NOTE: Some enforcement dates in this document have been extended as explained in the FDA Talk Paper of August 16, 2001, available at http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01098.html. For additional information about the enforcement extensions, see Letter to Hospitals (September 25, 2001), available at http://www.fda.gov/cdrh/reuse/reuse-letter-092501.html.

Guidance for Hospital Reprocessors
and for FDA Staff

Guidance on Adverse Event Reporting for Hospitals that Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use

Document issued on: April 24, 2001

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Reporting Systems Monitoring Branch
Division of Surveillance Systems
Office of Surveillance and Biometrics

Preface

Public Comment:

Comments and suggestions regarding this document should be submitted at any time for Agency consideration to Reporting Systems Monitoring Branch, HFZ-533, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact the Reporting Systems Monitoring Branch by fax at 301-827-0038.

Additional Copies:

World Wide Web/CDRH home page at http://www.fda.gov/cdrh/osb/guidance/1334.pdf or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1334 when prompted for the document shelf number.

Contents

Guidance on Adverse Events Reporting for Hospitals that Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use[1]

A. Introduction

On November 3, 1999, we (the Food and Drug Administration) announced that we intended to regulate original equipment manufacturers (OEMs), third parties, and hospitals that engage in reprocessing devices for single use in the same manner[2]. In the past, we regulated third party reprocessors in the same manner as OEMs under the Federal Food, Drug, and Cosmetic Act (the Act), except we did not actively enforce premarket requirements for third party reprocessors. We did not actively enforce any requirements for hospital reprocessors related to reprocessed single-use devices (SUDs). Under our proposed strategy to regulate the reprocessing and reuse of SUDs, we stated that we were considering actively enforcing all the requirements of the Act that apply including:

1. Registration and Device Listing (Section 510 of the Act; 21 Code of Federal Regulation (CFR) Part 807);
2. Medical Device Reporting (MDR) regulation (Sections 519(a), (b), and (c) of the Act; 21 CFR Part 803);
3. Medical Device Tracking (Section 519(e) of the Act; 21 CFR Part 821);
4. Medical Device Corrections and Removals (Section 519(f) of the Act; 21 CFR Part 806);
5. Quality System Regulation (QSR) (Section 520(f) of the Act; 21 CFR Part 820);
6. Labeling (Section 502 of the Act; 21 CFR Part 801); and
7. Premarket Requirements (Sections 510, 513, and 515 of the Act; 21 CFR Parts 807 and 814).

On August 14, 2000[3], we issued a guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (SUD enforcement guidance) which finalized our policy on how we intend to regulate third parties and hospitals engaged in reprocessing SUDs for reuse in humans. In this guidance document, we stated that we intend to enforce premarket submission requirements within six (6) months of issuance of the final SUD guidance for all class III devices; within twelve (12) months for class II non-exempt devices; and eighteen (18) months for class I non-exempt devices.

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[1] This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

[2] 64 FR 59782-59783, Nov. 3, 1999.

[3] 65 FR 49583-49585, Aug. 14, 2000.

The SUD enforcement guidance also stated our intent to continue to exercise our enforcement discretion with respect to the Act's non-premarket submission requirements for hospital reprocessors for one year from the issuance of the final SUD policy. These non-premarket requirements include establishment registration, device listing, adverse event reporting (MDR), tracking (which is triggered only by a specific FDA Tracking order), corrections and removals, and quality system.

A copy of the SUD enforcement guidance is available on FDA's web page at: **www.fda.gov/cdrh/comp/guidance/1168.pdf**.

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at **http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html**.

B. Purpose

In addition to their current obligation to report adverse events as user facilities[4], hospitals that engage in manufacturing activities, such as reprocessing, are subject to the manufacturer's reporting requirements (21 CFR Part 803) for adverse events involving SUDs that they reprocess. We recognize that hospital reprocessors may need additional guidance from us on how to submit adverse event reports as manufacturers. This guidance document serves two purposes:

1. To describe our Medical Device Reporting (MDR) requirements for device manufacturers (21 CFR Part 803) to SUD hospital reprocessors; and
2. To provide guidance to hospital SUD reprocessors on how to complete the Mandatory MedWatch report form (FDA Form 3500A) as device manufacturers.

C. Scope

This guidance document only applies to hospitals that are defined as manufacturers in accordance with 21 CFR Part 803. A manufacturer is defined in 21 CFR 803.3(o) as "any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure."

[4] The discretionary period for the MDR requirements for reporting adverse events related to SUDs that a hospital reprocesses only applies to manufacturer MDR reporting requirements (21 CFR 803 subpart E); it does not include user facility MDR reporting requirements (21 CFR 803 subpart C). FDA will continue to actively enforce device user facility MDR requirements for all device user facilities, including hospital reprocessors.

This guidance document does not apply to reprocessed SUDs that are "opened-but-unused"[5] or to health care facilities that are not hospitals[6].

D. Overview of Medical Device Reporting (MDR) Requirements

The objective of the MDR regulation is to provide a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices so that problems may be detected and corrected in a timely manner. The statutory authority for the MDR regulation are Sections 519 (a), (b), and (c) of the Act as amended by the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992. The final regulation for reporting adverse events involving medical devices was published on December 11, 1995, and became effective on July 31, 1996. This regulation implemented the reporting requirements for both health care (user) facilities and manufacturers.

The Food and Drug Modernization Act of 1997 made further changes to the MDR requirements. These changes were published as a Final Rule entitled "Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting" in the Federal Register on January 26, 2000 (65 FR 4112-4121). A copy of the December 1995 and January 2000 MDR Final Rule and other related MDR documents and guidances are available on FDA's web page at: **http://www.fda.gov/cdrh/mdr.html** (see Appendix A for a partial listing of these documents).

E. Reporting Adverse Events as a User Facility[7] and as a Manufacturer

1. What are the basic adverse event reporting obligations for user facilities and manufacturers?

A. Reports of individual adverse events required for user facilities and manufacturers:

User facilities and manufacturers report individual adverse events to us under a uniform, unified reporting system. Both user facilities and manufacturers report adverse events on the same MedWatch FDA form 3500A, the "Medication and Device Experience Report." (You can find a copy of the Mandatory MedWatch report form at www.fda.gov/cdrh/mdrforms.html.)

When a user facility receives information about a reportable adverse event, it must report the event to us and/or the manufacturer within ten (10) workdays. The user facility fills out certain parts of the MedWatch 3500A form and forwards copies of

[5] "Opened-but-unused" devices are single-use, disposable devices whose sterility has been breached or compromised, or whose sterile package was opened but not used on a patient, that is, they have not been in contact with blood or bodily fluids.

[6] For the purpose of this guidance, a "hospital" is defined as an acute health care facility.

[7] A "device user facility" is defined under 21 CFR Part 803.3(2)(f) as "a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatement facility … ." However, we would like to remind you that the focus of this guidance document are hospitals that are reprocessing SUDs for reuse.

the form to both FDA and the manufacturer if the adverse event involves a death. If the adverse event involves a serious injury, the user facility is required to report the event to the manufacturer within ten (10) workdays. If the identity of the manufacturer is unknown, the user facility must report the serious injury to us within ten (10) workdays.

The manufacturer, after receiving the report form from the user facility, further investigates the event and provides additional information on the MedWatch 3500A form. The manufacturer must submit a completed 3500A form to us within thirty (30) calendar days after becoming aware of the adverse event. Manufacturers also are obligated to submit a 3500A form to FDA within five (5) workdays of becoming aware of a reportable MDR event that requires remedial action in accordance with 21 CFR 803.53. This requirement is further discussed in question 7.D.

B. Other adverse event reports required for user facilities:

User facilities must complete and submit to FDA an annual report on January 1 of each year (see 21 CFR 803.33 – Annual reports). The information in the annual report must include:

- User facility's Health Care Financing Administration (HCFA) number or the number assigned by FDA for reporting purposes;
- Reporting year;
- Facility name and complete address;
- Total number of reports attached or summarized;
- Date of the annual report and the lowest and highest user facility report number of medical device reports submitted during the report period (for example, 123456790-2001-0001 through 0895);
- Name, position title, and complete address of the user facility contact person; and
- Information for each reportable event that occurred during the annual reporting period (see 21 CFR 803.33 (7) (i) to (vi) for details).

The annual report information may be submitted to us using FDA form 3419 or its electronic equivalent as approved by FDA under 21 CFR 803.14. If no reports are submitted to either FDA or manufacturers during these time periods, no annual report is required.

C. Other adverse event reports required for manufacturers:

Manufacturers are required to submit Baseline Reports (see 21 CFR 803.55(a) Baseline reports) and Supplemental Reports (see 21 CFR 803.56 – Supplemental reports). These requirements are further discussed in questions 15 and 17.

2. How does becoming a hospital reprocessor of a device originally marketed for single-use change my adverse event reporting obligations?

As a hospital reprocessor of a device that was previously marketed as single-use, your hospital has become the manufacturer of that device and, as such, is subject to the

manufacturer's adverse event reporting requirements. Accordingly, for adverse events involving SUDs that your hospital reprocessed, you must fulfill both the reporting requirements of a user facility and a manufacturer. This guidance document is intended to assist you in determining when a hospital must fulfill both the user facility and the manufacturer reporting requirements, and when the hospital only has to fulfill the user facility reporting requirements. Appendix B highlights major differences in MDR reporting requirements for adverse events involving SUDs reprocessed by the hospital and adverse events involving all other types of devices and SUDs that are not reprocessed by the hospital.

3. What are the major differences between the user facility and manufacturer adverse event reporting requirements?

There are several significant differences between reporting an adverse event to FDA as a user facility as opposed to being the device manufacturer. One basic difference is that device manufacturers are required to fill out additional sections of FDA form 3500A and to report device malfunctions and five (5) day remedial action event reports to the agency. In addition to filing the MedWatch 3500A form, manufacturers are required to submit an initial Baseline Report Form (FDA form 3417) and Supplemental MDR Reports as appropriate. (You can find a copy of the Baseline form and instructions for completing the form at **http://www.fda.gov/cdrh/mdr.html.)**

4. How do I know if I am required to report as a manufacturer or a user facility?

Whether you are required to fulfill the user facility adverse event reporting requirements only, or the manufacturer adverse event reporting requirements and the user facility requirements depends on whether the adverse event involved a reprocessed SUD. The answer to whether you report solely as a user facility or whether you also must report as a manufacturer depends on your answer to the following questions:

A. Does the reportable event involve a SUD that your hospital reprocessed?

If the reportable event involved a SUD that you reprocessed, you must fulfill the reporting requirements of a manufacturer and a user facility.

B. Does the reportable event involve a device that is not a SUD reprocessed by your hospital?

If the reportable event involved a device that was not a SUD that you reprocessed, you only have to fulfill the reporting requirements of a user facility[8].

5. Do I have to comply with manufacturing and user facility reporting requirements for all reprocessed devices?

No. If the device was intended to be reusable by the OEM, you do not have to fulfill the manufacturer adverse event reporting requirements. You only have to report as a

[8] The only exception to this might be if you have engaged in some other activities that would constitute remanufacturing, e.g., changing the intended use or changing the device's original specifications.

manufacturer and as a user facility if you are reprocessing a device that the OEM intended for single use. (Note: if a SUD reprocessed by a third party reprocessor is involved in a reportable event, you are only obligated to the user facility reporting requirements. However, remember that in this situation, the manufacturer of the reprocessed SUD is the third party reprocessor and not the OEM who originally manufactured the SUD (see questions 4.B and 6). Therefore, you should send your adverse event report to the reprocessor.)

6. What types of adverse events must I report when the event is not related to a SUD reprocessed by my hospital?

You are required to fulfill user facility adverse event reporting requirements for:

A. Deaths:

As a user facility, you are obligated to report adverse events to us, and to the manufacturer, if known, within ten (10) workdays when information reasonably suggests that a device has or may have caused or contributed to the death of a patient at your facility (see 21 CFR 803.30(a)(1)).

B. Serious Injuries:

As a user facility, you are obligated to report adverse events to the manufacturer, or to us if the identity of the manufacturer is not known, within ten (10) workdays when information reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient at your facility (see 21 CFR 803.30(a)(2)).

7. What types of events must I report as a manufacturer when the event is related to a SUD reprocessed by my hospital?

FDA considers reprocessing of a device originally intended for single-use for reuse in humans to be a manufacturing process. As such, any hospital that reprocesses SUDs for reuse is a manufacturer.

A. Deaths:

As the SUD hospital reprocessor, you are obligated to report adverse events to us within thirty (30) calendar days when information reasonably suggests that a SUD reprocessed by your hospital has or may have caused or contributed to the death of a patient at your facility (see 21 CFR 803.50(a)(1)).

B. Serious Injuries:

As a SUD hospital reprocessor, you are obligated to report adverse events to us within thirty (30) calendar days when information reasonably suggests that a SUD reprocessed by your hospital has or may have caused or contributed to a serious injury to a patient at your facility (see 21 CFR 803.50(a)(1)).

C. Malfunctions that do not result in death or serious injury:

As a SUD hospital reprocessor, you are obligated to report adverse events to us within thirty (30) calendar days when information reasonably suggests that the SUD device reprocessed by your hospital has malfunctioned and such device or similar SUD also reprocessed by your hospital would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur (21 CFR 803.50(a)(2)).

D. Remedial actions:

As a SUD hospital reprocessor, you are obligated to report adverse events to us within five (5) workdays of becoming aware of:

1. a reportable event(s) that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, or
2. a reportable event(s) for which we have made a written request (21 CFR 803.53(a) and (b)).

8. As a SUD reprocessor, I am obligated to report deaths, serious injuries, and malfunctions within 30 calendar days and remedial actions within five (5) workdays (see question 7 above) to the agency when the reportable adverse event involves a SUD reprocessed by my hospital. However, under the user facility reporting requirements, it appears that I must report all deaths to FDA within 10 workdays. Do I complete two separate MedWatch 3500A report forms for the same event?

As the user facility, you must complete sections A – F (skip section C) of the MedWatch 3500A form and submit reports of all deaths to both FDA and the device manufacturer within ten (10) workdays of becoming aware of the event.

As the SUD reprocessor, you must then complete sections G and H of the MedWatch 3500A form and submit a completed 3500A form to FDA within 30 calendar days of becoming aware of the event.

To avoid filing the same event twice, we suggest that you complete sections A – H (skip section C) of the MedWatch 3500A form and submit the completed form to the agency within ten (10) workdays if the event involves a patient death. Additional detail on which sections of the 3500A report form should be filled out are addressed in questions 11 and 12 below.

9. What is the definition of "Serious Injury"?

"Serious injury" is defined (in 21 CFR Part 803.3(bb)(1)), as an injury or illness that:

- is life-threatening;
- results in permanent[9] impairment of a body function or permanent damage to body structure; or

[9] "Permanent" means, for purposes of 21 CFR Part 803 Subpart A "General Provisions", irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage (21 CFR Part 803.3(bb)(2)).

- necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

10. What is the definition of "Malfunction"?

"Malfunction" is defined (in 21 CFR 803.3(n)) as the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed (see 21 CFR 801.4). Appendix C is an example of a malfunction adverse event that should be reported to FDA by the hospital reprocessor.

11. Which sections of the MedWatch 3500A form must I complete for a reportable adverse event that involves a device that is <u>not a SUD reprocessed</u> by the hospital?

A. On the upper right-hand corner on the front page of the 3500A form, enter your user facility number under *<u>UF/Dist report #</u>*. The *UF #* is a combination of your hospital's Health Care Financing Administration (HCFA) number (or a number FDA assigned to your hospital), the current 4-digit calendar year, and a 4-digit sequence number for each report filed during the current year (e.g., 1234567890-2001-0001, 1234567890-2001-0002, etc.).

B. Complete all items in section *<u>A. Patient information.</u>*

C. Complete all items in section *<u>B. Adverse event or product problem</u>*.

(Note: skip section *<u>C. Suspect medication(s)</u>*.)

D. Complete all items in section *<u>D. Suspect medical device</u>*. Note that specific device identification information should be entered exactly as it appears on the device or on the device labeling.

E. Complete all items in section *<u>E. Initial reporter</u>*. The initial reporter is the person who provided the information about the adverse event to the user facility.

F. Complete all items in section *<u>F. For use by user facility/distributor- devices only</u>*.

12. Which sections of the MedWatch 3500A form must I complete for a reportable adverse event that <u>involves</u> a SUD that my hospital reprocessed?

A. On the upper right-hand corner on the front page of the 3500A form, enter your establishment registration number under *<u>Mfr. report #</u>*. The *mfr. report #* is composed of the registration number that FDA assigned to your hospital when you registered and listed with the agency as a manufacturer, the current 4-digit calendar year, and the 5-digit sequence number for each report filed during the current year (e.g., 9876543210-2001-00001, 9876543210-2001-00002, etc.). You also

must enter your user facility report number under *Uf/Dist report #* of the MedWatch 3500A form (see 11A above).

B. Complete all items in section *A. Patient information*.

C. Complete all items in section *B. Adverse event or product problem*.

(Note: skip section *C. Suspect medications(s)*.)

D. Complete all items in section *D. Suspect medical device*. Note that specific device identification information should be entered exactly as it appears on the device or on the device labeling. For item *D.3. Manufacturer name and address* enter the name and address of the SUD reprocessor. You should enter the name and address of the SUD's OEM in section H.10.

E. Complete all items in section *E. Initial reporter*. The initial reporter is the person who provided the information about the adverse event to the user facility or manufacturer.

F. Complete items in section *F. For use by user facility/distributor-devices only*. As the SUD reprocessor, you must provide this information as specified in 21 CFR Part 803.52(f)(11). To facilitate reporting, enter the user facility data directly in Section F rather than in Block H.11 *Corrected data*.
   1. *F.13. Report sent to manufacturer?* The term "manufacturer" in this block refers to the SUD hospital reprocessor.
   2. *F.14: Manufacturer name/address*. The term "manufacturer" in this block refers to the SUD hospital reprocessor and this information should be entered in section G.1 *Contact office – name/address (& mfring site for devices)*. In section F.14 *Manufacturer name/address*, enter "see G.1."

G. Complete all items in section *G. All manufacturers*.
   1. *G.1: Contact office – name/address (& mfring site for devices)*. Information in this block refers to the SUD hospital reprocessor, therefore, enter the contact office, name, and address of the facility that is submitting the report of the SUD event. If the name and address of the reprocessing facility is different from the address of the reporting site, also enter the name and address of the reprocessing site in section G.1.
   2. *G.4: Date received by manufacturer (mo/day/yyyy)*. This is the date that the SUD hospital reprocessor became aware of the adverse event.
   3. *G.5, 6, and 8*. These blocks are not applicable to medical devices.
   4. *G.7: Type of report*. Only three (3) report types are applicable to SUD hospital reprocessors: *5-day*, *Initial (i.e., 30-day reports)*, and *Follow-up*. Select the report type that is applicable to the event that you are reporting.

H. Complete all blocks in section *H. Device manufacturers only*. As the SUD reprocessor, you must complete all sections regardless of where the device analysis was performed.

1. *H.4: Device manufacturing date (mo/yyyy).* For the purpose of this block, the manufacturing date is the date that the SUD was reprocessed by your hospital.
2. *H.7: If remedial action initiated, check type.* Select the most appropriate remedial action(s) that apply.

See Appendix C for a mock MedWatch 3500A report submitted to FDA for a device malfunction involving a SUD reprocessed by a hospital.

Detailed instructions for completing the MedWatch 3500A form are available in "Mandatory MedWatch Reporting Form 3500A Instructions and Code Manual (dated 4/11/01)". (You can find a copy of the instructions and codes at **http://www.fda.gov/cdrh/mdrforms.html**.)

13. When do I have to file reports of corrections and removals?

Under 21 CFR Part 806, you are required to submit a written report to us within ten (10) workdays of initiating a correction or removal action that was taken:

- to reduce a risk to health posed by the device; or
- to remedy a device problem which may present a risk to health unless you previously submitted the information as a 5-day report under 21 CFR Parts 803.53 – Five-day reports (see question 7 above).

14. If I file an adverse event report on MedWatch 3500A form for an adverse event related to a SUD that I reprocessed, do I have to file a corrections and removals report too?

No. If you have already filed an adverse event report on MedWatch 3500A form for an adverse event related to a SUD that you reprocessed, you do not have to file a corrections and removals report under 21 CFR Part 806 (see 21 CFR 806.10(f)) (see question 13 above).

15. What is the Initial Baseline Report form that I must complete as a SUD hospital reprocessor?

As a SUD hospital reprocessor, you must submit an Initial Baseline report on FDA form 3417 or its electronic equivalent as approved by the agency under 21 CFR 803.14, for each reprocessed SUD device model that you are reporting to FDA for the first time (see 21 CFR 803.55(a) Baseline reports). You are only required to provide the information described in 21 CFR 803.55 (b)(1)-(8) Baseline reports. You do not need to provide information stated in 21 CFR 803.55(b)(9) and (10). You must submit annual updates on FDA form 3417 when the information on the initial Baseline report changes (see 21 CFR 803.55(b)). (You can find a copy of the Baseline Report Form and instructions for completing the form at **http://www.fda.gov/cdrh/mdrforms.html**.)

16. Where can I obtain information on electronic equivalents?

To obtain information on submission of electronic equivalents, contact the Information Analysis Branch, Division of Surveillance Systems, Office of Surveillance and Biometrics at 301-827-7537 or by fax at 301-827-0038.

17. What are the Supplemental Reports that I must submit as a SUD hospital reprocessor?

As the SUD hospital reprocessor, you are obligated to file a Supplemental Report within thirty (30) calendar days with FDA when you obtain additional or updated information on an adverse event that was not available or known at the time you submitted the initial MedWatch 3500A report. Use the MedWatch 3500A form to report the supplemental information by providing the same user facility report number and manufacturer report number that was entered on the original submission by completing blocks *G.7 (Type of report) and G.9 (Mfr. report number)* and check the appropriate code in section *H.2.* (*If follow-up, what type?).* Only supplemental information should be entered on the 3500A form. Information that was previously submitted should not be repeated. A detailed description of Supplemental Reports is provided in 21 CFR 803.56.

18. Are there additional MDR requirements that apply to user facilities that reprocess SUDs?

Yes. You need to amend your current MDR procedures to include documentation of your MDR reporting obligations as the SUD reprocessor (see 21 CFR 803.17- Written MDR Procedures).

User facilities and manufacturers are required to establish and maintain MDR event files (see 21 CFR 803.18 –Files). For adverse events involving SUDs reprocessed by your hospital, you need to incorporate the additional requirements for manufacturers under 21 CFR 803.18 (e).

19. How may I request exemptions or alternative reporting options as a SUD hospital reprocessor?

Under 21 CFR 803.19(b) and (c), you may, as a hospital SUD reprocessor, request an exemption from any or all of the reporting requirements of 21 CFR Part 803. FDA may, at its discretion, grant an exemption or alternative form of reporting adverse events. When the agency grants an exemption or alternative form of reporting, it may impose other reporting requirements to ensure the protection of public health.

All inquires regarding exemptions and alternative reporting should be submitted in writing to CDRH's OSB Reporting Systems Monitoring Branch, HFZ-533, at 1350 Piccard Drive, Rockville, MD 20850 or by fax number at 301-827-0038.

20. Where can I get additional information on user facility or manufacturer MDR reporting requirements?

You may submit additional questions on MDR reporting as a hospital SUD reprocessor to the Reporting Systems Monitoring Branch at the address or fax number listed above; email RSMB@CDRH.FDA.GOV; or you may refer to our web site at **http://www.fda.gov/cdrh/mdr.html.**

Appendix A: List of references and documents related to MDR reporting

Copies of these documents are available at: http://www.fda.gov/cdrh/mdr.html

Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting. Federal Register, vol. 65, no. 17, Jan. 26, 2000, pages 4112-4121.

Medical Device Reporting for Manufacturers (dated March 1997).

Mandatory MedWatch Reporting Form 3500A Instructions and Codes Manual (4/11/01).

Abbreviated Instructions for FDA Form 3500A Specific to MDR.

MDR Baseline Report Form FDA 3417.

Instructions for Completing Form 3417- Baseline Reports (dated July 1, 1996; revised March 31, 1997).

Appendix B: Adverse event reporting requirements when the event involves:

	What types of device-related adverse events must be reported?	Who should receive a copy of the report?	What is the time frame for reporting the adverse event?	Which sections of the MedWatch 3500A form must be completed?
1. A SUD that your hospital reprocessed, that is, <u>you are reporting as a device manufacturer of the reprocessed SUD</u>	• Deaths	• FDA	• Within 10 workdays after becoming aware of the event.	For all reports: • A. Patient information;
	• Serious Injuries	• FDA	• Within 30 calendar days after becoming aware of the event.	• B. Adverse event or product problem; (Skip section C)
	• Malfunctions	• FDA	• Within 30 calendar days after becoming aware of the event.	• D. Suspect medical device; • E. Initial reporter;
	• Remedial actions that were taken to prevent an unreasonable risk of substantial harm to the public *or* as requested by FDA.	• FDA	• Within 5 workdays after becoming aware of the event.	• F. For use by user facility/distributor-devices only; • G. All manufacturers; and • H. Device manufacturers only.

Appendix B continued:

	What types of device-related adverse events must be reported?	Who should receive a copy of the report?	What is the time frame for reporting the adverse event?	Which sections of the MedWatch 3500A form must be completed?
2. A device that is not a SUD reprocessed by your hospital, that is, <u>you are only reporting as a user facility</u>	• Deaths • Serious Injuries • May voluntarily report malfunctions	• FDA *And* • Device Manufacturer • Device Manufacturer *Or* • FDA when the device manufacturer is unknown • FDA *Or* • Device Manufacturer	• Within 10 workdays after becoming aware of the event. • Within 10 workdays after becoming aware of the event. • Not applicable.	For all reports: • A. Patient information; • B. Adverse event or product problem; (Skip section C) • D. Suspect medical device; • E. Initial reporter; and • F. For use by user facility/distributor-devices only.

Appendix C: Mock MedWatch 3500A report of an adverse event (malfunction) involving a SUD reprocessed by a hospital reprocessor.

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

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Form Approved: OMB No. 0910-0291 Expires: 04/30/01
See OMB statement on reverse

mfr report #: 9876543210-2001-00001

IF/Dist report #: 1234567890-2001-0001

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
146-2569	54 or Date of birth:	[X] female [ ] male	120 lbs or ___ kgs

In confidence

B. Adverse event or product problem

1. [ ] Adverse event and/or [XX] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- [ ] death ___ (mo/day/yr)
- [ ] life-threatening
- [ ] hospitalization – initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [ ] other: N/A

3. Date of event (mo/day/yr): 02/01/2001

4. Date of this report (mo/day/yr): 02/10/2001

5. Describe event or problem

A urinary catheter was placed in a 54 year old female patient prior to surgery. The next morning, the nurse attempted to remove the catheter. The nurse was unable to deflate the balloon of the catheter after several attempts. A doctor was finally called in to remove the catheter. The doctor was able to partially deflate the catheter by using a guide wire to puncture the balloon. The partially deflated catheter was finally removed from the patient. The doctor noted that there was a small bulge in the balloon even though it was completely empty. The doctor also noted that there was a slight crack in the catheter and a hard ridge at the balloon site. The doctor noted that the balloon felt rigid. The patient suffered minor discomfort.

6. Relevant tests/laboratory data, including dates

N/A

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

N/A

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1
#2

2. Dose, frequency & route used
#1
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for use (indication)
#1
#2

5. Event abated after use stopped or dose reduced
#1 [ ] yes [ ] no [ ] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 [ ] yes [ ] no [ ] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

9. NDC # – for product problems only (if known)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name: Wet-free Urinary Catheter

2. Type of device: Urological catheter

3. Manufacturer name & address:
St. Mary's Hospital
3110 42nd Street
New Castle, NM 54321

4. Operator of device
[X] health professional
[ ] lay user/patient
[ ] other:

5. Expiration date (mo/day/yr): unk

6.
model #:
catalog #: 837-9001
serial #: unknown
lot #: LN76284
other #:

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr): N/A

9. Device available for evaluation? (Do not send to FDA)
[X] yes [ ] no [ ] returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)
N/A

E. Initial reporter

1. Name & address:
Sandra B. Jones
3110 42nd Street
New Castle, NM 54321

phone #: 993-555-9876

2. Health professional? [X] yes [ ] no

3. Occupation: Staff Nurse

4. Initial reporter also sent report to FDA [X] yes [ ] no [ ] unk

FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

Medication and Device Experience Report
(continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

FDA Use Only

F. For use by user facility/distributor–devices only

1. Check one: [X] user facility [ ] distributor
2. UF/Dist report number: 1234567890-2001-0001
3. User facility or distributor name/address:
St. Mary's Hospital
3110 42nd Street
New Castle, NM 54321
4. Contact person: Anne Smith, RN
5. Phone Number: 993-555-9001
6. Date user facility or distributor became aware of event (mo/day/yr): 02/01/2001
7. Type of report: [X] initial [ ] follow-up #
8. Date of this report (mo/day/yr): 02/10/2001
9. Approximate age of device: unknown
10. Event problem codes (refer to coding manual): patient code 2199; device code 1528 - 1354 - 1135
11. Report sent to FDA? [X] yes 02/10/2001 (mo/day/yr) [ ] no
12. Location where event occurred: [X] hospital [ ] outpatient diagnostic facility [ ] home [ ] nursing home [ ] ambulatory surgical facility [ ] outpatient treatment facility [ ] other: (specify)
13. Report sent to manufacturer? [X] yes 02/01/2001 (mo/day/yr) [ ] no
14. Manufacturer name/address: See G1

G. All manufacturers

1. Contact office – name/address (A entring site for devices):
John B. Hill
St. Mary's Hospital
3110 42nd Street
New Castle, NM 54321
2. Phone number: 993-535-9084
3. Report source (check all that apply): [ ] foreign [ ] study [ ] literature [ ] consumer [ ] health professional [X] user facility [ ] company representative [ ] distributor [ ] other:
4. Date received by manufacturer (mo/day/yr): 02/01/2001
5. (A) NDA # ____ IND # ____ PLA # ____ pre-1938 [ ] yes OTC product [ ] yes
6. If IND, protocol #
7. Type of report (check all that apply): [ ] 5-day [ ] 15-day [ ] 10-day [ ] periodic [X] initial [ ] follow-up # ____
8. Adverse event term(s)
9. Mfr. report number: 9876543210-2001-00001

H. Device manufacturers only

1. Type of reportable event: [ ] death [ ] serious injury [X] malfunction (see guidelines) [ ] other:
2. If follow-up, what type? [ ] correction [ ] additional information [ ] response to FDA request [ ] device evaluation
3. Device evaluated by mfr? [ ] not returned to mfr. [X] yes [ ] evaluation summary attached [ ] no (attach page to explain why not) or provide code:
4. Device manufacture date (mo/yr): 12/15/2000
5. Labeled for single use? [X] yes [ ] no
6. Evaluation codes (refer to coding manual): method 10 - 38; results 137; conclusions 43
7. If remedial action initiated, check type: [ ] recall [ ] notification [ ] repair [ ] inspection [ ] replace [ ] patient monitoring [ ] relabeling [ ] modification/adjustment [ ] other:
8. Usage of device: [ ] initial use of device [X] reuse [ ] unknown
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number: N/A
10. [X] Additional manufacturer narrative and/or 11. [ ] Corrected data

H.3
The urinary catheter was reprocessed by the hospital's Central Supply on 12/15/00. A review of the reprocessing records indicated that the technician evaluated the catheter after it was reprocessed. He determined that it met the department's criteria for reuse and placed it into service.

Analysis of the returned catheter indicated unanticipated material deterioration and Central Supply conducted a complete evaluation of the remaining stock for signs of defect.

D.3 Catheter Company
555 Catheter Place
Boston Common, MN 44332

Please DO NOT RETURN this form to this address.

FDA Form 3500A - back