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Letter to the Editor

In reference to: High-level disinfection, sterilization and hand hygiene: What do accreditation surveyors want to see?

Patricia Stone, PhD.
Editor.
American Journal of Infection Control.

Dear Editor:

The following is in reference to the article, *High-level disinfection, sterilization, and hand hygiene: What do accreditation surveyors want to see?* published in the October 2023 issue. The article describes a standardized approach to the development of infection prevention and control-related processes, policies and protocols and the hierarchy of documentation that The Joint Commission (TJC) uses in assessing organizational performance against TJC standards.

There has been confusion in the field over the use of evidence-based guidelines, standards and consensus documents. While the article was intended to alleviate that confusion, we are concerned by how American National Standards, particularly those developed by the Association for the Advancement of Medical Instrumentation (AAMI), were characterized.

The author equates the standards developed by AAMI with voluntary guidance developed by 2 professional societies by using all 3 as examples of *consensus documents*. While the process used to develop these documents may rely on consensus, this is where the similarities between an American National Standard and other types of documents developed by professional societies ends.

Standards are consensus documents that provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose. AAMI has been accredited by the American National Standards Institute (ANSI) to develop American national standards. To maintain this accreditation, an ANSI-Accredited Standards Developer must comply with a rigorous set of requirements. These requirements include[1]:

1) Due process: Any party (organization, company, government agency, individual, etc.) with a direct and material interest has a right to participate by: (1) expressing a position and its basis, (2) having that position considered, and (3) having the right to appeal.
2) Openness: Participation must be open to all parties who are directly and materially interested in the activity. There may be no undue financial barriers to participation. Voting membership on the consensus body may not be conditional upon membership in any organization, nor unreasonably restricted on the basis of technical qualifications or other requirements.
3) Lack of dominance: The standards development process may not be dominated by any single interest category, individual or organization.
4) Coordination and harmonization among existing American National Standards and candidate American National Standards.
5) Notification: Timely and adequate notice of standards development activity must be announced in media suitable to demonstrate that a meaningful opportunity for participation, debate and deliberation by all directly and materially interested parties in a fair and equitable manner was provided.
6) Consideration of views and objections: Prompt consideration must be given to the written views and objections of all participants,
7) Consensus Vote: Evidence of consensus in accordance with these requirements and the accredited procedures of the standards developer must be documented.
8) Appeals: Written procedures of an ANSI-Accredited Standards Developer must contain an identifiable, realistic, and readily available appeals mechanism for the impartial handling of procedural appeals regarding any action or inaction.
9) Written procedures: Written procedures shall govern the methods used for standards development and shall be available to any directly and materially interested party.

The resulting document, once the development process has been reviewed and approved by ANSI, becomes an American National Standard. Standards with an American National Standard designation have been written into United States law, formed the basis for international standardization and regulation and been referenced by countless professional organizations. Unlike most professional society guidance, the United States Federal government relies on AAMI standards (and other AAMI technical documents). The US Food and Drug Administration has formally recognized a number of standards developed or nationally adopted by AAMI, including ANSI/AAMI ST91, *Flexible and semi-rigid endoscope processing in health care facilities*.

While many professional societies claim to use a consensus process, the resulting documents often reflect the views of a small group, are developed without the opportunity for input from a larger community, and lack due process and transparency. Many do not even have a written process for development of these documents. While many of these documents are valuable additions to the practice of infection prevention, it is the rigor of the process accredited by ANSI that sets AAMI apart. To suggest that they are essentially the same is a false equivalence.

We urge the TJC to reconsider the hierarchy in Figure 1 of the article and appropriately distinguish AAMI standards from other consensus documents.

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Reference

1. American National Standards Institute (ANSI), New York, New York. https://www.ansi.org/american-national-standards/ans-introduction/essential-requirements.

Conflicts of interest: Amanda Benedict, MA, CStd,: Paid employee of the Association for the Advancement of Medical Instrumentation. Damien Berg, BA, BS, CRCST, AAMIF: AAMI committee member, has received travel reimbursement. Charles E. Edmiston, Jr., MS, PhD, CIC, FIDSA, FSHEA, FAPIC, FSIS: No conflict of interest. Maureen Spencer, Med, BSN, CIC, FAPIC: No conflict of interest. Lisa Waldowski, DNP, RN, CIC: No conflict of interest. Kathy Warye, BS: No conflict of interest.

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Letter to the Editor

Letter in response to the letter submitted by Warye et al (AAMI) criticizing the article by Sylvia Garcia-Houchins

Dear Editors,

The Joint Commission recognizes the exceptional work that the Association for the Advancement of Medical Instrumentation does to improve infection prevention and control through its rigorously developed standards. However, we disagree with your statement that in the article by Ms. Garcia-Houchins: "The author equates the standards developed by Association for the Advancement of Medical Instrumentation (AAMI) with voluntary guidance developed by two professional societies by using all three as examples of *consensus documents*."[1] There was no statement that directly or indirectly equate AAMI standards with others. After discussing the hierarchy of Rules and Regulations, Center for Medicare and Medicaid Conditions of Participation, and Manufacturer's Instructions for Use, the article simply stated, "When there is additional direction needed on a specific issue, healthcare organizations may choose to follow consensus documents to reduce patient risk," and then listed the 3 examples.

The rationale for discussing these examples together is that evidence-based guidelines and consensus documents, including American national standards, are voluntary. The hierarchy distinguishes *requirements* that must be followed (Rules and Regulations, Center for Medicare and Medicaid Conditions of Participation, and Manufacturer's Instructions for Use) from *recommendations* that organizations may choose to follow. We think health care organizations should routinely review AAMI standards when they are looking for additional guidance on a topic, but we continue to believe that it is best to group voluntary recommendations together. As stated in Ms. Garcia-Houchins' letter, "Unless required by regulation, Joint Commission standards or Instructions for Uses, organizations can choose which evidence-based guidelines and consensus documents they will follow."

Note: Ms. Garcia-Houchins is no longer employed by The Joint Commission.

Reference

1. Garcia-Houchins S. High-level disinfection, sterilization, and hand hygiene: what do accreditation surveyors want to see? *Am J Infect Control.* 2023;51:1182–1184.

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