

## **EXCERPTED MITA SERVICING STANDARD -SENT BY MITA on May 25, 2017**

**6.6. PROPER INSTALLATION** Service personnel shall establish, maintain, or acquire instructions and procedures for performing and verifying that the installation, inspection, and any required tests meets the specified requirements of the equipment. The service personnel installing the medical imaging equipment shall ensure that the installation, inspection, and any required testing are performed. The service personnel shall document the inspection and any test results to demonstrate proper installation. If the service provider supports relocation of medical imaging equipment, (e.g. moving the equipment from one healthcare facility to another) they shall provide information to the manufacturer as necessary to allow for recalls and updates. For installations involving x-ray emitting products, the service provider must comply with all applicable reporting requirements.

**6.7. PREVENTIVE MAINTENANCE (PM)** The medical and test equipment included in the scope of this standard have varied minimum PM requirements. PMs shall be performed according to the individual medical imaging equipment's procedures and timelines. The PM may be composed of, but not necessarily limited to: a. Electrical checks; b. Mechanical checks; c. Safety checks; d. Performance checks; e. Calibration; f. Software updates; g. Cleaning; h. Lubrication; and i. Replacement of consumable parts. The specific work performed and the results thereof during PMs shall be documented to demonstrate compliance with preventive maintenance requirements.

**SERVICING 7.1. INSTRUCTIONS** Each service provider shall establish, maintain, or acquire instructions and procedures for performing and verifying that the servicing meets the specified requirements of the equipment.

**11.1. CONTROL OF DESIGN AND DESIGN CHANGES** If the service provider makes design changes, they shall review, verify, and validate potential design changes to ensure that the safety and effectiveness requirements of the equipment are not changed from its original or applicable valid registration (e.g., IDE, 510(k), or PMA). All changes, including parts, must be evaluated to determine if the service provider needs registration, as he or she may become the legal manufacturer.

*(emphasis supplied)*