Medical Device Reporting (MDR): Electronic Report Submission (eMDR) (21 CFR Part 803)

Association of Medical Diagnostics Manufacturers (AMDM)
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MDR Regulation (MDR) – Current Requirements

- Food, Drug and Cosmetic Act , Sec. 519 establishes authority for MDR reporting
- Requirements for MDR are located in 21 CFR Part 803
- Reports are submitted on paper or electronically
- Reports contain information found on FDA Form 3500A

Who Must Submit MDRs to FDA?

Manufacturer

Importer

Device User Facility

- Hospital
- Ambulatory Surgical Facility
- Outpatient Diagnostic Facility
- Outpatient Treatment Facility
- Nursing Home
- NOT a physician's office

Mandatory Requirements for User Facilities

User Facilities are required to:

- **Report deaths** to FDA and manufacturer
- **Report serious injuries** to manufacturers (or FDA if manufacturer unknown)
- Submit events within 10 workdays
  (21 CFR Part 803.30)
- Submit Annual Reports to FDA (21 CFR Part 803.33)
- Have MDR procedures (21 CFR Part 803.17)
- Establish and maintain MDR event files (21 CFR Part 803.18)

Mandatory Requirements for Importers/Distributors

Importers are required to:

- **Report deaths** and **serious injuries** to the FDA and manufacturer
- **Report malfunctions** to the manufacturer
- Submit events within 30 calendar days
  (21 CFR Part 803.40)
- Have MDR procedures (21 CFR 803.17)

Importers and distributors are required to:

- Establish and maintain MDR event files (21 CFR Part 803.18)

Mandatory Requirements for Manufacturers

Manufacturers are required to:

- **Submit initial reports** of death, serious injury and malfunction within 30 calendar days (21 CFR Part 803.50)
- **Submit supplemental reports** within 30 calendar days of receipt of new/changed information (21 CFR Part 803.56)
- **Submit 5-day reports** within 5 work days (21 CFR Part 803.53)

  Work Day = Monday-Friday, excluding Federal holidays
- Have MDR procedures (21 CFR Part 803.17)
- Establish and maintain MDR event files (21 CFR Part 803.18)

Mandatory Requirements for Manufacturers…

Manufacturers are required to:

- **Investigate each event** to determine the cause of the event;
- **Provide all information reasonably known** about the event to FDA, including:
  - Any information that can be obtained by contacting the reporter
  - Any information in your possession - or-
  - Any information that can be obtained by analysis, testing or other evaluation;

Reporting Events to FDA

- User Facilities and Importers are required to report information listed in 21 CFR Part 803.32 and 803.42
- Information requested corresponds to FDA Form 3500A
  - A: Patient information
  - B: Adverse event or product problem
  - D: Suspect medical device
  - E: Initial reporter
  - F: For use by User Facility/Importer - devices only

Reporting Events to FDA…

- Manufacturers are required to report information listed in 21 CFR Part 803.52
- Information requested corresponds to FDA Form 3500A Sections:
  - A-E and G-H
  - H.10 - Additional narrative
  - H.11 - Corrections – Fill in to correct or add information to the original 3500A, including missing/incorrect codes from F.10

What Happened to Baseline Reports?

- Federal Register Direct to Final Rule published 6/13/2008
- Federal Register Notice 9/17/2008 confirmed **effective date of 10/27/2008**
- 21 CFR 803.55 removed
- Definition of “device family” was removed, but will reappear in future guidance.

Supplemental Reports

- Supplemental reports must be submitted:
  - whenever a manufacturer becomes aware of information that was not provided in the initial MDR
  - within 30 calendar days from receipt of the additional information
- Indicate on 3500A that report is supplement
- Provide the Manufacturer Report Number from the initial MDR
- Only fill in the Blocks on the 3500A that are changing

How to Submit Reports

MDR reports can be mailed to:

FDA/CDRH
Medical Device Reporting
P.O. Box 3002
Rockville, MD 20850

– Mark envelope with type of report (i.e. Initial, 5-day, or Supplemental)

You may submit MDR reports and supplements **electronically

Exemptions

Part 803.19 - Manufacturers can ask for:

- **Alternative Summary Reporting (ASR)** – a subset of the information required for FDA Form 3500A
- **Total exemption** for specific device and/or patient related events
- **Remedial Action Exemption (RAE)** for recalled products covered by 21 CFR Part 806 (Corrections and Removals)

Electronic Medical Device Reporting (eMDR)

- Notice of Proposed Rule Making
  Published August 21, 2009
  Docket Number FDA-2008-N-0393
- Comment Period Closed November 19, 2009
- eMDR Draft Guidance Document
  Notice of Availability Published
  August 21, 2009
  Docket Number FDA-2008-D-0395

Why Electronic Reporting?

- Fiscal Year 2009 – 603,188 Reports
  - 174,224 Individual Reports
  - 428,964 Summary Reports
- Reports transcribed into FDA's MAUDE database
- Data entry – 1 day to 6 months
- Number of individual reports increasing

Current Regulation

- **§ 803.12 Where and how do I submit reports and additional information?**

(a) You must submit any written report or additional information required under this part to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847–3002.

Proposed Regulation

- **§ 803.12 How do I submit reports and supplements?**

(a) Manufacturers, user facilities, and importers must submit initial and supplemental reports to FDA in an ***electronic format that FDA can process, review, and archive***. FDA will provide an update information on how to provide the electronic submission (e.g., preparation and organization of files, file formats, media and method of transmission).

Proposed Regulation – Additional Information

- Rule effective one year after publication of final rule
- Reporters should keep copies of all submitted reports and acknowledgments
- Reporters may request an exemption from electronic reporting
- Housekeeping changes
  - Eliminate unneeded definition
  - Incorporate § 303 of Medical Device User Fee and Modernization Act of 2002 (Reused Single Use Devices)
  - Change “Date of Report by the Initial Reporter” to “Date of Report”

Options for Electronic Reporting

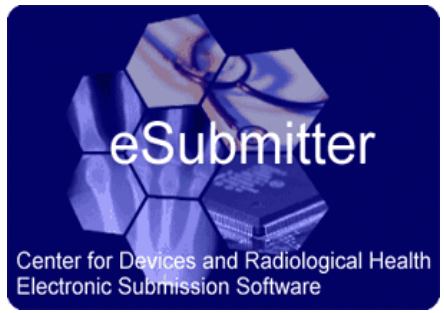
Multiple Reports

Single Reports

Batch

FDA Gateway

One report at a time



C·D·R·H Center for Devices and Radiological Health

MAUDE Database

Single Entry Reporting Option (CeSub)

- FDA developed and maintained
- Software free at: http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm
- Handles one report at a time
- Fillable version of FDA Form 3500A
- Validates all data
- Send the report to FDA Electronic Submissions Gateway

Single Submission Reporting Option

- Government Paperwork Elimination Act (**GPEA**) governs electronic records used and maintained by Government
- GPEA makes FDA responsible for proper operation and validation of CeSub software as long as it used for intended purpose
- Software does not create an electronic copy of the submission
- If you do not modify the software, your only responsibility is to make sure it loads properly

Batch Submission Option

- Based on Health Level 7 Standards Committee Individual Case Safety Report message
- Reporter develops software to extract data from reporter's database and prepare the electronic submission
- Capable of handling multiple report submissions at a time
- Minimal human interaction compared to CeSub
- Validation of your process is required.

Digital Certificates

- You will need a digital certificate to communicate with the FDA gateway
- Cost per certificate is about $20.00 per year
- The certificate will cover any electronic submission that uses the FDA gateway
- Information and instructions on setting up an account and communicating with the FDA gateway are available at:

FDA Electronic Gateway:

http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

MDR Regulation - Interpretation and Policy Questions?

Contact the Reporting Systems Monitoring Branch at:

Office of Surveillance & Biometrics
Division of Post Market Surveillance
MDR Policy Branch
10903 New Hampshire Avenue
WO Bldg. 66, Room 3217
Silver Spring, MD 20993-0002

Phone: 301-796-6670
Fax: 301-847-8135
E-Mail: rsmb@cdrh.fda.gov

Questions about eMDR?

- For technical questions about the HL7 or CeSub process, testing phases and electronic submissions; or how to sign up for eMDR please contact Marc Wilson at:
- **marc.wilson@fda.hhs.gov** or
- 301-796-6092

Helpful FDA Internet Sites

Contact information for RSMB, links to 3500A and other helpful documents:

- http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/default.htm

eMDR:

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm175805.htm

FDA Electronic Gateway:

http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

Helpful FDA Internet Sites…

Event Codes:

- http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/default.htm

Alternative Summary Reporting:

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072029.htm

Remedial Action Exemption:

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071354.htm

All OSB Guidance:

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm

- Sharon Kapsch has been with the FDA for 32 years, and is currently the Chief of the Reporting Systems Monitoring Branch in the Center for Devices and Radiological Health (CDRH). The Branch is responsible for the establishment, interpretation, and enforcement of the regulatory requirements for Medical Device Reporting (MDR). In addition the branch provides education and guidance to the medical device community to facilitate awareness and understanding of the reporting requirements.