



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



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

DITTA Update

Asian Harmonization Working Party

14 November 2019, Oman

Kelly Mallinger
DITTA





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DITTA GLOBAL PRESENCE



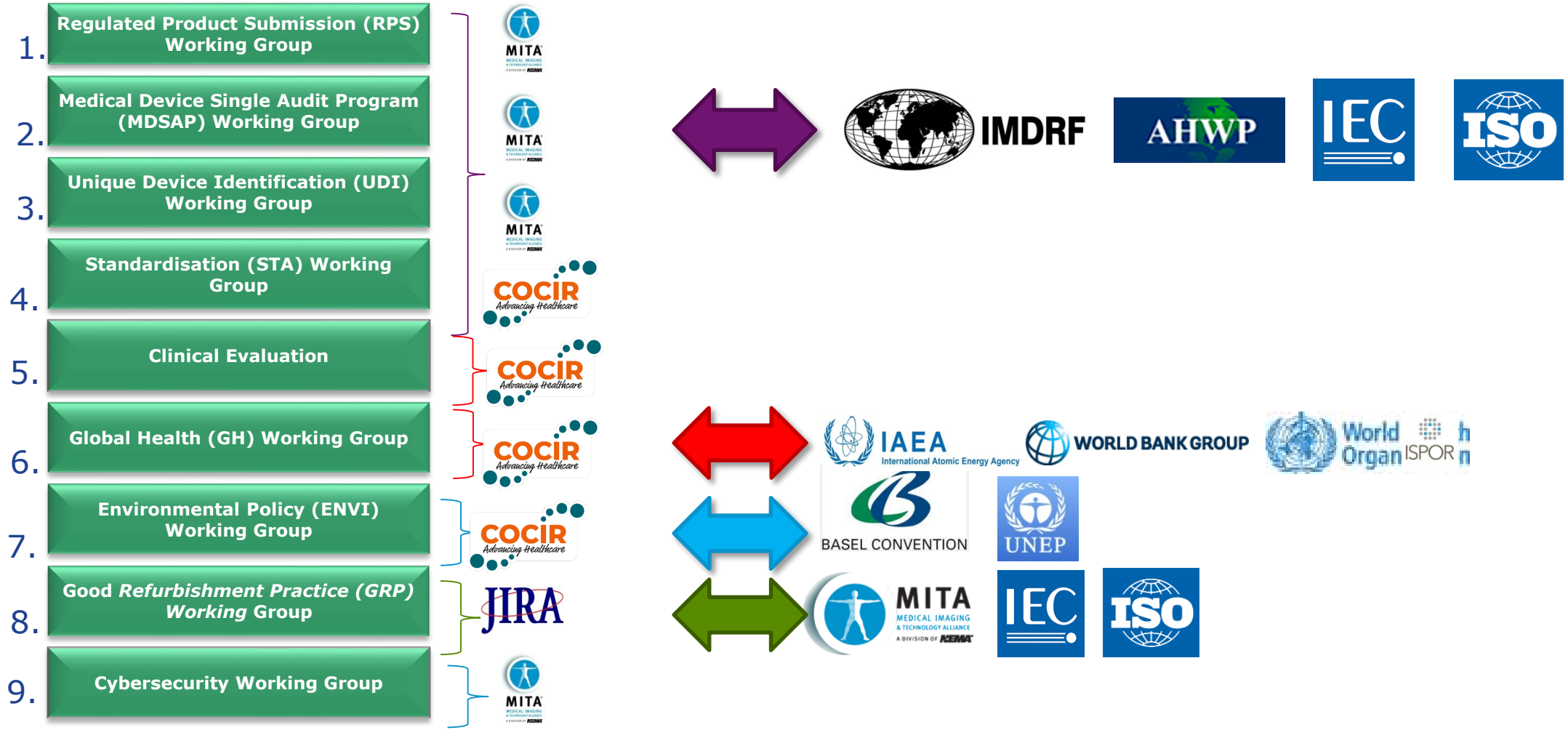
- 2018: DITTA as a recognized non state actor in official relations with WHO
- 2016: DITTA MoU with the World Bank
- 2015: DITTA was granted a NGO status with WHO
- 2014: DITTA has official liaison with AHWP





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DITTA: 9 WORKING GROUPS





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TABLE OF CONTENTS

- Cybersecurity
- Unique Device Identification (UDI)
- Nomenclatures
- Standardization
- Good Refurbishment Practice
- Medical Device Single Audit Program (MDSAP)
- Artificial Intelligence





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CYBERSECURITY

DITTA White Paper on Cybersecurity: Best Practices in the Medical Technology Manufacturing Environment

DITTA session at AHWP meeting 2019





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UNIQUE DEVICE IDENTIFICATION (UDI)

- Support consistent implementation of IMDRF guidance documents globally
- Principles: flexibility, availability of guidance and mapping documents
- Emphasize commonality for key aspects of a UDI system





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NOMENCLATURES

- DITTA considers proliferation of nomenclature systems undesirable as it will add burden on industry to use multiple systems.
- DITTA recommends a coordinated approach to ensure maximum benefit with minimal impact on stakeholders.





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STANDARDIZATION

IMDRF/DITTA workshop on standardization (March, Russia)

Key recommendations

- Advance harmonized use of standards in regulatory frameworks
- Build productive relationships between regulators and standards development organizations
- Long term goal: consistency in conformity assessment approaches





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GOOD REFURBISHMENT PRACTICE

- Successful workshop on import of refurbished medical devices to Vietnam (April, Hanoi)
- Promotion of IEC PAS 63077: 2016 “Good refurbishment practices for medical imaging equipment”





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MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)

- Continuing strong industry support for MDSAP program
- Desire to have additional jurisdictions accept MDSAP reports in place of their need for audits - opportunity of newly established category of “affiliate member”





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ARTIFICIAL INTELLIGENCE

IMDRF/DITTA Workshop (September, Russia): discussion on the opportunities and challenges of Artificial Intelligence in healthcare

Attendance: over 100 participants

Key Take-Aways:

- High level of interest and engagement from all stakeholders
- Necessity for harmonized healthcare-specific AI terminology
- Consider enriching existing IMDRF guidance to foster more convergence
- Issue of access to high-quality data



Find all presentations [here](#).





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THANK YOU!

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