DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION



# DITTA – STANDARDS

## What makes a standards a great standard

### Industry View

### September 2017 Ottawa, Canada

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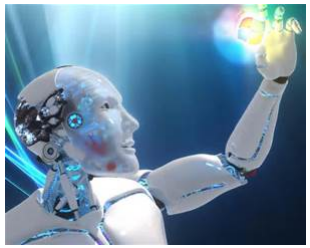
# MEDICAL DEVICE INDUSTRY PERSPECTIVE

- Introduction
- Value of standards
- Industry role in standards
- Considerations & Opportunities
- DITTA Priorities



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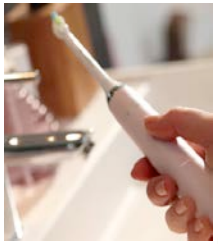
# Global Design, Manufacture, Distribution and Service

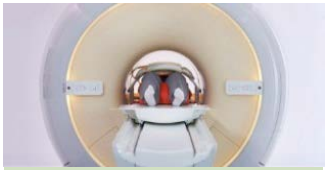
Healthy living | Prevention | Diagnosis | Treatment | Home care

Domestic Appliances



Rechargeable toothbrushe

Health & Wellness



Diagnostic Imaging

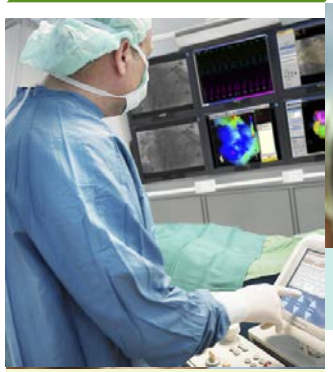
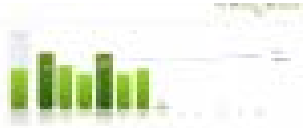


Image Guided Therapy

Sleep & Respiratory Car

Mother and child care



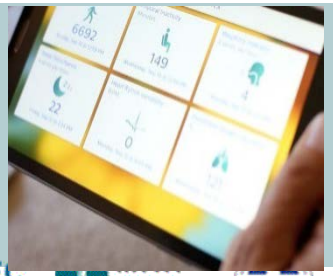
Personal Health Solutions

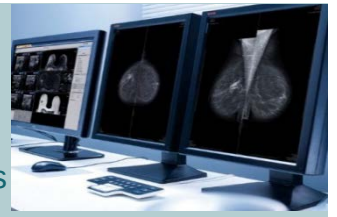
Ultrasound

Personal care

Kitchen appliances

Patient Care & Monitoring Solutions





Healthcare Informatics, Solutions & Services

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# WHY STANDARDS? WHAT IS THEIR VALUE?

**Access & Time to Market:** critical for healthcare system and business

- *Country requirements (laws and regulations) vary*
- *Process and documentation requirements differ*
- *Scope of verification and validation is not unified*
- *Even definition of medical device varies by jurisdiction*
- *Supports harmonization in requirements and testing*

***THEREFORE:***

**International convergence of requirements through standards is KEY**

**Standards help by bringing**:

- *Common & agreed language across stakeholders*
- *Basis for international trade agreements*
- *Testable or auditable requirements (potentially without submitting data)*
- *Cost saving for healthcare: improve patient access*
- *Support common terms through the continuum of life with well being and prevention being critical*

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# Why should we be interested in standards development?

- We are global manufacturers
- We are interested in high quality standards
- We want to be a responsible stakeholder – listen and learn from others
- We all have competence to share

**Proper development of good consensus standards helps write the details that regulate our products**

***(contributes to global regulatory convergence)***

- **EU**: Directives & Harmonized Standards
- **US-FDA**: "Recognized Consensus Standards"
- **Japan-MHLW**: International Standards Adoption
- **China**: Voluntary & Mandatory(Timing Varied)
- **India**: under development
- **LatAm**: risk of diverging regulations or implementations

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# *GOOD STANDARDS ARE EASY TO USE!*

## Recognition of standards by regulators varies

- *Mandatory vs. voluntary*
- *Interpretation in supporting guidance documents*
- *Level of details in annexes of harmonized standards*

## Transition phase of standards varies

- *Synchronization of multi-part standards*
- *Differing timeframes around the world*
- *Scope and implementation differences by jurisdiction*


***Note*** **–**

- **Regulations**: outcome of political process,
- **Standards**: outcome of technical discussions

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# CONSIDERATIONS FOR GOING FORWARD

- *All stakeholders input is required in standards development*
- *Interests & needs may conflict across stakeholders*
- *Look out for best practices and lessons learned*
- *Limited resources: "too many standards projects" Let's focus*
- *Long development time – Let's get creative*
- *Transition, recognition & regulatory needs do not always align*

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# SO WHAT CAN WE DO?

## Standards Development Process Improvement

- Alternatives should be considered
  - *Technology Opportunities*
  - *Sequencing / Concurrent Activities*
- Purpose of Standard
  - *Design vs. Conformity Assessment vs. Other*


## Cooperation & Engagement (within and across)

- *Standard Developing Organizations (SDO's)*
- *Regulators*
- *Industry*
- *Other Stakeholders : Patients, Caregivers, Consumers*

*A valuable thing to do is to leverage from other industries*

# STANDARDS COMMITTEE PRIORITIES – DITTA ORGANIZATIONS

**Goal**: Facilitate efficient and timely market access for member products by developing and promoting the use of appropriate standards.

**Advance Smart Dose Program:** In order to continue the success of XR-29, MITA needs to continue to focus on supporting and promoting the Smart Dose program and tying it to the other standards efforts.

**Industry Groups to be recognized thought leader**:

- Understand relevant SDO's for participation and alignment
- Review standards under development and potential standards to prioritize their development to open markets and add value to members.
- Coordinate and provide oversight into standards development within specific industry group
- (MITA) Developing a standard (annex) for radiology symbols not identified in existing standards. This will allow members to use these symbols without accompanying text per FDA rules.
- Engage with FDA to provide input on the Accreditation Scheme for Conformity Assessment (ASCA) program

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# THANK YOU!

www.globalditta.org

**Questions:**
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