Comprehensive guide to steam sterilization and sterility assurance in health care facilities, Amendment 1

Changes to this recommended practice are noted as follows:
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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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Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

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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Comprehensive guide to steam sterilization and sterility assurance in health care facilities, Amendment 1

Developed by
Association for the Advancement of Medical Instrumentation

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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Glossary of equivalent standards

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
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
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
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
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
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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

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.

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, ST79 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.

From this point foreword, only those pages of ANSI/AAMI ST79:2006 impacted by ANSI/AAMI ST79:2006/A1:2008 are provided.

Changes to this recommended practice are noted as follows:
Highlight for new info
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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~~N~~.

2 Definitions and abbreviations

2.1 absorbent surgical towel: Typically, a low-lint 100 % cotton surgical towel woven with a plain weave (1:1).

2.2 ambulatory care: Short-term treatment of medical, dental, or surgical needs within 24 hours in a medical office or clinic.

2.3 asepsis: Prevention of contact with microorganisms.

2.4 bacterial count: Method of estimating the number of bacteria per unit sample.

NOTE—The term also refers to the estimated number of bacteria per unit sample, usually expressed as number of colony-forming units (CFUs).

2.5 BI: Biological indicator. See 2.8.

2.6 bioburden: Population of viable microorganisms on a product and/or a package.

NOTE—When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units (cfus) per single item.

2.7 biofilm: Accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily (Donlan, 2002).

NOTE—Some microscopic organisms have the ability, when growing in water or water solutions or *in vivo* (e.g., the bloodstream), to adhere to a surface and then exude over themselves a polysaccharide matrix. The matrix contains cells, living and dead, as well as polysaccharide (sometimes referred to as glycocalyx) and prevents antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching the microbial cells.

2.8 biological indicator (BI): Test system containing viable microorganisms providing a defined resistance to a specified sterilization process.

NOTE 1—According to FDA, "a biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization." [21 CFR 880.2800(a)(1)]

NOTE 2—Biological indicators are intended to demonstrate whether or not the conditions were adequate to achieve sterilization. A negative BI does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

2.9 biological indicator control, positive: Biological indicator, from the same lot as a test biological indicator, which is left unexposed to the sterilization cycle and then incubated to verify the viability of the test BI.

2.10 Bowie-Dick test: Diagnostic test of a dynamic-air-removal steam sterilizer's ability to remove air from the chamber and prevent air re-entrainment.

2.11 case/cassette: Sterilization containment device that consists of a lid and base tray that has perforations to allow the sterilant to penetrate and that is enclosed in a sterilization wrap (or sterilization pouches suitable for specified sterilization method[s]) to maintain sterility.

2.12 catalase: Enzyme found in almost all cells except for certain anaerobic bacteria.

2.13 CDC: Centers for Disease Control and Prevention.

2.14 central service department: Department within a health care facility that processes, issues, and controls medical supplies, devices, and equipment, both sterile and nonsterile, for some or all patient care areas of the facility. Also known as **sterile processing department**.

2.15 challenge test pack: Pack used in qualification, installation, and routine quality assurance testing of hospital sterilizers. See also **process challenge device**.

2.16 chemical indicators (CIs): Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or are used in specific tests of sterilization equipment.

ANSI/AAMI ST60:1996, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, defines five classes of CIs and specifies performance requirements for them:

areas, trash and linen receptacles, and sorting areas. Provision should be made for the separation of contaminated items from items being removed from mechanical processing equipment and for the cleaning of transport carts.

Decontamination equipment that mechanically processes items and then automatically unloads them into the clean side is recommended. A pass-through window that is at equal counter height between the decontamination area and clean processing areas is also recommended. See Annex A.

There should be three functionally separate areas within the decontamination area: one for items that will require additional processing after decontamination and before patient reuse, one for items (e.g., powered equipment) that require manual disinfection after cleaning to render them safe for handling in the preparation and packaging area, and one for items that will not require additional processing. Receiving areas for surgical instruments and other devices requiring terminal sterilization after decontamination should be strictly separated from receiving areas for instruments and devices for which the decontamination process incorporates disinfection procedures and there is no need for additional disinfection or sterilization before patient use.

Figure 2 provides general schematics of appropriate workflow. Annex A provides examples of work area design and workflow patterns in health care facilities of various types and sizes.

NOTE—All figures in Annex A illustrate general principles and should not be interpreted as endorsements of specific designs.

Rationale: Separating “clean” and “dirty” areas limits environmental contamination and, therefore, the potential for bioburden on devices to be sterilized. Adherence to these functional design recommendations helps contain potential contaminants within a particular portion of the decontamination area and thus helps prevent cross-contamination or recontamination. Segregation of contaminated items from items being removed from mechanical processing equipment is necessary to protect the processed items (e.g., flexible endoscopes, respiratory therapy devices) from recontamination. Similarly, there is a significant risk of recontamination if receiving areas for items requiring different methods of reprocessing are not separated.

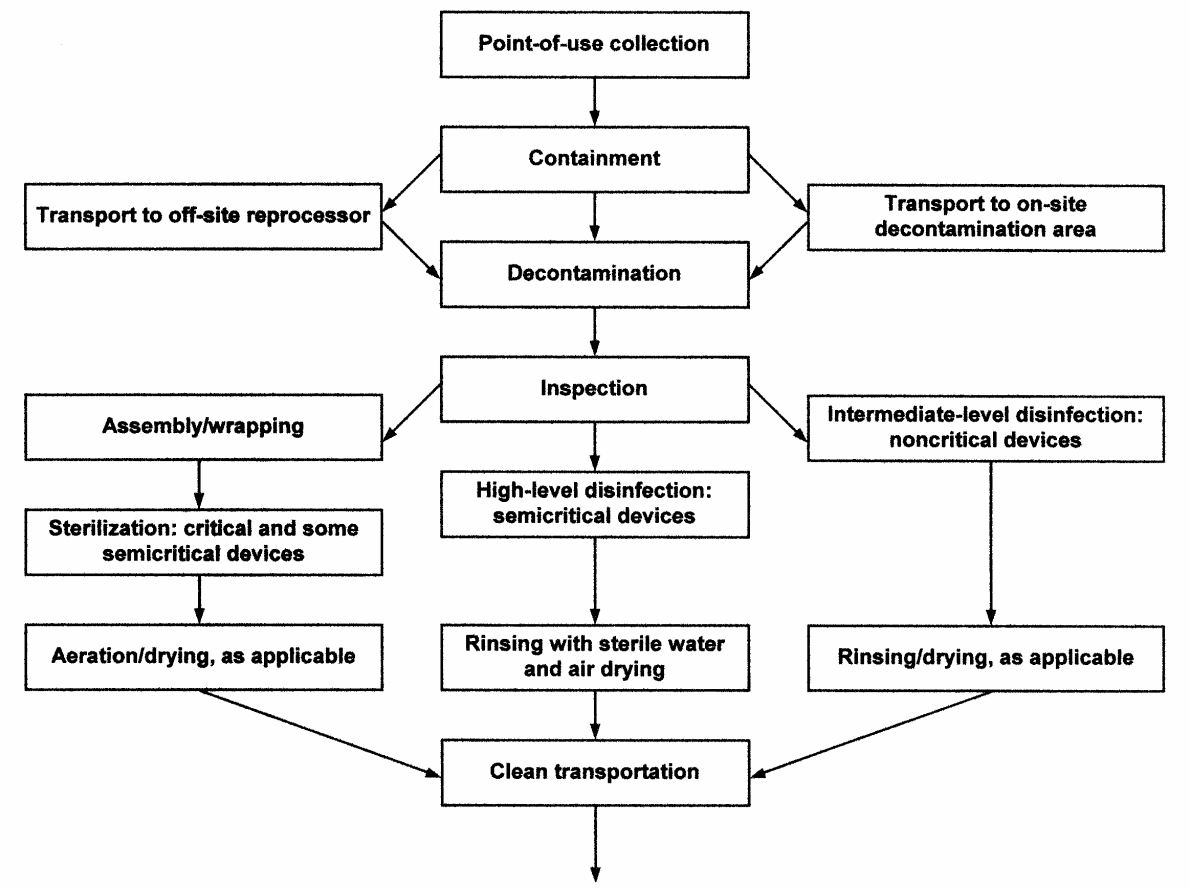
It is recognized that in existing facilities, it might not be feasible to fully comply with the recommendations for physical separation of functional work areas; however, compliance is practical and desirable during new construction and major modifications. Interim measures that allow for functional separation (e.g., through airflow patterns or separation of activities) should be considered until such time as physical separation can be achieved.

3.2.4 Traffic control

Traffic in all areas in which decontamination, preparation and packaging, sterilization processing, sterile storage, and distribution are carried out should be restricted to authorized personnel. Criteria for authorized entry, movement within processing areas, and attire should be specified in written policies and procedures. It is sometimes necessary for visitors to enter restricted areas; visitors should comply with the established dress code, as stated in the policies and procedures. (See also 4.5.)

The responsibility and authority for enforcing traffic-control policies and procedures should be specified, as should methods of compliance.

Rationale: Personnel and visitors can carry microorganisms into processing areas, thus increasing the potential for environmental contaminants in these areas. It is also important to protect personnel and visitors from the microorganisms present on contaminated items being processed in the decontamination area. Good traffic-control practices also minimize the potential for contamination of flash-sterilized items during removal from the sterilizer and transfer to the point of use. Recommendations for traffic patterns in the operating room have been provided by the Association of periOperative Registered Nurses (AORN, 2008f).



(a) Workflow in a sterile processing department

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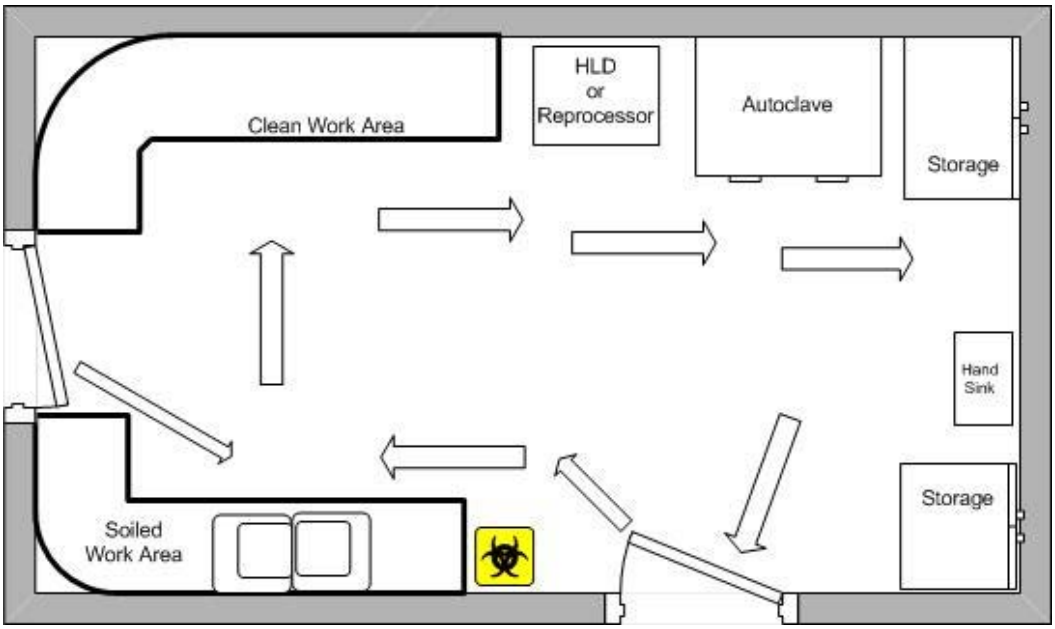

(b) Workflow in an office-based practice

Figure 2—Workflow

c) condensate return alkalinity, conductivity, sulfites, and pH.

Rationale: See 3.3.4.1.

3.3.5 Utility monitoring and alarm systems

A utility monitoring and alarm system (for steam, water, electricity, and air connected to sterilizers and washers) should be installed to alert operators to faults or failures of the supplied utilities.

Rationale: To perform to their specifications, sterilizers and washers require utilities functioning between minimum and maximum values. A monitoring and alarm system alerting operators to faults or failures allows a quick response to affected processing areas, ensuring satisfactory processing.

3.3.6 General area requirements

NOTE—Unless otherwise stated in 3.3.7, all processing work areas should conform to the following recommendations.

3.3.6.1 Floors and walls

Floors should be level (i.e., should have no ridges or bumps) and should be constructed of materials that will withstand daily or more frequent wet cleaning and the application of chemical cleaning agents. Carpet should not be used in work areas. Walls should be constructed of materials capable of withstanding frequent cleaning. Wall protectors should be installed at the level of possible cart impacts. Materials used in floors and walls should not be of a particulate- or fiber-shedding composition.

Rationale: Uneven floors make it difficult for personnel to push carts; also, uneven floors can cause items on carts to shake and even fall off the cart. All surfaces in work areas are subject to spills and splashing and should be regularly and thoroughly cleaned (see 3.4) to control microbial contamination and to eliminate accumulated dust, which could act as a carrier for microorganisms. Accordingly, the materials of construction of floors and walls should be able to withstand frequent cleaning and should not be adversely affected by the chemical agents typically used for environmental cleaning. Some sterilizer carts have blunt ends that can nick walls, eventually removing the cover material and exposing porous fibers that can shed into the environment.

3.3.6.2 Ceilings

Work area ceilings should be constructed to create a flush surface with recessed, enclosed fixtures. Pipes and other fixtures above work areas should also be enclosed. Ceilings should be constructed of materials that are not of a particulate- or fiber-shedding composition.

Rationale: A finished ceiling with enclosed fixtures limits condensation, dust accumulation, and other possible sources of contamination.

3.3.6.3 Doors

Doors should be made of a durable material that can withstand constant bumping from back tables and carts and that can be cleaned frequently. Doors should open easily following the one-way directional workflow and should not have thresholds.

Rationale: Carts and back tables are constantly being pushed from one area to the next, through the stages of processing from dirty to clean. Doors require frequent cleaning. It is cumbersome for personnel to pull open a door and push a cart through it. The constant bumping of doors by carts eventually wears away the finish. Bumping against a threshold can cause carts to spill or necessitate picking up the cart to traverse the threshold.

3.3.6.4 Ventilation

The ventilation system should be designed so that airflow patterns will not allow air contaminants to enter clean areas. Air should flow from areas of positive pressure to areas of negative pressure. Air from rooms or areas under negative pressure should be exhausted to the outside via a nonrecirculating system. The soiled and decontamination area should be designed so that air flows into the area (negative pressure), with a minimum of 10 air exchanges per hour, and so that all air is exhausted to the outside atmosphere. Whenever possible, dedicated local exhaust systems should be used in place of dilution ventilation to reduce exposure to hazardous gases, vapors, fumes, or mists. Each functional area has its own requirements for air flow, number of air exchanges, and exhaust (Table 3).

Table 3—Ventilation requirements for functional areas

Functional area	Airflow	Minimum number of air exchanges per hour (ANSI/AAMI ST79)	Minimum number of air exchanges per hour (AIA, 2001)	All air exhausted directly to the outdoors?
Soiled/ decontamination	Negative (in)	10	6	Yes
Sterilizer equipment access	Negative (in)	10	10	Yes
Sterilizer loading/ unloading	Positive (out)	10	---	Yes
Restrooms/ housekeeping	Negative (in)	10	10	Yes
Preparation and packaging	Positive (out)	10, down-draft type	4	No
Textile pack room	Positive (out)	10, down-draft type	---	No
Clean/sterile storage	Positive (out)	4, down-draft type	4	No

The exhaust system should be designed to permit a high volume of air to be exhausted from the clean work areas. Combining exhaust systems will enhance the efficiency of recovery devices required for energy conservation. The exhaust ducts should be located at floor level in the wall and should be designed so that effective filtering systems can be installed and maintained. The filtering system will vary, depending on whether the exhaust system is connected to a dedicated system that goes directly to the outside atmosphere or some of the exhausted air is recirculated. Duct covers or grids should be cleaned and filters should be changed on a scheduled basis as prescribed by the manufacturer.

Fresh air intakes should be located at least 25 feet (7.62 meters) from exhaust outlets of ventilation systems, combustion equipment stacks, medical-surgical vacuum systems, plumbing vents, or areas that may collect vehicular exhaust or other noxious fumes. Prevailing winds and/or proximity to other building structures might necessitate a longer distance.

Except for exhaust fans on ventilation systems and properly installed and operated fume control hoods, neither fixed nor portable fans should be permitted in any area of Central Service. Other aspects of ventilation should comply with the guidelines set forth by the American Institute of Architects (AIA, 2001). See also American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) (2007a~~1999~~) and ASHRAE (2007b~~1995~~).

Rationale: Construction materials, ventilation patterns, and other environmental controls affect the proliferation and spread of potentially dangerous microorganisms. Control of bioburden and environmental contaminants is essential to ensure that the subsequent sterilization process is effective. Down-draft-type air circulation systems limit contamination by carrying contaminants toward the floor and away from work surfaces. The recommended number of air exchanges per hour reflects the committee's consensus on the minimum air exchange rate necessary to effectively reduce environmental contamination by air dilution. Fans should not be permitted in any sterile processing area because they create highly turbulent air flow, which recirculates dust and microorganisms from the floor and work surfaces and thus interferes with designed airflow characteristics.

AIA (2001) recommends 6 air exchanges per hour in the decontamination area. However, an air exchange rate of 10 air exchanges per hour was judged by the AAMI committee to be the minimum necessary to effectively reduce environmental contamination by means of air dilution. In addition, the AAMI committee notes that AIA (2001) does recommend 10 air exchanges per hour for other soiled areas within health care facilities, that similar water and steam considerations apply to both the decontamination area and the sterilization area, and that AIA (2001) recommends 10 air exchanges per hour for the latter area.

AIA (2001) recommends 4 air exchanges per hour in the preparation and packaging area. However, an air exchange rate of 10 air exchanges per hour was judged by the AAMI committee to be more appropriate because the preparation and packaging area is contiguous with the sterilizer loading area, where the recommended air exchange rate is 10 air exchanges per hour.

4 Personnel considerations

4.1 General rationale

This section provides guidelines for personnel qualifications, training, and education, as well as minimum criteria for personnel health, personal hygiene, and attire. For reliable assurance of the sterility of processed items, it is important that all aspects of steam sterilization processing be performed and supervised by knowledgeable personnel. The other personnel considerations covered in this section are key elements in minimizing bioburden and containing environmental contamination, which are essential for effective sterilization.

4.2 Qualifications

4.2.1 Supervisory personnel

All preparation and sterilization activities, including decontamination, inspection, preparation, packaging, sterilization, storage, and distribution, should be supervised by competent, qualified personnel. Personnel assigned to supervisory functions should be prepared for this responsibility by education, training, and experience. Minimum recommended qualifications include

a) successful completion of a central service management certification examination;

NOTE—Information concerning certification of central service processing managers and technicians can be obtained from the Certification Board for Sterile Processing and Distribution (CBSPD) (~~121 Highway 31, Suite 500, Flemington, NJ 08822~~ 2 Industrial Park Road, Suite #3, Alpha, NJ 08865; 800-555-9765; http://www.sterileprocessing.org); the International Association of Healthcare Central Service Materiel Management (213 Institute Place, Suite 307, Chicago, IL 60610; 312-440-0078; http://www.iahcsmm.org); or the National Health Information Center (P.O. Box 1133, Washington, DC 20013; http://www.health.gov/nhic/).

b) demonstration of current knowledge and adequate relevant experience in health care or hospital-related work;

c) participation in continuing education programs and courses, including programs on federal and local regulations; personnel and material management programs; programs on financial management and leadership skills; and courses directly related to the management position, with special emphasis on infection control, safety, and the principles and methods of sterile processing; and

d) demonstration of comprehensive knowledge of pertinent state and federal regulations, particularly OSHA regulations related to occupational exposure to blood-borne pathogens (29 CFR 1910.1030), including the specified methods of compliance, such as an exposure control plan, the use of standard/transmission-based (enhanced) precautions, and engineering and work-practice controls.

Supervisory personnel should maintain competency throughout their tenure. In addition to participating in continuing education programs and courses, personnel should

a) participate in facility and departmental in-service and training programs; and

b) demonstrate and improve their expertise through participation (as a member or resource person) in committees within the health care facility (e.g., risk management, hazardous materials, quality improvement, infection control, safety, standardization, product evaluation, policies and procedures) and in quality improvement activities.

Rationale: The decontamination and subsequent sterilization of reusable medical devices is a complex process requiring supervision by competent personnel with relevant health care experience, especially in cleaning methods and products, containment of contaminated items, sterilization and disinfection methods, infection control, and standard/transmission-based (enhanced) precautions. Standard/transmission-based (enhanced) precautions address airborne, droplet, and contact issues. Compliance with OSHA regulations will lower the incidence of occupational exposure to blood-borne and other pathogens. Participation in the product evaluation committee can help avoid purchases of items that cannot be reprocessed by equipment currently available in the sterile processing department. Certification is a recognized method of initially determining competency.

4.2.2 Sterile processing personnel

The responsibility for sterile processing should be assigned to qualified individuals who have demonstrated competence in all aspects of sterile processing: decontamination, preparation, packaging, sterilization, sterile storage, and distribution of sterile medical devices. Qualifications include

a) demonstrated knowledge of and documented competence in all aspects of decontamination, including sorting, disassembly/reassembly, manual and mechanical cleaning methods, microbicidal processes,

equipment operation, standard/transmission-based (enhanced) precautions, and engineering and work-practice controls;

b) demonstrated knowledge of and documented competence in the operation of the specific steam sterilizing system used by the health care facility (there are a variety of systems in general use);

c) demonstrated knowledge of and documented competence in principles of sterilization and infectious disease transmission; infection control; and all aspects of steam sterilization (including decontamination, inspection, and packaging of items to be sterilized, sterilizing procedures, equipment operation, and safety precautions); and

d) demonstrated knowledge of and documented competence in worker safety as it relates to medical device processing and sterilization.

It is recommended that all personnel performing sterile processing activities be certified as a condition of employment. At a minimum, all such personnel should successfully complete a central service certification examination within two years of employment and should maintain that certification throughout their employment. See also 4.2.1(a).

Rationale: Advances in surgical and information technology, the emergence of new diseases and microorganisms, and the increased responsibility for all aspects of sterile processing have brought into focus how important it is for sterile processing personnel to be knowledgeable and competent. The protection of patients, employees, and other individuals in the hospital environment depends on the implementation of procedures designed to reduce the risk of exposure to potentially pathogenic microorganisms. Documentation of competence provides verification of qualifications and workplace training, as required by regulatory and accrediting agencies.

4.3 Training and continuing education

4.3.1 Sterile processing personnel

Personnel engaged in sterile processing should receive both an initial orientation and on-the-job training. A day-to-day orientation program is recommended and should be designed to lead to competency-based knowledge and skills in all tasks performed in the sterile processing department. It should also include orientation in facility and department policies and procedures regarding infection control, safety, attire, personal hygiene, and compliance with state and federal regulations. In addition, continuing education should be provided at regular intervals to review and update worker knowledge and skills and to maintain their competency and certification. Education and training materials and information are available from sterile processing vendors, associations, and journals; in addition, OSHA has educational materials available for loan. Personnel should receive in-service training for all new instrumentation, devices, and equipment. All orientation, on-the-job, and in-service training should be documented.

There should be a training manual that documents all aspects of training related to the on-site approved protocols. This manual should include checklists to document that training was performed and when competency was achieved. This training manual may reference guidance documents and/or training modules, but it should be based on the facility's policies and procedures, accepted standards of practice, and manufacturers' recommendations.

Rationale: Orientation training and on-the-job training establish the worker's base of knowledge, while continuing education increases knowledge and skills. Education and training decrease the possibility of operator error during preparation and sterilization processing and help ensure that personnel are conversant with the latest data and techniques. Also, education and training are the most important aspects of any program intended to protect employees from a potential safety hazard. Without it, the employee might not recognize unsafe conditions or work practices and might not know how, when, or why to employ protective measures. Hospital policies and procedures are a necessary part of any education and training program, and all personnel should be familiar with and adhere to these policies and procedures. Documentation of training and continuing education is required by the Joint Commission ~~on Accreditation of Healthcare Organizations~~ (Joint Commission~~CAHO~~, 2007~~5~~). Certification is a recognized method of determining initial competency. It is necessary to provide instructions to decontamination personnel regarding the processing recommendations of specific device and equipment manufacturers.

4.3.2 Service personnel

Education and training programs for service personnel should include information on the hazards associated with blood-borne pathogens, the requirements of the OSHA standard on occupational exposure to blood-borne pathogens (29 CFR 1910.1030), the importance of vaccinations as protective measures, standard/transmission-based (enhanced) precautions, protective work practices, the use of PPE, emergency procedures, and procedures to follow if an exposure occurs.

Rationale: Education and training are the most important aspects of a program intended to protect employees and users from a potential health hazard.

4.3.3 Other personnel

Personnel who are not assigned to the sterile processing area but who have access to the sterile storage area should receive initial orientation and on-the-job training on proper attire and on the proper care, handling, and transport of sterile items.

Rationale: In some health care facilities, the sterile storage area is not attended by sterile processing personnel 24 hours a day, so it might be necessary for personnel from other departments to have access to sterile items. To protect the integrity of sterile items, it is important that these personnel comply with the same attire and supply-handling procedures as do personnel regularly assigned to the central service department.

4.4 Health and personal hygiene

Written policies on personal hygiene should be developed and communicated to employees. Such policies should be approved by Infection Control, the office safety manager, or the designated person in charge of employee health. Handwashing procedures should be specified. Hair, body, and nails should be clean at all times. Neither nail polish nor artificial nails should be worn. Fingernails should be kept short and clean and should not extend beyond the fingertips (AORN, 2008e). Uniforms or other garments that become soiled or wet during wear should be changed immediately. In collaboration with the institution's infection control committee, the department should establish a written policy on the reporting, treatment, and disposition of employees who are at risk of acquiring or transmitting infections. Exposures to blood-borne diseases should be handled in accordance with OSHA regulations and current Centers for Disease Control and Prevention (CDC) recommendations.[1] Personnel who can potentially come into contact with items contaminated with blood or body fluids (occupational exposure) should be encouraged to accept hepatitis B immunization. Any employee who declines immunization should sign the hepatitis B vaccine declination statement required by OSHA.

Rationale: Careful attention to employee health, safety, and personal hygiene will minimize the potential for acquiring or transmitting disease. Nail polish can flake off, and the flakes can get into items being prepared; artificial nails can promote the growth of fungus under the nails (Baumgardner, et al., 1993; CDC, 2002a; Jeanes and Green, 2001; Porteous, 2002; Salman, et al., 2002). Vaccinations provide backup protection when there has been a failure in work practices or when an unexpected event occurs. Vaccination against hepatitis B will protect personnel from this serious disease, and OSHA requires that hepatitis B vaccination be offered free of charge to personnel who could come into contact with blood or other body fluids in performing their jobs (29 CFR 1910.1030). Other immunizations could become appropriate and/or mandatory in the future.

4.5 Attire

4.5.1 General considerations

All personnel entering the decontamination, preparation, sterilization, and sterile storage areas should wear clean uniforms that are provided by and donned at the facility. Attire should be changed daily or more often as needed (i.e., when wet, grossly soiled, or visibly contaminated with blood or body fluids). Reusable uniforms that are visibly contaminated by blood or body fluids must be laundered in the laundry facility or area designated by the health care facility for the decontamination of reusable surgical textiles (see ANSI/AAMI ST65).

Shoes worn in the department should be clean, should have non-skid soles, and should be sturdy enough to prevent injury if an item drops on the foot. All head and facial hair (except for eyebrows and eyelashes) should be completely covered with a surgical-type hair covering. Jewelry and wristwatches should not be worn in the decontamination, preparation, or sterilization area. The policy on use of cover apparel when employees leave the department to travel to other areas of the health care facility should be determined by each facility and should comply with state and local regulations. Employees should change into street clothes whenever they leave the health care facility or when traveling between buildings located on separate campuses.

Rationale: Appropriate, clean attire minimizes the introduction of microorganisms and lint from personnel to items being processed and to the environment. Controlled laundering of garments contaminated by blood or body fluids reduces the risk of transferring pathogenic microorganisms from the health care facility to home and family.

Jewelry should not be worn because it is not easily or routinely cleaned daily, it can harbor microorganisms, it can become dislodged and fall into processed items, and it can cause holes in gloves or other barrier protection. Wristwatches and rings, in particular, can catch on equipment or instruments, injuring personnel or damaging the item or packaging.

[1] Information on CDC recommendations regarding exposures to blood-borne diseases can be obtained by checking the CDC web site at http://www.cdc.gov/ncidod/dhqp/gl_occupational.html or by calling the CDC at 1-800-311-3435.

4.5.2 Decontamination area

The OSHA blood-borne pathogen regulation (29 CFR 1910.1030) requires that each facility have in place an exposure control plan that outlines the potential hazards that personnel may encounter while on the job. The plan must also identify the engineering controls, work-practice controls, and preventive and postexposure medical care procedures that will be used to maintain the safety and health of employees. In the decontamination area, these measures will include the use of PPE. In addition to the attire recommended in 4.5.1, personnel working in the decontamination area should wear general-purpose utility gloves and a liquid-resistant covering with sleeves (for example, a backless gown, jumpsuit, or surgical gown). If there is any risk of splash or aerosols, PPE should include a high-filtration-efficiency face mask and eye protection. PPE used to protect the eyes from splash and aerosols could include goggles, full-length face shields, or other devices that prevent exposure to splash from all angles.

Reusable gloves, glove liners, aprons, and eye-protection devices should be decontaminated, according to the manufacturer's instructions, at least daily and between employees. If their integrity is compromised, they should be discarded. Torn gloves should be replaced immediately after appropriate handwashing. Items worn or used in the decontamination area should be regarded as contaminated. Before leaving the decontamination area, employees should remove all protective attire, being careful not to contaminate the clothing beneath or their skin, and wash their hands. Employees should also remove and discard hair coverings before leaving the decontamination area. Appropriate areas, with the necessary containers, should be provided for donning and removing protective attire.

NOTE—Protective attire must be appropriate for the task being performed. In situations that require the highest level of protection (e.g., there is a possibility that attire can become soaked with blood or other potentially infectious material, as when items are being washed by hand), a Level 4 gown (as defined by ANSI/AAMI PB70) should be used.

Rationale: Contaminated instruments and other medical devices are sources of microorganisms to which personnel could be exposed through nicks, cuts, or abrasions in skin or through contact with the mucous membranes of the eyes, nose, or mouth. Appropriate attire will minimize the potential for employee exposure to blood-borne and other disease-producing organisms. PPE and hair coverings might become contaminated in the decontamination area and should be removed when employees leave the area; otherwise, contaminants could be shed onto uniforms or environmental surfaces.

Wearing heavy-duty, waterproof gloves while handling contaminated items greatly decreases the potential for puncture, limits the microbial burden on hands, and decreases the risk of cross-contamination. Gloves do not offer absolute protection, however, because they can develop small leaks due to the stresses of the cleaning process (DeGrott-Kosolcharoen and Jones, 1989); handwashing prevents any further contamination of the worker or environment. Personnel should use a style of glove that prevents contact with contaminated water; for example, gloves that are too short or lack cuffs allow water to enter when the arms move up and down. General-purpose utility gloves may be decontaminated and reused, but they should be discarded if there is evidence of deterioration (e.g., punctures, peeling, or cracking). When the integrity of reusable gloves, aprons, or protective eyewear is compromised, they cease to function as a protective barrier. See also FDA (1999).

High-filtration face masks limit the transfer of microorganisms to and from the respiratory tracts of personnel who are cleaning contaminated items. Eye protection reduces the risk of eye contact with microorganisms and eye injury from hazardous chemical agents. Liquid splashes and aerosols can contact the eyes from any direction, including settling out of the air from above. Liquids can act as vehicles for the transfer of microorganisms from soiled materials and from the skin of personnel; therefore, wet surgical attire should be considered contaminated.

Under OSHA regulations, some discretion is provided for the use of masks and eye protection. However, the committee feels that these protective devices should be worn any time biohazardous materials are being handled if exposure is not prevented by engineering controls (such as the use of pneumatic tubes with plastic shielding for sorting soiled laundry). Donning and removing PPE can itself be a source of contamination and thus should be minimized. Also, a face mask is considered contaminated upon use; it can promote the spread of microorganisms if it is worn hanging around the neck, stuffed into a pocket, or perched on the forehead.

4.5.3 Sterilization area (flash sterilization)

In addition to the attire recommended in 4.5.1, personnel working in areas where items are flash-sterilized should wear a liquid-resistant face mask. Other protective and/or sterile attire might also be necessary, depending on the method by which items are transferred from the sterilizer to the point of use (see 8.8.3, 8.8.4, and 8.8.5).

Rationale: Respiratory droplets can contaminate unprotected sterile items.

4.5.4 Service personnel

The health care facility is responsible for providing PPE for all service personnel and for ensuring that used, contaminated PPE is decontaminated and/or disposed of properly. Such equipment must comply with OSHA regulations and can include protective gloves, protective attire, face shields, and surgical face masks. PPE should be

5.2.4 Disposable items

After they have been removed from their external shipping containers, prepackaged sterile items or prepackaged clean, nonsterile items (e.g., 4x4 gauze sponges or packaging materials used for preparation of procedure trays) may be received directly into preparation or sterile storage areas without further cleaning.

Rationale: Sterile disposable items received from manufacturers are usually individually packaged for dispensing. Clean, nonsterile disposable items are usually packaged for sterilization, or they have been otherwise protected from contamination during transport. Also, they are generally manufactured in an environment in which the bioburden is controlled, so further cleaning is unnecessary.

5.3 Disposition of sterile items (issued but not used)

Unused items that previously have been packaged, sterilized, and issued to a controlled environment such as the OR may be returned to the sterile storage area if the integrity of the packaging has not been compromised and there is no evidence of contamination; such items should be the first to be dispensed when needed. Reusable items that have been opened or that have damaged packaging should be unwrapped and reprocessed through decontamination in accordance with departmental policies and procedures. Disposable items that have been opened or that have damaged packaging should be discarded; such items should not be reprocessed unless the manufacturer provides written reprocessing instructions and all FDA requirements for the reprocessing of single-use items are met (http://www.fda.gov/cdrh/reprocessing/~~use~~).

NOTE—Unused items returned from the OR or other areas with controlled environments should be transported on a clean closed or covered cart and should not enter the decontamination area.

Unused disposable items that previously have been packaged, sterilized, and issued to patient care units or other environmentally uncontrolled areas should be discarded unless the packaging is intact, impervious, and the previous storage conditions are known and acceptable. The items should be inspected carefully for visible soil, tears or holes, wrinkling, broken seals, or indications of wetness before they are returned to the sterile storage area.

Unused reusable items not meeting the above criteria should be unwrapped and reprocessed through the decontamination area.

Rationale: Many of the packaging materials used today are extremely durable. Unnecessary costs may accrue from the indiscriminate discarding of expensive, disposable medical supplies that are unused and returned in acceptable condition. The recommendations of 5.3 are based on the assumptions that an appropriate packaging material has protected unused sterile items unless the package has been opened or damaged and that the packaged items have been properly handled. Consequently, retrieving and reissuing unused sterile items are recommended only if the environment is controlled and if personnel are knowledgeable about the proper handling of sterile items. The more frequently sterile items are handled, the greater is the risk of contamination; therefore, reissued items should be used as promptly as possible.

The reprocessing of single-use devices by health care facilities is regulated by FDA, and all premarket and postmarket requirements must be met if a health care facility chooses to reprocess a single-use device. Health care facilities are encouraged to keep themselves informed on FDA regulations because changes might occur (see http://www.fda.gov/cdrh/reprocessing/~~use~~).

6 Handling, collection, and transport of contaminated items

6.1 General rationale

This section provides guidelines for segregating and handling contaminated items at the point of use and for the transport of contaminated items from the point of use to the decontamination area. The possibility of items being contaminated with infectious material is greatest at the point of use, where they have been in patient contact. Procedures for safely transporting contaminated items are important, because many people—workers, patients, and visitors—can be exposed to potentially disease-producing microorganisms during transport. In addition, the general environment of a health care facility is not controlled, and persons encountered during transport will not be wearing PPE.

Procedures must be developed, with support from the infection control and hazardous materials committees, to protect personnel, patients, and the environment from contamination and to comply with OSHA regulations limiting occupational exposure to blood-borne pathogens. Process audits should be performed to ensure that the procedures are being followed. Action plans should be developed to address problems noted during the audit, and a follow-up audit should be scheduled to ensure that the problems have been corrected.

6.2 Separation of waste and reusable items at point of use

Reusable items should be separated from waste at the point of use. Contaminated disposable items should be discarded into an appropriate container; puncture-resistant containers must be used for sharps. All items contaminated with blood, body fluids, and tissue must be placed in a leakproof container before transport. Contaminated reusable items should be contained in such a way that the contents of the containers are readily identifiable as contaminated by everyone who subsequently handles the items. When the outside of a transport container or cart is visibly soiled, it should be decontaminated, before transport, with an EPA-registered, intermediate-level disinfectant (see 2.65 and Annex E). Containment should comply with the health care facility's established infection control and hazardous waste management procedures. Procedures that reduce the potential for contamination of personnel, their clothing, and the environment should be developed and followed. Depending on the nature and amount of waste to be separated and on the possibility of contamination, it might be necessary for personnel to wear appropriate PPE, such as gloves, protective eyewear, a surgical face mask, and a protective backless gown, jumpsuit, or surgical gown (see 4.5). Other measures may also be adopted for infection control purposes or as part of hazardous waste management. Contaminated items should be handled as little as possible.

Rationale: Used, soiled, contaminated instruments, devices, and supplies are sources of microorganisms that could cause infections in personnel or patients. The infection hazard to personnel is greatest during the handling and segregation of soiled, contaminated items at the point of use. All medical devices are considered to be soiled and contaminated after each use and to be potential sources of infection caused by hepatitis C virus (HCV), hepatitis B virus (HBV), human immunodeficiency virus (HIV), and/or other pathogens. Segregation of soiled items and waste into separate streams of dispatch at the point of use will minimize handling and therefore minimize the possibility of subsequent personnel exposure to potentially pathogenic organisms. Separation is best done at the point of use by persons aware of the potential for injury from sharps and the potential infection hazards of the contaminated items. Contaminated reusable items, contaminated disposable items and waste, and tissue specimens are placed into specifically labeled containers to prevent exposure of personnel to potentially infectious materials and to prevent contamination of the environment. The specified characteristics of containers for sharps and other contaminated items are based on OSHA regulations (29 CFR 1910.1030).

6.3 Care and handling of contaminated reusable items at point of use

Contaminated reusable items should be handled as little as possible at the point of use. Soiled items should be immediately contained and transported to the decontamination area or soiled utility area, where cleaning procedures can be accomplished away from patient care. In many health care facilities, however, immediate containment, transportation, and cleaning might not be feasible, so gross soil should be removed at the point of use. When handling contaminated items, personnel should wear appropriate PPE (see 4.5) and use work-practice controls and engineering controls, as appropriate, to minimize the risk of injury. Soil should be removed by a method that does not promote cross-contamination; for example, personnel should avoid splashing water and thereby contaminating attire, the area near the sink, and other surfaces in the environment. A disposable sponge moistened with water (not saline) should be used to wipe gross soil from instruments. Gauze sponges and similar items used in the cleaning process are contaminated and should be handled, contained, and discarded according to the health care facility's policy for infectious wastes.

To prevent the formation of biofilm, definitive cleaning should occur as soon as possible. If processing is delayed, attention should be given to minimizing bacterial proliferation, including the use of precleaning disinfectants. Even with this step, extremely long delays in processing, such as might occur over a weekend, can result in the formation of tenacious and difficult-to-remove biofilm that will shield microorganisms from routine cleaning procedures and possibly interfere with disinfection or sterilization.

within the vehicle to prevent damage. Transport vehicles and handling practices should allow for ease of loading and unloading.

The design and materials used in the construction of all transport vehicles (motorized or manual) should allow for appropriate decontamination after use. Transport vehicles that are loaded and ready for transport should not be left unattended in unsecured areas. Transport vehicles should be completely enclosed to prevent leaks, and they should be checked periodically to ensure that there are no leaks. Doors should remain closed at all times except during loading and unloading.

The procedures for packaging and transporting contaminated items off-site for processing must comply with applicable Department of Transportation (DOT) and state regulations. See also Annex G.

Rationale: Clean and contaminated items should be separated to prevent cross-contamination during transport. Carts should be secured to prevent damage to contents and to prevent contamination by spills.

Certain contaminated, "nonwaste" products are considered to be "infectious substances" under DOT regulations. The DOT defines an infectious substance as a product contaminated with "viable microorganisms…which cause or may cause disease in humans…" (49 CFR 173.134 [a][1]). Such products qualify as Class 6, Division 6.2, hazardous materials and thus fall under DOT's regulations for "Infectious Substances (Etiologic Agents)." Certain states also have regulations that can affect the transport of contaminated items.

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7 Cleaning and other decontamination processes

7.1 General rationale

To assist health care personnel in the development of appropriate decontamination processes and procedures for the various types of medical devices, this section provides guidelines for the selection and use of available cleaning and microbicidal processes.

To be rendered safe to handle, some medical devices require only thorough cleaning; others, because of occupational exposure considerations, must be cleaned and subjected to a microbicidal process. Some devices can be prepared for patient reuse following the decontamination process (e.g., bedpans), while others must be prepared and subjected to terminal sterilization (e.g., steam sterilization of surgical instruments).

The type of decontamination required for a particular contaminated device depends on the biohazard that the device presents. The cleaning and/or microbicidal process appropriate for a particular device depends on

a) the device manufacturer's written instructions;

b) the necessary level of microbial kill; for example, a higher assurance of lethality is needed for items that have been in contact with body tissues, blood, or body fluids than for items that have only been in contact with unbroken skin;

c) the design of the device; for example, items that have been contaminated with blood or body fluids and that have sharp points or edges capable of puncturing or abrading the skin should be subjected to a decontamination process that includes disinfection or sterilization;

d) other characteristics of the device; for example, whether the materials from which the device is fabricated can tolerate high temperatures or whether the device is fully immersible; and

   NOTE—Health care personnel, including representatives of Central Service and Infection Control, should make a concerted effort to purchase only those devices that can be decontaminated appropriately by a method available in the health care facility. Device manufacturers have the responsibility to provide complete and comprehensive written instructions for the decontamination of their products, as well as a summary and interpretation of test results verifying that their products can be safely and effectively decontaminated. See AAMI TIR12 and FDA (1996a).

e) whether the device was exposed to prions, such as the prion that causes Creutzfeldt-Jakob disease (CJD), and thus will require specialized processing steps.

   NOTE—For information regarding the decontamination of devices exposed to prions, see Annex C, AORN (2008~~5~~a), Favero and Bond (2001), Rutala and Weber (2001), and the recommendations of CDC (http://www.cdc.gov) ~~the American Society for Healthcare Central Service Professionals (ASHCSP) (http://www.ashcsp.org),~~ and the International Association of Healthcare Central Service Materiel Management (IAHCSMM) (http://www.iahcsmm.org).

7.2 Policies, procedures, and manufacturers' instructions

7.2.1 Policies and procedures

Policies and procedures should be developed for all methods of decontamination of reusable items. Process audits to monitor compliance with the various policies and procedures should be performed on a scheduled basis, with appropriate follow-up addressing problems.

Rationale: Policies and procedures provide guidelines for maintaining control and determining methods of improving processes and products.

7.2.2 Manufacturers' instructions

The written recommendations of the device manufacturer should always be followed. The reusable medical device manufacturer is responsible for ensuring that the device can be effectively cleaned and sterilized. Sterilization qualification of a device requires microbiological, engineering, toxicological, and sometimes clinical evaluations of the device, which are well beyond the abilities of most health care facilities. The device labeling should identify specific methods of cleaning and sterilization that have been validated by the manufacturer. The manufacturer's written instructions should be kept on file and periodically reviewed for any updates. If there are no specific instructions in the labeling, then the manufacturer should be contacted directly to provide a documented method. See also AAMI TIR12 and FDA (1996a).

Rationale: To ensure patient safety, a reusable device must be capable of being thoroughly cleaned and sterilized. The manufacturer's written instructions for use are the basis for the department's policies and procedures and must be kept up-to-date.

The primary agent that affects cleaning is the detergent solution or the combination of detergent and enzymatic solution. The delivery system used to bring the detergent solution to the instruments should do so effectively, but the actual cleaning is done by the detergent solution.

Personnel should consult the device manufacturer's instructions to determine the appropriate type of cleaning agent. The cleaning agent manufacturer's instructions for use should be followed.

When choosing cleaning agents for use in health care facilities, it is important to remember that the agent should be compatible with the medical device to be cleaned as well as with the materials used in the cleaning equipment itself. For example, the chemicals should not cause corrosion in ultrasonic cleaning equipment, washer-disinfectors, or washer-sterilizers; and they should not promote electrolytic action between the equipment and the medical devices being cleaned. In addition, any chemical should be easily removable from the medical device by rinsing with readily available water of defined properties so that the device does not retain residual chemicals in amounts that could be harmful to patients, damage the device itself, or create other hazardous situations. An ideal cleaning agent would

a) be nonabrasive;

b) be low-foaming;

c) be free-rinsing;

d) be biodegradable;

e) rapidly dissolve/disperse soil;

f) be nontoxic;

g) be efficacious on all types of clinical soil;

h) have a long shelf life; and

i) be cost-effective.

Rationale: Certain detergents can damage metal or other device materials. It is the responsibility of device manufacturers to advise the user about cleaning agents that will and will not harm their products.

7.5.3 Methods of cleaning

7.5.3.1 Selection of an appropriate method

The appropriate cleaning method for a particular medical device depends on the device's characteristics and should be specified by the device manufacturer, who should communicate any updates or revisions of the cleaning method to the user. Cleaning may be accomplished manually, mechanically, or by a combination of both methods. The cleaning method or methods selected should be effective, should not affect the functionality of the device, and should be safe for the employee performing the task. It is the responsibility of the manufacturer of the reusable device to provide reprocessing instructions in the labeling of the device (e.g., in the instruction manual). (See 7.2.2.) These instructions should recommend use of a particular type of cleaning equipment and/or a particular cleaning agent. Before health care personnel elect to use alternative equipment and/or cleaning agents, they should consult the device manufacturer and the manufacturer of the cleaning equipment or product.

Rationale: Medical devices vary in size, complexity, fragility, sensitivity to cleaning agents, immersibility, and other properties that affect the choice of cleaning method. See also AAMI TIR12.

7.5.3.2 Manual cleaning

Any device should be able to be manually cleaned. Manual cleaning is often recommended for delicate or complex medical devices, such as microsurgical instruments, lensed instruments, and air-powered drills. Immersible devices should be cleaned under water to minimize aerosolization; devices that cannot be immersed should be cleaned in a manner that will not produce aerosols and should be rinsed and dried according to the device manufacturer's instructions. Lukewarm water and detergent solutions (at temperatures optimally in the range of 27 °C to 44 °C [80 °F to 110 °F], but not to exceed 60 °C [140 °F]) will prevent coagulation and thus assist in the removal of protein substances. The temperature of the soaking solution should be monitored and documented. Water hardness, pH, temperature, and the type of soil affect the effectiveness of enzyme cleaners and detergents; the detergent manufacturer's instructions should be consulted. After cleaning, devices should be thoroughly rinsed to remove debris and detergent residues.

Abrasive cleaning compounds and implements such as metal scouring pads can damage devices and should not be used without specific instructions from the device manufacturer. Brushes and other cleaning implements should be designed for use on medical devices. They should either be single-use, disposable items or, if reusable, be

decontaminated at least daily. The device manufacturer should provide information regarding brush size for cleaning devices with lumens.

NOTE—For information regarding the decontamination of cleaning implements for flexible endoscopes, see American Society for Gastrointestinal Endoscopy (2003).

Rationale: Microorganisms, patient tissue, blood, and lubricants on brushes and other cleaning implements could be transmitted from one device to the next during cleaning. In addition, accumulated microorganisms, patient blood, and patient tissue on cleaning implements could pose potential health risks to personnel.

7.5.3.3 Mechanical cleaning

Mechanical cleaning equipment removes soil and microorganisms through an automated cleaning and rinsing process. Some types of equipment incorporate thermal disinfection processes and/or chemical disinfectant rinses capable of destroying various numbers and types of microorganisms. Mechanical cleaning equipment includes utensil washers and cart washers, washer-sanitizers, pasteurization equipment, washer-disinfectors, washer-decontaminators, and washer-sterilizers (see also 7.6.2.3). Some types of mechanical cleaning equipment are designed to clean and/or disinfect specific kinds of medical devices, such as endoscopes.

Ultrasonic cleaners are designed for fine cleaning of medical devices, not for disinfection or sterilization. They are used to remove soil from joints, crevices, lumens, and other areas that are difficult to clean by other methods. Ultrasonic cleaning should be used only after gross soil has been removed from items. The cleaning solution should be changed before it becomes heavily soiled so that effective ultrasonic cleaning is not inhibited by soil and so that the risk of cross-contamination is minimized. In any case, ultrasonic cleaning should be followed by thorough rinsing to remove dislodged particles. Ultrasonic cleaners may require degassing when they are filled with water; the ultrasonic cleaner manufacturer's instructions for use should be followed. The medical device manufacturer's instructions should be followed to ensure that ultrasonic cleaning will not damage the device. Not all metals can be intermixed in the ultrasonic process, and the device manufacturer should specify any restrictions.

For any mechanical cleaning unit, regular preventive maintenance should be performed in accordance with the manufacturer's instructions.

Rationale: The ability to clean medical devices mechanically and to fine-clean by the ultrasonic process is of great value, considering the complexity of many devices and the heavy workload of the average sterile processing department. However, the variety of equipment available and the intricacy of many medical devices make it essential that manufacturers be consulted and their instructions followed for maximum effectiveness and to avoid expensive and unnecessary damage.

7.5.4 Rinsing

Whether manual or mechanical cleaning has been performed, the device should be thoroughly rinsed to ensure that loosened debris and detergents are adequately removed. Tap water can be used for rinsing to ensure that copious volumes are used. However, the final rinse should be performed with treated water that is of a quality that does not contribute to staining of the instrument. Sterile physiological saline should not be used for final rinsing as the salts in this solution will remain on the device after it dries and could eventually cause deterioration of the surfaces of surgical instruments; in addition, saline could interfere with disinfection and sterilization. Some automated washers can provide a final rinse with whatever grade of water is made available (e.g., deionized, distilled, or RO water). It should be recognized that deionized, distilled, or RO water might contain pyrogens, especially if the water treatment equipment is not properly maintained. Therefore, regular maintenance of the water treatment process is essential.

Rationale: The final rinse after cleaning is extremely important because any residuals after this stage will likely remain on the instrument and could therefore detrimentally affect disinfection and sterilization efficacy and/or cause adverse reactions in the patient that the instrument is subsequently used on. Tap water varies considerably, depending on the geographic location and season. However, it can still be used as part of the final rinse provided that the last water used in this final rinse stage is of adequate quality to ensure that there are no staining issues (i.e., use of treated water for the entire final rinse could be prohibitively costly, so users need guidance regarding rinse water options and when it is safe to use tap water).

7.5.5 Verification of the cleaning process

Cleaning encompasses the removal of both soil (patient secretions) and microorganisms (from the patient or from handling or water exposure during reprocessing). After completing the cleaning process, personnel should visually inspect each item carefully to detect any visible soil. Inspection using magnification may identify residues more readily than the unaided eye.

Although validation of the cleaning process may not be realistic in health care facilities, verification is possible (see Annex D). ~~However, few methods are currently available to ensure that medical devices are clean and free from soil~~

~~and microorganisms. One simplistic method involves exposing the cleaned medical device to a 2 % hydrogen peroxide solution to verify that all catalase-containing material (e.g., eukaryotic cells and some bacterial cells) has been removed. If the solution bubbles, then there is residual material on the device that contains catalase. Since blood or other cellular components are the most likely source, the presence of bubbles indicates that cleaning was inadequate.~~

Device manufacturers should provide any test procedures that can be easily replicated and that can help users recognize whether cleaning was effective for all device areas. Such tests are particularly important for devices with components that cannot be readily inspected for cleanliness (e.g., spring hinges, lumens, porous materials, crevices).

See Section 10.2 for recommendations concerning quality-control monitoring of mechanical cleaning equipment.

Rationale: Sterile processing personnel are increasingly aware of the need to control and standardize the steps taken to ensure the sterility of devices for patient use. Because disinfection and sterilization cannot be assured unless the cleaning process is successful, professionals in the field ought to seek out whatever means are available and practical to verify this function. A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically.

7.5.6 Cleaning of instruments

Instruments should be maintained as free of gross soil as possible during the surgical or other health care procedure. Cleaning and decontamination should begin as soon as possible after items have been used. Before they are cleaned, general operating instruments and utensils should be separated from delicate instruments or devices requiring special handling. The device manufacturer's instructions on cleaning and decontamination and on whether the device will tolerate immersion or high heat should be followed (air-powered instruments, for example, should not be immersed). To facilitate cleaning, all instruments or devices composed of more than one part should be disassembled, and all jointed instruments should be open to make sure that all surfaces are effectively cleaned.

An initial cold water rinse with an abundant amount of running tap water or an initial soak in cool water and/or a clinical-soil-dissolving enzymatic cleaner will help prevent coagulation of blood onto the device and help remove blood, tissue, and gross debris from device lumens, joints, and serrations. Protein enzyme substances may need to be dissolved first in hot water before the items to be cleaned are added; cool water may then be added to the enzymatic cleaner solution to fill the soaking pan or sink to an appropriate level for soaking of soiled items. The enzymatic cleaner manufacturer’s instructions should be followed.

After pretreatment, instruments may then be either processed mechanically or washed by hand. To be effective, cleaning agents and methods must remove residual organic soil without damaging the device. Warm water and the appropriate, low-foaming cleaning agent or detergent (i.e., one that is compatible with the specific materials of which the device is composed and with the cleaning/washing method selected) should be used in accordance with the instructions of the manufacturer of the cleaning agent. Certain metals cannot be mixed. Instruments with lumens should be brushed using a brush that is of the correct size for the lumen, then rinsed. To ensure that lumens have complete contact with the processing chemicals, the instruments should be soaked vertically or thoroughly flushed. The cleaning solution should be changed frequently (e.g., after each set of instruments).

All instruments should then be thoroughly rinsed. Water-soluble instrument lubricants, specifically designed for compatibility with sterilization, may be used; the manufacturer’s instructions for use should be followed. Instrument lubricants containing mineral oil or other oil bases should not be used, except to lubricate the internal mechanism of powered instruments as specified by the manufacturer. Instruments should be carefully inspected for flaws, damage, debris, detergent residue, and completeness, and then dried before packaging or sterilization.

NOTE— Devices with lumens should not be dried if they require moistening with distilled or demineralized water before sterilization.

Cloths used in decontamination should be clean and lint-free and should be changed frequently. Brushes should be clean and of the appropriate size and bristle type. Worn brushes should be discarded. Reusable brushes should be disinfected or sterilized at least daily. Towels should also be clean and lint-free. Disposable cleaning tools should be discarded after use. See also 7.5.3.2.

Rationale: Because effective sterilization depends on minimizing the contamination present on items before the sterilization cycle, thorough cleaning procedures are essential during presterilization processing. Not all cleaning and decontamination procedures and agents are appropriate for all types of devices. Adherence to the manufacturer’s instructions for the use of detergents and other aspects of the cleaning and decontamination process will avert damage to instruments, prolong their useful lives, and prevent the creation of crevices in which debris can collect.

Using a cleaning agent that produces bubbles makes it difficult to rinse instruments thoroughly. Vertically soaking lumened instruments prevents air bubbles, thus ensuring that all surfaces have contact with the solution. Soaking lumened instruments horizontally will cause air bubbles to become entrapped in the lumen. Thoroughly flushing

lumens helps ensure complete surface contact with the solution. Frequently changing the cleaning solution helps keep the bioburden low.

Oil-based instrument lubricants should not be used, because the oil will coat bacteria and the instrument surface, interfering with steam contact during sterilization. Ensuring the completeness of instrumentation helps reduce the number of lost instruments and instrument parts. Drying instruments before they are packaged reduces the chance of wet instrument packs after sterilization.

Cloths with lint may leave lint on instrumentation. Using cleaning implements that are clean reduces the bioburden. Using brushes of the correct size is very important. If a brush is too large, it will not fit into the lumen; if it is too small, it will not have complete contact with the lumen walls and, consequently, will not clean them thoroughly. Brushes used for decontamination must themselves be cleaned and disinfected or sterilized. Brushes that show wear will not clean thoroughly. Prompt cleaning of brushes and other cleaning implements reduces or eliminates biofilm-forming microorganisms and thus minimizes the formation of biofilm.

7.5.7 Utensils

Soiled utensils, such as basins, bedpans, and trays, whether received from patient care areas or surgical areas, should be processed through a mechanical washer, washer-sanitizer, washer-disinfector, or washer-sterilizer. Also, utensils may be washed by hand, although this is not usually cost-effective. In either case, warm water and an appropriate detergent should be used for cleaning.

Rationale: See the Rationale for 7.5.6.

7.5.8 Reusable textiles

Soiled textiles should be placed in a hamper bag that prevents leakage for transport to the laundry for processing. The washing process consists of a combination of mechanical action, water flow, water temperature, time, and chemicals to clean and further decontaminate soiled textiles. The steps in a washing process should be completely described, controlled, and monitored for each type of textile classification being processed. For guidelines on the proper handling and processing of reusable surgical textiles, see ANSI/AAMI ST65.

Rationale: See ANSI/AAMI ST65.

7.5.9 Rigid sterilization container systems

Rigid sterilization container systems should be cleaned carefully before sterilization even if they are to be returned immediately to use. Before acquiring container systems, the user should confirm that the manufacturer's validated cleaning method complies with the facility's procedures. Container systems can be cleaned by either manual or mechanical means. The container system manufacturer's instructions for cleaning and rinsing should be followed, as should accepted practices for decontamination and employee safety. Personnel who manually clean containers and contaminated contents of containers must wear appropriate PPE for the task they are performing.

Before it is cleaned, a container system should be disassembled. For container systems with filters, disposable filters should be removed or the filter protector/holder should be released. For container systems with valves, the valves should be cleaned according to the manufacturer's written instructions. Interior baskets should also be removed and cleaned. Process chemical indicators (CIs), disposable labels, and locks should be removed. It may be necessary to remove dividers and pins if they interfere with the cleaning process.

Most rigid sterilization container systems can be cleaned in mechanical equipment. The method selected depends on the container system manufacturer's instructions in conjunction with the mechanical cleaning equipment manufacturer's instructions. When positioning the outer container in a mechanical washer, personnel should take care to avoid the accumulation and subsequent retention of very hot water and to avoid damage to mating surfaces and gaskets.

The manufacturer's instructions for choice of detergent should be followed, and the container should be rinsed thoroughly after cleaning. After the cleaning process is completed, nuts, bolts, screws, rivets, filter retention mechanisms, gaskets, and permanent filters should be inspected for cleanliness and damage.

Rationale: Adequate cleaning is the first step in the decontamination and reuse process. Protective attire is necessary to avoid infection and comply with OSHA regulations (29 CFR 1910.1030). It is important to consult the manufacturer's instructions, because a particular rigid sterilization container system might not be compatible with certain cleaning methods or cleaning agents. Some cleaning agents can cause corrosion or deterioration of container surfaces, such as discoloration or stress cracking; for example, detergents that do not have a neutral or near-neutral pH can corrode metal, and specific additives can adversely affect some plastics.

Disassembly of a container system allows thorough cleaning. Removing disposable items reduces debris.

Process audits should be performed to ensure adherence to procedures related to the correct selection and use of packaging materials and their accessories, as well as the correct assembly of packs and sets.

Rationale: Temperature and humidity equilibration of packaging material and product is needed to permit adequate steam penetration and to avoid superheating. Temperature affects relative humidity, so a preconditioning temperature range is also recommended. Experience has shown that if the packaging and product are too dry, problems such as superheating and positive BIs can result. The suggested humidity and temperature ranges were chosen for consistency with the conditions recommended for general environmental control in work areas (see 3.3.6.5 and 3.3.6.6). The 2 hour preconditioning period is a minimum; some packaging materials might require a much longer equilibration time, depending on previous storage conditions. For sterility maintenance and aseptic presentation, certain items require double-wrapping. Rigid sterilization container systems vary in their mechanics, their specific performance characteristics, and their suitability for particular sterilization cycles. A change in the filter material (e.g., a change in brand) can affect air removal or sterilant penetration and evacuation in a container system. Filter material cannot be tested easily by health care personnel. There is no nationally recognized referee test for the microbial barrier performance of filters. However, as with any packaging system, inspection for integrity is part of a good quality assurance program.

Adherence to established policies and procedures is important in ensuring proper sterilization and drying. Steam entering packages containing metal instruments immediately condenses as its latent heat is transferred to the metal items. Over the course of the exposure period, all of the condensate might not return to a vapor and can remain trapped in the package in the form of water droplets. Elimination of the condensate is only possible with a sterilizer designed with heated drying capabilities. Inadequate drying could compromise the seal, the integrity, or the barrier protection ability of the package, and, therefore, sterility might not be maintained.

8.3.2 Package labels

Package labels (e.g., process indicators, labels for product identification and lot number, expiration statement labels) should be capable of remaining securely affixed to packages throughout the course of their handling from sterilization to use. If a marking pen is used to label paper-plastic pouches, the labeling information should be written only on the plastic side of the pouch. If a marking pen is used to label wrapped packs, basins, instruments, or other surgical supplies, the ink should be nontoxic, and the labeling information should be written on the indicator tape or affixed labels.

Rationale: Important identification information must not be lost during handling. Writing on the paper side of the pouch or on a wrapper (whether woven or nonwoven) could cause damage to the package (which might not be noticeable) and thereby compromise the barrier protection. Use of permanent markers with nontoxic ink is recommended to avoid toxins being deposited on packs or instruments.

8.3.3 Package closures

Accessories used to close or secure packages should be chosen to allow the steam sterilization process to occur, avoid constriction of the package, and maintain package integrity. Tape (other than sterilization indicator tape) should not be used to secure packages, nor should safety pins, paper clips, staples, or other sharp objects. Elastomer bands designed specifically for sterile packaging are acceptable as outside closures only if the wrapper manufacturer explicitly recommends their use and only if care is taken to choose the proper size (relative to the length and width of the package) so that the elastomer band fits snugly yet does not constrict the package (e.g., create an “hourglass” effect) or cause excessive wrinkles or folds in the package. Rubber bands or tape should not be used to hold instruments together in a group. Tip protectors, if used, should be steam-permeable, fit loosely, and be used according to the manufacturer’s instructions. The latching mechanism on rigid sterilization container systems should secure the lid so that it cannot move when locked.

Rationale: Tapes other than those designed to endure sterilization might not hold their seal when exposed to steam. Packages expand and contract during steam sterilization. Closures that restrict this action could interfere with air removal, steam penetration, and steam removal. Also, overly constrictive bands can stress packaging materials to the point of tearing during this expansion and contraction. Rubber bands or tape used to hold instruments together in a group could interfere with steam contact of the surfaces beneath them. If tip protectors are fabricated from inappropriate materials or if they fit too tightly, they could also interfere with steam contact. Sharp objects, such as pins, paper clips, and staples, can puncture the packaging material and thus compromise the sterile barrier.

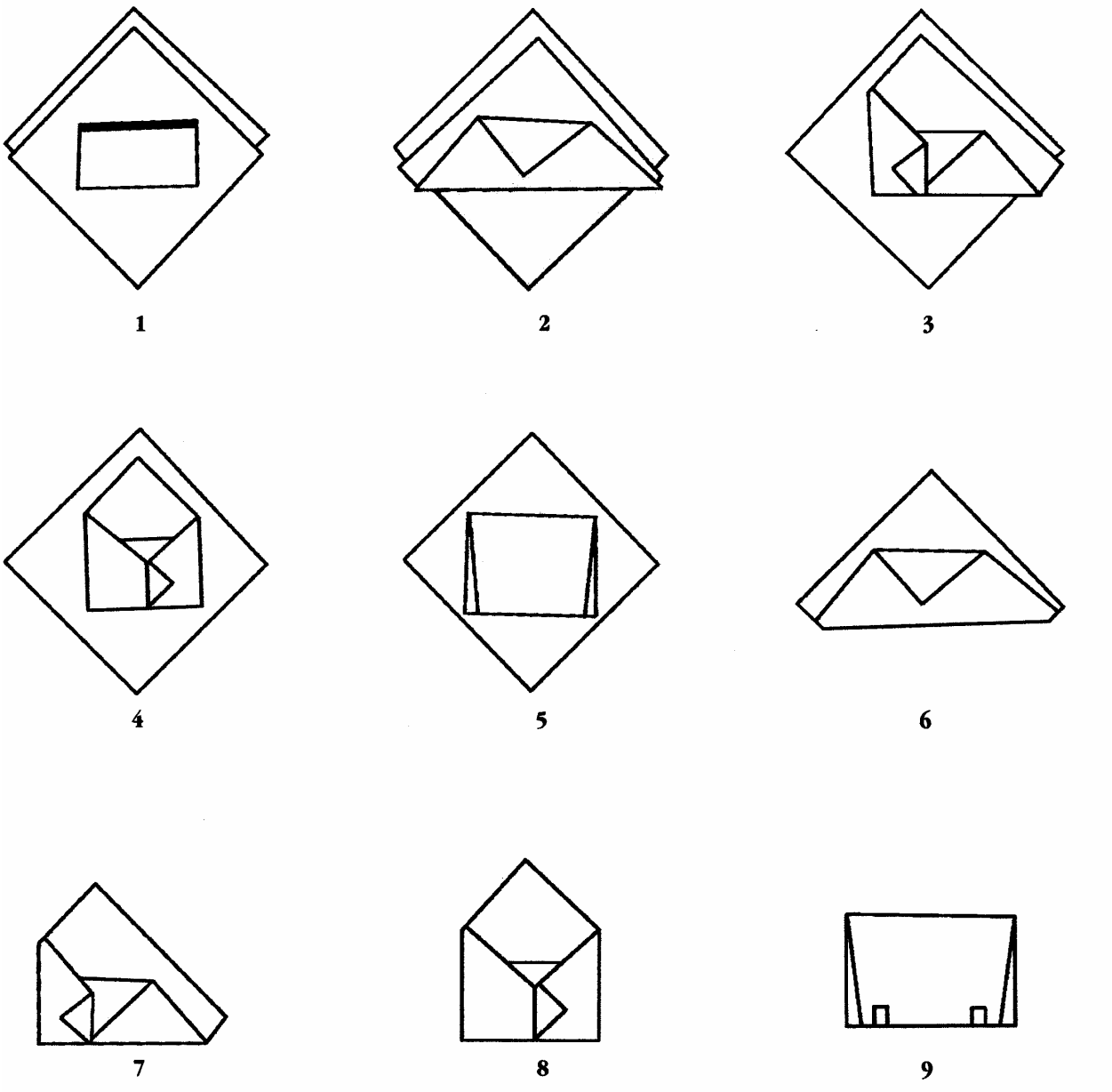

Figure 4—Sequential double-wrapping: envelope fold

[This figure replaces the previous one.]

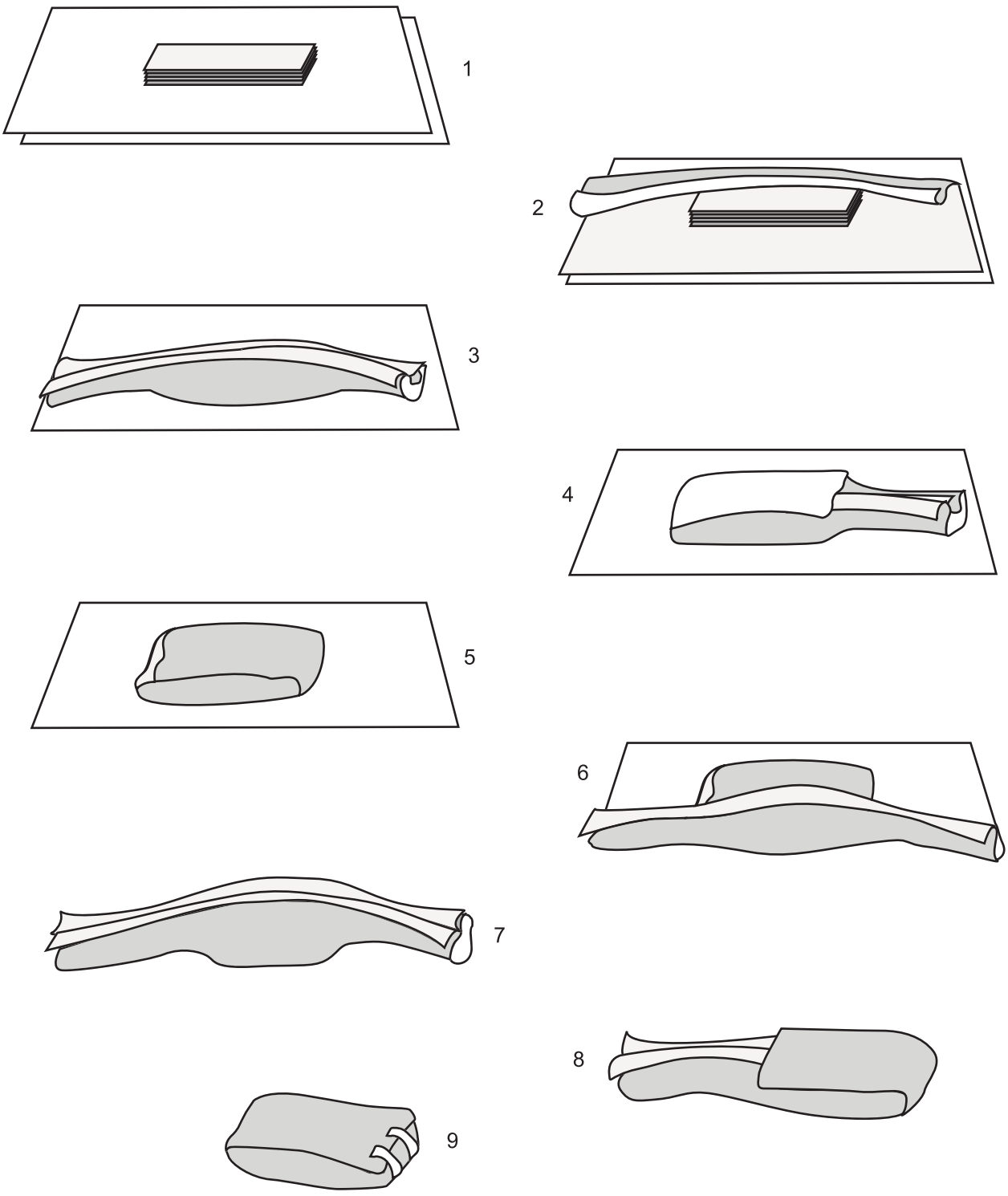

Figure 5—Sequential double-wrapping: square fold

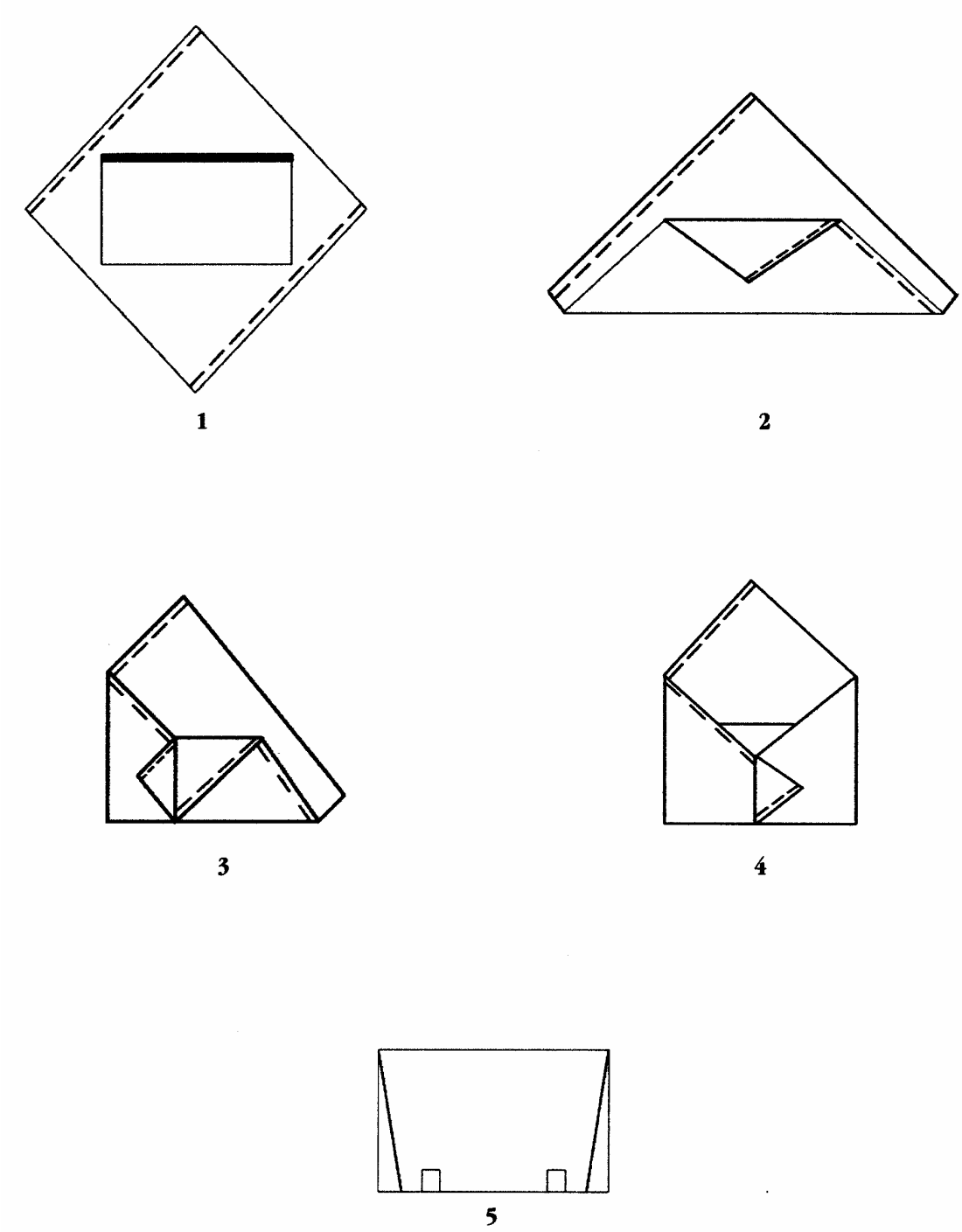

Figure 6—Simultaneous double-wrapping: envelope fold

[This figure replaces the previous one.]

A pack should be prepared with clean, preconditioned textiles. It might be necessary to separate tightly woven, liquid-resistant textile items in the pack with absorbent, less dense fabrics (e.g., surgical towels) in order to allow adequate air removal, steam penetration, and steam evacuation. The wrapper should be securely applied but not pulled in such a way that the contents are compressed. All textile packs should be temperature- and humidity-equilibrated, in accordance with 8.3.1, before sterilization.

The user should be knowledgeable regarding the effect that the materials and construction of the textiles used in pack preparation could have on the sterilization process, and evaluate each constructed pack for ease of air removal, steam penetration, and steam evacuation. When textiles other than those known to be readily steam-permeable are used, be they woven or nonwoven (laminated) reusable materials, some simple tests should be conducted in the health care facility to demonstrate their compatibility with the sterilization process. These tests help ensure that the wrapped packs can indeed be sterilized and thus that their specific configuration will be acceptable for steam sterilization. Textile packs should be evaluated for their suitability for particular sterilization cycles. Tests may include placing BIs in a sample pack to assess sterilant penetration (see 10.9), placing a Bowie-Dick test sheet in a sample pack to assess air removal, and measuring the weight of the pack before and after sterilization, using a scale calibrated in ounces or grams, to assess dryness. More sophisticated testing, such as the use of thermocouples to record real-time and temperature profiles within the pack during sterilization, can be performed in cooperation with the sterilizer manufacturer and the manufacturer of the textile product.

Rationale: The term *pack density* refers to the ratio of weight to volume and is affected by how textiles are arranged within a pack and by how tightly the pack is wrapped prior to sterilization. Historically, professional guidelines have recommended that the maximum weight of a textile pack should not exceed 12 pounds and that it should measure 12 inches wide by 12 inches high by 20 inches long to achieve a pack density of 7.2 pounds per cubic foot. These recommendations were developed for muslin drapes and wrappers only and do not apply to the preparation of packs using products composed of the very different materials used today. Therefore, instructions on pack preparation and density parameters should be sought from the various textile manufacturers.

Reusable textiles require inspection before use to ensure their effectiveness. Holes or other defects in a wrapper allow the contents of the pack to become contaminated.

Temperature and humidity equilibration is especially important for textile packs because of their large volume. A desiccated pack can lead to superheating and, consequently, sterilization failure and diminished useful life of the materials.

Because of the variety of textiles on the market, it is important for users to assess the various configurations of packs.

8.3.6 Basins and basin sets

Graduated nested basins should differ in diameter by at least one inch. Basin sets should be prepared so that all basins are placed in the same direction. Basin sets should be processed with nonlinting absorbent material between nested basins. Basin sets should be assembled so as to permit air removal, steam penetration, and steam removal during the sterilization and drying process. The weight of wrapped basin sets should not exceed 7 pounds, and the total number of basin sets per load should be evaluated to help ensure dry sets.

Rationale: Separating basins with absorbent material enhances adequate air removal and passage of steam to all surfaces, and it facilitates drying. It is important that the absorbent material be nonlinting because lint can carry microorganisms into the surgical site as well as cause foreign-body reactions. Proper alignment of basins, to prevent them from acting as reservoirs for moisture, is essential to achieving sterility. Excess metal mass may cause excessive condensation during heat-up, a slower temperature come-up time, and inefficient drying, because metal acts as a heat sink, taking heat from the saturated steam as it enters the sterilizer and causing the steam to “collapse” (i.e., change into liquid water).

8.3.7 Surgical supplies

Surgical supplies such as syringes, needles, dressings, cotton balls, and similar items should be individually packaged (or in some usable quantity per individual package per use); canisters with lids should not be used for these items. Syringes should be packaged so that the barrel lies next to the plunger, and stylets should be removed from needles.

Rationale: Maximum protection of the sterility of surgical supplies until use is best assured by individual packaging. Since it is necessary to remove the canister lid for the sterilization cycle, the sterility of items in the canister is compromised as soon as the sterilizer door is opened and the canister contents are exposed to the environment. Also, canisters with solid bottoms will not allow adequate air displacement. Syringes should be disassembled to ensure adequate steam contact with all surfaces.

8.3.8 Devices with lumens

Unless contraindicated by the device manufacturer's instructions, the lumens of devices such as catheters, needles, and tubings should be flushed with distilled or demineralized (treated) water before packaging, and any stylets or plugs should be removed. Sterilization should follow immediately.

Rationale: Moistening of lumens is required so that steam can be generated from within. Steam cannot penetrate from the outside of the catheter because the lumen is a diffusion restricter. Treated water should be used to flush lumens because tap water may contain pyrogens.

8.4 Preparation and assembly of surgical instrumentation

8.4.1 General considerations

The preparation and assembly of surgical instrumentation is a complex process, and various packaging methods are used. Instruments sets should be sterilized in perforated or wire-mesh-bottom trays or in containment devices such as specially designed rigid organizing trays or rigid sterilization container systems, with all instruments held open and unlocked. Multipart instruments should be disassembled for sterilization unless the device manufacturer has provided validated instructions to the contrary. If commercially customized organizing trays or cassettes are used, the health care facility should request scientific documentation from the manufacturer that demonstrates the efficacy of the tray or cassette instrumentation arrangement in the steam sterilization cycles available to the facility (see AAMI TIR12). Nonlinting absorbent material may be placed in the tray to facilitate drying. For adequate drying, it might also be necessary to wrap instruments of unusual design or high density with absorbent material (see also 8.4.5). Individual instruments may be packaged in an acceptable packaging material, with the instrument held open, unlocked, or disassembled, and sterilized in a position that ensures adequate steam contact with all surfaces.

Rationale: Preparing instruments in the manner described helps ensure that there will be adequate steam contact with all surfaces and reduces the potential for wet packs. Plastic organizing trays and cassettes can have significantly different drying characteristics than do metal perforated or wire-mesh-bottom trays. The design of, and arrangement of devices within, customized trays or cassettes can be restrictive to air removal, steam penetration, condensate drainage, and drying during steam sterilization. It is important that the absorbent material be nonlinting because lint can carry microorganisms into the surgical site as well as cause foreign-body reactions.

8.4.2 Weight and density of sets

The weight of an instrument set should be based on whether personnel can use proper body mechanics in carrying the set, on the design and density of the individual instruments comprising the set, on the recommendations of the medical device and sterilizer manufacturers, and on the distribution of mass (the density) in the set and sterilizer load. Instrument sets should be prepared in trays *large enough to equally distribute the mass;* set configuration should be evaluated to help ensure dry sets. The total number of sets per load should also be evaluated; in hospitals in which steam quality is less than optimal, load size could adversely affect drying time. For rigid sterilization container systems, the user should consult the container system manufacturer concerning the weight and density of instrument sets; however, it is the user's responsibility to determine that the instrument set can be effectively sterilized and dried. (See also Annexes I and J.)

Drying should be evaluated by controlled, random sampling and opening selected sets at the completion of the drying/cooling time. Health care facility policy will dictate the frequency of sampling. The documentation should be maintained within the sterilization department. This evaluation should be repeated any time there is a change to the set (e.g., adding instruments, changing the set configuration). A policy should be established for end users to report all instances of moist or wet sets to Central Service. Any set containing moisture or that has visible water inside the container system should be considered contaminated.

Rationale: Preparation and assembly procedures should take into account the ratio between the number of instruments and the total set weight and density. By considering the density of the individual instruments, the instrument set, and the sterilizer load, as well as the available steam quality, the user will be able to develop a total program that will yield sterile, dry instrument sets. When containment devices, including their contents and any accessories or wrappers, are too heavy, sterilization and/or drying may be compromised in commonly available hospital sterilization cycles. Additionally, there may be ergonomic issues associated with heavy, containerized instrument sets. A maximum weight limit of 25 pounds for containerized instrument sets has been recommended in ~~proposed~~ ANSI/AAMI ST77 and is consistent with other standards that address containment devices (e.g, DIN 58946-6, EN 868-8, CSA Z314.3, CSA 314.14). From an ergonomic standpoint, calculations from the NIOSH equation on manual lifting (Waters, et al., 1994) yield recommended weight limits intended to protect workers from injuries due to lifting. Unless random sampling of sets is performed, the facility might not be aware that there is a problem with wet sets. A wet set should be considered contaminated because there are no scientific studies to prove otherwise.

Table 6—Minimum cycle times for dynamic-air-removal steam sterilization cycles

Item	Exposure time at 132 °C (270 °F)	Exposure time at 135 °C (275 °F)	Drying times
Wrapped instruments	4 minutes		20 to 30 minutes
		3 minutes	16 minutes
Textile packs	4 minutes		5 to 20 minutes
		3 minutes	3 minutes
Wrapped utensils	4 minutes		20 minutes
		3 minutes	16 minutes
Unwrapped nonporous items (e.g., instruments)	3 minutes	3 minutes	NA
Unwrapped nonporous and porous items in mixed load	4 minutes	3 minutes	NA

NOTE—This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

8.6.2 Flash sterilization parameters

8.6.2.1 General considerations

The following paragraphs provide cycle times and temperatures for currently available flash sterilization cycles. The stated parameters are only intended to be general guidelines. The sterilizer manufacturer's written instructions and the device manufacturer's written instructions should always be followed.

Flash sterilization of implantables is not recommended.

NOTE—Health care personnel considering the use of flash sterilization should refer to the Introduction for information on the conditions under which flash sterilization is appropriate.

Rationale: The sterilizer manufacturer has validated the parameters for the particular sterilization cycles provided by the sterilizer. For certain devices, the exposure time might have to be extended; therefore, the device manufacturer's written instructions should also be consulted and followed.

NOTE—The flash method of steam sterilization of instruments and other selected devices must not be used to sterilize wrapped or containerized items (except as indicated in 8.6.2.4 and 8.6.2.5).

8.6.2.2 Gravity-displacement cycles for unwrapped porous and nonporous items

The minimum exposure time and temperature for nonporous items (e.g., routine metal instruments) is 3 min at 132 °C (270 °F) to 135 °C (275 °F). When nonporous items, porous items, and items with lumens are sterilized together, the minimum exposure time and temperature is 10 min at 132 °C (270 °F) to 135 °C (275 °F). See Table 5 and AORN (2008~~5~~d).

Rationale: Forceps, needle holders, scissors, and other routine metal instruments require surface sterilization only, and the specified exposure time and temperatures have been found to be adequate for this purpose. The addition of porous items (e.g., rubber or plastic items, items with lumens, items with sliding parts that prevent sterilant contact with surfaces) requires a longer exposure time to ensure adequate steam penetration. (See also Perkins, 1969.)

NOTE—Chemical indicators are not considered porous items, for purposes of determining cycle parameters.

8.6.2.3 Dynamic-air-removal cycles for unwrapped porous and nonporous items

The minimum exposure time and temperature for nonporous items (e.g., routine metal instruments) is 3 min at 132 °C (270 °F) or 135 °C (275 °F). When nonporous items, porous items, and items with lumens are sterilized together, the minimum exposure time and temperature is generally 4 min at 132 °C (270 °F) or 3 min at 135 °C (275 °F). See Table 6 and AORN (2008~~5~~d).

NOTE—These are minimum exposure times that may be exceeded, if necessary. Some prevacuum sterilizers have preset timers that fix exposure times at more than 3 min.

Rationale: As noted in 8.6.2.2, forceps, needle holders, scissors, and other routine metal instruments require surface sterilization only, and the specified exposure time and temperatures have been found to be adequate for this purpose. As in the case of gravity-displacement cycles, the addition of porous items (e.g., rubber or plastic items, items with lumens, items with sliding parts that prevent sterilant contact with surfaces) might necessitate a longer exposure time to ensure adequate steam penetration. However, a prevacuum sterilizer facilitates air removal and aids steam penetration, so the required exposure time can be minimized.

8.6.2.4 Flash cycles with single wrappers or other textile packaging

Some prevacuum and pulsing gravity-displacement steam sterilizers provide a cycle designed to permit flash sterilization using a *single* wrapper or other packaging on the instrument tray. The parameters for sterilization are established and preset by the sterilizer manufacturer, whose written directions and guidelines for use should be followed. These instructions should include recommendations concerning the type of wrapper or other packaging and the types of instruments that are suitable for flash sterilization using this method. The sterilizer or packaging manufacturer should supply supporting scientific data demonstrating that sterilization can be achieved when a single wrapper or other packaging is used in flash sterilization.

Rationale: Cycle parameters vary depending on the design of the sterilizer. Only the sterilizer manufacturer is able to establish the appropriate parameters. The single wrapper is intended to confine the sterilized items and protect them from environmental contaminants that might be encountered en route from the sterilizer to the point of use. It is important to follow the sterilizer manufacturer's instructions regarding the types of instruments that are suitable for this type of cycle, because in some cases instruments with lumens, powered equipment, and porous items cannot be processed by this method (due to potential difficulties with air removal and steam penetration).

8.6.2.5 Flash cycles with sealed containment devices

Some rigid reusable sealed containment devices are designed to be used in flash sterilization cycles, including prevacuum, pulsing gravity-displacement, and gravity-displacement cycles. Such containment devices are designed to permit flash sterilization of their contents, including single instruments and instruments sets. The containment device manufacturer should supply supporting scientific data demonstrating that sterilization can be achieved when a sealed containment device is used in flash sterilization and should recommend an appropriate PCD.

Rationale: Cycle parameters vary depending on the design of the sterilizer. Only the sterilizer manufacturer is able to establish the appropriate parameters. The containment device is intended to confine the sterilized items and protect them from environmental contaminants that might be encountered en route from the sterilizer to the point of use. It is important to follow the containment device manufacturer's instructions regarding the types of instruments that are suitable for this type of cycle, because in some cases instruments with lumens, power equipment, and porous items cannot be processed by this method (due to potential difficulties with air removal and steam penetration).

8.6.3 Specialty instruments

Sterilization of specialty instruments and devices, such as drills, could require extended exposure times. Certain manufacturers of such devices do not recommend flash sterilization. The device manufacturer's instructions should be followed. See also AORN (2008~~5~~a).

NOTE—For specialty instruments and devices, a drying time might be recommended by the device manufacturer, even though an unwrapped technique is used.

Rationale: The instrument or device manufacturer is best able to determine the required sterilization parameters. Drying is necessary for some devices in order to ensure longevity and proper performance.

8.7 Monitoring sterilization cycles

Quality control, including sterilization cycle monitoring, is addressed in Section 10.

8.8 Unloading the sterilizer

8.8.1 Large-chamber sterilizers

All items removed from the sterilizer after sterilization processing, including items packaged in rigid sterilization container systems, should remain on the sterilizer cart until adequately cooled. They should not be touched during the cooling process. Rigid sterilization container systems should remain on the sterilizer cart until container surfaces are cool to the touch and can be handled safely by the operator with bare hands. The cool-down period begins within the sterilizer chamber. The door may be opened slightly at the end of the cycle and the items left inside for a period of time in order to reduce the potential for condensation formation.

The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used. A minimum cooling time of 30 minutes is recommended. During cooling, the sterilizer cart should be placed in a low-traffic area

maintenance cover and, since the sterility maintenance cover is not sterile, contaminate the package contents. To be an effective barrier, the sterility maintenance cover has to be sealed. The sterility maintenance cover is only a protective device; the identity and traceability of the package within has to be maintained.

8.9.2 Storage facilities

Sterile items should be stored in a manner that reduces the potential for contamination. In general, the temperature in storage areas should be approximately 24 °C (75 °F). There should be at least 4 air exchanges per hour, and relative humidity should be controlled so that it does not exceed 70 % (AIA, 2001). Traffic should be controlled to limit access to sterile items to those individuals who know how to handle them properly. Sterile items should be stored far enough away from the floor, the ceiling, and outside walls to allow for adequate air circulation, ease of cleaning, and compliance with local fire codes. Sterile items should be stored at least 8 to 10 inches above the floor, at least 18 inches below the ceiling or the level of the sprinkler heads, and at least 2 inches from outside walls. The items should be positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised. Medical and surgical items, including those packaged in rigid sterilization container systems, should not be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they could become wet. Supplies should not be stored on floors, on windowsills, or in areas other than designated shelving, counters, or carts. Heavy instrument trays should be stored on middle shelves (but not stacked) for ease of handling by staff; transport trays with solid or perforated bottoms may be used to prevent tears in wrappers during handling. (See also 3.3.7.4.)

Closed or covered cabinets are recommended for the storage of seldom-used supplies. Open shelving may be used, but requires special attention to traffic control, area ventilation, and housekeeping. Shelving or carts used for sterile storage should be maintained in a clean and dry condition. For sterile and clean supplies stored on the bottom shelf of an open-shelf (wire) cart, there should be a physical barrier between the shelf and traffic or housekeeping activities. Outside shipping containers and corrugated cartons should not be used as containers in sterile storage areas. (See also 5.2.1.)

Shelving or racks used for the storage of rigid sterilization container systems should be designed for the weight and configuration of the containers. The racks or shelves should be kept clean and dry in a controlled environment. When stacking container systems, the user should take care to ensure that they are firmly seated one upon another and that they can be removed easily. Written policies and procedures for the storage, handling, rotation, and labeling of container systems should be developed and enforced.

Rationale: Adequate space is needed around sterile materials to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between sterile items and the condensation that might form on the interior surfaces of outside walls. Also, fire codes specify minimum distances below the ceiling (usually 18 inches) to ensure the effectiveness of sprinkler systems (see ~~National Fire Protection Association [NFPA], 1999~~. NFPA 13). Compression of packages can force air and microorganisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces. Sterile items should not be stored anywhere but on or in designated shelving, counters, or containers, because other areas might not be sufficiently clean, and because windowsills collect condensate that forms due to differences in temperature between inside and outside air.

Closed cabinets limit dust accumulation, discourage handling, and minimize inadvertent contact with sterile items. Shipping containers have been exposed to unknown and potentially high microbial contamination, and corrugated containers serve as generators of and reservoirs for dust; hence, shipping containers should never be allowed in the sterile storage area.

8.9.3 Shelf life

The shelf life of a packaged sterile item is event-related and depends on the quality of the packaging material, the storage conditions, the conditions during transport, and the amount of handling. Shelf life is not simply a matter of sterility maintenance but is also a function of device degradation and inventory control. There should be written policies and procedures for how shelf life is determined and how it is indicated on the product. When sterility maintenance covers are used, there should be specific policies and procedures for assessing shelf life in the event that the cover is removed but the packaged item is not used immediately. In general, stock should be rotated according to the principle “first in, first out.”

Rationale: The contamination of a sterile item is event-related, and the probability of its occurrence increases over time and with increased handling. See also Joint Commission~~CAHO~~ (2007~~5~~) and AORN (2008~~5~~b).

8.10 Distribution (general)

8.10.1 Handling and inspection

Supplies should be handled carefully. Care should be taken to avoid dragging, sliding, crushing, bending, compressing, or puncturing the packaging or otherwise compromising the sterility of the contents. Packaging should be thoroughly inspected visually for integrity and labeling before an item is issued.

Rationale: Excessive and improper handling of sterile packages can damage the barrier qualities of the packaging materials. Proper care and handling of sterile packages helps prevent contamination of the contents. Inspection of sterile packages will identify any damage to the integrity of the packaging materials before the items are dispensed. See also the rationale statement for 8.9.3.

8.10.2 Distribution containers

All clean or sterile items being transported in uncontrolled environments should be in a covered or enclosed cart with a solid bottom shelf. If items are placed inside plastic or paper bags or boxes for transport, they should be arranged within the containers so as to prevent them from being crushed or otherwise damaged or contaminated. Reusable covers for carts or other transport vehicles should be cleaned after each use and should have a reclosable opening. Carts should be decontaminated and dried before they are reused for transporting sterile supplies. For automated cart distribution systems and pneumatic systems, the manufacturer's instructions on distribution and decontamination procedures should be followed.

Rationale: Covered or enclosed carts protect sterile items from inadvertent contact with personnel and other sources of contamination and from environmental challenges that might exist along the transportation route. A solid bottom shelf on the cart prevents contamination via the so-called "rooster-tail effect," in which the wheels pick up contaminants from the floor and spin them upward. Surfaces that are in direct contact with sterile packaging should have minimum bioburden to decrease the risk of microbial penetration of the sterile barrier of the packaged items. Carts and reusable covers should be cleaned after each use because even though they are used for sterile items, contamination is picked up from the environment during transport outside the department.

8.11 Transport of sterile packaged items

8.11.1 General considerations

Sterile packaged items should be transported in a manner that will protect the items from puncture and from contamination by moisture, excessive humidity, condensation caused by exposure to temperature extremes, insects, vermin, dust and dirt, excessive air pressures, and microorganisms.

Rationale: Adequate protection during transport minimizes the potential for damage and helps prevent compromise of sterility. This rationale also holds for 8.11.2. through 8.11.6.

8.11.2 Tables and carts (open or closed)

Transport carts and tables should be large enough for all packages to be placed securely in the appropriate position (flat) without extending beyond the edge of the cart shelf or table surface.

8.11.3 Hand transport

Sterile packages that contain instrumentation and that are transported by hand should be maintained in a position parallel with the floor. The carrier should exercise good body mechanics.

8.11.4 Dedicated lifts

Sterile packages to be transported from the point of processing to the point of use by means of a dedicated clean lift (i.e., one used only for clean or sterile items) should be contained in a closed bin, a closed case cart, or a plastic bag. Dedicated clean lifts should only be located in areas designated as "clean."

8.11.5 Off-site transportation

Vehicles used to transport sterile packages between health care facilities should provide for the complete separation of clean and sterile items from contaminated items. Transport vehicles must be completely enclosed and should be checked periodically, at least annually and more frequently as needed, to ensure that they do not leak. Carts containing sterile packages should be secured within the vehicle to prevent damage or contamination. Transport vehicles and handling practices should allow for ease of loading and unloading.

NOTE—For the purposes of this paragraph, all external shipping cartons (corrugated or otherwise) are considered contaminated, even if they contain packaged sterile items.

When motor vehicles are used, environmental conditions should be assessed while the vehicle is in motion and when it is not in motion. Additionally, in geographical areas where high humidity is the norm, actual testing should be performed to determine the potential for absorbent items to become contaminated and for the contents of sterile packages to become wet from the condensate that can occur on metal or plastic surfaces that are moved from air-conditioned environments within the processing facility to the non-air-conditioned environment of transport vehicles to the air-conditioned storage area of the using facility. The design and materials used in the construction of all transport vehicles (motorized or manual) should allow for appropriate decontamination processes, especially if the vehicles are to be used alternately for the transport of sterile/clean items and soiled items. Transport vehicles (motorized or manual) that are loaded and ready for transport should not be left unattended in unsecured areas.

8.11.6 Policies and procedures

Written policies and procedures should be developed for the use of specific transport equipment, appropriate handling practices, and acceptable environmental conditions for the transport of sterile packages.

8.12 Aseptic presentation

8.12.1 Opening sterile packages

The following guidelines should be observed when opening sterile packages:

1) The sterile package should be positioned on a separate dry, flat surface at or above the level of the sterile field and at the edge of the surface nearest to the person who will be opening the pack.

2) Before it is opened, the package should be inspected for the appropriate appearance of the external CI(s) and the physical integrity of the packaging. If the packaging is a rigid sterilization container system, the external latch filters, valves, and tamper-evident devices should be inspected for integrity.

3) Wrapped sterile packages should be opened by breaking the seal of the exterior tape and unfolding the wrap, layer by layer, without touching the contents. Care should be taken to hold the wrap securely so that it does not spring back onto the package contents.

4) Envelopes containing sterile instrumentation or other items should be opened by carefully opening the top, folding down the sides halfway, and presenting the contents aseptically.

5) Rigid sterilization container systems should be opened by disengaging the tamper-evident device in accordance with the manufacturer's instructions. The external lid latches should be positioned as far away from the container system rim (seal) as possible. The manufacturer's recommendations for lid removal should be followed, and care should be taken to ensure that there is no contact between the lid and the inner rim, the sterile contents, or any part of the inside of the container system. The lid should be inspected for the integrity of the filter or valve and the gasket.

6) For all packaging, the internal CI should be checked to confirm the appropriate endpoint response.

Rationale: Opening packaging as recommended above facilitates aseptic removal of sterile items. External CIs are used to demonstrate that items have been exposed to a sterilization process (10.5.2). Internal CIs demonstrate that some or all of the conditions necessary for sterilization have been reached within the package (10.5.2). Sterility assurance is event-related and depends on maintenance of package integrity up to the time the package is opened intentionally. The exterior of the lid of a container system is not sterile; if it comes into contact with the interior of the container system or its sterile contents, the contents could be contaminated.

8.12.2 Removing items from sterile packaging and transferring them to the sterile field

The following guidelines should be observed when removing the contents from a sterile package and transferring the contents to the sterile field:

1) Before removing the sterile contents, the surgically attired scrub person should check the internal CI for the appropriate endpoint response.

2) Avoiding all contact with the table or external surfaces of the packaging, the scrub person should remove the contents of the package. If the packaging is a rigid sterilization container system, the scrub person should grasp the inner basket handles with both hands and lift the basket well above the container bottom, avoiding all contact with the upper rim of the container. For wrapped items and items in envelopes, the scrub person should avoid all contact with the packaging.

   NOTE—If multiple instrument baskets are stacked inside a container system, they should be removed individually to the sterile field.

3) Before the package contents are placed on the sterile field, the bottom of the wrapper or container system should be inspected visually for integrity and moisture.

4) The contents of the sterile packaging should be aseptically transported to the sterile field.

5) For container systems, the circulator should inspect the integrity and proper alignment of the plate and filter or valve in accordance with the manufacturer's instructions.

Rationale: Basic aseptic techniques and principles of sterilization are the same for all sterile packaging systems. See also AORN (2008c).

10 Quality control

10.1 General rationale

This section reviews monitoring of mechanical cleaning equipment; product identification and traceability; physical, chemical, and biological monitoring of steam sterilization cycles; residual air (Bowie-Dick type) testing of dynamic-air-removal sterilizers; periodic product quality assurance; product recalls; and related quality control measures. Sterility assurance requires continuous attention to sterilizer performance and to all aspects of the steam sterilization process. Abuse or misuse of sterile packaging or lack of a standardized inspection and monitoring program can lead to problems that can compromise the quality of the sterilization program.

NOTE—Quality control is usually thought of only as product and process monitoring, and Section 10 is primarily concerned with those applications. In its broadest sense, however, quality control involves continuous supervision of personnel performance and work practices and ongoing verification of adherence to established policies and procedures.

10.2 Monitoring of mechanical cleaning equipment

The first step in processing a medical device is decontamination (see Section 7). To ensure that mechanical cleaning equipment is working properly, and according to the manufacturer's specifications, health care personnel may perform verification tests as part of the overall quality assurance program. This verification may include the use of test devices that monitor the functionality of the cleaning equipment in cleaning surfaces and that ensure adequate fluid flow in equipment that has adaptors for lumened devices. In another method, brightly colored soil is applied to devices, which are then visually inspected after cleaning to determine if it has been well removed. However, this method has not been validated to determine the acceptable and unacceptable benchmarks. See Annex D.

Monitoring and verifying cleaning processes should be documented. Some mechanical washers have digital readouts and cycle printouts that should be reviewed for each cycle and initialed. Ideally, cleaned medical devices should be traceable to the patients on whom they are used.

Rationale: Monitoring and verifying the cleaning process are important elements of quality assurance. Reviewing and initialing the readouts and cycle printouts of mechanical washers confirms that the washer completed all the required phases of the cycle.

10.3 Product identification and traceability

10.3.1 Lot control numbers

Each item or package intended for use as a sterile product should be labeled with a lot control identifier. The lot control identifier should designate the sterilizer identification number or code, the date of sterilization, and the cycle number (cycle run of the sterilizer). The policy of the health care facility determines when the lot control label is affixed to the package. If packages are to be labeled before sterilization, the labeling should be done immediately before the load is processed. If it is the policy to label packages after sterilization, the labeling should not be done until the packages are cool and dry. Ideally, every reprocessed medical device, especially an implant, should be fully traceable to the patient on whom it is used or in whom it is implanted; such traceability can be accomplished by recording the sterilizer load identifier on the patient chart or the patient name on the load record.

For flash sterilization, labels with lot numbers are not used; however, a lot number should be assigned to each flash sterilization load and a load record should be generated for each sterilization cycle. The load record should document

a) the assigned lot number, including sterilizer identification and cycle number;

b) the general contents of the load;

c) the duration and temperature of the exposure phase of the cycle;

d) the signature or other identification of the operator; and

e) the date and time of the cycle.

Flash sterilization of implantable devices is not recommended; however, if it is unavoidable, full traceability to the patient should be maintained.

Rationale: Lot identification enables personnel to retrieve items in the event of a recall and to trace problems (e.g., wet packs) to their source. Presterilization labeling should be done after sterilizer and cycle assignment is determined and as the cart is loaded in order to avoid mix-ups between sterilized and nonsterilized loads. For poststerilization labeling, the packages should be cool and dry to prevent contamination.

Sterilization quality control relies heavily on historical data, especially when quality assurance measures yield conflicting evidence. Record-keeping is needed for both epidemiological tracking and ongoing assessment of the reliability of the sterilization process. Accountability to the patient and surgeon for the sterility of a reprocessed device requires documentation that can be directly traced to the patient. Traceability of implants is especially important because the consequences of implant-related infections are particularly severe and result in increased morbidity and mortality.

10.3.2 Sterilizer records

For each sterilization cycle, the following information should be recorded and maintained:

a) the lot number;

b) the specific contents of the lot or load, including quantity, department, and a specific description of the items (e.g., towel packs, type/name of instrument sets);

c) the exposure time and temperature, if not provided on the sterilizer recording chart;

d) the name or initials of the operator;

e) the results of biological testing, if applicable;

f) the results of Bowie-Dick testing, if applicable;

g) the response of the CI placed in the PCD (BI challenge test pack, BI challenge test tray, or CI challenge test pack), if applicable; and

h) any reports of inconclusive or nonresponsive CIs found later in the load (see also 10.5.2.2).

The time and temperature recording chart, printer, or tape should also be dated and maintained, and each cycle on the chart should be reviewed and signed by the operator. A record of repairs and preventive maintenance should be kept for each sterilizer (see 9.7). Information may be recorded in a paper or electronic log or filed as individual documentation records. Electronic records of sterilization process monitoring results, including specific load item identification, are recommended. The length of time that records must be retained varies throughout the country. Each health care facility is responsible for determining its record-retention policy based on state and local regulations, legal considerations (e.g., statutes of limitation for lawsuits), and its individual situation. Sterilization records should be retained according to the policy and procedure established by the individual health care facility.

Rationale: Documentation ensures that the sterilization process is monitored as it is occurring, ensures that cycle parameters have been met, and establishes accountability. In addition, documentation helps personnel determine whether a recall is necessary, should evidence subsequent to lot release, such as a positive BI or nonresponsive CI, suggest sterility problems. Knowing the contents of the lot or load enables personnel to identify the medical devices to be recalled. Digitization of this process will allow quick access to load information, facilitating a quick response. In addition, this documentation provides evidence of the department's quality control program. How long to retain sterilization records depends on many factors.

10.3.3 Expiration dating

Each item in a load should be labeled with a control date for stock rotation and the following statement (or its equivalent): "Contents sterile unless package is opened or damaged. Please check before using." This information can be incorporated into the lot identification on the label or imprinted or affixed separately on the outside of the package. If the product contains material that degrades over time (e.g., latex), the product package should be labeled with a clearly identifiable expiration date that takes this degradation into account or is based on the device manufacturer's instructions. If a time-related shelf-life system is used, the product package should be labeled with an expiration date.

Rationale: Labeling items with a lot control number and an expiration statement or (when applicable) expiration date is necessary for proper stock rotation. See also 8.9.3.

10.4 Overview of sterilization process monitoring

An essential element of sterility assurance is sterilization process monitoring, which consists of

- monitoring of every package and sterilization load (see Table 7 and 10.6);
- routine monitoring of sterilizer efficacy (see Table 7 and 10.7);
- qualification testing of the sterilizer after installation, relocation, sterilizer malfunction, major repairs, and sterilization process failures (see Table 7 and 10.8); and

- periodic product quality assurance testing (see Table 7 and 10.9).

Sterilization process monitoring devices include physical monitors, CIs, and BIs. Each of these devices plays a distinct and specific role in sterilization process monitoring, and each is indispensable to sterility assurance. Physical monitors verify that the parameters of the sterilization cycle have been met. Chemical indicators verify that one or more conditions necessary for sterilization have been achieved within the package and/or at a specific location within the load. Biological indicators verify that the conditions at a location within the load were adequate to kill a population of microorganisms resistant to the sterilization process and demonstrate the lethality of the sterilization process. Biological indicators and, in some cases, CIs are used within a PCD, an item that is designed to simulate the products to be sterilized and that constitutes a defined challenge to the sterilization process. Process challenge devices are described in 10.5.4.

As technology progresses, new sterilization process monitoring devices may be cleared by FDA and become available for use in health care facilities. Health care facilities should rely on the knowledge and expertise of their infection prevention and control, central service, and surgical services professionals in the selection and use of process monitoring devices. The choices made in the selection and use of sterilization process monitoring devices play a large role in determining the level of quality of the sterile processing function and thus should be made based on product performance characteristics and scientific data reviewed by those with technical knowledge and expertise, not merely economics.

Tables 7 and 8 summarize, respectively, the sterilization process monitoring recommendations of this recommended practice and the types and applications for use of sterilization process monitoring devices. See 10.5 through 10.10 for the detailed recommendations.

Table 7—Sterilization process monitoring recommendations

Routine load release (see 10.6)		**Routine sterilizer efficacy monitoring (see 10.7)**	**Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, steriliza-tion process failures) (see 10.8)**	**Periodic product quality assurance testing (see 10.9)**
Nonimplants	**Implants**			
Physical monitoring of cycle External and internal chemical indicator monitoring of packages Optional monitoring of the load with a PCD containing one of the following: • a BI • a BI and a Class 5 integrating indicator • a BI and an enzyme-only indicator • a Class 5 integrating indicator • an enzyme-only indicator	Physical monitoring of cycle External and internal chemical indicator monitoring of packages Monitoring of every load with a PCD containing a BI and a Class 5 integrating indicator or a PCD containing a BI and an enzyme-only indicator	Physical monitoring of cycle External and internal chemical indicator monitoring of packages Weekly, preferably daily (each day the sterilizer is used), monitoring of a full load with a PCD containing a BI. (The PCD may also contain a CI.) In flash sterilization cycles~~ors~~, monitoring is done in an empty chamber. For dynamic-air-removal sterilizers, daily Bowie-Dick testing in an empty chamber	Physical monitoring of cycle External and internal chemical indicator monitoring of packages For sterilizers larger than 2 cubic feet and for flash sterilization cycles, monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.) For table-top sterilizers, monitoring of three consecutive cycles in a fully loaded chamber with a PCD containing a BI. (The PCD may also contain a CI.) For dynamic-air-removal sterilizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack	Physical monitoring of cycle Placement of BIs and, CIs within product test samples

Table 8—Types and applications for use of sterilization monitoring devices

Monitor	Frequency of use	Application (release of sterilizer, package, load)
Physical monitors		
Time, temperature, and pressure recorders, displays, digital printouts, and gauges	Should be used for every load of every sterilizer.	Part of load release criteria.
Chemical indicators (CIs)		
External CIs Class I (process indicators)	Should be used on outside of every package.	Part of load and package release criteria.
Bowie-Dick-type indicators Class 2 (Bowie-Dick)	For routine sterilizer testing (dynamic-air-removal sterilizers only), should be run, within a test pack, each day in an empty sterilizer before the first processed load. For sterilizer qualification testing (dynamic-air-removal sterilizers only), should be run, within a test pack, after sterilizer installation, relocation, malfunction, and major repairs and after sterilization process failures; test should be run three times consecutively in an empty chamber after BI tests.	Test of sterilizer for efficacy of air removal and steam penetration; part of release criteria for using sterilizer for the day. Part of release criteria for placing sterilizer into service after qualification testing.
Internal CIs	Should be used inside each package. Should be used in periodic product quality assurance testing.	Part of package release criteria at use site. Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging. Release criteria should include BI results.
Class 3 (single-parameter indicator) Class 4 (multi-parameter indicator)	May be used to meet internal CI recommendation.	Part of package release criteria at use site; NOT to be used for release of loads.
Class 5 (integrating indicator) Enzyme-only indicator	May be used to meet internal CI recommendation. Within a PCD, may be used to monitor nonimplant sterilizer loads. Within a PCD, should be used to monitor each sterilizer load containing implants. The PCD should also contain a BI.	Part of package release criteria at use site. Part of load release criteria for nonimplant loads. Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known.
Biological indicators (BIs)	Within a PCD, may be used to monitor nonimplant loads. Within a PCD, should be used in every load containing implants. The PCD should also contain a Class 5 integrating indicator or an enzyme-only indicator. Within a PCD, should be used for weekly, preferably daily (each day the sterilizer is used), routine sterilizer efficacy testing. (The PCD may also contain a CI.) Should be run in a full load for wrapped items; for table-top sterilization, should be run in a fully loaded chamber; for flash sterilization, should be run in an empty chamber. Within a PCD, should be used for sterilizer qualification testing (after sterilizer installation, relocation, malfunction, major repairs, sterilization process failures). (The PCD may also contain a CI.) Test should be run three times consecutively in an empty chamber, except for table-top sterilizers, where the test should be run three times consecutively in a full load. Should be used for periodic product quality assurance testing.	Part of load release criteria. Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known. Part of sterilizer/load release and recall criteria. Part of release criteria for placing sterilizer into service after qualification testing. Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging.

10.5 Sterilization process monitoring devices

10.5.1 Physical monitors

Physical monitors include time, temperature, and pressure recorders; displays; digital printouts; and gauges. For sterilizers with recording charts, the operator should ensure that at the beginning of the cycle the chart is marked with the correct date and sterilizer number. For sterilizers with printouts, the printout should be checked to verify that the cycle identification number has been recorded and that the pen or printer is functioning properly. At the end of the cycle and before items are removed from the sterilizer, the operator should examine and interpret the chart or printout to verify that all cycle parameters were met and initial it to permit later identification of the operator (see 10.3.1 and 10.3.2). Sterilizers that do not have recording devices should not be used.

NOTE 1—It is important that the chart or printout is readable.

NOTE 2—Most temperature sensors indicate temperature at the drain or exhaust line of the sterilizer, not at the center of packs. Improper load configuration or package composition can interfere with air evacuation and steam penetration, conditions that will not be revealed in the temperature recording. Therefore, physical monitoring and other indicators of sterilizer performance should never be considered a substitute for careful adherence to prescribed packaging and loading procedures.

Rationale: Physical monitoring provides real-time assessment of the sterilization cycle conditions and provides permanent records by means of chart recordings or digital printouts. Physical monitoring is needed to detect malfunctions as soon as possible, so that appropriate corrective actions can be taken.

10.5.2 Chemical indicators (CIs)

10.5.2.1 General considerations

Chemical indicators are designed to respond with a chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile. The use of CIs is part of an effective quality assurance program; they should be used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process. All CIs should be used in accordance with the CI manufacturer's instructions.

ANSI/AAMI ST60:1996, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, defines five classes of CIs and specifies performance requirements for them:

Process indicators (Class 1) are intended for use with individual units (e.g., packs, containers) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units. These indicators are also referred to as external CIs.

Indicators for use in specific tests (Class 2) include Bowie-Dick-type indicators. See 10.7.6 for recommendations concerning the use of these indicators. See also ANSI/AAMI ST66:1999, *Sterilization of health care products—Chemical indicators—Part 2: Class 2 indicators for air removal test.*

Single-parameter indicators (Class 3) are designed to react to one of the critical parameters of sterilization and to indicate exposure to a sterilization cycle at a stated value of the chosen parameter.

Multi-parameter indicators (Class 4) are designed to react to two or more of the critical parameters of sterilization and to indicate exposure to a sterilization cycle at stated values of the chosen parameters.

Integrating indicators (Class 5) are designed to react to all critical parameters over a specified range of sterilization cycles, and their performance has been correlated to the performance of a BI under the labeled conditions of use.

Another type of CI, the enzyme-only indicator, is not covered by ANSI/AAMI ST60, but can be used to monitor the steam sterilization process. This indicator is comprised of multiple, interactive enzymes of bacterial origin; it does not contain spores, but its performance has been correlated to the performance of a BI.

Some CIs, such as Class 1 and Class 3 indicators, are sensitive only to certain parameters (e.g., temperature); others, such as Class 5 integrating indicators and enzyme-only indicators, integrate all critical process parameters. Health care personnel should obtain data from manufacturers on the reliability, safety, and performance characteristics of their products (e.g., how to interpret indicator results, the reliability of the indicator in maintaining endpoint response during storage of sterilized items, the sterilization conditions that the indicator will detect, the shelf life of the indicator, and the storage requirements for the indicator itself before and after sterilization). See also ANSI/AAMI ST60:1996.

Class 4 multi-parameter CIs, Class 5 integrating CIs, and enzyme-only indicators provide more information about the process than Class 3 single-parameter CIs and can provide additional quality assurance for the individual monitoring of such items as complex devices, surgical trays, and rigid sterilization container systems. When used within a PCD (see 10.5.4), Class 5 integrating indicators or enzyme-only indicators may be used for release of non-implant loads (see 10.6). In this application, they provide additional information about the critical parameters of the sterilization process to supplement the results of physical monitors and Class 1 process indicators. A Class 5 integrating CI or an enzyme-only indicator within a PCD (that also contains a BI) should be used to monitor each load containing implants and may be used as a basis for early load release in documented emergency situations only; however, loads containing implants should always be biologically monitored and, whenever possible, implants should be quarantined until the BI results (early readout or spore growth) are available (see 10.6.3).

Rationale: Various types of CIs are available, each with different response characteristics (i.e., they differ in the sterilizing conditions that they will detect and verify) and with different applications in sterilization process monitoring.

10.5.2.2 Using chemical indicators

10.5.2.2.1 External chemical indicators

To distinguish between processed and unprocessed items, a process indicator (Class 1 CI), in the form of sterilizer indicator tape, an indicating label, or an indicating printed legend, should be affixed to or printed on each hospital-assembled package or rigid sterilization container system intended for sterilization. Except for packages that allow visual inspection of an internal indicator, such as those with paper–plastic packaging, an external indicator should be used on all packages. The external CI should visually denote that the package has been exposed to physical conditions present in the steam sterilizer. The indicator should be examined after sterilization and also before use of the item to verify that the item has been exposed to the sterilization process.

Rationale: The purpose of an external CI is to differentiate between processed and unprocessed items, not to establish whether the parameters for adequate sterilization were met.

10.5.2.2.2 Internal chemical indicators

An internal CI should be used within each package, tray, or rigid sterilization container system to be sterilized. This internal CI may be a single-parameter indicator (Class 3 CI), multi-parameter indicator (Class 4 CI), integrating indicator (Class 5 CI), or enzyme-only indicator. The class of CI chosen will depend upon how many critical process variables~~parameters~~ are to be monitored and how much information is desired about the sterilization process. The CI should be placed in that area of the package, tray, or containment device (rigid sterilization container system, instrument case, cassette, or organizing tray)~~container system~~ considered to be least accessible to steam penetration; for a containment device, the manufacturer's instructions for placement of the CI should be consulted. This location might or might not be the center of the package, tray, or containment device ~~container system~~. Internal CIs should be used in the routine monitoring of items sterilized. See also 10.5.4 and 10.6.

The CI is retrieved at the time of use and is interpreted by the user. The user should be trained and knowledgeable about the performance characteristics of the monitoring system and should demonstrate competency.

If the interpretation of the CI suggests inadequate steam processing, the contents of the package should *not* be used. The interpreter should inform the appropriate supervisor, who should return the complete unused package, including load identification and the CI, for appropriate follow-up. The department head or designee in the sterilizing department should then decide whether to recall that sterilized load. This decision should be based on the results of physical monitoring (time and temperature recordings), the results of internal CIs elsewhere in the load, and, if applicable, the results of ~~biological monitoring~~ any PCDs in the load (a PCD containing a BI, a PCD containing a BI and either a Class 5 integrating indicator or an enzyme-only indicator, or a PCD containing either a Class 5 integrating indicator or an enzyme-only indicator). If the biological monitoring results of a PCD containing a BI are not yet available ~~was performed but the results are not yet available~~, the remaining packages from the same load should be quarantined and not used until the BI results are obtained.

Rationale: There are no practical means of verifying the sterility of individual items. Chemical indicators do not verify sterility, but some types may allow detection of equipment malfunctions (e.g., air leaks, wet steam, inadequate temperature or time), and they may assist in the identification of certain procedural errors. Internal CIs cannot be retrieved without compromising the sterile integrity of the packaging and thus must be retrieved and interpreted at the time of use.

If a CI is nonresponsive or inconclusive, it is possible that the entire load is not sterile (i.e., the sterilization process failed). It is also possible that errors in loading or packaging have resulted in sterilization failures in some, but not all, packages in the load. Therefore, a single nonresponsive or inconclusive CI should not be considered definitive evidence that the entire load is nonsterile. The supervisor should exercise professional judgment in determining whether to recall the entire load, taking into account all factors having a bearing on the efficacy of the cycle and all performance indicators (physical monitors, CIs, and BIs).

10.5.3 Biological indicators

10.5.3.1 General considerations

Biological indicators consist of spores in or on a carrier, sometimes (as in the case of self-contained BIs) accompanied by incubation media. Biological indicators provide the only direct measure of the lethality of the sterilization process. Biological indicators must be incubated for various periods of time (depending on the specific product) until it is determined whether the microorganisms grow (i.e., they survived the sterilization process) or fail to grow (i.e., they were killed by the sterilization process).

Some types of BIs contain spores with an enzyme-based early-readout capability. Periodic verification of the early readout with spore growth should be performed in accordance with the manufacturer's instructions and facility policy and procedures. For this verification, the BI with enzyme-based early-readout capability can be further incubated to demonstrate spore growth by a visible color change. In the event of a sterilization process failure, the sterilizer manufacturer may recommend additional ~~and/or alternative~~ biological testing to verify results.

Health care personnel should select BIs that consist of spores of *Geobacillus stearothermophilus* (formerly named *Bacillus stearothermophilus)* that comply with ANSI/AAMI/ISO 11138-3:2006 ~~ANSI/AAMI ST19:1999~~ and that are suitable for use in the specific sterilization cycle (see the written instructions of the BI manufacturer and the sterilizer manufacturer).

Data should be obtained from manufacturers on the reliability, safety, and performance characteristics of their products. Manufacturers of BIs are required to provide written instructions on the storage, handling, use, and microbiological testing of their products.

Biological indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization. A negative BI does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions. All BIs should be used in accordance with the BI manufacturer's instructions.

Rationale: Biological indicators are the only sterilization process monitoring device that provides a direct measure of the lethality of the process. Various types of BIs are available, each with different response characteristics and incubation requirements. To provide useful information about the lethality of the sterilization process, the appropriate BI must be chosen for the steam sterilization cycle being run and the BI must be used correctly (in accordance with the manufacturer's instructions).

10.5.3.2 Using biological indicators

Biological indicators should be used within PCDs (see 10.5.4, 10.7.2.1, 10.7.3.1, 10.7.4.1) for routine sterilizer efficacy monitoring at least weekly, but preferably every day that the sterilizer is in use (see 10.7). Additionally, BIs within PCDs should be used to monitor every load containing implants (see 10.6.1). Biological indicators within PCDs should also be used for sterilizer qualification testing (see 10.8) after sterilizer installation, relocation, malfunctions, and major repairs and after sterilization process failures. If a sterilizer is designed to be used for multiple types of cycles (gravity-displacement at 132 °C to 135 °C [270 °F to 275 °F], gravity-displacement at 121 °C [250 °F], dynamic-air-removal at 132 °C to 135 °C [270 °F to 275 °F], "flash" at 132 °C to 135 °C [270 °F to 275 °F], "flash" with single wrapper or other packaging), then each sterilization cycle type used ~~mode~~ should be tested.

NOTE 1—The methods of biologically monitoring cycles for wrapped items and cycles for unwrapped items (flash sterilization) differ.

NOTE 2—If a sterilizer will run the same type of cycle (e.g., dynamic-air-removal at 132 ºC to 135 ºC [270 ºF to 275 ºF] for different exposure times (e.g., 4 minutes and 10 minutes), then only the shortest cycle time needs to be tested.

NOTE 3—Refer to 10.7.4.1 for additional information on the use of BIs in flash sterilization cycles.

Biological indicators also should be used for periodic quality assurance testing of representative samples of actual products being sterilized (see 10.9 and 10.10). ~~Additionally, BIs within PCDs should be used to monitor every load containing implants (see 10.6.1).~~ Biological indicators within a PCD may be used as part of the criteria for release of nonimplant loads.

Rationale: The use of BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Biological monitoring provides the only direct measure of the lethality of a sterilization cycle. Sterilizer manufacturers validate their sterilization cycles using BIs; therefore, routine sterilizer efficacy monitoring in health care facilities should also be conducted using BIs. In addition, Garner and Favero (1985) and CDC (2003a) recommend routine biological monitoring of sterilizer efficacy. While the performance of Class 5 integrating CIs and enzyme-only indicators has been correlated to the performance of BIs, these sterilization monitoring devices do not contain spores and thus do not directly measure the lethality of a sterilization cycle; however, they provide additional information about the attainment of the critical parameters of the sterilization process.

10.5.4 Process challenge devices (PCDs)

A PCD is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed. Depending on the application in sterilization process monitoring, the PCD may contain

a) a BI,

b) a BI and a Class 5 integrating CI,

c) a BI and an enzyme-only indicator,

d) a Class 5 integrating CI, or

e) an enzyme-only indicator.

For routine release of loads containing nonimplantable items, the following PCDs may be used to provide additional assurance of the adequacy of the sterilization cycle:

a) a PCD containing a BI (BI challenge test pack),

b) a PCD containing a BI and either a Class 5 integrating CI or an enzyme-only indicator (BI challenge test pack), or

c) a PCD containing either a Class 5 integrating CI or an enzyme-only indicator (a CI challenge test pack).

For routine release of loads containing implantable devices, a PCD containing a BI and either a Class 5 integrating CI or an enzyme-only indicator (a BI challenge test pack) should be used to monitor the load (see 10.6.1). For routine sterilizer efficacy monitoring (see 10.7) and sterilizer qualification testing (see 10.8), the PCD should contain a BI and may contain one or more CIs as well.

A PCD may be a user-assembled challenge test pack or test tray or a commercially available, disposable, pre-assembled challenge test pack. For a commercial PCD intended for use in health care facilities, the manufacturer is required by FDA to submit a premarket [510(k)] notification and obtain FDA clearance. The premarket notification should include scientific evidence demonstrating that the commercial PCD is comparable in performance to the user-assembled challenge test pack defined in 10.7.2.1. Health care personnel should use commercially available PCDs only if they have been cleared by FDA for their intended use. Any manufacturer-supplied scientific data on equivalence should be reviewed. Manufacturers of PCDs should provide written instructions for the use, storage, handling, and testing of their products.

When selecting a commercial PCD, health care personnel should ask the manufacturer the following questions:

a) Is the PCD appropriate for the specific steam sterilization cycle being used?

b) Has the performance of the PCD been demonstrated to be equivalent to the performance of the user-assembled challenge test pack of 10.7.2.1?

c) What types of BIs and/or CIs are used in the PCD?

d) Can this PCD be used for routine sterilizer efficacy monitoring and sterilizer qualification testing, or is it only suitable for use in routine load release?

e) If the monitor in the PCD indicates a questionable sterilization cycle, what procedure should be followed to investigate the potential sterilization process failure?

f) Does the PCD have a specific shelf life? What are the specific storage requirements for the PCD?

Rationale: The condition of the sterilizer equipment, the expertise of the sterilizer operator, and other factors that determine the success or failure of a steam sterilization cycle could vary from one cycle to another. The less frequently the sterilizer is used, the greater the chance that an unnoticed event could affect sterilization. Therefore, it is necessary to regularly challenge the sterilizer and the sterilization process with a PCD. For commercial PCDs, it is important for health care personnel to obtain adequate information on their performance and intended use to ensure that they are suitable for the intended application and that they are used correctly.

10.6 Routine load release

10.6.1 Process monitoring devices

Every sterilization load should be physically monitored. Every packaged item should be labeled externally with a process indicator (Class 1 CI) and should contain an internal CI (Class 3 CI, Class 4 CI, Class 5 CI, or enzyme-only indicator). If desired, a PCD containing a BI (a BI challenge test pack) or a PCD containing either a Class 5 integrating CI or an enzyme-only indicator (a CI challenge test pack) may be placed in the area of the chamber and load considered least favorable to sterilization. The PCD should be equivalent to the BI challenge test pack described in 10.7.2.1.

Every sterilization load containing implants should be monitored with a PCD containing a BI (a BI challenge test pack). A Class 5 integrating CI or an enzyme-only indicator should be included in this PCD.

Rationale: The rationale for physical, chemical, and biological monitoring of sterilization processes generally is given in 10.5. With respect to implantable devices, biological monitoring is necessary to provide optimal sterility assurance (see also 10.6.3). A Class 5 CI or an enzyme-only indicator should be included with the BI in the PCD so that if an implant must be released on an emergency basis, additional information about the critical parameters of the sterilization process will be available and documented.

10.6.2 Release criteria for nonimplants

Load release should be an active decision based upon evaluation of all available data from the sterilization process for the particular load. The decision to release a load should be made by an experienced, knowledgeable person at the conclusion of the sterilization cycle. Loads that do not meet the criteria for release should be clearly identified so that they are not mistakenly distributed.

Rationale: Releasing sterilized devices based on all quality control measures is critical in providing safe and effective products for patient care.

10.6.3 Release criteria for implants

As with all cycles, the sterilizer operator should review the sterilizer chart or printout and the results of other indicators that have been used to monitor the sterilization process. The load should be quarantined until the results of the BI testing are available (CDC, 2003a).

When documented medical exceptions dictate (e.g., the need for trauma-related orthopedic screw-plate sets), it could be necessary to release an implantable device before the BI results are known. In this case, the release of the device before the BI results are known should be documented; the BI result obtained later should also be documented. (See Annex L for examples of an implant log and an exception form.) It is critical that this documentation be fully traceable to the patient. Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule. Emergency situations should be defined in written guidance developed in consultation with infection prevention and control, the surgeon, and risk management. Steps should be taken to reduce the frequency of emergency release of implantable items. For example, ongoing periodic reviews of the exception forms and implant logs could reveal consistent patterns of events that are causing emergency release and that could be corrected.

Rationale: Patient safety could be adversely affected by the implantation of a nonsterile device. The sterilization of implantables should be closely monitored and each load containing implants should be quarantined until it is verified that BI testing has yielded negative results. In defined emergency situations in which the quarantine of implants cannot be maintained, breaking of the quarantine is allowed for documented medical exceptions in accordance with facility policies and procedures. See also the rationale for 10.6.1.

10.6.4 Sterilization process failures

If physical monitoring during the cycle indicates any malfunction or suspicious operation, the department head or designee should be notified. After examination, if the malfunction cannot be corrected immediately, the cycle should be terminated in accordance with the sterilizer manufacturer's instructions. The load should be considered nonsterile, and the sterilizer should be removed from service. The hospital engineer or maintenance contract service should then be notified, the root cause should be identified, and the sterilization process failure should be corrected. Sterilization process failures can occur in a normally functioning sterilizer as a result of poor steam quality, operator error, or other factors. The same investigative procedure should be followed at the completion of the cycle if external CIs or the monitor in a PCD (BI challenge test pack or CI challenge test pack) indicates a questionable cycle. See also 10.7.5.

A faulty sterilizer cannot be made operational without identifying and correcting the underlying problem; merely extending the cycle time or increasing the cycle temperature, for example, is not appropriate. After a major repair of any type of steam sterilizer, three consecutive test cycles with a PCD containing a BI should be run, one right after the other, in an otherwise empty chamber for sterilizers larger than 2 cubic feet and for flash sterilization cycles and in a fully loaded chamber for table-top sterilizers (see 10.8). After a major repair to a dynamic-air-removal sterilizer, three consecutive Bowie-Dick test cycles should then be run in an empty chamber, one right after the other, and the test sheets examined (see 10.7.6). The test results should be obtained (i.e., the BI should be incubated according to the BI manufacturer's instructions) and be determined to be satisfactory before the sterilizer is returned to service.

A major repair is a repair outside the scope of normal maintenance, such as weld repairs of the pressure vessel; replacement of the chamber door, vacuum pump, or a major piping assembly; or rebuilds or upgrades of controls. Normal preventive maintenance, such as the rebuilding of solenoid valves or the replacement of gaskets, is not considered a major repair. When repairs involve parts normally replaced under preventive maintenance procedures, three Bowie-Dick tests and three BI tests are not required before the sterilizer is returned to service. Verification of the sterilizer's operation according to the sterilizer manufacturer's specifications is sufficient.

Rationale: Simply altering the cycle parameters of a malfunctioning sterilizer will not correct a problem; the sterility of future loads will be jeopardized if the sterilizer continues to be used without repair. To restore a sterilizer to proper performance, it is necessary to identify the exact cause of the malfunction. Common problems detected by physical and chemical monitoring include inadequate temperature, air removal, exposure time, and drying time.

10.7 Routine sterilizer efficacy monitoring

NOTE 1—See Section 10.4 for an overview of sterilization process monitoring as it applies to large sterilizers, table-top sterilizers, and flash sterilization cycles.

NOTE 2—All PCDs referred to in this section are BI challenge test packs or BI challenge test trays.

10.7.1 General considerations

All steam sterilizers should be routinely tested using appropriate PCDs (BI challenge test packs or BI challenge test trays) to ensure their effectiveness in sterilizing medical devices. If a sterilizer is designed to be used for multiple types of cycles (gravity-displacement at 132 °C to 135 °C [270 °F to 275 °F], gravity-displacement at 121 °C [250 °F], dynamic-air-removal at 132 °C to 135 °C [270 °F to 275 °F], "flash" at 132 °C to 135 °C [270 °F to 275 °F], "flash" with single wrapper or other packaging), then each sterilization cycle type used~~mode~~ should be tested.

NOTE—If a sterilizer will run the same type of cycle (e.g., dynamic-air-removal at 132 ºC to 135 ºC [270 ºF to 275 ºF]) for different exposure times (e.g., 4 minutes and 10 minutes), then only the shortest cycle time needs to be tested.

This section covers the use of PCDs (BI challenge test packs or BI challenge test trays) in routine sterilizer efficacy monitoring. While the focus here is on biological monitoring, the results of physical monitors and any CIs contained within the PCD should also be taken into account. When any variable of a sterilization process is outside its specified limits, a sterilization cycle should always be regarded as unsatisfactory, irrespective of the results obtained from BIs. This section also covers the routine monitoring of dynamic-air-removal sterilizers with Bowie-Dick test packs.

Rationale: The use of BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Biological monitoring provides the only direct measure of the lethality of a sterilization cycle. Sterilizer manufacturers validate their sterilization cycles using BIs; therefore, routine sterilizer efficacy monitoring in health care facilities also should be conducted using BIs. In addition, Garner and Favero (1985) and CDC (2003a) recommend routine biological monitoring of sterilizer efficacy. Although~~While~~ the performance of Class 5 integrating CIs and enzyme-only indicators has been correlated to the performance of BIs, these sterilization monitoring devices do not contain spores and thus do not directly measure the lethality of a sterilization cycle; however, they provide additional information about the attainment of the critical parameters of the sterilization process. The Bowie-Dick test is used to evaluate the efficacy of air removal and steam penetration in dynamic-air-removal steam sterilizers. It is *not* a sterility assurance test.

10.7.2 Routine biological monitoring of sterilizers larger than 2 cubic feet

10.7.2.1 Composition of the PCD (BI challenge test pack)

The PCD (BI challenge test pack) should consist of 16 clean, preconditioned, reusable huck or absorbent surgical towels, in good condition, each of which is approximately 16 inches by 26 inches (41 centimeters by 66 centimeters). Each towel is folded lengthwise into thirds and then folded widthwise in the middle (Figure 10). After they are folded, the towels are placed one on top of another, with folds opposite each other, to form a stack that is approximately 9 inches wide, 9 inches long, and 6 inches high (23 centimeters by 23 centimeters by 15 centimeters). One or more BIs are placed between the eighth and ninth towels in the approximate geometric center of the pack. If CIs are used, they should be placed adjacent to the BI(s). The pack is then taped in a manner that will yield the approximately 6 inch (15 centimeter) height. The pack should weigh approximately 3 pounds and should have a density of approximately 11.3 pounds per cubic foot. A wrapper should not be used for this PCD. (See Figure 10 and Annex K.)

NOTE—Fabric conditioners should not be used. They could affect the characteristics of the fabric and contain volatiles that will contribute noncondensable gases to the chamber.

Commercially available disposable PCDs (BI challenge test packs) may be used only if they are cleared by FDA for their intended use (see 10.5.4). Any manufacturer-supplied scientific data on equivalence should be reviewed. Manufacturers of disposable PCDs should provide written instructions for the use, storage, handling, and testing of their products.

Rationale: The 16 towel PCD (BI challenge test pack) provides a sterilization challenge for air removal and for steam penetration to the BI(s) and CI(s) within the PCD. Use of the PCD provides evidence of the microbial lethality of the process (see also 10.7.1). The 16 towel PCD is not wrapped, since the PCD is intended to provide a reproducible, well defined, easily constructed, standardized challenge to test sterilizer performance. Also, experience with the wrapped test pack specified in the first edition of this recommended practice (AAMI ST1:1980) showed that the wrapper adds another difficult-to-control variable. Only one BI needs to be used for the test in order to achieve a

Rationale: Since this is a challenge test, the operating conditions should be the same as those for normal use of the sterilizer.

10.7.4.4 Acceptance criteria

An acceptable process is evidenced by negative results from all BIs in the PCD and appropriate readings from physical monitors and CIs, showing that the sterilization cycle was correct and complete. All monitoring results, including results from BI controls, should be interpreted by a qualified individual and should be included in the sterilizer records.

10.7.5 Positive BI results

10.7.5.1 General procedure

The following actions should be taken if a BI tests positive:

a) Positive BI results (other than those from viability controls) should be immediately reported by phone or messenger to the appropriate supervisor and to the infection prevention and control department. This notification should be followed by a written report. The report and notification should include the following information:

   1) the time and date of the questionable sterilizer cycle;

   2) a description of the sterilizer and load, with reference to the appropriate lot control number;

   3) the results of physical and mechanical monitoring and of internal CIs (if applicable) as obtained from the user department; and

   4) any other information that could be useful in determining whether the report is valid or is questionable due to human error.

b) If it is determined that the sterilization failure was not the result of operator error (e.g., selection of the incorrect cycle), items processed in that sterilizer since the last negative BI results should be considered unsterile. They should be retrieved, if possible, and reprocessed (see 10.11). The sterilizer in question should be taken out of service.

c) The microbiology laboratory should perform a presumptive identification of the microorganisms present in the "failed" (positive) BI, in accordance with the BI manufacturer's instructions, and, if applicable, review the BI use and transfer techniques (see 10.7.5.2). The load recall should *not* be delayed during this testing.

d) The head of the microbiology department, the head of the sterilizing department, and the head of the infection prevention and control department, or their designees, with appropriate facility maintenance and sterilizer service personnel, should attempt to determine the cause of the positive BI/sterilization failure and arrange for corrective action.

e) After the cause of the sterilization failure has been determined and corrected, the sterilizer in question should be immediately rechallenged with a PCD (see 10.7.2.1, 10.7.3.1, or 10.7.4.1, as appropriate). For sterilizers larger than 2 cubic feet and for flash sterilization cycles, three consecutive cycles should be run in an empty chamber (see 10.8.2 and 10.8.4). For table-top sterilizers, three consecutive cycles should be run in a fully loaded chamber (see 10.8.3)~~in three consecutive empty chamber cycles (see 10.8)~~. For dynamic-air-removal sterilizers, a Bowie-Dick test pack should also be run in three consecutive empty-chamber cycles (see 10.7.6). Until the results of retesting are satisfactory (three cycles with negative BIs and, if applicable, three cycles with acceptable color change in the Bowie-Dick indicator), the performance of the sterilizer should be considered in question.

NOTE—Negative BI results from a cycle run with the open-tray configuration indicate that the cycle is killing microorganisms, as designed and validated. If the other configurations produce positive results on the same day in the same sterilizer, it is likely that the containment device is not permitting proper air removal and sterilant penetration.

Rationale: To ensure that patient care products are safe and effective, it is important to have a continuous quality improvement process. Conducting the above protocol when positive BI results occur will provide valuable data in support of correcting the problem and identifying potential improvements in work practices. False positives can be caused by contamination during the transfer of the BI to the growth media, by inconsistencies in BI performance, by mishandling of the BI, and by sterilizer operator errors.

10.7.5.2 Microbiological testing

For positive BIs, the microbiology laboratory should perform a presumptive identification according to the BI manufacturer's instructions to determine whether the recovered microorganism is indeed the test microorganism that was on the BI spore strip or is a laboratory contaminant. Two subcultures are made from the recovered culture (the manufacturer should be consulted for the culturing procedure). One subculture is incubated at 35 °C to 37 °C (95 °F to 99 °F) for 24 to 48 hours, and the other at 55 °C to 60 °C (131 °F to 140 °F) for 24 to 48 hours. Smears of the

incubated subcultures are prepared, stained by Gram's method, and microscopically examined. Presumptive identification should be considered positive for *Geobacillus stearothermophilus* (formerly named *Bacillus stearothermophilus)* if microscopic examination reveals Gram-positive/gram-variable, spore-bearing rods and if the results of the incubation studies demonstrate growth at 55 °C to 60 °C (131 °F to 140 °F) but no growth at 35 °C to 37 °C (95 °F to 99 °F). Any other Gram stain result (Gram-positive cocci or Gram-negative bacilli) should be considered a contaminant.

Rationale: Presumptive identification distinguishes accidental laboratory contamination from sterilization failure. In the latter case, there would be incomplete destruction of the test microorganisms on the BI.

10.7.6 Routine Bowie-Dick testing of dynamic-air-removal sterilizers

10.7.6.1 General considerations

The Bowie-Dick test should be carried out each day the sterilizer is used, before the first processed load. A Class 2 CI is used in conducting this test (see ANSI/AAMI ST66). A shortened cycle (i.e., a cycle omitting the drying phase) should be run first to properly heat the sterilizer. If the sterilizer is used continuously, the test may be performed at any time, but should be performed at the same time every day. The Bowie-Dick test also should be carried out during sterilizer qualification (10.8); during qualification testing, the Bowie-Dick test should be run three consecutive times after three consecutive tests using a PCD containing a BI.

NOTE—Bowie-Dick testing is not applicable to gravity-displacement sterilizers. For steam-flush pressure-pulse sterilizers, the manufacturer's recommendations should be followed regarding the usefulness of routine daily Bowie-Dick testing.

Rationale: A Bowie-Dick test is conducted every day, before the first processed load, because it is a sensitive and rapid means of detecting air leaks, inadequate air removal, and inadequate steam penetration. Insufficient air removal in a dynamic-air-removal sterilizer, particularly a prevacuum cycle, can defeat sterilization and result in nonsterile supplies if undetected. The test is conducted at the same time every day because standardization of the testing procedure reduces the opportunity for error. In qualification testing, it is preferable to run the Bowie-Dick test cycles after the BI PCD test cycles because it is important to establish first that the sterilizer is capable of achieving biological kill so that the subsequent Bowie-Dick test cycles will be run under "best-case" conditions. The results of later Bowie-Dick tests run during routine monitoring can then be compared to the results of the Bowie-Dick qualification testing, enabling the routine Bowie-Dick test results to be better interpreted. If during qualification testing, the Bowie-Dick test cycles are run first and the sterilizer then fails biological testing, the Bowie-Dick test results will not necessarily reflect the air removal characteristics of a properly functioning sterilizer. Therefore, if the user chooses to run the Bowie-Dick test cycles first (rather than in the recommended test sequence) and the sterilizer then fails biological testing, the Bowie-Dick test cycles will have to be repeated after corrective action has been taken and the sterilizer is functioning properly according to the biological testing.

Dynamic-air-removal sterilizers utilize preconditioning techniques to remove air from both the sterilizer chamber and the load prior to pressurization with steam to a sterilization exposure temperature. Effective removal of air is critical to predictable steam penetration and the resultant sterilization. There are numerous preconditioning methods used to remove air, including variations of prevacuum air removal or above-atmospheric-pressure processes such as the steam-flush pressure-pulse process.

The Bowie-Dick test was originally developed to detect air leaks and to evaluate the ability of prevacuum sterilizers to reduce air residuals in the chamber space sufficiently to prevent air compaction by reentrainment into a load (the "small-load effect") as steam is introduced after evacuation. It was later found that the same test could provide evidence of air leaks, ineffective air removal with other air removal techniques that do not utilize a deep vacuum, and the presence of noncondensable gases (i.e., air or gases from boiler additives). If there is insufficient air removal, steam will subsequently drive the available air back into the load, air pockets will occur, and sterilizing conditions will not be attained. Noncondensable gases can enter the chamber with the steam and inhibit proper steam penetration (Kirk, 2001).

10.7.6.2 Composition of the Bowie-Dick test pack

The Bowie-Dick test pack consists of folded 100 % cotton surgical towels that are clean and preconditioned. The towels should be folded to a size 9 inches (250 mm ± 20 mm) in one direction and 12 inches (300 mm ± 20 mm) in the other direction and placed one above another. The height of the test pack should be between 10 and 11 inches (250 and 280 mm). The weight of the pack should be 8.8 pounds (4 kilograms ± 5 %). (See Figure 12.)

NOTE—The total number of towels may vary from test to test, depending on towel thickness and wear.

A commercially available Bowie-Dick-type test sheet, complying with ANSI/AAMI ST66, should be placed in the center of the pack. A single two-ply fabric wrap made of 100 % cotton with a thread count both warp and weft of 5.5 mm should be loosely applied to wrap the test pack. The pack should be secured with tape.

Caution should be exercised in selecting test materials that could bias the test favorably with respect to the air reentrainment principle by preventing the reaccess of air from all directions. If test sheets are used, for example, it should be determined from the manufacturer whether their porosity equals or exceeds that of the stacked towels. The sensitivity of the indicating ink should also be ascertained. Some test materials may not reveal marginally poor conditions.

Commercially available, disposable Bowie-Dick-type test packs may be used only if in scientific experiments they have been proven to be equivalent to the test pack described here and they have been cleared by FDA.

Rationale: See 10.7.6.1.

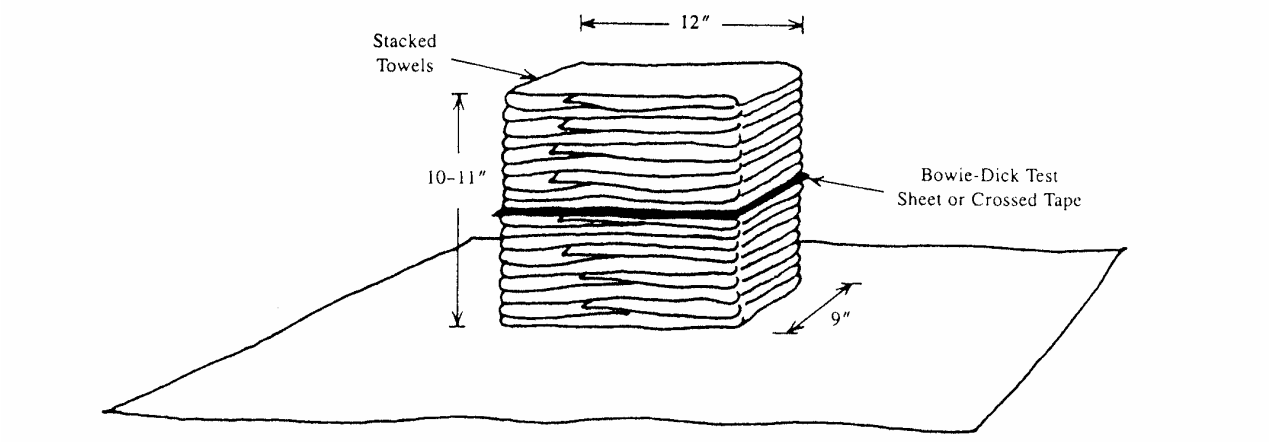

Figure 12—Composition of the Bowie-Dick test pack

10.7.6.3 Placement of the Bowie-Dick test pack

The test pack should be placed horizontally in the front, bottom section of the sterilizer rack, near the door and over the drain, in an otherwise empty chamber. (See Figure 13.)

NOTE 1—The test pack is the only item on the sterilizer cart.

NOTE 2—When sterilizers with removable loading carts are being tested, the loading cart should be removed from the chamber and allowed to cool to room temperature before the next cycle is run. Alternatively, a different loading cart that is already at room temperature can be used.

Rationale: The Bowie-Dick test is conducted in an empty chamber to maximize the potential for detecting any air that enters by means of a leak or is not removed because of malfunction of the air-removal system. Other packs in the chamber would entrain a percentage of the air and reduce the sensitivity of the test.

10.7.6.4 Test procedure

A cycle is run as specified by the sterilizer manufacturer. The recommended exposure time is 3.5 minutes, but if half-minute exposures cannot be selected on the sterilizer, a 4 minute exposure time may be used. The exposure time should never exceed 4 minutes at 134 °C (273 °F). (The specific instructions of the manufacturer should be followed.) Drying may be omitted to save time without affecting the outcome of the test. When removed from the sterilizer, the test pack might still be hot and should be opened carefully to avoid thermal injury to the hands or face. The test sheet should be removed from the pack and examined by a person trained in its interpretation.

Rationale: If longer exposure times are used, the test should be considered invalid and the results meaningless; even an extra minute could affect the results. A sterilizer tested from a “cold start” (after the sterilizer has been turned on and before a load is processed) might produce false failures unless it is preheated to operating temperature by running at least one empty-chamber cycle.

10.7.6.5 Acceptance criteria

Any unexpected color change, such as the center of the test sheet being paler or a different color than the edges (i.e., there is a nonuniform color change), indicates that there was an air pocket present during the cycle due to sterilizer

malfunction. Any test results that do not conform to the recommended color standards provided by the manufacturer of the test sheet should be reported to the supervisor on duty, who will determine the disposition of the sterilizer, i.e., whether it should be retested, serviced, or remain in use.

NOTE—For continuity of results, it may be useful to compare a particular test sheet result to the previous daily test sheet result and to all daily test sheet results back to the results of the three Bowie-Dick tests conducted during installation testing.

Rationale: If the sterilizer fails the Bowie-Dick test, it cannot be made functional merely by increasing the exposure time for sterilized items; such a sterilizer is in need of skilled attention.

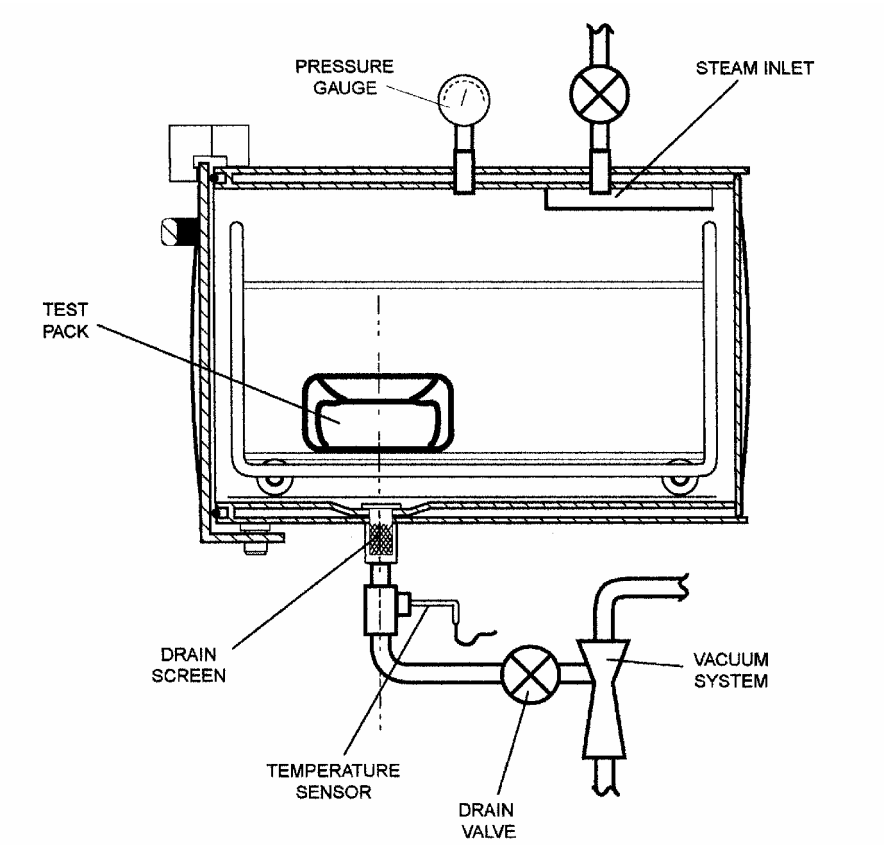

Figure 13—Placement of the Bowie-Dick test pack

10.8 Qualification testing

NOTE—All PCDs referred to in this section are BI challenge test packs or BI challenge test trays.

10.8.1 General considerations

All steam sterilizers should be tested using PCDs (BI challenge test packs or BI challenge test trays) after sterilizer installation, relocation, malfunctions, and major repairs, and after sterilization process failures. If a steam sterilizer is designed to be used for multiple types of cycles (gravity-displacement at 132 ºC to 135 ºC [270 ºF to 275 ºF], gravity-displacement at 121 ºC [250 ºF], dynamic-air-removal at 132 ºC to 135 ºC [270 ºF to 275 ºF], “flash” at 132 ºC to 135 ºC [270 ºF to 275 ºF], “flash” with single wrapper or other packaging), then each sterilization cycle type used should be tested. If a sterilizer will run the same type of cycle (e.g., dynamic-air-removal at 132 ºC to 135 ºC [270 ºF to 275 ºF] for different exposure times (e.g., 4 minutes and 10 minutes), then only the shortest cycle time needs to be tested. Dynamic-air-removal sterilizers should be tested using Bowie-Dick test packs after sterilizer installation, relocation, malfunctions, and major repairs and after sterilization process failures.

This qualification testing should be conducted in the health care facility by health care personnel in cooperation with the manufacturer. The testing should be performed between the time the steam sterilizer is installed, relocated, or repaired and the time it is released for use in the health care facility. For both gravity-displacement and dynamic-air-removal sterilizers, three consecutive cycles should be run, one right after the other, with a PCD (BI challenge test pack or BI challenge test tray) (see 10.7.2.1, 10.7.3.1, or 10.7.4.1, as appropriate), yielding negative results from all test BIs and appropriate readings from all physical monitors and CIs. For dynamic-air-removal sterilizers, three consecutive cycles should be run, one right after the other, with the Bowie-Dick test pack, with each test result demonstrating sufficient air removal (see 10.7.6); as in routine Bowie-Dick testing, an empty chamber should be used for the tests.

Rationale: Sterilizers larger than 2 cubic feet are routinely tested using the standardized PCD (BI challenge test pack) of 10.7.2.1. There are no universally accepted standardized PCDs for table-top, gravity-displacement-type sterilizers. Therefore, this recommended practice suggests that a representative package or tray that is to be routinely processed through the sterilizer be used as the PCD. The packages or trays used as PCDs will vary from facility to facility, depending on the types of items routinely sterilized. There are no data to support the need for more than one BI (but see 10.7.2.1).

10.8.3.2 Placement of the PCD (BI challenge test pack or BI challenge test tray)

Qualification testing is conducted in a fully loaded chamber. The PCD (BI challenge test pack or BI challenge test tray) should be placed on its edge if it is a small pack or flat if it is an instrument tray or large pack. It should be positioned in the area of the sterilizer chamber and load that is least favorable to sterilization. This area, the "cold point," varies with sterilizer design but is normally in the center of the load toward the front of the chamber.

Rationale: Small packs are routinely placed on edge to allow sufficient steam exposure. Larger packs or trays are routinely placed flat on the shelf because their size will not permit any other orientation in the relatively small chambers of table-top steam sterilizers. Placing the PCD in the coolest portion of the chamber presents the most severe challenge. Table-top steam sterilizers typically have a water reservoir that injects a set volume of water, which is used to create steam during the cycle. Because of the limited amount of water available to create steam, the greatest challenge to steam penetration is the amount of available steam. Therefore, the sterilizer should be tested under worst-case conditions: a full load.

10.8.3.3 Test procedure

The test procedure is as follows:

a) Before being exposed to the sterilization cycle, the PCD (BI challenge test pack or BI challenge test tray) is labeled with appropriate sterilizer information.

b) The PCD is positioned in the chamber according to 10.8.3.2.

c) The appropriate cycle is run according to the sterilizer manufacturer's instructions.

d) After being exposed to the sterilization cycle, the BIs are removed from the PCD and their identification noted. All BIs used in challenging the sterilization cycle and as controls should be accounted for. The BIs should be handled and incubated according to the BI manufacturer's instructions.

   NOTE—*Geobacillus stearothermophilus* (formerly named *Bacillus stearothermophilus)* does not grow at 35 °C to 37 °C (95 °F to 99 °F), the temperature of standard bacteriology laboratory incubators. A temperature of 55 °C to 60 °C (131 °F to 140 °F) is typically recommended. Consult the manufacturer's directions for the appropriate incubation time and temperature.

e) For each test BI that is run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control to verify the presterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the proper incubation temperature. Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are nonviable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the test repeated.

   NOTE—If several test BIs from the same lot are run at the same time, only one control BI from that lot need be used.

10.8.3.4 Acceptance criteria

Three consecutive test runs with negative results from the test BIs, along with appropriate CI results and cycle printout records demonstrating correct and complete sterilization cycles, provide verification that the sterilizer has been properly installed (or reinstalled after relocation) or repaired to the manufacturer's specifications and that it will function effectively in the facility in which it is installed. All packages or trays processed during qualification testing should be quarantined until the results of the BI testing of all three test runs are available.

10.8.4 Qualification testing of flash sterilization cycles

10.8.4.1 Composition of the PCD (BI challenge test tray)

One or more BIs and one or more CIs should be placed in the tray configuration that has been selected to be tested: a perforated, mesh-bottomed, open surgical tray; a rigid sterilization container system; a protective organizing case; or a single-wrapped surgical tray. The PCD (BI challenge test tray) should be of appropriate size for the sterilizer being tested. The BI(s) and CI(s) should be located in the most difficult-to-sterilize portion of the PCD. For open surgical trays, single-wrapped surgical trays, and protective organizing cases, the most difficult-to-sterilize area is the area nearest the sterilizer drain. For rigid sterilization container systems, the BI(s) should be placed in accordance with 10.10.3.2.2.

NOTE—The open surgical tray, rigid sterilization container system, protective organizing case, or single-wrapped surgical tray should be a product that has been validated by the manufacturer for use in sterilization.

Rationale: Only one BI need be used for the test in order to achieve a microbial challenge. There are no data to support the need for more than one BI (but see 10.7.2.1). It is recommended that one or more CIs be placed in the PCD, because CIs give immediate information regarding sterilization process efficacy. The area near the drain is usually the coolest portion of the sterilizer and therefore presents the greatest challenge.

10.8.4.2 Placement of the PCD (BI challenge test tray)

The PCD should be placed on the bottom shelf of an otherwise empty sterilizer, in the area least favorable to sterilization (i.e., in the area representing the greatest challenge to the BI). The sterilizer manufacturer should identify the exact location of this area, the "cold point," in the instruction manual and instruct users to place the PCD at this location. This area varies with sterilizer design, but is normally in the front, bottom section of the sterilizer, near the drain.

Rationale: The BI test is conducted in an otherwise empty sterilizer, rather than in one containing patient care items, because for flash sterilization this configuration is a more rigorous biological challenge to sterilizer performance than is a filled chamber. Performing the test in an empty chamber minimizes heat-up time (because there is little metal mass to absorb the heat) and, therefore, minimizes the lethality of the process and creates a greater challenge to the BI. Placement near the drain generally ensures that the PCD is in the coolest portion of the chamber, but the sterilizer manufacturer is best able to advise the user on the "cold point."

10.8.4.3 Test procedure

The test procedure is as follows:

a) Before being exposed to the sterilization cycle, the PCD (BI challenge test tray) is labeled with appropriate sterilizer information.

b) The PCD should be positioned in the chamber according to 10.8.4.2

c) The appropriate cycle is run, according to the manufacturer's instructions.

d) Upon completion of the sterilization cycle and adequate cooling of the PCD, the BI(s) should be removed, their identity noted, and all BIs accounted for. During the removal and transfer process, care should be taken to avoid contamination. The BI(s) should then be incubated according to the instructions of the BI manufacturer.

   NOTE—*Geobacillus stearothermophilus* (formerly named *Bacillus stearothermophilus)* does not grow at 35 °C to 37 °C (95 °F to 99 °F), the temperature of standard bacteriology laboratory incubators. A temperature of 55 °C to 60 °C (131 °F to 140 °F) is typically recommended. Consult the manufacturer's directions for the appropriate incubation time and temperature.

e) For each test BI that is run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control to verify the presterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the proper incubation temperature. Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are nonviable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the test repeated.

   NOTE—If several test BIs from the same lot are run on the same day, only one control BI from that lot need be used.

Rationale: Because this is a challenge test, the operating conditions should be the same as those for normal use of the sterilizer.

10.8.4.4 Acceptance criteria

All results of BIs, including those BIs used as positive controls, should be interpreted by qualified personnel and should be included in the sterilizer records. The test is satisfactory if the test BI is reported negative (no microbial growth), the control BI is reported positive (microbial growth), CI results are appropriate, and physical monitoring reveals that the cycle was correct and complete. If a positive culture is obtained from the test BI, a presumptive identification should be performed to determine whether the recovered microorganism is indeed the test microorganism from the BI or is a contaminant (see 10.7.5).

10.9 Periodic product quality assurance testing of routinely processed items

Quality assurance testing of routinely processed items should be performed on an ongoing basis. A program should be established to periodically test routinely sterilized products. Product testing should always be performed when

It is important to note that several recently published studies have demonstrated that alkaline detergent cleaners alone or in combination with hydrogen peroxide gas plasma or certain biocides can significantly reduce and inactivate prion challenges (Yan, et al., 2004; Baier, et al., 2004; Race and Raymond, 2004; Fichet, et al., 2004).

Some investigators also have found that combining sodium hydroxide (NaOH) with steam sterilization for 1 hour at 121 °C results in complete loss of infectivity. However, the combination of NaOH and steam sterilization can be deleterious to surgical instruments and sterilizers, as well as to sterilizer operators. In a recent paper (Brown, et al., 2004), FDA researchers pointed out that the World Health Organization and CDC have recommended that rigorous decontamination protocols be used on surgical instruments that have been exposed to tissue possibly contaminated with CJD. They performed a study designed to examine the effects of these protocols on various types of surgical instruments. The most important conclusions were (a) autoclaving in 1N NaOH will cause darkening of some instruments; (b) soaking in 1N NaOH at room temperature damages carbon steel but not stainless steel or titanium; and (c) soaking in chlorine bleach will badly corrode gold-plated instruments and will damage some, but not all, stainless steel instruments, especially welded and soldered joints. Damage became apparent after the first exposure, so long tests are not necessary to establish which instruments will be damaged.

Historically, recommendations for inactivating the agent of CJD have been based on studies using infected tissues and injecting animals known to be susceptible to CJD.

Many of the existing recommendations are based on the assumptions that exposure to any tissue, body fluid, secretion, or excretion from a CJD patient will result in a transmissible infectious dose of CJD, and that no conventional processing regimen of cleaning followed by disinfection or sterilization will be effective in rendering the device or fomites safe for reuse. However, based on the epidemiology of iatrogenic and health-care-associated (nosocomial) episodes of CJD mentioned above, it is clear that the only exposures in patient care settings that have resulted in infection are those instances involving devices that cannot be cleaned and that are contaminated with high-risk tissue from the central nervous system.

There have been other approaches that consider tissues containing the highest prion load to carry the highest risk of transmission by instruments (Geertsma and Asten, 1995; Favero, 1998; Favero and Bond, 2001).

The disinfection and sterilization recommendations for CJD in this guideline are based on the belief that infection prevention and control measures should be predicated on epidemiologic evidence linking specific body tissues or fluids to transmission of CJD, quantitative infectivity assays demonstrating that body tissues or fluids are contaminated with infectious prions, cleaning data using BIs and proteins, inactivation data on prions, the risk of disease transmission with the use of the instrument or device, and a review of other recommendations.

The three parameters considered in this guideline that are integrated into strategies for disinfection and sterilization processing are as follows:

a) Risk of the patient for having a prion disease: High-risk patients include those with known prion disease; those with rapidly progressive dementia consistent with possible prion disease; those with a familial history of CJD, GSS, or FFI; patients known to carry a mutation in the PrP gene involved in familial TSEs; patients with a history of dura mater transplants; and patients with a known history of cadaver-derived pituitary hormone injection.

b) Comparative infectivity of different body tissues (e.g., the prion load): High-risk tissues include brain, spinal cord, and eye. All other tissues are considered low or no risk (Rutala and Weber, 2001).

c) Intended use of the medical device: Critical devices are defined as devices that enter sterile tissue or the vascular system (e.g., implants, curettes). Semicritical devices are defined as devices that contact nonintact skin or mucous membranes (e.g., endoscopes).

C.2 Processing devices contaminated with high-risk tissue

The following recommendations apply to devices and equipment contaminated with high-risk tissues (defined as brain [including dura mater], spinal cord, and eye tissue) from high-risk patients (i.e., those known or suspected to have CJD):

1) Devices that are constructed so that cleaning procedures result in effective tissue removal (e.g., surgical instruments) can be cleaned and then steam sterilized at 134 °C for greater than or equal to 18 minutes in a prevacuum sterilizer or at 121 °C to 132 °C for 1 hour in a gravity-displacement sterilizer.

2) Devices that are impossible or difficult to clean can be discarded. Alternatively, the contaminated device can be placed in a container filled with a liquid (e.g., saline, water or phenolic solution) to retard adherence of material to the medical device, then initially decontaminated by steam sterilizing it at 134 °C for 18 minutes in a prevacuum sterilizer (liquids must be removed before the device is sterilized) or at 121 °C to 132 °C for

1 hour in a gravity-displacement sterilizer or by soaking it in 1N NaOH for 1 hour. The device is then cleaned, wrapped, and terminally sterilized by conventional means.

NOTE 1—Most steam sterilizers have multiple cycles that would allow an extended CJD cycle to be set by the operator. For those sterilizers that require exposure times and temperatures to be adjusted to other than manufacturer-recommended settings, users should reset the exposure and temperature settings.

NOTE 2—Under no circumstances should devices or instruments be placed in NaOH solutions and steam sterilized. This procedure can ruin sterilizers and instruments and is dangerous to staff members.

3) To minimize drying of tissues and body fluids on the object, devices should be kept moist until cleaned and decontaminated.

4) Flash sterilization should not be used for reprocessing these devices.

5) Contaminated items that have been in contact with high-risk tissue and have not been processed according to these recommendations (e.g., medical devices used for brain biopsy prior to diagnosis) should be recalled and appropriately reprocessed.

6) A tracking system should be in place that permits recall of devices used on high-risk tissue and high-risk patients. This tracking system should permit identification of the patient on which the devices were used, the date they were used, the procedure performed, and the surgeon's name. Facilities that do not have a commercially available or automated system should create a manual system. A simple system can be created using a steam-sterilizable two-part card, with an external CI that is affixed to the outside of instrument trays. When the tray is used, the bottom part of the card is removed and affixed to the patient's chart to identify all items used on the patient. To ensure accurate tracking of sets and devices, all items should be given a unique number. For example, if the facility has four craniotomy trays, they should be numbered #1, #2, #3, and #4 to identify the specific tray used on the patient.

7) Environmental surfaces (noncritical) contaminated with high-risk tissues (e.g., laboratory surfaces in contact with the brain tissue of a person infected with CJD) should be cleaned with a detergent and then spot-decontaminated with 5,000 ppm sodium hypochlorite. This concentration usually results from a 1/10 dilution of household bleach. However, the label should be checked for the amount of sodium hypochlorite present; concentrations in U.S. products can range from 3 % to more than 6 % sodium hypochlorite.

8) Noncritical equipment contaminated with high-risk tissue should be cleaned and then disinfected with 5,000 ppm hypochlorite or 1 N NaOH, depending on material compatibility. All contaminated surfaces must be exposed to the disinfectant.

9) Equipment that requires special prion reprocessing should be tagged after use. Clinicians and reprocessing technicians should be thoroughly trained on the proper tagging of equipment and on the special prion reprocessing protocols.

10) Use of power drills or saws that are likely to contact high-risk tissue should be avoided. Power drills and saws by their very nature and design are difficult to clean and too expensive to discard (AORN, 2008a).

C.3 Processing devices contaminated with low-risk tissue

The following recommendations apply to devices and equipment contaminated with low-risk tissues (defined as cerebrospinal fluid, kidney, liver, spleen, lung, and lymph node tissue) from high-risk patients.

1) Devices can be cleaned and disinfected or sterilized using conventional protocols of high-level disinfection, thermal sterilization, or chemical sterilization.

2) Environmental surfaces contaminated with low-risk tissues require only standard disinfection using disinfectants recommended by OSHA for decontaminating blood-contaminated surfaces (e.g., 500 to 5,000 ppm sodium hypochlorite).

C.4 Processing devices contaminated with no-risk tissue

The following recommendations apply to devices and equipment contaminated with no-risk tissue (defined as peripheral nerve tissue, intestinal tissue, bone marrow, blood, leukocytes, serum, thyroid gland tissue, adrenal gland tissue, heart tissue, skeletal muscle, adipose tissue, gingiva, prostate tissue, testicular tissue, placental tissue, tears, nasal mucus, saliva, sputum, urine, feces, semen, vaginal secretions, milk) from high-risk patients.

1) Devices can be cleaned and disinfected or sterilized using conventional protocols of high-level disinfection, thermal sterilization, or chemical sterilization.

Table D.1—In-use tests available to assess efficacy of cleaning of medical devices

Test method	Soil component tested	Limit of detection	Limitations	Length of test (after sample collection)
Ortho-phthaldialdehyde (OPA) method (Fengler, et al., 2001; Verjat, et al., 1999). Swab device or elute device with liquid, then test sample using OPA method.	Protein	0.01 µg/mL	Sensitivity unrealistic (i.e., routine handling with hands could trigger positive reaction).	~ 1 to 5 min
Biuret reaction (Kruger, 1997). Swab device, immerse in reagent, and assess for color development.	Protein	5.5 µg/cm^2	Not applicable to lumens. Author suggests that > 20 µg/cm^2 is unacceptably high for protein, but no rationale is given for this benchmark. Rust causes color interference.	10 min
Protein method. Swab device, immerse in reagent, and assess for color development.	Protein	Not indicated	Not applicable to lumens. No indication is given of what level of soiling is present for a positive test result.	Stated as "minutes"
ATP method. Swab device, extract ATP from swab, and determine ATP. Or use fluid rinse as sample.	ATP (present in eukaryotic cells and live bacteria)	Not indicated	Needs instrumentation to read test. Requires cells (eukaryotic or prokaryotic) to be present. No ATP is detected if only protein or carbohydrate is present.	30 seconds
ATP bioluminescence (Davidson, et al., 1999).	Bacteria (*S. aureus* and E. *coli*)	<10^4 cfu/ 100 cm^2	Not indicated.	Stated as "minutes"
Ninhydrin test (deBruin, 2002). Swab device, immerse swab in test reagent, and assess for color development.	Protein	2.5 µg/swab	Not applicable to lumens; interference in color detection by rust, etc., from cleaned devices that mask swab color.	20 min
UV-VIS spectroscopy (Kneiler, 2001).	Residual blood	Not indicated	Not indicated.	Not indicated
Limulus amoebocyte lysate assay (LAL). Elute device with liquid, then test sample using LAL method.	Endotoxin	0.0032 EU/mL	Sensitivity unrealistic (i.e., routine handling could trigger positive reaction); does not detect proteins, organic matter, or viable microorganisms.	10 to 30 min

NOTE—More comprehensive lists of test soils and test methods are provided in Tables 5 and 6 of AAMI TIR30.

Table D.2—In-use tests available to assess efficacy of washer-disinfectors used for medical device reprocessing

Test method	Soil component tested	Limit of detection	Limitations	Length of test (after machine protocol is finished)
Visible test soil. Paint colored paste onto medical device. After cleaning, visually inspect device to confirm removal of soil.	Artificial soil (not linked to specific soil components); detected as color being present or absent	Not indicated	Introduction of foreign material to medical devices that will subsequently be used on patients after cleaning.	~ 1 min
Coagulated blood test. Metal coupon with strip of coagulated blood soil. After cleaning, visually inspect with comparison to chart to confirm removal of soil. A lumen version is available for testing lumen washers.	Blood and protein; detected as visible red (blood) or visible "film" (fibrin, protein)	Not indicated	Valuable as a quality assurance indicator for functionality of washer-disinfector but *not* for cleaning verification for specific medical devices in the washer.	~ 1 min
Peroxidase reaction. Swab device, immerse in reagent, and assess for color change.	Hemoglobin	0.1 µg/swab	Applicable to blood-soiled surfaces such as instruments and instruments with lumens. Not applicable if oxidizing substances are used for disinfection (cannot detect "bleached" hemoglobin).	30 sec
Protein test pyromol-test. Swab device, immerse in reagent, and assess for color change.	Protein	1.0 µg/swab	Applicable to protein-soiled surfaces such as instruments and instruments with lumens. Rust or non-proteinous discoloration on the swab will interfere with the color change.	15 min

NOTE—More comprehensive lists of test soils and test methods are provided in Tables 5 and 6 of AAMI TIR30.

Annex E
(Informative)

Selection and use of chemical disinfectants

E.1 Introduction

This Annex describes factors to consider in the selection of a chemical disinfectant for a particular application.

E.2 Categories of items to be disinfected

Surgical instruments and other medical devices and equipment could pose a significant risk of transmitting infection to patients or health care personnel if they are not properly decontaminated and then disinfected or sterilized. Spaulding divided medical instruments and equipment into three categories (critical, semicritical, and noncritical) based on the risk of infection from contamination on the item (Spaulding, 1972). The Centers for Disease Control and Prevention (CDC) has described the level of disinfection or sterilization needed after decontamination and before patient use for the three Spaulding categories (Garner and Favero, 1985; CDC, 2003a) as well as a fourth category, environment surfaces (Favero and Bond, 1991, 2001):

a) **Critical devices** are instruments or objects that are introduced directly into the human body, either into or in contact with the bloodstream or other normally sterile areas of the body, and products with sterile fluid pathways. Examples of critical items include surgical instruments, needles, transfer forceps, cardiac catheters, implants, inner surface components of extracorporeal blood-flow devices such as heart-lung machines and blood oxygenators, and the blood compartments of hemodialyzers. Critical items present a high degree of risk of transmission of infection if contaminated and, therefore, must be sterile at the time of use.

b) **Semicritical devices** are instruments or objects that contact intact mucous membranes or nonintact skin of the patient during use, but do not usually penetrate the blood barrier or other normally sterile areas of the body. Examples include noninvasive, flexible and rigid fiberoptic endoscopes, endotracheal and aspirator tubes, bronchoscopes, laryngoscopes, respiratory therapy equipment, cystoscopes, vaginal specula, and urinary catheters. Semicritical devices should be sterilized, if possible. However, if sterilization is not feasible, the device, at a minimum, must be subjected to a high-level disinfection process that would be expected to destroy all microorganisms except for large numbers of bacterial spores. In most cases, meticulous physical cleaning followed by high-level disinfection provides reasonable assurance that the items are free of pathogenic microorganisms.

   NOTE—Unless contraindicated, steam sterilization is the preferred processing method. Low-temperature processes (e.g., EO sterilization and other processes with exposure temperatures lower than steam sterilization) can be used to sterilize some heat-labile devices when time between uses allows such processes to be used.

c) **Noncritical devices** are instruments or objects that usually contact only the intact skin of the patient. These items, which include surgical facemasks, blood pressure cuffs, most neurologic and cardiac diagnostic electrodes, and certain surfaces of roentgenographic machines, rarely, if ever, transmit infections directly to patients. Consequently, depending on the particular item and degree of contamination, cleaning with a detergent and warm water may be appropriate.

d) **Environmental surfaces** include a variety of surfaces that usually do not come in contact with patients or, if they do, only with intact skin. Environmental surfaces carry the least risk of infection transmission, but may contribute to secondary cross-contamination by the hands of health care workers or by contact with medical instruments that will subsequently come into contact with patients. These surfaces can be divided into two major subdivisions: (a) medical equipment surfaces (e.g., adjustment knobs or handles on hemodialysis machines, roentgenographic machines, instrument carts, and dental units); and (b) housekeeping surfaces (e.g., floors, walls, table-tops, and window sills). Depending on the specific surface and the nature and degree of contamination, medical equipment surfaces may require simple cleaning with soap and warm water, cleaning with a germicidal detergent, or cleaning with soap and water followed by application of a low- to intermediate-level chemical disinfectant, to achieve the level of safety needed. Housekeeping surfaces have the least potential for cross-contamination. These surfaces are maintained in a state of visible cleanliness by using water and a detergent or a hospital-grade disinfectant-detergent designed for general housekeeping purposes. All spills of blood, other potentially infectious body fluids, or laboratory cultures should be cleaned up with an intermediate-level chemical disinfectant.

This categorization of patient care items and knowledge of the antimicrobial activity of various types of disinfectants facilitate the selection of an appropriate chemical disinfectant. The disinfection method should be chosen based on the device manufacturer's instructions for use, how the device will contact the next patient, the physical configuration (cleanability) of the device, the type and degree of contamination after use, the physical and chemical stability of the device, and the ease or difficulty in removing (rinsing, aerating) the chemical agent after the necessary exposure time. As part of the quality assurance program, users should periodically reassess the intended use and appropriate category of patient care items.

E.3 Activity levels of disinfectants

Disinfectants can be classified as high-, intermediate-, or low-level disinfectants based on their ability to kill various microorganisms, including vegetative bacteria, mycobacteria, bacterial spores, fungi, and viruses.

When choosing a disinfectant for a particular application, the user may find the published descriptions of the effectiveness of various chemical agents (active ingredients) in disinfectants quite confusing. The ability of a specific chemical agent to kill or inactivate microorganisms is affected by factors such as the concentration of the chemical in the disinfectant, the contact temperature, and the exposure time. For example, a very low concentration of a particular agent may inactivate viruses, whereas a higher concentration, higher temperature, and/or longer exposure time may be required to inactivate other types of microorganisms, such as mycobacteria or bacterial spores. Also, some chemical agents are not capable of killing certain microorganisms under practical conditions, that is, at reasonable temperatures, concentrations, and exposure times.

The biocidal effectiveness of chemical agents can be described in several ways:

a) as data on the chemical agent with no mention of brand names or specific product formulations;

b) as label claims supported by technical data for a particular product formulation that contains the chemical agent; and

c) as the results of controlled studies by independent parties.

The first type of information is a guide to the expected efficacy of the active ingredient shown on the product label. To determine if the chemical agent in a product formulation will provide the level of decontamination required, the user should consult both the label claims and the current, relevant professional literature.

The 1985 CDC *Guidelines for Handwashing and Hospital Environmental Control* (Garner and Favero, 1985) and its subsequent edition (CDC, 2003a) recognized three levels of disinfection (Table E.1). If sterilization cannot be performed, the CDC recommends high-level disinfection of semicritical patient care items (items that will be in contact with intact mucous membranes and do not normally penetrate body surfaces). Intermediate- or low-level disinfection is considered suitable for noncritical items that come into direct contact with the patient but normally only touch intact skin.

NOTE—The unconventional agent that causes Creutzfeldt-Jakob disease (CJD) might not be inactivated by a high-level disinfection procedure; in fact, this agent is resistant to most commonly used sterilization methods. For information regarding the decontamination of devices exposed to prions, see Annex C, AORN (2008a), Favero & Bond (2001), Rutala and Weber (2001), and the recommendations of CDC (http://www.cdc.gov) ~~ASHCSP (http://www.ashcsp.org),~~ and IAHCSMM (http://www.iahcsmm.org).

E.4 Labeling of disinfectant products

The labeling of LCSs/HLDs that are intended to be used as the terminal step in processing reusable critical and semicritical medical devices is regulated by FDA. The labeling of these devices provides a guide for users in evaluating the activity levels of disinfectant products. Under FDA regulation, the labeling for a LCS/HLD must provide information relating to the safe and effective use of the product. The labeling should identify the lot number, the expiration date, the active ingredients and their concentrations, any dilution or activation required prior to use, and the required contact time and temperature. The labeling should also provide information on material and device compatibility, necessary PPE, and, for products that can be reused, the reuse life and instructions for determining whether the concentration of the active ingredient is at or above the MRC or MEC. The labeling includes the bottle label and any package insert, which may contain all of the above information as well as any supplemental information for the user. Labeling for FDA-regulated products uses disinfection terms defined by Spaulding (1972), such as "high-level-disinfection," to indicate product effectiveness. Terms previously allowed by EPA, such as "virucidal," "fungicidal," "bactericidal," and "tuberculocidal," have been phased out. In addition, FDA labeling policy does not permit references to specific diseases, such as AIDS and tuberculosis, unless effectiveness has been shown in clinical trials. FDA labeling guidance is provided in FDA (1997) and FDA (2000b). Guidance on FDA regulation of disinfectants is provided in FDA (2000b).

Annex N
(informative)

Toxic anterior segment syndrome (TASS) and the processing of intraocular surgical instruments

N.1 Introduction

Special considerations are associated with the processing of instruments used for intraocular surgery, both because of the nature of the instruments themselves and because of the sensitive nature of the eye. Many of the intraocular instruments currently in use are complex and delicate and cannot be processed by automated methods; therefore, they must be cleaned manually. Because manual cleaning methods may be less controlled than automated cleaning methods, additional care must be taken during processing to ensure effective cleaning. The situation is further compounded by the sensitivity of ocular tissue to the introduction of foreign material into the anterior chamber of the eye, which may result in an acute inflammatory response known as toxic anterior segment syndrome (TASS). This inflammatory response may lead to severe visual impairment if it is not recognized and treated in a timely manner.

While the induction of TASS may be associated with specific products such as contaminated balanced salt solution, which is used with ophthalmic instruments during surgery (Holland, et al., 2007), detergent residues, endotoxin, denatured ophthalmic viscoelastic devices (OVDs), preservatives, foreign matter, and residues from sterilization processing can all induce TASS and cause severe damage to ocular tissue (Mamalis, et al., 2006). Therefore, particular care must be taken in the processing of intraocular surgical instruments to ensure that foreign substances or materials associated with the instruments will not be introduced into the anterior chamber of the eye during surgery.

Outbreaks of TASS have often been linked to the failure to follow the processing procedures recommended by the instrument manufacturer and by organizations such as AAMI (ANSI/AAMI ST79), the Association of periOperative Registered Nurses (AORN, 2008a), the Centers for Disease Control and Prevention (CDC, 2003b), and the International Association of Healthcare Central Service Material Management (IAHCSMM, 2007). Specific instrument cleaning and sterilization recommendations intended to diminish the risk of TASS associated with intraocular surgical instruments have been compiled by a multidisciplinary panel and published by the American Society of Cataract and Refractive Surgery (ASCRS) and the American Society of Ophthalmic Registered Nurses (ASORN). See this document (ASCRS and ASORN, 2007) for additional details.

The purpose of this Annex is to highlight existing recommendations for reducing the risk of TASS and to provide additional guidance in the overall context of surgical instrument processing in health care facilities.

N.2 Processing recommendations

N.2.1 General considerations

Because health care facilities must process a wide range of surgical instrumentation, it is often difficult to implement specific cleaning procedures for a particular class of surgical instruments. However, in view of the sensitivity of ocular tissue to the presence of foreign substances or material, it is critical that the cleaning and sterilization procedures recommended both by the manufacturer of the intraocular surgical instruments and by professional societies such as ASCRS and ASORN be closely followed. In addition, ongoing education, training, and verification of competency in the cleaning and sterilization of intraocular surgical instruments are essential.

N.2.2 Important elements of a processing program for intraocular surgical instruments

N.2.2.1 Instrument inventory

An adequate inventory of the necessary intraocular surgical instruments should be maintained to allow for the timely processing of instruments between cases. Adequate time must be allowed for processing instruments according to the manufacturer's instructions; otherwise, the cleaning and sterilization of the instruments will be ineffective.

N.2.2.2 Designated cleaning area and equipment

A designated cleaning area and equipment dedicated to the cleaning of intraocular surgical instruments should be identified. Intraocular surgical instruments should be processed separately from general surgical instruments and equipment to reduce the potential for cross-contamination by material or residue from general surgical instruments. The recommendations provided in ANSI/AAMI ST79 for work area design, work flow, physical facilities, housekeeping, and personnel should be followed, because the same considerations apply to the processing of intraocular surgical instruments.

N.2.2.3 Manufacturer's instructions

The manufacturer's written instructions for the cleaning and sterilization of a particular intraocular surgical instrument should be read, understood, and followed by those responsible for processing the instrument; personnel training in the cleaning and sterilization procedure should be documented. All instructions should be readily accessible and periodically reviewed to ensure that they reflect the manufacturer's current recommendations. (Manufacturers frequently update their instructions to incorporate new information or to list newly approved cleaning products or procedures.) The cleaning process should be audited to ensure that the procedures being used comply with the manufacturer's instructions and that the personnel performing cleaning procedures have received documented training and have demonstrated competency in the cleaning process.

N.2.2.4 Precleaning

Instruments should be precleaned immediately following use. Gross debris should be removed, and instrument lumens should be flushed with sterile distilled water or another suitable agent as recommended by the manufacturer. The instruments should be maintained in a moist state before cleaning in order to prevent the drying of surgical debris onto or within them. In particular, OVDs may dry onto instruments very quickly following use and resist removal during subsequent cleaning.

N.2.2.5 Transport of instruments to the decontamination area

During transport of instruments from the point of use to the decontamination area, appropriate precautions (e.g., use of a closed transport container) should be taken to avoid personnel exposure to bloodborne pathogens, contamination of the work environment, and further contamination of the instruments. The time between using instruments and cleaning them should be kept to a minimum.

N.2.2.6 Personal protective equipment

Personnel who clean and process instruments should wear appropriate personal protective equipment (PPE) and avoid generating aerosols during the cleaning procedure. Aerosols can contaminate processing equipment and the work area and expose personnel to bloodborne pathogens.

N.2.2.7 Cleaning agents

Intraocular surgical instruments should be cleaned with the appropriate cleaning agent and with water of the appropriate quality, as specified in the instrument manufacturer's instructions. Only cleaning agents that have been recommended by the manufacturer should be used. Particular attention should be directed toward ensuring that the specified concentration of cleaning agent and water of the recommended water quality are used. Final rinsing of the instrument should be performed with the volume of sterile, distilled, or deionized water recommended by the manufacturer. The water used to clean or rinse instruments should be discarded after each use. If an ultrasonic cleaner is used to process the instruments, it should be emptied, cleaned, rinsed, and dried at least daily or, preferably, after each use. Brushes and other cleaning implements should be cleaned and decontaminated as recommended by the manufacturer at least daily or, preferably, after each use. Whenever possible, single-use brushes and other cleaning implements should be used and then disposed of afterwards.

N.2.2.8 Sterilization

Intraocular surgical instruments should be sterilized using the methods and conditions recommended in the instrument manufacturer's instructions. If there are discrepancies between the sterilizer manufacturer's instructions, the user's sterilization processing conditions or equipment, and the instrument manufacturer's instructions, the instrument manufacturer should be consulted before the items are processed. The sterilization process should be effective, monitored, and documented. ANSI/AAMI ST79 provides detailed recommendations for sterilization processing, including quality control and restrictions regarding the use of flash sterilization.

N.2.2.9 Maintenance of processing equipment

Cleaning and sterilization equipment, boilers, and water filtration systems should be properly maintained. Otherwise, foreign materials such as endotoxin, heavy metals, or chemical contaminants or impurities may be deposited onto the instruments during processing and induce TASS. Maintenance requirements vary, depending on the complexity of the equipment. The operator's manual provided by the equipment manufacturer should be consulted for the required frequency and type of maintenance activities. All maintenance and repair activities should be performed by qualified personnel and documented.

N.3 Resources and training

Facility-specific written policies and procedures that are both general and instrument-specific should clearly outline the important steps in instrument cleaning and sterilization. Processing personnel should not only follow the

appropriate processing procedures, but also maintain knowledge of those factors and practices that may have an impact on the efficacy of cleaning and sterilization. At each surgical center or other health care facility, at least one individual should be responsible for remaining current with recommendations for processing intraocular surgical instruments. Responsibility should also be designated for monitoring the continued competency of those who clean and sterilize surgical instruments. Useful sources of information on the processing of surgical instruments and the implementation of training programs include

a) Recommended practices, guidelines, procedures, and notifications published by government agencies and professional associations, e.g.:

- American Society for Cataract Refractive Surgery (http://www.ascrs.org)
- American Society of Ophthalmic Registered Nurses (http://webeye.ophth.uiowa.edu/ASORN)
- Association for the Advancement of Medical Instrumentation (http://www.aami.org)
- Association of periOperative Registered Nurses (http://www.aorn.org)
- Centers for Disease Control and Prevention (http://www.cdc.gov)
- Food and Drug Administration (http://www.fda.gov)
- International Association of Healthcare Central Service Materiel Management (http://iahcsmm.org)

b) Scientific publications and trade journals

c) Manufacturers of surgical instruments and processing equipment

d) Discussions with professional peers and associates

Training programs should include the means of verifying the efficacy of training and continued competency in instrument processing procedures; written examinations specific to intraocular surgical instrument processing procedures may be useful for documentation purposes. Periodic observation of cleaning and sterilization practices by training personnel and periodic audits of the cleanliness of processed instruments are essential. Section 10 and Annex D include information on quality control and user verification of the cleaning process.

N.4 Summary

Because many different materials can elicit a TASS response if they are inadvertently introduced into the anterior chamber of the eye, the importance of following the proper intraocular surgical instrument processing procedures cannot be overemphasized.

Annex O~~N~~
(informative)

Bibliography

O~~N~~.1 Cited references

Alfa MJ, Olson N, DeGagne P, and Jackson M. A survey of reprocessing methods, residual viable bioburden and soil levels in patient-ready endoscopic retrograde choliangiopancreatography duodenoscopes used in Canadian centers. *Infect Control Hosp Epidemiol,* 23:198–206, 2002.

American Conference of Governmental Industrial Hygienists. *2005 TLVs® and BEIs®: Threshold limit values for chemical substances and physical agents & biological exposure indices.* Cincinnati: ACGIH®, 2005.

American Institute of Architects Academy of Architecture for Healthcare. *Guidelines for design and construction of hospital and health care facilities.* Washington (D.C.): American Institute of Architects Press, 2001.

American National Standards Institute. *Emergency eyewash and shower equipment.* ANSI Z358.1:~~1998~~2004. 2nd ed. New York: ANSI, ~~1998~~2004.

American Society for Gastrointestinal Endoscopy. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointestinal Endoscopy*, 58(1):1–8, 2003.

American Society for Healthcare Central Service Professionals. *Training manual for central service technicians.* Chicago: American Hospital Association, 1997.

American Society of Cataract and Refractive Surgery and American Society of Ophthalmic Registered Nurses. Recommended practices for cleaning and sterilizing intraocular surgical instruments. *J Cataract Refract Surg,* 23:1095–1100, June 2007.

American Society of Heating, Refrigerating, and Air-Conditioning Engineers. *Ventilation for acceptable indoor air quality.* Standard 62.1-07~~-89~~. Atlanta: ASHRAE, 2007a~~1989~~.

American Society of Heating, Refrigerating, and Air-Conditioning Engineers. *2007~~1995~~ ASHRAE ~~Applications~~ handbook.* Atlanta: ASHRAE, 2007b~~1995~~.

Association for the Advancement of Medical Instrumentation. *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.* ANSI/AAMI PB70:2003. Arlington (VA): AAMI, 2003. American National Standard.

Association for the Advancement of Medical Instrumentation. *Hemodialysis systems.* 3rd ed. ANSI/AAMI RD5:2003. Arlington (VA): AAMI, 2003. American National Standard.

Association for the Advancement of Medical Instrumentation. *Hemodialyzer blood tubing.* 2nd ed. AAMI RD17:~~1994 (and AAMI RD17:1994/A1:2002)~~2005. Arlington (VA): AAMI, 2005~~2~~. AAMI Standard.

Association for the Advancement of Medical Instrumentation. *Reuse of hemodialyzers*. 3rd ed. ANSI/AAMI RD47:2002 (and ANSI/AAMI RD47:2002/A1:2003). Arlington (VA): AAMI, 2002. American National Standard.

Association for the Advancement of Medical Instrumentation. *Good hospital practice: Steam sterilization and sterility assurance.* AAMI ST1:1980. Arlington (VA): AAMI, 1980. AAMI Recommended Practice.

Association for the Advancement of Medical Instrumentation. *Hospital steam sterilizers.* ANSI/AAMI ST8:2001. Arlington (VA): AAMI, 2001. American National Standard.

~~Association for the Advancement of Medical Instrumentation. *Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization.* ANSI/AAMI ST19:1999. Arlington (VA): AAMI, 1999. American National Standard.~~

Association for the Advancement of Medical Instrumentation. *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities.* ANSI/AAMI ST33:1996. Arlington (VA): AAMI, 1996. American National Standard.

Association for the Advancement of Medical Instrumentation. *Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings.* ANSI/AAMI ST35:2002. Arlington (VA): AAMI, 2002. American National Standard.

Association for the Advancement of Medical Instrumentation. *Flash sterilization: Steam sterilization of patient care items for immediate use.* ANSI/AAMI ST37:1996. Arlington (VA): AAMI, 1996. American National Standard.

Association for the Advancement of Medical Instrumentation. *Table-top dry heat (heated air) sterilization and sterility assurance in dental and medical facilities.* ANSI/AAMI ST40:2004. Arlington (VA): AAMI, 2004. American National Standard.

Association for the Advancement of Medical Instrumentation. *Ethylene oxide sterilization in health care facilities: Safety and effectiveness.* ANSI/AAMI ST41:1999. Arlington (VA): AAMI, 1999. American National Standard.

Association for the Advancement of Medical Instrumentation. *Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities.* ANSI/AAMI ST42:1998. Arlington (VA): AAMI, 1998. American National Standard.

Association for the Advancement of Medical Instrumentation. *Steam sterilization and sterility assurance in health care facilities.* ANSI/AAMI ST46:2002. Arlington (VA): AAMI, 2002. American National Standard.

Association for the Advancement of Medical Instrumentation. *Table-top steam sterilizers.* ANSI/AAMI ST55:2003. Arlington (VA): AAMI, 2003. American National Standard.

Association for the Advancement of Medical Instrumentation. *Chemical sterilization and high-level disinfection in health care facilities.* ANSI/AAMI ST58:2005. Arlington (VA): AAMI, 2005. American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Chemical indicators—Part 1: General requirements.* ANSI/AAMI ST60:1996. Arlington (VA): AAMI, 1996. American National Standard.

Association for the Advancement of Medical Instrumentation. *Processing of reusable surgical textiles for use in health care facilities.* ANSI/AAMI ST65:2000. Arlington (VA): AAMI, 2000. American National Standard.

~~Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Chemical indicators—Part 2: Class 2 indicators for air removal test sheets and packs.* ANSI/AAMI ST66:1999. Arlington (VA): AAMI, 1999. American National Standard.~~

Association for the Advancement of Medical Instrumentation. *Containment devices for reusable medical device sterilization.* ANSI/AAMI ST77:2005 ~~(proposed)~~. Arlington (VA): AAMI, 2005. ~~Proposed~~ American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes.* ANSI/AAMI/ISO 11138-3:2006. Arlington (VA): AAMI, 2006. American National Standard.

Association for the Advancement of Medical Instrumentation. *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities*. AAMI TIR12:2004. Arlington (VA): AAMI, 2004. AAMI Technical Information Report.

Association for the Advancement of Medical Instrumentation. *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.* AAMI TIR30:2003. Arlington (VA): AAMI, 2003. AAMI Technical Information Report.

Association of periOperative Registered Nurses. Recommended practices for cleaning and caring for surgical instruments and powered equipment. January 2008~~November 2001~~ Revision. In: ~~*AORN*~~ *Perioperative standards and recommended practices~~, and guidelines~~.* Denver: AORN, 2008~~5~~a.

Association of periOperative Registered Nurses. Recommended practices for environmental cleaning in the surgical practice setting. January 2008~~December 2002~~ Revision. In: ~~*AORN*~~ *Perioperative standards and recommended practices~~, and guidelines~~*. Denver: AORN, 2008~~5~~b.

Association of periOperative Registered Nurses. Recommended practices for selection and use of packaging systems for sterilization. November~~December~~ 2006~~0~~ revision. In: ~~*AORN*~~ *Perioperative standards and recommended practices~~, and guidelines~~*. Denver: AORN, 2008~~5~~c.

Association of periOperative Registered Nurses. Recommended practices for sterilization in the perioperative practice setting~~s~~. January 2008~~August 1999~~ revision. In: ~~*AORN*~~ *Perioperative standards and recommended practices~~, and guidelines~~.* Denver: AORN, 2008~~5~~d.

Association of periOperative Registered Nurses. Recommended practices for surgical attire. November 2004 revision. In: ~~AORN~~ *Perioperative standards and recommended practices~~, and guidelines~~.* Denver: AORN, 2008~~5~~e.

Association of periOperative Registered Nurses. Recommended practices for traffic patterns in the perioperative practice setting. November~~February~~ 2005~~0~~ revision. In: ~~*AORN*~~ *Perioperative standards and recommended practices~~, and guidelines~~.* Denver: AORN, 2008~~5~~f.

Baier M, Schwarz A, Mielke M. Activity of an alkaline “cleaner” in the inactivation of the scrapie agent. *J Hosp Infect* 57:80–84, 2004.

Baron H, Safar J, Groth D, Dearmond SJ, and Prusiner SB. Prions. In: Block SS (ed.). *Disinfection, sterilization, and preservation.* 5th ed. Philadelphia: Lippincott Williams & Wilkins, 2001, pp. 659–674.

Baumgardner CA, et al. Effects of nail polish on microbial growth on fingernails. *AORN J,* 58:84–88, 1993.

Bernoulli C, Siegfried J, Baumgartner G, et al. Danger of accidental person-to-person transmission of Creutzfeldt-Jakob disease by surgery. *Lancet,* I (8009):478–9, 1977.

Block SS. *Disinfection, sterilization, and preservation.* 3rd ed. Philadelphia: Lea and Febiger, 1983.

Block SS. *Disinfection, sterilization, and preservation.* 5th ed. Philadelphia: Lippincott Williams & Wilkins 2001.

Bradley DW. Transmission, etiology, and pathogenesis of viral hepatitis non-A, non-B, in nonhuman primates. In: CHISARI F. (ed.) *Advances in hepatitis research.* New York: Masson Publishing, USA, Inc., 1984, pp. 268–80.

Brown P. Environmental causes of human spongiform encephalopathy. In: Baker H, and Ridley RM (eds.). *Methods in molecular medicine: prion diseases.* Totowa (NJ): Humana Press, 1996, pp. 139–54.

Brown P, Preece M, Brandel J-P, et al. Iatrogenic Creutzfeldt-Jakob disease at the millenium. *Neurol*, 5:1075–81, 2000.

Brown S, Merritt K, Woods T, Busick D. Effects on instruments of the World Health Organization-recommended protocols for decontamination after possible exposure to transmissible spongiform encephalopathy-contaminated tissue. *J Biomed Materials Research, Part B: Applied Biomaterials*, September 24, 2004. http://www3.interscience.wiley.com/cgi-bin/jhome/96516924.

Canadian Standards Association. *Decontamination of reusable medical devices:* CSA Z314.8-00 (R2005). Ontario, Canada: CSA, 2001(R2005).

Canadian Standards Association. *Effective sterilization in health care facilities by the steam process.* CSA Z314.3. Ontario, Canada: CSA, 2001.

Canadian Standards Association. *Selection and use of rigid sterilization containers.* CSA Z314.14. Ontario, Canada: CSA, 2004.

Centers for Disease Control. Recommendations for prevention of HIV transmission in healthcare settings. *Morbidity and Mortality Weekly Report (MMWR),* 36:10S–11S, 21 August 1987.

Centers for Disease Control. Surveillance for Creutzfeldt-Jakob disease: United States. *Morbidity and Mortality Weekly Report (MMWR),* 45:665–8, 1996.

Centers for Disease Control and Prevention. Guideline for hand hygiene in health-care settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *Morbidity and Mortality Weekly Report (MMWR),* 51(RR16):1–44, 2002a.

Centers for Disease Control and Prevention. Probable variant Creutzfeldt-Jakob disease in a U.S. resident – Florida. *Morbidity and Mortality Weekly Report (MMWR),* 51(41):927–9, 18 October 2002b.

Centers for Disease Control and Prevention. *Guidelines for infection control in dental health-care settings – 2003. Morbidity and Mortality Weekly Report (MMWR),* 52(RR-17), 19 December 2003a.

Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *Guidelines for environmental infection control in health-care facilities.* CDC, 2003b.

Chan-Myers H, McAlister D, and Antonoplos P. Natural bioburden levels detected on rigid lumened medical devices before and after cleaning. *Amer J Infect Control,* 25:471–6, 1997.

Committee for European Standardization. *Reusable sterilization containers for steam sterilizers conforming to EN 285. Requirements and test methods.* EN 868–8:1999. CEN, 1999.

Davidson CA, Griffith CJ, Peters AC, and Fielding LM. Evaluation of two methods for monitoring surface cleanliness—ATP bioluminescence and traditional hygiene swabbing. *Luminescence*, 14:33–38, 1999.

DeBruijn ACP, Orzechowski TJH, and Wassernaar C. Validation of the ninhydrin swab test to monitor cleaning of medical instruments. *Zentr Steril,* 9:235–47, 2001.

DeGrott-Kosolcharoen J and Jones JM. Permeability of latex and vinyl gloves to water and blood. *Amer J Infect Control*, 17(4):196–201, 1989.

Deutsche Institut fur Normalisation. *Sterilization ; steam sterilizers ; operating of big sterilizers.* DIN 58946-6. Berlin: DIN, 1990.

Donlan RM. Biofilms: Microbial life on surfaces. *Emerging Infectious Diseases*, 8(9):881–90, 2002.

Favero MS. Current issues in hospital hygiene and sterilization technology. *J Infect Control (Asia Pacific),*1:8–10, 1998.

Favero M and Bond W. Chemical disinfection of medical surgical material. In: Block SS. (ed.). *Disinfection, sterilization, and preservation.* 5th ed. Philadelphia: Lippincott, Williams & Wilkins, 2001, pp. 881–917.

Fengler TW, Pahlke H, Bisson S, and Michels W. Are processed surgical instruments free of protein? *Central Service,* 9:27–32, 2001.

Fichet G, Comoy E, Duval C, Antlogo K, Dehen C, Charbonnier A, McDonnell G, Brown P. Novel methods for disinfection of prion-contaminated medical devices. *Lancet* 364:521–6, 2004.

Garner JS and Favero MS. *Guideline for handwashing and hospital environmental control, 1985.* Atlanta: Centers for Disease Control, 1985.

Garner JS and Healthcare Infection Control Practice Advisory Committee (HICPAC). Guideline for isolation precautions in hospitals. *Amer J Infec Control*, 24:24–52, 1996.

Geertsma RE and Asten JAAM van. Sterilization of prions – requirements, implications, complications. *Zentr Steril,* 3:385–94, 1995.

Holland SP, Morck DW, and Lee TL. Update on toxic anterior segment syndrome. *Current Opinion in Ophthalmology,* 18(1):4–8, February 2007.

Ho DD, Moudgil T, and Alam M. Quantitation of human immunodeficiency virus type 1 in the blood of infected persons. *N Eng J Med,* 321(24):1621–25, December 1989.

International Association of Healthcare Central Service Materiel Management. *Central service technical manual.* 7th ed. Chicago: IAHCSMM, 2007.

International Organization for Standardization. *Sterilization of health care products – Requirements for validation and routine control of moist heat sterilization in health care facilities.* ISO 13683. Geneva: ISO, 1996.

Jeanes A and Green J. Nail art: A review of current infection control issues. *J Hosp Infect*, 249:139–142, 2001.

Joint Commission~~ on Accreditation of Healthcare Organizations~~. *2008~~5~~ Comprehensive accreditation manual for hospitals: The official handbook (CAMH).* Chicago: Joint Commission~~CAHO~~, 2007~~5~~.

Joslyn L. Sterilization by heat. In: Block SS. (ed.). *Disinfection, sterilization, and preservation.* 3rd ed. Philadelphia: Lea & Febiger, 1983, pp. 3–46.

Kirk B. Noncondensable gases (NCG) in the steam supply of a sterilizer. *Zentral Sterilisation*, 9(5): 317–34, 2001.

Krizek TJ and Robson MC. Evolution of quantitative bacteriology in wound management. *Amer J Surg*, 13):579–84, 1975.

Kruger S. Testing the cleaning efficacy in decontamination equipment. *Zentr. Steril.*, 5:332–44, 1997.

Lee S. Steam sterilization: Troubleshooting wet pack problems. In: Reichert M and Young JH. *Sterilization technology for the health care facility.* 2nd ed. Chapter 18. Gaithersburg (MD.): Aspen Publications, 1997.

Llewelyn CA, Hewitt PE, Knight RS, et al. Possible transmission of variant Creutzfeldt-Jakob disease by blood transfusion. *Lancet*, 363:417–21, 2004.

Malkin J. *Medical and dental space planning: A comprehensive guide to design, equipment and clinical procedures.* 3rd ed. New York: John Wiley & Sons, 2002.

Mamalis N, Edelhauser HF, Dawson DG, Chew J, LeBoyer RM, and Werner L. Toxic anterior segment syndrome. *J Cataract Refract Surg,* 32(2):324–333, 2006.

Merritt K, Hitchins VM, and Brown SA. Safety and cleaning of medical materials and devices. *J Biomed Material Research (Applied Biomaterials)*, 53:131–6, 2000.

National Fire Protection Association. *Installation of sprinkler systems.* NFPA 13. Quincy (MA): NFPA, 2002~~1999~~.

Occupational Safety and Health Administration. Eye and face protection standard. *Code of Federal Regulations,* Title 29, 1910.133.

Occupational Safety and Health Administration. Medical and first aid standard. *Code of Federal Regulations,* Title 29, 1910.151.

Occupational Safety and Health Administration. Air contaminants. *Code of Federal Regulations,* Title 29, Part 1910.1000.

Occupational Safety and Health Administration. Occupational exposure to blood-borne pathogens. *Code of Federal Regulations,* Title 29, 1910.1030.

Occupational Safety and Health Administration. Occupational exposure to ethylene oxide. *Code of Federal Regulations,* Title 29, Part 1910.1047.

Occupational Safety and Health Administration. Occupational exposure to formaldehyde. *Code of Federal Regulations,* Title 29, Part 1910.1048.

Perkins JJ. *Principles and methods of sterilization in health sciences.* 2nd ed. Springfield (IL): Charles C Thomas, 1969.

Porteous J. Artificial nails: Very real risks. *Canad OR Nurs J,* 20(3):16–17, 20-21, 2002.

Race RE and Raymond GJ. Inactivation of spongiform encephalopathy (prion) agents by Environ LpH. *J Virol*, 78:2164–65, 2004.

Rea MS. (ed.). *Lighting handbook: Reference and application.* 8th ed. New York: Illuminating Engineering Society of North America, 1993. (Reprinted 1995. Most corrections that were submitted to the IESNA by August 1, 1994, were included in this printing.)

Reichert M and Young JH. *Sterilization technology for the health care facility.* 2nd ed. Gaithersburg (MD): Aspen Publishing, 1997.

Rutala WA. APIC guideline for selection and use of disinfectants. *Amer J Infec Control*, 24:313–42, 1996.

Rutala WA,, and Weber DJ. Creutzfeldt-Jakob disease: Recommendations for disinfection and sterilization. *Clin Infect Diseases*, 32:1348–56, 2001.

Salman L, et al. Banning artificial nails from health care settings. *Amer J Infect Control*, 30:252–4, 2002.

Shikata T., et al. Hepatitis B antigen and infectivity of hepatitis B virus. *J Infec Diseases,* 136(4):571–6, 1977.

Soule BM. (ed.) *The APIC curriculum for infection control practice.* Vol. 1. Washington (DC): Association for Professionals in Infection Control and Epidemiology, 1983.

Spaulding EH. Chemical disinfection and antisepsis in the hospital. *J Hosp Res*, 9:5–31, 1972.

Stanier RY, Adelberg EA, and Ingraham JL. *The microbial world.* 4th ed. Englewood Cliffs (NJ): Prentice-Hall, 1976.

U.K. Advisory Committee on Dangerous Pathogens and Spongiform Encephalopathy. *Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection.* December 15, 2003.

U.S. Food and Drug Administration. *Labeling reusable medical devices for reprocessing in health care facilities.* Rockville (MD): FDA, April 1996a. FDA Reviewer Guidance.

U.S. Food and Drug Administration. *Medical device reporting for user facilities.* Rockville (MD): FDA, 1996b. FDA Guidance.

U.S. Food and Drug Administration. *Medical glove guidance manual*. Rockville (MD): FDA, 1999. Draft FDA Guidance Document.

U.S. Food and Drug Administration. General hospital and personal use devices: Classification of liquid chemical sterilants/high level disinfectants and general purpose disinfectants. *Federal Register,* 65 (111):36324–26, June 8, 2000a.

U.S. Food and Drug Administration. *Content and format of premarket notification [510(k)] submissions for liquid chemical sterilants/high level disinfectants.* January 3, 2000. Rockville (MD): FDA, 2000b.

U.S. Food and Drug Administration. *Guidance for industry and for FDA staff—Enforcement priorities for single-use devices reprocessed by third parties and hospitals.* FDA, August 14, 2000c. FDA Guidance.

U.S. Food and Drug Administration. Boiler water additives. *Code of Federal Regulations,* Title 21, Part 173.310.

U.S. Food and Drug Administration. Labeling. *Code of Federal Regulations,* Title 21, Part 801.

U.S. Food and Drug Administration. Medical devices; Adequate directions for use. *Code of Federal Regulations,* Title 21, Part 801.5.

U.S. Food and Drug Administration. Medical device reporting. *Code of Federal Regulations,* Title 21, Part 803.

U.S. Food and Drug Administration. Quality system regulation. *Code of Federal Regulations,* Title 21, Part 820.

U.S. Postal Service. *Domestic mail manual.* Issue 52. Washington (DC): U.S. Government Printing Office, 1999.

Verjat D, Prognon P, and Darbord JC. Fluorescence-assay on traces of protein on reusable medical devices: cleaning efficiency. *Internat J Pharmaceutics*, 179:267–71, 1999.

Waters TR, Putz-Anderson V, Garg A. *Applications manual for the revised NIOSH lifting equation.* Section I. DHHS (NIOSH) Publication No. 94-110. U.S. Department of Health and Human Services, 1994.

World Health Organization. *WHO infection control guidelines for transmissible spongiform encephalopathies.* WHO/CDS/CSR/APH/2000.3. Report of a WHO Consultation, 23-26 March 1999. Geneva: World Health Organization, 2000.

Yan Z, Stitz L, Heeg P, et al. Infectivity of prion protein bound to stainless steel wires: a model for testing decontamination procedures for transmissible spongiform encephalopathies. *Infect Control Hosp Epidemiol* 25:280–3, 2004.

Zuhlsdorf B, Emmrich M, Floss H, and Martiny H. Cleaning efficacy of nine different cleaners in a washer-disinfector designed for flexible endoscopes. *J Hosp Infect,* 52:206–11, 2002.

O~~N~~.2 For further reading

Alfa MJ, Olson N, DeGagne P, and Jackson M. Evaluation of rapid readout biological indicators for 132 °C vacuum-assisted steam sterilization cycles using a new automated fluorescent reader. *Infect Control Hosp Epidemiol*, 23(7):388–92, 2002.

Alvarado CJ and Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. *Amer J Infect Control,* 28(2):138–55, 2000.

American Dental Association. Infection control recommendations for the dental office and dental laboratory. *JADA,* 127(5):672–80, 1996.

~~American Society for Healthcare Central Service Professionals. *Training manual for central service technicians.* Chicago: American Hospital Association, 1997.~~

AOAC International. *Official methods of analysis of AOAC International.* 17th ed. Washington (DC): AOAC International, 2000.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Biological indicators—Part 1: General.* ANSI/AAMI ST59:1999. Arlington (VA): AAMI, 1999. American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products--Chemical indicators—Guidance for the selection, use, and interpretation of results.* 3rd ed. ANSI/AAMI/ISO 15882:2003. Arlington (VA): AAMI, 2003. American National Standard.

Association for the Advancement of Medical Instrumentation. *Selection and use of protective apparel and drapes in health care facilities.* AAMI TIR11:2005*.* Arlington (VA): AAMI, 2005. AAMI Technical Information Report.

Aycliffe GAJ. Equipment-related infection risks. *J Hosp Infect*, 11 (Suppl. A):279–84, 1988.

Baxter HC, Campbell GA, Whittaker AG, et al. Elimination of transmissible spongiform encephalopathy infectivity and decontamination of surgical instruments by using radio-frequency gas-plasma treatment *J Gen Virol* , 86:2393–99, 2005.

Bennett JV and Brachman PS. (eds.) *Hospital infections.* Boston/Toronto: Little, Brown and Company, 1986.

Block SS. *Disinfection, sterilization, and preservation.* 4th ed. Philadelphia: Lea and Febiger, 1991.

Bowie H, Kelsey JC, and Thompson GR. The Bowie and Dick autoclave tape test. *Lancet,* I:586–7, 1963a.

Bowie H, Kelsey JC, and Thompson GR. The Bowie and Dick autoclave tape test. *Lancet,* II:1215*,* 1963b.

Burlew J. *Care and handling of ophthalmic microsurgical instruments.* 2nd ed. San Francisco (CA): American Society of Ophthalmic Registered Nurses, 2006.

Centers for Disease Control and Prevention. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. *Morbidity and Mortality Weekly Report (MMWR),* 50(RR-11), 29 June 2001.

Cole EC, Rutala WA, Nessen L, Wannamaker NS, and Weber DJ. Effects of methodology, dilution, and exposure time on the tuberculocidal activity of glutaraldehyde-based disinfectants. *Appl Envir Microbiol,* 56(6):11813–17, 1990.

Danielson NE. *Ethylene oxide use in hospitals: A manual for health care personnel*. 3rd ed. Chicago: American Society for Healthcare Central Service Professionals of the American Hospital Association, 1998.

Graham GS. Decontamination: A microbiologist's perspective. *J Healthcare Matl Mgmt,* 6(1):36–41, 1988.

~~International Association of Healthcare Central Service Materiel Management. *Central service technical manual.* 5th ed. Chicago: IAHCSMM, 1998.~~

Jackson GS, McKintosh E, Flechsig E, et al. An enzyme-detergent method for effective prion decontamination of surgical steel. *J Gen Virol*, 86: 869–78, 2005.

Jordan SLP. The correct use of glutaraldehyde in the healthcare environment. *Gastroenterology Nursing,* 18:142–45, 1995.

Kelsey JC. The testing of sterilizers. *Lancet,* I:306, 1958.

Kelsey JC. Notes on steam sterilization. *Lancet,* II:1149, 1964.

Kelsey JC. The Bowie-Dick test. *Lancet,* II:911–12, 1966, vol. II.

Knieler R. Manual cleaning and disinfection of flexible endoscopes—an approach to evaluating a combined procedure. *J Hosp Infect,* 48(suppl):S84–S87, 2001.

Lanphear BP. Trends and patterns in the transmission of blood-borne pathogens to health care workers. *Epidemiologic Reviews,* 16(2):437–47, 1994.

Lemmer K, Mielke M, et al. Decontamination of surgical instruments from prion proteins: In vitro studies on the detachment, destabilization, and degradation of PrP^{Sc} bound to steel surfaces. *J Gen Virol*, 85:3805–16, 2004.

McCormick P, Finocchario C, Manchester R, et al. Qualification of a rapid readout biological indicator with moist heat sterilization. *PDA J Pharmaceutical Science and Technol*, 57(1):25–31, 2003.

Occupational Safety and Health Administration. Hazard communication standard. *Code of Federal Regulations*, Title 29, Part 1910.1200.

Peretz D, Supattapone S, Giles K, et al. Inactivation of prions by acidic sodium dodecyl sulfate. *J Virol.* 80:322–31, 2006.

Pflug IJ, and Schmidt CF. Thermal destruction of microorganisms. In: Block SS. (ed.) *Disinfection, sterilization, and preservation.* 2nd ed. Philadelphia: Lea & Febiger, 1968.

Russell AD. Bacterial spores and chemical sporicidal agents. *Clin Microbiol Reviews*, 3(2):99–119, 1990.

Rutala WA. Disinfection, sterilization, and waste disposal. In: Wenzel RP. (ed.). *Prevention and control of nosocomial infections.* Baltimore: Williams and Wilkins, 1987.

Rutala WA, Cole EC, Wannamaker NS, and Weber DJ. Inactivation of *Mycobacterium tuberculosis* and *Mycobacterium bovis* by 14 hospital disinfectants. *Amer J Med,* 91(3B):267S–271S, 1991a.

Rutala WA, Clontz EP, Weber DJ, and Hoffman KK. Disinfection practices for endoscopes and other semicritical items. *Infect Control and Hosp Epidemiol*, 12:282–88, 1991b.

Rutala WA, Gergen MF, and Weber DJ. Evaluation of a rapid readout biological indicator for flash sterilization with three biological indicators and three chemical indicators. *Infect Control and Hosp Epidemiol*, 14(7):390–93, 1993.

Rutala WA, Jones SM, and Weber DJ. Comparison of a rapid readout biological indicator for steam sterilization with four conventional biological indicators and five chemical indicators. *Infect Control and Hosp Epidemiol,* 17(7):423–82, 1996.

Rutala WA, Stiegel MM, Sarubbi FA, and Weber DJ. Susceptibility of antibiotic-susceptible and antibiotic-resistant hospital bacteria to disinfectants. *Infect Control and Hosp Epidemiol*, 18:417–21, 1997.

Society of Gastroenterology Nurses and Associates. *Standards of infection control in reprocessing of flexible gastrointestinal endoscopes.* Washington (DC): SGNA, 2000.

U.S. Food and Drug Administration. *Guidance on premarket notification [510(k)] submissions for sterilizers intended for use in health care facilities.* March 1993. Rockville (MD): FDA, 1993.

U.S. Pharmacopeial Convention. *United States Pharmacopeia 2000.* Vol. 24, Easton (PA): Mack Publishing Co., 2000.

Vesley D, Langholz AC, Rohlfling SR, and Foltz WE. Fluorimetric detection of a *Bacillus stearothermophilus* spore-bound enzyme, alpha-D-glucosidase, for rapid indicator of flash sterilization failure. *Applied & Environ Microbiol*, 58(2):717–19, 1992.

Vesley D, Nellis MA, and Allwood PB. Evaluation of a rapid readout biological indicator for 121 °C gravity and 132 °C vacuum-assisted steam sterilization cycles. *Infect Control and Hosp Epidemiol,* 16(5):281–86, 1995.