MDR Reporting in OIVD

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April 26, 2011

OIVD Postmarket Signals

- MDR reports from manufacturers
- MedSun/LabNet reports
- Trade complaints
- Voluntary MDR reporting from device users
- User facility reports
- Other

Medical Device Reports (MDRs)

21 CFR Part 803

Reports to FDA by user facility/manufacturer or voluntary reporters when a device:

- Caused or contributed, or may have caused or may have contributed to a death
- Caused or contributed, or may have caused or may have contributed to a serious injury
- Malfunctioned or failed to meet specifications (manufacturer only)
  - Recurrence could result in death or serious injury

Required timeframe for reporting

- 5-30 days, depending on severity
- Follow-ups when needed

Mandatory Requirements for Manufacturers

Manufacturers are required to:

- Submit initial reports of death, serious injury and malfunction within 30 days (21 CFR Part 803.50)
- Submit 5 day reports within 5 work days (21 CFR Part 803.53)
- Submit supplemental reports within 30 days (21 CFR Part 803.56)
- Have MDR procedures (21 CFR Part 803.17)
- Establish and maintain MDR event files (21 CFR Part 803.18)

Manufacturer and User Facility Device Experience Database (MAUDE)

MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.19.

21 C.F.R. § 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

Includes (see 803.52 for complete list):

- Description of the 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;
- Description of relevant tests, including dates and laboratory data; and
- Other relevant patient history including preexisting medical conditions.

21 C.F.R. § 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

Includes:

- Brand name
- Operator of the device (health professional, patient, lay user, other)
- Expiration date
- Model number, catalog number, serial number, **lot number**, or other identifying number

Where to find in depth information

- **CDRH Learn** on FDA website
- Valuable pre and post market information
- New courses on MDR and eMDR reporting added 11/19/2010
- http://www.fda.gov/Training/CDRHLearn/ucm162015.htm

Product codes for reporting IVDs

- MAUDE based on one procode
- If problem is related to reagent or assay, report under analyte procode
- Example: use MMI for Troponin
- If instrument problem, report under instrument procode.
- Example: hardware or software problem

MDR Analysts in OIVD

- OIVD MDR analysts – who are we?
- Cross-functional staff are familiar with devices
- All OIVD Divisions represented
- MDR analysts also function as:
  - Pre-market Reviewers
  - Consumer Safety Officers

MDR Policy Questions

- Contact: MDR Policy Branch, Division of Post-Market Surveillance (DPS), Office of Surveillance and Biometrics (OSB)

- Questions on what to report:

  email: MDRPolicy@fda.hhs.gov

OIVD MDR Reports

- **In 2009, OIVD received 29,822 (nearly 30,000) MDR reports**
- # 1 Glucose and glucose meters (67%)
- # 2 Chemistry Analyzer (11%)
- # 3 Coagulation testing devices (4%)
- # 4 Troponin (3%)
- # 5 Cell Counter – differential (2%)

How Does OIVD Use MDR Reports?

- Follow up all death reports, “code blue” and 5 day reports
- Request additional information
- Looking for trends (glucose meters)
- MDR reports related to recalls
- Perform analyses of data
- May lead to investigation of event

5 Day Reports

A manufacturer must submit a report within 5 work days of becoming aware of:

- A reportable event that necessitates remedial action to prevent unreasonable risk of substantial harm to the public health or
- A reportable event for which FDA has made a written request for 5-day reports

Code Blue Reports

- Pediatric deaths
- Exsanguination
- Explosion
- Fire
- Burns
- Electrocutions
- Anaphylaxis

MedSun-reports

- Web-based system for voluntary reporting by user facilities of adverse events related to devices
- 350 hospitals and nursing homes
- Identity of reporter kept confidential
- Early signals
  - Helps CDRH and participating organizations detect potential problems

LabNet

The MedSun Subproject For Diagnostic Devices used in Hospital Laboratories

- Provide more active surveillance of IVD's that are on the market than is currently available to FDA
- Cultivate a learning environment where the FDA and the clinical community may interact to discover, understand and solve problems with IVD's

LabNet reports

- Generated by users – not manufacturers
- Real-time adverse event reporting
- Important signals for OIVD
- OIVD works with MedSun staff
- Reports are followed up by OIVD staff
- Other signals looked at for “match”

Public MAUDE Information

- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
- Or go to FDA web page and search “MAUDE”
- Search by word/phrase/year
- Advanced search – more options
- Limitations:
  - Only redacted text in database
  - Updated once a month

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