

## § 803.21

## 21 CFR Ch. I (4–1–25 Edition)

device has or may have caused or contributed to a death or serious injury or

(ii) The manufacturer, no later than 30 calendar days after receiving information that a device you market has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(3) If you are a manufacturer, you must submit MDR reports to us:

(i) No later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury or

(ii) No later than 30 calendar days after the day that you become aware of information that reasonably suggests a device has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; or

(iii) Within 5 work days if required by § 803.53.

(c) *What kind of information reasonably suggests that a reportable event has occurred?*

(1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(2) If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a 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 (described in § 803.18) the information that the qualified person used to determine

whether or not a device-related event was reportable.

### **§ 803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?**

(a) The MedWatch Medical Device Reporting Code Instruction Manual contains adverse event codes for use with Form FDA 3500A. You may obtain the coding manual from FDA's website at: <https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/mdr-adverse-event-codes>.

(b) We may sometimes use additional coding of information on the reporting forms or modify the existing codes. If we do make modifications, we will ensure that we make the new coding information available to all reporters.

[79 FR 8846, Feb. 14, 2014, as amended at 85 FR 18441, Apr. 2, 2020]

### **§ 803.22 What are the circumstances in which I am not required to file a report?**

(a) If you become aware of information from multiple sources regarding the same patient and same reportable event, you may submit one medical device report.

(b) You are not required to submit a medical device report if:

(1) You are a user facility, importer, or manufacturer, and you determine that the information received is erroneous in that a device-related adverse event did not occur. You must retain documentation of these reports in your MDR files for the time periods specified in § 803.18.

(2) You are a manufacturer or importer and you did not manufacture or import the device about which you have adverse event information. When you receive reportable event information in error, you must forward this information to us with a cover letter explaining that you did not manufacture or import the device in question.

### **§ 803.23 Where can I find information on how to prepare and submit an MDR in electronic format?**

(a) You may obtain information on how to prepare and submit reports in an electronic format that FDA can process, review, and archive at: <http://>

[www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm](http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm).

(b) We may sometimes update information on how to prepare and submit reports electronically. If we do make modifications, we will ensure that we alert reporters by updating the eMDR Web page.

### Subpart C—User Facility Reporting Requirements

#### § 803.30 If I am a user facility, what reporting requirements apply to me?

(a) You must submit reports to the manufacturer or to us, or both, as specified in paragraphs (a)(1) and (a)(2) of this section as follows:

(1) *Reports of death.* You must submit a report to us as soon as practicable but no more than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of your facility. You must also submit the report to the device manufacturer, if known. You must submit the information required by § 803.32. Reports sent to the Agency must be submitted in accordance with the requirements of § 803.12(b).

(2) *Reports of serious injury.* You must submit a report to the manufacturer of the device no later than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of your facility. If the manufacturer is not known, you must submit the report to us. You must report information required by § 803.32. Reports sent to the Agency must be submitted in accordance with the requirements of § 803.12(b).

(b) *What information does FDA consider “reasonably known” to me?* You must submit all information required in this subpart C that is reasonably known to you. This information includes information found in documents that you possess and any information that becomes available as a result of reasonable followup within your facility. You are not required to evaluate or investigate the event by obtaining or

evaluating information that you do not reasonably know.

#### § 803.32 If I am a user facility, what information must I submit in my individual adverse event reports?

You must include the following information in your report, if reasonably known to you, as described in § 803.30(b). These types of information correspond generally to the elements of Form FDA 3500A:

(a) Patient information (Form FDA 3500A, Block A). You must submit the following:

- (1) Patient name or other identifier;
- (2) Patient age at the time of event, or date of birth;
- (3) Patient gender; and
- (4) Patient weight.

(b) Adverse event or product problem (Form FDA 3500A, Block B). You must submit the following:

(1) Identification of adverse event or product problem;

(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:

- (i) A life-threatening injury or illness;
- (ii) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
- (iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

- (3) Date of event;
- (4) Date of this report;
- (5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

- (6) Description of relevant tests, including dates and laboratory data; and
- (7) Description of other relevant history, including preexisting medical conditions.

(c) Device information (Form FDA 3500A, Block D). You must submit the following:

- (1) Brand name;
- (2) Product Code, if known, and Common Device Name;