FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING

USER facility Reporting

Issue No. 10 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Fall/Winter 1994

MDR FINAL REGULATION TO BE PUBLISHED SOON

by Chester T. Reynolds

Over the past few months, FDA has been "fine tuning" the final Medical Device Reporting (MDR) regulation for publication in the *Federal Register*. It should appear in the next several months and be effective 90 days later.

As readers of the Bulletin are aware, a proposed regulation was published in the *Federal Register* of November 26, 1991, as a result of the Safe Medical Devices Act of 1990 (SMDA). SMDA requires **user facilities** to report device-related deaths to FDA and to the manufacturer, if known. It also requires **user facilities** to report device-related serious injuries and serious illnesses to the manufacturer, or to FDA if the manufacturer is not known.

Under SMDA, **distributors** must also report device-related deaths, serious injuries, serious illnesses, and malfunctions to FDA with a copy to the manufacturer. **Manufacturers** and **importers** are currently required, under the 1984 MDR regulation, to report deaths, serious injuries, and certain types of malfunctions to FDA. Under the final regulation, **manufacturers** will be required to investigate, evaluate, and identify the underlying causes of any adverse event reported to them.

The final MDR regulation will consolidate all existing reporting requirements for user facilities, manufacturers, importers, and distributors — affecting over 90,000 potential reporting entities. It will also mandate the use of standardized forms for reporting. **User facilities will be required to use MedWatch Form 3500A for reporting individual adverse events and a new form to file their semi-annual reports.**

As soon as the regulation is published, FDA will launch an educational program to inform industry and the health care community about the reporting requirements.❖

Chester T. Reynolds is Associate Director for MDR Policy of the Office of Biometrics and Surveillance, CDRH.

PROBLEMS WITH BIOLOGICAL INDICATORS

On December 16, 1994, AMSCO voluntarily recalled its Proof Plus Self-Contained Biological Indicators (BI) used to validate and monitor steam and ethylene oxide sterilization processes. AMSCO supplies about 40 percent of the device user market and 400 industrial customers.

Healthcare facilities should replace the AMSCO BI with another manufacturer's BI. From the Food and Drug Administration's contacts, it appears that the demand can be met by other suppliers. If you have questions about this situation, please contact:

Virginia Chamberlain, Ph.D.
Sterilization and Toxicology
Project Officer
Center for Devices and
Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

FAX number: 301-594-4638❖

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ANALYSIS of BULLETIN QUESTIONNAIRES

By Glasco Smith and Kevin O'Reilly

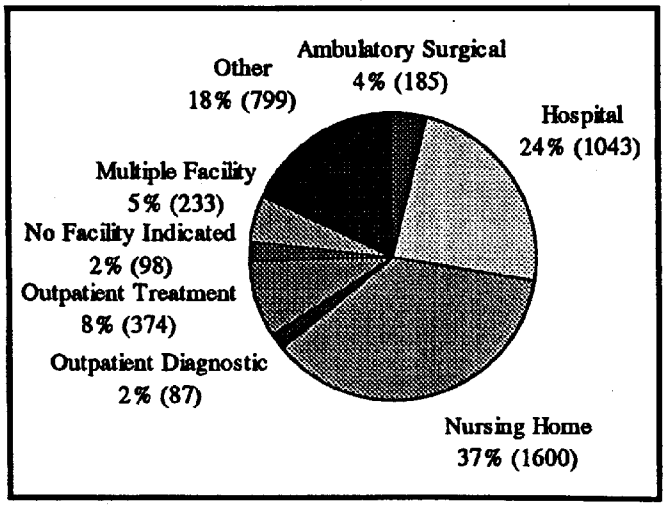
The Center for Devices and Radiological Health (CDRH) would like to thank the readers of the *User Facility Reporting Bulletin* for responding to the questionnaire that appeared in the Spring 1994 *Bulletin* (Issue 8). The survey was a success, with 4,419 questionnaires completed and returned to FDA.

The survey was designed to help determine the effectiveness of the *Bulletin* by asking:

- How well is FDA educating device user facilities concerning their reporting responsibilities under the Safe Medical Devices Act (SMDA)?
- How useful is the information in the *Bulletin*?
- Should FDA continue publishing the *Bulletin*? If so, how should the *Bulletin* be sent to readers?
- Do readers need more information about the procedures for medical device reporting?
- Within each device user facility, who should receive the *Bulletin*?
- Is more information needed about a particular subject?

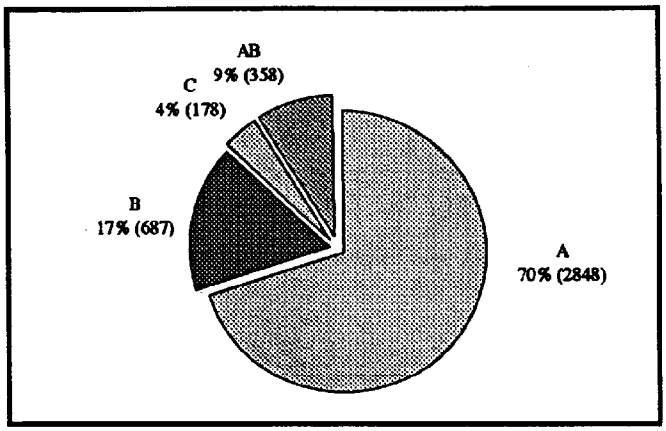
The 4,419 returned questionnaires represent 10 percent of the user facilities affected by SMDA. The breakdown of returns by facility type (Chart 1) shows a large enough response from each type to be representative. We believe the results would not change significantly if the response rate were increased.

Chart 1. Returns by Facility Type



The responses (Chart 2) indicate that the *Bulletin* has been effective in educating user facilities concerning their reporting responsibilities. Seventy percent (A) of readers reported that the *Bulletin* provides a lot of new information about user facility reporting; 17 percent (B) said it corroborates what they already know about user facility reporting; and 4 percent (C) said that it provides no new information about user facility reporting. Nine percent (AB) checked both A and B.

Chart 2. Usefulness of the Bulletin



Ninety-two percent of readers reported there is a need to continue publication of the *Bulletin*. Printed copy was the preferred form of transmission (83 percent), followed by FAX (8 percent), and electronic transmission, i.e., computer (3 percent). Six percent had no preference.

Respondents stated that the *Bulletin* is circulated within their facilities to: administration (2,726); nursing administration (2,134); quality assurance manager (1,788); risk manager (1,665); biomedical/clinical engineer (922); and other (665). "Not circulated" was checked by 398 respondents.

In answer to the question: "If only one person in your facility were to receive the *Bulletin*, who should it be?", 1,844 readers replied "facility administrator"; 866 replied "risk manager"; 658 replied "nurse administrator/manager"; 486 replied "quality assurance manager"; 380 replied "other"; and 234 replied "biomedical/clinical engineer."

(continued on page 3)

Analysis of Bulletin Questionnaires (continued from page 2)

Who completed and returned the questionnaire? Of the 4,419 returned questionnaires, the distribution by title of the respondent was:

Facility Administrator	1,742	39.4%
Other	785	17.8%
Nurse Administrator/Manager	741	16.8%
Risk Manager	406	9.2%
Multiple Titles Checked	280	6.3%
Quality Assurance Manager	217	4.9%
Biomedical/Clinical Engineer	153	3.5%
No Title Checked	95	2.1%
Total	4,419	100.0%

What are the topics about which readers want additional information? We learned that 2,330 respondents wanted more information about establishing internal processes/procedures to ensure facility compliance with SMDA; 642 wanted feedback from FDA on medical device reporting (MDR); 537 wanted summaries of FDA safety alerts; 295 wanted details of how to file an MDR submission; 42 wanted other topics; 40 wanted more information on medical device tracking; and 533 did not answer the question.

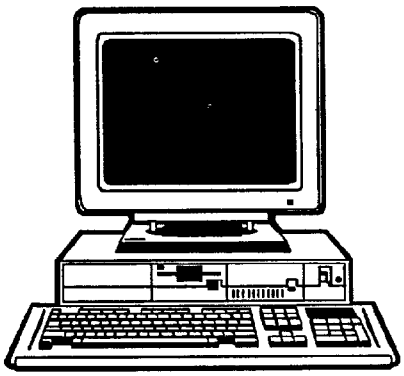
In summary, we now have a better idea of the topics about which our readers would like more information. We know more about where the *Bulletin* is being circulated within facilities and who is reading it. We plan to use this information in selecting topics for future issues of the *Bulletin* and refining our mailing lists.

Thank you for taking the time to complete the questionnaire. Please continue to correspond with us about any questions you have regarding medical device reporting. You may write to any of our authors directly or in care of the Editor. Please send address changes to the Editor. We look forward to hearing from you.❖

Glasco Smith, an Operations Research Analyst in the Office of Management Services, participated in the CDRH Three-State Study of the impact of user facility reporting. Kevin O'Reilly, in the Office of Health and Industry Programs, specializes in computer science.

MAUDE UPDATE

By Cathy Hix



Because it has been quite some time since the last MAUDE update, I'll start off by letting you know what's been entered into the MAUDE database. But first, a reminder of what MAUDE is: "MAUDE," which stands for Manufacturer and User Device Experience, is an automated system developed in response to the broadened reporting requirements of the Safe Medical Devices Act of 1990. The system is designed to capture, store, and analyze the information contained in reports of adverse events which device user facilities, distributors, and manufacturers will be required to submit.

MAUDE now contains over 14,000 event reports — approximately 7,600 submitted by user facilities and 2,400 from distributors, as well as 4,000 Product Reporting Program (PRP) voluntary reports. Of course, the numbers are expected to jump dramatically after the Medical Device Reporting (MDR) final regulation is published in the *Federal Register* sometime during Spring 1995. Ninety days after publication, the old MDR process will terminate, and manufacturers will begin submitting their reports on the MedWatch form. These will be captured in MAUDE, providing the final piece in a database that is truly "event-based." In other words, all the information submitted to us, from all the various sources, pertaining to a specific device event will be cross-referenced in our MAUDE system. This will allow our analysts to see a complete picture of a particular event.

Report Numbering

Now that you're up-to-date about the number of reports in our database, here are some reminders about constructing the numbers on those reports:

Some facilities are still submitting reports without report numbers or with improperly sequenced report numbers. The sequenced report numbers should consist of a facility's HCFA (Health Care Financing Administration) number, the year in which the report is being filed, and a four-digit sequence number. (continued on page 4)

MAUDE Update (continued from page 3)

For example, the first report filed in 1994 by a facility whose HCFA number is 1234567890 would be **1234567890-1994-0001.** When a new calendar year begins, sequence numbering should start over and begin at 0001 — for example, **1234567890-1995- 0001.** Some facilities are continuing the sequence even if the year has changed.

If you are not sure of your correct HCFA number, your MDR contact person (coordinator) can obtain this information from your billing department. Your official HCFA number is the number under which your facility bills HCFA for its Medicare payments. Hospitals should report using the HCFA number for their main facility, rather than for one of their smaller facilities (such as the renal dialysis facility or a particular laboratory), even if that is where the event occurred.

Some facilities have reported under two different HCFA numbers, especially when a new MDR coordinator wasn't aware of previous reporting records for that facility. If you're unsure, it's a good idea to check previous records for your facility before reporting.

Semi-annual Reports

Semi-annual reports covering the period July 1, 1994, through December 31, 1994, are due by January 31, 1995. Please make sure the cover letter — as well as a copy of each previously filed individual event report attached to it — is clearly labeled SEMI-ANNUAL REPORT. If your facility had no reportable events during a semi-annual reporting period, you should not file a semi-annual report for that period. Some facilities are continuing to report unnecessarily — listing report numbers 0000 to 0000.

Data Omissions

Data omissions are still occurring on certain fields on both MedWatch Form 3500 (voluntary) and MedWatch Form 3500A (mandatory). If data are not available for a particular device, the reporter should indicate NA for "not applicable"; NI for "no information at this time"; UNK for "unknown"; and dashes (- -) in any field that would otherwise be blank. The following is a list of fields often left blank (the letter and number in parentheses indicate the section of the MedWatch Form 3500A where the field is located):

Date of Report (B5)
Manufacturer Address (D3)
Operator of Device (D4)
Expiration Date (D5)
Model No (D6)
Catalog No (D6)
Serial No (D6)
Lot No (D6)
Other ID No (D6)
Reporter Occupation (E3)

Reminder:

Semi-Annual Reports Are Due January 31, 1995

Information on Forms

And finally, we still get a lot of questions from user facilities regarding where to send MedWatch Form 3500A (mandatory) reports. They should be sent to:

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

Also, we're often asked how to obtain MedWatch Form 3500A. To request up to 10 copies of the form, as well as instructions, call 1-800-638-2041 or write to:

Division of Small Manufacturers Assistance (HFZ-220)
FDA/CDRH
1350 Piccard Drive
Rockville, MD 20850

Bulk copies of MedWatch Form 3500A can be obtained from:

Consolidated Forms and Publications Distribution Center
Washington Commerce Center
3222 Hubbard Road
Landover, MD 20785

In the next issue of the *Bulletin*, I hope to have some news to report about the final MDR regulation and its impact on MAUDE.❖

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

HEALTHCARE COMMUNITY ALERTED TO DEVICE PROBLEMS DURING 1994

During 1994, FDA issued 2 safety alerts, 3 public health advisories, and a "Dear Doctor" letter/safety alert to the health care community about risks or potential risks associated with the use of medical devices. The Office of Surveillance and Biometrics in the Center for Devices and Radiological Health (CDRH) issues alerts and advisories directly to users of medical devices — doctors, nurses, hospital administrators, risk managers, and biomedical and clinical engineers — whenever an event takes place that warrants special attention.

Safety alerts differ from public health advisories in the degree and certainty of the risk. Generally, safety alerts discuss an occurrence that has actually caused or contributed to a death or serious injury, while public health advisories describe potential risk. Both recommend actions to prevent or minimize risk to patients and health professionals. Both affect a widespread and diverse user population and usually pertain to more than one make of a device. The following alerts and advisories were issued in 1994:

FDA Public Health Advisory: Avoidance of Serious X-Ray-Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures (September 30, 1994).

FDA received reports of occasional, but at times severe, radiation-induced skin injuries to patients resulting from prolonged, fluoroscopically-guided, invasive procedures. Procedures that potentially involve extended fluoroscopy time include:

- percutaneous transluminal angioplasty (coronary and other vessels),
- radiofrequency cardiac catheter ablation,
- vascular embolization,
- stent and filter placement,
- thrombolytic and fibrinolytic procedures,
- percutaneous transhepatic cholangiography,
- transjugular intrahepatic portosystemic shunt,
- percutaneous nephrostomy,
- biliary drainage, and
- urinary/biliary stone removal.

FDA suggests that facilities observe the following principles:

(1) Establish standard operating procedures and clinical protocols for each specific type of procedure performed;

(2) Know the radiation dose rates for the specific fluoroscopic system and for each mode of operation used during the clinical protocol;

(3) Assess the impact of each procedure's protocol on the potential for radiation injury to the patient;

(4) Modify the protocol, as appropriate, to limit the cumulative absorbed doses to any irradiated areas of the skin to the minimum necessary for the clinical task. Avoid approaching cumulative doses that would induce unacceptable adverse effects; and

(5) Enlist a qualified medical physicist to assist in implementing these principles in such a manner so as not to adversely affect the clinical objectives of the procedures.

"Dear Doctor" Letter/Safety Alert: Important Information About TMJ Implants (July 15, 1994).

Recommendations are given to orthopedic surgeons, otolaryngologists, and plastic and reconstructive surgeons to address the management of patients who have received temporomandibular joint (TMJ) implants.

Because asymptomatic patients may experience bone degeneration, FDA recommends that **all patients** with Proplast®-coated implants who have not had a radiograph taken within the past six months undergo immediate and appropriate radiographic examination.

FDA recommends:

(1) If loss of implant integrity or progressive bone degeneration is **not** occurring, regular radiographic examinations of the implant should be performed every six months for as long as it remains in the jaw; and

(2) If either loss of implant integrity or progressive bone degeneration is found, explantation may be appropriate. If explantation is chosen, patients should be evaluated to determine what alternative procedures might be appropriate, e.g., a non-Proplast®-coated implant, an autologous bone graft, or no replacement (systematic management).

(continued on page 6)

Healthcare Community Alerted (continued from page 5)

FDA Safety Alert: Hazards of Precipitation Associated with Parenteral Nutrition (April 18, 1994).

FDA received a report from one institution of 2 deaths and at least 2 cases of respiratory distress which developed during peripheral infusion of a three-in-one total parenteral nutrition (TPN) admixture. The admixture contained 10% FreAminine III, dextrose, calcium gluconate, potassium phosphate, other minerals, and a lipid emulsion — all of which were combined using an automated compounder. The solution may have contained a precipitate of calcium phosphate.

FDA urges that caution be taken to ensure that precipitates have not formed in any parenteral nutrition admixtures because of the potential for life-threatening events.

FDA suggests the following steps to decrease the risk of injuries:

(1) The solubility of the added calcium should be calculated from the volume at the time when the calcium is added. The line should be flushed between addition of any potentially incompatible components;

(2) Since a lipid emulsion in a three-in-one admixture obscures the presence of a precipitate, either use a two-in-one admixture with the lipid infused separately or add the calcium before the lipid emulsion;

(3) Automated compounding devices should be maintained and operated according to the manufacturer's recommendations. Step 2 should be considered when programming the device;

(4) During the mixing process, periodically agitate the admixture and check for precipitates. Patients and care givers should be trained to visually inspect for signs of precipitation and advised to stop the infusion and seek medical assistance if precipitates are noted;

(5) Use a filter when infusing either central or peripheral parenteral nutrition admixtures. A 1.2 micron air eliminating filter for lipid containing admixtures and a 0.22 micron air eliminating filter for nonlipid containing mixtures are recommended;

(6) If stored at room temperature, infuse admixtures within 24 hours after mixing and if stored at refrigerated temperatures, within 24 hours of rewarming; and

(7) Stop infusing if symptoms of acute respiratory distress, pulmonary embolus, or interstitial pneumonitis develop. Home care personnel and patients should immediately seek medical assistance.

FDA Public Health Advisory: Avoiding Injuries from Rapid Drug or I.V. Fluid Administration Associated with I.V. Pumps and Rate Controller Devices (March 1, 1994).

FDA received reports of injuries and deaths from uncontrolled, rapid infusion of medications or fluids with the use of I.V. pumps and rate control devices. In some cases, the I.V. tubing and bag were removed from the controller or infusion pump before the I.V. set clamp or thumb wheel was closed. This resulted in rapid, uncontrolled flow ("free flow").

FDA suggests the following precautions:

(1) Conduct in-service training and refresher classes on the correct use of infusion pumps;

(2) Place a prominent warning label on infusion pumps alerting users to close the administration set clamp prior to opening the infusion pump;

(3) Use infusion pumps and/or infusion sets with antifree-flow mechanisms;

(4) Use sets that incorporate limited volume reservoir chambers for the continuous administration of potentially toxic medications from large volume bags, e.g., lidocaine or theophylline;

(5) Limit the concentration of medication in the I.V. solution; and

(6) conduct regular inspection and maintenance of infusion pumps. (continued on page 7)

Healthcare Community Alerted (continued from page 6)

FDA Public Health Advisory: Occluded Endotracheal Tubes (February 28, 1994).

FDA received several reports of a colorless material inside endotracheal tubes that occludes the lumen and prevents adequate ventilation of the patient. This is a potentially serious problem. FDA recommends the following precautions when using pediatric endotracheal tubes:

(1) Check the patency of all endotracheal tubes (tube and connector) immediately prior to intubation;

(2) Do not allow solution/lubricants which can form film barriers to enter the lumen of the tube;

(3) If reconnecting the endotracheal tube and the connector, do not use solutions/lubricants that can form film barriers; and

(4) Do not use cellulose products (e.g., lidocaine jelly) when reconnecting and keep this material out of the lumen of the tube.

FDA Safety Alert: Laerdal Defibrillator (January 26, 1994).

Several problems are described concerning Laerdal's HeartStart (HS) Automatic and Semi-Automatic External Defibrillators, models HS 1000 (automatic), HS 1000S (semi-automatic), and HS 3000 (semi-automatic). FDA instructed the company to investigate the cause of the problems and the magnitude. In the meantime, the following precautions are suggested:

(1) Test the defibrillator at the beginning of each shift;

(2) Perform all periodic maintenance recommended by the manufacturer; and

(3) If using Model HS 1000S, check the patient for evidence of pulse and breathing before allowing the machine to deliver a second or repeated shock.❖

For copies of any of the above, contact the Office of Surveillance and Biometrics, HFZ-510, CDRH/FDA, 1350 Piccard Drive, Rockville, MD 20850, or FAX 301-594-2968.

FDA AND AAMI TO PRESENT A FORUM ON ELECTROMAGNETIC COMPATIBILITY FOR MEDICAL DEVICES

FDA and the Association for the Advancement of Medical Instrumentation (AAMI) will present a one-and-a-half day forum on May 24 and 25, 1995, immediately following the AAMI Annual Meeting and Exposition in Anaheim, California. Scientists, manufacturers, healthcare professionals, and regulatory experts will discuss EMI/EMC problems and potential solutions to ensure safer medical devices. The objectives of the conference are to:

- Increase the awareness of healthcare professionals (such as clinical/biomedical engineers, biomedical technicians, physicians, nurses, and risk managers), regulatory personnel, and device manufacturers and distributors regarding the potential for EMI/EMC problems;
- Discuss FDA plans and future activities for medical device EMC; and
- Foster open communication regarding EMI/EMC problems and possible solutions to ensure patient safety.

Break-out sessions and roundtables will address such topics as managing EMI in a variety of environments including healthcare institutions and the home; the problem of mobile patients and devices; designing for EMC including design techniques and considerations; managing EMC in existing devices including "retro-fixes," labeling, and educating users; new technologies and the implications for EMI; and failure investigation and remediation techniques.

For more information and to register for the conference, contact AAMI, Box 2942 Merrifield, VA 22116-2942; or call 1-800-332-2264 or 703-525-4890, ext. 260.❖

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