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# Post-market and Compliance

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**FDA/AAPM Symposium**
**August 2, 2016**

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1. Pre-market
2. Post-market
3. Regulatory research
4. Collaborations



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## Outline

- Postmarket Surveillance
  - Medical Device Reports (MDR)
  - Accidental Radiation Occurrences (ARO)
- Recalls
  - Medical Device (806) Corrections and Removals
  - Rad Health (EPRC) Defects and Failures to Comply
- Manufacturer Establishment Inspections
- Trade Complaints

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# Postmarket Surveillance

- Individual adverse event reports
- Reviewed by limited staff for trending and follow-up
- Can be used to influence premarket questions and decisions



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# Medical Device Reports (MDR)

- User facilities report to manufacturers:
  - Deaths
  - Serious injuries
- User facilities report to FDA:
  - Deaths
  - Serious injuries when manufacturer is unknown
- Manufacturers report to FDA:
  - Deaths, serious injuries, malfunctions

**Serious injury:** Life-threatening, results in permanent impairment or damage, or necessitated medical intervention



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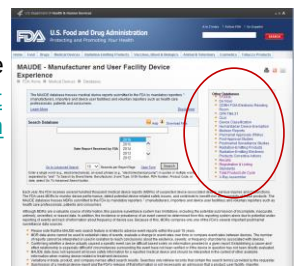
- Publically Available http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm



# AccidentalRadiation Occurrence (ARO)

- Manufacturers report to FDA:
  - Injurious or potentially injurious exposure to electronic product radiation
- Examples (x-ray):
  - Unexpected exposure
  - Intentional exposure but higher dose than expected
  - Accidental exposure at no fault of the machine





# MDR and ARO Reporting Criteria

- MDR Event
  - One (or more) events
  - Involving anyone
  - Not limited to radiation exposure
  - Involving a medical device
  - *Which may have contributed to death or serious injury (or could if recurred)*
  - Reported by a **user facility or manufacturer**
- Accidental Radiation Occurrence
  - One or more events
  - Involving anyone at any time
  - Resulting from machine produced radiation
  - Not limited to medical devices
  - *Which is injurious or potentially injurious*
  - Reported by **manufacturers**
  - Not required if the event meets reporting criteria for MDR





# FDA/CDRH's MedSun Program

- Network of 250 hospitals nationwide
- Provides CDRH direct communication with the reporting hospital
- Provides opportunities to obtain experience and expertise of both clinicians and technical staff

# Post-Market Information Follow-up

- There are several possible actions resulting from post-market information review:
  - MDR or ARO additional information letter
    - Requests clarification of submitted information
  - Initiate a recall
  - Asking questions in a premarket review
  - Broader discussion with industry





# Recalls





# Corrections & Removals (806)

- Reported to FDA if done to reduce risk or to correct a violation of the FD&C Act
- FDA evaluates risk and ensures that corrections were implemented
- Voluntary
- Information is publically available
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm

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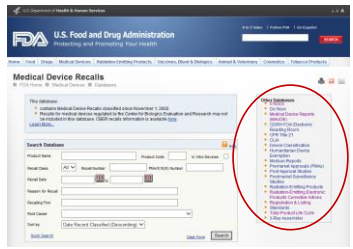




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# Defect/Failure to Comply (1003)

- Corrections related to Electronic Product Radiation emission and/or Performance Standards
- Corrective actions must be reviewed and approved by FDA
- Corrections made at no charge



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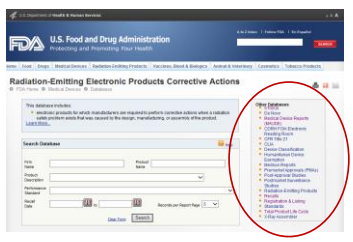
- Publically Available http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/rh_res.cfm



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# Inspections

- Field investigators perform site inspections
- Reports of findings are reviewed and corrections are enforced
- Evaluates the design and manufacturing process
  - Largely a visual and paperwork review
  - Little, if any, device testing is performed by investigators
- Significant enforcements are publically available
  http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/

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# Trade Complaints

- Can come from anyone, even ourselves
  http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095859.htm
- Followed up on an individual basis
- Can result in:
  - Product recalls
  - Simple questions to a manufacturer
  - Letters to industry
  http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm111104.htm

https://goo.gl/eg9hRv

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# What can you do?

- Send complaints to the manufacturer
- Identify safety problems with quality MDR reporting
  - Providing detailed device information
  - Detailed event description
- Identify safety signals to ensure safe and effective devices are on the market (trade complaints)

https://goo.gl/eg9hRv

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# References

- 21 Code of Federal Regulations
  http://www.ecfr.gov/cgi-bin/text-idx?SID=30f6447420c11e3a4b37caf5c1aa9a12&mc=true&tpl=/ecfrbrowse/Title21/21cfrv8_02.tpl#0
- Medical Device Reporting (MDR):
  http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm
  - Manufacturer and User Facility Device Experience (MAUDE)
    http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
  - MedSun Program
    http://www.fda.gov/medicaldevices/safety/medsunmedicalproductsafetynetwork/
- ARO Reporting
  http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/ucm202505.htm



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# References

- Corrections and Removals
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
- Defects/Failures to Comply
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/rh_res.cfm
- Enforcement Actions (Warning Letters)
  http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/
- Letters to Industry
  http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm111104.htm
- Submitting Trade Complaints
  http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095859.htm