American National Standard

ANSI/AAMI ST79:2006 and
ANSI/AAMI ST79/A1:2008
(Consolidated Text)

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

Association for the Advancement of Medical Instrumentation

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

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Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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(Consolidated Text)

(Revision of ANSI/AAMI ST33:1996,
ANSI/AAMI ST37:1996,
ANSI/AAMI ST42:1998,
ANSI/AAMI ST46:2002,
and a partial revision of ANSI/AAMI ST35:2002)

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

Developed by
Association for the Advancement of Medical Instrumentation

Approved **24 July 2006**
Amendment 1 Approved **27 August 2008** by
American National Standards Institute Inc.

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: cleaning, continuous quality improvement, decontamination, moist heat sterilization, packaging, quality control, quality system, saturated steam, sterile storage, surgical instruments, ambulatory care facilities, dentist office, flash sterilization, sterilization containers, table-top sterilizers

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International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

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

International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2006	ANSI/AAMI/IEC 60601-2-2:2006	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
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ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
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ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations

International designation	U.S. designation	Equivalency
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical

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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.

At the time that Amendment 1 of this recommended practice was published, the **AAMI Steam Sterilization Hospital Practices Working Group** had the following members:

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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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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.

Acknowledgments

The AAMI Steam Sterilization Hospital Practices Working Group gratefully acknowledges the important contributions of Neal Danielson, who cochaired the working group for many years and who prepared the first draft of this comprehensive guideline on steam sterilization in health care facilities. His contribution of time, effort, and expertise to the development of AAMI recommended practices and to the field of central service generally cannot be overstated. The working group also wishes to acknowledge the contributions of former working group member Dorothy Fogg, RN, who for many years represented the Association of periOperative Registered Nurses on the working group; former working group member Gregory Stecklein of Cardinal Health; and former working group member Retta C. Sengstock, RN, Implementation Specialists for Healthcare Inc. Martin S. Favero, PhD, of Advanced Sterilization Products served as industry cochair of the working group from 2000 to 2004, and the time and expertise that he devoted to the development of this recommended practice are very much appreciated by the working group. Finally, this recommended practice could not have come to fruition without the hard work and diplomatic skills of Barbara Goodman, RN, who cochaired the working group from 1995 to 2004; the working group is extremely grateful for her commitment and her immense contributions to this project.

Background on Amendment 1

As a continuously maintained Recommended Practice, this document consolidates the text of ST79:2006 and ST79:2006/A1:2008. Please see Amendment 1 to identify exactly what has changed. The amendment shows modifications to the 2006 edition of ST79 in redline/strikeout. Amendment 1 is available in print or as a free PDF at http://marketplace.aami.org.

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 committee has 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* (with respect to steam sterilization only)
- 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. Several annexes were added to provide additional information to users. The new 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.

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 in order 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; and “can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The provisions of this recommended practice should be reviewed 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.

This standard is maintained under continuous maintenance procedures. AAMI has created a notification registry that will send e-mail announcements when any maintenance activity occurs to the recommended practice. To register, visit www.aami.org/standards/st79.registry. Suggestions for improving this recommended practice are invited. Comments or proposals for revisions to any part of the standard may be submitted to AAMI any time. Written comments are to be sent to: Standards Dept., AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Comments may also be e-mailed to: standards@aami.org.

NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2006), 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

Overview:

Saturated steam under pressure is one of the oldest 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, properly preparing items for sterilization, selecting the appropriate 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 must 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 the following factors:

a) efficient facility design,

b) proper training of personnel,

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

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

e) appropriate 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 system, but it is not intended to provide comprehensive guidance on this subject.

NOTE—Quality systems are addressed in detail by ISO 13683 and other international standards.

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.

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 recommended practice encompasses steam sterilization in all health care facilities, including ambulatory-care and office-based facilities. It covers steam sterilization by both the wrapped and unwrapped (flash) methods and

provides detailed guidance on decontamination and packaging, with special reference to rigid sterilization container systems.

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 small table-top steam sterilizers. Office-based practices can differ greatly from hospitals in their physical design and in the training level of personnel. The general concepts in this recommended practice apply to these settings. In some sections, processes or equipment used most frequently within the office-based and ambulatory setting are specifically addressed.

Flash sterilization:

A flash sterilization cycle is one that has been designed to meet the following criteria:

a) The cycle is preprogrammed to a specific time–temperature setting established by the manufacturer based on the type of sterilizer control (i.e., gravity-displacement, dynamic-air-removal) and selected by the user based on the configuration of the load (i.e., the presence or absence of porous materials).

b) The items to be processed are usually unwrapped, although a single wrapper may be used in certain circumstances if the sterilizer or packaging manufacturer's instructions permit. Some rigid sterilization container systems have been designed and validated by the container manufacturer for use with flash cycles.

c) Since drying time is not usually part of a preprogrammed flash cycle, the items processed are assumed to be wet at the conclusion of the cycle.

d) The processed items(s) must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use, usually the sterile field in an ongoing surgical procedure. Regardless of whether the items are wrapped, there is no storage or shelf life of flash-sterilized items because of the higher probability of contamination after the sterilizer door is opened and the items are removed.

It is essential for health care personnel to properly carry out the complete multistep process (including decontamination and preparation) when flash sterilization is used, just as in the case of items to be processed using wrapped-goods sterilization cycles. In any method of sterilization, it is important to adhere to good processing practices. Such practices are particularly important in flash sterilization because of the difficulties associated with the aseptic delivery of devices sterilized by this method to the point of use. When performed correctly, flash sterilization is safe and effective for the sterilization of medical devices intended for use in contact with compromised tissue or the vascular system, as might occur during surgery or obstetrical delivery. The exposure times used in flash sterilization cycles are capable of producing appropriate lethality.

Several concerns stimulated the development of guidelines for flash sterilization. First, the committee was aware of inadequate cleaning and other decontamination processes in flash sterilization. Reduction of bioburden and removal of gross soil are essential steps in preparing an item for sterilization by any method. Decontamination procedures are also designed to protect the worker.

Second, documentation of the flash sterilization process is necessary and should be consistent with the requirements applicable to and the practices used in documenting the routine processing of wrapped loads.

Third, flash-sterilized items should be transported to the point of use in such a way that the potential for contamination is minimized. In deciding on transport techniques for a particular situation, personnel should consider the possible ways in which the items could become contaminated and the safety of workers handling the hot, wet, and possibly heavy trays. Contamination is an event-related process, with the probability of an event that could result in contamination increasing over time. When opened to the air, all sterile items will eventually become contaminated unless opened within and kept in a true HEPA-filtered, laminar-air-flow unit. Thus, any item that is opened and left on the back table of a surgical setup can become contaminated by particles settling on it. The longer an item is open, the greater the number of particles, with their accompanying microbiological flora.

The risk of contamination of flash-sterilized items increases if they are transported through areas where personnel are scrubbing or washing their hands, creating splashing or aerosolization. Transport through areas where air flow is not filtered to the degree present in the operating room (OR) can also increase the rate of contamination. Practitioners should examine their own situations and develop practices to minimize contamination. Some methods are placing flash sterilizers as close to the intended point of use as can be reasonably accomplished, using rigid sterilization container systems that have been specifically validated and labeled for use in flash sterilization, using the single-

wrapper technique in appropriate cycles, and aseptically placing a sterile covering completely around the sterilized item as it is removed from the sterilizer.

Finally, flash sterilization of instrumentation should be considered only if all the following conditions are met:

a) Work practices ensure proper cleaning and decontamination, inspection, and arrangement of instruments into the recommended sterilizing trays or other containment devices before sterilization.

b) The physical layout of the department or work area ensures direct delivery of sterilized items to the point of use (e.g., the sterilizer opens into an area either within or directly adjacent to the procedure room).

c) Procedures are developed, followed, and audited to ensure aseptic handling and personnel safety during transfer of the sterilized items from the sterilizer to the point of use.

d) The item is needed for use immediately following flash sterilization.

Implantables should not be flash-sterilized (Garner and Favero, 1985; CDC, 2003a, 2003b). The possible consequences to the patient from placing even a minimally contaminated device in an essentially avascular environment and leaving it there at the conclusion of the procedure are potentially severe. Although the risk of an unrecognized sterilization failure can be minimized if the physical parameters of time, temperature, and pressure are monitored and recorded and the results examined after each cycle, it is recommended that health care personnel quarantine implantable devices and await the outcome of biological monitoring of the cycle before releasing these items for use. Current technology allows for release of loads, even those containing implants, upon obtaining results from the early readout mechanism of a BI designed and labeled for such use. However, this technology does not solve the problems with using flash sterilization for implants. Concerns about aseptic transfer remain, especially if the sterilizer does not open directly into the room containing the sterile field where the device will be used or into an area either within or directly adjacent to the procedure room. Careful planning, appropriate packaging (e.g., packaging that allows the user to see the device for sizing and verification of features), and inventory management in cooperation with suppliers can eliminate the need to flash sterilize implantable items. This is a goal that all institutions should strive to achieve.

This recommended practice incorporates guidelines that are specifically applicable to flash sterilization.

Decontamination:

All microorganisms in health care facilities should be considered potentially pathogenic. Their ability to produce an infection or disease process depends on several factors, including the number and virulence of infectious organisms, the presence of a portal of entry, and the susceptibility of the host (see Annex B). Medical devices, instruments, and equipment used in patient care become contaminated with microorganisms and must be decontaminated.

Decontamination is the process by which medical devices, instruments, and equipment are rendered safe for personnel to handle. In some cases, the decontamination process is sufficient to render the items safe for reuse in patient care. The type and level of decontamination required is determined by the circumstances of device use, the type of patient contact, and the likelihood of biological hazard to personnel.

Infection prevention is enhanced when (a) soiled supplies and equipment are correctly and safely handled, and (b) reusable medical items are thoroughly cleaned. Whenever cleaning is not sufficient to render an item safe for personnel handling, the item is subjected to a subsequent microbicidal process that has been designed to provide an appropriate level of microbial lethality (kill). This process could be a disinfection process or a sterilization process. The microbicidal process might not be effective if soil has not been first removed by cleaning. When used for decontamination purposes, a microbicidal process does not necessarily make an item safe for patient use, because the level of microbial kill might not be sufficient for the intended use (as in the case of surgical instruments needed for sterile procedures).

Adherence to the principles of infection prevention and control will help prevent the spread of potentially infectious or disease-producing microorganisms from one person to another and will help ensure that all items are safe for handling during inspection, assembly, preparation, and packaging. In addition, adherence to these principles is one of the essential factors in achieving effective terminal sterilization processing, when appropriate for a particular reusable item.

The selection of an appropriate decontamination method is complex because of the huge variety of reusable items and the wide range of processes for achieving various levels of decontamination. There are diverse and often conflicting recommendations for handling supplies and equipment and for controlling biological hazards through decontamination methods. These diverse recommendations have been provided to health care personnel by professional organizations, government agencies, manufacturers of decontamination products and equipment,

medical device manufacturers, consultants, and educational speakers. There is clearly a need for consensus guidelines, with supporting rationale, for decontamination processing techniques.

The objectives of the guidelines provided in this recommended practice are to (a) help reduce the risk of cross-infection by pathogenic microorganisms to patients, personnel, and other persons; (b) assist in the development of decontamination procedures based on knowledge and scientific data; and (c) help ensure that all reusable medical devices are handled, transported, cleaned, biologically decontaminated, and reprocessed or examined under the best possible conditions for maximum safety.

Rigid sterilization container systems:

The packaging section of this recommended practice provides detailed guidelines on the selection and use of rigid sterilization container systems intended for use in steam sterilization. These systems serve as packaging for items before, during, and after sterilization. They may also be used to contain and transport contaminated items after use. Special considerations apply to these packaging systems to ensure adequate sterilant penetration and air removal.

1 Scope

1.1 General

This recommended practice provides guidelines for decontamination and steam sterilization processing in hospitals and other health care facilities. These guidelines are intended to promote sterility assurance and to assist health care personnel in the proper use of processing equipment.

NOTE—For purposes of this recommended practice, "health care facilities" means hospitals, nursing homes, extended-care facilities, free-standing surgical centers, clinics, and medical and dental offices. For convenience, the term "hospital" is sometimes used in this recommended practice; in all instances, this term should be taken to encompass all other health care facilities.

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; and

f) quality process improvement.

Definitions of terms, a bibliography, and informative annexes also are provided in this recommended practice.

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, or rigid, protective organizing cases that require wrapping prior to sterilization;

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 RD5, ANSI/AAMI RD47, and AAMI RD17, respectively);

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

f) guidelines for safe and effective ethylene oxide sterilization (see ANSI/AAMI ST41);

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

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 Annex O.