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FAQ – MITA Service Standard

1. **What is NEMA/MITA 2 – Requirements for Servicing of Medical Imaging Equipment?**
    a. NEMA/MITA 2 is a Standard which describes and defines the minimum quality management system (QMS) requirements for servicing of medical imaging devices to ensure return to a safe and effective condition for its intended use.
2. **Why did MITA develop this Standard?**
    a. Until now, there have not been any QMS Standards developed specifically for servicing of medical imaging devices. MITA saw this as a critical gap that needed to be filled in order to protect patient safety and device integrity.
3. **How is this Standard different than other quality management system standards?**
    a. NEMA/MITA 2 is the first QMS Standard developed specifically for medical imaging device servicing activities. ISO 9001 is a general quality system Standard which can be adopted by any type of organization. ISO 13485 is a quality system Standard for manufacturers of medical devices. Both of these Standards—as well as the FDA Quality System Regulation—were used as the basis for development of NEMA/MITA 2. Compliance with other QMS Standards does not necessarily constitute compliance with this Standard.
4. **Who is this Standard for?**
    a. The requirements of this Standard are intended to be applicable to any medical imaging equipment servicing organization, regardless of size, or the specific equipment maintenance services it provides. The provider of applicable services may be an individual organization or may be an operating unit within an organization.
5. **Why should an organization adopt NEMA/MITA 2?**
    a. Servicing a medical imaging device is a complex and often difficult activity that poses a range of serious risks to patients and operators if performed improperly. Performance of servicing activities within an appropriate QMS by properly trained personnel using qualified, properly sourced parts greatly reduces the risk of harm to the patient or operator and greatly improves the performance of the device. A QMS is a highly valuable tool for ensuring that medical imaging devices consistently meet applicable requirements and specifications. Further, a properly implemented and managed QMS will drive an organization to continually improve and consistently deliver quality service to its customers.
6. **Is adoption of this Standard mandatory?**
    a. No, Standards, including NEMA/MITA 2, are voluntary.
7. **Is this Standard the same as regulation?**
    a. No, this Standard does not have the force of law and does not come with government oversight.
8. **How does this Standard interact with regulation?**
    a. Requirements determined by authorities having jurisdiction take precedence in the event they conflict with this Standard.

9. **Can NEMA/MITA 2 be used in coordination with other Standards?**
    a. Yes, NEMA/MITA 2 was written with a number of other documents in mind. This Standard is intended to be used in conjunction with the following publications:
        - AAMI EQ56, Recommended practice for a medical equipment management program
        - AAMI EQ89, Guidance for the use of medical equipment maintenance strategies and procedures
        - IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
        - IEC 62353:2014, Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
        - IEC PAS 63077:2016, Good refurbishment practices for medical imaging equipment
        - ISO 13372:2012, Condition monitoring and diagnostics of machines -- Vocabulary
        - ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes
        - ISO 14971:2007, Medical devices -- Application of risk management to medical devices
        - ISO 10993-1, Biocompatibility of patient contact materials
        - United States Code of Federal Regulations Title 21 Part 820, Quality System Regulation
10. **Can this Standard be applied to servicing of other types of medical devices?**
    a. Although this Standard was developed by medical imaging device stakeholders, its principles and processes can be applied more broadly to other serviceable medical device types.