WHY STANDARDS THAT FOLLOW THE GUIDANCE ARE GOOD FOR BUSINESS?

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Member of IMDRF Standards WG
DITTA Standardization WG
1. Our vision

2. Challenge for Consensus Standards in regulatory use.

3. Good For Business

4. Challenge in the next step
1. OUR VISION

“Approved once, accepted everywhere”

→ Future Dream
• Standards are good tools to demonstrate to comply with essential principle for the medical devices in conformity assessment process in pre-market review.
• Their process is key elements for regulatory convergence.

In Real World; Reduce duplication!
→ MDSAP, Single Review Program in IMDRF
Role of Standards in Conformity Assessment System

• streamline the device review process
• improve the efficiency of regulations
• establish productive dialogue among RAs, manufacturers, conformity assessment organizations (including accreditation and testing professionals), clinicians and the public.
2. CHALLENGES

Contents of Standards

- Uncertain Rational for the requirements
- Uncertain Scope and residual risk
- Uncertain how to address the resulting risk as appropriate.
- Uncertain acceptance criteria and testing methods
- Competition of national and international standards
## Typical Example Implementation of IEC60601-1 Ed3 (Status in 2015)

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**Applicable edition**

**Proposed application / IEC stability date**

**Concurrent application**

* National deviations may apply

Information without guarantee
3. GOOD FOR BUSINESS

Expected affect after introducing this guidance document.

- Conformity Assessment system based on the essential principle with the consensus standards.
- Smooth introduction of international standards developed for regulatory use in each jurisdictions, and minimize the national deviations.
- Acceptance of outcome based on conformity assessment for the essential principle with the consensus standards.
- Avoid duplicative activities by agreeing which standards to use for regulatory framework.
3. GOOD FOR BUSINESS

Expected affect after introducing this guidance document.

- State of the art: standards represent the state of art in a technological field.
- Efficiency: they should also promote economic benefits, e.g., reducing redundant reporting requirements, etc.
- Verifiability: requirements include verifiable, objective measurements.
- Reproducibility: testing methods in standards yield consistent results across different test facilities.
- Risk Managements/Specific Requirement: When a standard identifies a hazard or a hazardous situation without giving a specific requirement.
3. GOOD FOR BUSINESS

Conformity Assessment in Review Organization

Competency of reviewer (IMDRF N40)

Consensus Standards (IMDRF N51)

Essential Principle (IMDRF N47)

Accepted Everywhere

Outcome for conformity assessment in premarket review

“Medical Device Premarket Review Organization Recognition Requirements and Processes” (IMDRF Nxx : NWIP)
CHALLENGE
IN THE NEXT STEP

• Establish IMDRF Liaison Program to support the developing process for regulatory use.

• Improvements the contents and the developing process for IEC60601-1 Ed4!

◆ But still uncertain transition rule in the revision of standards.
THANK YOU!
СПАСИБО!
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