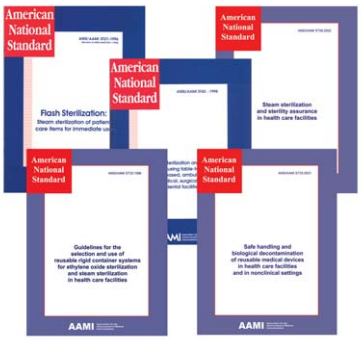
ST79: And Then There Was One

Kurt Larrick

AAMI's newest recommended practice, Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79:2006) is a breakthrough standard in terms of its scope, contents, and how AAMI plans to maintain it.

Because ST79 essentially consolidates five AAMI steam sterilization standards (whose content was reviewed and updated to reflect current good practice prior to being incorporated into ST79), it truly is a comprehensive guideline for all steam sterilization activities in healthcare facilities, regardless of the size of the sterilizer or the size of the facility, and provides a resource for all healthcare personnel who use steam for sterilization.



Four-Phase System

Saturated steam under pressure is one of the oldest methods used in healthcare facilities to sterilize medical devices. Because this method has been available for many years, it is thought to be a simple process–one that is well understood and controlled. However, the efficacy of any sterilization process, including saturated steam, depends on a consistent system for:

1) lowering and limiting bioburden before sterilization
2) properly preparing items for sterilization
3) selecting the appropriate sterilization parameters, and
4) establishing and implementing controls to maintain the sterility of sterilized items until they are used.

These four critically interdependent phases provide the framework for ST79. For a listing of specific areas covered in the recommended practice, see sidebar "Key Elements of ST79."

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Check Points

ANSI/AAMI ST79:2006 consolidates five AAMI steam sterilization standards:

- ✓ ANSI/AAMI ST46, Steam sterilization and sterility assurance in health care facilities
- ✓ ANSI/AAMI ST42, Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities
- ✓ ANSI/AAMI ST37, Flash sterilization: Steam sterilization of patient care items for immediate use
- ✓ ANSI/AAMI ST35, Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings
- ✓ ANSI/AAMI ST33, Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities

New Format, New Approach

Some of the challenges AAMI faced in compiling a document with so much information included making it durable and organizing it in such a manner that users could quickly and easily find what they were looking for. Thus, ST79 is the first AAMI standard to be available in loose-leaf binder format. (It is also available individually in PDF format and as part of AAMI's electronic CD and subscription products.) The binder features sturdy metal rings, ledger-weight pages, and a laminated tab for each section for easy navigation.

Another important aspect of ST79 is that it is the first AAMI standard to be part of the American National Standards Institute's "continuous maintenance" classification. Normally, AAMI standards undergo "periodic maintenance," which calls for review (and subsequent revision, reaffirmation, or withdrawal) of a standard every five years. With continuous maintenance, AAMI will consider requests for change at any time. If ST79 is updated as a result of a request for change, AAMI will issue revised pages that can be substituted into the binder. ■

Key elements of ST79

The recommendations in ST79 are divided into a number of key areas:

- Design considerations
  - o Work area design and functional work flow
  - o Physical facilities
  - o Housekeeping procedures
- Personnel considerations
  - o Qualifications, training, and continuing education
  - o Health and personal hygiene
  - o Attire
  - o Standard/transmission-based (enhanced) precautions
- Receiving
  - o Receiving of purchased or loaner items
  - o Disposition of sterile items (issued but not used)
- Handling, collection, and transport of contaminated items
  - o Separation of waste and reusable items at point of use
  - o Care and handling of contaminated reusable items at point of use
  - o Containment and transport
- Cleaning and other decontamination processes
  - o Policies, procedures, and manufacturers' instructions
  - o Presoaking
  - o Disassembly
  - o Cleaning, cleaning agents, and methods of cleaning
  - o Rinsing
  - o Verification of the cleaning process
  - o Utensils
  - o Reusable textiles
  - o Rigid sterilization container systems
  - o Microbicidal processes
  - o Servicing and repair of contaminated devices
- Packaging, preparation, and sterilization
  - o Selection of packaging materials
  - o Package configurations and preparation
  - o Preparation and assembly of surgical instrumentation
  - o Loading the sterilizer
  - o Sterilization parameters
  - o Monitoring sterilization cycles
  - o Unloading the sterilizer
  - o Sterile storage
  - o Distribution (general)
  - o Transport of sterile packaged items
  - o Aseptic presentation
- Installation, care, and maintenance of sterilizers
- Quality control
  - o Monitoring of mechanical cleaning equipment
  - o Product identification and traceability
  - o Overview of sterilization process monitoring
  - o Sterilization process monitoring devices
  - o Routine load release
  - o Routine sterilizer efficacy monitoring
  - o Qualification testing
  - o Periodic product quality assurance testing of routinely processed items
  - o Periodic product quality assurance testing of rigid sterilization container systems
  - o Product recalls
- Quality process improvement
- Annexes
  - o Examples of workplace design
  - o Infection transmission
  - o Processing CJD-contaminated patient-care equipment and environmental surfaces
  - o User verification of cleaning processes
  - o Selection and use of chemical disinfectants
  - o Thermal disinfection
  - o Devices returned to the manufacturer
  - o Occupational exposure to bloodborne pathogens (29 CFR Part 1910.1030)
  - o Development of a prepurchase evaluation protocol for rigid sterilization container systems
  - o Effect of containerized packaging on load heat-up time
  - o Development and qualification of the 16-towel biological-indicator challenge test pack
  - o Example of documentation of premature release of implants
  - o Steam quality
  - o Bibliography