On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

FDA notes that ISO 13485: 2016, Clause 3.4 defines the term "complaint." The requirements related to complaint handling found in the previous QS regulation are now described in ISO 13485:2016, Clause 8.2.2. Additional FDA requirements that apply to complaint records are set forth at 21 CFR 820.35(a).

Contains Nonbinding Recommendations

Medical Device Reporting for Manufacturers

Guidance for Industry and Food and Drug Administration Staff

Document issued on: November 8, 2016

The draft of this document was issued on July 9, 2013.

This document supersedes "Medical Device Reporting for Manufacturers" dated March 1997.

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

For questions about this document, contact the MDR Policy Branch, 301-796-6670, MDRPolicy@fda.hhs.gov.

US Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Surveillance and Biometrics
Division of Postmarket Surveillance
MDR Policy Branch

Preface

Public Comment

You may submit written comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number FDA–2013–D–0743. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1828 to identify the guidance you are requesting.

GRZAN

Table of Contents

1. Introduction 1
   1.1 What is the purpose of this guidance document? 1
   1.2 What is the purpose of the MDR regulation? 2
   1.3 What are the basic requirements of the MDR regulation that apply to me? 2
   1.4 What are "MDR reportable events"? 2
   1.5 Is this guidance also intended for user facilities, importers and distributors? 3
   1.6 Where can I obtain help if I have questions about this guidance document or the MDR regulation? 3
2. Manufacturer Reporting Requirements 4
   2.1 What are the reporting requirements that apply to me as a medical device manufacturer? 4
   2.2 Who is considered to be a manufacturer subject to the reporting requirements of the MDR regulation? 5
   2.3 When do I "become aware" that an MDR reportable event has occurred? 6
   2.4 What is "information that reasonably suggests" that an MDR reportable event has occurred? 6
   2.6 What is device "user error" and why do you want to know about events involving user error? 7
   2.7 What form must I use to submit an MDR reportable event? 7
   2.8 What information must be included in my report? 7
   2.9 Can I include multiple devices in the same report? 8
   2.10 What do you consider to be a device-related complaint and do I have to evaluate the complaint? 8
   2.11 Where will device-related complaints come from? 8
   2.12 What are my responsibilities for investigating a voluntary report when the source of the report is unknown to me? 10
   2.13 What is a "serious injury"? 10
   2.14 What is a malfunction and when must a malfunction be reported? 11
   2.15 How do I decide whether a malfunction is "likely to" cause or contribute to a death or serious injury? 12
   2.16 When does a complaint concerning a possible MDR reportable event not have to be reported? 13
   2.17 If I am a contract manufacturer, when do I need to obtain an exemption from reporting? 14
   2.18 What types of reports are required by the MDR regulation? 15
   2.19 What are 30-day reports? 15
   2.20 What are 5-day reports? 16
   2.21 What is a "remedial action," and are all adverse events associated with "remedial actions" reportable to FDA as 5-day reports? 16
   2.22 What are supplemental reports and when are these reports required to be made? 17
   2.23 What level of effort must I make to obtain additional information or previously unknown information about MDR reportable events? 18
   2.24 When will you request additional information from me about an event for which I submitted an MDR report? 18

2.25 Must reports be made in English? 19
2.26 Does the MDR regulation provide for any reporting exemptions, variances, or alternative forms of reporting? 19
2.27 What information should I include in a request for an exemption, variance, or alternative form of reporting and where should the request be sent? 20
2.28 Have you published any guidance documents describing the exemptions, variances, and alternative forms of reporting you have issued, and if so, where can I get this information? 21
2.29 Where do I send my MDR reports? 21
2.30 Where do I report a public health emergency? 22
2.31 Where can I find more detailed information on preparing an electronic MDR? 22
2.32 I'm a foreign manufacturer. Can the firm that imports my devices to the US file MDR reports that satisfy both the manufacturer and importer reporting requirements? What is the process to request this? 22
3. Written Procedures, Recordkeeping and Public Disclosure 23
3.1 What are my requirements for developing, maintaining, and implementing written MDR procedures? 23
3.2 What are my requirements for establishing and maintaining MDR files and records? 24
3.3 What information contained in my MDR reports is subject to public disclosure and what information will not be disclosed? 25
3.4 When I submit an MDR report, is the report considered an admission that my device caused or contributed to the reported event? 26
4. Specific Issues and Situations 27
4.1 Delay in Surgery 27
4.1.1 For several years our firm has submitted an MDR for any situation in which a surgery is delayed. What is your position on this issue? 27
4.2 Expected Life of the Device 27
4.2.1 Can the expected life of a device be determined by the warranty? 27
4.2.2 For devices intended for periodic preventive maintenance, or some sort of a scheduled calibration time, is the expected life one calibration, one preventive maintenance cycle, or the overall life of the product? 27
4.2.3 Does the expected life definition take into consideration routine maintenance recommendations that I make? 28
4.2.4 Am I required to report routine explants of implanted devices that have an expected life that is less than the life of the patient, such as tissue valves, vascular grafts, or routine revisions of orthopedic implants? 28
4.3 Device Labeling 28
4.3.1 If my device labeling addresses the risks and complications associated with the use of a device, is an MDR required when a listed complication occurs? 28
4.3.2 The labeling of my device states that another manufacturer's component is not compatible with my device and use of the two together would render my device inoperable. Would an adverse event resulting from this incompatibility be reportable under MDR? 28
4.4 Diagnostic Devices 29
4.4.1 Is an event indirectly caused by a failed diagnostic device reportable? 29
4.5 Difference of Medical Opinion 29

4.5.1 If there is a conflict of opinion about the role of my device in an adverse event, do I have to submit an MDR? For example, is an MDR required where a doctor performing a surgery does not believe my device malfunctioned, but another healthcare professional at the same facility says the device did malfunction? 29
4.6 Events Involving Same Patient on Different Days 29
4.6.1 How should I report adverse events involving the same patient and device that occur on different days? 29
4.7 Exemptions and Time Limits 30
4.7.1 How long is an exemption in effect once it is granted? 30
4.8 FDA Access to Electronic Files/Data 30
4.8.1 Am I required to provide FDA access to my electronic files as well as my hard copy complaint and MDR files during an inspection? 30
4.9.1 How much effort must I make to get information about an event, or even to get the device back? Sometimes when I call a user facility no one wants to talk to me. How many times must I call or write before I can close the file? 30
4.10 Devices under Investigational Device Exemption (IDE) 31
4.10.1 I'm a US manufacturer of a device that has been cleared or approved for marketing in the US, and is also being studied under an approved IDE. What are the requirements for reporting an event involving the investigational use of the marketed device? 31
4.11 Foreign Events 31
4.11.1 Does the MDR regulation apply to devices that are legally exported by US manufacturers to foreign locations if the device is not cleared or approved for marketing in the US? 31
4.11.2 I'm a US manufacturer of a device that has not been cleared or approved for marketing in the US, although the device is being studied in the US under an approved IDE. Is an event involving my device that occurred outside the US reportable under MDR in this situation? 32
4.11.3 I'm a foreign manufacturer of a device that has been cleared or approved in the US and is also lawfully marketed in a foreign country. If an adverse event occurs in a foreign country with the device, must the event in the foreign country be reported under the MDR regulation? 32
4.11.4 I'm a foreign manufacturer of a device that has not been cleared or approved for marketing in the US, although the device is being studied in the US under an approved IDE. Is an event involving my device that occurred outside the US reportable under MDR in this situation? 33
4.12 Manufacturer Ceased Marketing a Device 33
4.12.1 If I previously marketed a device that is still in commercial distribution, but have ceased manufacturing the device, do I still have an obligation to submit MDR reportable events? 33
4.12.2 Firm A manufactured and distributed a device that was cleared for marketing under its 510(k), but later sold the 510(k) to another firm (Firm B). Who should submit the MDR reports for adverse events that involve the devices that Firm A manufactured? 33
4.13 Medical Intervention 34

4.13.1 If a health care provider notices that a medical device is malfunctioning (i.e., not performing as intended) and intervenes before the malfunctioning device can harm the patient (i.e., can cause or contribute to a serious injury or death), is this reportable? 34
4.14 Patient Information 34
4.14.1 It is very difficult to obtain patient information due to patient confidentiality in the health care setting. Is this information always necessary? 34
4.15 Radiation Therapy 34
4.15.1 Exactly what constitutes an MDR reportable event involving my radiation therapy device where there was incorrect treatment but no demonstrable patient injury? 34
4.16 Reports Based On Literature 35
4.16.1 Must I investigate and submit reports on MDR reportable events reported in literature sources? 35
4.16.2 What guidance can you provide concerning how to report events found in scientific articles and other literature? 35
5. Questions Concerning Completion of the MDR Report 37
5.1 General Questions 37
5.1.1 When submitting my initial report why can't I just fill in the parts of the form for which I have the information requested, and leave the rest of the form blank? 37
5.1.2 What are the most common problems you see in the way manufacturers fill out Form 3500A? 38
5.2 Block A - Patient Information 41
5.2.1 How do I complete the field for patient name (Block A-1) when the patient is also the initial reporter (Block E)? 41
5.3 Block B - Adverse Event or Product Problem 41
5.3.1 What date is meant by “Date of this Report,” in Block B-4? 41
5.3.2 How much detail do I need to use to describe the event? 41
5.4 Block F - For Use By User Facility/Importer 41
5.4.1 If I complete Form 3500A for a user facility or importer event, do I include the information required by Block F in Block H-11, or should I complete Block F? 41
When you receive information from the user facility or importer (not on a Form 3500A) and you must complete Form 3500A, you must provide the information required by Blocks A, B, D and E in addition to Blocks G and H. Although you are not mandated to complete Section F, you should enter the patient and device codes that are required by Block F-10 in Block H. If you receive a copy of the user facility or importer report, you may attach a copy to your electronic MDR submission. For more information regarding electronic submissions, refer to the “Questions and Answers about eMDR - Electronic Medical Device Reporting - Guidance for Industry, User Facilities and FDA Staff” at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm175805.htm 41
5.4.2 Does the omission of the data elements on a user facility or importer malfunction report relieve me from follow up and reporting information requested on the Form 3500A? 42
5.5 Block H - Device Manufacturers Only 42
5.5.1 What is meant by “Evaluation codes” requested in Block H-6? 42

5.5.2 The instructions for completing Form 3500A state that conclusion codes should be entered even if the device is unable to be evaluated. How is this possible? If the actual device cannot be evaluated, shouldn't Block H-6 be left blank? 43
5.5.3 Because Block H-6 has 4 boxes for method, results and conclusions, do I put one number in each box or the entire code in one box? If I put the entire code in one box, am I then limited to just four codes for each category? 43
5.5.4 Should I check a box under H-7 to identify a correction I make to the device involved in the MDR report? When should I provide information under H-7? What should I report under H-9? 43
APPENDIX A 45
BASIC REQUIREMENTS FOR USER FACILITIES, IMPORTERS AND DISTRIBUTORS 45
A.1 Basic Requirements for User Facilities 45
A.2 Basic Requirements for Importers 45
A.3 Basic Requirements for Distributors 46

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Medical Device Reporting for Manufacturers

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

1.1 What is the purpose of this guidance document?

This guidance document describes and explains the Food and Drug Administration's (FDA, we, us) current regulation that addresses reporting and recordkeeping requirements applicable to manufacturers of medical devices for device-related adverse events and certain malfunctions.[1] These requirements are contained in our Medical Device Reporting (MDR) regulation at Title 21, Code of Federal Regulations (CFR), Part 803, as authorized by section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). References to FDA regulations and Federal Register documents, as well as cross-references within this guidance document, are hyperlinked for your convenience.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in guidance documents means that something is suggested or recommended, but not required.

[1] FDA published a final rule entitled "Medical Device Reporting: Electronic Submission Requirements" (79 Fed. Reg. 8832, February 14, 2014, http://www.gpo.gov/fdsys/pkg/FR-2014-02-14/html/2014-03279.htm). FDA has modified this guidance based on that final rulemaking to ensure that the recommendations in this guidance are consistent with the final rule.

1.2 What is the purpose of the MDR regulation?

The MDR regulation provides a mechanism that allows us (the FDA), as well as you (the device manufacturer), to identify and monitor adverse events (deaths and serious injuries) and certain malfunctions involving your medical devices. The goal is to detect and correct problems in a timely manner. The requirements of the MDR regulation are enforced under the authority of the FD&C Act. The enforcement mechanisms include seizure, injunction, civil money penalties, and criminal prosecution.

The MDR regulation also includes adverse event reporting and recordkeeping requirements for medical device user facilities (e.g., a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, outpatient treatment facility), importers of medical devices, and medical device distributors.

1.3 What are the basic requirements of the MDR regulation that apply to me?

Manufacturers, including foreign manufacturers**,** of legally marketed medical devices in the United States are required to:

- Submit to us reports of MDR reportable events[2] involving their medical devices [21 CFR 803.10(c) and 803.50];
- Develop, maintain, and implement written procedures for the identification and evaluation of all medical device events (e.g., malfunctions, serious injuries and deaths) to determine whether the event is an MDR reportable event [21 CFR 803.17] (for related information, see sections 2.10 and 3.1 of this guidance); and
- Establish and maintain complete files for all complaints concerning medical device events [21 CFR 803.18] (for related information, see section 3.2 of this guidance).

1.4 What are "MDR reportable events"?

For manufacturers, "MDR reportable events" are events that manufacturers become aware of that reasonably suggest that one of their marketed devices may have caused or contributed to a death or serious injury, or has malfunctioned and the malfunction of the device or a similar device that they market would be likely to cause or contribute to a

[2] The MDR regulation published on December 11, 1995 (60 FR 63578) also included requirements for manufacturers to submit Annual Certification using FDA Form 3381 and Baseline Reports using FDA Form 3417. The Annual Certification requirement was revoked by the Food and Drug Administration Modernization Act of 1997 and removed from the regulation as published on January 26, 2000 (65 FR 4112). The Baseline Reporting requirement was removed from the regulation effective October 27, 2008 (73 FR 33692 and 73 FR 53686).

death or serious injury if the malfunction were to recur [see 21 CFR 803.3] (see Section 2) of this guidance document for a description of "serious injury" and "malfunction" and information for determining when a device malfunction must be reported to us as an "MDR reportable event").

1.5 Is this guidance also intended for user facilities, importers and distributors?

No, this guidance document is intended for only medical device manufacturers. Certain requirements applicable to user facilities, importers, and distributors are summarized in Appendix A to facilitate better understanding of the requirements applicable to manufacturers because manufacturers may receive information about MDR reportable events from these entities. Note that this guidance does address manufacturing activities of user facilities, importers, and distributors that also manufacture devices.

1.6 Where can I obtain help if I have questions about this guidance document or the MDR regulation?

If you have any questions or concerns regarding this guidance document or the MDR regulation, contact:

MDR Policy Branch
Division of Postmarket Surveillance
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Building 66, Room 3217
Silver Spring, MD 20993-0002

Telephone: 301-796-6670 E-mail: MDRPolicy@fda.hhs.gov

2. Manufacturer Reporting Requirements

2.1 What are the reporting requirements that apply to me as a medical device manufacturer?

As a manufacturer of medical devices, you are required to submit reports to us of a reportable death, serious injury, or device malfunction [21 CFR 803.10(c)]. A reportable death, serious injury, or malfunction is based on information a manufacturer receives or otherwise becomes aware of, from any source, which reasonably suggests that one of its marketed devices:

- May have caused or contributed to a death or serious injury [21 CFR 803.3 and 803.50] (see also sections 2.5 and 2.13 of this guidance); or

- Malfunctioned and the malfunction of the device or a 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 [21 CFR 803.3 and 803.50] (see also section 2.14 of this guidance).

MDR reportable events generally must be submitted to us within 30 calendar days after the day you become aware of the event [21 CFR 803.10 and 803.50] and are referred to in this guidance document as "30-day reports" or "initial reports." Under some circumstances, a medical device report is required to be submitted within 5 work days after the day you become aware of the need to submit such a report [21 CFR 803.10 (c)(2) and 803.53].[3] Reports required to be submitted within 5 work days are referred to in this guidance document as "5-day reports" or "five-day reports." A "work day" is Monday through Friday, except Federal holidays [21 CFR 803.3]. All types of required reports are explained further in this guidance document (see Sections 2.18, 2.19, and 2.20 of this guidance).

As stated in the Federal Register Notice , 76 FR 12743, Title II/Section 227 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85), amended Section 519(a) of the FD&C Act, 21 U.S.C. 360i(a) in relation to certain malfunction reporting requirements. The FR notice explains that FDAAA changed malfunction reporting requirements to quarterly summary reporting for all class I devices and those class II devices that are not permanently implantable, life supporting or life sustaining. However, pending further FDA notice, these devices currently remain subject to individual reporting requirements under 21 CFR Part 803 in order to protect the public

[3] You must submit a 5-day report to us no later than 5 work days after the day that you become aware that: (a) an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health; or (b) we have made a written request for the submission of a 5-day report [21 CFR 803.53].

health. Consequently, malfunction reports for such devices are currently required to be reported under 21 CFR Part 803, as was required pre-FDAAA.

The notice also states that FDA intends to publish in the Federal Register a list of the types of devices that continue to be subject to 30-day reporting under 21 CFR part 803 in order to protect the public health under section 519(a)(1)(B)(i)(III) of the FD&C Act, 21 U.S.C. 360i(a)(1)(B)(i)(III). In addition, FDA intends to, by rulemaking, establish malfunction reporting criteria for devices subject to quarterly summary reporting per section 519(a)(1)(B)(ii) of the FD&C Act, 21 U.S.C. 360i(a)(1)(B)(ii).[80 FR 50010] In the interim, all device manufacturers and importers must continue to report malfunctions as individual reports in full compliance with 21 CFR part 803. FDA plans to modify this guidance based on any future notice to modify the types of devices subject to malfunction reporting under section 519(a)(1)(B)(i)(III) of the FD&C Act, 21 U.S.C. 360i(a)(1)(B)(i)(III), and any final rulemaking to establish criteria for malfunction reporting under section 519(a)(1)(B)(ii) of the FD&C Act, 21 U.S.C. 360i(a)(1)(B)(ii), to ensure, as needed, that the recommendations in this guidance are consistent with the final rule.

2.2 Who is considered to be a manufacturer subject to the reporting requirements of the MDR regulation?

A **"**manufacturer" is any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure [21 CFR 803.3]. The term includes any person who:

- Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;

- Initiates specifications for devices manufactured by a second party for subsequent distribution by the person initiating the specifications; or

- Manufactures components or accessories that are medical devices and that are (1) ready to be used and are intended to be commercially distributed and intended to be used as is, or (2) processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

All manufacturers of legally marketed medical devices in the US, including foreign manufacturers who export devices to the US, are subject to the MDR regulation and must submit required reports. US manufacturers of medical devices that are not cleared or approved in the US, but are exported to foreign locations, are also subject to the MDR regulation. Failure to submit required reports is a prohibited act [section 301(q) of the FD&C Act, 21 U.S.C. 331(q)] (however, see Section 4.11.1 of this guidance for the circumstances under which FDA generally does not intend to enforce MDR reporting requirements for those devices exported under sections 801(e) or 802 of the FD&C Act).

Any person who reprocesses a single use device for reuse in human beings becomes the manufacturer of the device and is subject to all the requirements applicable to the original manufacturer, including the requirements of the MDR regulation [69 FR 7490].

2.3 When do I "become aware" that an MDR reportable event has occurred?

As a manufacturer, you are considered to have "become aware" of an event whenever [21 CFR 803.3]:

- Any of your employees becomes aware of information that reasonably suggests that an event is required to be reported in a 30-day report or in a 5-day report that we have requested from you; or
- Any of your employees with management or supervisory responsibilities over persons with regulatory, scientific or technical responsibilities (including consultants or contractors) or whose duties relate to the collection and reporting of adverse events, becomes aware from any information (including any trend analysis) that an MDR reportable event(s) necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. In this case, you must submit a report no later than 5 work days after the day that you become aware.

Your MDR procedures should identify the roles and responsibilities of contractors or consultants that work for you or on your behalf to review and process complaints.

Please note: The Quality System (QS) regulation requires you to have a formally designated unit to receive, review and evaluate complaints [21 CFR 820.198(a)]. Manufacturers who are subject to the QS regulation should ask all of their employees to forward device-related complaints to that unit in a timely manner (see also sections 2.10, 2.11, 2.12 and 3.1 of this guidance). Complaints should be evaluated in order to determine if they represent a reportable event in accordance with 21 CFR 803.3(o).

2.4 What is "information that reasonably suggests" that an MDR reportable event has occurred?

This means any information, including professional, scientific, or medical facts, observations, or opinions that would cause you to come to a reasonable conclusion that a device has caused or may have caused or contributed to an MDR reportable event [21 CFR 803.20(c)]. For guidance on when an adverse event does not have to be reported to us, see section 2.16 of this guidance.

2.5 What is meant by "caused or contributed" to a death or serious injury?

This means that a death or serious injury was or may have been attributed to a medical device or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of [21 CFR 803.3]:

1. Failure;
2. Malfunction;
3. Improper or inadequate design;
4. Manufacture;
5. Labeling; or
6. User error.

2.6 What is device "user error" and why do you want to know about events involving user error?

We consider a device "user error" (or "use error") to mean a device-related error or mistake made by the person using the device. The error could be the sole cause of an MDR reportable event, or merely a contributing factor. Such errors often reflect problems with device labeling, the user interface, or other aspects of device design. Thus, FDA believes that these events should be reported in the same way as other adverse events which are caused or contributed to by the device. This is especially important for devices used in non-health care facility settings. If you determine that an event is solely the result of user error with no other performance issue, and there has been no device-related death or serious injury, you are not required to submit an MDR report, but you should retain the supporting information in your complaint files.

2.7 What form must I use to submit an MDR reportable event?

Your submission must use an electronic equivalent of Form 3500A which is approved by FDA [21 CFR 803.11 and 803.14]. We have identified mandatory adverse event and reportable malfunction event reports as types of documents that must be submitted electronically.[4] You must submit reports of individual adverse events to FDA in an electronic format in accordance with [21 CFR 803.12(a)] and [21 CFR 803.20], unless granted an exemption under [21 CFR 803.19]. (See also section 2.31 of this guidance for information about the electronic submission of MDR events).

2.8 What information must be included in my report?

Your report must contain all the information required by 21 CFR 803.52 that is known, or reasonably known to you. Information we consider reasonably known to you includes any information [21 CFR 803.50(b)]:

- That you can obtain by contacting a user facility, importer, or other initial reporter;

[4] The CDRH May 8, 2008 notification is posted on the Part 11 Docket at FDA-1992-S-0039-0054.

- That is in your possession; or
- That you can obtain by analysis, testing or other evaluation of the device.

Instructions for completing the Form 3500A, and information regarding codes to be used for specific sections of the form may be accessed via the following links:

Instructions for completing Form 3500A:
http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM387002.pdf.

Information on the current Event Problem Code Hierarchy:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/EventProblemCodes/ucm134751.htm.

Instructions for electronic reporting: electronic Medical Device Reporting (eMDR) - Home Page

2.9 Can I include multiple devices in the same report?

Although a user facility may submit one report for an adverse event that involves multiple suspect devices, a manufacturer should submit a separate report for each device involved in the MDR reportable event.[5] For example, if you receive a report from a user facility which indicates that more than one of your devices may have contributed to one MDR reportable event, and you cannot determine which device actually caused or contributed to the event or which device malfunctioned, you should submit a separate report for each device potentially involved in the event.

2.10 What do you consider to be a device-related complaint and do I have to evaluate the complaint?

For the purposes of this guidance document, we recommend that you use the definition of a complaint found in the QS regulation, which defines a complaint as:

> [A]ny written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution [21 CFR 820.3(b)].

You are required to review and evaluate all device-related complaints to determine whether the complaint represents an MDR reportable event [21 CFR 803.18(e) and 820.198].

2.11 Where will device-related complaints come from?

[5] See http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM387002.pdf.

You may receive complaint information from many different sources, including telephone calls or other verbal communication, FAX transmissions, written correspondence, e-mail notification, sales representative reports, service representative reports, scientific articles (literature), internal analyses, and legal documents. You may receive reports directly from user facilities, importers, or voluntary reporters. We may also send you a communication, such as a copy of a user facility or voluntary report.

FDA believes that manufacturers have a responsibility to inform all employees, including marketing, sales, engineering, manufacturing, regulatory, legal, installation, and service personnel, to immediately forward adverse event information to the appropriate person appointed by those entities to submit MDR reports. Thus, FDA generally considers that a manufacturer becomes aware of an adverse event whenever any employee becomes aware of an adverse event (see section 2.20 of this guidance for the specific employees FDA expects to be able to recognize that an adverse event requiring "remedial action" to prevent a risk of substantial harm to the public has occurred). Employees should be trained to properly identify, collect, and report complaints to your formally designated complaint handling unit [see 21 CFR 820.198(a) for requirements related to complaint files].

User facilities and importers have specific mandatory reporting requirements [e.g., 21 CFR 803.10, 803.11, 803.20, 803.30, and 803.40]. If a user facility notifies you of a death or serious injury and has not submitted a completed Form 3500A, we suggest that you remind the user facility of their obligation to do so within 10 work days after the day that it becomes aware of a reportable event. If the report involves a death, the user facility must also send the report to us.

If a user facility or importer uses the Form 3500A to report information to you about a reportable event, you can add your manufacturer information to that form and submit it to FDA (once you determine that you agree with the user facility that the event is reportable). If a user facility or importer does not use the Form 3500A to report information to you about an adverse event that is reportable under MDR, you need to provide information for all appropriate sections of the 3500A (or an electronic equivalent).

You may also receive adverse event information on a voluntary MedWatch Form 3500 or MedWatch Consumer Voluntary Reporting Form 3500B when there is no mandatory reporting obligation for the reporting entity (such as for user facilities reporting malfunctions or for physicians and consumers reporting deaths, serious injuries or malfunctions).

If the complaint information requires further investigation to determine if the event is MDR reportable, then your investigation should be conducted for the purpose of gathering enough evidence to support your decision to submit or not to submit an MDR report. This should be completed in a timely manner. Once you determine that the event is MDR reportable, you must submit the report to us within the required time frame [refer to 21 CFR 803.10, 803.11, 803.20, 803.50, and 803.52]. You must submit the report to

us within 30 calendar days or 5 work days, whichever period of time is applicable [see, i.e., 21 CFR 803.10, 803.20, 803.50, and 803.53].

2.12 What are my responsibilities for investigating a voluntary report when the source of the report is unknown to me?

You will need to evaluate the available information in the complaint to determine whether it represents an MDR reportable event [21 CFR 820.198(a) and 803.18]. Your evaluation must include information in your possession or that is reasonably available to you, such as information you can obtain by contacting a user facility, importer or other initial reporter related to the adverse event [21 CFR 803.50], if the source can be identified. Such information would include what is provided in the voluntary report, along with your knowledge of the device [21 CFR 803.18; see also 21 CFR 803.17, 803.50(b), and 820.198]. Your decision about whether or not the event is an MDR reportable event should be based on the findings of your evaluation.

2.13 What is a "serious injury"?

An injury must meet the definition of "serious injury" in 21 CFR 803.3 for an event to be reportable as a serious injury. A "serious injury" is an injury or illness that [21 CFR 803.3]:[6]

- Is life threatening;
- 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.

"Permanent" means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage [21 CFR 803.3]. Note that not all cosmetic damage will be considered trivial.[7] Furthermore, a life-threatening injury meets the definition of serious injury, regardless of whether the threat was "temporary."[8]

It should also be noted that a device does not have to malfunction for it to cause or contribute to a serious injury. Even though a device may function properly, it can still

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[6] One court agreed that "[a]lthough some of these consequences may be deemed clinically insignificant, they are considered to be serious injuries when coupled with the interventions, e.g. administration of antibiotics or other medications, explant, reconstruction, debridement, or revision surgery)." TMJ Implants, Inc. v. U.S. Dep't of Health & Hum. Servs., 584 F.3d 1290, 1301 (10th Cir. 2009).

[7] See the FDA response to comment 18 in Medical Devices; Medical User Facility and Manufacturer Reporting, Certification and Registration; Final Rule, 60 Fed. Reg. 63578, 63586 (Dec. 11, 1995).

[8] *See id.* at 63587.

cause or contribute to a death or serious injury (see section 2.5 of this guidance for further discussion about caused or contributed).

2.14 What is a malfunction and when must a malfunction be reported?

"Malfunction" means the failure of a device to meet its performance specifications or otherwise perform as intended [21 CFR 803.3]. Performance specifications include all claims made in the labeling for the device.

You do not need to assess the likelihood that a malfunction will recur. We presume that once the malfunction has occurred it will recur. In the preamble to the 1995 MDR final rule,[9] we stated that a malfunction is reportable if any one of the following is true:

- The chance of a death or serious injury occurring as a result of a recurrence of the malfunction is not remote;
- The consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury;
- The malfunction results in the failure of the device 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 or other significant adverse device experiences required by regulation. (The essential function of a device refers not only to the device's labeled use, but also to any use widely prescribed within the practice of medicine.);
- The malfunction involves:
  - a long-term implant or
  - a device that is considered to be life-supporting or life-sustaining and thus is essential to maintaining human life; or
- The manufacturer takes, or would be required to take, an action under section 518 or 519(g)[10] of the FD&C Act as a result of the malfunction of the device or other similar devices (see explanation of "similar device" below, and see section 2.21 of this guidance for an explanation of "remedial action").

Although some may read the fourth criteria above as suggesting that anytime a malfunction of a long-term implant occurs it is per se reportable, that is not our intent. The malfunction of a long-term implant is reportable only when the malfunction would be likely to cause or contribute to a death or serious injury if it were to recur.

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[9] *See id.* at 63585.

[10] The preamble reference is section 519(f), but the appropriate designation for the section is now section 519(g) due to amendments to the FD&C Act.

Malfunctions that are not likely to cause or contribute to a death or serious injury if they recur do not have to be reported.

We consider a malfunction that is or can be corrected during routine service or device maintenance to be an MDR reportable event if the recurrence of the malfunction is likely to cause or contribute to a death or serious injury. The fact that such a malfunction may be corrected does not change the fact that the device failed to meet its performance specifications or otherwise perform as intended.

We generally consider a device to be "similar" to another device if the devices have the same:

- Basic design and performance characteristics related to device safety and effectiveness; and
- Intended use and function; and
- Device classification and product code.

Devices that differ only in minor features unrelated to safety or effectiveness can be considered similar devices. Other factors that we recommend to be used to determine whether devices are similar include: brand name, common name, and whether the devices were introduced into commercial distribution under the same pre-market notification 510(k) (see 21 CFR Part 807) or the same pre-market approval (PMA) application number (see 21 CFR Part 814).

2.15 How do I decide whether a malfunction is "likely to" cause or contribute to a death or serious injury?

Malfunctions that are reportable are those that reasonably suggest that one of the manufacturer's marketed devices would be "likely to" cause or contribute to a death or serious injury if the malfunctions were to recur, even if the manufacturer may not have received information that the malfunction has caused or contributed to a death or serious injury. We describe certain malfunctions that we consider to be reportable in Section 2.14 of this guidance.

For malfunctions other than those described in Section 2.14 of this guidance, once the malfunction has caused or contributed to a death or serious injury, it is presumed that the malfunction is also "likely to" cause or contribute to a death or serious injury if it were to recur. Therefore, once a malfunction causes or contributes to a death or serious injury, you have an obligation to file MDRs for additional reports of that malfunction.

You should investigate and conduct follow-up to all additional complaints of such a malfunction to determine whether there have been any further deaths or serious injuries attributable to the same malfunction. A record of the investigation of the complaints

must be maintained as part of your MDR files in accordance with the MDR and QS regulations [21 CFR 803.18 and 820.198].

An MDR guidance for manufacturers issued in 1997 stated that once a malfunction has caused or contributed to a death or serious injury, a presumption that the malfunction is likely to cause or contribute to a death or serious injury has been established. This presumption will continue until either the malfunction has caused or contributed to no further deaths or serious injuries for two years, or the manufacturer can show through valid data that the likelihood of another death or serious injury as a result of the malfunction is remote.

We continue to recommend that a firm develop valid data or information specific to the device and malfunction to support a conclusion that the malfunction is no longer likely to cause or contribute to a reportable death or serious injury if it were to recur.

FDA recommends that you submit a notification to FDA with a summary of the data and the rationale for your decision to cease reporting at the end of two years. FDA may, in certain circumstances, request additional information about the firm's decision within 30 calendar days of FDA's receipt of the notification. Your signed notification should be on your firm's letterhead and include the manufacturer report number of the last malfunction MDR you submitted to us. For mailing instructions, please refer to section 2.27 of this guidance.

Alternatively, you can request an exemption under 21 CFR 803.19(d) from further reporting sooner than two years if your analysis of the data supports your conclusion that the malfunction has not caused or contributed to further deaths or serious injuries and that the likelihood of another death or serious injury occurring as a result of the malfunction is remote. Your exemption request should include information such as the characteristics of the device, incidence rate for the malfunction, and assurance that complaints were investigated to support the rationale for the decision to cease reporting. For further information on exemption requests, refer to section 2.27 of this guidance. In this situation, your firm should continue to report until FDA has responded and granted the exemption request.

2.16 When does a complaint concerning a possible MDR reportable event not have to be reported?

You must investigate all complaints of adverse events [21 CFR 803.17, 803.18, and 820.198]. However, you are not required to submit an MDR report when:

- You have information that would enable a person who is qualified to make a medical judgment to reasonably conclude that your device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury, if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. You must keep in your MDR event files the

information the qualified person used to make the reporting decision [21 CFR 803.20(c)(2)]. Your determination not to file an MDR should be supported by sufficient documentation to justify your decision. [21 CFR 820.198 and 803.18]

- You determine that the information that you received is erroneous in that a device-related adverse event did not occur [21 CFR 803.22(b)(1)].

- You determine that you did not manufacture the device [21 CFR 803.22(b)(2)].

- You become aware of information from multiple sources regarding the same patient and the same event [21 CFR 803.22(a)]. One report is required for the event when first reported and information from other sources may require the submission of a supplemental report to the initial MDR report.

You should retain documentation of erroneous complaints and your conclusion that an event is not an MDR reportable event in your MDR files for two years from the date of the event or a period equivalent to the expected life of the device, whichever is greater. The term "expected life" is explained in section 3.2 of this guidance [see 21 CFR 803.18(c), 803.20(c)(2), and 803.22(b)(1)]. In addition, any reportable event information that is erroneously sent to you because it is a device made by another manufacturer must be sent to us with a cover letter explaining that you do not make the device in question [21 CFR 803.22(b)(2)].

2.17 If I am a contract manufacturer, when do I need to obtain an exemption from reporting?

The MDR regulation at 21 CFR 803.3 defines a "manufacturer" to include a firm that initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications. A contract manufacturer who does not distribute or market the devices it manufactures for a specifications developer would not have an MDR reporting obligation under 21 CFR 803.50 and would not require an exemption. However, if the contract manufacturer (Firm A) distributes or markets the devices that it manufactures for the specifications developer (Firm B), then both would have an MDR reporting obligation.

If Firm A and Firm B decide that they want only Firm A or Firm B to file the reports for the device, then the firm seeking the exemption must submit a request to us for an exemption from filing under 21 CFR 803.19(b). We recommend that the two firms submit a joint request specifying which firm will submit the reports. Reporting exemptions are described in section 2.26 of this guidance. Instructions for submitting a request for exemption to us are in section 2.27 of this guidance. The request for exemption should provide a description of any agreement between the firms pertaining to MDR reporting for events involving the device. Both firms should maintain documentation of such agreement in their MDR procedures. Such an agreement does not negate a manufacturer's responsibilities to comply with any exemptions, variances, or reporting alternatives that the FDA grants, or any other applicable requirement.

Information about the events, including any information about root cause and corrections, should be maintained by both firms. Additional conditions for this type of exemption will be specified in our written response to your request.

We may condition our approval of such an exemption on agreement by the firm requesting the exemption from reporting to be responsible for ensuring that the required reports are, in fact, submitted to FDA. If Firm A is designated to submit the MDR reports, but failed to do so, we would consider such a failure to report to be sufficient grounds to revoke Firm B's exemption from reporting. If revoked, both Firms A and B would be required to report MDR reportable events in compliance with all applicable MDR regulations.

2.18 What types of reports are required by the MDR regulation?

You are required to submit three types of MDR reports. Each type of report must be submitted within the mandatory time frame. The following are the three types of reports:

1. 30-day (initial) reports [21 CFR 803.10(c). 803.20 and 803.50].
2. 5-day reports [21 CFR 803.10(c), 803.20 and 803.53].
3. Supplemental reports [21 CFR 803.10(c) and 803.56].

2.19 What are 30-day reports?

A "30-day report" is the initial MDR report that must be submitted within 30 calendar days after the day you become aware of a reportable device-related death or serious injury, or a reportable malfunction [21 CFR 803.10(c), 803.20 and 803.50]. The report must be submitted as described in section 2.7 of this guidance. You will ordinarily submit 30-day reports for MDR reportable events, but you may be required to submit 5-day reports under certain circumstances as described in section 2.20 of this guidance.

Information that must be provided in your initial report includes:

- Patient information [21 CFR 803.52(a)];
- Information about the adverse event or device problem [21 CFR 803.52(b)];
- Device information [21 CFR 803.52(c)];
- Initial reporter information [21 CFR 803.52(d)];
- Reporting information, including manufacturer contact information, and the report sources, date, type, and number [21 CFR 803.52(e)]; and
- Other information about the device and event [device manufacturer information, 21 CFR 803.52(f)].

2.20 What are 5-day reports?

A "5-day report" (or five-day report) is a report that must be submitted to us within five work days after the day you become aware of an MDR reportable event:

- That necessitates remedial action to prevent an unreasonable risk of substantial harm to public health (remedial action is described in section 2.21 of this guidance); or

- For which we have made a written request for the submission of 5-day reports [21 CFR 803.10(c), 803.20, 803.53].

We consider the 5-day time frame for a report of an event requiring remedial action, as in the first bullet above, to begin the day after an employee 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" of the event [21 CFR 803.3]. We do not expect employees such as non-technical staff to recognize that an adverse event(s) requires remedial action to prevent a risk of substantial harm to the public.[11]

However, when you receive a written request for 5-day reports from us, you must submit the applicable reports within 5 work days after the day any employee becomes aware of the event [21 CFR 803.10(c), 803.20, 803.53].

2.21 What is a "remedial action," and are all adverse events associated with "remedial actions" reportable to FDA as 5-day reports?

Under the MDR regulation, a "remedial action" is any action, other than routine maintenance or servicing of a device, necessary to prevent recurrence of an MDR reportable event [21 CFR 803.3]. FDA does not consider an action taken to correct only a single device involved in an MDR reportable event to be a remedial action.

A decision that a remedial action is necessary can be based on any information, including the occurrence of one or more MDR reportable events, or internal analyses, such as trend analyses, using appropriate statistical or other acceptable methodologies [21 CFR 803.53(a)]. Not all MDR reportable events requiring remedial actions need to be submitted as 5-day reports. Only events that require remedial actions to prevent an unreasonable risk of substantial harm to the public health or events for which FDA requests such a report must be submitted as 5-day reports [21 CFR 803.53]. When the remedial action taken is not required to address an unreasonable risk of substantial harm to the public health [21 CFR 803.50] the reportable adverse events should be submitted as 30-day reports instead of 5-day reports.

[11] See 60 Fed. Reg. at 63581-63582.

If your firm initiates a remedial action in response to an adverse event that FDA would consider a Class I recall because there is "a reasonable probability that the use of, or exposure to" the device "will cause serious adverse health consequences or death," your firm must submit the MDR report for the adverse event within 5 work days of the decision to initiate the remedial action because this is a remedial action to prevent an unreasonable risk of harm to the public health [21 CFR 7.3(m), 803.53].

If your firm has filed an initial MDR report for an event and later decides to take remedial action to address the reported device problem, your firm must file a supplemental MDR report that identifies the remedial action taken in response to the reported problem [21 CFR 803.10(c)(3), 803.56].

Once you have made a determination to initiate a remedial action to prevent an unreasonable risk of substantial harm to the public health, and have filed 5-day reports for the events that caused your firm to recognize the need for this remedial action, any subsequent additional reportable events associated with that specific remedial action (i.e., events that do not necessitate a new remedial action) should be filed as 30-day reports.

The Remedial Action Exemption (RAE) Guidance document [RAE Guidance] lists criteria under which FDA will consider granting an exemption from a reporting requirement under 21 CFR 803.19.

You are reminded that a report of correction or removal initiated to reduce a risk to health that the device poses or to remedy a violation of the FD&C Act caused by the device that may present a risk to health, unless already reported to FDA, must be reported to the appropriate FDA district office within 10 working days of initiating such correction or removal, and must contain the information required under 21 CFR 806.10.

2.22 What are supplemental reports and when are these reports required to be made?

A "supplemental" or "follow-up report" is a report you submit whenever you obtain information required under 21 CFR 803.50 that was not known or available to you at the time you submitted your initial 30-day or 5-day report [21 CFR 21 CFR 803.56]. We consider a supplemental report to be required when new facts prompt you to alter or supplement any information or conclusions contained in the original MDR or in any prior supplemental reports.

The supplemental information must be submitted within one month (30 calendar days) following receipt of the information [21 CFR 803.56]. Supplemental reports must be sent electronically even if the original report was submitted on paper. (See Section 2.31 of this guidance for information on electronic reporting of MDR events).

You must include only the new, changed or corrected information in the appropriate portions of the respective forms for reports that cross reference previous reports. [21 CFR 803.56(c)]. In your report, you must also [21 CFR 803.56]:

- Indicate in the report being submitted that your submission is a "supplemental" or "follow-up" report; and
- List the appropriate identification number of the report that you are updating with the supplemental information (i.e., the manufacturer report number of the initial MDR).

See 21 CFR 803.52 for additional requirements. You do not need to submit a supplemental report for new information if you would not have been required to report that information had it been known or available at the time you filed your initial MDR.

You must maintain all supplemental reports in your MDR files [21 CFR 803.18]. You must also document in your files when you decide not to submit any new information in a supplemental report [21 CFR 803.18].

2.23 What level of effort must I make to obtain additional information or previously unknown information about MDR reportable events?

The level of effort you make to obtain additional information depends largely on the nature and severity of the event reported. MDR follow-up investigations should involve a "good faith effort" to obtain information and should not focus only on the number of attempts to obtain such information.

A "good faith effort" to obtain additional information should include at least one written (including email) request for information. Your MDR files should include a record of each attempt to obtain information, and the nature of the response by the reporter [see 21 CFR 803.50(b)(3) and 803.18(e)]. You should make an effort to obtain correct and complete information about the patient outcome. If you receive a report of a device malfunction, you should determine if a patient was involved and, if so, what happened to the patient as a result of the malfunction. If the patient died or suffered a serious injury, then your initial report must reflect that fact [21 CFR 803.52(b)]. If your initial report was submitted as a malfunction and you learn a patient died or suffered a serious injury, then your supplemental report should change the event type to death or serious injury, as appropriate [21 CFR 803.52(f)(1)].

All of this information is subject to review by us to determine if you made a good faith effort to follow-up and obtain the requested information [21 CFR 803.18(b)(2)].

2.24 When will you request additional information from me about an event for which I submitted an MDR report?

We may request that you submit additional information if and when we determine that protection of the public health requires additional or clarifying information [21 CFR 803.15]. In these instances, we will notify you in writing about the additional information required. Any request we make will state the reason or purpose for requesting the information, specify the date by which the information is to be submitted,

and clearly relate the request to a reported event. We will confirm all verbal requests for additional information in writing, which may include email [21 CFR 803.15].

The request for additional information letter will specify how to respond and may provide an email address to use for the response.

2.25 Must reports be made in English?

Yes, all written or electronic MDR reports, including any supplemental reports or requested additional information must be in English [21 CFR 803.13(a)].

2.26 Does the MDR regulation provide for any reporting exemptions, variances, or alternative forms of reporting?

The regulation explicitly exempts the following three types of persons or entities [21 CFR 803.19(a)]:

- Licensed practitioners who prescribe or administer devices intended for use in humans, and who manufacture or import devices solely for use in diagnosing and treating persons with whom the practitioner has a "physician-patient" relationship;

- An individual who manufactures devices intended for use in humans solely for such person's use in research or teaching and not for sale, including any person who is subject to alternative reporting requirements under the Investigational Device Exemption (IDE) regulation (21 CFR part 812), which requires the reporting of all adverse device effects; and

- Dental or optical laboratories.

The regulation also allows you to submit a written request for an exemption, variance or alternative form of reporting for some or all of the requirements of the MDR regulation [21 CFR 803.19(b) and (c)]. We will review your request and will provide a written response to grant or deny, in whole or in part, such request. An exemption, variance, or alternative form of reporting can also be granted at our discretion in the absence of a request and may impose other reporting requirements to ensure the protection of the public health [21 CFR 803.19(c)]. We can revoke or modify in writing any grant of a written request for an exemption, variance, or alternative form of reporting if we decide that revocation or modification is necessary for the protection of the public health [21 CFR 803.19(d)].

Several variances have been issued with alternatives for providing the manufacturer report number (see Section 2.28 of this guidance). An alternative form of reporting may also allow for a modification in the timing of report submissions and may authorize a reduction in the data elements required by 21 CFR Part 803. For example, a firm may request that instead of reporting all of the required information for each event within 30

calendar days after becoming aware of the event, that the reports be submitted quarterly, semiannually or annually and contain only a subset of the data required by the MDR regulation.

You must submit any reports or information required and abide by any conditions specified in our response letter. The conditions imposed in our response will replace or supersede applicable reporting requirements under the MDR regulation until such conditions are revoked or modified [21 CFR 803.19(e)].

2.27 What information should I include in a request for an exemption, variance, or alternative form of reporting and where should the request be sent?

The requirements for exemptions and how to request one are found in 21 CFR 803.19(b). We have issued certain guidance documents for exemptions, such as the Alternative Summary Reporting (ASR) and Remedial Action Exemption (RAE) guidance documents (see section 2.28 of this guidance), which contain specific instructions for how you may request certain exemptions. For other exemption requests, you should provide the following information, as applicable:

1. Firm identification, including reporting site registration number and the name, address, and telephone number of the contact person;

2. Type of exemption requested. For example:

    - A total exemption from the MDR requirements, or

    - A request to designate an authorized reporter for manufacturer/importer (see Section 2.32 of this guidance) or specifications developer/contract manufacturer (see section 2.17 of this guidance), where both entities are subject to reporting;

3. Type of events involved (e.g., serious injuries, malfunctions);

4. Device identification such as brand name, model, or catalog number and product classification code;

5. Description of the specific type of device problem(s) or adverse event(s) you would like us to consider for the exemption or alternative reporting;

6. Justification for the request, including why you believe FDA does not need to receive the information required by 21 CFR 803.52for the affected events; and

7. Estimated number of MDR reports filed annually that will be affected by this exemption.

Your written request should be on your firm's letterhead with the original signature of the requester. You may call our MDR Policy Branch if you have any questions or need help. Our telephone number is (301) 796-6670.

You can mail your written request to:

MDR Policy Branch
Division of Postmarket Surveillance
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Building 66 - Room 3217
Silver Spring, MD 20993-0002

Alternatively, you can send a PDF version of your signed request letter in an e-mail to:

MDRPolicy@fda.hhs.gov

2.28 Have you published any guidance documents describing the exemptions, variances, and alternative forms of reporting you have issued, and if so, where can I get this information?

Yes, we have published the following guidance documents:

- Medical Device Reporting – Alternative Summary Reporting (ASR) Program.
- Medical Device Reporting - Remedial Action Exemption; Guidance for FDA and Industry [RAE Guidance Document].
- Needle sticks - Medical Device Reporting Guidance for User Facilities, Manufacturers, and Importers [Needle sticks].
- MDR Guidance Document No. 1 - IOL - E1996004 [IOL Exemption].
- Variance from Manufacturer Report Number Format (Variances Nos. 1-4) - [Report Number Variance].
- Variance from Manufacturer Report Number Format – No. 5 [Report Number Variance 5].
- Guidance for Industry, User Facilities and FDA Staff: Questions and Answers about eMDR - Electronic Medical Device Reporting.
- Guidance for Industry and FDA Staff: Medical Device Reporting for Manufacturers.

2.29 Where do I send my MDR reports?

All MDR reports from manufacturers must be submitted to FDA in an electronic format in accordance with 21 CFR803.12(a) and 803.20, unless granted an exemption under 21

CFR §803.19. (See section 2.31 of this guidance for more information about electronic submissions.

2.30 Where do I report a public health emergency?

If you believe that there is a public health emergency, you may contact: FDA's Office of Crisis Management, Emergency Operations Center by 24 hour telephone at: 301-796-8240 or toll free at 866-300-4374. You should follow your telephone contact with an e-mail to emergency.operations@fda.hhs.gov or a FAX to 301-847-8543 [21 CFR 803.12(c)].

If you make a report of an emergency by telephone, e-mail, or FAX, and the emergency concerns an MDR reportable event, you are still required to send the report to FDA in an electronic format. (See section 2.31 of this guidance for more information about electronic submissions).

2.31 Where can I find more detailed information on preparing an electronic MDR?

Information on how to prepare an electronic submission is available at CDRH: electronic Medical Device Reporting (eMDR) - Home Page and the FDA Electronic Submissions Gateway.

2.32 I'm a foreign manufacturer. Can the firm that imports my devices to the US file MDR reports that satisfy both the manufacturer and importer reporting requirements? What is the process to request this?

Under the MDR regulation, an importer is required to include the following information in its individual adverse event reports: Blocks A, B, D, E and F of the Form 3500A [21 CFR 803.42]. Importers must submit death and serious injury reports to us (with a copy to the manufacturer) and malfunction reports to the manufacturer [21 CFR 803.40].

Manufacturers (including foreign manufacturers) are required to submit information for Blocks G and H, in addition to Blocks A, B, D and E, of the Form 3500A [21 CFR 803.52]. Manufacturers must submit death, serious injury, and malfunction reports to us [21 CFR 803.50].

If a foreign manufacturer and importer decide they want the importer to submit the reports for adverse events involving a product for which they both have an MDR obligation, the foreign manufacturer must submit a request to us for an exemption from

filing under 21 CFR 803.19(b). However, we recommend that the importer and foreign manufacturer submit a joint request to us for an exemption from filing, specifying that the importer will submit the reports. The request should also specify whether the importer will submit the malfunction reports as well as the death and serious injury reports to us and whether the importer will submit the reports for reportable adverse events occurring outside the US as well as the US events. We will advise the firms of the special reporting requirements that must be met in the letter that grants the exemption (see section 2.27 of this guidance for instructions to request a reporting exemption). The importer will then be expected to submit information required by 21 CFR 803.42 and 21 CFR 803.52 that satisfies the obligations of both the importer and manufacturer.

If the importer is to submit the MDRs, the foreign manufacturer still bears responsibility for ensuring that the importer submits the MDR reports in compliance with all applicable MDR requirements. We would consider such a failure to report to be sufficient grounds to revoke the manufacturer's exemption from reporting. The relationship between the importer and the foreign manufacturer and how the MDR reporting obligation is to be handled should be addressed in the MDR reporting procedures for each of the firms. Note that when one part of the corporation becomes aware of an MDR reportable event, each part of the corporation responsible for that device is considered aware of the event and the reporting time clock starts. The MDR reporting procedures should address timely transmission of MDR reports to FDA.

3. Written Procedures, Recordkeeping and Public Disclosure

3.1 What are my requirements for developing, maintaining, and implementing written MDR procedures?

You are required to develop, maintain and implement written MDR procedures [21 CFR 803.17]. Your procedures must include internal systems that provide for the following [21 CFR 803.17(a)]:

- Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, including device-related complaints;[12]
- A standardized review process or procedure (based on the MDR regulation) for determining whether or not an event is an MDR reportable event; and
- Timely transmission of complete reports to us.

[12] The QS regulation requires that complaints be investigated by a formally designated unit [21 CFR 820.198]. Manufacturers must evaluate events that may be subject to MDR requirements in accordance with the complaint file requirements in 21 CFR 820.198 [21 CFR 803.18(e)].

Your procedures must also include documentation and recordkeeping requirements for [21 CFR 803.17(b)]:

- Information that was evaluated to determine if an event was reportable;
- All medical device reports and information submitted to us;
- Any information that was evaluated for the purpose of preparing the submission of annual reports[13]; and
- Systems that ensure access to information that facilitate timely follow-up and inspection by us.

Your written MDR procedures should establish policy and procedures that cover all the requirements of the MDR regulation. We recommend that you keep them as a separate document. If you combine them with other procedures (e.g., complaint handling or vigilance reports), the MDR portion should be located in a separate section. Your procedures must describe how you will conduct your investigations of events that may be reportable [21 CFR 803.17(a)(2)]. For example, you may need to make multiple attempts to contact the reporter either by phone, fax, or letter to obtain information about the event before the investigation is closed. We expect you to make a good faith effort to obtain additional information including, when needed, a written request for information (see section 2.23 of this guidance for more information on what we believe constitutes a good faith effort).

3.2 What are my requirements for establishing and maintaining MDR files and records?

You are required to establish and maintain complete MDR files in either written or electronic form and should identify them prominently as "MDR Files" so they can be located easily [21 CFR 803.18]. Your MDR files can be maintained as part of your complaint files required under the QS regulation. We will not consider an MDR report that you submit to be in compliance with the MDR regulation unless you evaluate the event or complaint in accordance with 21 CFR 820.198 of the QS regulation regarding investigation of device complaints [21 CFR 803.18(e)]. There must be a record of this investigation documented in the complaint file [21 CFR 803.18(e)].

Your files should include a record of each attempt to obtain information, and the nature of the response by the reporter. If MDR information cannot be obtained, you must document an explanation of why you could not obtain the required MDR information [21 CFR 803.17, 21 CFR 803.18, and 21 CFR 803.50(b)(3)]. This information should demonstrate that you made a reasonable attempt to follow up and obtain the relevant required information.

[13] Annual reports are required for user facilities under 21 CFR 803.33.

MDR files should be maintained for two years from the date of the event or a period equivalent to the expected life of the device, whichever is greater [see 21 CFR 803.18(c)], even if the event was determined to be not reportable or you have stopped manufacturing or distributing the device.

The "expected life of a device" is the time that a device is expected to remain functional after it is placed into use [21 CFR 803.3]. Certain implanted devices have specified "end of life" (EOL) dates. Other devices are not labeled with EOL dates, but are expected to remain operational through activities such as maintenance, repairs, or upgrades.

MDR files can incorporate references to other information sources, such as medical records, patient files, documents related to a lawsuit, and engineering reports, and must contain [see 21 CFR 803.18]:

- Information in your possession or references to information related to the adverse event (e.g., test, laboratory and service records and reports, and records of investigations), including all documentation of the deliberation and decision-making processes used to decide whether the event was or was not reportable. You should also include the name and title of the person who made the decision. When applicable, the final assessment should indicate the cause of the event and what action, if any, you took to assure that the cause of the event was corrected or otherwise mitigated.

- Copies of all MDR forms, as required by 21 CFR Part 803, including a copy of any Forms 3500A received from user facilities and importers, and other information related to the event that you submitted to us and other entities such as an importer or distributor. This information should include the original or a copy of the initial record and information related to the event. These records should include the available information needed to complete your report. The record may be a documented telephone call, a letter or fax, a service report, a voluntary Form 3500 received from a health care professional or consumer, or a mandatory Form 3500A received from a user facility and/or importer.

Your events must be evaluated in accordance with the applicable requirements of 21 CFR Part 820.

You must permit any of our authorized employees, at all reasonable times, to access, copy, and verify the records required by 21 CFR part 803, including MDR events [21 CFR 803.18(b)(2)].

3.3 What information contained in my MDR reports is subject to public disclosure and what information will not be disclosed?

Any report in our control, including a record of a telephone report, may be subject to public disclosure in response to a Freedom of Information Act request. However, before public disclosure of an MDR report, including any you have submitted to us and any

FDA record of a telephone report, we will delete the following information [21 CFR 803.9(b)]:

- Information that constitutes trade secret or confidential commercial or financial information under 21 CFR 20.61;

- Personal, medical, and similar information (including the serial number of implanted devices), which would constitute a clearly unwarranted invasion of personal privacy under 21 CFR 20.63 (this includes the identity of the patient as well); and

- Names and other identifying information of a third party that voluntarily submits an MDR report. This includes physicians, health care professionals, or other hospital employees.

We will disclose to a patient requesting a report, all information in the report concerning that patient, except for any trade secret or confidential commercial or financial information [21 CFR 803.9(b)(2)].

When a user facility submits a report concerning one of your devices, as required by the MDR regulation, we will not disclose the identity of the facility except in connection with [21 CFR 803.9(c)]:

- An action brought to enforce section 301(q)(1) of the FD&C Act, including the failure or refusal to furnish material or information required by section 519 of the Act;

- A communication to you concerning the report; or

- A disclosure to employees of the Department of Health and Human Services, the Department of Justice, or duly authorized committees and subcommittees of the Congress.

A publicly disclosable version of the medical device reports that we have received is available on the CDRH web page at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM, under the heading "Databases."

3.4 When I submit an MDR report, is the report considered an admission that my device caused or contributed to the reported event?

No, the submission of a report or related information to us and our release of that information is not necessarily an admission that you, your employees, or your device caused or contributed to the reportable event [21 CFR 803.16]. We have included such a disclaimer on FDAs public database, [MAUDE] – Manufacturer and User Facility Device Experience.

4. Specific Issues and Situations

4.1 Delay in Surgery

4.1.1 For several years our firm has submitted an MDR for any situation in which a surgery is delayed. What is your position on this issue?

The event will be an MDR reportable event if your awareness of such an event reasonably suggests that your device may have caused or contributed to a death or serious injury or that your device has malfunctioned and the device or a similar device marketed by you would be likely to cause or contribute to a death or serious injury if the malfunction recurred. An event should not be considered to be an MDR reportable event solely on the basis of a delay in surgery. For example, a delay of surgery due to the surgical team setting up the wrong size device (not a mislabeled product) and requiring time to obtain the correct size device for the patient would not be a reportable event if the patient remains stable with no adverse consequences. A delay of surgery due to a defective product, such as a broken suture, or other malfunction of the device where the patient remained stable with no adverse consequences may be MDR reportable as a malfunction.

Your firm should obtain details about the delay and the patient's condition to evaluate whether your device may have been a factor in a death or serious injury. If the failure of a device causes a delay in surgery and this delay may have caused or contributed to a death or serious injury to a patient, then this event would be reportable. If you determine that your device did not cause or contribute to a death or serious injury, the event may still be reportable if you determine that the device malfunctioned and the device, or similar device you market, would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

4.2 Expected Life of the Device

4.2.1 Can the expected life of a device be determined by the warranty?

No, the warranty period is not the same as expected life. The "expected life of a device" is the time that a device is expected to remain functional after it is placed into use [21 CFR 803.3]. You are not required by the MDR regulation to establish an expected life for a device.

4.2.2 For devices intended for periodic preventive maintenance, or some sort of a scheduled calibration time, is the expected life one calibration, one preventive maintenance cycle, or the overall life of the product?

We consider the "expected life of a device" to include the overall life of the product, not the time between calibrations or a preventive maintenance cycle (see section 3.2 of this guidance).

4.2.3 Does the expected life definition take into consideration routine maintenance recommendations that I make?

The expected life of a device may be established by assuming the device receives normal or recommended routine maintenance and service.

4.2.4 Am I required to report routine explants of implanted devices that have an expected life that is less than the life of the patient, such as tissue valves, vascular grafts, or routine revisions of orthopedic implants?

Certain implanted devices have a specified "end of life" date. If the implant has reached or is near the end of its established life expectancy, and is subsequently replaced without a device-related death or serious injury associated with the replacement, then it would not constitute a reportable event**,** even if surgery is involved. However, the event would be reportable if the device caused or contributed to or may have caused or contributed to a patient death or serious injury, or malfunctioned and the malfunction of the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if it were to recur.

4.3 Device Labeling

4.3.1 If my device labeling addresses the risks and complications associated with the use of a device, is an MDR required when a listed complication occurs?

Yes, the event would be reportable if the medical device caused or contributed to a death or serious injury, even if the complication was addressed in the device labeling. 21 CFR 803.3 defines "caused or contributed" to include a medical device that was or may have been a factor in a death or serious injury. Events that were anticipated or intrinsically caused by a device are not exempt from reporting.[14]

4.3.2 The labeling of my device states that another manufacturer's component is not compatible with my device and use of the two together would render my device inoperable. Would an adverse event resulting from this incompatibility be reportable under MDR?

[14] See 60 Fed. Reg. at 63582-63583.

The event would be reportable if a device-related death or serious injury may have occurred as a result of the incompatibility problem. However, because your labeling makes it clear that the devices should not be used together; the event would not be reportable as a device malfunction. FDA encourages you to consider submitting a voluntary report for this issue via the MedWatch Form FDA 3500.

4.4 Diagnostic Devices

4.4.1 Is an event indirectly caused by a failed diagnostic device reportable?

Yes, we consider the failure of a diagnostic device to be reportable when it indirectly causes or contributes to, or is a factor in, a death or serious injury, or would be likely to, if the failure were to recur.[15]

4.5 Difference of Medical Opinion

4.5.1 If there is a conflict of opinion about the role of my device in an adverse event, do I have to submit an MDR? For example, is an MDR required where a doctor performing a surgery does not believe my device malfunctioned, but another healthcare professional at the same facility says the device did malfunction?

If you become aware of information that one of your marketed devices may have malfunctioned, then you are required to investigate the situation and determine if the information you obtain reasonably suggests that the device did in fact malfunction and that the malfunction would be likely to cause or contribute to a death or serious injury if it were to recur [21 CFR 803.50]. Your investigation should include an evaluation of any differences in medical opinion. If, based on everything considered in your investigation, you determine that there was no device malfunction or that the device malfunctioned, but the malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur, then you would not have to submit a report [21 CFR 803.20(c)(2) and 803.22(b)(1)]. Otherwise, you would be required to submit an MDR report about the event.

4.6 Events Involving Same Patient on Different Days

4.6.1 How should I report adverse events involving the same patient and device that occur on different days?

[15] See 60 Fed. Reg. at 63582.

If a patient experiences adverse events on different days with the same device, and the events are reportable, each occurrence should be reported as a separate submission. The reports should be cross referenced in Section H.10.

4.7 Exemptions and Time Limits

4.7.1 How long is an exemption in effect once it is granted?

Exemptions will not typically be time limited; however, we may revoke or modify in writing an exemption, variance, or alternative reporting requirements if we determine that protection of the public health justifies the modification or a return to the generally applicable reporting requirements [21 CFR 803.19(d)]. When a request is granted, any appropriate conditions will be specified, including any other reporting requirements to ensure the protection of public health.

4.8 FDA Access to Electronic Files/Data

4.8.1 Am I required to provide FDA access to my electronic files as well as my hard copy complaint and MDR files during an inspection?

Yes, if your official file is an electronic file or includes electronic files, then you must allow FDA to inspect, review, and copy MDR event file records in a human readable form, (21 CFR 803.18) because that is what you have chosen to use to meet your MDR recordkeeping requirements. MDR event files are written or electronic files which you are required to maintain [21 CFR 803.18(b)(1)-(2)]. For additional guidance about electronic records, see the guidance document: "Guidance for Industry, Part 11, Electronic Records; Electronic Signatures – Scope and Application" available at the following FDA web site:
http://www.fda.gov/regulatoryinformation/guidances/ucm125067.htm

4.9 Follow-up Investigations

4.9.1 How much effort must I make to get information about an event, or even to get the device back? Sometimes when I call a user facility no one wants to talk to me. How many times must I call or write before I can close the file?

MDR files must contain an explanation of why any information required by the MDR regulation was not submitted or could not be obtained [21 CFR 803.18(e)]. You must conduct an investigation and evaluate the cause of each event [21 CFR 803.50(b)(3)]. As stated in sections 2.23 and 3.1 of this guidance, there is no specified number of attempts a manufacturer must make to obtain information. However, you should demonstrate a good faith effort. For example, calling a user facility during hours when you know someone is unable to respond would not be considered a good faith effort. In addition, if you are unable to obtain the information through phone calls, we would reasonably

expect you to try to contact the user facility in writing (including email) and specify a response date for the information you are requesting. In regard to getting the actual device for analysis, although we cannot mandate that a user facility return a device to you for analysis, we strongly encourage them to do so.[16] The fact that you do not get the device back, however, does not mean you do not have to analyze the event. We do not believe it is reasonable to close the files simply because the device was not returned. You should undertake activities such as review of other similar events, device history review, review of appropriate manufacturing processes, etc., where they will help you analyze the event (see also section 3.2 of this guidance).

4.10 Devices under Investigational Device Exemption (IDE)

4.10.1 I'm a US manufacturer of a device that has been cleared or approved for marketing in the US, and is also being studied under an approved IDE. What are the requirements for reporting an event involving the investigational use of the marketed device?

If a device is legally marketed in the US and is also under an Investigational Device Exemption (IDE) [21 CFR part 812], any adverse events that involve the investigational use of the marketed device are subject to reporting under both the IDE regulation and the MDR regulation. An individual who manufactures devices intended for use in humans solely for this person's use in research, that are not for sale, and who may be subject to alternative reporting requirements under the IDE regulations is exempt from MDR reporting requirements [21 CFR 803.19(a)(2)]. However, there is no exception to MDR reportable events under 21 CFR part 803 for devices that are marketed lawfully in the US and that are also used under an IDE. Further, there is no exception to unanticipated adverse device effect reporting under 21 CFR part 812 for "unanticipated adverse device effects"[17] associated with marketed devices that may be used as a control. Thus, certain events may be reportable under both IDE and MDR regulations.

4.11 Foreign Events

4.11.1 Does the MDR regulation apply to devices that are legally exported by US manufacturers to foreign locations if the device is not cleared or approved for marketing in the US?

If you manufacture a device that is exported under section 801(e) or 802 of the FD&C Act, you are subject to the MDR regulation as a manufacturer [21 CFR 803.1]. Failure to submit required reports is a prohibited act [section 301(q) of the FD&C Act, 21 U.S.C. 331(q)]. Therefore, manufacturers exporting devices under section 801(e) or 802 of the FD&C Act are required to comply with 21 CFR part 803, including the requirements for

[16] See 60 Fed. Reg. at 63589.
[17] *See* 21 CFR 812.3(s) for definition of "unanticipated adverse device effect."

written MDR procedures [21 CFR 803.17], MDR files or records [21 CFR 803.18], and MDR reporting requirements [21 CFR 803.10(c)]. However, FDA generally does not intend to enforce the MDR reporting requirements for those devices exported under section 801(e) or 802 of the FD&C Act, except under certain circumstances. The circumstances under which FDA generally intends to enforce the MDR reporting requirements for such devices includes situations where there has been a device concern identified that necessitates that FDA have information about exported device adverse events. When such a device issue is identified, FDA expects to notify the affected manufacturer(s) regarding the submission of MDR reports for their exported devices.

4.11.2 I'm a US manufacturer of a device that has not been cleared or approved for marketing in the US, although the device is being studied in the US under an approved IDE. Is an event involving my device that occurred outside the US reportable under MDR in this situation?

If you manufacture a device domestically that is exported under section 801(e) or 802 of the FD&C Act, you are considered a manufacturer and are thus subject to the MDR regulation [21 CFR 803.1]. Failure to submit required reports is a prohibited act [section 301(q) of the FD&C Act, 21 U.S.C. 331(q)]. Therefore, manufacturers exporting devices under section 801(e) or 802 of the FD&C Act are required to comply with 21 CFR part 803, including the requirements for written MDR procedures [21 CFR 803.17], MDR files or records [21 CFR 803.18], and MDR reporting requirements [21 CFR 803.10(c)]. However, FDA generally does not intend to enforce the MDR reporting requirements for those devices exported under section 801(e) or 802 of the FD&C Act, except under certain circumstances. The circumstances under which FDA generally intends to enforce the MDR reporting requirements for such devices includes situations where there has been a device concern identified that necessitates that FDA have information about exported device adverse events. When such a device issue is identified, FDA expects to notify the affected manufacturer(s) regarding the submission of MDR reports for their exported devices.

The adverse event that occurs outside the US should be reported to the IDE program in accordance with [21 CFR part 812].

4.11.3 I'm a foreign manufacturer of a device that has been cleared or approved in the US and is also lawfully marketed in a foreign country. If an adverse event occurs in a foreign country with the device, must the event in the foreign country be reported under the MDR regulation?

Yes, FDA considers an event that occurs in a foreign country reportable under the MDR regulation if it involves a device that has been cleared or approved in the US – or a device similar to a device marketed by the manufacturer that has been cleared or approved in the US – and is also lawfully marketed in a foreign country. Devices may be manufactured to slightly modified specifications to meet standards in different countries. If these changes do not substantially alter the performance of the device, then any device events

that are MDR reportable events relating to such modified devices should be reported under the MDR regulation (see section 2.14 of this guidance).

4.11.4 I'm a foreign manufacturer of a device that has not been cleared or approved for marketing in the US, although the device is being studied in the US under an approved IDE. Is an event involving my device that occurred outside the US reportable under MDR in this situation?

No, you would not be required to submit MDR reports for events occurring in other countries for a device that is manufactured in a foreign country and that is not cleared or approved for marketing in the US. However, if you become aware of information that reasonably suggests a device has malfunctioned and that a similar device that you market in the US would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, then you should report the device malfunction that occurred outside the US.

An adverse event that occurs outside the US should be reported to the IDE program in accordance with 21 CFR part 812.

4.12 Manufacturer Ceased Marketing a Device

4.12.1 If I previously marketed a device that is still in commercial distribution, but have ceased manufacturing the device, do I still have an obligation to submit MDR reportable events?

Yes, as long as you remain in business, you have an obligation to report events involving any device that you manufactured, even if you cease marketing the device. See also 4.12.2.

4.12.2 Firm A manufactured and distributed a device that was cleared for marketing under its 510(k), but later sold the 510(k) to another firm (Firm B). Who should submit the MDR reports for adverse events that involve the devices that Firm A manufactured?

Although Firm B is responsible for reporting adverse events for the devices it manufactures after it purchases the 510(k), Firm A remains obligated to report adverse events for the devices it manufactured. The packaging and labeling for the devices Firm A manufactured would identify Firm A as the manufacturer with corresponding address and contact information. If Firm B agrees to assume responsibility for reporting MDRs for the devices manufactured by Firm A, this arrangement should be documented with a written agreement between the two firms. Firm A should also request an exemption from FDA to end its MDR reporting obligation for the devices it manufactured. This guidance

also applies when a firm transfers ownership of the PMA for a device. (See 2.27 of this guidance for information on requesting an exemption.)

4.13 Medical Intervention

4.13.1 If a health care provider notices that a medical device is malfunctioning (i.e., not performing as intended) and intervenes before the malfunctioning device can harm the patient (i.e., can cause or contribute to a serious injury or death), is this reportable?

The event would be reportable as a malfunction if the malfunction would be likely to cause or contribute to a death or serious injury if it were to recur. If the device malfunctions but the user intervenes before there is any harm to the patient, the event should be reported as a malfunction if the manufacturer concludes that the malfunction is likely to cause or contribute to a death or serious injury if the malfunction recurred. Your investigation of the event should also confirm and document that in this instance; the device malfunction did not cause or contribute to any change in the patient's condition that would be considered a reportable serious injury (see section 2.13 of this guidance for the definition of "serious injury").

4.14 Patient Information

4.14.1 It is very difficult to obtain patient information due to patient confidentiality in the health care setting. Is this information always necessary?

It is necessary to attempt to obtain the patient information required by 21 CFR 803.52, including patient identification, especially if the event involved a death or serious injury. However, we request that the patient be identified only by code, not by an actual patient name.[18] This will protect the privacy of the patient. Other required information about the patient (e.g., age, sex, and weight) generally can be provided without affecting patient confidentiality.

4.15 Radiation Therapy

4.15.1 Exactly what constitutes an MDR reportable event involving my radiation therapy device where there was incorrect treatment but no demonstrable patient injury?

A radiation therapy or other radiation-emitting device (e.g., CT scanner, fluoroscope) intended for medical use is capable of causing or contributing to a radiation-related death

[18] See Instructions for FDA Form 3500A – Section A: Patient Information, A1: Patient identifier.

or serious injury. An event in which a person receives a radiation injury, such as a tissue reaction, would be reportable if the device may have caused or contributed to a death or serious injury or it has failed to perform as intended (malfunctioned) and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

At this time, we have not adopted a radiation exposure or dose threshold for such injuries. A malfunction or problem related to a radiation treatment or planning system would have to be evaluated to determine if the expected outcome of the device failure or problem would be likely to cause or contribute to a death or serious injury to the patient if it were to recur.

4.16 Reports Based On Literature

4.16.1 Must I investigate and submit reports on MDR reportable events reported in literature sources?

Yes, if the information in the literature source is made known to you or to any of your employees (i.e., you or they become aware of this information) and the information reasonably suggests that a reportable event or events may have occurred, then you must comply with the requirements of the MDR regulation and make a reasonable attempt to investigate each event [21 CFR 803.3(a)(1) and 21 CFR 803.18(e)]. The regulation identifies professional, scientific, or medical facts, observations, or opinions to be information that may reasonably suggest that a reportable event has occurred. [21 CFR 803.20(c)].

4.16.2 What guidance can you provide concerning how to report events found in scientific articles and other literature?

You must investigate each event reported in the literature source to determine if the information represents an MDR reportable event [21 CFR 803.18(e)]. If the information in the literature source and/or your investigation of the cited events reveals specific information about all or some of the reportable events, then you will need to report these events as individual reports. For example, you could contact the author of the literature source and request information about all or some of the patient and/or device-related events.

You should also try to determine if the events in the literature source match events otherwise made known to your firm, and whether the events may have been previously reported to us. If they do, then you do not have to submit a second initial report, but you do need to consider whether or not you are in receipt of additional information that should be submitted as a supplement [21 CFR 803.56] (see section 2.22 of this guidance).

We do realize that information from literature sources may not provide specifics about some or all of the events discussed and you may be able to provide us with only very limited information about each reportable event. For this reason, we would consider

accepting one report for multiple reportable events where the source of the information is a literature document and, after investigation, you cannot obtain enough information about each identified patient and/or device mentioned, in order to provide a complete report for each reportable event.

Our instructions for completing Form 3500A address submission of a report for reportable events where the source of the information is a literature review (see instructions for Block G-3). In addition, we recommend the following for all reportable events identified in literature sources (published or unpublished) when there is limited information about the device and/or the patient and follow up is not possible:

- Submit an individual report for each event type if more than one is identified. For example, if the literature source includes information about patient deaths, serious injuries and reportable malfunction events, you should submit three individual reports (one for each of these three event types).

- Submit an individual report for each device identified if the generic names of the devices are different. For example, if a literature source identifies your suspect devices as catheters and pacemakers, then you should submit two reports to cover these two different devices. You would also need to account for different event types (death, serious injury, or malfunction), as noted in the bullet above.

You should provide the following information in your submission:

- The most representative data available. For example, you should report the average patient age and weight, as well as the sex of the majority of patients involved. The date of the event should be reported as the date of the literature source, and the date of the report should be reported as the date that the literature first came to the attention of you or one of your employees.

- All the events covered by the report can be summarized in an ExcelEXCEL™ spreadsheet and attached to your report. You should include the following information in your summary:

    - Device identification information (brand name, model, or catalog number);

    - Patient and device problem codes; and

    - Manufacturer device evaluation and conclusion codes.

You should either attach a copy of the literature source to your report or provide the web address location for the article.

5. Questions Concerning Completion of the MDR Report

NOTE: There are instructions for completing Form 3500A and a website that identifies the codes to be used for specific blocks on the form.

The instructions for completing the form can be obtained at http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM387002.pdf.

A detailed description of Event Problem Code terminology can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/EventProblemCodes/ucm134751.htm.

The information in this Section is intended to clarify certain issues and answer questions about completion of the form. It is not intended to change or modify, in any way, Form 3500A or instructions for completing the form.

Note: The information required to be provided in the MDRs from manufacturers is described in 21 CFR 803.52. This information generally corresponds to the information required by the FDA Form 3500A. MDRs must be submitted to FDA in an electronic format in accordance with [§803.12(a) and §803.20, unless granted an exemption under §803.19].

Information about electronic reporting can be obtained at eMDR – Electronic Medical Device Reporting.

5.1 General Questions

5.1.1 When submitting my initial report why can't I just fill in the parts of the form for which I have the information requested, and leave the rest of the form blank?

If the fields are left blank, we cannot determine what information was unknown to you or what information was simply overlooked. By completing each requested data element, you assure us that all elements were considered and reviewed. Please see the instructions for completing reports at: http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM387002.pdf, or the information for electronic reporting at eMDR - Electronic Medical Device Reporting.

5.1.2 What are the most common problems you see in the way manufacturers fill out Form 3500A?

The most common problems that we encounter are as follows:

1. Duplicate report sequence numbers provided in the Manufacturer Report Number box and Block G-9.

   Each report must have its own sequence number to avoid confusion. [See 21 CFR 803.3 for the definition of "manufacturer report number."] You should not use the same sequence number on more than one report in any given year.

2. Multiple devices or events are included in the same report.

   If more than one of your devices is involved in a single MDR reportable event, and it is not apparent which device may have caused or contributed to the event, then you must submit a separate report for each of your devices involved in the event. [See 21 CFR 803.50] [See also the General Instructions section in the Instructions for Completing the FDA Form 3500A at: http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM387002.pdf].

   If a series of MDR reportable events occurs, the regulation requires a separate report for each event. In addition, if the series of events involves more than one of your devices, and it is not apparent which device may have caused or contributed to the event or which device malfunctioned, you must submit a separate report for each of your devices involved in each event, in accordance with the requirements of 21 CFR 803.50.

3. The Blocks in B-2 (Outcomes Attributed to Adverse Event) and B-5 (Description of Event or Problem) do not match or do not accurately represent the text contained in Blocks H-1 (Type of Reportable Event), H-10 (Additional Manufacturer Narrative), or H-11 (Corrected Data).

   If any information in Block B conflicts with the information in Block H, then you should provide an explanation in Block H-11 to address the conflict. For example, if a reporter marks "Death" in Block B-2 as the outcome, and after your investigation you determined that the patient did not die, you would provide this explanation in Block H-11.

4. Block D (Suspect Medical Device) is left blank or specific items within Block D are left blank.

   You should provide as much information as possible in this Block in order for us to properly identify the device and evaluate the event. It is important that you make a good faith effort to obtain the information.

5. An importer submits a report on behalf of the manufacturer without requesting an exemption.

   In order for an importer to be permitted to submit MDR reports that satisfy both the manufacturer and importer reporting requirements, the foreign manufacturer must first submit a request to us for an exemption from filing under 21 CFR 803.19. However, we recommend that the importer and the foreign manufacturer submit a joint request to us for an exemption from filing, specifying that the importer will submit the reports. The reporting firm must then complete Blocks A, B, D, E, F, G and H on the Form 3500A. See the discussion in section 2.32 of this guidance for more information on exemptions.

6. The contact name and telephone number are not provided in Blocks G-1 and G-2, respectively**.**

   This information is important if we need to follow up on your report, either in writing or by telephone.

7. A 5-day report is submitted for an event that does not meet the 5-day report criteria.

   As explained in section 2.20 of this guidance, 5-day reports are required for an event that either: (a) necessitates remedial action to prevent an unreasonable risk of substantial harm to public health, or (b) for which we have requested the submission of 5-day reports [21 CFR 803.53].

   If the event necessitated remedial action and a 5-day report is required, you should also make sure to provide information required in Blocks H-7 and H-9.

8. A report is marked as a "follow-up" report, but no follow-up sequence number is provided.

   The sequence number must be provided as 1, 2, 3, etc., beginning with the first follow-up report submitted (e.g., first follow-up report = follow-up #1, second follow-up report = follow-up #2, and so on) [see Instructions for Completing Form FDA 3500A, G7].

9. No box is marked, or more than one box is marked, in Block H-1 (Type of Reportable Event).

   A reportable event should not be reported as multiple types of events and only one of these boxes should be marked. If the device malfunctioned, and the malfunction may have caused or contributed to a death or serious injury, mark either the box labeled "Death" or the box labeled "Serious Injury" as appropriate, but do not also mark the "Malfunction" box.

If a single event caused or contributed to the death of one person and the serious injury of another, you should submit a separate report for each outcome. Furthermore, the box marked "Other" should not be used because, at this time, there are no "Other" types of events that are required to be reported by the MDR regulation. Events that do not involve an "MDR reportable event" should not be reported on Form 3500A.

10. Codes required to be entered in Block H-6 (Evaluation Codes) are put in boxes on the wrong row. For example, an evaluation method code might be entered in the space for evaluation results codes or evaluation conclusion codes.

    Make sure your codes are applicable and are placed in the proper space.

11. Block H-7 information (If Remedial Action Initiated, Check Type) is not provided when the event relates to a remedial action.

    As discussed under common problem number 7, if you are submitting a 5-day report because of a remedial action taken, you must check the appropriate box in Block H-7 and enter information in H-9.

    If you are submitting a 5-day report because we have requested that you do so, you should indicate in Block H-10 that we have requested the submission of a 5-day report for the event you are reporting. If the event is not associated with a remedial action, then you should not enter information in Block H-7 or H-9.

    If your report is not a 5-day report and it is your initial report of the event, you should mark the "Initial" box to identify a 30-day report in Block G-7. Any associated remedial action should be identified in Blocks H-7 and H-9.

12. Event problem codes (patient problem codes and/or device problem codes) are not provided in Block F-10 for a user facility or importer report or in Block H for a manufacturer report.

    These codes are important in helping us understand the adverse event and determining whether it presents a public health issue that needs to be addressed. When user facilities or importers fail to provide these codes to you, or they fail to provide correct or complete codes, you are required to provide the missing, incomplete, or corrected codes in Block H [21 CFR 803.52(f)]. The Form 3500A revised 2/13 now accepts theses codes in Block H-6. Often, codes are not provided or, when they are provided, patient codes will be recorded as device codes and vice versa. You should make an effort to provide applicable or corrected codes and to label them properly.
    As indicated in section 2.8 of this guidance, instructions on the use of patient and device codes is available on the CDRH web page at Coding Tools/Resource Files.

The revised hierarchy of patient and device codes was made available on July 1, 2009. As of April 2, 2010, only these new codes may be used. Information on the new codes and their use is available on the CDRH web page at MDR codes.

5.2 Block A - Patient Information

5.2.1 How do I complete the field for patient name (Block A-1) when the patient is also the initial reporter (Block E)?

You should not record the patient's name in Block A-1. You should instead use a patient identifier in Block A-1 that will be applicable only for that patient. Any code that will prevent identification of the patient by the patient's name can be used. When the initial reporter is also the patient, you should provide the initial reporter's information in Block E-1. However, you should not indicate that the reporter is also the patient. You should *not* leave the field blank, or it will appear that you forgot to supply the data, and you may get a letter from us requesting the missing data.

5.3 Block B - Adverse Event or Product Problem

5.3.1 What date is meant by "Date of this Report," in Block B-4?

The "Date of this Report" [21 CFR 803.52(b)(4)]in Block B-4 is intended to provide the reporting entity with a means of documenting the date that the MDR is submitted to FDA.

5.3.2 How much detail do I need to use to describe the event?

Block B-5 provides an open space for your description of the event or problem. You are encouraged to provide all information known about the event, including: (i) how the device was involved; (ii) the nature of the problem; (iii) the required patient treatment; (iv) the patient outcome or final condition; and (v) any environmental conditions that may have influenced the event.

5.4 Block F - For Use By User Facility/Importer

5.4.1 If I complete Form 3500A for a user facility or importer event, do I include the information required by Block F in Block H-11, or should I complete Block F?

When you receive information from the user facility or importer (not on a Form 3500A) and you must complete Form 3500A, you must provide the information required by Blocks A, B, D and E in addition to Blocks G and H. Although you are not mandated to complete Section F, you should enter the patient and device codes that are required by Block F-10 in Block H. If you receive a copy of the user facility or importer report, you may attach a copy to your electronic MDR submission. For more information regarding

electronic submissions, refer to the "Questions and Answers about eMDR - Electronic Medical Device Reporting - Guidance for Industry, User Facilities and FDA Staff" at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm175805.htm

5.4.2 Does the omission of the data elements on a user facility or importer malfunction report relieve me from follow up and reporting information requested on the Form 3500A?

No, it does not. The MDR regulation requires, and the instructions for completing the Form 3500A clarify, that the manufacturer is required to provide any information missing on the user facility or importer report [21 CFR 803.50(b)(2)] (see also Section 5.4.1 of this guidance).

5.5 Block H - Device Manufacturers Only

5.5.1 What is meant by "Evaluation codes" requested in Block H-6?

"Evaluation codes" are the manufacturer's perspective of the reported event. They are found in the Coding Manual (see the CDRH web page at:http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm106737.htm).

More specifically, the evaluation codes provide information about the:

(1) Method used to evaluate the medical device involved in the reported event (method of evaluation codes);

(2) Results of the evaluation (evaluation results codes); and

(3) Conclusions made concerning the relationship of the device to the reported event (evaluation conclusion codes).

The codes for method of evaluation are broken into two groups: (1) the source of the device evaluated, and (2) the type of evaluation performed.

The source of the device evaluated codes allow for the possibility that a device other than the specific device involved in the event could be evaluated, such as a device from the same lot, or a reserve sample.

Codes for the result of the evaluation are divided into three basic categories and two specific categories. The basic categories are problems related to the:

(1) Device,

(2) Use of the device, and

(3) Physiological/procedural factors.

The two specific categories are problems related to:

(1) Device components/subassembly failures, and

(2) Computers, imaging systems and microprocessors.

At least one code from one of the basic categories should be chosen if an evaluation was made. Additional codes from any or all of the basic categories may be entered, as appropriate. One or more codes from any of the specific categories may also be chosen, as appropriate.

5.5.2 The instructions for completing Form 3500A state that conclusion codes should be entered even if the device is unable to be evaluated. How is this possible? If the actual device cannot be evaluated, shouldn't Block H-6 be left blank?

You do not need to have access to the device in order to be able to draw a conclusion concerning the event. The conclusion codes provide for situations where the device may not be available for evaluation. In this case, you may select one or more of the applicable codes. In addition, conclusion codes may be drawn based upon evaluation of retention samples, or other information in your possession.

You must provide at least one evaluation conclusion code, even if the code for "no conclusion can be drawn" is the only code you can use. It is possible to have more than one evaluation conclusion code, but the field should not be left blank.

5.5.3 Because Block H-6 has 4 boxes for method, results and conclusions, do I put one number in each box or the entire code in one box? If I put the entire code in one box, am I then limited to just four codes for each category?

Each box should contain all the appropriate numbers for a complete code (you should not put only one number per box). Although the form has just four boxes per category, you may use more codes by entering the additional codes in Block H-10/11 or by attaching an addendum page to your report that provides the additional codes. For each additional evaluation code provided, please indicate whether it is a method, results, or conclusion code.

5.5.4 Should I check a box under H-7 to identify a correction I make to the device involved in the MDR report? When should I provide information under H-7? What should I report under H-9?

If your investigation of a device malfunction leads you to make a correction only to that one device, your correction would not be considered a remedial action that should be reported under H-7. Block H-7 should be used only to report a situation in which your firm takes action (other than routine maintenance or servicing of a device) to more than one device to prevent the recurrence of a reportable event.

Block H-9 should be used to provide FDA with the number of the report filed with the FDA in accordance with the Correction and Removal regulation, 21 CFR Part 806. As required by section 519(g) of the FD&C Act and 21 CFR 806.10, a firm that initiates a device correction or removal to (1) reduce a risk to health posed by the device or (2) to remedy a violation of the FD&C Act caused by the device which may present a risk to health, is required to report this action to FDA within 10 working days of initiating such correction or removal. The Reports of Correction and Removal regulation, 21 CFR Part 806, specifies the information that must be included in this report, as well as the format the firm should follow when assigning the correction/removal reporting number. This number consists of the registration number for the responsible firm, the date of the report using MM/DD/YY format, a 3 digit sequential number for each report made on that date (i.e., 001, 002, 003, etc.), and the report type designation (e.g., "C" for a report of correction or "R" for a report of removal).

You may need to submit an MDR report before the decision is made to implement a corrective action. In that case, a supplemental MDR should be filed within 30 days of the decision to take a remedial action.

If your firm is not initiating a remedial action in response to the MDR report you are filing, you should leave H-7 and H-9 blank.

APPENDIX A

BASIC REQUIREMENTS FOR USER FACILITIES, IMPORTERS AND DISTRIBUTORS

A.1 Basic Requirements for User Facilities

A “device user facility” is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician’s office [21 CFR 803.3]. A user facility does not include school nurse offices and employee health units. User facilities are required to submit MDR reportable events, within 10 work days after the day they become aware of a reportable event as follows:

- Reports of device-related deaths must be reported to us and to the device manufacturer, if known [21 CFR 803.10 and 21 CFR 803.30]; and

- Reports of device- related serious injuries must be reported to the manufacturer (or to us when the manufacturer is not known) [21 CFR 803.10 and 21 CFR 803.30].

User facilities are also required to:

(1) Submit to us, on an annual basis, a summary of all death and serious injury reports submitted during the reporting year [21 CFR 803.10(a)(2) and 21 CFR 803.33];

(2) Develop, maintain and implement written MDR procedures [21 CFR 803.17]; and

(3) Maintain files related to medical device adverse events [21 CFR 803.18].

A.2 Basic Requirements for Importers

An “importer” is any person who imports a device into the US and who furthers the marketing of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user of the device. It should be noted, however, that a person who repackages or otherwise changes the container, wrapper, or labeling of the device or device package is considered to be a manufacturer of the device [21 CFR 803.3].

Importers are required to submit MDR reportable events, within 30 calendar days after the day they become aware of a reportable event, as follows:

- Reports of device-related deaths and serious injuries must be reported to us and to the manufacturer [21 CFR 803.10 and 21 CFR 803.40]; and

- Reports of device-related malfunctions must be reported only to the manufacturer [21 CFR 803.10 and 21 CFR 803.40].

Importers are also required to:

(1) Develop, maintain and implement written MDR procedures [21 CFR 803.17]; and

(2) Maintain files related to medical device adverse events [21 CFR 803.18].

A.3 Basic Requirements for Distributors

A "distributor" is any person, other than the manufacturer or importer, who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user [21 CFR 803.3]. It should be noted, however, that, as is the case with importers, a person who repackages or otherwise changes the container, wrapper, or labeling of the device is considered to be a manufacturer of the device.

Distributors are only required to establish and maintain device complaint records (files) [21 CFR 803.18(d)].