Needlesticks

Medical Device Reporting Guidance for User Facilities, Manufacturers, and Importers

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This document supersedes MDR Guidance Document and Exemption No. 3 – Needlesticks and Blood Exposure E1996003



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

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. 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 at (301) 594-2735, by FAX at (301) 827-0038 or email at rsmb@cdrh.fda.gov or mail at:

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Needlesticks - Medical Device Reporting Guidance

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 Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Introduction

On August 9, 1996, the FDA published a guidance document entitled "MDR Guidance Document and Exemption – Needlesticks and Blood Exposure – E1996003." The document was designed to provide guidance to user facilities, manufacturers, and importers to use for determining when an adverse event involving a needlestick, or a device intended to prevent a needlestick, would require the submission of a mandatory medical device death, serious injury, or malfunction report to the FDA.

Needlestick-related injuries, and malfunctions of devices intended to prevent needlesticks, that result in occupational exposure to bloodborne pathogens, such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV), continue to be an important public health concern.

Healthcare workers are especially at risk from bloodborne pathogen exposure on a daily basis and may not be aware that needlestick-related adverse events are reportable to the FDA by user facilities, manufacturers and importers. In addition, healthcare workers may not be aware that FDA has a voluntary reporting program they can use to report their needlestick-related events.

Due to continuing health concerns related to needlesticks and the devices intended to prevent needlesticks, the FDA decided to update its 1996 Needlestick Guidance document. The purpose of this revised Needlestick Guidance document is to provide user facilities, manufacturers, and importers with user-friendly information about their roles and obligations for reporting adverse events related to these products. The revised document also provides information for healthcare workers to report adverse events to the FDA through the voluntary MedWatch reporting system. This document conforms to the requirements of the Good Guidance Practices (GGP) regulation.

The Least Burdensome Approach

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 the information requested in the guidance is not relevant to the decision-making process or 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/ombudsman/

Needlesticks - Medical Device Reporting Guidance

A. What are the mandatory requirements, under 21 CFR Part 803, for device user facilities, importers, and manufacturers to report needlestick-related adverse events to the FDA?

The Medical Device Reporting (MDR) regulation, 21 CFR Part 803, requires that **user facilities** must submit medical device adverse event reports, on FDA Form 3500A, to the FDA and the device manufacturer whenever the facility become aware that a device used at the facility may have caused or contributed to a patient death. User facilities must also report adverse events to the device manufacturer or to FDA (if the manufacturer is unknown) whenever they become aware that a device may have caused or contributed to a serious injury to a patient of the facility.

In addition, user facilities are required to submit an annual report on FDA Form 3419 summarizing the reports submitted by the user facility during the reporting period. 21 CFR Part 803.3

The MDR regulation requires that device **importers** must submit medical device adverse event reports, on FDA Form 3500A, to the FDA and the device manufacturer whenever they become aware that one of their imported devices may have caused or contributed to a death or serious injury. Device importers must also submit adverse event reports to the device manufacturer whenever they become aware that one of their imported devices has malfunctioned, and such a malfunction would be likely to cause or contribute to a death or serious injury if it were to recur.

The MDR regulation requires that device **manufacturers** must submit medical device adverse event reports to the FDA, on FDA Form 3500A, whenever the manufacturer becomes aware that one of their manufactured devices may have caused or contributed to a death or serious injury. Device manufacturers must also submit adverse event reports to FDA whenever they become aware that one of their manufactured devices has malfunctioned, and such a malfunction would be likely to cause or contribute to a death or serious injury if it were to recur.

In addition, the manufacturer is required to submit a baseline report, on FDA Form 3417, for a device when the device model is first reported as required by Parts 803.50 and 803.52. 21 CFR Part 803.55

B. Where can I find more information about the mandatory reporting requirements for device user facilities, importers and manufacturers?

The mandatory MDR requirements, forms, instructions for filling out the forms, guidance documents and Federal Register notices can be found on the *Reporting Problems with Medical Devices* homepage at: http://www.fda.gov/cdrh/mdr/

You may also submit questions to the Reporting Systems Monitoring Branch, Division of Surveillance Systems, Office of Surveillance and Biometrics e-mail account at: rsmb@cdrh.fda.gov or by contacting them directly at (301) 594-2735.

C. When to I have to report a needlestick-related event reportable under 21 CFR Part 803?

A needlestick-related event is reportable as a death, serious injury or malfunction as detailed below:

1. A death report should be submitted by a user facility, importer and manufacturer if the device may have caused or contributed to the death of the individual.

2. A serious injury report should be submitted by a user facility, importer and manufacturer if the device resulted in an injury to an individual and the injury was life-threatening, resulted in permanent impairment of a body function or permanent damage to a body structure, or necessitated medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

3. A device malfunction report should be submitted by an importer and manufacturer if the device failed to perform as intended and would be likely to cause or contribute to a death or serious injury if the needlestick event recurred.

If a person who is exposed to infectious materials via a needlestick that resulted from a device failure is subsequently treated medically or surgically to prevent permanent impairment, then the event becomes reportable by the user facility, importer, and manufacturer as a serious injury report.

We do not consider first aid to constitute medical intervention, and this type of intervention will not require an MDR report. Examples of first aid are the application of a bandage or simple cleaning of the site of a needlestick. In addition, we do not consider an in-vitro diagnostic test for blood-borne diseases to constitute medical intervention. However, administration of a tetanus shot, a gamma globulin shot or stitches is considered medical intervention. This type of intervention triggers the submission of a mandatory serious injury adverse event report by a device user facility, importer, or manufacturer.

D. What is a medical device malfunction?

A malfunction is the failure of a device to meet its performance specifications or to perform as intended. If you are an importer or manufacturer of a device, you must report a malfunction when it is likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Once a malfunction has caused or contributed to a death or serious injury, a presumption that the malfunction is likely to cause or contribute to a death or serious injury has been established. This presumption will continue until the malfunction has caused or contributed to no further deaths or serious injuries for a period of two years, or valid data shows that the likelihood of another death or serious injury because of the malfunction is remote.

A malfunction that is or can be corrected during routine service or device maintenance should be reported if the malfunction is likely to cause or contribute to a death or serious injury if it were to recur.

You do not need to report a malfunction if it is not likely to result in a death or serious injury.

If you are a user facility, you are not required to report *any* device malfunctions. However, we encourage you to report device malfunctions to the device manufacturer and/or to the FDA through the voluntary MedWatch program.

E. Do I have to report a needlestick-related event that involves blood spillage or splattering?

You do not need to report a device-related blood spillage or splattering event unless the incident is the result of a device malfunction. If you are a manufacturer or an importer, you should report any spillage or splattering malfunction event if a recurrence is likely to cause or contribute to a death or serious injury.

F. Do I have to report a needlestick-related event due solely to user error?

It depends on the severity of the event. Events involving a death or a serious injury where user error may have caused or contributed to a needlestick-related event are reportable by a user facility, importer, and manufacturer.

G. As a manufacturer, what type of follow-up investigation should I conduct for events involving needlestick-related devices?

We require that you make a "good faith effort" to obtain information about the event. 21 CFR 803.50. You should document all follow-up attempts and reasons why any of the required MDR information could not be obtained. You should include in your file a record of each attempt to obtain information, and the reporter's responses. We may review the documentation contained in your files to determine whether you have made a reasonable attempt to follow up and obtain the required information. If your firm determines that the event is not reportable under the MDR regulation, then your files should contain documentation supporting this decision.

The follow-up investigation should focus on obtaining as much information as possible.

H. How can I submit voluntary MedWatch reports concerning needlestick-related events to FDA when those events are not required to be reported by 21 CFR Part 803?

User facilities are not required to submit mandatory malfunction adverse event reports involving needlesticks to the FDA. However, we encourage healthcare workers to report malfunctions involving needlestick-related events to the device manufacturer or to the FDA through the FDA MedWatch Voluntary Reporting Program on FDA Form 3500. Information about the FDA MedWatch Voluntary Reporting program and the Form FDA 3500 Voluntary Reporting Form can be found on the FDA MedWatch home page at: www.fda.gov/medwatch/. **A voluntary report can be filled out on line** by accessing the MedWatch homepage and clicking on "Submit Reports" or by direct access at: www.accessdata.fda.gov/scripts/medwatch/. In lieu of submitting a voluntary report via the internet, you may report to us by dialing 1-800-FDA-1088 or 1-240-276-3000.