MEDICAL DEVICE REPORTING
User Facility Reporting

Issue No. 36 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Fall 2001

MEDICAL PRODUCT SURVEILLANCE NETWORK (MEDSUN) READY TO LAUNCH FIRST SEGMENT OF THE PHASE II PILOT

By Marilyn Flack

Background

At the Food and Drug Administration (FDA), the Center for Devices and Radiological Health (CDRH) sees first hand the technological advances in healthcare as new medical devices are reviewed and cleared for marketing. The increasing complexity of medical technology, perhaps coupled with economic pressures and organizational change within health care institutions, increases the potential for unanticipated and unintended consequences.[1] These changes demand that surveillance of marketed devices moves from a defensive to a proactive stance. This proactive strategy includes an understanding of how organizations encounter devices, how problems are perceived and reported, and what characteristics of the system contribute to any event.

To the extent possible to identify device failures before patients are injured, FDA can join with manufacturers and healthcare professionals in creating a safer healthcare environment. Along these lines, the Center has instituted as part of its planning process the concept of the Total Product Life Cycle (TPLC). TPLC follows the life of a medical device from its inception through its development and use, and finally its replacement by newer products.

Although there are mandatory reporting requirements for user facilities (under the Safe Medical Devices Act of 1990), there is evidence of significant under-reporting by the clinical community of adverse events associated with medical devices. FDA must have quality information about postmarket problems with devices, especially how they are used in the clinical setting, if it is to be successful in promoting patient safety.

The Food and Drug Modernization Act of 1997 mandated that FDA move away from the universal reporting requirement for user facilities to a smaller "sentinel-type" system. The current universal reporting system remains in place during the pilot stages of the new program and until FDA implements the new national system. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high quality data on medical devices in clinical use. This new system is called the Medical Product Surveillance Network (MedSun).

Before writing a regulation to implement the large-scale national MedSun reporting system, FDA plans to conduct a pilot project to ensure all aspects of the new system address the needs of both the reporting facilities

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In This Issue:

FDA SENDS ANOTHER LETTER TO HOSPITALS ABOUT REUSE OF SINGLE-USE DEVICES

Recently, FDA sent a letter to hospitals explaining the change in its enforcement approach for hospital SUD (single-use device) reprocessors. At the discretion of Department of Health and Human Services Secretary Tommy Thompson, hospital SUD reprocessors were granted another year before FDA actively enforces the non-premarket requirements with the exception of registration and listing. Premarket requirements are still being actively enforced. The complete text of the September 25th letter is on page 2.

MEDSUN - ***From Page 1***

and FDA. This pilot project will begin with a small sample (25) and increase to a larger sample (200) over a period of about three years. A regulation will then be promulgated reflecting the outcomes learned from the pilot project.

Goals for MedSun

- Collect high quality data about adverse medical device events;
- Analyze the data to identify newly emerging device problems and changes in device use;
- Serve as an advance warning system from the clinical community that would allow FDA to become aware of developing device problems and to prevent resulting injuries, or at least lessen the chances of such injuries recurring.
- Disseminate data regarding newly emerging device problems in a timely manner to concerned parties, especially healthcare professionals and the public;
- Apply the knowledge gained from the reported data to the device approval process and to prevention and control programs focused on patient safety;
- Provide the findings about emerging device problems to the medical device industry to aid them in making changes to design controls and human factor issues; and
- Provide a laboratory to conduct studies of device use errors and to conduct epidemiological studies. This could lead to a better understanding of the causes of adverse device events and point to ways of minimizing their occurrence and lessening their impact.

Launching Phase II

Currently, the system is undergoing testing by 10 hospitals (Phase I). Following this testing, 25 hospitals will launch Phase II of MedSun in November 2001. An additional 25 hospitals and 20 nursing homes will quickly join these 25 facilities. The participating facilities will increase to about 200 during the Phase II pilot.

Recruitment for the first 25 facilities is occurring now. Any hospital that would like to participate in this exciting project, or would like to learn more about it, should call Tina Powell at CODA (the contractor administering the program): 301-588-0177 or 1-800-859-9821. Reporting to MedSun fulfills a facility's SMDA reporting requirements.

How the program will work

During the pilot phase, up to 200 user facilities will send reports of deaths, serious injuries, and "close-call" events associated with medical devices to a secure web-server at the FDA via an Internet-based form. Two to three persons from each facility will be identified as the official MedSun participants and will have passwords to access the system. An important functionality of the software is that it is dynamic in nature. Certain questions appear only if particular responses were made to earlier questions, thus making it quick and efficient to complete. Further, it is constructed with the flexibility to permit FDA to design features that will permit specific questions to appear when certain medical devices are the topic of the report. For example, if the user facility is making a report about a catheter, the web site will automatically display several questions related to that device.

Feedback to the participating facilities is considered a key element in this new system. Information from the project about medical devices and related problems/health issues will be part of active outreach to the facilities. This may include newsletters, safety information, study data posted on the web site, etc. Types of feedback will be expanded as FDA learns from the participating facilities what type of information would be most useful to them.

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[1] Cook, Richard I., Woods, David D., Miller, Charlotte. A Tale of Two Stories: Contrasting Views of Patient Safety. Report from a Workshop; Assembling the Scientific Basis for Progress on Patient Safety, National Health Care Safety Council of the National Patient Safety Foundation at the American Medical Association, 1998.

Marilyn Flack is a Senior Public Health Analyst in the Center for Devices and Radiological Health's Office of Surveillance and Biometrics.

ELECTRONIC NOTIFICATION FOR THE *USER FACILITY REPORTING BULLETIN* IS NOW AVAILABLE

If you would like to be notified electronically (via e-mail) when a new issue of the *User Facility Reporting Bulletin* is released, you can sign-up for our List Service at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCDRHNew/listman.cfm

Please share this information with your colleagues. They'll thank you for it!

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Changes in Enforcement of FDA's Requirements on Reprocessing of Single-Use Devices

(You are encouraged to copy and distribute this information)

September 25, 2001

Dear Hospital Administrator and Hospital Risk Manager:

The purpose of this letter is to alert you to a change in FDA's policy on the reuse of single-use devices (SUDs) that will affect all hospital SUD reprocessors. Specifically, FDA is extending the deadline for active enforcement to August 14, 2002, for the following postmarket requirements: medical device reporting, tracking, corrections and removals, quality system, and labeling.

FDA's schedule for enforcement of other requirements remains unchanged. As previously announced, FDA plans to begin inspecting hospital SUD reprocessors shortly. FDA will immediately enforce the requirements for establishment registration and device listing. FDA is actively phasing-in enforcement of its premarket requirements (as described below).

Change in enforcement approach to hospital SUD reprocessors

Beginning this fall, FDA intends to inspect hospital SUD reprocessors. These inspections will cover all three classes (I, II, and III) of medical devices. The change in FDA's reuse policy concerns the focus and possible outcomes of these inspections. The focus will be to assess hospitals' compliance with the Agency's postmarket regulatory requirements. However, the Agency does not intend to take enforcement actions against hospitals if they are found not to be in compliance with these requirements. Rather, FDA plans to spend the next year educating hospitals on complying with the postmarket requirements. This policy will remain in effect until August 14, 2002, provided that the hospitals are taking steps to correct the violations noted during the inspection and that the violations do not pose a serious public health risk. <u>This revised policy does not apply to third party reprocessors.</u>

FDA will still enforce requirements for registration and device listing

As stated in the *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (SUD enforcement guidance),[1] which was published by FDA on August 14, 2000, the Agency will actively enforce registration and device listing requirements for all hospital SUD reprocessors. These requirements remain unchanged and will be actively enforced by FDA immediately.

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[1] A copy of the SUD enforcement guidance is available on FDA's Internet site: www.fda.gov/cdrh/reuse/index.shtml or by calling CDRH Facts on Demand at 1-800-899-0381 or by calling 301-827-0111, specify number 1168 when prompted for the document shelf number.

Examples of completed registration and device listing forms

To facilitate hospital SUD reprocessor registration and device listing, we have provided an example of a completed FDA Form 2891 "Initial Registration of Device Establishment" (see Attachment A). Hospital reprocessors that are registering for the first time with FDA must use this form. Also enclosed is an example of a completed FDA Form 2892 "Device Listing" (see Attachment B). This form must be used to identify the SUDs that a hospital reprocesses.

Additional details regarding registration and listing are available in "CDRH Guidance for Industry: Instructions for Completion of Medical Device Registration and Listing Forms FDA-2891, 2891a, and 2892." The guidance is available from FDA's Internet site www.fda.gov/cdrh/dsma/rlman.html. You may also obtain a copy by calling Facts-on-Demand at 1-800-899-0381 or 301-827-0111 (please specify number 012 when prompted for the document number).

Where to obtain registration and listing forms

Registration forms are available from FDA's Internet site www.fda.gov/cdrh/reglistpage.html. Because the device listing forms are uniquely numbered, they are not available from our Internet site.

You may obtain registration and listing forms from the Division of Small Manufacturers, International, and Consumer Assistance by e-mailing dsma@cdrh.fda.gov or by faxing 301-443-8818. Please provide your name, address, telephone number, and the quantity of forms you need. (Note that a separate FDA Form 2892 form must be submitted for each category or type of device that a hospital reprocesses.)

Completing and submitting registration and listing forms

FDA has created a new identification code to identify establishments that reprocess medical devices. The new code is "*MB*". When completing the establishment registration form, select the code "MB" under section "*9. Establishment Type*" and write in this code under section "*12. Establishment Name and Address*" on the device listing form. Please note that completed registration and listing forms must be submitted together. If you submit the forms separately, they will be returned to you.

FDA will still enforce requirements for premarket submissions

There are no changes to the premarket submission requirements or to FDA's timetable for enforcing these requirements. Hospital SUD reprocessors must submit to FDA, a PMA or a 510(k) for any class III, non-exempt class II, or non-exempt class I device that they reprocess. As described in the SUD enforcement guidance, FDA's deadline for enforcement of PMA or 510(k) submission requirements for class III devices was February 14, 2001. The enforcement date for the submission of a 510(k) for a non-exempt class II SUD was August 14, 2001. The enforcement date for the submission of a 510(k) for a non-exempt class I SUD is February 14, 2002. (See the SUD enforcement guidance for additional details.) FDA intends to **actively enforce** the premarket submission requirements.

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[2] The premarket requirements include the submission of a premarket approval application (PMA) or a premarket notification (510(k)) to FDA. The type of submission depends on the *Code of Federal Regulations* classification for the device.

Recommendations

If your hospital is reprocessing SUDs, we strongly encourage you to immediately register your facility and to list the devices that you are reprocessing with FDA, if you have not already done so. Failure to comply with this requirement may cause your devices to be violative under the Federal Food, Drug and Cosmetic Act.[3]

We also encourage you to explore our Internet site for information and guidance on the SUD reuse issue (www.fda.gov/cdrh/reuse). For additional information, you may consult with the Division of Small Manufacturers, International, and Consumer Assistance by calling 1-800-638-2041 or e-mailing DSMA@CDRH.fda.gov.

Sincerely yours,

/s/

David W. Feigal, Jr., MD, MPH
Director
Center for Devices and Radiological Health

Attachments (2)

[3] For additional information about types of FDA enforcement actions the Agency may take against non-compliant hospital SUD reprocessors, see the letter that FDA sent to all US hospitals on April 23, 001. A copy of this letter is available on FDA's Internet site www.fda.gov/cdrh/reuse/042301_reuse.html

Attachment A: Sample of a Completed Initial Registration Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

INITIAL REGISTRATION OF DEVICE ESTABLISHMENT

(Shaded Areas are for FDA Use Only)

Form Approved: OMB No. 0910-0387
Expiration Date: December 31, 2001

VALIDATION

RETURN THIS FORM TO: Food and Drug Administration, Center for Devices and Radiological Health, (HFZ-308), 9200 Corporate Blvd., Rockville, MD 20850-4015

1. **REGISTRATION NO.** *(Leave Blank)*

Public reporting burden for this collection of information is estimated to average .25 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2) and may be a violation of 18 U.S.C. 1001.

SECTION A

2. ESTABLISHMENT BUSINESS NAME		3. RECORD DATE (Mo.) (Day) (Yr.)	
ABC Hospital		*08 / 14 / 2001*	
4. NUMBER AND STREET	**5. CITY AND FOREIGN STATE**	**6. STATE**	**7.ZIP CODE**
9876 Jones Drive	*Randalstown*	*V / A*	*98765*
8. FOREIGN COUNTRY	**9. ESTABLISHMENT TYPE** *(See Instructions Booklet)*	**10. PREPRODUCTION REGISTRATION**	
	E M R S T X ID MB | | | | | | X | |	YES ☑ NO	

SECTION B

11. OWNER/OPERATOR BUSINESS NAME		12. OWNER/OPERATOR I.D.	
ABC Medical Center of the Greater Metro Area		*(Leave Blank)*	
13. NUMBER AND STREET	**14. CITY AND FOREIGN STATE**	**15. STATE**	**16.ZIPCODE**
1234 Corporate Drive	*Bethesda*	*V / A*	*12345*
17. FOREIGN COUNTRY	**18. TELEPHONE NUMBER-IF DIFFERENT FROM THAT OF OFFICIAL CORRESPONDENT** *(Area Code) (Number & Extension)*		
	301- 555-7777		

SECTION C

19. OFFICIAL CORRESPONDENT		20. REGISTRATION NUMBER	
Mrs. Dorothy Doe		*(LEAVE BLANK)*	
21. BUSINESS NAME			
ABC Medical Center of the Greater Metro Area			
22. NUMBER AND STREET	**23. CITY**	**24. STATE**	**25. ZIP CODE**
1234 Corporate Drive	*Bethesda*	*V / A*	*12345*
26. TELEPHONE NUMBER *(Area Code) (Number and Extension)*	**27. FAX NUMBER** *(Area Code) (Number)*		
301-555-7777	*301-555-8888*		

SECTION D

28. OTHER BUSINESS TRADING NAMES
(Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name).

SEQ	BUSINESS NAME	SEQ	BUSINESS NAME
SO1	*ABC Urgent Care*	SO4	
SO2	*ABC Surgical Outpatient Center*	SO5	
SO3		SO6	

SECTION E

29.SIGNATURE OF OFFICIAL CORRESPONDENT	30.TITLE
	Vice President, Hospital Administration

FORM FDA 2891 (8/00) **PREVIOUS EDITIONS ARE OBSOLETE.**

Attachment B: Sample of a Completed Device Listing Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DEVICE LISTING

Form Approved: OMB No. 0910-0387.
Expiration Date: December 31, 2001

Complete and Return to: Food and Drug Administration
Center for Devices and Radiological Health
Information Processing and Office Automation Branch (HFZ-308)
9200 Corporate Boulevard
Rockville, MD 20850-4015

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(g)(2) and may be a violation of 18 U.S.C. 1001.

1. DOCUMENT NUMBER
C_____
(each form pre-numbered)

2. REASON FOR SUBMISSION
☑ New Listing
Update to Device
Already Listed
Delete Listing

3. REPORT DATE

MO.	DAY	YR.
08	14	2001

4. OWNER/OPERATOR ID NUMBER
(Leave blank unless an ID number has been previously assigned to your owner/operator)

5. OWNER/OPERATOR NAME
ABC Medical Center of the Greater Metro Area

6. ADDRESS *(Check ☑ if same as submitted on FDA Form 2891)*
a. NUMBER and STREET
1234 Corporate Drive

b. CITY, STATE, ZIP CODE
Bethesda, Virginia 12345

c. FOREIGN COUNTRY

7. CLASSIFICATION NAME
CATHETERS, TRANSLUMINAL CORONARY ANGIOPLASTY, PERCUTANEOUS & OPERATIVE

8. CLASSIFICATION NUMBER
LOX

9. PROPRIETARY NAME ***(Brand Name)***
Multiple

10. COMMON OR USUAL NAME
PTCA Balloon Catheter

11. FOR U.S. DESIGNATED AGENTS OF FOREIGN ESTABLISHMENTS

a. NAME	B. REGISTRATION NUMBER
Not applicable	*Not applicable*

12.

REGISTRATION NO. TYPE	ESTABLISHMENT NAME AND ADDRESS *(Identification of Sites Where Listed Device is Produced)* (Name, Street Number, City, State or County, ZIP or Postal Code)	ESTABLISHMENT M	R	S	T	X	MB		
A *(Reprocessors should check or write-in "M B")*	*ABC Hospital, 9876 Jones Drive, Randalstown,VA 98765*						X		
B									
C									
D									

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:
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Center for Devices and Radiological Health
Information Processing and Office Automation Branch (HFZ-308)
9200 Corporate Boulevard
Rockville, MD 20850-4015

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please **DO NOT RETURN** this form to this address.

13.SIGNATURE | **14.TYPED OR PRINTED NAME**

FORM FDA 2892 (1/99) PREVIOUS EDITIONS ARE OBSOLETE. EF

ALARMING MONITOR ERROR*

By Beverly Gallauresi, R.N., M.P.H., B.S.

A 67-year-old man with a history of schwannoma tumors, hypertension, heart failure, hypertensive cardiomyopathy, and hyperlipidemia was admitted in serious condition to the intensive care unit. He developed a cardiac arrhythmia -- ventricular tachycardia that progressed to ventricular fibrillation -- but his bedside monitor never produced a "lethal-arrhythmia" alarm or printout. Several minutes elapsed before his condition was discovered and someone called for assistance. The patient died.

What went wrong?

The alarm never sounded because it was not turned on. According to the hospital's biomedical department, the alarm suspension log revealed that all alarms for this patient were turned off before he developed the arrhythmia. The manufacturer investigated and concluded that the device was performing to specifications and had not failed mechanically.

What precautions can you take?

Alarm modes vary according to the type of monitoring system, so become familiar with the ones you use.

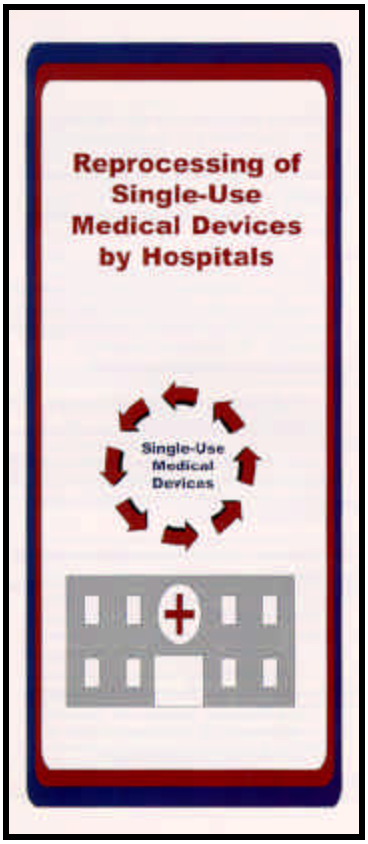
- Establish and maintain a working knowledge of all alarm settings for the telemetry and bedside monitoring systems used at your facility.
- Check the alarm system settings for each monitored patient at the beginning and end of each shift. Also check the settings before and after a patient is switched to a portable monitor (for example, when leaving the unit for a procedure).
- Promptly notify the proper person (such as someone in your facility's biomedical department) if a monitor malfunctions or fails in any way.

Although you need to support the adverse-event reporting policy of your healthcare facility, you may voluntarily report a problem with a medical device that does not perform as intended by calling MedWatch at 1-800-FDA-1088 (fax: 1-800-FDA-0178).

For more information about telemetry and bedside monitors reported to the Food and Drug Administration, please contact the author at BXG@CDRH.FDA.GOV.

Beverly Gallauresi, R.N., B.S., M.P.H., is a Nurse-Consultant in the Center for Devices and Radiological Health's Office of Surveillance and Biometrics.

**Adapted from the September issue of Nursing2001, Volume 31 Number 9.*



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.

SUBJECT MATTER INDEX TO UFR BULLETIN, ISSUES 1-36

UPCOMING REUSE EVENTS

November 4-7, 2001
RAPS 2001 Conference,
Baltimore, Maryland,
FDA Speaker: Lily Ng
For more information:
http://www.raps.org/educ/uprogs.cfm

November 14, 2001
Association for Professionals in Infection Control of Greater Detroit, Detroit, Michigan,
FDA Speaker: Eric Joneson
For more information go to their website: www.APICGD.org; or contact Lisa Sturm by electronic mail: lsturm@umich.edu.

For additional information about reuse, visit the Reuse Website 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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