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May 4,1996

Medical Device Reporting for Manufacturers

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

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HHS Publication FDA 96-____

Medical Device Reporting for Manufacturers

Prepared by
Division of Small Manufacturers Assistance
Office of Health and Industry Programs

May 1996

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
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 Safe Medical Devices Act of 1990 (SMDA) imposed significant new reporting requirements on the medical device industry and users of medical devices. This guidance document is based on the final Medical Device Reporting (MDR) rule which was published in the December 11, 1995, *Federal Register* (FR). The final rule also addresses changes mandated by 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, phone number, and (if applicable) FAX number with your questions.

This guidance for manufacturers is one of three documents written for a particular audience: user facilities, manufacturers, and distributors. 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 number (703) 487-4650. Other manufacturer MDR documents are:

- Mandatory MedWatch Form 3500A
- Baseline Report Form FDA 3417 and Instructions
- Annual Certification Form FDA 3381 and Instructions
- Abbreviated Instructions: Mandatory MedWatch Form 3500A
- Medical Devices User Facility and Manufacturer Reporting, Certification and Registration, December 11, 1995, *Federal Register*, pp. 63578-63607.

Joseph A. Levitt
Interim Director
Office of Health and Industry Programs

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Although this guidance does not create or confer any rights, for or on any person, and does not operate to bind FDA or the public it does represent the agency's current thinking on the Medical Device Reporting regulation. 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

On July 31, 1996, the effective date of the Medical Device Reporting (MDR) regulation, device user facilities, all domestic device manufacturers and U.S. designated agents of foreign manufacturers of medical devices are subject to its requirements. This document describes the new requirements for manufacturers.

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.

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 (SMDA) of 1990 which was further amended in 1992. The Act provides FDA with the authority to require manufacturers, distributors, U.S. designated agents and device user facilities to submit to the agency reports on certain types of device related adverse events.

The Safe Medical Devices Act of 1990 (SMDA) requires user facilities to report: 1) device-related deaths to FDA and the device manufacturer, 2) device-related serious injuries and serious illnesses to the manufacturer, or to FDA if the manufacturer is not known, and 3) submit to FDA, on a semiannual basis, a summary of all reports submitted during that time period. The user facility reporting section of SMDA became effective on November 28, 1991. Device manufacturers should familiarize themselves with the user facility requirements and read the guidance document entitled, “Medical Device Reporting for User Facilities” (see Chapter 11).

The SMDA added a requirement for device manufacturers to annually certify to FDA that MDR reports have been filed for all those events requiring such a report, or that no reportable events occurred during the 12-month certification period. Most of the requirements manufacturers have followed since 1984 were left unchanged by the passage of SMDA.

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

manufacturer that 5-day reports involving a particular type of medical device or type of event are required.

Since 1984, domestic manufacturers have been subject to the MDR regulation if they were required to register their establishment with the FDA. The revised MDR regulation eliminates the link with registration. All manufacturers of finished medical devices or components ready to be used, are now subject to the requirements of the MDR regulation, regardless of registration status.

Additional requirements for manufacturers and the U.S. designated agents include:

- baseline reporting.
- submission of supplemental information that becomes available after an initial MDR report is filed.
- written procedures for implementing the regulation.
- designation of a U.S. agent by foreign establishments.
- authorizing FDA to verbally request additional information about an event, and then confirm the request in writing.

Form FDA 3500A (the MedWatch form for mandatory reporting) is used to file individual/supplemental MDR reports. Forms have also been developed for filing the Baseline report and Annual Certification, Forms FDA 3417 and FDA 3381 respectively.

To implement the reporting provisions of SMDA, FDA published a tentative final rule in the *Federal Register* on November 26, 1991, and invited comments on the regulation. On June 16, 1992, the President signed into law the Medical Device Amendments of 1992 (Public Law 102-300; the Amendments of 1992), amending certain provisions (section 519 of the Food, Drug, and Cosmetic Act) relating to reporting of adverse events. The primary impact of the 1992 Amendments on user facility and manufacturer reporting was to define certain terms and to establish a single reporting standard for user facilities, manufacturers and importers. A final rule, published in the *Federal Register* on December 11, 1995 addresses the comments received by FDA on the 1991 proposed MDR regulation and the changes mandated by the Amendments of 1992.

The requirements of the MDR regulation are summarized in the tables on pages 3-5.

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SUMMARY OF MDR REPORTING REQUIREMENTS

REPORTER	REPORT WHAT?	TO WHOM?	WHEN?	CHANGES FROM 11/26/91 PROPOSAL
Manufacturer	30 day reports of deaths, serious injuries and malfunctions	FDA	30 calendar days from becoming aware	Eliminated Monthly report and all associated requirements. Replaced with 30 day report of each individual event. Serious injury definition no longer necessitates "immediate" intervention, just medical or surgical intervention
	Baseline report to identify and provide basic data on each device that is subject of a MDR report	FDA	With 30 calendar day report when device is reported for first time	Eliminated listing of remedial actions, and frequency and severity statement.
	5-day report on events that require immediate remedial action to prevent an unreasonable risk of substantial harm to the public health and other types of events designated by FDA	FDA	Within 5 work days	Replaces proposed 72-hour report of imminent hazard.
	Annual Certification	FDA	Coincides with firm's annual registration date.	Form FDA 3381 developed for reporting.

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SUMMARY OF MDR REPORTING REQUIREMENTS

REPORTER	REPORT WHAT?	TO WHOM?	WHEN?	CHANGES FROM 11/26/91 PROPOSAL
User Facility	Deaths	FDA & Manufacturer	Within 10 work days	Definition changed from "probability" to "has or may have caused or contributed".
	Serious injuries	Manufacturer. FDA only if manufacturer unknown.	Within 10 work days	Definition changed from "probability" to "has or may have caused or contributed." Serious illness merged with serious injury. Serious injury definition no longer necessitates "immediate" intervention, just medical or surgical intervention.
	Semi-annual Report of deaths & serious injuries	FDA	January 1 & July 1	Changed from January 31 & July 31.
Distributor (includes importers)	Deaths & serious injuries	FDA	Within 10 work days	Importers added as separate entity with different definitions than domestic distributors. For importers: definitions for death and serious injury say "may have caused or contributed." Serious injury definition no longer necessitates "immediate" intervention, just medical or surgical intervention.
	Deaths, serious injuries & malfunctions	Manufacturer	Within 10 work days	Importers added as separate entity with different definitions than domestic distributors. For importers: (1) definitions for death and serious injury say "may have caused or contributed," (2) malfunction definition says "would be likely to cause or contribute."
	Annual Certification	FDA	Annually	Form FDA 3381 developed for reporting but not required by 804. Voluntary use encouraged.

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SUMMARY OF OTHER MDR REQUIREMENTS

REQUIREMENT	APPLIES TO	SUMMARY	CHANGES FROM 11/26/91 PROPOSAL
Files	User facilities, distributors, and manufacturers	Records of complaints and MDR reports must be kept for a period of two years or, for manufacturers and distributors, the expected life of the device, if longer.	None
Written MDR Procedures	User facilities, distributors, 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. Distributor must have training and education programs regarding requirements of regulation.	Eliminated training and education programs for user facilities and manufacturers.
Exemptions, Variances and Alternative Reporting	User facilities, distributors, and manufacturers	Investigational devices and certain types of distributors 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	Added variances.
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. Agent subject to same requirements as a manufacturer.	Clearly delineates responsibilities of agent.

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2
WHO MUST REPORT?

All manufacturers of medical devices are required to comply with the MDR regulation. A manufacturer is defined as any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. This includes:

- manufacturers of finished medical devices;
- manufacturers of components or accessories to medical devices that are ready to be used and labeled for commercial distribution;
- initiators or developers of medical device specifications;
- repackagers and relabelers of medical devices; and
- the U.S. designated agent of a foreign manufacturer.

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3
TERMS AND DEFINITIONS

This section explains the meaning and intent of **certain** definitions that apply solely to manufacturers, as well as general terms and definitions.

3.1 Device Family

The **device family** concept is intended to provide a mechanism that will help FDA and manufacturers group similar models of a device for both identification and analysis. This information is required to be recorded on the manufacturer's baseline report (Form FDA 3417). This will aid in identifying the cause and nature of device-related problems associated with different models that are basically the same device.

FDA considers a device family to consist of devices having the same basic design and performance characteristics related to safety and effectiveness, intended use and function, and device classification and FDA product code. Devices that differ only in minor ways not related to safety or effectiveness can be considered to be in the same device family, e.g., differences in power supplies used in domestic versus exported products, cosmetic differences, and different sizes. Factors such as brand name and common name of the device, and whether the devices were introduced into commercial distribution under the same 510(k) or PMA, may be considered in grouping products into device families.

The **device family** designation may be a number(s), letter(s), word or alphanumeric.

FDA has the discretion to determine the appropriateness of a manufacturer's device family determination.

3.2 Shelf Life or Expected Life

Expected life and/or shelf life is reported to FDA on the baseline report form. The expected life of a device is the time it is expected to remain functional after it is placed into use. A manufacturer establishes an expected life through labeling or advertising or any other claims made with regard to expected life. The regulation does not require manufacturers to establish an expected life for a device.

Manufacturers must retain records required by 21 CFR 803.18 for 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. If the expected life of the product is indefinite, records should be maintained until the manufacturer goes out of business.

Similarly, the regulation does not require that the manufacturer establish a shelf life for a product since this concept is not appropriate for all devices. Shelf life is normally indicated on the product labeling.

3.3 MDR Reportable Events

MDR reportable events are the adverse events or problems that the medical device regulation requires to be reported. Manufacturers report device related deaths and serious injuries, and also device malfunctions which are likely to cause or contribute to a death or serious injury if they were to recur.

3.4 Serious Injury

There are three types of **serious injuries** and they are not mutually exclusive: (1) life threatening injuries, (2) injuries that result in permanent damage or impairment, and (3) 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.

3.5 Malfunction

A **malfunction** is failure of a device to meet its performance specifications or to perform as intended. Performance specifications include all claims made in the labeling of the device. The intended performance of the device refers to the intended use for which the device is labeled or marketed. A malfunction is reportable when it is likely to cause or contribute to a death or serious injury if it were to recur. Manufacturers should presume that a malfunction will recur.

A manufacturer should consider it likely that a malfunction will cause or contribute to a death or serious injury if the malfunction has actually caused or contributed to a death or serious injury in the past.

3.6 May Have

A report is required when the manufacturer has information that reasonably suggests that a device **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, manufacturers 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 in order for an event to be considered MDR reportable.

3.7 Reasonably Suggests

A report is required when a manufacturer 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 reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event.

A report is not required if 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. A decision not to report must be documented and retained in the MDR event file.

3.8 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 (1) failure or malfunction, (2) improper or inadequate design, (3) manufacture, or (4) labeling, or because of (5) user error.

3.9 Becomes Aware

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 an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

4
WHAT TO REPORT

There are three types of events that must be reported: Death, Serious injury and any Malfunction that is likely to cause or contribute to a serious injury if it were to recur:

- **Death** is self-explanatory.

- **Serious injury** means an injury or illness that:

  - is life threatening, even if temporary in nature;

  - results in permanent impairment of a body function or permanent damage to a body structure; or

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

FDA defines “permanent” as irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

Malfunctions are not reportable if they are not likely to cause or contribute to a death or serious injury. A malfunction which is or can be corrected during routine service or device maintenance must be reported if the recurrence of the malfunction is likely to cause or contribute to a death or serious injury if it were to recur.

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

- the chance of it causing or contributing to a death or serious injury 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 device that is considered to be life-supporting or life-sustaining, and thus essential to maintaining human life,

- the manufacturer takes or would be required to take action to reduce a risk to health as a result of the malfunction, or

- a malfunction of the same type has actually caused or contributed to a death or serious injury in the past.

FDA believes that under the current statutory reporting standard, once a malfunction has caused a death, or serious injury, it creates a presumption that any similar malfunction occurring thereafter is reportable.

5
TYPES OF REPORTS

There are five different types of reports that a manufacturer will file and each has an FDA form. The types of reports and corresponding form are as follows:

Type	Form FDA#
Individual adverse event 5-day report	FDA 3500A
Individual adverse event 30-day report	FDA 3500A
Supplemental reports to 5/30-day reports	FDA 3500A
Baseline report	FDA 3417
Annual certification	FDA 3381

5.1 Individual Adverse Event Report Form For 5-Work Day/30 Calendar Day Reports

Manufacturers must use Form FDA 3500A (the MedWatch form for mandatory reporting) to submit individual adverse event reports to FDA. This two page form is intended for mandatory reporting of problems involving products regulated by FDA.

5.2 Supplemental Reports

Manufacturers shall submit a supplemental report to provide information not known or not available at the time of the original report. This information must be submitted on the 3500A to FDA within one (1) month of its receipt.

5.3 Manufacturer Baseline Reports

Manufacturers must submit baseline reports, that provide basic device identification information including: brand name, device family designation, model number, catalog number, and any other device identification number. This information helps assure clear, unambiguous device identification.

A baseline report is submitted on a device when an adverse event involving the device is reported for the first time. This report can be updated either at the time of annual certification or on the anniversary month of the initial submission.

5.4 Manufacturer Annual Certification Report

Manufacturers submit this certification annually. The report provides FDA with a statement that the firm's management has submitted, to the best of their knowledge, MDR reports for all those adverse events requiring such a report, or that to the best of their knowledge no reportable events occurred during the 12-month period. Manufacturer annual certification reports are submitted on FDA Form 3381, using the annual registration schedule [807.21(a)].

6
The REPORTING PROCESS

The reporting process starts when an MDR reportable event is first recognized. Manufacturers are responsible for making sure its employees know how to recognize what may be reportable. Manufacturers should also emphasize that any employee may learn of an adverse event during a phone call, a sales visit, a professional conference, from correspondence received or from service/warranty orders.

This chapter will cover some of the changes introduced in the regulation including how information is received by the manufacturer and what to do when it is received.

6.1 Changes

The July 31, 1996 MDR regulation has a number of concepts about reporting that are different from the 1984 version. These changes are notable because they will cause manufacturers to change the decision trees or processes they use for complying with the 1984 MDR regulation.

- The five malfunction caveats [previously in 21 CFR 803.24(d)(3)(iii)] have been deleted. The deletion of the five caveats eliminates this mechanism from being used in determining whether or not to submit an MDR report when a malfunction is reported to the manufacturer.

- Manufacturers no longer have to automatically report every allegation that a device may have caused or contributed to a death or serious injury or malfunctioned because the information comes from a health care professional. Reports from health care professionals, however, may be more likely to be reportable. Manufacturers should carefully consider a decision not to report events from health care professionals device user facilities.

- Manufacturers who have employees or consultants who are health care professionals qualified to make a medical judgement can use this expertise to reasonably conclude that a device did not cause or contribute to a death or serious injury, or upon recurrence of a malfunction would not be likely to cause or contribute to a death or serious injury. This judgement, based on sound medical expertise and adequate investigation of the event, must be documented in the MDR event files, as described in 803.18.

- Manufacturers now automatically submit any required information they receive which was not available at the time the initial MDR report was submitted. Submission of additional information must be done within one month of receipt of the information.

- The regulation requires that manufacturers obtain and report all information to FDA regarding the MDR reportable event. If the 3500A received from a user facility or distributor is incomplete, the manufacturer must attempt to obtain the missing information or explain why they couldn't. All complaint investigations must be thoroughly documented.

- All reports must be written in English. Foreign literature articles, foreign complaints, etc. may need to be translated before submission.

6.2 Sources of Adverse Events

A manufacturer can receive information via telephone, facsimile, written correspondence, sales representatives, service representatives, scientific articles, and FDA or internal analyses. Information will also be submitted by user facilities and distributors on Form FDA 3500A. However, the manufacturer will find that user facilities and distributors may need some guidance regarding when to use the 3500A. For example, if a user facility calls in a death or serious injury report it behooves the manufacturer to remind the user facility to complete a 3500A immediately. Otherwise, it will be the responsibility of the manufacturer to complete and submit the 3500A within 30 days. FDA encourages manufacturers to assist user facilities in gaining an understanding of their obligations.

Manufacturers may also receive adverse event information from a voluntary MedWatch report form submitted to FDA. When the FDA MedWatch Program Office receives a FDA Form 3500 (voluntary MedWatch report) involving a medical device it is forwarded to CDRH for follow-up. The Office of Surveillance and Biometrics (OSB) will forward a copy of the 3500 report form to the manufacturer for evaluation. If the event is reportable, reporting time clock starts upon receipt of the form, since the manufacturer has "become aware" of the event. If a firm decides that the event may be reportable it must obtain all of the information required by the FDA Form 3500A and then submit the completed form to FDA.

In some cases the initial reporter may request confidentiality and the manufacturer may not be able to investigate the complaint. In these cases, the manufacturer must evaluate the reportability of the complaint based on the information they are able to obtain, including information given in the 3500 and its knowledge of the product, and base

the MDR reportability decision on this information. The FDA is encouraging user facilities to use the FDA Form 3500A to voluntarily report malfunctions to manufacturers.

6.3 Individual Adverse Event Reports

There are two types of individual adverse event reports that may be submitted by manufacturers. The 5 (work) day and 30 (calendar) day reports.

The 5-day report is for MDR reportable event(s) that require a remedial action to prevent an unreasonable risk of substantial harm to the public health or where FDA has specified that a 5-day report is needed. This situation may be identified by the manufacturer or FDA:

- If the manufacturer identifies the event and should initiate a remedial action to prevent an unreasonable risk of substantial harm to the public health, a 5-day report is submitted instead of the 30-day report. Information not available within the five days should be provided in a supplemental report.

- If FDA identifies the event, the manufacturer will receive a written request directing them to file a 5-day report for all subsequent events of the same nature that involve similar devices for a specified time period. The FDA identification may be a result of its review of 30-day reports, inspection reports, user facility reports, etc.

The 5-day "clock" starts the day after any employee, who is a person with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person who's duties relate to the collection and reporting of adverse events, becomes aware that a reportable MDR event or events, from any information, including any trend analysis, necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health.

A 30-day report is required once a manufacturer receives or otherwise becomes aware of information that reasonably suggests that a device they have marketed:

(1) has or may have caused or contributed to a death or serious injury; or

(2) has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

The 30-day "clock" starts the day after receipt by **any** employee of information that reasonably suggests that an MDR reportable event has occurred. FDA expects

manufacturers to train their employees to recognize that they have received information on an adverse event and to know to whom in the company to forward this information to for an MDR evaluation.

A firm is NOT required to file an MDR report:

- when it determines that a device related event did not occur, or
- when it determines that the device was made by another manufacturer.

In the second item, the regulation requires the manufacturer to forward whatever information they have to FDA with a cover letter explaining that they did not manufacture the device so that FDA can send it on to the correct manufacturer. In this case, a 3500A should not be completed. Manufacturers may also send voluntarily a copy of this information to the firm they identify as being the actual manufacturer.

6.4 Remedial Action/5 Day Report

Under 803.53, a manufacturer must submit a 5-day report within 5 work days after becoming aware that an MDR reportable event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

The MDR regulation defines **remedial action** as any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.

Not all remedial actions need to be submitted as 5-day reports. Only remedial actions that are necessary to prevent an unreasonable risk of substantial harm to the public health must be submitted. If a remedial action is taken, **but it is not to prevent an unreasonable risk of substantial harm to the public health** a 5-day report is not required. A 30-day report, however, may be required.

The discovery that a remedial action is necessary may be a direct result of one or more MDR reportable events occurring, or may be discovered through the performance of internal analyses using appropriate statistical or other acceptable methodologies.

Actions taken to fix a single device involved in the MDR reportable event are not remedial actions.

6.5 Manufacturer Report Number

The manufacturer report number that is entered in the top right hand corner of the FDA Form 3500A, and in Block G.9. replaces the FDA assigned MDR report accession number (1984 regulation). Manufacturers no longer have to wait for FDA to assign an MDR report a number since the "Mfr. report #" is self generated.

The report number has a specific scheme. It consists of the registration number of the manufacturing site, the four digit calendar year, and a five digit sequence number. The unique Medical Device Establishment Registration number issued to each manufacturing site is site and address specific so even if several different manufacturing sites are located at one address only one registration number is usually issued. This will require some manufacturers to coordinate the assigning of the sequence number portion of the "Mfr. report #" between different divisions or propose alternative mechanisms for assigning this number to the FDA.

6.6 Suggestions for Completing the FDA Form 3500A

The 3500A has complete instructions, but here are some points to be aware of when completing the form:

- The "Mfr. report #" uses the establishment registration number of the manufacturing site NOT the registration number of the reporting site, if they are different; and

- Manufacturers need to be aware that Block H.3 allows for more than one box to be checked, as follows:

  - Check "not returned" if no evaluation could be made because device was not available;

  - Check "yes" and "evaluation summary" if an evaluation was conducted;

  - Check "no" if an evaluation of the returned or a related device was not conducted, and attach an explanation or enter an FDA code which states why.

6.7 Baseline Report

A baseline report provides basic data, including identification information, on each device that is the subject of an MDR report. These data will allow FDA staff to better identify the product reported and make an analytic evaluation of the extent of the problem. A baseline report is due the first time a device is involved in an MDR reportable event. Production and distribution data, which are commercial confidential information, will provide FDA staff data needed to determine the magnitude and significance of the problem and, over time, identify upward or downward trends.

Baseline information includes estimates of the number of devices distributed and in current use. FDA does not prescribe the methodology used to calculate these estimates. The methodologies, however, should be reasonable and show that they are based on acceptable statistical, mathematical or test processes. For example, estimates might be based on shelf life, expected life, endurance testing, accelerated life testing, sales figures, or inventory turnover.

A baseline report is required the first time a device “model” is reported under 21 CFR 803.50 or 803.53. Device model is used generically in this context to indicate a unique device that may be identified by a model number, catalog number or other device identification. Baseline reports can be submitted on a “model” group rather than an individual “model” if the models in the group are all the same except for minor cosmetic variations not related to safety or effectiveness and have the same generic name, FDA product code and device family name. A list of all models in the group must be attached to the baseline report. Instructions for completing the baseline report when reporting a model group are contained in “Instructions for Completing the Medical Device Baseline Report, Form 3417".

The baseline form includes information on the shelf life of a device and/or its expected life. There is no intent by FDA to require that all products have a shelf life. If there is no shelf life, check “NA” in block 11a. This is also true for expected life. If no expected life has been established, then FDA considers the product to have an indefinite life or no established expected life. The absence of an expected life will affect how long a manufacturer maintains required MDR event files for the device.

6.8 Baseline Report Annual Updates

In an April 11, 1996, Federal Register notice, FDA stated that an acceptable interpretation of the regulation allows for submission of all annual baseline updates on a single anniversary date, instead of multiple ones. The annual updates can be submitted on the same schedule as the annual certification submission.

6.9 Annual Certification (803.57) (Form FDA 3381)

Each year all manufacturers are required to file an MDR annual certification report with FDA. The purpose of this report is to certify, to the best of the firm's management knowledge:

(1) the number of MDR reports that have been submitted and that reports for all events received that require such reporting have been filed; or

(2) that no reportable events were received during the previous 12-month period.

This certification is not just a numerical total of the number of MDR reports a firm has submitted over a 12-month period. It is a statement that means that to the best of the certifier's knowledge each and every complaint received has been evaluated for MDR reportability, and that to the best of his/her knowledge all events that meet the definition of a reportable event have had an MDR report submitted when one is required.

The certification report is made by completing form FDA 3381. The schedule of submission of the form coincides with the date for a firm's annual registration, as designated in 21 CFR 807.21. Those firms required to register annually should wait to receive their form FDA 2891a (annual registration) because the form FDA 3381 will be mailed with it. If the 3381 has not been received by the date it is needed, it is the responsibility of each firm to obtain one. See Chapter 11 for more information on how to obtain a copy of Form 3381. The certification period is the 12-month period ending one(1) month before the certification date. For example, the annual registration form mailed in March is returned to FDA within 30 days. Therefore, the form FDA 3381 should be returned as follows:

If the first letter of Owner or Operator name is:	Annual certification due in:	Reporting period:
A, B, C, D, E	April	April to March
F, G, H, I, J, K, L, M	July	July to June
N, O, P, Q, R	September	September to August
S, T, U, V, W, X, Y, Z	December	December to November

The table below shows the reporting sequence for annual certification for 1996 and 1997.

If the first letter of Owner or Operator name is:	Annual certification due in:	Reporting period for annual certification for 1996-1997
A, B, C, D, E	April 1997	July 31, 1996 - March 31, 1997
F, G, H, I, J, K, L, M	July 1997	July 31, 1996 - June 30, 1997
N, O, P, Q, R	September 1997	July 31, 1996 - August 31, 1997
S, T, U, V, W, X, Y, Z	December 1997	July 31, 1996 - November 30, 1997

The first annual certification report submitted by a firm may contain more or less than 12-months of data because the effective date of the regulation will not coincide with all the staggered annual registration periods. The first group of firms subject to this requirement will be those that submit their annual registration at least six (6) months after the effective date of the regulation, that is, after January 1997. This will allow firms the opportunity to implement and comply with the new requirements of the MDR regulation, and accumulate at least six months of data for certification.

For example, since the regulation is effective July 31, 1996, the first group of firms subject to the certification requirement after January 1997 will be those with a first letter of A through E. The first completed form FDA 3381 is due in April 1997 to cover the period July 31, 1996 through March 1997 (8 months). If the firm falls into the group with letters S-Z, the first completed 3381 is due in December 1997 to cover the period July 31, 1996 through November 1997 (16 months).

The MDR regulation designates that the certification must be signed by the president, chief executive officer, U.S. designated agent of a foreign manufacturer, or other official most directly responsible for the firm's operations, such as a senior-level manager.

Firms with multiple reporting sites and/or administrative offices responsible for handling complaints may elect to certify centrally or separately. The form FDA 3381 can be completed by each separate site which is registered with the FDA. A certifying site should register with FDA by submitting an Initial Establishment Registration form FDA 2891 prior to completing the first annual certification report. If a firm with numerous facilities wants to centrally certify, one form FDA 3381 can be completed with each of the registered sites listed according to the instructions on the form.

Foreign manufacturers must comply with the MDR reporting requirement through their U.S. designated agent.

6.10 Reporting for Foreign Manufacturers and U.S. Designated Agents (803.58, 807)

The MDR regulation places new requirements on foreign manufacturers. Foreign manufacturers are now required to have U.S. designated agents who are required to comply with all of the requirements of the MDR regulation. Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting. The U.S. designated agent accepts responsibility for the duties that such designation entails.

By July 31, 1996, foreign manufacturers must inform FDA, by letter, of the name and address of the U.S. agent designated under this section and 21 CFR 807.40, and shall update this information whenever necessary. A change in the name and/or address of the U.S. designated agent requires an update within 5 days of the change.

Foreign manufacturers including contract manufacturers who perform the functions specified in “Chapter 2 - Who Must Report?” must have a U.S. designated agent.

Any individual residing in the United States and subject to United States laws, may become a U.S. designated agent for a foreign manufacturer. The agent is required to:

(1) report to the FDA in accordance with sections 803.50, 803.52, 803.53, 803.55, and 803.56;

(2) conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of section 803.50;

(3) certify in accordance with section 803.57;

(4) forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement**;**

(5) maintain complaint files in accordance with section 803.18; and

(6) register and list in accordance with Part 807.

The U.S. designated agent does not have to be the initial importer of the device. The agent can be any individual willing and qualified to assume the responsibilities stated in the Parts 803 and 807.

A U.S. designated agent is defined as a manufacturer under Section 803.3(n)(4) and must register their establishments with the FDA by completing a Form FDA 2891, Initial Registration of Device Establishment. The agent indicates that its Establishment types are U (U.S. designated Agent) and C (MDR Reporting Site).

The U.S. designated agent may receive complaints directly from user facilities, distributors, consumers, etc. either because the manufacturer has informed customers to contact the agent first or because the identity of the agent is known. When this occurs, the agent shall forward the information to the foreign manufacturer for review.

The U.S. designated agent works with the foreign manufacturer to establish procedures that ensure that the foreign manufacturer, if it so chooses, is properly evaluating adverse events for MDR reportability and forwarding those complaints requiring MDR reports to the U.S. designated agent for filing with FDA.

For foreign manufacturers, the 30-day reporting time frame begins as soon as a foreign manufacturer “becomes aware” of a reportable event. The 30-days do not start from the time the foreign manufacturer first notifies its U.S. designated agent. Conversely, if the U.S. designated agent becomes aware and then informs the foreign manufacturer, the 30-days start with the U.S. designated agent.

Foreign manufacturers should have one U.S. designated agent for all requirements. Within the firm that is designated by the foreign manufacturer, one individual should be chosen to be the U.S. designated agent. This individual will be the Official Correspondent and MDR contact for all medical device matters involving the foreign manufacturer. Other individuals may contribute to the work but one individual should be responsible for signing and/or transmitting all documents.

If an agent is representing more than one foreign manufacturer, then he/she should keep all the required records separate by manufacturer for easy identification or access by FDA. The agent should also file a separate annual certification form for each foreign manufacturer he/she represents.

6.11 Disclaimer (803.16)

The MDR regulation and the FDA Form 3500A, contain a disclaimer statement. The disclaimer is provided so reporters are aware that the MDR information submitted to FDA does not necessarily reflect a conclusion by the reporter, or the FDA that the report or information constitutes an admission that the device, or the reporting entity or its employees, caused or contributed to the reportable event. In fact, the regulation states that the reporter may deny that the report or information submitted constitutes any type of admission.

The FDA 3500A disclaimer is:

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

The disclaimer in §803.16 is:

> "A report or other information submitted by a reporting entity under this part, and any release by FDA of that report or information, does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, or the reporting entity or its employees, caused or contributed to the reportable event. The reporting entity need not admit and may deny that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a reportable event."

A manufacturer may submit its own disclaimer. At the time the manufacturer submits the first disclaimer, it is entered into a computer database. Once the disclaimer is stored it will not be modified if the wording of the disclaimer changes with subsequent filings. A manufacturer should notify OSB in writing whenever the disclaimer changes. It is recommend that firms label the outside of the envelope containing such a change with the words, "DISCLAIMER UPDATE." Whenever a computer-generated copy of the MDR report is released under the Freedom of Information Act the FDA will duplicate the manufacturer's latest disclaimer on the copy.

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7
WHERE TO REPORT

7.1 Where to Obtain Forms, Instructions and Coding Manual

The FDA wants to assure access to copies of the MDR forms, the instructions for completing the forms, and the coding manual for Form FDA 3500A. You may request copies of these forms by following the instructions given in Chapter 11.

7.2 Where to Submit Forms and How to Label Envelopes

All MDR reports are sent to a single CDRH address. To facilitate the proper processing of all reports, the outside of the envelope must be labeled in a specific manner. The mailing and labeling requirements are as noted in the following table.

TYPE OF MDR REPORT	MAILING ADDRESS FOR FORMS	LABELING OF ENVELOPE (place in lower left-hand corner of envelope above bar code level)
5-DAY	Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002	5-day Report
30-DAY		30-day Manufacturer Report
SUPPLEMENTAL		Manufacturer Supplemental Report
BASELINE		Baseline Report or Annual Update-Baseline Report
ANNUAL CERTIFICATION		Manufacturer Annual Certification Report

The FDA will accept more than one type of report per envelope. If multiple types of reports are enclosed, then label the envelope to indicate all of the types included, e.g., 5-day report, Baseline report.

7.3 How to Obtain Fda Approval to Use a Computer-generated Facsimile of Any Form

The FDA encourages companies to computerize the required report forms, but a company may not make major changes to the appearance and format of the forms. Firms must receive written approval from the FDA prior to instituting the use of a computer-generated facsimile of any of the MDR forms.

A request for facsimile approval must be in writing and include a copy of the proposed facsimile. It is not necessary for a facsimile form to be generated as a two-sided document. Firms can also use programs that automatically create continuation pages when the text exceeds the amount of space allowed for a particular block of a form. The FDA is not accepting facsimiles that increase the size of a item block nor causes the original form to be significantly modified. The request for facsimile approval should be addressed to:

For MedWatch Form FDA 3500A or FDA 3500:
MEDWATCH: The FDA Medical Products Reporting Program
Office of the Commissioner, HF-2
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

For Forms FDA 3417 (Baseline) and 3381 (Annual Certification):
ATTN: Computer-generated Form Approval Request
Director, Division of Surveillance Systems
Office of Surveillance and Biometrics, HFZ-530
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

7.4 Where to Report a Public Health Emergency

Report all public health emergencies to:

FDA Emergency Operations Branch (HFC-162)
Office of Regional Operations
301.443.1240 (24 hours a day)
301.443.3757 FAX number

8
EXEMPTIONS, VARIANCES, AND ALTERNATIVE REPORTING REQUIREMENTS (803.19)

The MDR reporting regulation provides for various types of waivers from its requirements to accommodate the varied nature of device problem reporting. It is apparent that, under certain conditions, the requirements can be modified without adversely affecting the public health. The following describe the explicit exemptions and the types of waivers that may be initiated at the discretion of the FDA or by request from manufacturers.

8.1 Explicit Exemptions

The regulation contains three explicit exemptions:

A. An individual who is a licensed practitioner and

   1. prescribes or administers devices intended for use in humans, and

   2. who manufactures or imports devices solely for use in diagnosing & treating persons with whom the practitioner has a "physician-patient" relationship.

B. An individual who manufactures devices

   1. intended for use in humans solely for such person's use in research or teaching and not for sale, including

   2. any person who is subject to alternative reporting requirements under the investigational device exemption regulations, parts 21 CFR 812 and 813, which require reporting of unanticipated adverse device effects (21 CFR 812.46).

C. Dental laboratories, or optical laboratories

8.2 Requested Exemptions

Manufacturers and U.S. designated agents of foreign manufacturers can submit requests for exemptions from all, or part, of the requirements of the regulation.

EXAMPLE: Manufacturers can be exempted from MDR reporting in situations where the product or problem is the subject of a recall. A firm must submit a request for such an exemption and agree to meet certain conditions and provide certain information.

8.3 Variances

A variance is considered to be a modification in the reporting requirements and can be requested by manufacturers and U.S. designated agents. This includes modification of the data elements required on the mandatory reporting forms.

EXAMPLE: Manufacturers of breast implants have been offered the opportunity to submit summary reports instead of providing all of the data elements currently required under the MDR regulation.

8.4 Alternative Reporting

An alternative report allows a modification in the timing of report submissions and is a type of variance, i.e., 30 day reporting for manufacturers. The 5-day reporting requirement, due to the severity of events involved, is not eligible for alternative reporting. A firm may request, instead of reporting each event 30 days after becoming aware of an MDR reportable event, that the reports be submitted on a bi-monthly, quarterly, semi-annual, or annual basis.

Alternative reporting also includes the use of electronic media. CDRH is encouraging user facilities, manufacturers and distributors to submit reports electronically. CDRH is in the process of developing an Electronic Data Interchange (EDI) protocol to facilitate reporting. In addition, paperless submission by tape or disk, from large volume reporters, is also an option.

EXAMPLE: Manufacturers of pacemakers currently submit quarterly MDR reports of serious injuries and malfunctions on magnetic tape by prior agreement.

8.5 Granting an Exemption, Variance or Alternative Reporting

The FDA may grant, in writing, an exemption, variance or alternative reporting approval as outlined above, based on a written application or its own volition, with the following caveats:

A. Any exemption, variance or alternative reporting approval may be revoked, in writing, if it is determined that the protection of the public health justifies a return to the standard MDR requirements. Failure to follow the requirements specified in the approval may result in suspension and probable revocation of the approval.

B. Persons granted a reporting waiver shall comply with any requirements and provide any reports or other information specified in the approval letter. Once granted, the conditions in the approval letter will remain in effect until FDA revokes or modifies the respective option.

A request for an exemption, variance, or alternative reporting approval must be submitted in writing to:

Director
Division of Surveillance Systems (HFZ-530)
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

Submit an original and one copy of request, and label the lower left hand corner of the envelope with the type of request being made, e.g., Alternative Reporting Request.

Each request should include the following information:

1. Firm identification, including manufacturing site(s) of the device(s)
2. Complete product identification and description
3. Type of approval requested (i.e., exemption, variance, alternative reporting approval.
4. Type of report(s) involved (e.g., serious injuries, malfunctions)
5. Particular type of event(s) involved
6. Rationale for the request
7. Number of reports submitted to date and approximate number reported annually
8. Discussion of previous complaint history

Every request should include an explanation of the impact of the device problem on the patient and why the requested reporting approval is more appropriate than the standard MDR reporting requirements. CDRH staff will review each request and provide the requestor with a response as soon as possible. Manufacturers can contact OSB staff (301-594-2735) for guidance prior to submitting a written request if they have questions about the process.

8.6 Exemptions, Variances, Alternative Reporting Requests and Guidance Issued Under 1984 MDR Regulation

On July 31, 1996, all previously granted exemptions, variances, and alternative reporting requests from the 1984 MDR regulation will be superseded by the new regulation. FDA will review all active exemptions, variances and alternative reporting requests and contact firms regarding the reissuance of them. If firms do not hear from FDA, they will need to reapply in accordance with the new requirements provided in the final MDR regulation.

In addition, all existing 1984 MDR regulation policies and guidelines are null and void as of July 31, 1996. CDRH will reissue all four of the MDR guidance documents that currently exist after they have been modified to conform to the new requirements.

9
DISCLOSURE OF REPORTS

9.1 Information Available to the Public (803.9)

FDA will not release any confidential commercial and trade secret information submitted by device manufacturers to the public. The Freedom of Information Act (FOIA) and the FDA FOI regulation, 21 CFR 20, contain provisions to protect this type of information. Furthermore, FDA will not release to the public information that will constitute an unwarranted invasion of personal privacy.

FDA will not release to manufacturers or any member of the public, MDR information that can be used to identify patients or health care professionals (other than the MDR contact) without their consent. FDA has promulgated a regulation that extends protection against disclosure to voluntary reports held by medical device, pharmaceutical, and biologics manufacturers by preempting state discovery laws. FDA will release to an individual who submitted or is subject of a report the entire report after trade secret and confidential commercial information is deleted.

When a manufacturer submits an MDR report and it contains information from a user facility, the facility name and address and MDR contact for the facility will be released to the public when requested. FDA will not, however, release the identity of the patient or any information that can be used to identify the patient, such as the serial number of an implanted device. Nor will it release the name of any person other than the MDR contact.

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10
WRITTEN PROCEDURES AND RECORD KEEPING

10.1 Written MDR Procedures (803.17)

Manufacturers are required to develop, maintain and implement written MDR procedures that at a minimum:

A. Set up internal systems for:

- timely and effective identification, communication, and evaluation of any events that may be MDR reportable;
- a standardized review process/procedure for determining when an event meets the criteria for reporting under the MDR regulation; and
- timely transmission of a complete MDR report to FDA.

B. Set up documentation and recordkeeping for:

- information that was evaluated to determine if an event was MDR reportable;
- all MDR reports and information submitted to FDA;
- any information that was evaluated when preparing the annual certification report; and
- systems that ensure access to information that facilitates timely follow up and inspection by FDA.

Each manufacturer has certain discretion to determine the level of detail and depth of information that their written MDR procedures contain. FDA suggests that manufacturers provide policy and interpretation information regarding “typical” adverse events or product problems that may be MDR reportable. FDA also suggests that the procedures describe the investigation protocol that will be followed, e.g., two or three or four attempts will be made to contact the reporter either by phone, fax or letter before

investigation is closed; that the complaint records will contain a concise but thorough description of the adverse event or product problem, that the complaint records will be legible, etc.

In the past FDA has cited firms for GMP and MDR violations because the contents of the complaint records was a single word or sentence, and/or were illegible. It was impossible for FDA to evaluate the nature and seriousness of the complaints and whether they were MDR reportable. It was also impossible for the firm to demonstrate that its actions were in compliance with the requirements and that an MDR report was not needed. FDA expects manufacturers to document all MDR reports completely.

10.2 MDR Event Files (803.18)

Each event that requires a determination, regarding its MDR reportability, must be documented in an MDR event file (MEF). This MEF will be the basis for establishing compliance with the requirements of the MDR regulation. Files are to be accessible to FDA personnel for review and evaluation, as complete as possible, and clearly document MDR related actions and decisions. The following type of information should be in the MEF to assure that it complies with the MDR requirements:

a) The original or a copy of the initial record complaint/event. This record should include the available information needed to complete the Form FDA 3500A. The record may be a telephone call, a letter or facsimile, a service report, documents related to a lawsuit, a voluntary 3500 received from a health care professional or consumer, or mandatory 3500A received from a User Facility and/or a Distributor, etc.

b) Copies of any records documenting the firm's attempts to follow-up and obtain missing or additional information about the event. When information can not be obtained an explanation must be made part of the file. In addition, there must be an explanation of why any information required by the MDR regulation was not obtained and submitted.

c) Copies of any test reports, laboratory reports, service records and reports, records of investigation, etc.

d) Copies of all documentation involving the final assessment of the event, any deliberations and/or decision making processes used to determine whether an MDR report was or was not needed. When applicable, the final assessment should indicate what action (if any) the firm has taken to assure that the cause of the event is corrected or otherwise mitigated.

e) Copies of all 3500As submitted to FDA, when applicable. This includes a copy of any 3500As received from User Facilities and Distributors.

f) Documents verifying that the event has been evaluated in accordance with the applicable requirements of 21 Code of Federal Regulations (CFR), currently §§ 820.162 (Note: this number will likely change when the new GMP regulation is published) and 820.198.

g) References to any other relevant documents or information used during assessment.

10.3 How To Maintain MDR Event Files

The MEF can be written or electronic files. They may make reference to other information that was used during the investigational process, in lieu of copying and maintaining duplicates in the file. Any referenced material is to be made available to FDA personnel for review, copying and verification.

Each MEF must be retained for a period of two (2) years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. Each MEF file must be maintained for this period of time even if the device is no longer distributed by the firm.

The MEF may be maintained as part of the complaint file required by 21 Code of Federal Regulations (CFR) § 820.198 (Good Manufacturing Practices requirements)(GMP). However, the MEF files must be prominently identified.

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11
INFORMATION RESOURCES

The FDA realizes that manufacturers will need a variety of resources to assist them in understanding and complying with the MDR regulation. As a result, a number of different documents have been written to assist parties affected by the regulation. In addition, organizational components within the FDA have been identified to provide answers to policy questions, filing questions, etc. Additional documents will likely be developed as more experience with the new regulation is gained.

Information on how to obtain these documents is available through the CDRH Facts-On-Demand (FOD) system by calling 800.899.0381, 301.827.0111 and requesting shelf number 799.

11.1 Sources of MDR Related Documents

The documents related to the new Medical Device Reporting (MDR) regulation are listed below [with the code letters of their sources [ ]. Additional information for obtaining the documents [ ] from these sources [ ] is available from CDRH Facts-On-Demand as noted at bottom of this page [**E.**].

- Medical Device Reporting for User Facilities -- guidance document based on the final MDR regulation as it applies to user facilities. [Sources: A., B., C., D.]
- Medical Device Reporting for Manufacturers -- guidance document based on the final MDR regulation as it applies to manufacturers. [Sources: A., B., C., D.]
- Medical Device Reporting for Distributors -- guidance document based on the final MDR regulation as it applies to distributors. [Sources: A., B., C., D.]
- Medical Device Reporting: An overview -- summary of the MDR regulation as it applies to user facilities and manufacturers. [Sources: A., B., C., D.]
- Instructions for Completing Form 3500A (specific to Medical Device reporting) with Coding Manual for Form 3500A. [Sources: A., B., C., D.]
- Form 3500A, to be used by user facilities, manufacturers, and distributors. [Sources: A., B., C., E.]
- Abbreviated instructions for completing mandatory MedWatch Form 3500A. [Sources: A., B., C., D., E.]
- Baseline Report, Form FDA 3417. [Sources: A., B., C., E.]
- Annual Certification, Form FDA 3381. [Sources: A., B., C., E.]
- Semi-Annual Report, Form FDA 3419. [Sources: A., B., C., E.]

Sources to purchase these documents:

A. National Technical Information Service (NTIS) - For information on the NTIS system please call CDRH F-O-D (see **E.** below) and request Shelf number 3799. The NTIS Publication Numbers will be available May 15, 1996.

B. Health Care & Industry Organizations - For a list of organizations that have agreed to assist in the distribution of this information please call CDRH F-O-D (see **E.** below) and request Shelf number 4799. This list will be available May 1, 1996.

Sources to obtain copies free of charge:

C. World Wide Web (Internet) - FDA/CDRH maintains a World Wide Web (WWW) site for easy access to information. The home page may be accessed via FDA's home page at **http://www.fda.gov**. For additional information on the WWW site please call CDRH F-O-D (see **E.** below) and request Shelf number 1799.

D. CDRH Electronic Docket (ED) - ED is a computer bulletin board system which operates at a baud rate of 2400, 4800, or 9600. Dial **800.252.1366** or 301.594.2741 and a message will appear on the screen with the word **CONNECT** and other information. **AT THIS POINT PRESS ENTER** one or more times. For additional information on the ED system please call CDRH F-O-D (see **E.** below) and request Shelf number 2799.

E. CDRH Facts-On-Demand (F-O-D) - This automated fax system allows anyone to obtain CDRH information, 24 hours a day, 7 days a week by calling **800.899.0381** or **301.827.0111** from a touch-tone telephone. For additional information on the CDRH F-O-D system please call CDRH F-O-D and request Shelf number 5799 from DSMA Facts (1 at first voice prompt [VP], 2 at second VP, then follow subsequent VPs).

11.2 Whom To Contact If You Have MDR Questions

A. Policy and Interpretation Questions

Exemptions, Variances and Alternative Reporting Questions
ATTN: Questions
Division of Surveillance Systems (HFZ-533)
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850
301.594.2735
Fax 301.827.0038

B. Questions Regarding Filing of Forms FDA 3500A and FDA 3381

ATTN: Questions
Information and Analysis Team (HFZ-531)
Division of Surveillance Systems
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850
301.594.2731
Fax 301.827.0038

C. General Questions

Division of Small Manufacturers Assistance (HFZ-220)
Office of Health and Industry Programs
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850
FAX: 301.443.8818

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12
FREQUENTLY ASKED QUESTIONS AND ANSWERS

This chapter includes some of the questions and answers received to date. It is not intended to answer all of the policy and interpretation questions that may arise. It is a work in progress and will be developed into a separate Questions and Answers addendum over the next year or two. FDA is considering various ways of making updates to this chapter periodically available. The most likely mechanism will be to use the FDA Home Page. You may look for an MDR Questions and Answers item in the Medical Device Reporting Program Area on the CDRH portion of the FDA Home Page.

DEFINITIONS

How does FDA define "person qualified to make a medical judgement?" Can the person be a non-healthcare professional, for example, an experienced regulatory affairs professional?

FDA expects a "person qualified to make a medical judgement," to be a healthcare professional, e.g., doctor, nurse, biomedical engineer, risk manager. This person does not have to be an employee of the firm, but may be an outside consultant. The person should be qualified to make medical judgements in the medical specialty(ies) served by the firms products.

EXPECTED LIFE

Can the expected life of a device, like, an x-ray machine be indefinite because it can be serviced and repaired for a long time?

Yes, there are some categories of devices that will have an indefinite expected life since their end of life can not be estimated.

Is the expected life the same as the warranty period?

No, a warranty period is a service agreement and does not necessarily equate to the expected life of a device.

FDA FORM 3500A

The product expiration dates is asked for in Block D.5 of the FDA Form 3500A. Does this mean that FDA expects that all medical devices have expiration dates?

No, if the product does not have an expiration date enter “NA” in the block.

ANNUAL CERTIFICATION

May the president, CEO, U.S. designated agent of a foreign manufacturer, or other officials most directly responsible for the firm’s operations designate another employee to sign the annual certification?

No, the regulation specifically requires that an official directly responsible for the firm’s operation sign the annual certification.

The rule requires that a certification be submitted on the date for the firm's annual registration. Currently, manufacturers are sent a registration form approximately one month in advance of the date of registration. Will certification forms also be sent at this time?

FDA intends to send a certification form with the annual registration form. However, if a firm has not received a form in advance of the certification due date, it is responsible for obtaining one from CDRH (see Chapter 11).

REMEDIAL ACTION

What constitutes remedial action in the definition/submission of a 5 day report?

The definition of remedial action is any action other than routine service or maintenance of a device where such action is necessary to prevent recurrence of a reportable event. However, a 5-day report is not required for all remedial actions. A firm must only report remedial actions that are necessary to prevent an unreasonable risk of substantial harm to the public health.

Does completing Block H.7 on the 3500A automatically mean that the MDR report becomes a 5-day report because it is tied to a remedial action?

No, the test for whether or not it's a 5-day report is whether a remedial action is necessary to prevent an unreasonable risk of substantial harm to public health. So not every remedial action will require a 5-day report.

When does the 5-day clock start for reports involving remedial actions?

The 5-day clock starts when an employee with management or supervisory responsibilities over persons with regulatory, scientific or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware of an MDR reportable event that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

A manufacturer determines that remedial action is necessary based upon an MDR reportable event (or events). The manufacturer files a 5-day report. Are all subsequent events of the same nature involving the same (or a similar) device reportable within 5 days? 30 days?

No, once a 5-day report is made, another 5-day report would not be required if the remedial action addresses the public health hazard created by the event. Specifically, the remedial action must address the hazard or problem created by the event, any potential future events of the same nature and cover the device "model" involved in the event. In this case a 30-day report would be made for subsequent events unless FDA requested continued submission of 5-day reports under the authority of 21 CFR 803.53(b).

BASELINE REPORT

What product codes should be used for the purposes of defining a device family? Is this a reference to the FDA device classification codes or to some manufacturer number?

The product code is the classification code that FDA has assigned each medical device. It is the same code used on the Device Listing Form (Form FDA 2892), or in a 510(k) submission to identify the device's generic name. The 510(k) substantial equivalence letter provides this code, as do PMA approval letters. The CDRH

publication, “Classification Names for Medical Devices and In Vitro Diagnostic Products, FDA 95-4246,” contains a list of available product codes and corresponding device types. This publication is available from the Division of Small Manufacturers Assistance, OHIP.

Why is FDA requesting the number of devices manufactured during the last 12 months? Isn’t it the number distributed that is important?

FDA believes that both numbers are needed for its analysis of MDR reports. There may be a situation where a large number of products are manufactured but they have not yet been distributed. Our analysis would take into account that many additional products will be entering the distribution channel.

In preparing a baseline report, the new rules require information regarding number of devices manufactured/distributed in the last 12 months and the number of devices in current use. Are these numbers intended to apply to the device model or the device family? To what extent can rough estimates be provided to reflect these numbers?

The regulation requires that a baseline report be submitted based on device model. However, FDA will accept a baseline report to be submitted on a group of models that are the same except for minor differences not related to safety and effectiveness. The manufacturer can provide an estimate of the number of devices distributed in the last 12 months and the number of devices in current use provided the manufacturer submits a description of the method used to make the estimate. FDA expects that the manufacturer will use reasonable and sound methods to make such estimates. FDA would be particularly concerned with extreme over estimates of the numbers of devices distributed or in current use since this would inaccurately reflect the significance of use complications and failures.

If several different medical devices are sold as a system, and one is involved in a reportable event, is a baseline report required for the system or the component?

If the component is a finished device bearing its own unique device identifier and is ready to be used, then a baseline report is submitted for the component. If only the system has a device model number or the component involved can not be identified, then file a baseline on the system.

When completing Part 2, Blocks 10 and 12 on the baseline report, if there are multiple 510(k)s for a family of products, how should this be dealt with? Does the 510(k) number used depend upon which indication for use the event concerns and which 510(k) contains this indication?

The 510(k) number for the device model being reported should be used. This will require manufacturers to keep track of which models are cleared under which of the multiple 510(k)s they have for a device family. If the same device model is covered by more than one 510(k), then choose the earliest number and use it for all reports submitted for that model, regardless of indication for use.

The new rules state that baseline information must be provided at the time the first MDR for a device model is filed. If the first MDR for a device model is a 5-day report, must the baseline report be filed at that time with the 5-day report?

A baseline report must be filed with a 5-day report if the model that is the subject of the 5-day report is being reported for the first time. If any information required by the baseline can not be obtained at time of filing, the manufacturer should submit as much information as can be obtained, explain in a cover letter that all information cannot be obtained within the reporting time frames, and provide an estimated date for submission of the remaining information. As a minimum, the initial baseline report should provide the device identification information, i.e., brand, model number, catalog number, product code, device family, etc.

In preparing a baseline report, the regulation requires information regarding the expected life of the device. What is a manufacturer to do if the expected life of the device is unknown?

The baseline report contains a box to check if the expected life has not been determined or is indefinite. In that case records required by 803.18 must be kept until the manufacturer goes out of business.

INDIVIDUAL ADVERSE EVENT REPORTS (5 OR 30 DAYS)

Is a 30-day report required to be made within 30 work days or 30 calendar days?

A 30-day report is to be made within 30 calendar days, not work days.

Under what circumstances will FDA request 5-day reports?

5-day report requests will generally be related to severe, unusual or unexpected events. A possible scenario would be that there were a few unexplained pediatric deaths associated with the use of a particular medical device. FDA meets with the manufacturer and no reason can be determined for the deaths. At this point, FDA may decide that it wants 5-days reports on any other unexplained pediatric deaths for a specified period of time, e.g., six months. This will allow FDA to determine earlier if these deaths are an anomaly or caused or contributed to by the device.

A manufacturer receives FDA Form 3500A from a user facility. The user facility has only filled out some portion of Block F. When the manufacturer gets additional information from the user facility, is the manufacturer supposed to put that additional information into Block F, or is the manufacturer supposed to use the narrative space at the end of Block H?

When manufacturers add or correct information in Blocks A, B, D, E or F they should do so on their own FDA Form 3500A, not the one the user facility or distributor sent them. This is the only way that FDA will know which entity reported what information. **DO NOT MAKE CORRECTIONS ON THE ORIGINAL 3500A RECEIVED FROM THE USER FACILITY OR DISTRIBUTOR.** The manufacturer may put the information in Block H.11 or in the corresponding Block F items.

Will FDA continue to issue accession numbers for each MDR report?

No, the accession number has been replaced by the "Mfr. report #" that appears in the top right hand corner of the FDA Form 3500A, and in Block G.9. Manufacturers will no longer have to wait for FDA to assign their MDR report a number since the "Mfr. report #" is self generated.

SUPPLEMENTAL REPORTS

Are supplemental reports required whenever a firm receives additional information on an event for which a 30-day report was submitted?

If the initial report contained all the required information and the new information does not change the facts and/or conclusion reported in the 30-day report, it need not be reported. The new information is maintained in your MDR files.

However, if the new information will provide information that was previously noted as being UNK (unknown) or NI (no information at this time) or changes the information or conclusions previously provided, then a supplemental report is required.

The new rule requires that a supplemental report be prepared within one month. Is this 30 calendar days?

Yes, supplemental reports must be submitted within 30 calendar days following receipt of the information.

ISSUES ASSOCIATED WITH THE SALE OF A COMPANY

What happens if the device manufacturer and distributor transfer ownership to another company? For example, the product is sold to another company.

As long as a firm remains in business and its name is on a product, complaints will continue to come to that firm as will devices sold prior to the transfer. Therefore, the original manufacturer remains responsible for compliance with the MDR regulation for all the products sold and distributed before the new company took over.

LITERATURE ARTICLES

Will manufacturers be required to monitor all current medical publications for MDR reportable events?

Manufacturers are not required to monitor all current medical publications. However, if a manufacturer becomes aware of an article in a medical publication involving its device, then the manufacturer must assess the need for submitting an MDR report.

CODING MANUAL

How can manufacturers request that additional codes be added to the Coding Manual?

Such requests should be sent to:

MDR Coding Manual Coordinator, HFZ-533
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

U.S. DESIGNATED AGENT

What happens when someone ceases to be the U.S. designated Agent for a foreign manufacturer? Who is responsible for filing subsequent baseline reports, the old or new agent?

The new agent is responsible for filing subsequent baseline reports and annual updates of previously submitted baseline reports. The foreign manufacturer should make sure that its U.S. designated agent agreement includes a provision requiring all records to be transferred to the new agent. In lieu of this, the foreign manufacturer should maintain a duplicate set of all the records kept by their U.S. designated agent.

If a foreign manufacturer designates its U.S. importer as its U.S. agent, is the U.S. importer required to submit both distributor (as the initial importer) and manufacturer medical device reports (MDRs)? If the importer is a wholly-owned subsidiary of the foreign firm would they report as a distributor and a manufacturer for the same events?

An agent of a foreign manufacturer who is also the distributor/importer of the products does not have to submit distributor reports on MDR reportable events involving the imported devices. It will suffice to submit reports on behalf of the foreign manufacturer.

Can a responsible official of a foreign manufacturer provide the certification that reports of all reportable events have been submitted to the FDA, or must the certification be provided by the U.S. designated agent?

Annual certification for a foreign manufacturer must be signed and submitted by the U.S. designated agent.

Are there any circumstances in which a foreign device manufacturer will be relieved of the obligation to designate a U.S. agent?

FDA is not aware of any circumstances at this time that would warrant a variance or exemption, but will accept requests for variances.

Is the U.S. agent of a foreign manufacturer subject to penalties for violation of the regulation irrespective of its efforts to discharge its duty? If the U.S. agent's obligation is framed in terms of "due diligence" or "reasonable efforts" or the like, can any guidance be offered as to the minimum elements required? For example, will FDA require a periodic physical inspection of the foreign manufacturer's records by the U.S. agent, and will it be adequate that the U.S. agent has a written agreement with its client that the client will disclose all relevant information?

Since 21 CFR 803.3(n) defines the U.S. agent as a manufacturer, an agent would be subject to the same types of penalties and sanctions as a domestic manufacturer. These penalties/sanctions include injunctions and seizures as well as civil money penalties authorized by Section 303 of the Food, Drug and Cosmetic Act.

FDA can offer no guidance at this time as to what the U.S. agent should do as a minimum other than comply with the requirements of the regulation for U.S. designated agents contained in 21 CFR 803.58, 807.3(r), 807.20, 807.22, and 807.40. It is certainly desirable for the foreign manufacturer and the agent to develop and implement a written agreement. Since the agent is acting on behalf of the foreign manufacturer, the foreign manufacturer must provide the agent with all information necessary to allow the agent to fully comply with the reporting requirements. The agent and the foreign manufacturer should develop policies and procedures to ensure a complete exchange of information.

FDA does not require U.S. agents to make periodic inspections of the foreign manufacturer's records. Such requirement could be incorporated into any agreement between the agent and the manufacturer. However, FDA does make inspections of foreign manufacturing plants. If the FDA determines during an inspection that a foreign manufacturer is withholding information about MDR reportable events from its U.S. agent, FDA may take action to prevent the manufacturer's products from being imported into the United States.

What are the circumstances under which a foreign device manufacturer that is exclusively an OEM manufacturer --namely, that sells only to U.S.-based companies that sell the devices under their own names -- will not be required by FDA to have a U.S. designated agent to submit MDR reports?

If the foreign manufacturer exports to the U.S. stand alone devices that are completely assembled and ready to use, they must have a U.S. designated agent to submit MDR reports. It does not matter whose name the manufacturer places on the device labeling. If the device when exported is not complete and would not be considered a

stand-alone device, then the firm that completes the manufacturing operation in the U.S. would be considered the manufacturer and have the reporting responsibility.

May the foreign manufacturer's reporting obligation be relieved if the U.S. customer agrees to assume those obligations, and the U.S. manufacturer in fact completely satisfies the reporting requirements?

The foreign manufacturer must designate a U.S. agent and that agent could be the U.S. customer, who would be responsible for reporting on behalf of the foreign manufacturer. If the U.S. customer performs some act, such as relabeling, that makes the customer also a manufacturer with respect to that device, then the customer would have reporting responsibility as a manufacturer. The agency may accept, in this case, a reporting agreement between the two parties to avoid dual reporting as long as the reporting entity is legally responsible under the Act. However, as a general rule, reporting obligations under the regulation cannot be transferred by agreement between the manufacturer and a third party.

Do U.S. designated agents need their own written MDR procedures?

Yes, since the U.S. designated agent is a manufacturer by definition and must have written MDR procedures.

MDR EVENT FILES

The new rules require that MDR files include documentation of deliberations regarding potentially reportable events. Where is a company to draw the line in determining when to document a deliberative process regarding a complaint that is determined not to be reportable?

For example, should documentation be included in MDR files when an injury occurs but does not meet the definition of serious injury? When a death or serious injury occurs but the company determines that the device did not cause or contribute to the death or serious injury? When a device fails to meet performance specifications, no matter how minor?

Manufacturers are required to establish and maintain files documenting their deliberations and decision making processes used to determine if an event is reportable. Written procedures must be established to accomplish this. (See 21 CFR 803.17 and 803.18). These procedures should include processes for recognizing and evaluating complaints and potentially reportable events from any source including

service/maintenance records, legal files, literature articles, etc. Criteria for recognizing potentially reportable events must be documented. All known facts, information and deliberations concerning an event that was evaluated to determine if it was reportable must be included in the MDR event file.

If a manufacturer has, for example, established procedures and criteria for screening service records to identify malfunctions that are potentially reportable for subsequent in-depth evaluation, the procedures and criteria used in the screening must be documented and maintained. The results of the in-depth evaluation of service records that were identified as potentially reportable must be documented and maintained in the MDR event file even if the manufacturer concludes that a malfunction report is not required.

A manufacturer must evaluate each reportable or potentially reportable event in accordance the GMP requirements (21 CFR 820.162 and 820.198). Failure to do so is considered to be a failure to comply with the GMP requirements and with the reporting requirements of 803. A manufacturer's MDR files shall also contain an explanation of why any information required to be submitted could not be obtained and the results of each event evaluation.

MISCELLANEOUS

The preamble states that "reasonably known" includes information that "can be obtained" from other reporting entities or from analysis/testing. Please confirm that this can be interpreted to mean information that can be <u>reasonably</u> obtained.

The type of information that is "reasonably known" to the manufacturer is listed in 21 CFR 803.50(b)(I)-(iii). It includes information that can be obtained by contacting a user facility, distributor and/or initial reporter, any information in the manufacturer's possession, or any information that can be obtained by analysis, testing or other evaluation of the device. In applying this requirement FDA will not ask the manufacturer to obtain information that it was not possible for the manufacturer to obtain.

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APPENDIX
MEDICAL DEVICE REPORTING REGULATION WITH PREAMBLE

The final version of this document will include a copy of the December 11, 1995 and April 11, 1996, Federal Register notices.