

# Medical Imaging and Technology Alliance (MITA) Standards

Carolyn Hull, DICOM General  
Secretary/Manager, Global Regulatory  
Standards



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reduce regulatory barriers...establish standards....advocate for medical imaging industry

# MITA Overview

- The collective voice of medical imaging equipment, radiopharmaceutical manufacturers, innovators and product developers. Represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology.
- MITA is also the Secretariat for the DICOM® Standard



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# MITA Technologies Include

- Medical X-ray equipment
- Computed tomography (CT) scanners
- Ultrasound
- Nuclear medicine
- Positron emission tomography (PET)
- Radiopharmaceuticals
- Magnetic resonance imaging (MRI)
- Imaging information systems
- Focused Ultrasound



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# Committees and Sections

## Committees

- Technical and Regulatory
- Government Relations
- Standards
- Coverage

## Sections

- Specific product types
- Standards are drafted here
- X-Ray
- Magnetic Resonance
- Molecular Imaging
- Focused Ultrasound
- Medical Imaging Informatics



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# MITA- Dual Roles

- Standards developer
  - A division of NEMA
- A trade association
- Procedures
- Some of our standards you may be familiar with are:
  - NEMA XR-29: “Smart Dose”
  - NEMA XR-26: Access Controls for Computed Tomography— Identification, Interlocks, and Logs



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# Why Do We Draft Standards?

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# Some Reasons We Draft a Standard

- New Technology
- Request from US FDA
  - E.g., safety concern
- Updates to existing Standard



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# Types of Standards

## NEMA/MITA Standard

- MITA members draft these
- Using MITA rules
- E.g. : MS-4: Acoustic Noise Measurement Procedure for Diagnostic MRI Devices

## American National Standard (ANSI)

- May include other stakeholders
- Falls under the rules for Consensus Body, etc.
- E.g.: ANSI/NEMA SC 1-2020 on Supplier Credentialing



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# Relationships with International Standards

- MITA strongly supports harmonization of regulations, especially via standardization
- Many Standards are involved in the development of medical devices
- NEMA/MITA Standards-drafted to later include in an IEC Standard
  - E.g. ISO 13485, IEC 60601 series
- Many members also participate in IEC, ISO, ASTM, and AAMI Standards efforts
- MITA also serves as the TAG Secretariat (Mirror Committee) for many IEC and ISO Standards



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# MITA, DITTA, and IMDRF

MITA is also a member of DITTA

Together, we monitor and comment on International Medical Device Regulators Forum (IMDRF) activity. MITA members participate where permitted.

IMDRF documents support regulatory harmonization and convergence

Other members of DITTA from the Americas include ABIMED from Brazil and MedTech Canada



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# Learning Opportunities for Standardization



Participate!



IEC Academy



ISO Resources/Toolkits



Young Professionals Opportunities

# Thank you/Gracias/Obrigada!



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