Instead, it can arrive quarterly at your personal FAX machine, but here's the catch: **You must provide us with your FAX number!** If we have your FAX number, you will receive the Fall issue via your FAX . (See page 7.)

Time, technology, and budget restrictions have come together in the Food and Drug Administration (FDA). Ten years ago, our computer capability allowed us to communicate only within FDA. Now, with advanced computer technology we can globally communicate through the Internet and through FAX machines.

As you would expect, Congressional budget cuts have affected all parts of government. FDA did not

(Continued on page 5)

In This Issue:

Review Of MDR Reports Reinforces Concern About Emi 1
Last Printing Of User Facility Reporting Bulletin 1
Two Ways To Get The Bulletin In The Future 2
Accessing User Facility Reporting 3
Information On The World Wide Web..... 3
What Does FDA Do With Adverse Event Reports?..... 4
FDA Warns About Radioactivity In Radiation Protection Devices..... 5
Readers Exchange 6
Steam Resterilization Roughens Surface Of Zirconia Ceramic Femoral Heads 7
Directions For Completing FAX Form On Page 8..... 7
Form For Submitting Your Fax Number..... 8

FDA CONCERN ABOUT EMI - *(from page 1)*

reports, it appeared that the EMI left the device inoperable. The other two main sources of interference with pacemakers and ICDs were internal and external defibrillators (50 or 11% of 456 reports) and permanent magnets (45 or 10% of 456). In 73 (16%) of the 456 reports, the source of the EMI was unknown or unreported.

Most of the pacemaker/ICD reports were coded with a patient outcome of "intervention required to prevent adverse outcome." This included pacemakers/ICDs that needed to be replaced after exposure to electrosurgical units, and pacemakers/ICDs that needed to be reprogrammed after inadvertently being turned off or misprogrammed by exposure to a magnet or other unknown source.

Returning to the 576 EMI related reports, other devices most frequently cited included 46 reports (8%) that involved external defibrillators and 29 (5%) that involved cardiac monitors. The 46 (8%) remaining reports cited various other devices such as pulse oximeters, balloon pump controllers, pacemaker programmers, and blood pumps.

Death was coded as the patient outcome in 25 of the 576 related reports. However, given the general nature of MDR reports, it is often difficult to directly attribute a death to the device malfunction. Of these reports, seven involved pacemakers; six of the seven were related to EMI from electrosurgical units and one report cited interference from a permanent magnet. Two of the 25 reports involved cardiac monitors: in one, the reported source of EMI was the device itself; in the other, AC power-line interference was reported.

The remaining 16 reports associated with patient death involved external defibrillators. A variety of sources of the EMI were mentioned in the reports: 12 interferences were from an unknown source; two involved AC power-line problems; one was from a mobile transmitter; and one cited "other non-medical device."

The review of the MDR cardiovascular device database is an initial step in the committee's plan for identifying EMI-related reports. Future plans include looking at other device areas. By using the experience from this review of adverse event reports, CDRH hopes to enhance reporting of EMI problems in the cardiovascular area and to aid device users in addressing these problems.

Nancy Pressly is a Biomedical Engineer on the Issues Management Staff of CDRH's Office of Surveillance and Biometrics.

TWO WAYS TO GET THE BULLETIN IN THE FUTURE

- You can access the *Bulletin* on the Internet at http://www.fda.gov/cdrh/fusenews.html

- Using a touch-tone telephone, you can obtain the *Bulletin* and other related 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. To get an Index of Bulletins available though FOD, select 3 (DUPSA) at the first voice prompt, select 1 at the second prompt, and follow subsequent prompts. After you receive your Index, make your selection and call the 800 or 301 number to order the Bulletin issues that you want.

You may order one document per telephone call. Indexes and documents of less than 30 pages are FAXed as soon as one of our 15 FAX lines is available. Longer documents are FAXed after 5:00 p.m. EST.

We're hoping that these alternate ways of getting the *Bulletin* will keep you as readers. Please send us your comments.

ACCESSING USER FACILITY REPORTING INFORMATION ON THE WORLD WIDE WEB

by Kevin O'Reilly

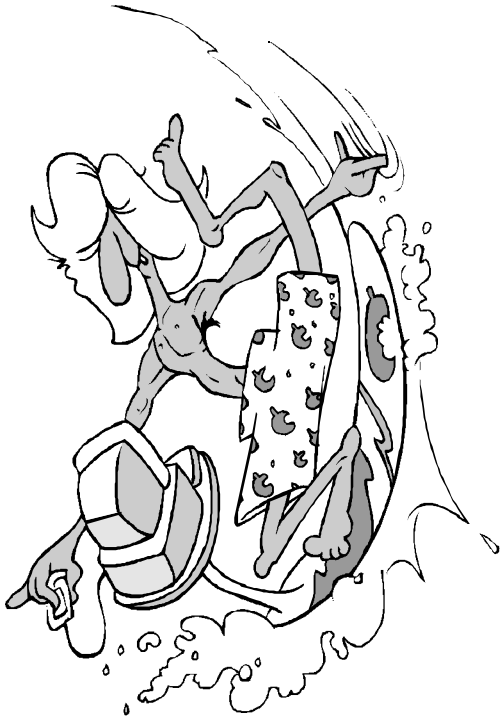
The Medical Device Reporting (MDR) Webpage has been up on the Internet (World Wide Web) for several months now. The MDR Webpage contains links that enable you to access:

General Information
MDR Reporting Forms and Instructions
MDR Reporting Guidance Documents
User Facility Reporting Bulletins
Federal Register Notices
MDR Related Publications and Videotapes

The MDR Webpage can be found at the following address:
http://www.fda.gov/cdrh/mdr.html

You may want to save the location of this page . If you are using Netscape Navigator, go up to Bookmarks, then choose Add Bookmark. If you are using Microsoft Internet Explorer, go up to Favorites, then Add to Favorites.

Some of the documents are in Portable Document Format (PDF), so you will need to download and use the program called Adobe Acrobat.



From the MDR Webpage, download the Acrobat Reader program as follows:

1. Click on the link **PDF Reader** at the top of the MDR Webpage.
2. Click on **Free readers for PDF files and more information about PDF**.
3. Although not required, you might want to register with Adobe.
4. Go to Step 2 on the Adobe Homepage.

- The top box is a drop-down menu with choices of programs to download. Choose Acrobat Reader.
- Underneath that box are 2 more boxes. The one on the left is the platform or environment that is running on your machine. If you are not using Windows 95, click on the ▼ and choose the appropriate response.
- The box on the right is for other languages. English is the default language.

5. Click on the Download button.
6. On the next screen, scroll down to the downloading link from either Japan or USA. Click on the ar32e301.exe link for USA.
7. A dialog box will appear. Select the "Save it to Disk" option and click OK.
8. The next box asks where to save the file.

- Save the the file to your harddrive (the C: drive). Remember the directory where it is stored.
- If you have a Macintosh, please consult your Information Systems Specialist (ISS).

9. Wait as it downloads.
10. When the download is finished, exit the Web browser.
11. To run the downloaded file,

- **for Windows 95 or Windows NT**, click on Start. Then, choose Run and type in the whole file name including paths, for example, C:\temp\ar32e301.exe
- **for Windows 3.1**, from the main Windows screen, choose File, then Run. Type in the complete file name including paths.

12. Follow the prompts for installing the program.

Once you have finished installing the Adobe Acrobat Reader, return to the MDR webpage. Select User Facility Reporting Bulletin. Choose an issue (all are PDF files). This should automatically start up the Acrobat Reader which will display the file for you.

You should now be able to view AND print all the PDF files that exist on the World Wide Web. If you have questions, please consult the ISS in your facility. HAPPY SURFING! ❀

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

WHAT DOES FDA DO WITH ADVERSE EVENT REPORTS?

by Suzanne Rich, R.N.

FDA receives both voluntary and mandatory adverse event reports through its MedWatch program. These reports are entered in a computerized adverse event database and later retrieved from the adverse event database for review and evaluation. Our evaluation staff consists of 14 nurses and 1 nuclear medicine technologist. Each analyst is responsible for reviewing all events involving devices in a particular category (e.g., orthopedics or cardiology). Our analysts use their clinical experience, knowledge, and expertise to evaluate the nature, scope, and magnitude of each reported event. They also use other FDA information resources such as premarket submissions on similar devices and recall information. In addition, they conduct literature reviews of reported problems.

In addition to entering, reviewing, and evaluating individual adverse event reports, our analysts use computer programs to identify any trends that might suggest problems. For example, a number of adverse events might be identified with a particular manufacturer, type of device, type of institution, type of patient, or geographic region. Complications and problems known to be associated with a particular type of device can be searched by computer in a sample of the reports assigned to the analyst for review. As soon as reports of particular significance are received, such as those involving pediatric deaths, they are automatically sent to the appropriate analyst. This allows the analyst to begin investigating the event while the report is being entered into the database. FDA is developing a program that will enable the computer to identify any adverse event report that indicates a potential problem. These reports will then receive priority for evaluation.

Based upon the evaluation of a reported event, an analyst determines if any followup investigation is warranted and plans the nature and substance of such an investigation. To initiate an investigation, an analyst will send a letter to the manufacturer, the user facility, or a voluntary reporter requesting specific additional information on a reported event. The nature of these investigative actions varies according to the type of adverse event reported, the potential public health risk, and the completeness of the report originally submitted.

The letter may request patient data such as evaluations of the reported event by healthcare practitioners, patient history, underlying diagnosis, and autopsy results relevant to the reported event. FDA may request device data, including product identifiers (such as model, lot, and catalog number), the length of time a device was implanted, disposition of a device involved in a reportable event, results of any manufacturer failure analysis testing, and copies of device labeling and instructions for use. This information helps the analyst to assess the cause of an adverse event. The analyst may also ask the manufacturer to provide information on the frequency and severity of other adverse events reported for this or similar devices, as well as any corrective action taken.

The analyst may ask the FDA staff to perform a directed establishment inspection (DEI) of either the device manufacturer or the user facility. FDA sometimes uses the DEI instead of a letter to the manufacturer to obtain specific information when the reported event suggests the need for **immediate** followup review of records at the manufacturer's facility.

After assembling and reviewing all the information related to a reported adverse event, including that obtained from a letter request or a DEI, the FDA analyst evaluates the data and determines whether further FDA action is needed. If appropriate, the adverse event report and any related information are forwarded to the appropriate group within FDA for possible regulatory action (e.g., recall), user notification (e.g., safety alert or public health advisory), or a press release to warn the public of potential hazards associated with the use of a device. Even if no further immediate action is warranted, the adverse event report remains in the database, enabling future research and evaluation of trends. ❀

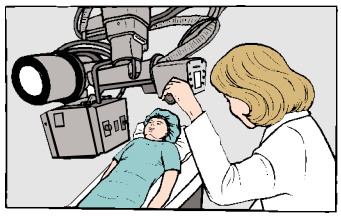
Suzanne Rich is a nurse consultant and team leader in CDRH's Office of Surveillance and Biometrics.

FDA WARNS ABOUT RADIOACTIVITY IN RADIATION PROTECTION DEVICES

FDA issued a Public Health Notice in June 1997 to alert health-care facilities that some shielding products used for radiation protection contain lead contaminated with small amounts of naturally occurring radionuclides. The radioactivity in the affected products is very small, and the contaminants are not transferable to patients, personnel, or equipment through ordinary use. The medical devices possibly containing lead contaminants that have been identified to date are lead aprons, gonad shields, and thyroid shields manufactured after October 1, 1996.

Because the standard radiation safety practice is to avoid unnecessary exposure to radiation, the use of contaminated products should be discontinued. However, if there is no alternative shielding available, FDA recommends **temporarily** using the contaminated products during therapeutic and diagnostic pro-cedures until the healthcare facility can obtain replacements.

Investigations are underway to identify all firms that received the contaminated tin-lead alloy which was imported from Brazil by Midco Industries (St. Louis, MO). The alloy was processed to powder and sold



to 19 firms. Some of these 19 firms supplied the contaminated lead or lead products to a number of other companies, including medical device manufacturers.

Medical device manufacturers are initiating recalls. Some manufacturers have already voluntarily recalled contaminated products. Other manufacturer recalls are following. If you have purchased any of these affected products, you should receive a notice from your supplier with instructions for disposal or return of the device and, perhaps, replacement information.

FDA recommends that suspect devices be surveyed by qualified personnel using suitable equipment such as a thin window Geiger Mueller (G-M) survey meter. If the survey results indicate contamination, contact your supplier for further instructions. If you cannot survey the devices, and they were manufactured after Oct. 1, 1996, contact your radiation protection device supplier for additional instructions. If you receive a letter from the supplier, carefully follow their disposition instructions.

FDA is working with the Conference of Radiation Control Program Directors to identify all contaminated lead products that have been introduced into commercial distribution. As medical device manufacturers are identified, FDA will post an updated list on our Website: **http://www.fda.gov/cdrh/safety.html**; additional information on these products and other recalls can be found on **http://www.fda.gov.opacom/enforce.html**

FDA requests that you report any discovery of contaminated lead products to our voluntary MedWatch system. Please submit these reports to MedWatch by phone at 1-800-594-2968, by FAX at 1-800-FDA-0178, or by mail to:

MedWatch, FDA
5600 Fishers Lane, HF-2
Rockville, MD 20852-9787

If you have any questions about information in this article, contact Sherry Purvis-Wynn at FDA's Center for Devices and Radiological Health by E-mail: slp@cdrh.fda.gov or by FAX: 301-594-2968.

LAST PRINTING OF BULLETIN - *(from page 1)*

escape these cuts. In the search for ways to reduce our expenses, printing and mailing costs for distribution of publications in traditional paper form have come to be viewed as an extravagant expenditure.

In past years, we sent the *Bulletin* to about 77,000 subscribers. Because of reduced printing funds, we asked our readers in Issue 17 to return a retention notice if they wished to remain on the mailing list. Readers who did not reply were deleted from the list. This reduction made our mailing list affordable enough to print a few more issues. Now, budget restrictions prevent future distribution in paper form.

We regret the need to move to this new technology if it means that many of our current readers will no longer have access to the *Bulletin*. We would like to remind you that you can also obtain copies through our Facts-on-Demand System or the World Wide Web. See related article on page 2.

READERS EXCHANGE

The following letter was received from a reader with experience in returning failed devices.

Dear Editor:

On page 3 of the Spring 1997 issue in heavy outline was an admonition from FDA to users "PLEASE DO NOT SEND FAILED DEVICE TO FDA." We can appreciate FDA's position in advising users that it is not appropriate nor necessarily safe to send failed devices to FDA, but it would be helpful for FDA to guide users who are obviously perplexed about how to proceed.

Users who experience adverse incidents potentially related to failed medical devices should:

1. Assure that the failed device is taken out of service immediately with all attachments, disposables and packaging and without changing any settings or configurations;
2. Assure that all sharps and/or potentially contaminated products are handled, packaged, stored and, if necessary, shipped safely;
3. Contact the appropriate authority within the facility (e.g., biomedical or clinical engineering, risk management, quality assurance, hospital legal counsel) to advise them of the incident and to seek their guidance concerning how to proceed;
4. If advised by the proper facility authority (and we highly advise cooperation as follows), contact the manufacturer(s) of the product to advise them of the incident and to seek their guidance concerning how to proceed;
5. Complete the MedWatch Form with the assistance of the appropriate authority within the facility and submit the form to FDA and/or the manufacturer as required by the mandatory device reporting requirements within the Safe Medical Devices Act.

It is important to understand that these steps help to:

- Assure that the failed product is not utilized on a second patient or used by another staff member;
- Assure that neither staff (including shipping and handling personnel on both the shipping and receiving sides) nor investigators are unnecessarily exposed to sharps or potentially contaminated material;
- Assure that the product (and serial and lot numbers via packaging) as it was in use can be inspected and tested to determine if accessories, control settings or a myriad of other factors may have contributed to the failure;
- Maintain the integrity of the facility's risk management program and litigation position and allow internal review of the situation by knowledgeable professionals;
- Assure that manufacturers are advised as soon as possible so that similar incidents in other facilities may be avoided;
- Assure that manufacturer expertise in determining causation and in assuring safety in handling and return packaging can be brought to bear; and
- Assure that an independent overseer (i.e., in this case, FDA) is made aware of the incident and can monitor the steps taken to determine causation and desirable steps to avoid the occurrence of similar incidents.

Facilities may wish to seek the counsel of an independent third party to determine and manage how to proceed.

Our thanks for your willingness to consider our thoughts.

Gary H. Harding,
Director, Technical Services
Greener Pastures, Inc.

Alice L. Epstein
Risk Management Consultant to CAN HealthPro

STEAM RESTERILIZATION ROUGHENS SURFACE OF ZIRCONIA CERAMIC FEMORAL HEADS

by Paula Simenauer and Mary Ann Wollerton, M.P.A.

The United Kingdom's Medical Devices Agency has recently linked steam sterilization with surface roughening of zirconia ceramic femoral head components of total hip prostheses.[1] Surface roughening from exposure to steam and high heat may cause increased wear of the acetabular component; premature failure and early revision may result.

Before marketing, manufacturers of hip prostheses with zirconia femoral heads sterilize them with ethylene oxide. If these devices require resterilization because the packaging has been damaged or opened, FDA cautions healthcare facilities against using steam sterilization. Instead, we urge you to contact the manufacturer for further instructions.

If during revision surgery a practitioner observes unusual damage or premature failure of any zirconia femoral head, it should be reported to the healthcare facility's adverse event coordinator (MDR contact) to determine if it is a reportable event. Under the Safe Medical Devices Act of 1990 (SMDA), all hospitals and other user facilities are required to report medical device-related deaths to FDA and deaths and serious injuries to the manufacturer. Practitioners should follow the procedures established by their facility for this mandatory reporting.

For problems or malfunctions not required to be reported under SMDA, we encourage you to report directly to FDA's voluntary MedWatch program in one of the following ways:

Telephone: 1-800-FDA-1088
FAX: 1-800-FDA-0178
Mail: MedWatch
Food and Drug Administration
5600 Fishers Lane (HF-2)
Rockville, MD 20857

If you have questions about zirconia femoral heads, please contact Gary Fischman at:

Center for Devices and Radiological Health
Office of Science and Technology (HFZ-150)
12200 Wilkins Avenue
Rockville, MD 20852
FAX : 301-443-5259

[1]U.K. Medical Devices Agency, Adverse Incidents Centre. Safety Notice MDA SN 9617, "Zirconia Ceramic Heads for Modular Total Hip Femoral Components: Advice to Users on Re-Sterilization."

Paula Simenauer is a Senior Mechanical Engineer on the Issues Management Staff in CDRH's Office of Surveillance and Biometrics. Mary Ann Wollerton is a Public Health Advisor in CDRH's Office of Health and Industry Programs.

DIRECTIONS FOR COMPLETING FAX FORM ON PAGE 8

To receive your Fall issue:

- Copy the User Facility ID number from the top right corner of the mailing label of **this** *Bulletin* (beginning with "UFid").
- Complete the rest of the form as applicable.
- Be sure to double check your FAX number.
- FAX the form to (301) 827-3761 by November 15, 1997.

FORM FOR SUBMITTING YOUR FAX NUMBER

(See Instructions on page 7)

Your Label ID Number:

U F i d | F | D | A | | | | | | | |

or

U F i d | | | | | | | | | | |

or

U F i d | N | S | L | _____

Your FAX Number: __ __ __ - __ __ __ - __ __ __ __

area code

Your Name:_____

Title:_____

Facility/Business Name:_____

Street Address:_____

City: _____ **State:** _____ **Zip:**_____

Please check the type of your facility:

	ambulatory surgical facility		*outpatient diagnostic facility*
	hospital		*outpatient treatment facility*
	nursing home		*other (please specify)*

FAX to: (301) 827-3761

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.

Editor: Nancy Lowe
Assistant Editors: Herb Spark
Mary Ann Wollerton
Publication Design: Edie Seligson

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health, HFZ-230
Rockville, MD 20857
FAX: (301) 594-0067
E-mail: nsl@cdrh.fda.gov

Also route to:
□ Biomedical/Clinical Engineer
□ Facility Administrator
□ Nurse Administrator/Manager
□ Quality Assurance Manager
□ Risk Manager

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

ATTN: Editor, User Facility Reporting Bulletin

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-230)
5600 Fishers Lane
Rockville, Maryland 20857

FIRST CLASS
POSTAGE AND FEES
PAID
PHS/FDA
PERMIT NO. G-285