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What makes a Standard a Great Standard?

Musings from a Health Canada Pre-Market Division Regulatory Manager

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YOUR HEALTH AND SAFETY... OUR PRIORITY.

Outline of the Presentation

- Overview and Perspective
  - Disclaimers too
- Ideal Regulatory Standard
- Practical Realities
- Conclusions

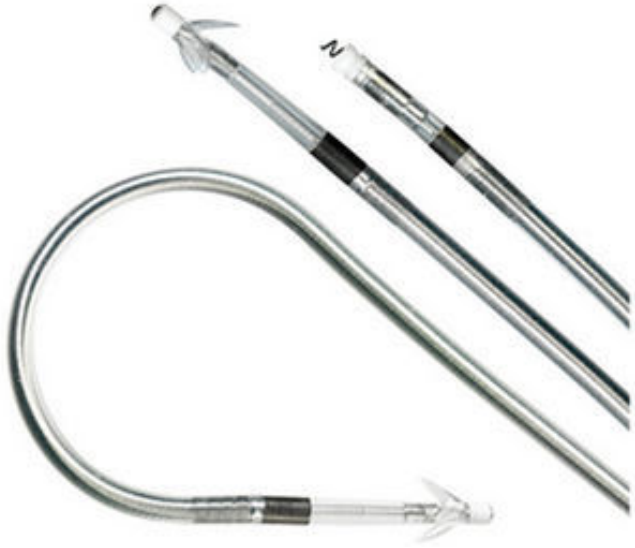
Overview and Perspective

- Key Regulatory Considerations (Health Canada)
  - Safety and Effectiveness (Essential Principles)
  - Consistency for all stakeholders
  - Same device; same risks and benefits; same minimum requirements
  - Can’t tell one manufacturer what you know other manufacturers are doing
- Final decision is Binary – Licence or Don’t Licence
- Opinions presented are my own (CV Devices)

Ideal Regulatory Standard

- Scope of the standard should be clear
  - What does the standard cover?
    - Regulatory requirements, design assumptions, etc.
  - What does the standard NOT cover?
    - National requirements, specific design aspects, etc.
  - What aspects of the device are safe and effective if it meets the standard?
    - Standards generally don't fully cover the S&E of a device
- Acceptance criteria (if provided) should be clear
  - What tests did the device pass for the standard?
  - Should include best available science
  - How were the acceptance criteria validated?

Ideal Regulatory Standard



- Example #1 – Cardiac Leads
  ISO 14708-2
  - Mechanical testing of leads through accelerated means
    - Two tests require 47,000 cycles and 82,000 cycles
    - Existing leads have passed tests but failed clinically
    - Industry has been testing to better test levels with better test methods for many years (not best science)
  - Testing for flexural strength is limited to the conductor and is silent on the insulation (scope)
    - Tensile testing is for both conductor and insulation

Ideal Regulatory Standard

- Example #2 – Usability/Human Factors

  IEC 60601-1-6 (IEC 62366)

  – Many problems encountered with Med. Elect. Equipment are associated with Human Factors

  – IEC 62366 includes lots of requirements to have specifications, processes, and plans

  "Compliance is checked by inspection of the USABILITY ENGINEERING FILE."

Ideal Regulatory Standard

- Example #2 – Usability (e.g. Patient Monitor)
- NEW Touch-Screen Model with Wi-Fi connection to a central monitor
  - COMPANY ABC: All 'Human Factors' testing done with software staff in simulations; justification for acceptability based on similarities to other systems
  - COMPANY XYZ: Detailed Human Factors study with appropriate patient populations and multiple use scenarios
  - Both companies claim conformity to IEC 62366
  - Significantly reduced level of testing by ABC
  - Greater uncertainty with the product made by ABC

Practical Realities for Standard Development

- Standards provide a very good basis for much of the testing required for Medical Devices
  - Clear acceptance criteria are not always present
  - Reliance on risk management – inherently subjective
  - Hard to ensure best current scientific understanding
- Standards are reflecting and accommodating the rapid evolution of Medical Device Technology
- Industry has responsibilities to stakeholders
- Restrictions based on intellectual property and trade secrets
- Not everyone has time and $ to participate

Conclusions – Recommendations/Considerations

- Validated acceptance criteria should be included in standards
- Reduce the reliance of standards on Risk Management
  - Flexibility in the application of standards reduces their ability to be used for regulatory purposes
  - ISO 14971 covers Risk Management
- Design standards with conformity assessment in mind
- Keep process standards limited to processes, and keep product standards limited to products

Conclusions

- Standards will continue to be an essential corner-stone of the regulatory approval process
- Standards can provide excellent guidance for Industry and for Regulators
- A declaration of conformity may not provide sufficient evidence of safety and effectiveness
- Regulators and Industry will continue to work together to assess and define minimum acceptance criteria both in standards, and during the regulatory review process