ANSI/AAMI ST79:2017

& 2020 Amendments A1, A2, A3, A4 (Consolidated Text)

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

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American National Standard **ANSI/AAMI ST79:2017**
(Revision of ANSI/AAMI ST79:2010/(R)2014 & A1:2010 & A2:2011 & A3:2012 & A4:2013)

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

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

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

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www.aami.org

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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, FAAN
Cynthia Spry, MA, MS, RN, CNOR(E), CSPDT

Members:
Steven Adams
Anas Aljabo, SteriPro Canada Inc
Rajee Arunan, Mercy Medical Center
Richard Bancroft, STERIS Corporation
Ralph J. Basile, MBA, Healthmark Industries Company Inc
Nola Bayes, MBA, Sanford Health
Gary Benning, Midmark Corporation
Damien Berg, CRCST, St. Anthony Hospital
Holger Biering, PhD
Hassan Bilal, Medline Industries Inc
Dave Billman, Innovative Sterilization Technologies LLC
Jennifer Burrell, St Lukes Hospital and Health Network
Bradley J. Bushman, Standard Textile Co Inc
Mike Cain, Getinge USA
Dennis Champagne, Avista Pharma Solutions
Karen Cherry, SIPS Consults Corp
Nancy Chobin, RN, CSPDM, Sterile Processing University LLC
Fiona Collins, American Dental Association
Linda Condon, Johns Hopkins Hospital
Ramona Conner, RN, MSN, CNOR, FAAN, Association of periOperative Registered Nurses
Lena Cordie, Qualitas Professional Services LLC
Gaye Currier
Jacqueline Daley, Sharp Metropolitan Medical Campus
Courtney Mace Davis, University of Iowa Hospitals and Clinics
Michael D'Onofrio, Presage Health
Jennifer Durbin, Mary Rutan Hospital
Mark Duro, CRCST, FCS, Crosstex/A Cantel Medical Company
Lee Ford, Floyd Medical Center
Brian Fortier, Quality Processing Resource Group LLC
Sarah Friedberg, Stryker Instruments Division
Marcia Ann Frieze, Case Medical Inc.
Joel R. Gorski, PhD, NAMSA
Sharon Hadley, Integrated Medical Systems
Barbara Ann Harmer, RN, BSN, MHA
Seth Hendee, The University of Vermont Medical Center Inc
Rachel Hill, Becton Dickinson & Company
David M. Jagrosse, Middlesex Hospital
Nupur Jain, Intuitive Surgical Inc
Jackie Johnson, Flexible Packaging Association
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service Materiel Management
Marcy Konja, CRCST, CSPDT, CHL, CSPDM, SpecialtyCare
Mary Kneece Lane, BS, MHA, CSPDS, CSPDM
Jack LeClair
Angela M. Lewellyn, LPN, CSPDT, CRCST, Advantage Support Services Inc
Steve Loes, Sterilucent Inc
JoAnn Maltais, Maltais Consulting
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Gerry McDonnell, PhD, Johnson & Johnson

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Kathleen McMullen, Association for Professionals in Infection Control and Epidemiology
Megan Middaugh, Cardinal Health
Emily Mitzel, MS, Nelson Laboratories Inc.
Thomas K. "Chip" Moore, Consultant
Clarence Murray, FDA/CDRH
Frank Myers, UC San Diego Healthcare System
Karen Nauss, CRCST, Mount Auburn Hospital
John Nies, Belimed Inc
Lawayne Perkins, Advantage Support Services Inc
Adrian Ponce, Verrix LLC
Janet M. Prust, 3M Healthcare
Melinda Rogers, Northside Hospital Forsyth
Cheron Rojo, Valley Childrens Hospital
Don Rotter, Ecolab
Rose E. Seavey, RN, MBA, CNOR, CRCST, Seavey Healthcare Consulting LLC
Andrew Sharavara, PhD, Propper Manufacturing Co. Inc
Chuck Sidebottom, PPO Standards LLC
Frank Sizemore, Wake Forest University Baptist Medical Center
Gary Socola, HIGHPOWER Validation Testing & Lab Services Inc
Alison Sonstelie, Sanford Health
Joan M. Spear, B Braun of America Inc.
Steve Spencer, Halyard Health
Cynthia Spry, MA, MS, RN, CNOR(E), CSPDT, Independent Clinical Consultant
James Stanicki, Cleveland Clinic Foundation
Suzanne Stefanik
Andy Sun, SciCan Ltd
Karen Swanson, Connecticut Childrens Medical Center
Donna Swenson (Independent Expert)
Jania Torreblanca, University of Michigan Health System
Mary Velasco, Henry Ford Macomb Hospital
P. Richard Warburton, ChemDAQ Inc
Jill Warren, WuXi AppTec Inc
Sid Wiggs (Independent Expert)
Don Williams, Swedish Medical Center/Cherry Hill Campus
Roberto Zumbado, Philips

Alternates:

Cheri Ackert-Burr, Cantel Inc
Stacey Burgardt, Cardinal Health
John Erickson, Univeristy of Iowa Hopsitals and Clinics
Nancy Fellows, Johnson & Johnson
Susan Flynn, 3M Healthcare David Hilliker, ChemDAQ Inc
Stephen M. Kovach, Healthmark Industries Company Inc
Kristie Kunzer, Bausch & Lomb Inc
Natalie Lind, International Association of Healthcare Central Service Materiel Management
Tania Lupu, Case Medical Inc.
Viktoriya Lusignan, Getinge USA
Kelly Makimoto, SciCan Ltd
Roger Martin, Sterilucent Inc
Christena Nash, Halyard Health
Ed Nuber, B Braun of America Inc
Walt Oko, Innovative Sterilization Technologies LLC
Ramesh Panguluri, FDA/CDRH
Rod Parker, Stryker Instruments Division
Alpa Patel, Nelson Laboratories LLC
Kim Patton, Becton Dickinson & Company
Mandy Ryan, Stryker Instruments Division
Richard Schule, STERIS Corporation
Krista Schulte, Boston Scientific Corporation
Jana Silor, Zimmer Inc
Frank Smith, Department of Veterans Affairs
Joe Smith, Belimed Inc
Leslie Tavares, WuXi AppTec Inc
Dawn Tomac, Association for Professionals in Infection Control
Janelle Trboyevich, Boston Scientific Corporation
Don Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc

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Sharon Van Wicklin, Association of periOperative Registered Nurses
Kristy Vogt, American Dental Association
Brian Wallace, Intuitive Surgical Inc
Ann Young, The University of Vermont Medical Center Inc

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AAMI Sterilization Standards Committee

Cochair: Michael H. Scholla, MS, PhD

Members:
Anas Aljabo, PhD, SteriPro Canada Inc
Brett Anderson, Cochlear Ltd
Hank Balch, University Health System
Richard Bancroft, STERIS Corporation
Trabue D. Bryans, BryKor LLC
Tim Carlson, Becton Dickinson & Company
Phil Cogdill, Medtronic Inc
Sean Colwell, WuXi AppTec Inc
Ramona Conner, RN, MSN, CNOR, FAAN, Association of periOperative Registered Nurses
Lena Cordie, Qualitas Professional Services LLC
Jacqueline Daley, Sharp Metropolitan Medical Campus
Gordon Ely, MiMedx Group
Lisa Foster, Adiuvo QS & SA Consulting
Joel R. Gorski, PhD, NAMSA
Stephanie Homuth (Independent Expert)
Clark Houghtling, Cosmed Group Inc
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service Materiel Management
Byron J. Lambert, PhD, Abbott Laboratories
Michelle Luebke, Baxter Healthcare Corporation
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Gerry McDonnell, PhD, Johnson & Johnson
Gerry O'Dell, Gerry O'Dell Consulting
Adrian Ponce, Verrix LLC
Janet Prust, 3M Healthcare
Nancy Rakiewicz, IUVO BioScience
Michael H. Scholla, MS, PhD, Dupont Protection Technologies
Joan Spear, B Braun of America Inc
Sid Wiggs (Independent Expert)
Martell Kress Winters, SM, Nelson Laboratories LLC
Stephen Yeadon, Boston Scientific Corporation
William E. Young, Sterigenics International
Roberto Zumbado, Philips

Alternates:
Stacy Bohl, Boston Scientific Corporation
Jonathan Bull, Johnson & Johnson
Greg Crego, IUVO BioScience
Niki Fidopiastis, Sterigenics International
Jeffrey Marx, STERIS Corporation
Kimberly Patton, Becton Dickinson & Company
Christine Render, Cosmed Group Inc
Michael Sadowski, Baxter Healthcare Corporation
Sharon Van Wicklin, Association of periOperative Registered Nurses

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Foreword

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

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

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

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

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

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

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

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

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

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

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

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

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

Introduction: Need for the recommended practice

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

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

a) efficient facility design,

b) equipment, personnel and other resources,

c) education and training of personnel,

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

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

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

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

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

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

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

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

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

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

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1 Scope

1.1 General

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

1.2 Inclusions

This recommended practice specifically addresses

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

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

c) processing recommendations;

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

e) quality control;

f) product evaluation; and

g) quality process improvement.

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

1.3 Exclusions

This recommended practice does not cover

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

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

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

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

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

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

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

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

i) aseptic presentation.

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

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2 Definitions and abbreviations

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

2.1 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.

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

2.3 biological indicator (BI): Biological sterilization process indicator 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—See ANSI/AAMI/ISO 14161 for information on the selection, use, and interpretation of biological indicators.

2.4 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.

2.5 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.

2.6 case/cassette: 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 rigid sterilization container system (or sterilization pouch suitable for a specified sterilization method[s]).

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

2.8 CDC: Centers for Disease Control and Prevention.

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

2.10 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 used in specific tests of sterilization equipment.

ANSI/AAMI/ISO 11140-1:2014, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, defines six types of CIs and specifies performance requirements for them:

> **Type 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.
>
> **Type 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).
>
> **Type 3 (single critical process 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.
>
> **Type 4 (multicritical process 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.
>
> **Type 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 ANSI/AAMI/ISO 11138 series for BIs.
>
> **Type 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 1—FDA recognition of chemical indicators is limited to Type 1 process indicators; Type 2 indicators for use with special tests; and Type 6 emulating indicators (ANSI/ AAMI/ISO 11140-1:2014).

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NOTE 2—The International Standards Organization published a revised version of ISO 11140-1, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, in 2014. The ISO document was adopted by the Association for the Advancement of Medical Instrumentation (AAMI) and subsequently approved as an American National Standard, ANSI/AAMI/ISO 11140-1:2014. A key change in the 2014 version of the standard is the use of the term "type" rather than the term "class" of chemical indicator. As chemical indicator manufacturers update their device labeling to reflect the new standard, there will be a transition period during which end-users will observe some chemical indicators labeled as "Class X" and others labeled with the new term "Type X" in the marketplace.

2.11 clean work room: Area of a health care facility where devices are inspected, assembled, and prepared for disinfection and/or sterilization.

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

2.13 come-up time: Time required for the parameters necessary for the selected sterilization cycle to be reached.

2.14 containment device: Instrument case, cassette, or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization.

2.15 contaminated: Presence of potentially infectious, pathogenic organisms (e.g., found in blood or other potentially infectious material) in or on an object.

2.16 critical water: Water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, deionization [DI], and reverse osmosis [RO] or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process. This water is mainly used for the final rinse or for steam generation.

NOTE—See AAMI TIR34 for specifications.

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

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

2.19 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).

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

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

2.22 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.

2.23 decontamination: Process of cleaning and disinfecting soiled medical devices to render then safe for handling and to the extent necessary for subsequent processing.

2.24 decontamination room: Room designated for collection, retention, and cleaning of soiled and/or contaminated items.

2.25 density: Mass per unit of volume.

2.26 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.

2.27 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.

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

NOTE—As used in relation to gravity-displacement table-top sterilizers (sterilizers with a chamber volume of less than or equal to 2 cubic feet) and sterilizers without an active drying cycle, drying time refers to the time that the sterilizer door is left open to complete the drying of sterilized items.

2.29 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.

2.30 engineering controls: Safety-engineered devices designed to prevent or reduce the incidence of worker injury and blood-borne pathogen exposure.

2.31 entrainment: 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.

2.32 EPA: U.S. Environmental Protection Agency.

2.33 event-related sterility maintenance: Sterility maintenance that is not based on expiration dating but rather on factors such as the quality of the packaging material, the storage conditions, the methods and conditions of transport, and the amount and conditions of handling.

2.34 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.

2.35 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.

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

2.37 exposure time: Period for which the process parameters are maintained within their specified tolerances. In a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

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

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

2.40 free rinsing: Removal of any residue of cleaning agents and chemicals remaining after the cleaning process.

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

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

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

2.44 gravity-displacement cycle: Steam sterilization cycle in which incoming steam displaces residual air by gravity through a port or drain located in or near the bottom of the sterilizer chamber.

2.45 handwashing station: Area that provides a sink with a faucet that can be operated without using hands. The station also provides cleansing agents and a means of drying hands.

2.46 health care products: Medical devices, including in vitro diagnostic medical devices, or medicinal products, including biopharmaceuticals.

2.47 health care facility: Specialized facility where professionals deliver services utilizing medical devices.

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.

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

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2.49 huck towel: All-cotton surgical towel with a tight-knit weave to limit linting.

2.50 immediate-use steam sterilization (IUSS): Sterilization method that involves the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item intended for immediate use is not stored for future use nor held from one case to another. Immediacy, rather than being defined according to a specific time frame, is established through the critical analysis and expert collaboration of the health care team.

2.51 implant/implantable device: "A 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)].

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

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

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

2.55 instructions for use (IFU): Written recommendations provided by the manufacturer that provide instructions for operation and safe and effective use of its device.

2.56 instrument air: Medical gas that falls under the general requirements for medical gases as defined by NFPA 99 (*Health care facilities code*), is not respired, is compliant with the ANSI/ISA 7.0.01 (*Quality standard for instrument air*), and is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40ºC (-40ºF).

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

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

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

2.60 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.

2.61 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.

2.62 loaned items: Medical devices used in health care facilities that are not owned by the facility

2.63 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.

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

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

2.66 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.

2.67 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

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- 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.

2.68 medical washer: Device that is intended for general medical purposes to clean and dry surgical instruments, anesthesia equipment, hollowware (e.g., basins, medicine cups), and other medical devices [21 CFR 880.6991(a)].

2.69 medium: See **culture medium**.

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

2.71 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]

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

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

2.74 new product: New product or technology that has been FDA cleared but for which AAMI does not offer guidance for application.

2.75 nonporous device: Item that is not permeable or capable of being penetrated.

2.76 nonwoven: Engineered sheet or web structures bonded together by entangling fiber or filaments (and by perforating films) mechanically, thermally, or chemically.

2.77 occupational exposure: Contact, through inhalation, ingestion, skin contact, or absorption, with a potentially hazardous material during the course of employment.

2.78 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).

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

2.80 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 packaged.

2.81 OSHA: Occupational Safety and Health Administration.

2.82 packaging system: Combination of the sterile barrier system and protective packaging. [ANSI/AAMI/ISO TIR11139:2006]

2.83 paper–plastic pouches: 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.

2.84 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).

2.85 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.

2.86 personal protective equipment (PPE): Specialized clothing or equipment worn for protection against hazardous materials, blood-borne pathogens, or other potentially infectious materials.

2.87 porous device: Item that is permeable or capable of being penetrated.

2.88 positive control (biological indicator): 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.

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2.89 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.

2.90 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]

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

2.92 process failure: Condition in which one or more monitored parameters of cleaning, sterilization, or packaging is outside the defined specification for that parameter.

2.93 product family: Group or subgroup of product that is characterized by similar attributes, such as mass, material, construction, set weight, shape, presence of lumens, and type of sterile barrier system, and that presents a similar challenge to the sterilization process.

2.94 protective packaging: Configuration of materials designed to prevent damage to the sterile barrier system and its contents until the point of use. [ANSI/AAMI/ISO TIR11139:2006]

2.95 psi: Pounds per square inch. More specific designations are pounds per square inch absolute (psia, referenced to an absolute vacuum) and pounds per square inch gauge (psig, referenced to atmospheric pressure).

2.96 pyrogen: Fever-producing substance.

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

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

2.98 restricted area: Area where access and traffic are limited to authorized personnel and where special attire is required.

2.99 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.

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

2.101 satellite sterile processing room: Room located in departments outside the main sterile processing department (SPD), such as the operating room or obstetric department, which is designed and intended to be functionally equivalent to SPD for decontamination and sterilization of surgical instruments.

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

2.103 sharp: Any object that can penetrate the skin, including, but not limited to, needles, scalpels, scalpel blades, broken glass, broken capillary tubes, and exposed ends of dental wires.

2.104 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.

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

2.106 standard precautions: "Group of infection prevention practices that apply to all patients, regardless of suspected or confirmed diagnosis or presumed infection status. Standard Precautions is a combination and expansion of Universal Precautions and Body Substance Isolation. Standard Precautions is based on the principle that all blood, body fluids, secretions, excretions except sweat, nonintact skin, and mucous membranes may contain transmissible infectious agents. Standard Precautions includes hand hygiene, and depending on the anticipated exposure, use of gloves, gown, mask, eye protection, or face shield. Also, equipment or items in the patient environment likely to have been contaminated with infectious fluids must be handled in a manner to prevent transmission of infectious agents (e.g., wear gloves for handling, contain heavily soiled equipment, properly clean and disinfect or sterilize reusable equipment before use on another patient)." (CDC, 2007)

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

2.108 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).

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

2.110 sterile: Free from viable microorganisms.

2.111 sterile barrier system: Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use. [ANSI/AAMI/ISO TIR11139:2006]

2.112 sterile processing department/area: Area within a health care facility that processes and controls medical supplies, devices, and equipment, sterile and not sterile, for some or all patient care areas of the facility.

2.113 sterile storage room: Room designed to store clean and sterile items and protect them from contamination.

2.114 sterility assurance level (SAL): Probability of a single viable microorganism occurring on an item after sterilization. SAL is normally expressed as 10^{-n}. 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.

2.115 sterility maintenance cover: Product designed and intended for sterility maintenance. See **dust cover.**

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

2.117 sterilization cycle: Defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber.

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

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

2.120. sterilizer service access room: Room located behind a sterilizer to provide access to the sterilizer equipment for service and maintenance.

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 less than or equal to 2 cubic feet and that generates its own steam when distilled or deionized water is added by the user.

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

2.125 terminal sterilization: Process by which the product is sterilized within a sterile barrier system that permits storage for use at a later time.

2.126 transmission-based 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 health care facilities. There are three types of transmission-based precautions: airborne precautions, droplet precautions, and contact precautions.

2.127 treated water: Water that has been filtered, deionized, distilled, or subjected to reverse osmosis to reduce impurities.

2.128 unrestricted area: Area where traffic is not limited and where attire is not prescribed.

2.129 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.

2.130 utility water: Water that comes from the tap, for flushing, washing, or rinsing.

NOTE—See AAMI TIR34 for specifications.

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

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

2.133 washer–disinfector: Mechanical equipment used to wash soiled instruments with water and detergent or other cleaning agent. A microbial destruction process is used for decontamination purposes so the instruments are safe to handle.

2.134 washer–pasteurizer: Mechanical equipment used to wash soiled instruments with water and detergent or other cleaning agent. It also performs pasteurization by exposing the items to hot water at ~ 70°C (158°F) for 30 minutes. This equipment is typically used to reprocess respiratory therapy equipment.

2.135 work practice controls: Safe work practices that reduce the risk of exposure to blood-borne pathogens and other potentially hazardous materials.

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3 Design considerations

3.1 General considerations

This section provides guidance for the design and maintenance of the workplace to facilitate effective and efficient processing, promote personnel safety and standardization of procedures, minimize environmental contamination, and maintain the sterility of processed items. Centralized processing (i.e., decontamination, preparation and packaging) is encouraged in one location, whenever possible. Sterilization is a complex process requiring environmental controls (e.g., controlled air changes, heating, ventilation and air conditioning [HVAC] parameters 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 considerations for chemical sterilization and high-level disinfection processes.

3.2 Work area design and functional workflow

NOTE—See Annex A for illustrations of examples of the functional work areas of a sterile processing area.

3.2.1 Design criteria

3.2.1.1 General considerations

The physical design of the sterile processing department/area should support safe patient care, workplace safety, and security. The health care organization should create a multidisciplinary team that is responsible for the oversight of any sterile processing area construction or renovation project.

During the design phase of the project, the team should determine

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

b) the type of distribution system that will be used (e.g., vertical, horizontal, case cart, exchange cart, par level, requisition);

c) required equipment (e.g., sterilizers, washer–disinfectors, washer–decontaminators, single- or multi-chamber tunnel washers, cart washers, ultrasonic cleaners, automated endoscope processors);

d) space and equipment requirements for processing reusable textiles (e.g., receiving, transporting, collecting, storing);

e) HVAC and other utility requirements, including

- environmental controls and monitoring systems,
- emergency power supply,
- location of instrument air,
- water quality for various decontamination processes and water quality monitoring systems,
- air handling and ventilation requirements,
- communication systems, and
- data lines and power for computers;

f) steam requirements, including

- a facility design that will 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.)

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- total steam demand and the corresponding necessary capacity, and
- a system that will ensure constant steam pressure at all times and under all conditions of steam demand;

g) internal and external communication requirements;

h) information system requirements (e.g., data drops, requisition and dispatch, equipment/instrument tracking, documentation, and record retention);

i) location of support areas;

j) storage requirements (e.g., patient care equipment, packaging material supplies, sterilization process indicators, case carts, sterilizer carts);

k) space and equipment requirements for management of infectious waste, hazardous waste, and recyclable materials;

l) security requirements; and

m) traffic patterns.

NOTE—Not all of the considerations noted above will apply to every health care facility, nor is this intended to be an exhaustive list. It is the responsibility of the multidisciplinary team to determine the needs of that facility.

3.2.1.2 Decontamination area/room

During the design of the decontamination area/room, the team should determine the method(s) of processing and transporting contaminated medical equipment and reusable products to the decontamination area/room.

Design considerations should include

a) whether decontamination will be centralized (performed in one department), decentralized (performed in several departments, such as the OR, the labor–delivery suite, the sterile processing department), or both;

b) containment systems that must meet OSHA standards for contaminated items at the point of use;

c) locations for receipt and holding of medical devices, case carts, and other transport devices that are awaiting processing;

d) methods and equipment (i.e., types and sizes of case carts, soiled pickup carts, elevators, lifts, automated systems) that will be used to transport contaminated items to the decontamination room/area;

e) space for a cart washer or other system for cleaning transportation carts between uses;

f) whether a pass-through system will be included to move equipment and instruments from the decontamination room/area to the clean room/area;

g) space for the collection of disposable medical devices that are sent to a third-party reprocessor;

h) space, location, and utilities for all equipment that will be used;

i) space and location for vertical soaking containers;

j) personnel comfort and safety requirements, including

- a system to separate soiled, in-use bottles of detergents, disinfectants, and other such supplies from extra supplies in storage so that personnel not wearing PPE can acquire the supplies for other areas without being exposed to contaminated items,
- PPE requirements, including space for donning and removing, disposal, and storage;

k) quantity and placement of hand sanitizers and sinks designated only for hand hygiene;

l) provision for the disposal of liquid and solid body wastes;

m) storage requirements, including space for

- decontamination supplies,

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- chemicals,
- environmental cleaning supplies that will be used only in the decontamination area,
- safety data sheets (SDSs) for decontamination chemicals,
- manufacturers' written instructions for use (IFU), and
- linen storage and trash disposal;

n) projected changes in the health care delivery system that might affect the space, equipment, and processing needs of the decontamination room/area.

NOTE—Not all of the considerations noted above will apply to every health care facility, nor is this intended to be an exhaustive list. It is the responsibility of the multidisciplinary team to determine the needs of that facility. Smaller facilities might only have a decontamination area, not a dedicated room.

3.2.2 Functional workflow patterns

The sterile processing department/area should include

a) functionally separate areas within the decontamination area/room for
   - receipt and processing of contaminated items that require terminal sterilization after decontamination,
   - receipt and processing of contaminated items for which the decontamination process incorporates disinfection procedures (i.e., terminal sterilization is not required),
   - receipt and processing of equipment (e.g., powered equipment) that require manual disinfection after cleaning;

b) a designated, separate clean work room for packaging, sterilization, and storage of clean items;

c) walls or partitions between functional work areas to control contaminants generated during the phases of reprocessing;

d) adequate space for all functions and equipment, with related functions in close proximity to maximize efficiency;

e) systems to contain contaminants and minimize employee exposure to bloodborne and other potentially infectious organisms; and

f) a workflow pattern that allows items to move progressively from being contaminated to being safe to handle, whether manually (i.e., a pass-through window) or via mechanical cleaning equipment.

In hospitals, the decontamination area/room and the packaging, sterilization, and sterile storage rooms should be in physically separate rooms. In ambulatory surgery and office-based surgical facilities where separate rooms might not be possible, the decontamination sink should be separated from the clean work area by either a 4-foot distance from the edge of the sink or a separating wall or screen. If a screen is used, it should extend a minimum of 4 feet above the sink rim. (Facilities Guidelines Institute, 2014*)*.

Figure 1 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 amount of 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 might not be feasible for existing facilities 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.

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3.2.3 Traffic control

Traffic patterns should be designed to facilitate movement of personnel, equipment, and supplies into, through, and out of defined areas within the sterile processing department/area. The sterile processing department/area design should include two designated areas that are defined by the activities performed in each area:

- **Unrestricted areas:** These areas include locker rooms, break rooms, meeting rooms, offices, and sterilizer service access rooms. Street clothes are permitted in these areas. Public access to these areas may be limited based on the facility's policies and procedures. The specific areas where food and drink are permitted (e.g., break rooms, meeting rooms, offices) should be identified in the facility's policies and procedures.
- **Restricted areas:** Areas in which decontamination, preparation and packaging, sterilization processing, sterile storage, and distribution are carried out. Personnel in the restricted areas should wear surgical attire and cover head and facial hair. Only authorized personnel and visitors accompanied by authorized personnel should be admitted to this area.

Written policies and procedures regarding traffic control should

a) limit access to restricted areas to authorized personnel;

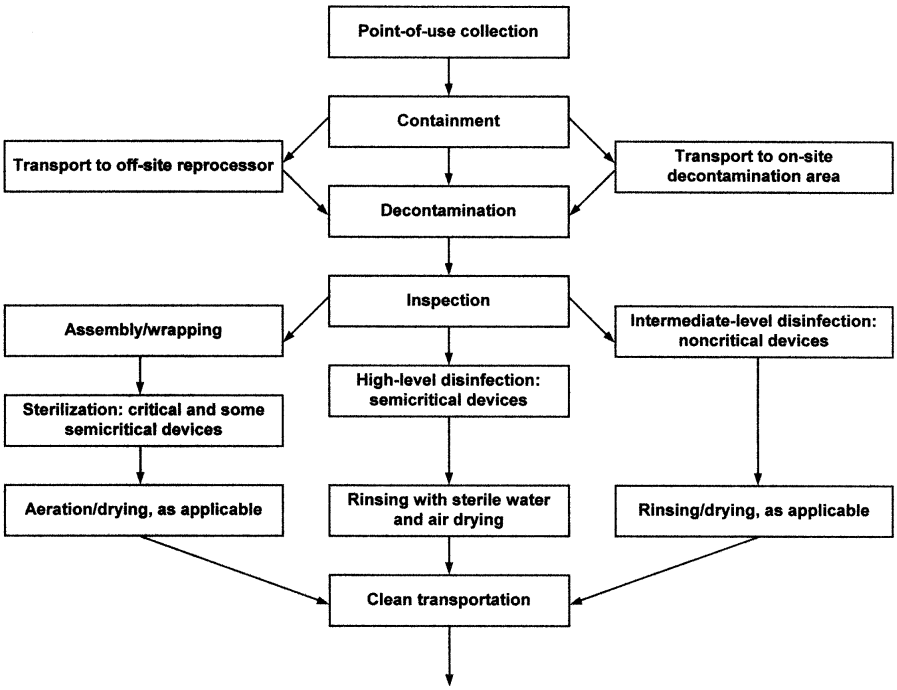
b) specify criteria for authorized entry, movement within processing areas, and attire;

c) establish a dress code for all personnel and visitors who enter restricted areas (see also 4.5); and

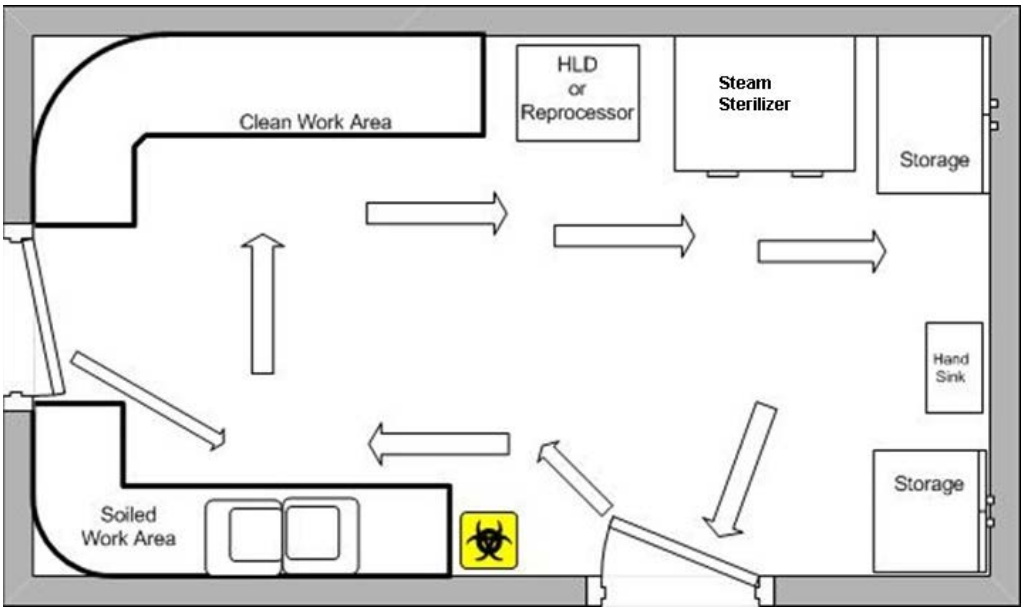
d) specify the responsibility and authority for enforcing traffic-control policies and procedures.

Rationale: Personnel and visitors can carry microorganisms into processing areas, thus increasing the potential for environmental contaminants in these areas. It is important to protect personnel and visitors from the microorganisms present on contaminated items being processed in the decontamination area.

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(a) Workflow in a sterile processing area
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(b) Workflow in an office-based practice

Figure 1—Workflow

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3.3 Utilities

3.3.1 Mechanical systems

A multidisciplinary team should collaborate to determine any mechanical system needs, including

a) pressurized systems such as instrument air;

b) vacuum systems; and

c) distilled or deionized water systems.

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.

3.3.2 Electrical systems

Electrical engineers and operations managers should collaborate to design electrical systems that

a) allow for the safe and effective operation of the equipment (e.g., cleaning equipment, sterilization equipment, computers, telephones, lighting) used in the sterile processing department;

b) allow for the emergency power service of the facility to be extended to include processing equipment; and

c) provide uninterrupted power sources to all critical equipment.

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

3.3.3 Steam for sterile processing

3.3.3.1 General considerations

The system for steam delivery should be designed, monitored, and maintained to ensure that the quality, purity, and quantity of the steam provided are appropriate for effective sterile processing. There are two common sources for steam used for sterile processing: hospital steam boiler systems and self-contained electric boilers. Both systems should include a treated water supply to remove total dissolved solids. See AAMI TIR34:2014, *Water for reprocessing of medical devices*.

Steam sterilizers having a chamber volume less than or equal to 2 cubic feet generate their own steam. The user should follow the sterilizer manufacturer's written IFU regarding water purity requirements, filling, draining, and general maintenance of the system. Distilled or deionized water might be 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 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.

3.3.3.2 Steam quality

Facility engineering personnel should ensure steam quality by

a) monitoring, controlling, and documenting the process of generating steam;

b) testing steam against the following critical variables:

- steam dryness between 97% and 100%,
- noncondensable gases (e.g., air) at a level (less than 3.5% v/v condensate) that will not impair steam penetration into sterilization loads,
- superheat of steam (expressed as a temperature in degrees above saturation point) of less than 25°C (77°F);

c) maintaining steam traps and boilers/generators; and

d) assessing and documenting the steam quality upon installation or relocation of the sterilizer and after any change to the steam distribution lines or boiler supply water.

Rationale: Steam that is too dry can contribute to superheating and, consequently, to suboptimal steam sterilization conditions. Steam that is too wet can lead to wet packs after sterilization and compromise sterility.

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3.3.3.3 Steam purity

To maintain steam purity and minimize the presence of potential contaminants in the steam, facility engineering personnel should

a) treat the feedwater with boiler additives and/or feedwater conditioners so that its condition and/or chemistry do not damage the boiler or steam lines;

b) monitor boiler additives and feedwater conditioners;

c) use only additives and conditioners approved for use in the food and drug industries (21 CFR 173.310 and 21 CFR 200.11);

d) install in-line filters that are as close to the sterilizer as possible and include a drip leg or trap for condensate material; and

e) develop procedures to monitor steam purity and provide corrective action.

Facilities should not

a) use boiler additives and feedwater conditioners on a batch basis;

b) add boiler additives or feedwater conditioners to the steam in the steam distribution system; or

c) use amines for conditioning steam lines (as opposed to the use of amines in feedwater treatment).

Rationale: It is important that boiler additives and feedwater conditioners be monitored to prevent carryover of excessive chemicals into the steam used for sterilization. Additives can cause pack and instrument staining and/or instrument damage. Amines can stain packaged items within the sterilizer.

3.3.3.4 Monitoring steam systems

Health care facilities should provide 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 3.3.3.3 and Annex L.) 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 3.3.3.1.

3.3.4 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.

3.3.5 General facility design requirements

All surfaces (e.g., floors, walls, ceilings, cabinets) should be durable, smooth, and cleanable. Unless otherwise stated in 3.3.7, all processing work areas should conform to the following recommendations.

Rationale: Surfaces that are durable, smooth, and cleanable allow for ease of cleaning and assist in preventing buildup of dirt and debris in crevices.

3.3.5.1 Floors

Floors should

a) be level (i.e., should have no ridges or bumps);

b) be constructed of non particulate- or non-fiber shedding materials that will withstand daily or more frequent wet cleaning and the application of chemical cleaning agents; and

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c) be uncarpeted in restricted areas.

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.

3.3.5.2 Walls

Walls should

a) be constructed of non particulate- or non-fiber shedding materials that will withstand frequent cleaning; and

b) be designed to protect from cart and other equipment impacts.

Rationale: All surfaces in work areas are subject to spills and splashing and should be regularly and thoroughly cleaned to control microbial contamination and to eliminate accumulated dust, which could act as a carrier for microorganisms. 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.

3.3.5.3 Ceilings

Restricted-area ceilings should

a) be constructed to create a flush surface with recessed, enclosed fixtures;

b) enclose pipes and duct work above work areas; and

c) 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.

3.3.5.4 Doors

Doors should

a) be made of a durable material that can withstand impacts from back tables and carts and that can be cleaned frequently; and

b) open easily following the one-way directional workflow and should not have thresholds.

Rationale: Carts and other equipment 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.

3.3.5.5 Heating, ventilation, and air conditioning (HVAC) operating parameters

The health care organization should identify which version of ANSI/ASHRAE/ASHE 170 will be used based on when the HVAC system was initially installed or last upgraded. The health care facility should establish and implement systematic processes for monitoring HVAC performance parameters and a mechanism for identifying and resolving variances within the rooms throughout the facility where sterile processing occurs.

Facility engineering personnel or designated responsible personnel should establish policies and procedures for monitoring and maintaining HVAC parameters within the sterile processing areas. Procedures should include maintaining records of monitoring results that are retrievable either from a central system or a local log.

If a variance in the HVAC parameters occurs, sterile processing personnel in combination with a multidisciplinary team (e.g., facility engineer, infection preventionist, risk manager, sterile processing manager or other designated personnel) should conduct a risk assessment. The sterile processing department is defined by ANSI/ASHRAE/ASHE 170 as a critical area.

See also Annex Q.

Rationale: The effect of the HVAC system parameters falling out of range is variable. A small variance for a short period of time might not be of clinical concern, whereas a large variance for a longer period could have clinical significance. A risk assessment provides necessary information to guide appropriate response measures.

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3.3.5.6 Lighting

Adequate lighting of work surfaces should be provided in accordance with the recommendations of the Illuminating Engineering Society of North America (IES) for minimum levels of illuminance for various categories of work environments (Table 1) (Rea, 1993).

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)

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)

d) An illumination engineer, in consultation with the department manager, should determine the appropriate illuminance for each work area within the processing area. Generally, all functions performed within a processing area 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.

NOTE—Large areas of stainless steel surfaces found in sterile processing areas can affect lighting. The amount of stainless steel typically used in a processing area is enough to turn a warm color cool; therefore, the lighting should take into account the types of materials in the area.

Table 1—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)

Rationale: Adequate lighting is essential to the proper performance of decontamination, preparation, inspection, and other processing tasks.

3.3.5.7 Handwashing stations

Handwashing stations (sinks and waterless alcohol-based hand rub dispensers) should

a) 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);

b) be considered in the design or renovation of a sterile processing department/area; and

c) have a backup system for operation during power outages, if electronic sensors are used.

NOTE—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. Alcohol-based hand hygiene agents must have an alcohol concentration of 60% to 95% to be effective. State regulations might dictate when and where such agents may be used and placed within the facility.

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Rationale: The availability of handwashing stations in work areas can help increase compliance with hand hygiene policies and procedures. 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.

3.3.6 Special area requirements and restrictions

3.3.6.1 Decontamination area/room

3.3.6.1.1 Design considerations

The decontamination area/room should

a) be physically separate from all other processing areas and from areas in which clean or sterilization procedures are carried out, with any connecting doors and pass-through windows remaining closed.

NOTE—In non-hospital health care facilities, clinics, and dental or medical offices, it might not be possible to physically separate the decontamination area from the clean work 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; that work practices promote the changing of PPE when personnel complete decontamination activities and perform clean (e.g., high-level disinfection) activities; and that ventilation and air-handling systems move air from the clean side of the room to the decontamination side of the room and not the reverse.

b) be accessible from a service corridor;

c) have a door providing access to the clean work room (a pass-through window is also convenient for delicate instrumentation and water-sensitive equipment that have been manually decontaminated);

d) have three-section sinks that

- are approximately 36 inches (91 centimeters [cm]) from the floor and 8 to 10 inches (20 to 25 cm) deep;
- include attached solid counters or adjacent work surfaces on which to place soiled and clean items separately; and
- are large enough to allow a tray or container basket of instruments to be placed flat for pretreatment or manual cleaning;

and have two-section sinks available for soaking and rinsing prior to cleaning;

e) have instrument air available;

f) have recessed and sealed lights and other fixtures to prevent the accumulation of dust or soil and to facilitate cleaning;

g) have a source of critical water for final rinsing (see AAMI TIR34).

h) have a lift dedicated to the transport of contaminated items, if applicable; and

i) be designed for 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.

Rationale: Airborne microbial and particulate contamination is likely to be high in the decontamination area/room 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.

3.3.6.1.2 Space considerations

The decontamination room/area should include designated space for

a) record-keeping;

b) storage of PPE, cleaning supplies, record-keeping, and cleaning verification supplies;

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c) trash containers for nonregulated waste (paper towels, wrappers);

d) OSHA or EPA compliant containers for regulated waste (blood and body substances);

e) containers for collection for devices for third-party reprocessing and sharps;

f) hampers for soiled linen;

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

h) ultrasonic cleaning devices, automatic washer accessories (e.g., ultrasonic cleaning solution, detergents, loading baskets, carts, and equipment);

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

j) processing patient care equipment;

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

l) hazardous waste disposal systems;

m) computers; and

n) the receipt of loaned instrumentation.

Rationale: Designing the room to provide adequate space for necessary equipment reduces the potential for cross-contamination and enhances safe work practices and efficiency.

3.3.6.1.3 Ergonomic considerations

Ergonomic factors affecting worker safety and comfort should be considered when designing work spaces in the decontamination area, including

a) adjustable counters, sinks, and work surfaces positioned at heights that take into account the average height of the employees and the tasks to be performed at each location;

b) adequate space to maneuver, queue, and unload carts or other transportation means at times of average daily peak workload; and

c) anti-fatigue mats, constructed of materials capable of withstanding frequent cleaning, in areas where prolonged standing is required.

Rationale: Considering human factors during the design phase can help prevent worker injury.

3.3.6.2 Clean work area/room

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

Preparation of textile packs and of individual wrapped textiles, when performed in the clean work area/room, should be carried out in an enclosed space separate from the remainder of the clean work area/room. 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 (3.3.5.5). 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.

The clean work area/room should include space for

a) storage of attire for visitors (e.g., head covers, cover gowns);

b) supplies for cleaning the preparation area (e.g., detergents, towels);

c) monitoring and record-keeping supplies (e.g., sterilization process monitoring devices, log books);

d) packaging materials and preparation supplies (e.g., cotton balls, gauze dressing, tip protectors);

e) computers, if used, along with computer accessories (e.g., printer, bar code printer, scanner data ports);

f) incubators for BIs;

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g) magnifying lights;

h) heat sealers;

i) instrument storage and repair boxes;

j) transfer carts;

k) processing tables, which should be made of nonporous materials (e.g., stainless steel), ergonomic, and, preferably, height-adjustable;

l) a station for instrument lubrication;

m) testing equipment;

n) battery rechargers; and

o) handwashing stations.

Rationale: Lint and airborne particles can carry microorganisms. A relatively lint-free environment is also important to the comfort and safety of employees. 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.

3.3.6.3 Sterilization area

The sterilization area should

a) be a designated area located within the clean work room;

b) be designed so that material flows from the preparation and packaging area to the sterilization area and then on to sterile storage or distribution;

c) allow space for all methods of sterilization; the staging and loading of sterilizer carts; the storage of long, heat-resistant gloves, sterilizer cleaning supplies, and record-keeping supplies; and handwashing stations; and

d) provide a holding area for load cooling on sterilizer carts.

Sterilizers should be located in a restricted-access area and not 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.

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 sterilizer manufacturer's written IFU.

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.

The ventilation system should be designed to meet design recommendations and be consistent with equipment manufacturers' recommended environmental operating conditions (Facility Guidelines Institute, 2014). Improperly designed sterilization work areas or improperly installed equipment can expose personnel to occupational hazards.

3.3.6.4 Sterile storage

The sterile storage room 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 area is intended to store sterile and clean products that have been removed from the external shipping containers. See also 11.1.

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

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attention is given to traffic control, area ventilation, and housekeeping. Storage areas should be designed to protect sterile items and their packaging from damage.

See 3.3.5.5 for temperature values. When supplies sensitive to extremes of relative humidity (RH) are stored in the room, the relative humidity should be maintained at the level recommended by the product manufacturer.

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. Some products commonly used within the SPD are sensitive to variations in environmental conditions. Manufacturers of biological indicators (BIs) and chemical indicators (CIs) commonly recommend that these products be stored in locations where the RH does not fall below 30%.

3.3.6.5 Breakout area/room

A breakout area/room should be located near or adjacent to a surgical or supply processing department. The purpose of this area/room is to remove items from external shipping cartons, as shipping cartons can harbor and transport dust and debris that should not enter a sterile processing department.

Rationale: To eliminate the risk of introducing contaminants that could be present on external shipping cartons, these cartons should not be permitted in clean/sterile storage areas/rooms. External shipping containers and web-edged (corrugated) boxes can collect dust, debris, and insects during shipment and can carry contaminants into the area.

3.3.7 Emergency eyewash/shower equipment

Eyewash/shower equipment must be available within 10 seconds' travel time, with unobstructed access, for immediate emergency use in all locations where potentially damaging chemicals (e.g., corrosive cleaning solutions) are used. When the chemical is not corrosive, one intervening door can be present, provided that it opens in the same direction of travel as the person attempting to reach the emergency eyewash/shower equipment and the door is equipped with a closing mechanism that cannot be locked to impede access to the equipment.

The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units and shower equipment (ANSI/ISEA Z358.1). ANSI/ISEA 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. The eyewash facilities should be identified with a highly visible sign, should be maintained in accordance with the manufacturer's written IFU, 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.

Eyewash stations should not be in a location that requires flushing of the eyes in a decontamination sink.

Plumbed eyewashes/facewashes and showers should be activated weekly for a period long enough to verify operation and ensure that the flushing solution is available. When activating plumbed eyewashes, eye/face washes, and showers, personnel should also verify that they are providing lukewarm, tepid water (between 15°C and 43°C [60°F and 100°F]). (ANSI/ISEA Z358.1) Routine testing should be documented.

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/ISEA Z358.1.

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4 Personnel considerations

4.1 General considerations

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 sterile processing be performed and supervised by qualified personnel. Other personnel considerations addressed in this section are key elements in minimizing bioburden and containing environmental contamination, which are essential for effective medical device reprocessing.

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 sterile processing management certification examination;

NOTE—Information concerning certification of sterile processing managers and technicians can be obtained from the Certification Board for Sterile Processing and Distribution (CBSPD) (http://www.sterileprocessing.org), and the International Association of Healthcare Central Service Materiel Management (http://www.iahcsmm.org).

b) demonstration of current knowledge and adequate relevant experience in health-care-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 and transmission-based precautions, and engineering and work-practice controls.

Supervisory personnel should maintain competency throughout their tenure through

1) participation in continuing education programs and courses;

2) participation in facility and departmental in-service and training programs; and

3) demonstration of and improvement of 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 reprocessing 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 precautions. Participation in multidisciplinary committees within the health care facility can help avoid purchases of items that cannot be reprocessed by equipment currently available in the sterile processing area. Certification is a recognized method of competency verification.

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, including biohazard transportation, decontamination, preparation, packaging, sterilization, sterile storage, and distribution of sterile medical devices. Qualifications include demonstrated knowledge of and documented competence in

a) all aspects of decontamination, including sorting, disassembly/reassembly, manual and mechanical cleaning methods, microbicidal processes, equipment operation, standard and transmission-based precautions, and engineering and work-practice controls;

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

c) the 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) worker safety as it relates to medical device processing and sterilization.

All personnel performing sterile processing activities should be certified 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 Education and training

4.3.1 Sterile processing personnel

Sterile processing personnel should receive

a) an initial orientation covering all tasks performed in the sterile processing area, including orientation in policies and procedures regarding infection prevention and control, safety, attire, personal hygiene, and compliance with state and federal regulations;

b) continuing education at regular intervals to review and update knowledge and skills and to maintain competency and certification; and

c) in-service training on all new instrumentation, devices, and equipment.

The health care facility should have a written standardized program that includes

1) aspects of education and training related to facility policies and procedures;

2) tools to document that education and training were performed and competency was verified; and

3) the facility's policies and procedures, accepted standards of practice, and manufacturers' recommendations.

Rationale: Orientation, education, and training provide workers with essential information to perform their assigned responsibilities. Education, training, and standardized work practices decrease the risk of operator error during reprocessing and help ensure that personnel are conversant with the latest data and techniques. Education and training are an important aspect 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. The health care organization's 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 education and training is required by accrediting agencies.

4.3.2 Service personnel

Education and training programs for service personnel should include

a) information on the hazards associated with blood-borne pathogens;

b) the requirements of the OSHA standard on occupational exposure to blood-borne pathogens (29 CFR 1910.1030);

c) the requirements of the OSHA Hazard Communication Standard (29 CFR 1910.1200);

d) the importance of vaccinations as protective measures;

e) standard and transmission-based precautions;

f) protective work practices;

g) the use of PPE;

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h) emergency procedures; and

i) procedures to follow if an exposure occurs.

Rationale: Education and training are 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 safety, attire, and other aspects related to their assigned responsibilities.

Rationale: In some health care facilities, the sterile storage area is not attended by sterile processing personnel 24 hours a day. It could be necessary for personnel from other departments to have access. It is important that these personnel comply with the same attire and supply-handling procedures as do personnel regularly assigned to the sterile processing area.

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 personnel, the office safety manager, or the designated person in charge of employee health.

Personnel should be instructed regarding hand hygiene techniques, including the following:

a) Washing hands 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

b) Decontaminating not visibly soiled hands with alcohol-based, waterless hand hygiene agents containing emollients

Personnel should comply with facility guidance on hand hygiene. 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 (CDC, 2002a; CDC, 2003; AORN, 2017f).

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. Personnel who can potentially come into contact with items contaminated with blood or body fluids (i.e., are at risk of 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 pathogenic micro-organisms under the nails (Baumgardner, et al., 1993; CDC, 2002a; CDC, 2003; Jeanes and Green, 2001; Porteous, 2002; Salman, et al., 2002; WHO, 2000).

4.5 Attire

4.5.1 General considerations

Persons entering the restricted areas within the sterile processing area should wear clean surgical attire that is provided by and donned at the health care facility. (AORN, 2017f).

Recommendations regarding attire include the following:

a) Surgical attire should be laundered after each use in a health-care-accredited laundry facility.

b) Attire should be changed daily or more often as needed (i.e., when wet, grossly soiled, or visibly contaminated with blood or other bodily fluids).

c) Reusable uniforms that are visibly contaminated by blood or other potentially infectious material must be laundered in the laundry facility or area designated by the health care facility for the decontamination of reusable surgical textiles 29 CFR 1910.1030).

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d) Shoes worn in the area should be clean, closed (i.e., no open toes or other areas), have non-skid soles, and be sturdy enough to prevent injury if an item drops on the foot.

e) All head and facial hair (except for eyebrows and eyelashes) should be completely covered.

f) Personnel should not wear jewelry (e.g., rings, watches, bracelets) on the hands or wrists.

g) Personal electronic devices should not be brought into the processing areas. Exceptions should be noted in the organization's policies.

h) The policy on use of cover apparel when employees leave the department to travel to other areas of the health care facility should be determined by each facility and should comply with state and local regulations.

i) Personnel should change into street clothes whenever they leave the health care facility or when traveling between buildings or 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 is not easily or routinely cleaned daily, can harbor microorganisms, can become dislodged and fall into processed items, and 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. Personal electronic devices could become contaminated in the decontamination area.

4.5.2 Decontamination area/room

When personnel are performing decontamination activities, PPE is required. The OSHA Bloodborne Pathogens Standard (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 post-exposure medical care procedures that will be used to maintain the safety and health of employees. In the decontamination area/room, these measures will include the use of PPE.

In addition to the attire recommended in 4.5.1, personnel working in the decontamination area/room should wear PPE including

a) utility gloves that are fitted at the wrist, prevent contact of the wearer's skin with contaminated water, and have cuffs that extend beyond the cuff of the gown;

NOTE—A medical examination glove should not be used in decontamination, as it is not puncture- or cut-resistant.

b) a liquid-resistant covering with sleeves (e.g., a backless protective gown, jumpsuit, or surgical gown);

c) liquid-resistant shoe covers if there is potential for shoes becoming contaminated and/or soaked with blood or other bodily fluids;

d) a fluid-resistant face mask and eye protection if there is anticipated risk of splash or splatter; and

e) eye protection, which may 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 IFU, at least daily and between employees. If their integrity is compromised, they should be discarded. Torn gloves should be removed immediately, appropriate hand hygiene performed, and replacement gloves donned. Items worn or used in the decontamination area/room should be regarded as contaminated.

Before leaving the decontamination area/room, personnel should remove all protective attire, being careful not to contaminate the clothing beneath or their skin, and wash their hands. Designated areas for donning and removing protective attire should be provided.

Personnel should use a style of glove that prevents contact with contaminated water; for example, gloves that are too short allow water to enter when the arms move up and down.

General-purpose utility gloves may be decontaminated and reused in accordance with the manufacturer's written IFU. They should be discarded if there is evidence of deterioration (e.g., punctures, peeling, or cracking).

Fluid-resistant face masks should be worn by personnel cleaning contaminated items.

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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. PPE will minimize the potential for occupational exposure to blood-borne and other disease-producing organisms.

Wearing heavy-duty, waterproof gloves while handling contaminated items 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; hand hygiene can help prevent any further contamination of the worker or environment.

When the integrity of reusable gloves, aprons, or protective eyewear is compromised, they cease to function as a protective barrier.

Fluid-resistant face masks can help protect personnel from splash or splatter that could contain pathogens. 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.

NOTE—ANSI/AAMI PB70, *Liquid barrier performance and classification of protective apparel and drape intended for use in health care facilities*, provides further guidance for PPE, including that for decontamination personnel.

4.6 Standard and transmission-based precautions

Standard precautions should be practiced by all processing personnel involved in sterilization processes. In addition, when required, processing personnel should practice transmission-based precautions.

Standard precautions are primary strategies for preventing transmission of health-care-associated infections. Standard precautions emphasize the use of PPE based on the assessed risk of exposure to blood and other potentially infectious materials and hand hygiene.

Rationale: Standard precautions represent a philosophy that assumes that all patients are potentially infectious. Standard precautions apply to all body fluids, secretions and excretions (except sweat), nonintact skin and mucous membranes. Transmission-based precautions might be necessary to prevent the transmission of specific diseases or microorganisms that are spread by contact, droplet, and airborne transmission.

Standard precautions contain key elements of infection prevention and control practices, such as hand hygiene and wearing PPE. When required, transmission-based precautions supplement standard precautions, infection prevention and control practices such as hand hygiene and wearing PPE to avoid contact with contaminated items, blood, or other bodily 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 Bloodborne Pathogens Standard (29 CFR 1910.1030) includes the following requirements:

a) Precautions must be taken to prevent injuries from sharp objects (e.g., needles, scalpels, broken glass).

b) Contaminated needles should not be recapped. When performed, recapping must be done by using a mechanical device designed to hold the needle during one-handed recapping, a one-handed scoop technique, or an engineered sharps injury protection device.

c) Needles must not be bent, broken, or manipulated by hand.

d) Sharps must be placed in puncture-resistant sharps containers that are OSHA compliant.

e) Appropriate PPE must be used to prevent exposure to blood and other potentially infectious materials.

f) Hands and other skin surfaces that are contaminated with potentially infectious fluids must be immediately and thoroughly washed.

g) 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.

h) 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.

i) Health care personnel who are occupationally exposed to blood or other potentially infectious materials must receive training before assignment to tasks where occupational exposure may occur, at least annually thereafter, and when changes to procedures or tasks affect occupational exposure.

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5 Receiving

5.1 General considerations

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

5.2 Receiving of purchased or loaned items

5.2.1 General considerations

Policies and procedures for the receipt of purchased or loaned items should be developed, implemented, and audited. Audits should be scheduled and documented.

When loaned items are delivered to the receiving area, personnel should document that according to the packing slip, the correct number of packages has been received.

The unopened packaged items, along with any IFU accompanying the items, should be delivered to the sterile processing/decontamination area as soon as possible.

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 sterile processing and storage areas within the facility should be removed from their external shipping containers before they enter the storage areas.

Rationale: External shipping containers could 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 New, repaired, and refurbished reusable items

Before use in a health care facility, new, repaired, and refurbished instruments should be examined, cleaned, and sterilized according to the manufacturers' written IFU. When new, repaired, or refurbished instruments are received into a facility, all moving parts (e.g., tips, box locks, ratchets, screws, and cutting edges) should be examined for defects and to ensure proper working order.

When indicated, new instruments should be pretreated according to the manufacturer's written IFU.

Rationale: Inspecting the instrument helps to verify that the instrument has no obvious defects and has not sustained damage during shipping; if it do not meet the required specifications, it can be returned to the manufacturer. 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. Cleaning can help to reduce the bioburden and ensure that sterility can be achieved. 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 could interfere with sterilization if they are not removed.

5.2.3 Loaned or borrowed instrumentation

5.2.3.1 Formalized program

A formalized program between the health care organization and health care industry representatives should be established for the receipt and use of loaned instrumentation.

Rationale: Implementation of tracking and quality controls and procedures is necessary to manage instrumentation and implants that are brought in from outside organizations and companies. The systematic management of loaned instrumentation reduces loss and ensures proper decontamination and sterilization through increased collaboration, communication, and accountability.

5.2.3.2 Loaned instrumentation policy

The loaned instrumentation policy should include processes to

a) request loaned instrumentation or implants in sufficient time to process them upon receipt;

b) receive loaned items, including a detailed inventory list;

c) log in and inventory loaned instruments within the receiving facility before use;

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d) obtain manufacturers' written IFU before the loaned items are received;

e) determine responsibility for ensuring that sets weigh no more than 25 pounds;

f) clean, decontaminate, and sterilize loaned instrumentation at the receiving facility;

g) quarantine any loaned instrument sets containing implants until a negative BI result is obtained for the sterilization cycle;

h) transport processed loaned instrumentation to the point of use;

i) return items to the sterile processing area after the surgical procedure for decontamination, reprocessing, inventorying, and return to the lender; and

j) maintain records of transactions.

Rationale: Advanced delivery of instructions for cleaning, packaging, and sterilizing is useful in determining whether a facility has the required equipment and resources to process loaned instruments according to the device manufacturer's written IFU. Advanced delivery of loaned items to the receiving health care organization ensures sufficient time to permit in-house disassembly, cleaning, packaging, quality assurance testing, and sterilization of the instruments before scheduled procedures.

5.2.3.3 Avoiding the need for immediate-use steam sterilization

Personnel requesting loaned items should specify quantities, estimated time of use and return, and restocking requirements to circumvent the need for immediate-use steam sterilization (IUSS). Late receipt of loaned instruments should not be used to justify IUSS.

5.2.3.4 Decontamination of loaned instruments

Sterility assurance related to loaned instruments should begin at the point at which the health care organization assumes responsibility for the items. All loaned instruments, regardless of whether they were processed in another health care facility, should be considered contaminated and delivered directly to the sterile processing area for decontamination. Instruments should be thoroughly cleaned and dried before sterilization.

Rationale: It is not possible to know under what conditions instruments were processed at another facility. Sterilized instruments may become contaminated during transport.

Newly manufactured loaned items should be decontaminated before sterilization to remove bioburden and substances (e.g., oil, grease) that may remain on the item from the manufacturing process.

Loaned instruments should be removed from external shipping containers before transport to the sterile processing area. External shipping containers may have potentially high microbial contamination because of environmental exposure during transport.

5.2.4 Rigid sterilization container systems

Each rigid sterilization container system should be thoroughly inspected upon receipt to verify that

a) all gaskets are free of breaks, cracks, or cuts and that each gasket is secured and mates evenly at joining surfaces;

b) all filter material completely covers the perforated area, and the device holding the filter in place provides a secure, uniform mating surface that keeps the filter from dislodging;

c) the latching mechanism secures 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 function properly and move freely with no sign of damage; and

e) sealed rivets and screws are secure and show no evidence of damage or corrosion.

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

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

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5.2.5 Disposable items

After removal from 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 have been otherwise protected from contamination during transport. Disposable items 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 the decontamination area in accordance with facility 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 IFU for reprocessing and all FDA requirements for the reprocessing of single-use items are met.

Unused items returned from the OR or other areas of the facility 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

a) discarded unless the packaging is intact, impervious, and the previous storage conditions are known and did not compromise the package integrity; and

b) 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 is 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 need to be used as soon 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 may occur.

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6 Handling, collection, and transport of contaminated items

6.1 General considerations

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 personnel, to protect personnel, patients, and the environment from contamination and to comply with OSHA regulations limiting occupational exposure to blood-borne pathogens (29 CFR Part 1910.1030).

The health care facility should

a) perform a risk analysis to ensure that the procedures are being followed;

b) develop action plans to address problems noted during the analysis; and

c) schedule a follow-up analysis to help ensure that the problems have been corrected.

6.2 Separation of waste and reusable items at point of use

At the point of use,

a) items should be separated into reusable items, single-use disposable items, and waste categories;

b) disposable items should be separated by waste categories and disposed of in accordance with all federal, state, and local regulations; and

c) sharps must be placed in puncture-resistant sharps containers that are OSHA compliant.

Contaminated items should be handled as little as possible. Contaminated reusable items should be contained

a) in such a way that the contents of the containers are readily identifiable as contaminated by everyone who subsequently handles the items; and

b) in a containment device that complies with the health care facility's established infection prevention and control and hazardous waste management procedures.

Health care facilities should develop and follow procedures that reduce the potential for contamination of personnel, their clothing, and the environment, including the following:

a) 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 Annex E).

b) Handling of waste might require PPE (see 4.5).

c) Other measures might also be adopted for infection prevention and control purposes or as part of hazardous waste management.

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. 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 help 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

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contamination of the environment. Disposable items must be placed in an OSHA or EPA compliant biohazard container.

6.3 Point-of-use care and handling of contaminated reusable items

6.3.1 Handling of instruments during surgical procedure

Throughout the surgical or invasive procedure,

a) instruments should be wiped, as needed, with sterile moistened surgical sponges to remove gross soil; and

b) cannulated instruments or instruments with lumens should be irrigated with sterile water, as needed, without creating aerosols.

Rationale: Blood, other bodily fluids, and saline are highly corrosive and can cause pitting of instruments. If left to dry, they can be difficult to remove and can prevent sterilization. Cannulated instruments or instruments with lumens can become obstructed with organic material. Irrigating these instruments with sterile water helps remove residue.

Preparation for decontamination of instruments should begin at the point of use. To prevent the formation of biofilm and to reduce the risk of corrosion, cleaning and decontamination should occur as soon as possible after instruments and equipment are used.

NOTE—Some microorganisms have the ability to adhere to a surface and then exude over themselves a polysaccharide matrix. 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 area and of preventing antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching the microbial cells. 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 the population of microorganisms and thus helps to prevent the formation of biofilm.

6.3.2 Removal of gross soil

Gross soil should be removed as soon as possible to

a) reduce the number of microorganisms on the item;

b) reduce the nutrient material that supports microbial growth;

c) prevent it from drying on;

d) reduce the potential for environmental contamination by aerosolization or spillage;

e) remove all disposables including disposable sharps; and

f) minimize corrosion risk and 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.

Rationale: Removing gross soil and moistening soil at the point of use improves the efficiency and effectiveness of decontamination and might extend the life of the instrument.

6.3.3 Instruments opened but not used

All instruments opened in the operating or procedure room should be considered contaminated whether or not they have been used.

Rationale: Scrubbed persons might touch instruments without being aware of it. Used instruments also might come in contact with other instruments.

6.3.4 Disassembly of instruments

When instruments are composed of more than one piece, they should be opened, disassembled according to the manufacturer's written IFU, and arranged in an orderly fashion.

Rationale: Disassembling and opening of instruments followed by their placement into the original set configuration minimizes the risk of instrument displacement and improves the efficiency of reprocessing.

6.3.5 Prevention of instrument damage

After precleaning at the point of use, personnel should

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