



[pweems@medicalimaging.org](mailto:pweems@medicalimaging.org)

Mr. Peter Weems  
Director of Policy and Strategy  
Medical Imaging & Technology Alliance,  
1300 North 17<sup>th</sup> Street, Suite 900  
Arlington, VA 22209

May 31, 2017

Re: MITA Efforts To Develop American Standard For Servicing Of Medical Imaging Devices

Dear Peter:

Thank you for forwarding on May 25, 2017 a copy of the revised MITA Servicing Standard. However, I was quite disappointed to continue to observe that trade and commerce elements are contained throughout the Standard including:

1. The Manufacturer is not required to provide any information;
2. The Standard imposes responsibilities on the Independent Servicer for **Proper Installation** to meet the 'specified requirements of the equipment' ¶6;
3. The Standard imposes responsibilities on the Independent Servicer for **Preventive Maintenance** to 'be performed according to the individual medical imaging equipment procedures and timelines'. See ¶7.1;
4. The Standard imposes responsibilities on the Independent Servicer to maintain procedures for **performing and verifying that the servicing meets the specified requirements of the equipment.**;
5. The Standard imposes responsibilities on the Independent Servicer for control of Design Changes to ensure that the requirements of the equipment are not changed from its original registration. ¶11.1.

There are also responsibilities for complaint management and root cause analysis, all of which require cooperation from the manufacturer to provide passwords, equipment manuals, schematics and service keys.

If the purpose of the MITA Servicing Standard is about patient safety, why has MITA elected to omit reference to any manufacturer responsibility to provide information necessary to address the Servicing Standard to be imposed?

Very truly yours,



Robert J. Kerwin  
General Counsel

International Association of Medical Equipment Remarketers and Servicers, Inc.

Cc: Ms. Diana Upton, President, IAMERS  
Mr. Steve Campbell, AAMI Chief Operating Officer  
Mr. Petr Kresta, President, ACCE