

Welcome to today's FDA/CDRH Webinar

*Thank you for your patience while we register all of
today's participants.*

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Medical Device Reporting for Manufacturers

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November 30, 2016 CDRH Webinar



Medical Device Reporting Regulation

Medical Device Reporting (MDR, 21 CFR Part 803)

- Establishes the reporting requirements for device user facilities, manufacturers and importers.
- A mechanism for FDA and manufacturers to identify and monitor significant adverse events involving marketed medical devices.

What Types of Events Must Be Reported to FDA?

- If device may have **caused or contributed** to a death or serious injury.
- Certain malfunctions must also be reported.

Additional requirements:

- Device manufacturer must conduct a complete investigation of each event (as per 21 CFR Part 820.198)
- All information required in 21 CFR Part 803.52
- Develop and implement written MDR Procedures (21 CFR Part 803.17)
- Establish and maintain MDR event files
- Have a system in place that ensures access to information that facilitates timely follow-up/inspection by FDA.

“Caused Or Contributed”

- Death or serious injury was or may have been attributed to a medical device;

or

- A medical device was or may have been a factor in a death or serious injury, including events resulting from:
 - * -Failure
 - * -Malfunction
 - * -Improper or inadequate design
 - * -Manufacturing (problems)
 - * -Labeling (problems)
 - * -Use error

What Is A Serious Injury?

A reportable serious injury is defined as:

An injury or illness that is:

- Life-threatening

or

- Results in permanent impairment or damage to a body function or structure,

or

- Requires medical or surgical intervention to preclude permanent impairment or damage to a body function or structure



When Is a Device Malfunction Reportable?

- The device fails to meet its performance specifications or otherwise perform as intended

and

- The device is likely to cause or contribute to a death or serious injury if the malfunction were to recur

21 CFR Part 803: Medical Device Reporting Requirements



REPORTER	WHAT TO REPORT	WHERE	WHEN
Manufacturer (Mfr) (Domestic and Foreign)	Deaths, Serious Injuries, Malfunctions	FDA	Within 30 calendar days of becoming aware
	Events that require remedial action to prevent an unreasonable risk of substantial harm	FDA	Within 5 working days of becoming aware
User Facility	Deaths	FDA and Mfr	Within 10 working days
	Serious Injuries	Mfr (FDA if unknown)	Within 10 working days
Importer	Deaths and Serious Injuries	FDA and Mfr	Within 30 calendar days
	Malfunctions	Mfr	Within 30 calendar days
Voluntary	Any type of event	FDA	Any time



What's new since the 1997 MDR Guidance Document?

Clarification of several topics

- When a firm “becomes aware” that an MDR reportable event has occurred.
- MDR submission rules involving a marketed device studied under an investigational device exemption (IDE).
- MDR submission rules involving adverse events that occur outside the United States.
- Exemption request process for MDR reporting for a contract manufacturer
- Clarification of the submission of 5-day reports and remedial actions.
- Clarification on the 2-year presumption for reportable malfunctions.

“Becoming Aware”

- A firm becomes aware of an event whenever
 - Any of your employees become aware of information that reasonably suggest 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.

MDRs for IDE situations

- If a device is legally **marketed** in the US and is also under an Investigational Device Exemption (IDE), any adverse event that involves the investigational use of the marketed device are subject to reporting under both the IDE regulation and the MDR regulation. (APPLIES TO NON-INVESTIGATIONAL DEVICE)
- If the device is **under study** it should be reported under the IDE only. (21 CFR Part 812) (APPLIES TO INVESTIGATIONAL DEVICE)
- If a marketed device is used as an investigational device (i.e. under a new indication for use), and if the adverse event results from the labeled marketed use of the device, it must be reported as an MDR.

MDR from Outside US (OUS)

- If a foreign adverse event occurs, this chart specifies the MDR reporting obligation of the foreign event.

Firm is	Market Status in US	Market Status in OUS country	Report Foreign Event?
US	No	Yes	Yes, when requested.
US	Yes	Yes	Yes
OUS	Yes	Yes	Yes
OUS	Under Study	Yes	Yes (only if a similar device marketed in US by the same manufacturer)



Exemption Request for Contract Manufacturer

- Any 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 and would not require an exemption.
- If the contract manufacturer markets the devices that it manufactures, then both the contract manufacturer and the specifications developer have MDR reporting obligations.
- If either the contract manufacturer or specifications developer wants to report on behalf of the other, an exemption is needed.

5-day Reports and Remedial Action

- A “5-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 needed); or
 - For which we have made a written request for the submission of 5-day reports.
- 5-days begin the day after an employee with management of 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. 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.
- This is NOT the same “become aware” date for normal 30-day reporting. If 6 days after a firm becomes aware of an adverse event that is MDR reportable the firm determines that it meets the definition of a 5-day report, they have until Day 11 to file this 5-day report.

5-day Reports and Remedial Action

- A “remedial action” is any action, other than routine maintenance or servicing of a device, necessary to prevent recurrence of an MDR reportable event. FDA does not consider an action taken to correct only a single device involved in an MDR reportable event to be a remedial action.
- 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.
- When the remedial action taken is not required to address an unreasonable risk of substantial harm to the public health the reportable adverse events should be submitted as 30-day reports instead of 5-day reports.

2- Year Presumption

- 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.
- Either:

Report for 2 year
and
Notify FDA with data and
rationale for
discontinuation

OR

Request an **exemption**
sooner than 2 years with
data showing incidence
rate and evidence that
malfunction cannot recur.

Questions?

MDR help desk: MDRPolicy@fda.hhs.gov

Phone (unattended, voice mail only): 301-796-6670

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Under Heading: Post-Market Activities; Sub-heading:
Medical Device Reporting (MDR)