

## BALLOT for adoption of NEMA/MITA 2-201X Requirements for Servicing of Medical Imaging Equipment

**Canvass Member:** Stephen Grimes on behalf of the American College of Clinical Engineering (ACCE)

**Vote:** Negative

**Reasons for Vote:**

We do support the development of a QMS for medical equipment servicers

We are supportive of the development of a *quality management system* (QMS) standard for all medical equipment servicers (in-house, independent service organizations, OEMs) where adherence to such a standard would help ensure that medical equipment is maintained in a safe and effective manner.

Our reason for supporting the development of a QMS for medical equipment servicers

Currently available published analyses of millions of medical equipment-related adverse events occurring over the past decade suggest that servicing was a contributing factor in less than 0.005% of those events. Since the evidence suggests that servicing was a statistically insignificant factor in past adverse events, there is no reason to believe that servicers adherence to a QMS standard in the past would have made any measurable improvement in medical equipment safety or efficacy. However, we see the increasing sophistication, complexity, and criticality of new medical technologies. We believe that formalizing a QMS for servicers is a proactive step that could help minimize the possibility of an increase in service-related compromises to the safety and efficacy of these evolving technologies.

We agree the scope of a QMS standard should be for servicers providing *medical equipment maintenance services*. *Medical equipment maintenance services* include scheduled and corrective maintenance (e.g., testing, inspection, calibration, repair, or any patching or updating performed as per the original manufacturer's instructions) where those maintenance services do not change the features of a medical device nor do they change the original intended use/purpose. However in developing the QMS standard for these servicers, we should account for the fact that some who provide *medical equipment maintenance* (and therefore are covered by the QMS standard) may be doing so on an "incident by incident" basis (i.e., the servicer's involvement with an item of equipment may be limited to a maintenance "incident"). Maintenance done by a servicer on an "incident" basis may afford the servicer little or no opportunity to know of or track service histories. Also, not all servicers providing *medical equipment maintenance* also provide *medical equipment management services*. *Medical equipment management services* may be performed by different parties (e.g., owner/operators or agents contracted for the purpose). Examples of *medical equipment management services* include acquisition planning, operator education, maintenance management, incident investigation, hazard/recall management, security management, capacity management, emergency management, compliance. Any effective QMS approach for medical equipment servicers should consider how to effectively delineate QMS requirements between the servicers providing equipment maintenance and the servicers providing equipment management since they can be (and often are) different parties.

Our reasons for "Negative" vote on adoption of the current draft standard

### **a) The current draft limits itself to medical imaging equipment.**

The majority of medical equipment servicers actually maintain a broad spectrum of diagnostic and therapeutic medical equipment (e.g., laboratory, monitoring, life-support, surgical, imaging, etc.). Many of these other equipment modalities have safety implications at least as significant as imaging equipment ... and therefore these other modalities should logically be covered by any QMS standard developed for servicers. We know there are industry segments pressuring regulators to adopt the finalized standard as a requirement. If the standard does become a requirement, we believe that servicers supporting the broad spectrum of medical equipment would likely find themselves challenged to adhere to an imaging equipment standard and yet another QMS standard that had been designed for servicing of *all* medical equipment. That challenge would likely be made greater by the probability of conflicts between elements of the two standards. **We believe any QMS standard should apply to servicers of any type medical equipment.**

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### b) **The current draft was largely based on a QMS regulation tailored for manufacturers.**

The current draft was largely derived from 21 CFR Part 820, a federal QMS and Good Manufacturing Practice (GMP) regulation primarily designed for medical equipment manufacturers. While manufacturers and servicers have a limited number of practices in common, the original version of the draft standard had major sections lifted from 21 CFR 820 with the only change being the replacement of the word “manufacturer” with the word “servicer.” The result was passages originally intended for manufacturers took on a new meaning when applied to servicers. The committee reviewing the draft did make many subsequent modifications to the draft in an attempt to clear up those irrelevant sections but some of the subtler irrelevancies remain. To address this, early on in the review process we suggested that the standards committee consider deriving its draft from the current ISO 9001 QMS standard (as 21 CFR 820 had been derived from an earlier version of 9001 many years ago). We renew our recommendation that any new QMS standard for servicers be derived from ISO 9001:2015 and be adapted in a manner making it relevant to servicers (rather than using a manufacturers’ QMS regulation or standard as a source). This doesn’t mean we ignore 21 CFR 820 altogether or ignore the more recent AAMI 13485:2016 QMS standard developed for medical equipment manufacturers ... but we should use these regulations/standards as a reference point (where we see some merit) rather than a source. **We believe a QMS standard for medical equipment servicers should be derived from a broader and more current standard (e.g., ISO 9001:2015) and should be refined and adapted to servicers.**

### c) **The current draft includes requirements that would not demonstrably improve safety and effectiveness**

Well-designed QMS standards that promote important and relevant practices can help guarantee safe and effective use of technology in patient care. However, if adopted by regulators, QMS standards with requirements that are irrelevant or don’t measurably contribute to quality and safety can unnecessarily divert resources (e.g., staff, finances) from otherwise addressing the *real* safety and quality issues we all agree we should be focusing on. We recognize that any finalized QMS standard for servicers can be (and would likely be) adopted by regulators. Requiring the adoption of a QMS standard by imaging equipment servicers will result in some servicers exiting the medical imaging equipment segment of the service market and discourage still other servicers from entering the medical imaging equipment service market. Those results will lead to the reduction in availability of servicers and an increase in cost to consumers of medical imaging equipment maintenance. We believe that imposing additional QMS related requirements on medical equipment servicers will be justified as long as the those requirements have demonstrable benefits that outweigh any new limitations incurred by the industry. **The requirements spelled in the proposed standard should be reviewed to ensure that the potential safety and quality benefits realized through enforcement of those requirements outweigh any burdens those requirements place on servicers.**