Medical Device Reporting (MDR) for CBER In Vitro Diagnostic Devices (IVDs)

Bima Patel
Consumer Safety Officer
Program Surveillance Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

July 15, 2019

MDR Regulation

The Federal Food, Drug and Cosmetic Act, Section 519 grants FDA authority to require mandatory MDRs

- Manufacturers
- Importers
- Device User Facilities

Requirements for MDR are found in 21 CFR Part 803

- Applicable to both licensed and unlicensed devices

MDR Requirement for Manufactures

Manufacturers are required to:

- Submit to FDA **initial reports (30 day reports)** of death, serious injury and malfunction within 30 calendar days of becoming aware of an event (§803.50)

- Submit to FDA **5-day reports** within 5 working days of becoming aware of death, serious injury or malfunction event that require remedial action to prevent an unreasonable risk of substantial harm (§803.53)

- Submit to FDA **supplemental reports** within 30 calendar days of receipt of new/changed information (§803.56)

MDR Requirements for Importers and User Facility

Importers are required to (§803.40 and §803.42) :

- Report device related **deaths** and **serious injuries** to the FDA and manufacturer within 30 calendar days of becoming aware of an event using Form FDA 3500A
- Report **malfunctions** to manufacturer within 30 calendar days of becoming aware of an event using Form FDA 3500A

User Facilities are required to (§803.30 and §803.32):

- Report device related **deaths** to FDA and Manufacturer within 10 work days of becoming aware using Form FDA 3500A
- Report device related **serious injuries** to manufacturer within 10 work days of becoming aware using Form FDA 3500A (**FDA only if manufacturer is unknown)**
- Report annual summary of death and serious injury reports January 1 for the preceding year using Form FDA 3419 (§803.33)

NOTE: Although user facilities are not required to report device malfunctions, voluntary reporting of device problems are encouraged through MedWatch

MDR Requirements for Manufacturers, User Facility and Importers

REPORTER	WHAT TO REPORT	WHERE	WHEN
Manufacturer	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 Manufacturer	Within 10 calendar days
	Serious injuries	Manufacturer (FDA only if manufacturer is unknown)	Within 10 calendar days
Importer	Deaths and Serious injuries	FDA and Manufacturer	Within 30 calendar days
	Malfunctions	Manufacturer	Within 30 calendar days

Submission of MDRs

When would an MDR not be required?

- A manufacturer receives erroneous information and a device–related event did not occur.

- A manufacturer determines that the device was manufactured or imported by another firm.
  - When a manufacturer receives this type of report, it must forward the report to the FDA with a cover letter.

Submission of MDRs

- Two options for electronic submission of MDRs
  1. FDA eSubmitter Software
     - Allows submission of one MDR at a time
     - Generates an electronic of Form FDA 3500A which is submitted to FDA using the FDA electronic submission gateway (ESG)
  2. Health Level Seven Individual Case Safety Reporting (HL7ICSR)
     - Allows submission of one MDR at a time

- Additional information on electronic submission of MDRs is available on the eMDR website: https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities

Submission of MDRs

General instructions to keep in mind when submitting MDRs

1. Section B-5 (Describe Event or Problem)
   - Provide all information known about the event, including
     - How the device was involved
     - Nature of the problem
     - Required patient treatment
     - Patient's outcome or final condition

2. Section D (Suspect Medical Device)
   - Include device brand name, common name, **device procode***, device model, serial, or lot number and manufacturer's information including email address

3. Section G-5 (All Manufacturers)
   - Identify the device by entering the premarket application (PMA) or Pre-market notification (510K) submission number for approved/cleared devices
   - For IVDs licensed under the biologics license application (BLA), indicate the BLA number

*Procodes are included in the device approval. However, devices licensed as biological products under the PHS Act do not currently have three letter product codes assigned.

Submission of MDRs

Recommendations for submitting MDRs for licensed IVDs:

1. Choose procode that best fits the device from the product code file available on FDA web. (https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051637.htm)
2. Include brand name and common name of the device
3. Include BLA number

Questions about MDR can be sent to:

Email: MDRPolicy@fda.hhs.gov or write to:

Food and Drug Administration
Center for Devices and Radiological Health
MDR Policy Branch
10903 New Hampshire Avenue
WO Bldg. 66, Room 3217
Silver Spring, MD 20993-0002

Resource Websites

- Guidance Document: Medical Device Reporting for Manufacturers

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-reporting-manufacturers

- eMDR -Electronic Medical Device Reporting Guidance Document:

http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm175805.htm

- Medical Device Reporting (MDR): How to report Medical Device Problems

https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems