MEDICAL DEVICE REPORTING
FDA MEDICINE MANUFACTURERS

User Facility Reporting

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PMA SUBMISSIONS NOW DUE FOR REPROCESSED CLASS III SINGLE-USE DEVICES

As of February 14, 2001, hospitals that reprocess class III single-use devices (SUDs) for reuse in humans are now required to submit premarket approval (PMA) submissions to the Food and Drug Administration (FDA). Class III devices are those medical devices generally considered to pose the greatest potential risk to the health of the public and require the most regulation. Three examples of class III devices are:

- percutaneous transluminal coronary angioplasty (PTCA) catheters,
- implanted programable infusion pumps, and
- endotracheal tube changers.

FDA's basis for approval of a PMA submission is a finding that the device has a reasonable assurance of safety and effectiveness for its intended use based on valid scientific evidence. Clinical data may be necessary to establish the safety and effectiveness of a reprocessed SUD. The PMA submission also should evaluate the unique characteristics of the reprocessed SUD. A description of what FDA considers a complete PMA submission is given in the PMA regulation (21 CFR 814.20). FDA has general guidance on the required information in a PMA submission (see "Guidance for Preparation of PMA Manufacturing Information" at http://www.fda.gov/cdrh/ode/448.pdf).

The **February 14, 2001**, date is the first of FDA's announced enforcement dates for reprocessors of SUDs. On August 14, 2001, premarket notification submissions, also known as 510(k)s, will be required for all non-exempt class II devices. The non-premarket requirements which include registration, listing, medical device reporting, tracking (if applicable), corrections and removals, quality system, and labeling will also be required on **August 14, 2001.** Finally, on **February 14, 2002**, 510(k)s will be required for all class I non-exempt devices. To obtain a copy of the August 14, 2000, SUD reuse guidance document, see http://www.fda.gov/cdrh/reuse/index.shtml.

Dates to Remember

February 14, 2001
- Premarket Approval (PMA) submissions due for **class III** SUDs

August 14, 2001
- Premarket Notification [510(k)] submissions due for non-exempt **class II** SUDs
- Enforcement begins for non-premarket requirements (i.e., establishment registration, device listing, quality system, medical device reporting (MDR), medical device tracking, and corrections and removals).

February 14, 2002
- Premarket Notification [510(k)] submissions due for non-exempt **class I** devices.

In This Issue:

REUSE OF SINGLE-USE DEVICES WORKSHOPS

May 10 & 11, 2001 - Orlando, Florida
May 30 & 31, 2001 - Phoenix, Arizona*

The **Center for Devices and Radiological Health's (CDRH)** Division of Small Manufacturers Assistance (DSMA), the Office of Device Evaluation (ODE), and the FDA District Offices will conduct two regulatory workshops for third-party reprocessors and hospitals that reprocess single-use devices. Workshop sessions will run from 8:30 a.m. to 5:00 p.m. on Day 1 and from 8:30 a.m. to 3:00 p.m. on Day 2 at:

SHERATON SAFARI HOTEL
12205 Apopka-Vineland Road
Orlando, FL 32836
(407) 239-0444

MARRIOTT AIRPORT HOTEL
1101 North 44th Street
Phoenix, AZ 85008
(602) 273-7373

DAY 1 - Regulatory Requirements for Medical Devices

Agenda items include: enforcement guidance for reprocessing single-use devices (SUDs), registration, listing, premarket notification [510(k)] and premarket approval (PMA) submissions, labeling, and medical device reporting. Also, the Association of Medical Device Reprocessors will talk about its third-party reprocessing experiences.

DAY 2 - Quality System Regulation/Good Manufacturing Practices (GMP)

Agenda items will cover quality assurance procedures for the reprocessing of SUDs, establishment inspections, and enforcement actions.

Registration Information

Pre-registration is required by April 23 for the Orlando Workshop and **by May 11 for the Phoenix Workshop**.* Send your name, company, and number attending to JVP@cdrh.fda.gov or send a FAX to 301-443-8818, Attention Joseph Puleo or Blix Winston.

If you have any questions, contact Joseph Puleo at 1-800-638-2041, ext. 109, JVP@cdrh.fda.gov; or Blix Winston at 1-800-638-2041, ext. 116, FBW@cdrh.fda.gov.

Information for Orlando Florida

For your convenience, the Sheraton Safari Hotel will provide a continental breakfast, coffee breaks, and luncheon both days for a fee of $80.00. The Sheraton Safari Hotel will collect this fee at check-in time.

If you are not staying at the Sheraton Safari Hotel but would like the food and beverage package, please send a check for $80.00 payable to the Sheraton Safari Hotel to Miss Yamile Rivera, or call her at 407-239-0444 Ext. 1078 to use a major credit card.

A block of rooms has been reserved at the Sheraton Safari Hotel at the guest room rate of $86.00 per night. Reservations must be made by **April 9** to receive this special rate. These rates will be in effect 3 days prior and 3 days after the workshop. Guests must make their own reservations by calling the hotel at **1-800-423-3297** and identifying themselves as members of the **FDA Reuse Workshop Group**.

***Information on the Phoenix, Arizona Workshop (May 30 & 31)** will be posted on the Reuse web page at http://www.fda.gov/cdrh/reuse/index.shtml as soon as it becomes available.

CENTRAL VENOUS CATHETERS AND CARDIAC TAMPONADE*

by Deborah Yoder Blum, R.N., C.I.C.

An infant born at 28 weeks gestation had an extremely low birth weight and respiratory distress syndrome. A central venous line was placed in the right atrium to infuse total parenteral nutrition. The infant developed apnea and bradycardia after 3 days, and, despite resuscitation efforts, died.

What went wrong?

Cardiac tamponade occurs when sudden fluid accumulation in the pericardial space compresses the heart. An autopsy on the infant showed that the catheter tip in the right atrium eroded the myocardial wall, allowing fluid to enter the pericardium.

What precautions can be taken?

- To avoid triggering a tamponade when placing a central line in a child's arm, immobilize the limb containing the catheter.
- Obtain either an anterior/posterior (AP) or a posterior/anterior (PA) X-ray, along with a lateral chest X-ray, to confirm catheter tip location when a central line is inserted or any time the tip position is uncertain.
- Regularly verify blood return to ensure proper catheter tip placement and to monitor for perforation. Do not infuse fluids or medications through the catheter until you confirm blood return. If there is no blood return, obtain X-rays and consider withdrawing or removing the central line.
- Suspect cardiac tamponade in any patient with a central venous catheter whose condition suddenly deteriorates. Common signs included cyanosis, dilated neck veins, increased intravascular pressure, decreased arterial pressure, muffled heart sounds, sudden respiratory changes, sudden and dramatic changes in pulse rate or strength (including pulsus paradoxus), and unanticipated cardiac arrest.

Deborah Yoder Blum, R.N, C.I.C., is a Nurse Consultant in CDRH's Office of Surveillance and Biometrics.

**Adapted from the November issue of Nursing 2000.*

Get this brochure from the FDA Reuse website at: http://www.fda.gov/cdrh/reuse/trifold1.pdf or by sending an e-mail to dsma@cdrh.fda.gov or a FAX to 301-443-8818.

CHECK THESE OUT! Brochures available on the Internet

Get this brochure from the FDA Hospital Bed website at: http://www.fda.gov/cdrh/beds or by sending an e-mail to dsma@cdrh.fda.gov or a FAX to 301-443-8818.

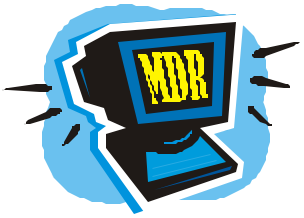
HANDLING ADVERSE EVENTS REPORTS*

by Suzanne Rich, R.N., B.A.

What happens after you report an adverse event involving a medical device to MedWatch, the Food and Drug Administrations' (FDA) Medical Products Reporting System?

The FDA's Center for Devices and Radiological Health (CDRH) handles the report. As the process begins, the information is entered in a database and a clinical analyst is assigned to review the report. The pool of analysts consists of a nuclear medicine technologist and 14 nurses with advanced degrees or expertise in specific areas. The analyst evaluates the nature, scope, and magnitude of the reported event. Next, FDA's adverse-event database is reviewed for similar events to determine if a follow-up investigation is warranted.

If an immediate review of the manufacturing and complaint records is needed, FDA may inspect the site where the device was manufactured. In most cases,



the FDA analyst sends letters to the manufacturer and the facility where the incident occurred (or to the person who reported the incident) asking for more specific information. The manufacturer may also be asked about any other adverse events reported for the involved or similar device(s) and what corrective actions were taken. This information is then reviewed to determine if further FDA action is needed. Corrective measures may include regulatory actions (such as a recall), user notification of a problem, or a press release warning the public of potential hazards associated with the device. Even if no immediate action is warranted, the report of the event remains in the database for future research and monitoring.

If a death, serious injury, or malfunction involving a medical device occurs where you practice, notify the person at your facility who is responsible for reporting such problems or call MedWatch at 1-800-FDA-1088. Visit the FDA/CDRH homepage at http://www.fda.gov/cdrh/safety.html to learn about FDA safety alerts and public health advisories.

Suzanne Rich, R.N., B.A., is a Nurse Consultant and Branch Chief in CDRH's Office of Surveillance and Biometrics.

**Adapted from the November issue of Nursing 2000.*

FDA will continue to actively enforce the Medical Device Reporting (MDR) requirements for **all** device users facilities, including hospital SUD reprocessors.

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

MedWatch Reporting Forms

MedWatch Reporting forms are available in PDF (Acrobat) format. Download the form(s) to your computer from the links below. PC Users: right click the link and select "Save Target As..." (IE 4/5 users) or "Save As..." (Netscape 4/6 users). Mac users may click and hold the link and select "Download Link to disk..." (IE4) or "Save This Link As..." (Netscape 4).

- Form 3500 (Voluntary Reporting) http://www.fda.gov/medwatch/safety/3500.pdf
- Form 3500a (Mandatory Reporting) http://www.fda.gov/medwatch/safety/3500a.pdf

SENDING THE WRONG SIGNALS*

by Diane Dwyer, R.N., B.S.N.

A patient in the operating room receiving mechanical ventilation had something in common with a patient connected to a cardiac monitoring system in the critical care unit. Both patients had implanted pacemakers, and both had experienced unintended maximum pacing rates up to 120 beats per minute. Medical intervention was needed to turn off the minute ventilation sensor in each pacemaker. When the sensors were turned off, the patients' heart rates returned to normal.

What went wrong?

Minute ventilation sensor-driven pacemakers set their pacing rates by measuring thoracic impedance and adjusting pacing outputs accordingly. Some medical devices, including cardiac monitors and mechanical ventilators, emit weak electrical currents that may interfere with minute ventilation sensors. In the above cases, such interference appears to have led to incorrect measurement of thoracic impedance and pacemaker rate increases.

Devices That May Interfere with Pacing Rates

- Cardiac monitors
- Respiratory monitors
- Apnea monitors
- External defibrillators
- Mechanical ventilators
- Echocardiography machines

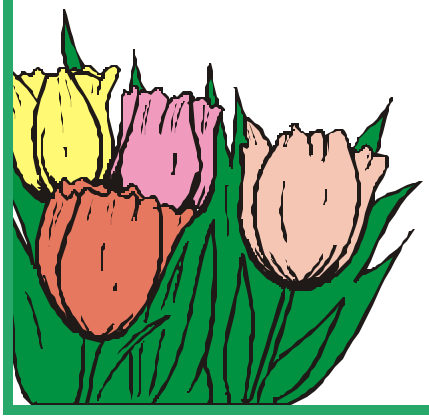
What precautions can be taken?

If a patient has an implanted pacemaker, document the type when admitted to the facility. Record the manufacturer, model, and sensor type. Make sure the minute ventilation rate-adaptive sensor mode is turned off while the patient is connected to any equipment that could interfere with the pacemaker. Carefully monitor heart and respiratory rate.

Share with the patient and your colleagues the Food and Drug Administrative Public Health Advisory "Interaction Between Minute Ventilation Rate-Adaptive Pacemakers and Cardiac Monitoring and Diagnostic Equipment." You can get a copy at http://www.fda.gov/cdrh/safety.html by scrolling down to and clicking on 10-14-98.

Diane Dwyer, R.N., B.S.N., is a Nurse Consultant in CDRH's Office of Surveillance and Biometrics.

**Adapted from the September issue of Nursing 2000.*



The Spring Issue will be devoted entirely to reprocessing and reuse of single-use devices.

SAFEGUARDING CONTRAST MEDIA INJECTIONS

by Beverly Albrecht Gallauresi, R.N., B.S., M.P.H.

A 62-year-old man came to the Emergency Department complaining of mid-sternal pain, shortness of breath, diaphoresis, and nausea after shoveling snow. A diagnostic cardiac catheterization indicated arterial blockage. The patient underwent angioplasty without incident. A venogram was performed afterward to evaluate left ventricular function. During the procedure, the patient experienced cardiac arrest and died.

What went wrong?

This event was directly attributed to error by medical personnel. The biomedical engineering department at the facility evaluated the contrast medium injector device involved in the event and found no malfunctions that could have been responsible. The manufacturer performed a failure analysis and concurred with the facility.

Further investigation revealed that the disposable syringe used during the venogram was not filled with contrast medium before the procedure. At least 30 cc of air was injected directly into the patient's left ventricle causing an air embolism that led to cardiac arrest.

What precautions can be taken?

- Carefully review the operator's instructions before using any invasive diagnostic equipment.
- If possible, assign one person to always be responsible for filling the contrast injector.
- Have a second person confirm the correct filling of the injector and check it again just before the medium is injected.

If a death, serious injury, or malfunction involving a contrast medium injector occurs where you practice, notify the person at your facility who is responsible for reporting such problems or call MedWatch at 1-800-FDA-1088. To learn about the FDA Center for Devices and Radiological Health (CDRH), visit our homepage at http://www.fda.gov/cdrh.

Beverly Albrecht Gallauresi, R.N., B.A., M.P.H., is a Nurse Consultant in CDRH's Office of Surveillance and Biometrics.

**Adapted from the January issue of Nursing 2001.*

UPCOMING REUSE EVENTS

April 23, 2001, New Jersey Healthcare Central Service Association, Atlantic City, New Jersey - FDA Speaker: Larry Kessler

May 10-11, 2001, FDA Workshop: Reuse of Single-Use Devices, Orlando, Florida

May 23-26, 2001, Club Espanol de Esterilizacion, Salamanca, Spain - FDA Speaker: Larry Spears

May 30-31, 2001, FDA Workshop: Reuse of Single-Use Devices, Phoenix, Arizona

November 9-10, 2001, Japanese Association for Operative Medicine, Tokyo, Japan, - FDA Speaker: Tim Ulatowski

For more information visit the Reuse Home Page at: http://www.fda.gov/cdrh/reuse/index.shtml

USER FACILITY REPORTING BULLETIN

FDA produces the *User Facility Reporting Bulletin* quarterly 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, the Medical Device Amendments of 1992, and the Food and Drug Administration Modernization Act of 1997. The *Bulletin's* contents may be freely reproduced. Comments should be sent to the Editor.

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