Applying Standards in Sterile Processing: What Technicians Must Know

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LEARNING OBJECTIVES

1. Identify the multiple standards and guidelines that apply to Sterile Processing
2. Understand the meaning of directive words in the recommendations
3. Learn how standards and guidelines serve as the basis for departmental policies and operating procedures

Sterile Processing (SP) is a complex, fast-paced and critical department that helps ensure safe patient care by providing medical devices and related items that are properly processed and well-functioning. The Sterile Processing department (SPD) also serves a key infection prevention function, ensuring that infections are not caused or transmitted by the devices used for patient care.

Recognized standards and clinical practice guidelines provide accepted recommendations and requirements and serve as primary references in developing and following departmental policies and operational procedures. Standards and guidelines are often quite lengthy, cover distinct aspects of device processing for different settings, and are authored by different organizations using different processes. Keeping up with standard and guideline updates and interpreting the recommendations for each setting can be challenging. This lesson aims to familiarize SP technicians with the different types of documents, increasing understanding of key aspects of these important references as they are applied to the SPD or patient care settings.

Objective 1: Identify the multiple standards and guidelines that apply to Sterile Processing

Some documents are created by standards development organizations (SDOs), entities whose primary purpose is to develop consensus-based standards with multiple stakeholders participating. Stakeholders are people with a strong interest in the subject of the standard, who have expertise on the topic and represent one of four categories:

- Users of the guidance document, including SP personnel and other healthcare professionals

- Regulators such as the U.S. Food and Drug Administration (FDA)
- Industry representatives, including vendors
- Independent experts

Consensus documents are sterilization-related standards written by committees of SP personnel. See **Table 1** for other common terms and definitions related to the process.

Clinical practice guidelines are developed by clinical or medical professional organizations, typically for a specific practice setting, and are authored by a group of clinical professionals from that setting. For example, the Association of periOperative Registered Nurses (AORN) authors clinical practice guidelines specific to the Operating Room (OR) environment; the Society of Gastrointestinal Nursing and Associates (SGNA) authors guidelines for the endoscopy setting; and the Association for the Advancement of Medical Instrumentation (AAMI) authors comprehensive consensus-based documents that apply to all practice settings where device processing is performed.

The process of drafting the documents and determining who participates in, reviews and endorses the documents differs between SDOs and clinical professional organizations. Both groups, however, strive to develop practical, evidence-based documents. They work to ensure the documents are updated to reflect the current types of devices and processing methods available, incorporate new evidence as it is published, and include legal requirements established by regulatory agencies from the U.S. government such the FDA and Occupational Safety and Health Administration (OSHA). **Table 2** provides a comparison of development factors for standards and clinical practice guidelines.

Term	Definition
Consensus	Consensus is defined as **general agreement** but not necessarily unanimity. During the development of consensus, comments and objections are considered using fair, impartial, open and transparent processes.[1]
Consensus report	A consensus report provides concise, prompt and practical guidance on narrowly focused topics of high importance to the health technology community.[2]
Standard	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.[2]
Clinical practice guideline	Clinical practice guidelines are statements that include recommendations intended to optimize patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.[3]
Evidence-based guideline	Evidence-based guidelines are statements that describe a specific prevention, treatment or policy action. The scientific evidence underlying these statements is typically obtained through a systematic review of the literature and organized in evidence summaries.[4]

Table 1: Terms and definitions related to standards and guidelines

	Standard	Clinical Practice Guideline
Requires full stakeholder participation	Yes, including Sterile Processing personnel	No. Other stakeholders may provide input during public review.
Developed and published by a standards development organization	Yes	No. Developed by a professional or medical society or collaboration of multiple societies. Published by the society or in a society journal.
Recommendations for Sterile Processing practices	Yes, AAMI standards	Yes. AORN standards and other medical societies for specific devices or settings
Guidance for product or process performance requirements	Yes	No. Strong reference to product manufacturers' instructions for use
Basis for content	Expert consensus, data, regulatory requirements and evidence	Published evidence with expert opinion of strength of evidence or options where evidence is lacking

Table 2: Differences between standards and guidelines

Objective 2: Understand the meaning of directive words in the recommendations

Due to the complex, multi-step processes that take place in the SPD, the department has long been recognized as an area where standards can help improve practices and quality outcomes. The first comprehensive document from AAMI for steam sterilization was published in 1992 and titled ANSI/AAMI ST46 *Steam sterilization and sterility assurance in health care facilities*. Since then, that evolved to ANSI/AAMI ST79:2017/(R)2022 w/ AMDs A1:2020, A2:2020, A3:2020, A4:2020 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*.

Multiple other standards and guidelines that apply to SP areas have also been published. The following is a list of the key processing-related documents that facilities should be aware of and use when developing and maintaining departmental policies and operating procedures.

AAMI[2]

- ANSI/AAMI ST79:2017/(R)2022 w/ AMDs A1:2020, A2:2020, A3:2020, A4:2020 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
- ANSI/AAMI ST58:2013/(R)2018 *Chemical sterilization and high-level disinfection in health care facilities**
- ANSI/AAMI ST41:2008/(R)2018 *Ethylene oxide sterilization in health care facilities: Safety and effectiveness**
- ANSI/AAMI ST90:2017 *Processing of health care products—Quality management systems for processing in health care facilities*
- ANSI/AAMI ST91:2021 *Flexible and semi-rigid endoscope processing in health care facilities*
- ANSI/AAMI ST108:2023 *Water for the processing of medical devices*
- ANSI/AAMI ST65:2008/(R)2018 *Processing of reusable surgical textiles for use in health care facilities*
- ANSI/AAMI ST40:2004/(R)2018 *Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities*

* ST58 and ST41 have been combined by AAMI Standard Workgroup (ST/WG) 61 Chemical Sterilants Hospital Practice. The updated ST58 is expected to be published in 2024.

Note: While these documents are specific to practices in the healthcare setting, there are other AAMI standards intended for manufacturers of medical devices. These standards provide specific directions to manufacturers that impact the processing of the device and help the manufacturer better understand the environment and variation of the environments where their device will be used and processed.

AORN[6]

- *Guideline for Environmental Cleaning*
- *Guideline for Flexible Endoscopes*
- *Guideline for High-Level Disinfection*
- *Guideline for Instrument Cleaning*
- *Guideline for Packaging Systems*
- *Guideline for Sterilization*

CDC[5]

Guideline for Disinfection and Sterilization in Healthcare Facilities (2008), minor update published in 2019

Standards and guidelines may use different words to express how important it is to follow the requirements or recommendations. While the exact terms used vary between SDOs and clinical professional organizations, the intent is similar: the stronger the language, the more justification there is to perform the task in the manner described in the guidance document.

Whenever "shall" or "shall not" is used in a document, it is an actual requirement, often because there is a law or regulation that must be followed. OSHA, for example, has established requirements related to SP settings that are intended to keep healthcare professionals safe from occupational hazards. "Shall" is also used when there is strong published technical data or research-based or clinical evidence that supports the requirement.

The directive words to pay close attention to in any standard or guideline can include the following. This list is from ANSI/AAMI ST79:

- "Shall" and "shall not" are used to express requirements.
- "Should" and "should not" are used to express recommendations.
- "May" and "may not" are used to express permission.
- "Can" and "cannot" are used as statements of possibility or capability.
- "Might" and "might not" are used to express possibility.

Other word combinations are recommendations where there is some basis for making that statement. These words carry through to departmental policies and operating procedures aligned with the standards or guidelines referenced.

Objective 3: Learn how standards and guidelines serve as the basis for departmental policies and operating procedures

Healthcare facilities vary widely in design, equipment, funding, staffing, training programs and competency assessment. Establishing facility and its departmental policies and operating procedures helps address the variances between the facility and departments and provides direction on how to properly perform each task in the

best interest of the patient, healthcare professionals and facility. Policies and operating procedures are developed by the facility or department based on other policies (e.g., infection prevention and control policies), established standards and guidelines, and manufacturers' instructions for use (IFU).

Compliance organizations, or organizations that audit healthcare facilities, such as The Joint Commission (TJC) and Det Norske Veritas (DNV), expect SPDs and other processing areas to have written policies and procedures based on national and local laws, standards, evidence-based guidelines and manufacturers' IFU.[6] SPD policies use information from these sources and transform it into a reference that SP professionals learn and follow to ensure consistent, safe and effective device processing for patient care. SPD policies and procedures should be reviewed annually, updated as needed, used to train, support competency assessment, and made readily available to all SP staff.

Policies and procedures are specific to tasks performed in the department. Separate SP policies are often established for transport and receiving; cleaning and decontamination; inspection, preparation, and packaging; disinfection (intermediate and high-level); sterilization; quality control or recordkeeping; storage and distribution; attire; training and competency assessment; recall procedures; immediate-use steam sterilization; preventive maintenance of processing equipment; processing in dental or clinic settings; flexible endoscope processing; and loaned devices. Others are developed based on the facility or organization's specific needs (e.g., setting and types of devices processed). These are key documents to help ensure every staff member performs each task the same way.[6]

Rules and Regulations (e.g., national, state, local laws)
The Centers for Medicare & Medicaid Services Requirements
Manufacturers' Written Instructions for Use
Evidence-Based Guidelines and National Standards
Consensus Documents
Organization's Infection Prevention and Control Processes, Policies and Procedures

Table 3: The Joint Commission's Hierarchy to Comply with Infection Prevention and Control Requirements
Note: This lesson's author recreated this from the information found at www.jointcommission.org/resources/patient-safety-topics/infection-prevention-and-control/infection-prevention-and-control-hierarchy/

Accrediting organizations periodically visit facilities to inspect or audit them according to regulations, manufacturers' IFU, and the facility's and department's policies. Healthcare facilities contract to become certified to the requirements established by the accrediting organization. While the certification process is voluntary, the Centers for Medicare and Medicaid Services (CMS) requires that a facility is accredited to receive payment for services for patients with those healthcare plans.[8] Many private healthcare insurance companies also require accreditation to receive payment for services.

Policies and procedures will often include these sections for the specific topic or area to which the policy applies:

1. Effective date
2. Title
3. Purpose (brief description of the task or process and the reason for it)
4. Policy (typically written in bullet points to identify what is to be done)
5. Scope (who is/which departments are affected)
6. Procedures (detailed instructions on how to complete the task that meets the policy)
7. Definitions
8. Referenced standards, guidelines or other publications (basis for the policy)
9. Materials needed
10. Referenced manufacturers' IFU that apply to the policy and procedures
11. Approvers
12. Revision history

The inclusion, format and order of sections will vary by facility. All policies and procedures should be comprehensive, written for the employees performing the task, and readily available.

The standards and guidelines referenced are used to describe the procedure, serve as a source for the definitions and help to define the resources needed to support the types of materials used. If the referenced standard provided a "should" recommendation, the policy needs to reflect that same strength level of language.

TJC published a helpful chart to understand how their accreditors look at the strength of several types of documents.[9] The hierarchy aligns with the common language used in key standards ("should" requirements).

Conclusion

There is no shortage of published standards and guidelines for the SP setting. These documents are based on technical data, science and clinical evidence. Understanding the terminology

used in standards and guidelines is critical. The language used has a direct effect on the policies and procedures needed to comply with infection prevention and control requirements and align with recognized practices that promote quality patient care.

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