American National Standard

ANSI/AAMI ST79:2010 & A1:2010
(Consolidated Text)

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

Association for the Advancement
of Medical Instrumentation

Objectives and uses of AAMI standards and recommended practices

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

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

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

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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(Revision of ANSI/AAMI ST79:2006 and
A1:2008 & A2:2009)

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

Developed by
Association for the Advancement of Medical Instrumentation

Approved 4 August 2010 by
Amendment 1 Approved 24 September 2010 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: ambulatory care facilities, cleaning, continuous quality improvement, decontamination, dental office, flash sterilization, moist heat sterilization, packaging, quality control, quality system, saturated steam, sterile storage, sterilization containers, surgical instruments, table-top sterilizers

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Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Dr., Suite 301
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 1–57020–389–X

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International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation. The code in the US column, "(R)20xx" indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

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 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005 and ANSI/AAMI ES60601-1:2005/A2:2010 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003/(R)2010	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/ C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2010	ANSI/AAMI/ISO 8637:2010	Identical
ISO 8638:2010	ANSI/AAMI/ISO 8638:2010	Identical
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:2009	ANSI/AAMI/ISO 10993-9:2009	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	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 10993-16:2010	ANSI/AAMI/ISO 10993-16:2010	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical

International designation	U.S. designation	Equivalency
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006/(R)2010	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/(R)2010	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006/(R)2010	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006/(R)2010	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006/(R)2010	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006/(R)2010	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005/(R)2010	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 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14708-5:2010	ANSI/AAMI /ISO 14708-5:2010	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	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 15223-2:2010	ANSI/AAMI/ISO 15223-2:2010	Identical
ISO 15225:2010	ANSI/AAMI/ISO 15225:2010	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
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 (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	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/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 27186:2010	ANSI/AAMI/ISO 27186:2010	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	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 this recommended practice was published, the **AAMI Steam Sterilization Hospital Practices Working Group** had the following members:

Cochairs:
Ramona Conner, RN, MSN, CNOR
Cynthia Spry, RN, MSN, CNOR

Members:
Loran H. Bruso, BS MBA, Steritec Products Manufacturing Co. Inc.
Kathy M. Bury, INOVA Alexandria Hospital
Bradley J. Bushman, Standard Textile Co. Inc.
Mike Carragher, Getinge USA
Edward P. Casey, CSPDM, The Hospital of Central Connecticut
Bradley J. Catalone, PhD, Olympus America Inc.
Harriet Chan-Myers, Johnson & Johnson
David Chapman, Roche Molecular Systems
Marc Chaunet, TSO3 Inc.
Nancy Chobin, RN, CSPDM, St. Barnabas Health Care System
Ramona Conner, RN, MSN, CNOR, Association of Perioperative Registered Nurses
Jacqueline Daley, Association for Professionals in Infection Control and Epidemiology
Diana Davis, Brunswick Community Hospital
Michele Dawn Demeo, CRCST, CSPDT, Memorial Hospital
Shawn A. Doyle, Sterilator Company Inc.
Mark Duro, New England Baptist Hospital
Betty D. Edge, Northshore University Hospital
Rosie Fardo, RN, BSN, CIC, CHSP, Department of Veterans Affairs Medical Center
Jeff Felgar, Zimmer Inc.
Marcia Ann Frieze, Case Medical Inc.
Charles Oren Hancock, RAC, H&W Technology LLC
Barbara Ann Harmer, RN, BSN, MHA
Jennifer Harte, DDS, MS, American Dental Association
Rachel Hill, CareFusion
Charles A. Hughes, SPS Medical Supply Corp
David M. Jagrosse, Middlesex Hospital
Nupur Jain, Stryker Instruments Division
Nyla Skee Japp, PhD, RN, CSPDM, Integrated Medical Systems
David W. Johnson, Kimberly-Clark Corporation
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service Materiel Management
Colleen Patricia Landers, RN, Canadian Standards Association
Mary Kneece Lane, BS, MHA, CSPDS, CSPDM, The Medical University of South Carolina
Angela M. Lewellyn, LPN, CSPDT, CRCST, Advantage Support Services, Inc.
Chris Mannarino, Belimed Inc.
Teckla A. Maresca, LPN, CSPDM, St. Clare's Health System
Ruby Martinez, Cardinal Health (MP&S)
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Candace McManus, PhD, FDA/CDRH
Emily Mitzel, MS, Nelson Laboratories Inc.
Thomas K. Moore
Karen Nauss, CRCST, Mount Auburn Hospital
Scott Pignatella
Janet M. Prust, 3M Healthcare
Shaundrea L. Rechsteiner, NAMSA
Cheron Rojo, Childrens Hospital of Central California
Wendy Royalty, Raven Biological Laboratories
Rose E. Seavey, RN, MBA, CNOR, CRCST, Seavey Healthcare Consulting, Inc.

Andrew Sharavara, PhD, Propper Manufacturing Co. Inc.
Frank Sizemore, Wake Forest Univeristy - Baptist Medical Center
Linda Slone, RN, BSPA, CNOR
Joan M. Spear, Aesculap Inc.
Cynthia Spry, RN, Independent Clinical Consultant
Betty Strickland, Pryce Consultants
Donna Swenson, BS, CSPDM, West Suburban Medical Center
Mary Velasco, Henry Ford Macomb Hospital
P. Richard Warburton, ChemDAQ Inc.
Nora E. Wikander, RN, CSPDM, St. Joseph's Wayne Hospital, Wayne, NJ

Alternates:
Denise Adams, Aesculap Inc.
Richard P. Blasko, Steris Corporation
Annette Bojanski, Raven Biological Laboratories
Laureen C. Clark, M.T., Kimberly-Clark Corporation
Linda Clement, CRCST, Steris Corporation
Julie M. Conyer, Bausch & Lomb Inc.
Susan Flynn, 3M Healthcare
Joel R. Gorski, PhD, NAMSA
Thomas Grobaski, Belimed Inc.
Peter Hudnut, Getinge USA
Danny Hutson, CareFusion
Stephen M. Kovach, Healthmark Ind Co. Inc.
Natalie Lind, International Association of Healthcare Central Service Materiel Management
Tania Lupu, Case Medical Inc.
Sheila A. Murphey, FDA/CDRH
Charles D. Paige, Department of Veterans Affairs National Center for Patient Safety
Mahesh Patel, Propper Manufacturing Co. Inc.
Jason Pope, Nelson Laboratories Inc.
Elizabeth A. Riegel, FDA/CDRH
Kristen Singleton, PhD, Steritec Products Manufacturing Co. Inc.
Gary J. Socola, SPS Medical Supply Corp.
R. Brent Sweet, Zimmer Inc.
Raymond Taurasi, Healthmark Ind. Co. Inc.
Jeff Teeter, CareFusion
Martha Young, 3M Healthcare

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.

AAMI Sterilization Standards Committee

Cochairs:
Victoria M. Hitchins, PhD
William E. Young

Members:
Trabue D. Bryans, WuXi AppTec
Peter A. Burke, PhD, Steris Corporation
Nancy Chobin, RN, CSPDM, St. Barnabas Health Care System
Charles Cogdill, Boston Scientific Corporation
Ramona Conner, RN, MSN, CNOR, Association of Perioperative Registered Nurses
Jacqueline Daley, Association for Professionals in Infection Control and Epidemiology
Kimbrell Darnell, CR Bard
Dave Dion, Cardinal Health (MP&S)
Lisa Foster, Sterigenics International
Joel R. Gorski, PhD, NAMSA
Deborah A. Havlik, Hospira Worldwide Inc.
Victoria M. Hitchins, PhD, FDA/CDRH
Lois Atkinson Jones, MS
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service Materiel Management
Byron J. Lambert, PhD, Abbott Laboratories
Colleen Patricia Landers, RN, Canadian Standards Association
Lisa N. Macdonald, Becton Dickinson & Company

Jeff Martin, Alcon Laboratories Inc.
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Rainer Newman, Johnson & Johnson
Janet M. Prust, 3M Healthcare
Nancy Rakiewicz, Ethox International Inc.
Michael H. Scholla, Dupont Nonwovens
Mark Seybold, Baxter Healthcare Corporation
Andrew Sharavara, PhD, Propper Manufacturing Co. Inc.
Mark N. Smith, Getinge USA
William N. Thompson, Covidien
James L. Whitby, MA, MB, FRCPt
Martell Kress Winters, BS, SM, Nelson Laboratories Inc.
William E. Young

Alternates:
Lloyd Brown, Covidien
Glenn W. Calvert, Becton Dickinson & Company
Steven J. Elliott, WuXi AppTec
Thomas J. Frazar, Johnson & Johnson
Kathy Hoffman, Sterigenics International
Jim Kaiser, Bausch & Lomb Inc.
Joseph J. Lasich, BS, Alcon Laboratories Inc.
Natalie Lind, International Association of Healthcare Central Service Materiel Management
Reynaldo Lopez, Cardinal Health (MP&S)
Ralph Makinen, Boston Scientific Corporation
Mary S. Mayo, CR Bard
David Ford McGoldrick, BS, Abbott Laboratories
Jerry R. Nelson, PhD, Nelson Laboratories Inc.
Karen Polkinghorne, Dupont Nonwovens
Mike Sadowski, Baxter Healthcare Corporation
John R. Scoville, Jr., Steris Corporation
Jason Voisinet, Ethox International Inc.
Craig A. Wallace, 3M Healthcare
Valerie Welter, Hospira Worldwide Inc.

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Acknowledgments

The AAMI Steam Sterilization Hospital Practices Working Group gratefully acknowledges the important contributions of both current and former Working Group members, who have been instrumental in preparing the first edition of this document, the 2008 and 2009 amendments, and this editorial revision, which offers users a comprehensive document on steam sterilization practices. The continuous maintenance process, which keeps this document current, demands a great deal of Working Group members' time, and all involved have willingly donated their time and expertise. The Working Group also gratefully acknowledges Judy Veale, the AAMI staff liaison who was invaluable in keeping this document, and the Working Group, on track through the amendment and revision process.

Foreword

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

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

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

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

In 2008 and 2009, numerous amendments of the document were adopted as part of the AAMI continuous maintenance process. These amendments addressed such topics as toxic anterior segment syndrome (TASS), paper−plastic pouches, steam quality, devices with lumens, chemical indicators, sterilization process failures, product families, evaluation of sterilization container systems, risk analysis, and verification of cleaning. This second edition of ANSI/AAMI ST79 incorporates these amendments, as well as additional changes in the provisions regarding steam quality. In addition, the document reflects general editorial revisions (e.g., updating of references).

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

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

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

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

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 http://www.aami.org/standards/st79.registry.html. Suggestions for improving this recommended practice are invited. Comments or proposals for revisions to any part of the standard may be submitted to AAMI at any time. Written comments are to be sent to: Standards Dept., AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633. Comments may also be e-mailed to: standards@aami.org.

NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79 and ST79/A1), but it does provide important information about the development and intended use of the document.

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

Introduction: Need for the recommended practice

Overview:

Saturated steam under pressure is one of the oldest methods used in health care facilities to sterilize medical devices. Because this method has been available for so many years, it is thought to be a simple process, one that is well understood and controlled. However, the efficacy of any sterilization process, including saturated steam, depends on a consistent system for lowering and limiting bioburden before sterilization, properly preparing items for sterilization, selecting the appropriate sterilization parameters, and establishing and implementing controls to maintain the sterility of sterilized items until they are used. These four phases are critically interdependent, and each must be accomplished to produce and maintain a sterile product.

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

a) efficient facility design,

b) proper training of personnel,

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

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

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

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

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

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

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

This recommended practice encompasses steam sterilization in all health care facilities, including ambulatory-care and office-based facilities. It covers steam sterilization by both the wrapped and unwrapped (flash) methods and provides detailed guidance on decontamination and packaging, with special reference to rigid sterilization container systems.

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

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

Flash sterilization:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Implantables should not be flash-sterilized (CDC, 2008). The possible consequences to the patient from placing even a minimally contaminated device in an essentially avascular environment and leaving it there at the conclusion of the procedure are potentially severe. Although the risk of an unrecognized sterilization failure can be minimized if the physical parameters of time, temperature, and pressure are monitored and recorded and the results examined after each cycle, it is recommended that health care personnel quarantine implantable devices and await the outcome of biological monitoring of the cycle before releasing these items for use. Current technology allows for release of loads, even those containing implants, upon obtaining results from the early readout mechanism of a BI designed and labeled for such use. However, this technology does not solve the problems associated with using flash sterilization for implants. Concerns about aseptic transfer remain, especially if the sterilizer does not open directly into the room containing the sterile field where the device will be used or into an area either within or directly adjacent to the procedure room. Careful planning, appropriate packaging (e.g., packaging that allows the user to see the device for sizing and verification of features), and inventory management in cooperation with suppliers can eliminate the need to flash sterilize implantable items. This is a goal that all health care facilities should strive to achieve.

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

Decontamination:

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

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

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

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

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

professional organizations, government agencies, manufacturers of decontamination products and equipment, medical device manufacturers, consultants, and educational speakers. There is clearly a need for consensus guidelines, with supporting rationale, for decontamination processing techniques.

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

Rigid sterilization container systems:

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

1 Scope

1.1 General

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

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

1.2 Inclusions

This recommended practice specifically addresses

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

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

c) processing recommendations;

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

e) quality control; and

f) quality process improvement.

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

1.3 Exclusions

This recommended practice does not cover

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

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

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

d) decontamination of hemodialysis machines, hemodialyzers, and hemodialyzer blood tubing (see ANSI/AAMI RD5, ANSI/AAMI RD47, and ANSI/AAMI/ISO 8638, respectively);

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

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

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

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

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.

NOTES

2 Definitions and abbreviations

For the purposes of this recommended practice, the following definitions apply.

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 bioburden: Population of viable microorganisms on a product and/or a sterile barrier system.

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

2.6 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.

2.7 biological indicators (BIs): Test systems 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.

NOTE 3—See ANSI/AAMI/ISO 14161 for information on the selection, use, and interpretation of biological indicators.

2.8 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.

2.9 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.

2.10 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 pouch suitable for specified sterilization method[s]) to maintain sterility.

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

2.12 CDC: Centers for Disease Control and Prevention.

2.13 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**.

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

2.15 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/ISO 11140-1:2005, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, defines six classes of CIs and specifies performance requirements for them:

Class 1 (process indicators): chemical indicators intended for use with individual units (e.g., packs, containers) to indicate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.

Class 2 (Bowie-Dick test indicators): chemical indicators intended for use in a specific test procedure (e.g., the Bowie-Dick test used to determine if air removal has been adequate in a steam sterilization process).

Class 3 (single-variable indicators): chemical indicators designed to react to one of the critical variables and intended to indicate exposure to a sterilization process at a stated value of the chosen variable.

Class 4 (multi-variable indicators): chemical indicators designed to react to two or more of the critical variables and intended to indicate exposure to a sterilization process at stated values of the chosen variables.

Class 5 (integrating indicators): chemical indicators designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for BIs.

Class 6 (emulating indicators): chemical indicators designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specified sterilization process. ANSI/AAMI/ISO 11140-1 refers to these indicators as cycle verification indicators.

NOTE—See ANSI/AAMI/ISO 15882 for information on the selection, use, and interpretation of chemical indicators.

See also 10.5.2.

2.16 chemical vapor sterilization: Specific sterilization process that uses a solution of alcohol, water, and inert ingredients, with trace formaldehyde (less than 0.25%), which is heated to produce an unsaturated vapor with temperature, pressure, and exposure time within specified limits.

NOTE—Although "chemical vapor" can be taken to refer to gaseous chemical sterilants in general, the term is used here as it is commonly used in the health care community, to refer to a specific process.

2.17 cleaning: Removal of contamination from an item to the extent necessary for further processing or for the intended use.

NOTE—In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent organic and inorganic soil (e.g., blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

2.18 clinical soil: Substance consisting of the inorganic, organic, and biological matter typically found on medical instruments after clinical use.

2.19 container system, rigid sterilization: Sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents.

NOTE—The system generally consists of a bottom or base with carrying handles and a lid that is secured to the base by means of a latching mechanism. A basket or tray to hold instruments or other items to be sterilized is placed inside. A filter or valve system is incorporated into the lid and/or base to provide for air evacuation and sterilant penetration during the sterilization cycle and to act as a barrier to microorganisms during storage, handling, and transport.

2.20 containment device: Reusable rigid sterilization container, instrument case, cassette, or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization.

2.21 contaminated: State of having been actually or potentially in contact with microorganisms.

NOTE—As used in health care, the term generally refers to microorganisms that could be capable of producing disease or infection.

2.22 culture: Growth of microorganisms in or on a nutrient medium that supports their multiplication; to grow microorganisms in or on such a medium.

2.23 culture medium: Substance or preparation used to grow and cultivate microorganisms.

2.24 cycle, steam sterilization, dynamic-air-removal type: One of two types of sterilization cycles in which air is removed from the chamber and the load by means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure-pulse [SFPP] cycle).

NOTE 1—The dynamic-air-removal cycle is generally preferred to a gravity-displacement cycle because of more efficient air removal, a shorter exposure time at higher temperatures, and a vacuum drying phase, resulting in an overall reduction in cycle time.

NOTE 2—Typical operating temperatures are 132°C to 135°C (270°F to 275°F).

2.25 cycle, steam sterilization, gravity-displacement type: Type of sterilization cycle in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber.

NOTE—Typical operating temperatures are 121°C to 123°C (250°F to 254°F) and 132°C to 135°C (270°F to 275°F).

2.26 cycle, sterilization: Defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber. See also **cycle time**.

2.27 cycle time: Total elapsed time of a sterilization cycle from the time the process is initiated until the cycle is completed.

NOTE—Cycle time can include come-up time, exposure time, come-down time, cooling or drying time, and, in prevacuum sterilizers, pre- and post-vacuum time.

2.28 D value: Time or dose required to achieve inactivation of 90% of a population of the test microorganism under stated conditions.

NOTE—The larger the D value, the more resistant the microorganism is to destruction. The value can be derived by plotting the logarithm of the number of microbial survivors against sterilization exposure time; the time corresponding to a 1-logarithm reduction in numbers can then be directly measured.

2.29 decasing/breakout area or space: Unpacking area or space where products are removed from their external shipping containers before being taken into the preparation and packaging area or the sterile storage area.

2.30 decontamination: According to OSHA, “the use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.” [29 CFR 1910.1030]

NOTE—The term is generally used in health care facilities to refer to all pathogenic organisms, not just those transmitted by blood.

2.31 decontamination area: Area of a health care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

2.32 density: Mass per unit of volume.

2.33 disinfection: Process that kills pathogenic and other microorganisms by physical or chemical means.

NOTE—Disinfection destroys most recognized pathogenic microorganisms but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes.

2.34 distilled water: Water that has been heated to the boiling point, vaporized to remove nonvolatile impurities, cooled, condensed into a liquid condensate, and collected so that no impurities are reintroduced.

2.35 drying time: Time required to dry steam-sterilized items before they are handled.

NOTE—As used in relation to gravity-displacement table-top steam sterilizers and sterilizers without active drying, drying time refers to the time that the sterilizer door is left open to complete the drying of sterilized items.

2.36 dust cover: Protective plastic bag used to protect sterile items from environmental contamination such as moisture, dust, and lint; also known as a sterility maintenance cover.

2.37 engineering controls: According to OSHA, “controls (e.g., sharps disposal containers, self-sheathing needles) that isolate or remove the blood-borne pathogens hazard from the workplace.” [29 CFR 1910.1030]

NOTE—More generally, the term also refers to controls that reduce or remove other workplace hazards, such as exposure to toxic chemicals.

2.38 entrainment: Collecting or transporting of solid particles or a second fluid or vapor by the flow of the primary fluid or vapor.

NOTE—As the term is used in sterilization science, entrainment generally refers to the process by which steam can carry residual chamber air or water droplets from the jacket or supply lines into packs or the process by which changes in air pressure can carry environmental contaminants into a package.

2.39 EPA: U.S. Environmental Protection Agency.

2.40 eukaryotic cell: Cell with a true nucleus containing chromosomes. The cells of higher plants and animals, fungi, protozoa, and most algae are eukaryotic.

2.41 expiration date: Date that is calculated by adding a specific period of time to the date of manufacture or sterilization of a medical device or component and that defines its estimated useful life.

2.42 expiration statement: Statement, also known as a day-to-day expiration date, indicating that the contents of a package are sterile indefinitely unless the integrity of the package is compromised.

2.43 exposure control plan: According to OSHA, “a written [plan] designed to eliminate or minimize employee exposure.” [29 CFR 1910.1030]

2.44 exposure time: Period for which the process parameters are maintained within their specified tolerances.

NOTE—In a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

2.45 FDA: U.S. Food and Drug Administration.

2.46 filter, container: Device secured to the rigid sterilization container system lid and/or bottom that serves to allow passage of air and sterilants yet provides a microbial barrier.

NOTE—The filter media could be reusable, disposable, or permanently affixed to the container system.

2.47 filter retention system, container: Mechanism that secures disposable filters in place.

NOTE—The filter retention system could be a retention plate or a retaining ring. It is disengaged to release used filters for disposal and reengaged to secure new filters.

2.48 flash sterilization: Process designed for the steam sterilization of patient care items for immediate use.

NOTE—See also “Introduction: Need for the recommended practice.”

2.49 foot-candle: Standard unit of illumination equivalent to the light produced by one standard candle at a distance of 1 foot.

2.50 gasket, container: Pliable strip that serves as a seal between the lid and the base of a reusable rigid sterilization container to prevent entry of microorganisms.

2.51 Gram-negative bacteria: Bacteria that are decolorized when stained by Gram’s method, but take on the color of the counterstain.

2.52 Gram-positive bacteria: Bacteria that are not decolorized by Gram’s method, but retain the original violet color.

2.53 Gram’s method of staining: Method of differential staining used in microbiological identification. See also Stanier, et al. (1976).

2.54 health care product: Medical device(s), including in vitro diagnostic medical device(s), or medicinal product(s), including biopharmaceutical(s).

2.55 heat sink: Heat-absorbent material; a mass that readily absorbs heat.

2.56 heat-up time: Time required for the entire load to reach the selected sterilizing temperature after the chamber has reached that temperature.

NOTE—Heat-up time is the same as temperature penetration time.

2.57 high-level disinfection: Process that kills all microbial organisms but not necessarily large numbers of bacterial spores.

NOTE—For a process that can be used for both liquid chemical sterilization and high-level disinfection, the contact time for high-level disinfection is shorter than that necessary for sterilization, under otherwise identical conditions.

2.58 huck towel: All-cotton surgical towel with a honeycomb-effect weave.

2.59 implant/implantable device: According to FDA, "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also 'implants.' " [21 CFR 812.3(d)].

2.60 incubator: Apparatus for maintaining a constant and suitable temperature for the growth and cultivation of microorganisms.

2.61 infectious microorganisms: Microorganisms capable of producing disease in the appropriate hosts.

2.62 installation qualification (IQ): Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications.

2.63 intermediate-level disinfection: Process that kills viruses, mycobacteria, fungi, and vegetative bacteria, but not necessarily bacterial spores.

2.64 labeling: Any legend, work, or mark attached to, included in, belonging to, or accompanying any medical device or product.

NOTE—According to FDA, labeling includes any literature provided with a device as well as all advertising claims published by the manufacturer.

2.65 latching mechanism, container: Mechanical device that secures the lid of a reusable rigid sterilization container system to the bottom of the container.

2.66 liquid-proof material: Material historically considered to provide the highest level of barrier protection. According to ANSI/AAMI PB70, a liquid-proof material would be defined as a Level 4 barrier material.

2.67 liquid-resistant material: Material that inhibits the penetration of liquids. According to ANSI/AAMI PB70, a liquid-resistant material would be defined as a Level 1, 2, or 3 barrier material.

2.68 lot control number (load control number): Numbers, letters, or a combination of both, by which a particular group of products can be traced to a particular manufacturing or sterilization operation.

2.69 low-level disinfection: Process that kills most vegetative bacteria, some viruses, and some fungi, but not mycobacteria or bacterial spores.

2.70 lux: Approximately one tenth of a foot-candle.

2.71 master product: (Sterilization) product designated as representative of all members of a product family. This product has the most difficult-to-sterilize attributes of any member of the family.

2.72 medical device: Instrument, apparatus, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;
- investigation, replacement, or modification of the anatomy or of a physiological process; or
- control of conception

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

2.73 medium: See **culture medium**.

2.74 microbicidal process: Process designed to provide a particular level of microbial lethality (kill).

NOTE—Depending on the level of decontamination needed, this process could be a disinfection process or a sterilization process. The type and level of microbial kill achieved depends on factors such as the type and population of microorganisms present, the type of antimicrobial agent, the concentration of the antimicrobial agent, the exposure time, and the exposure temperature. When used for decontamination purposes, a microbicidal process does not necessarily yield an item that is safe for patient use.

2.75 microorganism: Entity of microscopic size, encompassing bacteria, fungi, protozoa, and viruses.

2.76 minimum effective concentration (MEC): "Minimum concentration of a liquid chemical sterilant/high-level disinfectant that achieves the claimed microbicidal activity; the MEC is determined by dose response testing." [FDA, 2000b].

2.77 minimum recommended concentration (MRC): Minimum concentration at which the manufacturer of a liquid chemical sterilant or high-level disinfectant tested the product and validated its performance.

NOTE—The term "minimum effective concentration" (MEC) is sometimes used interchangeably with "minimum recommended concentration." The MRC is not necessarily an MEC as determined by dose response testing.

2.78 muslin: Broad term describing a wide variety of plain-weave cotton or cotton/polyester fabrics having approximately 140 threads per square inch.

2.79 new product: A new product or technology that has been FDA cleared but for which AAMI does not offer guidance for application. See Section 12.

2.80 nonrestricted area: Area where traffic is not limited and where attire is not prescribed.

2.81 nonreturn/nonrecirculating ventilation system: Ventilation system that exhausts 100% of the air supplied to a space to the outside environment.

2.82 occupational exposure: Contact, through inhalation, ingestion, skin contact, or absorption, with a potentially hazardous material during the course of employment. Occupational exposure to hazardous materials, including chemical and biological agents and potentially infectious materials, is regulated by OSHA (29 CFR Part 1910). See Annex H.

NOTE—The OSHA blood-borne pathogens standard (29 CFR 1910.1030) specifically defines occupational exposure as "reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties."

2.83 office-based health care facility: Health care facility designed for short-term treatment of ambulatory patients (e.g., freestanding surgical centers, clinics, and medical and dental offices).

2.84 operational qualification (OQ): Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

2.85 organizing case: Reusable metal or plastic containment device that organizes and protects instruments and components in specified locations within the device, and that is usually wrapped with an approved wrapping material.

2.86 OSHA: Occupational Safety and Health Administration.

2.87 paper–plastic packaging: Single-use packaging, including preformed pouches, with a clear plastic side to permit visibility of the contents and an opaque paper side that can be penetrated by air or steam or other sterilant.

2.88 par level: Optimum supply level, usually applicable to inventory, that is based on predetermined quotas established from usage studies.

2.89 parenteral: Situated or occurring outside of the intestines; injection of substances into the body through any route other than the alimentary canal (e.g., subcutaneous, intravenous, intramuscular, or intrathecal injection).

2.90 pasteurization: Disinfection process using hot water at temperatures of 65°C to 77°C (150°F to 170°F) for a contact time of at least 30 minutes (min).

2.91 performance qualification (PQ): Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

NOTE—As the term is used in health care facilities, PQ is performed by department personnel with normal sterilization loads.

2.92 personal protective equipment (PPE): According to OSHA, "specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment." [29 CFR 1910.1030].

2.93 preconditioned: Held at room temperature (18°C to 24°C [65°F to 75°F]) and at a relative humidity ranging from 30% to 60% for a minimum of 2 hours.

2.94 prions: Transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including scrapie in sheep and goats, bovine spongiform encephalopathy (BSE) in cattle, and Creutzfeldt-Jakob disease (CJD) in humans. They are unlike any other infectious pathogens, including viruses, because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (PrP). Prion diseases are disorders of protein configuration involving template-assisted replication and resulting in abnormal protein accumulation in the brain, which causes neuronal dysfunction, degeneration, and death. Prions are extremely resistant to inactivation by heat and disinfecting agents. [Baron, et al., 2001]

2.95 process challenge device (PCD): Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.

NOTE—For purposes of this recommended practice, a PCD is a challenge test pack or test tray that contains a BI or a Class 5 integrating indicator. A PCD containing a BI is referred to here as a BI challenge test pack or BI challenge test tray. A PCD containing only a Class 5 integrating indicator is referred to as a CI challenge test pack.

2.96 processing area: Area of a health care facility in which decontaminated, clean instruments, and other medical and surgical supplies are inspected, assembled into sets and trays, and wrapped, packaged, or placed into rigid sterilization container systems for subsequent sterilization.

NOTE—This area is commonly referred to as the "preparation and packaging area" if it is part of Central Service and as a "pack room" if textile packs are assembled there.

2.97 product family: (Sterilization) group or subgroup of product that is characterized by similar attributes, such as mass, material, construction, set weight, shapes, lumens, and packaging system, and that presents a similar challenge to the sterilization process.

NOTE—In grouping products by construction, it is necessary to consider size and/or surface area, surface finish or texture, and the presence of any cannulations, lumens, or mated surfaces.

2.98 psi: Pounds per square inch. More specific designations are pounds per square inch absolute (psia, referenced to an absolute vacuum), pounds per square inch gauge (psig, referenced to atmospheric pressure), and kiloPascals (kPa, referenced to absolute vacuum). Typical values of pressure for saturated steam sterilization are given in Table 1:

Table 1—Saturated steam pressure conversion units at sea level

psia	psig	kPa
29.8	15.1	205.5
41.9	27.2	288.9
45.4	30.7	313.0
53.3	38.6	367.5

2.99 pyrogen: Fever-producing substance.

NOTE—Debris from killed microorganisms can be pyrogenic. Limiting the bioburden before sterilization minimizes this debris.

2.100 qualified: As the term is used with respect to personnel, prepared by training and experience to perform a specified task.

2.101 restricted area: Area where access and traffic are limited to authorized personnel and where attire might be prescribed.

2.102 reusable medical device: Device intended for repeated use on different patients, with appropriate decontamination and other processing between uses.

NOTE—Examples include surgical instruments, endoscopes, basins, and electromedical equipment.

2.103 sanitization: Act of reducing the number of bacterial contaminants in the environment to a safe or relatively safe level as may be judged by public health requirements or at least to a significant degree where public health standards have not been established (Block, 2001). Block (1983) qualifies the definition of a sanitizer in that such an agent is ordinarily used on an inanimate surface.

2.104 saturated steam: Water vapor in a state of equilibrium between condensation and evaporation.

2.105 sharps: As defined by the U.S. Postal Service (1999), "devices having a projecting cutting edge or fine point that have been used in animal or patient care or treatment, in medical research, or in industrial laboratories, including but not limited to hypodermic needles, syringes (with or without the attached needles), Pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of the presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides or cover slips."

2.106 shelf life: When the term is used with respect to a sterilized medical device, the period of time during which the item is considered safe to use.

2.107 spore strip: Paper strip that is impregnated with a known population of microorganisms and that meets the definition of **biological indicator**.

2.108 standard precautions: Method of using appropriate barriers to prevent transmission of infectious organisms from contact with blood and all other body fluids, nonintact skin, and mucous membranes. It applies to all patients, regardless of diagnosis or presumed infectious status. The precautions consist of appropriate handwashing, gloves when touching the above materials, facial protection when there is a chance of splashing of body substances into one's face, and gowns when there is a chance of splashing of body substances onto one's clothing. Precautions also include appropriate disinfection of medical devices, appropriate handling of soiled textiles, prevention of needlesticks and other injuries from sharps, and appropriate handling and disposal of sharps, all without regard to the patient's diagnosis. See also **transmission-based (enhanced) precautions**.

2.109 steam purity: Degree to which steam is free of dissolved and suspended particles, water treatment chemicals, and other contaminants.

2.110 steam quality: Steam characteristic reflecting the dryness fraction (weight of dry steam present in a mixture of dry saturated steam and entrained water) and the level of noncondensable gas (air or other gas that will not condense under the conditions of temperature and pressure used during the sterilization process).

NOTE—The dryness fraction (i.e., the proportion of completely dry steam in the steam being considered) should not fall below 97%.

2.111 steam sterilization: Sterilization process that uses saturated steam under pressure, for a specified exposure time and at a specified temperature, as the sterilizing agent.

2.112 sterile: Free from viable microorganisms.

NOTE—In practice, no such absolute statement regarding the absence of microorganisms can be proven. See **sterilization**.

2.113 sterile processing 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 **central service department**.

2.114 sterile storage area: Area of a health care facility designed to store clean and sterile items and protect them from contamination.

2.115 sterility assurance level (SAL): Probability of a single viable microorganism occurring on an item after sterilization.

NOTE 1—SAL is normally expressed as 10^{-n}.

NOTE 2—A SAL of 10^{-6} means that there is less than or equal to one chance in a million that a single viable microorganism is present on a sterilized item. It is generally accepted that a SAL of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (that is, tissue that has lost the integrity of the natural body barriers). A SAL of 10^{-3} (a one in a thousand chance of a surviving microorganism) is considered acceptable for items not intended to come into contact with compromised tissue.

NOTE 3—SAL cannot be directly measured by a sterilization indicator.

2.116 sterilization: Validated process used to render a product free from viable microorganisms.

NOTE—In a sterilization process, the nature of microbiological inactivation is described by an exponential function. Therefore, the presence of a viable microorganism on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero. See also **sterility assurance level**.

2.117 sterilization area: Area of a health care facility where sterilization activities take place.

2.118 sterilization cycle: See **cycle, sterilization**.

2.119 sterilizer: Apparatus used to sterilize medical devices, equipment, and supplies by direct exposure to the sterilizing agent.

2.120 sterilizer, steam: Sterilizer that uses saturated steam under pressure as the sterilant.

2.121 strike-through: Passage of a liquid that could contain microorganisms through a barrier product, including its seams and/or points of attachment.

2.122 superheat: Temperature excess above the temperature of saturated steam at the same pressure.

2.123 table-top sterilizer: Compact steam sterilizer that has a chamber volume of not more than 2 cubic feet and that generates its own steam when distilled or deionized water is added by the user.

2.124 tamper-evident device, container: Seal or disposable “lock” that is generally secured on the container latching mechanism and that indicates whether the container has been opened.

NOTE—A tamper-evident device is designed so that it cannot be resealed after opening. It is intended to indicate that the container has not been opened intentionally or accidentally and therefore exposed to potential contamination before use.

2.125 terminal sterilization: Process whereby product is sterilized within its sterile barrier system.

2.126 transmission-based (enhanced) precautions: Precautions designed for patients documented or suspected to be infected with highly transmissible or epidemiologically important pathogens for which additional precautions beyond standard precautions are used to interrupt transmission in hospitals. There are three types of transmission-based (enhanced) precautions: airborne precautions, droplet precautions, and contact precautions.

2.127 treated water: Water that has been processed to reduce impurities.

NOTE—Typical water treatment can employ filtration, deionization, distillation, or reverse osmosis (RO), singly or in combination.

2.128 user verification: Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met.

2.129 validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

NOTE 1—Validation covers three activities: installation qualification, operational qualification, and performance qualification.

NOTE 2—Validation is performed by the device manufacturer.

2.130 valve, container: Mechanical device that opens during sterilization to allow air evacuation and sterilant penetration and closes after sterilization to prevent contamination.

2.131 work practice controls: According to OSHA, “controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).” [29 CFR 1910.1030]

NOTES

NOTES

3 Design considerations

3.1 General rationale

This section provides guidelines for the design and maintenance of the workplace to facilitate effective and efficient processing, promote personnel safety, minimize environmental contamination, and maintain the sterility of processed items. Whenever possible, centralized processing (i.e., decontamination, preparation and packaging, and sterilization processing in one department) is encouraged. Sterilization is a complex process requiring environmental controls (e.g., controlled air changes, exhaust ventilation, temperature, and humidity, as recommended in 3.3); appropriate equipment and supplies; adequate space; qualified, competent personnel who are provided with ongoing training and personal protective equipment (PPE); and monitoring for quality assurance. From both safety and cost-effectiveness standpoints, centralizing these functions is preferred to replicating them in several areas of the health care facility. Depending on the particular characteristics of the health care facility, there might be situations in which centralization of sterilization processing is not possible. If so, consistent policies and procedures should be maintained throughout the health care facility, sterilization processing should be under centralized control, and the work practices recommended here should be followed.

NOTE—See ANSI/AAMI ST41 for design recommendations for ethylene oxide (EO) sterilization facilities and ANSI/AAMI ST58 for design recommendations for other types of chemical sterilization.

3.2 Work area design and functional workflow

3.2.1 Definitions of work areas

a) *Central service department:* Department within a health care facility that processes and controls medical supplies, devices, and equipment, sterile and nonsterile, for some or all patient care areas of the facility.

b) *Decasing/breakout area:* Area or space where products are removed from their external shipping containers before entry into the preparation and packaging area or sterile storage area.

c) *Receiving, cleaning, and decontamination area:* Area or space where reusable instruments, supplies, equipment, and carts are received, sorted, cleaned, and decontaminated. (The area for cleaning carts and associated equipment might be adjacent to the decontamination area.)

NOTE—For reusable textiles, this area is the laundry.

d) *Personnel support area:* Area providing toilet, shower, and locker facilities for employees.

e) *Preparation and packaging area:* Area or space where decontaminated instruments, clean instruments, and other medical and surgical supplies are inspected; are assembled into sets and trays; and are wrapped, packaged, or placed into rigid sterilization container systems for sterilization.

f) *Textile assembly area (pack room):* Area or space where clean reusable textiles are inspected, patched, folded, assembled into packs, and wrapped. One or more of these functions might be performed in a central service or laundry facility. (See ANSI/AAMI ST65.)

g) *Sterilization area:* Area or space where sterilizers (steam and EO and other low-temperature processes) are located, including the space for loading, unloading, and lining up carts and for cool-down.

NOTE—Enclosed containment areas with additional ventilation requirements are recommended for EO sterilizers and other chemical sterilizing agents.

h) *Sterile storage area:* Area or space of the health care facility designed to store clean and sterile items before their selection and distribution for use in procedures.

i) *Equipment and cart holding area:* Holding area for clean medical equipment and carts before storage or issue.

j) *Equipment storage area:* Area, located within Central Service or elsewhere in the distribution system, where clean medical equipment is stored until issued.

k) *Administrative area:* Office space for the department supervisor and support personnel.

l) *Housekeeping equipment storage area:* Area or space where housekeeping items are stored.

NOTE—The decontamination area and “clean” areas should each have dedicated housekeeping storage areas.

Figure 1 illustrates the functional work areas of a sterile processing department.

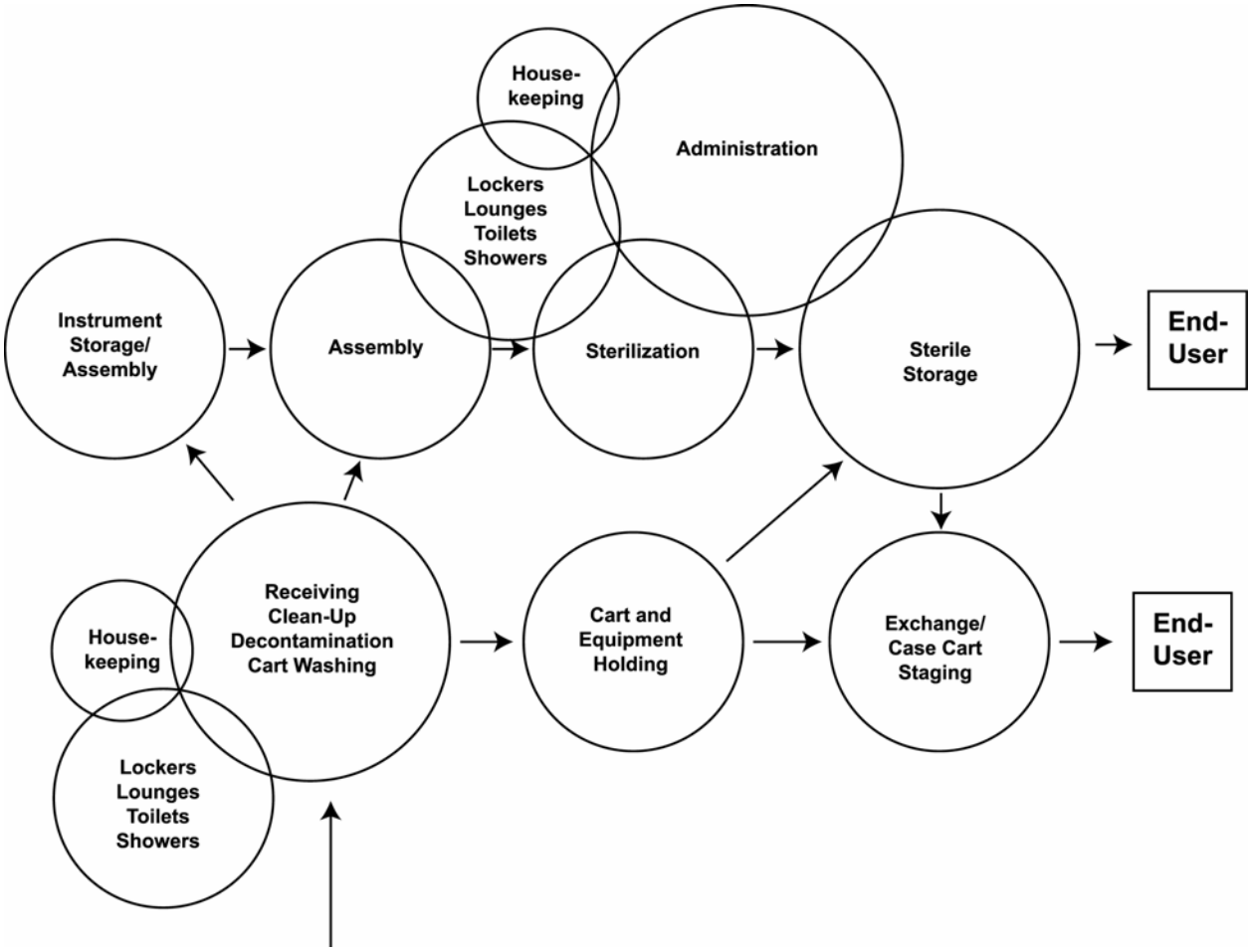


Figure 1—Functional work areas of a sterile processing department

3.2.2 Design criteria

3.2.2.1 General area considerations

During the initial design of sterilization processing areas, basic concepts of operation should be defined, the inventory of sterile supplies (including disposables) should be projected, the type of distribution system to be used should be selected, adequate space should be allocated for equipment, and the functional work areas should be designed accordingly. Some of the specific factors involved are

a) the anticipated volume of work and the departments to be served (e.g., OR, anesthesia, delivery room, emergency room, trauma unit, specialty units);

b) the types of processing equipment to be used (e.g., washer-sterilizers, washer-disinfectors, washer-decontaminators, single- or multi-chamber tunnel washers, ultrasonic cleaners, endoscope processors);

c) the types of packaging to be used (e.g., disposable wraps and pouches, reusable wraps, rigid sterilization container systems);

d) the technology to be used for sterilization (e.g., EO, other chemical sterilants, steam);

e) the anticipated inventory storage;

f) the types and volume of patient care equipment (e.g., suction, chest drainage, heat therapy, intravenous therapy);

g) the requisition and dispatch methods to be used;

h) the anticipated volume of consumable supplies (e.g., CIs, BIs, disposable packaging);

i) the type of distribution system that will be used (e.g., vertical, horizontal, case cart, exchange cart, par level, requisition) for ORs, patient care areas, and specialty departments;

j) the processing needs for reusable textiles (receiving, transporting, collecting, storing);

k) the amount of space needed for management of infectious waste, hazardous waste, and recyclable trash;

l) the type of documentation and record-retention system to be used (manual vs. computerized); and

m) electronic and communication needs.

3.2.2.2 Decontamination area

Special considerations apply to the decontamination area. The following are some of the key issues to be considered:

a) Will decontamination be centralized (performed in one department) or decentralized (performed in several departments, such as the OR, the labor-delivery suite, the central service department, and the medical device reprocessing room), or will a combination of approaches be used?

b) Which departments will be served?

c) How will contaminated items be contained at the point of use?

d) Will emergency or short-term processing be needed at the point of use? If so, what method of processing will take place at the point of use?

e) What type of transport system (i.e., types and sizes of case carts, soiled pickup carts, elevators, lifts, automated systems) will be used to deliver contaminated items to the decontamination area?

f) How will transportation carts be cleaned between uses?

g) Where will reusable medical devices, case carts, and so forth be received and held in the decontamination area before processing?

h) Will a cart washer be installed?

i) Will a steam-gun room be needed for patient care equipment (necessitating appropriate space, ventilation, drainage, and nonskid flooring)?

j) Will rigid sterilization container systems be used? If so, what will be the impact on manual and mechanical processing, equipment utilization, and the space needed to queue items?

k) Will automated systems be used to feed baskets of instruments, basins, utensils, and so forth into mechanical washers? If so, how much additional space will be needed?

l) Will the decontamination process be performed manually, mechanically, or by a combination of those methods?

m) What types and quantities of reusable supplies, instruments, and equipment will be decontaminated?

n) Where will reusable patient care equipment be decontaminated? What level of decontamination will be required for each type of patient care equipment?

o) What inventory levels of cleaning supplies will be maintained in the decontamination area?

p) How will soiled, in-use bottles of detergents, disinfectants, and other such supplies be separated from extra supplies in storage so that personnel not wearing PPE can acquire the supplies for other areas without being exposed to contaminated items?

q) What types of PPE will be needed? What will be the storage requirements? Which equipment will be reusable and what care will the reusable equipment require? Which PPE will be disposable and how will that disposal be handled?

r) Where will housekeeping supplies dedicated for use only in the decontamination area be stored?

s) How much adjacent space will be needed for personnel to don and remove PPE?

t) How many sinks will be needed for handwashing? What type of sinks? Where will they be located? How will handwashing sinks be separated from those used for decontamination processes?

u) What provision will be made for the disposal of liquid and solid body wastes?

v) Will any projected changes in the health care delivery system affect the space, equipment, and processing needs of the decontamination area? (Projected changes should be considered now to simplify and accommodate expansion in the future.)

w) What environmental controls will be required? (Environmental conditions [temperature and humidity] should be displayed accurately within the decontamination area.)

x) What provision must be made for emergency power backup?

y) Where will the material safety data sheets (MSDSs) for decontamination chemicals be stored?

z) Will compressed air or forced air be needed? Where will it be located?

aa) What is the quality of water required for the various decontamination processes, manual and mechanical? What methods will be employed to monitor the quality of water?

bb) Can a pass-through system be used so that equipment and instruments can be passed through from the decontamination room to clean areas without entering a hallway?

cc) Where will the manufacturer's written instructions for cleaning for each medical device be located?

dd) What provisions will be made for linen storage and trash disposal?

ee) What are the air-handling and other ventilation requirements for the general area and for the various manual and mechanical decontamination processes?

ff) Is there a need for a communication system? Which areas should be included?

gg) Will a lighted magnifying glass be needed? Where will it be located?

hh) Will an ultrasonic cleaner be needed? Where will it be located?

ii) Will an area be required for the collection of disposable medical devices to be sent to a third-party reprocessor?

jj) Will automatic testing equipment be needed (e.g., leak testers, suction machines)? Where should the equipment be located?

kk) Should vertical soaking containers be considered? Where should they be located?

ll) Will an instrument tracking system or other type of computer system be used?

mm) What type of cleaning-chemicals delivery system will be used for the automated washer? Will space be needed to stage large volumes of automatic washer cleaning chemicals (5- to 20-gallon containers)?

Rationale: Because quality systems for sterility assurance involve pre- and post-sterilization processing functions and controls, as well as the sterilization process itself, all of the preceding factors must be considered in the design of the workplace.

3.2.3 Functional workflow patterns

The sterile processing department should be designed to separate areas in which contaminated items are received and processed from areas in which clean items are packaged, sterilized, and stored. Functional work areas should be physically separated by walls or partitions to control contaminants generated during the phases of reprocessing. Work area design also should allow adequate space for all functions and should promote efficiency by minimizing distances between related areas.

NOTE—In office-based facilities, physical separation of functional work areas (e.g., the decontamination and clean/sterile areas) is desirable, but spatial separation could be satisfactory if accompanied by good workflow patterns, airflow characteristics, and work practices. See Figure 2.

Workflow patterns should be designed to ensure that contaminants are contained and employee exposure to blood-borne and other disease-producing organisms is minimized. Workflow patterns should also be designed so that items are moved progressively from being contaminated to being safe to handle. Of particular importance are the locations of elevators used to transport soiled items, elevators used to transport clean items, case-cart queuing and unloading 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.

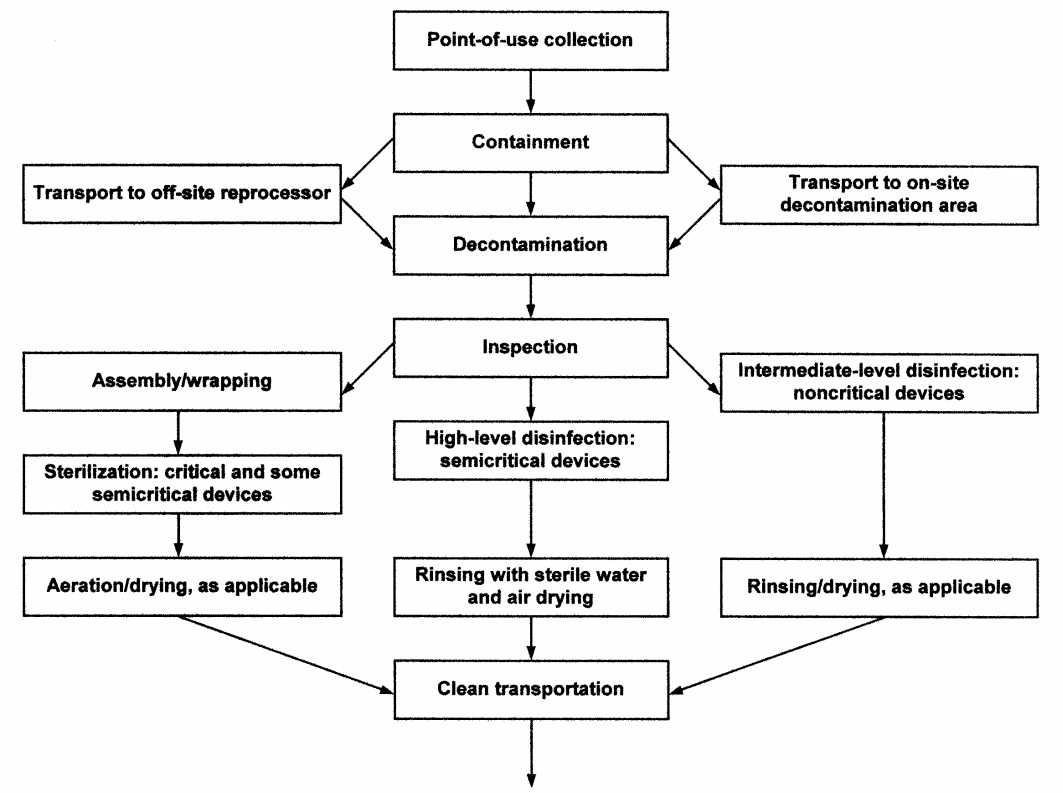
3.2.4 Traffic control

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, 2010f).



(a) Workflow in a sterile processing department

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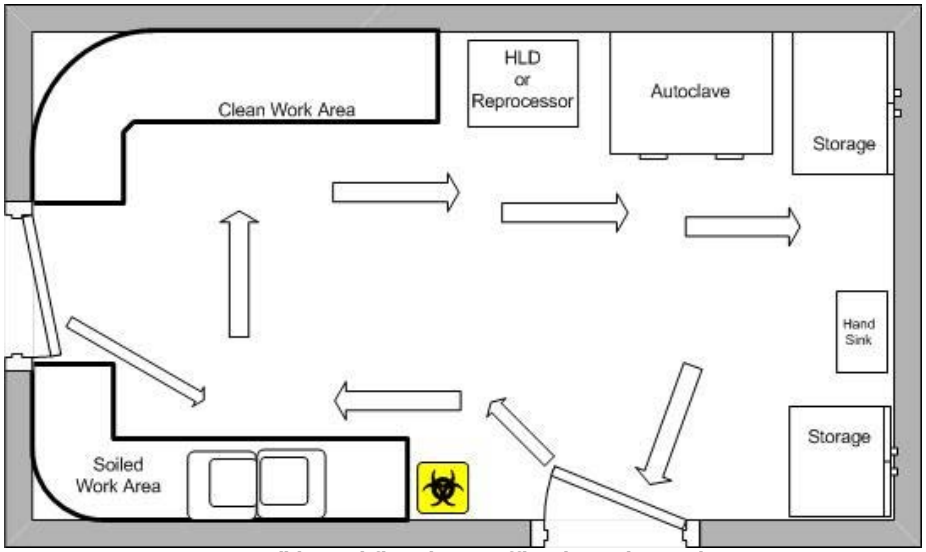

(b) Workflow in an office-based practice

Figure 2—Workflow

3.3 Physical facilities

3.3.1 Space requirements

The needs of each health care facility should determine the size of processing areas. Considerations are the operational systems, equipment, and workload expected of each functional work area. Space should be provided in proportion to the volume of work anticipated, the amount of product that will be routinely stored, and disposal needs. The degree of mechanization, the product mix (e.g., reusables vs. disposables), and the storage and distribution methods used affect space requirements and might change over time. Walls or partitions should separate functional work areas to control traffic flow and contain contaminants generated during processing.

Rationale: Depending on the specific processing needs of the health care facility, space requirements can vary significantly and are often underestimated during the planning process.

3.3.2 Mechanical systems

In addition to the routine plumbing and steam mechanical systems, the processing facility might need pressurized systems such as compressed air (high-pressure, low-pressure, or both), nitrogen (high-pressure, medium-pressure, or both), and vacuum systems. A source of distilled or deionized water might also be needed.

Rationale: Because of the increased sophistication of today's medical technology, complex equipment and systems might be needed to inspect, maintain, or verify device performance.

3.3.3 Electrical systems

Electrical systems should be designed to allow for the safe and effective operation of the equipment (e.g., cleaning equipment, sterilization equipment, computers, telephones, lighting) used in the department. The emergency power service of the facility should be extended to include sterilization processing equipment. The electrical engineers involved in the design process should be aware of the work of the department and collaborate with the operations manager of the department. For some equipment, uninterruptible power sources are recommended.

Rationale: The complexity of processing and sterilization technologies, as well as patient and employee safety, requires adequate, safe, and reliable electrical service.

3.3.4 Steam for sterile processing

3.3.4.1 General considerations

There are two common sources for steam used for sterile processing: hospital steam boiler systems and self-contained electric boilers. In both cases, a treated water supply is necessary to remove total dissolved solids (TDS). Each system should be designed, monitored, and maintained to ensure that the quality, purity, and quantity of the steam provided are appropriate for effective sterile processing. In certain circumstances, "house" steam from hospital steam boiler systems might not be acceptable for sterile processing because of the design of the overall system and the type and method of using boiler feedwater treatment chemicals.

NOTE—Table-top steam sterilizers generate their own steam. The user should carefully follow the sterilizer manufacturer's written instructions regarding water purity requirements, filling, draining, and general maintenance of the system. Distilled or deionized water is generally recommended to help prevent the buildup of minerals in the sterilizing system and to ensure the purity of the steam generated for sterilization.

Rationale: Steam used for sterilization is often at the end of a long steam pipeline, and sterilization is not the primary use of the steam carried in that line. Steam quality, purity, and quantity can be affected by the design, use, and maintenance of the overall steam system, which includes the boilers and steam distribution lines.

3.3.4.2 Steam quality

Steam systems should be designed to ensure that a continuous and adequate supply of saturated steam is available to the sterilizer in accordance with the sterilizer manufacturer's specifications. The steam delivered to the sterilizer should be at a steady, not fluctuating, pressure within the range of the manufacturer's recommendations.

The critical variables of steam quality are as follows:

a) The dryness of the steam, expressed as a dryness fraction. Steam dryness should be between 97% and 100%.

b) The level of noncondensable gases (NCGs), expressed as a fraction by volume. Noncondensable gases (e.g., air) should be at a level (less than 3.5% v/v condensate) that will not impair steam penetration into sterilization loads.

c) Superheat of steam expressed as a temperature in degrees above saturation point. This value should be less than 25°C (77°F).

These conditions require an adequate steam capability, appropriately placed steam traps, and insulated steam lines, especially in situations where the steam is generated in a location remote from the sterilizer. Upon installation or relocation of the sterilizer and after any change to the steam distribution lines or boiler supply water, an assessment of the steam quality (including dryness, NCGs, and superheat conditions) should be made and documented. The testing should be performed at the steam connection to the sterilizer. Steam quality should be maintained by monitoring, controlling, and documenting the process of generating steam, maintaining steam traps and boilers/generators in good working order, and periodically assessing sterilization loads for the presence of "wet packs." Additional information on achieving and maintaining adequate steam quality is provided in Annex M.

NOTE—Because table-top sterilizers generate steam within the sterilizer, they are generally less prone to variations in steam quality. However, it is still important to maintain the sterilizer according to the manufacturer's written instructions.

Rationale: Steam that is too dry can contribute to superheating and, consequently, to suboptimal steam sterilization conditions. On the other hand, steam that is too wet can lead to wet packs after sterilization.

3.3.4.3 Steam purity

The boiler feedwater source, treatment chemicals used, and the design and maintenance of the steam supply system should minimize the presence of potential contaminants in the steam. The feedwater should be treated so that its condition and/or chemistry do not damage the boiler or the steam lines. Boiler additives and feedwater conditioners should be monitored. The use of such compounds on a batch basis is not recommended for sterile processing applications. Only additives and conditioners approved for use in the food and drug industries should be used (21 CFR 173.310 and 21 CFR 200.11). The addition of similar additives or conditioners to the steam in the steam distribution system is also not recommended, because it can cause pack and instrument staining and/or instrument damage.

Steam lines should be designed to eliminate "dead legs," which can harbor and propagate contaminants, including microorganisms. (A "dead leg" is a section of pipe that leads nowhere and does not form part of a constant circulation system; in a steam line, condensate can form in a dead leg and become stagnant.) Procedures to monitor steam purity and, when necessary, provide corrective action should be established and performed on a regular basis. In-line filters should be used to remove particulate matter, such as scaling that can occur as systems age. In-line filters should be installed as close to the sterilizer as possible, and they should include a drip leg or trap for condensate removal.

Caution is advised in the use of amines for conditioning steam lines (as opposed to the use of amines in feedwater treatment) because amines can stain packaged items within the sterilizer.

Rationale: The hardness and pH of the water affect the purity of the steam generated in the boiler. It is important that boiler additives and feedwater conditioners be monitored to prevent carryover of excessive chemicals into the steam used for sterilization.

3.3.4.4 Steam quantity

Total steam demand and the corresponding necessary capacity should be determined so that the steam supply system can be designed and built to meet the peak demands of the facility. This information should be used to ensure that constant steam pressure (meeting the manufacturer's recommendations for minimum pressure) is available, at all times and under all conditions of steam demand, to properly operate sterilizers.

Rationale: Undersized steam supply systems lacking the capacity to properly meet sterilizer requirements can lead to multiple problems, including, but not limited to, malfunction or aborting of sterilization cycles, poor steam quality, and damage to boiler and distribution systems.

3.3.4.5 Monitoring steam systems

Procedures should be in place for the preventive maintenance, repair, and monitoring of boilers and steam distribution lines that provide steam for sterile processing and for the documentation of corrective actions. (See also 3.3.4.3 and Annex M.) The monitoring and testing program for boilers should generally include determination of

a) incoming water hardness, pH, iron content, and alkalinity;

b) boiler water alkalinity and pH; and

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 the minimum 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 2).

Table 2—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, 2006)	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 might 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, 2006). See also American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) (2007a) and ASHRAE (2007b).

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 (2006) 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 (2006) 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 (2006) recommends 10 air exchanges per hour for the latter area.

AIA (2006) 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.

3.3.6.5 Temperature

General work areas should have a temperature controlled between 20°C and 23°C (68°F and 73°F). The decontamination area should have a temperature controlled between 16°C and 18°C (60°F and 65°F). The temperature in sterilization equipment access rooms should be controlled between 24°C and 29°C (75°F and 85°F) or as recommended by the equipment manufacturer. The temperature in sterile storage and personnel support areas (e.g., toilets, showers, locker rooms) may be as high as 24°C (75°F). Independent monitors should be located in each of the areas where temperature should be controlled; temperature should be recorded daily. Processing personnel in each work area are responsible for monitoring and recording the temperature to ensure that the correct temperature is being achieved.

Rationale: Work areas should be comfortable for properly attired personnel. Comfort is a particular consideration in the decontamination area, where PPE is worn for long periods of time and where temperatures suitable for general work areas might be uncomfortably hot. Also, bacteria thrive at high temperatures; cool temperatures in the decontamination area might help minimize bioburden. Although AIA (2006) allows the temperature in clean work areas to be as high as 24°C (75°F), the consensus of the AAMI committee was to recommend consistent temperature ranges for all general work areas. Controlling the temperature in sterilization equipment access rooms promotes higher efficiency of the equipment contained within the enclosures. For additional information on temperature control, see AIA (2006).

3.3.6.6 Relative humidity

Relative humidity should be controlled between 30% and 60% in all work areas except the sterile storage area, where the relative humidity should not exceed 70%. An independent humidity monitor should be located in each area that requires controlled relative humidity. Relative humidity should be recorded daily. Processing personnel in each work area are responsible for monitoring and recording the relative humidity to ensure that the correct relative humidity is being achieved.

NOTE—Ideal relative humidity in the preparation and packaging area is 50% and should not be less than 35% for best results in achieving sterilization. In the decontamination area, the recommended range of relative humidity should be maintained to the extent possible, but temporary elevations might occur because of the type and quantity of cleaning and decontamination equipment.

Humidifiers may be installed to maintain the recommended humidity level seasonally (e.g., during the winter months, when the heating system is functioning). If duct humidifiers are located upstream of the final filters, they should be placed at least 15 feet (4.57 meters) upstream of the final filters. For ductwork with duct-mounted humidifiers, there should be a means of water removal. An adjustable high-limit humidistat should be located downstream of the humidifier to reduce the potential for condensation inside the duct. All duct takeoffs should be sufficiently downstream of the humidifier to ensure complete moisture absorption. Steam humidifiers should be used. Reservoir-type water spray or evaporative pan humidifiers should not be used.

Rationale: Relative humidities higher than those recommended can promote microbial growth and thus increase bioburden. Relative humidity lower than 30% will permit absorbent materials to become excessively dry, which can adversely affect certain sterilization parameters (such as steam penetration) and the performance of some products (such as BIs and CIs). Thus, for best results, the committee recommends an ideal relative humidity level of 50% and a minimum level of 35%. The recommended range for relative humidity was largely based on AIA (2006).

3.3.6.7 Lighting

Adequate lighting of work surfaces should be provided in accordance with the engineering practices outlined in Rea (1993), which describes the recommendations of the Illuminating Engineering Society of North America (IES) for minimum levels of illuminance for various categories of work environments (Table 3).

The three levels of lighting for each category were calculated on the basis of the following factors:

a) the age of the workers (persons under 40 years of age require the least amount of illuminance, persons 40 to 55 years of age require an average amount of illuminance, and persons more than 55 years of age require the highest amount of illuminance);

b) the importance of speed or accuracy of the work done in the area (the greater the importance of speed or accuracy, the more illuminance needed); and

c) the amount of light reflection in the work area (lighter colors reflect light; darker colors absorb light; the greater the reflectance, the less illuminance required).

Table 3—IES-recommended illuminance levels for work environments

Work area/function	Least illuminance	Average illuminance	Highest illuminance
General inspection	500 lux (50 foot-candles)	750 lux (75 foot-candles)	1,000 lux (100 foot-candles)
Detailed inspection	1,000 lux (100 foot-candles)	1,500 lux (150 foot-candles)	2,000 lux (200 foot-candles)
Sink areas	500 lux (50 foot-candles)	750 lux (75 foot-candles)	1,000 lux (100 foot-candles)
General work areas	200 lux (20 foot-candles)	300 lux (30 foot-candles)	500 lux (50 foot-candles)
Processed storage	200 lux (20 foot-candles)	300 lux (30 foot-candles)	500 lux (50 foot-candles)

The IES recommendations do not mention this consideration, but an important factor in lighting work areas is the effect of the large areas of stainless steel surfaces found in sterile processing areas. The amount of stainless steel typically used in a processing area is enough to turn a warm color cool; therefore, the type of fluorescent lighting (cool or warm); the color of the walls (white, light warm colors, or dark colors); and the type and color of work surfaces (stainless steel, shiny and matte laminate) will affect the type and amount of illuminance required.

A qualified illumination engineer, in consultation with the department manager, should determine the appropriate illuminance for each work area within the processing department. Generally, all functions performed within a processing department require detailed inspection and accuracy. Ancillary lighting should be considered for areas where instruments are manually cleaned and inspected. Lighting fixtures should be selected and mounted in positions that focus the light in front of the employee so that they are not working in their own shadows. The design of lighting fixtures should minimize the accumulation of dust.

Rationale: Adequate lighting is essential to the proper performance of decontamination, preparation, inspection, and other processing tasks. Dust on lighting fixtures can act as a carrier of microorganisms.

3.3.6.8 Handwashing facilities

Handwashing facilities should be conveniently located and designed to allow good handwashing practices. They should be located in or near all areas in which instruments and other devices are decontaminated and prepared for sterilization, as well as in all personnel support areas (e.g., toilets, lounges). Personnel should be instructed regarding handwashing techniques. The installation of hands-free equipment (e.g., foot controls, electronic sensors) for use with sinks, towel dispensers, and soap dispensers should be considered during the design of new facilities. If electronic sensors are used, there should be a backup system for operation during power outages.

Hands should be washed when visibly soiled, after gloves are removed for any reason, after the removal of other PPE, and in accordance with good personal hygiene practices and departmental policy.

Hands that are not visibly soiled may be decontaminated with alcohol-based, waterless hand hygiene agents containing emollients; such agents should be made available to health care personnel. It should be noted that alcohols are flammable. Flash points of alcohol-based hand rubs range from 21°C to 24°C (70°F to 75°F), depending on the type and concentration of alcohol present. State regulations might dictate when and where such agents may be used and placed within the facility. The health department of the particular state should be consulted for specific regulations. Alcohol-based hand hygiene agents must have an alcohol concentration of more than 60% by volume to be effective.

Rationale: Such handwashing facilities will promote appropriate hand hygiene. The use of alcohol-based, waterless hand hygiene agents is an effective means of hand decontamination when hands are not visibly soiled. Such agents have been shown to decrease the dryness and irritation associated with traditional handwashing. Additionally, increasing the availability of these agents in the work area can increase compliance with hand decontamination policies and procedures. Therefore, both traditional handwashing and the use of waterless hand hygiene agents should be encouraged to reduce the risk that personnel could transmit microorganisms with their hands. Hands-free equipment helps personnel avoid touching faucet handles, towel dispensers, or soap dispensers, thus minimizing microorganism transfer among patients, personnel, and inanimate objects. Some electronic sinks and towel dispensers operate only by the use of electricity and cannot function if the electrical power is off; a backup power system for hands-free equipment will ensure its continued operation.

3.3.7 Special area requirements and restrictions

3.3.7.1 Decontamination area

Ideally, the area in which instruments and other devices are decontaminated should be physically separate from all other processing areas and from areas in which clean or sterile patient care procedures are carried out. The decontamination area should be accessible from a service corridor. Doors and pass-through windows separating the decontamination area from adjoining clean spaces should remain closed. If a lift is used for transport, it should be dedicated to the transport of contaminated items only.

In small health care facilities, clinics, and dental or medical offices, it might not be possible to physically separate the decontamination area. In such cases, procedural barrier separation, although not generally desirable, could be adequate, provided that work practices prevent splashing, the production of aerosols, and the contamination of clean items and work surfaces, and provided that work practices promote the changing of PPE when personnel leave the decontamination area and enter clean areas. In surgical facilities, the decontamination area should be physically separated from other areas by doors, service windows, and/or pass-through equipment. (For example, the area where flexible endoscopes are decontaminated should be separate from the endoscopic procedure area.) Automatic doors are preferable because most of the traffic will consist of carts. When procedural barrier separation is used, it is essential that ventilation and air-handling systems move air from the clean side of the room to the soiled processing side of the room and not the reverse (see 3.3.6.4).

The floor, walls, ceiling, and work surfaces should be constructed of nonporous materials that will withstand frequent cleaning and wet conditions (see 3.3.6.1, 3.3.6.2, and 3.4). All air from the decontamination area should be exhausted to the outdoors without recirculation (see 3.3.6.4 and AIA [2006]).

The area should be designed to take into account the following workflow: from the receiving of soiled items; to the removal of linens, fluids, and trash; to manual decontamination tasks (e.g., sorting); to the automatic washer or pass-through window. Space should be allowed for record-keeping throughout the process. The decontamination area should also include space for

a) storage of PPE (e.g., gloves, face masks, eye protection, protective attire), cleaning supplies (e.g., brushes, towels, detergents), and record-keeping supplies (e.g., scanners, equipment tags, processing forms);

b) trash containers for nonregulated waste (paper towels, wrappers), regulated waste (blood and body substances), and sharps;

c) soiled linen hampers;

d) automated testing equipment (e.g., leak testers, suction machines);

e) automatic washer accessories (e.g., detergents, loading baskets, carts, and equipment);

f) transport cart storage and washing (manual or automatic);

g) work tables made of nonporous materials (e.g., stainless steel);

h) handwashing facilities;

i) body-fluid disposal systems;

j) third-party collection units; and

k) computers.

The decontamination area must have an emergency eyewash/shower station (3.3.8). A door should provide access to the preparation area; a pass-through window is also convenient for delicate instrumentation and water-sensitive equipment that have been manually decontaminated.

Ergonomic factors affecting worker safety and comfort should be considered when designing work spaces. For example, counters and work surfaces should be positioned at heights that take into account the average height of the employees and the tasks to be performed at each location. To the extent possible, employees should avoid lifting and carrying items. Therefore, there should be adequate space to maneuver, queue, and unload carts or other transportation means at times of average daily peak workload.

Sinks should not be so deep that personnel must bend over to clean instruments. An ideal decontamination sink is approximately 36 inches (91 centimeters [cm]) from the floor and 8 to 10 inches (20 to 25 cm) deep, enabling a person of average size to work comfortably without undue strain on his or her back; foot stools should be readily available to accommodate shorter employees. The sink should be of a width and length to allow a tray or container basket of instruments to be placed flat for pretreatment or manual cleaning. The sink should be constructed with three sections—for soaking, washing, and rinsing—and it should have water ports to facilitate the flushing of instruments with lumens. If a three-section sink is not available, there should be enough sinks to accommodate concurrent soaking, washing, and rinsing. Sinks should be large enough to contain large utensils and instruments. A source of deionized, distilled, or reverse osmosis (RO) water for final rinsing should be provided in appropriate locations.

Forced air should be provided at the sink, as well as faucets or manifold systems for flushing lumened devices. Sinks should have attached solid counters or adjacent work surfaces on which to place soiled and clean items separately. Lights and other fixtures should be recessed and sealed to prevent the accumulation of dust or soil and to facilitate cleaning.

The need for floor drains depends on the potential for liquid spillage from decontamination procedures and equipment. Floor drains should be properly placed and large enough to accommodate any fluid or water runoff.

NOTE—For laundries that decontaminate and clean soiled textile items, see ANSI/AAMI ST65 for special or modified facility needs.

Rationale: Airborne microbial and particulate contamination is likely to be high in the decontamination area because of the type of work done there (e.g., staging of grossly soiled items and equipment before cleaning, manual cleaning that produces aerosols, and, in some facilities, trash and linen handling from surgical case carts). Contamination can also be spread by personnel who indiscriminately touch environmental surfaces, other devices, or other personnel with contaminated hands. Regular cleaning is necessary to control environmental contaminants. Physical enclosure of the decontamination area is necessary because contaminated aerosols, droplet nuclei, and dust particles can be carried from “dirty” to “clean” areas by air currents. Exhausting air directly to the outside prevents the reintroduction of contaminants onto clean items and into clean work spaces where they could pose a risk to personnel and patients.

Designing the area to facilitate proper workflow and to provide adequate space for necessary equipment reduces the potential for cross-contamination and enhances efficiency. For the rationale for the emergency eyewash/shower station, see 3.3.8.

The design and location of sinks can facilitate proper cleaning as well as employee safety. Sinks located too high or too low increase the risk of back injury or strain. Sinks need to be deep enough to allow items to be cleaned beneath the surface of the water. Considering human factors during the design phase can help prevent worker injury.

3.3.7.2 Preparation area

The area used for the preparation and assembly of instruments and other items to be sterilized should be physically separate from the decontamination area. If physical separation of these areas is not possible (as could be the case in ambulatory-care or office-based facilities), the preparation area should be thoroughly cleaned and decontaminated before being used for clean preparation and assembly tasks.

The ventilation system should be designed so that air flows out of the preparation area (via positive pressure).

Preparation of textile packs and of individual wrapped textiles, when performed in the preparation area, should be carried out in an enclosed space separate from the remainder of the preparation area. The air flow should be of a down-draft type, and the number of air exchanges per hour should be sufficient to minimize lint particles in the air (3.3.6.4). There should be sufficient space for clean textile storage (both before and after assembly into packs), an illuminated inspection table, and patching equipment. For additional information, see ANSI/AAMI ST65.

If uncased bulk supplies for processing trays, sets, and single items are maintained in a separate, enclosed area, this area should also conform to the ventilation requirements of 3.3.6.4.

The preparation area should include space for

a) storage of attire for visitors (e.g., head covers, cover gowns); supplies for cleaning the preparation area (e.g., detergents, towels); monitoring and record-keeping supplies (e.g., sterilization process monitoring devices, log books); packaging materials and preparation supplies (e.g., cotton balls, gauze dressing, tip protectors);

b) computers, if used;

c) incubators for BIs;

d) magnifying lights;

e) heat sealers;

f) instrument storage and repair boxes;

g) transfer carts;

h) processing tables made of nonporous materials (e.g., stainless steel);

i) a station for instrument lubrication;

j) testing equipment; and

k) battery rechargers.

Rationale: Lint and airborne particles can carry microorganisms. A relatively lint-free environment is also important to the comfort and safety of employees. Because bulk supplies will be used to prepare items for sterilization, they should be stored in an environment that limits potential contamination. Providing adequate space for supplies and equipment and designing the layout to facilitate the flow of work through the various steps of preparation contributes to the efficiency and accuracy of the sterile processing staff. See also 3.3.6.4.

3.3.7.3 Sterilization area

The sterilization area should be adjacent to the preparation and packaging area. Material should flow from the preparation and packaging area to the sterilization area and then on to storage or distribution. The floors, walls, and ceiling surfaces should be constructed of nonporous material that will withstand frequent cleaning and wet conditions (see also 3.3.6.1 and 3.3.6.2). Adequate space should be allowed for sterilizers and aerators; the staging and loading of sterilizer carts; the storage of long, heat-resistant gloves, sterilizer cleaning supplies, and record-keeping supplies; and handwashing facilities. Preferably, sterilizers should be located in a restricted-access area. Sterilizers should *not* be located in high-traffic areas or near any potential sources of contamination, such as scrub sinks, clinical sinks or hoppers, wash sinks, or containers for the disposal of linen and trash.

Sterilizers to be used for flash sterilization of unwrapped items for immediate use should be located in the restricted area of the surgical suite or treatment site, where personnel are required to wear full surgical attire, to cover all head and facial hair, including sideburns and necklines, and to wear masks in the vicinity of open sterile supplies.

Because of the increased complexity of instrumentation, consideration may be given to the installation of a separate steam sterilizer designated for use on medical devices requiring nonroutine cycles.

NOTE—Policies and procedures should be in place to ensure that sterilization cycle parameters are verified before each use.

Air intake or return ducts should not be located in the area designated for cool-down. The temperature in the sterilizer access area should not exceed that specified in the manufacturer's written instructions.

NOTE—If EO sterilizers and other chemical sterilants are used in the same area as steam sterilizers, the area must be designed and engineering controls must be established to comply with OSHA regulations for control of occupational exposure to EO (29 CFR 1910.1047), formaldehyde (29 CFR 1910.1048), and other air contaminants (29 CFR 1910.1000).

Rationale: The correct design of the sterilization area and its proper placement in relation to other processing areas contribute to work efficiency and personnel safety, help minimize bioburden on items before sterilization, and help reduce the potential for contamination of items after sterilization. It is particularly important that sterilization of unwrapped items for immediate use be carried out in a clean environment and that devices processed by this method be transported as short a distance as possible. Because these items are not protected by packaging, they are extremely vulnerable to contamination en route to the point of use.

The ventilation system should be designed and balanced to provide controlled, directional air flow from the sterilization area to the access area, both to remove EO and other air contaminants and to minimize microbial contaminants in the area (AIA, 2006). The air exhausted from EO sterilizers could expose personnel to excessive levels of EO. See also ANSI/AAMI ST41.

3.3.7.4 Sterile storage

The sterile storage area should be located adjacent to the sterilization area, preferably in a separate, enclosed, limited-access area, the only function of which is to store sterile and clean supplies. The storage system (e.g., open wire shelves, open solid shelves, or closed cabinets) should be selected on the basis of the environment in which it will be used, the packaging materials and systems used, the types of devices packaged, and the handling procedures employed at the health care facility. Closed or covered cabinets are preferable for high-traffic areas. Open or wire shelving is suitable for confined storage areas, provided that proper attention is given to traffic control, area ventilation, and housekeeping. Storage areas should be designed to protect sterile items and their packaging from damage. The ventilation system should be designed so that air flows out of the sterile storage area (via positive pressure). Other aspects of ventilation should comply with the guidelines set forth in AIA (2006) for OR environments. See also 8.9.2.

Rationale: Maintenance of the sterility of a device to the point of use is essential. Because most packaging does not provide an absolute microbial barrier, it is important that environmental contamination be minimized to avoid compromising the sterility of devices during storage.

3.3.8 Emergency eyewash/shower equipment

Suitable eyewash/shower equipment must be available, with unobstructed access, for immediate emergency use in all locations where potentially damaging chemicals (e.g., instrument cleaning solutions and disinfectants, EO) are used.

The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units and shower equipment (ANSI Z358.1). ANSI Z358.1 requires that eyewash units provide a minimum of 0.4 gallons per minute continuously for at least 15 minutes, that they be designed to flush both eyes simultaneously, and that they have a "hands-free, stay open" feature once activated. Under the ANSI standard, drench hoses or eyewash bottles are not acceptable emergency eyewash units. Emergency eyewash units should be located within 10 seconds' travel time of all chemical usage locations; for a strong acid or strong caustic, the eyewash unit should be immediately adjacent to the hazard. The eyewash facilities should be identified with a highly visible sign, should be maintained in accordance with the manufacturer's written instructions, and should be tested routinely to ensure proper operation. Before attempting to implement the ANSI standard, health care personnel should consult the standard to familiarize themselves with all of its provisions.

Rationale: Emergency eyewash and shower equipment should be readily accessible in order to provide first aid to employees exposed to injurious chemicals and materials. The availability of eyewash units for immediate emergency use is required by OSHA. Proper maintenance of eyewash units is necessary to ensure adequate performance and to prevent contamination. See also OSHA's Eye and Face Protection Standard (29 CFR 1910.133), OSHA's Medical and First Aid Standard (29 CFR 1910.151), and ANSI Z358.1.

3.4 Housekeeping procedures

Housekeeping procedures in areas used for any aspect of decontamination, preparation, or sterilization should be the same as those used to clean operating and delivery rooms and should ensure a high level of cleanliness at all times. Floors and horizontal work surfaces should be cleaned at least daily. Other surfaces, such as walls,

storage shelves, and air intake and return ducts, should be cleaned on a regularly scheduled basis and more often if needed. Stained ceiling tiles should be replaced, and any leaks causing the stains should be repaired. Lighting fixtures or covers should be cleaned at least once every six months.

Care should be taken to avoid compromising the integrity of packaging during cleaning. Special attention should be paid to the sequence of cleaning to avoid transferring contaminants from “dirty” to “clean” areas and surfaces. It is good practice to provide separate housekeeping facilities for the decontamination and clean areas. If cleaning is contracted, appropriate written instructions that reflect these guidelines should be given to the contractor.

Rationale: Cleaning removes soil and reduces environmental contaminants, thus reducing the risk of transmission of microorganisms.

NOTES

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) (148 Main Street, Suite B-1, Lebanon, NJ 08833; 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 prevention and 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 prevention and 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 prevention and 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 prevention and 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 prevention and 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, whereas 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 (Joint Commission, 2009). 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 Prevention and 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, 2010f). Uniforms or other garments that become soiled or wet during wear should be changed immediately. In collaboration with the health care facility's infection prevention and 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

[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.

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.

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 might 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 splatter, PPE should include a fluid-resistant face mask and eye protection. PPE used to protect the eyes from splash 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 written 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 because of 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 (2008).

Fluid-resistant face masks protect personnel who are cleaning contaminated items from splash or splatter that could contain pathogens. See also the CDC guideline on isolation precautions (Siegel, et al., 2007). 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. For more information on proper removal of PPE, see the CDC slide show entitled *Guidance for the Selection and Use of Personal Protective Equipment in Health Care Settings,* available at http://www.cdc.gov/ncidod/dhqp/ppe.html.

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 worn whenever the service person is working on or demonstrating equipment that might be contaminated and whenever the service person is in doubt about the safety of a particular piece of equipment.

Rationale: Personal protective equipment will minimize the possibility of acquiring infectious diseases. The selection and proper use by the worker of the appropriate PPE for the activity being performed are important in protecting service personnel from blood-borne pathogens. Even employees who are adequately protected against hepatitis B by vaccination are at risk of exposure to other infectious diseases.

4.6 Standard/transmission-based (enhanced) precautions

Standard/transmission-based (enhanced) precautions are intended to supplement, not replace, infection prevention and control practices such as washing hands and wearing PPE to avoid contact with contaminated items, blood, or body fluids. Because it is not possible to specify a protective barrier that is appropriate for every situation that can occur, some judgment is required on the part of the employee. The OSHA blood-borne pathogen regulation (29 CFR 1910.1030) (see Annex H) includes the following requirements:

- Precautions must be taken to prevent injuries from sharp objects (e.g., needles, scalpels, broken glass).
- In general, contaminated needles should not be recapped. If recapping is necessary, however, it must be accomplished by using a mechanical device or a one-handed technique.
- Needles must not be bent, broken, or manipulated by hand.
- Sharp objects must be placed in puncture-resistant containers.
- Appropriate PPE must be used to prevent exposure to blood or body fluids.
- Hands and other skin surfaces that are contaminated with potentially infectious fluids must be immediately and thoroughly washed.
- Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses must be prohibited in work areas where there is a reasonable likelihood of occupational exposure to chemical or biological materials.
- Food and drink must not be kept in refrigerators, freezers, or cabinets or on shelves, countertops, or benchtops where blood or other potentially infectious materials are present.
- Employees must receive training on blood-borne pathogens.

See also Garner (1996), CDC (2002a), and CDC (2007).

Rationale: Standard/transmission-based (enhanced) precautions represent a philosophy that assumes that all body fluids and items that have contacted body fluids are potentially infectious. If all items are treated as infectious, then personnel will be assured of protection, especially when handling items from patients whose infection status is unknown.

NOTES

5 Receiving

5.1 General rationale

Sterility assurance “begins at the loading dock,” i.e., at the point at which the health care facility assumes responsibility for incoming medical equipment, devices, and supplies. Therefore, sterility assurance measures should be used from the time that items are received into the health care facility until they are used.

5.2 Receiving of purchased or loaner items

5.2.1 General considerations

Policies and procedures for the receipt of purchased or loaner items should be developed, implemented, and audited. Audits should be scheduled and documented. Clean or sterile items should be handled separately from foodstuffs, waste material, soiled laundry, and other potential sources of contamination. To protect individual items, bulk items may be stored in shipping cartons in the central receiving area. Clean or sterile items to be transported to central processing and storage areas within the facility should be removed from their external shipping containers before they enter the storage areas of the department. Any instructions for use accompanying the items should be kept with the items. When loaner items are delivered to the receiving area, personnel should document that according to the packing slip, the correct number of packages has been received. Under no circumstances should the packages be opened. The packaged items, along with any instructions for use, should be delivered to the Central Service processing/decontamination area as soon as possible.

Rationale: External shipping containers have been exposed to unknown and potentially high microbial contamination. Also, shipping cartons, especially those made of corrugated material, serve as generators of and reservoirs for dust.

5.2.2 Newly purchased reusable items and repaired reusable items

Newly purchased reusable surgical instruments require decontamination before sterilization. After instruments are removed from the external shipping containers, personnel should inspect them to ensure that they meet the required specifications and that written instructions for use have been provided and then transport them, together with the instructions, directly to the decontamination area. The manufacturer’s written processing instructions should be followed.

Rationale: Many reusable medical devices are manufactured in an environment in which bioburden is not rigorously controlled, and some are handled extensively during the manufacturing process. Consequently, to ensure that sterility can be achieved, the bioburden should be reduced by cleaning before the device is packaged for sterilization. Also, anticorrosive agents such as oils or greases might have been left on the device by the manufacturer to protect it during shipping, and such agents will interfere with sterilization if they are not removed. External shipping containers should be removed before items are transported to processing areas because the containers have been exposed to unknown and potentially high microbial contamination. In addition, shipping cartons, especially those made of corrugated material, serve as generators of and reservoirs for dust. New or repaired items should be inspected before decontamination so that they can be returned to the vendor in the condition and packaging in which they were received if they do not meet the required specifications.

5.2.3 Rigid sterilization container systems

Each rigid sterilization container system should be thoroughly inspected upon receipt:

a) All gaskets should be free of breaks, cracks, or cuts. Each gasket should be properly secured and should mate evenly at joining surfaces.

b) All filter material should completely cover the perforated area, and the device holding the filter in place should provide a tight, uniform seal that keeps the filter from dislodging.

c) The latching mechanism should secure the lid so that it cannot move when locked. A method of demonstrating that the latching mechanism has not been opened after sterilization and before use is preferred.

d) Mechanical valves should function properly; they should move freely with no sign of damage.

e) Rivets and screws should be secure and show no evidence of damage or corrosion.

Rigid sterilization container systems should be cleaned and decontaminated according to the manufacturer’s written instructions before initial use.

Rationale: Inspection verifies that the rigid sterilization container system has arrived in proper working order.

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/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ default.htm).

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 might 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/).

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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 prevention and 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 prevention and 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 might also be adopted for infection prevention and 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.

Rationale: Contaminated items must always be handled so as to minimize potential exposure of workers to disease-producing organisms and contamination of the environment. Immediate containment and transport to a designated area minimizes the risk of employee contact with contaminants and allows the cleaning process to be performed in a controlled environment by personnel who are protected by PPE.

Gross soil is removed as soon as possible in order to (a) reduce the number of microorganisms on the item, (b) reduce the nutrient material that might support microbial growth, (c) reduce the potential for environmental contamination by aerosolization or spillage, and (d) minimize damage to devices from such substances as blood, saline, iodine, and radiological dyes or from the subsequent vigorous cleaning processes needed to remove encrusted material. Because it cannot be known for certain which patients harbor blood-borne viruses or disease-producing bacteria, the use of PPE is necessary for the protection of the health care worker.

Biofilm consists of an accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily. Biofilm has the effect of protecting microorganisms from attempts to remove them by ordinary cleaning methods used in the sterile processing department. Biofilm can form on many surfaces but is particularly problematic in devices with lumens. Once biofilm forms, direct friction and/or oxidizing chemicals are needed to remove it. Prompt cleaning reduces or eliminates the population of biofilm-forming microorganisms and thus prevents the formation of biofilm. Precleaning disinfectants are appropriate for use in the event of processing delays; however, some disinfectants (e.g., aldehyde-based products) will act as fixatives for debris and make cleaning more of a problem (Merritt, et al., 2000).

6.4 Containment

Contaminated items should be contained during their transport from the point of use to the decontamination area. Containment may be accomplished by any means that adequately prevents personnel contact with the contaminated items during transfer. Containers, devices, or carts must be marked with a biohazard label or other means of identifying contaminated contents; a red bag or container may also be used to denote that the contents are hazardous. The type of container that should be used depends on the items being transported. Bins with lids, enclosed or covered carts, rigid sterilization container systems, and impermeable bags are among the types of containers that may be used alone or in combination to transport contaminated items. Puncture-resistant, leak-proof, closable, and labeled containers must be used for devices with edges or points capable of penetrating container or skin.

If the manufacturer's written instructions permit, rigid sterilization container systems with closed valves or intact, dry filters can be used to contain contaminated items for transport with no further coverings, provided that the external surfaces of the container have not been contaminated by blood or body fluids. Such contamination should be presumed to have occurred if the external surfaces of the container have been touched by persons or items that might have contacted blood or body fluids. Examples include the scrub person in the OR who is still wearing gown and gloves or the circulating nurse assisting with procedure cleanup who might have donned gloves to handle sponges or specimens and has not removed them before touching the container. If such external contamination is present, the reassembled container system should be further enclosed for transport by placing it in a plastic bag, a bin with a lid, or a closed or covered cart.

Immediately after use, items should be kept moist in the transport container by adding a towel moistened with water (not saline) or a foam, spray, or gel product specifically intended for this use. Transporting contaminated items in liquid should be avoided; if items are soaked in water or an enzymatic solution at the point of use, the liquid should be discarded by properly attired personnel before transport.

Reusable collection containers for holding contaminated items should be made of material that can be effectively decontaminated; containers designated for single use should be made of material that can be incinerated or otherwise disposed of following use. Environmental issues and hazardous waste policies should be considered before single-use containers are selected as a containment method.

Rationale: Materials contaminated with blood or body fluids can serve as sources of infection to personnel unless the materials are properly contained. Containment minimizes the possibility of airborne or contact spread of microorganisms. Keeping items moist prevents soil from drying on device surfaces and facilitates the decontamination process. In general, contaminated items should not be transported in liquid because of the risk of spills, the promotion of biofilm formation, and the possibility of employee injury from lifting a heavy container.

Some manufacturers instruct users not to use the same rigid sterilization container system for transport of contaminated items as for sterilization, so it is important to consult the labeling. If the outer surfaces of the container are touched with gloved, soiled hands, then the entire container is considered contaminated.

6.5 Transport

6.5.1 Segregation of clean/sterile items

During transport, clean/sterile items should be contained and segregated from contaminated items, trash, and food.

Rationale: Transporting clean/sterile items in proximity to contaminated items, trash, or food could contaminate the clean/sterile items.

6.5.2 Transportation scheduling and routes

The pickup and transport of soiled items from each area should be scheduled so that the items are transported and cleaned as soon as possible after becoming soiled. Transport routes should be designed to facilitate efficient pickup and delivery to the decontamination area and, whenever possible, should avoid areas of high traffic.

Rationale: The amount of time between use and decontamination should be minimized because the soil on items provides an excellent medium for microbial reproduction. Also, cleaning items as soon as possible helps prevent the formation of biofilm and the drying of blood, tissue, and mucus on the items, which make cleaning even more difficult to perform.

6.5.3 Transportation equipment

The transport system should be designed to prevent items from falling over or off during transport. Carts should be large enough to maintain the security and package integrity of the items being transported. A covered or closed transport cart is desirable. Carts, reusable covers, and bins and other containers should be decontaminated after each use. The wheels of transport carts should turn easily and should be routinely cleaned.

Rationale: Transportation equipment of appropriate design will help prevent damage to reusable items and avoid contamination of the environment. Decontamination of transportation equipment after each use helps prevent cross-contamination of items transported at a later time. The wheels of a transport cart should turn easily to help prevent items from falling off the cart. Routine cleaning of the wheels removes the string and other debris that can interfere with the wheels' movement.

6.5.4 Hand transport

Containers used to transport contaminated items by hand should be maintained in a position parallel to the floor. The carrier should exercise good body mechanics (e.g., bend at the knees when lifting an item, hold the item close to the body).

Rationale: Keeping containers parallel to the floor prevents the dislodging of or potential damage to the items within them. Good body mechanics promote worker safety.

6.5.5 Dedicated lifts

Dedicated, soiled lifts should always be located in the decontamination area. If containers of contaminated items are transported directly from the point of use to the point of decontamination by means of a dedicated, soiled lift, the lift may be considered equivalent to a closed cart. If the external surfaces of the containers are contaminated, the containers should be placed in plastic bags or bins with lids before being placed in the lift. The lift should be large enough to allow the containers to be placed securely in the appropriate position. Dedicated, soiled lifts should be periodically decontaminated to remove gross contamination that could build up over time and use. Clean or sterile items should not be distributed from a dedicated, soiled lift.

Rationale: Using dedicated lifts and equipment of appropriate design will help prevent damage to reusable items and avoid contamination of the environment. General cleanliness is maintained by periodic and spot cleaning.

6.5.6 Transport between buildings

The transportation system must be enclosed and designed to minimize the risk of personnel exposure to blood-borne and other disease-producing organisms and the possibility of damage to the instruments and other items being transported. Consideration should be given to the containment or packaging of the items, loading procedures, temperature control in transportation vehicles, and other relevant factors. Vehicles used for transporting contaminated items between buildings should provide for the complete separation of contaminated

items from clean and sterile items. Because contamination of the vehicle might have occurred, transportation vehicles should be decontaminated between trips and in the event of spills. Transportation personnel should receive training in basic infection prevention and control principles related to their responsibilities. PPE and a biohazardous spill kit should be available in transportation vehicles.

Rationale: Additional factors, such as temperature changes that might enhance microbial growth, should be considered when contaminated items are transported outside the controlled environment of the health care facility. Clean and contaminated items should be separated to prevent cross-contamination during transport. Training is needed to help reduce the risk that transportation personnel will be exposed to blood-borne and other pathogens. PPE should be available for use in the event of spills of contaminated items or fluids.

6.5.7 Off-site transportation

Vehicles used for transporting contaminated items between health care facilities should provide for the complete separation of contaminated items from clean and sterile items. Carts housing contaminated items should be secured 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, whereas 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 of Infection Prevention and 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 (2010a), Favero and Bond (2001), Rutala and Weber (2001), Rutala and Weber (2010), and the recommendations of CDC (http://www.cdc.gov) 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 instructions 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 Annex D, 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.

7.3 Presoaking

Presoaking with a specialized product (e.g., an enzymatic solution) is generally recommended. When presoaking instruments, personnel should refer to the solution manufacturer's written instructions for the correct dilution, temperature, and soak time. Instruments should be thoroughly rinsed after presoaking. Presoaking should begin as soon as possible after an instrument is used.

Rationale: Presoaking instruments moistens and loosens the soil, thus making the cleaning step more efficient. Rinsing thoroughly ensures the removal of any potentially harmful residue from the soaking solution (e.g., detergent enzymes, which are proteins, and/or patient secretions).

7.4 Disassembly

7.4.1 Sorting and disassembly of instrumentation

Upon arrival in the decontamination area, contaminated items should be removed from their transport containers, sorted, and prepared for cleaning. Surgical instruments and other items composed of more than one part or piece (e.g., metal tracheostomy tubes, procedure needles, dental handpieces, laparoscopic instrumentation, trumpet valves) should be disassembled to expose all surfaces to the cleaning process. Device manufacturers' written instructions for disassembly and reassembly of all processed items should be included in the procedure manual for the decontamination area. Care should be taken to ensure that all small parts (e.g., screws, nuts, and washers) are contained to prevent loss. Noninterchangeable components of assemblies, such as parts of a metal stopcock, should be kept together to ensure correct reassembly. Procedures should be developed to ensure that personnel do not reach by hand into the container to retrieve reusable sharps that might be hazardous and contaminated with blood or other potentially infectious material.

Rationale: Hidden surfaces and crevices can prevent thorough cleaning. Residual organic matter or large numbers of microorganisms can significantly reduce the effectiveness of the subsequent microbicidal process. The recommended procedures for disassembly and reassembly are intended to help ensure that reassembly can be accomplished without loss of time or damage to important equipment. The recommendation concerning reusable sharps is based on OSHA regulations (29 CFR 1910.1030).

7.4.2 Disassembly of rigid sterilization container systems

7.4.2.1 Removable filters

If the rigid sterilization container system is provided with removable filters, the filter protectors or holders (retention plates) should be removed or released to disengage the filter media. If disposable, the entire filter should be disposed of according to the policies and procedures of the health care facility. Removable, reusable filters should be disassembled, cleaned, and replaced according to the manufacturer's written instructions.

Rationale: Filters, by their nature, can be reservoirs of contamination, especially when the container system is used to collect or transport used instruments. A disposable filter might not maintain its barrier effectiveness for more than one cycle, and reuse could result in improper sterilization or contamination of the container system contents.

7.4.2.2 Valves

If the rigid sterilization container system is provided with valve-type closures, the manufacturer's written instructions for frequency and method of removal, disassembly, and cleaning should be followed.

Rationale: Improperly maintained valves can interfere with sterilant penetration or allow microbial contamination of container system contents.

7.4.2.3 Interior baskets

The interior basket should always be removed from the rigid sterilization container system for decontamination. Depending on the type of basket and instrument set, the user might need to remove the instruments from the basket before proceeding with the cleaning and decontamination process. In most cases, the interior basket can be processed with the instruments in the basket according to the health care facility's usual routine.

Rationale: Separation of the basket from the container system allows for effective decontamination. The interior basket functions as a tray, much like the mesh-bottomed pan used in a conventionally wrapped set.

7.4.2.4 Labeling

Reusable identification labels might be affixed to rigid sterilization container systems. Depending on the health care facility's procedure, the user might need to remove the labeling before further processing. If a particular container system is always used for the same set of instruments, it could be important to keep the label with the container system.

Rationale: Labeling enables the identification of container system contents.

7.4.2.5 Process indicators, disposable labels, and disposable locks

Process indicators, disposable labels, and disposable locks should be removed before any cleaning of the rigid sterilization container system.

Rationale: The presence of process indicators or fragments of disposable labels or locking mechanisms on the surface of the container system impedes decontamination and the proper functioning of mechanical processing equipment.

7.4.2.6 Dividers and sorting pins

It might be necessary to dismantle dividers and sorting pins that are part of instrument baskets if the dividers and pins will interfere with the proper cleaning of the baskets.

Rationale: If the position of the dividers and pins interferes with cleaning of the baskets, the effectiveness of sterilization could be compromised.

7.5 Cleaning

7.5.1 General considerations

For all reusable medical devices, the first and most important step in decontamination is thorough cleaning and rinsing. Cleaning primarily removes rather than kills microorganisms. Because the cleaning process is not microbicidal, a subsequent disinfection or sterilization process might be necessary to ensure that an item is safe for handling. Effective cleaning is a multistep process that relies on several interdependent factors: the quality of the water; the quality, concentration, and type of detergent or enzymatic cleaner; an acceptable washing method; proper rinsing and drying; correct preparation of items to be processed by cleaning equipment; the time and temperature parameters and load capacity of the equipment; and operator performance.

Rationale: The purpose of cleaning and rinsing is to remove all visible debris from an item and to reduce the number of particulates, microorganisms, and potential pyrogens. The accepted standard for the degree of cleanliness is "visibly clean." Thorough cleaning and rinsing are vital to the effectiveness of subsequent microbicidal processes used for decontamination, disinfection, and/or sterilization. The amount of residue that remains will vary depending on the conditions of use of the cleaning agents, the specific component materials of the reprocessed devices, and the methods used to reduce residuals before reuse. Any organic material or residual cleaning agents remaining on an item can inactivate chemical disinfectants or sterilants as well as protect microorganisms from destruction. In addition, debris could become dislodged and could cause potential health risks, such as a foreign-body reaction or a breeding place for an infection. The water used to perform the final rinse of the device should have a low endotoxin content so as not to cause levels of pyrogens on processed devices that could cause pyrogenic reactions (i.e., fever) in patients. Adequate cleaning and rinsing should result in low bioburden, which is essential to the effectiveness of terminal sterilization and to the protection of patients from pyrogens.

7.5.2 Cleaning agents

Many types of soil could be present on reusable medical devices, but dried blood is especially difficult to remove. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to cleaning. It must be rehydrated and then washed away. Blood adheres to surfaces through mechanical and chemical means. Fibrin filaments in coagulated blood pack themselves into microscopic irregularities in the surface of instruments and have to be mechanically scrubbed away or chemically treated. High pH detergents, enzymatic solutions, mechanical scrubbing, and high-pressure water spray perform this function. Neutral pH detergents do not dissolve fibrin filaments but work well in combination with enzymatic solutions.

Proteinaceous blood components such as albumin are water-soluble and simple to wash away unless they have been denatured (made insoluble) through thermal or chemical means. Hot water, concentrated alcohol, and certain liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) (e.g., glutaraldehyde, ortho-phthalaldehyde) can denature blood proteins, making cleaning much more difficult. An initial cool-water rinse can wash away blood's water-soluble proteins and prevent denaturing. Soaking in concentrated alcohol should be avoided. Solutions that contain alcohol should be diluted according to the manufacturer's specifications before contact with instruments soiled with blood. Heat from excessively long exposure to ultrasonic cleaning can also denature blood. Ultrasonic cleaning procedures should not allow blood to be exposed to temperatures higher than 60°C (140°F) to prevent coagulation (Perkins, 1969).

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 written instructions to determine the appropriate type of cleaning agent. The cleaning agent manufacturer's written 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.

The PPE and safe work practices should be reviewed whenever a new cleaning agent is introduced into the cleaning process.

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 written 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 written 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 written 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 designed for cleaning medical devices are used for fine cleaning, 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 might require degassing when they are filled with water; the ultrasonic cleaner manufacturer's written instructions for use should be followed. The medical device manufacturer's written 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.

Blood is composed primarily of water-soluble proteins. If blood remains on an instrument after the wash phase of a mechanical cleaning equipment cycle, the water-soluble proteins will be denatured in any subsequent heated process, such as the hot disinfection phase of a washer-disinfector or washer-sterilizer cycle or a steam sterilization process. Denaturing proteins creates a soil that is much harder to clean the next time through the washing process. It is imperative that all traces of blood, body fluids, and debris be removed during the wash phase of a mechanical cleaning equipment cycle. Failure to do so could result in undetected bioburden that could pose a risk to employee health or result in a patient infection.

Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment. Examples include replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, or computer control or an upgrade to software.

For any mechanical cleaning unit, regular preventive maintenance should be performed in accordance with the manufacturer's written 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 written instructions followed for maximum effectiveness and to avoid expensive and unnecessary damage. Testing the equipment upon installation, during routine use, and after repairs allows the user to verify its continued effectiveness (AORN, 2010b).

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 or contamination 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 patient secretions and excretions and of 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 might identify residues more readily than the unaided eye.

Although validation of the cleaning process might not be realistic in health care facilities, verification is possible (see Annex D).

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 written 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 according to the device manufacturer’s written instructions, 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 might 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 written instructions should be followed.

After pretreatment, instruments may be processed either manually or mechanically. 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 written 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 written 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 deionized water before sterilization (see 8.3.8).

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 written 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 might 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 written 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 might 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 written instructions in conjunction with the mechanical cleaning equipment manufacturer's written 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 written 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 written 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.

Very hot water can cause burns; spilled water can cause personnel to slip and fall. If mating surfaces and gaskets are damaged, sterility maintenance could be compromised.

Thorough rinsing is essential for removal of cleaning agents. Hidden surfaces and crevices can make thorough cleaning difficult. Residual organic matter can significantly reduce the efficacy of the decontamination process. Damaged components of container systems could interfere with the sterilization process or allow contamination of the contents.

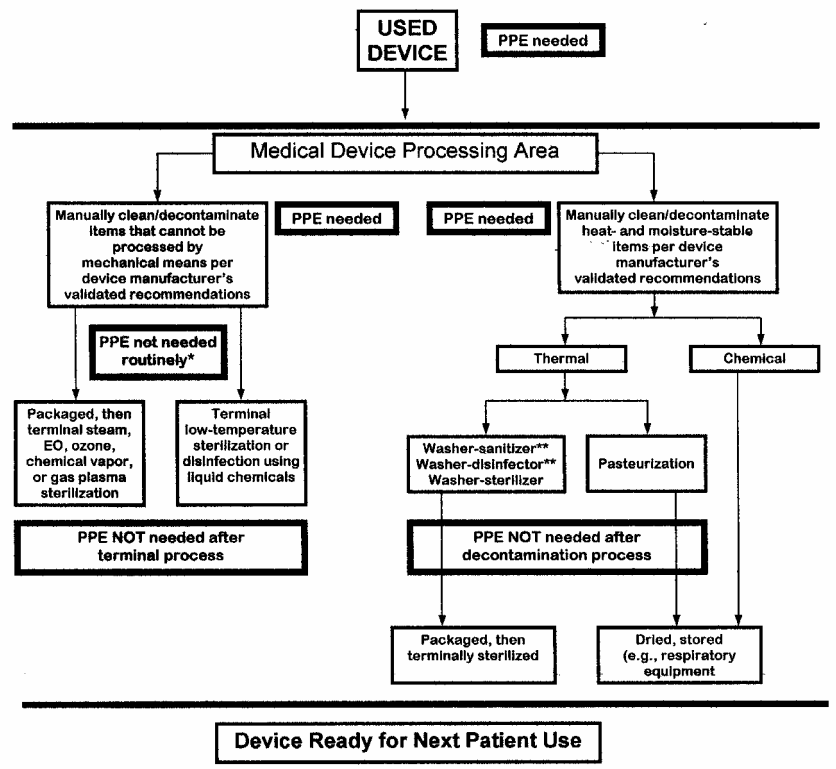
7.6 Microbicidal processes

7.6.1 General considerations

Cleaning alone might not adequately decontaminate items that, by their design, the nature of their contamination, and/or their intended use, present a high risk of disease transmission to workers or patients. Such items include devices that have been in contact with blood or other body fluids (e.g., surgical instruments) and devices that can cause cuts or puncture wounds (e.g., reusable needles and sharp-edged devices). After such items have been cleaned, they should be subjected to a microbicidal process. Microbicidal processes include disinfection and sterilization by thermal or chemical means. See Figure 3 for a flow chart illustrating the use of microbicidal processes to help ensure that items are safe for personnel to handle and indicating the processing stages at which PPE is required.

NOTE—Refer to the device manufacturer's written instructions to determine whether decontamination using microbicidal processes is required after cleaning and before terminal sterilization.

Rationale: Compared with cleaning alone, decontamination using microbicidal processes provides a higher assurance of microbial kill and, thus, an increased margin of safety for personnel who will be handling items that pose a high risk of disease transmission. It is not possible to eliminate all risk. A realistic goal is to develop a process that provides a high level of confidence that the decontamination procedures produce a reasonable level of safety without compromising processing efficiency.



*In certain circumstances (e.g., the processing of endoscopes, respiratory devices, and devices that are grossly contaminated), PPE might be required. The device manufacturer's written instructions should be followed.
**Might include chemical treatment and/or high temperature as the method of decontamination.

Figure 3—Microbicidal processes and use of PPE

7.6.2 Processes to decontaminate devices so that they are safe to handle

7.6.2.1 Chemical disinfection

Chemical disinfection can be performed by manually soaking an item in a basin of liquid chemical germicide solution or by means of automated equipment such as washer-disinfectors, which provide a cycle of cleaning, rinsing, disinfection, and drying. Commonly used liquid chemical disinfectants contain agents such as glutaraldehyde, chlorine compounds, phenols, quaternary ammonium compounds, ortho-phthalaldehyde, and hydrogen peroxide, singly or in combination. After chemical disinfection, the medical device should be thoroughly rinsed of all chemicals and then dried before undergoing sterilization. Any chemical residues left on a medical device could affect the sterilization process and potentially harm the patient or personnel.

Depending on its intended use, a liquid chemical germicide might be regulated solely by FDA, solely by EPA, or by both agencies. Germicides that are intended for use as the terminal step in processing reusable critical and semicritical medical devices before patient use are regulated by FDA as medical devices (21 CFR 880.6885), and they require premarket clearance as described in the FDA guidance document, *Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants* (FDA, 2000b). The Food Quality Protection Act of 1996 removed LCSs/HLDs used to process critical and semicritical medical devices from

the definition of “pesticide” under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As a result, these products are no longer subject to regulation by EPA. General-purpose disinfectants must be registered as pesticides by EPA. They are exempt from FDA premarket notification requirements, but must be manufactured in compliance with the FDA quality system regulation (21 CFR 820). Disinfectants that are intended for use only on environmental surfaces are regulated by EPA. Occupational exposure to some chemical disinfectants is regulated by OSHA. Additional information on government regulation of liquid chemical germicides can be found in ANSI/AAMI ST58.

LCS/HLD labeling 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 before 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 shelf-life and instructions for determining whether the concentration of the active ingredient is above the minimum recommended concentration (MRC) or minimum effective concentration (MEC). The labeling includes the bottle label and any package insert, which might contain both the above information and 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 reference to specific diseases, such as AIDS and tuberculosis, unless effectiveness has been shown in clinical trials. For some products, OSHA requires the manufacturer to supply an MSDS (see 29 CFR 1910.1200). FDA labeling guidance is provided in FDA (2000b).

Knowledge of the range of antimicrobial activity of disinfectant formulations is critical in selecting an appropriate disinfectant for the level of decontamination required for the devices being processed. For automated chemical disinfection systems, the effectiveness of the process relies heavily on coordinating the recommendations of the device manufacturer, the disinfection equipment manufacturer, and the manufacturer of the disinfectant solution. For any automated chemical disinfection unit, regular preventive maintenance should be performed in accordance with the equipment manufacturer's written instructions. To avoid potential health hazards, it is essential for personnel to use chemical disinfectants with care and to follow the disinfectant manufacturer’s written instructions for rinsing. Annex E provides guidelines on the selection and use of chemical disinfectants.

7.6.2.2 Chemical sterilization for decontamination

Liquid chemical sterilants include glutaraldehyde, hydrogen peroxide, hydrogen peroxide-peracetic acid combinations, sodium hypochlorite, and peracetic acid. These chemical agents are most often used as HLDs for semicritical medical devices. When used as sterilants, these agents must be used for significantly longer exposure times than when they are used as HLDs. Gaseous chemical sterilants include EO, hydrogen peroxide, chemical vapor combinations, and ozone. As described in 7.6.2.1, FDA has regulatory authority for LCSs and their labeling. Occupational exposure to sterilants is regulated by OSHA (29 CFR 1910.1000, 1910.1047 [EO], and 1910.1048 [formaldehyde]); for some products, OSHA requires the manufacturer to supply an MSDS.

Items should be thoroughly cleaned and dried before they are placed in the sterilant or sterilizer. To document the decontamination or sterilization process, personnel should monitor chemical sterilants in accordance with the sterilant manufacturer’s written instructions.

It is essential to use chemical sterilants with care to avoid potential health hazards. To remove toxic residues that might harm workers or patients, it might be necessary to mechanically aerate items that have been processed with a gaseous chemical sterilant (e.g., EO) or to rinse, with sterile water, items that have been processed with a LCS. The sterilant manufacturer’s written instructions for use should be followed.

Additional guidelines on the selection and use of chemical sterilants are provided in ANSI/AAMI ST58 and Rutala (1996).

7.6.2.3 Thermal (hot water) disinfection

Thermal disinfection is commonly accomplished with automated equipment such as washer-sanitizers, pasteurization equipment, washer-decontaminators, and washer-disinfectors. The level of disinfection achieved depends on the water temperature and contact time. Contact time is inversely related to temperature; i.e., for equivalent microbial kill, substantially longer exposure times might be required when the temperature is reduced. Recommended water temperatures and contact times vary from manufacturer to manufacturer and among the major categories of equipment. In general, however, the following categories of equipment are associated with increasing levels of disinfection, with washer-sanitizers providing the lowest level and washer-disinfectors the highest.

a) Washer-sanitizers, washer-decontaminators, utensil washers, and cart washers reduce microbial contamination by means of cleaning agents, hot water, rinsing, and drying. Some types of equipment include chemical disinfectant rinses. No specific claims of microbicidal efficacy are generally made for this type of equipment, and the actual results might range from low-level disinfection to intermediate-level disinfection.

b) Pasteurization equipment provides cleaning and high-level disinfection at water temperatures of 65°C to 77°C (150°F to 170°F) for a contact time of at least 30 minutes.

c) Washer-disinfectors provide a cycle of cleaning, rinsing, disinfection, and drying at temperatures that are usually higher than those of washer-sanitizers. Some types of equipment can be programmed to alter temperature and/or contact time, and some incorporate chemical disinfectant rinses. Washer-disinfectors can provide high-level disinfection, depending on the moist heat exposure time and temperature. Washer- disinfectors that use disinfecting chemicals can also provide high-level disinfection, depending on the exposure time and the disinfecting agent used.

To ensure that the equipment is functioning properly, the temperature should be monitored. Irreversible thermometers as well as remote sensing equipment are now available to monitor and document the temperature of the thermal disinfection rinse of automated washers. Equipment that uses spray arms should be checked at least daily to ensure that the arms are completely free-turning and that the spray nozzles are not clogged. For equipment with strainers, the strainers should be cleaned at least daily or when there is visible debris. For any thermal disinfection equipment, regular preventive maintenance should be performed in accordance with the manufacturer's written instructions. Further information about thermal disinfection is provided in Annex F.

Rationale: The CDC guidelines prescribe the proper level of final processing between patient uses for critical, semicritical, and noncritical items (CDC, 2003a). Thermal disinfection is usually an interim step in the processing of medical devices; that is, it is intended to render the items safe to handle by personnel not wearing protective attire, not to process them fully for reuse in patient care. Even if steam sterilization is used as a decontamination step, as in a washer-sterilizer, the items are not considered patient-ready. Critical items should always be subjected to a sterilization process after decontamination is complete, and semicritical items should usually be subjected to either sterilization or high-level chemical disinfection. An exception is made for some semicritical items undergoing pasteurization. Although the characteristics of pasteurization do not support a claim of high-level disinfection according to the CDC guidelines (the ability to kill all microbial life except large populations of bacterial spores), many semicritical items such as respiratory therapy and anesthesia devices are ready for patient use after cleaning and pasteurization. High numbers of bacterial spores are not generally found on this equipment after use, cleaning before pasteurization reduces the bioload substantially, and the low numbers of spores that might be present on a properly processed device would not present an infective dose when contacting intact mucous membranes. The FDA has cleared one or more devices that incorporate processes using pasteurization time-temperature relationships as high-level disinfection. For noncritical items, processing through a washer-decontaminator or washer-disinfector provides more than adequate sanitization, even if heavily contaminated with blood or other potentially infectious materials.

Temperature monitoring and appropriate equipment maintenance help ensure that thermal disinfection equipment is performing effectively. Verifying that spray arms achieve full rotation and that the nozzles are clean will help ensure effective cleaning action.

7.6.2.4 Thermal sterilization for decontamination

Saturated steam can be used to decontaminate devices capable of withstanding high temperatures (121°C to 135°C [250°F to 275°F]) and pressures (16 to 35 psig). Washer-sterilizers provide cleaning and rinsing followed by exposure to saturated steam at temperatures of 121°C to 135°C (250°F to 275°F). The washer-sterilization process should not be used as terminal sterilization. Devices that must be sterile for patient use should be inspected and prepared for further processing in a steam sterilizer.

7.6.3 Terminal sterilization processes to prepare devices for the next patient use

7.6.3.1 General considerations

After decontamination, all items should be inspected for cleanliness and functionality. If the items are intended for noncritical use (e.g., bedpans, other patient utensils), no further processing is necessary. (For additional information, see Annex E.2.)

When mechanical cleaning and a sterilization process are combined and performed in a single machine, the items processed by this means are generally not suitable for immediate use in a sterile procedure. For example, an

instrument set processed through a washer-sterilizer should not be considered safe and sterile for patient use, although it is safe for personnel to handle.

7.6.3.2 Chemical terminal sterilization

A process using a machine specifically designed to clean and sterilize or high-level disinfect a particular type of device, such as a flexible endoscope, can result in an item that is safe to use in patient care where contact with compromised tissue is anticipated. Manufacturers of equipment labeled as combining cleaning and sterilization or high-level disinfection should present to the user scientific evidence that the equipment will perform as intended under usual conditions of use in health care facilities and that the processed items can be confirmed as patient-ready.

Some devices cannot tolerate mechanical washing or thermal decontamination. Such devices are first thoroughly cleaned, rinsed, inspected, assembled, and (if applicable) packaged by personnel wearing appropriate PPE and then processed through a chemical sterilization process, such as EO, peracetic acid, hydrogen peroxide, ozone, or chemical vapor combinations (see ANSI/AAMI ST41 and ANSI/AAMI ST58). In these cases, the sterilization process is both the final step in decontamination and the preparation for patient use.

Rationale: If a device has not been thoroughly cleaned and rinsed first, dead organisms in soil or organic debris can cause pyrogenic or foreign-body reactions if the sterilized item is used in an invasive procedure. Functionality of the device could also be compromised; for example, the box lock of a hemostat might not close because of residual soil, or the lumen of an item might be occluded. Although a process designed only to decontaminate could actually yield a sterile item, a sufficiently high sterility assurance level (SAL) cannot be assumed because of the unknown and presumably high bioburden present at the beginning of the cycle. It is difficult to achieve both cleaning and patient-ready sterility or high-level disinfection in a single process. Generally, it can only be done when the process is specifically designed and validated for application to a particular device or family of devices. Combining the biocidal step in decontamination and the terminal sterilization process will yield patient-ready sterile items only if devices are thoroughly cleaned.

7.6.3.3 Thermal terminal sterilization

The most common type of thermal terminal sterilization is steam sterilization. See Section 8.

Dry heat sterilization is another method of thermal terminal sterilization. See ANSI/AAMI ST40.

7.7 Servicing and repair of devices in the health care facility

7.7.1 General considerations

Medical devices or equipment can be serviced or repaired on-site (i.e., within the health care facility) by hospital employees, manufacturers' representatives, or contract service representatives. Service personnel can potentially be exposed to infectious agents, which can be present either on contaminated devices or in the environment in which the devices are used. Device manufacturers should provide training for their service personnel and instructions to users to help prevent such exposure. Likewise, health care facilities should establish policies and procedures to help ensure that service personnel, whether manufacturers' representatives, in-house clinical engineers and biomedical equipment technicians, or third-party service providers, are not exposed to infectious agents.

7.7.2 Potential for exposure

There are numerous occupational activities in which service or sales personnel can potentially encounter blood-borne pathogens or other infectious agents, such as *Mycobacterium tuberculosis*. These activities include

a) servicing or repairing equipment contaminated with blood or other body fluids or located in isolation rooms;

b) demonstrating equipment during surgical procedures;

c) installing or removing equipment; and

d) inadvertently contacting sharp objects (e.g., needles left in equipment, broken glass, sharp equipment edges).

Some types of equipment present a relatively high potential risk of exposure to service personnel. Equipment in all clinical areas can present exposure risks, particularly where blood and body fluids flow (e.g., ORs, emergency

rooms, labor and delivery rooms). Such equipment includes surgical tables (especially the portion beneath the surgical drapes), surgical lights, and warming cabinets. Surfaces remote from the patient can be contaminated by the hands of individuals who have contacted the patient's blood, or the blood can spray or drip onto the equipment. Equipment used in patient transportation, such as stretchers and wheelchairs, can be contaminated in areas not accessible to normal cleaning processes. Because dialyzers come into direct contact with patient blood, much of the equipment in dialysis units should be considered a high-risk source of infection. Care should be taken to prevent exposure when dismantling any equipment used within the health care environment.

Equipment in decontamination areas of central service departments presents relatively high risks to personnel. Cleaning and decontamination equipment found in the decontamination area can well be contaminated, of course, and there might be sharps and other potential hazardous devices in the environment. The nonclean end of sterilizers and sterilizer accessories, such as loading tables, shelving, and transfer carriages, is also of concern.

Clinical laboratories can present significant risk. Any equipment that comes into direct contact with blood, body fluids, body tissues, or other potentially infectious materials is particularly hazardous.

Respiratory protection for service personnel must be provided by the health care facility in isolation rooms or areas occupied by patients with airborne diseases. Personnel who require access to equipment needing repair in isolation rooms should follow hospital policies and procedures.

7.7.3 Protective measures for service personnel

7.7.3.1 General

Service personnel who might be exposed to infectious agents should receive training on how to recognize potentially unsafe conditions, when and how to use safety equipment, and how to decontaminate surfaces when this is practical. As an additional safety measure, manufacturers and health care facilities should offer hepatitis B immunization to their service staff.

7.7.3.2 Education and training

See 4.3.2.

7.7.3.3 Vaccination

See 4.4.

7.7.3.4 Personal protective equipment

See 4.5.4.

7.7.3.5 Work practices

Before beginning any repair, service, or maintenance task, personnel should ascertain whether the user has cleaned and decontaminated the equipment or rendered it safe to handle. Cleaning/decontamination of equipment should be performed by personnel familiar with the appropriate processes. The equipment should be clearly tagged, indicating the extent of decontamination (i.e., surface decontaminated only or internally/externally decontaminated). If no tag is present, it must be assumed that the item has not been decontaminated.

Service personnel should not handle potentially infectious materials. Users or other appropriately designated personnel (e.g., a spill team) are responsible for removing, containing, and disposing of infectious or potentially infectious materials. Anyone handling infectious materials should be attired in the appropriate PPE (see 4.5.4) and should use the containment and transport methods designated by the hospital.

7.7.4 Postexposure program

Procedures should be established for handling actual exposure incidents. Such procedures should comply with current CDC recommendations and OSHA regulations.

7.7.5 Devices that cannot be repaired in-house

See Annex G for guidelines on returning devices to the manufacturer.

NOTES

8 Packaging, preparation, and sterilization

8.1 General rationale

This section covers the various methods and techniques used in packaging medical devices, the assembly and preparation of surgical instrumentation for sterilization, the sterilization process, sterile storage, and distribution.

8.2 Selection of packaging materials

An effective packaging material for steam sterilization processing should, as a minimum

a) allow adequate air removal from and steam penetration of the package contents;

b) provide an adequate barrier to microorganisms or their vehicles;

c) resist tearing or puncture;

d) allow a method of sealing that results in a complete seal that is tamper-evident and provides seal integrity;

e) allow for ease of aseptic presentation;

f) be free of toxic ingredients and nonfast dyes;

g) be non-linting; and

h) be shown by value analysis to be cost-effective.

Personnel should understand how the sterilization method and the items being sterilized affect the selection of the appropriate packaging method and how the packaging method affects sterilization parameters. When selecting a packaging system, personnel should obtain and keep on file the manufacturer's test data, instructions for use, and care and handling instructions. Packaging policies and procedures should be based on the manufacturer's written instructions for use.

Rationale: The primary functions of a package containing a medical item are to allow the sterilization of the contents, to maintain the sterility of the contents until the package is opened, and to provide for the removal of the contents without contamination. It should be noted that packaging provides some resistance to the sterilizing agent, which could necessitate increased exposure time. Documentation of the manufacturer's test data provides assurance that the packaging system selected meets the criteria required, such as linting level, barrier efficacy, puncture resistance, fluid resistance, and sterilant penetration and removal. Not all packaging systems are suitable for all types of sterilization methods. (For example, some rigid sterilization container systems can only be used in prevacuum steam sterilizers; and some types of packaging might require an increased drying time.) Certain chemical cleaners might be needed for some types of packaging (e.g., rigid sterilization container systems), or special storage conditions might be required (see 8.3.1 and 8.3.5).

8.3 Package configurations and preparation

8.3.1 General considerations

Before use, packaging materials should be held at room temperature (20°C to 23°C [68°F to 73°F]) and at a relative humidity ranging from 30% to 60% for a minimum of 2 hours. All packaging materials, woven or nonwoven, should be examined regularly for defects and extraneous matter. Policies and procedures should be developed for packaging techniques and should be consistent with the manufacturer's recommendations. Examples of sequential double-wrapping are provided in Figures 4 and 5. Examples of simultaneous double-wrapping are provided in Figures 6 and 7. Examples of single- and double-pouching are provided in Figure 8.

Wrappers should be kept snug to prevent low spots that could collect condensate on the exterior of the package; however, care should be taken not to wrap too tightly, because strike-through could occur. Rigid sterilization container systems should be scientifically proven to be suitable for the specific sterilization cycle to be used; when items are being prepared for sterilization, the container system should be verified as the correct one for the cycle (see 8.6.1). Only filter materials that have been tested and documented to be efficacious in the specific container system should be used. Before use, filters should be inspected for visible holes. Also, for container systems designed for terminal sterilization (not flash sterilization), the user should obtain and follow the manufacturer's written instructions to ascertain that the valve system opened for sterilization and closed after the drying cycle.

If “wet packs” are observed, they should not be released. They should be reprocessed in a manner that ensures that excess moisture/condensation does not occur. They should be repackaged (including the outer wrapper), and the CIs should be replaced with new ones. Sterilized textiles should be removed and replaced with freshly laundered textiles that have not been ironed. Disposable products such as gauze and cotton balls should be discarded.

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. For reusable wrappers, a tab should be created for easy removal of the tape. It is not necessary to tab single-use wrappers; when they are opened for use, the sterilization indicator tape is simply torn. 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 written 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.

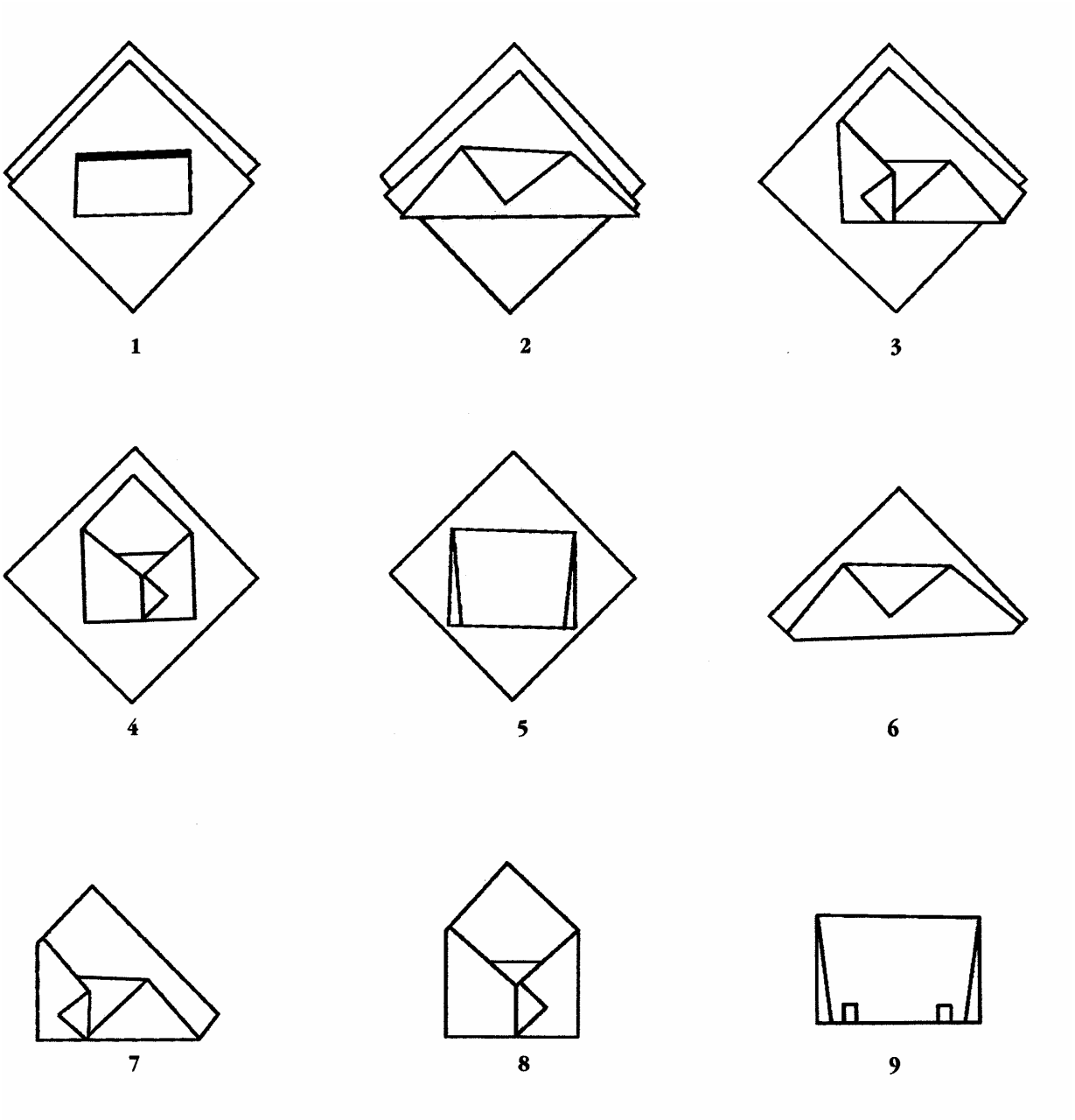


Figure 4—Sequential double-wrapping: envelope fold

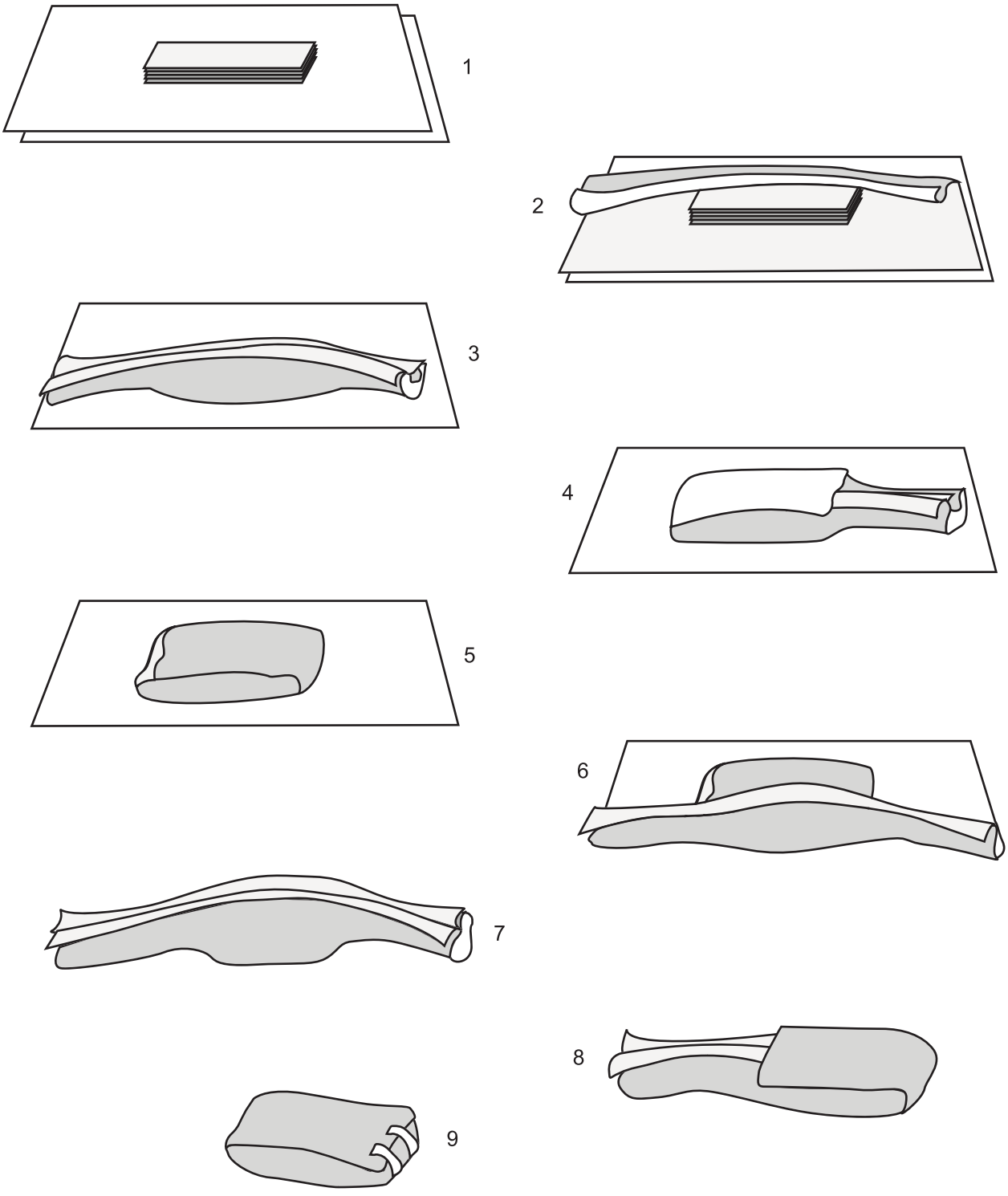


Figure 5—Sequential double-wrapping: square fold

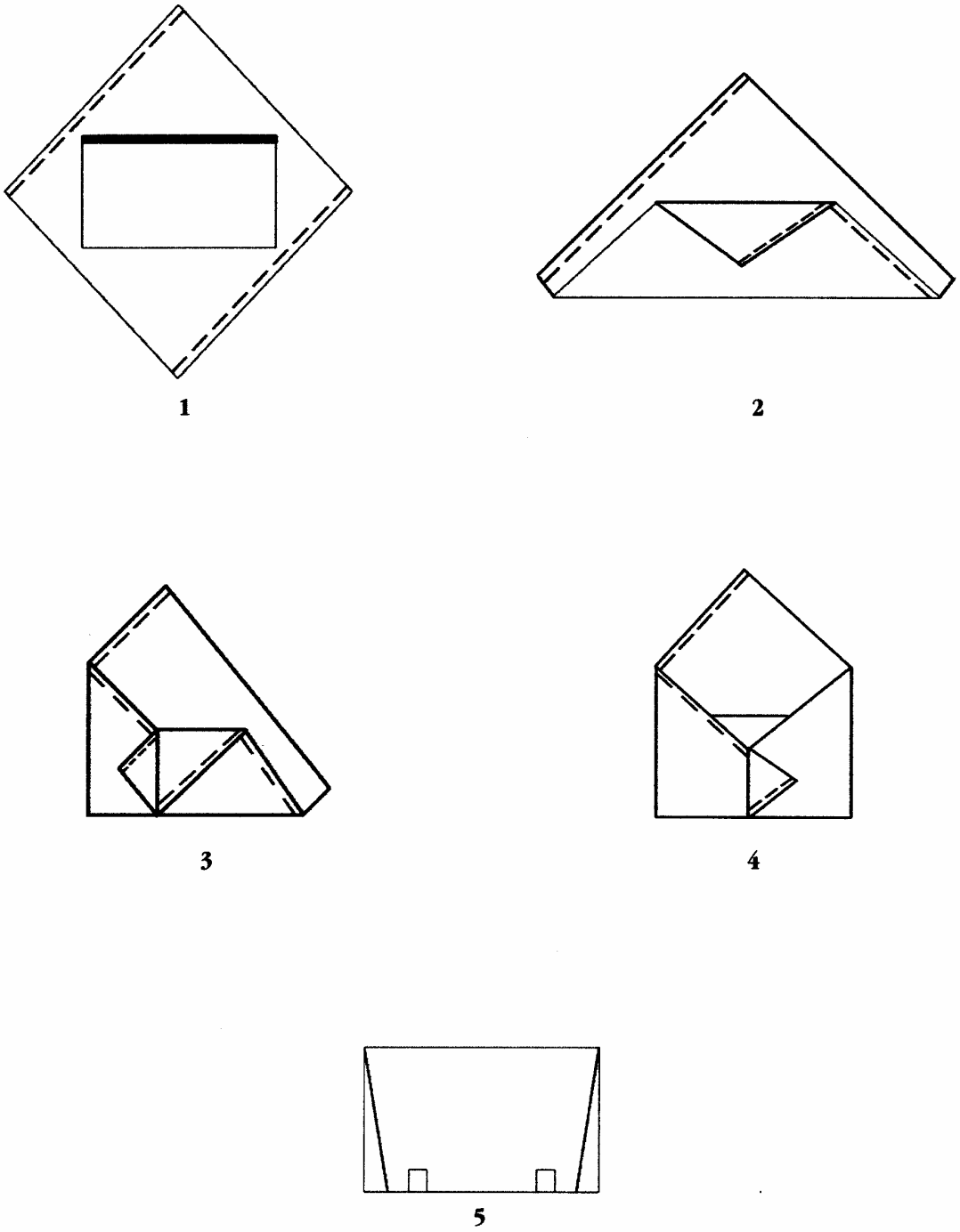


Figure 6—Simultaneous double-wrapping: envelope fold

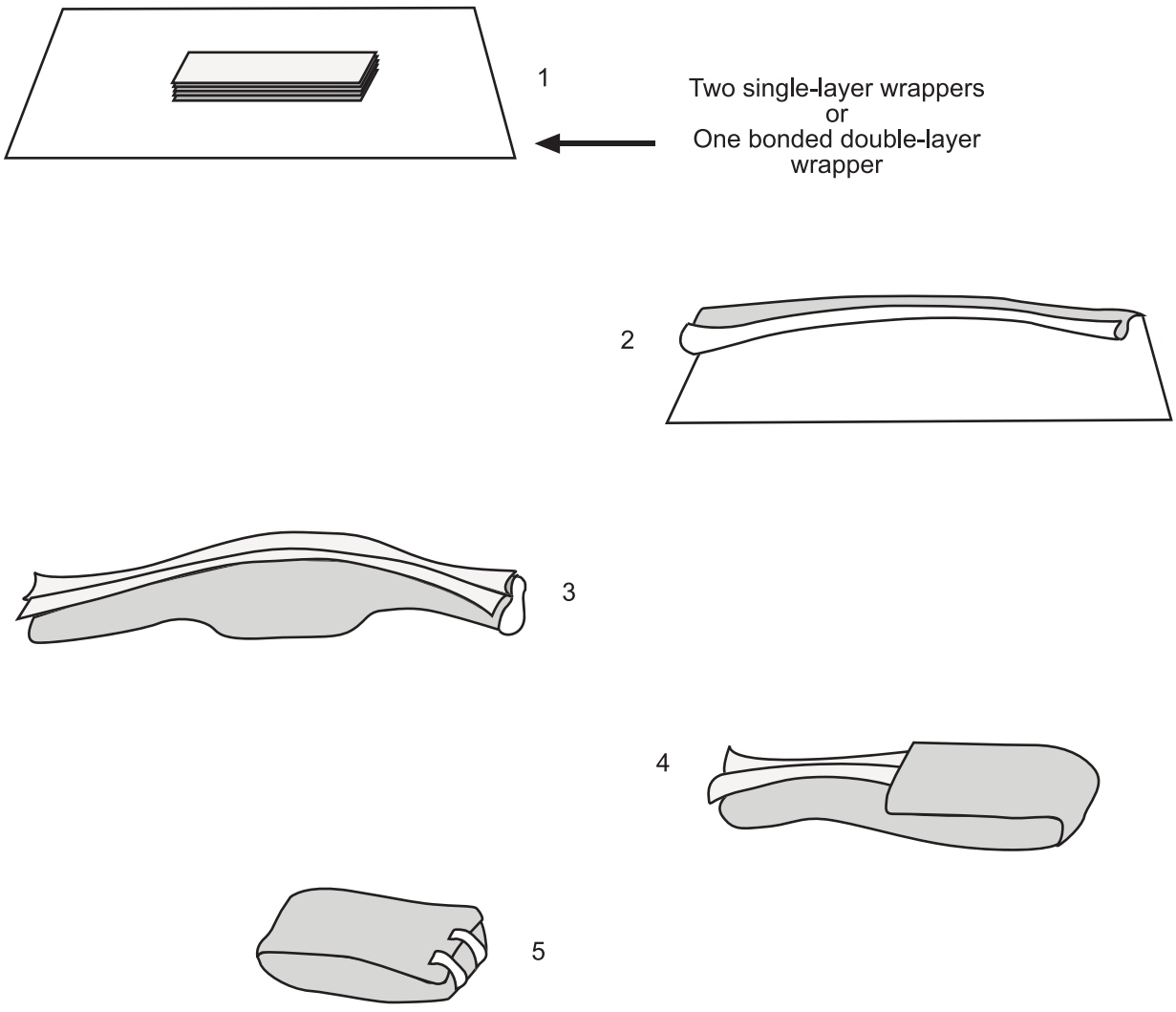


Figure 7—Simultaneous double-wrapping: square fold

8.3.4 Paper–plastic pouches

Paper–plastic pouches should be used for small, lightweight, low-profile items (e.g., one or two clamps or Army-Navy instruments) (Figure 8). If the item is to be double-packaged, two sequentially sized pouches should be used (i.e., the sealed inner pouch should fit inside the other pouch without folding). The pouches should be positioned so that plastic faces plastic and paper faces paper. Paper–plastic pouches are not appropriate for use within wrapped sets or containment devices.

NOTE 1—Small, perforated mesh-bottom baskets with lids can be used instead of paper–plastic pouches to contain small items in sets. Small items or instruments can also be placed in an all-paper bag, an absorbent, single-layer, flat wrap, or in an appropriate foam product. A CI should be placed inside these inner packages.

NOTE 2—Double packaging in paper–plastic pouches should not be performed without documentation from the manufacturer that the paper–plastic pouch has been validated for this use.

Rationale: The use of paper–plastic pouches with heavy metal instruments (e.g., orthopedic drills, weighted speculums, orthodontic pliers) could result in problems with sterility maintenance, such as inadequate drying of the package after sterilization (see 8.3.1). Proper sizing and application of pouches allows for adequate air removal, steam penetration, and drying. Validation by the manufacturer that a paper–plastic pouch is suitable for double packaging is important because otherwise the capability of the packaging material could be exceeded. It is inadvisable to use paper–plastic pouches within wrapped sets or containment devices because the pouches cannot be positioned to ensure adequate air removal, steam contact, and drying. The plastic laminate used in paper–plastic pouches is impervious to the sterilant and, therefore, might prevent the sterilant from reaching the surface of anything with which the plastic side is in physical contact. Therefore, paper–plastic pouches should not be used within wrapped sets or containment devices unless the practice has been validated by the packaging manufacturer and verified by product testing in the health care facility.

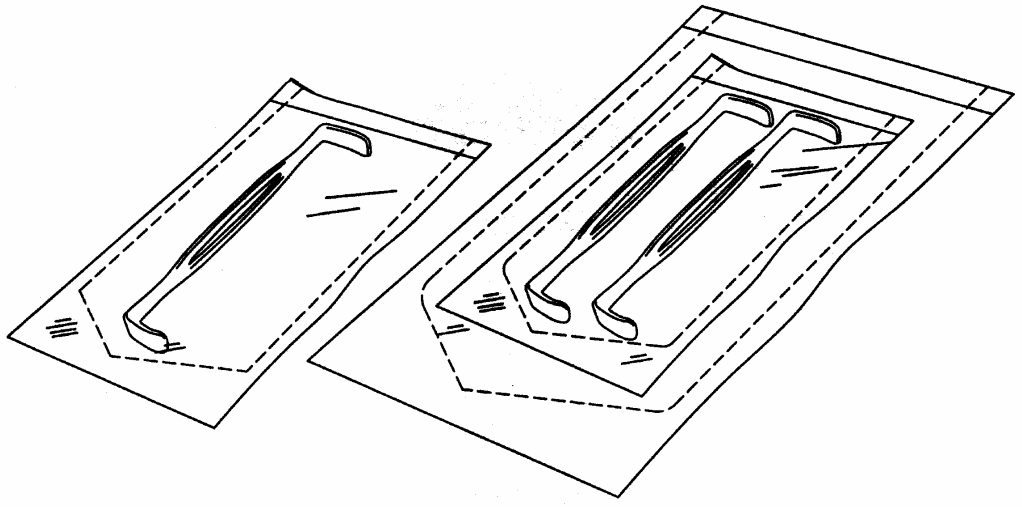


Figure 8—Example of single- and double-packaging with paper–plastic pouches
NOTE—Instruments should be oriented within paper–plastic pouches according to the health care facility's policies and procedures.

8.3.5 Textile packs

Textile products and wrappers should be made of materials that will allow adequate air removal, steam penetration, and steam evacuation (for drying) when the package has been properly assembled. The textile product manufacturer should be consulted for recommendations on the pack size and density that have been validated using hospital steam sterilization cycles.

Wrappers made of woven textiles are reusable. The barrier qualities of new textile wraps are diminished by repeated laundering and sterilization cycles. Before each use, textile wraps should be laundered, delinted, and inspected (over illuminated tables) for holes, worn spots, breaks in or separation of the fabric, and stains. Holes in wrappers should never be repaired or mended by stitching. Small holes and worn spots can be mended with vulcanized or thermoseal patches. The advisability of patching depends on the extent of wear, the location and size of holes and tears, the effectiveness of the wrap after patching, the maximum allowable number of patches, and the security of the patch after sterilization. The number of uses of textiles that have a defined use life should be monitored. See also ANSI/AAMI ST65.

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 could 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 before 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, written 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 might 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. Because 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

Any stylets or plugs should be removed from devices with lumens, such as catheters, needles, and tubings. For gravity-displacement steam sterilization, such devices might need to be flushed with distilled or deionized (treated) water before they are packaged. However, moisture should not be added to any lumen before sterilization unless recommended by the manufacturer of the lumened device. If moistening of the lumen is recommended by the device manufacturer, sterilization should follow immediately.

Rationale: The lumens of devices such as catheters, needles, and tubings pose a challenge to sterilant penetration, especially in certain types of gravity-displacement cycles, because they restrict diffusion. In the past, AAMI has recommended that all lumens be moistened before steam sterilization; on the basis of current scientific evidence, however, the committee now judges that this procedure is likely to be necessary only for complex lumened devices to be sterilized in certain gravity-displacement cycles. As always, the device manufacturer's written instructions should be followed. If it is necessary to flush the lumen, distilled or deionized water is recommended because tap water might contain various unwanted components, such as organisms or foreign organic material that could be pyrogenic, and/or high concentrations of inorganic components that could lead to corrosive deposits (AAMI TIR34, Table 1).

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. Excess moisture from cleaning and rinsing should be removed using filtered, medical-grade, compressed air. When instrument trays are reprocessed, all disposable items in the tray (e.g., towels, gauze) should be removed and replaced. 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. Excess moisture should be removed because it can adversely affect the drying process; using methods other than compressed air for drying can adversely affect the device or contaminate it. 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 could be compromised in commonly available hospital sterilization cycles. Additionally, there might be ergonomic issues associated with heavy, containerized instrument sets. A maximum weight limit of 25 pounds for containerized instrument sets has been recommended in 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 Z314.14). 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 caused by 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.

8.4.3 Inspection

Instruments should be carefully inspected for cleanliness and flaws or damage and dried before packaging. Before each use, the perforated or wire-mesh-bottom trays should be inspected for any sharp edges, nicks, or loose wire-mesh to prevent tearing or puncturing of the wrapper(s). Special rigid organizing trays, if used, should be inspected for any sharp edges or nicks that will puncture or tear the wrapper(s). If a rigid sterilization container system is used, the latching mechanism or closure should be checked to ensure that it will remain secure. The sealing or mating surfaces or edges of the container system and lid should be checked to ensure that they are not dented or chipped. Filter retention mechanisms and fasteners such as screws and rivets should be secure and should not be distorted or burred; the securing mechanism should function properly, and the filter media should be examined for integrity. The gaskets should be pliable, securely fastened, and without breaks or cuts. The valves should work freely and should be without breaks, cuts, chips, or dents.

Rationale: Inspecting trays that require wrapping for sharp edges, nicks, or loose parts will prevent the tearing or puncturing of the wrapper(s) during and after the sterilization process. To ensure the operating efficiency of a rigid sterilization container system, a thorough and clearly delineated inspection procedure is necessary. All of the container system's components (top, bottom, valve or filter mechanisms, securing or latching mechanisms) must function effectively as a unit. It is vital to the maintenance of sterility that these components work together to allow air removal, to facilitate sterilant penetration and removal, and to inhibit microbial migration and contamination.

8.4.4 Instrument placement

Instruments to be sterilized should be arranged according to the following guidelines:

a) If a rigid sterilization container system is used, the basket(s) placed in the container system should be large enough to allow the metal mass of instruments and devices to be distributed equally in the basket(s). Woven mesh-bottom trays or baskets generally are acceptable for use.

   NOTE—The use of some nonabsorbent tray liners (e.g., plastic- or silicone-fingered organizing mats) can cause condensate to pool. See also 8.4.5.

b) Instruments should be positioned to allow the sterilant to come into contact with all surfaces.

c) All jointed instruments should be in the open or unlocked position with ratchets not engaged. Racks, pins, stringers, or other specifically designed devices can be used to hold the instruments in the open position.

d) Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled unless the device manufacturer provides specific written instructions, supported by test data, to the contrary.

e) Instruments should not be held together with rubber bands.

f) Care should be taken in the placement of items made of glass, rubber, or, in the case of surgical instruments, dissimilar metals.

g) Items with concave surfaces and/or broad, flat surfaces that will retain water should be placed on edge so that these surfaces will drain water or condensate.

h) Heavy instruments should be placed in such a way that they will not damage more delicate items. Lighter instruments should be positioned to protect tips and to prevent damage from changes in position.

i) Complex instruments (e.g., air-powered instruments, endoscopes, and instruments with lumens or channels) should be prepared and sterilized according to the device manufacturer's written instructions. When combining complex instruments in a set, the user might have to test and evaluate the effectiveness of sterilization and drying (see 10.9).

j) Small, basket-type accessory containers with covers or lids (e.g., nail or bone-screw holders), protective organizing baskets, trays, or cases (e.g., microsurgery instrument cases, air-powered equipment sets, orthopedic instrument organizing sets) should be placed into rigid sterilization container systems only if the container systems have been specifically designed and tested for this purpose. Collaborative testing should be performed by the device manufacturer, the manufacturer of the protective organizing case, and the container system manufacturer. The user has the responsibility to test and evaluate the effectiveness of sterilization and drying of protective organizing cases during the specific sterilizer cycles to be used for sterilization processing. Before preparation and sterilization of multipart sets or complex instruments, processing personnel should review the specific written instructions that apply.

k) When rigid sterilization container systems are used, all items should be contained in the basket or tray within the container system.

If a rigid sterilization container system is used, the manufacturer's written instructions regarding set preparation and assembly should be followed. Whenever items are prepared for sterilization, the user should verify that the container system and the medical device to be sterilized have been tested and validated for the preset standard steam sterilization cycle to be used. If the container system manufacturer or the medical device manufacturer recommends a cycle other than a preset standard steam sterilization cycle, the recommended cycle should be one that can be calibrated and verified by health care personnel and that does not invalidate the warranty of the sterilizer. The design, density, and weight distribution of the contents also should be considered when selecting the cycle. Sterilization cycles not specifically recommended by the container system manufacturer should not be used. If there is any doubt about the appropriateness of any container system for a specific sterilization cycle, the container system manufacturer should be consulted.

Rationale: Sterilization depends on contact of the sterilizing agent with all surfaces for the prescribed time. Air removal, steam penetration, and condensate drainage are enhanced by proper positioning and by the use of perforated or mesh-bottomed trays or baskets. Provision for condensate drainage is especially important for flash sterilization cycles, which do not provide for drying the items; visible moisture (condensation) is normally found on items following the flash sterilization process.

Improper positioning or abrupt changes in positioning can result in damage to the instrument or the rigid sterilization container system and can prevent adequate sterilant penetration and contact during processing. Devices made of glass can be damaged if positioned incorrectly; rubber can become tacky because of the heat generated by hot metal instruments; and devices made of dissimilar metals can be damaged because of material interactions.

Instruments with concave or broad, flat surfaces that are not placed standing on edge during processing can retain pools of water that might not drain off or revaporize completely at the end of the cycle.

For complex instruments, the device manufacturer is best able to specify packaging requirements and sterilization methods, including the type of cycle, sterilization temperature, exposure time, and drying time required because of instrument configuration. As with any other packaging method, containment devices such as protective organizing baskets, trays, or cases should not be used without consulting the containment device manufacturer or conducting specific testing, because these devices can affect the dynamics of the sterilization and drying process. Containment devices such as protective organizing baskets, trays, or cases can impede air removal, steam

penetration, and steam evacuation (for drying) and thus prevent sterilization from being accomplished in the specified cycle time.

8.4.5 Use of tray liners or containment devices

The judicious use of tray liners or other absorbent material can alleviate drying problems. Absorbent inner wraps can also assist in the aseptic presentation of instruments. Containment devices such as organizing trays can help keep items in place but should ensure adequate sterilant contact. The recommendations of the packaging manufacturer concerning the use of containment devices or inner absorbent material should be consulted, and the user should evaluate the effectiveness of the sterilization and drying process when such devices or materials are used.

Rationale: Absorbent material wicks condensate away from instruments and disperses it over a greater surface area for more efficient drying. However, an excessive amount of absorbent material or the incorrect type of absorbent material can impede air removal and sterilant penetration and interfere with proper drying. Containment devices can also impede sterilant contact and the drying process. As is always the case in the sterilization process, a delicate balance is necessary and requires the special attention of the user.

8.5 Loading the sterilizer

8.5.1 General considerations

Similar items requiring the same cycle parameters (i.e., sterilization exposure time and temperature, cycle drying and/or cool-down time) should be grouped together. Procedures describing load contents and placement configurations should be developed. If a cart shelf liner is used, it should be made of a nonlinting, absorbent material that will dry in the drying time selected for the rest of the load. Load configurations should ensure adequate air removal, penetration of steam into each package, and steam evacuation. Items capable of holding water, such as solid-bottomed pans, basins, and trays, should be positioned so that they are oriented in the same direction and so that condensate can be eliminated (i.e., arranged in such a way – normally on their sides – that if water is present, it will drain out). (See Figures 9[a] through 9[f] for examples of proper loading.) Placing metal items above textile items should be avoided. In loading any sterilizer, the sterilizer manufacturer's *written* instructions should be followed; however, the recommendations of 8.5.2 to 8.5.6 address some general aspects of sterilizer loading. Procedures for configuring mixed or heterogeneous loads should be developed, and process audits should be performed and documented to ensure compliance.

Rationale: Loading the sterilizer in this fashion allows adequate air elimination and drainage of condensate, which are needed to attain product sterility. Absorbent cart shelf liners can be helpful in drying a load; the material should be nonlinting because lint can carry microorganisms into the surgical site and cause foreign-body reactions. Orienting items such as solid-bottomed pans in the same direction allows rapid, even distribution of steam throughout the load, with the least amount of interference. Placing metal items below textile items enables condensate to drain out without wetting other items in the load. Sterilizers differ in design and operating characteristics, so it is important that the manufacturer's written instructions be carefully followed.

8.5.2 Paper–plastic pouches

Paper-plastic pouches should stand on edge in relation to the cart or shelf, with the paper side of one pouch next to the plastic side of the next pouch; holding racks or baskets specifically designed for pouches can be used.

Rationale: Special racks or baskets facilitate placing paper–plastic pouches on edge and properly spaced in the sterilizer for adequate sterilant contact and drying. They are also helpful in keeping similar small packages in position during the sterilization process.

8.5.3 Instrument sets

Wrapped and unwrapped instrument sets in perforated trays or rigid sterilization container systems should be placed on the sterilizer shelf or cart so that the bottom of the tray or container system is parallel to the shelf.

Rationale: This position maintains distribution of metal mass and allows air removal, sterilant penetration, condensate drainage, and drying. It also helps keep instruments in orderly arrangement, prevents instrument damage, and ensures access to the set or tray for removal from the sterilizer.

8.5.4 Textile packs

Textile packs should be loosely loaded. They should be positioned standing on edge so that all fabric layers are perpendicular to the shelf (not stacked one upon the other) (see Figure 9[f]).

Rationale: Loading textile packs in the manner recommended facilitates air removal and steam penetration during the sterilization process, as well as steam evacuation for drying.

8.5.5 Utensils and glassware

Materials capable of holding water, such as solid-bottom pans, bowls, and trays, should be positioned tilted on edge and oriented in the same direction (see Figure 9[a]).

Rationale: Positioning utensils and glassware in the manner recommended allows for efficient displacement of air and the rapid, even distribution of steam throughout the load with the least amount of interference. The pooling of condensate is also prevented.

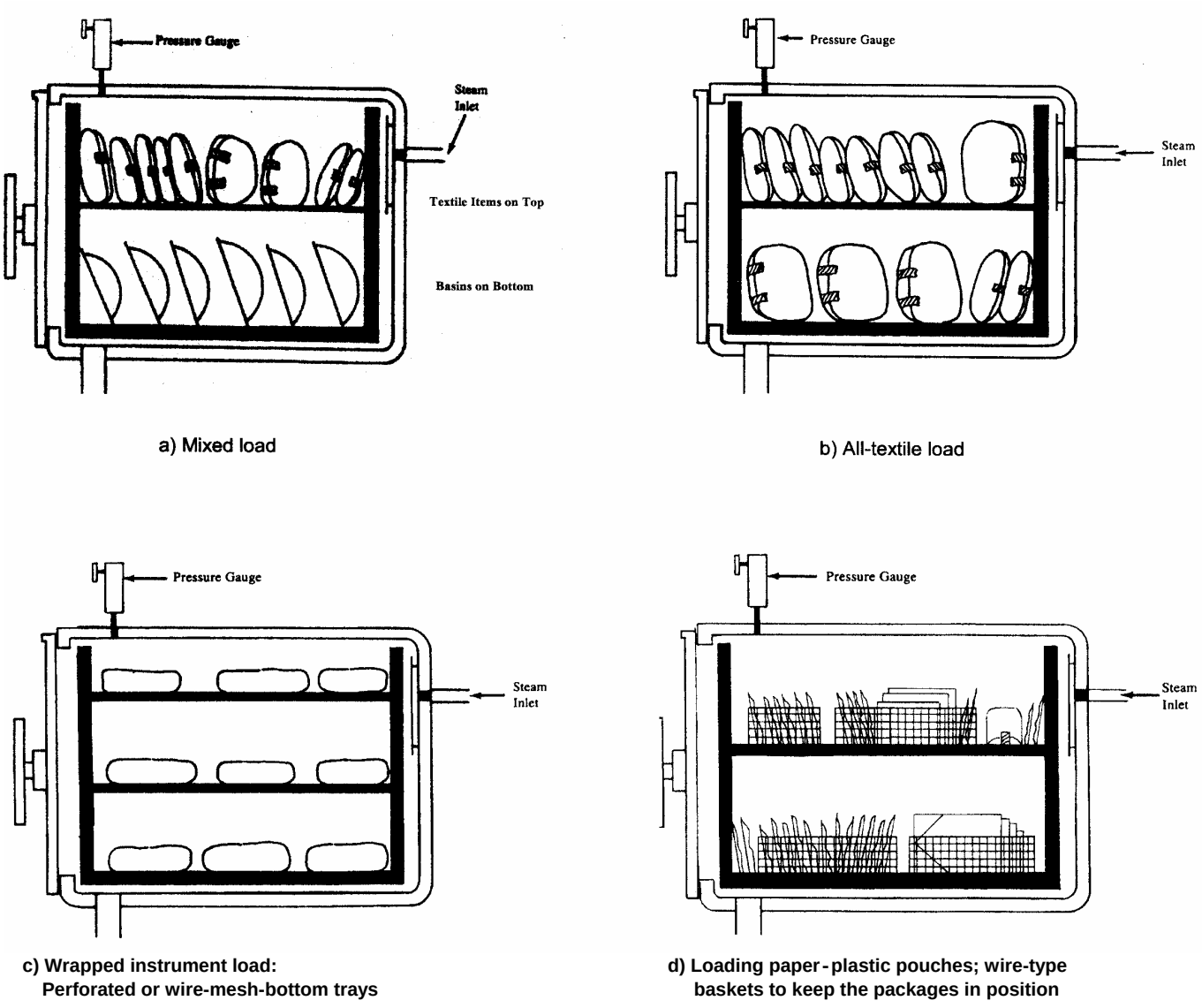
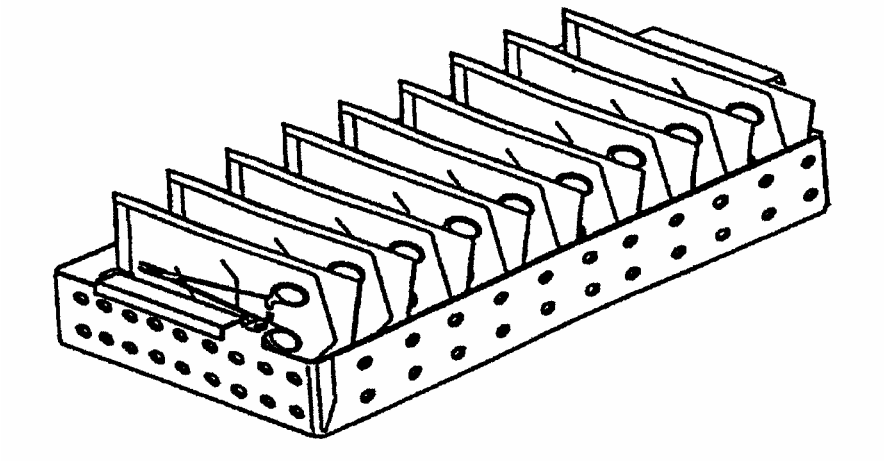
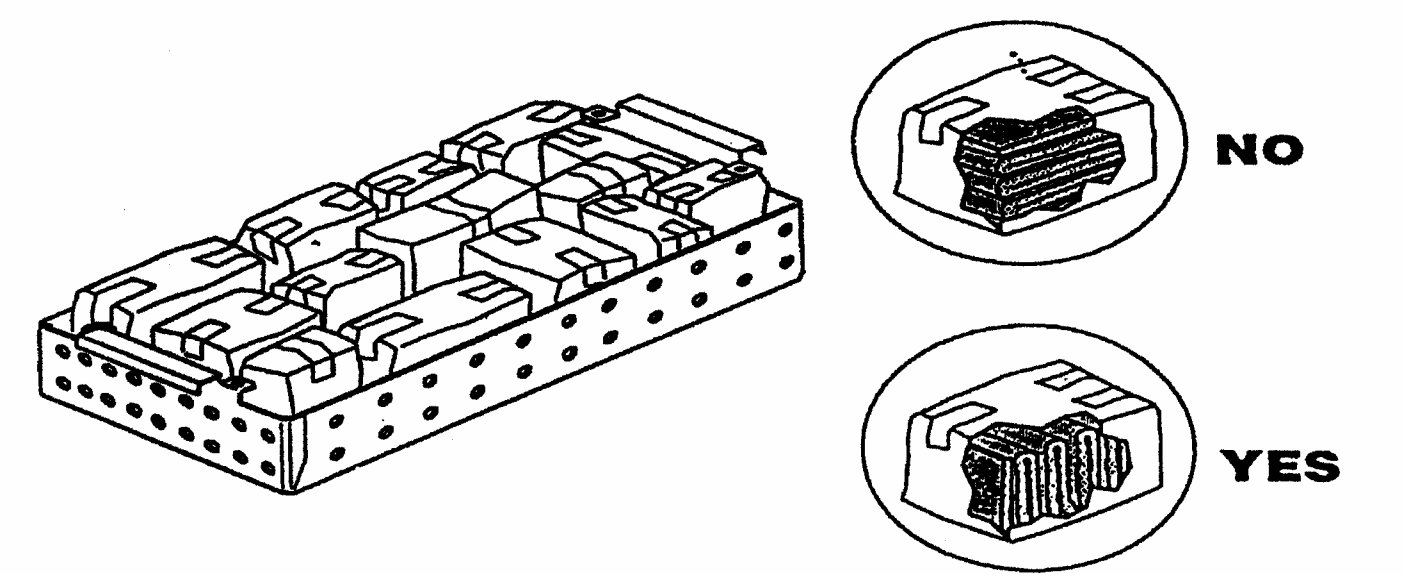


Figure 9—Loading the sterilizer



(e) Paper–plastic peel pouches (placed on edge)



(f) Wrapped packs (placed on edge)

Figure 9 *(continued)* – Loading the sterilizer

8.5.6 Rigid sterilization container systems

Rigid sterilization container systems can be sterilized safely and economically in the same load as other supplies that require a common exposure cycle. Container systems should be placed on shelves below absorbent items, as should other metal items. Before stacking container systems for sterilization, the user should consult the manufacturer's recommendations and documentation. The user should also conduct verification testing in the sterilizer to be used (see also 10.10.3).

NOTE—Users are cautioned that stacking container systems of differing manufacture is not advisable because the configurations might not be compatible. Recommendations from both manufacturers should be obtained, and verification testing should be conducted in the sterilizers to be used.

Rationale: Placing rigid sterilization container systems below absorbent items prevents the wetting of the absorbent items by condensate from the container systems. Stacking container systems in the sterilizer could

interfere with air evacuation, sterilant penetration, and drying or aeration. The appropriateness of stacking container systems in the sterilizer depends on the design of the container system and the method of sterilization.

8.5.7 Liquids and solutions

Primarily for personnel safety reasons, inhospital preparation and sterilization of parenteral and irrigation liquids is discouraged. When solutions are processed in the hospital (i.e., in emergency situations), processing should be performed only by trained personnel familiar with the following guidelines:

a) Solutions should be sterilized separately from all other items in a cycle specifically designated for liquids.

b) Solutions should be processed in flasks (e.g., Kimax® or Type 1 borosilicate [Pyrex®] glass) with automatically venting and sealing flask closures (caps) specifically designed for this purpose. *Screw caps or rubber stoppers with crimped seals must not be used.*

c) Vacuum cycles must never be used for sterilizing fluids.

See also Perkins (1969) for additional information on emergency processing of solutions.

NOTE—FDA does not review validation data for sterilization cycles designated for liquids and recommends that a labeling caution be added stating that if such cycles are run, the resulting solutions should not be used in patient care activities.

Rationale: Unloading steam-sterilized bottles of liquids poses a great potential for serious injury to personnel. If inhospital processing of solutions is absolutely necessary, personnel should be thoroughly conversant with the hazards and with the special safety precautions needed to avoid injury. Because solutions must undergo a slow exhaust cycle and special cooling process, they should not be sterilized with other items, but rather in a dedicated load subjected to a cycle specifically designed for solutions (Perkins, 1969). Special flasks and closures are needed for processing solutions because screw caps or rubber stoppers are not secure enough to maintain sterility without creating an explosion hazard. Postvacuum cycles will cause solution containers to explode. The sterilizer manufacturer's written instructions should be carefully followed to minimize the hazard to personnel. An additional reason why inhospital sterilization of solutions is discouraged is that health care facilities are not equipped to perform the quality control procedures (e.g., pyrogen testing) necessary for processing parenteral and irrigation liquids.

8.5.8 Powders and oils

Powders (such as talc) and oils cannot be steam-sterilized. They should be processed by dry heat (ANSI/AAMI ST40) or commercially sterilized.

Rationale: Powders and oils are impermeable to steam (Joslyn, 1983).

8.6 Sterilization parameters

NOTE—Care should be taken to ensure that all devices in a load have the same exposure time, as specified in the device manufacturers' written instructions.

8.6.1 Sterilization parameters for wrapped or containerized items

Steam sterilization cycles typically used in health care facilities include the gravity-displacement cycle and two types of dynamic-air-removal cycles. One type of dynamic-air-removal cycle, the prevacuum cycle, removes air from the chamber and load by means of pressure and vacuum excursions. The other type, the steam-flush pressure-pulse (SFPP) cycle, removes air with a series of steam flushes and pressure pulses above atmospheric pressure. The sterilizer manufacturer's operator's manual should be consulted for specific exposure times, temperatures, and drying times. However, Tables 4 and 5 describe the most common temperature and time parameters for various types of loads.

The sterilizer manufacturer's written instructions for cycle parameters should be followed. Programmed cycle selections should be used. Any differences between the programmed cycle parameters and the cycle parameters recommended by the medical device manufacturer should be investigated and resolved before the items are sterilized. Procedures for correct cycle selection should be developed and implemented, and process audits should be conducted to ensure compliance. Procedures for cycle modification should specify use of an appropriate process challenge device (PCD), i.e., one that provides an adequate challenge in a cycle with extended exposure time; also, the user should ensure that the packaging material can withstand an extended cycle.

If a rigid sterilization container system or a sealed containment device designed for flash sterilization is used as packaging, the container system manufacturer's written recommendations regarding exposure time should be consulted and reconciled with those of the sterilizer manufacturer. The correct cycle parameters should be selected and verified on the basis of the results of product testing (see 10.9 and 10.10). In addition, certain types of medical equipment (e.g., some air-powered instruments) might require prolonged exposure times (see 8.6.3).

Rationale: Sterilizers vary in design and performance characteristics, so cycle parameters should always be verified against the sterilizer manufacturer's written instructions for the specific sterilizer and load configuration being used. The use of rigid sterilization container systems or sealed containment devices designed for flash sterilization could affect come-up and exposure times in steam sterilizers, depending on the efficiency of air removal from and steam penetration into the container systems. Therefore, it is important to verify that containerized devices can be effectively sterilized by the cycle parameters selected. The design of some medical devices will itself hinder air removal and steam penetration, making sterilization more difficult. The device manufacturer is in the best position to specify the conditions necessary for steam sterilization of a particular device.

Table 4—Minimum cycle times for gravity-displacement steam sterilization cycles

Item	Exposure time at 121°C (250°F)	Exposure time at 132°C (270°F)	Exposure time at 135°C (275°F)	Drying times
Wrapped instruments	30 minutes	15 minutes		15−30 minutes
			10 minutes	30 minutes
Textile packs	30 minutes	25 minutes		15 minutes
			10 minutes	30 minutes
Wrapped utensils	30 minutes	15 minutes		15–30 minutes
			10 minutes	30 minutes
Unwrapped nonporous items (e.g., instruments)		3 minutes	3 minutes	0−1 minute
Unwrapped nonporous and porous items in mixed load		10 minutes	10 minutes	0−1 minute

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.

Table 5—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 1—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.

NOTE 2—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).

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.

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 minutes at 132°C to 135°C (270°F to 275°F). When nonporous items, porous items, and items with lumens are sterilized together, the minimum exposure time and temperature is 10 minutes at 132°C to 135°C (270°F to 275°F). See Table 4 and AORN (2010e).

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

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.)

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 minutes 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 minutes at 132°C (270°F) or 3 minutes at 135°C (275°F). See Table 5 and AORN (2010e).

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 written 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 (because of 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 instrument 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 written 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 (because of 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 written instructions should be followed. See also AORN (2010a).

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 where there are no air-conditioning or other cold-air vents in close proximity. Warm items should never be transferred from the cart to cold metal racks or shelves for cooling or placed within dust covers before completion of the cooling process (see 8.9.1).

Rationale: Seasonal and geographic variations in ambient temperature and humidity affect cooling time, as do other factors unique to the individual facility. The type of sterilizer used can also affect cooling time, depending on how hot items are when they leave the sterilizer. Consequently, the time allowed for cooling has to be based on professional judgment and experience. Although a minimum cooling time of 30 minutes is recommended, adequate cooling could require 2 hours or more. Packages contain a significant amount of moisture after being exposed to steam. That moisture migrates out of the package as a gas or water vapor during both the drying phase and the cooling phase. Packages should not be touched until they are cool because a hand can act as a point of condensation for the warm water vapor emanating from the package, thereby creating a moist area on the outside of the package. This moist area can act as a wick to draw bacteria from the hands into the package. Placing the sterilizer cart in a low-traffic area reduces exposure of the items to particles settling from the environment and minimizes the possibility of inadvertent personnel contact with the sterilized items when they are especially vulnerable to contamination. Placing a warm pack on a cool surface could cause condensate to form, resulting in contamination of the pack.

If rigid sterilization container systems are not properly cooled before they are removed from the sterilizer cart, recondensation of steam vapor can occur. Because the materials used for containers are not absorbent, condensate can appear as small droplets on or within the container system. Condensate on the outside of a container system can flow downward toward the filter of another container and contaminate it. Condensate can also run down the sides and onto noncontainerized packages below, contaminating them. Condensate within any container system can compromise the sterility of the contents if the condensate is able to come into contact with outside contaminants. The potential for outside contamination depends on several factors, such as the type of filter media and the seal of the filter or valve. The potential for contamination also depends on the construction of the container system, e.g., whether the container system has a solid bottom or feet to raise it above contaminated surfaces. Because some of the materials used in rigid sterilization container systems can burn the operator when hot, care should be exercised in handling them.

Opening the door for a period of time at the end of the sterilization cycle and before the container systems are removed from the chamber allows the sterilizer jacket to continue warming the load through radiant heating from the sides, top, and bottom of the chamber. This radiant heating replaces heat lost through evaporation of condensate and promotes continuing evaporation after the cycle ends. Containers made from thermally insulating materials such as plastic do not benefit as much from external radiant heat and, therefore, might require modification of a drying protocol.

8.8.2 Table-top sterilizers

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 10 minutes is recommended.

Items or packs removed from the sterilizer should be visibly dry. Care should be taken to avoid directly touching the items while they are hot. When the loading tray is being removed, a tray handle or long, thermal-protective gloves can be used to prevent thermal injury to personnel.

Rationale: Moisture will wick contaminants into package contents. Unwrapped items are vulnerable to contamination. Sterile items are contaminated when they come into contact with a nonsterile surface. Metal items retain heat and can cause burns.

8.8.3 Open-tray flash cycles

Flash-sterilized items should be used immediately, not stored for later use. Procedures for transferring the items from the sterilizer to the point of use should be based on the assumption that condensate will be present within the tray so care should be taken to avoid contamination of the sterilized items. The tray and the items within it will also be hot, so care should be taken to avoid thermal injury. Personnel should wear sterile gloves and may use sterile towels as “potholders” when removing items from the sterilizer. The tray should never be placed on a nonsterile surface. These procedures should be developed in consultation with the supervisor of the department and the infection prevention and control professional, with the objective of ensuring the best practice possible for aseptic transfer within the physical constraints of the facility.

Rationale: It is particularly important that the flash sterilization method of steam sterilization processing be carried out in a clean environment and that devices processed by this method be transferred and handled as little as possible, because the items are not protected by packaging before or after the sterilization process.

8.8.4 Flash cycles with single wrappers or other textile packaging

Flash-sterilized items are to be used immediately, not stored for later use. For flash cycles with single wrappers or other packaging, special precautions should be taken to ensure that these wrapped/packaged trays are differentiated from wrapped or packaged trays processed conventionally. Procedures for transferring the items from the sterilizer to the point of use should be based on the assumption that condensate will be present within the tray (as is typical of flash sterilization). Moisture can strike through the wrapper or other packaging, so care should be taken to avoid contamination by contact with nonsterile surfaces. The wrapper or other packaging and the item within it also will be hot. Personnel should wear sterile gloves and may use sterile towels as “potholders” when removing items from the sterilizer. The wrapped/packaged tray should never be placed on a nonsterile surface. A sterile, impervious drape, placed on a surface separate from the sterile field, should be used so that the wrapped/packaged tray can be placed there and then opened by the circulator. The sterile items may then be removed from the tray by the scrub person and taken to the sterile field. These procedures should be developed in consultation with the supervisor of the department and the infection prevention and control professional, with the objective of ensuring the best practice possible for aseptic transfer within the physical constraints of the facility.

Rationale: This type of flash cycle includes a very brief drying time. At the end of the cycle, however, the wrapper or other packaging could be wet on the bottom, depending on the amount of condensation created by the types and number of instruments within the tray. Also, even if the wrapper or other packaging appears dry when the sterilizer is opened, handling of the wrapped/packaged item can cause the wrapper or other packaging to become wet in spots. Therefore, the precautions recommended above should be taken.

8.8.5 Flash cycles with sealed containment devices

Flash-sterilized items are to be used immediately, not stored for later use. For flash cycles with sealed containment devices, special precautions should be taken to ensure that these devices are differentiated from wrapped or packaged trays that are processed conventionally. Procedures for transferring the items from the sterilizer to the point of use should be based on the assumption that condensate will be present within the containment device (as is typical of flash sterilization). The containment device and its contents also will be hot. Personnel may wear sterile gloves or use sterile towels as “potholders” when removing items from the sterilizer. The containerized items should never be placed on a nonsterile surface. The sterile items may be removed from the containment device by the scrub person and taken to the sterile field. These procedures should be developed in consultation with the supervisor of the department and the infection prevention and control professional, with the objective of ensuring the best practice possible for aseptic transfer within the physical constraints of the facility.

Rationale: This type of flash cycle includes a very brief drying time. At the end of the cycle, however, the interior of the containment device could be wet on the bottom, depending on the amount of condensation created by the types and number of instruments being sterilized. Therefore, the precautions recommended above should be taken.

8.8.6 Handling and inspection

Written procedures should stress minimizing the handling of all sterile items. As items are removed from the sterilizer cart, they should be visually inspected. Any items with torn packaging or with packaging that appears to be wet should not be used. If an item is dropped on the floor and the integrity of its packaging is compromised, it should be returned to the decontamination area for reprocessing.

Rationale: Items with torn or wet packaging are considered contaminated. Wet packaging might indicate problems with package composition, loading procedures, sterilizer performance or operation, or the steam generation and distribution system. See IAHCSMM (2007) for further information.

8.9 Sterile storage

8.9.1 Sterility maintenance covers

Sterility maintenance covers (dust covers) may be used to protect and extend the shelf life of properly packaged and sterilized items that could be subjected to environmental challenges or multiple handling before use. Only products specifically labeled as sterility maintenance covers should be used for this purpose. A sterility maintenance cover or dust cover should be clearly designated as such to prevent its being mistaken for a sterile wrap. Sterility maintenance covers are designed to provide protection against outside elements (e.g., dust), not to provide a microbiological barrier. If sterility maintenance covers are to be applied to sterilized packages, they should be applied as soon as possible after sterilization, but not before the items are thoroughly cool and dry. Sterilized packages should be handled as little as possible.

The sterility maintenance cover is sealed using either a heat sealer designed to seal plastic to plastic or an alternative method that is similarly effective; a self-sealing cover also may be used. The lot or load control number and expiration statement should be visible through the sterility maintenance cover, or an additional label should be used on the sterility maintenance cover. (See also 10.3.)

Rationale: Plastic provides a barrier to moisture and dust; this barrier might be necessary to preserve the sterile integrity of the package, especially one that is not going to be used immediately or that will be subjected to uncontrolled environments (e.g., during transport between facilities). Because a sterility maintenance cover is applied after sterilization, the outer surface of the actual packaging material should be considered contaminated for purposes of sterile presentation.

Applying sterility maintenance covers soon after sterilization enhances sterility maintenance. However, placing a sterility maintenance cover on a package that is not cool and dry could result in condensation inside the sterility maintenance cover and, because 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, 2006). 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 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 because of 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 (2009) and AORN (2010b).

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 written 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 written 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 written instructions.

Rationale: Basic aseptic techniques and principles of sterilization are the same for all sterile packaging systems. See also AORN (2010d).

NOTES

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9 Installation, care, and maintenance of sterilizers

9.1 General rationale

This section broadly covers care and maintenance procedures applicable to steam sterilizers. Proper attention to equipment maintenance minimizes sterilizer downtime and helps prevent sterilizer malfunctions.

NOTE 1—Performance claims for sterilizers are based on specific product design. The manufacturer's maintenance schedule and procedures should be followed, whether the sterilizer is new, remanufactured, refurbished, or reconditioned.

NOTE 2—For guidance on the installation, care, and maintenance of decontamination equipment (e.g., washer-sterilizers, washer- decontaminators, ultrasonic cleaners), the manufacturer's instruction manual should be consulted.

9.2 Instruction manuals

The purchaser should require that the sterilizer manufacturer provide a comprehensive instruction manual. The care and maintenance section of the manual should include, at a minimum, all information necessary to carry out the procedures recommended in 9.3 and 9.4 and should specify the frequency with which these procedures should be performed. Specific rather than general information should be provided for each equipment model. The user should keep the manufacturer's instructions for as long as the equipment is in service.

Rationale: Detailed and complete information is needed because preventive maintenance, calibration, and repair might be performed by personnel other than the manufacturer's employees or representatives.

9.3 Installation

Sterilizers should be installed according to the manufacturer's written instructions. Particular care should be taken never to install any sterilizer in areas where explosive or flammable materials or anesthetics are used or stored. The sterilizer should not be connected to an electrical circuit with other appliances or equipment unless the circuit is rated for the additional load. A table-top sterilizer should be placed on a level, heat-resistant surface. If a table-top sterilizer is mounted on a counter beneath a cabinet or other overhang, there should be sufficient clearance for adequate access to the sterilizer. The area in front of the sterilizer should be clear of any obstruction. After installation and before the health care facility either takes possession of the sterilizer or puts it into routine service, qualification testing should be carried out according to the procedures outlined in 10.8.

Rationale: Proper installation is necessary to ensure that the sterilizer will perform correctly. The recommendations for placement of the sterilizer are intended to help ensure that explosion and fire hazards are minimized and, for table-top sterilizers, to help ensure that there is proper water distribution in the chamber, that cleaning and water replenishment can be accomplished readily, and that the operator can step away from the unit, when opening the sterilizer door, if a puff of steam is emitted. Proper performance of a steam sterilizer is a function not only of its design, but also of the steam generation and distribution system with which it is used, the electrical system, and other mechanical systems unique to the health care facility. The compatibility of the sterilizer with these systems – and its overall effectiveness – can only be verified in the actual environment in which it will be used.

9.4 Routine care

Sterilizers should be inspected and cleaned daily according to the manufacturer's written instructions (see 9.2). Examples of items requiring daily care and/or cleaning are recording charts, printers, printer ribbons, marking pens and ink, door gaskets, the chamber drain screen, the internal chamber, and external surfaces. Weekly or other prescribed inspection and cleaning should be performed as specified in the manufacturer's written instructions.

Rationale: Periodic inspection and cleaning reduce the frequency of equipment malfunction and the risk of accidental contamination of sterile items.

9.5 Preventive maintenance

9.5.1 General considerations

The manufacturer of the sterilizer should provide written instructions for preventive maintenance of the equipment. This maintenance should be carried out by a qualified individual. Particular attention should be given to the inspection, maintenance, and replacement of components subject to wear, such as recording devices (as applicable), filters, steam traps, drain pipes, valves, and door gaskets. Simple charts showing the locations and replacement dates of components will show trends in deterioration and provide the framework of a preventive maintenance program. The maintenance program may be in-house or contracted with the equipment

manufacturer or other qualified service company. Preventive maintenance and repair records should be retained (see 9.7).

Rationale: Malfunction of critical components can cause sterilization failures or failures of the sterilization parameter recording system. Sterilizer manufacturers generally recommend that preventive maintenance and repair records be maintained for the life of the equipment.

9.5.2 Scheduled maintenance

Lubrication of appropriate parts and replacement of expendable parts, such as steam traps, should be performed, as needed, by qualified personnel. Certain maintenance tasks that require special tools or calibration equipment not available in the health care facility should be performed by the manufacturer, the manufacturer's representative, or another qualified service provider. The frequency of maintenance depends on how often the equipment is used and might vary from facility to facility; the manufacturer's written instructions should be consulted for guidance.

Rationale: It might not be economical for health care facilities to acquire expensive, rarely used special tools or calibration equipment. The normal service life of mechanical components sometimes depends solely on frequency of use, sometimes on age, and sometimes on both.

9.6 Calibration

Periodic calibration should be performed as specified in the manufacturer's instruction manual (see 9.2), and the results should be documented. Examples of items requiring calibration are pressure- and temperature-sensing devices, timers, controls, and recording devices. The instruments used for calibration should be traceable to the primary standards of the National Institute for Standards and Technology. In the event of a sterilizer malfunction or the repair or replacement of any component affecting sterilizer performance, appropriate recalibration should be performed. Calibration may be performed by the manufacturer, the manufacturer's representative, the health care facility's engineering staff, or contract service personnel. Individuals performing the service should have sufficient training to understand the operation and calibration of the specific sterilizer type.

Rationale: Proper calibration of controls, indicators, and recording devices is critical for effective and reliable sterilization. Because the repair or replacement of components often has subtle effects on other seemingly unrelated devices, it is imperative that calibration be performed only by qualified personnel.

9.7 Record-keeping

A maintenance record, in either paper or electronic format, should be kept for each sterilizer. This record should be maintained by the supervisor responsible for the equipment, by the hospital engineering staff, by the service person or organization that performed the servicing, and/or by whomever else is deemed appropriate by the health care facility. The maintenance record should include sufficient information to identify the equipment and to establish a continuous history of all scheduled and unscheduled service. At least the following information should be recorded:

a) the date on which service was requested;

b) the model and serial number of the sterilizer;

c) the location of the equipment (hospital identification, if applicable);

d) the name of the individual from the health care facility who requested and authorized the service;

e) the reason for the service request;

f) a description of the service performed (e.g., calibration, repair);

g) the types and quantities of parts replaced;

h) the name of the person who performed the service;

i) the date the work was completed;

j) the handwritten or electronic signature and title of the person who acknowledged completion of the work; and

k) the results of any post-maintenance testing performed, if needed, before the sterilizer was returned to service.

These records must be maintained by the health care facility. 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 on the basis of state and local regulations, legal considerations (e.g., statutes of limitation for lawsuits), and its individual situation. Sterilization records should be retained in accordance with the policy and procedure established by the individual health care facility.

Rationale: Accurate and complete records are required for process verification and are useful in malfunction analysis.

NOTES

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. Methods of verification include the use of devices that directly test individual instruments for residual soils, challenge cleaning effectiveness with standardized test methods, or measure specific key parameters to evaluate the functionality of the cleaning equipment. Key performance outcomes include clean surfaces and adequate fluid flow in equipment that has adaptors for lumened devices. See Annex D.

Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment. Examples include replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, or computer control or an upgrade to software.

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. Testing the equipment upon installation, during routine use, and after repairs allows the user to verify its continued effectiveness (AORN, 2010a). 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 on the basis of 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 written 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 6 and 10.6);
- routine monitoring of sterilizer efficacy (see Table 6 and 10.7);
- qualification testing of the sterilizer after installation, relocation, sterilizer malfunction, major repairs, and sterilization process failures (see Table 6 and 10.8); and
- periodic product quality assurance testing (see Table 6 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 might 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 on the basis of product performance characteristics and scientific data reviewed by those with technical knowledge and expertise, not merely economics.

Tables 6 and 7 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 6—Sterilization process monitoring recommendations

Routine load release (see 10.5 and 10.6)		Routine sterilizer efficacy monitoring (see 10.7)	Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, sterilization process failures) (see 10.8)	Periodic product quality assurance testing (see 10.9)
Nonimplants	**Implants**			
Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle
External and internal chemical indicator monitoring of packages	External and internal chemical indicator monitoring of packages	External and internal chemical indicator monitoring of packages	External and internal chemical indicator monitoring of packages	Placement of BIs and, CIs within product test samples
Optional monitoring of the load with a PCD containing one of the following: • a BI • a BI and a Class 5 integrating indicator • a Class 5 integrating indicator • a Class 6 emulating indicator	Monitoring of every load with a PCD containing a BI and a Class 5 integrating indicator	Weekly, preferably daily (each day the sterilizer is used), monitoring with a PCD containing a BI. (The PCD may also contain a CI.) For sterilizers larger than 2 cubic feet and for table-top sterilizers, monitoring is done in a fully loaded chamber. In flash sterilization cycles, monitoring is done in an empty chamber. For dynamic-air-removal sterilizers, daily Bowie-Dick testing in an empty chamber	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	

NOTE 1—See Section 12 (New product evaluation) for general guidelines on how to assess the specific label claims of new products that become commercially available.

Table 7—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 unless the internal CI is visible.	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-variable indicator) Class 4 (multi-variable 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)	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.
Class 6 (emulating indicator)	May be used to meet internal CI recommendation. Within a PCD, may be used to monitor sterilizer loads.	Part of package release criteria at use site. Part of load release criteria for nonimplant loads. Part of release criteria for loads containing implants. Implants should be quarantined until BI results are known, except in emergency situations.
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. 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.)	Part of load release criteria. Part of release criteria for loads containing implants. Implants should be quarantined until BI results are known, except in emergency situations. 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.

Table 7—Types and applications for use of sterilization monitoring devices *(continued)*

	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 release criteria for changes made to routinely sterilized items, load configuration, and/or packaging.

NOTE 1—See Section 12 (New product evaluation) for general guidelines on how to assess the specific label claims of new products that become commercially available.

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 check that the pen is functioning properly and ensure that when the chart is inserted, it 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 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.

If the interpretation of the physical monitors suggests inadequate steam processing, the contents of the load should not be dispensed or used. The interpreter should inform the appropriate supervisor, who should initiate appropriate follow-up measures.

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 written instructions.

ANSI/AAMI/ISO 11140-1:2005, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, defines six 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 indicate 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) are intended for use in specific test procedures (e.g., the Bowie-Dick test) as defined in relevant sterilizer/sterilization standards. See 10.7.6 for recommendations concerning the use of these indicators. See also ANSI/AAMI/ISO 11140-5, *Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs.*

Single-variable indicators (Class 3) are designed to react to one of the critical variables and intended to indicate exposure to a sterilization process at a stated value of the chosen variable.

Multi-variable indicators (Class 4) are designed to react to two or more of the critical variables and intended to indicate exposure to a sterilization process at stated values of the chosen variables.

Integrating indicators (Class 5) are designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for BIs.

Emulating indicators (Class 6) are chemical indicators designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specific sterilization process. ANSI/AAMI/ISO 11140-1 refers to these indicators as cycle verification indicators.

NOTE—See ANSI/AAMI/ISO 15882 for information on the selection, use, and interpretation of chemical indicators.

Some CIs, such as Class 1 and Class 3 chemical indicators, are sensitive only to certain variables (e.g., temperature); others, such as Class 5 integrating indicators and Class 6 emulating indicators, integrate all critical variables. Health care personnel should select CIs that are suitable for use in the specific sterilization cycle (see the written instructions of the CI manufacturer and the sterilizer manufacturer). Data should be obtained on the reliability, safety, performance characteristics, and use 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). Manufacturers of CIs are required to provide written instructions on the storage, handling, and use of their products. See also ANSI/AAMI/ISO 11140-1:2005.

Class 4 multi-variable CIs, Class 5 integrating CIs, and Class 6 emulating CIs provide more information about the process than Class 3 single-variable 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 and Class 6 emulating indicators may be used for release of nonimplant 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 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. Implants should be quarantined until the BI results (early readout or spore growth) are available. In an emergency situation, implants may be released before the BI results are available (see 10.6.3); however, the BI should continue to be incubated. A Class 6 emulating indicator within a PCD may be used as part of the release criteria for loads containing implants (see Section 10.6.3). All loads containing implants should contain a BI.

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. If the interpretation of the CI suggests inadequate steam processing, the contents of the package should not be dispensed or used. If already dispensed, the interpreter should inform the appropriate supervisor and return the complete unused package, including load identification and the CI, for appropriate follow-up.

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-variable indicator (Class 3 CI), multi-variable indicator (Class 4 CI), integrating indicator (Class 5 CI), or emulating indicator (Class 6 CI). It should be noted that Class 6 emulating indicators are cycle-specific; that is, they should be used only in the specific cycles for which they are labeled.

The class of CI chosen will depend upon how many critical process variables 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) considered least accessible to steam penetration; for a containment device, the manufacturer's written 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. 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 at the point of use should inform the appropriate supervisor of the inadequate steam processing and return the complete unused package, including load identification and the CI, to the sterilizing department. The appropriate supervisor should then initiate appropriate follow-up measures. 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 any PCDs in the load (a PCD containing a BI, a PCD containing a BI and a Class 5 integrating indicator, a PCD containing a Class 5 integrating indicator, or a PCD containing a Class 6 emulating indicator). If the results of a PCD containing a BI 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 written 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 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 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 written 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 written 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); implants should be quarantined until the results of the BI testing are available (CDC, 2008). 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 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°C to 135°C [270°F to 275°F]) 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). 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. Although the performance of Class 5 integrating CIs 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. Likewise, although Class 6 emulating indicators (a different technology than Class 5 integrating indicators) are designed to react to all critical variables of specified sterilization cycles, they do not directly measure the lethality of a cycle and they are not intended to be used as the sole means of routinely verifying sterilizer efficacy or of qualifying sterilizer performance after installation, repair, or relocation.

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, or

c) a Class 5 integrating CI.

d) a Class 6 emulating indicator.

NOTE—At this time, there are no commercially available PCDs containing a BI and a Class 6 emulating indicator, and there are no guidelines on how health care personnel can create or verify one.

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 a Class 5 integrating CI (BI challenge test pack), or

c) a PCD containing a Class 5 integrating CI or a Class 6 emulating CI (a CI challenge test pack).

For routine release of loads containing implantable devices, a PCD containing a BI and a Class 5 integrating CI (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.

NOTE—See Section 12 (New product evaluation) for general guidelines on how to assess the specific label claims of new products that become commercially available.

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 Class 6 CI). If desired, a PCD containing a BI (a BI challenge test pack) or a PCD containing a Class 5 integrating CI or Class 6 emulating CI (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 should be included in this PCD. Implants should be quarantined until the results of the BI testing are available (CDC, 2008).

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 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 that is based on 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 on the basis of 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, an experienced, knowledgeable person should review the sterilizer chart or printout at the end of the sterilization cycle, as well as 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, 2008).

Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule. 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. 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.

NOTE—See Section 12 (New product evaluation) for general guidelines on how to assess the specific label claims of new products that become commercially available.

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

Sterilization process failures can occur for a number of reasons. A malfunction in the sterilization cycle could occur. Other possible reasons include poor steam quality, operator error, and related factors. 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 written instructions. The load should be considered nonsterile, and the sterilizer should be removed from service. The load should be removed from the sterilizer and quarantined so that it is not inadvertently released for use. 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. 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 or the utilities connected to the 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 written instructions) and be determined to be satisfactory before the sterilizer is returned to service.

A major repair to the sterilizer 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.

The performance of the sterilizer also depends on the utilities connected to it. The sterilizer manufacturer specifies certain utility line sizes, maximum and minimum pressures, and dynamic flow requirements for the required utilities. The steam supply should consist of saturated, condensate-free steam with a minimum dryness factor of 97% (see also 3.3.4). Water quality also might be specified, especially for stand-alone steam generators (which are typically shut down on weekends). Sterilizers are designed to function with a nominal electrical supply and can be operated within a specified range of that nominal value. Significant changes to the utilities connected to the sterilizer (e.g., changes necessitated by water-main breaks, annual boiler maintenance, or additional equipment loads) could affect sterilizer performance. Major repairs of or changes to the utilities (e.g., the installation of new boilers) should be treated as major repairs to the sterilizer, and sterilizer testing should be performed as defined in this section to provide the necessary qualification for use.

Rationale: A faulty sterilizer cannot be made operational without identifying the exact cause of the malfunction and correcting it. 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. Sterilizer testing after major repairs of the sterilizer itself or its utilities is intended to ensure that the sterilizer performs to specifications after the correction of a malfunction. Common problems detected by physical, chemical, and biological 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 should be tested.

NOTE—If a sterilizer will run the same type of cycle (e.g., dynamic-air-removal at 132°C to 135°C [270°F to 275°F]) 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. Although 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 the performance of Class 5 integrating CIs 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 cm by 66 cm). (Preconditioning consists of holding the towels at room temperature—18°C to 24°C [65°F to 75°F]—and a relative

humidity of at least 35% for at least 2 hours.) 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 cm by 23 cm by 15 cm). One or more BIs are placed between the eighth and ninth towels in the approximate geometric center of the pack. The pack is then taped in a manner that will yield the approximately 6 inch (15 cm) 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) 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 because 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 microbial challenge. There are no data to support the need for more than one BI. However, there are several reasons to consider using more than one BI:

a) Multiple BIs may provide additional information for a marginal cycle.

b) They may provide information on the achievement of adequate sterilization conditions in different locations.

c) They may minimize the effects of errors in laboratory culturing.

d) They may increase the confidence level for a quicker readout and, therefore, a shorter turnaround time for BI results (check the BI manufacturer's written instructions).

See Annex K for information on the development and qualification of the 16 towel PCD.

10.7.2.2 Placement of the PCD (BI challenge test pack)

Routine sterilizer efficacy monitoring is performed in a fully loaded chamber. The PCD (BI challenge test pack) should be placed flat (layers of towels horizontal if the 16 towel PCD is being used) in the area of the sterilizer chamber and load that is least favorable to sterilization (i.e., 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 test pack at this location. This area varies with sterilizer design, but is normally in the front, bottom section of the sterilizer, near the drain. (See Figure 11.)

Rationale: See 10.7.2.1.

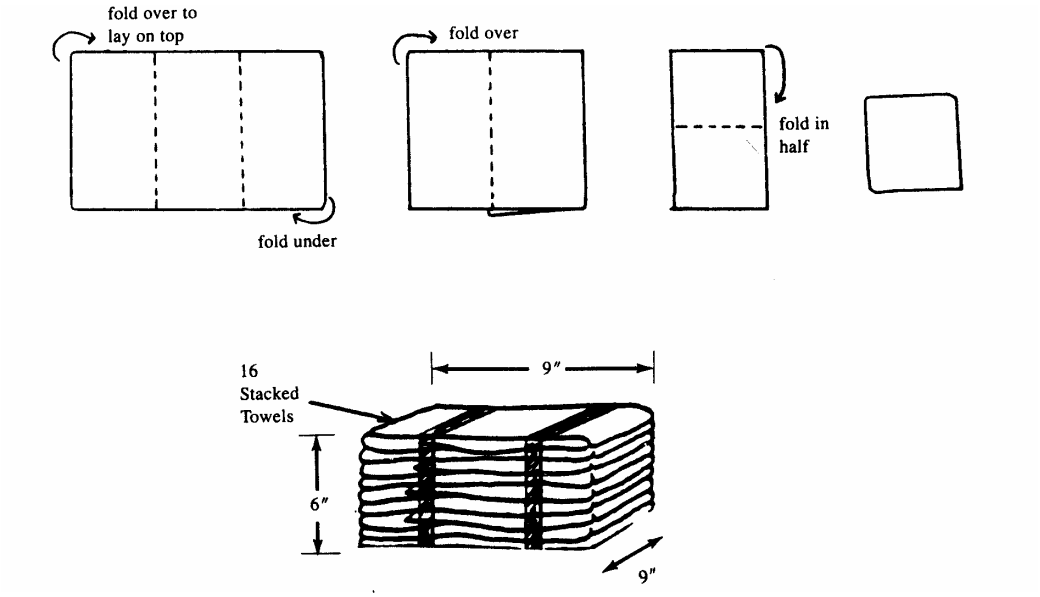

Figure 10—Preparation of the 16 towel PCD (BI challenge test pack)

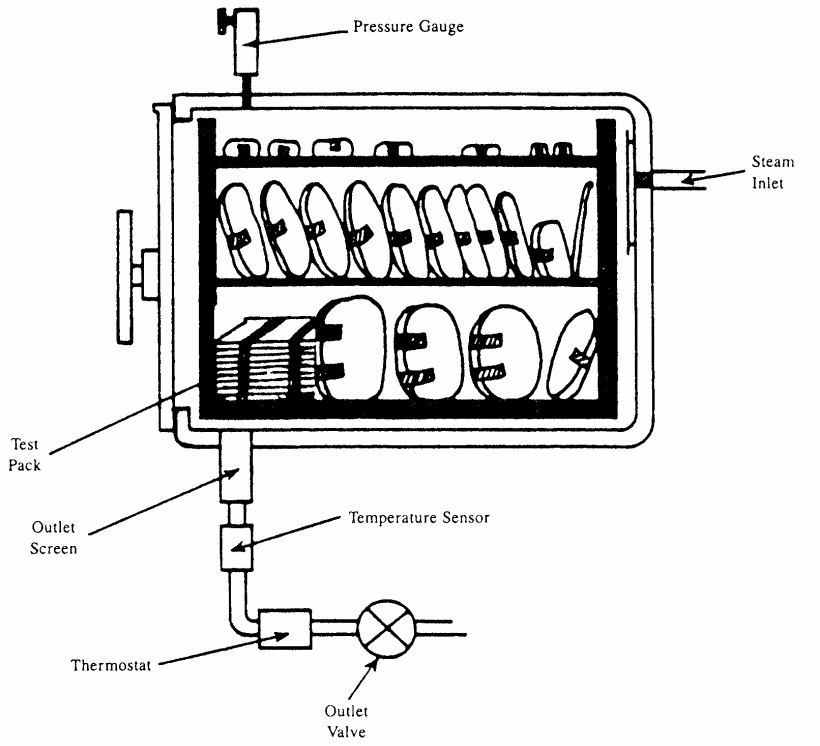

Figure 11—Placement of the 16 towel PCD (BI challenge test pack) for routine biological monitoring of sterilizers larger than 2 cubic feet

10.7.2.3 Test procedure

The test procedure is as follows:

a) Before being exposed to the sterilization cycle, the PCD (BI challenge test pack) should be labeled with appropriate sterilizer lot and load information.

b) The PCD should be positioned in the load according to 10.7.2.2.

c) A normal cycle should be run, according to the sterilizer and device manufacturers' written instructions.

d) Upon completion of the sterilization cycle and adequate cooling of the PCD, the BI(s) should be removed, their identity recorded, 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 manufacturer's written 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) Each day that test BIs are 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 in each incubator 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.

10.7.2.4 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 included in the sterilizer records.

10.7.3 Routine biological monitoring of table-top sterilizers

10.7.3.1 Composition of the PCD (BI challenge test pack or BI challenge test tray)

A representative of the same type of package or tray to be routinely processed through the sterilizer should be selected to serve as the PCD (BI challenge test pack or BI challenge test tray) for routine sterilizer efficacy monitoring. The PCD should contain one or more BIs and one or more CIs. The package or tray considered to be the most difficult to sterilize should be selected from those most frequently processed. The package or tray selected should contain the items normally present during routine sterilization. Characteristics that should be considered when selecting PCDs include multiple layers of dressing materials, large metal masses, and mixed packs incorporating both.

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).

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

Routine biological monitoring 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 a 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 adequate 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.

10.7.3.3 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 10.7.3.2.

c) A normal cycle should be run, according to the sterilizer and device manufacturers' written instructions.

d) Upon completion of the sterilization cycle and adequate cooling of the PCD, the BIs and CIs should be removed from the PCD and their identification recorded. The CI manufacturer's written instructions for interpretation of CI results should be followed. 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 written 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) Each day that test BIs are 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 in each incubator 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.

10.7.3.4 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.

10.7.4 Routine biological monitoring of flash sterilization cycles

10.7.4.1 Composition of the PCD (BI challenge test tray)

A representative of the same type of tray to be routinely processed through the flash sterilizer should be selected to serve as the PCD (BI challenge test tray). Each type of tray configuration in routine use for flash sterilization should be tested separately. One or more BIs and one or more CIs should be placed in the empty tray configuration 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 10.10.3.2.2.1.

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: Each type of tray configuration used should be tested because it poses a barrier to air removal and sterilant penetration during the sterilization process. It is possible for the cycle to pass the open-tray test, indicating that the cycle parameters are adequate for microbial kill, yet fail when other configurations are used in the same sterilizer on the same day. 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 CI(s) 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.

10.7.4.2 Placement of the PCD (BI challenge test tray)

The PCD (BI challenge test tray) 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."

10.7.4.3 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 10.7.4.2

c) A normal cycle should be run, according to the sterilizer and device manufacturers' written instructions.

d) Upon completion of the sterilization cycle and adequate cooling of the PCD, the BI(s) and CI(s) should be removed from the PCD and their identification recorded. The CI manufacturer's written instructions for interpretation of CI results should be followed. All BIs used in challenging the sterilization cycle and as controls should be accounted for. The BI(s) should be handled and incubated according to the BI manufacturer's written 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) Each day that test BIs are 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 in each incubator 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.

Rationale: Because 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 Actions to take when biological indicators, chemical indicators, or physical monitors indicate failure

10.7.5.1 General procedure

a) PCDs (BI challenge test packs and CI challenge test packs) are used to release sterilized loads, and BI challenge test packs are used to routinely test sterilizer efficacy. A processed PCD with a positive BI (BI challenge test pack) or a failed Class 5 integrating CI or Class 6 emulating indicator (CI challenge test pack) is demonstrating a failure for the entire load and 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 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 because of operator error.

b) If the cause of failure is immediately identified (usually operator error) and confined to one load or one item in the load (i.e., an item with a nonresponsive internal CI), the cause of the failure should be corrected and the load should be reprocessed. If the cause of the failure is not immediately identified, the load should be quarantined, and all loads back to the last negative BI should be recalled. Items in these loads should be retrieved, if possible, and reprocessed (see 10.11). The sterilizer in question should be taken out of service for further investigation of root causes. See Figure 12 and Table 8 for guidance on how to conduct this investigation.

c) If the PCD failure involved a positive BI, the microbiology laboratory should perform a presumptive identification of the microorganisms present in the “failed” (positive) BI, in accordance with the BI manufacturer’s written 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 heads of the microbiology department, sterilizing department, and infection prevention and control department, or their designees, with appropriate facility maintenance and sterilizer service personnel, should attempt to determine the root cause of the sterilization process failure and arrange for corrective action.

e) If the root cause of the sterilization failure has been determined to be a sterilizer malfunction and major repair is required for correction 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) in three consecutive cycles (see 10.8). 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). For dynamic-air-removal sterilizers, a Bowie-Dick test pack should then 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 1—The flash sterilization test might yield inconclusive results; e.g., an open-mesh test tray could indicate “passing” conditions, whereas a different test tray configuration could indicate “failing” conditions. In such situations, it is likely that the test tray configuration demonstrating “fail” results presents a tougher challenge to proper air removal and steam penetration than the open-mesh tray. The sterilizer might be functioning appropriately, but the test tray configuration is not able to be flash sterilized under these conditions. The device manufacturer’s written instructions for flash sterilization should be consulted to ensure that the appropriate sterilization cycle is being performed for that tray configuration. That tray configuration should not be used until product testing (10.9) has demonstrated satisfactory, reproducible sterilization results.

NOTE 2—Steam quality can contribute significantly to sterilization process failures indicated by PCDs. Assessment of the entire steam delivery system might be necessary.

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 whenever a PCD has a positive BI (BI challenge test pack) or a failed Class 5 integrating indicator (CI challenge test pack) will provide valuable data in support of correcting the problem and identifying potential improvements in work practices.

10.7.5.2 Microbiological testing

For positive BIs, the microbiology laboratory should perform a presumptive identification according to the BI manufacturer's written 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.

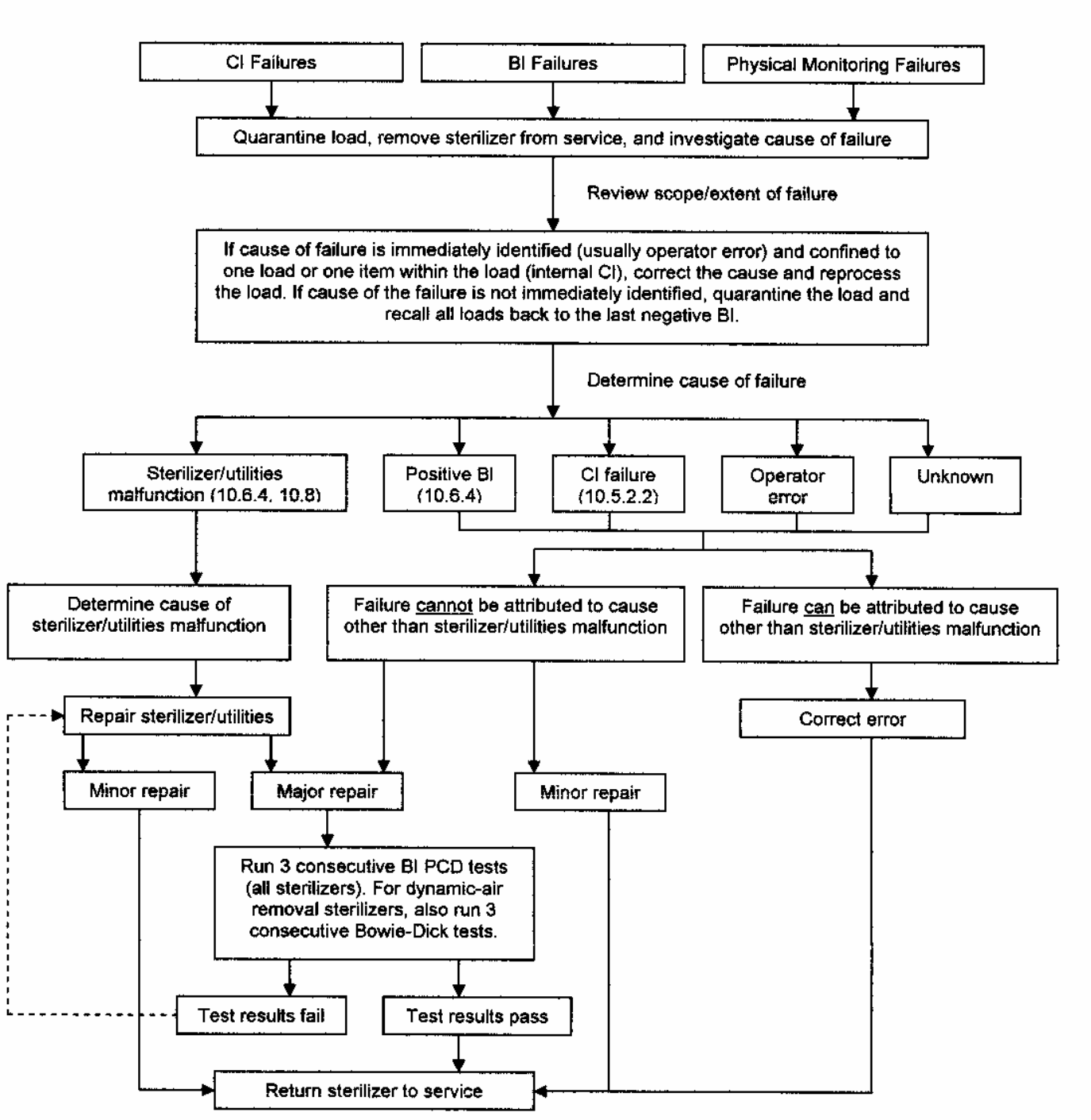

Figure 12—Decision tree for conducting investigations of steam sterilization process failures

Table 8—Checklist for identifying reasons for steam sterilization process failures

Operator errors
Incorrect use and interpretation of monitoring tools • Incorrect physical monitors for the load • Incorrect use of BI or BI PCD - Incorrect selection of BI or BI PCD for the load - Incorrect placement of BI PCD in the load (e.g., another pack was placed on top of the PCD) - Incorrect incubation of BI - Misinterpretation of BI result - Incorrect documentation of BI result • Incorrect use of Class 5 integrating CI PCD or Class 6 emulating CI PCD - Incorrect selection of CI PCD for the load. - Incorrect placement of CI PCD in the load (e.g., another pack was placed on top of the PCD) - Misinterpretation of Class 5 integrating CI result or Class 6 emulating CI result - Incorrect documentation of Class 5 integrating CI result or Class 6 emulating CI result • Incorrect use of internal CI - Incorrect selection of internal CI for the load - Misinterpretation of internal CI result - Incorrect documentation of internal CI results • Incorrect storage of any CIs or BIs • Failure to check physical monitors for functionality before running cycle • Use of broken media ampoule or ampoule with missing spore strip • Use of BI PCD or CI PCD that is missing the BI or CI • Use of defective CI (e.g., a CI that is expired, faded, shows a partial color change because of incorrect storage, or has been previously exposed to the sterilant)
Selection of incorrect cycle for load contents (containment device or medical device manufacturer's instructions for use not followed)
Use of inappropriate packaging materials or packaging technique • Incorrect packaging or containment device for the cycle parameters • Incorrect preparation of containment device for use (e.g., incorrect filters, valves, or bottom tray) • Use of a paper–plastic pouch, woven or nonwoven wrapper, or towel in a 270°F to 275°F (132°C to 135°C) gravity-displacement cycle • Use of a tray that does not allow air removal and steam penetration • Use of a wrapper that is too large for the application • Placement of a folded paper–plastic pouch inside another paper–plastic pouch • Placement of a paper–plastic pouch inside a wrapped set or containment device without verification of adequate air removal and steam penetration by product testing • Incorrect placement of basins in set (i.e., basins are not aligned in the same direction) • Failure to use nonlinting absorbent material between nested basins • Preparation of textile packs that are too dense to sterilize with the cycle parameters chosen • Inadequate preconditioning of packaging materials (i.e., not holding package materials at 68°F to 73°F (20°C to 23°C) for 2 hours before use)
Incorrect loading of sterilizer • Stacking of containment devices if not recommended by manufacturer • Stacking of perforated instrument trays • Incorrect placement of instrument trays (i.e., not laying instrument trays flat or parallel to the shelf) • Incorrect placement of paper–plastic pouches (e.g., placing pouches flat instead of on edge; not allowing sufficient space between pouches; not placing pouches with plastic sides facing one direction) • Incorrect placement of basins (i.e., not placing basins on their sides so that water can drain) • Incorrect placement of textile packs (i.e., not placing them on edge) • Placement of packages too close together, impeding air removal and sterilant penetration in the load

Table 8—Checklist for identifying reasons for steam sterilization process failures *(continued)*

Sterilizer or utility malfunctions
Poor steam quality or quantity • Wet steam - Improper insulation of steam lines - Malfunction of trap in steam line or no trap in steam line - Malfunction of drain check valve or no drain check valve - Steam contact with a cold load - Too much water in steam produced at boiler • Superheated steam - Improper heatup of chamber - Desiccated packaging materials (e.g., towels) - Steam pressure too low for the temperature - Excessive reduction of steam pressure too close to sterilizer - Faulty steam control valve or pressure reducer control valve • Other steam problems - Variations in steam pressure because of clogged filter, poorly engineered piping, or excessive demands - Out-of-calibration pressure gauges and controllers - Clogged steam lines - Clogged steam supply strainer - Clogged chamber drain line, strainer, or chamber drain screen - Malfunction of valves
Incomplete air removal • Inadequate vacuum or vacuum depth or other air removal system • Clogged chamber drain line, strainer, or chamber drain screen • Clogged vent lines • Leak caused by faulty door gasket • Leak in other areas of chamber • Plugged, faulty or incorrectly adjusted control valves • Low steam pressure • High water temperature • Inadequate water supply pressure • Clogged water supply strainer • Trapping of air by the load • Incorrect cycle parameters for the load
Inadequate cycle temperature • Out-of-calibration temperature gauge • Long heatup time for large loads (i.e., heat lag) • Clogged chamber drain line, strainer, or chamber drain screen • Variations in steam pressure because of clogged filter, poorly engineered piping, or excessive demands on steam supply • Presence of noncondensable gases in steam line and load • Inadequate steam supply pressure • Clogged steam supply strainer
Insufficient time at temperature • Out-of-calibration control timer • Inappropriate cycle parameters for the load being processed • Come-up time of less than 1.5 minutes in a 270°F to 275°F (132°C to 135°C) gravity-displacement cycle • Oversized load

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/ISO 11140-5). 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, inadequate steam penetration, and noncondensable gases (e.g., air or gas from boiler additives). Insufficient air removal in a dynamic-air-removal sterilizer, particularly a prevacuum cycle, can defeat sterilization and result in nonsterile supplies if undetected. An improperly heated sterilizer could cause false Bowie-Dick test failures. 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 before 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. (Preconditioning consists of holding the towels at room temperature—18°C to 24°C [65°F to 75°F]—and a relative humidity of at least 35% for at least 2 hours.) The towels should be folded to a size 9 inches (250 millimeters [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 13.)

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

A commercially available Bowie-Dick-type test sheet, complying with ANSI/AAMI/ISO 11140-5, 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.

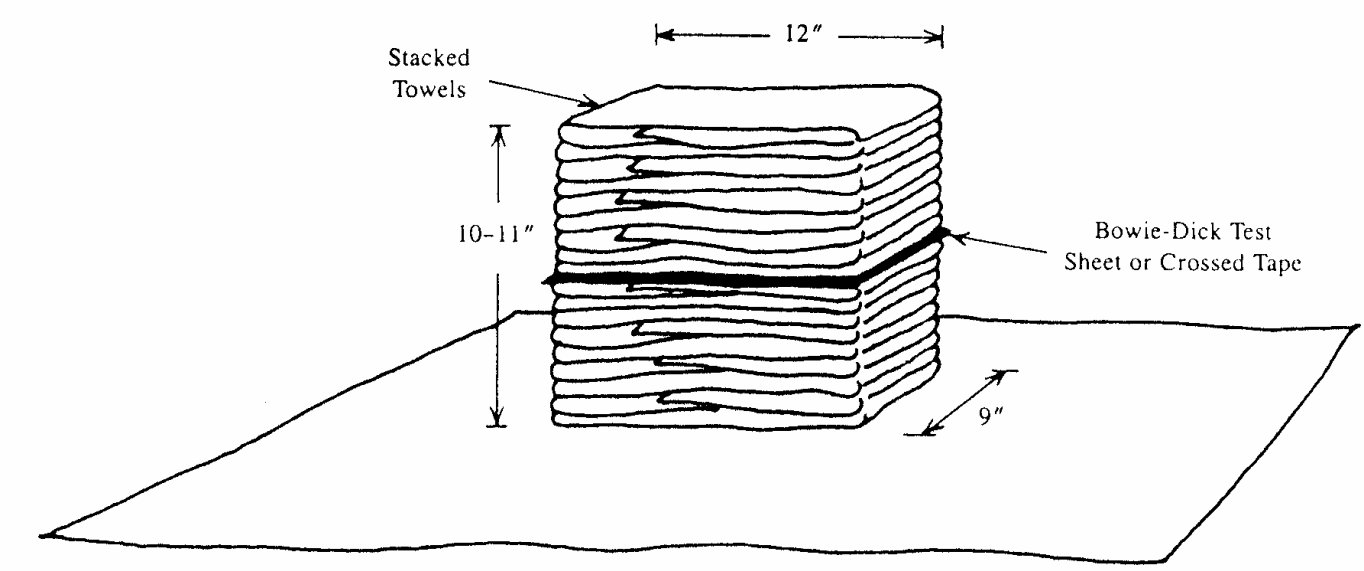

Figure 13—Composition of the Bowie-Dick test pack

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 14.)

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

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 written 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 because of 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 might 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.

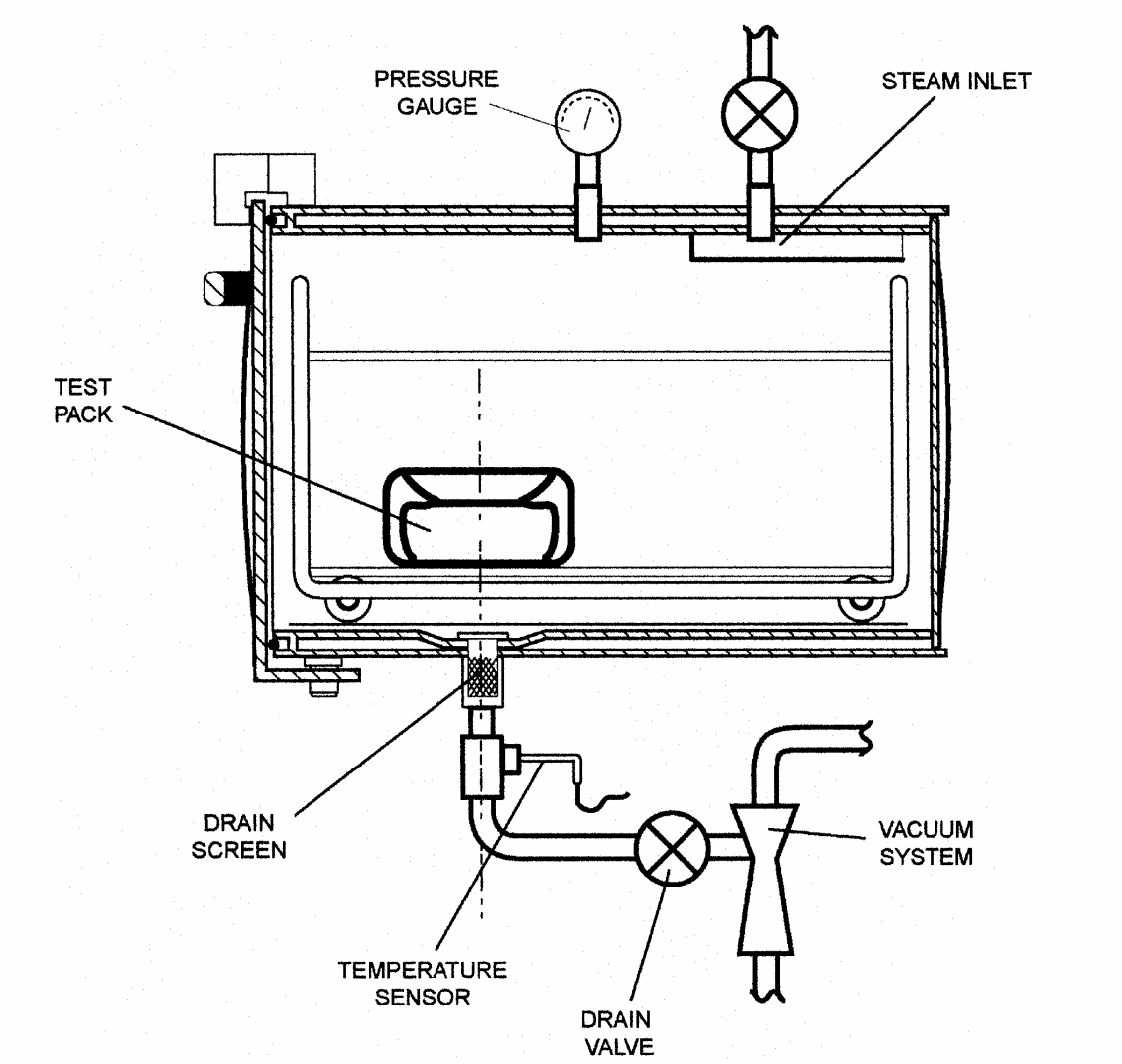

Figure 14—Placement of the Bowie-Dick test pack

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°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 should be tested. If a sterilizer will run the same type of cycle (e.g., dynamic-air-removal at 132°C to 135°C [270°F to 275°F] 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.

As described in 10.6.4, 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 major repair. When repairs involve parts normally replaced under preventive maintenance procedures, three BI tests and three Bowie-Dick tests are not required before the sterilizer is returned to service. Verification of the sterilizer's operation according to the manufacturer's specifications is sufficient.

The performance of the sterilizer depends on the utilities connected to it. The sterilizer manufacturer specifies certain utility line sizes, maximum and minimum pressures, and dynamic flow requirements for the required utilities. The steam supply should consist of saturated, condensate-free steam with a minimum dryness factor of 97% (see also 3.3.4). Water quality also might be specified, especially for stand-alone steam generators (which are typically shut down on weekends). Sterilizers are designed to function with a nominal electrical supply and can be operated within a specified range of that nominal value. Significant changes to the utilities connected to the sterilizer (e.g., changes necessitated by water-main breaks, annual boiler maintenance, or additional equipment loads) could affect sterilizer performance. Major repairs of or changes to the utilities (e.g., the installation of new boilers) should be treated as major repairs to the sterilizer, and sterilizer testing should be performed as defined in this section to provide the necessary qualification for use.

Rationale: The purpose of qualification testing of a sterilizer after installation or relocation is to assess sterilizer performance in the environment in which it will be used. Satisfactory test runs verify that the sterilizer is in good working condition after shipment from the manufacturer or relocation from its previous site and that it will function effectively. Sterilizer testing after major repairs of the sterilizer itself or its utilities is intended to ensure that the sterilizer performs to specifications after the correction of a malfunction or sterilization process failure. The PCDs are designed to create a significant challenge to air removal and steam penetration. Biological-indicator testing should not be confused with Bowie-Dick testing, which is designed to detect air leaks and reentrainment that can occur in a dynamic-air-removal sterilizer.

10.8.2 Qualification testing of sterilizers larger than 2 cubic feet

10.8.2.1 Composition of the PCD (BI challenge test pack)

The 16 towel PCD (BI challenge test pack) of 10.7.2.1 or an equivalent commercial PCD should be used.

10.8.2.2 Placement of the PCD (BI challenge test pack)

The PCD (BI challenge test pack) should be placed *flat* (layers of towels horizontal if the 16 towel PCD is being used) on a rack or shelf in an otherwise empty sterilizer chamber, in the area least favorable to sterilization (i.e., the area representing the greatest challenge to the BI) (see Figure 15). 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: In the qualification testing that compared the performance of the 16 towel PCD to that of the original, 12 × 12 × 20 inch pack (see Annex K), the 16 towel PCD was positioned flat in the chamber. Placing the PCD horizontally, instead of on edge, presents a greater challenge to the sterilizer. The horizontal configuration contradicts recommended loading practices, but is necessary to accentuate the biological challenge to sterilant penetration so that this smaller homogeneous pack will perform comparably to the original, 12 × 12 × 20 inch heterogeneous pack. 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."

10.8.2.3 Test procedure

The test procedure is as follows:

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

b) The PCD should be positioned in the chamber according to 10.8.2.2.

c) The appropriate cycle should be run, according to the sterilizer manufacturer's written instructions.

d) Upon completion of the sterilization cycle and adequate cooling of the PCD, the BI(s) should be removed, their identity recorded, 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 written instructions of the 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) Each day that test BIs are 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 in each incubator 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 not viable 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.

10.8.2.4 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.

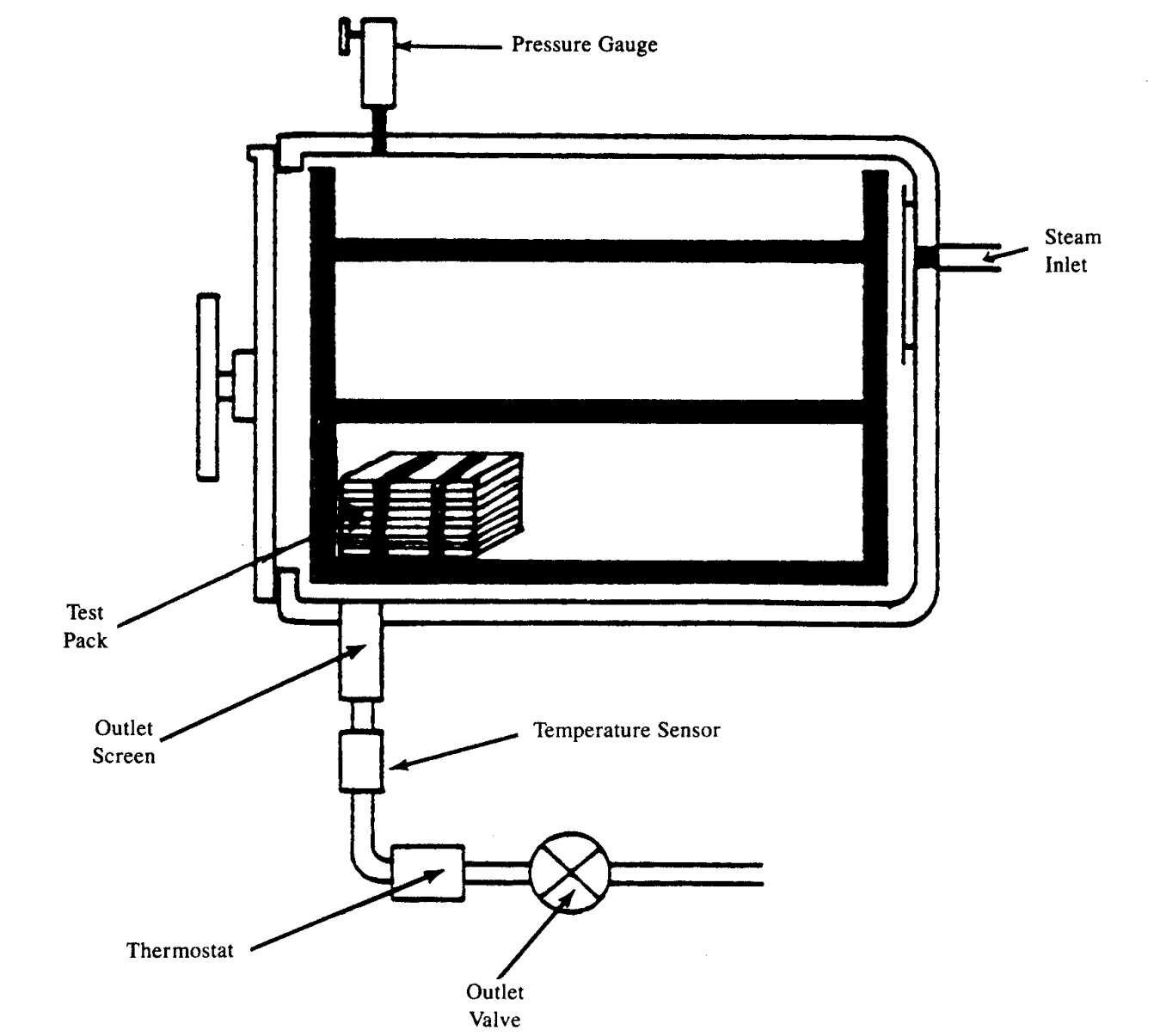

Figure 15—Placement of the 16 towel PCD (BI challenge test pack) for qualification testing

10.8.3 Qualification testing of table-top sterilizers

10.8.3.1 Composition of the PCD (BI challenge test pack or BI challenge test tray)

A representative of the same type of package or tray to be routinely processed through the sterilizer should be selected to serve as the PCD (BI challenge test pack or BI challenge test tray) for qualification testing. The PCD should contain one or more BIs and one or more CIs. The package or tray considered to be the most difficult to sterilize should be selected from those most frequently processed. The package or tray selected should contain the items normally present during routine sterilization. Characteristics that should be considered when selecting PCDs include multiple layers of dressing materials, large metal masses, and mixed packs incorporating both.

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 written 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 written 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 written instructions for the appropriate incubation time and temperature.

e) Each day that test BIs are 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 in each incubator 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 written 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 written 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) Each day that test BIs are 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 in each incubator 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

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.

10.9 Periodic product quality assurance testing of routinely processed items

Quality assurance testing of routinely processed items representing a product family should be performed on an ongoing basis. A program should be established to periodically test routinely sterilized products. Before newly purchased or loaner sets are placed into routine use, they should be evaluated to determine if the existing product testing is applicable to these sets. If the existing product testing is applicable, then the sterilization cycle used for the applicable product family should be used for the new or loaner set. If the existing product testing is not applicable to these sets, then product testing should be performed before they are placed into routine use. Whenever changes are made in a product family's composition, designated master product, or written sterilization instructions, then product testing should be repeated. Product testing should always be performed when major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper. The test program should include both BI and CI testing and an evaluation of post-sterilization moisture content (i.e., the occurrence of "wet packs").

NOTE—The following product characteristics should be considered when evaluating new or loaner sets to determine whether they belong to an existing product family: design configuration, number of components, materials of construction, size and/or surface area, need for disassembly, surface finish or texture, the presence of cannulations, lumens or mated surfaces, and the written reprocessing instructions provided by the manufacturer. If the new or loaner set does not fit within an existing product family, then a new product family should be established, with the new or loaner set becoming the master product for that family. Medical device manufacturers can assist in the identification of the product family and master product.

Biological indicators should be placed within the product test samples; Class 3 CIs, Class 4 CIs, or Class 5 integrating CIs, or Class 6 emulating indicators also should be used. The number of BIs and CIs used within each product test sample will depend on the size and configuration of the pack being tested. Medical device manufacturers can assist in the identification of the areas in which to place BIs and CIs. Product test samples should be properly identified and placed among other products in a routine sterilizer load. The product test samples should be placed strategically throughout the load at the points most difficult to sterilize (i.e., the most resistant to steam penetration). After inspection and retrieval of the BIs and CIs, sample packs used in product testing should be disassembled and the contents either reprocessed or discarded, as appropriate. Examples of product testing are as follows:

a) For textile packs wrapped in woven or nonwoven materials, the BIs and CIs are placed between the layers of a folded surgical gown within the pack, between multiple layers of draping material, or between layers of surgical towels.

b) For basin sets wrapped in woven or nonwoven materials, the BIs and CIs are placed in locations within the set where air pockets could form, such as the area between nested basins. In tests of this nature, it might be appropriate to use BIs contained in glassine envelopes rather than BIs in ampules, because the latter could separate the basins, permitting more steam contact, and because the ampules could break.

c) For an instrument set, the BIs and CIs should be placed at each end of the tray and among the instruments that are placed on stringers.

d) For containment devices, the BIs and CIs should be placed in the areas recommended by the containment device manufacturer. (See 10.10.3.2.2.1.)

e) For multilayered instrument sets in containment devices, the BIs and CIs should be placed in the locations determined by the product manufacturer to create the greatest challenge to the sterilization process. It might be necessary to use BIs contained in glassine envelopes rather than BIs in ampules if test areas cannot accommodate BI ampules (e.g., inside multilayered trays with sliding lids).

f) For other types of items (e.g., bulk packages of sponges or dressings, reusable syringe sets), the BIs and CIs should be placed in the area of the load least accessible to steam penetration.

There should be no evidence of moisture if the sterilizer is performing properly and if the correct procedures have been followed before, during, and after the sterilization cycle (i.e., proper assembly, loading, selection of cycle parameters, drying, unloading, and cooling). If moisture is observed, steps should be taken to remedy the problem. See also Reichert and Young (1997).

Any test results that indicate a problem, such as positive BIs, unresponsive CIs, or wet packs, should be thoroughly investigated. It might be necessary to change the configuration of the load and/or of items within the package or to service the sterilizer. Product use should be discontinued until the problem is resolved. (See also Section 8 and Lee [1997].) The test protocol, the test results, and any corrective actions taken should be documented and maintained as part of the sterilization log or quality assurance program data.

Documentation of product testing activities should be maintained, including the date the testing was performed, the name of the set, tray, or item, identification of the location of BIs and CIs within the tray, and the test results.

Rationale: The standardized PCD (BI challenge test pack) of 10.7.2.1 presents a known challenge to the sterilization process. However, this pack does not necessarily reflect the same challenge as the items routinely processed in a health care facility. Therefore, product testing is recommended as part of a complete quality assurance program to ensure the effectiveness of the sterilization process and to avoid wet packs. The products to be tested will vary from facility to facility, depending on the types of products routinely sterilized. The contents of the sample packs are exposed to a larger population of bacterial spores than are other products and, therefore, should not be used in patient care unless they are reprocessed; also, inspecting the pack and retrieving the BIs and CIs contaminates the contents.

The concept of product families is used to group products similar in construction, materials, size, and packaging. The most difficult-to-sterilize device in each group is designated the master product and is used as the PCD for that family when product testing is performed. The sterilization process used for the master product can then be applied to all members of its product family. The concept of product families enables the health care facility to ensure a high level of sterility assurance without testing all products being sterilized.

10.10 Periodic product quality assurance testing of rigid sterilization container systems

10.10.1 General considerations

Rigid sterilization container systems vary widely in design, mechanics, and materials of construction. Work practices, sterilizer performance characteristics, and the function of the health care facility utilities supplying the sterilizer can also affect the dynamics of the sterilization process. These factors can markedly affect the specific performance characteristics of rigid sterilization container systems and their suitability for particular sterilization methods and cycles. This section covers the responsibilities of manufacturers and users in matching rigid sterilization container systems and sterilization cycles.

NOTE—Certain aspects of the following protocol for the testing of rigid sterilization container systems might apply to other product testing within a health care facility.

10.10.2 Responsibilities of the manufacturer

10.10.2.1 Suitability of the container system for specific sterilization cycles

The manufacturer of a rigid sterilization container system should demonstrate by scientific evidence that the system is suitable for the specific sterilization methods and cycles for which it is designed and recommended. The manufacturer should provide the user with complete written instructions for use and in-service education, as well as documentation of the methodology and results of performance testing of the container system. This documentation should cover the following aspects of performance: sterilization (10.10.2.2), drying (if applicable) (10.10.2.3), and sterility maintenance (10.10.2.4).

Rationale: Ongoing instruction and in-service education help ensure the effective use of rigid sterilization container systems. Documentation of test methodology and results enables users to compare the performance of

various container systems and verify that a particular container system is suitable for the health care facility's applications.

10.10.2.2 Sterilization

Documentation of the manufacturer's test methodology and results should include information verifying that the sterilization efficacy of the rigid sterilization container system has been qualified in standard hospital sterilization cycles and has passed standard AAMI challenge tests for each method of sterilization for which the container system is labeled. At least the following information should be made available to the user:

a) the types of cycles (e.g., gravity-displacement steam sterilization, dynamic-air-removal steam sterilization);

b) the test equipment nomenclature and equipment cycle performance verification test data, including the manufacturers, types, model numbers, chamber sizes, cycle sequence, and parameters (e.g., pressures, temperatures, number of pulses, time intervals) of the sterilizers used;

c) the types, sizes, and placement of filters or valve assemblies in the container system;

d) the weight and distribution of the contents of the container system (e.g., the separation of the contents into layered baskets or other accessories);

e) the types, placement, and rationale for the use of any inner wrapping or absorbent materials included in the contents that could affect sterilization and, if applicable, drying;

f) the types, number, placement sites, and performance characteristics (e.g., D value) of the BIs and, if applicable, CIs used for validation of cycle processing;

g) the methodology used for retrieving and culturing BIs and the results;

h) if applicable, the results of chemical monitoring;

i) the sterilizer load configuration, including the recommended container stacking pattern if stacking has been validated;

j) load preheating time before cycle start (if the load was preheated during testing and if preheating is recommended to diminish the formation of condensate during the sterilization cycle);

k) the methodology used for obtaining time-at-temperature profiles of the container system and contents during the sterilization cycle (e.g., use and placement of thermocouples inside containers);

l) the rationale for the recommended sterilization exposure time; and

m) any other factors that influence the sterilization time required for each type of sterilization cycle for which the container system is recommended.

10.10.2.3 Drying (if applicable)

Documentation of the test methodology and results should include at least the following information:

a) if applicable, the level of pressure attained during the drying phase of the cycle, including the multiple excursions used in a pulsing cycle;

b) the time of the drying phase;

c) the factors that can influence the drying time of the container system and its contents, such as the following:

- the materials of construction of the container system;
- the size and contents of the container system;
- the number of container systems in the load;
- the temperature of the container system and contents at the beginning of each test;
- whether the load was preheated and to what temperature;

- the steam quality;
- whether the sterilizer door was “cracked” after the drying phase of the cycle (to allow slower cooling of the container systems and to minimize condensate formation) and for how long;
- the environmental conditions (temperature, relative humidity, air exchange rate) of the cool-down area;
- the duration of cool-down between the time the container system was removed from the sterilizer and the time it was opened to determine the dryness of the contents and inner container surfaces;
- the use of any inner wrapping or absorbent materials within the contents; and

d) the methodology used to test and validate the conditions necessary to ensure consistent and effective drying of the container system and its contents.

10.10.2.4 Sterility maintenance

Maintenance of sterility is event-related, and the probability of occurrence of a contaminating event increases over time and with handling, whether woven or nonwoven materials, pouches, or rigid sterilization container systems are used as the packaging method. Manufacturers of rigid sterilization container systems should provide test data that support the ability of the correctly assembled system to inhibit microbial migration. Documentation of the test methodology and results should include at least the following information:

a) the design characteristics of the container system that limit microbial migration and penetration of contaminants to the contents (e.g., the tortuous pathways afforded by the filter system or valves);

b) the factors that limit or minimize the potential for contamination of the inside of the container system and its contents;

c) the potential causes of contamination of the inside of the container system and its contents (e.g., filter puncture or dislodgment, inadvertent opening of the container, or any other conditions that compromise the integrity of the packaging);

d) the environmental conditions that affect recondensation on inner surfaces of the container system or the contents; and

e) test documentation demonstrating sterility maintenance, such as real-time shelf-life studies, physical whole-package challenge studies, or microbial whole-package challenge studies.

10.10.3 User responsibilities

10.10.3.1 General considerations

Health care personnel bear the ultimate responsibility for ensuring that *any* packaging method or material, including a rigid sterilization container system, is suitable for use in sterilization processing and sterility maintenance. Before purchasing any packaging system, the user should gather information and perform testing to ensure that items to be packaged can be sterilized by the specific sterilizers and/or sterilization methods to be used within the facility. The interaction of container system, medical device, and sterilizer technologies is complex. A container system to be used for steam sterilization needs to allow complete air removal, adequate steam penetration, and drying.

The specific design of the rigid sterilization container system needs to be compatible with the design and performance characteristics of the sterilizer(s) in which it is used. Prepurchase evaluation assures that the particular container system being considered will be acceptable to all prospective users in the facility and that it will perform properly in the health care facility’s sterilizing equipment. The testing that should be performed by users, which is described in 10.10.3.2, is not a substitute for the more extensive validation testing conducted by manufacturers to qualify their products.

Rationale: Manufacturers of container systems can only test properly designed and operating sterilization equipment. Various sizes of sterilizers having the same sterilization cycle could have different air-removal efficiencies. Manufacturers cannot possibly test all combinations of sterilizer sizes, cycles, and process efficiencies. Health care personnel need to perform testing to verify that there are no problems or to identify technical problems to be resolved in consultation with the container system manufacturer, the sterilizer manufacturer, and consultants.

10.10.3.2 Prepurchase evaluation

10.10.3.2.1 General

Users should conduct a prepurchase product evaluation of any rigid sterilization container system being considered for use in sterilization processing. Before a rigid sterilization container system is purchased, users should determine whether the health care facility can verify the manufacturer's test results. If not, users should seek advice from the manufacturer concerning instructions and guidelines for use of the system.

Testing should be conducted in the health care facility to ensure that the conditions essential to sterilization can be achieved and that the specific configuration of the container contents is acceptable for the sterilization process and for the requirements at the point of use. The instructions for use, test methodology, and test data supplied by the manufacturer should be assessed in relation to the environment in which the container system will be used and in relation to the sterilizer to be used for the processing of containerized instruments and procedural trays. See also Section 12 and Annex I.

Rationale: See 10.10.3.1.

10.10.3.2.2 Aspects of sterilization to be investigated

10.10.3.2.2.1 Evaluation of sterilization efficacy

Sterilization process conditions such as exposure time should be evaluated by physical, biological, and chemical monitoring. In each rigid sterilization container system to be tested, BIs and CIs should be placed strategically alongside each other at locations that present the greatest challenge to air evacuation and sterilant penetration. Particularly in gravity-displacement steam sterilizers, the corners of the container system and the underside of the lid, away from the filters, are the likeliest locations for air pockets. Because the areas of greatest challenge to steam penetration and air removal vary from one rigid sterilization container system to another, the container manufacturer should be consulted for appropriate monitoring locations and placement of chemical and biological indicators.

NOTE—The test rigid sterilization container system should contain instruments, and if the system requires filters, the filters must be in place.

Some rigid sterilization container manufacturers might require suspending a BI from the under side of the container lid as part of the testing process. The BI manufacturer should be consulted for guidance on performing this type of testing.

After the sterilization cycle, the user should retrieve and incubate the BIs according to the BI manufacturer's written instructions. The test container and instruments should be reprocessed before use in patient care. Positive BIs can indicate a sterilization process failure and should be thoroughly investigated.

See also 10.10.3.2.3, 10.10.3.2.4, and 10.10.3.2.5.

Rationale: This testing helps ensure adequate sterilant penetration and demonstrates that items processed in containment devices can be sterilized reliably. The testing is *not* a substitute for routine monitoring (see 10.6 and 10.7), qualification testing (see 10.8), or the containment device manufacturer's validation testing.

10.10.3.2.2.2 Evaluation of minimum drying times

The use of rigid sterilization container systems occasionally requires extending the drying times normally used for wrapped items. Steam quality, the design and composition of the container system, the type, number, and configuration of instruments, and the ways that excess water vapor can escape are all factors that have to be considered in the evaluation or selection of drying time. In addition, for each location within the health care facility, it could be important to evaluate the following factors: distance from the steam source, effectiveness of moisture removal from the incoming steam, and the potential differences between sterilizers.

For rigid sterilization container systems with valves, water vapor can only escape and the contents dry if the valves are open. Some valves are designed to close when pressure equalization occurs within the container during the drying/cooling phase. An alternative design incorporates a thermostatic valve that closes at a specific temperature; the valve remains open after the pressure phase and the steam is vented from the container system. All moisture might not be eliminated before the valves close. Moisture or water droplets might be seen within the container and its contents when it is opened for use.

Rationale: The combined metal mass of instruments and metal container systems could cause excessive condensation formation during the heat-up phase of the cycle. The metal mass also can cause a slower temperature come-up time and a longer drying time. Metal acts as a heat sink, taking heat from the saturated steam as it enters the sterilizer and causing the steam to collapse (turn into liquid water). The steam supply system, delivery lines, steam traps, sterilizer location, and other factors affect steam quality and the amount of moisture transported in the steam. Plastic and metal do not wick moisture as an absorbent wrapper does; consequently, it might be necessary to extend the drying time. The design of a container system, especially the routes by which water vapor escapes, also can affect drying time.

10.10.3.2.2.3 Other considerations

It also could be desirable or necessary to

a) evaluate whether preheating the load helps diminish the formation of condensate during the prevacuum pulsing and load-heating phases of the cycle;

b) evaluate the weight and density of instrument sets;

c) evaluate the use of optional absorbent materials (e.g., cotton towels, instrument tray liners, inner wraps) to aid in the drying of inner container surfaces and contents;

   NOTE—Absorbent materials sometimes hinder the drying process by preventing the escape of condensate from the rigid sterilization container system and its contents. Moisture retained in the materials might not be easily detectable. The container system manufacturer should be consulted for recommendations regarding the use of absorbent materials.

d) develop a policy and procedure regarding the sterility and use of the contents of container systems that appear to have retained moisture. Container systems can prevent contact contamination, but internal condensate can damage instrumentation if contact with moisture is prolonged, and the acceptability of the item could be questioned by the practitioner who opens the set for use.

10.10.3.2.3 Prepurchase evaluation test protocols

Paragraphs 10.10.3.2.4 and 10.10.3.2.5 describe recommended test protocols (summarized in Table 9) for prepurchase evaluation of rigid sterilization container systems intended for use in dynamic-air-removal steam sterilization processes (10.10.3.2.4) and gravity-displacement steam sterilization processes (10.10.3.2.5). Container systems should only be evaluated and used in cycles recommended by the container system manufacturer.

NOTE—These test protocols only address prepurchase evaluation as it relates to verifying sterilization efficacy and drying. See Annex I for guidelines on the development of a detailed, more comprehensive prepurchase evaluation protocol that covers other aspects of container system use.

Rationale: Most rigid sterilization container systems are designed for use in prevacuum steam sterilizers. The container system manufacturer might not recommend use in other sterilization processes.

Table 9—Summary of test configurations for prepurchase evaluation of rigid sterilization container systems

Sterilizer type	Cycle type	Number of container systems tested
Dynamic-air-removal	Wrapped	Maximum load
		Small load
Dynamic air-removal	Unwrapped	Small load
Gravity-displacement	Wrapped	Maximum load
		Small load

NOTE—The test container system is prepared with the largest instrument set (including any optional absorbent material) recommended by the container system manufacturer. BIs and CIs should be placed as described in 10.10.3.2.2.1.

10.10.3.2.4 Dynamic-air-removal steam sterilizers

10.10.3.2.4.1 Intent

The testing recommended here is intended to enable the user to assess four fundamentally essential aspects of the use of rigid sterilization container systems in dynamic-air-removal steam sterilization:

a) Will the container system design permit adequate air removal from the container system when the sterilizer chamber has reached the point of maximum air removal?

b) Does the container system design allow adequate steam penetration to reach equilibrium between the sterilizer chamber and the interior and contents of the container?

c) Will the combination of sterilizer and container system design achieve sterilization conditions?

d) Will the combination of sterilizer and container system design permit adequate drying and thus help promote sterility maintenance?

10.10.3.2.4.2 Test container system

For evaluation of container system performance in dynamic-air-removal steam sterilizers, container systems are prepared with the largest instrument sets (including any optional absorbent material) recommended by the container system manufacturer and with BIs and CIs placed as described in 10.10.3.2.2.1. The container systems should represent the sizes that are available in the system being evaluated and that will be used for routine processing in the health care facility.

Rationale: Sterilant enters through discrete portals in a container system and then must diffuse throughout the inside of the container system and finally to the items being sterilized. Thus, there are two barriers to be overcome before the inside of the container system reaches equilibrium with the sterilizer chamber. In this respect, container systems are very different from flexible wraps in which the entire barrier is permeable. In a sense, flexible wraps are more forgiving, because the tendency to retain air is lessened because of displacement or removal across the entire barrier surface and throughout the sterilization cycle. In a container system, entrained or retained air not completely removed by vacuum or displacement will interfere with steam contact and, thus, with sterilization. In other words, the container system can be viewed as a chamber within a chamber, and both chambers have to be tested.

10.10.3.2.4.3 Procedure

A maximum-load test and a small-load test should be run for representative sterilizers; for the remaining sterilizers, it is necessary only to run the small-load test. For the maximum-load test, the user places two test container systems on the bottom shelf over the drain and two test container systems on each of the other sterilizer shelves (if space permits). (For example, to test a sterilizer having three shelves, six container systems will be needed.) The chamber is otherwise fully loaded with conventionally packaged items. See Table 9. In the small-load test, one test container system is placed on the bottom shelf over the drain in an otherwise empty chamber. A sterilization cycle is run with the exposure time recommended by the container system manufacturer. Upon completion of the cycle, the CIs are checked, and the BIs are retrieved and incubated.

Rationale: In general, the recommended number of test container systems is sufficient to evaluate sterilizer and container system compatibility. A maximum load is tested to ensure that the large volume of air in this type of load is removed adequately and that the steam supply is sufficient to achieve sterilization in a load in which the considerable mass results in significant condensation. Maximum-load testing also permits the user to determine if additional steps are necessary to achieve adequate drying. The small-load test identifies any problems associated with the small-load effect, a phenomenon in sterilizers having dynamic air removal in which residual air in the chamber can become entrained in packaged items as steam enters the chamber.

10.10.3.2.4.4 Interpretation of results

To qualify the container system−sterilizer combination, all BIs should be negative and all CIs should show complete endpoint responses. In the maximum-load test, positive BIs or incompletely responding CIs suggest that the sterilization process is inadequate; there could be a problem with the sterilizer itself, the container system, or the sterilizer-container system combination. In the small-load test, failures indicate insufficient steam penetration or air removal, which could be caused by the sterilizer, the container system, or the sterilizer-container system combination.

To investigate any apparent sterilization failures, the first step is to check the physical monitors to ensure that the cycle parameters were correct. If the cycle parameters were correct, then the sterilizer should be evaluated with BI test packs and Bowie-Dick test packs to identify any equipment malfunction. Container systems should not be used in this evaluation.

The sterilizer manufacturer should be consulted if the performance of the sterilizer is questionable. If the sterilizer appears to be functioning properly, the container system manufacturer should be consulted for assistance in resolving the problem.

10.10.3.2.5 Gravity-displacement steam sterilizers

10.10.3.2.5.1 Intent

The testing recommended here is intended to enable the user to assess the same aspects of the gravity-displacement steam sterilization process as are important in dynamic-air-removal steam sterilization: air removal from the container system, steam penetration into the contents of the container system, sterilization cycle conditions, drying, and sterility maintenance. However, the evaluation of the container system and sterilizer combination is especially important in gravity-displacement steam sterilization because of the relative inefficiency of air removal in this sterilization process. In particular, the user should review the data upon which the container system manufacturer bases the recommended cycle time and verify those results in the health care facility's sterilizers.

NOTE—Most gravity-displacement steam sterilizers employ an initial steam purge and multiple positive pulses to remove air more effectively. These more efficient systems should be evaluated according to the same procedures as conventional gravity-displacement steam sterilizers.

10.10.3.2.5.2 Test container system

To evaluate container system performance in gravity-displacement steam sterilizers, container systems are prepared with the largest instrument sets (including any optional absorbent material) recommended by the container system manufacturer and with BIs and CIs placed according to the container manufacturer's written instructions (10.10.3.2.2.1). Where specified in the test procedure, the test container systems should be of the size and design representing the smallest sterilant penetration area relative to container volume. The container system to choose can be determined by calculating the ratio between the number of holes in the filter area of the lid and the volume of the container system. For example, a container system that is 6 inches deep, 11 inches wide, and 17 inches long has a volume of 1122 cubic inches ($6 \times 11 \times 17$). If the container system has 420 holes in the filter area, the ratio of sterilant penetration area to volume would be 0.37 ($420 \div 1122$). For a container system having the same dimensions but fewer holes, the ratio would be smaller. For a container system having the same dimensions but more holes, the ratio would be larger. If container systems of different sizes have the same sterilant penetration area to volume ratio, the container system having the largest total volume should be chosen for test purposes.

NOTE 1—The formula described above is based on the assumption that all holes are the same size in all container systems of a given manufacturer's product line; therefore, it is not necessary to measure the holes to determine the sterilant penetration area. If the holes are not all the same size, the manufacturer should be consulted to determine which container system size or design configuration has the smallest ratio of sterilant penetration area to volume.

NOTE 2—The formula described above can be used as a reference but each container manufacturer should provide the maximum load for each size container that has been validated.

Rationale: The sterilant enters through discrete portals in a container system and then must diffuse throughout the inside of the container system and finally to the items being sterilized. Thus, there are two barriers to be overcome before the inside of the container system reaches equilibrium with the sterilizer chamber. In this respect, container systems are very different from flexible wraps, in which the entire barrier is permeable. In a sense, flexible wraps are more forgiving, because the tendency to retain air is lessened because of displacement or removal across the entire barrier surface and throughout the sterilization cycle. In a container system, entrained or retained air not completely removed by vacuum or displacement will interfere with steam contact and thus with sterilization. In other words, the container system can be viewed as a chamber within a chamber, and both chambers have to be tested.

A container system with the smallest ratio of sterilant penetration area to volume represents a worst-case challenge to the sterilization process. Thus, the container system will help detect any problems associated with the relative inefficiency of air removal in a gravity-displacement steam sterilizer.

10.10.3.2.5.3 Procedure

A maximum-load test and a small-load test should be run for each gravity-displacement steam sterilizer in which container systems will be used. In the maximum-load test, two test container systems are placed on the bottom shelf over the drain and two test container systems are placed on each of the other sterilizer shelves (if space permits). The container systems placed on the bottom shelf should be of the size and design determined to have the lowest ratio of sterilant penetration area to volume (10.10.3.2.5.2). The remaining container systems should be chosen from the other sizes available in the system being evaluated. The chamber is otherwise fully loaded with conventionally packaged items.

In the small-load test, one test container system is used. It is placed on the bottom shelf over the drain in an otherwise empty chamber. The container system should be of the size and design determined to have the smallest ratio of sterilant penetration area to volume.

A gravity-displacement cycle is run according to the container system manufacturer's recommendations. Upon completion of the cycle, the CIs are checked, and the BIs are retrieved and incubated.

Rationale: Extensive testing of all gravity-displacement steam sterilizers is recommended because of the potential problem with air removal from containers in gravity-displacement steam sterilization (see Annex J). The maximum-load test is designed to challenge the steam supply, ensure that a full-load configuration permits adequate steam diffusion, and detect pockets of residual air that would defeat sterilization. The test also challenges the container system design to ensure that steam diffusion into the container system is sufficient to remove enough air to permit steam contact with the container system contents. The small-load test demonstrates that air evacuation and load heat-up occur nearly simultaneously in the load and container system. A significant lag in container system heat-up or air evacuation can result in sterilization failure. Such a lag can occur if the thermostatic chamber drain closes and the exposure time begins before the container system contents have reached process temperature.

10.10.3.2.5.4 Interpretation of results

To qualify the container system and sterilizer combination, all BIs should be negative, and all CIs should show complete endpoint responses. A positive BI or a failed CI could mean that there is a problem with the sterilizer, the container system, or the sterilizer and container system combination.

To investigate any apparent sterilization failures, the first step is to check the mechanical monitors to ensure that the cycle parameters were correct. If the cycle parameters were correct, then the sterilizer should be evaluated with BI test packs to identify any equipment malfunction. Container systems should not be used in this evaluation.

The sterilizer manufacturer should be consulted if the performance of the sterilizer is questionable. If the sterilizer appears to be functioning properly, the container system manufacturer should be consulted for assistance in resolving the problem.

10.11 Product recalls

10.11.1 General considerations

Written policies and procedures for the recall of items from issued or stored loads should be developed in cooperation with the infection prevention and control committee and risk management of the individual health care facility. These policies and procedures should be documented, and records should be maintained. The department head or designee should decide, on the basis of the health care facility's policies and procedures, when a recall of processed supplies should be implemented. Whenever there is evidence of a sterilization failure, the infection prevention and control professional should be notified so that follow-up surveillance of patients can be conducted. Written policies and procedures should be developed for compliance with the Safe Medical Devices Act of 1990 as it pertains to failures of reusable medical devices (i.e., the Medical Device Reporting [MDR] regulations of 21 CFR 803). For additional information on user facility MDR requirements, see FDA (1996b).

Rationale: To ensure patient safety and compliance with the user facility reporting requirements of the Safe Medical Devices Act of 1990, the health care facility should establish recall procedures to expedite the retrieval of processed items that are suspected to be nonsterile and to ensure adequate follow-up actions such as quarantine of the sterilizer, notification of physicians and affected clinical departments, and surveillance of patients.

10.11.2 Recall procedure

A recall procedure should

a) be written;

b) outline the circumstances for issuing a recall order;

c) designate the person(s) authorized to issue a recall order; and

d) designate the person(s) responsible for reporting on the execution of a recall order.

10.11.3 Recall order

A recall order should

a) include all items processed back to the last negative BI;

b) be immediately communicated to affected departments and followed by a written order;

c) identify by sterilization lot number the products to be recalled;

d) identify the persons or departments to whom the order is addressed;

e) require the recording, in terms of kind and quantity, of the products obtained in the recall; and

f) specify the action to be taken by the persons receiving the order (e.g., destruction or return of product).

10.11.4 Recall report

A report of a recall order should

a) identify the circumstances that prompted the recall order;

b) specify the corrective action(s) taken to prevent a recurrence;

c) state, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall; and

d) provide verification that the recalled items were reprocessed or destroyed, as appropriate.

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11 Quality process improvement

11.1 General rationale

This section identifies performance measures and process monitors that can be used for continuous quality improvement (CQI) programs. Continuous quality improvement programs are recognized as an effective means of improving the performance of any process. For steam sterilization, a CQI program encompasses the entire process of decontamination, preparation and packaging, sterilization, quality control, sterile storage, and product distribution.

11.2 Quality process

11.2.1 General considerations

Procedures for steam sterilization should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with appropriate departments and integrated into the overall quality process in the health care facility. Variables in the system can be controlled to achieve assurance of product quality and process efficacy. Monitoring frequency will vary, depending on the quality improvement goals, on health care facility policies and procedures for the handling of unfavorable/unplanned events, and on the type of process variable.

A problem analysis should be completed for any problem relating to any aspect of steam sterilization processing that could pose a risk to personnel or patients. The problem analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected.

There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Quality processes can be enhanced by audits that are conducted on a regular basis. The information from these activities should be summarized and made available to appropriate individuals or groups/teams.

According to FDA, a quality audit “means a systematic, independent examination of a manufacturer’s quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.” [21 CFR 820.3(t)]

Rationale: Measurements of process performance allow the steam sterilization process to be monitored against a predetermined level of quality. Evaluation of findings provides a method of identifying problems or shifts in activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data essential to assess the effectiveness of the processes and to make improvements in performance.

11.2.2 Risk analysis

A sterile medical device is one that is free of viable microorganisms. The definition of a sterile medical device is the overriding definition dictating sterilization processing. However, it is recognized that the effectiveness of certain processes cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process is monitored routinely, and the equipment is maintained.

The quality system model used for reprocessing medical devices in health care facilities is a validated system in which

a) the sterilizer manufacturer and appropriate representatives of the health care facility conduct installation qualification and operational qualification; and

b) the individual medical device manufacturer, the manufacturer of the packaging (wrap, container, or pouch), and the sterilizer manufacturer recommend validated means of sterilizing the specific devices to be reprocessed, in lieu of a formal performance qualification.

NOTE—The “validated cycle” provided by the medical device manufacturer is often based on the assumption that the device is to be processed alone, not as part of a set of instruments. Unless the user actually tests the contents of the various packs being processed, there is no documented evidence of a successful outcome for packs assembled in-house.

In health care facilities, sterilization risk analysis, in its broadest sense, includes risk assessment, risk management, and risk communication:

a) ***Risk assessment*** involves identifying the source of a sterilization failure, estimating the likelihood that such a failure will occur, assessing the consequences if that failure does occur, and assessing how prepared the facility is to manage the failure. Because sterility assurance is a probability function, it must be assumed that at some time a failure will occur.

b) ***Risk management*** entails determining which of the sterilization failures identified in the risk assessment process require management and selecting and implementing the plans or actions that are needed to ensure that those sterilization failures are controlled. Essentially, ANSI/AAMI ST79 describes the accepted means of managing these risks.

c) ***Risk communication*** involves an interactive dialogue between sterile processing personnel, operating room personnel, and infection prevention and control professionals (infection preventionists) that actively informs the other concerned parties (patients). This process is the facility's recall procedure.

The sterilization risk analysis should be part of the health care facility's overall infection prevention and control risk analysis in accordance with accreditation agency requirements. It should be performed at least annually and should be reevaluated whenever significant changes occur.

Risk analysis = risk assessment + risk management + risk communication

11.2.3 Decontamination

Procedures for decontamination should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with the appropriate departments and should be integrated into the overall quality process in the health care facility. Written policies and procedures should take into account federal, state, and local regulations; the recommendations of the Centers for Disease Control and Prevention; national voluntary standards and recommended practices; and device/equipment manufacturers' recommendations. Variables in the system should be controlled to achieve assurance of quality and process efficacy. Performance measures should be developed to monitor environmental, performance, and process factors, including tests for monitoring and verifying the parameters of the cleaning process. Monitoring frequency will vary, depending on the quality improvement goals, on hospital policy and procedures for the handling of untoward events, and on the type of performance measure.

a) **Design of the decontamination area (Sections 3.2.2, 3.3.6, and 3.3.7.1)** Performance measures should include, but are not limited to: condition of floors, walls, ceilings, and work stations; ventilation, including air exchanges per hour and air flow pattern; temperature and humidity readings; traffic control; handwashing facilities; and area cleanliness.

b) **Personnel (Section 4)** Performance measures should include, but are not limited to: staff education, development, training, and continuing education; verification of competency of personnel; health and personal hygiene; and proper attire, including PPE.

c) **Handling of contaminated items at point of use, containment, and transport (Section 6)** Performance measures should include, but are not limited to: placement of contaminated items within the containment system; security of containment system; labeling of contaminated items; placement of items on transport carts; security of items on transport carts; and condition of items upon receipt in the decontamination area.

d) **Decontamination processes (Section 7)** Performance measures should include, but are not limited to: selection and use of appropriate PPE; sorting and disassembly of instruments; selection and use of cleaning agents; manual cleaning and rinsing; water quality; care of cleaning tools; preparation of items for automatic cleaning and disinfection; correct loading of items into decontamination equipment and selection of appropriate cycle parameters (time and temperature); accessibility of equipment instrument manuals; verification of installation testing and acceptance, routine inspection and cleaning, routine replacement of parts as recommended by the manufacturer, and routine maintenance recommended by the equipment manufacturer (e.g., lubrication, calibration); inspection of decontaminated items.

e) **Documentation of cleaning verification (Section 7.5.5, Annex D)** The effectiveness of both manual and mechanical cleaning processes should be monitored and documented on an ongoing, periodic basis.

f) **Documentation of decontamination processing parameters (Section 7)** It is essential that decontamination processing parameters be monitored and documented, whether the process is accomplished by hand or mechanically.

g) **Servicing and repair (Section 7.7)** Performance measures should include, but are not limited to: education and training of service personnel; selection and use of PPE by service personnel; safety of work practices; and adequacy of the post-exposure program.

A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected. There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Auditing results should be routinely summarized and submitted to Infection Prevention and Control for review.

Rationale: Measurements of process performance allow the system to be monitored and the results compared to a predetermined level of quality. Evaluation of the findings provides a method of identifying problems or shifts in activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data to assess the effectiveness of the process and make ongoing improvements in performance.

11.2.4 Rigid sterilization container systems

Procedures for the use of rigid sterilization container systems should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with the appropriate departments and should be integrated into the overall quality process in the health care facility. Monitoring frequency will vary depending on the quality improvement goals, the number of container systems used, the frequency of use, and the type of performance measure.

a) **Transfer of contaminated items to the decontamination area (Sections 6.4, 6.5)** Performance measures should include, but are not limited to, the rigid sterilization container system's ability to secure contaminated instruments and medical devices, the labeling of contaminated items, placement of the container system on the transportation cart, and proper PPE.

b) **Decontamination processes (Sections 7.4.2, 7.5)** Performance measures should include, but are not limited to, compliance with the manufacturer's recommendations in all aspects of the decontamination process, including removal of filters, selection and use of cleaning agents, manual cleaning and rinsing, preparation of container systems for mechanical cleaning and disinfection, correct loading of container systems into decontamination equipment, and selection of appropriate cycle parameters.

c) **Inspection of rigid sterilization container systems (Section 7.5.9)** Performance measures should include, but are not limited to, checking the sealing, mating surfaces, and edges of the container system and lid to ensure that they are not dented or chipped; checking that filter retention mechanisms and fasteners, such as screws and rivets, are secure and not distorted or burred; checking that securing mechanisms are functioning properly; checking that the integrity of the filter media is not compromised; checking that gaskets are pliable, securely fastened, and without breaks or cuts; and checking that valves work freely.

d) **Configuration of instrument sets (Section 8.4)** Performance measures should include, but are not limited to, monitoring to ensure that the weight and density of instrument sets allow for effective sterilization and drying; placement of basket(s) in the container system to allow even distribution of instruments and devices; positioning of instruments so that sterilant comes in contact with all surfaces; opening or unlocking jointed instruments; disassembly of multiple-part instruments; correct placement of instruments made of glass, rubber, or dissimilar metals; treatment of lumens; protection of delicate and light instruments; and compliance with the manufacturer's written instructions for complex instruments and specialized instrument container systems (e.g., organizing trays).

e) **Sterilizer loading and unloading (Sections 8.5.6, 8.8.1)** Performance measures should include, but are not limited to, correct number of container systems in the sterilizer load; correct placement of container systems on the sterilizer rack and in mixed loads (container systems are placed below absorbent towels); stacking of container systems (done only after reviewing the manufacturer's written instructions and documentation, followed by verification testing in the sterilizer to be used); and cooling time before containers are handled.

f) **Matching the rigid sterilization container system and the sterilization cycle (product testing) (Section 10.10)** Performance measures should include, but are not limited to, the methods of sterilization and types of cycles and the equipment cycle performance verification test data.

g) **Sterility maintenance (Sections 8.9, 10.10)** Performance measures should include, but are not limited to, container system storage conditions (designed to minimize the potential for contamination of contents) and test documentation demonstrating sterility maintenance (such as real-time shelf-life studies or aerosol-challenge evaluations).

A problem analysis should be completed for any problem with any aspect of the use of rigid sterilization container systems that could pose a risk to patients. The problem analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected. There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Auditing results should be routinely summarized and submitted to Infection Prevention and Control for review.

Rationale: Variables in the system must be controlled to assure quality and process efficacy. Assurance that sterility has been achieved will minimize the potential risk to patients. Measurements of process performance allow the system to be monitored and the results compared to a predetermined level of quality. Analysis of this information provides a method of identifying problems or shifts in activities and making improvements in the system.

11.2.5 Flash sterilization

Procedures for flash sterilization should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with the appropriate using departments and should be integrated into the overall quality process in the health care facility. Monitoring frequency will vary, depending on the quality improvement goals, on facility policy and procedures for the handling of untoward events, and on the type of performance measure.

a) **Decontamination area (Section 3.3.7.1)** Performance measures should include, but are not limited to, traffic control; condition of floors, walls, and ceilings; temperature and humidity readings; lighting; and ventilation, including air exchanges per hour and air flow pattern.

b) **Containment of contaminated items (Section 6.4)** Performance measures should include, but are not limited to, placement of contaminated items within the containment system, security of the containment system, labeling of contaminated items, placement on the transport cart, security of items on the transport cart, and condition of items upon receipt in the decontamination area.

c) **Work practices (Sections 7 and 8)** Performance measures should include, but are not limited to, selection and use of appropriate PPE; soiled to clean workflow during instrument disassembly; manual cleaning and rinsing; preparation of items for automated cleaning; instrument reassembly, inspection, and preparation of items for flash sterilization (including positioning of instruments in the basket or tray); and compliance with the manufacturers' recommendations for complex instruments.

d) **Installation, care, and maintenance of sterilizers (Section 9)** Performance measures should include, but are not limited to, accessibility of the manufacturer's instruction manual, verification of installation testing and acceptance, verification of routine inspection and cleaning, verification of routine replacement of parts as recommended by the sterilizer manufacturer, and verification of routine maintenance (such as lubrication and calibration) as recommended by the manufacturer.

e) **Sterilization process (Section 8)** Performance measures should include, but are not limited to, verification of training and continuing education, correct loading of items into the sterilizer chamber, accurate load records, selection of appropriate sterilization cycle parameters (time and temperature), selection and use of CIs and BIs, and documentation of physical, chemical, and biological monitoring.

f) **Aseptic handling and transfer (Sections 8.8.3, 8.8.4)** Performance measures should include, but are not limited to, selection and use of proper attire and correct techniques for unloading the sterilizer and transferring sterilized items to the point of use.

A problem analysis should be completed for any problem with any aspect of flash sterilization that could pose a risk to patients. The problem analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected. There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Auditing results should be routinely summarized and submitted to Infection Prevention and Control for review.

Rationale: Measurements of process performance allow the system to be monitored and the results compared to a predetermined level of quality. Evaluation of findings provides a method of identifying problems or shifts in

activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data to assess the effectiveness of the process and make ongoing improvements in performance.

11.3 Functional areas for product and process improvements

11.3.1 Workplace design

Optimization of product and process performance relies on efficient workplace design. Problems such as cross-contamination, excessive processing costs, product failures, inefficient time usage, and so on can be created or aggravated by poor workplace design. Workplace design encompasses the physical layout of the reprocessing area, the functional workflow patterns, the physical facilities (e.g., the mechanical and electrical systems, lighting, plumbing, ventilation, environmental controls), and the types and locations of processing equipment and supplies. The adequacy of the workplace design should be assessed by such means as employee input, accident records, and evaluation of the workplace in terms of the recommendations of Section 3.

11.3.2 Processing policies and procedures

Evaluating and monitoring the effectiveness of the process should be an ongoing effort and is critical to maintaining control over and determining methods for improvement of the product and process. The review of records and of documented quality control procedures that have been implemented should serve as the basis for monitoring and evaluating the process. Written procedures should be reviewed, and current practices audited for compliance in the areas included in the CQI program, for example

a) training and continuing education (see Section 4.3);

b) medical device processing protocols (see Sections 5 through 8);

c) maintenance of sterilizers (see Section 9);

d) product identification and traceability, i.e., lot control numbers (see Section 10.3.1) and load records (see Section 10.3.2);

e) sterilizer physical monitoring records (Section 10.4);

f) sterilization process indicator records (Section 10.5);

g) sterilizer efficacy monitoring and qualification testing records (Sections 10.7 and 10.8); and

h) product testing records (Sections 10.9 and 10.10).

11.3.3 Product use

Evaluating the performance of products that have been or will be used can offer important feedback on the effectiveness of the process and/or the appropriateness of the products selected. Performance measures can come from internal evaluations, end-user feedback, and/or supplier testing.

a) **Internal evaluations** Internal evaluations can be used to audit the quality of finished products. For example, instrument packs can be evaluated by observing the number, type, and configuration of their components. Preprocessing decontamination can be evaluated by visually examining instruments for contamination. Product recalls can be evaluated by reviewing records of actions following documented sterilization cycle failures. Periodic product monitoring can be evaluated on the basis of the appropriateness of the loads tested and the actions taken as a result of failures.

b) **End-user feedback** A formal, documented system to log, investigate, and resolve complaints and/or product failures should be established. Issues such as patient infections, PPE failures, inoperative instruments and equipment, incorrect pack configurations, and dispensing of incorrect products should be documented, monitored, and tracked over time. A procedure should be established for investigation and remediation of serious and repeat problems.

c) **Supplier testing** Concerns relative to the performance of products, supplies, or services should be evaluated by the manufacturer through testing. There should be a written request to and response from any vendor whose products, supplies, or services are in question. All correspondence should be filed with the corresponding complaint, including details of the investigation, the findings, and any actions taken by the vendor for resolution of the problem.

d) **Repair records** Review of instrument repair records might show a pattern. Once identified, the cause for the repair can be reviewed, corrected, then monitored to assure the problem has been resolved.

11.4 Implementing product and process improvements

There is no single right way to implement a CQI program. The program should be customized to the individual facility. However, a team approach has been proven to be successful, because it allows direct input from multiple employees and results in a superior program.

Employees who are actively involved in and responsible for the day-to-day functions outlined in the plan should be members of the team. This approach generates input from those most knowledgeable in methods of effectively improving the program. Additionally, such involvement promotes in those individuals a sense of ownership and tends to lead to a higher degree of commitment on the part of the employees implementing the program.

The single most important issue for those charged with implementing a CQI program is the accurate collection of data using the facility plan for documenting process monitoring and product performance (developed as part of the CQI program). The frequency and type of information generated will vary depending on the level of control established in the documentation plan. Facilities with processes that are uncontrolled or highly variable will require increased process monitoring and documentation, which can be reduced over time as the program brings these processes under improved control.

The CQI program should assess all components of the sterilization process for the ongoing ability to achieve the desired outcome of consistently delivering a sterile product to the user. Performance improvement plans, when needed, should be implemented to enhance the sterilization process on the basis of this assessment. Trending data for the number of BI tests, number of BI failures for each sterilizer, education compliance (percent attending or percent passing tests or competency measures), time and completeness of sterilizer preventive maintenance, ability to locate all items during recalls, and completeness of test records are examples of measures to be considered when assessing the process.

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12 New product evaluation

12.1 General rationale

Periodically, new products enter the market for which AAMI does not offer guidance for application. Some products do not fall within AAMI's purview. For those that do, AAMI applies a rigorous consensus review process that includes committee discussion, balloting, public review, and subsequent publication; this consensus review process can be quite lengthy. When any product is being considered for use within a facility, it is the responsibility of the intended users to evaluate the product using a systematic process of product evaluation and to establish policies and procedures that reflect this process and that are appropriate to the health care organization. This is especially true when the health care organization is considering a product for which there are no guidelines from AAMI or other similar professional organizations.

12.2 Considerations

The following are considerations associated with conducting a product evaluation.

1) Establish a multidisciplinary committee with representation from those who will be affected by the new product. For example, for a product related to steam sterilization, representation could include, but not necessarily be limited to, Infection Prevention and Control, Operating Room, Sterile Processing, Risk Management, and Staff Development/Education.

2) Collect and distribute to the committee information related to the product. Such data should include, but not necessarily be limited to, the following:

   - FDA clearance documentation
   - Relevant research articles published in peer-reviewed journals
   - Manufacturers' literature and instructions for use
   - Experts' opinions
   - Reports from peers who are using or have trialed the product

3) In addition to evaluating the product's intended application, consider the following:

   - Contribution to patient safety
   - Any legal implications associated with use of the product
   - Cost/value analysis (return on investment)
   - Personnel education necessary to implement use
   - Ease of use of the product
   - Related safety issues
   - Compatibility of the product with existing equipment and products
   - Environmental impact
   - Availability of ongoing support from the vendor for such services as maintenance
   - Impact on standardization of product inventory

4) If a product trial is indicated, the following guidelines apply:

   - Establish a time limit for the trial.
   - Identify the personnel and departments that should trial the product.
   - Establish the amount of product that should be evaluated.
   - Develop evaluation tools through the multidisciplinary committee identified above.
   - Determine and implement the education and demonstrations needed for the trial.

- Define the desired outcome.
- Analyze the data and compare the actual outcome with the desired outcome.

For more comprehensive information on the evaluation of new products, see 11.2.2 and AORN (2010a).

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Annex A
(Informative)

Examples of workplace design

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

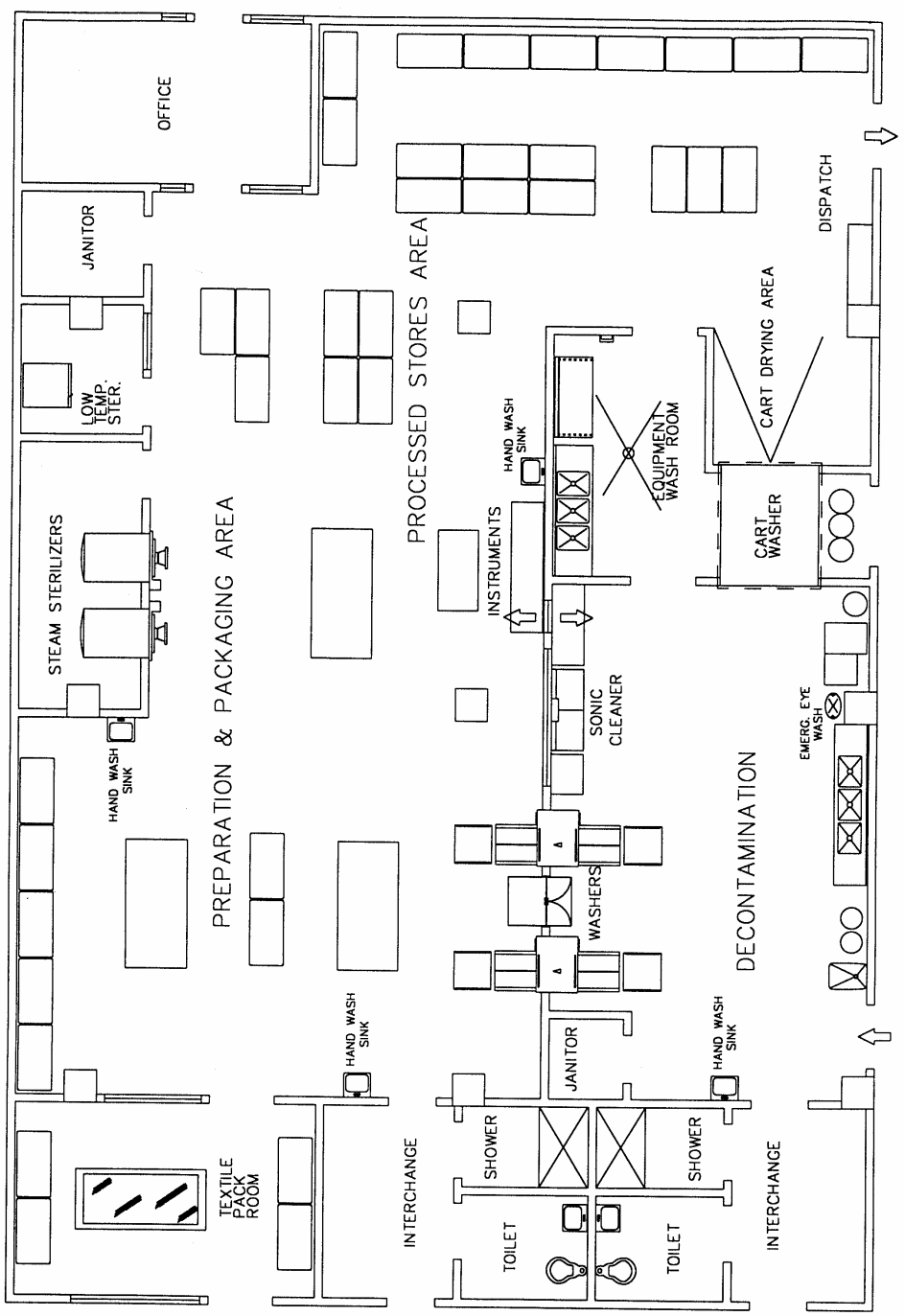

Figure A.1—Example of a work area design and workflow pattern for a sterile processing department in a typical small hospital

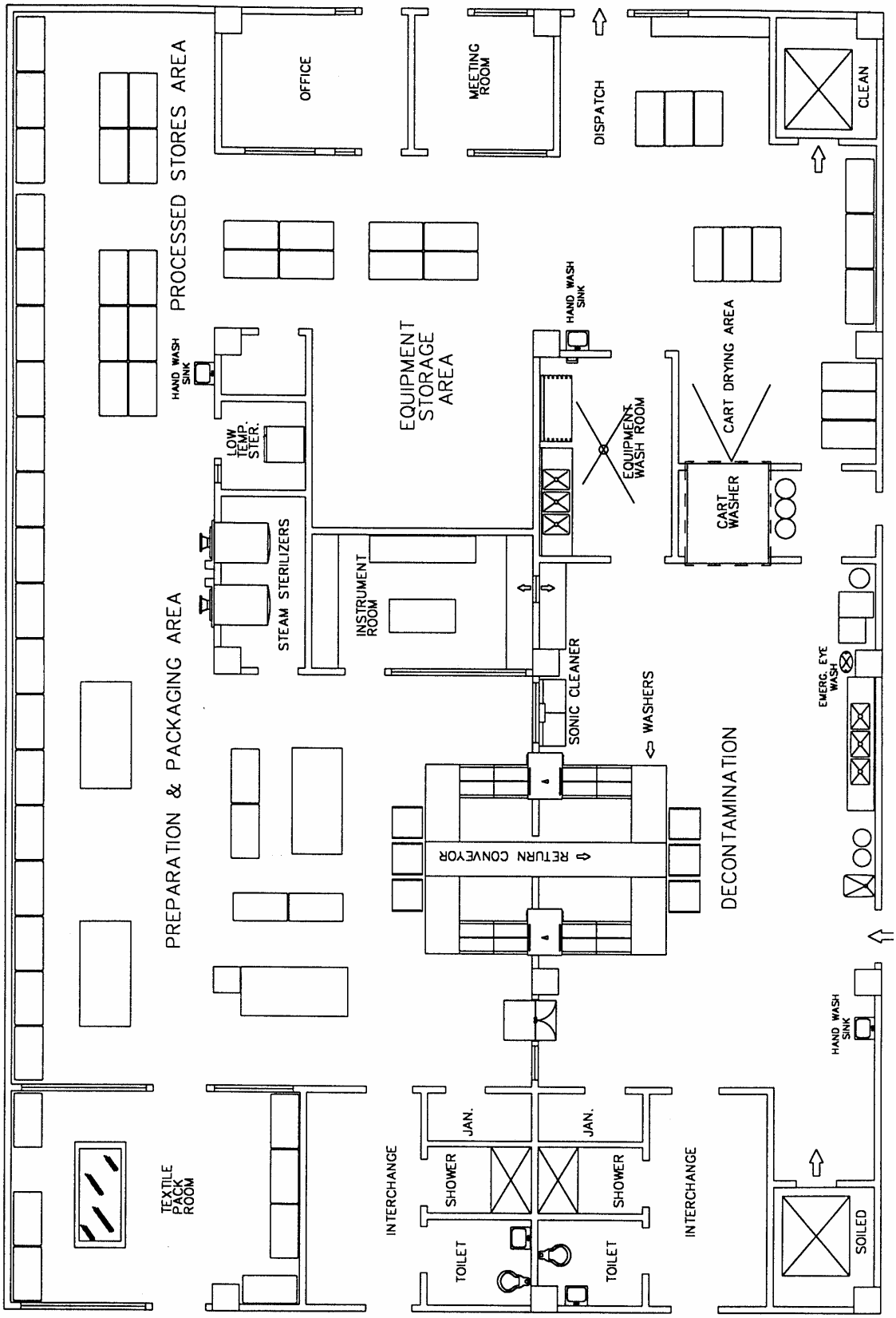

Figure A.2—Example of a work area design and workflow pattern for a sterile processing department in a typical medium-sized hospital

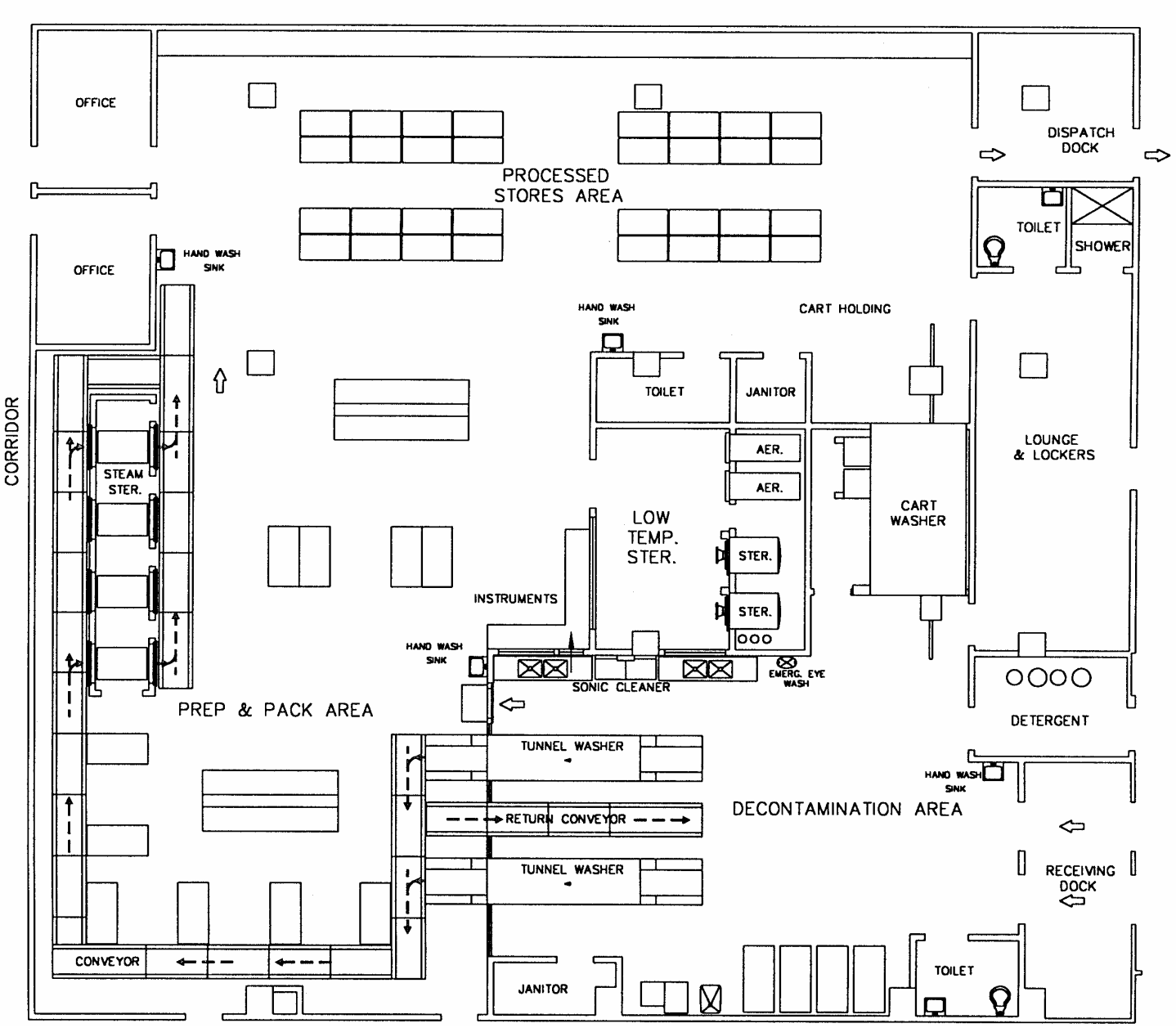

Figure A.3—Example of a work area design and workflow pattern for a sterile processing department in a typical regional processing center

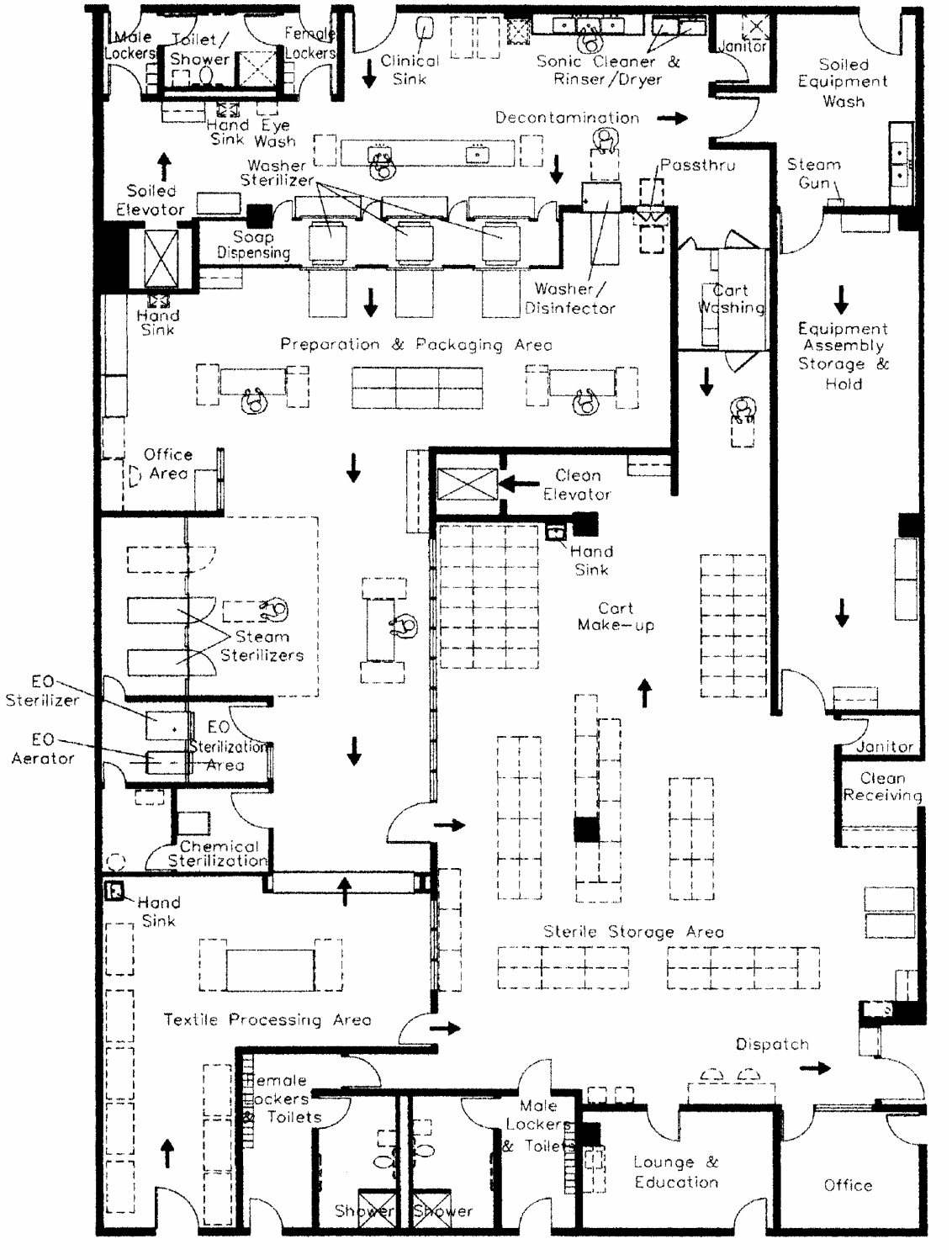

Figure A.4—Example of a work area design and workflow pattern for a sterile processing department

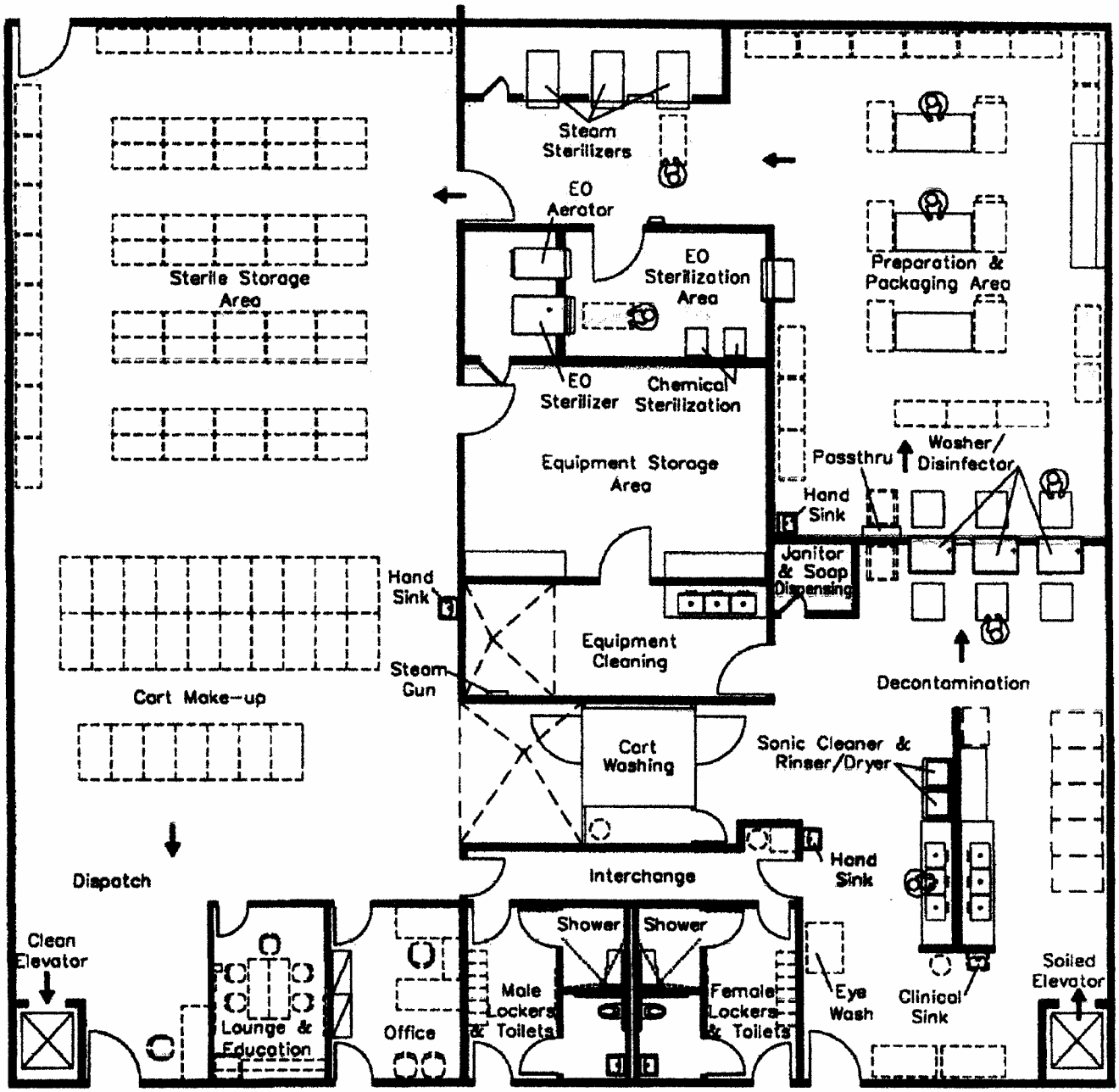

Figure A.5—Example of a work area design and workflow pattern for a sterile processing department

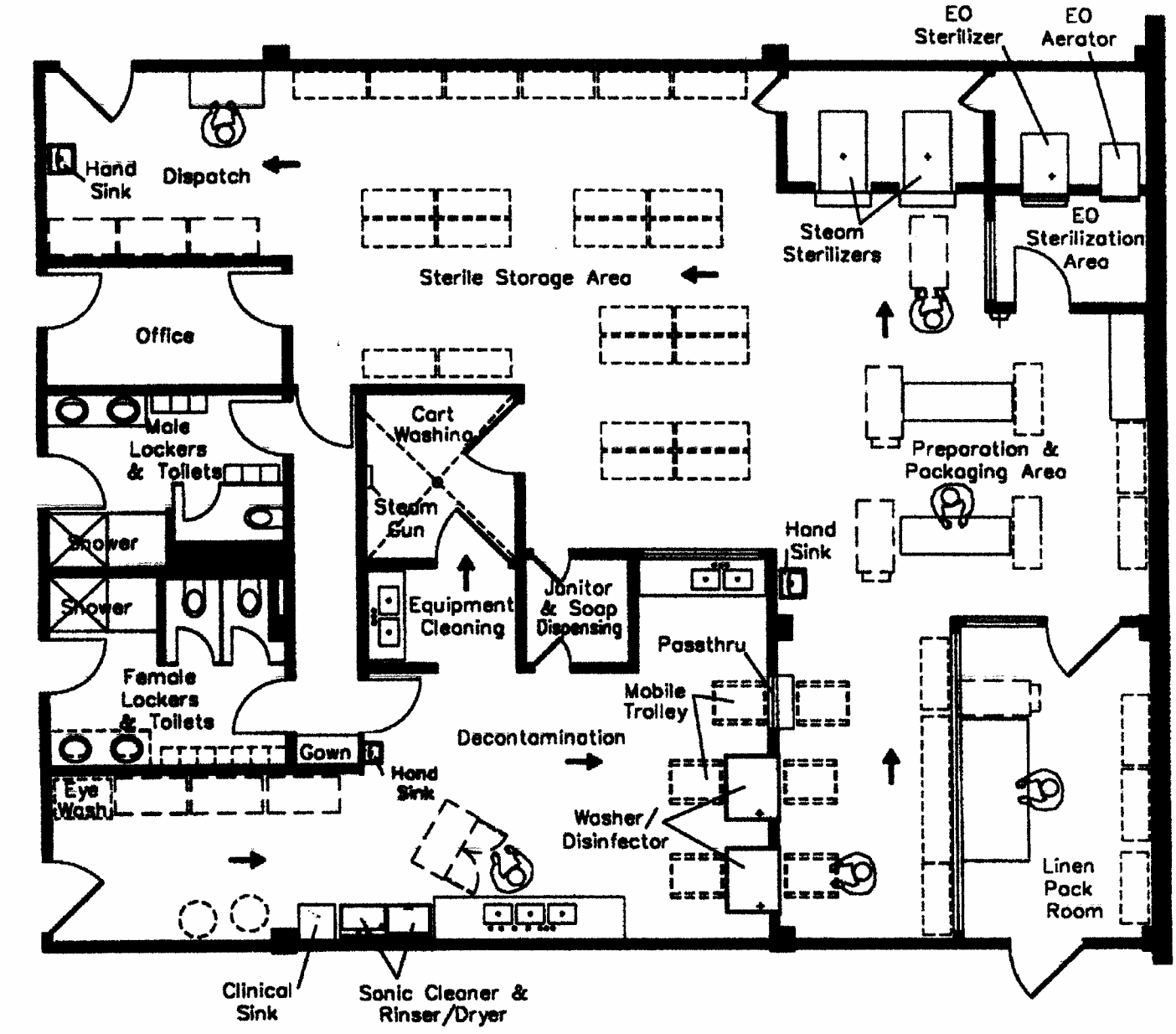

Figure A.6—Example of a work area design and workflow pattern for a sterile processing department

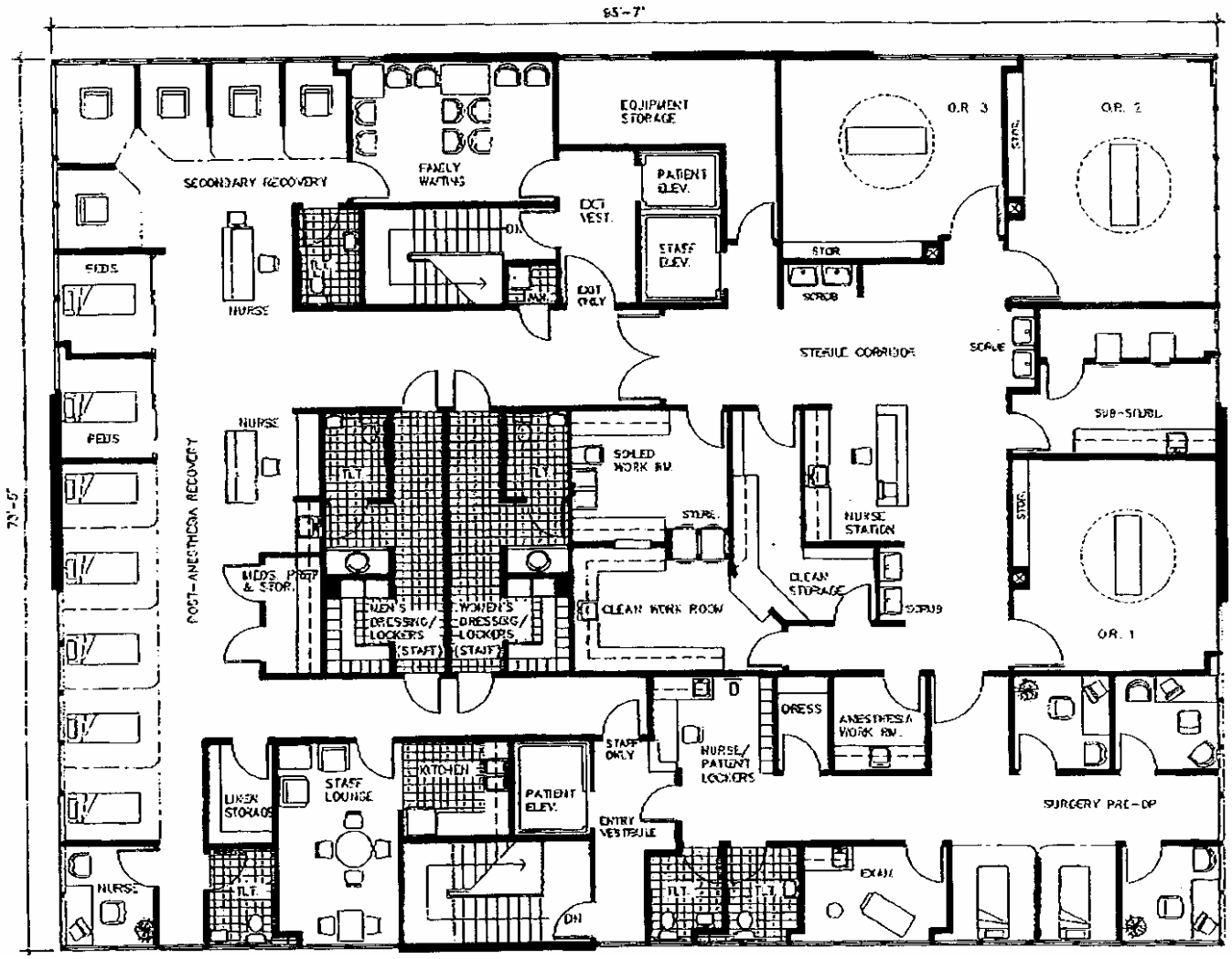

Figure A.7—Example of an ambulatory surgery facility

From: Medical and dental space planning: A comprehensive guide to design, equipment and clinical procedures. 3rd ed. By Jain Malkin. © John Wiley & Sons, Inc. Reprinted with permission of John Wiley & Sons, Inc.

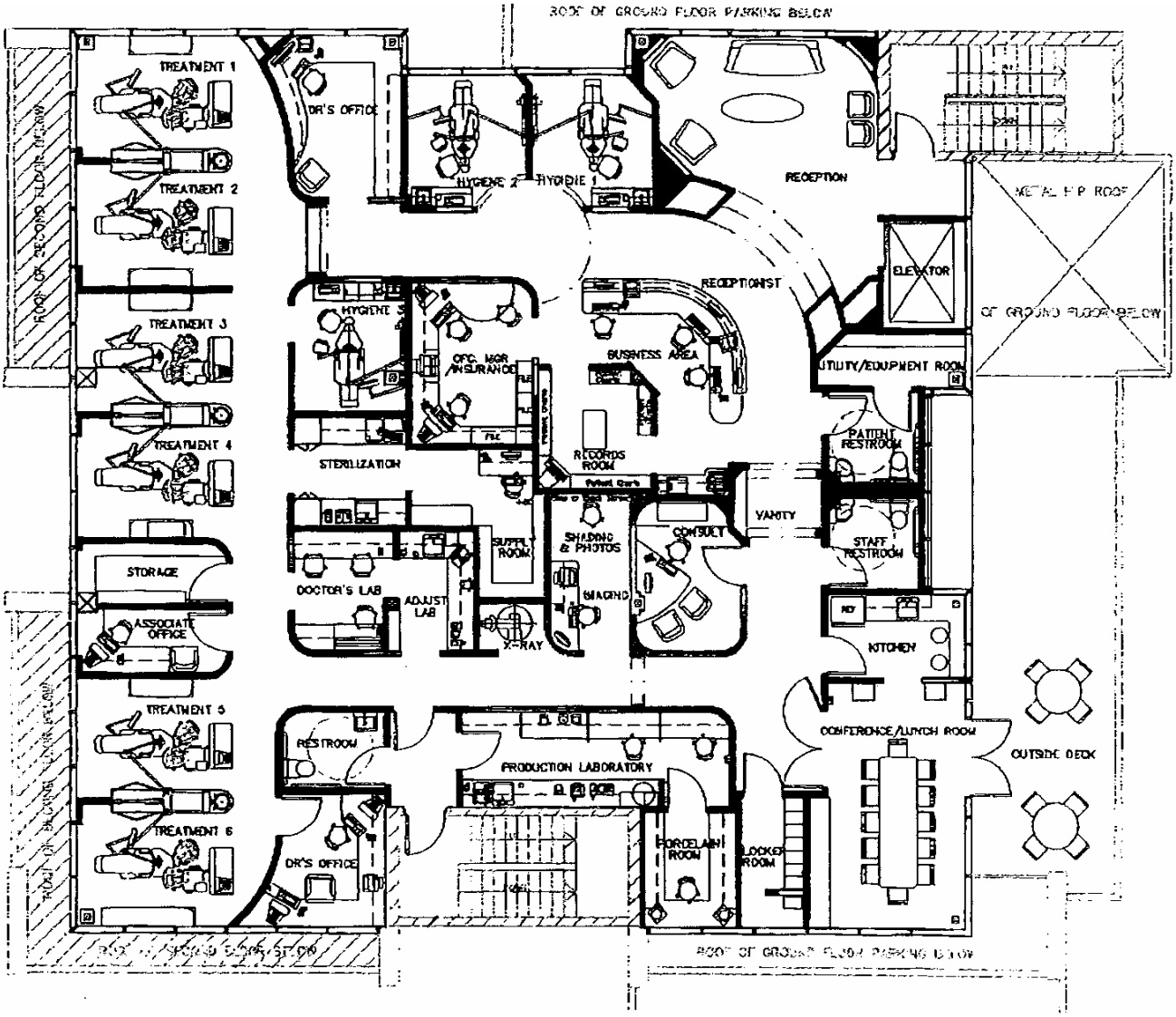

Figure A.8—Example of a dental facility

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Annex B
(Informative)

Infection transmission

B.1 Introduction

The purpose of the decontamination process in a health care facility is to prevent the transmission of disease. Health-care-associated infections can occur because of the presence of infectious agents, multiple modes of transmission, and a population of susceptible individuals. An understanding of the chain of infection enables health care professionals to develop and implement policies and procedures that will reduce the risk of infection transmission.

Health-care-associated infections are those that manifest themselves after a patient is admitted to the facility and that were not incubating at the time of admission. Such infections involve not only patients but also others present in the facility, principally health care workers.

There are six main factors in the chain of infection: the etiologic agent, a reservoir, the portal of exit, the mode of transmission, the portal of entry, and a susceptible host. (See Figure B.1.) Each of these factors is vitally important and must be present for an infection to take place.

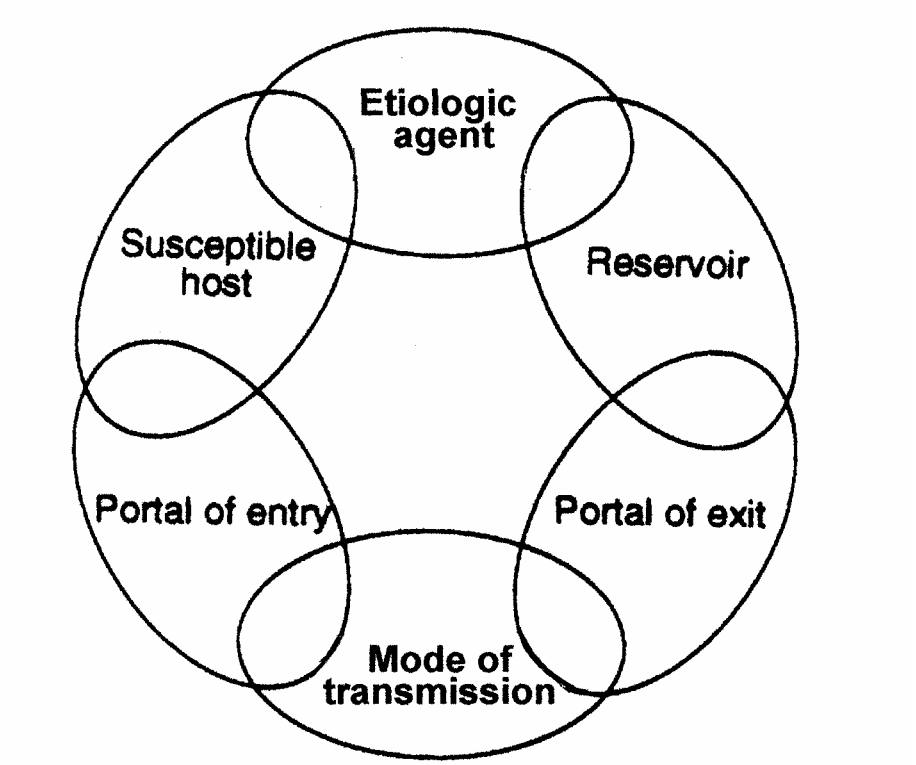


Figure B.1—The chain of infection, components of the infectious disease process

(Adapted, with permission of the publisher, from: Soule BM, ed. *The APIC Curriculum for Infection Control Practice,* Vol. 1. Washington (DC): Association for Professionals in Infection Control and Epidemiology, Inc., 1983.)

B.2 Chain of infection

B.2.1 Etiologic agent

B.2.1.1 General

The first link in the chain of infection is the etiologic agent itself: any bacterium, virus, fungus, or other microorganism. Most pathogenic microorganisms of concern with respect to patient care equipment are included in one of the following four classes: (a) spore-forming bacteria such as *Bacillus anthracis, Clostridium botulinum, Clostridium perfringens,* and *Clostridium tetani;* (b) vegetative bacteria such as *Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus,* and *Mycobacterium tuberculosis*; (c) viruses such as the human immunodeficiency virus (HIV) and the herpes simplex, polio, and hepatitis B viruses; and (d) fungi such as *Candida albicans, Coccidioides, Aspergillus,* and *Alternaria.*

B.2.1.2 Pathogenicity

Not only must the infectious agent be present, it also must be pathogenic (capable of causing disease). The ability of a microorganism to cause disease depends upon its virulence and its invasiveness.

Virulence is the degree of pathogenicity of a given microorganism, as indicated by morbidity and mortality case rates. Invasiveness is the ability of a microorganism to invade tissues of the body. Organisms that can penetrate the body's intact barriers are generally of more concern than those that cannot. However, some microorganisms need not directly attack intact body tissues in order to cause disease. For example, *Vibrio cholerae* is noninvasive in the gastrointestinal tract but produces toxins that react with the mucosa and cause diarrhea. In contrast, *Shigella* organisms cause disease by actually invading the gastrointestinal submucosa.

B.2.1.3 Dose

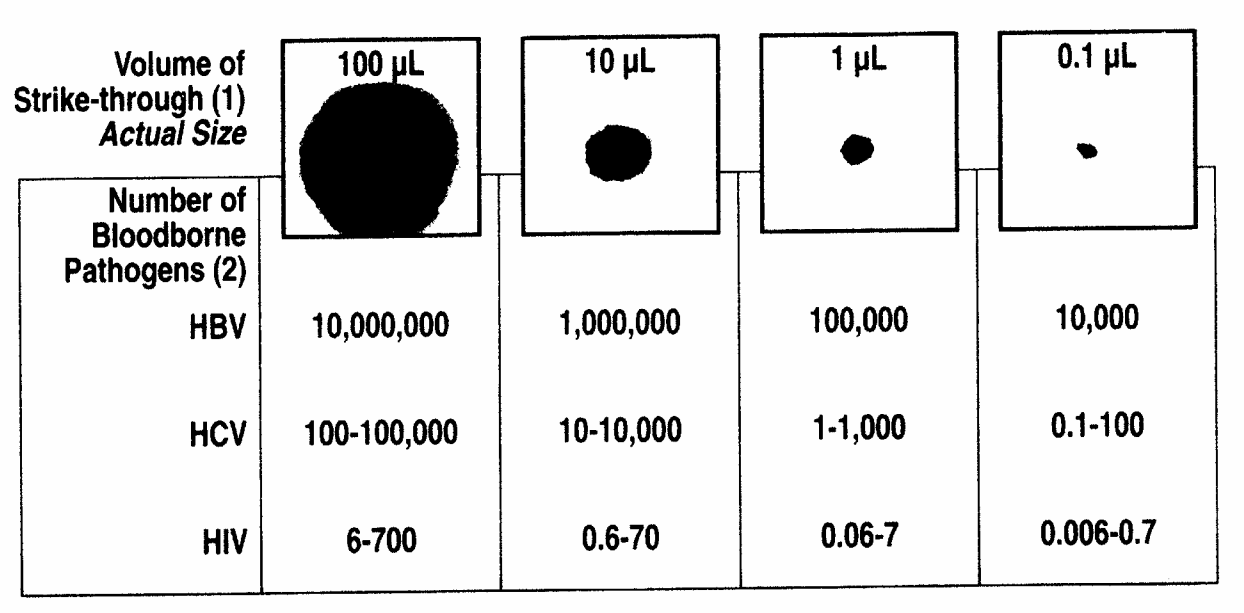
A third factor critical to this particular link involves a phenomenon referred to as the "infectious dose." The infectious dose is the minimum number of a given microorganism needed to cause infection. This number varies from organism to organism and from host to host. However, seldom has the transmission of disease resulted from the transfer of a single microorganism. It usually requires thousands to millions of these agents before infection can actually take place. For example, that number for staphylococci has been estimated to be as high as 10^7 (Krizek and Robson, 1975), whereas the number for hepatitis A could be as low as 10 to 100 virus particles. Some viral diseases can be accompanied by extremely high viral concentrations in body fluids such as blood; consequently, a significant number of microorganisms can be carried in a very minute volume of liquid. (See Figure B.2.) The concept of infectious dose is particularly important to understand when considering the importance and efficacy of good handwashing practices. Although properly performed handwashing does not eliminate all organisms from the skin, it does reduce their numbers to a level far below the infectious dose needed for the transfer of most diseases.

B.2.2 Reservoir

The second major link in the chain of infection involves the presence of a reservoir or source that will allow for microbial survival and, perhaps, even multiplication of a potential pathogen. Common reservoirs include the multitude of supplies and equipment used in patient care. However, the role played by food and drink, linen, and other inanimate objects is of comparatively minor significance when measured against that played by the main reservoir, man himself. Studies have shown that normal human skin harbors approximately 10,000 organisms per square inch, equivalent to nearly 20 million microorganisms over the surface of the entire body. The oral cavity is thought to harbor an additional 100 million organisms and the gastrointestinal tract to contain another 100 million in each gram of stool. Thus, on and within the human body, well over a trillion microorganisms can be found, and therein lies one of the main reasons for the use of gloves any time that contact with body fluids is anticipated. It is a well-documented fact that most health-care-associated infections are indeed caused by the patient's own microbial flora. This is not to imply that such infections cannot be prevented, simply that they are usually the result of prior microbial colonization of the patient.

B.2.3 Portal of exit

The third link requires the presence of a source from which the pathogen can emerge, a portal of exit. Obvious portals of exit include the respiratory tract, blood vascular system, skin, and mucous membranes, as well as the gastrointestinal and genitourinary tracts. In addition, contact of patient care supplies and equipment with any portal of exit will invariably result in potential contamination and the subsequent possibility of disease transfer.



NOTE 1—Volume of red 40 dyne/cm synthetic blood delivered to white blotter papers.
NOTE 2—Based on documented whole blood concentrations of infected patients.

Figure B.2—Blood-borne pathogen strike-through conversion chart

Figure B.2 converts the amount of strike-through to the amount of potential blood-borne pathogen contamination. The four spots at the top were formed from premeasured droplets of synthetic blood and are marked in microliters ranging from 100 microliters to 0.1 microliter. Listed on the left are the three primary blood-borne pathogens: HBV, HCV, and HIV. The approximate number of infectious units that could be present in each spot, on the basis of documented whole blood concentrations in infected patients, is shown for each type of virus. These data were derived from Bradley (1984), Ho, et al. (1989), and Shikata, et al. (1977). A study of transmission of blood-borne pathogens to health care workers found serum concentrations of HBV, HCV, and HIV to be as high as 10^8, 10^6, and 10^3 viral particles per milliliter, respectively (Lanphear, 1994). (Figure courtesy of W.L. Gore & Associates, Inc.)

B.2.4 Mode of transmission

Although several potential mechanisms for transmission exist, the main mode of disease transfer involves contact transmission, either through direct or indirect contact with the patient or through droplet spread via contact with exhaled respiratory secretions. Direct-contact transmission primarily involves person-to-person spread such as contact with the unwashed hands of a health care worker. Indirect-contact transmission can be the result of contact with a contaminated intermediate object such as a catheter, dressing, or surgical instrument. Droplet spread occurs through contact of the conjunctivae or the mucous membranes of the nose or mouth with large (greater than 5 microns) droplets of respiratory secretions. Such droplets are generated primarily during coughing, sneezing, or talking. Typical examples of illnesses transmitted in this manner include streptococcal pharyngitis, mumps, and influenza.

Three additional means by which diseases can be transmitted are airborne, vehicular, and vector transmission. Airborne transmission occurs by means of the dissemination of either very small (less than 5 microns) droplet nuclei resulting from respiratory secretions or dust particles containing the infectious agent. Typical diseases transmitted in this manner include tuberculosis, measles, and chicken pox.

Vehicular transmission involves the spread of disease-causing organisms through some secondary route, usually environmental objects such as contaminated medications or antiseptics (e.g., eyedrops, multidose vials), food (e.g., hepatitis A or staphylococcal food poisoning), or water (e.g., giardiasis). Such diseases are very rarely the result of health care delivery.

Vector transmission involves the spread of pathogenic agents through secondary, animate hosts, such as insects and rodents or other small animals. Typical examples of vector-borne diseases include malaria, rabies, plague, and Lyme disease. As with vehicular transmission of disease, vector transmission associated with the delivery of health care is extremely rare, if not nonexistent, in the United States.

B.2.5 Portal of entry

The fifth link in the chain of infection is a suitable portal of entry. The avenues for gaining entry into the body are, in most instances, identical to the portals of exit. It is important to understand that each of these portals is usually peculiar to given diseases and that, for any given disease, there is usually a very specific portal of exit and entry. For example, tuberculosis and influenza involve only the respiratory tract and typhoid fever the gastrointestinal tract. Hepatitis B involves transmission by blood. Most infectious diseases and conditions require very specific portals of both entry and exit.

B.2.6 Susceptible host

The last link is a susceptible host, someone who lacks effective resistance to a given pathogenic agent. A variety of host factors must be present before infection can occur. Very few organisms can gain entrance through normal intact skin. Most require some breach in skin integrity. Other less obvious lines of defense include tears, gastric acid, and the cilia of the nose and upper respiratory tract. One's ability to mount a local inflammatory response provides yet another nonspecific host defense mechanism. Patients who are immunocompromised (e.g., the very young, the elderly, those who are undergoing immunosuppressive therapy, those with disorders of the immune system) are susceptible hosts.

B.3 Barrier protection and protective clothing

Protective clothing is often used to limit or prevent contact transmission of microorganisms. Strategies employed in the laboratory evaluation of protective clothing materials and the resulting understanding of performance expectations are very important when deciding which products are suitable for which applications. Such strategies need to consider both the modes of transmission (e.g., liquid-borne, aerosol-borne) and the perceived risk associated with varying types of microorganisms (e.g., viruses, bacteria, fungi). It is extremely difficult to duplicate the myriad of physical, chemical, and thermal stresses placed on protective clothing in an actual setting. Nonetheless, the goal of laboratory testing is to provide information that will allow a realistic estimation of the performance of protective clothing during actual use.

NOTE 1—The Food and Drug Administration maintains a list of recognized standards, including standards applicable to protective clothing and barrier integrity testing. This list can be accessed at http://www.fda.gov/cdrh/stdsprog.html.

NOTE 2—ANSI/AAMI PB70 classifies surgical gowns, other protective attire, surgical drapes, and drape accessories according to barrier performance determined by specified laboratory test methods. This standard has been recognized by FDA.

Annex C
(Informative)

Processing CJD-contaminated patient care equipment and environmental surfaces

C.1 Introduction

The purpose of this Annex is to provide general guidance to hospital central service departments for reprocessing instruments and medical devices that have been exposed to patients known or suspected to have Creutzfeldt-Jakob disease (CJD). This Annex is not intended to provide a detailed review. Health care facilities may consider other procedures as technologies are developed to inactivate prions. The recommendations in this Annex are based on information from the scientific literature and various health care authorities and are subject to ongoing review and modification. The reader is urged to check with health care agencies such as the CDC for current recommendations regarding the processing of devices and equipment contaminated with high-risk tissue from high-risk patients. See also Rutala and Weber (2010) for such guidance.

NOTE—FDA does not current recognize any method of "reducing prion infectivity" to be adequately validated and does not permit statements about specific decontamination recommendations in device labeling.

CJD is a degenerative neurological disorder of humans with an incidence in the United States of approximately one case per million population per year (CDC, 1996). The disease is thought to be caused by a proteinaceous infectious agent or prion. CJD is related to other human transmissible spongiform encephalopathies (TSEs) that include kuru (0 incidence, now eradicated), Gertsmann-Straussler-Sheinker (GSS) syndrome (1 case per billion), and fatal insomnia syndrome (FFI) (less than 1 case per billion). Prion diseases do not elicit an immune response, result in a noninflammatory pathologic process confined to the central nervous system, have an incubation period of years, and usually are fatal within one year of diagnosis.

A recently recognized new variant form of CJD (vCJD) is acquired from cattle with bovine spongiform encephalopathy (BSE) or "mad-cow" disease. As of January 24, 2003, a total of 139 vCJD cases had been reported worldwide, 129 in the United Kingdom (UK), six in France, and one each in Italy, Ireland, Canada, and the United States (CDC, 2002b). Each of the latter three patients had resided in the United Kingdom during the UK outbreak of BSE. Compared with CJD patients, vCJD patients are younger (29 vs. 65 years of age), have a longer duration of illness (14 vs. 4.5 months), and present with sensory and psychiatric symptoms that are uncommon with CJD. A probable case of transfusion-related disease caused by vCJD was recently reported (Llewelyn, et al., 2004).

The agents of CJD and other TSEs exhibit an unusual resistance to conventional chemical and physical decontamination methods. Because the CJD agent is not readily inactivated by conventional disinfection and sterilization procedures and because of the invariably fatal outcome of CJD, the procedures for disinfection and sterilization of the CJD prion have been both cautious and controversial for many years.

CJD occurs as both a sporadic and familial disease. Less than 1% of CJD episodes have resulted from health-care-associated transmission and only two confirmed cases and four unconfirmed cases have been associated with reprocessed surgical instruments; these cases occurred more than 25 years ago in Europe. No cases of CJD or vCJD associated with surgical or medical instruments have been reported since that time.

The vast majority of health-care-associated transmission cases have resulted from use of contaminated tissues or grafts. Iatrogenic CJD has been described in humans in three circumstances:

a) after patients received extracted pituitary hormones (more than 130 cases);

b) after patients received an implant of contaminated grafts from humans (cornea, three cases; dura mater, more than 110 cases);

c) and, as mentioned above, after use of contaminated medical equipment and surgical instruments on patients undergoing invasive procedures (two confirmed and four unconfirmed cases) (World Health Organization, 2000; Brown, et al., 2000).

All known instances of iatrogenic CJD have resulted from exposure to infectious brain, pituitary, or eye tissue. Tissue infectivity studies in experimental animals have determined the infectiousness of different body tissues (Brown, 1996). Tissues that have the highest prion concentration are brain and dura mater. Transmissibility is directly related to the concentration of prions in tissues.

Transmission via stereotactic electrodes is the only convincing example of transmission via a medical device (Bernoulli, et al., 1977). The electrodes had been implanted in a patient with known CJD. The electrodes were cleaned with benzene and then "sterilized" by soaking them in 70% alcohol and exposing them, during storage at room temperature, to formaldehyde vapor produced by a formaldehyde generator using solid paraformaldehyde. Two years later, these electrodes were retrieved and implanted into a chimpanzee in which the disease developed. The method used to "sterilize" these electrodes would not currently be considered an adequate method for sterilizing medical devices.

Retrospective studies suggest that four other episodes could have resulted from use of contaminated instruments in neurosurgical operations (Rutala and Weber, 2001). An index CJD case was identified in only one case; and in this instance, the surgical instruments were cleaned with soap and water and then exposed to dry heat for an unspecified time and temperature. The other three cases had no associated index case; these patients did have a neurosurgical procedure within a two-year period before being diagnosed with CJD.

All six cases of CJD associated with neurosurgical instruments occurred in Europe between 1953 and 1976, and details of the reprocessing methods for the instruments are incomplete. There are no known episodes of CJD attributable to the reuse of devices contaminated with blood or to transfusion of blood products.

The infrequent transmission of CJD via contaminated medical devices probably reflects the inefficiency of transmission except for neural tissue and the effectiveness of conventional cleaning and current disinfection and sterilization procedures (Rutala and Weber, 2001).

To minimize the possibility of use of neurosurgical instruments that have been potentially contaminated during procedures performed on patients in whom CJD is later diagnosed, health care facilities should consider using the sterilization guidelines outlined below for neurosurgical instruments used during brain biopsy done on patients in whom a specific lesion has not been demonstrated (e.g., by magnetic resonance imaging or computerized tomography scans). Alternatively, neurosurgical instruments used in such patients could be disposable or the instruments could be quarantined until the pathology of the brain biopsy is reviewed and CJD excluded (Rutala and Weber, 2001).

Several investigators have studied the inactivation of prions by disinfection and sterilization processes, but these studies do not reflect the reprocessing procedures in a clinical setting:

a) These studies have not incorporated a cleaning procedure that normally reduces microbial contamination by 4 $\log_{10}$ and reduces protein contamination (Rutala and Weber, 2001).

b) The prion studies have been done with tissue homogenates dried onto carriers. The protective effect of the tissue and the drying of the tissue might explain, in part, why the CJD agent is difficult to inactivate in these experimental studies.

c) Results of inactivation studies of prions have been inconsistent because of the use of differing methodologies, which have varied by prion strain, prion concentration, test tissue (intact brain tissue, brain homogenates, partially purified preparations), test animals, duration of follow-up of inoculated animals, exposure container, method of calculating log-reductions in infectivity, concentration of the disinfectant at the beginning and end of an experiment, cycle parameters of the sterilizer, and exposure conditions.

Despite these limitations, there is some consistency in the results (reviewed by Rutala and Weber [2001]). In order to provide scientifically-based recommendations, research should be undertaken in which actual medical instruments are contaminated with prions (including variant CJD), cleaned, and then subjected to either conventional sterilization or disinfection or special prion reprocessing.

The disinfection studies mentioned above showed that many, but not all, disinfection processes fail to inactivate clinically significant numbers of prions. There are four chemicals that reduce the prion titer by more than 3 $\log_{10}$ in 1 hour: chlorine (sodium hypochlorite), a phenolic (based on ortho-phenylphenol, p-tertiary-amylphenol, and ortho-benzyl-para-chlorophenol) at concentrations greater than 0.9%, guanidine thiocyanante, and sodium hydroxide. Of these four chemical compounds, chlorine has provided the most consistent prion inactivation results. However, the corrosive nature of chlorine makes it unsuitable for many devices, such as surgical instruments and endoscopes.

Prions also exhibit an unusual resistance to conventional physical decontamination methods (Rutala and Weber, 2001). Although there is some disagreement on the ideal time and temperature cycle for steam sterilization, the recommendation for 134°C for greater than or equal to 18 minutes (prevacuum) and 132°C for 60 minutes (gravity-displacement) are based on the scientific literature (Rutala and Weber, 2001) and have been shown to provide significant but not complete reduction of infectivity under worst-case conditions (World Health Organization, 2000).

A recent report in the United Kingdom, "Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection" (published December 15, 2003, by the Advisory Committee on Dangerous Pathogens and Spongiform Encephalopathy) indicated that currently there is no sterilization procedure known to be completely effective against prions and prion-related diseases. See http://www.dh.gov.uk/ab/acdp/tseguidance.index.htm.

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 before 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, 2010a).

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.

2) Endoscopes (except neurosurgical endoscopes) are likely to be contaminated only with no-risk materials; hence, standard cleaning and high-level disinfection protocols are adequate for reprocessing.

3) Environmental surfaces contaminated with no-risk tissues or fluids require only standard disinfection using disinfectants recommended by OSHA for decontaminating blood-contaminated surfaces (e.g., 500 to 5,000 ppm sodium hypochlorite).

NOTES

Annex D
(Informative)

User verification of cleaning processes[2]

D.1 General considerations

Verification of a cleaning process consists of

a) defining a cleaning process and its critical aspects so that each step is fully verifiable through personnel training and observation to ensure that it can be followed completely, accurately, and without variation by all individuals who perform it; and

b) providing process controls along with validation and verification methodologies that ensure adequate, consistent cleaning levels.

Two principles are involved in verifying a cleaning process. The first consists of establishing, clarifying, and documenting a standard cleaning process that is based on published and validated recommended practices or guidelines. The second concerns measuring and evaluating residual contaminants on medical devices after applying the established cleaning process.

The U.S. Food and Drug Administration (FDA) places the primary responsibility for developing and validating methods for effective reprocessing of a reusable medical device on the manufacturer of the device. The manufacturer is expected to validate that the device can be cleaned and disinfected or sterilized adequately to allow the device to be reused. As outlined in FDA (1996a), the manufacturer must test and validate any labeling claims of fitness for reuse that are provided in the written instructions for the handling, cleaning, disinfection, packaging, and sterilization of medical devices in a health care facility. To demonstrate compliance with label claims, manufacturers of cleaning agents must validate that their cleaners provide the expected level of soil removal and determine its materials compatibility. (AAMI TIR30 addresses the issues related to manufacturers' validation testing for cleaning of medical devices.)

Medical device manufacturers should be familiar with cleaning, disinfection, and sterilization technologies used in health care facilities and with the kinds of soil and microbial contamination encountered as a result of patient use. Organic soil such as blood, serum, lipids, tissue fragments, and inorganic salts can impede the disinfection or sterilization process if it is not removed during cleaning. Most of these soil components are substrates for the sterilants used for disinfection or sterilization; that is, they are competitors for sterilant action. If these soil components are insufficiently removed, they can also protect microorganisms from inactivation by limiting the diffusion of the sterilant to the microorganisms' location on the medical device.

Users must establish an appropriate cleaning protocol for the reusable medical devices used at their sites. The procedures should be based on the recommendations of the device manufacturer and the cleaner manufacturer, published data on cleaner efficacy for the medical devices (if available), and published, validated, recommended practices or guidelines. Cleaning efficacy tests that are performed following reprocessing are used to verify the ability of a cleaning process to remove or reduce to an acceptable level the organic soil and microbial contamination that occurs during the use of reusable devices. A number of methods can be used to evaluate the results of the cleaning process. The most common method is a visual inspection, sometimes involving the use of a lighted magnifying glass. Health care personnel inspect every device for visible organic soil and contamination in a simple functionality check, usually as part of the inspection, preparation, and packaging procedure. However, residual organic soil and microbial contamination might be present on an accessible surface even though the device "looks clean." Furthermore, visual inspection is not possible for the inner components of medical devices that have lumens or that are of nonsealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices, biopsy forceps). Ideally, cleaning verification by users should include (a) visual inspection combined with other verification methods that allow the assessment of both external surfaces and inner housing and channels of medical devices, (b) testing the cleaning efficacy of equipment, and (c) monitoring key cleaning parameters (e.g., temperature). Manufacturers should strive to provide users with such tests so that medical devices can be tested directly after cleaning in a way that will not damage the device or require recleaning.

[2] Adapted from AAMI TIR30, Section 5.4.

A more objective and sensitive method than visual inspection is to measure the levels of organic soil and microbial contamination on the cleaned device. Currently, there are no validated test methods that allow users to rapidly verify that adequate cleaning has been performed. However, methods of measuring several soil components to determine the presence of nonvisible levels of organic soil and microbial contamination have been studied (see AAMI TIR30), and tests for some organic soils are commercially available.

A critical aspect of in-use reprocessing is for users to verify that staff members who perform the reprocessing of medical devices using the selected protocol are consistently achieving the expected level of cleaning. Furthermore, a facility's on-site quality assurance program should include ways to verify that the cleaning equipment used for reprocessing of medical devices is working properly. Testing the equipment upon installation, during routine use, and after repairs allows the user to verify its continued effectiveness (AORN, 2010a). Zuhlsdorf, et al. (2002) have shown that in cleaning tubular devices the achievement of visible cleanliness and adequate microbial reduction varies greatly, depending on the type of water and detergent used for cleaning. The variability of results for lumens cleaned by automated washers (Zuhlsdorf, et al., 2002) underscores the importance of in-use verification for manual cleaning, which is generally less efficient than automated cleaning. In-use verification of staff competency and of continued compliance with cleaning guidelines is rarely performed, primarily because methods of testing cleaning efficacy are not readily available or are not applicable to users. Many of the available test methods are research tools or are more appropriate for manufacturers to use to validate cleaning efficacy (e.g., destructive testing methods or sample methods involving the use of chemicals such as sodium dodecyl sulfate [SDS] to strip soil components from devices). Similarly, few methods are available for in-use verification that washer-disinfectors are working properly.

Two basic components of user verification of cleaning efficacy are

a) establishing reasonable benchmarks for the level of cleaning that can be achieved consistently using specific soil markers relevant to devices used for patients; and

b) developing rapid, easy-to-perform test methods that reliably demonstrate that the cleaning benchmarks have been achieved.

D.2 Markers

Cleaning is the removal of organic material (e.g., patient secretions), inorganic material (e.g., salts), and microbial contamination (acquired from the patient procedure or during handling) to ensure that adequate disinfection or sterilization can be achieved, thereby making the device safe for subsequent use on patients. The few published studies that have evaluated the specific markers that can be used to determine cleaning efficacy have indicated that the following soil markers are useful for benchmarking purposes:

a) protein,

b) carbohydrate,

c) hemoglobin (blood),

d) endotoxin,

e) lipid,

f) sodium ion, and

g) bioburden.

Protein is the marker most commonly used to evaluate cleaning efficacy. Although counts of viable organisms are useful for manufacturers' validation studies, they should not be used as the sole marker for cleaning, because although any reprocessing method that results in loss of viability will show decreased levels of organisms, this decrease might not reflect actual "removal" but rather residual dead organisms that cannot be detected by viability assays. For in-use evaluation, viable counts are rarely used as markers for cleaning, because this method would require an incubation step that would make the evaluation far too time-consuming for users. However, for flexible endoscopes, where dry storage is critical, users can evaluate samples of channels from stored scopes to determine the level of viable organisms and, therefore, whether microbial growth during storage is occurring.

What is not well established is the "benchmark," or acceptable, residual level of markers that should be achieved by cleaning. Realistic benchmarks depend on what can be achieved by routine cleaning and the limit of detection of the assay method used. Validation to establish benchmark levels for cleaning processes and residual soil has not yet been achieved. Current data (Alfa, et al., 2002) indicate that for flexible endoscopes that have been

cleaned after use on patients, the average levels of soil markers are as follows: protein, < 6.4 µg/cm^2; carbohydrate, < 1.8 µg/cm^2; hemoglobin, < 2.2 µg/cm^2; sodium ion, < 1 µmole/cm^2; and endotoxin, < 2.2 EU/cm^2 in the biopsy/suction channel. Furthermore, it has been reported that cleaning should be able to achieve at least a 3 $\log_{10}$ reduction in recoverable viable bacteria (total aerobic bacterial count) such that $\leq$ 4 $\log_{10}$ colony-forming units per square centimeter (cfu/cm^2) (corresponding to $\leq 10^5$ cfu/device) remain inside the biopsy/suction channel after cleaning. For other medical devices, such as laparoscopic accessory devices or surgical instruments that do not have lumens, the appropriate benchmarks could be different. Although there are few published studies to validate soil cleaning benchmarks for surgical instruments, Kruger (1997) has suggested that > 20 µg/cm^2 of protein remaining on surgical instruments is unacceptable; however, the rationale for this benchmark is not given. Chan-Myers, et al. (1997) have shown that for rigid, lumened medical devices, there is $\leq 10^3$ cfu/device after cleaning. The benchmarks for residual soil and bioburden levels after cleaning might become more definitive as more data become available and/or more efficient cleaning methods are developed.

D.3 Cleaning verification tests for users

Assay methods exist for all of the markers described in D.2, but few commercially available tests can be adapted by users to verify in-use cleaning compliance. Many existing test methods have not yet been validated to demonstrate that they can achieve the post-cleaning levels that have been published. Tables D.1 and D.2 summarize the currently available test methods that apply to in-use evaluation of, respectively, efficacy of cleaning of medical devices and efficacy of washer-disinfectors used for medical device reprocessing. Few of the in-use test methods listed in the tables have been assessed to determine their correlation with the post-cleaning levels indicated above.

Ideally, cleaning tests for in-use verification of medical device reprocessing should be

a) rapid,

b) easy to perform,

c) sensitive (i.e., meet realistic benchmarks),

d) accurate,

e) repeatable,

f) free of interfering substances, and

g) robust (i.e., do not require exacting conditions or time constraints that cannot be achieved in routine reprocessing areas).

Manufacturers should provide users with cleaning verification tests that enable them to quickly test medical devices directly after cleaning and in a way that will not damage the device or require recleaning. It is important to note that eluting samples from used medical devices using an SDS solution requires that the device be recleaned after testing. Consequently, although this sampling method is useful for research purposes because it facilitates sample collection, it has little value for in-use testing because the medical device would need to be recleaned to remove any residual SDS. Moreover, easy-to-perform tests are needed that will verify the functionality of automated washers. Such tests should not lead to the introduction of interfering or extraneous materials that could remain on medical devices post-testing.

For verification of routine cleaning processes, users should incorporate test methods that verify the functionality of the automated washer (if used) and the cleanliness of specific devices after manual or automated cleaning is completed. These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks, once these benchmarks have been defined.

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
Expose cleaned medical device to a 2% hydrogen peroxide solution. If the solution bubbles, then there is residual material on the device that contains catalase. Because blood or other cellular components are the most likely source, the presence of bubbles indicates that cleaning was inadequate. (AAMI TIR12)	Catalase containing material (e.g., eukaryotic cells and some bacterial cells)	Not indicated	Instruments must be further cleaned to remove hydrogen peroxide residue.	~ 1 to 5 min

NOTE—More comprehensive lists of test soils and test methods are provided in 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
Blood test soil pre-applied to thin metal coupon in reusable holder. Provides feedback and permanent record. Lumen version available.	Water-insoluble protein with physical properties similar to blood fibrin; detected as visible red	Not indicated	Valuable as a quality assurance indicator of functionality of washer-disinfector but not for cleaning verification of specific medical devices in the washer.	~ 1 min

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

NOTES

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) on the basis of 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, 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 face masks, 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 could 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 might 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 might 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. Such 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 on the basis of the device manufacturer's written 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 might 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 might inactivate viruses, whereas a higher concentration, higher temperature, and/or longer exposure time might 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 (2010a), Favero & Bond (2001), Rutala and Weber (2001), Rutala and Weber (2010), and the recommendations of CDC (http://www.cdc.gov) 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 before 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 might 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).

Table E.1—Levels of disinfection according to type of microorganism[1)]

Levels	Bacteria			Fungi[2)]	Viruses	
	Vegetative	Mycobacteria	Spores		Lipid (Medium)	Nonlipid (Small)
High	+[3)]	+	+[4)]	+	+	+
Intermediate	+	+	±[5)]	+	+	±[6)]
Low	+	–	–	±[7)]	+	–

NOTE 1—Adapted from CDC (2003a).
NOTE 2—Includes asexual spores but not necessarily chlamydospores or sexual spores.
NOTE 3—Plus sign (+) indicates that a killing effect can be expected when the normal use-concentrations of chemical disinfectants or pasteurization are properly employed; a negative sign (–) indicates little or no killing effect.
NOTE 4—Only with extended exposure times are high-level disinfectant chemicals capable of killing high levels of bacterial spores in laboratory tests; they are, however, capable of sporicidal activity.
NOTE 5—Certain intermediate-level disinfectants (e.g., hypochlorites) can be expected to exhibit some sporicidal action; others (e.g., alcohols, phenolics) have no demonstrated sporicidal activity.
NOTE 6—Some intermediate-level disinfectants might have limited virucidal activity.
NOTE 7—Some low-level disinfectants might have limited fungicidal activity.

General-purpose disinfectants that are intended to process noncritical medical devices and medical equipment surfaces or to preclean or decontaminate critical or semicritical medical devices before terminal sterilization or high-level disinfection are Class 1 medical devices and are exempt from FDA's 510(k) premarket notification requirements. These general-purpose disinfectants are regulated by EPA under FIFRA. The EPA-required labeling for a disinfectant includes the product name, the EPA product registration and establishment numbers, the EPA-approved biocidal claims (e.g., "fungicidal," "bactericidal"), an ingredient statement identifying the active ingredient in the formulation, directions for use, the name and address of the manufacturer or distributor, and safety and precautionary information.

The safety precautions provided in the labeling address such matters as the need for eye protection or gloves when the user is handling the solution. A warning section might state that the solution can cause eye irritation, and it might contain first-aid recommendations. A section on materials compatibility could identify materials or devices with which the solution is incompatible.

The directions for use indicate the use pattern and reuse life of the disinfectant. For example, the label could state that the use-life is 28 days after activation and that the solution is reusable for 28 days. The label should also describe how the use-life can be monitored by determining the concentration of the active ingredient using an appropriate solution test strip.

E.5 Criteria for selecting a chemical disinfectant

As noted in E.2, the choice of disinfecting method should be based on the device manufacturer's written reprocessing instructions, 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.

The product label should be examined for information on the use pattern, reuse life, and storage life of the product. It is important to distinguish between the reuse life of a disinfectant and its use pattern. The reuse life of a disinfectant is the period of time after required activation or dilution of the product or, for ready-to-use products, the day the bottle is opened, for which the disinfectant solution can be used, provided that the concentration of active ingredients remains above the MRC or MEC. The reuse life can be 1 day, 14 days, 28 days, or whatever period is indicated on the label. The actual reuse life could be shorter than stated on the label because dilution, the presence of organic material, or residual detergent could alter the effectiveness of the solution as it is being used (see E.7). For this reason, a disinfectant solution should be monitored with an appropriate solution test strip every time it is used throughout the reuse period. If the test strip shows that the active ingredient is below the MRC or MEC, the solution should be discarded regardless of the number of days it has been in use.

The use pattern refers to how many times the solution can be used; it might be used one time only, or it might be reused for the period of its reuse life. The use pattern also can be expressed in terms of the number of disinfection cycles. The storage life, which is determined by the expiration date and which could be a year or more if the product is stored according to the manufacturer's written instructions, is the time period after which the unused, unopened product is no longer deemed effective.

Both the manufacturer of the disinfectant and the manufacturer of the device to be decontaminated should provide information on materials compatibility. The data should support the safety of a solution with respect to the materials from which a particular device is constructed (e.g., metal, alloys, plated metals, plastics, and combinations thereof). The information should state whether materials compatibility is affected by exposure time, exposure temperature, or concentration. Certain chemicals, especially when dissolved in water, are capable of corroding metals; this is particularly true of strong oxidizing agents, such as products that contain chlorine. Certain metals in contact with one another tend to corrode more rapidly than each metal alone. Certain plastics can become brittle if exposed to particular chemical agents. Some items requiring decontamination are very expensive (e.g., endoscopes), so the user should contact the manufacturer of the device to determine if the materials in the device have been tested and found to be compatible with the disinfectant product.

E.6 Quality control in chemical disinfection

The user should be aware of factors that can alter the effectiveness of a chemical disinfectant:

a) **Use pattern** Only those disinfectants labeled for reuse should be reused. A reuse claim on the product label indicates that the manufacturer has documented that, after a simulated reusing of the disinfectant for the period of time specified in the manufacturer's study, the disinfectant was effective in killing the microorganism types shown on the label. Use-pattern is event-related, not time-related.

b) **Reuse life** The reuse life stated on the label must not be exceeded. Reuse life is event-related as well as time-related. The reuse life could be shorter than what is stated on the label because of events that alter the concentration of the liquid chemical germicide.

c) **Bioburden** The process has been tested against a known number of microorganisms, and its success depends on the cleanliness of the items to be processed.

d) **Water and extraneous materials** Organic matter in the form of serum, blood, pus, or fecal material can protect microorganisms and might consume or inactivate the active chemical agent in the disinfectant. Soaps, detergents, cork, cotton, lint, cotton wool, cellulose sponges, and the minerals found in hard water can also interfere with the effectiveness of the disinfectant. The manufacturer of the disinfectant should be consulted for information on the appropriate water, soaps, and detergents to be used in conjunction with the disinfectant.

   NOTE—The disinfectant manufacturer might not have included organic matter or extraneous materials in challenge tests of antimicrobial efficacy. Even if simulated soil was used to challenge the disinfectant (see AAMI TIR12 and AAMI TIR30), the amount of organic or foreign material used in the testing might not be comparable to that encountered in actual use conditions.

e) **Dilution and MEC/MRC monitoring** The disinfectant is diluted by water remaining on surfaces and in the lumens of devices immersed in the disinfectant. Dilution can be very significant in the long-term use and reuse of a chemical disinfectant and can potentially reduce the concentration of the chemical agent to a level too low to be effective in killing a sufficient number of certain microorganisms in the recommended exposure time. To avoid dilution of the disinfectant, excess moisture should be removed after cleaning. Disinfectant solutions must not be used at concentrations below the MEC or MRC stated on the label. An MEC or MRC statement is required by FDA. As part of a health care facility's quality control program, LCS/HLD solutions such as glutaraldehyde should be monitored upon activation and before each use in order to detect unexpected dilution of the solution.

f) **Temperature** The antimicrobial claims stated on the product label are determined according to exposure time and temperature. For example, the label might state: "To kill *M. tuberculosis*, immerse the device for 1 hour at 25°C (77°F)." This label claim will have been fully documented. If the temperature of the solution is at any time lower than the temperature indicated on the product label, then complete disinfection might not be achieved during the prescribed time period. On the other hand, the temperature should not be high enough for the active ingredients to evaporate appreciably. A thermometer should be used to monitor the solution temperature.

g) **Evaporation and light** Evaporation can occur from a solution in an uncovered container. If the chemical agent is more volatile than the diluent (a gas dissolved in water is more volatile than water), then loss of the agent by evaporation can be very important. Chlorine products are especially susceptible to evaporation effects. Exposure to light can also affect chlorine products and disinfectants.

h) **pH** Disinfectants can be formulated over a range of pH values, depending on the chemical agent used. Some agents are more effective in killing microorganisms under alkaline conditions (a pH higher than 7), whereas others work best under acidic conditions (a pH lower than 7). The introduction of detergents to the disinfectant solution, which can occur if the device is inadequately rinsed after cleaning, can alter the pH of the solution and reduce its effectiveness.

i) **Device characteristics** A disinfectant solution is only effective if it can contact all surfaces of the item to be disinfected. The FDA recommends that medical device manufacturers perform testing that assesses the compatibility of the device with cleaning and defoaming agents and materials, including in-use testing of devices with complex design configurations that could impede penetration by cleaning and disinfectant agents.

j) **Rinsing** Inadequate quality of the rinse water used could result in recontamination of the medical device. If the medical device is required to be sterile and undergoes liquid chemical sterilization, then it should be rinsed with sterile water (0.2µm filtered water is acceptable, provided that the filtration systems are adequately maintained). If high-level disinfection is used, the device can be rinsed with potable tap water, provided that the final drying step includes flushing all channels with 70% alcohol followed by forced-air drying. The alcohol will help kill any microorganisms introduced by the tap water rinse and will facilitate the drying with forced air.

E.7 Safety considerations in chemical disinfection

The user should consult the MSDS supplied by the disinfectant manufacturer and observe the recommended safety precautions. In general, the following factors should be considered:

a) adequate ventilation and, if necessary, a vented hood in the disinfection area to evacuate the chemical vapors from glutaraldehyde and other products;

b) the use of covered containers for the disinfectant solution, when appropriate;

c) appropriate procedures and PPE for the user, such as gloves, eye protection, surgical face masks, and liquid-resistant gowns or aprons, as required by OSHA (29 CFR 1910.1030); and

d) adequate rinsing of devices with sterile distilled water after disinfection.

OSHA has established occupational exposure limits for several agents used in chemical sterilants and disinfectants. Employers are required by law to ensure compliance with these limits by implementing engineering controls, defining procedures for safe employee work practices, establishing medical surveillance programs, employing methods for monitoring for occupational exposure, providing respiratory protection, and taking other measures to the extent specified by OSHA to provide a safe work environment. In addition, product manufacturers might be subject to certain labeling requirements.

Limits established by OSHA for airborne contaminants, including some LCSs/HLDs and gaseous sterilant chemicals, are set forth in 29 CFR 1910.1000. Separate standards limiting occupational exposure to EO and formaldehyde are set forth in 29 CFR 1910.1047 and 29 CFR 1910.1048, respectively. In 1989, OSHA adopted a final rule for air contaminants in which permissible exposure limits (PELs) for hundreds of chemicals were revised or added to the Air Contaminants Standard in 29 CFR 1910.1000 (OSHA 1989). These limits were based largely on the recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH). In 1992, the 11th Circuit Court of Appeals ruled that OSHA did not sufficiently demonstrate that the new PELs were necessary or feasible. As a result of the Court's decision to vacate the new limits, OSHA was forced to return to the original limits published in 1971. However, OSHA can invoke the General Duty Clause of the Occupational Safety and Health Act of 1970 to regulate employee exposure to hazardous chemicals for which OSHA-established limits do not exist. For example, before 1989, the Air Contaminants Standard did not include exposure levels for glutaraldehyde, and there are no current OSHA-established exposure limits for glutaraldehyde. However, OSHA has invoked the General Duty Clause to regulate employee exposure and has recommended that exposures be controlled to the ACGIH-recommended TLVs for glutaraldehyde (Table E.2). Also, states with federally approved state OSHA programs may independently decide to enforce the PELs originally promulgated in the 1989 rule for air contaminants.

Limits on occupational exposure to chemical agents are commonly defined in terms of the maximum amount of chemical to which an employee can be exposed over a specified period of time. For example, OSHA mandates PELs calculated as an 8-hour time-weighted average (TWA) exposure. For some chemicals, a "short-term exposure limit" (STEL), which is based on a 15 minute exposure, has been established. For certain chemicals, including EO and formaldehyde, OSHA has established an "action level" (AL), which is the 8 hour TWA exposure level above which employers must initiate certain compliance activities, such as periodic employee exposure monitoring and medical surveillance. "Excursion limit" (EL) is a term adopted by OSHA specifically for defining a short-term exposure limit for EO. Like a STEL, an EL is the maximum 15 minute exposure to which a worker may be subjected. ACGIH, a private professional organization, recommends "threshold limit values" (TLVs), defined in terms of 8 hour TWAs, 15-minute STELs, and/or ceiling limits, for a large number of chemical substances and physical agents.

Table E.2 lists chemical agents found in LCSs/HLDs and gaseous chemical sterilants and the exposure limits currently mandated by OSHA and recommended by ACGIH. Additional information on OSHA requirements can be found on the OSHA Internet page at http://www.osha.gov. Additional information on ACGIH recommendations can be found in ACGIH (2010).

Table E.2—Occupational exposure limits for some chemical sterilants and disinfectants

Chemical Agent	OSHA PEL	ACGIH TLV
Acetic acid	10 ppm TWA 25 mg/m^3 TWA	10 ppm TWA 15 ppm STEL
Alcohols	Various[1)]	Various[1)]
Formaldehyde	0.75 ppm TWA 2 ppm STEL 0.5 ppm AL	0.3 ppm ceiling
Glutaraldehyde	None[2)]	0.05 ppm ceiling
Hydrogen peroxide	1 ppm TWA 1.4 mg/m^3 TWA	1 ppm TWA
Ortho-phthalaldehyde	None	None
Peracetic acid	—[3)]	—[3)]

NOTE 1—Various types of alcohol are used in sterilant formulations, and the occupational exposure limits vary. Refer to the product label for the active ingredients, and consult the latest ACGIH recommendations and OSHA regulations.
NOTE 2—No exposure limits have been established by OSHA. However, OSHA can invoke the General Duty Clause of the Occupational Safety and Health Act of 1970 to regulate exposure to glutaraldehyde and has recommended that the ACGIH TLVs be followed.
NOTE 3—Peracetic acid exists in equilibrium with hydrogen peroxide and acetic acid, so occupational exposure limits for both hydrogen peroxide and acetic acid apply.

Annex F
(Informative)

Thermal disinfection

F.1 Introduction

This Annex describes factors to consider when applying thermal (hot water) disinfection processes to the decontamination of reusable medical devices. Thermal disinfection selectively destroys microorganisms. The number and types of microorganisms killed on clean items—and, thus, the level of decontamination achieved—depend on exposure time and exposure temperature.

F.2 Microbial destruction by heat

Microbial resistance to thermal death depends on the state of the microorganism; vegetative bacteria are much easier to kill by heat than spores. The inherent resistance of different species of microorganisms also varies; for example, certain species have a waxy coating that provides brief protection against heat. In general, bacterial spores and certain viruses are the most resistant to heat, followed by most fungi and some viruses; vegetative bacteria are the least resistant.

F.3 Items suitable for thermal sanitization/disinfection

Thermal sanitization and disinfection equipment employ hot water temperatures of 60°C to 95°C (140°F to 203°F). (By contrast, sterilizers employing saturated steam typically operate with temperatures of 121°C to 135°C [250°F to 275°F].) Thermal sanitization equipment generally operates at somewhat lower temperatures or for shorter exposure times than disinfection equipment, but there is no agreement on precisely when sanitization stops and disinfection begins.

Instruments, devices, and equipment that are heat- and moisture-stable may be decontaminated by thermal sanitization or disinfection processes. The choice of method depends on factors such as the level of risk to personnel and patients, the ease with which an item can be cleaned and inspected, and the relative cost-effectiveness of using washer-sanitizers or washer-disinfectors versus washer-sterilizers or steam sterilizers.

F.4 Manufacturers' instructions

The user should carefully follow the written operating instructions supplied by the thermal disinfection equipment manufacturer as well as any instructions supplied by the manufacturer of the device to be decontaminated. If the equipment provides a washing or cleaning process, the following factors should also be taken into account: the type of soil, the quality of the water, the force and direction of the water, the choice of cleaning agent, the exposure time, and the water temperature.

F.5 Quality control in thermal disinfection

Time and temperature should be monitored. Some types of equipment provide timers and temperature gauges for this purpose. Temperature-sensitive indicators are also available to monitor the internal temperature achieved during processing.

F.6 Safety considerations in thermal disinfection

Personnel should be careful to avoid burns when removing hot items from thermal sanitization or disinfection equipment. Wet items can drip, which can lead to slippery floors or work surfaces.

NOTES

Annex G
(Informative)

Devices returned to the manufacturer

G.1 Introduction

A medical device that has been used in patient care is contaminated with potentially infectious microorganisms and, therefore, could pose hazards to health care and other personnel if the device is not handled and decontaminated properly. The main text of this recommended practice addresses the decontamination of devices intended for reuse in patient care within a health care facility. However, additional guidance is needed on the safe handling and decontamination of devices that are returned to the manufacturer for servicing or for evaluation of suspected malfunctions. Such devices can pose health hazards to postal and shipping personnel and to the manufacturer's employees. Special considerations also apply to devices returned to third parties (e.g., test laboratories) and to samples, loaners, and investigational devices that might be returned to the manufacturer or transferred from hospital to hospital. This Annex is intended to provide assistance to device manufacturers, health care personnel, and third parties in the development of appropriate handling and decontamination procedures.

G.2 Overview

After use in patient care, a medical device might be returned to the manufacturer for servicing or for the evaluation of a suspected malfunction or failure. Ideally, such devices should be decontaminated by the user before they are shipped. In some instances, however, a decontamination procedure could obscure the cause of the malfunction or failure and inhibit the manufacturer's follow-up evaluation. In other instances, the device might not be capable of being appropriately decontaminated at the user facility, or health care personnel could simply neglect to decontaminate the device properly. Manufacturers should establish procedures for the protection of their personnel and should provide appropriate written instructions to users for the handling, decontamination, and shipment of devices that require servicing or failure investigation. For their part, health care personnel should develop their own procedures for the handling and decontamination of such devices in accordance with the manufacturer's written instructions. Both manufacturers and health care facilities must comply with OSHA regulations limiting occupational exposure of employees to blood-borne pathogens (29 CFR 1910.1030).

NOTE—The guidelines provided here are written in the context of devices returned to manufacturers for servicing, repair, or failure investigation. However, the same considerations apply to devices sent to testing laboratories or other third-party organizations.

G.3 Manufacturer's instructions to the user

Manufacturers that require their devices to be returned from the field to facilitate servicing or to investigate a device failure are obliged to provide the user with specific, written instructions for the safe handling and return shipment of each device. These instructions should include at least the following information (additional guidelines on these topics are provided in subsequent sections of this Annex):

a) who to contact at the company for assistance;

b) the recommended method of decontamination, with disassembly instructions if required, and any limitations associated with it;

c) any actions that could result in the inadvertent destruction of evidence pertaining to the cause of the suspected failure or malfunction;

d) directions for the documentation that should accompany the device; and

e) recommended instructions for packaging, labeling, and shipping, including instructions to verify compliance with local regulations.

The manufacturer should ensure that adequate resources are in place to assist users in complying with the manufacturer's requirements. That is, the manufacturer should have adequate personnel, with identified responsibilities, to handle inquiries about devices to be returned and to supply information. The manufacturer can choose to provide return product kits, which include written instructions approved by the manufacturer, data forms containing all information necessary for processing the returned device, appropriate shipping containers to protect

the device during transport, and all hazard labels. The manufacturer is responsible for verifying that the recommended decontamination procedures are effective for the device.

G.4 User responsibilities

G.4.1 General

Users are responsible for verifying that appropriate written instructions are supplied with the device; if no instructions or incomplete instructions are provided, the user should attempt to contact the manufacturer for return authorization and further instructions. The user is also responsible for processing the device according to the manufacturer's recommendations. All documentation requested by the manufacturer should be accurately completed. In addition, the user should identify for the manufacturer the nature of the device malfunction or failure and should provide information on whom to contact at the user facility. If the user is aware of additional information that might assist the manufacturer in servicing or evaluating the returned device or that could suggest the need for special handling of the device at the manufacturer's facility, this information should be provided; for example, the user should notify the manufacturer if the device has been exposed to a known infectious agent. All documentation pertaining to the returned device should be packaged separately from the device but provided in or on the same shipping container.

G.4.2 Decontamination at the health care facility

Appropriate handling and decontamination of a medical device will depend on whether the device is being returned to the manufacturer for repair, service, or failure investigation.

The user should contact the device manufacturer for handling and decontamination methods appropriate for the device in question.

The user should document how the device was used in patient care, how it was decontaminated, the date of processing, and a means of identifying the person who decontaminated the device. (If the device is being returned to the manufacturer for failure investigation, it might be appropriate to photograph or draw the device before decontaminating it.) This information, along with an explanation of the reason for returning the device to the manufacturer and an accurate description of any defects, should accompany the device when it is shipped. This documentation should be positioned to protect it from contamination and to allow easy retrieval by the manufacturer.

G.4.3 Packaging, labeling, and shipment to the manufacturer's facility

G.4.3.1 General

Whether or not it has been subjected to a decontamination process, a contaminated device to be returned to the manufacturer should be placed in a securely sealed and leakproof primary container or as specified by the device manufacturer. The package must be clearly identified as contaminated material and must be packaged, labeled, and shipped in accordance with the manufacturer's written instructions, with the requirements of the carrier (U.S. Postal Service or private carrier), and with the applicable U.S. Department of Transportation (DOT) regulations (49 CFR 170–178). In most cases, it is advisable to pack the medical device while it is dry. However, there might be special circumstances in which the device might need to be kept moist; if so, the user should request information from the manufacturer on how to ship the device in the moist state.

G.4.3.2 Postal regulations

Postal regulations require that sharps and other medical devices be sent using First-Class or Priority mail in packaging that meets the specifications described later in this section; that all packaging used for the mailing of sharps be "type-tested" and certified by an independent organization; and that the package bear a U.S. Postal Service authorization number on a label that cannot be removed intact. Appropriate documentation should be affixed to the outer shipping container; this documentation should include (in case of package damage or leakage), a 24 hour telephone number at the destination facility. Packages also should be labeled with a complete return address and the proper shipping name of the contents. Section 124.38 of the *Domestic Mail Manual* contains the complete requirements for the shipping of sharps and other medical devices.

If the device to be returned is a sharp, then the primary container should be puncture-resistant and placed into a watertight secondary containment system. This secondary containment system may consist of more than one component; however, if one of the components is a plastic bag, the bag should be at least 3 mils thick and reinforced with a fiberboard sleeve. The primary container and/or secondary containment system should be packed in an outer shipping container designed to prevent breakage during ordinary processing and comprised of

at least 200 pound-grade corrugated material or a material of equivalent strength. More than one primary container may be sent in a parcel; however, the net contents of liquid in each primary container should not exceed 50 milliliters, and enough absorbent material should be present to absorb three times the total volume of liquid in the secondary containment system or outer shipping container.

Coolant material, if used, should be packaged in such a way that if it melts or condenses, the liquid produced will not escape from the outer shipping container. If ice or dry ice is used, shock-absorbent material should be placed so as to immobilize the inner container as the ice or dry ice melts or sublimates. Packages containing dry ice should be packed in containers that permit the venting of carbon dioxide gas and should be marked DRY ICE and labeled with the net weight of the dry ice.

G.4.3.3 DOT regulations

The pertinent DOT regulations are Hazardous Materials Regulation 126 (HM126) and Hazardous Materials Regulation 181 (HM181). These regulations are codified in Title 49, Parts 170 through 178, of the *Code of Federal Regulations.* Among other things, the DOT requires formal training of all persons who are in any way involved in the shipping process, including anyone who prepares hazardous items for shipment or prepares shipping documents. Several levels of training are specified in the law, ranging from "general awareness" to "function-specific." The required training must include safety issues and must be documented. If training records are not complete, the shipper is subject to significant penalties.

The shipper is responsible for the correct packaging and labeling of items entering interstate commerce. If the manufacturer provides inadequate or incorrect shipping instructions, the law still holds the shipper responsible. Thus, the shipper must take responsibility for making certain that the documents and packaging are correct. The shipper may rely on the manufacturer's information as a starting point, but should take some documented action to verify that the information is correct. The law places personal responsibility and liability on persons who improperly ship hazardous materials and/or on the individuals responsible for supervising these persons. Depending on the severity of the violation and the pattern of violations, personal fines and/or imprisonment can be assigned to anyone from the shipping clerk to the chief executive officer.

G.5 Receiving at the manufacturer's facility

When a problem occurs in the clinical use of a device, the manufacturer might request that it be returned for investigation and resolution of the problem. Decontamination processes used in the health care facility might not be compatible with the device; for example, the decontamination process could melt the device, the chemical agents could react with materials used to construct the device, or the decontamination process might not be capable of rendering the device safe. For this and other reasons, a device being returned to the manufacturer from the clinical end user could be contaminated with disease-producing microorganisms. The OSHA regulations limiting occupational exposure to blood-borne pathogens (29 CFR 1910.1030) require that all employees who might come in contact with the contaminated device must apply standard/transmission-based (enhanced) precautions, including the wearing of PPE. In addition, the manufacturer is responsible for ensuring that all employees who will be handling the contaminated device (e.g., receivers, unpackers, laboratory personnel performing testing) receive the required educational preparation as prescribed by OSHA; this training must be documented. (It should be noted that not all disease-producing microorganisms are transmitted by blood, and varying levels of precautions could be needed, depending on the intended use of the device.)

Policies and procedures for the care and handling of contaminated devices should be specific (i.e., compliance must be observable or measurable), incorporate the requirements established by OSHA, and address at least the following functions:

a) control of the receiving/unpacking area;

b) receipt of the contaminated device;

c) disposition upon receipt;

d) examination of accompanying paperwork;

e) PPE;

f) disposal of all contaminated materials, including the primary packaging, the secondary packaging, and, after it has been examined, the device;

g) environmental controls (barrier walls, room with negative air flow, environmental chamber);

h) containment of the device after it is unpacked;

i) method of transport through the process;

j) area decontamination procedures;

k) exposure response; and

l) record-keeping.

G.6 Cleaning, decontamination, and sterilization methods at the manufacturer's facility

If possible, the device should be decontaminated according to the manufacturer's established policies and procedures. If decontaminated, the device should then be placed in a clean container that is labeled to indicate that the device has been decontaminated.

The method of decontamination should render the device safe to handle regardless of the type of biological tissue that has come in contact with the device.

NOTE—In some cases, decontamination can interfere with failure investigation of a device. If so, the device must remain in a biohazard bag and personnel handling the device must be safeguarded by appropriate PPE and engineering controls.

Other factors to take into account, some of which should be considered during product design, are as follows:

a) the configuration of the device (the preferred disinfectant might not be able to penetrate all areas of the device that require decontamination);

b) the materials from which the device is fabricated (the materials in the device might be heat-labile or susceptible to damage by particular chemical disinfectants);

c) the cleanliness of the device (disinfectants and sterilants are only effective if the surfaces to be decontaminated are clean);

d) the biocompatibility or safety of the disinfectant or sterilant and whether it can be completely removed before the next use (if applicable); whether the disinfectant or sterilant is toxic is also important from the standpoint of health risks to employees who have to inspect or test the returned device.

By considering these factors in the design phase, the manufacturer can address and pre-establish handling and decontamination instructions and verify them before production and release. Such care will protect both the user and the manufacturer's employees.

Additional information on decontamination is provided in the main text of the recommended practice. The properties of chemical disinfectants and sterilants are discussed in some detail in Annex E and in ANSI/AAMI ST58.

G.7 Personal protective equipment at the manufacturer's facility

Personnel should wear appropriate PPE, commensurate with the degree of risk, when handling contaminated devices. Such attire might include gloves, gowns, laboratory coats, head and foot coverings, face shields or surgical face masks, eye protection, and respiratory protection. All reusable attire should be cleaned or sanitized regularly.

Gloves should be worn when there is a potential for direct skin contact with a medical device. Disposable decontamination gloves should be replaced as soon as their ability to function as a barrier is compromised; they should not be washed or disinfected for reuse. Heavy-duty, reusable decontamination gloves may be disinfected for reuse if the integrity of the gloves is not compromised; however, they should be discarded if they are cracked, peeling, discolored, torn, punctured, or exhibit other signs of deterioration.

Gowns, lab coats, aprons, or similar clothing should be changed whenever soiled and in accordance with the manufacturer's established procedures. Such clothing should not be worn outside the immediate work area. Liquid-resistant clothing should be worn if there is potential for splashing or splattering of blood or other potentially infectious materials. Protective clothing should be liquid-proof if there is a possibility that attire might become soaked with blood or other potentially infectious material. Liquid-proof shoe covers should be worn if there is potential for shoes becoming contaminated and/or soaked with blood or other body fluids.

G.8 Work practices for infection prevention and control at the manufacturer's facility

Handwashing facilities should be readily accessible to employees so that when their hands have been in contact with potentially infectious medical material, they can wash their hands as soon as possible after they remove gloves or other PPE. Antiseptic towels or alcohol-based, waterless, hand-hygiene agents can be used as an interim precaution until the employee can reach a handwashing area.

Once removed, contaminated protective attire and equipment should be placed in a clearly marked container or designated area for storage, washing, decontamination, or disposal. To determine when PPE should be used, the employer should evaluate the circumstances of potential exposure and significant employee risk.

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses should be prohibited in work areas where there is a risk of occupational exposure to chemical or biological materials. Food and drink should not be stored in places where infectious materials are located. Employees wearing PPE should not enter designated lunchrooms or break areas.

All procedures involving the handling of contaminated devices should be performed so as to minimize splashing, spraying, or aerosolization of infectious materials.

Work areas should be posted as restricted-access (including, but not limited to, access only to authorized personnel) because of the presence of infectious materials. If a work area is enclosed, the doors should be kept closed when personnel are working with potentially contaminated medical devices. Personnel working in these restricted occupational exposure areas must have received formal training, as specified by OSHA (29 CFR 1910.1030), and documentation of this training must be kept on file.

Whenever there is a potential for contamination from a medical device, a warning sign incorporating the universal biohazard symbol should be posted on all access doors.

All activities involving potentially infectious aerosols (e.g., packaging, unpacking, and examination of contaminated devices) should be conducted in biological safety cabinets or physical containment devices. Such work should not be conducted on an open bench. Devices should be transferred to containment areas in leakproof, sealed containers.

All materials to be removed from a biological safety cabinet or other containment area should be surface sprayed or wiped with an appropriate disinfectant before removal.

A clearly written company policy should be established to specify the procedures to be followed for spills, accidents, and immediate cleanup of potentially infectious materials.

G.9 Housekeeping and waste disposal

During housekeeping and waste disposal procedures, personnel should wear appropriate PPE such as gloves, aprons, laboratory coats, and head and foot coverings. Face shields or surgical face masks, eye protection, and/or respiratory protection should be worn if there is potential for aerosol generation or splashing during cleanup (e.g., scraping).

All work sites should be maintained in a clean and sanitary condition. All equipment and work surfaces associated with the handling of contaminated devices should be decontaminated by cleaning and the application of an appropriate disinfectant after completion of procedures or as soon as feasible. Immediate cleaning is essential, especially when surfaces are visibly soiled, after any spill of blood or other potentially infectious material, and at the end of the work shift.

Disinfecting solutions should be used in accordance with the solution manufacturer's written instructions for preparation, contact time, length of effectiveness, expiration time, and disposal. If toxic vapors might be present, containers (e.g., pans) used for soaking equipment in disinfecting solutions should be placed in a system that will remove vapors, such as a ventilated fume hood. Solutions of ethanol, isopropanol, sodium hypochlorite, or hydrogen peroxide can be poured down the sanitary sewer. Solutions of glutaraldehyde, formaldehyde, or iodophors should be properly discarded in accordance with the manufacturer's written instructions and local regulations. Care should be taken to prevent fires when flammable disinfecting solutions are used (e.g., ethanol, isopropanol, 8% formaldehyde/70% ethanol or isopropanol).

Equipment and tools that can become contaminated from use during examination or repair of returned medical devices should be routinely cleaned and decontaminated after use and before servicing other medical devices. Small hand tools, such as forceps, hemostats, brushes, dustpans, and shears, should be immersed in a

disinfecting solution, or they should be cleaned, wrapped, and sterilized. Appropriate disinfecting solutions include, but are not limited to: 2% glutaraldehyde, 8% formaldehyde plus 70% ethanol or isopropanol, 6% hydrogen peroxide, 70% to 80% ethanol or isopropanol, and iodophor disinfectants. (Iodophor formulations that are EPA-registered as disinfectants should be used, not iodophors formulated as skin antiseptics; the manufacturer's written instructions for dilution and use should be followed.) Household bleach containing sodium hypochlorite may also be used. Bleach will not have label directions for this application. However, it can be effective, it is readily available, and it is inexpensive. Commercially available solutions are generally formulated at a concentration of 5.25% v/v. A 1:10 dilution of the commercial product, freshly prepared with tap water for each application, should be used. The undiluted bleach should be stored in an opaque container because light degrades its potency.

Large equipment that cannot be sterilized or soaked in disinfectant should be sprayed or wiped down on all exposed, potentially exposed, and/or contaminated surfaces with an appropriate disinfectant solution.

Bins, pails, cans, and other receptacles intended for reuse should be inspected, cleaned, and decontaminated on a regularly scheduled basis (at least daily); and they should be cleaned and decontaminated immediately or as soon as possible upon visible contamination.

Any materials to be decontaminated at a site away from the work area should be placed in durable, leakproof containers, and the containers should be closed before they are removed from the work area. Reusable sharps that are contaminated with blood or other potentially infectious materials should not be stored or processed in a manner that requires employees to reach into the container by hand to retrieve the sharp.

Immediately after use, sharps should be placed in closable, puncture-resistant containers that are leakproof on the sides and bottom and that are labeled with an appropriate hazard warning. These containers should be located in the immediate area of use so that they are easily accessible. The containers should be replaced routinely and not allowed to overfill.

Broken, contaminated glassware should not be picked up directly with bare hands. The glassware should be cleaned up by mechanical means using at least a dust pan and brush, tongs, toweling, or forceps. Glass should be disposed of in a container the same as or similar to that used to confine other sharps.

All infectious waste should be disposed of in accordance with OSHA regulations (29 CFR 1910.1030) and other applicable federal, state, and local regulations.

Contaminated laundry should be handled as little as possible, with a minimum of agitation, bagged or contained at the point of use, and labeled as biohazardous or otherwise identified as requiring standard precautions. It should not be sorted or rinsed at the location of use but placed and transported in bags or containers that prevent soak-through or leakage of fluids to the exterior. Personnel who have contact with contaminated laundry should wear appropriate protective attire.

G.10 Device failure investigation

Observations and findings should be recorded orally for later transcription so that documents that could be subsequently handled by other departments will not be contaminated.

The documentation should include at least the following:

a) date received;

b) condition of shipping container(s);

c) shipping label information;

d) information received from the user;

e) visual condition of the device;

f) initial specific, pre-established investigational procedure implemented for the device; and

g) correlation, as appropriate, with MDR information required by FDA.

The manufacturer should have policies and procedures in place for the retention of all documentation regarding the findings and the device. The policies and procedures should comply with FDA regulations promulgated under the Safe Medical Devices Act of 1990.

G.11 Documentation to the user

If the device is to be returned to the user, it should be accompanied by documentation of any decontamination procedures performed by the manufacturer, of the servicing performed (e.g., any parts replaced), and, if applicable, of the failure investigation (e.g., problems identified, suggested measures for preventing such problems in the future).

If the device is not to be returned to the user, the user should be informed of the results of the investigation.

NOTES

Annex H
(Informative)

Occupational exposure to blood-borne pathogens (29 CFR Part 1910.1030)[1]

§1910.1030 Blood-borne pathogens

(a) *Scope and Application.* This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) *Definitions.* For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

Blood means human blood, human blood components, and products made from human blood.

Blood-borne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineering sharps injury protections and needleless systems) that isolate or remove the blood-borne pathogens hazard from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, nonintact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Handwashing Facilities means a facility providing an adequate supply of running potable water, soap, and single use towels or hot air drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-Up.

HBV means hepatitis B virus.

[1] The regulation quoted here is current as of the publication date of this recommended practice. To check for any subsequent changes, refer to the *Code of Federal Regulations,* 29 CFR Part 1910.1030.

HIV means human immunodeficiency virus.

Needleless systems means a device that does not use needles for

(1) the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;

(2) the administration of medication or fluids; or

(3) any other procedure involving the potential for occupational exposure to blood-borne pathogens due to percutaneous injuries from contaminated sharps.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

Other Potentially Infectious Materials means

(1) the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(2) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated Waste means liquid or semiliquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semiliquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV, but not in the volume found in production facilities.

Sharps with engineering sharps injury protections means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection prevention and control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other blood-borne pathogens.

Work Practice Controls means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

(c) *Exposure control*—(1) *Exposure Control Plan.* (i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

(ii) The Exposure Control Plan shall contain at least the following elements:

(A) the exposure determination required by paragraph (c)(2);

(B) the schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping of this standard, and

(C) the procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

(iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).

(iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

(A) reflect changes in technology that eliminate or reduce exposure to blood-borne pathogens; and

(B) Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

(v) An employer who is required to establish an Exposure Control Plan shall solicit input from nonmanagerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control plan.

(vi) The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

(2) *Exposure determination.* (i) Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

(A) a list of all job classifications in which all employees in those job classifications have occupational exposure;

(B) a list of job classifications in which some employees have occupational exposure; and

(C) a list of all tasks and procedures or groups of closely related tasks and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

(ii) This exposure determination shall be made without regard to the use of personal protective equipment.

(d) *Methods of compliance*—(1) *General.* Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

(2) *Engineering and work practice controls.* (i) Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment also shall be used.

(ii) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(iii) Employers shall provide handwashing facilities which are readily accessible to employees.

(iv) When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

(v) Employers shall ensure that employees wash hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

(vi) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

(vii) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

(A) Contaminated needles and other contaminated sharps shall not be recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure.

(B) Such recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

(viii) Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be

(A) puncture resistant;

(B) labeled or color-coded in accordance with this standard;

(C) leakproof on the sides and bottom; and

(D) in accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

(ix) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

(x) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

(xi) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

(xii) Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

(xiii) Specimens of blood or other potentially infectious materials shall be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

(A) The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

(B) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

(C) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

(xiv) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

(A) A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

(B) The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

(3) *Personal protective equipment* (i) Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the protective equipment will be used.

(ii) Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgment, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

(iii) Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the work site or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

(iv) Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

(v) Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

(vi) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

(vii) All personal protective equipment shall be removed prior to leaving the work area.

(viii) When personal protective equipment is removed, it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

(ix) Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and nonintact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

(A) Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

(B) Disposable (single use) gloves shall not be washed or decontaminated for reuse.

(C) Utility gloves may be decontaminated for reuse if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

(D) If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall

(1) periodically reevaluate this policy;

(2) make gloves available to all employees who wish to use them for phlebotomy;

(3) not discourage the use of gloves for phlebotomy; and

(4) require that gloves be used for phlebotomy in the following circumstances:

(i) When the employee has cuts, scratches, or other breaks in his or her skin;

(ii) When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

(iii) When the employee is receiving training in phlebotomy.

(x) Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

(xi) Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

(xii) Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

(4) *Housekeeping.* (i) General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

(ii) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

(A) Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

(B) Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the work shift if they may have become contaminated during the shift.

(C) All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

(D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means such as a brush and dust pan, tongs, or forceps.

(E) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

(iii) Regulated Waste.

(A) Contaminated Sharps Discarding and Containment. (1) Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are

(i) closable;

(ii) puncture resistant;

(iii) leakproof on sides and bottom; and

(iv) labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

(2) During use, containers for contaminated sharps shall be

(i) easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);

(ii) maintained upright throughout use; and

(iii) replaced routinely and not be allowed to overfill.

(3) When moving containers of contaminated sharps from the area of use, the containers shall be

(i) closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;

(ii) placed in a secondary container if leakage is possible. The second container shall be

(A) closable;

(B) constructed to container all contents and prevent leakage during handling, storage, transport, or shipping; and

(C) labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

(4) Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner that would expose employees to the risk of percutaneous injury.

(B) Other Regulated Waste Containment. (1) Regulated waste shall be placed in containers that are:

(i) closable;

(ii) constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping;

(iii) labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

(iv) closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(2) If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be

(i) closable;

(ii) constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping;

(iii) labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

(iv) closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

(iv) Laundry.

(A) Contaminated laundry shall be handled as little as possible with a minimum of agitation. (1) Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

(2) Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

(3) Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers that prevent soak-through and/or leakage of fluids to the exterior.

(B) The employer shall ensure that the employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

(C) When a facility ships contaminated laundry off-site to a second facility that does not utilize Universal Precautions in the handling of laundry, the facility generating the contaminated laundry must place such laundry in bags or containers that are labeled or color-coded in accordance with paragraph (g)(1)(i).

(e) *HIV and HBV Research Laboratories and Production Facilities.*

(1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

(2) Research laboratories and production facilities shall meet the following criteria:

(i) Standard microbiological practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy blood-borne pathogens.

(ii) Special practices.

(A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

(B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

(C) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(D) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(i) of this standard.

(E) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

(F) Laboratory coats, gown, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

(G) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

(H) Before disposal, all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy blood-borne pathogens.

(I) Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and that are checked routinely and maintained or replaced as necessary.

(J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

(K) All spills shall be contained immediately and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

(L) A spill or accident that results in an exposure incident shall be reported immediately to the laboratory director or other responsible person.

(M) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(iii) Containment equipment. (A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for

all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

(B) Biological safety cabinets shall be certified when installed, whenever they are moved, and at least annually.

(3) HIV and HBV research laboratories shall meet the following criteria:

(i) Each laboratory shall contain a facility for handwashing and an eye wash facility that is readily available within the work area.

(ii) An autoclave for decontamination of regulated waste shall be available.

(4) HIV and HBV production facilities shall meet the following criteria:

(i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

(ii) The surfaces of doors, walls, floors, and ceilings in the work area shall be water resistant so that they can be cleaned easily. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

(iii) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

(iv) Access doors to the work area or containment module shall be self-closing.

(v) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

(vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

(5) *Training Requirements.* Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

(f) *Hepatitis B Vaccination and Postexposure Evaluation and Follow-up*—(1) *General.*

(i) The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and postexposure evaluation and follow-up to all employees who have had an exposure incident.

(ii) The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and postexposure evaluation and follow-up, including prophylaxis, are:

(A) made available at no cost to the employee;

(B) made available to the employee at a reasonable time and place;

(C) performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

(D) provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

(iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

(2) *Hepatitis B Vaccination.* (i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B

vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

(ii) The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

(iii) If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

(iv) The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in appendix A.

(v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

(3) *Postexposure Evaluation and Follow-up.* Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

(i) documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

(ii) identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

(A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

(B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

(C) Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(iii) Collection and testing of blood for HBV and HIV serological status:

(A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

(B) If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

(iv) postexposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

(v) counseling; and

(vi) evaluation of reported illnesses.

(4) *Information Provided to the Healthcare Professional.* (i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

(ii) The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

(A) A copy of this regulation;

(B) A description of the exposed employee's duties as they relate to the exposure incident;

(C) Documentation of the route(s) of exposure and circumstances under which exposure occurred;

(D) Results of the source individual's blood testing, if available; and

(E) All medical records relevant to the appropriate treatment of the employee, including vaccination status, that are the employer's responsibility to maintain.

(5) *Healthcare Professional's Written Opinion.* The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

(i) The healthcare professional's written opinion for hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

(ii) The healthcare professional's written opinion for postexposure evaluation and follow-up shall be limited to the following information:

(A) That the employee has been informed of the results of the evaluation; and

(B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials, which require further evaluation or treatment.

(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(6) *Medical Recordkeeping.* Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

(g) *Communication of Hazards to Employees*—(1) *Labels and Signs.* (i) Labels. (A) Warning labels shall be affixed to containers of regulated waste, refrigerators, and freezers containing blood or other potentially infectious materials, and other containers used to store, transport, or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F), and (G).

(B) Labels required by this section shall include the following legend:

BIOHAZARD

(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering or symbols in a contrasting color.

(D) Labels required by this standard shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(E) Red bags or red containers may be substituted for labels.

(F) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

(G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment, or disposal are exempted from the labeling requirement.

(H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

(I) Regulated waste that has been decontaminated need not be labeled or color-coded.

(ii) Signs. (A) The employer shall post signs at the entrance to work areas specified in paragraph (e). HIV and HBV Research Laboratory and Production Facilities, that shall bear the following legend:

[Name of the Infectious Agent]

(Special requirements for entering the area)

(Name, telephone number of the laboratory director or other responsible person)

(B) These signs shall be fluorescent orange-red or predominantly so, with lettering or symbols in a contrasting color.

(2) *Information and Training.* (i) Employers shall ensure that all employees with occupational exposure participate in a training program that must be provided at no cost to the employee and during working hours.

(ii) Training shall be provided as follows:

(A) at the time of initial assignment to tasks where occupational exposure may take place;

(B) within 90 days after the effective date of the standard; and

(C) at least annually thereafter.

(iii) For employees who have received training on blood-borne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of this standard that were not included need be provided.

(iv) Annual training for all employees shall be provided within one year of their previous training.

(v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

(vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

(vii) The training program shall contain at a minimum the following elements:

(A) an accessible copy of the regulatory text of this standard and an explanation of its contents;

(B) a general explanation of the epidemiology and symptoms of blood-borne diseases;

(C) an explanation of the modes of transmission of blood-borne pathogens;

(D) an explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

(E) an explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

(F) an explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

(G) information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

(H) an explanation of the basis for selection of personal protective equipment;

(I) information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

(J) information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

(K) an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

(L) information on the postexposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

(M) an explanation of the signs and labels and/or color-coding required by paragraph (g)(1); and

(N) an opportunity for interactive questions and answers with the person conducting the training session.

(viii) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(ix) Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

(A) The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

(B) The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

(C) The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

(h) *Recordkeeping*—(1) *Medical Records.* (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.20.

(ii) This record shall include

(A) the name and Social Security number of the employee;

(B) a copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

(C) a copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3).

(D) the employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

(E) A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B), (C), and (D).

(iii) Confidentiality. The employer shall ensure that employee medical records required by paragraphs (k)(1) are:

(A) kept confidential; and

(B) are not disclosed or reported without the employee's express written consent to any persons within or outside the workplace except as required by this section or as may be required by law.

(iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

(2) *Training Records.* (i) Training records shall include the following information:

(A) the dates of the training sessions;

(B) the contents or a summary of the training sessions;

(C) the names and qualifications of persons conducting the training; and

(D) the names and job titles of all persons attending the training sessions.

(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

(3) *Availability*. (i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(4) *Transfer of Records.* (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.20(h).

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so within that three month period.

(5) *Sharps Injury Log*. (i) The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

(A) the type and brand of device involved in the incident,

(B) the department or work area where the exposure incident occurred, and

(C) an explanation of how the incident occurred.

(ii) The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

(iii) The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

(i) *Dates*—(1) *Effective Date.* The standard shall become effective on March 6, 1992.

(2) The Exposure Control Plan required by paragraph (c)(2) of this section shall be completed on or before May 5, 1992.

(3) Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.

(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Postexposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992.

Appendix A to Section 1910.1030—Hepatitis B Vaccine Declination (Mandatory)

I understand that due to my occupational exposure to blood or other potentially infectious materials, I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue

to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

NOTES

Annex I
(Informative)

Development of a prepurchase evaluation protocol for rigid sterilization container systems

I.1 Introduction

I.1.1 A variety of reusable rigid sterilization container systems have become commercially available. They are being implemented into processing systems in health care facilities for a number of reasons:

a) reduction of certain types of operating expenses;

b) environmental issues associated with reusable and disposable packaging materials;

c) improvement of sterility assurance and better protection of sterile items afforded by the rigid design of container systems;

d) standardization and organization of surgical instrument sets and equipment;

e) improvement of storage space utilization;

f) reduction of space needed to store wrappers; and/or

g) containment of contaminated instruments.

I.1.2 The decision to evaluate the use of reusable rigid sterilization container systems should be followed by the development of a specific protocol or plan by the health care facility. The answers to the following questions will assist in the development of an evaluation protocol:

a) What are the reasons for considering reusable rigid sterilization container systems? Can these reasons be quantified?

b) How much time will be necessary to evaluate each container system?

c) Who will be involved in the evaluation process? Infection prevention and control, operating room, central processing, other user departments, purchasing? (Generally, it will be appropriate to include all departments that would be handling or using the product.)

d) What are the comparative costs of all the packaging methods under consideration (disposable wrapping material, reusable wrapping material, container systems)? How does the current cost-benefit ratio compare with the projected cost-benefit ratio of a new system?

e) If one type of container system currently is in use, what will be the impact of a second type of container system (i.e., one of different manufacture)?

f) What key points will be critical in the evaluation?

g) How many of each type of container system will be needed for the evaluation?

h) What information will be needed from whom to prepare the assessment?

The evaluation protocol should include specific questionnaires concerning product needs or problems in each use and handling area. Additionally, a detailed plan regarding the actual evaluation process in each area of use or handling should be included.

The following text presents a number of questions and statements that personnel might use as guidelines when developing a health care facility's prepurchase evaluation protocol for reusable rigid sterilization container systems.

I.2 General considerations

a) Has the container system been FDA-cleared for use in a sterilization process?

b) Have the scientific data to support label claims (e.g., specific sterilization methods and cycle parameters) been provided by the container system manufacturer?

c) Was the testing performed with biological spore strips or inoculated devices?

d) Does the documentation address sufficiently all performance elements in sterilization (via steam or EO, including aeration), drying, and sterility maintenance?

e) Was the testing representative of the types of items that will be sterilized routinely?

f) Is the container system suitable for use in the steam sterilizers available in the health care facility (gravity-displacement, prevacuum, steam-flush pressure-pulse)?

g) Have complete written instructions been provided? Are they illustrated and easy to follow?

h) Will knowledgeable and qualified assistance (technical support) be readily available during the evaluation process; for employee education; during implementation; and for follow-up, troubleshooting, and problem solving? What is the scope of service after the sale?

i) Are container systems available in appropriate sizes for the items to be sterilized? Is it important that one container system meet everyone's needs? (Be certain that the container systems are acceptable to all users.)

j) What is the estimated or expected life of the container system and its parts? What kinds of warranties, preventive maintenance assistance, replacement parts, and refurbishment services are available from the manufacturer?

k) Is the total system cost-effective for the health care facility?

I.3 Instruments and devices to be containerized

a) Will all surgical instruments and equipment be containerized or only delicate instruments (e.g., microsurgical or plastic instruments) or certain specialty items (e.g., powered instruments, orthopedic instruments, cardiac instruments, neurosurgical instruments)?

b) Will holders, clips, or other retaining or protective devices be needed to customize trays for specialty instruments?

c) Will all the instruments being used in one room be prepared in container systems?

d) Will emergency room, obstetrical, ambulatory surgery, respiratory therapy, or radiology instrumentation be containerized?

e) What is the maximum number of instrument sets arriving from the operating room or other user departments within 30 minutes?

f) Will container systems be used as procedural trays (e.g., for cut-down, lumbar puncture, chest tube insertion, or cardiac catheter procedures)? That is, can the inner container be used as a sterile field?

g) Will instruments be organized into standard sets that travel through the system as complete units with their assigned containers?

I.4 Cleaning and decontamination considerations

a) Can the container system be disassembled easily for cleaning? Will any parts interfere with adequate cleaning?

b) Can the container system, interior baskets, and accessories be processed manually or in a cart washer, washer-decontaminator, or washer-sterilizer? Will the design of the container system, baskets, or accessories create a barrier to effective cleaning by any of these methods when the generic recommendations for cycle times are used?

c) Will it be necessary to change the detergents or disinfectants that are used currently in order to avoid harming the container system? Is special handling necessary?

d) Is there adequate workspace in decontamination areas to break down and queue container systems for processing?

e) Will the addition of container systems have an impact on the decontamination workload? Are there sufficient processing equipment, utilization time, and personnel available to accommodate an additional workload using manual or mechanical cleaning or decontamination methods?

f) Is the processing equipment adequate to handle the container systems? Will special holders for container systems be required? Is there adequate equipment cycle time for processing the container systems?

g) Can the container system be used to confine and transport contaminated items?

I.5 Preparation and assembly considerations

a) Is the container system easy to assemble? Are the lid and bottom interchangeable or easily identifiable? Are the top and bottom filter-retaining plates interchangeable or easily identifiable for proper placement? Are parts interchangeable among the various sizes of container systems?

b) Can damage to parts such as gaskets, sealing edges, filter-retention plates, filter-holding rings, valves, and locking mechanisms be recognized easily?

c) Are accessories available to organize and secure instruments in the proper position for sterilization and for the protection of the instruments? Has testing been performed to assure that these accessories will not impede contact with the sterilant?

d) Is there a maximum weight recommended by the manufacturer, with supporting documentation, for the amount of instrumentation that can be placed into a container system for sterilization and drying or aeration? Does the recommended weight refer only to the instruments or to the combined weight of the instruments and the container system? Does the recommended weight relate to sterilization and drying, personnel safety when lifting, or both?

e) Are there any special instructions regarding the distribution of dense masses of metal (e.g., orthopedic instruments) when assembling the instrument set in the basket?

f) Can instrument trays or baskets other than those designed for the container system be used if they fit the container system? What is the impact on sterilization and drying?

g) Can specialty instrument organizing or protecting trays (e.g., orthopedic implant sets) be used with the container system if they fit? What is the impact on sterilization and drying?

h) What is the manufacturer's advice concerning the use of absorbent material (e.g., surgical towels) within the set to facilitate drying? If the use of absorbent material is recommended, where should it be placed (e.g., in the basket, in the tray, in the bottom of the container system)?

i) Are there any special recommendations regarding the placement of internal CIs and BIs?

j) Can the container system be easily closed, secured, and labeled?

k) Do the external label and CI meet the requirements established within the health care facility?

I.6 Matching the rigid sterilization container system and sterilization cycle

NOTE—See Section I.2 of this Annex and Section 10.10 of the main text.

a) What sterilization processes are compatible with the container system? Are there any special considerations for each process?

b) Has the compatibility of the container system been tested with BIs in each type of sterilizer in the facility and in each appropriate sterilization cycle?

I.7 Loading the sterilizer

a) Can the container systems be positioned flat on sterilizer loading shelves without touching chamber walls?

b) Does the size of the container system optimize the available shelf space on the sterilizer loading cart?

c) Will the placement allow personnel to use good body mechanics when loading and unloading the container systems from the cart?

d) Are there any special considerations related to dedicated loads, mixed loads, the positioning of container systems on shelves, or other aspects of sterilizer loading? For example, will a mixed load tend to produce wet packs or other drying difficulties?

e) In general, is there a maximum number of container systems per usable sterilizer volume or load? Is there a maximum weight per load?

f) Does the manufacturer recommend the use of absorbent sterilizer shelf covers to facilitate drying? Are there shelf liner materials that are contraindicated?

g) Can the container systems be stacked? If so, in which type of sterilization process (gravity-displacement steam sterilization, dynamic-air-removal steam sterilization)? In what configuration ("one over one" or "offset, straddling two")? How many can be stacked? Can two different types of container systems be stacked?

h) Has product testing demonstrated effective sterilization and drying or aeration when container systems are stacked? Were the items used in the testing representative of the items that will be processed in the container system?

I.8 Choosing the appropriate exposure and drying times

NOTE—See Section I.2 of this Annex and Section 10.10 of the main text.

a) Can routine sterilization cycles recommended for wrapped packs by the sterilizer manufacturer be used?

b) Does the container system manufacturer provide a method of testing the efficacy of the sterilizer in which the container systems will be processed?

c) According to the container system manufacturer's studies, is it necessary to extend exposure or drying time to accomplish sterilization and drying? Is documentation available of the testing done to determine appropriate parameters? Has the documentation been reviewed?

d) To produce a dry set at the end of the cycle, is it recommended or necessary that the load be preheated before the cycle is initiated? Is it recommended or necessary that the load be dried by leaving the container systems in the sterilizer chamber for a specified period of time before they are unloaded? Are test data available?

e) Does the manufacturer provide a method of determining and verifying the effectiveness of the drying process?

f) Has the compatibility of the container system with the chosen sterilization process and cycle been verified by testing at the health care facility?

I.9 Unloading the sterilizer and cooling the load

a) Are there any special instructions regarding how soon container systems can be touched once the cycle has been completed or the loading cart has been removed from the sterilizer? How should the container systems be handled?

b) What are the manufacturer's recommendations for cool-down? Do the recommendations pertain to personnel safety (i.e., the avoidance of thermal burns from touching metal that is too hot), condensation, or both? Are there recommendations regarding the environment in which a container system should be cooled?

I.10 Sterility maintenance

a) Can the manufacturer produce test data that support the effectiveness of the container system as a microbial barrier? Do the test results demonstrate satisfactorily the container system's ability to prevent contamination during normal handling and storage? Do the test methods used by the manufacturer simulate the environment and activities within the health care facility?

b) What are the potential causes of barrier failure (e.g., slipped filter, failure of the gasket to seal, failure of the locking mechanism, loosened screws or rivets)? Has the manufacturer provided inspection criteria to ensure that the container system is functioning effectively?

c) Is moisture within the container system after sterilization considered a potential source of contamination? Or is the set to be considered sterile? Are data and documentation available to support the claim?

I.11 Sterile storage

a) Are there any special requirements for the storage area?

b) Are special storage systems necessary? Are special carts or racks available for storage of sterilized container systems? Will they minimize handling?

c) Will existing storage shelving and space in all areas of use or handling accommodate the container systems?

d) Will the added weight of the container systems require reinforcement of the existing storage system?

e) Can personnel easily place the container systems into storage units and remove them using good body mechanics and infection prevention and control practices? Can the container systems be stacked? Are there any limitations?

f) Will the container systems fit into case carts?

I.12 Transportation

a) Are there any special recommendations or requirements for handling transportation?

b) Are special transportation carts or other vehicles necessary for on-site or off-site delivery? Would the vehicles differ from those used for packaged items?

I.13 Aseptic presentation

a) Is the container system easy for personnel to handle?

b) Are the container system locks and handles easy to remove or open?

c) Are the labeling and external indicator located in a place that is convenient for the user to check?

d) Can the lid be removed easily without contaminating the contents or the scrub person's hands?

e) Can the instrument baskets be removed easily without contaminating the contents or the scrub person's hands?

f) Can filters, retaining mechanisms, and valves be easily identified and inspected for security?

g) If an internal wrap is used, can it be opened easily without contaminating the contents or the scrub person?

I.14 Conclusion

You have a choice. Make one that clearly will satisfy your needs.

NOTES

Annex J
(Informative)

Effect of containerized packaging on load heat-up time

Rigid sterilization container systems are commonly used in the United States. For most applications, both the method of use and the mode of sterilization are similar to those used for wrapped instrument sets. However, one significant difference has to be accounted for in gravity-displacement steam sterilization. More air is trapped within a container system than in a conventional wrapped set. In gravity-displacement steam sterilization, it takes longer to remove this air. Consequently, the temperature within the container rises more slowly than that in a wrapped set. This difference holds true for all container systems that use nonwoven filters or do not provide a means of rapid air removal during the air-displacement phase of the steam sterilization process. Figure J.1, Figure J.2, and Figure J.3 illustrate this phenomenon.

Figure J.1 and Figure J.2, respectively, contrast the temperature profiles of containerized versus wrapped instrument sets in a gravity-displacement cycle at 121°C (250°F). There is a delay in the heat-up time for the containerized load. For this reason, the container system manufacturer should be consulted for a documented recommendation as to the time and temperature cycle to be used. Although it is preferable to operate at the highest practical temperature available, each cycle should be verified by appropriate tests conducted in each sterilizer in which the use of container systems is anticipated.

A delay in heat-up time is not seen in container systems processed in a prevacuum sterilization cycle (Figure J.3). Therefore, it is usually unnecessary to extend the cycle time in prevacuum sterilizers. Container systems designed with perforations in both the top and bottom, as well as those with perforations only in the top, can be used safely in conventional prevacuum cycles.

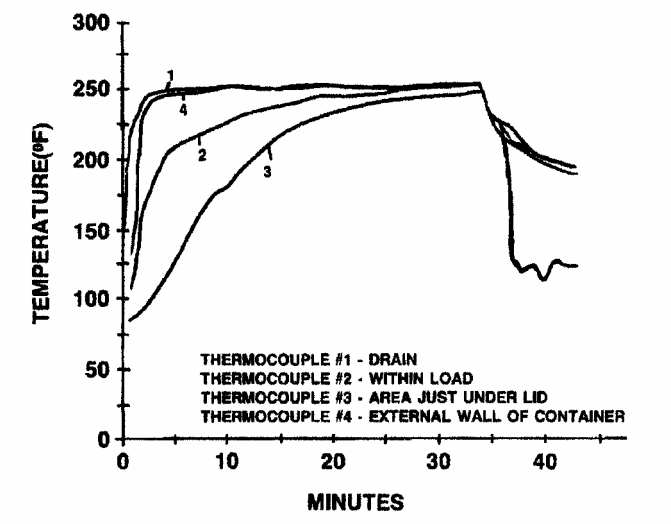


Figure J.1—Typical rigid sterilization container system processed in a gravity-displacement cycle at 121°C (250°F)

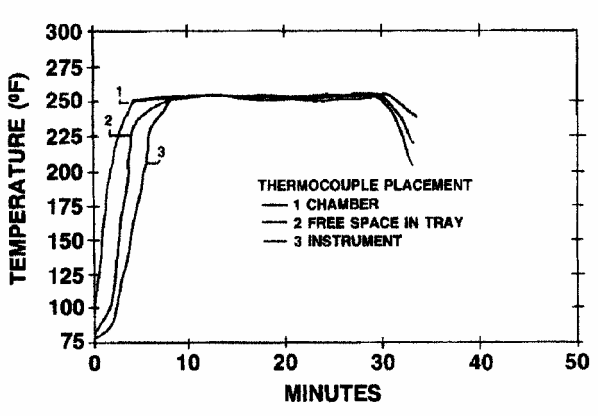


Figure J.2—Muslin-wrapped, 16 pound instrument set processed in a gravity-displacement cycle at 121°C (250°F)

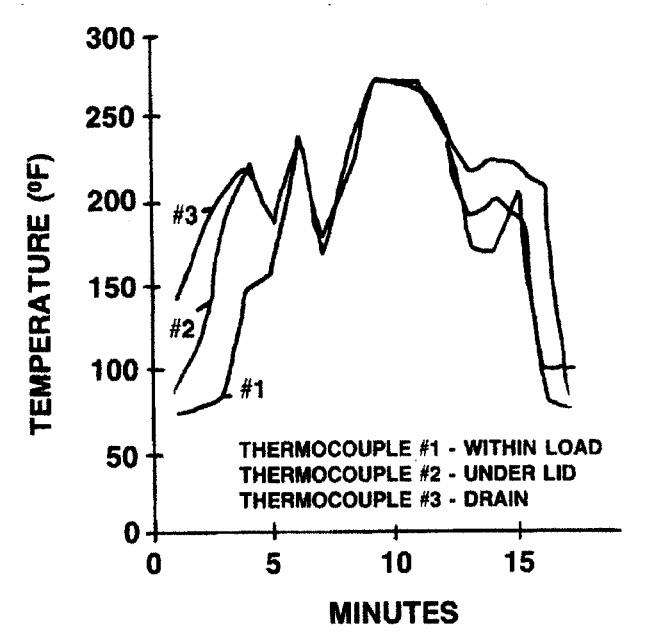


Figure J.3—Typical rigid sterilization container system processed in a prevacuum cycle at 132°C (270°F)

Annex K
(Informative)

Development and qualification of the 16 towel PCD (biological-indicator challenge test pack)

K.1 Introduction

The first edition of this recommended practice (AAMI ST1:1980) recommended the use of a heterogeneous challenge test pack consisting of 3 muslin surgical gowns, 12 huck or absorbent surgical towels, 30 gauze sponges, 5 lap sponges, and 1 muslin surgical drape, and sequentially wrapped with 2 muslin wrappers. The test pack was recommended to be approximately 12 × 12 × 20 inches in size and to weigh 10 to 12 pounds, for a resulting pack density of 7.2 pounds per cubic foot. The pack specifications were based on Perkin's work to restrict the size and density of processed packs so that standard sterilization cycle parameters would have an adequate margin of safety (Perkins, 1969). This pack was adopted by various other organizations (e.g., AORN, 1982) and by individual health care facilities and became a hospital standard for biological monitoring.

In the years following adoption of the 12 × 12 × 20 inch test pack, numerous comments were raised concerning difficulties in obtaining items to make up the pack, the placement of BIs within the pack, the appropriateness of the muslin wrapper, and the rationale for the pack contents. The Hospital Practices Working Group of the AAMI Steam Sterilization Subcommittee formed a task force to investigate these issues. The results of a survey of hospital personnel revealed a need for a simpler steam BI test pack with more readily available contents. Respondents to the survey recommended that (a) the new pack consist of materials whose properties could be specified so that critical parameters affecting steam penetration and air removal are controlled; (b) rationale and documentation be developed to specify BI placement within the pack; and (c) the pack exhibit performance characteristics essentially equivalent to the current test pack.

Through a cooperative effort among hospital personnel, industrial representatives, and independent consultants, testing was conducted to develop a new BI test pack for evaluation of steam sterilizers within health care facilities. The new pack was to have performance characteristics similar to the old pack and consist of materials readily available to hospital personnel. This Annex summarizes the testing that resulted in the new 16 towel PCD (BI challenge test pack) recommended as an alternative to the original pack in the second edition of the recommended practice (AAMI SSSA:1988) and recommended in subsequent editions as the sole PCD.

K.2 Survey and preliminary testing

Before any laboratory testing was performed, a questionnaire was distributed to health care personnel to solicit their thoughts on the original 12 × 12 × 20 inch pack and their ideas concerning a new test pack. The questionnaire results confirmed that all of the materials needed for the 12 × 12 × 20 inch pack were not available in most hospitals, in part because such items as lap sponges were being purchased as sterile, single-use items. The majority of respondents wanted a test pack that was well defined in terms of content, size, and BI placement. Surgical towels were identified as the material most readily available within health care facilities for making a test pack. Because surgical towels also were used in the Bowie-Dick test pack and recommended for use in EO test packs (AAMI EOTP:1985), the Working Group decided to investigate the use of surgical towels for the BI test pack.

Questions arose about the variability of surgical towels used by health care facilities and how this might affect test pack performance. More than 20 test packs were obtained from health care facilities throughout the country. All towels had been washed and were in routine use at the various institutions. Average surgical towel dimensions were 16.5 by 26.3 inches.

In the 12 × 12 × 20 inch heterogeneous pack, the materials were arranged in two stacks with a space between. The two stacks act as virtually independent challenges to air evacuation and steam penetration, as measured by temperature profiles, even though they are contained in the same wrapper. Preliminary testing was conducted in a 121°C (250°F) gravity cycle to determine the number of towels and the size of test pack needed to yield performance characteristics similar to those of the 12 × 12 × 20 inch pack.

Figure K.1 shows temperature profiles from 12 × 12 × 20 inch packs prepared and run at two different test laboratories. Significantly different profiles were observed, even though both laboratories prepared their packs in accordance with the 1980 AAMI recommendations. The packs differed in size of wrapper used, method of folding

towels, and type of surgical gowns used. None of these parameters were specified in descriptions of the 12 × 12 × 20 inch pack.

It was agreed that the performance of the new towel pack should approximate that of the slower-to-heat 12 × 12 × 20 inch pack illustrated in Figure K.1. The preliminary testing indicated that 16 surgical towels folded to produce a pack with overall pack dimensions of 9 by 9 by 6 inches yielded thermal come-up profiles and BI results comparable to the 12 × 12 × 20 inch pack with the slowest heat-up time.

Tests were run to compare horizontal (flat) versus vertical (on edge) placement of the towel pack. As expected, horizontal placement provided more of a challenge to sterilization in a gravity cycle, as indicated by a longer come-up time (1 to 2 minutes) and by the BI results. Tests also were run with the towel pack in a fully loaded chamber and with the towel pack in an otherwise empty chamber. The use of a single pack was more of a challenge to the sterilizer, because the chamber reached temperature faster, thereby activating the exposure timer sooner. The center of the pack, on the other hand, took the same time to reach temperature whether the chamber contained one pack or was fully loaded.

Table K.1 summarizes characteristics of the 16 towel packs that were tested. The average pack dimensions were 9.4 by 8.9 by 6.1 inches. The average weight and density of the packs were 3.3 pounds and 11.3 pounds per cubic foot, respectively. Questions arose concerning the differences between huck and absorbent surgical towels used to make up a 16 towel pack. Figure K.2 shows the average temperature profiles in a gravity cycle for the two types of packs. No significant differences were observed.

Table K.1—16 towel pack survey

Towel size		**Average pack size**			**Average pack weight (lbs)**	**Average pack density (lbs/ft^3)**
Length (inches)	Width (inches)	Length (inches)	Width (inches)	Height (inches)		
26.3 ± 2.1[1)]	16.5 ± 1.3[1)]	9.4	8.9	6.1	3.3[2)]	11.3

NOTE 1—Average ± one standard deviation.
NOTE 2—Pack weights ranged from 2.6 to 3.7 lbs.

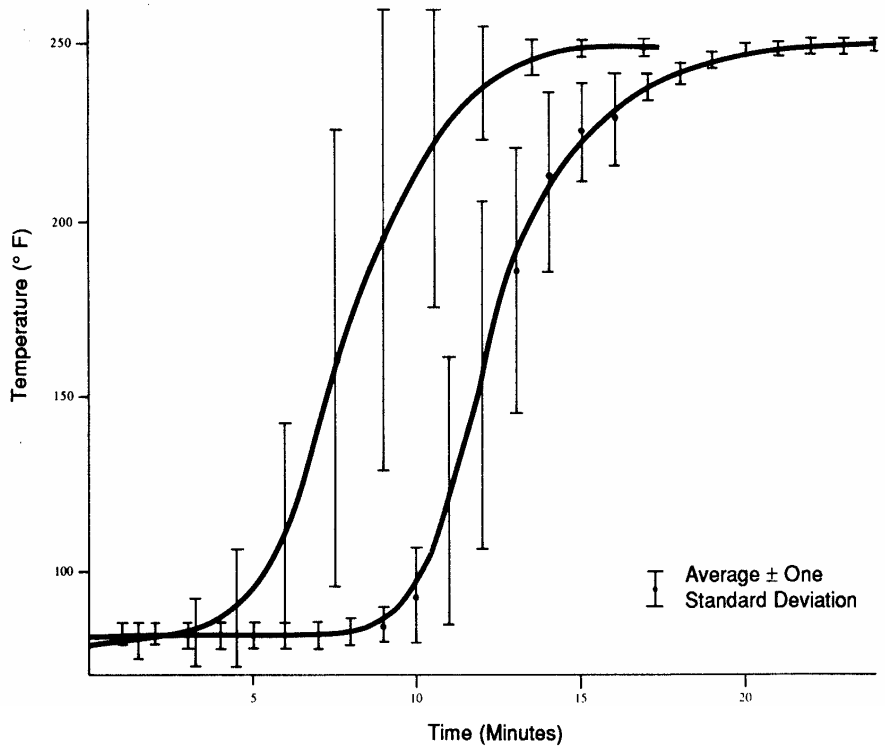
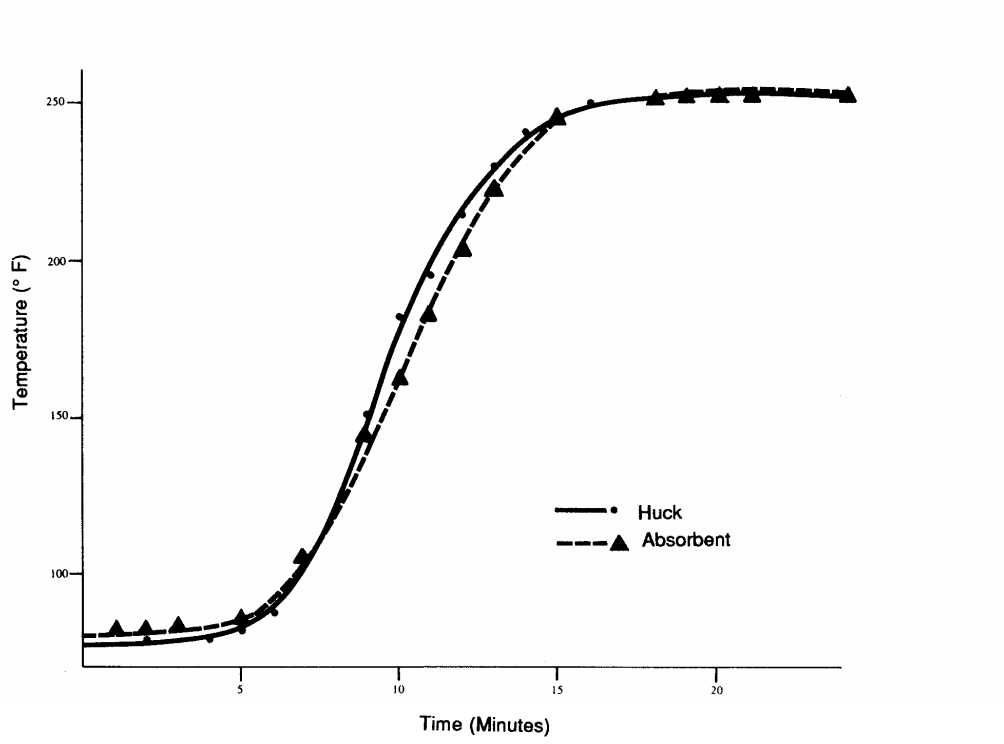


Figure K.1—Temperature profiles for two different configurations of 12 × 12 × 20 inch packs



in a 121°C (250°F) gravity cycle

Figure K.2—Temperature profiles for huck and absorbent 16 towel packs in a 121°C (250°F) gravity cycle

K.3 Validation testing in gravity cycles

The 16 towel test packs were processed in 121°C (250°F) gravity cycles. Thermocouples and BIs were placed in the center of each pack. The 12 × 12 × 20 inch packs were similarly instrumented to permit a direct comparison of the two types of packs. The 12 × 12 × 20 inch packs were placed vertically (on edge) in the sterilizer, and the 16 towel packs were placed horizontally (flat). The packs were evaluated at three different laboratories. Figure K.3 shows the average temperature profile for the 16 towel pack, which is very similar to the profile shown in Figure K.1 for the slowest-to-heat 12 × 12 × 20 inch pack. The pack-to-pack variation for the 16 towel pack was significantly less than for the 12 × 12 × 20 inch pack, as evidenced by the standard deviations. Table K.2 shows the BI results; the 16 towel pack was less resistant than the 12 × 12 × 20 inch pack in a 121°C (250°F) gravity cycle.

Table K.2—Biological-indicator results from 121°C (250°F) gravity cycle

Exposure time (minutes)	Biological-indicator response[1)]			
	12 × 12 × by 20 inch pack		16 towel pack	
	Spore strips			
16	nt[2)]		4/4	(100%)
18	2/2	(100%)	1/4	(25%)
20	5/12	(42%)	8/16	(50%)
22	3/4	(75%)	nt[2)]	
25	0/12	(0%)	0/10	(0%)
	Self-contained			
16	nt[2)]		5/8	(63%)
18	4/4	(100%)	2/8	(25%)
20	11/16	(69%)	7/24	(29%)
22	4/8	(50%)	nt[2)]	
25	0/16	(0%)	0/12	(0%)

NOTE 1—Number positive per number exposed (% positive).
NOTE 2—Not tested.

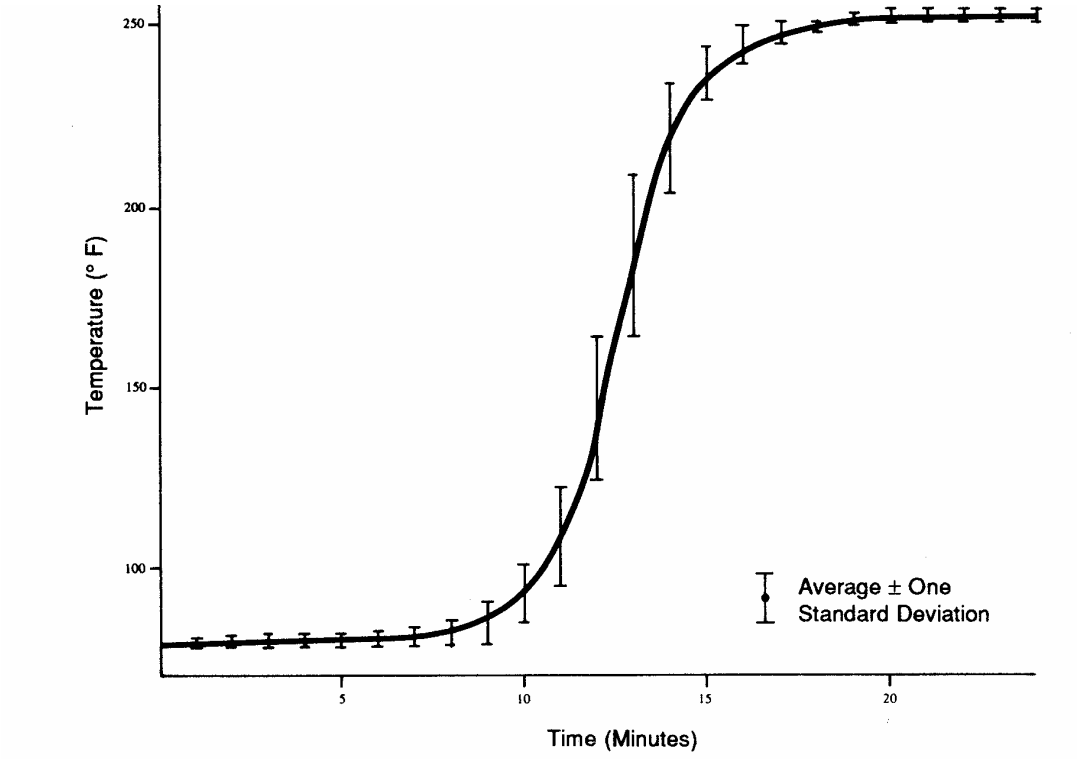


Figure K.3—Average temperature profile for the 16 towel pack in a 121°C (250°F) gravity cycle

K.4 Validation testing in prevacuum cycles

Both deep-vacuum and pulsing prevacuum sterilizers were used for the evaluations. In general, the center-of-pack temperatures closely followed the sterilizer drainline temperature. The temperature profiles of the 12 × 12 × 20 inch pack and the 16 towel pack were identical, or the 16 towel pack lagged behind the 12 × 12 × 20 inch pack by a maximum of 30 seconds. Table K.3 summarizes the BI results from a deep-vacuum sterilizer. Spore strips were sterile with exposure times of 2 min or less, and self-contained indicators were killed with exposure times of 3 to 4 min. Table K.4 summarizes the BI results when test packs were run in a pulsing vacuum cycle at 132°C (270°F).

Table K.3—Biological-indicator results from 132°C (270°F) deep-vacuum cycle

Exposure time (minutes)	Biological-indicator response[1)]			
	12 × 12 × 20 inch pack		16 towel pack	
	Spore strips			
0	3/4	(75%)	4/4	(100%)
0.5	5/14	(36%)	4/18	(22%)
2	0/18	(0%)	0/18	(0%)
3	0/16	(0%)	0/16	(0%)
4[2)]	0/16	(0%)	0/16	(0%)
	Self-contained			
0	8/8	(100%)	8/8	(100%)
0.5	20/28	(71%)	26/28	(93%)
2	4/28	(14%)	14/28	(50%)
3	5/32	(16%)	11/32	(34%)
4[2)]	0/32	(0%)	0/32	(0%)

NOTE 1—Number positive per number exposed (% positive).
NOTE 2—Recommended exposure.

Table K.4—Biological-indicator results from 132°C (270°F) pulsing vacuum cycle

Exposure time (minutes)	Biological-indicator response[1)]			
	12 × 12 × 20 inch pack		16 towel pack	
	Spore strips			
1	1/9	(11%)	0/17	(0%)
2	0/3	(0%)	1/16	(6%)
3	0/4	(0%)	0/14	(0%)
	Self-contained			
1	3/17	(18%)	7/28	(25%)
2	0/11	(0%)	5/31	(16%)
3	0/8	(0%)	0/22	(0%)

NOTE 1—Number positive per number exposed (% positive).

K.5 Direct comparison of the 12 × 12 × 20 inch and 16 towel test packs

In noncollaborative testing, the foregoing BI and thermocouple testing was conducted with each test pack placed individually in an otherwise empty chamber. To reduce some of the cycle-to-cycle variation inherent in the testing, a final series of test cycles was run with both a 16 towel pack and a 12 × 12 × 20 inch pack present in the chamber at the same time.

In one test series, five BIs were used per test pack. After exposure to the sterilization cycle, two of the five BIs were cultured for sterility and three were assessed by the Most Probable Number (MPN) technique, as described in United States Pharmacopeia (1984).

In the second test series, all five BIs were cultured for sterility after exposure, and three CIs were scored on a ranking scale. The ranking scale was 0 to 13, with 13 equal to a complete change of the CI. A thermocouple was located approximately 2 inches from the chamber drain, and temperature readings were taken at 1 min intervals to calculate an F_o value for each cycle.

The results of the first and second series of tests are shown in Table K.5 and Table K.6. The data shown in Table K.6 were evaluated statistically to determine if performance between the two packs differed significantly. An F-test showed homogenicity of variance for both the fraction-value and CI data. A series of paired or unpaired t-tests, using data with F_o values in the range of 18 to 27 min or 26 ± 1 min, showed no significant differences between the 16 towel pack and the 12 × 12 × 20 inch pack (t = 0.124 to 0.402, p 0.05, 4 or 5 d.f.). The Mann-Whitney U-test also showed no significant differences between the two types of pack (p 0.35, $n_1 = n_2 = 5$, U = 10). There was minimal correlation between the independent variables (steam exposure time or F_o value) and the dependent variables (fraction-value or CI results), with t-values in the range of 0.176 to 0.834 (p 0.5 to 0.1, 3 d.f.).

Overall, these data provide little or no support for a rejection of the null hypothesis of no difference between the 16 towel test pack and the 12 × 12 × 20 inch test pack at the p = 0.1 level; that is, no statistically significant differences were found in the performance of the two packs.

Table K.5—Comparison of the 16 towel pack with the 12 × 12 × 20 inch pack by Most Probable Number and sterility assessment of spore strips (121°C [250°F] gravity cycle)[1)]

Exposure time at 121°C (250°F)	Most Probable Number assessment			Sterility assessment (survivors per number tested)
	Spore strip	Suspending fluid	MPN value	
14 minutes				
16 towel pack	#1	+	800	3/3
	#2	+	460	
12 × 12 × 20 inch pack[2)]	#1	+	460	3/3
	#2	+	3,000	
15 minutes				
16 towel pack	#1	+	460	1/3
	#2	+	< 460	
12 × 12 × 20 inch pack[2)]	#1	+	460	2/3
	#2	+	460	
16 minutes				
16 towel pack	#1	+	460	nt[3)]
	#2	+	< 460	
12 × 12 × 20 inch pack[2)]	#1	+	460	nt[3)]
	#2	+	460	

NOTE 1—Noncollaborative data gathered by Sterilization Technical Services.
NOTE 2—52- by 52-inch wrap.
NOTE 3—Not tested.

Table K.6—Fraction-negative results in a 121°C (250°F) gravity cycle[1)]

F_o value	Intended exposure time at 250°F (minutes)	16 towel pack				12 × 12 × 20 inch pack[2)]			
		Spore strip	Chemical indicator[3)]			Spore strip	Chemical indicator[3)]		
			1	2	3		1	2	3
18.8	16	4/5	0	0	0	5/5	1	9	2
25.7	15	3/5	4.5	5	4	1/5	11	9.5	8
26.2	18	4/5	12	9	8.5	5/5	7	6	12
26.4	17	5/5	4	4	11	3/5	2	2	3
26.8	19	2/5	13	12	9	2/5	7	4	6
Total		18/25	96.5			16/25	89.5		

NOTE 1—Noncollaborative data gathered by Sterilization Technical Services.
NOTE 2—50- by 64-inch wrap.
NOTE 3—Scale of CI response: 0 = no evidence of sterilization; 13 = complete response, indicating sterilization conditions met.

K.6 Summary of round-robin testing

The results of testing showed significant variation in the performance of the 12 × 12 × 20 inch pack, depending on how the pack was constructed. Overall, the 16 towel pack performed similarly to one of the more difficult configurations of the 12 × 12 × 20 inch pack. Although the two types of packs differed somewhat in specific types of sterilization cycles, the 16 towel pack showed less run-to-run variation. The committee decided to recommend the 16 towel pack for use in biological monitoring, because the 16 towel pack gives more reproducible results and can be more easily constructed than the 12 × 12 × 20 inch pack.

K.7 Supplemental data for steam-flush pressure-pulsing cycles

Subsequent to the round-robin testing to qualify the 16 towel test pack, noncollaborative data were collected to compare the 16 towel test pack and the 12 × 12 × 20 inch test pack in steam-flush pressure-pulse cycles. The two types of test packs were processed in 121°C (250°F) cycles. Biological indicators were placed in the center of each pack. The two packs were placed horizontally (flat) in the sterilizer. There was no discernible difference between the two packs in BI results—all of the BIs were killed in the test exposure times (Table K.7). Similar testing was performed for 132°C (270°F) cycles. Spore strips were found to be sterile after exposure times of 0.5 min or more. Self-contained BIs were killed with exposure times of 2 min or more. There was no discernible difference between the two packs in microbial kill (Table K.8).

Table K.7—Biological-indicator results from 121°C (250°F) steam-flush pressure-pulse cycle[1)]

Exposure time (minutes)	Biological-indicator response[2)]			
	12 × 12 × 20 inch pack		16 towel pack	
	Spore strips			
8	17/18	(94.4%)	18/18	(100%)
10	0/18	(0%)	0/18	(0%)
12	0/18	(0%)	0/18	(0%)
14	0/18	(0%)	0/18	(0%)
	Self-contained			
8	18/18	(100%)	18/18	(100%)
10	3/18	(16.6%)	6/18	(33.3%)
12	0/18	(0%)	0/18	(0%)
14	0/18	(0%)	0/18	(0%)

NOTE 1—Noncollaborative data gathered by Joslyn Sterilizer Company.
NOTE 2—Number positive per number exposed (% positive).

Table K.8—Biological-indicator results from 132°C (270°F) steam-flush pressure-pulse cycle[1)]

Exposure time (minutes)	Biological-indicator response[2)]			
	12 × 12 × 20 inch pack		16 towel pack	
	Spore strips			
0.5	0/18	(0%)	0/18	(0%)
2	0/18	(0%)	0/18	(0%)
3	0/18	(0%)	0/18	(0%)
4	0/18	(0%)	0/18	(0%)
	Self-contained			
0.5	18/18	(100%)	18/18	(100%)
2	0/18	(0%)	0/18	(0%)
3	0/18	(0%)	0/18	(0%)
4	0/18	(0%)	0/18	(0%)

NOTE 1—Noncollaborative data gathered by Joslyn Sterilizer Company.
NOTE 2—Number positive per number exposed (% positive).

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NOTES

Annex L
(Informative)

Example of documentation of premature release of implants

This Annex provides an Implantable Devices Load Record and an Exception Form for Premature Release of Implantable Device/Tray, as examples of the forms recommended in Section 10.6.3.

Implantable Devices Load Record

Date	Description of implants	Dept.	Time sterilized (specify AM/PM)	Sterilizer #	Load #	Date/time BI in incubator	Date/time and BI result	Early release?	Date/time released to OR	Released by (full name)

Figure L.1—Implantable devices load record

Exception Form for Premature Release of Implantable Device/Tray

NOTE—In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form should accompany the implant to the Operating Room. Operating Room personnel should complete this form and return it to Central Service within 24 hours.

PLEASE COMPLETE ALL INFORMATION:

DATE: _____ **SHIFT:** _____ **TIME:** _____ **AM PM**

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: _____

The following implantable devices/trays were prematurely released to the Operating Room:

_____

_____

_____

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES:

_____

OPERATING ROOM REPORT:

PATIENT NAME: _____

SURGEON NAME: _____

TIME OF PROCEDURE: _____ AM PM DATE: _____

REASON PREMATURE RELEASE WAS NEEDED: _____

_____

_____

_____

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE/TRAY? _____

_____

_____

_____

NAME OF OR PERSON COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____ FORM RETURNED TO CENTRAL SERVICE ON: _____

_____

Figure L.2—Exception form for premature release of implantable device/tray

Annex M
(informative)

Steam quality

M.1 Introduction

This Annex provides guidelines on how to achieve and maintain adequate steam quality for steam sterilization processes.

M.2 General considerations

As recommended in 3.3.4.2 of the main text, steam systems should be designed to ensure that a continuous and adequate supply of saturated steam is available to the sterilizer. The critical variables are the dryness of the steam, expressed as a dryness fraction, and the level of noncondensable gas (such as air), expressed as a fraction by volume. Steam dryness should be at a value between 97% and 100%, and the level of noncondensable gas should be at a level at which it will not impair steam penetration into sterilization loads.

Steam pipework should be insulated, and it should be designed so that any condensate flows by gravity in the same direction as the steam, except for vertical rises between floors. This general principle applies equally to steam mains, branch connections, and pipework on the sterilizer itself, especially in situations where the steam is generated in a location remotely located from the sterilizer. Air vents and steam traps should be fitted at each vertical rise. Care should be taken to trap, drain, and return any condensate that might be collected in pockets in the pipework. Dead legs should be avoided. (A “dead leg” is a section of pipe that leads nowhere and does not form part of a constant circulation system; in a steam line, condensate can form in a dead leg and become stagnant.) Branch steam lines should exist from the top of the main lines to reduce condensate carryover. The accumulation of condensate during the periods when the sterilizer is not in operation should be avoided, particularly in any part of the pipework and fittings between the take-off from the manifold and the sterilizer chamber. This can be achieved by the correct declination of each portion of pipework and by adequate trapping throughout the steam distribution system.

At installation, an assessment of the steam quality should be made and documented. Steam quality should be maintained by monitoring and controlling the process of generating steam; maintaining steam traps, boilers, and generators in good working order; and periodically assessing sterilization loads for wet packs. In some circumstances, a steam separator might be used to remove entrained water and increase the degree of steam saturation. If used, the separator should be placed in the steam supply piping as close as possible to the sterilizer.

M.3 Steam dryness

The dryness of the steam is of vital importance to the performance of any steam sterilizer. Excess moisture can cause damp loads in porous materials and uneven temperature distribution in nonporous materials, particularly those containing a large number of small items. Sterilizing conditions might not be attained if the moisture contained in the steam supply is insufficient to prevent the steam from becoming superheated when it expands into the chamber. Significant deviations in steam dryness are likely to cause the following problems:

a) wet loads, resulting from a dryness value that is too low;

b) superheating, resulting from either a dryness value that is too high before the pressure-reducing system or from excessive pressure reduction through the valve (superheating can be severe if both conditions are present simultaneously); and/or

c) difficulties with operation of the pressure-reducing system, resulting from a low pressure-reduction ratio, water hammer, water logging, and/or dirt and other carryover.

If wet steam continues to be a problem, “priming” could be occurring in the boiler, causing water droplets to be delivered in the steam. Modern compact, high-rated boilers and steam generators are particularly sensitive to the quality of feedwater and are much more likely to prime than boilers of traditional design. Priming or foaming (which results in carryover of boiler water) can result from

a) treating feedwater incorrectly;

b) setting the boiler water level too high;

c) forcing a boiler that needs internal cleaning;

d) violent boiling under fluctuating load conditions; and/or

e) a high level of total dissolved solids (typically 2,000 ppm).

Superheated steam is an unsuitable medium for steam sterilization and can cause failure to sterilize, scorching of textiles and paper, and rapid deterioration of rubber. Superheat conditions within the load and chamber could result from adiabatic expansion, exothermic reaction, or both. Superheating caused by **adiabatic expansion** (high-pressure steam entering a low-pressure chamber) is usually the result of an excessive reduction in pressure through a throttling device, such as a pressure-reducing system or a partially closed main steam valve. It is unlikely to be of significance in the circumstances normally encountered in hospital steam distribution systems, but superheating might arise if the main steam supply is dry or the pressure is unusually high before the throttling device. Superheating arising from **exothermic reaction** (rise in temperature from absorption of moisture) might occur during sterilization as a result of rehydration of exceptionally dry hygroscopic material.

M.4 Noncondensable gases

Noncondensable gases (NCGs) are defined as gases that cannot be liquefied by compression under the conditions of temperature and pressure used during the sterilization process. They can be simplistically described as air in a steam supply. Low levels of NCGs contained in steam supplied to sterilizers can markedly affect the performance of the sterilizer and the efficacy of the process and lead to inconsistencies in the performance of the sterilizer and in Bowie-Dick test results.

The main source of NCGs in the steam supply is the boiler feedwater, and the level will be greatly influenced by the water treatment used. In some cases, a study by a water-treatment specialist will be necessary. The study should cover analysis of the water, venting characteristics, and the blow-down regime required to ensure protection of the boiler against corrosion while minimizing the entrainment of NCGs in the steam supply. If antifoaming agents and oxygen-scavenging agents (such as sodium sulfite) are used, it is essential to ensure that the dosages are accurate.

Water-softening treatment is required to prevent the formation of scale. Except in hard-water areas, a simple base-exchange system, in which bicarbonate ions are effectively converted into sludge-forming carbonates, is usually adequate. This process releases carbon dioxide into the water. A properly managed blow-down regime is essential to remove the accumulated sludge. The most effective way of driving off dissolved air, carbon dioxide, and other NCGs is to degas the boiler feedwater before use by heating it in a vented tank (a hot well). This process will also break down bicarbonate ions, driving off more carbon dioxide. For the degassing to be effective, it is important that the temperature of the feedwater remain high.

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 might 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 could result in an acute inflammatory response known as toxic anterior segment syndrome (TASS). This inflammatory response could lead to severe visual impairment if it is not recognized and treated in a timely manner.

Although the induction of TASS might 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, 2010a), 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 written 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 can 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 blood-borne 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 blood-borne 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 written 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 written 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 could 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 could 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 might 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.

NOTES

Annex O
(informative)

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