What makes a Standard a Great Standard?
Musings from a Health Canada Pre-Market Division Regulatory Manager

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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 cornerstone 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