Simplifying the Semantics

by Stephen Kovach

Q "I was just told by a sales representative that I must use their product, and I must test my cleaning equipment each day that it is used, with their product only. Is this really a requirement?"

A In general, the terms "must", "shall", "should", "can", and "may" (within the standards) are not clearly understood, because they are defined in the introduction, and people tend not to read that section.

In the standards (i.e., AAMI and ANSI), there are five terms used that have universal meaning. Here's how they are used in writing [*not in any particular order*]:

1. **Shall:** Indicates requirements strictly to be followed to conform to the recommended practice.
2. **Should:** Among several possibilities, one is recommended as particularly suitable:
   a. Without mentioning or excluding others
   b. A certain course of action is preferred but not necessarily required
   c. (In the negative form), a certain possibility or course of action should be avoided, but is not prohibited.
3. **May:** Indicates that a course of action is permissible within the limits of the recommended practice.
4. **Can:** As a statement of possibility and capability
5. **Must**: *Only* used to describe "unavoidable" situations—including those mandated by government regulation.

Therefore, to answer your questions about a salesperson saying you "must use their test," and you "must test at a certain frequency," here is how I look at your question. In this specific concern, the standards (as they pertain to the United States market) are clear—the term "should" is to be used, not "must" (ANSI/AAMI ST 79 -13.2)—when it comes to testing and monitoring your cleaning equipment.

Concerning the statement, you "must use their [test]," to me, that is a gray area. I would think you would use a clinically relevant and evidence-based test to challenge your equipment. A department has the right to use the product they feel is best for their process based on all available information. It would not have to be *that company's test*, unless they had all the information you requested to make the best choice.

An example for a sterilizer, many people make biological and chemical indicators, but they are not always from the same company as the sterilizer manufacturer. However, they are still used because the department feels it is the best product for their practice. The same should be true for cleaning equipment verification. Again, use the best product that is clinically relevant, and evidence based.

Q "Can you help me understand the difference between regulations, standards, and guidelines?"

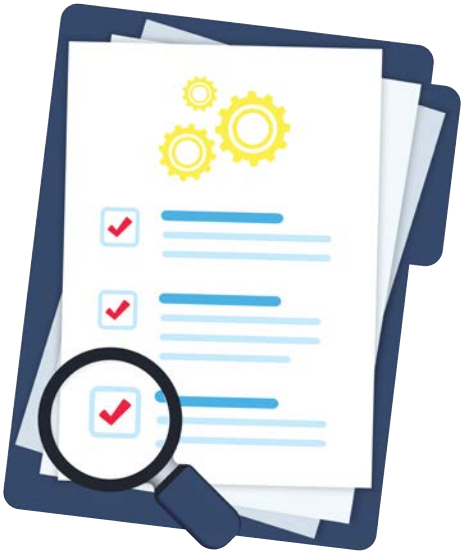
A

- **Regulations**:
  - A rule or directive made and maintained by an authority.
  - Mandatory (must).
  - Think OSHA, CMS.
- **Standards**:
  - Requirements and specifications to ensure consistency and fit for purpose.
  - Voluntary, but can become mandatory.
  - Think ANSI/AAMI Documents.
- **Guidelines, Recommended Practices, Technical Information Reports**:
  - Technical guidance, information, or preferred procedures about a given topic.
  - Voluntary, but with interpretation.
  - Think AORN, SGNA, AST.

In today's world, many of the documents mentioned above are in Portable Digital Format (PDF), which means they are easy to search/find information and store on a computer. My recommendation is to get these documents in PDF format when purchasing. HPN

Reference

AAMI. (2017). ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Section 13.2. [n.p.].



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