

MDR Reportability Decision Checklist

For complaint handlers assessing medical device events under FDA 21 CFR Part 803

Fill it in on screen or print it. One checklist per complaint, kept in the MDR event file.

1. Complaint details

COMPLAINT ID

DEVICE NAME AND MODEL

AWARENESS DATE

ASSESSED BY

ROLE

DATE OF ASSESSMENT

The awareness date is the day any employee of the manufacturer first received information that reasonably suggests a reportable event. Your deadline counts from this date, even if the complaint reached the quality team later.

2. Information gathered before deciding

Tick each item you have reviewed. Missing information does not pause the deadline.

- ☐ Event description from the reporter, in their own words
- ☐ Patient outcome, including any medical or surgical intervention
- ☐ Device identification: model, lot or serial number, software version
- ☐ Device evaluation status: returned, under investigation, or not available
- ☐ Similar past complaints and the hazards already listed in the risk file

3. The decision questions

Answer in order. Each answer tells you where to go next. Record a short reason for every answer.

- 1 Are you the manufacturer, or otherwise responsible for MDR reporting for this device?** ☐ Yes ☐ No

No: record who is responsible and why. Yes: continue.

Reason:

- 2 Is the device subject to FDA MDR requirements?** ☐ Yes ☐ No

Applies to devices marketed in the US, or the same as or similar to one that is. No: record why. Yes: continue.

Reason:

- 3 Does the information reasonably suggest the device caused or contributed to a death or serious injury?** ☐ Yes ☐ No

Serious injury: life-threatening, permanent impairment or damage, or needing medical or surgical intervention to prevent it. Yes: reportable, 30-day unless Q7 or Q8 applies.

Reason:

- 4 Was the event solely attributable to use error, with no device-related performance issue?** ☐ Yes ☐ No

Check whether instructions, labeling, controls or design contributed. If they did, answer No and continue.

Reason:

5 Did a device malfunction occur?

☐ Yes ☐ No

A failure to meet performance specifications or to perform as intended. No, and Q3 is No: likely not reportable; record your reasoning.

Reason:

6 If the malfunction recurred, could it cause or contribute to a death or serious injury?

☐ Yes ☐ No

Answer this even when nobody was hurt. Check the hazards in the risk file. Yes: reportable, 30-day unless Q7 or Q8 applies.

Reason:

7 Is remedial action necessary to prevent an unreasonable risk of substantial harm to public health?

☐ Yes ☐ No

Yes: 5-day report.

Reason:

8 Has FDA requested 5-day reports in writing for this device or event type?

☐ Yes ☐ No

Yes: 5-day report.

Reason:

4. Outcome and deadline

- ☐ **Not reportable** Record the reasoning in the MDR event file (21 CFR 803.18)
- ☐ **30-day report** Due 30 calendar days from the awareness date (21 CFR 803.50)
- ☐ **5-day report** Due 5 work days from the awareness date (21 CFR 803.53)

REPORTING DUE DATE

REPORT REFERENCE (IF REPORTABLE)

SUPPLEMENTAL REPORT NEEDED?

New information on an event you have already reported? A supplemental report is due within 30 calendar days of receiving it (21 CFR 803.56).

5. Four checks before you close the assessment

- ☐ **No injury does not mean not reportable.**
Q6 applies to every malfunction, whether or not anyone was harmed.
- ☐ **"Reasonably suggests" is a lower bar than proof.**
Report on the information you have; the investigation can continue alongside.
- ☐ **Use error rarely ends the assessment on its own.**
If labeling, instructions or design contributed, the device played a part.
- ☐ **The clock started at awareness.**
Check that the due date counts from the first employee who knew, not the quality team.

6. Review and sign-off

FDA expects the MDR event file to show the deliberations behind every decision, including decisions not to report (21 CFR 803.18).

REVIEWED BY (REGULATORY)

SIGNATURE

DATE