Medical Device Approval and Standards

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Medical Devices

- FDA regulates the medical devices in the US
- Devices are broken into classes I, II, and III
  - Class I is the lowest risk (i.e. toothbrush); Class III is the highest
  - Some devices exempt from 510(k)/PMA
    - See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm
- Higher risk devices require the longer, arduous Pre-Market Approval (PMA) while some can claim substantial equivalence and follow 510(k) process
- Class I- some 510(k) -> Class III – most require PMA
Determining Device Classification

• Go to FDA classification database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

• Locate appropriate Code of Federal Regulations (CFR) which defines the device class

• Class and application process (510(k) or PMA) identified

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Standards Referenced by FDA

- In the 510(k) checklist, electrical safety (IEC60601-1) and EMC testing (IEC60601-1-2 or equivalent) are specifically referenced.
Brief Standards List
Medical Standards

- IEC 60601-1 – Medical Equipment Part 1 – General requirements for safety
  - Attempts to reduce electrical shock, mechanical, radiation, fire, and excessive energy output hazards
- IEC 60601-1-6 – Usability Safety Requirements
- IEC 60601-1-8 – Alarm Systems in Medical Equipment
  - Specify visual and auditory alarm conventions
- IEC 60812 – Failure Modes, Effects, and Criticality Analysis (FMECA)
  - Defines the process and requirements to identify failure modes, determine risks, and feed it back into the design process
- AAMI ST67 – Guidance for declaring a product “sterile”
Medical Standards

• IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use
• IEC 61508 – Functional safety
  – E.g. add power supply voltage monitoring overcurrent
• IEC 61558-1 – Safety of power transforms, power supplies, reactors and similar products
• IEC TR 60878 – Graphic symbols for electrical equipment in medical practice

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Quality Standards (relevant to Medical Devices)

• IEC/ANSI/AAMI 62304 – Software lifecycle process
  - This is accepted by the FDA and used as a “yardstick” for other development processes
  - Defines software process as requirements, architecture, detailed design, unit implementation and verification, unit integration and test, system testing, ...

• ISO 14971 – Risk Management
  - Process of identifying hazards of the system and mitigations

• ISO 13485 – Quality Management Systems
Environmental Testing

Tests developed to examine durability of device under “normal” handling

• IEC 60068-2-6 Vibration test
• IEC 60068-2-32 Free fall test
Emissions/Susceptibility

• FCC 47 CFR Part 15 – regulation of commercial device emissions
Electronics Standards

- ROHS – Restriction of Hazardous Substances
- IEC 60062 – Standard markings of resistors and capacitors
- IPC Standards (various)
  - PCB Design, Manufacturing, Assembly, Testing
  - IPC 2221A – Generic Standard on Printed Board Design
    - Includes conductor thickness and spacing guidance

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Communication/Signaling Standards

• Serial – RS232, RS485, I2C, USB, Firewire, ...
• Bluetooth
• Ethernet (802.3)
• Wifi (802.11)
• LVDS (TIA/EIA-644)
Programming languages

- C (i.e. C11)
- C++ (i.e. C++11)

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Other Potential Useful Standards

• IEC 60417 - Graphical symbols for use on equipment
• ISO 7000 – Graphics symbols for use on electrical equipment
• IEC 60335-1 Household and similar electrical appliances – Safety – General Requirements
  – Provides marking guidance, temperature limits, creepage distances,...

• Sleep apnea – AASM Manual for Scoring of Sleep and Related Events