PROPOSED MDR GUIDANCE

CDRH 7-9-13

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WHY IS THIS ON THE AGENDA!

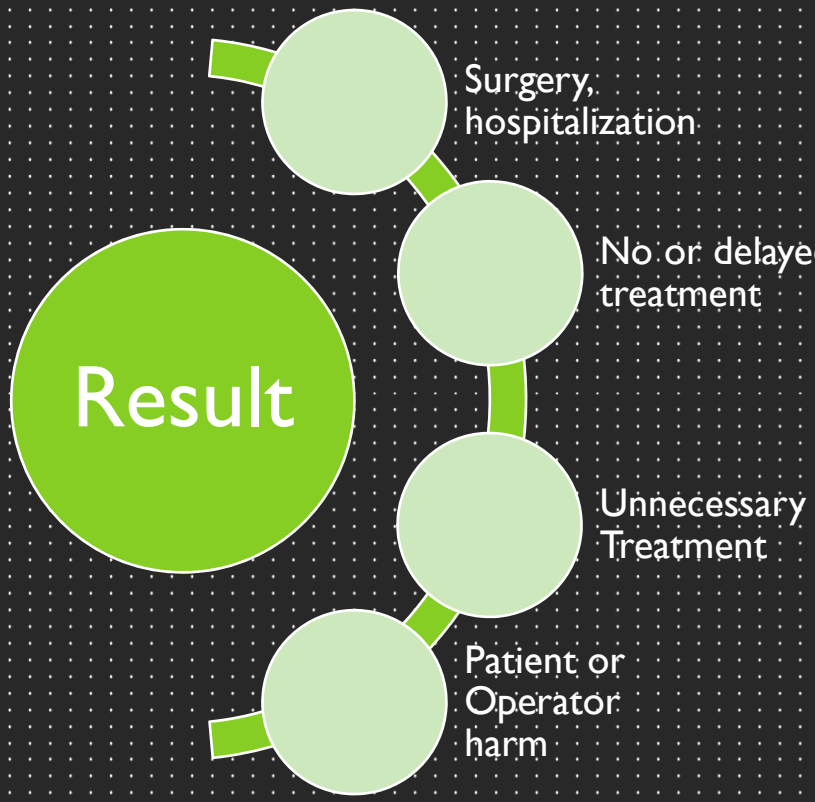
- MDR has been around a long time
- Most of the audience are IVD Industry
  - Always been a little grey
  - Pretty comfortable with FDA expectations
  - Large firms have robust reporting programs
- July 9, 2013: New proposed guidance document issued 1st in 16 years
- A few significant issues

MDR & IVD DEVICES

"I'm supposed to look at MDRs, but I don't suspect you have any. I mean what could happen? The instrument falls off the lab bench and breaks the Tech's foot." *Ha Ha*

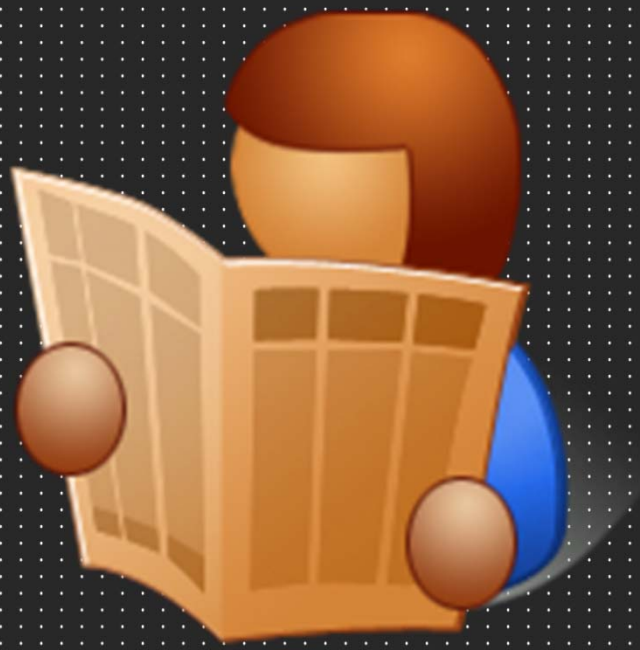
Incorrect or misleading test results impact patient management

MDR & IVD DEVICES



READ IT

- Available on Website
- Comments closed
- Non-binding
- Q&A format
- ~ 50 pages
- Lots of language from 21 CFR Part 803 & 1997 guidance
- Good list of 3500A mistakes



SIGNIFICANT PROVISIONS

MDR APPLIES TO ALL DEVICES

- FDAAA 2007 statutory requirement for summary, periodic reports ONLY for
  - Class 1 & 2
  - Non-life supporting, non-life sustaining or not permanently implanted
  - Big deal for IVD
- No mention of timeline for this rule change
- FDA is supposed to issue a ruling, and missed this opportunity

HOUSEKEEPING

Annual Certification

Baseline Reporting

DUAL REPORTING BURDEN

- Foreign Manufacturer + Importer
- Contract Manufacturer + Spec Developer

- Both have to report
- Need to obtain FDA exemption for filing
- Joint Request

THE 2-YEAR RULE TODAY

- Once a MALFUNCTION has caused or contributed to a serious injury or death
- Presumption that future occurrences of the malfunction are LIKELY to cause or contribute again
- Thus all recurrences of the malfunction are REPORTABLE
- If after 2 years from the first report there have been NO recurrences, the presumption is gone

THE 2-YEAR RULE FUTURE

- The 2 year rule is gone!
- Manufacturers have an "OBLIGATION" to continue to report all recurrences …

BUT

- A manufacturer may submit "DOCUMENTATION" that the malfunction has not caused or contributed to additional serious injuries or death, and apply for an exemption

IMPORTANT CLARIFICATIONS

BE CAREFUL WHAT YOU ASK FOR

IMPORTANT CLARIFICATIONS I

- What does "LIKELY" mean?
  - Soft Language retained
  - Catastrophic (to the device) Malfunctions that "may" lead…
  - Failure of the device that "could" lead…
- User Error
  - Incorrect Use if *likely to cause*

IMPORTANT CLARIFICATIONS 2

- Delay of surgery
  - No longer need to report based ONLY on delay
  - Delay has to be *likely to cause*
- Manufacturer's Investigation of MDR Complaints
  - Good Faith Effort includes a minimum of 1 written request to obtain more info
  - Firm must analyze even if the device is not returned *w/* similar devices

IMPORTANT CLARIFICATIONS 3

- Expected device life (record keeping)
  - Cannot use warranty period
  - Time expected to remain functional including maintenance and calibration cycles
- Alarms
  - If an alarm alerts the user before there is any harm, reportable as a malfunction if *likely to cause*

IMPORTANT CLARIFICATIONS 4

- Risks or Complications in labeling
  - "Anticipated or intrinsically caused . . . not exempt
  - What does this mean for IVD limitations?
  - Only time will tell . . .

SUMMARY

- Loss of the 2-year rule increases burden
- Lack of language supporting FDAAA 2007 is disappointing for IVD Manufacturers
- Clarification in the Q&A format:
  - Mixed Blessing
  - Greater Understanding = Less Interpretation

THANK YOU FOR YOUR ATTENTION