5. FDA Mandatory Reporting of Device Related Adverse effects

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ANNUAL REVIEW:

REVIEWED	Sanford N. Bauby, M.D signature/title	July 15-2025 Date
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SUPERSEDES: Procedure titled _____

Purpose

This policy is for all laboratory staff to get know that they should report any defect observe with the performance of any procedure that **might be a cause of harm**.

Scope

This program applies to all employee in the laboratory and make sure to report defect in procedures or instruments to FDA as per the appropriate channel and procedure.

Abbreviation

FDA- Food and drug administration
MDR - Medical Device Reporting

POLICY:

Each year, the FDA receives several hundred thousand medical device reports of suspected device-associated deaths, serious injuries and malfunctions. Medical Device Reporting (MDR) is one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

Mandatory reporters (i.e., manufacturers, device user facilities, and importers) are required to submit certain types of reports for adverse events and product problems to the FDA about medical devices. In addition, the FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.

MDR regulations require User Facilities (e.g., hospitals, laboratories) to report **suspected medical device related deaths** to both the FDA and the manufacturers. User facilities must report medical device related serious injuries to the manufacturer.

There are clinical settings which are exempt from MDR reporting requirement. These facilities include offices of physicians, dentists, chiropractors, optometrists,nurse practitioners, school-based clinics, employee health clinics, and freestanding care units.

Serious Patient Injury

The definition of a serious adverse event is broadly defined within **voluntary reporting** to include any patient outcome that results in death, a life-threatening event , hospitalization (initial or prolonged),disability, a congenital anomaly, or if medical or surgical intervention was required to prevent permanent damage. Health professionals do not need to prove causality; a suspected possible association between a product and an adverse patient outcome is sufficient reason to report. FDA is also interested in reports of product problems such as inaccurate or unreadable labeling, packaging or product mix-up, contamination or stability problems, defective devices, or product confusion (caused by name, labeling, design, or packaging).

The FDA defines “serious patient injury” as one that is life threatening, or results in permanent impairment of body function or structure, or necessitates medical or surgical intervention. Reportable device malfunctions or problems may relate to any aspect of a test, including hardware, labeling, reagents or calibration or to user error. Non reportable events are those that may have resulted from inherent limitations in an analytic system.

Device User Facility Reporting Requirements

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. User facilities **must report a suspected medical device-related death to both the FDA and the manufacturer**. User facilities must report a medical device-related **serious injury** to the manufacturer, or to the FDA if the medical device manufacturer is unknown.

User facilities must also submit annual reports to the FDA by January 1 of each year as described in 803.33.

Although a user facility is not required to report a device malfunction, they can voluntarily inform the FDA of such product problems through MedWatch, the FDA’s Safety Information and Adverse Event Reporting Program.

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
User Facility	Device-related Death	Form FDA 3500A	FDA & Manufacturer	Within 10 work days of becoming aware
User Facility	Device-related Serious injury	Form FDA 3500A	Manufacturer. FDA only if manufacturer unknown	Within 10 work days of becoming aware
User Facility	Annual summary of death & serious injury reports	Form FDA 3419	FDA	January 1 for the preceding year

HOW TO OBTAIN FORMS AND INSTRUCTIONS

Mandatory (F DA 3500A) form for reporting by **user facilities :**
Instruction of how to fill the form:
https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500

• By mail or fa x : call 1-800-FDA-1088 (press "0" during the initial message)
• By intern e t : www.f da.gov (cl i ck on “Medical Dev i c e s / Radiological Health,” “ Program Are a s ,” “Medical Device Reporting,” and
"Forms and Instructions." Print the form or download as a PDF file. There is also form software which can be downloaded and used to
complete the forms using a personal c o m p u t e r. After the initial entries are made, the completed form can be printed and mailed to
FDA and/ or the manufacturer. This software does not permit electronic submission of reports. If you prefer a copy of the free software
on disk, call 1-800-FDA-1088 (press 0), or e--mail MedWatch (medwatch @ b a n gat e. f d a . gov). Note: the form software contains both

the FDA 3500 and the F DA 3500A forms .

HOW TO REPORT TO FDA

Mandatory (3500A):
• By mail:
FDA Center for Devices & Radiological Health
MDR Reporting
PO Box 3002
Rockville, MD 20847-3002
Mark the envelope:
"User Facility Report"

QUESTIONS ABOUT REPORTING?

Mandatory: Reporting Systems & Monitoring Branch (HFZ-533)
FDA, CDRH
1350 Piccard Drive
Rockville, MD 20850

Individual 3500A or semi-annual reports
(301) 827-0038 (fax) (301) 594-2731 (voice)

Personnel Training: All personnel will be instructed on the FDA reporting requirements and training documented.

References:

FDA Website: www.fda.gov/medwatch/report