October 1, 2013

Mr. Thomas Hamilton
Department of Health & Human Services
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality/Survey & Certification Group
7500 Security Boulevard
Baltimore, MD 21244

Re: AAMI EQ56 Standards on Hospital Equipment Maintenance

Dear Mr. Hamilton:

Although we, the undersigned organizations, continue to be disappointed that the Centers for Medicare & Medicaid Services ("CMS") is unwilling to meet with any of us to discuss the important issue of equipment maintenance and repair standards under the Medicare hospital conditions of participation, you have indicated that the agency is considering adopting the Association for the Advancement of Medical Instrumentation ("AAMI") EQ56:2013 standards. We note that these AAMI standards are not publicly available and that they were only approved on March 13, 2013. As such, the standards neither provide a transparent mechanism for setting expectations nor have they been studied or tested to assess their appropriateness or impact. This letter reflects the comments of the undersigned organizations, all of which play a leading role in ensuring the safe and effective use of medical imaging equipment. At least as applied to medical imaging equipment, we collectively believe, in the strongest terms possible, that the adoption of these untested AAMI standards would be a disservice to the Medicare program and would put patients at risk.

These "standards" effectively provide no standard at all, as they merely suggest that health care organizations develop their own procedures. As the inspection and maintenance section to the standards states, the standards merely encourage a health care organization to "identify its own needs for the scheduled testing or inspection of equipment". Id., Section 7 at 16. The standards on inspection and maintenance state, even more clearly, that "[i]t is up to each health care organization … to identify the steps it will take as part of its testing or inspection procedures." Id. The standardless nature of these "standards" is also reflected in the notes to the inspection section stating that "[t]he recommended practice is not intended to require that any specific test be included in any inspection procedure". Id. at 16. Literally every facility in the United States could determine it will take an approach different from every other one, and each could still claim it had met the "standard".

The absence of any real standard is further reflected in the fact that there is no obligation that any health care organization even consider manufacturer recommendations or FDA clearance conditions. Id. Neither manufacturer nor FDA requirements are even mentioned in the inspection and maintenance section of the document.

Incredibly, while failing to require that either manufacturer requirements or FDA mandates be considered, the standards also permit users to take no action whatsoever to improve inspection and maintenance procedures

in the face of even repeated equipment failures. Id. at 17. As the standards bluntly concede, they "do[] not require a change in [inspection and maintenance] intervals in response to one or multiple failures." Id.

The standards with respect to repair programs are no better. See id., Section 8 at 18. There, too, the standards merely call upon health care organizations to develop written procedures, the sufficiency of which is entirely for the organization to determine for itself. The standards leave the development and content of those procedures to those organizations, despite the fact that they have a financial interest in minimizing the steps that they are required to take and despite the risk that this self-interest creates for patients and their own staff.

Although the repair standards note that "[e]quipment manufacturers can often provide information on which parts might be critical to performance or safety", absolutely nothing in the standards requires users to adopt manufacturer standards or even to consider them. Id. at 18. Further, in deciding whether to retire old equipment, users are not required to apply criteria examining "the dependability of the equipment" or its "compatibility with other equipment", including "sterilization modalities, interface with information systems, etc.". Id.

Significantly, even as the standards seek to loosen the existing protections that CMS and others currently establish and enforce, the standards themselves concede the failure of many health care organizations to meet appropriate standards at present. For instance, the standards acknowledge that "[a] particular concern in some health care organizations is the tendency to continue using old equipment even after it has been determined that the equipment is no longer safe or no longer working appropriately." Id. at 19-20. The standards also concede that health care organizations have equipment "placed in storage for use as back-up equipment" that may not be safe for use and that this practice is "due to cost" considerations. Id. at 20. The standards admit that this practice is problematic because "[e]quipment placed in storage will often deteriorate" and because stored equipment may have "regular program[s] of equipment inspections … suspended". Id. Despite the recognition here that cost considerations can lead to health and safety risks, the standards as a whole invite users to consider their own costs in exercising the unfettered discretion conferred by the standards.

The lack of any real content in the standards and the risk that this inevitably creates for patients and equipment users is evident on the face of the standards themselves. As the standards clearly state, they "do[] not in any respect preclude anyone, whether they have approved the recommended practice or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the recommended practice." Id. at ii. Under the plain language of the standards, the discretion of health care facilities is ultimately unlimited; according to the standards, even recommended practices are "solely within the discretion and professional judgment of the user of the document." Id. This will be true regardless of whether or not a user's policy fails to protect patients and providers.

The standards repeatedly state that they are not intended to do anything more than create a "minimum standard". In doing so, the standards concede that this "minimum" standard is below the established practice in following manufacturer recommendations at many sites and the standards already established by CMS, professional organizations, manufacturers, and others. For instance, the standards concede that "[m]any existing programs exceed these standards by very wide margins." Id. at viii. The standards also admit that the American Osteopathic Association ("AOA"), quite unlike these AAMI standards, has "[e]stablished scheduled preventive maintenance program[s] for all biomedical equipment in accordance with manufacturer's recommendations." Id. at 28. That same concession is made in connection with the repair standards, where the document concedes that CMS, DNV Healthcare, and the AOA all require these activities to be undertaken "per manufacturer's recommendations". Id. at 30.

Although AAMI acknowledges a few of the stakeholders who endorse manufacturer requirements as a minimum protection, AAMI fails to list most of the organizations that disagree with its position, indicating that AAMI failed to consider the existing standards of numerous accreditation organizations and others. The "crosswalk" to other standards that AAMI includes in its document fails to list the accreditation systems offered

by the American College of Radiology, the Intersocietal Accreditation Commission, the American Institute of Ultrasound in Medicine, and many others. This fact shows a fundamental flaw in the process used to arrive at these standards, which purport, largely on the work of a single committee, to reflect a "consensus". The crosswalk's failure to consider multiple existing standards and the fact that, incomplete as it is, it shows that multiple existing stakeholders do require adherence to manufacturer recommendations, belies the standard's assertion that it reflects a "consensus".

For all of these reasons, the undersigned organizations urge CMS not to weaken the existing protections that apply to imaging equipment by adopting the AAMI standards. Simply put, doing so would put the Medicare program and its beneficiaries at risk.

Sincerely,

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cc: Centers for Medicare & Medicaid Services:
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