

Complaints and Adverse Events

**FDA Small Business
Regulatory Education for Industry (REdI)
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Learning Objectives

- Understand what a complaint is and how it relates to adverse event reporting
- Understand mandatory adverse event reporting requirements
- Learn the basics of the “*Medical Device Reporting: Electronic Submission Requirements Final Rule*”
- Review the basic process for preparing and submitting electronic Medical Device Reports (eMDRs)



Complaint Files

21 CFR 820.198

Complaint Files

- A **complaint** is:
Any communication that alleges deficiencies of a device after release for distribution.
- All manufacturers must:
 - Maintain complaint files
 - Make complaint files accessible
 - Designate a formal complaint handling unit
 - Establish and maintain procedures for processing complaints

Complaint Files continued

Procedures must ensure:

- Complaints processed in a uniform and timely manner
- Oral complaints are documented upon receipt
- Complaints are reviewed to determine if investigation is necessary
 - If no investigation, manufacturers must maintain record of reason why, and name the individual responsible for the decision

Complaint Files continued

Records of investigation will include determination of:

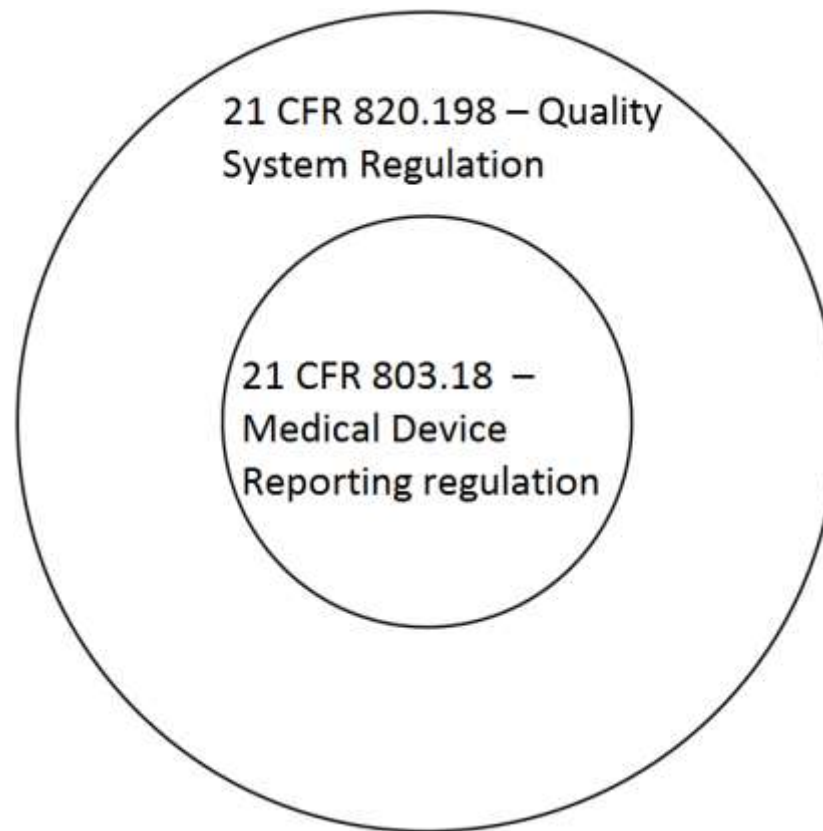
- Identifiers related to the device and reported event
- If MDR reportable:
 - Whether the device failed to meet specifications
 - Whether the device was used for treatment or diagnosis
 - If applicable, relationship of device to reported event

Complaint Files continued

Procedures must ensure:

- Complaints are evaluated to determine if it represents a reportable event, also known as a Medical Device Report , according to 21 CFR 803
- Complaints representing an MDR will be promptly reviewed, evaluated, and investigated
 - Should be maintained in a separate portion of the complaint file or otherwise clearly identified

Complaint Files in Relation to MDR



Medical Device Reporting (MDR)

Mandatory MDR Reporting

An **MDR Reportable Event** is an event that reasonably suggests a marketed device:

- May have caused or contributed to a death or serious injury, or
- Malfunctioned and ... would likely cause or contribute to a death or serious injury if it recurred

Timeframe: **30 calendar days** after the day that your company becomes aware of the adverse event.

eMDR Final Rule & Guidance Overview



eMDR Final Rule

- Manufacturers must submit all reports to FDA in an electronic format that FDA can process, review, and archive
- Requirements of final rule took effect on **Aug 14, 2015**
- Does not change requirements for report contents or submission deadlines

eMDR Final Rule Continued

Record Keeping Changes:

- Must keep copies of all reports submitted to FDA (paper or electronic)
- Must retain all acknowledgments FDA sends to the manufacturer or importer
- Must produce a human readable copy of any reports sent to FDA if requested by an investigator

See 803.18(b)(1)(ii-iii)



Submitting eMDRs to FDA



Electronic Submission Gateway (ESG)

- The FDA ESG is the central transmission point for sending information electronically to the FDA
- Relays product specific report to the appropriate FDA center
- Digital certificate required for submitters
- A secure entry point for all electronic submissions to the Agency

Poll

D2S6

View Votes

Edit

End Poll

D2S6: Does your company have a WebTrader Account?

<input type="radio"/> Yes	<div></div>	0%	(0)
<input type="radio"/> No	<div></div>	0%	(0)
<input type="radio"/> I do not know what WebTrader is	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results

WebTrader Account

- Obtain a Web Trader Account from the ESG
 - Detailed instructions are accessible via FDA's "Setting up a Web Trader Account Checklist" webpage
- Contact ESGHelpDesk@fda.hhs.gov in order to:
 - Request a WebTrader account
 - Request assistance with the registration or testing process
 - Ask policy questions regarding the ESG Gateway



Electronic Submission Gateway (ESG) continued

- **Acknowledgment 1:** Submission received by FDA ESG
- **Acknowledgment 2:** Submission reached CDRH
- **Acknowledgment 3:** Submission was successfully loaded into MAUDE **OR** contained errors
- If there are no errors, the acknowledgment letters will be generated within **24 hours** of submission

Electronic Submission Gateway (ESG) continued

- Contact the ESG Staff (ESGHelpDesk@fda.hhs.gov) if ESG is operating normally but you did not receive Acknowledgment 1 or 2
- Contact eMDR@fda.hhs.gov if:
 - the eMDR System is operating normally but you did not receive Acknowledgment 3
 - Acknowledgment 3 error message(s) for an adverse event report is unclear

Health Level Seven (HL7)

- Standard for the capture of the information needed to support the submission of MDR reportable events
- eMDRs can be submitted in large batches or individually
- Allows for extraction of information directly from the reporter's database to populate and transmit eMDRs to the FDA ESG



eSubmitter

- Standard software that eases the technical burden
- This option is suitable for reporters that want to submit MDRs individually
- Software generates an electronic version of Form 3500A in zip file format that is sent via ESG. Attachments can be included with submission
- Please utilize the link in the “Resources Websites” section for the eSubmitter software and instructions for installation

Poll

D2S6-2

View Votes
Edit
End Poll

D2S6-2: Which method is your company using or planning to use to submit MDRs to FDA?

<input type="radio"/> eSubmitter	<div></div>	0%	(0)
<input type="radio"/> Develop in-house HL7	<div></div>	0%	(0)
<input type="radio"/> Third Party Submitter	<div></div>	0%	(0)
<input type="radio"/> I don't know	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results

Other eMDR Considerations

- FDA considers an eMDR report filed as of the date it is accepted at the ESG, as long as the report is later accepted by the CDRH database.
 - The report date is the local date (not the hour)
- If unable to submit a report on time due to an outage of the ESG or eMDR processing system:
 - the submitter may document attempts in Block H10

Other eMDR Considerations continued

Updating a Report:

- Include the initial report number and identify submission type as a follow-up report
- Limit additional entries to those where you need to update or correct previously-provided information

Other eMDR Considerations continued

Third-Party Submitter Companies:

- May submit eMDRs on client's behalf if third-party company has permission from client
- May NOT use client's WebTrader account to submit the reports
- Must use their own WebTrader account to submit eMDRs

Summary

- 21 CFR 820.198 is intertwined with 21 CFR 803
- The method for submitting MDRs to FDA has changed; other MDR requirements generally have not changed
- May use eSubmitter or HL7 to submit eMDRs to FDA

Resource Websites

- Medical Device Reporting (MDR):
www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm
- How to Enroll in eMDR Program:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR%E2%80%93ElectronicMedicalDeviceReporting/ucm475298.htm
- Guidance Document: Medical Device Reporting for Manufacturers:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359130.htm
- eMDR Final Rule:
www.gpo.gov/fdsys/pkg/FR-2014-02-14/pdf/2014-03279.pdf
- eSubmitter Download and Installation
www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm
- Health Level Seven (HL7) Individual Case Safety Reporting
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR%E2%80%93ElectronicMedicalDeviceReporting/ucm127948.htm
- Setting up a Web Trader Account Checklist:
www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm

Questions?

- **General MDR questions: Division of Industry and Consumer Education (DICE)**

Email: DICE@fda.hhs.gov

Phone: (800) 638-2041

- **Interpretations on MDR policy: MDR Policy Group**

Phone: (301) 796-6670 (voice)

Email: MDRPolicy@fda.hhs.gov

Questions?

Please complete the session survey:

surveymonkey.com/r/DEV-D2S6

Call to Action

- Understand your responsibilities for how to handle complaints about your medical devices.
- Set up your ESG account now! Do NOT wait until your company receives an MDR reportable complaint.

