medical devices

Medical Device Reporting: An Overview

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

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Medical Device Reporting: An Overview

Prepared by
Office of Surveillance and Biometrics
Systems Division of Surveillance

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Services
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

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FOREWORD

The Center for Devices and Radiological Health (CDRH), part of the Food and Drug Administration (FDA), develops and implements national programs and regulations to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness, and proper labeling of medical and radiation-emitting devices.

The Center publishes the results of its work in scientific journals and in its own technical reports. Through these reports, CDRH also provides assistance to industry and to the medical and health professional communities in complying with the laws and regulations mandated by Congress. The reports are sold by the Government Printing Office (GPO) and by the National Technical Information Service (NTIS). Many reports are also available on the Internet/World Wide Web.

We welcome your comments and requests for further information.

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

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PREFACE

The final regulation for reporting adverse events involving medical devices, applicable to both device user facilities and manufacturers, was published on December 11, 1995, and becomes effective on July 31, 1996. This regulation implements the reporting requirements contained in the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992.

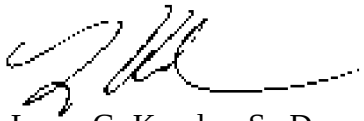
Much of the information in this document is general in nature and may not apply to a specific situation. Questions should be sent by facsimile (FAX) to (301) 827-0039 or mailed to:

Food and Drug Administration
Center for Devices and Radiological Health
Division of Surveillance Systems (HFZ-530)
Medical Device Reporting (MDR) Inquiries
1350 Piccard Drive
Rockville, MD 20850

Please include your name, return address, telephone number, and (if applicable) FAX number with your questions.

This overview of the medical device reporting (MDR) regulation is one of a series of documents clarifying the final rule. All are available through the Internet/World Wide Web at: **http://www.fda.gov** and after June 1996, from the National Technical Information Service, Springfield, Virginia 22161, telephone no. (703) 487-4650. Other MDR documents are:

- Medical Device User Facility and Manufacturer Reporting, Certification and Registration . . . Final Rules. December 11, 1995, *Federal Register*, pp. 63578-63607.
- FDA Form 3500A (Mandatory MedWatch form)
- Instructions for Completing Form 3500A with Coding Manual for Form 3500A
- Abbreviated Instructions for FDA Form 3500A Specific to MDR
- MDR Semiannual Report Form FDA 3419
- MDR Baseline Report Form FDA 3417
- MDR Annual Certification Form FDA 3381
- Medical Device Reporting for User Facilities
- Medical Device Reporting for Distributors
- Medical Device Reporting for Manufacturers (draft)
- *User Facility Reporting Bulletin* - all issues



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CONTENTS

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This guidance does not create or confer any rights, privileges or benefits for or on any person, nor does it operate to bind FDA or any other person. The agency will consider individual circumstances on a case-by-case basis. Where this document reiterates a requirement imposed by statute or regulation, the force and effect as law of the requirement is not changed in any way by virtue of its inclusion in this document.

1. INTRODUCTION

This document is intended to help manufacturers and user facilities understand the basic requirements for reporting adverse events involving medical devices as required by the Medical Device Reporting (MDR) Regulation (Title 21, Code of Federal Regulations, Part 803). The final MDR rule, which was published in the *Federal Register* on December 11, 1995, becomes effective on July 31, 1996. This document is to be used to supplement and not replace the MDR regulation. The MDR regulation will take precedence over this document in resolving any conflict between them.

Distributors are subject to Title 21, Code of Federal Regulations, Part 804, which was published September 1, 1993. Distributors should consult that regulation and other guidelines/ documents published by FDA to address requirements for distributor reporting of medical device adverse events.

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2. BRIEF OVERVIEW OF REGULATION

Table 1 shows a summary of requirements for reports submitted under 21 CFR 803. Table 2 shows a summary of other requirements of the MDR regulation.

2.1 Objective

The MDR regulation provides a mechanism for the Food and Drug Administration (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. Although the requirements of the regulation can be enforced through legal sanctions authorized by the Food, Drug and Cosmetic Act (FD&C Act), FDA relies on the good will and cooperation of all affected groups to accomplish the objective of the regulation.

2.2 Authority

The statutory authority for the MDR regulation is Section 519 of the FD&C Act (the Act) as amended by the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992. The Act provides FDA the authority to require manufacturers, distributors, and device user facilities to submit to the agency reports on certain types of medical device-related adverse events.

2.3 Basic reporting scheme for adverse events

■ Medical facilities (device user facilities)

The MDR regulation conforms to the reporting scheme contained in the Act. It requires certain types of medical facilities (referred to as device user facilities) to report to the device manufacturer when the facility determines that a device has or may have caused or contributed to a patient death or serious injury. In the case of a death, the facility must also send a report to FDA. All reports of death or serious injury are to be submitted on FDA Form 3500A (see 2.7 and Appendix A) within **10 work days** from the time that any medical personnel employed by or affiliated with the facility becomes aware that the device may have caused or contributed to a death or injury.

Device user facilities are hospitals, outpatient diagnostic or treatment facilities, nursing homes, and ambulatory surgical facilities. Outpatient treatment facilities include ambulance providers, rescue services, and home healthcare groups. Nursing homes include hospice care for the terminally ill and services for the rehabilitation of injured, disabled, or sick. However, private physician offices and private offices of other health care practitioners are not considered to be device user facilities.

■ Manufacturers

Manufacturers of medical devices are required to report a device-related death, serious injury, or malfunction to FDA using FDA Form 3500A within 30 days after becoming aware of the event. However, if the event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, then a report must be submitted within five (5) work days. These reports must also be submitted when FDA notifies the manufacturer that 5-day reports involving a

particular type of medical device or type of event are required.

2.4 Other types of reports/submissions

■ User facility semiannual reports

In addition to individual device reports, device user facilities must submit to FDA, using Form FDA 3419 (see 2.7), a semiannual summary of all reports sent to manufacturers and FDA in the applicable 6-month reporting period. In lieu of a summary, they may submit a copy of the reports actually sent to FDA and manufacturers. If no reports were submitted during the reporting period, a semiannual report is not required. This requirement, which is contained in the Act, was intended to help FDA monitor the compliance of manufacturers and determine how well the regulation is working.

■ Manufacturer annual certification

Manufacturers must annually certify the number of medical device reports submitted to FDA during the previous 12-month period and that all reports required to be submitted were, in fact, submitted. The certification must be submitted on Form FDA 3381 (see 2.7).

■ Manufacturer baseline reports

Manufacturers must submit baseline reports that provide basic device identification information including: (1) brand name, (2) device family designation, (3) model number, (4) catalog number, and (5) any other device identification number. This helps assure clear, unambiguous device identification. Baseline reports also contain other important information about the device including:

- regulatory basis for marketing the device;
- shelf life or expected life of the device;
- date device was first marketed and when marketing stopped, if applicable;
- number of devices manufactured and distributed in the last 12 months; and
- number of devices estimated to be in current use.

A baseline report is to be submitted for a device when an adverse event involving the device is reported for the first time and is to be updated annually. However, FDA will allow annual updates to be done on the date on which the annual certification is due.

2.5 Record-keeping requirements

Device user facilities and manufacturers are required to establish and maintain files related to reportable events. The files must be prominently identified, facilitate timely access, and must contain:

- information related to the event or reference to the location of the information. This includes all documentation of the reporting decisions and decision-making process;
- copies of all completed MDR forms and other information submitted to FDA, distributors, and manufacturers; and,
- for manufacturers only, an explanation of why any required information was not submitted

with the report or why it could not be obtained and the results of the evaluation of the event.

User facilities must keep records related to an event for two (2) years. Manufacturers must keep such records for two (2) years or a period of time equivalent to the expected life of the device, whichever is greater.

Authorized FDA employees are permitted to have access to all required records at all reasonable times to copy and verify them.

2.6 Written procedures

User facilities and manufacturers must develop, implement, and maintain written procedures for reporting adverse medical device events. They are to include:

- procedures for timely and effective identification and evaluation of events;
- a standardized review process and procedure for determining whether or not events are reportable; and
- procedures to assure the timely submission of complete reports.

Written procedures must also be established to assure compliance with documentation and record-keeping requirements.

2.7 Reporting forms

- **Individual adverse event report form**

User facilities and manufacturers must use FDA Form 3500A (the mandatory MedWatch form) to submit individual adverse event reports. This two-page form is intended for required reporting of problems with FDA regulated products. It is divided into eight sections or blocks, seven for reporting medical device problems. Five blocks are used primarily by user facilities/distributors and two blocks are used by device manufacturers.

Information to be reported by user **facilities and distributors** includes:

- information about the patient;
- type of adverse event;
- a description of the event;
- relevant laboratory/test data and patient history;
- manufacturer and identification of the suspect device and certain other information about the device;
- initial reporter of the event;
- user facility/distributor name, address, and contact;
- event problem codes for the device and patient; and
- where and when the report was sent.

Information to be reported by the **manufacturer** includes:

- any information not contained in the user facility or distributor report;
- manufacturer name, address, and contact;

- source of reported information;
- type of report;
- type of reportable event;
- date of device manufacture;
- whether or not the device is labeled for single use and was it the initial use of the device;
- whether the device was returned to the manufacturer and evaluated;
- method used to evaluate the device, results of the evaluation, and conclusions drawn by the manufacturer;
- type of remedial action taken, if applicable; and
- additional and corrected data.

■ **Semiannual report form**

A semiannual report is to be submitted on Form FDA 3419 on January 1 and July 1 and must contain:

- Health Care Finance Administration (HCFA) provider number or FDA assigned reporting number;
- reporting year, reporting period, and report date;
- complete name and address of the user facility;
- name, title, and address of the contact person;
- lowest and highest report numbers of the reports submitted to the FDA and/ or manufacturer during the reporting period; and
- basic information about each reported event or a copy of FDA Form 3500A that was submitted for each event.

■ **Annual manufacturer/distributor certification form**

Manufacturers are required to submit their annual certification on Form FDA 3381. Manufacturers are to certify at the time of annual registration with FDA. The certification form requests:

- the name, address, telephone number, and registration or FDA assigned identification number of the firm; and
- a statement certifying, to the best of the reporters knowledge, the number of reports submitted to FDA and that these reports were all the reports required to be submitted. The certification is to be signed by the firm president, chief executive officer, or other official most directly responsible for the firm's operations.

■ **Manufacturer baseline report form**

Manufacturer baseline reports are to be submitted on Form FDA 3417 and must include:

- name, address, and FDA registration number of the manufacturer's reporting site;
- registration number of each site where the device is manufactured;

- name, address, and telephone number of the contact person;

- basic identification information for the device to include the device family name, product code, brand and generic name, model number, catalog number, and any other identification number;

- identification of any other device previously reported in a baseline report that is substantially similar to the current device;

- regulatory basis for marketing;

- date device was first marketed and ceased being marketed;

- shelf life and expected life of the device;

- number of devices manufactured and distributed in the last 12 months;

- estimated number of devices in current use; and

- description of any methods used to estimate the number of devices distributed and/or in current use.

■ **Supplemental reports**

Manufacturers must submit supplemental reports on FDA Form 3500A to provide information not known or not available when the original reports were submitted. This information must be

submitted to FDA within one (1) month of its receipt by the manufacturer.

2.8 Special requirements for foreign manufacturers

Foreign device manufacturers are required to designate an agent in the United States who will act on their behalf with regard to MDR reporting responsibilities and to notify FDA within 5 days of such designation. The designated U.S. agent must:

- register with FDA;

- file 30-day, 5-day, baseline, and supplemental reports;

- conduct investigations of complaints and/or obtain investigation results from the foreign manufacturer;

- forward a copy of any MDR reports and complaints to the foreign manufacturer;

- establish and maintain complaint files; and

- submit the annual certification (2.7).

2.9 Exemptions, variances, and alternative reporting

Certain persons are exempt from the MDR reporting regulations. These include:

- licensed practitioners who manufacture or import devices solely for use in diagnosis or treatment of their patients;

- persons who manufacture or import a device solely for their research oreaching provided the device is not for sale; and

- dental or optical laboratories.

In addition to these specific exemptions, FDA may, upon written request or at its own discretion, grant to user facilities or manufacturers an exemption, variance, or alternative form of reporting from, or for, any or all of the reporting requirements and may change the frequency of reporting. When FDA grants an exemption, variance, or alternative form of reporting, it may impose other reporting requirements to ensure the protection of public health and may revoke or modify any exemption, variance, or alternative form of reporting.

Table 1 - Summary of MDR Reporting Requirements

REPORTER	REPORT WHAT?	TO WHOM?	WHEN?
User Facility	Deaths	FDA and Manufacturer	Within 10 work days
	Serious injuries*	Manufacturer FDA only if manufacturer unknown	Within 10 work days
	Semiannual report of deaths and serious injuries	FDA	January 1 and July 1
Manufacturer	30-day reports of deaths, serious injuries* and malfunctions	FDA	30 days from becoming aware
	Baseline report to identify and provide basic data on each device that is subject of a report	FDA	With 30-day report when device is reported for first time
	5-day report on events that require immediate remedial action and other types of events designated by FDA	FDA	Within 5 work days
	Annual certification of compliance with regulation	FDA	When firm submits annual registration

* Serious injury definition no longer necessitates “immediate” intervention, just medical or surgical intervention.

Table 2 - Summary of Other MDR Requirements

REQUIREMENT	APPLIES TO	SUMMARY
Files	User facilities and manufacturers	Records of complaints and MDR reports must be kept for a period of two years or, for manufacturers, the expected life of the device, if longer.
Written MDR Procedures	User facilities and manufacturers	Written procedures must be developed, maintained and implemented for (1) identification, evaluation, and timely submission of MDR reports, and (2) compliance with record keeping requirements.
Exemptions, Variances and Alternative Reporting	User facilities and manufacturers	Investigational devices are exempt. Exemptions, variances or alternatives to any or all of the reporting requirements may be granted upon request or at the discretion of FDA.
Designation of U.S. Agent	Foreign manufacturers	Foreign manufacturers must designate an agent in the U.S. who will register and submit MDR reports, conduct or obtain information about investigations, forward reports to the manufacturer, and maintain complaint files on behalf of the manufacturer.

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3. GENERAL TERMS AND DEFINITIONS

The MDR regulation contains general terms or definitions that apply to user facilities and manufacturers.

3.1 MDR reportable events

"MDR reportable events" are the adverse events or problems that the medical device regulation requires to be reported. For user facilities, MDR reportable events include patient deaths and serious injuries that medical devices have or may have caused or contributed to, i.e., the devices may have directly caused the events or played a role in the events. Manufacturers must report device-related deaths, serious injuries, and device malfunctions which are likely to cause or contribute to a death or serious injury if they were to recur.

3.2 Serious injury

There are three possible types of serious injuries, and they are not mutually exclusive:

- life threatening injuries;
- injuries that result in permanent damage or impairment; and
- injuries that require medical intervention to preclude permanent damage or impairment. Permanent damage or impairment is defined as irreversible damage or impairment that is not trivial.

3.3 Malfunction

A malfunction is the failure of a device to meet its performance specifications or to perform as intended. A malfunction is reportable when it is likely to cause or contribute to a death or serious injury if it were to recur. The regulation assumes that a malfunction will recur.

A malfunction is considered reportable if any one of the following is true:

- the chance of it causing such event is not remote or minute;
- it affects the device in a catastrophic manner that may lead to a death or serious injury;
- it causes the device to fail to perform its essential function and compromises the device's therapeutic, monitoring, or diagnostic effectiveness which could cause or contribute to a death or serious injury;
- the device involves a long-term implant or a device that is considered to be life-supporting, or life-sustaining;
- the manufacturer takes or would be required to take action to reduce a risk to health as a result of the mal-function; or
- a malfunction of the same type has actually caused or contributed to a death or serious injury in the past.

3.4 Concept of "may have"

A report is required when a user facility or manufacturer has information that reason-ably suggests that a device has or "may have" caused or contributed to a death or serious injury of a patient.

If there is a reasonable possibility that the device caused or contributed to the death or serious injury, then the event should be reported. However, reporting entities should not assume unreasonable or unrealistic cause/effect relationships between devices and events. If the chance that a device may have caused or contributed to an event is very remote or very unlikely, the event should not be reported. Conversely, the "may have" caused or contributed to standard should not be construed as requiring absolute certainty that an event was device related.

3.5 Reasonably suggests

A report is required when a reporting entity receives information that "reasonably suggests" that a device may have caused or contributed to an MDR reportable event. Information that "reasonably suggests" includes any information such as professional, scientific or medical facts and observations or opinions that would reasonable suggest that a device has caused or may have caused or contributed to a MDR reportable event.

A report does not have to be submitted when there is information that would cause a person, qualified to make a medical judgment, to reach a reasonable conclusion that a device did **not** cause or contribute to a death or serious injury or that a malfunction would not cause or contribute to a death or serious injury if it were to recur.

3.6 Caused or contributed to

A device may have "caused or contributed to" a patient death or serious injury if the death or serious injury was or may be attributed to the device, or the device may have been a factor in the death or serious injury because of device failure or malfunction, improper or inadequate design, manufacture, labeling, or user error.

3.7 Becomes aware

A user facility "becomes aware" of an MDR reportable event when medical personnel who are employed by or otherwise formally affiliated with the facility acquire information that reasonably suggests that a reportable event occurred. Medical personnel include persons who are licensed, registered, or certified to administer health-care, who have received a diploma or a degree in a professional or scientific discipline, or who are responsible for receiving medical complaints or adverse event reports or who supervise such persons.

A manufacturer "becomes aware" of an MDR reportable event when: (1) any employee becomes aware of a reportable event that is required to be reported within 30 days or required to be reported within 5 days when FDA has requested submission of 5-day reports; and (2) any employee, who is a person with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, becomes aware that a MDR report-able event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

3.8 Patient of the facility

A patient of the user facility is any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. This includes facility employees, who in the course of their duties suffer

device-related deaths or serious injuries that have or may have been caused or contributed to by medical devices used at the facility.

APPENDIX A

Form Approved: OMB No. 0910-0291 Expires: 1/31/96
See OMB statement on reverse

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Page ___ of ___

Mfr report #

UF/Dist report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. Patient information

1. Patient identifier
In confidence

2. Age at time of event:
or
Date of birth:

3. Sex
☐ female
☐ male

4. Weight
___ lbs
or
___ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ 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: ___

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

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

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

2. Type of device

3. Manufacturer name & address

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other: ___

5. Expiration date (mo/day/yr)

6.
model # ___
catalog # ___
serial # ___
lot # ___
other # ___

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

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

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

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

E. Initial reporter

1. Name & address

phone #

2. Health professional?
☐ yes ☐ no

3. Occupation

4 Initial reporter also sent report to FDA
☐ yes ☐ no ☐ unk

FDA

FDA Form 3500A (6/93)

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