Meeting your Electrical Safety Testing & Quality Requirements

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Contents

Intent of Consensus Standards

Standards Don't Just Apply to Medical Devices

- Compliance Demonstrates Safety
- Performance Standards Demonstrate Effectiveness
- Some (not all) are recognized by FDA
- Alternatively, FDA has own Guidance Documents, which are usually complimentary
- Some standards are very prescriptive & Compliance can be demonstrated via testing
- Others are more concerned about development Process & compliance must be demonstrated by documentation (DHF/Technical File)

Key Standards

Important Standards for Medical Device Development

- ISO14971: Risk Management for Medical Devices
- IEC60601: A Series of Medical Electrical Equipment Standards:
  - 60601-1: General requirements for Basic Safety & Essential Performance. All electrical Medical Devices must comply.
  - 60601-1-11: Requirements for Home Healthcare Medical Devices
  - Plus many others…
- Software Life Cycle Process
  - IEC62304: Medical device software – Software life cycle
  - FDA ucm089543 – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- IEC62366: Application of Usability Engineering to Medical Devices
- ISO10993: Biological evaluation of Medical Devices
  - Particularly Relevant for applied parts to a patient, but also Operators

History of IEC60601

Published by International Electrotechnical Commission

- 1st Ed published 1977 as IEC601-1: ’Medical Electrical Equipment’
  - Introduced Creepage and Clearance for Patient and Operator
  - Maximum temperatures
  - Introduced leakage currents
- 2nd Ed published 1988: ‘Medical Electrical Equipment – Part1: General Requirements for Safety’
  - Introduced 3 approaches to safety: insulation, protective earthing & protective impedance, and required at least 2 Means of Protection (MoP)
  - Single fault protection
  - Allowed to fail safe
- 3rd Ed published 2005: ‘Medical electrical equipment – Part 1: General requirements for basic safety and essential performance’
  - Requires Essential performance to be defined and maintained (Functional safety, not fail safe)
  - Requires Risk Management according to ISO14971
  - Introduces Operator & Patient Means of Protection
  - Requires Usability process to IEC60601-1-6, similar to IEC62366
  - Requires Alarms to conform to IEC60601-1-8
  - Requires PEMS (Software) to be designed using a Life Cycle process, such as IEC62304

IEC60601 Structure

IEC60601 Represents a family of standards

General Standard (Part 1)

IEC60601-1

Collateral Standards – General Requirements

- **General Reqs. For EMC IEC60601-1-2**
- **Usability Eng. Process IEC60601-1-6**
- **Reqs. For Home Healthcare IEC60601-1-11**
- **Collateral IEC60601-1-XX**

Part 2 Standards – Particular Requirements

- **IEC60601-2-1** — Particular Reqs. For Electron Accelerators
- **IEC60601-2-2** — Particular Reqs. For HF Surgical Equipment
- **IEC60601-2-66** — Particular Reqs. For Hearing Instruments
- **IEC80601-2-30** — Particular Reqs. For Automated Sphygmomanometers
- **ISO80601-2-61** — Particular Reqs. For Pulse Oximeters

Note: List is far from Exhaustive…

IEC60601-1 vs AAMI/ANSI ES60601-1

FDA No longer recognizes IEC60601-1 Ed 2, never recognized Ed 3

- FDA only recognizes AAMI/ANSI ES60601-1 Ed. 3 (Recognition #5-77)
- Existing equipment ‘Grandfathered’ by FDA (Dec 31, 2013 cutoff)
  - But, any change requiring new regulatory submission must conform to 3rd Ed
  - 3rd Ed mandatory for all Products in EU - Even previously marketed
- Minor Differences Between Clauses, e.g.
  - Includes ANSI standards in addition to IEC & ISO
  - Supply voltage differences
  - Minor variations in leakage currents
  - Specific wiring codes for permanently installed equipment
  - Differences in colours for medical gases
  - Hospital grade connections
- Test house can simultaneously test to both IEC & ANSI/AAMI
- **Note**: OSHA only recently accepted 3rd edition 60601

IEC60601-1 Edition 3

Overview

- General Requirements
  - **Requires Risk Management process in-line with ISO14971**
  - **Requirements for Programmable Electrical Medical Systems (PEMS)**
  - **Defines notion of Essential Performance**
  - Defines air clearance required between conductors
  - Defines creepage (distance over an insulator) required between conductors
  - Defines insulation requirements for different devices types i.e. mains able to withstand 5,000V RMS for 1 minute without harming patient
  - Defines mechanical requirements for safety i.e. strength, impact, drop test etc
  - Environmental testing (Humidity, Temperature, Altitude)
  - Thermal & Radiation Limits
- Labelling Requirements
  - Defines required labels applied to device
  - Defines requirements for Instruction for Use (IFU)
- Compliance evaluated by Accredited Test House & DHF inspection

ISO14971

Application of Risk Management to Medical Devices

- Why Risk Management?
  - All Regulatory bodies require Devices to be Safe & Effective
  - Risk Management identifies & mitigates the Hazards & Risk of harm associated with the Device, in use or otherwise
- ISO14971 defines process requirements for risk management system in Medical Device design and development
- Risk Management Procedure defines risk management process that is followed during design
- Mandated by
  - ISO13485 – Health Canada, amongst others
  - European Medical Device Directive (EN 2012)
  - 60601-1, IEC62366, IEC62304

Risk Management File

New for 60601-1, mandatory for Europe CE Mark

- Risk Management Plan (can include as part of the Design Plan)
  - Activities to reduce risk & demonstrate risk has been reduced

- Hazard Identification – formally document applicable Hazards
- Risk Analysis – Quantify Risk of Harm to Patient or Operator
- Mitigations & Verification of Safety features
- Assessments of Residual Risks in a Summary Report

- Process must be traceable
  - Hazard identification -> Risk Analysis line items -> Detailed Specifications for any required mitigations -> Mitigation Verification -> Risk management Report

Hazard Identification

Thorough Review to Identify Applicable Hazards

- Review Safety Databases for Similar Products
  - FDA MAUDE, Medical & Radiation Emitting Device Recalls
  - MHRA
  - SwissMedic
- Usability Hazards: Intended Use & Foreseeable Misuse
  - Hence Workflow & Usability as defined in IEC62366
- Review, Define & Document Applicable Hazards
  - clauses in 60601-1 & Particulars that refer to the RMF
  - Classes of Hazards in ISO14971 Table E.1
  - Classify software per IEC62304
  - Classify software per FDA guidance

Risk Analysis

Documenting Process is the key

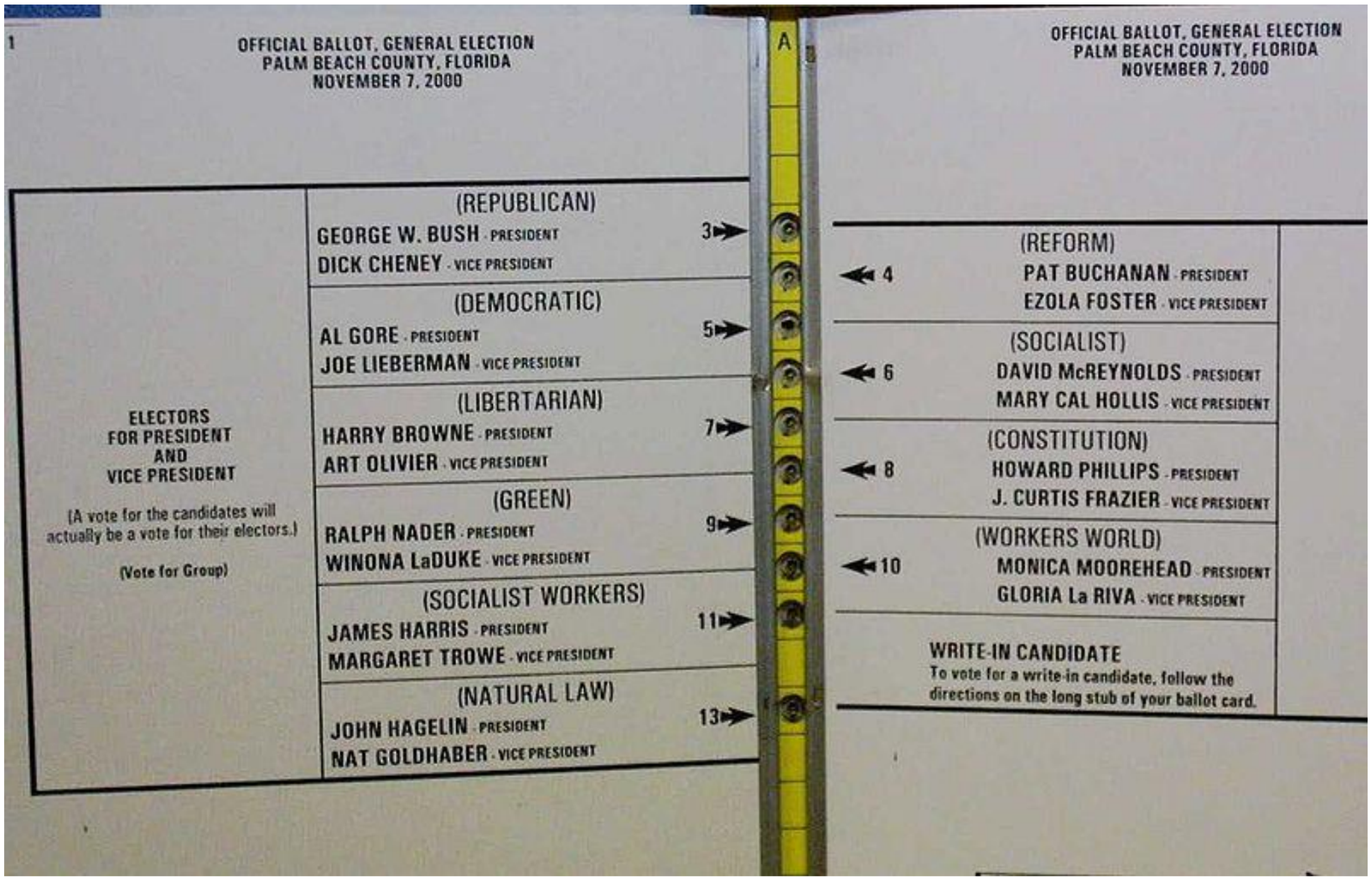
- Identify appropriate Hazards
- Evaluate whether Risk Reduction is necessary
  - Probability
  - Severity
  - Detectability (optional, but good for finer grading)
- Define Mitigations & re-evaluate the Risk
- Evaluate whether the mitigation has introduced new risks
- Justify any residual risks in the Risk Management Report
- Justify the combination of residual risks in the Risk Management Report

IEC62366

Application of Usability Engineering to Medical Devices

- ‘User Error’ is a Design Flaw – ‘Use error’ is preferred term
- 62366 Describes a Usability Engineering *Process*
  - Usability Engineering process intended to achieve reasonable usability, reducing use errors and associated risks
  - Calls on ISO14971 risk assessment
- Usability Engineering Plan – part of Part of Design Plan
  - Identify
    - Use Scenarios with Stakeholder Focus Groups (Documented)
    - Frequently Used functions, Foreseeable Misuse & Routine Violations
    - Usability relating to markings and labeling (includes IFU)
  - Assess Usability in Risk Management
  - Develop Usability specifications & Validation Plan
  - Usability Validation Activity – Actors/Users/Clinicians
  - Usability Validation Report

Use Error Examples



Pat Buchanan received many more votes than expected

Device	Use Error	Root Cause
IV Pump	Fluid Tube pinched by Hinged cover	User must pull tube away from door before closing
Dialysis Machine	User closed red clamp instead of Green	Red/Green colour blindness common in Men
Heart Assist Pump	User Permanently Disabled Alarms instead of Temporary Silence	Symbols indicating Alarm off vs Alarm Suspended confusing
Insulin Pump	User Set 7pm instead of 7am	Display is small, target user was elderly, 24hr clock not common in N America

IEC62304

Medical Device Software – Software Life Cycle process

- Defines the Design & Development Process for Medical Device Software
  - Requires Software Risk Analysis according to ISO14971: assumes 100% probability of software to behave as specified
  - Software that controls features which could cause harm preferably mitigated in Hardware – otherwise partitioned systems, extensive Unit verification
- Summary Software Development Process
  - Software Development Planning – Software Risk Analysis, Requirements, traceability, change control, verification planning, documentation & others
  - Develop Software Requirements & Usability Requirements
  - Transform software requirements into Software Architecture
  - For Medium/High Risk software, decompose architecture into Items & Units
  - Classify Software Units with a Safety Class according to Risk
  - Code/Implement units, Code review, iterate as required, documenting as you go
  - High Risk software requires Software Units to be individually Verified
  - Verify Integrated Software
  - Evaluate residual anomalies for risk, repeat if risks not acceptable, else Release
  - Validate Software System

2nd Edition Gap Analysis

For A Well documented, recent DHF this can be an Effective Solution

- TR62348 (2006) Mapping between the clauses of the 3rd Edition of IEC60601-1 and the 1988 Edition as amended
  - Free download from www.IEC.ch (withdrawn), ~100 pages (English)
  - 1:1 mapping with equivalent/new clauses
  - Practically speaking, requires one to keep in mind all 3 documents

- Good solution for:
  - May need updates for Usability/Essential Performance
  - Electromechanical device, or with non-critical software
  - You have already: Requirements, Risk Analysis, Specs, Verification & Validation documentation

- Particular Problem for Software
  - How to demonstrate software lifecycle process was followed after the fact?

Table 4 *(continued)*

IEC 60601-1:2005		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
3.17	COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS		New
3.18	CONTINUOUS OPERATION	2.10.2	"Continuous operation"
3.19	CREEPAGE DISTANCE	2.3.3	"Creepage distance"
3.20	DEFIBRILLATION-PROOF APPLIED PART	2.1.27	"Defibrillation-proof applied part"
3.21	DETACHABLE POWER SUPPLY CORD	2.7.6	"Detachable power supply cord"
3.22	DIRECT CARDIAC APPLICATION	2.2.7	"Direct cardiac application"
3.23	DOUBLE INSULATION	2.3.4	"Double insulation"
3.24	DUTY CYCLE	2.10.5	"Duty cycle"
3.25	EARTH LEAKAGE CURRENT	2.5.1	"Earth leakage current"
3.26	ENCLOSURE	2.1.6	"Enclosure"
3.27	ESSENTIAL PERFORMANCE		New
3.28	EXPECTED SERVICE LIFE		New
3.29	F-TYPE ISOLATED (floating) APPLIED PART	2.1.7	"F-type isolated (floating) applied part"
3.30	FIXED	2.2.12	"Fixed equipment"
3.31	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR	2.12.15	"Flammable anaesthetic mixture with air"
3.32	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE	2.12.16	"Flammable anaesthetic mixture with oxygen or nitrous oxide"

Legacy Products & 60601-1

Older products, Less well documented DHF

- Review Existing DHF – Bottom Up documentation strategy
- Review Mechanical Drawings for compliance – Safety Factors (Sec 9.8)
  - Requires 2.5+ for ductile or 4+ for brittle parts (Depending on knowledge)
  - Either update drawings, remanufacture parts with improved safety factors
  - Alternatively risk analysis line item which evaluates risk of using 2x safety factor & justifies with historical data e.g. 10,000 units in the field for 20 years
- Review Electrical schematics and assembly drawings for compliance
  - MOPP/MOOP: Creepage, clearance, solid insulation etc
  - May need to up-rev & modify design e.g. transformers, plastic covers (reinforced)
  - Alternatively risk analysis line item – evaluate risk of harm and justify safe with historical data. May be more difficult to justify due to prescriptive standard (current)
- Review Failure Modes
  - Fail safe: particular standard states essential performance
  - What to do if not compliant?
- Gotchas:
  - Mechanical strength, vibration, shock – rough handling, steps, lips, push, impact

Legacy Products Software & 60601-1

Demonstrating Software Life Cycle for 10 year old Binaries

- Typical problems:
  - Worst case: Assembly Source & Ancient Binaries
  - Original Programmer has left the building
  - Mixed Requirements, design rationale, specs, no design reviews
  - Poorly structured software – ‘make it work’ rather than designed
  - Obsolete tools makes it difficult to recreate same binary
- Solutions
  - Decompose existing software
    - Takes a long time – 100hrs to develop flowcharts for a 3x CPU system
    - Instrument software for debug/verification information – not always possible (e.g. no comms.)
    - Develop Software Requirement, Specs, perform code design reviews
    - May identify safety issues – Either solve with additional hardware or risk analysis line item
    - Verify and Validate software: Include Software Usability if GUI
  - Alternatives: Start Again
    - Forward design process – Requirements, Architecture, Risk analysis, specs, verification
    - Could use Same processor – obsolescence & tools issue
    - Different processor: plug in CPU module, PCB board revision

New Product Development & 60601-1

60601-1 E$^{d.}$ 3 Compliance Designed in from the Outset

- Design Plan
  - Describes appropriate Standards (e.g. Part 1, Part 1-2, Part 1-11)
  - Design Plan describes documentation Hierarchy
  - 80601/60601-2xx Particular Standards for Basic Safety and Essential Performance
- Risk Management Plan describes risk management process
- Develop Product Requirements
- Develop System Architecture compatible with 60601-1
  - E.g. Low voltage external 60601 certified PSU provides 1 means of protection
  - E.g. 15W or less power source removes some requirements
- Perform Preliminary Hazard Identification
- Perform Risk Analysis Engagement to Quantify Risk of Harm
- Modify Architecture, develop specs
- Verify, Validate (Usability and Software)

Reliability Testing

Reliability Testing required for Compliance

- General standard has shock/impact/vibration requirements (15.3)
  - Push Test
  - Impact Test
  - Drop test
  - Rough Handling (Ascending/Descending steps, ledges, door frames)

- Particular standard may have additional requirements e.g.:
  - IEC60601-1-11 – Home Healthcare Environment
    - Section 10.1.3: Peak Acceleration, broad-band vibration, fall height
  - ISO80601-2-61 – Pulse Oximetry equipment
    - Section 201.15.3.5.101: Peak Acceleration, broad-band vibration, fall height

Conclusions

60601-1 E$^{d.}$ 3 Required Documentation is Majority of DHF

- A typical 60601-1 Submission, the following documents are required
- Risk Management File (Section 4.2) – Shall includes at least:
  - Risk Management Plan
  - Hazard Identification
  - Risk Analysis
  - Risk Management Report
- PEMS Lifecycle File (Clause 14) – forms part of Risk Management, typically requires:
  - Software Requirements
  - Software Architecture
  - Software Risk Assessment
  - Software Specification (with sub-systems verification as required)
  - Software Verification Plan & Report
  - Software Validation Plan & Report referring to Basic Safety and Essential performance
- Usability File (Section 12.2) –
  - Usability Requirements – may form part of Product Requirements
  - Use error, foreseeable misuse & Routine violations in Risk Assessment
  - Usability Validation Plan & Report
  - Particular standards (e.g.Home Use) may require Validation of Labeling (particularly IFU)

Suggestions

Ways to make your life easier (potentially)…

- Read the Standard(s)!
- Obtain Test house 60601-1 Checklist
- 60601-1 has a lot to say on mechanical design
  - If you cant meet these, either redesign or risk analysis
- Legacy Devices
  - Gap analysis may be simplest for Electromechanical device with recent DHF
  - For complex software e.g. software controlling safety or performance:
    - Carefully assess the amount of effort required to retroactively generate DHF
    - Sometimes starting Software Development again is quicker and less expensive
  - It may not be possible to mitigate existing risks (particularly software)
    - Preferentially implement hardware risk mitigation
    - Alternatively include Risk Analysis lines with historical data
- New Product Development
  - Follow conventional Watefall/V model
  - Mitigate risk by system architecture
    - Safe by Design
    - Software not controlling critical aspects for safety or performance

Questions?

Additional Materials at

- StarFish Medical - http://starfishmedical.com/
- ISO14971 Webinar - http://www.youtube.com/watch?v=S80ZqpNkrF8
- FDA Risk Management - http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073511.pdf
- FDA Use Errors - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm
- FDA Guidance for Software Contained in Medical Devices - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm
- US FDA Maude website: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
- US Recall website www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
- MHRA Recall website www.mhra.gov.uk/SearchHelp/Search/index.htm
- SwissMedic website: www.swissmedic.ch/rueckrufe_medizinprodukte/index.html?lang=en

About the speaker

Vincent Crabtree is a Project Manager and Regulatory Advisor, with an emphasis on Project Leadership ensuring projects conform to consensus standards such as ISO14971, IEC60601-1 and managing clients setting-up Quality Management Systems that comply with ISO13485 and FDA Quality System Regulations. He is passionate about commercializing innovative technology, and brings an entrepreneurial perspective.

Vincent has a Diploma and Bachelor's Degree in Electrical Engineering, and a PhD in Optical Biomedical Engineering with over 20 years of experience in Electronics development, 17 years in Healthcare technology R&D and 10 years in medical device development and commercialization.

StarFish Medical is a Medical Device Design company with a full complement of design, development, and manufacturing services. We use the PathFinder™ process to reduce wasted effort and increase success for medical device product definition, technical engineering, and product development. Prototype and volume production are delivered in an ISO 13485 certified Quality Management System and FDA registered manufacturing and clean room facility.