



Medical Device Reporting 21 CFR 803 Updates

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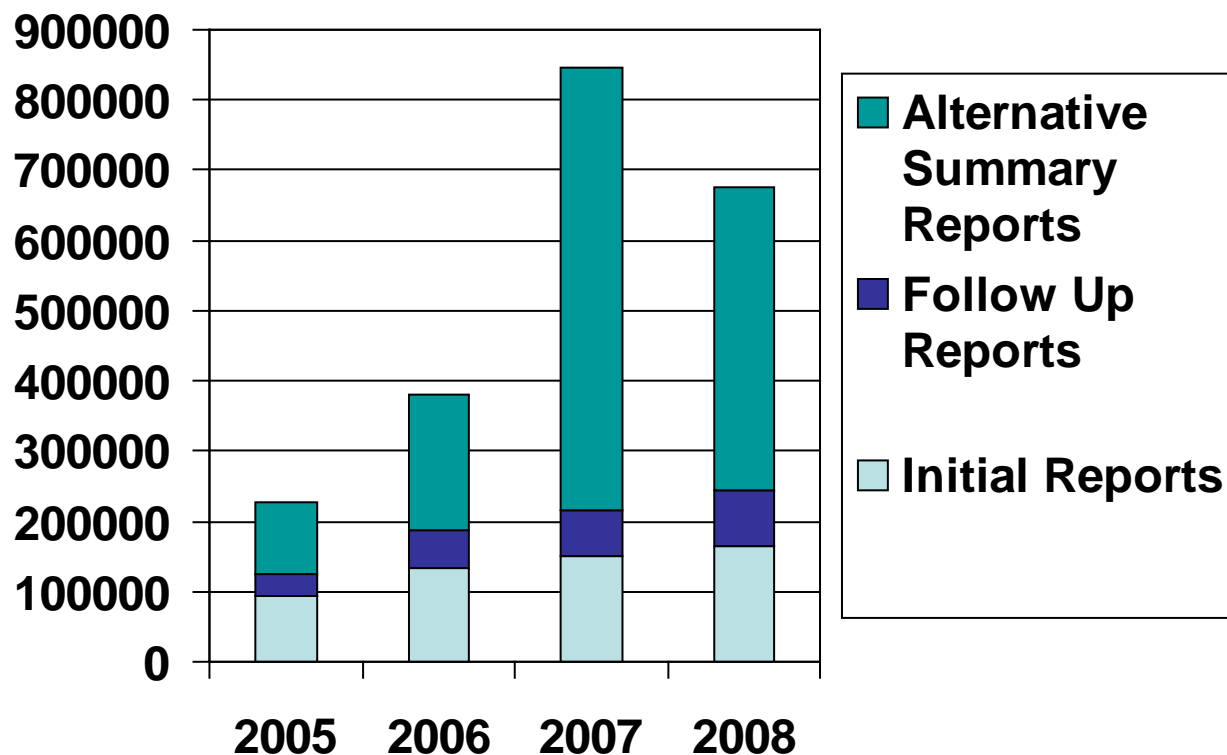
So, What's New in 2009

- Regulation and Legislative Updates
 - eMDR
 - Baseline
 - Summary reporting
 - CDRH event problem codes
 - Guidance documents
- Briefly review key elements of 803
- Identify most common MDR issues seen by RSMB
- RSMB contact information

eMDR Background

- Section 519 of Federal Food Drug and Cosmetic Act requires reports to FDA when a medical device may have caused or contributed to a death, serious injury, or malfunction.
- Reports transcribed into FDA's MAUDE database
- Data entry – 1 day to 6 months
- Number of individual reports increasing

Reports by Calendar Year





FDA MedWatch Form 3500A

Form Approved: OMB No. 0910-0201, Expire: 10/5/09
See OMB statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

For use by user-facilities,
importers, distributors and manufacturers
for MANDATORY reporting

MEDWATCH
FORM FDA 3500A (10/05)

Page ___ of ___

Mfr Report # _____
UF/Importer Report # _____
FDA Use Only

A. PATIENT INFORMATION			
1. Patient Identifier	2. Age at Time of Event: or _____ Date of Birth: _____	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight ____ lb or ____ kg
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)			
2. Outcome Attributed to Adverse Event (Check all that apply)			
<input type="checkbox"/> Death: _____ (mm/dd/yyyy) <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (DeVos)			
3. Date of Event (mm/dd/yyyy)		4. Date of This Report (mm/dd/yyyy)	
5. Describe Event or Problem			
<div style="writing-mode: vertical-rl; transform: rotate(180deg); position: absolute; left: -40px; top: 50%; font-size: small;">PLEASE TYPE OR USE BLACK INK</div>			
C. SUSPECT PRODUCT(S)			
1. Name (Give labeled strength & mfr/labeler)			
#1 _____			
#2 _____			
2. Dose, Frequency & Route Used		3. Therapy Dates (If unknown, give duration) Form(s) (or best estimate)	
#1 _____		#1 _____	
#2 _____		#2 _____	
4. Diagnosis for Use (Initials)		5. Event Abated After Use Stopped or Dose Reduced?	
#1 _____		#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2 _____		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot #		7. Exp. Date	
#1 _____		#1 _____	
#2 _____		#2 _____	
8. Event Reappeared After Reintroduction?		9. NDC# or Unique ID	
#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply		#1 _____	
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply		#2 _____	
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)			
D. SUSPECT MEDICAL DEVICE			
1. Brand Name			
2. Common Device Name			
3. Manufacturer Name, City and State			
4. Model #		5. Operator of Device	
Catalog #		<input type="checkbox"/> Health Professional	
Serial #		<input type="checkbox"/> Lay User/Patient	
Other #		Other: _____	
6. If Implanted, Give Date (mm/dd/yyyy)		7. If Explanted, Give Date (mm/dd/yyyy)	
#1 _____		#1 _____	
#2 _____		#2 _____	
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?			
<input type="checkbox"/> Yes <input type="checkbox"/> No			
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor			
10. Device Available for Evaluation? (Do not send to FDA)			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on: _____ (mm/dd/yyyy)			
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)			
E. INITIAL REPORTER			
1. Name and Address			Phone #
2. Health Professional?		3. Occupation	
<input type="checkbox"/> Yes <input type="checkbox"/> No		4. Initial Reporter Also Sent Report to FDA	
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk.	

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Proposed eMDR Changes to 21 CFR 803

- Revise MDR Regulation to require reports be submitted in an electronic format that FDA can process, review, and archive.
- Ninety Day comment period
- Rule effective one year after publication of final rule

Options for Electronic Reporting

Large Volume Reporting



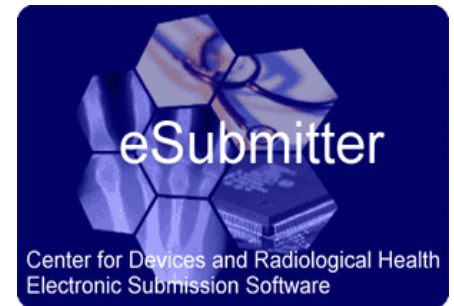
Batch
⇒

FDA Gateway



←
One report
at a time

Small Volume Reporting



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



⇓
MAUDE Database

Low Volume Reporting Option

- FDA developed and maintained
- Free at <http://www.fda.gov/cdrh/cesub/>
- Handles one report at a time
- Fillable version of FDA Form 3500A
- Validates all data
- Send the report to FDA Electronic Submissions Gateway
- FDA responsible for proper operation and validation if you use it as is

High Volume 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 electronic submission
- Capable of sending multiple report submissions at a time
- Minimal human interaction compared to low volume option

eMDR Pilot Program

- May 2007 solicited volunteers to help test electronic submission
- May 2008 announced electronic MDR submission is an acceptable alternative to filing reports on paper
- Low Volume option - 21 firms indicated interest 29 firms actively submitting
- High Volume option - 8 firms indicated interest 4 firm actively submitting
- Three third party complaint handling software developers adding electronic submission option to their systems

No More Baseline Reports!

- Federal Register Proposed Rule and 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 deleted

Summary Reporting...

- FDAAA 2007 - Sec. 227 - Reporting Frequency
- Firms submit reports quarterly in summary form for devices not subject to individual reporting
- FDA is considering options for implementing this legislation

CDRH Event Problem Codes

- CDRH Event Problem Code initiative to update the codes
- Website:
<http://www.fda.gov/cdrh/problemcode>
- July 1, 2009: FDA accepting new codes
- April 2, 2010: Target date to reject all inactivated and retired codes

MDR Guidance Documents

Updating and incorporating Good Guidance Practices Principles

- Medical Device Reporting for
Manufacturers
- Medical Device Reporting for User
Facilities

Data Flow and Reporting Timeframes



User Facility

Death & Serious Injury - 10 work days

Deaths (all), Serious Injury (when mfr unknown) - 10 work days



Importer

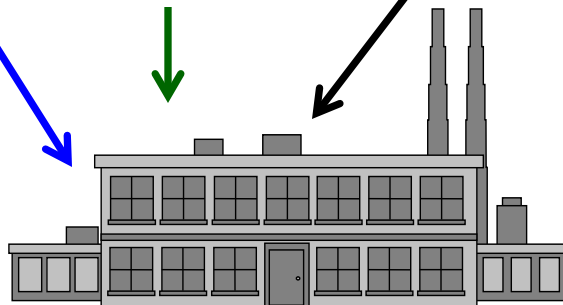
Death, Serious Injury & Malfunctions - 30 calendar days

D & SI →

Other Sources

Deaths & Serious Injuries

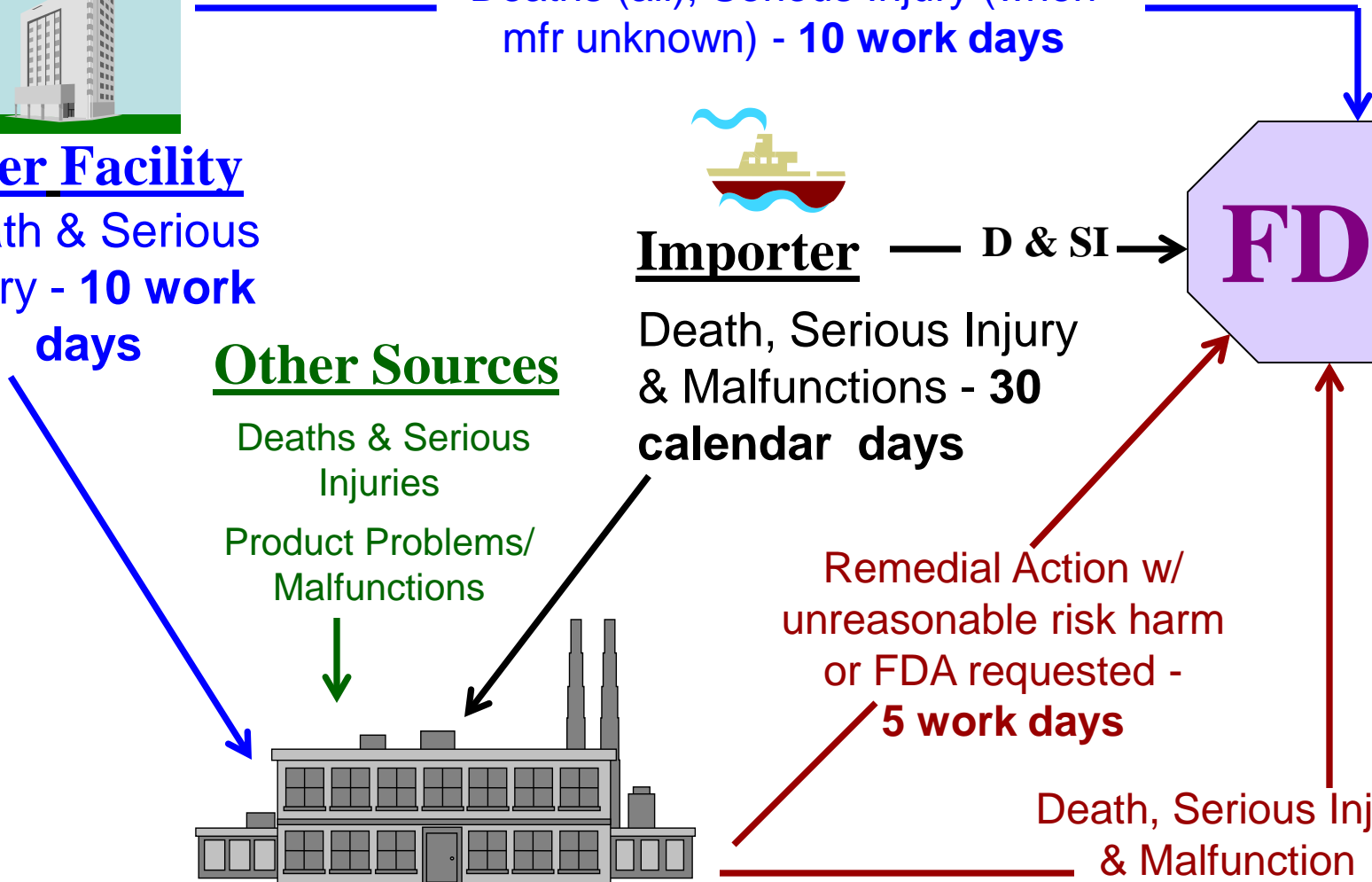
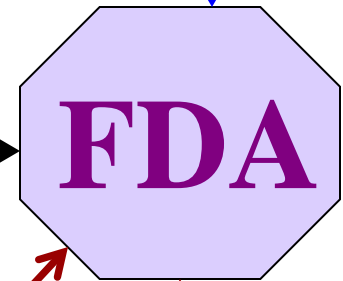
Product Problems/ Malfunctions



Manufacturer

Remedial Action w/ unreasonable risk harm or FDA requested - 5 work days

Death, Serious Injury & Malfunction - 30 calendar days¹⁵



What is a Serious Injury ? (§803.3)

A reportable serious injury is defined as an injury or illness that is:

- life-threatening; **or**
- results in permanent impairment or damage to a body function or structure; **or**
- requires medical or surgical intervention to preclude permanent impairment or damage to a body function or structure

“Caused or Contributed”

Caused or contributed is defined as:

- death or serious injury that was or may have been attributed to a medical device **or**;
- a medical device that was or may have been a factor in a death or serious injury, *including* events resulting from:
 - Failure
 - Improper / inadequate design
 - Malfunction
 - Manufacturing (problems)
 - Labeling (problems)
 - User error

What is a Malfunction ? (§803.3)

A reportable device malfunction is:

- Failure of a device to meet its performance specifications or otherwise perform as intended **and**;
- Likely to cause or contribute to a death or serious injury if the malfunction were to recur



Preamble Guidance On Malfunctions

A malfunction is reportable if any one of the following is true:

- (1) The chance of a death or serious injury ...is not remote;
- (2) ... affect the device in a catastrophic manner ...
- (3) ... failure of the device to perform its essential function and compromises the device's therapeutic, monitoring or diagnostic effectiveness ..., not only to the device's labeled use, but for any use widely prescribed within the practice of medicine);

WWW.GPOACCESS.GOV/FR

ADVANCED SEARCH; 1995 VOL 60; "MEDICAL DEVICE REPORT"

Preamble Guidance On Malfunctions (Cont.)

- (4) ... long- term implant or ... life-supporting or life-sustaining ...; or
- (5) the manufacturer takes or would be required to take an action under sections 518 or 519(f) of the act as a result of the malfunction of the device or other similar devices.

Common MDR Issues...

- MDR procedures are inadequate to comply with the MDR requirements
- Procedures are inconsistent among different reporting divisions within a single medical device company
- MDR reporting procedures contain elements not included in 21 CFR Part 803
 - Mixing foreign requirements with FDA requirements
 - Sometimes same term has different regulatory meanings

Common MDR Issues...

- Failure to investigate complaints
- Complaint files do not include MDR decision-making process
- Failure to consider whether a device caused or contributed to an event
- Misunderstanding of the definition of reportable malfunction, and when to file a malfunction MDR
- Complaint information identifies a reportable event – No FDA Form 3500A filed

Common MDR Issues...

- Incomplete event descriptions
 - Serious injury or death – **what happened to patient before, during and after the event?**
 - Medical/surgical intervention required?
- Incorrect classification of events
 - Use of “Other” for mandatory report types
 - Filing device related death or serious injury adverse events as malfunction MDRs
- Missing or incomplete Block H device evaluation and conclusion information

Common MDR Issues...

- Inappropriate use of Block H7 & H9 of FDA Form 3500A – re: Remedial Action
 - Should identify an action other than routine maintenance or servicing of a device to prevent recurrence of a reportable event
 - Action taken to fix a single device involved in an MDR reportable event is not a remedial action

Common MDR Issues

- Incorrect completion of Block D8 of FDA Form 3500A – re: Reuse of Single-use device
 - The question reads “Is this a Single use Device that was Reprocessed and Reused on a Patient?”
 - Mark yes if the device was a single-use device that was reprocessed and reused on a patient
 - Otherwise, mark no



MDR Regulation Interpretation and Policy Questions:?

Contact the Reporting Systems Monitoring Branch

Phone:

Fax:

Email: rsmb@cdrh.fda.gov



Mail address: RSMB, CDRH/FDA, WO 66, Room 3208, 10903
New Hampshire Ave., Silver Spring, MD 20993-0002

For MDR materials and information on-line, go to:

<http://www.fda.gov/cdrh/mdr>

CDRH's New Home



CDRH/FDA, WO 66, 10903 New Hampshire Ave.,
Silver Spring, MD 20993-0002