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/cfpcd/315.cfm
    - E.g. Medication Reminder (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?ID=2533)
- 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

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

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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
  - Brief overview provided at http://www.cs.au.dk/~dsound/DigitalAudio.dir/Papers/Audible%20Alarms%20in%20Medical%20Equipment.pdf
- 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"
  - Overview of sterilization at http://www.webbertraining.com/files/library/docs/255.pdf

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
  - For an overview, refer to http://www.mtl-inst.com/images/uploads/datasheets/App_Notes/AN9025.pdf
- IEC 61558-1 – Safety of power transforms, power supplies, reactors and similar products
- IEC TR 60878 – Graphic symbols for electrical equipment in medical practice

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

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)

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