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Comprehensive guide to steam sterilization and sterility assurance in health care facilities

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Standard

American National Standard **ANSI/AAMI ST79:2017**
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Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Abstract: This recommended practice covers steam sterilization in health care facilities. The recommendations are intended to promote sterility assurance and to guide health care personnel in the proper use of processing equipment. Included within the scope of the recommended practice are functional and physical design criteria for sterilization processing areas (decontamination, preparation, sterilization, and sterile storage areas); staff qualifications, education, and other personnel considerations; processing procedures; installation, care, and maintenance of steam sterilizers; quality control; and quality process improvement.

Keywords: ambulatory care facilities, cleaning, continuous quality improvement, decontamination, dental office, immediate-use steam sterilization (IUSS), moist heat sterilization, packaging, quality control, quality system, saturated steam, sterile storage, sterilization containers, surgical instruments, table-top sterilizers

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Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Steam Sterilization Hospital Practices Working Group

This recommended practice was developed by the AAMI Steam Sterilization Hospital Practices Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the recommended practice does not necessarily mean that all working group members voted for its approval.

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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

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Foreword

This recommended practice was developed by the Steam Sterilization Hospital Practices Working Group of the AAMI Sterilization Standards Committee. The purpose of the guidelines in this document is to help ensure the steam sterilization of products in health care facilities and the maintenance of the sterility of processed items until the point of use.

To facilitate user access to all AAMI consensus recommendations for steam sterilization in health care facilities, the first edition of ANSI/AAMI ST79, published in 2006, consolidated into one comprehensive guide the following AAMI recommended practices:

- 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*

In the course of the consolidation process, the five recommended practices listed above were updated and revised to reflect current good practice, and several annexes were added to provide additional information to users. The recommended practice serves as a comprehensive guideline for all steam sterilization activities in health care facilities, regardless of the size of the sterilizer or the size of the facility, and provides a resource for all health care personnel who use steam for sterilization.

From 2010 to 2013, numerous amendments of the document were adopted. This third edition of ANSI/AAMI ST79 incorporates these amendments, as well as additional changes such as guidance pertaining to heating, ventilation, and air conditioning (HVAC) and a new Annex on keeping cool in the sterile processing environment. In addition, the document reflects general editorial revisions (e.g., updating of references) and reorganization of content.

This recommended practice reflects the conscientious efforts of health care professionals, in cooperation with medical device and equipment manufacturers, to develop recommendations for optimum performance levels in the processing of reusable medical devices to be steam sterilized. It is not intended that these recommendations be construed as universally applicable in all circumstances. Also, it is recognized that in many cases these recommendations might not be immediately achievable. Therefore, the document should be used to guide personnel towards desirable performance objectives, and all of its provisions should be considered and applied in the light of professional judgment and experience.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The provisions of this recommended practice should be reviewed routinely by departmental managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with appropriate hospital committees (e.g., safety, infection prevention and control, and hazardous materials).

The concepts incorporated in this recommended practice should be considered flexible and dynamic. The recommendations set forth in this document are reviewed and updated periodically to assimilate progressive technological developments. AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every five years.

AAMI has created a notification registry that will send e-mail announcements when new ST79 publication formats are available. To register, visit http://www.aami.org/ST79Notify. Suggestions for improving this recommended practice are invited. Comments or proposals for revisions to any part of the standard may be submitted to AAMI at any time.

Written comments are to be sent to: Standards Dept., AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633. Comments may also be e-mailed to: standards@aami.org.

NOTE—This foreword does not contain provisions of the American National Standard, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2017), but it does provide important information about the development and intended use of the document.

Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Introduction: Need for the recommended practice

Saturated steam under pressure is one of the oldest and safest methods used in health care facilities to sterilize medical devices. Because this method has been available for so 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 lowering and limiting bioburden before sterilization, preparing items for sterilization, selecting the sterilization parameters, and establishing and implementing controls to maintain the sterility of sterilized items until they are used. These four phases are critically interdependent, and each should be accomplished to produce and maintain a sterile product.

The delivery of sterile health care products for use in patient care depends not only on the efficacy of the sterilization process itself but also on

a) efficient facility design,

b) equipment, personnel and other resources,

c) education and training of personnel,

d) infection prevention and control practices designed to prevent health-care-associated infections,

e) effective quality control and process improvement systems that encompass all aspects of device reprocessing from point of use through sterilization to reuse, and

f) documentation and reporting practices that enable traceability of each facility-sterilized medical device to the patient on whom it was used.

Health care facilities differ in their physical design and equipment and in the level of personnel expertise, competence, and training. This recommended practice has been developed to set forth guidelines for facility design, work practices, and process controls that will help ensure that sterile items are consistently produced using saturated steam under pressure.

This recommended practice addresses elements of a quality management system, but it is not intended to provide comprehensive guidance on this subject.

Many of the activities that affect sterilization processing occur in areas separate from the location where sterilization is actually carried out. Therefore, the policies and procedures governing sterilization processing should be developed in consultation with the managers of areas that use sterile medical devices and with appropriate committees or functional groups within the facility (e.g., infection prevention and control, safety, hazardous materials, risk management). In addition, the support of the facility's administration is vital, especially in those facilities where the establishment of a quality system to implement steam sterilization process validation and parametric release is being considered (ANSI/AAMI/ISO TIR17665-2).

It might not be possible for a health care facility to implement all the provisions of this recommended practice because of environmental restrictions and/or limitations in capital funding. However, it is recommended that the health care facility's administration be made aware of any current deficiencies so that the allocation of needed resources can be planned.

This comprehensive guide encompasses cleaning, transport, quality monitoring, storage, product evaluation, equipment maintenance, personnel considerations, and steam sterilization in all health care facilities, including, but not limited to, hospitals, ambulatory surgery facilities, physicians' offices, cardiac catheterization laboratories, endoscopy suites, radiology departments, dental offices, and other areas where sterile products are reprocessed, stored, and used.

Steam sterilization in office-based, ambulatory-care medical, surgical, and dental facilities

Advances in medical, surgical, and dental practice have led to the increased use of alternative health care sites, such as offices, ambulatory-care clinics, and similar clinical settings; many such facilities use table-top steam sterilizers (less than or equal to 2 cubic feet). Office-based practices can differ greatly from hospitals in their physical design and in the education and training of personnel. The general concepts in this comprehensive guide apply to these settings. In some sections, processes or equipment used most frequently within the office-based and ambulatory setting are specifically addressed.

1 Scope

1.1 General

This document includes guidance for sterile processing facility design, personnel, receiving, transporting, handling, cleaning, decontamination, preparation, packaging, steam sterilization of reusable medical devices, quality process improvement and new product evaluation.

1.2 Inclusions

This recommended practice specifically addresses

a) functional and physical design criteria for sterilization processing areas;

b) staff qualifications, education, and other personnel considerations;

c) processing recommendations;

d) installation, care, and maintenance of steam sterilizers;

e) quality control;

f) product evaluation; and

g) quality process improvement.

Definitions of terms, a bibliography, and informative annexes also are provided.

1.3 Exclusions

This recommended practice does not cover

a) specific construction and performance criteria for steam sterilizers (see ANSI/AAMI ST8 and ANSI/AAMI ST55), rigid sterilization container systems (see ANSI/AAMI ST77), or rigid, protective organizing cases that require wrapping before sterilization (see ANSI/AAMI ST77);

b) the use of containment devices for packaging items other than instrument sets or procedural trays;

c) procedures and techniques for handling and laundering contaminated reusable surgical textiles (see ANSI/AAMI ST65), reusable laboratory items, food service items, and items assigned to a patient for the length of stay (e.g., bedpans, thermometers);

d) decontamination of hemodialysis machines, hemodialyzers, and hemodialyzer blood tubing (see ANSI/AAMI/IEC 60601-2-16, ANSI/AAMI RD47, and ANSI/AAMI/ISO 8638, respectively);

e) the use of dry heat for decontamination purposes or for terminal sterilization of reusable medical devices (see ANSI/AAMI ST40);

f) the use of ethylene oxide sterilization in health care facilities for other than decontamination purposes (see ANSI/AAMI ST41);

g) the use of chemical sterilization and high-level disinfection in health care facilities for other than decontamination purposes (see ANSI/AAMI ST58);

h) the reprocessing of devices labeled for single use only (see Food and Drug Administration [FDA], 2000c); and

i) aseptic presentation.

NOTE—For more information on the subjects excluded from the scope of this recommended practice, and for additional background information on the inclusions, refer to the references listed in the bibliography.