Industrial Standards

Industrial Standards

- In addition to meeting design specs, products must met industry standards
  - Operational standards
  - Safety Standards
  - Quality Process
- US standards vs. International standards

Operational standards

- Examples of Operational Standards
    - EMI
    - EMC
    - EMP
- FCC
- ASTM Formerly a USA Standards Body now international
- NIST
- ASME
- ANSI/IEEE
- ISO International Organization for Standardization

Safety standards

- Examples
  - Electrical
  - Human Consumption
- FDA
- OSHA
- ADA
- UL Underwriters Laboratory
- ISO

FCC

- Federal Communications Commission (FCC)
  - Electromagnetic Interference - EMI – from portable radio transmitters (cell phones, radios, etc.)
    - Defibrillator failed to resuscitate a patient
    - Wheelchair suddenly moved towards traffic
    - Laser beam went into the audience area of a light show
    - Radiation beam shutter failed to close
  - Devices must show Electromagnetic Compatibility (EMC)

Medical Device Standards

- ASTM American Society for Testing and Materials
  - Develops and publishes voluntary consensus technical standards for a wide variety of materials, products, systems and services.
  - astm.org
  - Book of Standards
  - Section: 13 Medical Devices and Services.

Medical Device Standards

- American Society of Mechanical Engineers
- Promotes the art, science, and practice of multidisciplinary engineering and allied sciences around the globe
  - asme.org
  - Bioprocessing Equipment

Medical Device Standards

- NIST The National Institute of Standards and Technology
  - Physical Sciences laboratory and non-regulatory agency of the US Dept of Commerce to promote innovation and industrial competitiveness
  - nist.gov
  - Biomaterials
  - Biomolecular characterization
  - Cell Biology
  - Bioprocessing

Medical Device Standards

- ANSI American National Standards Institute
- Oversees standards conformity assessment activities in the US
  - ansi.org
  - Biological Evaluation of Medical Devices

Medical Safety Standards

- OSHA Occupational Safety and Health Administration

- Large regulatory agency of the US Dept of Labor

  – osha.org

  – Biological agents

  – Handling Blood

  – Eye and face protection

  – First aid

Medical Safety Standards

- ADA American Disabilities Act of 1990
- Reasonable accommodations for employees with disabilities
- Information and Technical Assistance of the Americans with Disabilities Act
  - ada.gov
  - Medical Care for individual with mobility disabilities
  - Wheel chairs, Mobility Aids, Power Driven Mobility Aids

Quality Process standards

- Does the company design and manufacturing processes meet quality standards
  - Are all design and manufacturing processes documented so that workers know how to do their jobs?
    - E.g., Mission, Goals,
  - Does the organization have a method of continuous quality improvement?
- ISO 9000
- Malcolm Baldrige
- Internal organization quality standards

Regulatory Issues and Liability

- Federal Communications Commission (FCC)
  - Electromagnetic Interference - EMI – from portable radio transmitters (cell phones, radios, etc.)
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- Tort Liability: "Defensive Innovation"
  - "Decisions by manufacturers not to innovate for fear of future litigation"
  - Product liability laws different in each state
  - The Biomaterials Access Assurance Act of 1998
    - Protect suppliers of bulk components and raw materials for implants from lawsuits

Homework Assignment

- For both Safety and Operational standards find a specific standard that you may have to write a test for in your test plan which affects your product's design.

- For the Safety and Operational standards use a Standards Organization listed and a second Organization not listed in this presentation.

- Name the Standards Organization and the identifier of the specific standard.

- Provide a short description of the standard, why it applies to your product and what sort of test you will execute to prove that your product meets this standard.