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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