MEDICAL IMAGING & TECHNOLOGY ALLIANCE

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MITA®
MEDICAL IMAGING & TECHNOLOGY ALLIANCE
A DIVISION OF NEMA®

General

- MITA views the relationship between regulators and industry as a way to achieve our shared common goal of greater patient safety with improved access to high quality innovative technologies
- We believe a direct pathway to achieve that goal is through a strong commitment of international harmonization of regulations and standards

MITA Standards Activities

- MITA is the leading standards development organization for medical imaging systems
  - Develop and publish industry standards for imaging systems under NEMA's accreditation
  - Coordinate industry input into standards, practice guides, and other manuals development by professional societies and other SDOs
  - Administers several US TAGs to IEC 62 and coordinates US comments on relevant IEC documents and processes
  - Serves as secretariat for DICOM

MITA's Standards Goal

- Drive patient safety
- Improve quality care
- Promote patient access to the latest technologies
- Support regulatory efficiency

MITA Believes

- Reliance on consensus-based international standards:
  - is superior to reliance on particular federal performance standards
  - benefits all stakeholders
  - reduces burden on both manufacturers and regulators
  - Protects the public health
- Developing duplicative or competing performance standards would be a disservice to all stakeholders

MITA Believes

- Whenever possible, MITA supports IEC standardization and agrees that reliance on an international standard is preferable, however,
- MITA recommends reliance on consensus-based, recognized standards which would include standards developed by the IEC as well as other standards developers, such as MITA, NEMA, AAMI, ISO, IEEE, etc.
- Ultimate goal: alignment with international standards and reduction of burden for regulators and manufacturers, while maintaining quality, safety, and promoting patient access

NAFTA 2.0 - General

- MITA supports provisions to guarantee that regulatory and coverage systems in the signatory countries are more transparent, predictable, and in line with global best practices and international standards
- Medical device regulations are to harmonized with international best practices, such as IMDRF
- This will enable companies to comply with one set of regulations, but be able to sell products into any signatory country

Goals of NAFTA 2.0

- Good Refurbishment Practices (GRP) Standard (NEMA MITA 1-2015)
  - Refurbishment is the process during the expected service life to restore used medical imaging equipment to a condition of safety and effectiveness comparable to when new
  - Clearly defining used, refurbished, remanufactured
  - Market access in Mexico
- Implementation of WTO TBT Cmte. Decision on international standards
- Increased regulatory coherence
- Improving transparency with respect to reimbursement and pricing

Conclusion

- MITA views relationship between regulators and industry as a way to achieve our shared common goal of greater patient safety with improved access to high quality innovative technologies
- We believe a direct pathway to achieve that goal is through a strong commitment of international harmonization of regulations and standards
- We look forward to continuing to build on our collaborative relationship to achieve international harmonization to improve patient access to high quality, safe medical technologies

GRACIAS & THANK YOU

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