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# Standardization Gaps in Instrument Reprocessing: A Comparative Review of U.S. and International Sterile Processing Practices

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## Abstract

Sterile instrument assurance is the basis for safety during surgical procedures, but standards for instrument processing lack standardization at both the global and national levels. The objective of this paper is to perform a gap analysis of sterile processing (SP) between the United States (US) and comparable, high-resource nations through a focused literature review. Recommendations are offered with an eye toward future regulatory improvements in the US. The US system is based on voluntary professional guidance issued by the Association for the Advancement of Medical Instrumentation (AAMI), which forms the core for practices that are not otherwise prescriptively mandated by state or facility policies. In contrast, other developed nations, most notably Germany, the United Kingdom, and Canada, have centralized and national standards with which SPs must comply. This paper reviews literature on the characteristics of each model and provides insights into the structural and educational differences that impact how SP departments are staffed, accredited, held accountable, and incentivized to adopt innovative equipment and technology. The current voluntary structure in the US results in vulnerabilities that are avoidable and contribute to preventable patient harm. The authors propose a shift in regulatory structure that considers best practices from global partners to promote more standardized practices across hospitals to enhance safety.

**Keywords:** Sterile Processing Standards; Medical Device Reprocessing; AAMI ST79; International Healthcare Regulation; Centralized vs. Decentralized Regulation; Patient Safety Standards

## Introduction

The chain of custody for reusable medical device reprocessing is a detailed and multi-step procedure where even a single point of failure can result in catastrophic patient safety outcomes, such as surgical site infections (SSI) and cross-contamination. In this age of increased access to global health care and rapidly advancing technology, one would expect standards for instrument reprocessing to be strict and consistently applied. In reality, significant standardization gaps exist within and between countries. In the US, instrument processing operates on a combination of voluntary guidelines, non-binding state and facility requirements, and policy mandates, resulting in disparate practice. In several peer countries, SP practices are bound to a centralized and mandatory regulatory system. In this analysis of best practices in high-resource countries, we

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compare the differing approaches used to regulate SP practices and their impacts on patient safety. We then provide a future-focused discussion of gaps that remain in standardization in the US, including recommendations for a more standardized and secure national structure.

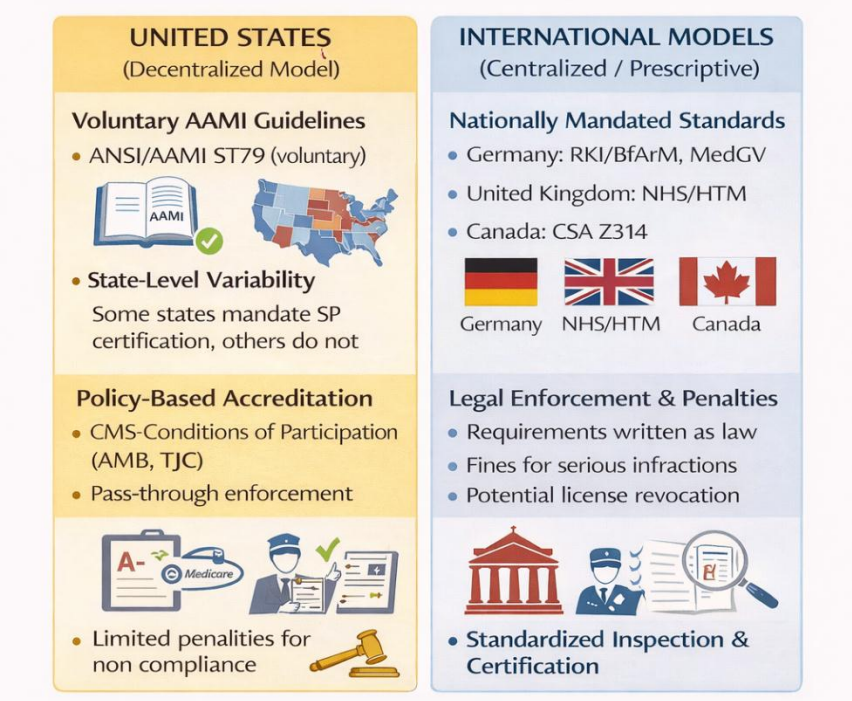


*Figure 1. Comparison of decentralized, guideline-based sterile processing regulation in the United States with centralized, prescriptive regulatory models used in peer countries.*

**The U.S. Model: Decentralized, Guideline-Based Framework**

No single federal regulation exists in the US for sterile processing departments that is applicable across all healthcare facilities

- **Predominantly Follows AAMI Standards:** The national "standard" is the voluntary consensus guidelines published by AAMI for steam sterilization (ANSI/AAMI ST79 series; AAMI, 2022). These are the most comprehensive, evidence-based set of recommendations but are not federal law.
- **Regulation through Other Federal Agencies:** Oversight of SP is indirect, with Centers for Medicare & Medicaid Services (CMS) exerting most influence through its "Conditions of Participation." These require hospitals to have infection control programs but do not give specific guidance on SP. CMS or accrediting bodies (eg, The Joint Commission [TJC]) survey SP departments by examining if a facility is "doing what they

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say they are doing" in writing. TJC/TJC typically require each department to have written policies/procedures that address key elements of SP operations, often based on AAMI guidelines but not always necessarily in line with current best practices (Rutala & Weber, 2019). Therefore, if a hospital has a written policy on water testing and performs the tests monthly, the TJC surveyor will likely not probe any further despite the practice not being in accordance with AAMI recommendations (Ofstead et al., 2018). This is the "pass through" model of accreditation enforcement.

- **Individual State Laws and Requirements:** States have the ability to pass their own laws for SP technicians, which include requirements for training hours/certification and department licensure or registration. Some states have no regulations for SP departments, whereas states like New Jersey and New York have created extensive administrative codes (HSPA, 2023). This results in nonuniform requirements for mobile workers and creates significant challenges to ensuring a nationally competent workforce.

**International Models: Prescriptive, Centralized Regulatory Systems**
Germany, United Kingdom, and Canada have a top-down approach to the regulation of SP and use centralized, often legally binding policies that drive the adoption of best practices and have consequences for non-adherence.

- **Germany:** Largescale sterilization and reprocessing is regulated by the Robert Koch Institute (RKI) as well as the Medical Devices Operator Ordinance. Germany has national, prescriptive regulations that are legally enforceable. These contain highly detailed mandates for specific validation of washer-disinfectors, sterilizer cycles, and water quality standards. In addition, personal certification is needed, and each healthcare facility must be certified by their state-level health department. Inspections are unannounced and assess technical parameters of the SP department such as water samples, temperature, air exchange rates, as well as processing records and documentation (Medical Devices Act, 2021).

- **United Kingdom:** In the UK, the independent regulatory body for medical devices is the MHRA, which gives detailed recommendations for SP. The use of these guidelines is mandated for all National Health Service (NHS) trusts. The NHS has established a national, centralized decontamination strategy with identified high-volume hubs for processing of higher risk devices such as powered instruments (NHS England, 2021). This centralized approach allows greater standardization of processing activities and technical expertise for challenging equipment. Technical staff competency frameworks are national.

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- **Canada:** The regulation of reprocessing is at the provincial level under provincial health authorities, but there is significant national harmonization across provinces. Canada has national standards published by Standards Council Canada that are commonly adopted by provinces (eg, CAN/CSA-Z314) and incorporated into accreditation requirements, resulting in greater standardization of practice than in the United States (Accreditation Canada, 2022).

**Comparisons of Gaps in Standardization between the US and Other Countries**
This structural heterogeneity impacts operations and patient safety.
*Table 1. Comparison of regulatory structures, enforcement mechanisms, and workforce requirements for sterile processing in the United States and selected peer countries.*

| Dimension | United States | Germany | United Kingdom | Canada |
|---|---|---|---|---|
| **Regulatory basis** | Voluntary (AAMI) | National law | National mandate | Provincial + national |
| **Enforcement** | Accreditation-based | Legal inspections | NHS enforcement | Accreditation |
| **Technician certification** | Variable | Mandatory | Mandatory | Largely mandatory |
| **Inspection style** | Policy review | Technical audit | Technical audit | Mixed |
| **Penalties for non-compliance** | Limited | Yes | Yes | Yes |

1. **Education and Competency of the Workforce**
    - US Gap: Technician training is variable in the US, and many jurisdictions do not even require technicians to hold a certification in steam sterilization (Chow & Hon, 2022). In general, there is no requirement at the federal level for a credential. Validation of competencies is left to the facility.
    - International Contrast: Other countries such as Germany and the UK require a formal apprenticeship or nationally standardized vocational qualifications. The result is a uniformly trained workforce.

2. **Accreditation and Oversight of the SP Department**
    - **US Gap:** Accreditation surveys (eg, TJC) focus primarily on policies and process flow and give limited attention to technical skills, operator knowledge, or currency of the processes to the latest available evidence. A completely accredited department could follow less than ideal practices (eg, weekly water testing or no

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independent spore testing) if these were outlined in policy and consistently executed.

- **International Contrast:** In most other countries' systems, inspection is done in combination with direct audit of equipment performance logs, biological and chemical monitoring records, sterilization cycle parameters, water and chemical concentrations, and so on by a team of specialized inspectors (eg, health department in Germany) in addition to personnel credentialing and technical documentation review.

3. **Adoption of Technologies and Best Practices**
    - **US Gap:** Voluntary consensus standards are subject to implementation timelines and do not have to be universally adopted, which delays the ability to employ certain best practices, such as the routine use of protein residue test strips or AERs with data connectivity. Further, decisions to invest in emerging technologies are facility-level.
    - **International Contrast:** National programs can more quickly issue directives for new technology adoption (eg, mandates to use track-and-trace systems with sterilization) for all facilities under their governance as seen in parts of Europe.

4. **Compliance and Enforcement**
    - US Gap: Enforcement of requirements in the US is typically reactive and in response to an adverse event or outbreak. Proactive, unannounced technical inspection of departments is a significant gap in our system (Ofstead et al., 2018).
    - International Contrast: In prescriptive regulations, there is often a legal mandate and associated penalty for non-compliance. This drives a much more proactive culture of compliance.

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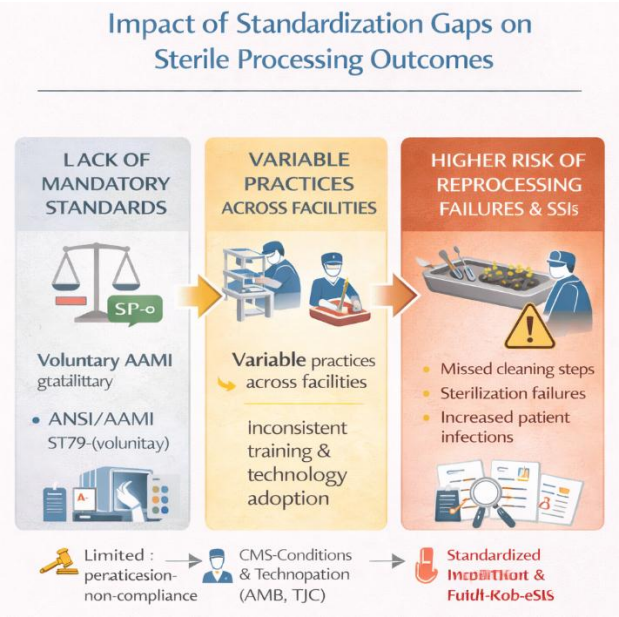


*Figure 2. Causal pathway demonstrating how lack of mandatory national standards in sterile processing contributes to variability in practice and increased patient safety risk.*

## Recommendations for a Path Forward in the U.S.

The gaps that exist in the United States as compared to peer countries can be closed by shifting to a more prescriptive model. We make the following recommendations for this to occur.

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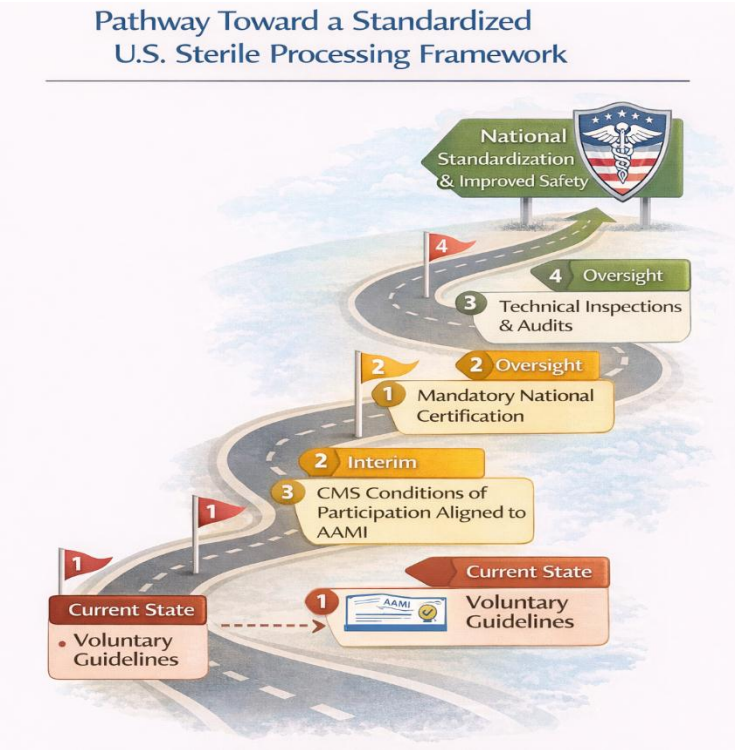


*Figure 3. Proposed pathway for transitioning the United States from a decentralized, guideline-based sterile processing system to a standardized, nationally regulated framework.*

1. Call for CMS to move from practice guidelines to more specific "Conditions of Participation" for sterile processing, deferring to and making specific AAMI standards mandatory for conformance.
2. Require national certification for all SP technicians, with a nationally mandated and accredited certification and supporting standardized core curricula.
3. Strengthen the accreditation process by giving accrediting organizations the authority to do more technically based and competency focused CSPD surveys through direct observation and data auditing in addition to document review.
4. Establish a consortium of organizations (AAMI, CDC, FDA, HSPA, et al) that could issue a single, authoritative, and timely national advisory for new device types or pathogens.

## Conclusion

As compared to peer countries, the U.S. approach is more decentralized and guidelines-based and, in contrast to these other countries, lacks standardization and mandatory regulatory

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compliance. This is problematic since variability is the enemy of safety and quality, which must be aspired to in healthcare. While U.S. standards for sterile processing as published by AAMI are excellent and technically sound, their utility is stymied by lack of required universal adoption. Recommendations for narrowing these gaps include moving to more specific regulatory language from CMS, development of nationally required certification programs for sterile processing technicians, improving technical and competency-based on-site accreditation surveys, and having an official body for official recommendations from the government on specific device reprocessing or pathogen outbreaks.

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