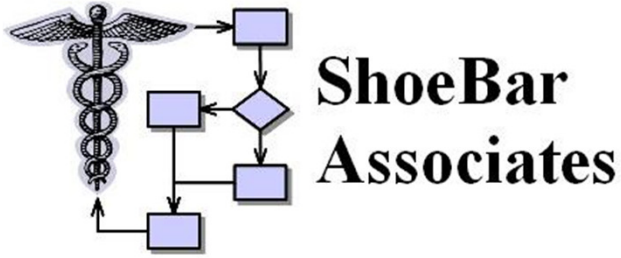

The Shifting Picture of Software Compliance, at Home and Abroad

Brian Shoemaker, Ph.D. *ShoeBar Associates*

Dan Sterling, *Sterling Smartware Solutions*

Who We Are - Brian

- Originally an analytical chemist
- 15 y in clinical diagnostics (immunoassay):
  analytical support → assay development → instrument software validation
- 6 y as SW quality manager (5 in clinical trial related SW)
- 5 y as independent validation consultant to FDA-regulated companies – mostly medical device
- Active in: software validation, Part 11 evaluation, software quality systems, auditing, training

Who We Are - Dan

- Founder of Sterling Smartware Solutions
  - Medical Device Software and Electronics Development and Testing
  - Quality System Setup, Consulting
  - ISO 13485 Registered
  - IEC 62304, ISO 14971 & 60601 Compliant

- Experience
  - Since 1998, Exclusively Medical Device
  - Over 200 Projects Completed
  - Numerous FDA and CE approvals
  - Class I, II, III – Implants, Externals, Telemedicine, HIS
  - Imaging, Pumps, Ablation, Ultrasound, Pacer/Simulators, etc.
  - Diagnostics and Therapeutics

Disclaimer

Our strength is in software development and quality, and we work closely with medical device regulatory experts. However, for specific issues of regulatory strategy or general device regulations, please consult your company's regulatory affairs specialists or consultants.

The Shifting Picture of Software Compliance

- **History: SW errors can create safety concerns**
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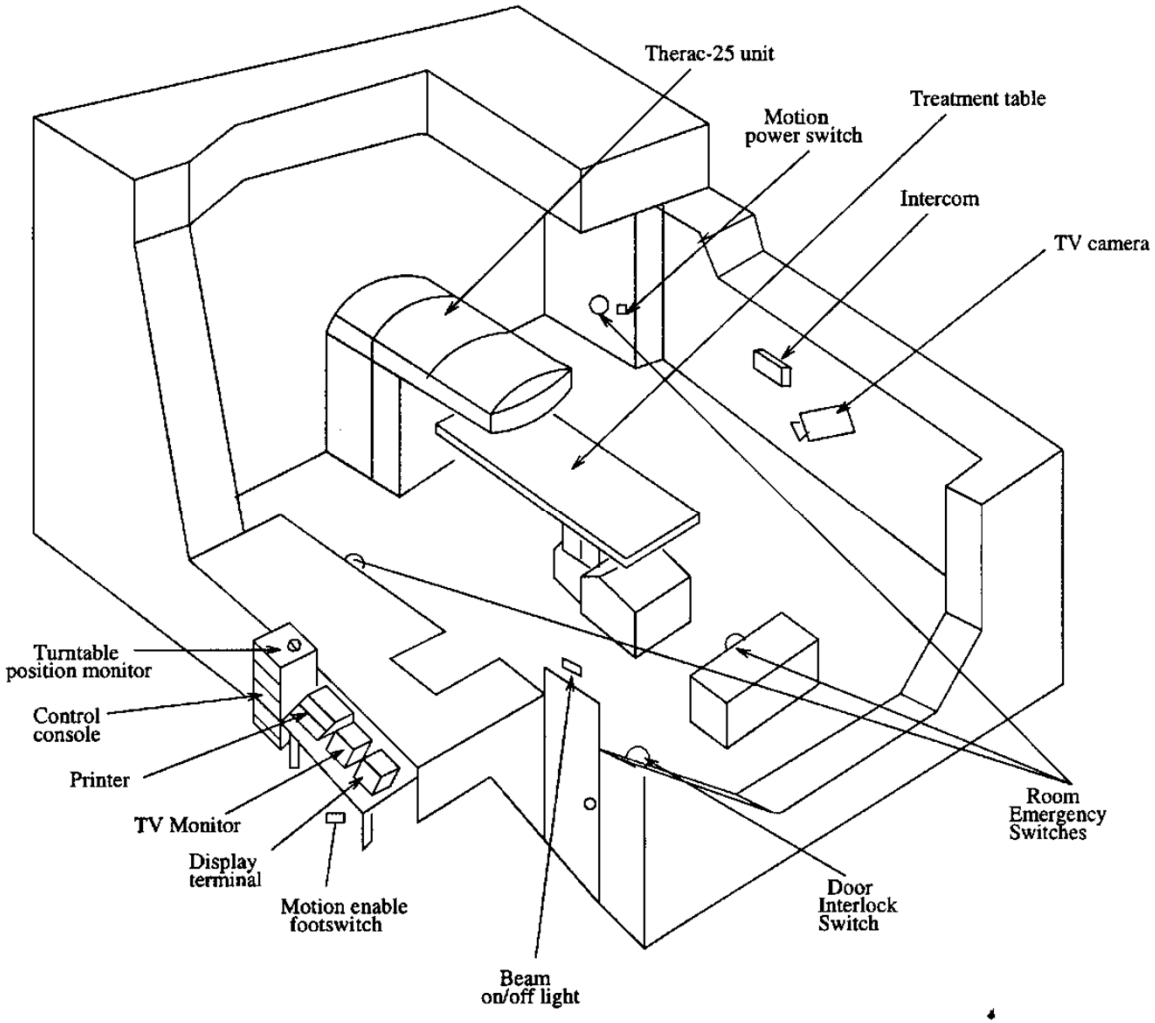
Therac-25: The lessons are still valid



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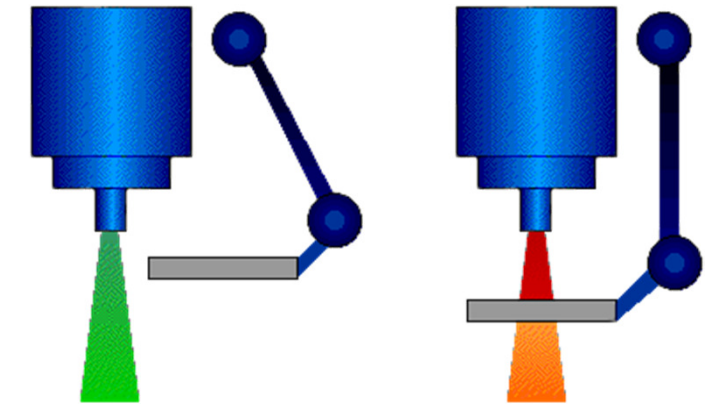
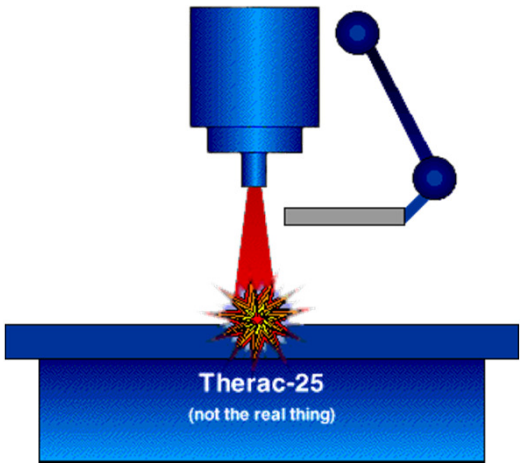
Therac-25: Brief Summary

- Linear accelerator system built for cancer therapy
- Instrument was further advancement of earlier models (controlled entirely through software)
- 11 Units installed in US / Canada; hundreds of patients treated (thousands of treatments)
- Mechanism: radiation beam destroys cancer tissue
  - Electron beam treats shallow tissue
  - X-rays penetrate deeper, minimal damage to overlying area
  - X-rays produced by hitting metal target with high-energy electrons
- Six overdose accidents (3 fatal): June 1985, July 1985, December 1985, March 1986, April 1986, January 1987
- Overdoses (~100x intended dose, ~20x lethal whole-body dose) traced to two specific software errors

The Therac-25 Safety Issue

- Single electron gun produces both modes
- In x-ray mode, electron energy must be ~100x higher (target is a good attenuator)
- Low energy + target = underdose
  High energy + no target = huge overdose





More Recent Examples Abound (1)

- **November 5, 2010: Pole-mounted infusion pumps recalled**
  http://www.fda.gov/Safety/Recalls/ucm232983.htm
  Nationwide recall of a specific model of pole-mount infusion pump after discovery of a problem with the pump door open alarm. If pump door is not closed and latched properly, door open alarm may not alert the user to the problem. If door is not closed, pump may not be engaged and gravity flow can occur, possibly resulting in over-infusion of medication.
- **July 20, 2010 - MHRA Issues Alert for EEG Recorder**
  http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON088079
  UK Medicines and Healthcare products Regulatory Agency (MHRA) issued an alert for a specific model of EEG Recorder. The standard system has a left/right headbox configuration, but systems with software versions 5.3, 5.4 and 5.7 also have right/left headbox configurations. Operators could potentially confuse EEG outputs from the left and right sides of the brain when using the right/left configurations.
- **July 13, 2010 - Class I Medical Device Recall: Infusion Pump PC Units**
  http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm229651.htm
  Under certain wireless network conditions, a communication error can occur, which freezes the PC Unit screen. This error may result in a delay of therapy and inability to make programming changes to current infusions. If the communication error occurs during infusion, infusion continues on all channels, as originally programmed, but cannot be modified. When this error occurs, stopping the infusion to make any modification or programming changes causes the PC unit to shut down resulting in a delay or interruption in therapy. This could lead to serious injury and/or death.

More Recent Examples Abound (2)

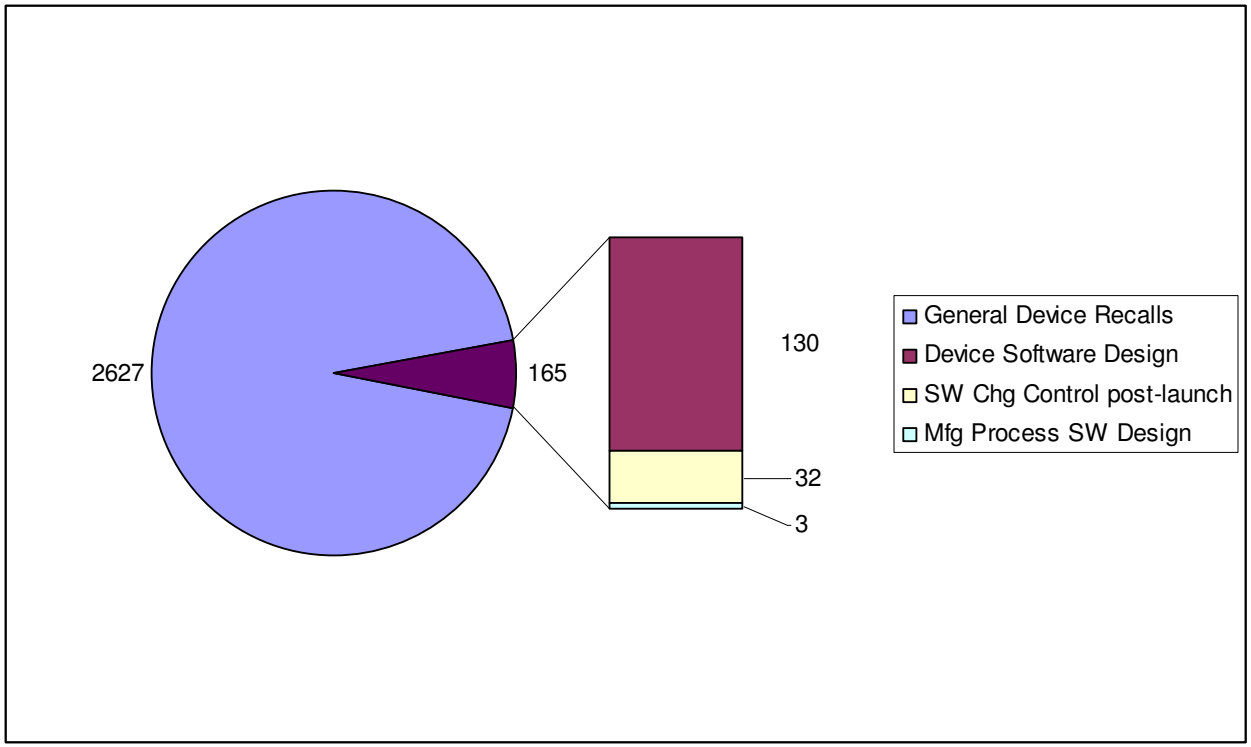
- **July 12, 2010 - Alert Issued for Linear Accelerators**
  http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON087777&RevisionSelectionMethod=LatestReleased
  In a specific linear accelerator system, if a patient treated in a system with software version 6.X is then treated in another using version 7.X, the device could run the patient into the gantry. This is due to differences in the remote auto motion settings and rules between the software versions.
- **April 30, 2010 - Class I Medical Device Recall: Vision System**
  http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm219660.htm
  Manufacturer identified both software and hardware problems associated with unexpected system power loss (shutdowns), unintended system error messages, unresponsive touchscreens, and system setting and infusion performance problems. Events may cause eye injuries, including blindness.
- **March 2, 2010 - In-home dialysis machines recalled**
  http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm202871.htm
  Peritoneal dialysis devices removed from the market after reports of serious injury and one patient death over the last two years (Class I recall). FDA said the company's in-home dialysis machines are linked to an increased risk of "overfill" of fluid in a patient's stomach. Planned corrective actions include a software update and additional training to address the issue.

Safety Issues – Even Standalone S/W

- **June 2001: Radiation treatment planning software**
  http://www-pub.iaea.org/MTCD/publications/PDF/Pub1114_scr.pdf
  Software used to calculate dose duration for radiation treatment of cancer would allow use of no more than four protective blocks (stated in the user guide). Physicians at Natl. Cancer Institute in Panama devised a way to "fool" the software into using five blocks, by entering data as if they were a single shape. If coordinates entered a specific way, the calculated dose would be as much as twice that intended. Users did not confirm calculated results; at least five patients died as a direct result of overexposure to radiation.

CDRH First Analyzed Software Recalls

CDRH study: 2792 total medical device recalls, 1983-1991



- 165 recalls (6% of total) software-related

Of the 165:

- 133 (81%) Inadequate software design
- 32 (19%) Post-launch software change control

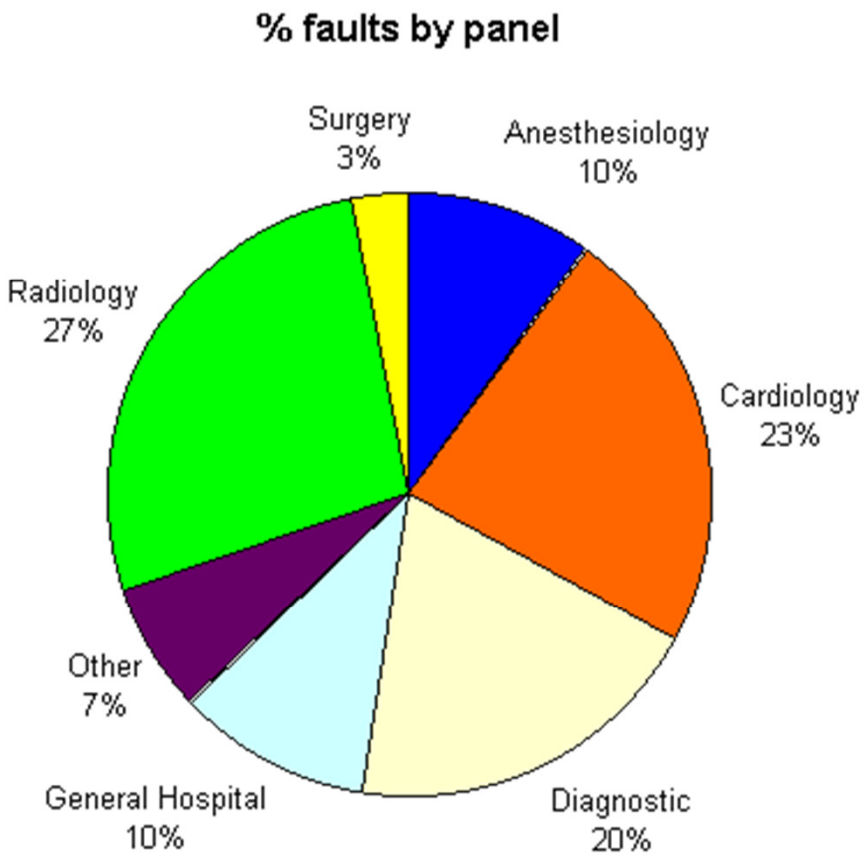
Source: FDA CDRH, 1992.

NIST SW recall study: most extensive

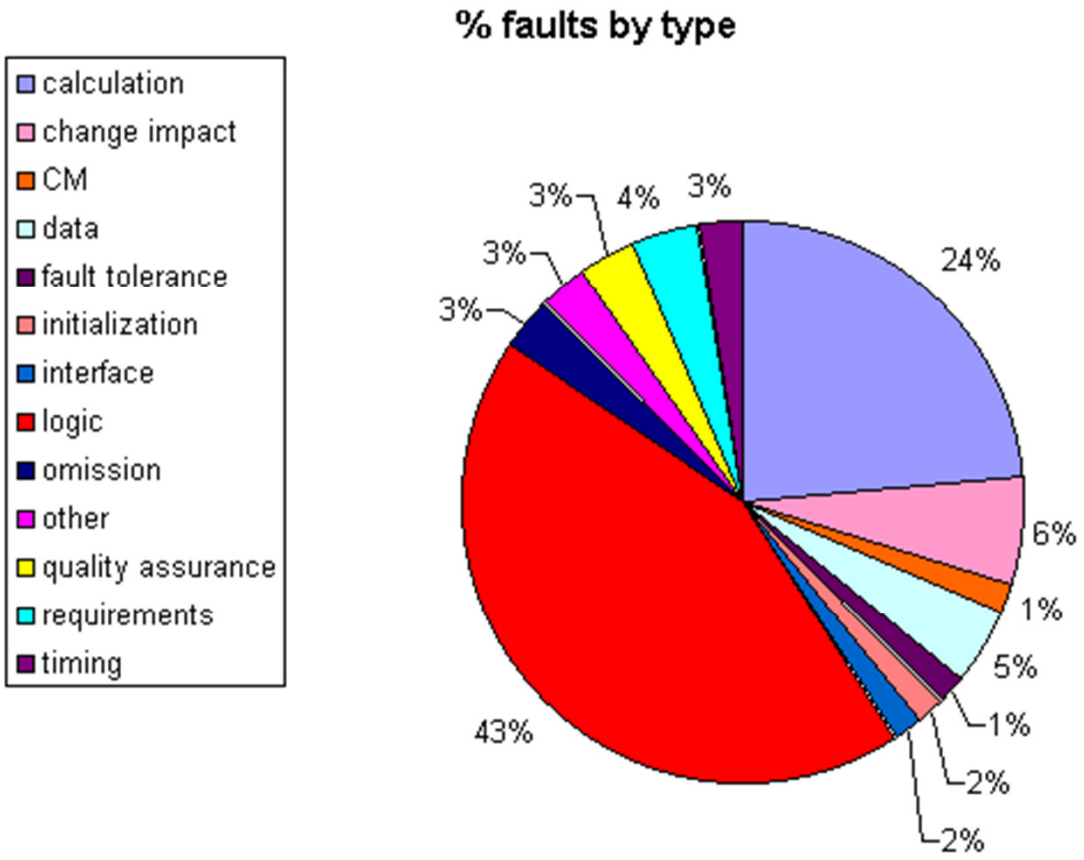
D. Wallace & R. Kuhn (NIST, 1999):

- 383 SW-related device recalls
- Manufacturer recalls 1983-1997
- No deaths or serious injuries
- Data only from FDA records
- Could only classify fault type for 342

NIST Recall Study – Device Types



NIST Recall Study – Fault Types



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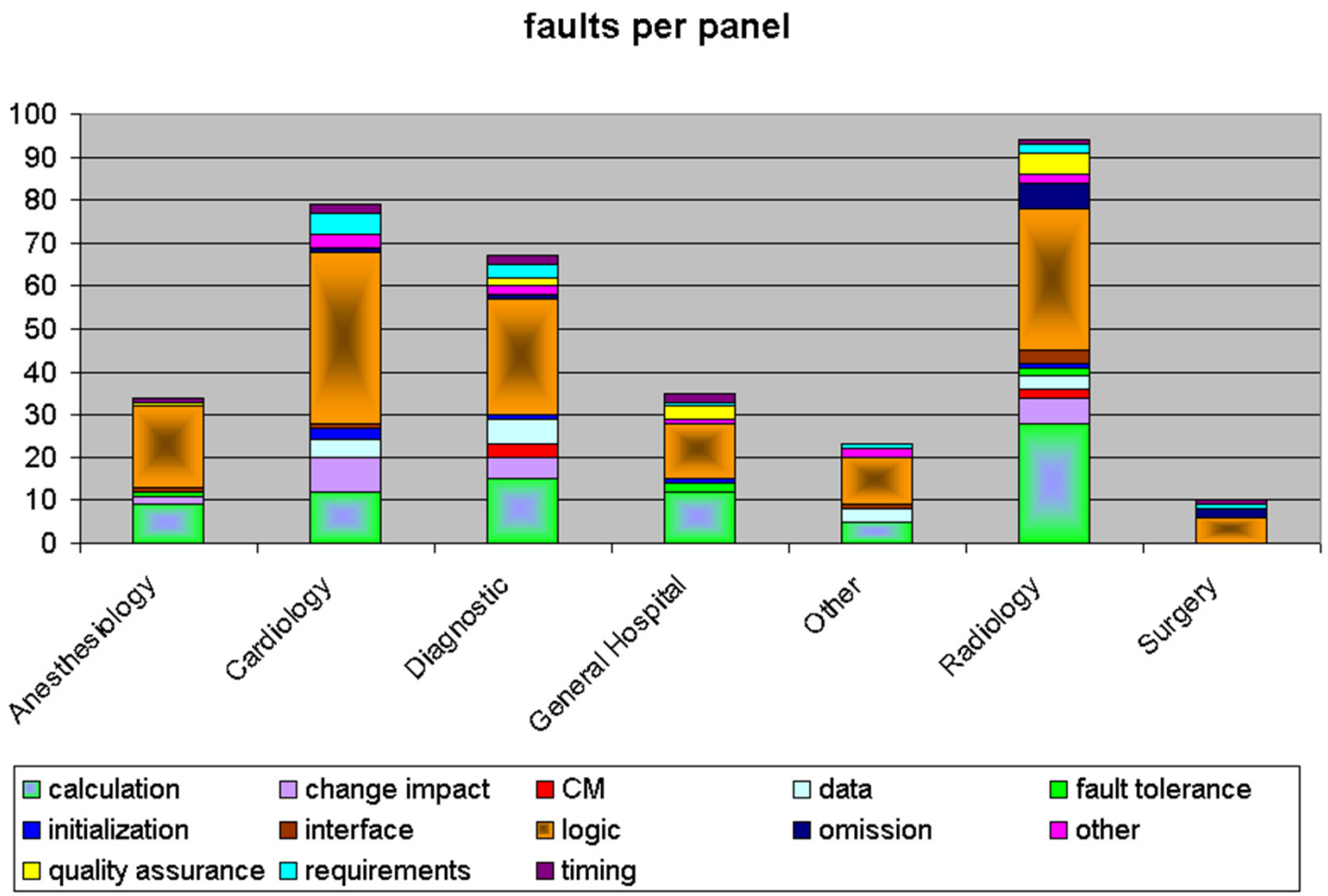
NIST Recall Study – Fault Distribution



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NIST Recall Study: Practices Suggested

- Development / Maintenance – *prevent errors*
  (complete rqmts, traceability, config mgmt, change impact analysis, domain expertise)
- Quality Assurance – *prevent errors, at another level*
  (inspection/review, mental execution of trouble spots, code reading, simulating complex situations)
- Testing – *detect errors*
  (build cases to elicit known problems, stress test, regression test, focus on interface values in integration tests, record test results, esp. failures)
- Authors have placed paper, and failure types / prevention techniques for C++ and OO, on an NIST site (http://hissa.nist.gov/effProject/handbook/)

Recent Studies – More Limited

Bliznakov et al.: data from 1999-2005 (>3700 recalls)

- Not clear how recalls were attributed to SW
- (*SW failure recalls*)/(*total device recalls*) and (*Recalls of SW-contg devices*)/(*total device recalls*) both generally increasing
- Concluded: (a) significant increase, device recalls for SW failures, (b) ~1/3 recalled devices use SW, (c) one of every 3 SW-contg devices has failed due to SW

Yang and Hyman: data from 2009 only (2355 recalls)

- Searched only for word “software” – many others could be SW related, not caught
- Classified failures by symptoms (system, function, data, dislpay, alarm/alert, approval, documentn, other)

FDA – Various Regulations / Guidance

- 21 CFR Part 820 Quality Systems Regulation
- 21 CFR Part 814 Pre-market approval of Medical Devices
- 21CFR Part 11 Electronic Records, Electronic Signatures
- FDA Glossary of Computerized System and Software Development Terminology
- General Principles of Software Validation; Final Guidance
- Guidance, Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software
- Guidance for Off-The-Shelf Software Use in Medical Devices
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Key Points

- Part 820: have a quality system
  (patterned after ISO 9000)
- General Principles of SW Validation:
  Include standard, accepted activities in software development lifecycle
- OTS Software Guidance:
  You, the device maker, are responsible, no matter who wrote the code!
- Premarket Submissions Guidance:
  Docs to submit based on "Level of Concern"

The Shifting Picture of Software Compliance

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FDA has two main charges

- Protect the public health
  - Food: contamination (BSE, salmonella, mercury) or adulteration
  - Drugs: contamination, dangerous AEs, counterfit products
  - Devices: dangers from malfunction or misuse
- Promote innovation in medical technologies
- For devices, benefit vs. risk weighs:
  - **Safety**: can malfunction/misuse harm patient, caregiver, or bystander?
  - **Effectiveness**: Does the device achieve the claimed result?

History: Increasing FDA Device Authority

- 1938: Food, Drug, and Cosmetic Act
  Regulation of medical devices limited to postmarket - adulteration or misbranding
- 1976: Medical Device Amendments
  Today's 3-tiered framework established; two paths to market set up
- 1986: Substantial Equivalence guidance issued
  Questions & flowchart for determining SE – intended use, technological characteristics
- 1990: Safe Medical Devices Act
  Statutory defn of SE; special controls, postmarket surveillance
- 1997: FDA Modernization Act
  "Least burdensome" provision (among others)
  also *Design Control Guidance* and *Genl Principles SW Validation*

Foundation: Risk Classification

- **Class I: low risk**
  pH meter; manual toothbrush; examination gloves
- **Class II: moderate risk**
  Autotransfusion apparatus; OTC pregnancy test; wireless esophageal imaging system; pediatric open hospital bed; implanted spinal cord stimulator
- **Class III: high risk**
  Hip or knee prosthesis; neurosurgical laser; needle destruction device; dental implant; artificial heart; implanted programmable infusion pump

Risk Class → Path to Market

- Many class I: premarket submission not required (i.e. exempt)
- Most class II: 510(k) premarket submission for clearance to market (substantial equivalence to predicate)
- Class III: premarket approval – patient data, clinical trial (almost always)

Cost, Speed make 510(k) Preferred

- Substantial Equivalence:
  intended use, technology, same questions of safety / effectiveness (i.e. engineering & labeling)
- Premkt Approval: clinical studies (time, $$)
- Review time goals
  510(k) = 90 days
  PMA = 180 days
  Though typical reviews longer for both
- Approx. 90% devices cleared by 510(k)

Even 510(k) becoming tighter

- Devices with history of problems: FDA instituting "Improvement Initiatives"
  - Engineering info AND clinical data
  - Infusion pumps, automated external defibrillators
- As well, "human factors" emphasis requires usability studies
- Congress pressuring FDA to tighten device clearance / approval process
- Notion spreading that 510(k) is "less stringent" (than PMA) and therefore more likely to allow unsafe devices to be marketed

Device Mfrs Complaining about 510(k)

- Reviewers have become risk-averse
- Overall review times extremely long
- Reviewer questions / requests for data increased
- Suggestions made in “pre-IDE” meetings but later rejected
- In general, process viewed as frustrating and unpredictable

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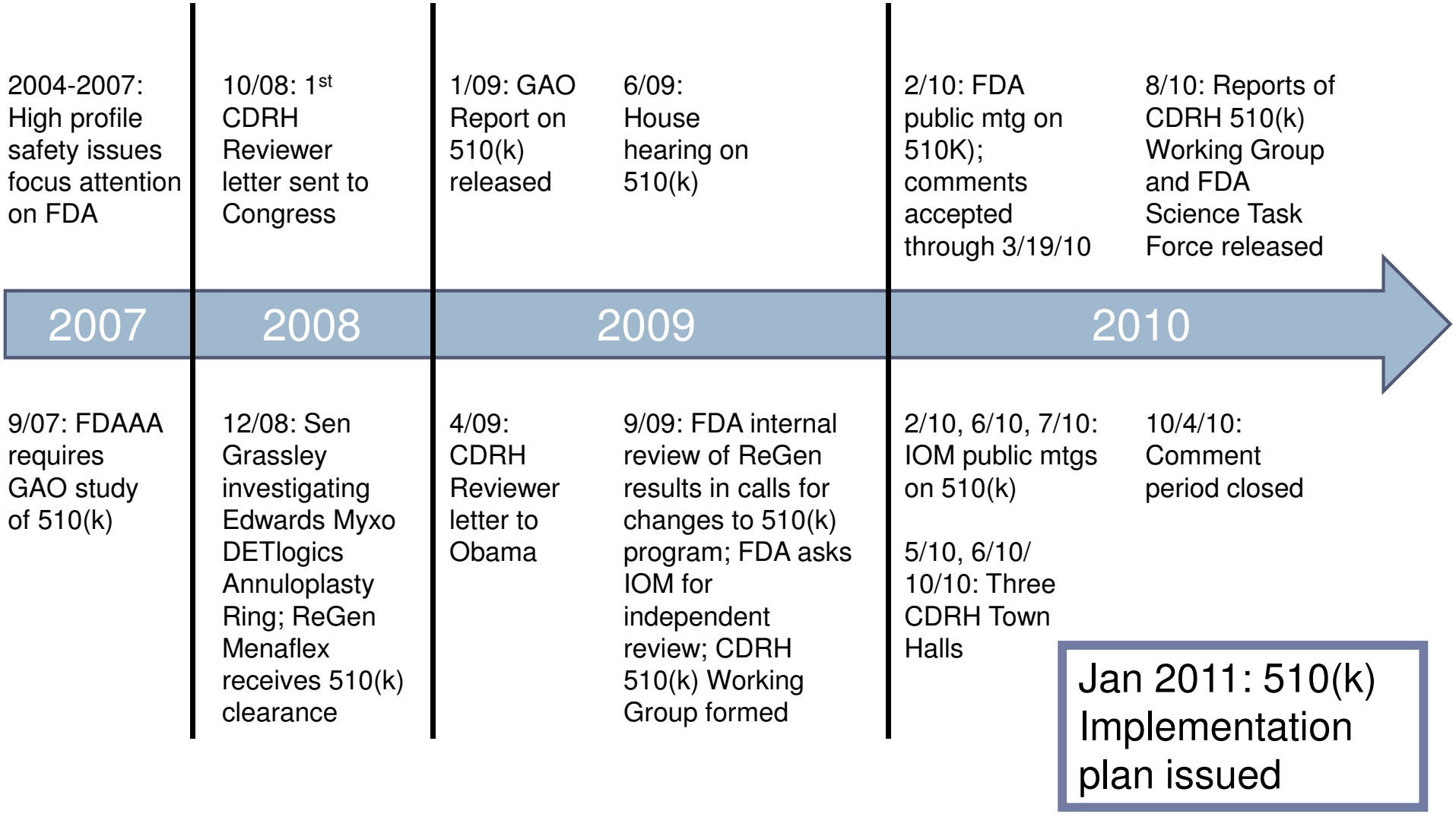
Recent: LOTS of focus on 510(k) Process



Reports Present Grouped Proposals

- Ensure 510(k) review standard is clear and consistently interpreted
- Improve CDRH's ability to make well-informed decisions
- Subject CDRH decisions to continuous quality assurance
- Enhance CDRH knowledge base
- Respond to new scientific information and communicate new thinking by the agency

In following slides, bolded proposals relate to SW

Clear / Consistent Review Standard

Clarify "Substantial Equivalence"

- *Consolidate "indications for use" / "intended use"*
- *Guidance on characteristics included in "intended use"*
- *Staff training on "Intended Use"*
- *Possible amendment, off-label use*

* **Reconcile language in 510(k) flowchart w/statute** (technological characteristics vs. diff questions of safety & effectiveness)
* **Revise guidance for clear criteria on "different questions of safety & effectiveness"**

- *Staff training on "different questions of safety & effectiveness"*

Clear / Consistent Review Standard

Improve Predicate Comparisons

- *Provide guidance on when a device should no longer be used as predicate*
- *Possible regulation for rescinding 510(k) clearance*
- *Guidance, appropriate use of multiple predicates*
- *Staff training, appropriate use of multiple predicates*
- *Analyze multiple predicates vs. adverse event frequency*

Reform the de novo process

Well-Informed CDRH Decisions

Improve 510(k) Information

- **Clarify which device mods do not need a 510(k)**
  - *Possible: require periodic device-mod updates*
- **Assurance Case framework for submissions**
  - *Have submitters provide photos or schematics & retain one copy each device*
- **Guidance & training on declarations of conformity to recognized standard**
  - *Revise reg: require list/description of ALL scientific info on device safety / effectiveness*

Well-Informed CDRH Decisions

Improve 510(k) Information

- **Define a "class IIb" (higher risk; typically require clinical or other data for SE determination)**
  - *Provide staff & industry training, class IIa vs. class IIb*
- **Greater clarity: when clinical data required for 510(k)**
  - *Greater use of postmarket authority (requirement for clearance)*
- **Continue effort to implement Universal Device Identification system**
  - *Guidance: when mfg process info needed for clearance (part of Class IIb definition)*
  - *Clarify: when appropriate to withhold clearance for failure to comply with GMP (part of Class IIb definition)*

Well-Informed CDRH Decisions

Improve internal & public information systems

- *Guidance / SOPs on assignment of product codes*
- *Staff training, assignment of product codes*
- *Develop improved 510(k) database*
- *Guidance / SOPs on 510(k) summaries*
- *Guidance: submitting product labeling & keeping up to date*
- *Guidance / regulations: documenting transfer of 510(k) ownership*

Continuous Quality Assurance

Enhance training, professional development and knowledge sharing

- **Enhance recruitment, training, professional development of review staff**
- **Center Science Council: share knowledge across CDRH**
  - *Develop process for regularly evaluating device types eligible for 3rd-party review*
  - *Enhance 3rd-party reviewer training program*

Enhance QA Systems / Metrics

- *Develop metrics – 510(k) program*
- *Audit 510(k) decisions periodically*

Enhance CDRH Knowledge Base

Improve ability to access high-quality info

- *Revise "least burdensome" guidance*
- *Guidance, clinical trial design for PMA; expert trial-review team*
- *Analyze root causes of challenges in IDE decision making*
- *Mechanism: assemble ad-hoc teams of experienced reviewers (assist in heavy workloads)*
- *Evaluate, mitigate challenges in timely IDE review*
- *Improve postmarket data collection/analysis*

Enhance CDRH Knowledge Base

- *Evaluate staffing needs*
- *Enhance integration, knowledge management across CDRH*
- **Develop body of external experts**
- **Best practices for engaging with external experts**

Respond to New Info / Comm New Thinking

Respond to new scientific information

- **Develop process for response to new scientific information**
- **Enhance data sources / capabilities to synthesize new knowledge**

Communicate new & evolving thinking

- *Streamline guidance process*
- *Communicate via "Notice to Industry" letters*
- *Improve device labeling, and develop online labeling repository*
- *SOP: process for responding to new scientific information*
- *Up-to-date info through CDRH Transparency web site*

What these could mean

Reconcile language in 510(k) flowchart Criteria, “diff quest safety & effectiveness”	Clearer criteria
Guidance, mods which need 510(k)	Attn to software updates
Assurance Case submissions	Logical presntn, risk mgmt
Declaration of conformity, recognized std	Show conformance, 62304?
Class II b When clinical data needed	Non-PMA: more data, use data, though class II
UDI System	Will UDI be required in SW?
Better staff training Center Science Council Body of extnl experts (& how to engage)	Better FDA comprehension of software issues
Process, response to new scientific info	Info as requirements shift
Data sources / ability to synthesize	Better-informed FDA review

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EU – Several Key Docs Updated

- **Medical Device Directive**:
  Dir. 93/42/EEC (14.Jun.1993) amended by dir. 98/79/EC, dir. 2000/70/EC, dir. 2001/104/EC, reg. 1882/2003, and dir. 2007/47/EC (5-Sep-2007)
- **IEC 60601-1, 3rd edition**, harmonized 2006
  (*Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*. Prev. edition to be retired by 2012)
- **IEC 62304** (2006)
  (*Medical device software – software life cycle processes*)
- "**Annex 11**"
  (*EudraLex: the Rules Governing Medicinal Products in the European Union, vol 4: Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use - Annex 11: Computerised Systems*. Issued Jan. 2011; adoption by 30-Jun-2011)
- **ISO 14155:2011**
  (*Clinical Investigation of medical devices for human subjects – Good Clinical Practice.* Published 25-Mar-2011; adoption: essentially immediately)

EU Medical Device Directive

- "... software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification."
  NOTE: "state of the art" loosely defined as compliance to relevant harmonized standards, i.e. 62304.
- "Stand alone software is considered to be an active medical device."
- SW driving a device or influencing its use falls in the same class as the device itself (i.e. active med device, active therapeutic, implantable device, active device for diagnosis, etc.)

IEC 60601-1

- Previously, software ("programmable electrical medical systems" or PEMS) addressed in separate collateral standard – now covered in main document
- Standard specifically requires application of a "risk management process in accordance with ISO 14971"
- Specifically references 62304 for lifecycle activities
- Addresses hazards from network connections of PEMS to other equipment

IEC 62304

- Intended to provide “a common framework of life cycle processes with activities and tasks necessary for the safe design and maintenance of medical device software”
- Presumes a quality management system and a risk management system; references ISO 14971 for risk management
- Sets out three software safety classes; required processes based on safety class
- Annex C provides relationships with ISO 13485, ISO 14971, IEC 60601-1, IEC 61010-1, IEC 12207, IEC 61508

EudraLex Annex 11

- Europe's answer to 21 CFR Part 11
- Applies to manufacturing systems for medicinal products
- Risk management explicitly added
- Suppliers & service providers addressed
- Validation processes, and life cycle activities, clearly spelled out
- Expectations spelled out for audit trails, security, electronic signatures
- Processes also specified include change management / configuration management, incident management, and data archiving

ISO 14155:2001

- Replaces two previous stds: ISO 14155-1 and 14155-2
- Addresses design, conduct, recording, and reporting of device clinical trials
- Concerned human subject protection and integrity / credibility of trial results – not directly with software development or QA
- However, risk analysis report required prior to trial – FMEA would need to consider software, if part of design
- Does ***NOT*** distinguish between studies of non-significant risk and significant risk, where FDA (21 CFR part 812, for IDE) differentiates the two.

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Non-FDA Stds: Increasing Risk Focus

- ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 14971:2009 – Medical devices – Application of risk management to medical devices
- IEC 60812:2006 (2nd ed) Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)
- ANSI/AAMI/IEC 62304:2006 Medical devices – Software life cycle processes
- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- ANSI/AAMI/IEC TIR80002-1 Medical Device Software – Part 1: Guidance on the application of ISO 14971 to medical device software
- AAMI TIR 36:2007 Validation of software for regulated processes

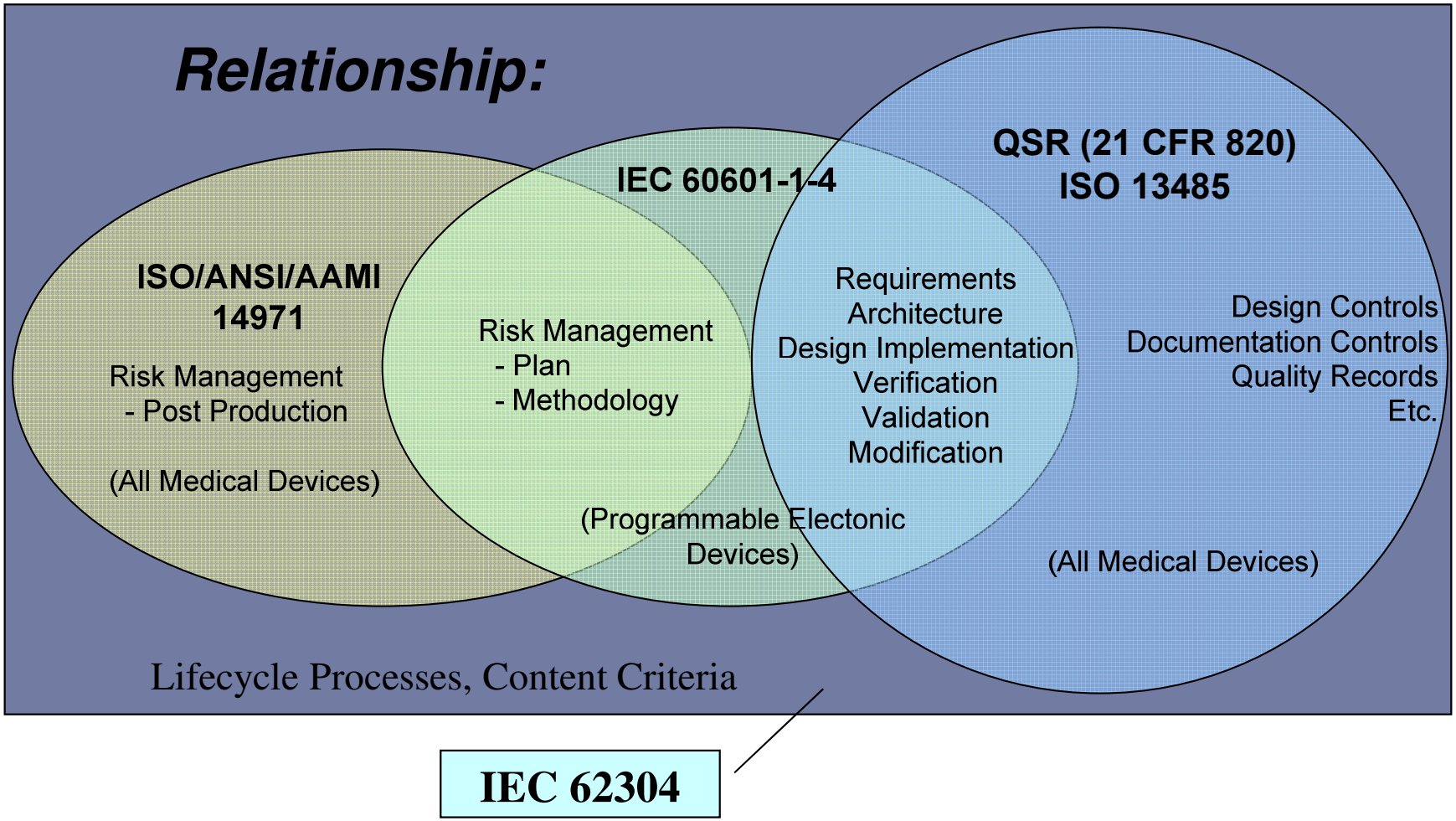
Key Points: Non-FDA

- ISO 13485:
  ISO 9001 with specifics for medical devices
- ISO 14971:
  Overall risk management process for med devices; for HOW to do FMEA or FTA, look elsewhere
- IEC 62304:
  Software lifecycle activities, based on risk level
- IEC TIR80002-1:
  Relate risk mgmt (14971) to med device SW

IEC 80002-1: Applies 14971 to Software

- Incorporates text of ISO 14971; discusses software considerations for each section
- Example: under *Risk Management*, topics discussed are
  - Iteration
  - Pro-active or reactive design approach to safety
  - Characteristics of safe systems incorporating software
- Under *Intended Use and identification of characteristics related to the safety of the medical device*, topics include
  - User interface
  - Medical device interconnection
- Annex B provides an extensive and thought-stimulating table of "Examples of software causes"
- Annex C provides a table of "Potential software-related pitfalls to avoid"

Relationship among standards



Class Exercise

- Software FMEA, using concepts from ISO 14971 and IEC 80002-1

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Today's Regulatory Picture – Device SW

- Software-related recalls not only continue, but are growing in proportion to the number of devices with software
- Evolving device regulations have become stricter, more specific over time
- Proposed 510(k) changes in part aimed to give CDRH better input and more clearly spell out safety
- Meanwhile, EU is paying more attention to device software and risk management
- U.S. public starting to believe that 510(k) is the less stringent path, more likely to release unsafe devices

What we need – some thoughts

- Risk evaluation and management: universal part of device SW development
- UI design: recognize Use Error (not “user error”) as significant component of risk
- Self-regulation is often more effective than regulation from “outside” – can we in industry set the standards and tell FDA what will work?
- On similar lines, how can we establish cross-industry lessons learned in software safety – medical, nuclear, transportation, aerospace

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Contact Information

Dan Sterling
Sterling Smartware Solutions
17 Legion Place, Rochelle Park, NJ 07662
201-227-7569 x111
dan@sterlingtechsoftware.com
http://www.sterlingtechsoftware.com

Brian Shoemaker, Ph.D.
Principal Consultant, ShoeBar Associates
199 Needham St, Dedham MA 02026
781-929-5927
bshoemaker@shoebarassoc.com
http://www.shoebarassoc.com