WSC High Level Workshop On

INTERNATIONAL STANDARDS FOR MEDICAL TECHNOLOGIES

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Geneva

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The National Electrical Manufacturers Association

National Electrical Manufacturers Association
NEMA

- Major SDO for the U.S. Electroindustry
- Membership of 400 manufacturers
- Inventory of 500 Standards
- Product Scope
  - Wire and Cable
  - Switches and Fuses
  - Lamps and Fixtures
  - Electric Motors
  - Medical Equipment

NEMA

IEC/ISO Chairmen, Secretariats and TAG Administrators.

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- **7 Secretariats**
  - 6 IEC Technical Committees & Subcommittees
    - 2J, 15C, 22G, 37, 37B, 72, 98
  - 1 ISO Technical Committee
    - TC 184/SC 5
- **4 IEC Chairmen**
  - 33, 34, 35, 36C
- **63 TAG Administrators**
  - 56 IEC, 7 ISO Technical Committees & Subcommittees
  - 2, 2G, 13, 14, 16, 17 (2groups), 17A, 17B, 17C, 17D, 20, 21A, 22, 22E, 22G, 22H, 23, 23A, 23B, 23C, 23E, 23F, 23G, 23H, 26, 32, 32A, 32B, 33, 34, 34A, 34B, 34C, 34D,35, 36, 36A, 36B, 36C, 37, 37A, 37B, 38, 44, 55,62B, 62C, 64, 65B,70, 72, 77C, 87, 96, 98, 109, ISO TC44/SC4, TC145, TC145/SC1, TC145/SC2, TC184, TC184/SC1, TC184/SC5

NEMA's Healthcare Standards

Product Scope

Medical Imaging and Therapy Systems

Standards Activity

- Magnetic Resonance (11)
- Nuclear Medicine (2)
- Positron Emission Tomography (1)
- Ultrasound (2)
- X-Ray (13)
- Most link to IEC

NEMA's Healthcare Standards

- Secretariat to the DICOM Standards Committee
- DSC is independent and international
- DICOM allows for transmission of images between devices and facilities.
- Closely coordinated with IHE & HL-7
- Considering link to ISO

Links Between Regulators and Standards Developers

- Standards Development
  - Reasons standards are developed
  - When International Standards can serve regulatory needs
  - Level of Consensus Needed
- Standards Implementation
  - Harmonized Conformity Assessment Frameworks
  - Conclusion

Reasons Standards Are Developed

- Commercial
- Safety
- Performance
- Legislative mandates
- Regulatory requirements

Commercial

- Compatibility (parts comp need to fit)
- Standard definitions
- Standard terminology
- Standard units of measurement
- Some commercial requirements may be safety issues

Safety

- Risks to patients or operators has been defined
- Need to balance benefit and risk
- Define limits or range of risk
- Specify equipment requirements to minimize risk
- Specify measurements methods for equipment requirements
- Do not standardize equipment design

Performance

- To compare equipment of different vendors
- Equipment to perform sufficiently to accomplish its intended purpose
- Some performance requirements may be safety issues

Legislative Mandates

- Legislation may provide regulators authority to regulate utilizing standards e.g., US-FDA, Class II Devices, also EU; meeting Enorms (Standards) will mean meeting EU Essential Requirements

Regulatory Requirements

- Regulators may see standards as a way to
  - eliminate safety issues
  - simplifying the evaluation of technologically complex medical devices
  - standardize safety expectations and measurement methodologies

When International Standards Can Serve Regulatory Needs

- Standard was written primarily for safety; OK to contain commercial and performance.
- Standard addresses all or most safety issues for identified product
- Standard has no design requirements

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When International Standards Can Serve Regulatory Needs

- To the extent possible, regulators should use international standards because –
  - Vendors need to comply to one set or series of standards (exception for climate, etc.)
  - International Q.S. standards allows for exchange of data between regulators and reductions in the number of Q.S. audits
  - Both have the effect of reducing health care costs.

Level of Consensus Needed

- Standards W.G.s should be balanced regulators, vendors, clinicians
- Regulators participate as individual experts, they do not speak for the Agency
- Regulatory participants should provide continuous feedback to their Agency

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Level of Consensus Needed

- Vendor should provide continuous feedback to their trade associations
- When seeking consensus, regulators should strive to assure adequate safety requirements are incorporated in the standards

Standards Implementation

Harmonized Conformity Assessment Frameworks

- Regulators should adopt GHTF Guidance Documents
- Developing regulatory agencies formulating legislation can adopt GHTF Documents easily
- Established regulatory agencies may have to consider legislative change
- GHTF Guidance includes classification , principles of safety and performance, use of standards, device event reporting, quality systems, Q.S. auditing and many others.

Conclusion

Regulators should

- utilize international standards where possible
- follow the guidance provided by the Global harmonization Task Force