



ANSI/AAMI ST79:2017

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

**American
National
Standard**

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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Contents

Page

Glossary of equivalent standards	ix
Committee representation	xii
Foreword	xv
Introduction: Need for the recommended practice	1
1 Scope	3
1.1 General	3
1.2 Inclusions	3
1.3 Exclusions	3
2 Definitions and abbreviations	4
3 Design considerations	12
3.1 General considerations	12
3.2 Work area design and functional workflow	12
3.2.1 Design criteria	12
3.2.2 Functional workflow patterns	14
3.2.3 Traffic control	15
3.3 Utilities	17
3.3.1 Mechanical systems	17
3.3.2 Electrical systems	17
3.3.3 Steam for sterile processing	17
3.3.4 Utility monitoring and alarm systems	18
3.3.5 General facility design requirements	18
3.3.6 Special area requirements and restrictions	21
3.3.7 Emergency eyewash/shower equipment	24
4 Personnel considerations	25
4.1 General considerations	25
4.2 Qualifications	25
4.2.1 Supervisory personnel	25
4.2.2 Sterile processing personnel	25
4.3 Education and training	26
4.3.1 Sterile processing personnel	26
4.3.2 Service personnel	26
4.3.3 Other personnel	27
4.4 Health and personal hygiene	27
4.5 Attire	27
4.5.1 General considerations	27
4.5.2 Decontamination area/room	28
4.6 Standard and transmission-based precautions	29
5 Receiving	30
5.1 General considerations	30
5.2 Receiving of purchased or loaned items	30
5.2.1 General considerations	30
5.2.2 New, repaired, and refurbished reusable items	30
5.2.3 Loaned or borrowed instrumentation	30
5.2.4 Rigid sterilization container systems	31
5.2.5 Disposable items	32
5.3 Disposition of sterile items (issued but not used)	32
6 Handling, collection, and transport of contaminated items	33
6.1 General considerations	33
6.2 Separation of waste and reusable items at point of use	33
6.3 Point-of-use care and handling of contaminated reusable items	34
6.4 Containment	35
6.5 Transport	36

6.5.1	Segregation of clean/sterile items.....	36
6.5.2	Transportation scheduling and routes	36
6.5.3	Transportation equipment.....	36
6.5.4	Hand transport.....	36
6.5.5	Dedicated lifts.....	37
6.5.6	Transport between buildings.....	37
6.5.7	Off-site transportation.....	37
7	Cleaning, disinfection (microbicidal processes), and other decontamination steps	39
7.1	General considerations.....	39
7.2	Policies and procedures	39
7.3	Manufacturer's written IFU.....	40
7.4	Decontamination.....	40
7.4.1	General considerations for all devices and utensils.....	40
7.4.2	Special considerations.....	41
7.5	Preparation for cleaning.....	41
7.5.1	Presoaking.....	41
7.5.2	Sorting and disassembly	41
7.6	Cleaning	43
7.6.1	General considerations.....	43
7.6.2	Devices with lumens.....	44
7.6.3	Cleaning agents.....	44
7.6.4	Methods of cleaning	44
8	Preparation and assembly of instruments.....	50
8.1	General considerations.....	50
8.2	Instruments.....	50
8.3	Devices with lumens.....	51
8.4	Basins and basin sets.....	51
8.5	Textile packs.....	51
9	Packaging.....	52
9.1	General considerations.....	52
9.2	Selection of sterile barrier systems.....	52
9.3	Package labeling	52
9.4	Package closures	53
9.5	Sterilization wrap	53
9.5.1	General considerations.....	53
9.5.2	Woven wraps.....	53
9.5.3	Nonwoven wraps.....	53
9.5.4	Paper-plastic pouches	54
9.6	Wrapping techniques.....	55
9.6.1	Simultaneous double-wrapping: envelope fold.....	55
9.6.2	Simultaneous double-wrapping: square fold.....	56
9.6.3	Sequential wrapping: envelope fold.....	57
9.6.4	Sequential wrapping: square fold	58
9.7	Sterility maintenance covers.....	59
9.8	Rigid sterilization container systems.....	59
10	Sterilization	61
10.1	Loading the sterilizer.....	61
10.1.1	General considerations.....	61
10.1.2	Paper-plastic pouches	61
10.1.3	Instrument sets.....	61
10.1.4	Textile packs.....	61
10.1.5	Utensils and glassware.....	61
10.1.6	Rigid sterilization container systems.....	62
10.1.7	Liquids	62
10.1.8	Powders and oils	63
10.2	Sterilization parameters.....	63
10.2.1	General considerations.....	63
10.2.2	Sterilization cycles.....	63
10.2.3	Immediate-use steam sterilization	63

10.3	Unloading the sterilizer	64
10.3.1	Unloading sterilizers having a chamber volume larger than 2 cubic feet	64
10.3.2	Unloading table-top sterilizers (sterilizers having a chamber volume of less than or equal to 2 cubic feet)	64
10.4	Handling and inspection after unloading the sterilizer	65
11	Storage and transportation	66
11.1	Sterile storage	66
11.1.1	Storage facilities	66
11.1.2	Sterility maintenance covers	66
11.1.3	Shelf life	66
11.2	Distribution	67
11.2.1	Handling and inspection	67
11.2.2	Distribution containers	67
11.3	Transport of sterile packaged items	67
11.3.1	General considerations	67
11.3.2	Tables and carts (open or closed)	67
11.3.3	Hand transport	67
11.3.4	Dedicated lifts	68
11.3.5	Off-site transportation	68
12	Installation, care, and maintenance of sterilizers	69
12.1	General rationale	69
12.2	Instruction manuals	69
12.3	Installation	69
12.4	Routine care	69
12.5	Preventive maintenance	70
12.5.1	General considerations	70
12.5.2	Scheduled maintenance	70
12.6	Calibration	70
12.7	Record-keeping	70
13	Process monitoring, testing, and quality control	72
13.1	General considerations	72
13.2	Monitoring of mechanical cleaning equipment	72
13.3	Product identification and traceability	72
13.3.1	General considerations	72
13.3.2	Package labeling and expiration dating, if applicable	72
13.3.3	Sterilizer records	73
13.3.4	Record retention	73
13.4	Sterilization process monitoring	73
13.5	Sterilization process monitoring devices	77
13.5.1	Physical monitors	77
13.5.2	Chemical indicators	77
13.5.3	Biological indicators	80
13.5.4	Process challenge devices	81
13.6	Routine load release	82
13.6.1	Process monitoring devices	82
13.6.2	Release criteria for nonimplants	82
13.6.3	Release criteria for implants	82
13.6.4	Sterilization process failure	83
13.7	Routine sterilizer efficacy monitoring	84
13.7.1	General considerations	84
13.7.2	Routine biological monitoring of sterilizers larger than 2 cubic feet	84
13.7.3	Routine biological monitoring of table-top sterilizers (less than or equal to 2 cubic feet)	87
13.7.4	Routine biological sterilizer efficacy monitoring of gravity-displacement cycles	88
13.7.5	Actions to take when BIs, CIs, or physical monitors indicate a sterilization process failure	89
13.7.6	Routine Bowie-Dick testing of dynamic-air-removal sterilizers	94
13.8	Qualification testing	97
13.8.1	General considerations	97
13.8.2	Qualification testing of sterilizers have a chamber volume larger than 2 cubic feet	97
13.8.3	Qualification testing of table-top sterilizers (sterilizers having a chamber volume less than or equal to 2 cubic feet)	99
13.9	Periodic product quality assurance testing of routinely processed items	101

13.9.1	General considerations.....	101
13.9.2	Process verification	102
13.9.3	Product families	102
13.9.4	Verification testing procedure	103
13.10	Periodic product quality assurance testing of rigid sterilization container systems	104
13.10.1	General considerations.....	104
13.10.2	User responsibilities	104
14	Quality process improvement	106
14.1	General considerations.....	106
14.2	Quality process.....	106
14.2.1	General considerations.....	106
14.2.2	Quality system model	106
14.2.3	Risk analysis.....	107
14.3	Supplier communication	110
14.4	Repair records	110
14.5	Processing policies and procedures	110
15	New product evaluation	111
15.1	General rationale	111
15.2	Considerations.....	111

Tables

1	IES-recommended illuminance levels for work environments.....	20
2	Sterilization process monitoring recommendations.....	75
3	Types and applications for use of sterilization monitoring devices.....	76
4	Potential causes to be investigated for steam sterilization process failures.....	92
5	Summary of test configurations for prepurchase evaluation of rigid sterilization container systems.....	105
E.1	Levels of disinfection according to type of microorganism	131
E.2	Occupational exposure limits for some chemical sterilants and disinfectants	134
J.1	16 towel pack survey	150
J.2	Biological-indicator results from 121°C (250°F) gravity-displacement cycle	152
J.3	Biological-indicator results from 132°C (270°F) deep-vacuum cycle	153
J.4	Biological-indicator results from 132°C (270°F) pulsing vacuum cycle	153
J.5	Comparison of the 16 towel pack with the 12 × 12 × 20 inch pack by Most Probable Number and sterility assessment of spore strips (121°C [250°F] gravity-displacement cycle)	154
J.6	Fraction-negative results in a 121°C (250°F) gravity-displacement cycle	154
J.7	Biological-indicator results from 121°C (250°F) steam-flush pressure-pulse cycle	155
J.8	Biological-indicator results from 132°C (270°F) steam-flush pressure-pulse cycle	155
N.1	Comparison of terminology and differences between performance requirements of ANSI/AAMI/ISO 11140-1 and FDA (2003) guidance recommendations	165
O.1	Moisture assessment check list	167

Figures

1	Workflow	16
2	Example of single- and double-packaging with paper-plastic pouches	54
3	Simultaneous double-wrapping: envelope fold	55
4	Simultaneous double-wrapping: square fold	56
5	Sequential wrapping: envelope fold	57

6	Sequential wrapping: square fold.....	58
7	Examples of sterilizer cart loads	62
8	Preparation of the 16 towel PCD (BI challenge test pack)	85
9	Placement of the 16 towel PCD (BI challenge test pack) for routine biological monitoring of sterilizers larger than 2 cubic feet	86
10	Decision tree for conducting investigations of steam sterilization process failures	91
11	Composition of the Bowie-Dick test pack.....	95
12	Placement of the Bowie-Dick test pack.....	96
13	Placement of the 16 towel PCD (BI challenge test pack) for qualification testing	99
A.1	Example of a work area design and workflow pattern for a sterile processing area in a typical small hospital	112
A.2	Example of a work area design and workflow pattern for a sterile processing area in a typical medium-sized hospital	113
A.3	Example of a work area design and workflow pattern for a sterile processing area in a typical regional processing center.....	114
A.4	Example of an ambulatory surgery facility	115
A.5	Example of a dental facility	116
B.1	The chain of infection, components of the infectious disease process	117
B.2	Blood-borne pathogen strike-through conversion chart	119
I.1	Typical rigid sterilization container system processed in a gravity-displacement cycle at 121°C (250°F).....	147
I.2	Muslin-wrapped, 16 pound instrument set processed in a gravity-displacement cycle at 121°C (250°F).....	148
I.3	Typical rigid sterilization container system processed in a prevacuum cycle at 132°C (270°F).....	148
J.1	Temperature profiles for two different configurations of 12 × 12 × 20 inch packs	151
J.2	Temperature profiles for huck and absorbent 16 towel packs in a 121°C (250°F) gravity-displacement cycle	151
J.3	Average temperature profile for the 16 towel pack in a 121°C (250°F) gravity-displacement cycle	152
K.1	Exception form for emergency release of sterilizer load	156
O.1	Moisture assessment flow chart.....	170

Annexes

A	Examples of workplace design	112
B	Infection transmission and standard precautions.....	117
C	Processing CJD-contaminated patient care equipment and environmental surfaces	121
D	User verification of cleaning processes.....	126
E	Selection and use of chemical disinfectants	129
F	Thermal disinfection.....	135
G	Devices returned to the manufacturer.....	136
H	Development of a prepurchase evaluation protocol for rigid sterilization container systems	142
I	Effect of container systems on load come-up time	147
J	Development and qualification of the 16 towel PCD (biological-indicator challenge test pack).....	149
K	Example of documentation of emergency release of implants.....	156

L Steam quality 157

M Toxic anterior segment syndrome (TASS) and the processing of intraocular surgical instruments 159

N Comparison of the differences between AAMI and FDA classifications of chemical indicators 162

O Moisture assessment..... 166

P General considerations for cleaning and disinfection..... 171

Q Alternatives for keeping cool in the sterile processing environment..... 175

Bibliography 177

Glossary of equivalent standards

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

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

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Steam Sterilization Hospital Practices Working Group

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

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

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

Foreword

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

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

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

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

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

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

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

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

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

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

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

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

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

Introduction: Need for the recommended practice

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

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

- a) efficient facility design,
- b) equipment, personnel and other resources,
- c) education and training of personnel,
- d) infection prevention and control practices designed to prevent health-care-associated infections,
- e) effective quality control and process improvement systems that encompass all aspects of device reprocessing from point of use through sterilization to reuse, and
- f) documentation and reporting practices that enable traceability of each facility-sterilized medical device to the patient on whom it was used.

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

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

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

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

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

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

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

1 Scope

1.1 General

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

1.2 Inclusions

This recommended practice specifically addresses

- a) functional and physical design criteria for sterilization processing areas;
- b) staff qualifications, education, and other personnel considerations;
- c) processing recommendations;
- d) installation, care, and maintenance of steam sterilizers;
- e) quality control;
- f) product evaluation; and
- g) quality process improvement.

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

1.3 Exclusions

This recommended practice does not cover

- a) specific construction and performance criteria for steam sterilizers (see ANSI/AAMI ST8 and ANSI/AAMI ST55), rigid sterilization container systems (see ANSI/AAMI ST77), or rigid, protective organizing cases that require wrapping before sterilization (see ANSI/AAMI ST77);
- b) the use of containment devices for packaging items other than instrument sets or procedural trays;
- c) procedures and techniques for handling and laundering contaminated reusable surgical textiles (see ANSI/AAMI ST65), reusable laboratory items, food service items, and items assigned to a patient for the length of stay (e.g., bedpans, thermometers);
- d) decontamination of hemodialysis machines, hemodialyzers, and hemodialyzer blood tubing (see ANSI/AAMI/IEC 60601-2-16, ANSI/AAMI RD47, and ANSI/AAMI/ISO 8638, respectively);
- e) the use of dry heat for decontamination purposes or for terminal sterilization of reusable medical devices (see ANSI/AAMI ST40);
- f) the use of ethylene oxide sterilization in health care facilities for other than decontamination purposes (see ANSI/AAMI ST41);
- g) the use of chemical sterilization and high-level disinfection in health care facilities for other than decontamination purposes (see ANSI/AAMI ST58);
- h) the reprocessing of devices labeled for single use only (see Food and Drug Administration [FDA], 2000c); and
- i) aseptic presentation.

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

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).

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 them 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.

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.

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 -40°C (-40°F).

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

- 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.

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)

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.

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.

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.)

- 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,

- 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.

3.2.3 Traffic control

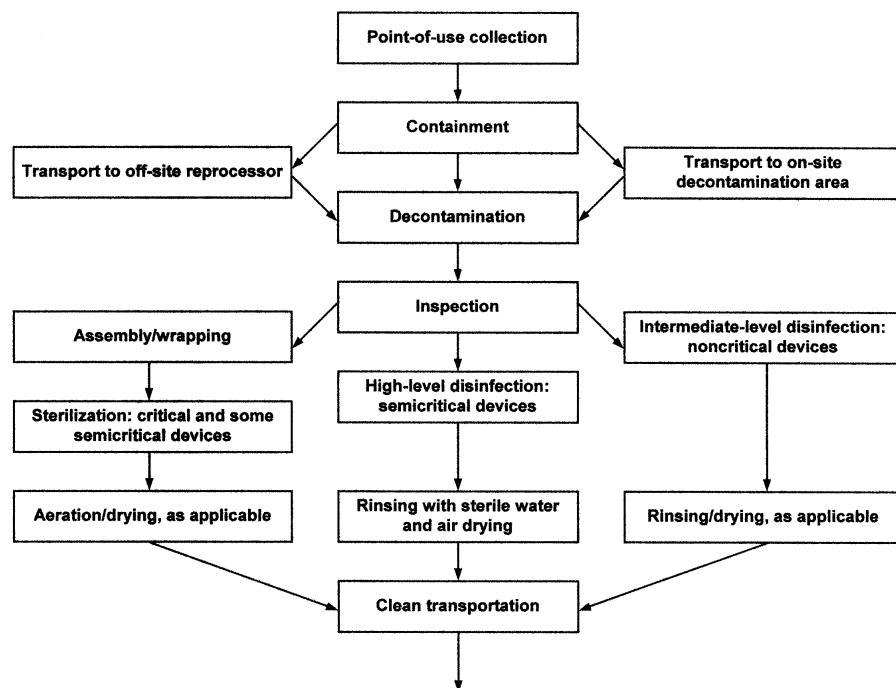
Traffic patterns should be designed to facilitate movement of personnel, equipment, and supplies into, through, and out of defined areas within the sterile processing department/area. The sterile processing department/area design should include two designated areas that are defined by the activities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

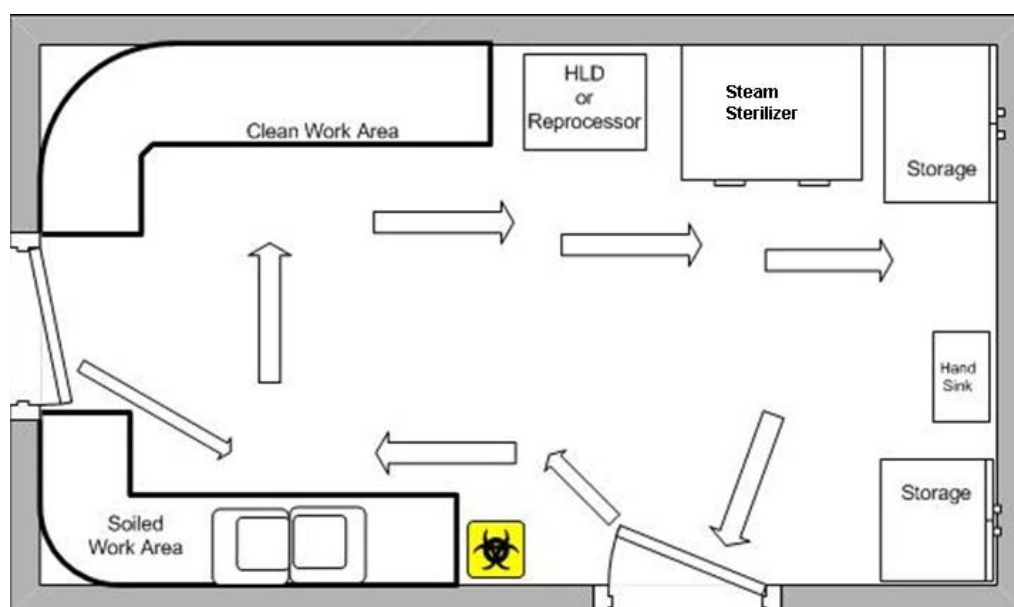
Written policies and procedures regarding traffic control should

- 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.



(a) Workflow in a sterile processing area
(© 2000 Canadian Standards Association)



(b) Workflow in an office-based practice

Figure 1—Workflow

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.

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

- 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.

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:

- 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)
- 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)
- 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)
- 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

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

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;

- 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;

- 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

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.

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, microbicide processes, equipment operation, standard and transmission-based precautions, and engineering and work-practice controls;

- 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;

- 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).

- 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.

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.

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;

- 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.

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.

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

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

- a) place instruments into their respective containers, instrument pans, or other transportation pans so as to prevent damage to the instrumentation;
- b) have a process in place to identify instruments in need of repair/maintenance and removal from service (for example, a tag);
- c) protect delicate instruments from damage (e.g., microsurgical instruments and endoscopes);
- d) segregate reusable sharp instruments inside the container; and
- e) place heavy instrumentation on the bottom and lighter, delicate instruments on top.

Rationale: Instrument damage is often due to care and handling issues. Proper preparation at the point of use reduces instrument damage. Instruments can shift during transport. Keeping the instrumentation in an orderly fashion will help prevent instrument damage.

Contaminated items should always be handled in a manner that reduces the potential exposure of workers to disease-producing organisms and contamination of the environment. When handling contaminated items, personnel should

- a) wear appropriate PPE (see 4.5);
- b) use work-practice controls and engineering controls to minimize the risk of injury;
- c) remove soil by a method that does not promote cross-contamination (e.g., personnel should avoid splashing water and thereby contaminating attire, the area near the sink, and other surfaces in the environment); and
- d) contain and discard gauze sponges and similar items used in the cleaning process according to the health care facility's policy for infectious wastes.

Prior to transport, instruments should be prepared in such a way as to prevent organic soils from drying by

- a) placing a towel moistened with water (not saline) over the instrument;
- b) placing items inside a package designed to maintain humid conditions; or
- c) applying a product designed for pretreatment.

Rationale: Immediate containment and transport to a designated area minimizes the risk of employee contact with contaminants and allows the cleaning process to be performed in a controlled environment by personnel who are protected by PPE. Saline can be corrosive to instruments. Long delays in processing can result in the formation of tenacious and difficult-to-remove biofilm that will shield microorganisms from routine cleaning procedures and possibly interfere with disinfection or sterilization.

6.4 Containment

Contaminated items should be contained during transport from the point of use to the decontamination area. Containment may be accomplished by any means that prevents personnel contact with the contaminated items during transfer.

NOTE—The type of container used depends on the items being transported. Bins with lids, enclosed or covered carts, rigid sterilization container systems, and impermeable bags are among the types of containers that may be used alone or in combination to transport contaminated items.

OSHA requires that

- a) all containers, devices, or carts used for containing contaminated items be marked with a biohazard label, a red bag, or other means of identifying contaminated contents; and
- b) puncture-resistant, leak-proof on the sides and bottom, closable, and labeled containers must be used for devices with edges or points capable of penetrating container or skin.

Contaminated items should be kept moist in the transport container by adding a towel moistened with water (not saline) or a pretreatment product specifically intended for this use, or by placing items inside a package that can maintain moist conditions.

Containers used for holding contaminated items should be

- a) made of material that can be effectively decontaminated; or

- b) designated for single use and made of material that can be incinerated or otherwise disposed of following use.

Environmental issues and hazardous waste policies should be considered before single-use containers are selected as a containment method.

If the container manufacturer's written IFU permit, rigid sterilization container systems with closed valves or intact, dry filters can be used to contain contaminated items for transport with no further coverings, provided that the external surfaces of the container have not been contaminated by blood or body fluids. Such contamination should be presumed to have occurred if the external surfaces of the container have been touched by persons or items that could have contacted blood or other bodily fluids.

If such external contamination is present, the reassembled container system should be further enclosed for transport by placing it in a plastic bag, a bin with a lid, or a closed or covered cart labeled as biohazardous (29 CFR 1910.1030).

Rationale: Materials contaminated with blood or other bodily fluids can serve as sources of infection to personnel unless the materials are completely contained. Containment minimizes the possibility of airborne or contact spread of microorganisms. Keeping items moist prevents soil from drying on device surfaces and facilitates the decontamination process.

6.5 Transport

6.5.1 Segregation of clean/sterile items

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

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

6.5.2 Transportation scheduling and routes

The amount of time between use and decontamination should be minimized because the soil on items provides an ideal medium for microbial reproduction and increases the risk of corrosion. Biofilm can begin to form within minutes and is difficult to remove. In addition, soil can dry on the instrument if left standing, making it difficult to remove. Health care personnel should schedule the pickup and transport of soiled items from each area so that the items are transported and cleaned as soon as possible after becoming soiled. Transport routes should

- a) be designed to facilitate efficient pickup and delivery to the decontamination area; and
- b) avoid areas of high traffic.

Rationale: Cleaning items as soon as possible helps prevent the formation of biofilm and the drying of blood, tissue, and mucus on the items, which can increase the risk of corrosion and make cleaning even more difficult to perform.

6.5.3 Transportation equipment

To help prevent damage to reusable items and avoid contamination of the environment, transport carts or other system should

- a) be designed to prevent items from falling over or off during transport;
- b) be large enough to maintain the security and package integrity of the items being transported;
- c) be covered or closed;
- d) be decontaminated after each use; and
- e) have wheels that turn easily and are routinely cleaned.

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

6.5.4 Hand transport

Prior to transportation, items contaminated with blood and other potentially infectious materials should be placed in a container that is puncture-resistant, leak-proof on the bottom and sides, labeled as biohazardous, and sealed. Containers used to transport contaminated items by hand should be carried in a position parallel to the floor. The

carrier should exercise good body mechanics (e.g., bend at the knees when lifting an item, hold the item close to the body).

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

6.5.5 Dedicated lifts

Dedicated, soiled lifts should

- a) be located in the decontamination area;
- b) be large enough to allow the containers to be positioned securely;
- c) be cleaned on a routine basis, according to the organization's policy, to remove gross contamination that could build up over time and use; and
- d) not be used to distribute clean or sterile items.

If containers of contaminated items are transported directly from the point of use to the point of decontamination by means of a dedicated, soiled lift, the lift may be considered equivalent to a closed cart.

Rationale: Using dedicated lifts and equipment as described in this subsection helps prevent damage to reusable items and avoid contamination of the environment. General cleanliness is maintained by periodic and spot cleaning.

6.5.6 Transport between buildings

When contaminated items are transported outside the controlled environment of the health care facility consideration should be given to

- a) the containment or packaging of the items;
- b) loading procedures;
- c) temperature control in transportation vehicles;
- d) temperature changes that could enhance microbial growth; and
- e) separation of clean and contaminated items.

The transportation system should be enclosed and designed to minimize

- a) the risk of personnel exposure to blood-borne pathogens and other disease-producing organisms; and
- b) the possibility of damage to the instruments and other items being transported.

Vehicles used for transporting contaminated items between buildings should provide for the complete separation of contaminated items from clean and sterile items. Because contamination of the vehicle could have occurred, transportation vehicles should be decontaminated between trips and after any spill.

Transportation personnel should receive training in basic infection prevention and control principles related to their responsibilities. PPE and a biohazardous spill kit should be available in transportation vehicles.

Rationale: Separation of clean and contaminated items helps to prevent cross-contamination during transport. Training is needed to help reduce the risk that transportation personnel will be exposed to blood-borne and other pathogens.

6.5.7 Off-site transportation

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

Certain contaminated, "nonwaste" products are considered to be "infectious substances" under DOT regulations. The DOT defines an infectious substance as a "material known or reasonably expected to contain a pathogen. A pathogen is a microorganism . . . that can cause disease in humans or animals" (49 CFR 173.134 [a][1]). Such products qualify as Class 6, Division 6.2, hazardous materials and thus fall under DOT's regulations for "Infectious Substances (Etiologic Agents)." Certain states also have regulations that can affect the transport of contaminated items.

Clean and contaminated items should be separated to prevent cross-contamination during transport.

Vehicles (motorized or manual) used for transporting contaminated items between health care facilities should

- a) provide for the complete separation of contaminated items from clean and sterile items;
- b) be secured within the vehicle to prevent damage to contents and to prevent contamination by spills;
- c) allow for ease of loading and unloading;
- d) allow for decontamination after use;
- e) remain closed at all times except during loading and unloading;
- f) be completely enclosed to prevent leaks; and
- g) be checked periodically to ensure that there are no leaks.

Transport vehicles that are loaded and ready for transport should not be left unattended in unsecured areas.

7 Cleaning, disinfection (microbicidal processes), and other decontamination steps

7.1 General considerations

This section provides guidance for the selection and use of cleaning, disinfection, and other decontamination steps for medical devices. The first and most important step in reprocessing reusable medical devices is thorough cleaning and rinsing. Cleaning removes microorganisms and other organic and inorganic materials. Cleaning does not kill microorganisms and a subsequent disinfection or sterilization process might be necessary to render the item safe for next use. Rinsing removes detergent and other residues that might interfere with subsequent processes.

All microorganisms in health care facilities should be considered potentially pathogenic. Their ability to cause an infection or disease depends on several factors, including the number and virulence of infectious organisms, the presence of a portal of entry, and the susceptibility of the host (see Annex B). Medical devices, instruments, and equipment used in patient care become contaminated with microorganisms and should be decontaminated. Infection prevention and control is enhanced when soiled supplies and equipment are correctly and safely handled, and when reusable medical items are thoroughly cleaned. The type and level of decontamination required is determined by the circumstances of device use, the type of patient contact, and the risk of biological hazard to personnel. Whenever cleaning is not sufficient to render an item safe for handling, the item is subjected to a subsequent microbicidal process that has been designed to provide an appropriate level of microbial lethality, one sufficient to inactivate potentially infectious or disease-producing microorganisms. This process could be a disinfection process or a sterilization process. The microbicidal process might not be effective if soil has not been first removed by cleaning. When used for decontamination purposes, a microbicidal process is intended to render a device safe for handling and subsequent processing, but the level of microbial inactivation might not be sufficient for the intended use (as in the case of surgical instruments needed for sterile procedures).

Adherence to the principles of infection prevention and control will help prevent the spread of potentially infectious or disease-producing microorganisms from one person to another and will help ensure that all items are safe for handling during inspection, assembly, preparation, and packaging. In addition, adherence to these principles is one of the essential factors in achieving effective steam sterilization for a reusable medical device. The selection of a decontamination method is complex because of the huge variety of reusable items and the wide range of processes for achieving various levels of decontamination. The health care organization, including representatives of sterile processing and of infection prevention and control, should purchase only those devices that can be decontaminated appropriately by a method available in the health care facility. Personnel performing decontamination and cleaning tasks must wear PPE and be trained to safely perform decontamination-related tasks. (See 29 CFR 1910.1030.)

To be rendered safe to handle, some medical devices require only thorough cleaning; others, because of occupational exposure considerations (such as potential exposure to Ebola or *Clostridium difficile*), should be cleaned and subjected to a microbicidal process.

Some devices can be prepared for patient reuse following the decontamination process, whereas others should be prepared and subjected to terminal sterilization (e.g., steam sterilization of surgical instruments). The type of decontamination required for a particular contaminated device depends on the biohazard that the device presents. The cleaning and/or microbicidal process appropriate for a particular device depends on

- a) the device manufacturer's written IFU;
- b) the necessary level of microbial lethality (CDC, 2008); for example, a higher assurance of lethality is needed for items that have been in contact with body tissues, blood, or other bodily fluids than for items that have only been in contact with unbroken skin;
- c) the design of the device;
- d) the materials from which the device is fabricated (e.g., whether the device can tolerate high temperatures, whether the device is fully immersible);
- e) the intended use of the device; and
- f) whether the device was exposed to prions, such as the prion that causes Creutzfeldt-Jakob disease (CJD), and thus will require specialized processing steps (see Annex C).

7.2 Policies and procedures

The health care organization should establish policies and procedures for all methods of cleaning and decontamination of reusable items.

Process audits to monitor compliance with the various policies and procedures should be performed on a scheduled basis, with appropriate follow-up to address problems.

Rationale: Policies and procedures provide facility instructions for maintaining consistency and effectiveness of the cleaning and decontamination processes consistent with applicable standards and recommended practices. Audits of the process can help to identify gaps so methods can be identified to improve the process.

7.3 Manufacturer's written IFU

The device manufacturer's current written IFU should be accessible, reviewed, and followed. If there are no specific written IFU in the labeling, then the manufacturer should be contacted and requested to provide a documented method of cleaning.

Rationale: The device manufacturer is responsible for ensuring that the device can be effectively cleaned and sterilized with the means and methods available in health care facilities. Sterilization validation of a device requires microbiological, engineering, toxicological, and sometimes clinical evaluations of the device, which are beyond the abilities of most health care facilities. To ensure patient safety, a reusable device needs to be capable of being thoroughly cleaned and sterilized. The device labeling describes specific methods of cleaning and sterilization that have been validated by the manufacturer.

7.4 Decontamination

7.4.1 General considerations for all devices and utensils

To help ensure effective decontamination of devices, sterile processing personnel should

- a) follow the device manufacturer's written IFU to ensure proper decontamination and disinfection of the device;
- b) collaborate with clinical personnel to help ensure that instruments are kept as free of gross soil as possible during the surgical or other procedure;
- c) begin decontamination as soon as possible after the items have been used or as directed by the instrument or device manufacturer;
- d) separate general operating instruments and utensils from delicate instruments or devices that require special handling;
- e) disassemble all instruments or devices comprising more than one part according to manufacturers' written IFU;
- f) open all jointed instruments;
- g) pretreat the device according to the manufacturer's written IFU;
- h) use a cleaning solution that is compatible with the device and follow the cleaning product manufacturer's written IFU for proper dilution, concentration, temperature, and contact time;
- i) before manual cleaning, ensure that the cleaning solution is clean and change it when it appears soiled, which could be after one use; and
- j) rinse with water of the quality specified by the device manufacturer. When the water quality is not specified by the device manufacturer, refer to AAMI TIR34.

Instruments and devices should not be treated with any additional chemical (e.g., alcohol, disinfectant wipes) unless such treatment is specifically recommended in the manufacturer's written IFU.

Cloths used in decontamination should be clean and nonlinting and should be changed frequently. Brushes should be clean and of the appropriate size and bristle type. Worn brushes should be discarded. Reusable brushes should be cleaned after each use and disinfected or sterilized at least once a day. Single-use cleaning implements (e.g., single-use wipes) should be discarded after each use. See also 7.6.1.

Instruments should be carefully inspected for flaws, damage, debris, detergent residue, and completeness, then dried. Instrument tape and plastic dipping material, when used properly, are ways of identifying specific instruments. These types of marking products wear out over time and staff need to inspect them each time the instrument is processed, check them for wear according to the IFU of the product used, and replace them as often as needed.

Rationale: Because effective sterilization depends on minimizing the contamination present on items before the sterilization cycle, thorough cleaning procedures are essential during presterilization processing. Not all cleaning and

decontamination procedures and agents are appropriate for all types of devices. Adherence to the manufacturer's written IFU for detergents and other aspects of the cleaning and decontamination process can help avert damage to instruments, prolong their use life, and prevent the creation of crevices in which debris can collect. Ensuring the completeness of instrumentation helps reduce the number of lost instruments and instrument parts. Drying instruments before they are packaged can reduce the incidence of wet packs after sterilization and can help prevent corrosion of instruments. Cloths with lint can leave lint on instrumentation. Using cleaning implements that are clean reduces the bioburden. If a brush is too large, it will not fit into the lumen; if it is too small, it will not have complete contact with the lumen walls and, consequently, will not clean them thoroughly. Brushes used for decontamination need to be cleaned themselves and disinfected or sterilized. Brushes that show wear will not clean thoroughly. Prompt cleaning of brushes and other cleaning implements reduces or eliminates biofilm-forming microorganisms and thus minimizes the formation of biofilm.

7.4.2 Special considerations

7.4.2.1 Reusable textiles

Used textiles should be placed in a hamper bag that prevents leakage for transport to the laundry for processing. For guidelines on handling and reprocessing of reusable surgical textiles, see ANSI/AAMI ST65.

7.4.2.2 Instrument lubricants

Instrument lubricants should be specifically designed for their intended use and compatible with the processing method being used. The lubricant manufacturer should provide evidence to support material compatibility and biocompatibility (e.g., lack of cytotoxicity) of the lubricant for its intended use (e.g., following sterilization). Lubricants should be used according to the device manufacturer's instructions.

7.5 Preparation for cleaning

7.5.1 Presoaking

Following point-of-use cleaning (see 6.3), instruments should be presoaked as soon as possible after use with a product intended to loosen soil. Instruments should not be presoaked if presoaking is contraindicated in the instrument manufacturer's written IFU.

The presoak solution manufacturer's written IFU should be reviewed and followed for the correct dilution, temperature, and contact time. Saline and other solutions that might cause corrosion should not be used in the presoaking process.

Instruments should be thoroughly rinsed after presoaking.

Rationale: Presoaking instruments moistens and loosens the soil, thus making the cleaning step more effective and efficient. Thorough rinsing removes potentially harmful residues and blood and other potentially infectious material. Alcohol and other disinfectants might affix biofilm to surfaces and make it difficult to remove.

7.5.2 Sorting and disassembly

7.5.2.1 General considerations

Following transport to the decontamination area, contaminated items should be handled as follows:

- a) Contaminated items should be removed from their transport containers.
- b) Contaminated items should be sorted. General operating instruments should be segregated from delicate items that require special handling, sharp items, and those identified for repair. Repair tags that are designed for surgical instrumentation should remain on the instrumentation throughout the cleaning process.
- c) All disposable products (e.g., tip protectors and CIs) should be removed.
- d) Unless otherwise directed by the manufacturer, instruments should be disassembled in preparation for cleaning according to the manufacturer's written IFU.
 - Protective devices (e.g., silicone mats, dividers) should be removed, as appropriate.
 - Device and instrument manufacturers' written IFU for disassembly and reassembly of all processed items should be reviewed and followed.
 - All small parts (e.g., screws, nuts, and washers) should be contained to prevent loss.

- Non-interchangeable components, such as parts of a metal stopcock, should be kept together to ensure correct reassembly.
- Procedures should be established and followed to ensure that personnel do not reach by hand into the container to retrieve reusable sharps as this will pose a risk for occupational injury.

Rationale: Differentiating instruments identified for repair from functional instruments during the cleaning process can reduce the risk of defective instruments being returned to the user before repairs have been made. Disassembly of instruments and other items composed of more than one part or piece (e.g., metal tracheostomy tubes, procedure needles, dental handpieces, laparoscopic instrumentation, trumpet valves) exposes surfaces to the cleaning process. Hidden surfaces and crevices can prevent thorough cleaning. Residual organic matter or large numbers of microorganisms can significantly reduce the effectiveness of the subsequent microbicidal process. The recommended procedures for disassembly and reassembly are intended to help ensure that reassembly can be accomplished without damage to the device. The recommendation concerning reusable sharps is based on OSHA regulations (29 CFR 1910.1030).

7.5.2.2 Rigid sterilization container systems

7.5.2.2.1 General considerations

Before acquiring rigid sterilization container systems, the health care facility (or organization) should confirm that the facility has the capability to follow the manufacturer's validated decontamination methods.

The method selected should be guided by the container system manufacturer's written IFU in conjunction with the mechanical cleaning equipment manufacturer's written IFU.

Rigid sterilization container systems should be cleaned

- a) before sterilization, either manually or mechanically;
- b) according to the container system manufacturer's written IFU; and
- c) by personnel following accepted practices for decontamination and employee safety, including PPE.

Only cleaning agents intended for cleaning rigid sterilization containers and not contraindicated in the device manufacturer's validated IFU should be used.

After the cleaning process is completed, nuts, bolts, screws, rivets, filter retention mechanisms, gaskets, and permanent filters should be inspected for cleanliness and damage.

Rationale: Certain cleaning methods or cleaning agents might not be compatible with a particular rigid sterilization container system. Some cleaning agents can cause corrosion or deterioration of container surfaces, such as discoloration or stress cracking; for example, some detergents that do not have a neutral or near-neutral pH might corrode more sensitive metals, and specific additives can adversely affect some plastics and gasket materials. Thorough rinsing is essential for removal of detergent and other residues. Hidden surfaces and crevices can make thorough cleaning difficult. Residual organic matter can significantly reduce the efficacy of the decontamination process. Damaged components of container systems could interfere with the sterilization process or allow contamination of the contents.

7.5.2.2.2 Removable filters

Removable filters and filter protectors or holders (retention plates) should be removed or released to disengage the filter media to allow for cleaning.

Disposable filters should be discarded.

Reusable filters should be disassembled, cleaned, and replaced according to the manufacturer's written IFU.

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

7.5.2.2.3 Valves

Valves should be removed, disassembled, and cleaned according to the manufacturer's written IFU.

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

7.5.2.2.4 Interior baskets

The interior basket should be removed from the external container.

The container manufacturer's written IFU should be followed to determine whether instruments can be decontaminated in the basket or should be removed.

Rationale: Separation of the internal basket from the external container allows for effective decontamination.

7.5.2.2.5 Process indicators, disposable labels, and disposable locks

Process indicators, disposable labels, and disposable locks should be removed and discarded.

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

7.5.2.2.6 Container accessories

Protective mats, dividers, and sorting pins that are not affixed to the tray should be disassembled or removed according to the manufacturer's written IFU.

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

7.6 Cleaning

7.6.1 General considerations

Effective sterilization depends on minimizing the contamination, including detergent and water residues present on items before the sterilization cycle, and thorough cleaning procedures are essential during presterilization processing. Not all cleaning and decontamination procedures and agents are appropriate for all types of devices. Adherence to the manufacturer's written IFU for detergents and other aspects of the cleaning and decontamination process can help avert damage to devices, prolong their use life, and prevent the creation of crevices in which debris can collect.

- a) Items should be pretreated with an initial cold water rinse with running tap water or an initial soak in cool water and/or a clinical-soil-dissolving pretreatment product (e.g., an enzymatic cleaner or pH neutral detergent).
- b) After pretreatment, devices should be cleaned according to the manufacturers' IFU.
- c) Devices should be thoroughly rinsed. If a basin is used, the rinse water should be changed after each use. The final rinse (mechanical or manual) should be with purified water (e.g., distilled, or RO water). See TIR34 for recommendations on the use of critical water.
- d) Cloths and towels used in decontamination should be clean and nonlinting (e.g., microfiber cloth or cellulose sponge) and should be changed at regular established intervals and when they are soiled or wet.
- e) Brushes should be checked for visible soil and damage following each use and should be frequently cleaned and disinfected. Brushes should be stored clean and dry.
- f) Single-use cleaning implements should be discarded after each use.
- g) Devices should be inspected for flaws, damage, debris, detergent residue, and completeness, then dried.
- h) Brushing is a cleaning function and should only be done in the decontamination area and not in the clean (preparation and assembly) area. If a medical device is found to be dirty upon inspection in the assembly area, it should be returned to the decontamination area for recleaning.

Rationale: A cold water rinse and the use of a pretreatment product will help prevent coagulation of blood onto the device and help remove blood, tissue, and gross debris from device lumens, joints, and serrations. Precleaning solutions can interfere with subsequent cleaning steps. Mechanical washers are programmed for specific cycles with specific cleaning agents. Introducing a presoak spray or gel can interfere with the function of these preprogrammed cycle steps and the cleaning agents used. If the spray or gel is not rinsed off during manual cleaning it can interfere with the subsequent steps in the cleaning process.

Cloths with lint can leave lint on instrumentation. Using cleaning implements that are clean reduces bioburden. Brushes used for decontamination need to be cleaned themselves and disinfected or sterilized. Brushes that show

wear will not clean thoroughly. Prompt cleaning of brushes and other cleaning implements reduces or eliminates biofilm-forming microorganisms and thus minimizes the risk of formation of biofilm.

7.6.2 Devices with lumens

When decontaminating devices with lumens, personnel should

- a) soak and flush the lumen according to the manufacturer's written IFU;
- b) brush the lumen with a brush that is of the correct size (diameter and length) and bristle type and material for the lumen, then rinse it; and
- c) if using a pressurized lumen-flushing device, verify that it is connected correctly and follow manufacturer's written IFU.

Rationale: Thoroughly flushing lumens helps ensure complete surface contact with the solution. If a brush is too large, it will not fit into the lumen; if it is too small, it will not have complete contact with the lumen walls and, consequently, will not clean them thoroughly.

7.6.3 Cleaning agents

Cleaning agents recommended in the device manufacturer's written IFU should be used. The cleaning agent should

- a) be compatible with the medical device or container system to be cleaned as well as with the materials used in the cleaning equipment itself;
- b) be efficacious on the types of clinical soil typically found on medical instruments after clinical use;
- c) be nonabrasive;
- d) be low-foaming;
- e) be free-rinsing (i.e., easily removed from the medical device);
- f) be biodegradable;
- g) rapidly dissolve/disperse soil;
- h) be nontoxic; and
- i) have a shelf life and use-life consistent with the anticipated clinical use.

The volume and temperature of water used in the cleaning sink or other cleaning container is very important for the efficacy of the process. The appropriate dilution should be calculated according to the volume of the sink to ensure consistent and accurate cleaning solution concentration.

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

When using an automated chemical delivery system/device or sink proportioner, personnel should routinely verify or calibrate the automated doser. Calculation of sink volume might or might not be necessary.

Rationale: Using a free-rinsing detergent facilitates the removal of residual chemicals, soil or bioburden in amounts that could be harmful to patients or damage the device. Certain detergents can damage metal or other device materials.

7.6.4 Methods of cleaning

7.6.4.1 Selection of an appropriate method

Personnel should use the cleaning method or methods (manual, mechanical, or a combination) specified in the device manufacturer's written IFU.

Prior to acquisition of a device, the device manufacturer's written IFU should be reviewed to confirm the availability of the mechanical cleaning equipment, cleaning devices, and methods required to safely reprocess the device.

Before health care personnel elect to use alternative equipment and/or cleaning agents, they should consult the device manufacturer, the manufacturer of the cleaning equipment, and the manufacturer of the cleaning agent.

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

7.6.4.2 Manual cleaning

Manual cleaning should be performed on all instruments if automatic cleaning equipment is not available. Manual cleaning might be recommended by manufacturers of delicate or complex medical devices, such as microsurgical instruments, lensed instruments, and air-powered drills.

When manually cleaning devices, personnel should

- a) wear appropriate PPE;
- b) follow the detergent manufacturer's written IFU for water hardness, pH, temperature, and the type(s) of soil the detergent is suitable for removing;
- c) clean lumened items with a brush of the recommended type, size (diameter and length), and bristle type and material, flush the lumen with the recommended cleaning solution, and then rinse the lumen, preferably with treated water (unless otherwise specified in the manufacturer's written IFU) (see 7.6.2);
- d) clean immersible devices under water to minimize aerosolization;
- e) clean devices that cannot be immersed in a manner that will not produce aerosols;
- f) use brushes and other cleaning implements intended for use on medical devices; brushes should be checked for visible soil and damage following each use and should be frequently cleaned and disinfected. If the device manufacturer specifies a specific brush or cleaning implement, the brush or an equivalent should be used;
- g) avoid abrasive cleaning compounds and implements such as metal scouring pads, unless specified in the device manufacturer's written IFU;
- h) thoroughly rinse and dry devices following the decontamination process using a nonlinting cloth or instrument air;
- i) monitor the water temperature as required in the manufacturer's written IFU; and

NOTE—Lukewarm water and detergent solutions (at temperatures optimally in the range of 27°C to 44°C [80°F to 110°F], but not to exceed 60°C [140°F]) will prevent coagulation and thus assist in the removal of protein substances.

- j) change the solution after every use (a "use" should be defined in the health care facility's policies and procedures).

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

7.6.4.3 Mechanical cleaning, disinfection, and other decontamination steps

7.6.4.3.1 General considerations

Mechanical cleaning is a documented, reproducible, automated, or semi-automated (partially manual) cleaning process that is validated for use with specific medical devices and yields a device(s) that is safe to handle for subsequent processing, as defined by its Spaulding classification and intended use. See Annex P.

The equipment manufacturer's written IFU should be reviewed and followed for indications for use and operation, including loading practices, use of accessories, and cycle selection.

Rationale: Mechanical cleaning methods minimize personnel risk of cross-contamination, improve cleaning effectiveness, increase productivity, and are more easily monitored for quality performance. Additional information is in Annex P.

7.6.4.3.2 Maintenance of mechanical cleaning and disinfection equipment

Decontamination equipment should be used, cleaned, disinfected, and maintained according to the manufacturer's written IFU. Personnel should

- a) verify that the equipment is functioning according to the manufacturer's written specifications;
- b) check the spray arms (if applicable) at least daily to ensure that the arms are completely free-turning and that spray nozzles are not clogged;

- c) clean strainers (if applicable) at least daily or when there is visible debris;
- d) ensure that regular preventive maintenance is performed;
- e) clean external surfaces when soiled and at least daily; and
- f) verify that settings are held constant and have not been changed after repair or maintenance by manufacturers, users, or technicians unless there was an identified need that was recorded.

Rationale: Maintaining the equipment according to the manufacturer's written IFU will help ensure optimal performance.

7.6.4.3.3 Selection of mechanical cleaning and disinfection equipment

Selection of mechanical cleaning equipment should be based on the requirements for cleaning of the devices to be processed. The mechanical cleaning equipment currently available for reprocessing medical devices that are moisture-, detergent-, and temperature-stable include the following:

- a) Ultrasonic cleaning equipment
- b) Irrigator cleaners
- c) Ultrasonic irrigators
- d) Ultrasonic irrigator washers
- e) Ultrasonic irrigator washer–disinfectors
- f) Floor-mounted cart washer–disinfectors
- g) Single-chamber washer–disinfectors
- h) Multi-chamber washer–disinfectors
- i) Medical washers

7.6.4.3.4 Loading mechanical cleaning and disinfection equipment

When loading mechanical cleaning and disinfection equipment, personnel should do the following:

- a) Remove gross debris.
- b) Remove all presoak chemicals, either manually or mechanically.
- c) Follow the loading procedure described in the manufacturer's written IFU.
- d) To facilitate cleaning, disassemble all devices composed of more than one part according the device manufacturer's written IFU.
- e) Connect lumened instruments to irrigation ports, if available.
- f) Open all hinged surgical instruments with handles, such as scissors, hemostats, and forceps, to full extension unless contraindicated by the manufacturers' written IFU.
- g) Position devices to prevent damage. Heavy devices should be placed on the bottom. Position items such as rigid sterilization container and basins to avoid the accumulation and retention of water.
- h) In consultation with the equipment manufacturer, develop a mechanism to verify the dosing of the detergent.
- i) Check that the spinning arms are unobstructed.
- j) Place delicate devices in a perforated basket and secure them to prevent them from moving around.
- k) Position items so they do not protrude from the washer baskets.
- l) Use hold-down screens or other retaining systems to prevent dislodging and improper movement of devices during the process.
- m) Separate multi-level sets so that all surfaces are exposed to impingement action.
- n) Open trays with lids/covers so that the contents are exposed and water can drain freely.

- o) Remove silicone and rubber mats from the set to permit full impingement action.
- p) Load utensils so that the spray can easily reach all surfaces and so that water can drain out.
- q) Remove disposable items such as filters and chemical indicators.
- r) Remove debris from the bottom of the washer and clean the filter at least daily when there is visible debris present.
- s) Verify that the correct cycle and dry time are selected for the load.
- t) Avoid mixed loads (e.g., instruments and utensils) to ensure that the correct wash cycle parameters are applied to each device.

Rationale: Gross debris left on devices will circulate through the washer and be deposited onto the other devices, impeding the cleaning action. For washing to be effective, all surfaces of the device should have contact with the cleaning solutions. Devices are loaded to prevent instrument damage. Disposable items placed into the washer can clog the washer and become debris, preventing full impingement action. Hold-down screens prevent items from tipping over during the wash cycle. Shortened cycles can negatively affect cleaning outcomes.

7.6.4.3.5 Unloading mechanical cleaning and disinfection equipment

If the cleaning equipment provides cycle verification, the cycle selection should be checked, before the devices are unloaded, to ensure that the correct cycle was used. The printout should be saved for the period of time specified by the facility or by state and/or local regulations. As devices are unloaded, they should be inspected for debris and wetness.

The drain strainer should be checked for debris and cleaned if debris is present.

After the wash cycle, devices are hot and might be wet. They should be removed carefully to prevent worker thermal injury.

7.6.4.4 Ultrasonic cleaning equipment

7.6.4.4.1 General considerations

Ultrasonic cleaning equipment designed for cleaning medical devices is used for fine cleaning to remove soil from joints, crevices, lumens, and other areas that are difficult to clean by other methods.

Ultrasonic cleaning should be

- a) used only for those devices for which ultrasonic cleaning has not been contraindicated in the device manufacturer's written IFU;
- b) used only after gross soil and detergents have been removed from items;
- c) performed using cleaning solutions labeled for use in ultrasonic cleaning equipment;
- d) performed with fresh cleaning solution; solution should be changed after each use (a "use" should be defined in the health care facility's policies and procedures); and
- e) followed by thorough clean water rinsing or detergent washing to remove ultrasonic cleaning equipment bath residues and contaminants.

Ultrasonic cleaning equipment should be cleaned every day that it is used according to the manufacturer's written IFU.

In addition to following the manufacturer's written IFU, the following actions should be taken:

- a) Request performance verification test methods from the ultrasonic equipment manufacturer.
- b) Perform cavitation testing daily whenever the equipment is in use.
- c) Prior to using it, degas the solution in accordance with the ultrasonic equipment manufacturer's IFU.
- d) Avoid placing plastics and soft metal (e.g., lead hands) in the ultrasonic cleaner.
- e) Keep the lid closed when the ultrasonic cleaner is in use unless otherwise directed by the device manufacturer's written IFU.

Rationale: The ability to clean medical devices mechanically and to fine-clean by the ultrasonic cleaning process is beneficial because of the complexity of many devices. The variety of equipment available and the intricacy of many medical devices make it essential that manufacturers be consulted and their written IFU reviewed and followed for maximum effectiveness and to avoid expensive and unnecessary damage. Changing the cleaning solution after each use will minimize cross-contamination of instrumentation. The cavitation process has a tendency to create aerosols (particles of cleaning solution released into the air). To contain these aerosols and other contaminants, the ultrasonic cleaner should have a lid and the lid should remain closed during the cleaning process. Degassing the cleaning solution in the ultrasonic cleaner will remove gases from utility water that can interfere with the cavitation process. Plastic materials can absorb the sound waves interfering with cleaning.

7.6.4.4.2 Loading

When loading an ultrasonic cleaning equipment, personnel should

- a) place devices in open-weave or perforated metal baskets below the water level;
- b) place devices in an open position;
- c) place heavy items on the bottom;
- d) remove rubber or silicone mats;
- e) when required, connect lumen devices to flushing ports by tubing and adapters, and follow the device manufacturer's written IFU for mechanical cleaning using ultrasonic equipment with pressurized lumen irrigation or disinfection parameters;

NOTE—This step also applies to mechanical irrigation cleaners that do not include an ultrasonic function.

- f) follow the ultrasonic cleaner manufacturer's instructions for loading and placement of devices in the cleaner.

Rationale: Long, hollow, small-lumen, and ported devices are generally difficult to clean. Specific validated IFU should be followed in order to thoroughly clean these complicated and advanced devices thoroughly.

7.6.4.4.3 Unloading

When unloading medical devices from ultrasonic cleaning equipment, personnel should carefully remove devices from the ultrasonic cleaner:

- a) If the device is connected to any flushing ports, disconnect it first before removing it from the ultrasonic cleaner;
- b) If the ultrasonic cleaning equipment does not have a rinse cycle, rinse the devices before inspecting them for cleanliness;
- c) After ensuring that the devices have been thoroughly rinsed, inspect them for cleanliness according to the medical device manufacturer's written IFU.

If the medical devices are deemed clean, they can now proceed to the next step in their reprocessing cycle.

7.6.4.5 Verification of the cleaning process

After completing the cleaning process, personnel should visually inspect each item carefully to detect any visible soil.

Mechanical cleaning equipment performance should be tested each day it is used and all results should be recorded.

Users should ask device manufacturers to provide test procedures that can be easily replicated and that can assist users in recognizing whether cleaning was effective for all device areas. Such tests are particularly important for devices with components that cannot be readily inspected for cleanliness (e.g., spring hinges, lumens, porous material, crevices). See Section 13.2 for recommendations concerning quality-control monitoring of mechanical cleaning equipment.

Rationale: Steam sterilization cannot be assured unless proper cleaning of the device and reduced bioburden and soil was achieved. Verification and documentation of automated cleaning processes through objective means is an important aspect of quality control. Cleaning encompasses the removal of organic residues (e.g., blood, tissues, bone fragments, secretions and excretions) and microorganisms from the patient, from handling, or from water exposure during reprocessing. Inspection using enhanced visualization tools such as lighted magnification and video borescopes might identify residues not observable by the unaided eye. Visual inspection alone might not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure or detect

organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures (see Annex D for available methods). Appropriate testing is based on the type of equipment. See Annex D for guidance on testing ultrasonic cleaners.

8 Preparation and assembly of instruments

8.1 General considerations

In preparation for sterilization, devices should be

- a) cleaned;
- b) dried;
- c) inspected for cleanliness, flaws, and damage;
- d) assembled; and
- e) packaged according to the manufacturer's written IFU.

Individual instruments should be packaged in an acceptable packaging material that ensures adequate sterilant contact with all surfaces.

8.2 Instruments

For some devices, there might be special instructions regarding placement in an instrument set. Only devices and accessories designed and intended for medical device sterilization should be used. The device manufacturer's written IFU for placement should be followed, in addition to the following recommendations:

- a) The assembler should verify that the items to be sterilized and any containers or organizing accessories being used are compatible with the intended sterilization cycle.
- b) Instruments should be positioned to allow the sterilant to come into contact with all surfaces.
- c) Lumened ports should be opened.
- d) Ratcheted instruments should be unlatched. Racks, pins, stringers, or other specifically designed devices can be used to hold the instruments in the unlatched position.
- e) Instruments comprising more than one part or with sliding pieces or removable parts should be disassembled if it is so specified in the manufacturer's written IFU.
- f) Sharp items should be protected from damage. Tip protectors, if used, should be steam-permeable, fit loosely, and be used according to the manufacturer's written IFU.
- g) Instruments should not be held together with rubber bands.
- h) Items with concave surfaces and/or broad, flat surfaces that will retain water should be placed on edge.
- i) Heavy instruments should be placed in such a way that they will not damage more delicate items. Lighter instruments should be positioned to protect tips and to prevent damage from changes in position.
- j) Instrument sets, including the sterile barrier system, should weigh no more than 11 kg (25 lb) (ANSI/AAMI ST77).
- k) Organizing containers and other organizing accessories may be placed in the set if they are designed and intended for sterilization. Paper-plastic sterilization pouches should not be used as organizing accessories (see 9.5.4).
- l) Tray liners designed and intended for sterilization may be used to protect instruments from damage and/or absorb moisture.
- m) When rigid sterilization container systems are used, all items should be contained in the basket or tray within the container system.
- n) The instrument tray should be large enough to permit equal distribution of the contents in terms of weight and metal mass.
- o) If a mat is used within an instrument containment device or tray, the container, mat, and device manufacturers' written IFU should all be followed.

Rationale: Sterilization depends on contact of the sterilizing agent with all surfaces for the prescribed time. Proper placement of instruments within a set can help ensure sterilant contact and prevent damage to the instruments.

Instruments with concave or broad, flat surfaces that are not placed standing on edge during processing can retain pools of water that might not drain off or revaporize completely at the end of the cycle. Absorbent tray liners can absorb condensation and reduce the incidents of wet packs. Nonabsorbent tray liners can prevent damage to instruments. When sterile barrier systems, including their contents and any accessories or wrappers, are too heavy, sterilization and/or drying could be compromised in commonly available hospital sterilization cycles. Additionally, there could be ergonomic issues associated with heavy containment devices.

8.3 Devices with lumens

When processing devices with lumens, such as catheters, needles, and tubings, sterile processing personnel should

- a) remove any stylets or plugs;
- b) open stopcocks or valves; and
- c) sterilize such devices in a dynamic-air-removal sterilizer unless otherwise specified in the device manufacturer's written IFU.

Moisture should not be added to any lumen before sterilization unless recommended by the manufacturer of the lumened device. If moistening of the lumen is recommended by the device manufacturer, sterilization should follow immediately.

Rationale: Lumens pose a challenge to sterilant penetration, especially in certain types of gravity-displacement cycles, because they restrict diffusion.

8.4 Basins and basin sets

Basin sets should

- a) be prepared so that all basins are placed in the same direction;
- b) be processed with nonlinting absorbent material between nested basins; and
- c) be assembled so as to permit air removal, steam penetration, and steam removal during the sterilization and drying process.

Small items such as medicine cups should not be placed inside basin sets unless they can be oriented to ensure drainage of condensate.

Rationale: Separating basins with absorbent material enhances adequate air removal and passage of steam to all surfaces, and facilitates drying. Nonlinting materials are recommended because lint can be introduced into a patient's wound and cause a foreign-body reaction. Proper alignment of basins, to prevent them from acting as reservoirs for moisture, is essential to achieving sterility.

8.5 Textile packs

The textile product manufacturer should be consulted for recommendations on the pack size, dimensions, and density that have been validated for the steam sterilization cycles intended to be used.

A pack should be prepared with freshly laundered textiles.

The wrapper should be securely applied but not pulled in such a way that the contents are compressed.

Rationale: Freshly laundered textiles are recommended because the material needs to be rehydrated before use to prevent superheating, sterilization failure, and diminished useful life of the materials.

9 Packaging

9.1 General considerations

Packaging is intended to maintain the sterility of an item and protect the contents until use. Many different types of packaging systems are available for purchase, each with its own set of specific IFU. Following packaging IFU is critical to maintaining sterility of sterilized items.

9.2 Selection of sterile barrier systems

When selecting a sterile barrier system, personnel should obtain the current written IFU and have it readily accessible.

A sterile barrier system should

- a) allow air removal to permit sterilant penetration of the package contents;
- b) provide a barrier to microorganisms during sterilization processing, handling, distribution, transport, and storage;
- c) resist tearing or puncture;
- d) allow a method of sealing that results in a complete seal that is tamper-evident and provides seal integrity;
- e) maintain protection for the sterile contents during storage and transportation to the point of use;
- f) allow for aseptic presentation;
- g) be free of toxic components and nonfast dyes;
- h) be nonlinting; and
- i) be compatible with the intended methods of sterilization, sterilization parameters, and the devices to be sterilized.

Packaging policies and procedures and packaging techniques should be based on the sterile barrier system manufacturer's written IFU.

9.3 Package labeling

Packages should be labeled before sterilization.

Package labels should

- a) be visible and legible;
- b) consist of non-toxic materials and ink;
- c) be written only on the non-porous side of the pouch (for paper-plastic pouches);
- d) be written on indicator tape or affixed labels (for wrapped packs, basins, instruments, or other surgical supplies);
- e) indicate the sterilizer unique identifier;
- f) indicate cycle and load number;
- g) indicate date of sterilization;
- h) include a description of the contents;
- i) identify the operator/person responsible for preparation and packaging; and
- j) remain securely adhered to the sterile barrier system through the sterilization process and storage to the point of use.

NOTE—An instrument tracking system that provides traceability of the sterilizer unique identifier and cycle and load number may be used. An additional sterilizer load label might not be required. See 13.3, Product identification and traceability.

Rationale: Accurate labeling provides identification of the package contents as well as information that enables tracking of the sterilizer, sterilization cycle, and personnel involved in the sterilization process. Using nontoxic, nonbleeding ink can help prevent toxic deposits on or in sterile packages. Using indelible ink might help prevent loss of labeling information.

9.4 Package closures

Package closures should

- a) be designed and intended for sterile processing;
- b) be tamper-evident;
- c) allow the sterilization process to occur;
- d) not constrict or compress the package; and
- e) maintain package integrity during use.

Tape used on reusable wrap should have a tab for easy removal.

Rationale: Package closures not intended for sterilization might not perform as intended. Packages expand and contract during steam sterilization. Closures that restrict this action could interfere with air removal, steam penetration, and steam removal. Overly constrictive bands can stress packaging materials to the point of tearing during this expansion and contraction.

9.5 Sterilization wrap

9.5.1 General considerations

Woven and nonwoven wraps should be

- a) FDA cleared as medical sterilization packaging systems for use in health care facilities;
- b) stored and maintained according to the manufacturer's written IFU;
- c) examined prior to use for defects and debris; and
- d) selected according to the size, shape, and weight of the medical device to be processed.

Items should be wrapped securely to prevent gaps in the wrap material. Items should not be wrapped too tightly because tears and punctures could occur.

Guidance for sequential double-wrapping and simultaneous double-wrapping is provided in 9.6.

9.5.2 Woven wraps

Woven wraps should be made of materials that will allow adequate air removal, steam penetration, and steam evacuation (for drying) when the package has been properly assembled.

When using woven wraps, sterile processing personnel should

- a) track the number of launderings and sterilization cycles to which each wrap has been subjected;
- b) inspect wraps before each use for holes, worn spots, and stains;
- c) only use woven wraps that have been laundered between each sterilization cycle; and
- d) consult the wrap manufacturer for guidance on mending or patching damaged wraps.

Rationale: The barrier qualities of new textile wraps are diminished by repeated laundering and sterilization cycles. Holes or other defects in a wrapper allow the contents of the pack to become contaminated.

9.5.3 Nonwoven wraps

Nonwoven wraps may be single sheets or bonded constructions.

When choosing and using nonwoven wraps, sterile processing personnel should

- a) choose the grade of sterilization wrap according to the size, shape and weight of the medical devices to be wrapped, the guidelines within the health care facility, and the wrap manufacturer's written IFU.
- b) inspect the wrap to ensure that it is free of defects that could have an adverse effect on the performance of the material; and
- c) confirm that the wrap is free of nonfast dyes and is designed to minimize the generation and shedding of fibers or particulates (lint) during normal use.

9.5.4 Paper-plastic pouches

Paper-plastic pouches are generally used for small, lightweight, low-profile items.

The paper-plastic pouch should

- a) be used, filled, and opened according to the pouch manufacturer's written IFU;
- b) be of a size and strength to accommodate the item being packaged; and
- c) be closed so that all pouch seals are smooth (i.e., without folds, bubbles, or wrinkles).

Double packaging in paper-plastic pouches should only be performed if the pouch manufacturer has validated the product for this use. If the item is to be double-packaged, two sequentially sized pouches should be used (i.e., the sealed inner pouch should fit inside the other pouch without folding). The pouches should be positioned so that plastic faces plastic.

Paper-plastic pouches should not be placed within wrapped sets or containment devices unless the practice has been validated by the pouch packaging manufacturer and verified by product testing in the health care facility.

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

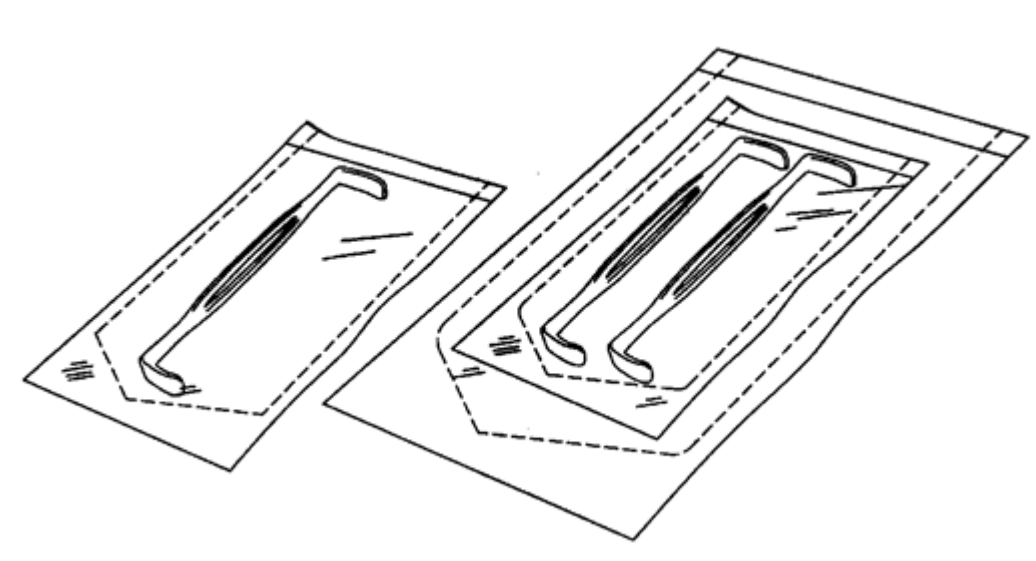
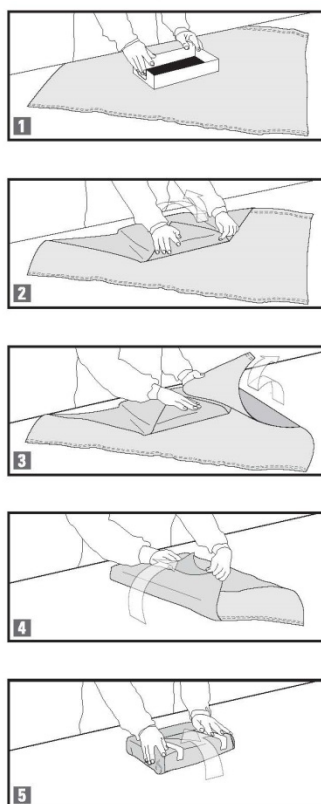


Figure 2—Example of single- and double-packaging with paper-plastic pouches

NOTE—Instruments should be oriented within paper-plastic pouches according to the health care facility's policies and procedures.

9.6 Wrapping techniques

9.6.1 Simultaneous double-wrapping: envelope fold



Two single-layer wrappers or
One bonded double-layer wrapper

Figure 3—Simultaneous double-wrapping: envelope fold

Only wrappers validated for use in simultaneous double-wrapping should be used. Two single-layer wrappers or one bonded double-layer wrapper can be used. Simultaneous double-wrapping refers to wrapping two layers of wrap material together simultaneously. Simultaneous double-wrapping using the envelope-fold technique is shown in Figure 3. The procedure is as follows:

- 1) Place the wrap sheets on the table to form a diamond shape. Place the device(s) to be wrapped in the center of the wrap, parallel with the edge of the table.
- 2) Bring the lower corner up to completely cover the contents and fold the tip back on itself to form a tab or flap (which is used later to assist in opening the pack aseptically).
- 3) Fold the left corner over the contents and fold the tip back on itself to form a tab.
- 4) Fold the right corner over the left fold and fold the tip back on itself to form a tab.
- 5) Bring the top corner down over the contents and tuck the corner under the right and left folds. A small tab may be incorporated for easy opening. Secure with two pieces of chemical indicator tape as shown in Figure 3 (one piece of tape might be sufficient for smaller packages).

9.6.2 Simultaneous double-wrapping: square fold

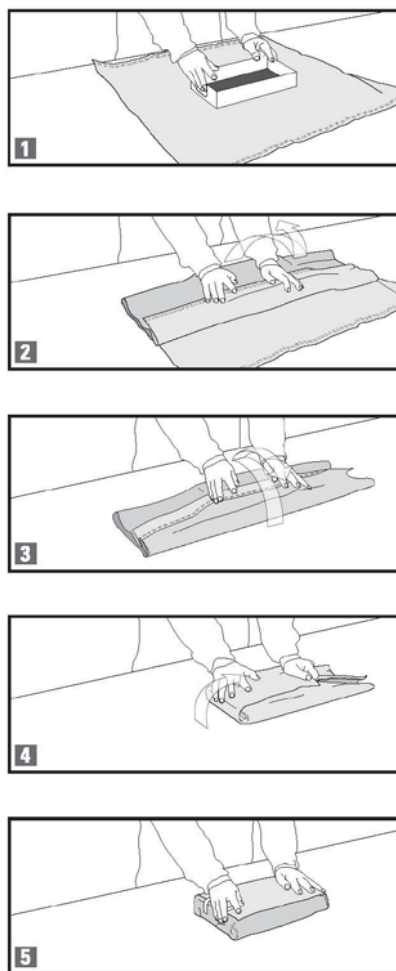


Figure 4—Simultaneous double-wrapping: square fold

Only wrappers validated for use in simultaneous double-wrapping should be used. Two single-layer wrappers or one bonded double-layer wrapper can be used. Simultaneous double-wrapping refers to wrapping two layers of wrap material together simultaneously. Simultaneous double-wrapping using the square-fold technique is shown in Figure 4. The procedure is as follows:

- 1) Place the edge of the wrapper parallel with the edge of the table. Place the device in the center of the wrapper parallel with the edge of the wrapper.
- 2) Fold the edge of the wrapper over the top of the contents, covering the entire item. Fold the edge back over itself (toward the technician) to form a cuff, which will facilitate aseptic opening of the pack when used.
- 3) Bring the upper edge of the wrap down completely over the contents and fold it back on itself to form another cuff, overlapping the original.
- 4) Fold the left edge of the wrapper snugly over the pack and back on itself to form a cuff.
- 5) Fold the right side of the wrapper over the pack, overlapping the previous fold and folded back to form a cuff, or tuck under and secure with indicator tape.

9.6.3 Sequential wrapping: envelope fold

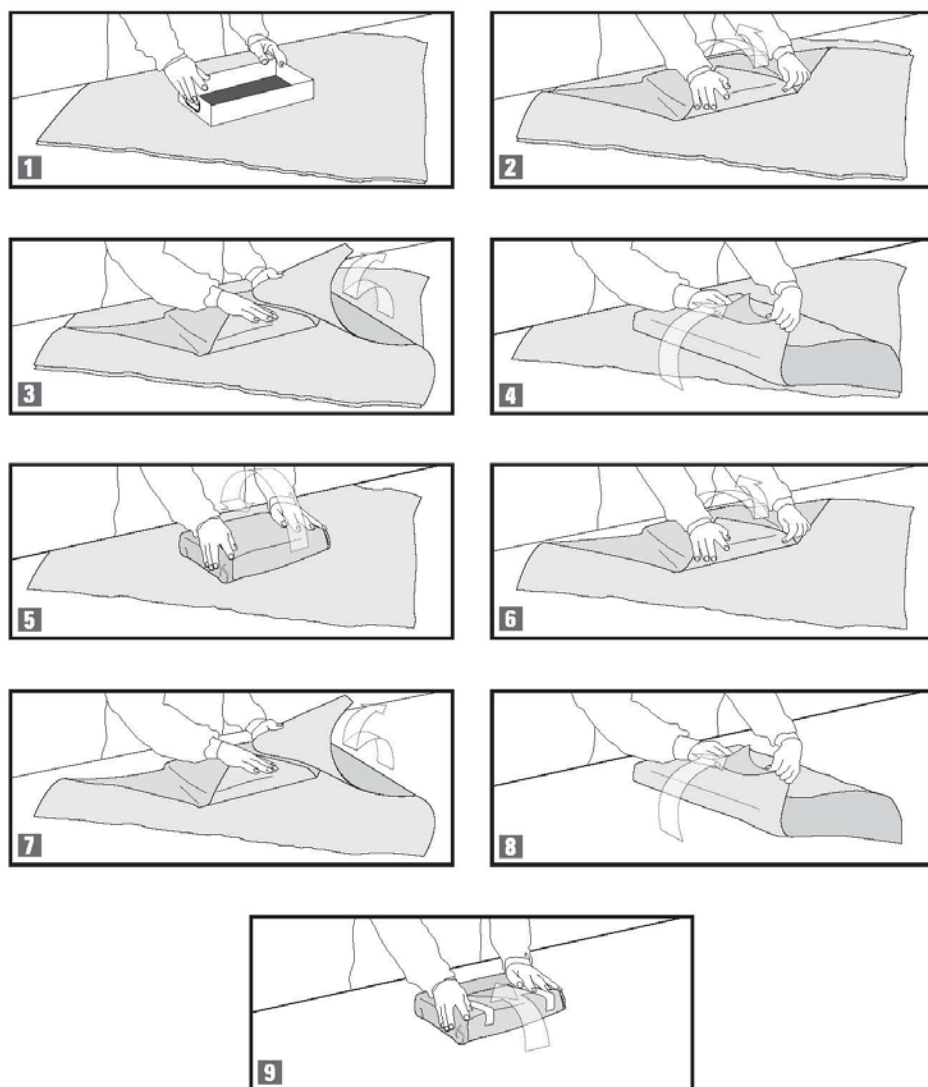


Figure 5—Sequential wrapping: envelope fold

Sequential wrapping refers to wrapping two layers of wrap material individually. Sequential wrapping using the envelope-fold technique shown in Figure 5. The procedure is as follows:

- 1) Place the wrap on the table to form a diamond shape. Place the device(s) to be wrapped in the center of the wrap, parallel with the edge of the table.
- 2) Bring the lower corner up to cover the contents and fold the tip back on itself to form a tab or flap (which is used later to assist in opening the pack aseptically).
- 3) Fold the left corner over the contents and fold the tip back to form a tab.
- 4) Fold the right corner over the left fold and fold the tip back on itself to form a tab.
- 5) Bring the top corner down over the contents and tuck the corner under the right and left folds, leaving a small tab visible for easy opening.

- 6) Apply the second wrap by placing the single wrapped device in the center of the remaining wrap and repeating the wrap sequence to form a package within a package. Bring the lower corner is brought up to cover the single wrapped item and the tip is folded back on itself to form a tab or flap.
- 7) Fold the left corner over the single wrapped item and fold the tip back to form a tab.
- 8) Fold the right corner over the left fold and fold the tip back on itself to form a tab.
- 9) Bring the top corner down over the single wrapped item and tuck the corner under the right and left folds, leaving a small tab visible for easy opening. Secure with chemical indicator tape.

9.6.4 Sequential wrapping: square fold

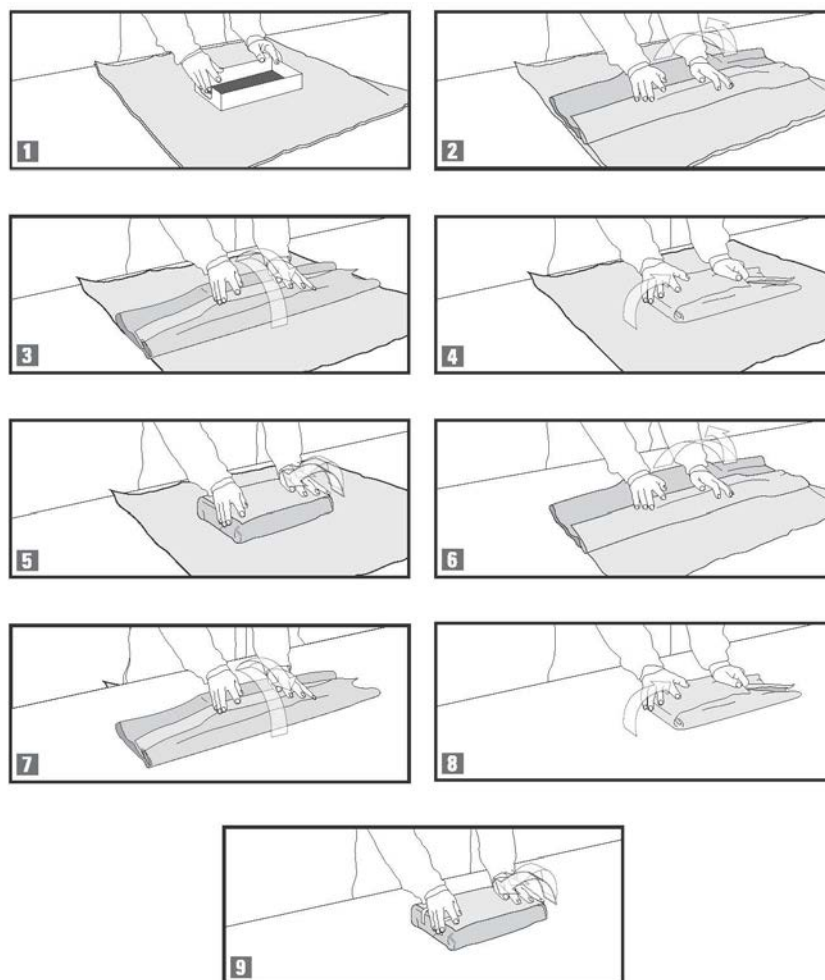


Figure 6—Sequential wrapping: square fold

Sequential wrapping refers to wrapping two layers of wrap material individually. Sequential wrapping using the square-fold technique is shown in Figure 6. The procedure is as follows:

- 1) The edge of the wrapper is placed parallel with the edge of the table. The device is placed in the center of the wrapper parallel with the edge of the wrapper.
- 2) The edge of the wrapper is folded over the top of the contents, covering the lower half. The edge is then folded back over itself (back toward the technician) to form a cuff, which will facilitate aseptic opening of the pack when used.

- 3) The upper edge of the wrap is brought down over the upper half of the contents and is folded back on itself to form another cuff, overlapping the original cuff, to prevent a gap between the upper and lower folds.
- 4) The left edge of the wrapper is folded snugly over the pack and back on itself to form a cuff.
- 5) The right side of the wrapper is folded over the pack, overlapping the previous fold, and folded back to form a cuff.
- 6) The second wrap is applied by placing the single wrapped item in the center of the wrap and repeating the steps performed for the first wrap to create a package within a package. The edge of the second wrapper is folded over the single wrapped item, covering the lower half. The edge is then folded back over itself (back toward the technician) to form a cuff.
- 7) The upper edge of the wrap is brought down over the upper half of the single wrapped item and folded back on itself to form another cuff, overlapping the original cuff, to prevent a gap between the upper and lower folds.
- 8) The left edge of the wrapper is folded snugly over the pack and back on itself to form a cuff.
- 9) The right side of the wrapper is folded over the pack, overlapping the previous fold and folded back. The package is usually secured with indicator tape.

9.7 Sterility maintenance covers

Sterility maintenance covers (dust covers) may be used as protective packaging for sterilized items that could be subjected to environmental challenges or multiple handling before use. Only products designed and intended for sterility maintenance should be used for this purpose.

Sterility maintenance covers are not a substitute for a sterile barrier system.

Sterility maintenance covers should be applied as soon as possible after sterilization, but not before the items are cool and dry.

The sterility maintenance cover should be sealed according to the manufacturer's written IFU.

The package content label should be visible through the sterility maintenance cover, or a duplicate label should be placed on the sterility maintenance cover. (See 13.3.)

Rationale: Sterility maintenance covers are designed to provide protection against environmental contaminants (e.g., dust), not to provide a microbial barrier. Plastic provides a barrier to moisture and dust; this barrier might be necessary to preserve the sterile integrity of the package, especially one that is not going to be used immediately or that will be subjected to uncontrolled environments (e.g., during transport between facilities).

Applying sterility maintenance covers soon after sterilization enhances sterility maintenance. However, placing a sterility maintenance cover on a package that is not cool and dry could result in condensation inside the sterility maintenance cover and, because the sterility maintenance cover is not sterile, contaminate the package contents. To be an effective barrier, the sterility maintenance cover has to be sealed. The sterility maintenance cover is only a protective device; the identity and traceability of the package within has to be maintained.

9.8 Rigid sterilization container systems

Sterile processing personnel should ensure that the rigid sterilization container system selected is suitable for the proposed sterilization use and is compatible with the devices and sterilizers in use.

A rigid sterilization container system should be inspected before use to ensure that

- a) the latching mechanism or closure will remain secure during the sterilization process;
- b) the sealing or mating surfaces or edges of the container system and lid are not dented or chipped;
- c) filter retention mechanisms and fasteners such as screws and rivets are secure and are not distorted or burred, the securing mechanism functions properly, and the filter medium is not damaged;
- d) the gaskets are pliable, securely fastened, and without breaks or cuts; and
- e) the valves work freely and are not broken, cut, chipped, or dented.

Only filters recommended by the rigid sterilization container manufacturer should be used.

The rigid container system should be cleaned after each use in accordance with 7.5.2.2.

Rationale: To ensure the operating efficiency of a rigid sterilization container system, a thorough and clearly delineated inspection procedure is necessary. Rigid sterilization container systems vary in their mechanics, their specific performance characteristics, and their suitability for particular sterilization cycles. A change in the filter material (e.g., a change in brand) can affect air removal or sterilant penetration and evacuation in a container system. Filter material cannot be tested easily by health care personnel. There is no nationally recognized referee test for the microbial barrier performance of filters. However, as with any sterile barrier or packaging system, inspection for integrity is part of a good quality assurance program.

10 Sterilization

10.1 Loading the sterilizer

10.1.1 General considerations

The following should be considered when loading a sterilizer for processing:

- a) The facility should establish written policies and procedures for loading sterilizers.
- b) The sterilizer manufacturer's written IFU can be referenced for proper use of the sterilizer accessories (e.g., carts and carriages) and sterilizer control operation.
- c) Items requiring the same cycle parameters should be processed in the same load.
- d) Load configurations should ensure adequate air removal, penetration of steam into each package, and steam evacuation.
- e) Cart shelf liners that have been validated for this purpose may be used and should be made of a nonlinting, absorbent material that will dry in the drying time selected for the rest of the load. Follow the liner manufacturer's written IFU for use and replacement instructions.
- f) Heavier items should be placed on the bottom of the sterilizer racks and the weight distributed evenly. (See Figure 7 for examples of proper loading.)
- g) Stacking of items should be avoided unless the packaging manufacturer's written IFU supports such practice.

NOTE—Guidance on the choice of sterilizer cycles and cycle parameters is provided in 10.2.

Rationale: Loading the sterilizer in this fashion allows adequate air elimination and drainage of condensate, which are needed to attain product sterility. Nonlinting, absorbent cart shelf liners can be helpful in drying a load. Nonlinting materials are recommended because lint can be introduced into a patient's wound and cause a foreign-body reaction. Placing metal items below textile items enables condensate to drain out without dripping onto items below.

10.1.2 Paper-plastic pouches

Paper-plastic pouches should stand on edge in relation to the cart or shelf, with the paper side of one pouch next to the plastic side of the next pouch.

Holding racks or baskets specifically designed for paper-plastic pouches may be used.

Rationale: Racks or baskets hold paper-plastic pouches on edge and properly spaced in the sterilizer for adequate sterilant contact and drying.

10.1.3 Instrument sets

Instrument sets in wrapped, perforated trays or rigid sterilization container systems should be placed horizontally on the sterilizer shelf or cart so that the set is level.

Rationale: A horizontal, level position prevents shifting of the set contents and facilitates air removal, sterilant penetration, condensate drainage, and drying.

10.1.4 Textile packs

Textile packs should be loosely loaded. They should be positioned standing on edge so that all fabric layers are perpendicular to the shelf (not stacked one upon the other) (see Figure 7).

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

10.1.5 Utensils and glassware

Items capable of holding water, such as solid-bottom pans, bowls, and trays, should be positioned tilted on edge and oriented in the same direction so that condensate can drain (see Figure 7).

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

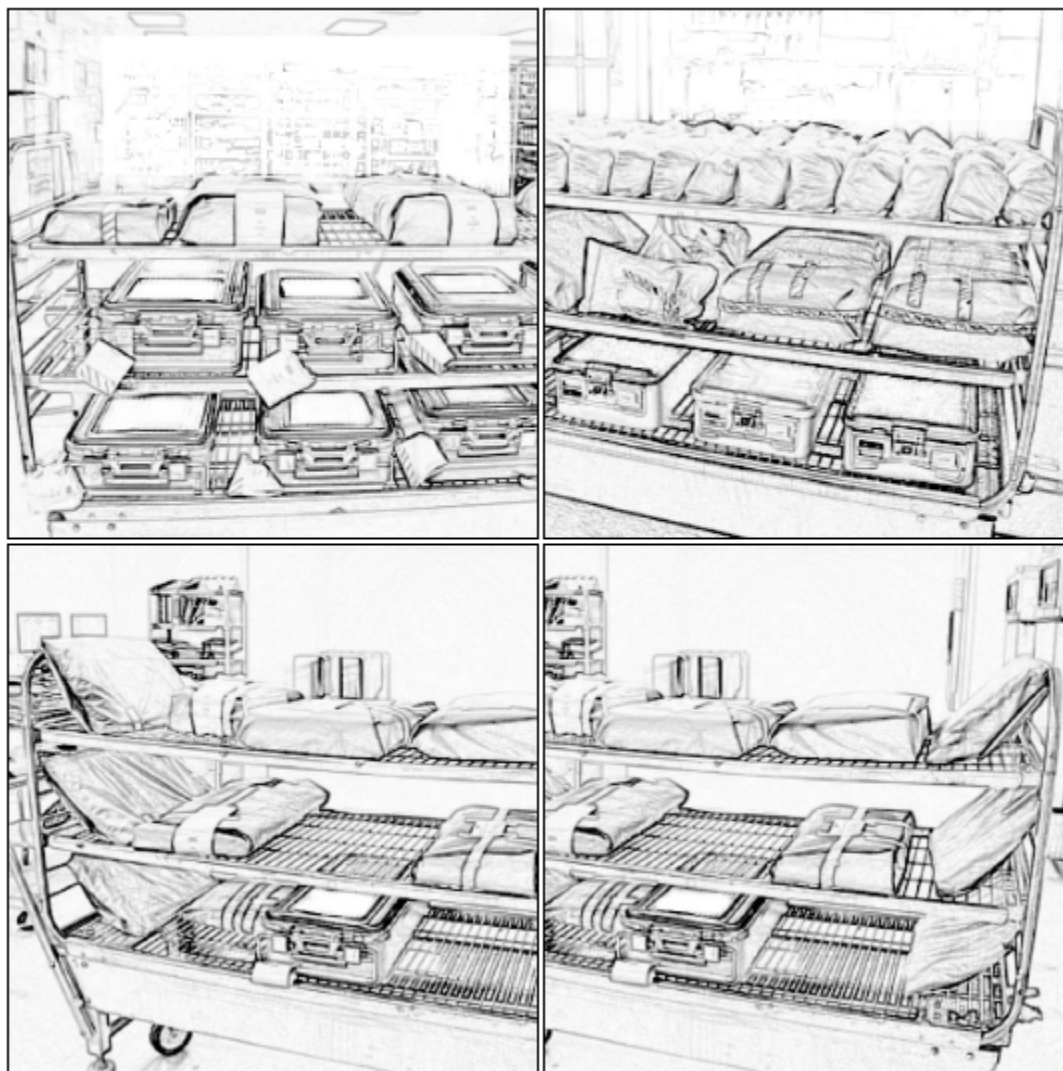


Figure 7—Examples of sterilizer cart loads
(Figure courtesy of STERIS Corporation)

10.1.6 Rigid sterilization container systems

Rigid sterilization container systems should be placed on shelves below absorbent items.

Containers may be stacked if indicated in the container manufacturer's written IFU. Containers from different manufacturers should not be stacked.

Rationale: Stacking container systems in configurations not indicated in the IFU could interfere with air evacuation, sterilant penetration, and drying. Container design varies among manufacturers and containers might not be compatible with one another.

10.1.7 Liquids

Sterilization of liquids in the health care facility should be avoided. If determined to be clinically necessary and there is no alternative:

- a) Liquids should be sterilized separately from all other items in a cycle and sterilizer specifically designed for sterilization of liquids.
- b) Liquids should be processed in containers designed and intended for sterilization of liquids.

- c) Sterilization should be performed by personnel knowledgeable and competent in the performance of liquid sterilization and the special safety precautions needed to avoid injury.

Rationale: Health care facilities are normally not equipped to safely sterilize liquids. Sterilization of liquids poses a significant risk of injury from exploding containers and hot solutions. Containers not designed to withstand the conditions of sterilization of liquids can explode.

10.1.8 Powders and oils

If sterile powders or oils are needed, commercially prepared products should be used.

Rationale: Powders and oils cannot be steam sterilized.

10.2 Sterilization parameters

10.2.1 General considerations

Steam sterilization cycles typically used in health care facilities include the gravity-displacement cycle and two types of dynamic-air-removal cycles. One type of dynamic-air-removal cycle, the prevacuum cycle, removes air from the chamber and load by means of pressure and vacuum excursions. The other type, the steam-flush pressure-pulse (SFPP) cycle, removes air with a series of steam flushes and pressure pulses above atmospheric pressure.

The sterile processing professional should verify that the sterile barrier system and the item to be sterilized have been validated for the steam sterilization cycle to be used.

10.2.2 Sterilization cycles

The sterilizer manufacturer's written IFU should be followed for operation of the sterilizer and indications for use.

- a) Differences between the programmed cycle and the cycle parameters recommended by the device manufacturer should be investigated and, if possible, reconciled before the items are sterilized. If differing instructions cannot be resolved, the device manufacturer's IFU should be followed.
- b) If a rigid sterilization container system or a sealed containment device designed for IUSS is used as packaging, the container system manufacturer's written IFU regarding exposure time should be consulted and reconciled with that of the sterilizer manufacturer.

See AAMI TIR12 and FDA (2015) for information about sterilizer cycles. For a specific sterilizer, consult that sterilizer manufacturer's written IFU.

NOTE—Sterilizer design and process/cycle parameters must be cleared by the FDA. Steam sterilizer cycles are developed for specific load configurations specified by the manufacturer, and these cycle parameters should not be modified without consultation with the sterilizer manufacturer. The sterilizer cycle conditions include parameters for conditioning (e.g., gravity-displacement, dynamic-air-removal), sterilization (pressure, temperature and time), and drying (temperature, time). It is not sufficient to consider only sterilization temperature and time to ensure a successful cycle. Device manufacturers' instructions for steam sterilization can vary considerably. Standard cycles can be found in ANSI/AAMI ST8, ANSI/AAMI ST55, and FDA (2015).

Rationale: Sterilizers and devices vary in design and performance characteristics. The device manufacturer performs the validation for sterilization of its specific device and determines the parameters required for sterilization of that device.

10.2.2.1 Sterilization cycles and accessories

The sterilization cycles used by the health care facility should be FDA cleared and should incorporate sterilization monitoring accessories (e.g., CIs, BIs, process challenge devices [PCDs]) and sterilization packaging labeled and cleared for that sterilization cycle.

10.2.3 Immediate-use steam sterilization

Immediate-use steam sterilization (IUSS) should not be used for purposes of convenience or as a substitute for sufficient instrumentation. Instrument inventories should be sufficient to meet anticipated surgical volume and to ensure that there is enough time to complete all critical elements of reprocessing.

Immediate-use steam sterilization should be kept to a minimum and should be used only in urgent clinical situations.

Items processed by IUSS should be

- a) decontaminated as specified in Section 7;

- b) placed in a rigid sterilization container system that is intended for the cycle parameters to be used;
- c) used immediately and not stored for later use or held from one procedure to another; and
- d) identified as IUSS.

Rationale: Rigid sterilization container systems protect the sterilized item from environmental contaminants during transfer from the sterilizer chamber to the point of use.

10.3 Unloading the sterilizer

At the end of the sterilization cycle, the sterilization parameters should be checked to ensure that the correct sterilization parameters were met. See 13.3.3 for additional guidance on sterilizer records.

10.3.1 Unloading sterilizers having a chamber volume larger than 2 cubic feet

Terminally sterilized items should be allowed to cool to room temperature before handling. An infrared gun or temperature-sensing device may be used to verify that sterilized items have reached a defined temperature (e.g., 24°C [75°F]). The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used.

Items should not be touched during the cooling process.

A sterilizer cart or carriage and/or a validated transport tray should be used for all terminally sterilized items. Items removed from the sterilizer after sterilization processing, including items packaged in rigid sterilization container systems, should remain on the cart until cooled. During cooling, the sterilizer cart should be placed in a low-traffic area and away from air-conditioning or other cold-air vents.

Warm items should not be transferred from the cart to cold metal racks or shelves for cooling or placed within dust covers before completion of the cooling process (see 9.7).

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

If rigid sterilization container systems are not properly cooled before they are removed from the sterilizer cart, condensation due to rapid cooling of hot materials can occur. Because the materials used for containers are not absorbent, condensate can appear as small droplets on or within the container system. Condensate on the outside of a container system can flow downward toward the filter of another container and contaminate it. Condensate can also run down the sides and onto noncontainerized packages below, contaminating them. Condensate within any container system can compromise the sterility of the contents if the condensate is able to come into contact with outside contaminants. The potential for outside contamination depends on several factors, such as the type of filter media and the seal of the filter or valve.

10.3.2 Unloading table-top sterilizers (sterilizers having a chamber volume of less than or equal to 2 cubic feet)

Sterilized items should be allowed to cool before handling. The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used.

The sterilizer manufacturer might recommend opening the door slightly at the end of the cycle and leaving the items inside for a period of time in order to reduce the potential for condensation formation.

Warm items should not be transferred from the sterilizer to cold metal racks or shelves for cooling.

Items should not be touched during the cooling process.

Rationale: See the rationale for 10.3.1.

10.4 Handling and inspection after unloading the sterilizer

As sterile packages are removed from the sterilizer cart or carriage and/or validated transport tray, they should be inspected for the following:

- a) Damage (e.g., holes, staining, tears, non-intact seals, missing security locks)
- b) Package identification
- c) Visual change of the external indicator
- d) Moisture

Any items with damaged packaging or with packaging that appears to be wet should not be used. If an item is dropped on the floor and the integrity of its packaging is compromised, it should be returned to the decontamination area for reprocessing.

Rationale: Items with torn or wet packaging are considered contaminated. Wet packaging might indicate problems with package composition, loading procedures, sterilizer performance or operation, or the steam generation and distribution system.

11 Storage and transportation

11.1 Sterile storage

11.1.1 Storage facilities

Sterile items should be stored under environmentally controlled conditions in a manner that reduces the potential for contamination.

Sterile storage areas should be kept clean and dry.

Sterile items should be

- 1) stored far enough away from the floor, the ceiling, and outside walls to allow for adequate air circulation, ease of cleaning, and compliance with local fire codes;
- 2) stored at least 8 to 10 inches above the floor, at least 18 inches below the ceiling or the level of the sprinkler heads, and at least 2 inches from outside walls;
- 3) stored in such a way that wrapped packages are not stored beneath rigid sterilization containers on the same shelf; and
- 4) positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised.

Access to the sterile storage area should be restricted to authorized personnel.

Sterile items, including those packaged in rigid sterilization container systems, should not be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they could become wet.

Sterile items should not be stored on floors, on windowsills, or in areas other than designated shelving, counters, or carts. For safety and ease of handling, heavy instrument trays should be stored on middle shelves; transport trays with solid or perforated bottoms may be used to prevent tears in wrappers during handling. (See also section 3.3.6.4.)

The wrap manufacturer's IFU should be consulted for guidance on stacking trays.

Closed or covered cabinets are recommended for sterile storage. Open shelving may be used, but requires special attention to traffic control, area ventilation, and environmental services.

Shelving, carts, and bins used for sterile storage should be maintained organized, clean, and dry. The bottom shelf of storage carts or shelving should be solid. The shelving or carts should be designed for the weight and configuration of the load.

Supplies should be removed from external and web-edged shipping container before transport to any restricted area (see section 3.3.6.5 and 5.2.1).

Rationale: Adequate space is needed around sterile materials to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between sterile items and the condensation that might form on the interior surfaces of outside walls. Also, fire codes specify minimum distances below the ceiling (usually 18 inches) to ensure the effectiveness of sprinkler systems (NFPA 13, NFPA 99). Compression of packages can force air and microorganisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces. Stacking can result in damage to the wrap caused by undue pressure from the weight. Closed cabinets limit dust accumulation, discourage handling, and minimize inadvertent contact with sterile items. External shipping containers and web-edged corrugated cardboard boxes can collect dust, debris, or insects during shipment and bring contaminants into the facility.

11.1.2 Sterility maintenance covers

See 9.7.

11.1.3 Shelf life

The health care facility should establish policies and procedures for determining shelf life.

The shelf life of facility-sterilized items is event-related and should be based on the quality of the packaging material, the storage conditions, the methods and conditions of transport, and the amount and conditions of handling.

Inventory should be rotated on a "first in, first out" basis.

Rationale: Shelf life is not simply a matter of sterility maintenance but is also a function of device degradation and inventory control. The contamination of a sterile item is event-related, and the probability of its occurrence increases over time and with increased handling. See also Joint Commission (2016) and AORN (2017b).

11.2 Distribution

11.2.1 Handling and inspection

Sterile items should be handled in a manner that avoids dragging, sliding, crushing, bending, compressing, or puncturing the packaging or otherwise compromising the sterility of the contents.

Packaging should be thoroughly inspected visually for integrity and labeling before an item is issued.

Rationale: Excessive and improper handling of sterile packages can damage the barrier qualities of the packaging materials. Proper care and handling of sterile packages helps prevent contamination of the contents. Inspection of sterile packages will identify any damage to the integrity of the packaging materials before the items are dispensed. See also the rationale statement for 11.1.3.

11.2.2 Distribution containers

All clean or sterile items being transported in uncontrolled environments should be in a covered or enclosed cart with a solid bottom shelf.

If items are placed inside plastic or paper bags or boxes for transport, they should be arranged within the containers so as to prevent them from being crushed or otherwise damaged or contaminated.

Reusable covers for carts or other transport vehicles should be cleaned after each use and should have a reclosable opening.

Carts should be decontaminated and dried before they are reused for transporting sterile supplies.

For automated cart distribution systems and pneumatic systems, the manufacturer's written IFU on distribution and decontamination procedures should be followed.

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

11.3 Transport of sterile packaged items

11.3.1 General considerations

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

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

Rationale: Adequate protection during transport minimizes the potential for damage and helps maintain sterility.

11.3.2 Tables and carts (open or closed)

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

Rationale: See the rationale for 11.3.1.

11.3.3 Hand transport

Sterile packages that contain instrumentation and that are transported by hand should be carried in a position parallel with the floor.

Rationale: See the rationale for 11.3.1.

11.3.4 Dedicated lifts

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

Rationale: See the rationale for 11.3.1.

11.3.5 Off-site transportation

The design and materials used in the construction of all transport vehicles (motorized or manual) should allow for appropriate decontamination, especially if the vehicles are to be used alternately for the transport of sterile/clean items and soiled items.

Vehicles used to transport sterile packages between health care facilities should

- a) provide for the complete separation of clean and sterile items from contaminated items;
- b) have a storage compartment that is completely enclosed; and
- c) allow for ease of loading and unloading.

Carts containing sterile packages should be secured within the vehicle to prevent damage or contamination.

NOTE—All external shipping cartons are considered contaminated, even if they contain packaged sterile items.

When vehicles are used, environmental conditions should be assessed while the vehicle is in motion and when it is not in motion. In geographical areas where high humidity is the norm, testing should be performed to determine the potential for absorbent items to become contaminated and for the contents of sterile packages to become wet from the condensate that can occur on metal or plastic surfaces.

Vehicles that are loaded and ready for transport should not be left unattended in unsecured areas.

Rationale: See the rationale for 11.3.1.

12 Installation, care, and maintenance of sterilizers

12.1 General rationale

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

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

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

12.2 Instruction manuals

The purchaser should require that the sterilizer manufacturer provide a comprehensive instruction manual. The care and maintenance section of the manual should include, at a minimum, all information necessary to carry out the procedures recommended in 12.3, 12.4, 12.5, and 12.6 and should specify the frequency with which these procedures should be performed. Specific rather than general information should be provided for each equipment model. The user should keep the manufacturer's written IFU for as long as the equipment is in service.

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

12.3 Installation

Sterilizers should be

- a) installed according to the manufacturer's written IFU;
- b) installed in areas where explosive or flammable materials or anesthetics are not used or stored;
- c) connected to an electrical circuit with other appliances only if the circuit is rated for the additional load;
- d) placed on a level, heat-resistant surface, if a table-top sterilizer (a sterilizer with a chamber volume less than or equal to 2 cubic feet);
- e) installed with sufficient clearance for adequate access, if a table-top sterilizer mounted on a counter beneath a cabinet or other overhang; and
- f) clear of any obstruction in the area in front of the sterilizer.

After installation and before the health care facility either takes possession of the sterilizer or puts it into routine service, qualification testing should be carried out according to the procedures outlined in section 13.8.

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

12.4 Routine care

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

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

12.5 Preventive maintenance

12.5.1 General considerations

The manufacturer of the sterilizer should provide written IFU for preventive maintenance of the equipment. This maintenance should be carried out by a qualified individual. Particular attention should be given to the inspection, maintenance, and replacement of components subject to wear, such as recording devices (as applicable), filters, steam traps, drain pipes, valves, and door gaskets. Simple charts showing the locations and replacement dates of components will show trends in deterioration and provide the framework of a preventive maintenance program. The maintenance program may be in-house or contracted with the equipment manufacturer or other qualified service company. Preventive maintenance and repair records should be retained (see 12.7).

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

12.5.2 Scheduled maintenance

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

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

12.6 Calibration

Periodic calibration should be performed as specified in the manufacturer's written IFU (see 12.2), and the results should be documented. Examples of items requiring calibration are pressure- and temperature-sensing devices, timers, controls, and recording devices. The instruments used for calibration should be traceable to the primary standards of the National Institute for Standards and Technology. In the event of a sterilizer malfunction or the repair or replacement of any component affecting sterilizer performance, appropriate recalibration should be performed. Calibration may be performed by the manufacturer, the manufacturer's representative, the health care facility's engineering staff, or contract service personnel. Individuals performing the service should have sufficient training to understand the operation and calibration of the specific sterilizer type.

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

12.7 Record-keeping

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

- a) The date on which service was requested
- b) The model and serial number of the sterilizer
- c) The location of the equipment (facility identification, if applicable)
- d) The name of the individual from the health care facility who requested and authorized the service
- e) The reason for the service request
- f) A description of the service performed (e.g., calibration, repair)
- g) The types and quantities of parts replaced
- h) The name of the person who performed the service

- i) The date the work was completed
- j) The handwritten or electronic signature and title of the person who acknowledged completion of the work
- k) The results of any post-maintenance testing performed, if needed, before the sterilizer was returned to service

These records must be maintained by the health care facility. The length of time that records must be retained varies throughout the country. Each health care facility is responsible for determining its record-retention policy on the basis of state and local regulations, legal considerations (e.g., statutes of limitation for lawsuits), and its individual situation. Sterilization records should be retained in accordance with the policy and procedure established by the individual health care facility.

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

13 Process monitoring, testing, and quality control

13.1 General considerations

The assurance of sterility for reusable instrumentation requires continuous attention to all aspects of both the reprocessing process and the equipment used for cleaning and sterilization. This section addresses monitoring of mechanical cleaning equipment; product identification and traceability; physical, chemical, and biological monitoring of steam sterilization cycles; residual air (Bowie-Dick type) testing of dynamic-air-removal sterilizers; periodic product quality assurance; product recalls; and related quality control measures.

13.2 Monitoring of mechanical cleaning equipment

This section addresses washer–disinfectors, automated endoscope reprocessors (AERs), ultrasonic cleaners, and other mechanical cleaning equipment.

Health care personnel should perform verification testing on all mechanical cleaning equipment as part of the overall quality assurance program. Methods of verification include

- a) directly testing individual instruments for residual soils (e.g., adenosine triphosphate [ATP], protein, hemoglobin);
- b) employing a test device that is a consistent and repeatable challenge to the cleaning effectiveness of the equipment; and
- c) monitoring critical parameters to evaluate the performance of the mechanical cleaning equipment.

Mechanical cleaning equipment should be tested upon installation, each day that it is used, and after major repairs. When evaluating or changing to a new type of cleaning solution and after all major repairs, all cycles used should be tested to ensure that the cleaning solution and cleaning action are effective. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment. Examples include a software upgrade or the replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, ultrasonic generators, or computer controls.

Monitoring and verification of cleaning processes should be documented. Some mechanical washers have digital readouts and cycle printouts that should be reviewed for each cycle and initialed by the operator to indicate an acceptable cycle. Cycle printouts or cycle recording devices should be located on the clean side of pass-through mechanical washers.

Key performance outcomes include clean surfaces and adequate fluid flow in equipment that has adaptors for lumened devices. See Annex D.

Rationale: To ensure that mechanical cleaning equipment is working properly and according to the manufacturer's specifications, routine monitoring is required. Testing the equipment upon installation, during routine use, and after repairs allows the user to verify its continued effectiveness (AORN, 2017a). Reviewing and initialing the readouts and cycle printouts confirms that the mechanical equipment completed all the required phases of the cycle.

13.3 Product identification and traceability

13.3.1 General considerations

Each item or package intended for use as a sterile product should be labeled with a lot control identifier to allow full traceability of that item to the patient; alternately, an instrument tracking system may be used. Each load should have a load control record that includes a detailed content list, including specific identification of sets and the contents of sealable pouches.

13.3.2 Package labeling and expiration dating, if applicable

Each item or package intended for use as a sterile product should be labeled with a lot control identifier prior to sterilization. The lot control identifier should identify

- a) the sterilizer identification number or code;
- b) a detailed list of the contents (e.g., identification of multiple sets and the contents of paper–plastic pouches);
- c) the person who assembled the package;
- d) the date of sterilization;

- e) the cycle number (cycle run of the sterilizer); and
- f) the patient, if applicable. Items processed for immediate use should include a patient identifier.

For items intended to be stored, not used immediately, the labeling should also include the following, as applicable:

- a) If an event-related shelf-life system is used, an expiration statement. Each item in a load may be labeled with the following statement (or its equivalent): "Contents sterile unless package is opened or damaged. Please check before using." This information can be incorporated into the lot identification on the label or imprinted or affixed separately on the outside of the package.
- b) An expiration date on the product package label, if a time-related shelf-life system is used
- c) A clearly identifiable expiration date on the product package label, which is based on the manufacturer's written IFU, if the product contains material that degrades over time (e.g., latex)

This labeling should be done immediately before the load is processed. Ideally, every reprocessed medical device, especially an implant, should be fully traceable to the patient on whom it is used or in whom it is implanted; such traceability can be accomplished by recording the sterilizer load identifier on the patient chart or the patient name on the load record.

Rationale: Labeling items with a lot control number and an expiration statement or (when applicable) expiration date is necessary for proper stock rotation. See also 11.1.3. Lot identification enables personnel to retrieve items in the event of a recall and to trace problems (e.g., wet packs) to the source. Presterilization labeling can be done after sterilizer and cycle assignment is determined and as the cart is loaded. Accountability to the patient and surgeon for the sterility of a reprocessed device requires documentation that can be traced to the patient. Traceability is especially important as the consequences of infection can result in increased morbidity and mortality.

13.3.3 Sterilizer records

The process critical parameters (time and temperature) provided on the recording chart, printer, or tape should be reviewed, signed, and dated by the operator to indicate an acceptable cycle. For each sterilization cycle, the following information should be recorded:

- a) the load number;
- b) the specific contents of the lot or load, including quantity, department, and a specific description of the items (e.g., towel packs, type/name of instrument sets);
- c) the exposure time and temperature, if not provided on the sterilizer recording chart;
- d) operator identification;
- e) the results of biological testing, if applicable;
- f) the results of Bowie-Dick testing, if applicable;
- g) the response of the CI placed in the PCD, if applicable; and
- h) any reports of inconclusive or nonresponsive CIs found later in the processed devices (see also 13.5.2.2).

13.3.4 Record retention

The requirements for the length of time that records must be retained varies. Sterilization records should be retained according to the policy established by the individual health care facility; this policy should be based on local, state, federal, and accrediting agency requirements.

Information may be recorded in a paper or electronic log or filed as individual documentation records. Electronic records of sterilization process monitoring results, including specific load item identification, are recommended.

A record of repairs and preventive maintenance should be kept for each sterilizer (see 12.7).

Rationale: Documentation demonstrates compliance with regulatory and accrediting requirements and identifies trends for quality improvement opportunities.

13.4 Sterilization process monitoring

Sterilization process monitoring devices include physical monitors, CIs, and BIs. BIs and, in some cases, CIs are used within a PCD, an item that is designed to constitute a defined challenge to the sterilization process (see 13.5.4).

Each of these devices plays a distinct and specific role in sterilization process monitoring, and each is indispensable to sterility assurance. Sterilization process monitoring should include

- a) monitoring of every package and sterilization load (see Table 2 and 13.6);
- b) routine monitoring of sterilizer efficacy (see Table 2 and 13.7);
- c) qualification testing of the sterilizer after installation, relocation, sterilizer malfunction, major repairs, and sterilization process failures (see Table 2 and 13.8); and
- d) periodic product quality assurance testing (see Table 2 and 13.9).

New sterilization process monitoring devices should be evaluated prior to purchase by a multidisciplinary team, including infection preventionists, sterile processing personnel, and surgical services professionals. See Section 15 for general guidelines on how to assess the specific label claims of new products that become commercially available.

Rationale: Physical monitors verify that the parameters of the sterilization cycle have been met. Chemical indicators verify that one or more conditions necessary for sterilization have been achieved within the package and/or at a specific location within the load. Biological indicators verify that the conditions at a location within the load were adequate to kill a population of microorganisms resistant to the sterilization process and demonstrate the lethality of the sterilization process. The choices made in the selection and use of sterilization process monitoring devices play a large role in determining the level of quality of the sterile processing function and thus should be made on the basis of product performance characteristics and scientific data reviewed by those with technical knowledge and expertise, not merely economics.

Tables 2 and 3 summarize, respectively, the sterilization process monitoring recommendations of this recommended practice and the types and applications for use of sterilization process monitoring devices. See 13.5 through 13.10 for the detailed recommendations.

Table 2—Sterilization process monitoring recommendations

Routine load release (see 13.5 and 13.6)		Routine sterilizer efficacy monitoring (see 13.7)	Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, sterilization process failures) (see 13.8)	Periodic product quality assurance testing (see 13.9)
Nonimplants	Implants			
<p>Physical monitoring of cycle</p> <p>External and internal CI monitoring of packages</p> <p>Optional monitoring of the load with a PCD containing one of the following:</p> <ul style="list-style-type: none"> • a BI • a BI and a Type 5 integrating indicator • a Type 5 integrating indicator • a Type 6 emulating indicator 	<p>Physical monitoring of cycle</p> <p>External and internal CI monitoring of packages</p> <p>Monitoring of every load with a PCD containing a BI and a Type 5 integrating indicator</p>	<p>Physical monitoring of cycle</p> <p>External and internal CI monitoring of packages</p> <p>Weekly, preferably daily (each day the sterilizer is used), monitoring with a PCD containing a BI. (The PCD may also contain a CI.)</p> <p>For sterilizers larger than 2 cubic feet and for table-top sterilizers, monitoring is done in a fully loaded chamber.</p> <p>In IUSS cycles, monitoring may be done in an empty chamber.</p> <p>For dynamic-air-removal sterilizers, daily Bowie-Dick testing in an empty chamber, if applicable (see 13.7.6)</p>	<p>Physical monitoring of cycle</p> <p>External and internal CI monitoring of packages</p> <p>For sterilizers larger than 2 cubic feet and for IUSS cycles, monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.)</p> <p>For table-top sterilizers, monitoring of three consecutive cycles in a fully loaded chamber with a PCD containing a BI. (The PCD may also contain a CI.)</p> <p>For dynamic-air-removal sterilizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack, if applicable (see 13.7.6)</p>	<p>Physical monitoring of cycle</p> <p>Placement of BIs and, CIs within product test samples</p>

NOTE—See Section 15 for general guidelines on how to assess the specific label claims of new products that become commercially available.

Table 3—Types and applications for use of sterilization monitoring devices

Monitor	Frequency of use	Application (release of sterilizer, package, load)
Physical monitors		
Time, temperature, and pressure recorders, displays, digital printouts, electronic recording/data capture, and gauges	Should be used for every load of every sterilizer.	Part of load release criteria.
Chemical indicators (CIs)		
External CIs Type 1 (process indicators)	Should be used on outside of every package unless the internal CI is visible.	Part of load and package release criteria.
Bowie-Dick-type indicators Type 2 (Bowie-Dick)	For routine sterilizer testing (dynamic-air-removal sterilizers only if applicable, see 13.7.6), should be run, within a test pack, each day in an empty sterilizer before the first processed load. For sterilizer qualification testing (dynamic-air-removal sterilizers only if applicable, see 13.7.6), should be run, within a test pack, after sterilizer installation, relocation, malfunction, and major repairs and after sterilization process failures; test should be run three times consecutively in an empty chamber after BI tests.	Test of sterilizer for efficacy of air removal and steam penetration; part of release criteria for using sterilizer for the day. Part of release criteria for placing sterilizer into service after qualification testing.
Internal CIs	Should be used inside each package. Should be used in periodic product quality assurance testing.	Part of package release criteria at use site. Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging. Release criteria should include BI results.
Type 3 (single critical process variable indicator) Type 4 (multicritical process variable indicator)	May be used to meet internal CI recommendation.	Part of package release criteria at use site; NOT to be used for release of loads.
Type 5 (integrating indicator)	May be used to meet internal CI recommendation. Within a PCD, may be used to monitor nonimplant sterilizer loads. Within a PCD, should be used to monitor each sterilizer load containing implants. The PCD should also contain a BI.	Part of package release criteria at use site. Part of load release criteria for nonimplant loads. Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known.
Type 6 (emulating indicator)	May be used to meet internal CI recommendation. Within a PCD, may be used to monitor sterilizer loads.	Part of package release criteria at use site. Part of load release criteria for nonimplant loads. Part of release criteria for loads containing implants. Implants should be quarantined until BI results are known, except in emergency situations.
Biological indicators (BIs)	Within a PCD, may be used to monitor nonimplant loads. Within a PCD, should be used in every load containing implants. The PCD should also contain a Type 5 integrating indicator. Within a PCD, should be used for weekly, preferably daily (each day the sterilizer is used), routine sterilizer efficacy testing. (The PCD may also contain a CI.) Should be run in a full load for sterilizers larger than 2 cubic feet; for table-top sterilization, should be run in a fully loaded chamber; for IUSS, should be run in an empty chamber.	Part of load release criteria. Part of release criteria for loads containing implants. Implants should be quarantined until BI results are known, except in emergency situations. Part of sterilizer/load release and recall criteria. Part of release criteria for placing sterilizer into

	<p>Within a PCD, should be used for sterilizer qualification testing (after sterilizer installation, relocation, malfunction, major repairs, sterilization process failures). (The PCD may also contain a CI.) Test should be run three times consecutively in an empty chamber, except for table-top sterilizers, where the test should be run three times consecutively in a full load.</p> <p>Should be used for periodic product quality assurance testing.</p>	<p>service after qualification testing.</p> <p>Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging.</p>
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NOTE—See Section 15 for general guidelines on how to assess the specific label claims of new products that become commercially available.

13.5 Sterilization process monitoring devices

13.5.1 Physical monitors

Physical monitors should be used to monitor sterilizer performance. These include time, temperature, and pressure monitors. The output of these monitors may be recorded by way of charts, printouts, or digital data. The operator should

- verify that the recording device is functioning properly; and
- examine and interpret the chart, printout, or data to verify that all cycle parameters were met.

Confirmation that the cycle parameters were met should be documented by the operator signing the chart or printout or by suitable electronic means for data (see 13.3.3).

Sterilizers that do not have recording devices should not be used, with the exception of sterilizers used together with accessory recording devices or printouts.

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

NOTE 2—Most temperature sensors indicate temperature at the drain or exhaust line of the sterilizer, not at the center of packs. Improper load configuration or package composition can interfere with air evacuation and steam penetration, conditions that will not be revealed in the temperature recording. Therefore, physical monitoring and other indicators of sterilizer performance are not a substitute for careful adherence to prescribed packaging and loading procedures.

If the interpretation of the physical monitors suggests inadequate processing, the contents of the load should not be released or used. The operator should inform the appropriate supervisor, who should initiate appropriate follow-up measures as dictated by the health care facility policy and procedure.

Rationale: Physical monitors and associated recording devices provide real-time assessment of the sterilization cycle conditions and a permanent record by means of charts, printouts, or digital data. Physical monitoring is needed to detect malfunctions as soon as possible, so that appropriate corrective actions can be taken (see 13.7.5).

13.5.2 Chemical indicators

13.5.2.1 General considerations

Chemical indicators should be

- used to assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer;
- used in accordance with the CI manufacturer's written IFU;
- used as part of an effective quality assurance program; and
- used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile.

ANSI/AAMI/ISO 11140-1, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, defines six types of CIs and specifies performance requirements for them. This document provides recommendations for the following types of CIs.

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

Indicators for use in specific tests (Type 2) are intended for use in specific test procedures (e.g., the Bowie-Dick test) as defined in relevant sterilizer/sterilization standards. See 13.7.6 for recommendations concerning the use of these indicators. See also ANSI/AAMI/ISO 11140-5, *Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs*.

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

Multicritical process variable indicators (Type 4) are designed to react to two or more of the critical process variables and intended to indicate exposure to a sterilization process at SVs of the chosen critical process variables.

Integrating indicators (Type 5) are designed to react to all critical process variables. The SVs are generated to be equivalent to, or exceed, the performance requirements given in the ANSI/AAMI/ISO 11138 series for BIs.

NOTE—The SVs demonstrate how the indicator integrates over the entire temperature range.

Emulating indicators (Type 6) are designed to react to all critical process variables for specified sterilization processes.

NOTE 1—See ANSI/AAMI/ISO 15882 for information on the selection, use, and interpretation of chemical indicators.

NOTE 2—The International Organization for Standardization (ISO) 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.

CIs marketed in the United States must be cleared by FDA. The requirements in FDA's guidance document (FDA, 2003) differ in some aspects from ANSI/AAMI/ISO categories and the performance requirements described in ANSI/AAMI/ISO 11140-1. Annex N provides information explaining the differences between the two sets of performance requirements. For the purposes of this document, ANSI/AAMI/ISO categories are used to refer to the various types of chemical indicators, including use and application guidance.

Health care personnel should

- a) use CIs that are labeled for use in the selected sterilization cycle (see the written IFU of the CI manufacturer and the sterilizer manufacturer); and
- b) obtain data from the manufacturer on the reliability, safety, performance characteristics, and use of their products (e.g., how to interpret indicator results, the reliability of the indicator in maintaining endpoint response during storage of sterilized items, the sterilization conditions that the indicator will detect, the shelf life of the indicator, and the storage requirements for the indicator itself before and after sterilization).

Some CIs, such as Type 1 and Type 3 chemical indicators, are sensitive only to certain variables (e.g., temperature); others, such as Type 5 integrating indicators and Type 6 emulating indicators, integrate all critical variables. Manufacturers of CIs are required to provide written IFU on the storage, handling, and use of their products. See also ANSI/AAMI/ISO 11140-1.

Type 4 multicritical process variable CIs, Type 5 integrating CIs, and Type 6 emulating CIs provide more information about the process than Type 3 single critical process variable CIs and can provide additional quality assurance for the individual monitoring of such items as complex devices, surgical trays, and rigid sterilization container systems. When used within a PCD (see 13.5.4), Type 5 integrating indicators and Type 6 emulating indicators may be used for release of nonimplant loads (see 13.6). In this application, they provide additional information about the critical parameters of the sterilization process to supplement the results of physical monitors and Type 1 process indicators. A Type 5 integrating CI within a PCD (that also contains a BI) should be used to monitor each load containing implants and may be used as a basis for early load release in documented emergency situations only; however, loads containing implants should always be biologically monitored. Implants should be quarantined until the BI results (early readout or spore growth) are available. In an emergency situation, implants may be released before the BI results are available (see 13.6.3); however, the BI should continue to be incubated. A Type 6 emulating indicator

within a PCD may be used as part of the release criteria for loads containing implants (see 13.6.3). All loads containing implants should contain a BI PCD.

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

13.5.2.2 Using chemical indicators

13.5.2.2.1 External chemical indicators

A Type 1 CI (process indicator) should be present on the external surface of each package or rigid container. The Type 1 CI may be in the form of

- a) indicator tape;
- b) an indicator label;
- c) a container identification card; or
- d) a tamper-evident device.

The external CI should visually denote that the package has been exposed to a steam sterilization process.

Except for packages that allow visual inspection of an internal indicator, such as those with paper-plastic pouches, a Type 1 indicator should be used on all packages.

A user knowledgeable about the performance characteristics of the CI being used should examine the indicator after sterilization and before use of the item to verify that the item has been processed. If the interpretation of the CI suggests inadequate steam processing, the contents of the package should *not* be dispensed or used. If the package has already been dispensed, the interpreter should inform the appropriate supervisor and return the complete unused package, including load identification and the CI for the appropriate follow-up.

Rationale: The purpose of an external process indicator (Type 1 CI) is to differentiate between processed and unprocessed items, not to establish whether the parameters for adequate sterilization were met.

13.5.2.2.2 Internal chemical indicators

One or more internal chemical indicators should be placed within each package, tray, or rigid container. These indicators can be any type (Type 3, 4, 5, or 6) but preferably a Type 5 or Type 6 indicator because these types of CIs provide the user with more information on the critical steam sterilization parameters. All indicators should be used for the cycle(s) for which they are labeled and used in accordance with the manufacturer's written IFU.

NOTE—Type 6 emulating indicators are cycle-specific.

Internal CIs should be placed

- a) so that one CI is visible to the person opening the package;
- b) in the area or areas considered least accessible to steam penetration; and
- c) in accordance with all applicable written IFU.

After the package or rigid container is opened, the CI(s) should be retrieved and interpreted by a user knowledgeable about the performance characteristics of the CI being used.

If the interpretation of the CI suggests inadequate processing, the following steps should be taken:

- a) The contents of the package should *not* be used.
- b) The interpreter at the point of use should inform the appropriate supervisor of the inadequate processing and return the complete unused package, including load identification and the CI, to the sterile processing area.
- c) The appropriate supervisor should then initiate follow-up measures in accordance with health care facility policy and procedure (see 13.7.5).
- d) The department head or designee in the sterile processing area should then decide whether to recall that load, basing the decision on the results of physical monitoring (time and temperature recordings), the results of internal CIs elsewhere in the load, and, if applicable, the results of any PCDs in the load (see 13.5.4).

- e) If the results of a PCD containing a BI are not yet available, the remaining packages from the same load should be quarantined and not used until the BI results are known.

A single nonresponsive or inconclusive CI should not be considered definitive evidence that the entire load is nonsterile. It is possible that the entire load is not sterile (i.e., the sterilization process failed). It is also possible that errors in loading or packaging have resulted in sterilization failures in some, but not all, packages in the load. Professional judgment should be used to determine whether to recall the entire load, taking into account all factors having a bearing on the efficacy of the cycle and all performance indicators (physical monitors, CIs, and BIs). A decision tree for conducting investigations of steam sterilization failures is shown in Figure 10.

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

13.5.3 Biological indicators

13.5.3.1 General considerations

Health care personnel should select BIs that consist of spores of *Geobacillus stearothermophilus*, that comply with ANSI/AAMI/ISO 11138-3, and that are suitable for use in the specific sterilization cycle (see the written IFU of the BI manufacturer and the sterilizer manufacturer).

Data should be obtained from manufacturers on the reliability, safety, and performance characteristics of their products.

For BIs that contain spores with an enzyme-based early-readout capability, periodic verification of the early readout with spore growth should be performed in accordance with the manufacturer's written IFU and facility policy and procedures. For this verification, the BI with enzyme-based early-readout capability can be further incubated to demonstrate spore growth by a visible color change. In the event of a sterilization process failure, the sterilizer manufacturer might recommend additional biological testing to verify results.

All BIs should be used in accordance with the BI manufacturer's written IFU.

Rationale: Biological indicators are the only sterilization process monitoring devices that provide a direct measure of the lethality of the process. Various types of BIs are available, each with different response characteristics and incubation requirements. To provide useful information about the lethality of the sterilization process, the appropriate BI must be chosen for the steam sterilization cycle being run and used correctly (in accordance with the manufacturer's written IFU). Manufacturers of BIs are required to provide written instructions on the storage, handling, use, and microbiological testing of their products. Biological indicators consist of spores in or on a carrier and provide a direct measure of lethality of a cycle. Self-contained BIs (SCBIs) include incubation media with the spore carrier in a single vial. Biological indicators are incubated for various periods of time (depending on the specific product) until it is determined whether the microorganisms grow (i.e., they survived the sterilization process) or fail to grow (i.e., they were killed by the sterilization process). Biological indicators are intended to demonstrate whether the conditions were adequate to kill a large number of highly resistant bacterial spores. A negative BI does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

13.5.3.2 Using biological indicators

Biological indicators should be used within PCDs (see 13.5.4, 13.7.2.1, 13.7.3.1, and 13.7.4.1) for routine sterilizer efficacy monitoring at least weekly, but preferably every day that the sterilizer is in use (see 13.7). Biological indicators within a PCD may be used as part of the criteria for release of loads. Additionally, BIs with Type 5 integrating indicators within PCDs should be used to monitor every load containing implants; implants should be quarantined until the results of the BI testing are available. (CDC, 2008).

If a PCD containing only a BI is used to release a load, the load should be quarantined until the result of the BI is known.

Biological indicators within PCDs should be used for sterilizer qualification testing (see 13.8) after

- a) sterilizer installation;
- b) sterilizer relocation;
- c) sterilizer malfunctions;
- d) major repairs to the sterilizer; and

- e) sterilization process failures.

Each sterilization cycle type that is used should be tested. If a sterilizer will run the same type of cycle (e.g., dynamic-air-removal at 132°C to 135°C [270°F to 275°F]) for different exposure times (e.g., 4 minutes and 10 minutes), then only the shortest cycle time should be tested.

Biological indicators should be used for periodic quality assurance testing of representative samples of actual products being sterilized (see 13.9 and 13.10).

Rationale: BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Biological monitoring provides the only direct measure of the lethality of a sterilization cycle. Sterilizer manufacturers utilize BIs as part of the validation of their sterilization cycles during the half-cycle validation testing; therefore, routine sterilizer efficacy monitoring in health care facilities should also be conducted using BIs. Although the performance of Type 5 integrating CIs has been correlated to the performance of BIs, these sterilization monitoring devices do not contain spores and thus do not directly measure the lethality of a sterilization cycle; however, they provide additional information about the attainment of the critical parameters of the sterilization process. Likewise, although Type 6 emulating indicators (a different technology than Type 5 integrating indicators) are designed to react to all critical variables of specified sterilization cycles, they do not directly measure the lethality of a cycle and they are not intended to be used as the sole means of routinely verifying sterilizer efficacy or of qualifying sterilizer performance after installation, repair, or relocation.

13.5.4 Process challenge devices

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

- a) a BI,
- b) a BI and a Type 5 integrating CI,
- c) a Type 5 integrating CI, or
- d) a Type 6 emulating indicator.

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

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

- a) a PCD containing a BI (BI challenge test pack),
- b) a PCD containing a BI and a Type 5 integrating CI (BI and CI challenge test pack), or
- c) a PCD containing a Type 5 integrating CI or a Type 6 emulating CI (a CI challenge test pack).

For routine release of loads containing implantable devices, a PCD containing a BI and a Type 5 integrating CI (a BI challenge test pack) should be used to monitor the load (see 13.6.1). For routine sterilizer efficacy monitoring (see 13.7) and sterilizer qualification testing (see 13.8), the PCD should contain a BI and may contain one or more CIs as well.

NOTE—See Section 15 for general guidelines on how to assess the specific label claims of new products that become commercially available.

A PCD may be a user-assembled challenge test pack or test tray or a commercially available, disposable, pre-assembled challenge test pack. The premarket [510(k)] notification submitted by the manufacturer to FDA should include scientific evidence demonstrating that the commercial PCD is comparable in performance to the user-assembled challenge test pack defined in 13.7.2.2. Health care personnel should use commercially available PCDs only if they have been cleared by FDA for their intended use. Any manufacturer-supplied scientific data on equivalence should be reviewed.

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

- a) Is the PCD appropriate for the specific steam sterilization cycle being used?
- b) Has the performance of the PCD been demonstrated to be equivalent to the performance of the user-assembled challenge test pack of 13.7.2.2?

- c) What types of BIs and/or CIs are used in the PCD?
- d) Can this PCD be used for routine sterilizer efficacy monitoring and sterilizer qualification testing, or is it only suitable for use in routine load release?
- e) If the monitor in the PCD indicates a questionable sterilization cycle, what procedure should be followed to investigate the potential sterilization process failure?
- f) Does the PCD have a specific shelf life? What are the specific storage requirements for the PCD?

Rationale: The condition of the sterilizer equipment, the expertise of the sterilizer operator, and other factors that determine the success or failure of a steam sterilization cycle could vary from one cycle to another. The less frequently the sterilizer is used, the greater the chance that an unnoticed event could affect sterilization. Therefore, it is necessary to regularly challenge the sterilizer and the sterilization process with a PCD. For commercial PCDs, it is important for health care personnel to obtain adequate information on their performance and intended use to ensure that they are suitable for the intended application and that they are used correctly. For a commercial PCD intended for use in health care facilities, the manufacturer is required by FDA to submit a premarket [510(k)] notification and obtain FDA clearance. Manufacturers of PCDs should provide written instructions for the use, storage, handling, and testing of their products.

13.6 Routine load release

13.6.1 Process monitoring devices

Every sterilization load should be monitored with a physical monitor and a chemical indicator monitor.

Every sterilization load may be monitored with a PCD containing

- a) a BI;
- b) a BI and a Type 5 CI (integrating indicator);
- c) a BI and a Type 6 CI (emulating indicator);
- d) a Type 5 CI (integrating indicator); or
- e) a Type 6 CI (emulating indicator).

A BI PCD should be used at least weekly and preferably daily.

13.6.2 Release criteria for nonimplants

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

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

13.6.3 Release criteria for implants

As with all cycles, an experienced, knowledgeable person should review the sterilizer chart or printout at the end of the sterilization cycle, as well as the results of other indicators that have been used to monitor the sterilization process. The load should be quarantined until the results of the BI testing are available (CDC, 2008).

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

NOTE—See Section 15 for general guidelines on how to assess the specific label claims of new products that become commercially available.

Rationale: Patient risk of infection is greatly increased by the implantation of a nonsterile device (CDC, 2008). The sterilization of implantables should be closely monitored and each load containing implants should be quarantined until it is verified that BI testing has yielded negative results. In defined emergency situations in which the quarantine of implants cannot be maintained, breaking of the quarantine is allowed for documented medical exceptions in accordance with facility policies and procedures. See also the rationale for 13.6.2.

13.6.4 Sterilization process failure

Sterilization process failures can occur for a number of reasons. A malfunction in the sterilization cycle could occur. Other possible reasons include poor steam quality, operator error, and related factors.

If physical monitoring during the cycle indicates any malfunction or suspicious operation, the following steps should be taken:

- a) The department head or designee should be notified.
- b) If overloading is suspected, the sterilizer should be reloaded and the cycle rerun.
- c) After examination, if the malfunction cannot be corrected immediately, the cycle should be terminated in accordance with the sterilizer manufacturer's written IFU.
- d) The load should be considered nonsterile, and the sterilizer should be removed from service.
- e) The load should be removed from the sterilizer and quarantined so that it is not inadvertently released for use.
- f) The hospital engineer or maintenance contract service should then be notified, the root cause should be identified, and the sterilization process failure should be corrected.
- g) The same investigative procedure should be followed at the completion of the cycle if the physical monitors, external CIs, or the monitor in a PCD (BI challenge test pack or CI challenge test pack) indicates a questionable cycle. See also 13.7.5.

A faulty sterilizer cannot be made operational without identifying and correcting the underlying problem; merely extending the cycle time or increasing the cycle temperature, for example, is not appropriate. After a major repair of any type of steam sterilizer or the utilities connected to the sterilizer, three consecutive test cycles with a PCD containing a BI should be run, one right after the other, in an otherwise empty chamber for sterilizers larger than 2 cubic feet and for IUSS cycles and in a fully loaded chamber for table-top sterilizers (see 13.8). After a major repair to a dynamic-air-removal sterilizer, three consecutive Bowie-Dick test cycles should then be run in an empty chamber, one right after the other, and the test sheets examined (see 13.7.6). The BI test results should be obtained (i.e., the BI should be incubated according to the BI manufacturer's written IFU) and be determined to be satisfactory before the sterilizer is returned to service.

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

The performance of the sterilizer also depends on the utilities connected to it. The sterilizer manufacturer specifies certain utility line sizes, maximum and minimum pressures, and dynamic flow requirements for the required utilities. The steam supply should consist of saturated, condensate-free steam with a minimum dryness factor of 97% (see also 3.3.3). Water quality also might be specified, especially for stand-alone steam generators (which are typically shut down on weekends). Sterilizers are designed to function with a nominal electrical supply and can be operated within a specified range of that nominal value. Significant changes to the utilities connected to the sterilizer (e.g., changes necessitated by water-main breaks, annual boiler maintenance, or additional equipment loads) could affect sterilizer performance. Major repairs of or changes to the utilities (e.g., the installation of new boilers) should be treated as major repairs to the sterilizer, and sterilizer testing should be performed as defined in this section to provide the necessary qualification for use.

Rationale: A faulty sterilizer cannot be made operational without identifying the exact cause of the malfunction and correcting it. Simply altering the cycle parameters of a malfunctioning sterilizer will not correct a problem; the sterility of future loads will be jeopardized if the sterilizer continues to be used without repair. Sterilizer testing after major repairs of the sterilizer itself or its utilities is intended to ensure that the sterilizer performs to specifications after the correction of a malfunction. Common problems detected by physical, chemical, and biological monitoring include inadequate temperature, air removal, exposure time, and drying time.

13.7 Routine sterilizer efficacy monitoring

13.7.1 General considerations

Sterilizers should be routinely tested using PCDs. If a sterilizer is designed to be used for multiple types of cycles, each sterilization cycle type used by the health care facility should be tested. If a sterilizer will run the same type of cycle (e.g., dynamic-air-removal at 132°C to 135°C [270°F to 275°F]) for different exposure times (e.g., 4 minutes and 10 minutes), then only the shortest cycle time should be tested.

Rationale: Testing a single cycle for routine efficacy with PCDs is inadequate to determine if all cycles are functioning properly. Gravity-displacement and dynamic-air-removal cycles must be tested to determine if all sensors, controls, indicators and charts are functioning properly. The shortest cycle can be considered representative of the other longer cycles.

13.7.2 Routine biological monitoring of sterilizers larger than 2 cubic feet

13.7.2.1 General considerations

For routine sterilizer efficacy monitoring (see 13.5.4), the AAMI 16-towel test pack is considered the representative standard for the appropriate worst-case challenge to steam sterilization cycles. The design of the original test pack was developed by Perkins in the 1960s and since has been evaluated and redesigned to allow users to assemble an appropriate challenge pack with standardized materials readily available in health care facilities (see Annex J). Alternatively, a pre-assembled, commercially available PCD that has demonstrated equivalence to the 16-towel PCD and is cleared by the FDA may be used.

A BI PCD should be used for routine monitoring of sterilizers larger than 2 cubic feet. Commercially available PCDs are recommended; however, a facility-assembled PCD may be used (see 13.7.2.2).

Rationale: Commercially available disposable PCDs (BI challenge test packs) provide standardization and reduce variability and potential for error.

13.7.2.2 Composition of the user-assembled PCD

The PCD should consist of 16 clean, preconditioned, reusable huck or absorbent surgical towels, in good condition, each of which is approximately 16 inches by 26 inches (41 cm by 66 cm). (Preconditioning consists of holding the towels at room temperature—18°C to 24°C [65°F to 75°F]—and a relative humidity of at least 35% for at least 2 hours.) Each towel is folded lengthwise into thirds and then folded widthwise in the middle (Figure 8). After they are folded, the towels are placed one on top of another, with folds opposite each other, to form a stack that is approximately 9 inches wide, 9 inches long, and 6 inches high (23 cm by 23 cm by 15 cm). One BI and one CI are placed between the eighth and ninth towels in the approximate geometric center of the pack. The pack is then taped in a manner that will yield the approximately 6 inch (15 cm) height. The pack should weigh approximately 3 pounds and should have a density of approximately 11.3 pounds per cubic foot. A wrapper should not be used for this PCD. (See Figure 8 and Annex J.)

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

Rationale: The 16 towel PCD (BI challenge test pack) provides a sterilization challenge for air removal and for steam penetration to the BI(s) within the PCD. Use of the PCD provides evidence of the microbial lethality of the process (see also 13.7.1). The 16 towel PCD is not wrapped because the PCD is intended to provide a reproducible, well defined, easily constructed, standardized challenge to test sterilizer performance. Also, experience with the wrapped test pack specified in the first edition of this recommended practice (AAMI ST1:1980) showed that the wrapper adds another difficult-to-control variable. Only one BI needs to be used for the test in order to achieve a microbial challenge. There are no data to support the need for more than one BI.

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

13.7.2.3 Placement of the PCD

Routine sterilizer efficacy monitoring should be performed in a loaded chamber. The PCD should be

- placed flat (layers of towels horizontal if the 16 towel PCD is being used) on the sterilizer cart, before the cart is loaded with other packs, in the area of the sterilizer chamber and load that is least favorable to sterilization (i.e., the area representing the greatest challenge to the BI); and
- placed so that it is not on top of or underneath a package or sideways on the sterilizer cart.

The sterilizer manufacturer should identify the exact location of the area least favorable to sterilization, the "cold point," in the instruction manual and instruct users to place the test pack at this location. This area varies with sterilizer design, but is normally in the front, bottom section of the sterilizer, near the drain. (See Figure 9.)

Rationale: Placing the 16 towel pack over the chamber drain maximizes the opportunity for air within the sterilizer to be detected by the pack.

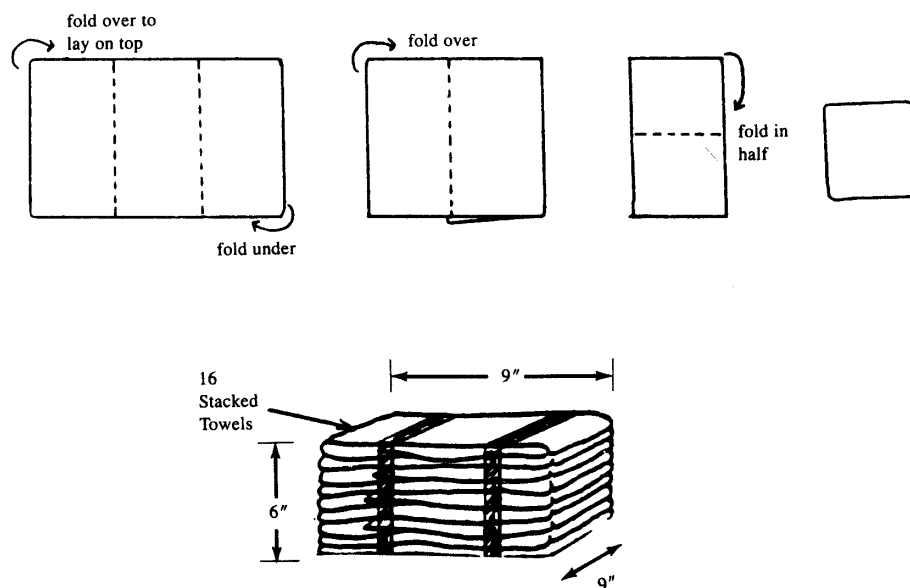


Figure 8—Preparation of the 16 towel PCD (BI challenge test pack)

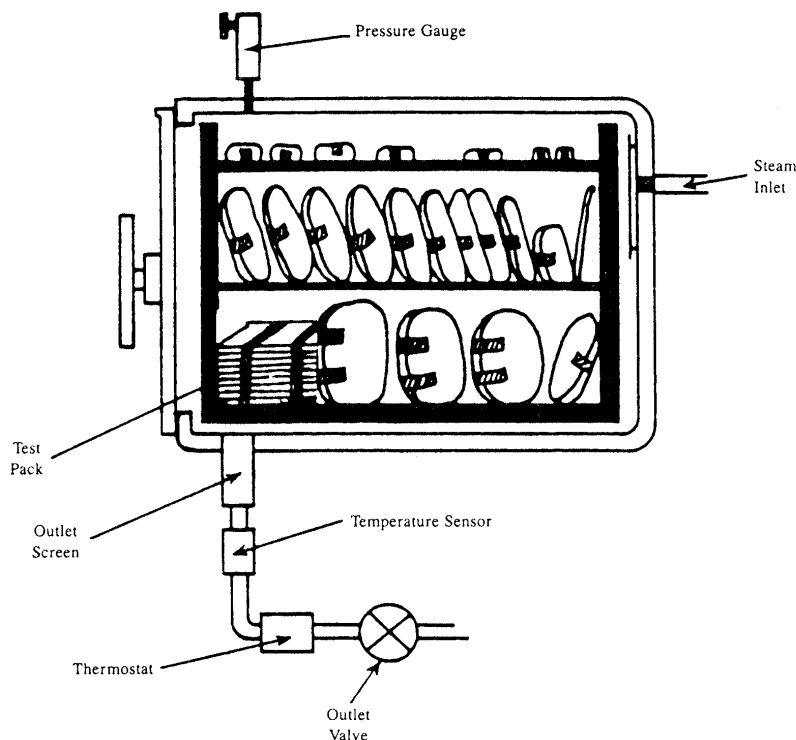


Figure 9—Placement of the 16 towel PCD (BI challenge test pack) for routine biological monitoring of sterilizers larger than 2 cubic feet

13.7.2.4 Test procedure

The test procedure is as follows:

- 1) Before being exposed to the sterilization cycle, the PCD should be labeled to identify the date, the sterilizer, and the cycle being tested.
- 2) The PCD should be positioned in the chamber according to 13.7.2.3.
- 3) A normal cycle should be run, according to the sterilizer and device manufacturers' written IFU.
- 4) Upon completion of the sterilization cycle and cooling of the PCD, the BI(s) and CI(s) should be removed from the PCD and their identification recorded. The CI manufacturer's written IFU for interpretation of CI results should be followed. The BI(s) should be handled and incubated according to the BI manufacturer's written IFU.

NOTE—*Geobacillus stearothermophilus* does not grow at 35°C to 37°C (95°F to 99°F), the temperature of standard bacteriology laboratory incubators. A temperature in the range of 55°C to 60°C (131°F to 140°F) is typically recommended by BI manufacturers. Consult the manufacturer's written IFU for the incubation time and temperature.

- 5) Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control in each incubator. For control BIs placed in an electronic early-readout incubator, the electronic incubator manufacturer's written IFU for incubation of control BIs should be followed. Both the test and control BI lot numbers should be documented. Upon completion of the incubation period, the test and control BI results should be read and recorded. If the control BI from a lot fails to grow, the results from the test BIs should be considered invalid and a root cause analysis should be performed and corrective action taken.

Rationale: Positive BI controls provide evidence of the viability of the test organism, the ability of the media to promote growth of the test organism, achievement of the recommended incubation temperature range, and detection of user error.

13.7.2.5 Acceptance criteria

An acceptable process is evidenced by negative results from all test BIs, positive (growth) results from all control BIs, and appropriate readings from physical monitors and CIs, showing that the sterilization cycle was correct and

complete. All monitoring results, including results from BI controls, should be interpreted by a qualified individual and included in the sterilizer records.

13.7.3 Routine biological monitoring of table-top sterilizers (less than or equal to 2 cubic feet)

13.7.3.1 Composition of the PCD

The composition of the PCD is as follows:

- 1) A representative of the same type of package or tray to be routinely processed through the sterilizer should be selected to serve as the PCD for routine sterilizer efficacy monitoring.
- 2) The PCD should contain a BI and a CI.
- 3) The package or tray considered to be the most difficult to sterilize should be selected from those most frequently processed.
- 4) The package or tray selected should contain the items normally present during routine sterilization.
- 5) Characteristics that should be considered when selecting PCDs include multiple layers of dressing materials, large metal masses, and mixed packs incorporating both.

Rationale: Table-top sterilizers are not routinely tested using the standardized PCD described in 13.7.2.2 because it does not fit into the chamber. There are no universally accepted standardized PCDs for table-top sterilizers. Therefore, this recommended practice suggests that a representative package or tray that is to be routinely processed through the sterilizer be used as the PCD. The packages or trays used as PCDs will vary from facility to facility, depending on the types of items routinely sterilized. There are no data to support the need for more than one BI.

13.7.3.2 Placement of the PCD

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

Rationale: Small packs are routinely placed on edge to allow adequate steam exposure. Larger packs or trays are routinely placed flat on the shelf because their size will not permit any other orientation in the relatively small chambers of table-top steam sterilizers (less than or equal to 2 cubic feet). Placing the PCD in the coolest portion of the chamber presents the most severe challenge. Table-top steam sterilizers typically have a water reservoir that injects a set volume of water, which is used to create steam during the cycle. Because of the limited amount of water available to create steam, the greatest challenge to steam penetration is the amount of available steam.

13.7.3.3 Test procedure

The test procedure is as follows:

- 1) Before being exposed to the sterilization cycle, the PCD should be labeled to identify the date, the sterilizer, and the cycle being tested.
- 2) The PCD should be positioned in the chamber according to 13.7.3.2.
- 3) A normal cycle should be run, according to the sterilizer and device manufacturers' written IFU.
- 4) Upon completion of the sterilization cycle and cooling of the PCD, the BI(s) and CI(s) should be removed from the PCD and their identification recorded. The CI manufacturer's written IFU for interpretation of CI results should be followed. The BI(s) should be handled and incubated according to the BI manufacturer's written IFU.

NOTE—*Geobacillus stearothermophilus* does not grow at 35°C to 37°C (95°F to 99°F), the temperature of standard bacteriology laboratory incubators. A temperature in the range of 55°C to 60°C (131°F to 140°F) is typically recommended by BI manufacturers. Consult the manufacturer's written IFU for the incubation time and temperature.

- 5) Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control in each incubator. Both the test and control lot numbers should be documented. Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, the results from the test BIs should be considered invalid and a root cause analysis should be performed and corrective action taken.

Rationale: Positive BI controls provide evidence of the viability of the test organism, the ability of the media to promote growth of the test organism, achievement of the recommended incubation temperature range, and detection of user error.

13.7.3.4 Acceptance criteria

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

13.7.4 Routine biological sterilizer efficacy monitoring of gravity-displacement cycles

13.7.4.1 Composition of the PCD

For routine monitoring of gravity-displacement cycles, a representative of the same type of tray to be routinely processed by gravity-displacement cycles should be selected to serve as the PCD. Each type of tray configuration routinely used for gravity-displacement cycles should be tested separately. The BI(s) and CI(s) should be placed in the most difficult-to-sterilize portion of the PCD. For rigid sterilization container systems, the BI(s) should be placed in accordance with 13.7.3.2.

Rationale: The test tray provides a sterilization challenge for air removal and for steam penetration to the BI(s) within the PCD. Use of the PCD provides evidence of the microbial lethality of the process (see also 13.7.1).

13.7.4.2 Placement of the PCD

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

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

13.7.4.3 Test procedure

The test procedure is as follows:

- 1) Before being exposed to the sterilization cycle, the PCD should be labeled to identify the date, the sterilizer, and the cycle being tested.
- 2) The PCD should be positioned in the chamber according to 13.7.4.2.
- 3) A normal cycle should be run, according to the sterilizer and device manufacturers' written IFU.
- 4) Upon completion of the sterilization cycle and cooling of the PCD, the BI(s) and CI(s) should be removed from the PCD and their identification recorded. The CI manufacturer's written IFU for interpretation of CI results should be followed. The BI(s) should be handled and incubated according to the BI manufacturer's written IFU.

NOTE—*Geobacillus stearothermophilus* does not grow at 35°C to 37°C (95°F to 99°F), the temperature of standard bacteriology laboratory incubators. A temperature in the range of 55°C to 60°C (131°F to 140°F) is typically recommended by BI manufacturers. Consult the manufacturer's written IFU for the incubation time and temperature.

- 5) Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control in each incubator. Both the test and control lot numbers should be documented. Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, the results from the test BIs should be considered invalid and a root cause analysis should be performed and corrective action taken.

Rationale: Positive BI controls provide evidence of the viability of the test organism, the ability of the media to promote growth of the test organism, achievement of the recommended incubation temperature range, and detection of user error.

13.7.4.4 Acceptance criteria

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

13.7.5 Actions to take when BIs, CIs, or physical monitors indicate a sterilization process failure

13.7.5.1 General procedure

See Figure 10 and Table 4 for guidance on how to conduct an investigation into a sterilization process failure. In general, the procedure is as follows:

- a) A processed PCD with a positive BI, a failed Type 5 integrating CI or Type 6 emulating indicator, or a failed physical monitor should be immediately reported in accordance with facility policy. The following information should be included in the initial notification (generally verbal) and subsequent written documentation:
 - the time and date of the incident, including the sterilizer identification number and load control number;
 - a description of the incident, including any information about patient(s) potentially affected (see Table 4);
 - the results of physical monitoring and of internal CIs (if applicable); and
 - additional relevant information (e.g., evidence of operator error).
- b) If the cause of failure is immediately identified and confined to one load or one item in the load (e.g., an item with a nonresponsive internal CI), the cause of the failure should be corrected and the load or item should be reprocessed.
- c) If the cause of the failure is not immediately identified, the load should be quarantined, and all loads back to the last negative BI should be recalled. Items in these loads should be retrieved, if possible, and reprocessed (see 13.7.5.2). The sterilizer in question should be taken out of service until the cause of the failure is identified and corrected.
- d) If the PCD failure involved a positive BI, a microbiology laboratory may perform a presumptive identification of the microorganisms present in the "failed" (positive) BI, in accordance with the BI manufacturer's written IFU (see 13.7.5.4), and, if applicable, review the BI use and transfer techniques. The load recall should not be delayed during this testing. If laboratory testing shows a false positive, the recall may be discontinued and documented as such. Further investigation of user error and/or the BI manufacturer's written IFU is warranted.
- e) A multidisciplinary team should attempt to determine the root cause of the sterilization process failure and implement corrective action.
- f) If the root cause of the sterilization process failure has been determined to be a sterilizer malfunction and a major repair is required for correction, the sterilizer in question should be immediately rechallenged with a PCD (see 13.7.2.1, 13.7.3.1, or 13.7.4.1, as applicable) in three consecutive cycles (see 13.8). For sterilizers larger than 2 cubic feet, three consecutive cycles should be run in an empty chamber (see 13.8.2 and 13.8.4). For table-top sterilizers (less than or equal to 2 cubic feet), three consecutive cycles should be run in a fully loaded chamber (see 13.8.3). For dynamic-air-removal sterilizers, a Bowie-Dick test pack should then be run in three consecutive empty-chamber cycles (see 13.7.6). Until the results of retesting are satisfactory (three cycles with negative BIs and, if applicable, three cycles with acceptable color change in the Bowie-Dick indicator), the performance of the sterilizer should be considered in question.

Rationale: Conducting the above protocol whenever sterilization process failure is indicated by a CI, BI, or physical monitor will provide data useful in the sterilization process failure investigation and subsequent corrective action.

13.7.5.2 Recall of items processed by the health care facility

13.7.5.2.1 General considerations

The health care facility should establish written policies and procedures for the recall of items that have been processed and issued or stored for later use.

The policies and procedures should

- a) be developed in collaboration with the infection prevention and control committee and risk management of the health care facility;
- b) outline the circumstances for issuing a recall;
- c) designate the department or individual(s) responsible for initiating the recall when there is evidence of a sterilization failure; and
- d) establish notification procedures in compliance with regulatory (federal, state, local) and accrediting agency requirements.

Rationale: Recall policies and procedures can help expedite the retrieval of processed items that are suspected to be nonsterile and to ensure adequate follow-up actions, such as quarantine of the sterilizer, notification of physicians and affected clinical departments, and surveillance of patients.

13.7.5.2.2 Recall procedure

If processed items are suspected to be nonsterile, a recall should be issued that

- a) may include quarantine and retrieval of items processed back to the last negative BI;
- b) is immediately communicated to affected departments and followed by a written order;
- c) identifies by sterilization lot number the products to be recalled;
- d) identifies the persons or departments to whom the order is addressed;
- e) requires the recording, in terms of kind and quantity, of the products obtained in the recall; and
- f) specifies the action to be taken by the persons receiving the order (e.g., destruction or return of product).

13.7.5.2.3 Recall report

A report of a recall should

- a) identify the circumstances that prompted the recall order;
- b) include documentation of microbiological test results when a positive BI initiated the recall;
- c) specify the corrective action(s) taken to prevent a recurrence;
- d) state, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall; and
- e) provide verification that the recalled items were reprocessed or destroyed, as appropriate.

13.7.5.3 Microbiological testing

For positive BIs, the test procedure is as follows:

- a) The microbiology laboratory should perform a presumptive identification according to the BI manufacturer's written IFU to determine whether the recovered microorganism is indeed the test microorganism that was on the BI spore strip or is a laboratory contaminant.
- b) Two subcultures should be made from the recovered culture (the manufacturer should be consulted for the culturing procedure).
- c) One subculture should be incubated at 35°C to 37°C (95°F to 99°F) for 24 to 48 hours, and the other at 55°C to 60°C (131°F to 140°F) for 24 to 48 hours.
- d) Smears of the incubated subcultures should be prepared, stained by Gram's method, and microscopically examined.
- e) Presumptive identification should be considered positive for *Geobacillus stearothermophilus* if microscopic examination reveals Gram-positive/gram-variable, spore-bearing rods and if the results of the incubation studies demonstrate growth at 55°C to 60°C (131°F to 140°F) but no growth at 35°C to 37°C (95°F to 99°F).
- f) Any other Gram stain result (Gram-positive cocci or Gram-negative bacilli) should be considered a contaminant.

BIs with early-readout systems need incubation for visual spore growth prior to microbiological testing.

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

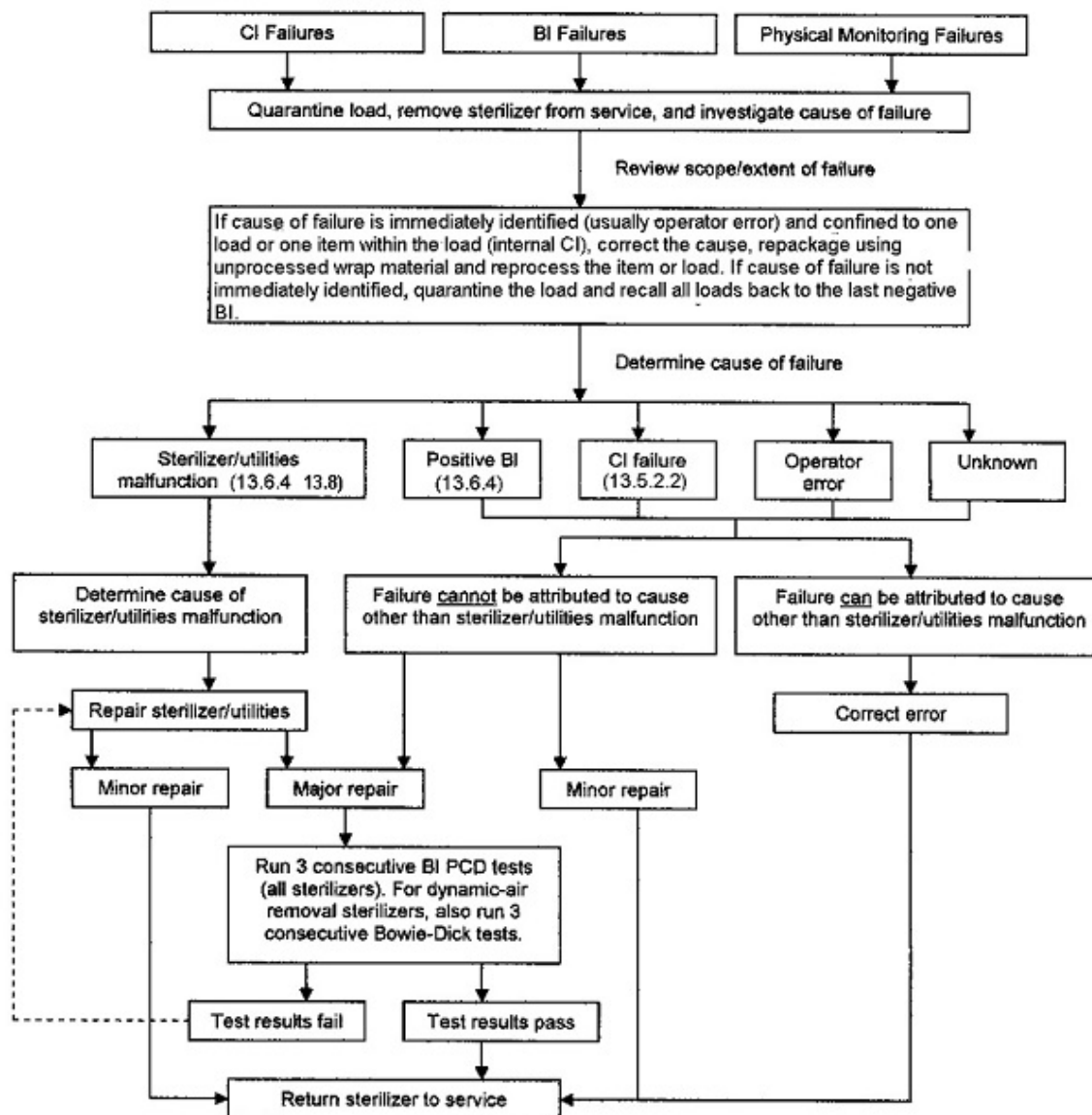


Figure 10—Decision tree for conducting investigations of steam sterilization process failures

Table 4—Potential causes to be investigated for steam sterilization process failures

Operator errors
<p>Incorrect use and interpretation of monitoring tools</p> <ul style="list-style-type: none"> • Incorrect physical monitors for the load • Incorrect use of BI or BI PCD <ul style="list-style-type: none"> – Incorrect selection of BI or BI PCD for the load – Incorrect placement of BI PCD in the load (e.g., another pack was placed on top of the PCD) – Incorrect incubation of BI – Misinterpretation of BI result – Incorrect documentation of BI result • Incorrect use of Type 5 integrating CI PCD or Type 6 emulating CI PCD <ul style="list-style-type: none"> – Incorrect selection of CI PCD for the load. – Incorrect placement of CI PCD in the load (e.g., another pack was placed on top of the PCD) – Misinterpretation of Type 5 integrating CI result or Type 6 emulating CI result – Incorrect documentation of Type 5 integrating CI result or Type 6 emulating CI result • Incorrect use of internal CI <ul style="list-style-type: none"> – Incorrect selection of internal CI for the load – Misinterpretation of internal CI result – Incorrect documentation of internal CI results • Incorrect storage of any CIs or BIs • Failure to check physical monitors for functionality before running cycle • Use of broken BI media ampoule or ampoule with missing spore strip or spore carrier • Use of BI PCD or CI PCD that is missing the BI or CI • Use of defective CI (e.g., a CI that is expired, faded, shows a partial color change because of incorrect storage, or has been previously exposed to the sterilant) <p>Selection of incorrect cycle for load contents (containment device or medical device manufacturer's written IFU not followed)</p> <p>Use of inappropriate packaging materials or packaging technique</p> <ul style="list-style-type: none"> • Incorrect packaging or containment device for the cycle parameters • Incorrect preparation of containment device for use (e.g., incorrect filters, valves, or bottom tray) • Use of a paper–plastic pouch, woven or nonwoven wrapper, or towel in a 132°C to 135°C (270°F to 275°F) gravity-displacement cycle • Use of a tray that does not allow air removal and steam penetration • Use of a wrapper that is too large for the application • Placement of a folded paper–plastic pouch inside another paper–plastic pouch • Placement of a paper–plastic pouch inside a wrapped set or containment device without verification of adequate air removal and steam penetration by product testing • Incorrect placement of basins in set (e.g., basins are not aligned in the same direction) • Failure to use nonlinting absorbent material between nested basins • Preparation of textile packs that are too dense to sterilize with the cycle parameters chosen • Inadequate preconditioning of packaging materials (i.e., not holding package materials at 20°C to 23°C [68°F to 73°F] for 2 hours before use) <p>Incorrect loading of sterilizer</p> <ul style="list-style-type: none"> • Stacking of containment devices if not recommended by manufacturer • Stacking of perforated instrument trays • Incorrect placement of instrument trays (e.g., not laying instrument trays flat or parallel to the shelf) • Incorrect placement of paper–plastic pouches (e.g., placing pouches flat instead of on edge; not allowing sufficient space between pouches; not placing pouches with plastic sides facing one direction) • Incorrect placement of basins (e.g., not placing basins on their sides so that water can drain) • Incorrect placement of textile packs (e.g., not placing them on edge) • Placement of packages too close together, impeding air removal and sterilant penetration in the load

**Table 4—Potential causes to be investigated for steam sterilization process failures
(continued)**

Sterilizer or utility malfunctions
<p>Poor steam quality or quantity</p> <ul style="list-style-type: none"> • Wet steam <ul style="list-style-type: none"> – Improper insulation of steam lines – Malfunction of trap in steam line or no trap in steam line – Malfunction of drain check valve or no drain check valve – Steam contact with a cold load – Too much water in steam produced at boiler • Superheated steam <ul style="list-style-type: none"> – Improper come-up of chamber – Desiccated packaging materials (e.g., towels) – Steam pressure too low for the temperature – Excessive reduction of steam pressure too close to sterilizer – Faulty steam control valve or pressure reducer control valve • Other steam problems <ul style="list-style-type: none"> – Variations in steam pressure because of clogged filter, poorly engineered piping, or excessive demands – Out-of-calibration pressure gauges and controllers – Clogged steam lines – Clogged steam supply strainer – Clogged chamber drain line, strainer, or chamber drain screen – Malfunction of valves <p>Incomplete air removal</p> <ul style="list-style-type: none"> • Inadequate vacuum or vacuum depth or other air removal system • Clogged chamber drain line, strainer, or chamber drain screen • Clogged vent lines • Leak caused by faulty door gasket • Leak in other areas of chamber • Plugged, faulty or incorrectly adjusted control valves • Low steam pressure • High water temperature • Inadequate water supply pressure • Clogged water supply strainer • Trapping of air by the load • Incorrect cycle parameters for the load <p>Inadequate cycle temperature</p> <ul style="list-style-type: none"> • Out-of-calibration temperature gauge • Long come-up time for large loads (i.e., heat lag) • Clogged chamber drain line, strainer, or chamber drain screen • Variations in steam pressure because of clogged filter, poorly engineered piping, or excessive demands on steam supply • Presence of noncondensable gases in steam line and load • Inadequate steam supply pressure • Clogged steam supply strainer <p>Insufficient time at temperature</p> <ul style="list-style-type: none"> • Out-of-calibration control timer • Inappropriate cycle parameters for the load being processed • Oversized load

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

13.7.6.1 General considerations

A Bowie-Dick (Type 2 CI) test should be performed each day the sterilizer is used, before the first processed load. A Bowie-Dick test pack is used in conducting this test (see ANSI/AAMI/ISO 11140-5). A shortened cycle (i.e., a cycle omitting the drying phase) should be run first to heat the sterilizer. If the sterilizer is used continuously, the test may be performed at any time, but should be performed at the same time every day. The Bowie-Dick test also should be carried out during sterilizer qualification (13.8); during qualification testing, three consecutive BI challenge tests and three consecutive Bowie-Dick tests should be run.

For steam-flush pressure-pulse cycles, the manufacturer's recommendations should be followed regarding Bowie-Dick testing.

NOTE—There is not an air-removal test available for gravity-displacement cycles. Dynamic-air-removal sterilizers utilize preconditioning techniques to remove air from both the sterilizer chamber and the load before pressurization with steam to a sterilization exposure temperature. Effective removal of air is critical to predictable steam penetration and the resultant sterilization. There are numerous preconditioning methods used to remove air, including variations of prevacuum air removal or above-atmospheric-pressure processes such as the steam-flush pressure-pulse process.

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

Rationale: A Bowie-Dick test is conducted every day the sterilizer is used, before the first processed load or at the same time each day, and during sterilizer qualification testing because it is a sensitive and rapid means of detecting air leaks, inadequate air removal, inadequate steam penetration, and noncondensable gases. Insufficient air removal in a dynamic-air-removal sterilizer, particularly a prevacuum cycle, can defeat sterilization and result in nonsterile supplies if undetected. An improperly heated sterilizer could cause false Bowie-Dick test failures. The test is conducted at the same time every day because standardization of the testing procedure reduces the opportunity for error.

13.7.6.2 Composition of the Bowie-Dick test pack

A commercially available pre-assembled Bowie-Dick test pack should be used, or the facility may assemble its own cotton surgical towel test pack in accordance with the following guidance, using commercially available test sheets. Health care personnel should obtain and review the manufacturers' written IFU for storage, handling, and testing of their products.

The cotton surgical towel Bowie-Dick test pack should

- a) consist of clean and preconditioned 100% cotton surgical towels, which are folded to a size 250 millimeters [mm] \pm 20 mm (9 inches) in one direction and 300 mm \pm 20 mm (12 inches) in the other direction and placed one above another;

NOTE—Preconditioning consists of holding the towels at room temperature—18°C to 24°C [65°F to 75°F]—and a relative humidity of at least 35% for at least 2 hours.

- b) be between 250 and 280 mm (10 and 11 inches) high;
- c) weigh 4 kilograms \pm .2 kilograms (8.8 pounds);
- d) contain a commercially available Bowie-Dick-type test sheet, complying with ANSI/AAMI/ISO 11140-5, which is placed in the center of the pack;
- e) be loosely wrapped in a single two-ply fabric wrap made of 100% cotton with a thread count both warp and weft of 5.5/mm; and
- f) be secured with indicator tape not exceeding 25 mm (1 inch) in width.

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

See Figure 11.

Rationale: See 13.7.6.1.

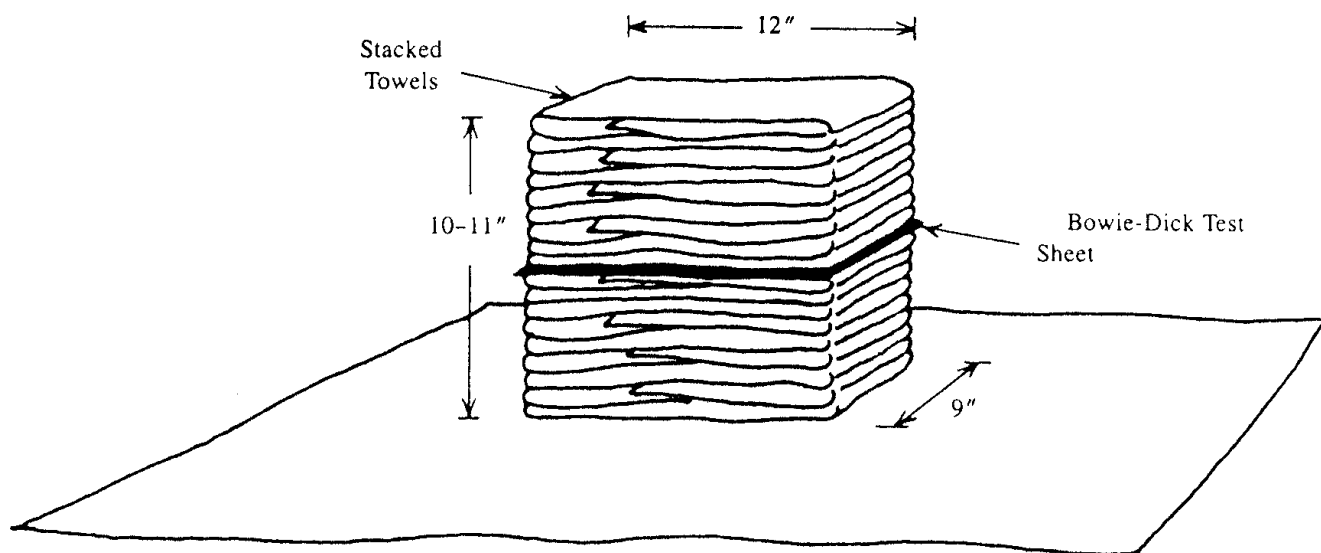


Figure 11—Composition of the Bowie-Dick test pack

13.7.6.3 Placement of the Bowie-Dick test pack

The Bowie-Dick test pack should be placed in a preheated chamber on a cart or shelf, over the drain (not on the sterilizer chamber floor) or as near as possible without obstructing the drain. The test pack should be placed horizontally in an otherwise empty chamber. (See Figure 12.)

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

13.7.6.4 Test procedure

The following procedure for the Bowie-Dick test should be followed:

- 1) Select the cycle specified by the sterilizer manufacturer.
- 2) Perform the test in accordance with the Bowie-Dick test pack manufacturer's written IFU. The exposure time should be 3.5 to 4 minutes. (The exposure should not exceed 4 minutes at 134°C [273°F].)
- 3) At the conclusion of the cycle, open the the test pack carefully because it might be hot.
- 4) Remove the test sheet and interpret and record the result.

NOTE—Drying may be omitted to save time without affecting the outcome of the test.

Rationale: If longer exposure times are used, the test is invalid. A sterilizer tested before it is heated may produce an invalid result.

13.7.6.5 Acceptance criteria

Test results that do not conform to the recommended color standards provided by the manufacturer of the test sheet should be reported as defined in facility policy and a determination made as to whether the sterilizer should be retested, serviced, or remain in use.

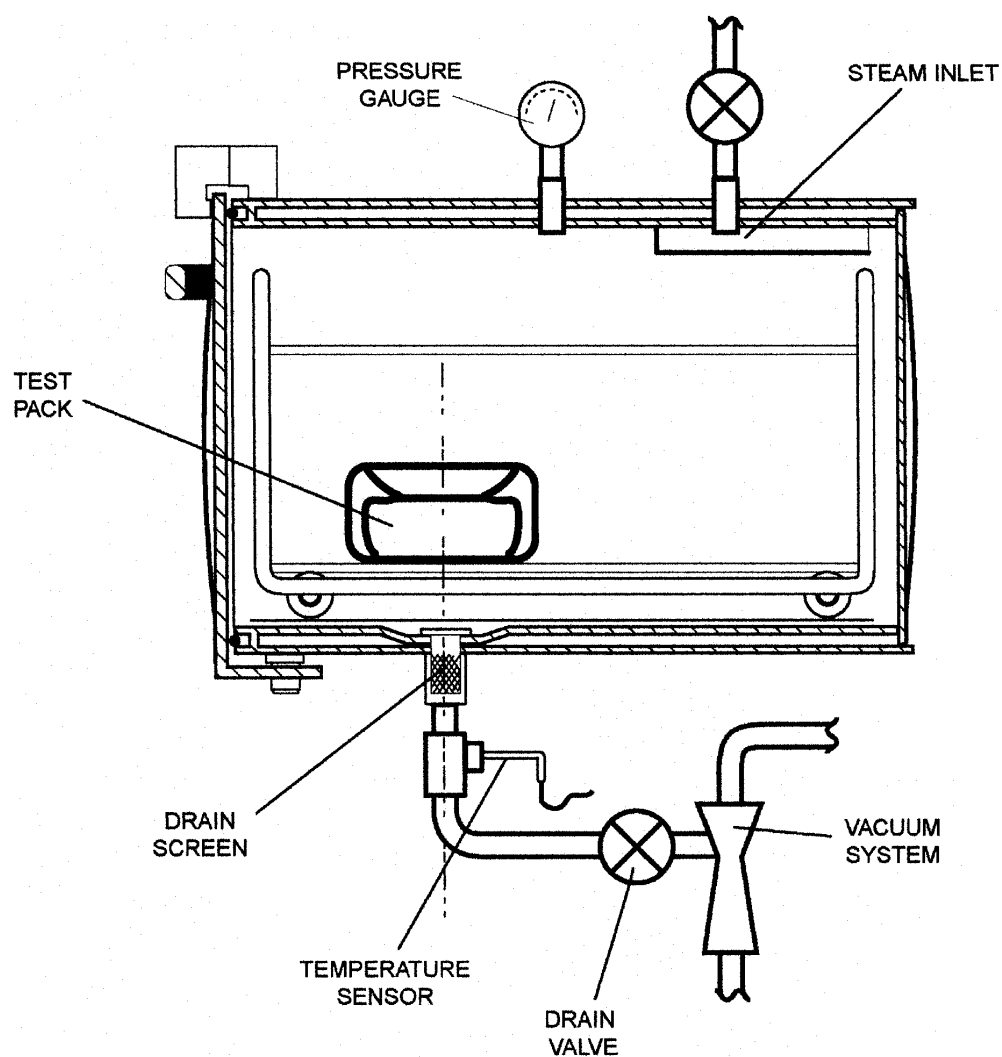


Figure 12—Placement of the Bowie-Dick test pack

13.8 Qualification testing

13.8.1 General considerations

Qualification testing with a BI PCD should be performed on all sterilizers after sterilizer installation, relocation, malfunctions, major repairs, sterilization process failures, or changes to the utilities (e.g., steam or water supply). If a steam sterilizer is designed to be used for multiple types of cycles, then each sterilization cycle type used should be tested. If a sterilizer will run the same type of cycle (e.g., dynamic-air-removal at 132°C to 135°C [270°F to 275°F]) for different exposure times (e.g., 4 minutes and 10 minutes), then only the shortest cycle time should be tested.

If applicable (see 13.7.6), dynamic-air-removal cycles should also be tested using Bowie-Dick test packs after sterilizer installation, relocation, malfunctions, and major repairs and after sterilization process failures.

Qualification testing should be

- a) conducted by health care personnel in cooperation with the manufacturer; and
- b) performed between the time the steam sterilizer is installed, relocated, or repaired and the time it is released for use in the health care facility.

For gravity-displacement sterilizers, three consecutive cycles should be run, one right after the other, with a PCD (see 13.7.2.2, 13.7.3.1, and 13.7.4.1), yielding negative results from all test BIs and appropriate readings from all physical monitors and CIs.

For dynamic-air-removal sterilizers, three consecutive cycles should be run, one right after the other, with a PCD (see 13.7.2.2, 13.7.3.1, and 13.7.4.1), yielding negative results from all test BIs and appropriate readings from all physical monitors and CIs. In addition, three consecutive Bowie-Dick tests should be run, one right after the other with each test result demonstrating sufficient air removal (see 13.7.6); as in routine Bowie-Dick testing, an empty chamber should be used for the tests.

Rationale: Testing in this order presents the greatest challenge.

As described in 13.6.4, a major repair is a repair outside the scope of normal maintenance, such as weld repairs of the pressure vessel; replacement of the chamber door, vacuum pump, or a major piping assembly; or rebuilds or upgrades of controls. Normal preventive maintenance, such as the rebuilding of solenoid valves or the replacement of gaskets, is not considered a major repair.

Major repairs of or changes to the utilities (e.g., the installation of new boilers) should be treated as major repairs to the sterilizer, and sterilizer testing should be performed as defined in this section to provide the necessary qualification for use.

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

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

The performance of the sterilizer depends on the utilities connected to it. The sterilizer manufacturer specifies certain utility line sizes, maximum and minimum pressures, and dynamic flow requirements for the required utilities. Water quality also might be specified, especially for stand-alone steam generators (which are typically shut down on weekends). Sterilizers are designed to function with a nominal electrical supply and can be operated within a specified range of that nominal value. Significant changes to the utilities connected to the sterilizer (e.g., changes necessitated by water-main breaks, annual boiler maintenance, or additional equipment loads) could affect sterilizer performance.

13.8.2 Qualification testing of sterilizers have a chamber volume larger than 2 cubic feet

13.8.2.1 Composition of the PCD

The 16 towel PCD (BI challenge test pack) of 13.7.2.2 or an equivalent commercial PCD should be used.

13.8.2.2 Placement of the PCD

The PCD should be placed *flat* (layers of towels horizontal if the 16 towel PCD is being used) on a rack or shelf in an otherwise empty chamber, in the area least favorable to sterilization (i.e., the area representing the greatest challenge to the BI) (see Figure 13).

The sterilizer manufacturer should identify the exact location of this area, the "cold point," in the IFU and instruct users to place the PCD at this location. This area varies with sterilizer design, but is normally in the front, bottom section of the sterilizer, near the drain.

Rationale: In the qualification testing that compared the performance of the 16 towel PCD to that of the original, 12 × 12 × 20 inch pack (see Annex J), the 16 towel PCD was positioned flat in the chamber. Placing the PCD horizontally, instead of on edge, presents a greater challenge to the sterilizer. The horizontal configuration contradicts recommended loading practices, but is necessary to accentuate the biological challenge to sterilant penetration so that this smaller homogeneous pack will perform comparably to the original, 12 × 12 × 20 inch heterogeneous pack. Placement near the drain generally ensures that the PCD is in the coolest portion of the chamber, but the sterilizer manufacturer is best able to advise the user on the "cold point." Qualification testing in sterilizers larger than 2 cubic feet is done in an otherwise empty chamber because it creates the greatest challenge to air removal, minimizes come-up time (because there is little metal mass to absorb the heat), and creates the greatest challenge to the BI.

13.8.2.3 BI PCD test procedure

The test procedure should include the following steps:

- 1) The PCD should be labeled with the sterilizer, the date, and the load number before being exposed to the sterilization cycle.
- 2) The PCD should be positioned in the chamber according to 13.8.2.2.
- 3) The cycle should be run according to the sterilizer manufacturer's written IFU.
- 4) After being exposed to the sterilization cycle, the BI should be removed from the PCD and the BI labeled with the sterilizer, the date, and the load number. All BIs used in challenging the sterilization cycle and as controls should be accounted for. The BIs should be handled and incubated according to the BI manufacturer's written IFU.

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

- 5) Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control in each incubator to verify the presterilization viability of the test spores and incubator function.

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

- 6) The number of both test BIs and control BIs should be documented.
- 7) Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are nonviable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the test repeated.

13.8.2.4 Acceptance criteria

All monitoring results, including results from BI controls, should be interpreted by a qualified individual and included in the sterilizer records. An acceptable test is evidenced by negative results from the test BIs from all three consecutive test runs, positive (growth) results from all control BIs, and appropriate readings from physical monitors and CIs, showing that the sterilizer has been properly installed (or reinstalled after relocation) or repaired satisfactorily and that it will function effectively.

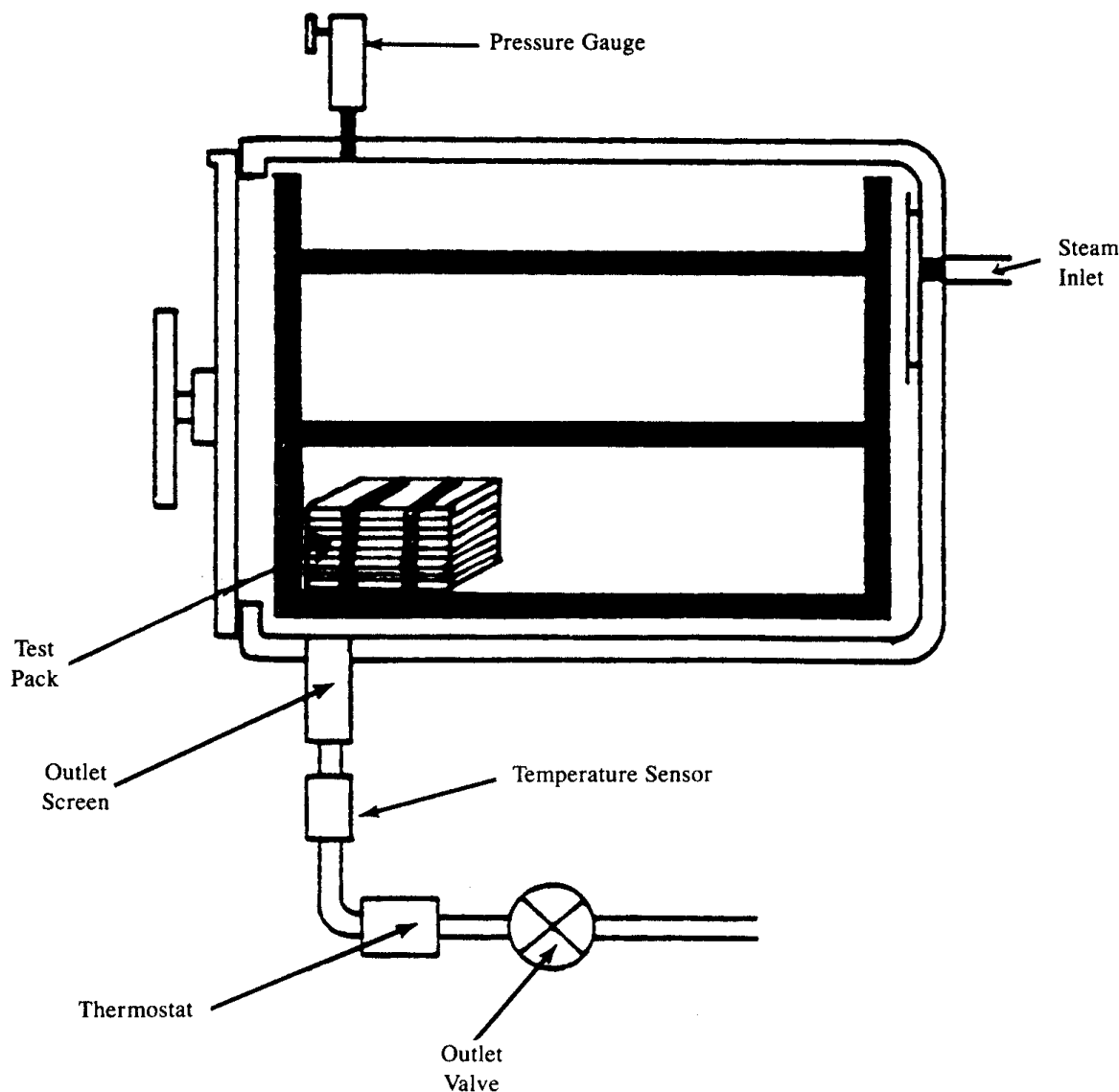


Figure 13—Placement of the 16 towel PCD (BI challenge test pack) for qualification testing

13.8.3 Qualification testing of table-top sterilizers (sterilizers having a chamber volume less than or equal to 2 cubic feet)

13.8.3.1 Composition of the PCD

The PCD should be representative of the items routinely processed in the sterilizer and contain a BI and CI (see 13.7.3.1).

Rationale: There currently are no standardized PCDs for table-top sterilizers. Therefore, a representative package or tray that is routinely processed in the sterilizer is used as the PCD.

13.8.3.2 Placement of the PCD

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

Rationale: Small packs are routinely placed on edge to allow adequate steam exposure. Larger packs or trays are routinely placed flat on the shelf because their size will not permit any other orientation in the relatively small chamber of table-top steam sterilizers (less than or equal to 2 cubic feet). Placing the PCD in the coolest portion of the chamber presents the most severe challenge. Table-top steam sterilizers typically have a water reservoir that injects a set volume of water, which is used to create steam during the cycle. Because of the limited amount of water available to create steam, the greatest challenge to steam penetration is the amount of available steam. Therefore, the sterilizer should be tested under worst-case conditions: a full load.

13.8.3.3 Test procedure

The test procedure should include the following steps:

- 1) The PCD should be labeled with the sterilizer, the date, and the load number before being exposed to the sterilization cycle.
- 2) The PCD should be positioned in the chamber according to 13.8.3.2.
- 3) The cycle should be run according to the sterilizer manufacturer's written IFU.
- 4) After being exposed to the sterilization cycle, the BI should be removed from the PCD and the BI labeled with the sterilizer, the date, and the load number. All BIs used in challenging the sterilization cycle and as controls should be accounted for. The BIs should be handled and incubated according to the BI manufacturer's written IFU.

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

- 5) Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control in each incubator to verify the presterilization viability of the test spores and incubator function.

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

- 6) The number of both test BIs and control BIs should be documented.
- 7) Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are nonviable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the test repeated.

13.8.3.4 Acceptance criteria

All monitoring results, including results from BI controls, should be interpreted by a qualified individual and included in the sterilizer records. An acceptable test is evidenced by negative results from the test BIs from all three consecutive test runs, positive (growth) results from all control BIs, and appropriate readings from physical monitors and CIs, showing that the sterilizer has been properly installed (or reinstalled after relocation) or repaired satisfactorily and that it will function effectively.

13.8.4 Qualification testing of IUSS cycles

13.8.4.1 Composition of the PCD

A BI test pack as described in 13.7.2.2 or a commercially available disposable BI PCD should be used to test the dynamic-air-removal cycle for IUSS.

For qualification testing of gravity-displacement cycles for IUSS, one BI and one or more CIs should be placed in the tray configuration that has been selected to be tested. The PCD (BI challenge test tray) should be of appropriate size for the sterilizer being tested. The BI and CI(s) should be located in the most difficult-to-sterilize portion of the PCD.

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

Rationale: Only one BI need be used for the test in order to achieve a microbial challenge. There are no data to support the need for more than one BI. It is recommended that one or more CIs be placed in the PCD, because CIs give immediate information regarding sterilization process efficacy.

13.8.4.2 Placement of the PCD

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

Rationale: The BI test is conducted in an otherwise empty chamber, rather than in one containing patient care items, because for IUSS this configuration is a more rigorous biological challenge to sterilizer performance than is a filled chamber. Performing the test in an empty chamber minimizes come-up time (because there is little metal mass to absorb the heat) and, therefore, minimizes the lethality of the process and creates a greater challenge to the BI. The area near the drain is usually the coolest portion of the sterilizer and therefore presents the greatest challenge.

13.8.4.3 Test procedure

The test procedure is as follows:

- a) Before being exposed to the sterilization cycle, the PCD (the BI challenge test tray for gravity-displacement and single-wrap IUSS cycles or the BI challenge test pack for dynamic-air-removal IUSS cycles) is labeled with appropriate sterilizer information.
- b) The PCD should be positioned in the chamber according to 13.8.4.2
- c) The appropriate cycle is run, according to the manufacturer's written IFU.
- d) Upon completion of the sterilization cycle and adequate cooling of the PCD, the BIs should be removed, their identity noted, and all BIs accounted for. During the removal and transfer process, care should be taken to avoid contamination. The BIs should then be incubated according to the written IFU of the BI manufacturer.

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

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

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

13.8.4.4 Acceptance criteria

An acceptable test is evidenced by negative results from the test BIs from all three consecutive test runs, positive (growth) results from all control BIs, and appropriate readings from physical monitors and CIs, showing that the sterilizer has been properly installed (or reinstalled after relocation) or repaired satisfactorily and that it will function effectively. All monitoring results, including results from BI controls, should be interpreted by a qualified individual and included in the sterilizer records.

13.9 Periodic product quality assurance testing of routinely processed items

13.9.1 General considerations

Product testing consists of a series of procedures used to verify that manufacturers' written IFU can be successfully performed in the user facility. Sterilization processes generally provide restrictive requirements for the types of devices and loads that can be reprocessed in the manufacturer's written IFU. It is not necessary to conduct product testing of medical devices on an ongoing basis, unless recommended by the applicable manufacturer. The following guidelines are given for when product testing is conducted.

Product testing is not a substitute for the more extensive validation testing conducted by manufacturers to qualify their products. Product testing does not allow a health care facility to validate a change in the medical device manufacturer's written IFU for packaging, loading, type of process, or critical process parameters. Product testing can only be used to verify the information provided in the manufacturer's written, validated IFU.

Not all medical devices processed need to be product-tested. Instead, medical devices are typically placed into product families. The most challenging device to process from each family can be identified as the master product, which represents the entire family of devices during testing. A product family can be based on the manufacturer's defined product family. For example, surgical powered equipment and batteries from vendor A could be a family of products and surgical powered equipment and batteries from vendor B could be another family of products that require steam sterilization.

Consideration should also be given to the load requirements specified by the manufacturer (e.g., number of devices, load weight).

The following product characteristics can be considered when evaluating new medical devices to determine whether they belong to an existing product family or a new product family must be established to ensure that they can be safely reprocessed according to the device manufacturer's instructions:

- a) Design configuration
- b) Number of components
- c) Materials of construction
- d) Size and/or surface area
- e) Need for disassembly
- f) Surface finish or texture
- g) Presence of cannulations, lumens, or mated surfaces
- h) Written reprocessing instructions provided by the manufacturers

Some products might not belong to an easily identified product family and the user will need to work with the device manufacturer to identify the appropriate family of products and master product using the characteristics listed above. If the new medical device does not fit within an existing product family, then a new product family might need to be established, with the new medical device becoming the master product for that family. Product testing should be done initially on all the master products designed for each identified family of products processed within the health care facility.

Before a newly purchased medical device is placed into routine use, the user should determine which existing family of products it belongs to and if the existing product testing is applicable to that device. If this newly purchased medical device is less of a challenge than the master product previously tested for the designated family for a specific process and parameters, then product testing does not need to be performed. If this newly purchased medical device is a greater challenge than the master product previous tested for the designated family, then product testing should be performed before the product is placed into routine use.

Product testing should be repeated whenever changes are made to a product family's composition, designated master product, or written IFU or if a new sterilizer or other piece of processing equipment is purchased.

A limited program should be established to periodically test products that are routinely processed to ensure that the process and related factors have not changed since the initial product testing. For example, a program could be established to test one master product of one family each month.

13.9.2 Process verification

The health care organization should establish a program for periodic quality assurance testing of routinely processed items on an ongoing basis.

Product testing should be performed

- a) when major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper; and
- b) on newly purchased or loaned devices before they are put into use, unless the device fits into an established product family (see 13.9.3).

13.9.3 Product families

The concept of product families may be used in the product quality assurance testing program for the following purposes:

- a) To group routinely processed items that are similar in construction, materials, size, and packaging into a product family. Other considerations could include design configuration, number of components, need for disassembly, surface finish or texture, the presence of lumens, and the written IFU for reprocessing provided by the manufacturer.
- b) To designate the most difficult-to-sterilize device in each group as the master product, which should be used as the PCD for that family when product testing is performed.
- c) To apply the sterilization process used for the master product to all members of its product family.

If the existing product testing is applicable, then the sterilization cycle used for the applicable product family should be used for the new or loaner set.

Whenever changes are made in a product family's composition, designated master product, or written IFU, then product testing should be repeated.

NOTE—Medical device manufacturers can assist in the identification of the product family and master product.

Rationale: The concept of product families enables the health care facility to ensure a high level of sterility assurance without testing all products being sterilized. See also ANSI/AAMI/ISO TIR17665-3.

13.9.4 Verification testing procedure

The test procedure should include both BI and CI testing and an evaluation of post-sterilization moisture content (i.e., the occurrence of "wet packs").

Biological and chemical indicators should be placed within the product test samples. The number of BIs and CIs used within each product test sample will depend on the size and configuration of the pack being tested.

Product test samples should be labeled as such and placed among other items in a routine sterilizer load. The product test samples should be placed throughout the load at the points most difficult to sterilize (i.e., the most resistant to steam penetration). Medical device manufacturers can assist in the identification of the areas in which to place BIs and CIs.

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

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

Product test samples are for testing only and should not be released for use.

Examples of product testing include the following:

- a) For textile packs wrapped in woven or nonwoven materials, the BIs and CIs are placed between the layers of a folded surgical gown within the pack, between multiple layers of draping material, or between layers of surgical towels.
- b) For basin sets wrapped in woven or nonwoven materials, the BIs and CIs are placed in locations within the set where air pockets could form, such as the area between nested basins. In tests of this nature, it might be appropriate to use BIs contained in glassine envelopes rather than SCBIs because the latter could separate the basins, permitting more steam contact, and because the media ampoules within the SCBIs could break.
- c) For an instrument set, the BIs and CIs are placed at each end of the tray and among the instruments that are placed on stringers.
- d) For containment devices, the BIs and CIs are placed in the areas recommended by the containment device manufacturer.
- e) For multilayered instrument sets in containment devices, the BIs and CIs are placed in the locations determined by the product manufacturer to create the greatest challenge to the sterilization process. It might be necessary to use BIs contained in glassine envelopes rather than SCBIs if test areas cannot accommodate the size of the SCBI (e.g., inside multilayered trays with sliding lids).

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

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

Rationale: The standardized PCD of 13.7.2.1 presents a known challenge to the sterilization process. However, this pack does not necessarily reflect the same challenge as the items routinely processed in a health care facility. Therefore, product testing is recommended as part of a complete quality assurance program to ensure the effectiveness of the sterilization process and to avoid wet packs. The products to be tested will vary from facility to facility, depending on the types of products routinely sterilized. The contents of the sample packs are exposed to a larger population of bacterial spores than are other products and, therefore, should not be used in patient care unless they are reprocessed; also, inspecting the pack and retrieving the BIs and CIs contaminates the contents.

13.10 Periodic product quality assurance testing of rigid sterilization container systems

13.10.1 General considerations

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

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

13.10.2 User responsibilities

13.10.2.1 General considerations

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

Prepurchase evaluation ensures that the particular container system being considered will be acceptable to all prospective users in the facility and that it will perform properly in the health care facility's sterilizing equipment. The testing that should be performed by users, which is described in 13.10.2.2, is not a substitute for the more extensive validation testing conducted by manufacturers to qualify their products.

13.10.2.2 Prepurchase evaluation

13.10.2.2.1 General

The specific design of the rigid sterilization container system should be compatible with the design and performance characteristics of the sterilizer(s) in which it is used.

Users should conduct a prepurchase product evaluation of any rigid sterilization container system being considered for use in sterilization processing. See also Section 15.

Testing should be conducted in the health care facility to ensure that the conditions essential to sterilization can be achieved and that the specific configuration of the container contents is acceptable for the sterilization process and for the requirements at the point of use. The IFU, test methodology, and test data supplied by the manufacturer should be assessed in relation to the environment in which the container system will be used and in relation to the sterilizer to be used for the processing of containerized instruments and procedural trays. See also Section 15 and Annex H.

13.10.2.2.2 Performance verification under conditions of use

Each rigid sterilization container system should be tested using BIs and CIs indicated for the cycle being used.

The rigid sterilization container system manufacturer should be consulted regarding the test procedures.

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

After the sterilization cycle, the user should

- a) retrieve the CIs and incubate the BIs according to the BI manufacturer's written IFU; and
- b) evaluate the container and load for retained moisture.

The test container and instruments should be reprocessed before use in patient care. Positive BIs can indicate a sterilization process failure and should be investigated.

Rationale: This testing verifies that the rigid sterilization container system will perform as intended by the manufacturer. Manufacturers of container systems can only test properly designed and operating sterilization equipment. Various sizes of sterilizers having the same sterilization cycle could have different air-removal efficiencies. Manufacturers cannot possibly test all combinations of sterilizer sizes, cycles, and process efficiencies. Outcomes of testing are dependent on multiple variables unique to the health care facility, including the load composition, sterilizer, and steam supply. The use of rigid sterilization container systems occasionally requires extending the drying times normally used for wrapped items. Retained moisture can damage instrumentation if contact with moisture is prolonged and wet packs are contaminated.

13.10.2.2.3 Prepurchase evaluation test protocols

Table 5 summarizes recommended test protocols for prepurchase evaluation of rigid sterilization container systems intended for use in dynamic-air-removal steam sterilization processes and gravity-displacement steam sterilization processes. Container systems should only be evaluated and used in cycles recommended by the container system manufacturer.

NOTE 1—These test protocols only address prepurchase evaluation as it relates to verifying sterilization efficacy and drying. See Annex H for guidelines on the development of a detailed, more comprehensive prepurchase evaluation protocol that covers other aspects of container system use.

NOTE 2—Most rigid sterilization container systems are designed for use in dynamic-air-removal steam sterilizers. The container system manufacturer might not recommend use in other sterilization processes.

Table 5—Summary of test configurations for prepurchase evaluation of rigid sterilization container systems

Sterilizer type	Cycle type	Number of container systems tested
Dynamic-air-removal	Packaged	Maximum load
		Small load
Dynamic-air-removal	Unpackaged	Small load
Gravity-displacement	Packaged	Maximum load
		Small load

NOTE—The test container system is prepared with the largest instrument set (including any optional absorbent material) recommended by the container system manufacturer.

14 Quality process improvement

14.1 General considerations

This section identifies performance measures and process monitors that can be used for continuous quality improvement (CQI) programs. Continuous quality improvement programs are recognized as an effective means of improving the performance of any process. For steam sterilization, a CQI program encompasses the entire process of decontamination, preparation and packaging, sterilization, quality control, sterile storage, and product distribution.

14.2 Quality process

14.2.1 General considerations

Procedures for steam sterilization should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with appropriate departments and integrated into the overall quality process in the health care facility. Variables in the system can be controlled to achieve assurance of product quality and process efficacy. Monitoring frequency will vary, depending on the quality improvement goals, on health care facility policies and procedures for the handling of unfavorable/unplanned events, and on the type of process variable.

A risk analysis should be completed for all aspects of steam sterilization to identify any risk that could occur to personnel or patients. The problem risk analysis should identify, define and quantify the risk and identify actions that can be taken to resolve or prevent the risk. The system should be monitored to ensure that the risk has been corrected or prevented.

There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Quality processes can be enhanced by audits that are conducted on a regular basis. The information from these activities should be summarized and made available to appropriate individuals or groups/teams.

According to FDA, a quality audit "means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives." [21 CFR 820.3(t)]

Rationale: Measurements of process performance allow the steam sterilization process to be monitored against a predetermined level of quality. Evaluation of findings provides a method of identifying problems or shifts in activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data essential to assess the effectiveness of the processes and to make improvements in performance.

14.2.2 Quality system model

A sterile medical device is one that is free of viable microorganisms. The definition of a sterile medical device is the overriding definition dictating sterilization processing. However, it is recognized that the effectiveness of certain processes cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process is monitored routinely, and the equipment is maintained.

The quality system model should

- a) involve the sterilizer manufacturer, who is responsible for
 - conducting installation, qualification, and operational qualification; and
 - recommending validated means of sterilizing the specific devices to be reprocessed, in lieu of a formal performance qualification;
- b) include development of performance measures to monitor environmental, performance, and process factors;
- c) include monitoring of compliance of decentralized sterilization processing with established policies and procedures (to include facility processing departments outside of SPD, as well as off-site sterilization facilities);
- d) include written policies and procedures that take into account
 - federal, state, and local regulations;
 - national voluntary standards and recommendations; and

- manufacturers' written IFU.

Rationale: Sterilizer manufacturers have the expertise necessary to perform installation, operational, and performance qualification. Performance measures facilitate evaluation of quality. Policies and procedures establish authority, responsibility, and accountability within the organization. Policies and procedures also serve as operational guidelines.

14.2.3 Risk analysis

14.2.3.1 General considerations

A CQI program should include a risk analysis that

- follows all applicable regulatory guidance (e.g., Centers for Medicare and Medicaid Services [CMS], state, and local requirements);
- is performed at least annually;
- is re-evaluated whenever there are significant changes; and
- includes risk assessment, risk management, and risk communication.

Rationale: Risk analysis is a means to involve a cross-functional team in an activity to set policies to identify the potential risk of sterilization failures and other defects in reprocessing practice. It allows identification and implementation of procedures for risk avoidance or mitigation actions to be put in place that can reduce the overall likelihood of a risk. It is also important because sterilization assurance is a probability function, and, therefore, it is assumed that at some time a failure will occur.

Risk assessment should include

- 1) identifying the source of the sterilization failure;
- 2) estimating the likelihood that such a sterilization failure will occur;
- 3) assessing the consequences if that sterilization failure occurs; and
- 4) assessing how prepared the facility is to manage the failure.

Risk management should include determining which of the potential sterilization failures identified in the risk assessment process require management and selecting and implementing plans and corrective action.

Risk communication should include an interactive dialogue between SPD, user areas, and infection prevention personnel.

A sterile processing CQI program could also include review of aspects of design, decontamination processes, personnel, handling of contaminated items, packaging, sterilizer loading and unloading, IUSS, sterility maintenance, and problem investigation.

14.2.3.2 Design

Performance measures for aspects of design should include

- the condition of floors, walls, ceilings, and work stations;
- ventilation characteristics, including air exchanges per hour and airflow pattern (i.e., negative and positive air pressure);
- temperature and humidity control;
- traffic patterns and access control; and
- handwashing stations.

See also 3.2.3 and 3.3.5.

14.2.3.3 Decontamination

Performance measures for decontamination should include

- sorting and disassembly of instruments;

- b) selection and use of cleaning agents;
- c) manual cleaning and rinsing;
- d) water quality;
- e) care of cleaning tools;
- f) preparation of items for automatic cleaning and disinfection;
- g) loading of items into decontamination equipment;
- h) selection of appropriate cycle parameters (time and temperature);
- i) accessibility of equipment and instrument manuals;
- j) verification of installation testing and acceptance;
- k) routine inspection and cleaning of the decontamination environment;
- l) routine parts replacement as per manufacturer recommendations;
- m) routine maintenance as per manufacturer recommendations;
- n) inspection of decontaminated items;
- o) effectiveness of manual and automated decontamination systems; and
- p) documentation of cleaning verification.

See also Section 7.

14.2.3.4 Personnel

Performance measures for personnel should include

- a) education, development, and training, including continuing education;
- b) verification of competency for work responsibilities;
- c) selection and use of PPE; and
- d) measures to prevent exposure to potentially infectious and other hazardous materials.

See also Section 4.

14.2.3.5 Handling of contaminated items

Performance measures for the handling of contaminated items at the point of use should include:

- a) placement of contaminated items within the containment system;
- b) security of the containment system;
- c) labeling of contaminated items;
- d) placement of items on transport carts;
- e) security of items on transport cart; and
- f) condition of items upon receipt in the decontamination area.

See also Section 6.

14.2.3.6 Packaging

Performance measures for packaging should include:

- a) set weight;
- b) density and configuration of devices;

- c) placement of containment devices within rigid sterilization container systems and other packaging;
- d) disassembly of devices;
- e) opening of devices within sterile barrier and/or packaging system;
- f) placement of items made of glass, rubber, or dissimilar metals within package systems;
- g) protection of delicate and light instruments within package systems;
- h) compliance with recommendations for sterile barrier systems and device manufacturers' written IFU;
- i) maintenance of rigid sterilization container system, including
 - removal and replacement of filters;
 - inspection of seals, mating surfaces, edges and lid integrity, filter retention mechanisms, rivets and screws, locking mechanisms, gaskets; and
 - testing of valves to ensure they move freely;
- j) labeling.

See also Sections 8 and 9.

14.2.3.7 Sterilizer loading and unloading

Performance measures for sterilizer loading and unloading should include:

- a) number of containers within the sterilizer load;
- b) placement of packages within the sterilizer (e.g., container systems below soft goods); and
- c) cooling of sterilized loads.

See also 10.1 and 10.3.

14.2.3.8 Immediate-use steam sterilization

Performance measures for IUSS should include:

- a) frequency of IUSS;
- b) reasons for IUSS;
- c) cleaning and decontamination of items in preparation for IUSS;
- d) use of PPE;
- e) selection and monitoring of cycle; and
- f) documentation of IUSS.

14.2.3.9 Sterility maintenance

Performance measures for sterility maintenance should include:

- a) storage conditions;
- b) temperature;
- c) humidity;
- d) ventilation;
- e) traffic control;
- f) package placement within bins and on shelves; and
- g) stock rotation.

14.2.3.10 Problem investigation

Performance measures for problem investigation should include:

- a) a formal, documented system to log, investigate, and resolve complaints and/or product failures;
- b) investigation of issues such as surgical site infections (SSIs);
- c) instrument and equipment damage or failure;
- d) incorrect pack configurations;
- e) dispensing of incorrect or incomplete products; and
- f) investigation and remediation of serious and repeat problems.

Rationale: A system to investigate and document product failures helps to identify issues that can be addressed through a CQI initiative.

14.3 Supplier communication

Concerns relative to the performance of products, supplies, or services should be

- a) reported to and evaluated by the manufacturer; and
- b) documented, including all correspondence and the details of the investigation, the findings, and any actions taken for resolution of the issue.

Rationale: Reporting and documentation of product performance problems might help identify issues for the manufacturer to address in product quality improvement initiatives.

14.4 Repair records

Equipment and instrument repair records should be maintained and periodically reviewed.

Rationale: Review of repair records could show a pattern of failure. Once identified, the cause for the repair can be reviewed, trended, corrected, and monitored to ensure that the problem has been resolved.

14.5 Processing policies and procedures

Policies and procedures for sterilization and sterilization-related processes and practices should:

- a) be written;
- b) be reviewed periodically;
- c) be revised as necessary;
- d) be readily available to personnel; and
- e) address the following:
 - training and education;
 - medical device processing protocols;
 - equipment maintenance;
 - product identification and traceability;
 - physical, chemical, and biological monitoring;
 - personnel safety and exposure prevention; and
 - sterilization failures (recalls).

Rationale: Policies and procedures provide guidance to personnel and can facilitate consistency in practice. Periodic review and revision of policies and procedures is necessary as new information and research that supports changes in practice becomes available.

15 New product evaluation

15.1 General rationale

Periodically, new products enter the market for which AAMI does not offer guidance for application. Some products do not fall within AAMI's purview. For those that do, AAMI applies a rigorous consensus review process that includes committee discussion, balloting, public review, and subsequent publication; this consensus review process can be quite lengthy. When any product is being considered for use within a facility, it is the responsibility of the intended users to evaluate the product using a systematic process of product evaluation and to establish policies and procedures that reflect this process and that are appropriate to the health care organization. This is especially true when the health care organization is considering a product for which there are no guidelines from AAMI or other similar professional organizations.

15.2 Considerations

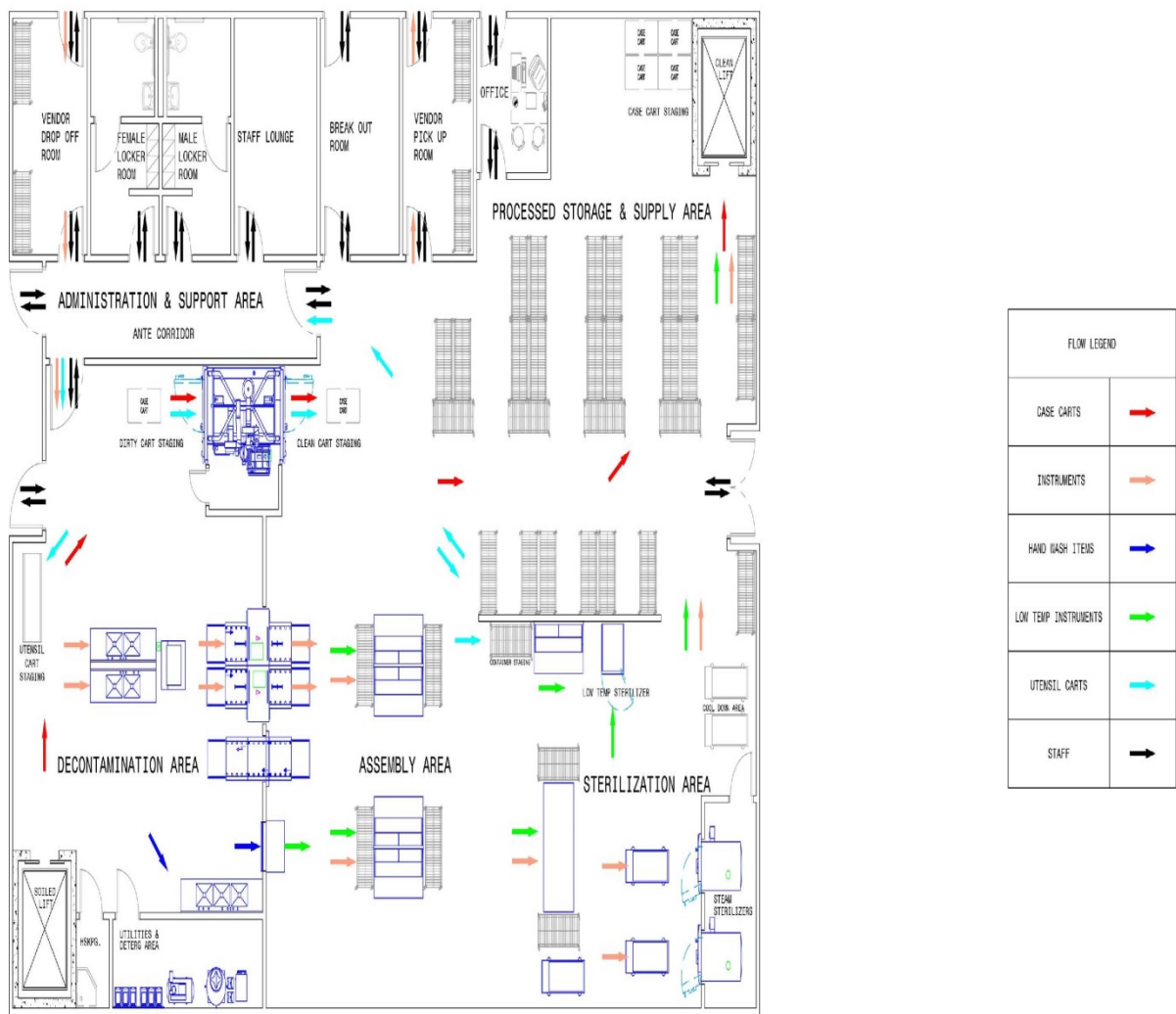
The following are considerations associated with conducting a product evaluation:

- a) Establish a multidisciplinary committee with representation from those who will be affected by the new product. For example, for a product related to steam sterilization, representation could include, but not necessarily be limited to, Infection Prevention and Control, Operating Room, Sterile Processing, Risk Management, and Staff Development/Education.
- b) Collect and distribute to the committee information related to the product. Such data should include, but not necessarily be limited to, the following:
 - FDA clearance documentation
 - Relevant research articles published in peer-reviewed journals
 - Manufacturers' literature and written IFU
 - Experts' opinions
 - Reports from peers who are using or have trialed the product
- c) In addition to evaluating the product's intended application, consider the following:
 - Contribution to patient safety
 - Any legal implications associated with use of the product
 - Cost/value analysis (return on investment)
 - Personnel education necessary to implement use
 - Ease of use of the product
 - Related safety issues
 - Compatibility of the product with existing equipment and products
 - Environmental impact
 - Availability of ongoing support from the vendor for such services as maintenance
 - Impact on standardization of product inventory
- d) If a product trial is indicated, the following guidelines apply:
 - Establish a time limit for the trial.
 - Identify the personnel and departments that should trial the product.
 - Establish the amount of product that should be evaluated.
 - Develop evaluation tools through the multidisciplinary committee identified above.
 - Determine and implement the education and demonstrations needed for the trial.
 - Define the desired outcome.
 - Analyze the data and compare the actual outcome with the desired outcome.

Annex A (informative)

Examples of workplace design

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



STERILE PROCESSING DEPARTMENTAL FLOW

Figure A.1—Example of a work area design and workflow pattern for a sterile processing area in a typical small hospital (Figure courtesy of STERIS Corporation)



STERILE PROCESSING DEPARTMENTAL FLOW

Figure A.2—Example of a work area design and workflow pattern for a sterile processing area in a typical medium-sized hospital
(Figure courtesy of STERIS Corporation)

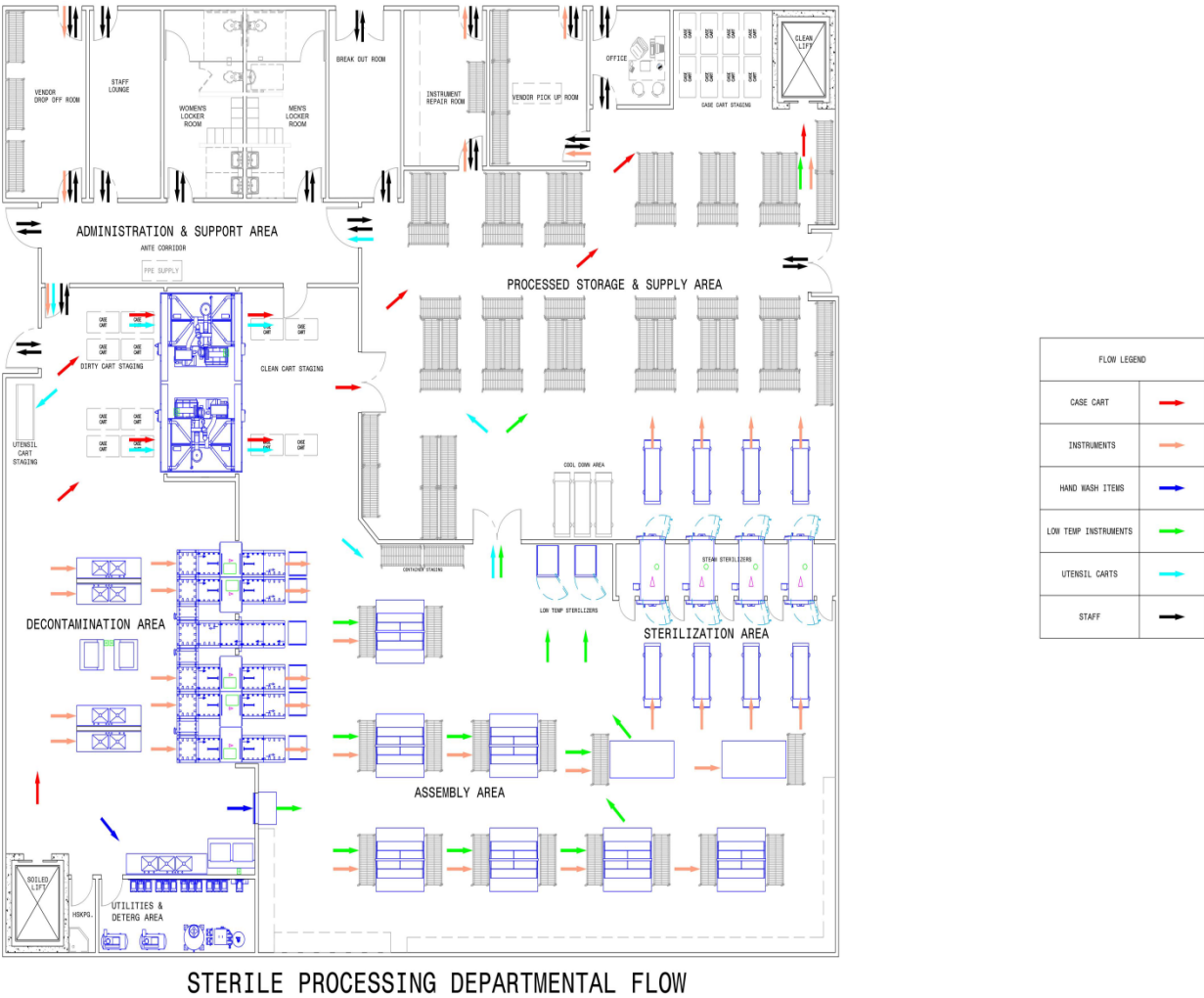


Figure A.3—Example of a work area design and workflow pattern for a sterile processing area in a typical regional processing center
(Figure courtesy of STERIS Corporation)

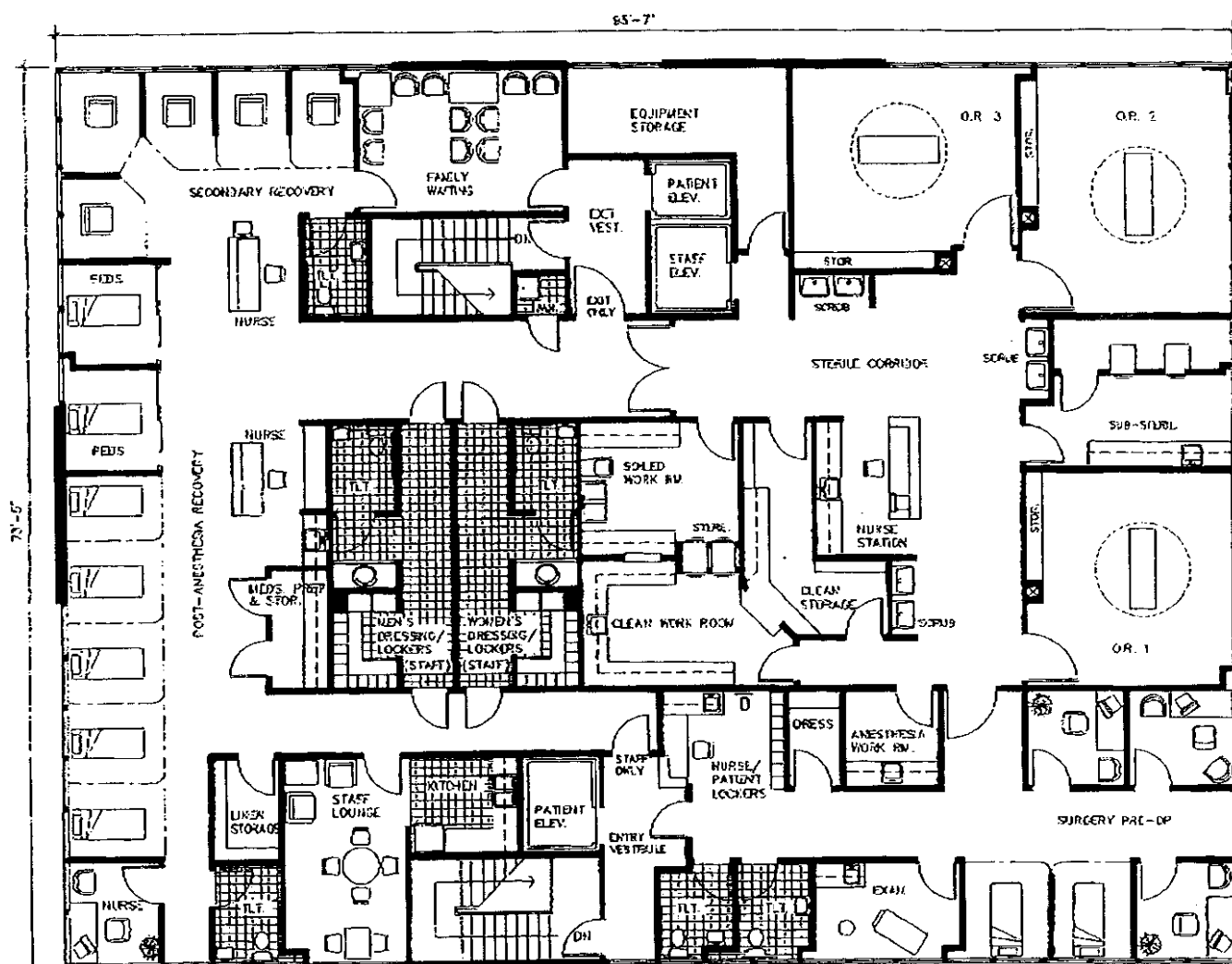


Figure A.4—Example of an ambulatory surgery facility

(From: *Medical and Dental Space Planning: A Comprehensive Guide to Design, Equipment and Clinical Procedures*. 3rd ed. By Jain Malkin. © John Wiley & Sons, Inc. Reprinted with permission of John Wiley & Sons, Inc.)

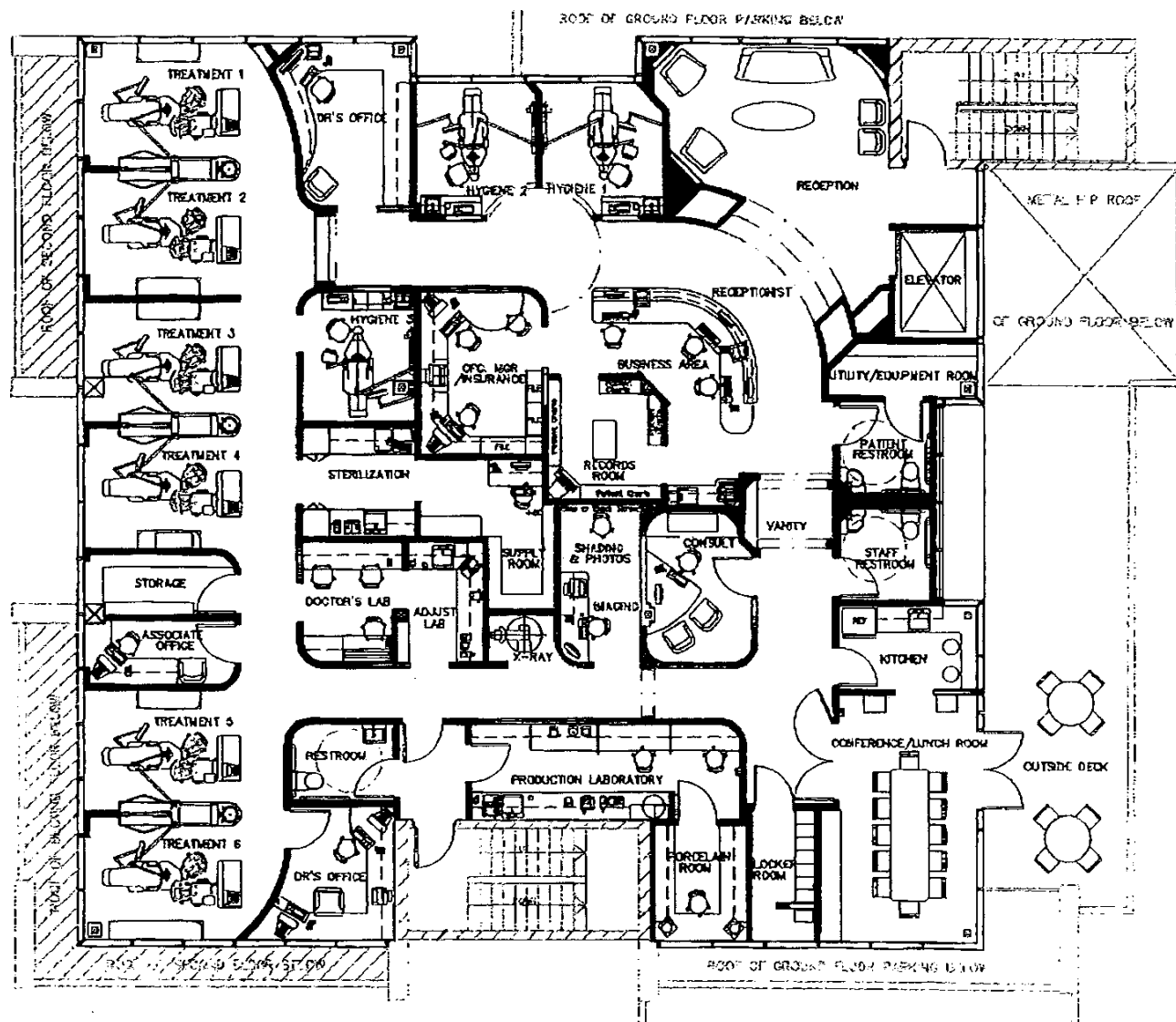


Figure A.5—Example of a dental facility

(From: *Medical and Dental Space Planning: A Comprehensive Guide to Design, Equipment and Clinical Procedures*. 3rd ed. By Jain Malkin. © John Wiley & Sons, Inc. Reprinted with permission of John Wiley & Sons, Inc.)

Annex B (informative)

Infection transmission and standard precautions

B.1 Introduction

Properly performing decontamination is a critical component of public health. The purpose of the decontamination process in a health care facility is to prevent the transmission of disease. Health-care-associated infections can occur because of the presence of infectious agents, multiple modes of transmission, and a population of susceptible individuals. An understanding of the chain of infection enables health care professionals to develop and implement policies and procedures that will reduce the risk of infection transmission.

Health-care-associated infections are those that manifest themselves after a patient is admitted to the facility and that were not incubating at the time of admission. Such infections involve not only patients but also others present in the facility, principally health care workers.

There are six main factors in the chain of infection: the etiologic agent, a reservoir, the portal of exit, the mode of transmission, the portal of entry, and a susceptible host. (See Figure B.1.) Each of these factors is vitally important and must be present for an infection to take place.

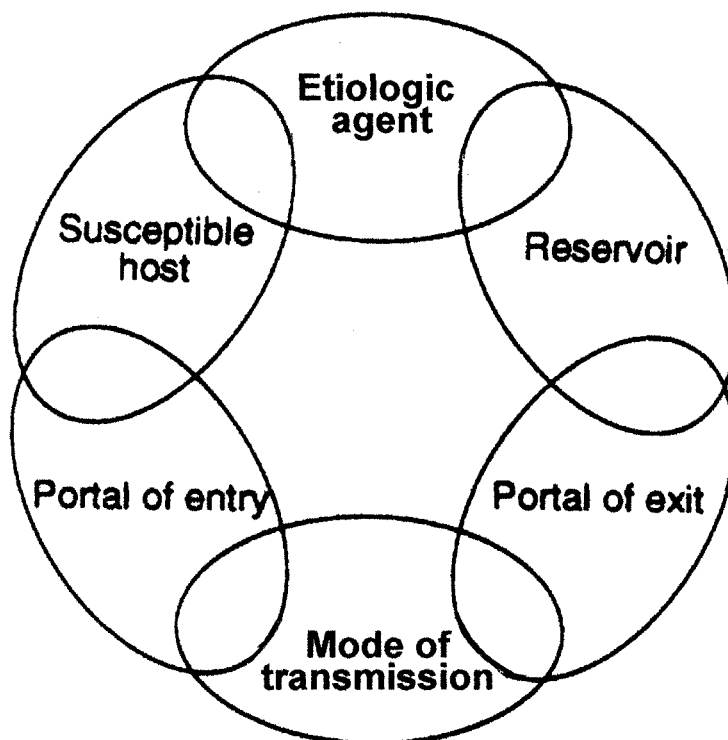


Figure B.1—The chain of infection, components of the infectious disease process

(Adapted with permission from *APIC Text of Infection Control and Epidemiology*, 4th edition © 2014 Association for Professionals in Infection Control and Epidemiology.)

B.2 Chain of infection

B.2.1 Etiologic agent

B.2.1.1 General

The first link in the chain of infection is the etiologic agent itself: any bacterium, virus, fungus, or other microorganism. Most pathogenic microorganisms of concern with respect to patient care equipment are included in one of the following four classes: (a) spore-forming bacteria such as *Bacillus anthracis*, *Clostridium botulinum*, *Clostridium perfringens*, and *Clostridium tetani*; (b) vegetative bacteria such as *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Mycobacterium tuberculosis*; (c) viruses such as the human immunodeficiency virus (HIV) and the herpes simplex, polio, and hepatitis B viruses; and (d) fungi such as *Candida albicans*, *Coccidioides*, *Aspergillus*, and *Alternaria*. Also of importance are prions, small proteinaceous agents believed to be the smallest infectious particles. Prions are neither bacterial, fungal, nor viral and contain no genetic materials. They have been held responsible for a number of degenerative diseases involving the brain, including Creutzfeldt-Jakob disease, variant Creutzfeldt-Jakob disease (also known as bovine spongiform encephalopathy or "mad cow" disease), fatal familial insomnia, kuru, and an unusual form of heredity dementia known as Gertsmann-Straeussler Scheinkler disease.

B.2.1.2 Pathogenicity

Not only must the infectious agent be present, it also must be pathogenic (capable of causing disease). The ability of a microorganism to cause disease depends upon its virulence and its invasiveness.

Virulence is the degree of pathogenicity of a given microorganism, as indicated by morbidity and mortality case rates. Invasiveness is the ability of a microorganism to invade tissues of the body. Organisms that can penetrate the body's intact barriers are generally of more concern than those that cannot. However, some microorganisms need not directly attack intact body tissues in order to cause disease. For example, *Vibrio cholerae* is noninvasive in the gastrointestinal tract but produces toxins that react with the mucosa and cause diarrhea. In contrast, *Shigella* organisms cause disease by actually invading the gastrointestinal submucosa.

B.2.1.3 Dose

A third factor critical to this particular link involves a phenomenon referred to as the "infectious dose." The infectious dose is the minimum number of a given microorganism needed to cause infection. This number varies from organism to organism and from host to host. However, seldom has the transmission of disease resulted from the transfer of a single microorganism. It usually requires thousands to millions of these agents before infection can actually take place. However, some pathogens can begin an infection with only a small number of cells in the initial inoculum. Enterohemorrhagic strains of *Escherichia coli* require an infective dose of only about ten cells, whereas other pathogens, including *Vibrio cholera*, require a large number of cells (10^3 to 10^8 cells) in the inoculum to successfully infect a host (Schmid-Hempel and Frank, 2007). Some viral diseases can be accompanied by extremely high viral concentrations in body fluids such as blood; consequently, a significant number of microorganisms can be carried in a very minute volume of liquid. (See Figure B.2.) The concept of infectious dose is particularly important to understand when considering the importance and efficacy of good hand hygiene practices. Although properly performed hand hygiene does not eliminate all organisms from the skin, it does reduce their numbers to a level far below the infectious dose needed for the transfer of most diseases.

B.2.2 Reservoir

The second major link in the chain of infection involves the presence of a reservoir or source that will allow for microbial survival and, perhaps, even multiplication of a potential pathogen. Common reservoirs include the multitude of supplies and equipment used in patient care. However, the role played by food and drink, linen, and other inanimate objects is of comparatively minor significance when measured against that played by the main reservoir, man himself. Studies have shown that normal human skin harbors approximately 10,000 organisms per square inch, equivalent to nearly 20 million microorganisms over the surface of the entire body. The oral cavity is thought to harbor an additional 100 million organisms and the gastrointestinal tract to contain another 100 million in each gram of stool. Thus, on and within the human body, well over a trillion microorganisms can be found, and therein lies one of the main reasons for the use of gloves any time that contact with body fluids is anticipated. It is a well-documented fact that most health-care-associated infections are indeed caused by the patient's own microbial flora. This is not to imply that such infections cannot be prevented, simply that they are usually the result of prior microbial colonization of the patient.

B.2.3 Portal of exit

The third link requires the presence of a source from which the pathogen can emerge, a portal of exit. Obvious portals of exit include the respiratory tract, blood vascular system, skin, and mucous membranes, as well as the

gastrointestinal and genitourinary tracts. In addition, contact of patient care supplies and equipment with any portal of exit will invariably result in potential contamination and the subsequent possibility of disease transfer.

Volume of Strike-through (1) Actual Size	100 μ L	10 μ L	1 μ L	0.1 μ L
Number of Bloodborne Pathogens (2)				
HBV	10,000,000	1,000,000	100,000	10,000
HCV	100-100,000	10-10,000	1-1,000	0.1-100
HIV	6-700	0.6-70	0.06-7	0.006-0.7

NOTE 1—Volume of red 40 dyne/cm synthetic blood delivered to white blotter papers.

NOTE 2—Based on documented whole blood concentrations of infected patients.

Figure B.2—Blood-borne pathogen strike-through conversion chart

Figure B.2 converts the amount of strike-through to the amount of potential blood-borne pathogen contamination. The four spots at the top were formed from premeasured droplets of synthetic blood and are marked in microliters ranging from 100 microliters to 0.1 microliter. Listed on the left are the three primary blood-borne pathogens: HBV, HCV, and HIV. The approximate number of infectious units that could be present in each spot, on the basis of documented whole blood concentrations in infected patients, is shown for each type of virus. These data were derived from Bradley (1984), Ho et al. (1989), and Shikata et al. (1977). A study of transmission of blood-borne pathogens to health care workers found serum concentrations of HBV, HCV, and HIV to be as high as 10^8 , 10^6 , and 10^3 viral particles per milliliter, respectively (Lanphear, 1994). (Figure courtesy of W.L. Gore & Associates, Inc.)

B.2.4 Mode of transmission

Although several potential mechanisms for transmission exist, the main mode of disease transfer involves contact transmission, either through direct or indirect contact with the patient or through droplet spread via contact with exhaled respiratory secretions. Direct-contact transmission primarily involves person-to-person spread such as contact with the unwashed hands of a health care worker. Indirect-contact transmission can be the result of contact with a contaminated intermediate object such as a catheter, dressing, or surgical instrument. Droplet spread occurs through contact of the conjunctivae or the mucous membranes of the nose or mouth with large (greater than 5 microns) droplets of respiratory secretions. Such droplets are generated primarily during coughing, sneezing, or talking. Typical examples of illnesses transmitted in this manner include streptococcal pharyngitis, mumps, and influenza.

Three additional means by which diseases can be transmitted are airborne, vehicular, and vector transmission. Airborne transmission occurs by means of the dissemination of either very small (less than 5 microns) droplet nuclei resulting from respiratory secretions or dust particles containing the infectious agent. Typical diseases transmitted in this manner include tuberculosis, measles, and chicken pox.

Vehicular transmission involves the spread of disease-causing organisms through some secondary route, usually environmental objects such as contaminated medications or antiseptics (e.g., eyedrops, multidose vials), food (e.g., hepatitis A or staphylococcal food poisoning), or water (e.g., giardiasis). Such diseases are very rarely the result of health care delivery.

Vector transmission involves the spread of pathogenic agents through secondary, animate hosts, such as insects and rodents or other small animals. Typical examples of vector-borne diseases include malaria, rabies, plague, and Lyme

disease. As with vehicular transmission of disease, vector transmission associated with the delivery of health care is extremely rare, if not nonexistent, in the United States.

B.2.5 Portal of entry

The fifth link in the chain of infection is a suitable portal of entry. The avenues for gaining entry into the body are, in most instances, identical to the portals of exit. It is important to understand that each of these portals is usually peculiar to given diseases and that, for any given disease, there is usually a very specific portal of exit and entry. For example, tuberculosis and influenza involve only the respiratory tract and typhoid fever the gastrointestinal tract. Hepatitis B involves transmission by blood. Most infectious diseases and conditions require very specific portals of both entry and exit.

B.2.6 Susceptible host

The last link is a susceptible host, someone who lacks effective resistance to a given pathogenic agent. A variety of host factors must be present before infection can occur. Very few organisms can gain entrance through normal intact skin. Most require some breach in skin integrity. Other less obvious lines of defense include tears, gastric acid, and the cilia of the nose and upper respiratory tract. One's ability to mount a local inflammatory response provides yet another nonspecific host defense mechanism. Patients who are immunocompromised (e.g., the very young, the elderly, those who are undergoing immunosuppressive therapy, those with disorders of the immune system) are susceptible hosts.

B.3 Barrier protection and protective clothing

Protective clothing is often used to limit or prevent contact transmission of microorganisms. Strategies employed in the laboratory evaluation of protective clothing materials and the resulting understanding of performance expectations are very important when deciding which products are suitable for which applications. Such strategies need to consider both the modes of transmission (e.g., liquid-borne, aerosol-borne) and the perceived risk associated with varying types of microorganisms (e.g., viruses, bacteria, fungi). It is extremely difficult to duplicate the myriad of physical, chemical, and thermal stresses placed on protective clothing in an actual setting. Nonetheless, the goal of laboratory testing is to provide information that will allow a realistic estimation of the performance of protective clothing during actual use.

NOTE 1—The Food and Drug Administration maintains a list of recognized standards, including standards applicable to protective clothing and barrier integrity testing. This list can be accessed at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/results.cfm>.

NOTE 2—ANSI/AAMI PB70 classifies surgical gowns, other protective attire, surgical drapes, and drape accessories according to barrier performance determined by specified laboratory test methods. This standard has been recognized by FDA.

Annex C (informative)

Processing CJD-contaminated patient care equipment and environmental surfaces

C.1 Introduction

The purpose of this Annex is to provide general guidance for reprocessing instruments and medical devices that have been exposed to patients known or suspected to have Creutzfeldt-Jakob disease (CJD). This Annex is not intended to provide a detailed review. Health care facilities may consider other procedures as technologies are developed to inactivate prions. The recommendations in this Annex are based on information from the scientific literature and various health care authorities and are subject to ongoing review and modification. The reader is urged to check with health care agencies such as the Centers for Disease Control and Prevention (CDC) for current recommendations regarding the processing of devices and equipment contaminated with high-risk tissue from high-risk patients. See also Rutala and Weber (2010) for such guidance.

NOTE—FDA does not currently recognize or regulate any method of “reducing prion infectivity” and at the time of this writing does not permit statements about specific decontamination recommendations related to CJD in device labeling.

CJD is a degenerative neurological disorder of humans with an incidence in the United States of approximately one case per million population per year (CDC, 2010). The true rates of CJD are not known, because of the inherent difficulties in diagnosis, and estimates based on closer surveillance have been up to 3.2 cases in a million population per year (Klug et al., 2013). The disease is thought to be caused by a proteinaceous infectious agent or prion. CJD is related to other human transmissible spongiform encephalopathies (TSEs) that include kuru (0 incidence, now considered eradicated), Gertsmann-Straussler-Sheinker (GSS) syndrome (1 case per billion), and fatal familial insomnia (FFI) syndrome (less than 1 case per billion). Prion diseases do not elicit an immune response, result in a noninflammatory pathologic process confined to the central nervous system, have an incubation period of years, and usually are fatal within one year of diagnosis.

A recently recognized new variant form of CJD (vCJD) is acquired from cattle with bovine spongiform encephalopathy (BSE) or “mad cow” disease. By March 2012, 173 cases of vCJD had been recorded in Great Britain, 25 cases had occurred in France, and 1 to 5 cases had been reported in Spain, Ireland, Italy, the United States, Canada, Saudi Arabia, Japan, the Netherlands, Portugal, and Taiwan (Ironside, 2012). Compared with CJD patients, vCJD patients are younger (29 vs. 65 years of age), have a longer duration of illness (14 vs. 4.5 months), and present with sensory and psychiatric symptoms that are uncommon with CJD. From the initial outbreak, the reported cases of vCJD have continued to decline, but it is also speculated that there might be a greater number of preclinical vCJD cases in an unknown proportion of the U.K. population, recently evaluated with a prevalence of 1 in 4,000 according to a study with appendix tissues (Wadsworth et al., 2011). Further studies on tissue distribution continue to highlight the potential risk associated with CJD and vCJD, including the demonstration of blood and muscle transmission (World Health Organization, 2010). Transfusion-related disease caused by vCJD has been confirmed (Llewelyn et al., 2004; Hewitt et al., 2006). Although vCJD is often considered to be separate from CJD, the distribution of prions in cases of both CJD and vCJD in various tissues during and at the end of disease progression is constantly changing and under review (World Health Organization, 2010). The agents of CJD and other TSEs exhibit an unusual resistance to conventional chemical and physical decontamination methods (Taylor, 2000; McDonnell and Sheard, 2012). Because the CJD agent is not readily inactivated by conventional disinfection and sterilization procedures and because of the invariably fatal outcome of CJD, the procedures for disinfection and sterilization of the CJD prion have been both cautious and controversial for many years.

CJD occurs as both a sporadic and familial disease. The number of CJD episodes that have resulted from health-care-associated transmission is unknown, but confirmed cases have been rare. Only two confirmed cases and four unconfirmed cases have been associated with reprocessed surgical instruments; these cases occurred more than 25 years ago in Europe. No cases of CJD or vCJD associated with surgical or medical instruments have been reported since that time, but the sources of sporadic cases of CJD are generally unknown.

The vast majority of confirmed health-care-associated transmission cases have resulted from use of contaminated tissues or grafts. Iatrogenic CJD has been described in humans in three circumstances:

- a) After patients received extracted pituitary hormones (more than 130 cases)

- b) After patients received an implant of contaminated grafts from humans (cornea, three cases; dura mater, more than 110 cases)
- c) As mentioned above, after use of contaminated medical equipment and surgical instruments on patients undergoing invasive procedures (two confirmed and four unconfirmed cases) (World Health Organization, 2000; Brown, et al., 2000; McDonnell and Sheard, 2012).

All known instances of iatrogenic CJD have resulted from exposure to infectious brain, pituitary, or eye tissue. Tissue infectivity studies in experimental animals have determined the infectiousness of different body tissues (Brown, 1996). Tissues that have the highest prion concentration are brain and dura mater. Transmissibility is directly related to the concentration of prions in tissues, but with improvements in detection technologies and pathologies the range of implicated tissues continues to be debated (World Health Organization, 2010).

Transmission via stereotactic electrodes is an interesting example of transmission via a medical device (Bernoulli, et al., 1977). The electrodes had been implanted in a patient with known CJD. The electrodes were cleaned (to include treatment with benzene) and then "sterilized" by soaking them in 70% alcohol and exposing them, during storage at room temperature, to formaldehyde vapor produced by a formaldehyde generator using solid paraformaldehyde. Two years later, these electrodes were retrieved and implanted into a chimpanzee in which the disease developed. The methods used to clean and "sterilize" these electrodes would not currently be considered an adequate method for sterilizing medical devices in the USA.

Retrospective studies suggest that four other episodes could have resulted from use of contaminated instruments in neurosurgical operations (reviewed by Rutala and Weber, 2001). An index CJD case was identified in only one case; and, in this instance, the surgical instruments were cleaned with soap and water and then exposed to dry heat for an unspecified time and temperature. The other three cases had no associated index case; these patients did have a neurosurgical procedure within a two-year period before being diagnosed with CJD.

All six cases of CJD associated with neurosurgical instruments occurred in Europe between 1953 and 1976, and details of the reprocessing methods for the instruments are incomplete. There are no known episodes of CJD attributable to the reuse of devices contaminated with blood or to transfusion of blood products. Experimental evidence, primarily with contaminated brain tissue, has confirmed the transmissible nature of prions on simulated device surfaces even at relatively low concentrations (Fichet et al., 2004).

The infrequent transmission of CJD via contaminated medical devices probably reflects the inefficiency of transmission except for neural tissue and the effectiveness of conventional cleaning and current disinfection and sterilization procedures (Rutala and Weber, 2001). Despite this, the unknown sources for sporadic cases of CJD and their persistent nature on surfaces even in the presence of conventional cleaning, disinfection and sterilization procedures is a concern (McDonnell, 2008).

To minimize the possibility of use of neurosurgical instruments that have been potentially contaminated during procedures performed on patients in whom CJD is later diagnosed, health care facilities should consider using the sterilization guidelines outlined in C.2 for neurosurgical instruments used during brain biopsy done on patients in whom a specific lesion has not been demonstrated (e.g., by magnetic resonance imaging or computerized tomography scans). Alternatively, neurosurgical instruments used in such patients could be disposable or the instruments could be quarantined until the pathology of the brain biopsy is reviewed and CJD excluded (Rutala and Weber, 2001; Rutala and Weber, 2010).

Several investigators have studied the inactivation of prions by cleaning, disinfection, and sterilization processes, but these studies do not reflect the reprocessing procedures in a clinical setting:

- a) These studies have not incorporated a cleaning procedure that might reduce bacterial contamination by 4 log₁₀ and can reduce protein contamination (Rutala and Weber, 2001), but these results do not necessarily correlate with prion reduction (Fichet et al., 2007a).
- b) The prion studies have been done with tissue homogenates dried onto carriers. The protective effect of the tissue and the drying of the tissue might explain, in part, why the CJD agent is difficult to inactivate in these experimental studies.
- c) Results of inactivation studies of prions have been inconsistent because of the use of differing methodologies, which have varied by prion strain, prion concentration, test tissue (intact brain tissue, brain homogenates, partially purified preparations), test animals, duration of follow-up of inoculated animals, exposure container, method of calculating log-reductions in infectivity, concentration of the disinfectant at the beginning and end of an experiment, cycle parameters of the sterilizer, and exposure conditions.

Despite these limitations, there is some consistency in the results (reviewed by Rutala and Weber, 2001, and McDonnell and Sheard, 2012). In order to provide scientifically based recommendations, research should be

undertaken in which actual medical instruments are contaminated with prions (including variant CJD), cleaned, and then subjected to either conventional sterilization or disinfection or special prion reprocessing.

Cleaning studies with prion-contaminated surfaces have shown that cleaning alone can have a dramatic effect on reducing the risk of prion contamination (reviewed by Fichet et al., 2007a; however, this will vary considerably depending on the cleaning process used. Prion infectivity is considered hydrophobic and can tightly attach to device surfaces, rendering the infectious material difficult to remove from surfaces. Protein removal studies do not correlate with prion infectivity reduction; therefore, cleaning processes can only be confirmed as having any benefit in reducing contamination risks when directly tested in bioassays. The formulation of the cleaning chemistry can also have an impact, with some alkaline-based cleaners showing significant benefits (Yan, et al., 2004; Baier, et al., 2004; Fichet et al., 2004). But at the same time, some cleaning formulations have been demonstrated to have negative effects, rendering prion contamination more resistant to subsequent steam sterilization (Fichet et al., 2004; Yan et al., 2004). Overall, the safe cleaning of prion-contaminated surfaces can only be confirmed by direct testing in bioassays and preferably by simulating the full recommended reprocessing procedure (cleaning and sterilization).

The disinfection studies mentioned above showed that many, but not all, disinfection processes fail to inactivate clinically significant numbers of prions. These disinfection processes include thermal disinfection, which has little to no benefit in reducing prion infectivity. There are four chemicals that reduce the prion titer by more than 3 log₁₀ in 1 hour or less: 1) chlorine (sodium hypochlorite), 2) a phenolic disinfectant formulation (based on ortho-phenylphenol, p-tertiary-amylphenol, and ortho-benzyl-para-chlorophenol) at concentrations greater than 0.9%, 3) guanidine thiocyanate, and 4) sodium hydroxide. Of these, chlorine and sodium hydroxide have been the most extensively tested and show variable results. Both are unsuitable for many devices, such as surgical instruments and endoscopes. Any disinfectants that have a mode of action associated with protein cross-linking (e.g., formaldehyde, glutaraldehyde, ortho-phthalaldehyde [OPA] and alcohol) should not be used because of the risk of fixing prions to device surfaces, which can then remain infectious over time.

Prions also exhibit an unusual resistance to conventional physical and chemical sterilization methods (McDonnell and Sheard, 2012). Steam is an effective process but is dependent on correct cleaning prior to sterilization. There is some debate on the ideal time-and-temperature cycle for steam sterilization of prion-contaminated devices; the recommendations of 134°C (273°F) for at least 18 minutes (dynamic-air-removal cycles) and 132°C (270°F) for 60 minutes (gravity-displacement cycles) are based on the scientific literature (Rutala and Weber, 2001). These cycles have been shown to provide significant but not complete reduction of infectivity under worst-case conditions (World Health Organization, 2000). Unlike microorganisms, there is not necessarily a correlation between the steam temperature and time necessary to ensure reductions in prion infectivity (Fernie et al., 2007). Some studies have shown that with the correct cleaning process, conventional steam sterilization cycles can be effective and may be used as a standard precaution against unknown prion contamination.

Some investigators also have found that combining sodium hydroxide (NaOH) with steam sterilization for 1 hour at 121°C (250°F) results in loss of infectivity. However, the combination of NaOH and steam sterilization can be deleterious to surgical instruments and sterilizers, as well as to sterilizer operators (Brown et al., 2004). Damage might not be apparent after the first exposure, but can result in damage over time that can lead to device failure (McDonnell and Burke, 2003).

Many traditional low-temperature sterilization methods, including ethylene oxide, formaldehyde, and radiation, have been shown to have little to no effect on prions (McDonnell and Sheard, 2012). Recent reports have shown that some hydrogen peroxide gas sterilization processes might be effective (Rogez-Kreuz et al., 2009, Fichet et al., 2007b), but other, similar processes might not be effective (Yan et al., 2004). Ozone-based process have not been shown to be effective to date.

Historically, recommendations for inactivating the agent of CJD have been based on studies using infected tissues and injecting animals known to be susceptible to CJD. These have not been replaced with surface-based methods that allow for the evaluation of partial and full reprocessing cycles, including cleaning, disinfection, and/or sterilization, as appropriate.

The cleaning, disinfection, and sterilization recommendations for processing prion-contaminated devices, given in C.2, are based on the belief that infection prevention and control measures should be predicated on epidemiologic evidence linking specific body tissues or fluids to transmission of CJD, quantitative infectivity assays demonstrating that body tissues or fluids are contaminated with infectious prions, cleaning data, inactivation data on prions, the risk of disease transmission with the use of the instrument or device, and a review of other recommendations (in particular, Rutala and Weber, 2010).

The three parameters that are integrated into the strategies for reprocessing given here are as follows:

- a) **Risk of the patient having a prion disease:** High-risk patients include those with known prion disease; those with rapidly progressive dementia consistent with possible prion disease; those with a familial history of CJD, GSS, or FFI; patients known to carry a mutation in the PrP gene involved in familial TSEs; patients

with a history of dura mater transplants; and patients with a known history of cadaver-derived pituitary hormone injection.

- b) **Comparative infectivity of different body tissues (i.e., the prion load):** High-risk tissues include brain, spinal cord, and eye. All other tissues may be considered low- or no-risk, but recent guidelines should be considered (World Health Organization, 2010).
- c) **Intended use of the medical device:** Critical devices are defined as devices that enter sterile tissue or the vascular system (e.g., implants, curettes). Semicritical devices are defined as devices that contact nonintact skin or mucous membranes (e.g., endoscopes).

C.2 Processing devices contaminated with high-risk tissue

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

- 1) Devices that are constructed so that cleaning procedures result in effective tissue removal (e.g., surgical instruments) can be cleaned with a chemistry shown to safely reduce prion infectivity and then steam sterilized at 134°C (273°F) for greater than or equal to 18 minutes in a dynamic-air-removal sterilizer or at 121°C to 132°C (250°F to 270°F) for 1 hour in a gravity-displacement sterilizer.
- 2) Devices that are impossible or difficult to clean should be discarded. In some cases, the contaminated device may be placed in a container filled with a liquid (e.g., saline, water, or a cleaning solution known to safely reduce the risks of prion contamination) to prevent drying, then initially decontaminated by steam sterilizing it at 134°C (273°F) for 18 minutes in a dynamic-air-removal sterilizer (liquids must be removed before the device is sterilized) or at 121°C to 132°C (250°F to 270°F) for 1 hour in a gravity-displacement sterilizer or by soaking it in 1N NaOH for 1 hour. The device is then cleaned, wrapped, and terminally sterilized as described in 1).

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

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

- 3) To minimize drying of tissues and body fluids on the object, devices should be kept moist until cleaned and sterilized.
- 4) IUSS should not be used for reprocessing these devices.
- 5) Contaminated items that have been in contact with high-risk tissue and have not been processed according to these recommendations (e.g., medical devices used for brain biopsy before diagnosis) should be recalled and appropriately reprocessed. If these items have been treated with chemicals known to cross-link protein (such as aldehydes and alcohols), they should be discarded.
- 6) A tracking system should be in place that permits recall of devices used on high-risk tissue and high-risk patients. This tracking system should permit identification of the patient on which the devices were used, the date they were used, the procedure performed, and the surgeon's name. Facilities that do not have a commercially available or automated tracking system should create a manual system. A simple system can be created using a steam-sterilizable two-part card, with an external CI that is affixed to the outside of instrument trays. When the tray is used, the bottom part of the card is removed and affixed to the patient's chart to identify all items used on the patient. To ensure accurate tracking of sets and devices, all items should be given a unique number. For example, if the facility has four craniotomy trays, they should be numbered #1, #2, #3, and #4 to identify the specific tray used on the patient.
- 7) Environmental surfaces (noncritical) contaminated with high-risk tissues (e.g., laboratory surfaces in contact with the brain tissue of a person infected with CJD) should be cleaned with a detergent and then spot-decontaminated with freshly prepared 5,000 ppm sodium hypochlorite (leaving it moist on the surface for 1 hour). This concentration usually results from a 1/10 dilution of household bleach. However, the label should be checked for the amount of sodium hypochlorite present; concentrations in U.S. products can range from 3% to more than 6% sodium hypochlorite.
- 8) Noncritical equipment contaminated with high-risk tissue should be cleaned and then disinfected with 5,000 ppm hypochlorite or 1 N NaOH (leaving it moist on the surface for 1 hour), depending on material compatibility. All contaminated surfaces must be exposed to the chemical.

- 9) Equipment that requires special prion reprocessing should be tagged after use. Clinicians and reprocessing technicians should be thoroughly trained on the proper tagging of equipment and on the special prion reprocessing protocols.
- 10) Use of power drills or saws that are likely to contact high-risk tissue should be avoided. Power drills and saws by their very nature and design are difficult to clean and expensive to discard (AORN, 2017a).

C.3 Processing devices contaminated with low-risk tissue

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

- 1) Devices can be cleaned and disinfected or sterilized using conventional protocols of high-level disinfection, thermal sterilization, or chemical sterilization. It is recommended that devices are cleaned with a chemistry shown to safely reduce prion infectivity. Steam sterilization or hydrogen peroxide gas sterilization processes shown to have safely reduced prion infectivity are preferred.
- 2) Environmental surfaces contaminated with low-risk tissues require only standard disinfection using disinfectants recommended by OSHA for decontaminating blood-contaminated surfaces (preferably with 500 to 5,000 ppm sodium hypochlorite).

C.4 Processing devices contaminated with no-risk tissue

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

- 1) Devices can be cleaned and disinfected or sterilized using conventional protocols of high-level disinfection, thermal sterilization, or chemical sterilization, as described in C.3.
- 2) Most endoscopes (except neurosurgical endoscopes) are likely to be contaminated only with no-risk materials. It is preferable that cleaning and sterilization processes shown to reduce the risk of prion infectivity are used. In some cases, standard cleaning and high-level disinfection protocols may be considered for reprocessing.
- 3) Environmental surfaces contaminated with no-risk tissues or fluids require only standard disinfection using disinfectants recommended by OSHA for decontaminating blood-contaminated surfaces (preferably 500 to 5,000 ppm sodium hypochlorite).

C.5 Update of recommendations

Considering the ongoing research on the risks of prion contamination and on effective reprocessing methods, these recommendations are likely to be periodically updated. Useful sources of reliable information include the CDC, the World Health Organization, and the peer-reviewed literature.

Annex D (informative)

User verification of cleaning processes²

D.1 General considerations

Verification of a cleaning process consists of

- a) defining a cleaning process and its critical aspects so that each step is fully verifiable through personnel training and observation to ensure that it can be followed completely, accurately, and without variation by all individuals who perform it; and
- b) providing process controls along with verification methodologies that ensure adequate, consistent cleaning levels.

Two principles are involved in verifying a cleaning process. The first consists of establishing, clarifying, and documenting a standard cleaning process that is based on device manufacturers' written IFU and published recommended practices or guidelines. The second concerns measuring and evaluating residual contaminants on medical devices after applying the established cleaning process.

The U.S. Food and Drug Administration (FDA) places the primary responsibility for developing and validating methods for effective reprocessing of a reusable medical device on the manufacturer of the device. The manufacturer is expected to validate that the device can be cleaned and disinfected or sterilized adequately to allow the device to be reused. As outlined in FDA (2015), the manufacturer must test and validate any labeling claims of fitness for reuse that are provided in the written instructions for the handling, cleaning, disinfection, packaging, and sterilization of medical devices in a health care facility. To demonstrate compliance with label claims, manufacturers of cleaning agents must validate that their cleaners provide the expected level of soil removal and determine its materials compatibility. (AAMI TIR12 and AAMI TIR30 address the issues related to manufacturers' validation testing for cleaning of medical devices.)

Medical device manufacturers should be familiar with cleaning, disinfection, and sterilization technologies used in health care facilities and with the kinds of soil and microbial contamination encountered as a result of patient use.

Users must establish an appropriate cleaning policy and procedures for the reusable medical devices they process. The procedures should be based on the validated recommendations of the device manufacturer and the cleaning solution manufacturer, published data on the cleaning efficacy for the medical devices (if available), and published recommended practices or guidelines. Cleaning efficacy tests that are performed following reprocessing are used to verify the ability of a cleaning process to remove or reduce to an acceptable level the organic soil and microbial contamination that occurs during the use of reusable devices. A number of methods can be used to evaluate the results of the cleaning process. The most common method is a visual inspection, sometimes involving the use of a lighted magnifying glass for inspecting cleanliness of device surfaces or the use of borescope cameras for inspecting the internal channels of lumened instruments. Health care personnel inspect every device for visible organic soil and contamination in a simple functionality check, usually as part of the inspection, preparation, and packaging procedure. However, residual organic soil and microbial contamination could be present on an accessible surface even though the device "looks clean." Furthermore, direct visual inspection is not possible for the inner components of medical devices that have lumens or that are of nonsealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices, biopsy forceps). Ideally, cleaning verification by users should include (a) visual inspection combined with other verification methods that allow the assessment of both external surfaces and the inner housing and channels of medical devices, (b) testing the cleaning efficacy of equipment, and (c) monitoring key cleaning parameters (e.g., temperature). Manufacturers should strive to provide users with such tests so that medical devices can be tested directly after cleaning in a way that will not damage the device or require recleaning.

A more objective and sensitive method than visual inspection is to measure the levels of organic soil and microbial contamination on the cleaned device. There are commercially available tests for residual bioburden that allow users to rapidly verify that cleaning has been performed.

A critical aspect of in-use reprocessing is for users to verify that staff members who perform the reprocessing of medical devices using the selected protocol are consistently achieving the expected level of cleaning. Furthermore, a

² Adapted from AAMI TIR30:2011, Section 5.4.

facility's on-site quality assurance program should include ways to verify that the cleaning equipment used for reprocessing of medical devices is working properly. Testing the equipment upon installation, during routine use, and after repairs allows the user to verify its continued effectiveness (AORN, 2017a). Zuhlsdorf et al. (2002) have shown that in cleaning tubular devices the achievement of visible cleanliness and adequate microbial reduction varies greatly, depending on the type of water and detergent used for cleaning. The variability of results for lumens cleaned by automated washers (Zuhlsdorf et al., 2002) underscores the importance of in-use verification of manual cleaning, which is generally less efficient than automated cleaning. The commercial availability of simple monitoring tools that provide objective, real-time feedback now makes possible the verification of staff competency and compliance with cleaning guidelines.

Two basic components of user verification of cleaning efficacy are

- a) establishing reasonable benchmarks for the level of cleaning that can be achieved consistently using specific soil markers relevant to devices used for patients; and
- b) using rapid, easy-to-perform tests that reliably demonstrate that the cleaning benchmarks have been achieved.

D.2 Markers

Cleaning is the removal of organic material (e.g., patient secretions), inorganic material (e.g., salts), and microbial contamination (acquired from the patient procedure or during handling) to ensure that adequate disinfection or sterilization can be achieved, thereby making the device safe for subsequent use on patients. Published studies that have evaluated the specific markers that can be used to determine cleaning efficacy have indicated that the following markers are useful for benchmarking purposes:

- a) Protein
- b) Carbohydrate
- c) Hemoglobin (blood)
- d) Endotoxin
- e) Lipid
- f) Sodium ion
- g) Bioburden
- h) Adenosine triphosphate (ATP)

Protein is a marker commonly used to evaluate cleaning efficacy.

Different cleaning verification methods have benchmarks that have been established and, in some cases, validated by the cleaning indicator manufacturer or through independent studies.

Realistic benchmarks depend on what can be achieved by routine cleaning and the limit of detection of the method used. Data indicate that for flexible endoscopes that have been cleaned after use on patients, the average level of soil markers in the suction/biopsy channel are as follows: protein, $<6.4 \mu\text{g}/\text{cm}^2$, carbohydrate, $<1.8 \mu\text{g}/\text{cm}^2$, haemoglobin, $<2.2 \mu\text{g}/\text{cm}^2$; sodium ion, $<1 \text{ umole}/\text{cm}^2$; endotoxin, $<2.2 \text{ EU}/\text{cm}^2$; and ATP, 200 relative light units (RLU) (Alfa et al., 2002, 2012b, 2013).

NOTE—ATP test manufacturers use varying scales. Check with the ATP test manufacturer for the recommended benchmark.

D.3 Cleaning verification tests for users

There are a number of commercially available validated test methods for rapid detection of organic residues on surgical instruments.

Ideally, cleaning tests for in-use verification of medical device reprocessing should be

- a) rapid,
- b) easy to perform,
- c) sensitive (i.e., meet realistic benchmarks),

- d) accurate,
- e) repeatable,
- f) free of interfering substances, and
- g) robust (i.e., do not require exacting conditions or time constraints that cannot be achieved in routine reprocessing areas),

Manufacturers should provide users with cleaning verification tests that enable them to quickly test medical devices directly after cleaning and in a way that will not damage the device or require recleaning. It is important to note that eluting samples from used medical devices using a sodium dodecyl sulfate (SDS) solution requires that the device be recleaned after testing. Consequently, although this sampling method is useful for research purposes because it facilitates sample collection, it has little value for in-use testing because the medical device would need to be recleaned to remove any residual SDS. Moreover, easy-to-perform tests are also needed to verify the functionality of automated washers. Such tests should not lead to the introduction of interfering or extraneous materials that could remain on medical devices post-testing.

For verification of routine cleaning processes, users should incorporate test methods that verify the functionality of the mechanical cleaning equipment (if used) and the cleanliness of specific devices after manual or mechanical cleaning is completed. These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks, once these benchmarks have been defined.

Verification tests for ultrasonic cleaners

Test for cavitation in ultrasonic bath: Indication can be physical measurement or visual assessment.

Test for soil removal (external) in ultrasonic bath: Indication is visual assessment or absence of marker on a coupon placed in the ultrasonic bath.

Test for soil removal (internal within lumens) in ultrasonic bath: Indication is visual assessment or absence of marker on a coupon placed in the ultrasonic bath.

Verification test for mechanical washers

Test for soil removal: Indication is visual assessment or absence of marker on a coupon placed in the washer.

Chemical tests for residual soil markers

Protein detection by chemical reaction interpreted as a visible color change or a quantitative measure of residue (utilizing a color chart [semi-quantitative] or photometric device). Samples may be collected by swabbing, flushing, or direct application of reagent.

Detection of ATP by chemical reaction. Measurement of fluorescent light reported as a numeric value. Samples may be collected by swabbing or flushing.

Hemoglobin detection by chemical reaction. Interpreted as a visible color change or a quantitative measure of residues. Samples may be collected by swabbing or flushing.

Annex E (informative)

Selection and use of chemical disinfectants

E.1 Introduction

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

E.2 Categories of items to be disinfected

Surgical instruments and other medical devices and equipment could pose a significant risk of transmitting infection to patients or health care personnel if they are not properly decontaminated and then disinfected or sterilized. Spaulding divided medical instruments and equipment into three categories (critical, semicritical, and noncritical) on the basis of the risk of infection from contamination on the item (Spaulding, 1972). The Centers for Disease Control and Prevention (CDC) has described the level of disinfection or sterilization needed after decontamination and before patient use for the three Spaulding categories (Garner and Favero, 1985; CDC, 2003, 2008), as well as a fourth category, environment surfaces (Favero and Bond, 2001):

- a) **Critical devices** are instruments or objects that are introduced directly into the human body, either into or in contact with the bloodstream or other normally sterile areas of the body, and products with sterile fluid pathways. Examples of critical items include surgical instruments, needles, transfer forceps, cardiac catheters, implants, inner surface components of extracorporeal blood-flow devices such as heart–lung machines and blood oxygenators, and the blood compartments of hemodialyzers. Critical items present a high degree of risk of transmission of infection if contaminated and, therefore, must be sterile at the time of use.
- b) **Semicritical devices** are instruments or objects that contact intact mucous membranes or nonintact skin of the patient during use, but do not usually penetrate the blood barrier or other normally sterile areas of the body. Examples include noninvasive flexible and rigid fiberoptic endoscopes, endotracheal and aspirator tubes, bronchoscopes, laryngoscopes, respiratory therapy equipment, cystoscopes, vaginal specula, and urinary catheters. Semicritical devices should be sterilized, if possible. However, if sterilization is not feasible, the device, at a minimum, must be subjected to a high-level disinfection process that would be expected to destroy all microorganisms except for large numbers of bacterial spores. In most cases, meticulous physical cleaning followed by high-level disinfection provides reasonable assurance that the items are free of pathogenic microorganisms.

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

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

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

E.3 Activity levels of disinfectants

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

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

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

- a) as data on the chemical agent with no mention of brand names or specific product formulations;
- b) as label claims supported by technical data for a particular product formulation that contains the chemical agent; and
- c) as the results of controlled studies by independent parties.

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

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

NOTE—The unconventional agent that causes Creutzfeldt-Jakob disease (CJD) might not be inactivated by a high-level disinfection procedure; in fact, this agent is resistant to most commonly used sterilization methods. For information regarding the decontamination of devices exposed to prions, see Annex C, AORN (2017a), Favero and Bond (2001), Rutala and Weber (2001), Rutala and Weber (2010), and the recommendations of CDC (<http://www.cdc.gov>) and IAHCSMM (<http://www.iahcsmm.org>).

E.4 Labeling of disinfectant products

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

Table E.1—Levels of disinfection according to type of microorganism¹⁾

Levels	Bacteria			Fungi ²⁾	Viruses	
	Vegetative	Mycobacteria	Spores		Lipid (Medium)	Nonlipid (Small)
High	+ ³⁾	+	+ ⁴⁾	+	+	+
Intermediate	+	+	± ⁵⁾	+	+	± ⁶⁾
Low	+	—	—	± ⁷⁾	+	—
NOTE 1—Data from CDC (2003). NOTE 2—Includes asexual spores but not necessarily chlamydospores or sexual spores. NOTE 3—Plus sign (+) indicates that a killing effect can be expected when the normal use-concentrations of chemical disinfectants or pasteurization are properly employed; a negative sign (–) indicates little or no killing effect. NOTE 4—Only with extended exposure times are high-level disinfectant chemicals capable of killing high levels of bacterial spores in laboratory tests; they are, however, capable of sporicidal activity. NOTE 5—Certain intermediate-level disinfectants (e.g., hypochlorites) can be expected to exhibit some sporicidal action; others (e.g., alcohols, phenolics) have no demonstrated sporicidal activity. NOTE 6—Some intermediate-level disinfectants might have limited virucidal activity. NOTE 7—Some low-level disinfectants might have limited fungicidal activity.						

General-purpose disinfectants that are intended to process noncritical medical devices and medical equipment surfaces or to preclean or decontaminate critical or semicritical medical devices before terminal sterilization or high-level disinfection are Class 1 medical devices and are exempt from FDA's 510(k) premarket notification requirements. These general-purpose disinfectants are regulated by EPA under FIFRA. The EPA-required labeling for a disinfectant includes the product name, the EPA product registration and establishment numbers, the EPA-approved biocidal claims (e.g., "fungicidal," "bactericidal"), an ingredient statement identifying the active ingredient in the formulation, directions for use, the name and address of the manufacturer or distributor, and safety and precautionary information.

The safety precautions provided in the labeling address such matters as the need for eye protection or gloves when the user is handling the solution. A warning section could state that the solution can cause eye irritation, and it could contain first-aid recommendations. A section on materials compatibility could identify materials or devices with which the solution is incompatible.

The directions for use indicate the use pattern and reuse life of the disinfectant. For example, the label could state that the use-life is 28 days after activation and that the solution is reusable for 28 days. The label should also describe how the use-life can be monitored by determining the concentration of the active ingredient using an appropriate solution test strip.

E.5 Criteria for selecting a chemical disinfectant

As noted in E.2, the choice of disinfecting method should be based on the device manufacturer's written reprocessing instructions, how the device will contact the next patient, the physical configuration (cleanability) of the device, the type and degree of contamination after use, the physical and chemical stability of the device, and the ease or difficulty of removing (rinsing, aerating) the chemical agent after the necessary exposure time.

The product label should be examined for information on the use pattern, reuse life, and storage life of the product. It is important to distinguish between the reuse life of a disinfectant and its use pattern. The reuse life of a disinfectant is the period of time after required activation or dilution of the product or, for ready-to-use products, the day the bottle is opened, for which the disinfectant solution can be used, provided that the concentration of active ingredients remains above the MRC or MEC. The reuse life can be 1 day, 14 days, 28 days, or whatever period is indicated on the label. The actual reuse life could be shorter than stated on the label because dilution, the presence of organic material, or residual detergent could alter the effectiveness of the solution as it is being used (see E.7). For this reason, a disinfectant solution should be monitored with an appropriate solution test strip every time it is used throughout the reuse period. If the test strip shows that the active ingredient is below the MRC or MEC, the solution should be discarded regardless of the number of days it has been in use.

The use pattern refers to how many times the solution can be used; it might be used one time only, or it might be reused for the period of its reuse life. The use pattern also can be expressed in terms of the number of disinfection cycles. The storage life, which is determined by the expiration date and which could be a year or more if the product is stored according to the manufacturer's written IFU, is the time period after which the unused, unopened product is no longer deemed effective.

Both the manufacturer of the disinfectant and the manufacturer of the device to be decontaminated should provide information on materials compatibility. The data should support the safety of a solution with respect to the materials from which a particular device is constructed (e.g., metal, alloys, plated metals, plastics, and combinations thereof). The information should state whether materials compatibility is affected by exposure time, exposure temperature, or concentration. Certain chemicals, especially when dissolved in water, are capable of corroding metals; this is particularly true of strong oxidizing agents, such as products that contain chlorine. Certain metals in contact with one another tend to corrode more rapidly than each metal alone. Certain plastics can become brittle if exposed to particular chemical agents. Some items requiring decontamination are very expensive (e.g., endoscopes), so the user should contact the manufacturer of the device to determine if the materials in the device have been tested and found to be compatible with the disinfectant product.

E.6 Quality control in chemical disinfection

The user should be aware of factors that can alter the effectiveness of a chemical disinfectant:

- a) **Use pattern:** Only those disinfectants labeled for reuse should be reused. A reuse claim on the product label indicates that the manufacturer has documented that, after a simulated reusing of the disinfectant for the period of time specified in the manufacturer's study, the disinfectant was effective in killing the microorganism types shown on the label. Use-pattern is event-related, not time-related.
- b) **Reuse life:** The reuse life stated on the label must not be exceeded. Reuse life is event-related as well as time-related. The reuse life could be shorter than what is stated on the label because of events that alter the concentration of the liquid chemical germicide.
- c) **Bioburden:** The process has been tested against a known number of microorganisms, and its success depends on the cleanliness of the items to be processed.
- d) **Water and extraneous materials:** Organic matter in the form of serum, blood, pus, or fecal material can protect microorganisms and consume or inactivate the active chemical agent in the disinfectant. Soaps, detergents, cork, cotton, lint, cotton wool, cellulose sponges, and the minerals found in hard water can also interfere with the effectiveness of the disinfectant. The manufacturer of the disinfectant should be consulted for information on the appropriate water, soaps, and detergents to be used in conjunction with the disinfectant.

NOTE—The disinfectant manufacturer might not have included organic matter or extraneous materials in challenge tests of antimicrobial efficacy. Even if simulated soil was used to challenge the disinfectant (see AAMI TIR12 and AAMI TIR30), the amount of organic or foreign material used in the testing might not be comparable to that encountered in actual use conditions.

- e) **Dilution and MEC/MRC monitoring:** The disinfectant is diluted by water remaining on surfaces and in the lumens of devices immersed in the disinfectant. Dilution can be very significant in the long-term use and reuse of a chemical disinfectant and can potentially reduce the concentration of the chemical agent to a level too low to be effective in killing a sufficient number of certain microorganisms in the recommended exposure time. To avoid dilution of the disinfectant, excess moisture should be removed after cleaning. Disinfectant solutions must not be used at concentrations below the MEC or MRC stated on the label. An MEC or MRC statement is required by FDA. As part of a health care facility's quality control program, LCS/HLD solutions such as glutaraldehyde should be monitored upon activation and before each use in order to detect unexpected dilution of the solution.
- f) **Temperature:** The antimicrobial claims stated on the product label are determined according to exposure time and temperature. For example, the label might state: "To kill *M. tuberculosis*, immerse the device for 1 hour at 25°C (77°F)." This label claim will have been fully documented. If the temperature of the solution is at any time lower than the temperature indicated on the product label, then complete disinfection might not be achieved during the prescribed time period. On the other hand, the temperature should not be high enough for the active ingredients to evaporate appreciably. A thermometer should be used to monitor the solution temperature.
- g) **Evaporation and light:** Evaporation can occur from a solution in an uncovered container. If the chemical agent is more volatile than the diluent (a gas dissolved in water is more volatile than water), then loss of the agent by evaporation can be very important. Chlorine products are especially susceptible to evaporation effects. Exposure to light can also affect chlorine products and disinfectants.
- h) **pH:** Disinfectants can be formulated over a range of pH values, depending on the chemical agent used. Some agents are more effective in killing microorganisms under alkaline conditions (a pH higher than 7), whereas others work best under acidic conditions (a pH lower than 7). The introduction of detergents to the disinfectant solution, which can occur if the device is inadequately rinsed after cleaning, can alter the pH of the solution and reduce its effectiveness.

- i) **Device characteristics:** A disinfectant solution is only effective if it can contact all surfaces of the item to be disinfected. The FDA recommends that medical device manufacturers perform testing that assesses the compatibility of the device with cleaning and defoaming agents and materials, including in-use testing of devices with complex design configurations that could impede penetration by cleaning and disinfectant agents.
- j) **Rinsing:** Inadequate quality of the rinse water used could result in recontamination of the medical device. If the medical device is required to be sterile and undergoes liquid chemical sterilization, then it should be rinsed with sterile water (0.2 μm filtered water is acceptable, provided that the filtration systems are adequately maintained). If high-level disinfection is used, the device can be rinsed with potable tap water, provided that the final drying step includes flushing all channels with 70% alcohol followed by forced-air drying. The alcohol will help kill any microorganisms introduced by the tap water rinse and will facilitate the drying with forced air.

E.7 Safety considerations in chemical disinfection

The user should consult the SDS supplied by the disinfectant manufacturer, determine if hazards exist, and observe the recommended safety precautions. In general, the following factors should be considered:

- a) Engineering controls, as required, such as adequate ventilation and/or a vented hood in the disinfection area to evacuate the chemical vapors
- b) The use of covered containers for the disinfectant solution, when appropriate
- c) Appropriate procedures and PPE for the user, such as gloves, eye protection, surgical face masks, and liquid-resistant gowns or aprons, as required by OSHA (29 CFR 1910.1030)
- d) Adequate rinsing of devices with sterile distilled water after disinfection

OSHA has established occupational exposure limits for several agents used in chemical sterilants and disinfectants. Employers are required by law to ensure compliance with these limits by implementing engineering controls, defining procedures for safe employee work practices, establishing medical surveillance programs, employing methods for monitoring for occupational exposure, providing respiratory protection, and taking other measures to the extent specified by OSHA to provide a safe work environment.

Limits on occupational exposure to chemical agents are commonly defined in terms of the maximum amount of chemical to which an employee can be exposed over a specified period of time. For example, OSHA mandates permissible exposure limits (PELs) calculated as an 8-hour time-weighted average (TWA) exposure. For some chemicals, a "short-term exposure limit" (STEL), which is based on a 15-minute exposure, has been established. For certain chemicals, including EO and formaldehyde, OSHA has established an "action level" (AL), which is the 8-hour TWA exposure level above which employers must initiate certain compliance activities, such as periodic employee exposure monitoring and medical surveillance. "Excursion limit" (EL) is a term adopted by OSHA specifically for defining a short-term exposure limit for EO. Like a STEL, an EL is the maximum 15-minute exposure to which a worker may be subjected. ACGIH, a private professional organization, recommends "threshold limit values" (TLVs), defined in terms of 8-hour TWAs, 15-minute STELs, and/or ceiling limits, for a large number of chemical substances and physical agents.

Limits established by OSHA for airborne contaminants, including some LCSs/HLDs and gaseous sterilant chemicals, are set forth in 29 CFR 1910.1000. Separate standards limiting occupational exposure to EO and formaldehyde are set forth in 29 CFR 1910.1047 and 29 CFR 1910.1048, respectively. However, OSHA can invoke the General Duty Clause of the Occupational Safety and Health Act of 1970 to regulate employee exposure to hazardous chemicals for which OSHA-established limits do not exist. For example, before 1989, the Air Contaminants Standard did not include exposure levels for glutaraldehyde, and there are no current OSHA-established exposure limits for glutaraldehyde. However, OSHA has invoked the General Duty Clause to regulate employee exposure and has recommended that exposures be controlled to the ACGIH-recommended TLVs for glutaraldehyde (Table E.2). Also, states with federally approved state OSHA programs may independently decide to enforce the PELs originally promulgated in the 1989 rule for air contaminants.

Table E.2 lists chemical agents found in LCSs/HLDs and gaseous chemical sterilants and the exposure limits currently mandated by OSHA and recommended by ACGIH. Additional information on OSHA requirements can be found on the OSHA Internet page at <http://www.osha.gov>. Additional information on ACGIH recommendations can be found in ACGIH (2017).

Table E.2—Occupational exposure limits for some chemical sterilants and disinfectants

Chemical Agent	OSHA PEL	ACGIH TLV
Acetic acid	10 ppm TWA 25 mg/m ³ TWA	10 ppm TWA 15 ppm STEL
Alcohols	Various ¹⁾	Various ¹⁾
Formaldehyde	0.75 ppm TWA 2 ppm STEL 0.5 ppm AL	0.3 ppm ceiling
Glutaraldehyde	None ²⁾	0.05 ppm ceiling
Hydrogen peroxide	1 ppm TWA 1.4 mg/m ³ TWA	1 ppm TWA
Ortho-phthalaldehyde	None	None
Peracetic acid	— ³⁾	— ³⁾
<p>NOTE 1—Various types of alcohol are used in sterilant formulations, and the occupational exposure limits vary. Refer to the product label for the active ingredients, and consult the latest ACGIH recommendations and OSHA regulations.</p> <p>NOTE 2—No exposure limits have been established by OSHA. However, OSHA can invoke the General Duty Clause of the Occupational Safety and Health Act of 1970 to regulate exposure to chemical sterilants and has recommended that the ACGIH TLVs be followed.</p> <p>NOTE 3—Peracetic acid exists in equilibrium with hydrogen peroxide and acetic acid, so occupational exposure limits for both hydrogen peroxide and acetic acid apply.</p> <p>NOTE 4—See Annexes B–G in ANSI/AAMI ST58 for additional information related to occupational exposure to chemical sterilants and high-level disinfectants.</p>		

Annex F **(informative)**

Thermal disinfection

F.1 Introduction

This Annex describes factors to consider when applying thermal (hot water) disinfection processes to the decontamination of reusable medical devices. Thermal disinfection selectively destroys microorganisms. The number and types of microorganisms killed on clean items—and, thus, the level of decontamination achieved—depend on exposure time and exposure temperature.

F.2 Microbial destruction by heat

Microbial resistance to thermal death depends on the state of the microorganism; vegetative bacteria are much easier to kill by heat than spores. The inherent resistance of different species of microorganisms also varies; for example, certain species have a waxy coating that provides brief protection against heat. In general, bacterial spores and certain viruses are the most resistant to heat, followed by most fungi and some viruses; vegetative bacteria are the least resistant.

F.3 Items suitable for thermal disinfection

Thermal disinfection and disinfection equipment employ hot water temperatures of 60°C to 95°C (140°F to 203°F). (By contrast, sterilizers employing saturated steam typically operate with temperatures of 121°C to 135°C [250°F to 275°F].) Thermal disinfection equipment generally operates at somewhat lower temperatures or for shorter exposure times than disinfection equipment, but there is no agreement on precisely when disinfection stops and disinfection begins.

Instruments, devices, and equipment that are heat- and moisture-stable may be decontaminated by thermal disinfection processes. The choice of method depends on factors such as the level of risk to personnel and patients, the ease with which an item can be cleaned and inspected, and the relative cost-effectiveness of using washer-sanitizers or washer-disinfectors vs. steam sterilizers.

F.4 Manufacturers' written IFU

The user should carefully follow the written IFU supplied by the thermal disinfection equipment manufacturer as well as any instructions supplied by the manufacturer of the device to be decontaminated. If the equipment provides a washing or cleaning process, the following factors should also be taken into account: the type of soil, the quality of the water, the force and direction of the water, the choice of cleaning agent, the exposure time, and the water temperature.

F.5 Quality control in thermal disinfection

Time and temperature should be monitored. Some types of equipment provide timers and temperature gauges for this purpose. Temperature-sensitive indicators are also available to monitor the internal temperature achieved during processing.

F.6 Safety considerations in thermal disinfection

Personnel should be careful to avoid burns when removing hot items from thermal disinfection equipment. Wet items can drip, which can lead to slippery floors or work surfaces.

Annex G (informative)

Devices returned to the manufacturer

G.1 Introduction

A medical device that has been used in patient care is contaminated with potentially infectious microorganisms and, therefore, could pose hazards to health care and other personnel if the device is not handled and decontaminated properly. The main text of this recommended practice addresses the decontamination of devices intended for reuse in patient care within a health care facility. However, additional guidance is needed on the safe handling and decontamination of devices that are returned to the manufacturer for servicing or for evaluation of suspected malfunctions. Such devices can pose health hazards to postal and shipping personnel and to the manufacturer's employees. Special considerations also apply to devices returned to third parties (e.g., test laboratories) and to samples, loaners, and investigational devices that could be returned to the manufacturer or transferred from hospital to hospital. This Annex is intended to provide assistance to device manufacturers, health care personnel, and third parties in the development of appropriate handling and decontamination procedures.

G.2 Overview

After use in patient care, a medical device might be returned to the manufacturer for servicing or for the evaluation of a suspected malfunction or failure. Ideally, such devices should be decontaminated by the user before they are shipped. In some instances, however, a decontamination procedure could obscure the cause of the malfunction or failure and inhibit the manufacturer's follow-up evaluation. In other instances, the device might not be capable of being appropriately decontaminated at the user facility, or health care personnel could simply neglect to decontaminate the device properly. Manufacturers should establish procedures for the protection of their personnel and should provide appropriate written IFU to users for the handling, decontamination, and shipment of devices that require servicing or failure investigation. For their part, health care personnel should develop their own procedures for the handling and decontamination of such devices in accordance with the manufacturer's written IFU. Both manufacturers and health care facilities must comply with OSHA regulations limiting occupational exposure of employees to blood-borne pathogens (29 CFR 1910.1030).

NOTE—The guidelines provided here are written in the context of devices returned to manufacturers for servicing, repair, or failure investigation. However, the same considerations apply to devices sent to testing laboratories or other third-party organizations.

G.3 Manufacturer's instructions to the user

Manufacturers that require their devices to be returned from the field to facilitate servicing or to investigate a device failure are obliged to provide the user with specific, written IFU for the safe handling and return shipment of each device. These written IFU should include at least the following information (additional guidelines on these topics are provided in subsequent sections of this Annex):

- a) Who to contact at the company for assistance
- b) The recommended method of decontamination, with disassembly instructions if required, and any limitations associated with it
- c) Any actions that could result in the inadvertent destruction of evidence pertaining to the cause of the suspected failure or malfunction
- d) Directions for the documentation that should accompany the device
- e) Instructions for packaging, labeling, and shipping, including instructions to verify compliance with local regulations.

The manufacturer should ensure that adequate resources are in place to assist users in complying with the manufacturer's requirements. That is, the manufacturer should have adequate personnel, with identified responsibilities, to handle inquiries about devices to be returned and to supply information. The manufacturer can choose to provide return product kits, which include written IFU approved by the manufacturer, data forms containing all information necessary for processing the returned device, appropriate shipping containers to protect the device during transport, and all hazard labels. The manufacturer is responsible for verifying that the recommended decontamination procedures are effective for the device.

G.4 User responsibilities

G.4.1 General

Users are responsible for verifying that appropriate written IFU are supplied with the device; if no written IFU or incomplete written IFU are provided, the user should attempt to contact the manufacturer for return authorization and further instructions. The user is also responsible for processing the device according to the manufacturer's recommendations. All documentation requested by the manufacturer should be accurately completed. In addition, the user should identify for the manufacturer the nature of the device malfunction or failure and should provide information on whom to contact at the user facility. If the user is aware of additional information that could assist the manufacturer in servicing or evaluating the returned device or that could suggest the need for special handling of the device at the manufacturer's facility, this information should be provided; for example, the user should notify the manufacturer if the device has been exposed to a known infectious agent. All documentation pertaining to the returned device should be packaged separately from the device but provided in or on the same shipping container.

G.4.2 Decontamination at the health care facility

Appropriate handling and decontamination of a medical device will depend on whether the device is being returned to the manufacturer for repair, service, or failure investigation.

The user should contact the device manufacturer for handling and decontamination methods appropriate for the device in question.

The user should document how the device was used in patient care, how it was decontaminated, the date of processing, and a means of identifying the person who decontaminated the device. (If the device is being returned to the manufacturer for failure investigation, it could be appropriate to photograph or draw the device before decontaminating it.) This information, along with an explanation of the reason for returning the device to the manufacturer and an accurate description of any defects, should accompany the device when it is shipped. This documentation should be positioned to protect it from contamination and to allow easy retrieval by the manufacturer.

G.4.3 Packaging, labeling, and shipment to the manufacturer's facility

G.4.3.1 General considerations

Whether or not it has been subjected to a decontamination process, a contaminated device to be returned to the manufacturer should be placed in a securely sealed and leak-proof primary container or as specified by the device manufacturer. The package must be clearly identified as contaminated material and must be packaged, labeled, and shipped in accordance with the manufacturer's written IFU, with the requirements of the carrier (U.S. Postal Service or private carrier), and with the applicable U.S. Department of Transportation (DOT) regulations (49 CFR 170–178). In most cases, it is advisable to pack the medical device while it is dry. However, there could be special circumstances in which the device might need to be kept moist; if so, the user should request information from the manufacturer on how to ship the device in the moist state.

G.4.3.2 Postal regulations

Postal regulations require that sharps and other medical devices be sent using First Class or Priority mail in packaging that meets the specifications described later in this section; that all packaging used for the mailing of sharps be "type-tested" and certified by an independent organization; and that the package bear a U.S. Postal Service authorization number on a label that cannot be removed intact. Appropriate documentation should be affixed to the outer shipping container; this documentation should include (in case of package damage or leakage), a 24-hour telephone number at the destination facility. Packages also should be labeled with a complete return address and the proper shipping name of the contents. Section 124.38 of the *Domestic Mail Manual* contains the complete requirements for the shipping of sharps and other medical devices.

If the device to be returned is a sharp, then the primary container should be puncture-resistant and placed into a watertight secondary containment system. This secondary containment system may consist of more than one component; however, if one of the components is a plastic bag, the bag should be at least 3 mils thick and reinforced with a fiberboard sleeve. The primary container and/or secondary containment system should be packed in an outer shipping container designed to prevent breakage during ordinary processing and comprised of at least 200 pound-grade corrugated material or a material of equivalent strength. More than one primary container may be sent in a parcel; however, the net contents of liquid in each primary container should not exceed 50 milliliters, and enough absorbent material should be present to absorb three times the total volume of liquid in the secondary containment system or outer shipping container.

Coolant material, if used, should be packaged in such a way that if it melts or condenses, the liquid produced will not escape from the outer shipping container. If ice or dry ice is used, shock-absorbent material should be placed so as to immobilize the inner container as the ice or dry ice melts or sublimates. Packages containing dry ice should be

packed in containers that permit the venting of carbon dioxide gas and should be marked DRY ICE and labeled with the net weight of the dry ice.

G.4.3.3 DOT regulations

The pertinent DOT regulations are Hazardous Materials Regulation 126 (HM126) and Hazardous Materials Regulation 181 (HM181). These regulations are codified in Title 49, Parts 170 through 178, of the *Code of Federal Regulations*. Among other things, the DOT requires formal training of all persons who are in any way involved in the shipping process, including anyone who prepares hazardous items for shipment or prepares shipping documents. Several levels of training are specified in the law, ranging from "general awareness" to "function-specific." The required training must include safety issues and must be documented. If training records are not complete, the shipper is subject to significant penalties.

The shipper is responsible for the correct packaging and labeling of items entering interstate commerce. If the manufacturer provides inadequate or incorrect shipping instructions, the law still holds the shipper responsible. Thus, the shipper must take responsibility for making certain that the documents and packaging are correct. The shipper may rely on the manufacturer's information as a starting point, but should take some documented action to verify that the information is correct. The law places personal responsibility and liability on persons who improperly ship hazardous materials and/or on the individuals responsible for supervising these persons. Depending on the severity of the violation and the pattern of violations, personal fines and/or imprisonment can be assigned to anyone from the shipping clerk to the chief executive officer.

G.5 Receiving at the manufacturer's facility

When a problem occurs in the clinical use of a device, the manufacturer could request that it be returned for investigation and resolution of the problem. Decontamination processes used in the health care facility might not be compatible with the device; for example, the decontamination process could melt the device, the chemical agents could react with materials used to construct the device, or the decontamination process might not be capable of rendering the device safe. For this and other reasons, a device being returned to the manufacturer from the clinical end user could be contaminated with disease-producing microorganisms. The OSHA regulations limiting occupational exposure to blood-borne pathogens (29 CFR 1910.1030) require that all employees who could come in contact with the contaminated device must apply standard and transmission-based precautions, including the wearing of PPE. In addition, the manufacturer is responsible for ensuring that all employees who will be handling the contaminated device (e.g., receivers, unpackers, laboratory personnel performing testing) receive the required educational preparation as prescribed by OSHA; this training must be documented. (It should be noted that not all disease-producing microorganisms are transmitted by blood, and varying levels of precautions could be needed, depending on the intended use of the device.)

Policies and procedures for the care and handling of contaminated devices should be specific (i.e., compliance must be observable or measurable), incorporate the requirements established by OSHA, and address at least the following functions:

- a) Control of the receiving/unpacking area
- b) Receipt of the contaminated device
- c) Disposition upon receipt
- d) Examination of accompanying paperwork
- e) PPE
- f) Disposal of all contaminated materials, including the primary packaging, the secondary packaging, and, after it has been examined, the device
- g) Environmental controls (barrier walls, room with negative air flow, environmental chamber)
- h) Containment of the device after it is unpacked
- i) Method of transport through the process
- j) Area decontamination procedures
- k) Exposure response
- l) Record-keeping

G.6 Cleaning, decontamination, and sterilization methods at the manufacturer's facility

If possible, the device should be decontaminated according to the manufacturer's established policies and procedures. If decontaminated, the device should then be placed in a clean container that is labeled to indicate that the device has been decontaminated.

The method of decontamination should render the device safe to handle regardless of the type of biological tissue that has come in contact with the device.

NOTE—In some cases, decontamination can interfere with failure investigation of a device. If so, the device must remain in a biohazard bag and personnel handling the device must be safeguarded by appropriate PPE and engineering controls.

Other factors to take into account, some of which should be considered during product design, are as follows:

- a) The configuration of the device (the preferred disinfectant might not be able to penetrate all areas of the device that require decontamination)
- b) The materials from which the device is fabricated (the materials in the device could be heat-labile or susceptible to damage by particular chemical disinfectants)
- c) The cleanliness of the device (disinfectants and sterilants are only effective if the surfaces to be decontaminated are clean)
- d) The biocompatibility or safety of the disinfectant or sterilant and whether it can be completely removed before the next use (if applicable); whether the disinfectant or sterilant is toxic is also important from the standpoint of health risks to employees who have to inspect or test the returned device.

By considering these factors in the design phase, the manufacturer can address and pre-establish handling and decontamination instructions and verify them before production and release. Such care will protect both the user and the manufacturer's employees.

Additional information on decontamination is provided in the main text of the recommended practice. The properties of chemical disinfectants and sterilants are discussed in some detail in Annex E and in ANSI/AAMI ST58.

G.7 Personal protective equipment at the manufacturer's facility

Personnel should wear appropriate PPE, commensurate with the degree of risk, when handling contaminated devices. Such attire could include gloves, gowns, laboratory coats, head and foot coverings, face shields or surgical face masks, eye protection, and respiratory protection. All reusable attire should be cleaned or sanitized regularly.

Gloves should be worn when there is a potential for direct skin contact with a medical device. Disposable decontamination gloves should be replaced as soon as their ability to function as a barrier is compromised; they should not be washed or disinfected for reuse. Heavy-duty, reusable decontamination gloves may be disinfected for reuse if the integrity of the gloves is not compromised; however, they should be discarded if they are cracked, peeling, discolored, torn, punctured, or exhibit other signs of deterioration.

Gowns, lab coats, aprons, or similar clothing should be changed whenever soiled and in accordance with the manufacturer's established procedures. Such clothing should not be worn outside the immediate work area. Liquid-resistant clothing should be worn if there is potential for splashing or splattering of blood or other potentially infectious materials. Protective clothing should be liquid-proof if there is a possibility that attire could become soaked with blood or other potentially infectious material. Liquid-proof shoe covers should be worn if there is potential for shoes becoming contaminated and/or soaked with blood or other body fluids.

G.8 Work practices for infection prevention and control at the manufacturer's facility

Handwashing stations should be readily accessible to employees so that when their hands have been in contact with potentially infectious medical material, they can wash their hands as soon as possible after they remove gloves or other PPE. Antiseptic towels or alcohol-based, waterless, hand-hygiene agents can be used as an interim precaution until the employee can reach a handwashing station.

Once removed, contaminated protective attire and equipment should be placed in a clearly marked container or designated area for storage, washing, decontamination, or disposal. To determine when PPE should be used, the employer should evaluate the circumstances of potential exposure and significant employee risk.

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses should be prohibited in work areas where there is a risk of occupational exposure to chemical or biological materials. Food and drink should not be stored in places where infectious materials are located. Employees wearing PPE should not enter designated lunchrooms or break areas.

All procedures involving the handling of contaminated devices should be performed so as to minimize splashing, spraying, or aerosolization of infectious materials.

Work areas should be posted as restricted-access (including, but not limited to, access only to authorized personnel) because of the presence of infectious materials. If a work area is enclosed, the doors should be kept closed when personnel are working with potentially contaminated medical devices. Personnel working in these restricted occupational exposure areas must have received formal training, as specified by OSHA (29 CFR 1910.1030), and documentation of this training must be kept on file.

Whenever there is a potential for contamination from a medical device, a warning sign incorporating the universal biohazard symbol should be posted on all access doors.

All activities involving potentially infectious aerosols (e.g., packaging, unpacking, and examination of contaminated devices) should be conducted in biological safety cabinets or physical containment devices. Such work should not be conducted on an open bench. Devices should be transferred to containment areas in leak-proof, sealed containers.

All materials to be removed from a biological safety cabinet or other containment area should be surface sprayed or wiped with an appropriate disinfectant before removal.

A clearly written company policy should be established to specify the procedures to be followed for spills, accidents, and immediate cleanup of potentially infectious materials.

G.9 Housekeeping and waste disposal

During housekeeping and waste disposal procedures, personnel should wear appropriate PPE such as gloves, aprons, laboratory coats, and head and foot coverings. Face shields or surgical face masks, eye protection, and/or respiratory protection should be worn if there is potential for aerosol generation or splashing during cleanup (e.g., scraping).

All work sites should be maintained in a clean and sanitary condition. All equipment and work surfaces associated with the handling of contaminated devices should be decontaminated by cleaning and the application of an appropriate disinfectant after completion of procedures or as soon as feasible. Immediate cleaning is essential, especially when surfaces are visibly soiled, after any spill of blood or other potentially infectious material, and at the end of the work shift.

Disinfecting solutions should be used in accordance with the solution manufacturer's written IFU for preparation, contact time, length of effectiveness, expiration time, and disposal. If toxic vapors could be present, containers (e.g., pans) used for soaking equipment in disinfecting solutions should be placed in a system that will remove vapors, such as a ventilated fume hood. Solutions of ethanol, isopropanol, sodium hypochlorite, or hydrogen peroxide can be poured down the sanitary sewer. Solutions of glutaraldehyde, formaldehyde, or iodophors should be properly discarded in accordance with the manufacturer's written IFU and local regulations. Care should be taken to prevent fires when flammable disinfecting solutions are used (e.g., ethanol, isopropanol, 8% formaldehyde/70% ethanol or isopropanol).

Equipment and tools that can become contaminated from use during examination or repair of returned medical devices should be routinely cleaned and decontaminated after use and before servicing other medical devices. Small hand tools, such as forceps, hemostats, brushes, dustpans, and shears, should be immersed in a disinfecting solution, or they should be cleaned, wrapped, and sterilized. Appropriate disinfecting solutions include, but are not limited to: 2% glutaraldehyde, 8% formaldehyde plus 70% ethanol or isopropanol, 6% hydrogen peroxide, 70% to 80% ethanol or isopropanol, and iodophor disinfectants. (Iodophor formulations that are EPA-registered as disinfectants should be used, not iodophors formulated as skin antiseptics; the manufacturer's written IFU should be followed.) Household bleach containing sodium hypochlorite may also be used. Bleach will not have label directions for this application. However, it can be effective, it is readily available, and it is inexpensive. Commercially available solutions are generally formulated at a concentration of 5.25% v/v. A 1:10 dilution of the commercial product, freshly prepared with tap water for each application, should be used. The undiluted bleach should be stored in an opaque container because light degrades its potency.

Large equipment that cannot be sterilized or soaked in disinfectant should be sprayed or wiped down on all exposed, potentially exposed, and/or contaminated surfaces with an appropriate disinfectant solution.

Bins, pails, cans, and other receptacles intended for reuse should be inspected, cleaned, and decontaminated on a regularly scheduled basis (at least daily); and they should be cleaned and decontaminated immediately or as soon as possible upon visible contamination.

Any materials to be decontaminated at a site away from the work area should be placed in durable, leak-proof containers, and the containers should be closed before they are removed from the work area. Reusable sharps that

are contaminated with blood or other potentially infectious materials should not be stored or processed in a manner that requires employees to reach into the container by hand to retrieve the sharp.

Immediately after use, sharps should be placed in closable, puncture-resistant containers that are leak-proof on the sides and bottom and that are labeled with an appropriate hazard warning. These containers should be located in the immediate area of use so that they are easily accessible. The containers should be replaced routinely and not allowed to overfill.

Broken, contaminated glassware should not be picked up directly with bare hands. The glassware should be cleaned up by mechanical means using at least a dust pan and brush, tongs, toweling, or forceps. Glass should be disposed of in a container the same as or similar to that used to confine other sharps.

All infectious waste should be disposed of in accordance with OSHA regulations (29 CFR 1910.1030) and other applicable federal, state, and local regulations.

Contaminated laundry should be handled as little as possible, with a minimum of agitation, bagged or contained at the point of use, and labeled as biohazardous or otherwise identified as requiring standard precautions. It should not be sorted or rinsed at the location of use but placed and transported in bags or containers that prevent soak-through or leakage of fluids to the exterior. Personnel who have contact with contaminated laundry should wear appropriate protective attire.

G.10 Device failure investigation

Observations and findings should be recorded orally for later transcription so that documents that could be subsequently handled by other departments will not be contaminated.

The documentation should include at least the following:

- a) Date received
- b) Condition of shipping container(s)
- c) Shipping label information
- d) Information received from the user
- e) Visual condition of the device
- f) Initial specific, pre-established investigational procedure implemented for the device
- g) Correlation, as appropriate, with medical device reporting (MDR) information required by FDA

The manufacturer should have policies and procedures in place for the retention of all documentation regarding the findings and the device. The policies and procedures should comply with FDA regulations promulgated under the Safe Medical Devices Act of 1990.

G.11 Documentation to the user

If the device is to be returned to the user, it should be accompanied by documentation of any decontamination procedures performed by the manufacturer, of the servicing performed (e.g., any parts replaced), and, if applicable, of the failure investigation (e.g., problems identified, suggested measures for preventing such problems in the future).

If the device is not to be returned to the user, the user should be informed of the results of the investigation.

Annex H (informative)

Development of a prepurchase evaluation protocol for rigid sterilization container systems

H.1 Introduction

H.1.1 A variety of reusable rigid sterilization container systems have become commercially available. They are being implemented into processing systems in health care facilities for a number of reasons:

- a) Reduction of certain types of operating expenses
- b) Environmental issues associated with reusable and disposable packaging materials
- c) Improvement of sterility assurance and better protection of sterile items afforded by the rigid design of container systems
- d) Standardization and organization of surgical instrument sets and equipment
- e) Improvement of storage space utilization
- f) Reduction of space needed to store wrappers
- g) Containment of contaminated instruments

H.1.2 The decision to evaluate the use of reusable rigid sterilization container systems should be followed by the development of a specific protocol or plan by the health care facility. The answers to the following questions will assist in the development of an evaluation protocol:

- a) What are the reasons for considering reusable rigid sterilization container systems? Can these reasons be quantified?
- b) How much time will be necessary to evaluate each container system?
- c) Who will be involved in the evaluation process? Infection prevention and control, operating room, central processing, other user departments, purchasing? (Generally, it will be appropriate to include all departments that would be handling or using the product.)
- d) What are the comparative costs of all the packaging methods under consideration (disposable wrapping material, reusable wrapping material, container systems)? How does the current cost–benefit ratio compare with the projected cost–benefit ratio of a new system?
- e) If one type of container system currently is in use, what will be the impact of a second type of container system (i.e., one of different manufacture)?
- f) What key points will be critical in the evaluation?
- g) How many of each type of container system will be needed for the evaluation?
- h) What information will be needed from whom to prepare the assessment?

The evaluation protocol should include specific questionnaires concerning product needs or problems in each use and handling area. Additionally, a detailed plan regarding the actual evaluation process in each area of use or handling should be included.

The following text presents a number of questions and statements that personnel can use as guidelines when developing a health care facility's prepurchase evaluation protocol for reusable rigid sterilization container systems.

H.2 General considerations

- a) Has the container system been FDA-cleared for use in a sterilization process?
- b) Have the scientific data to support label claims (e.g., specific sterilization methods and cycle parameters) been provided by the container system manufacturer?
- c) Was the testing performed with biological spore strips or inoculated devices?
- d) Does the documentation address sufficiently all performance elements in sterilization (via steam or EO, including aeration), drying, and sterility maintenance?
- e) Was the testing representative of the types of items that will be sterilized routinely?
- f) Is the container system suitable for use in the steam sterilization cycles available in the health care facility (gravity-displacement, prevacuum, steam-flush pressure-pulse)?
- g) Have complete written IFU been provided? Are they illustrated and easy to follow?
- h) Will knowledgeable and qualified assistance (technical support) be readily available during the evaluation process; for employee education; during implementation; and for follow-up, troubleshooting, and problem solving? What is the scope of service after the sale?
- i) Are container systems available in appropriate sizes for the items to be sterilized? Is it important that one container system meet everyone's needs? (Be certain that the container systems are acceptable to all users.)
- j) What is the estimated or expected life of the container system and its parts? What kinds of warranties, preventive maintenance assistance, replacement parts, and refurbishment services are available from the manufacturer?
- k) Is the total system cost-effective for the health care facility?

H.3 Instruments and devices to be containerized

- a) Will all surgical instruments and equipment be containerized or only delicate instruments (e.g., microsurgical or plastic instruments) or certain specialty items (e.g., powered instruments, orthopedic instruments, cardiac instruments, neurosurgical instruments)?
- b) Will holders, clips, or other retaining or protective devices be needed to customize trays for specialty instruments?
- c) Will all the instruments being used in one room be prepared in container systems?
- d) Will emergency room, obstetrical, ambulatory surgery, respiratory therapy, or radiology instrumentation be containerized?
- e) What is the maximum number of instrument sets arriving from the operating room or other user departments within 30 minutes?
- f) Will container systems be used as procedural trays (e.g., for cut-down, lumbar puncture, chest tube insertion, or cardiac catheter procedures)? That is, can the inner container be used as a sterile field?
- g) Will instruments be organized into standard sets that travel through the system as complete units with their assigned containers?

H.4 Cleaning and decontamination considerations

- a) Can the container system be disassembled easily for cleaning? Will any parts interfere with adequate cleaning?
- b) Can the container system, interior baskets, and accessories be processed manually or in a cart washer or washer-decontaminator? Will the design of the container system, baskets, or accessories create a barrier to effective cleaning by any of these methods when the generic recommendations for cycle times are used?
- c) Will it be necessary to change the detergents or disinfectants that are used currently in order to avoid harming the container system? Is special handling necessary?

- d) Is there adequate workspace in decontamination areas to break down and queue container systems for processing?
- e) Will the addition of container systems have an impact on the decontamination workload? Are there sufficient processing equipment, utilization time, and personnel available to accommodate an additional workload using manual or mechanical cleaning or decontamination methods?
- f) Is the processing equipment adequate to handle the container systems? Will special holders for container systems be required? Is there adequate equipment cycle time for processing the container systems?
- g) Can the container system be used to confine and transport contaminated items?

H.5 Preparation and assembly considerations

- a) Is the container system easy to assemble? Are the lid and bottom interchangeable or easily identifiable? Are the top and bottom filter-retaining plates interchangeable or easily identifiable for proper placement? Are parts interchangeable among the various sizes of container systems?
- b) Can damage to parts such as gaskets, sealing edges, filter-retention plates, filter-holding rings, valves, and locking mechanisms be recognized easily?
- c) Are accessories available to organize and secure instruments in the proper position for sterilization and for the protection of the instruments? Has testing been performed to ensure that these accessories will not impede contact with the sterilant?
- d) Is there a maximum weight recommended by the manufacturer, with supporting documentation, for the amount of instrumentation that can be placed into a container system for sterilization and drying or aeration? Does the recommended weight refer only to the instruments or to the combined weight of the instruments and the container system? Does the recommended weight relate to sterilization and drying, personnel safety when lifting, or both?
- e) Are there any special instructions regarding the distribution of dense masses of metal (e.g., orthopedic instruments) when assembling the instrument set in the basket?
- f) Can instrument trays or baskets other than those designed for the container system be used if they fit the container system? What is the impact on sterilization and drying?
- g) Can specialty instrument organizing or protecting trays (e.g., orthopedic implant sets) be used with the container system if they fit? What is the impact on sterilization and drying?
- h) What is the manufacturer's advice concerning the use of absorbent material (e.g., surgical towels) within the set to facilitate drying? If the use of absorbent material is recommended, where should it be placed (e.g., in the basket, in the tray, in the bottom of the container system)?
- i) Are there any special recommendations regarding the placement of internal CIs and BIs?
- j) Can the container system be easily closed, secured, and labeled?
- k) Do the external label and CI meet the requirements established within the health care facility?

H.6 Matching the rigid sterilization container system and sterilization cycle

NOTE—See Section H.2 of this Annex and Section 13.10 of the main text.

- a) What sterilization processes are compatible with the container system? Are there any special considerations for each process?
- b) Has the compatibility of the container system been tested with BIs in each type of sterilizer in the facility and in each appropriate sterilization cycle?

H.7 Loading the sterilizer

- a) Can the container systems be positioned flat on sterilizer loading shelves without touching chamber walls?
- b) Does the size of the container system optimize the available shelf space on the sterilizer loading cart?
- c) Will the placement allow personnel to use good body mechanics when loading and unloading the container systems from the cart?

- d) Are there any special considerations related to dedicated loads, mixed loads, the positioning of container systems on shelves, or other aspects of sterilizer loading? For example, will a mixed load tend to produce wet packs or other drying difficulties?
- e) In general, is there a maximum number of container systems per usable sterilizer volume or load? Is there a maximum weight per load?
- f) Does the manufacturer recommend the use of absorbent sterilizer shelf covers to facilitate drying? Are there shelf liner materials that are contraindicated?
- g) Can the container systems be stacked? If so, in which type of sterilization process (gravity-displacement steam sterilization, dynamic-air-removal steam sterilization)? In what configuration ("one over one" or "offset, straddling two")? How many can be stacked? Can two different types of container systems be stacked?
- h) Has product testing demonstrated effective sterilization and drying or aeration when container systems are stacked? Were the items used in the testing representative of the items that will be processed in the container system?

H.8 Choosing the appropriate exposure and drying times

NOTE—See Section H.2 of this Annex and Section 13.10 of the main text.

- a) Can routine sterilization cycles recommended for wrapped packs by the sterilizer manufacturer be used?
- b) Does the container system manufacturer provide a method of testing the efficacy of the sterilizer in which the container systems will be processed?
- c) According to the container system manufacturer's studies, is it necessary to extend exposure or drying time to accomplish sterilization and drying? Is documentation available of the testing done to determine appropriate parameters? Has the documentation been reviewed?
- d) To produce a dry set at the end of the cycle, is it recommended or necessary that the load be preheated before the cycle is initiated? Is it recommended or necessary that the load be dried by leaving the container systems in the sterilizer chamber for a specified period of time before they are unloaded? Are test data available?
- e) Does the manufacturer provide a method of determining and verifying the effectiveness of the drying process?
- f) Has the compatibility of the container system with the chosen sterilization process and cycle been verified by testing at the health care facility?

H.9 Unloading the sterilizer and cooling the load

- a) Are there any special instructions regarding how soon container systems can be touched once the cycle has been completed or the loading cart has been removed from the sterilizer? How should the container systems be handled?
- b) What are the manufacturer's recommendations for cool-down? Do the recommendations pertain to personnel safety (i.e., the avoidance of thermal burns from touching metal that is too hot), condensation, or both? Are there recommendations regarding the environment in which a container system should be cooled?

H.10 Sterility maintenance

- a) Can the manufacturer produce test data that support the effectiveness of the container system as a microbial barrier? Do the test results demonstrate satisfactorily the container system's ability to prevent contamination during normal handling and storage? Do the test methods used by the manufacturer simulate the environment and activities within the health care facility?
- b) What are the potential causes of barrier failure (e.g., slipped filter, failure of the gasket to seal, failure of the locking mechanism, loosened screws or rivets)? Has the manufacturer provided inspection criteria to ensure that the container system is functioning effectively?
- c) Is moisture within the container system after sterilization considered a potential source of contamination? Or is the set to be considered sterile? Are data and documentation available to support the claim?

H.11 Sterile storage

- a) Are there any special requirements for the storage area?
- b) Are special storage systems necessary? Are special carts or racks available for storage of sterilized container systems? Will they minimize handling?
- c) Will existing storage shelving and space in all areas of use or handling accommodate the container systems?
- d) Will the added weight of the container systems require reinforcement of the existing storage system?
- e) Can personnel easily place the container systems into storage units and remove them using good body mechanics and infection prevention and control practices? Can the container systems be stacked? Are there any limitations?
- f) Will the container systems fit into case carts?

H.12 Transportation

- a) Are there any special recommendations or requirements for handling transportation?
- b) Are special transportation carts or other vehicles necessary for on-site or off-site delivery? Would the vehicles differ from those used for packaged items?

H.13 Aseptic presentation

- a) Is the container system easy for personnel to handle?
- b) Are the container system locks and handles easy to remove or open?
- c) Are the labeling and external indicator located in a place that is convenient for the user to check?
- d) Can the lid be removed easily without contaminating the contents or the scrub person's hands?
- e) Can the instrument baskets be removed easily without contaminating the contents or the scrub person's hands?
- f) Can filters, retaining mechanisms, and valves be easily identified and inspected for security?
- g) If an internal wrap is used, can it be opened easily without contaminating the contents or the scrub person?

H.14 Conclusion

You have a choice. Make one that clearly will satisfy your needs.

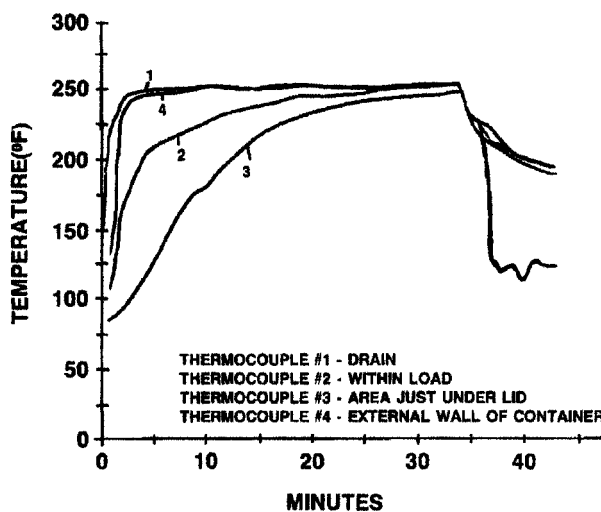
Annex I (informative)

Effect of container systems on load come-up time

Rigid sterilization container systems are commonly used in the United States. For most applications, both the method of use and the mode of sterilization are similar to those used for wrapped instrument sets. However, one significant difference has to be accounted for in gravity-displacement steam sterilization. More air is trapped within a container system than in a conventional wrapped set. In gravity-displacement steam sterilization, it takes longer to remove this air. Consequently, the temperature within the container rises more slowly than that in a wrapped set. This difference holds true for all container systems that use nonwoven filters or do not provide a means of rapid air removal during the air-displacement phase of the steam sterilization process. Figure I.1, Figure I.2, and Figure I.3 illustrate this phenomenon.

Figure I.1 and Figure I.2, respectively, contrast the temperature profiles of containerized vs. wrapped instrument sets in a gravity-displacement cycle at 121°C (250°F). There is a delay in the come-up time for the containerized load. For this reason, the container system manufacturer should be consulted for a documented recommendation as to the time-and-temperature cycle to be used. Although it is preferable to operate at the highest practical temperature available, each cycle should be verified by appropriate tests conducted in each sterilizer in which the use of container systems is anticipated.

A delay in come-up time is not seen in container systems processed in a prevacuum sterilization cycle (Figure I.3). Therefore, it is usually unnecessary to extend the cycle time in dynamic-air-removal sterilizers. Container systems designed with perforations in both the top and bottom, as well as those with perforations only in the top, can be used safely in conventional prevacuum cycles.



**Figure I.1—Typical rigid sterilization container system processed
in a gravity-displacement cycle at 121°C (250°F)**

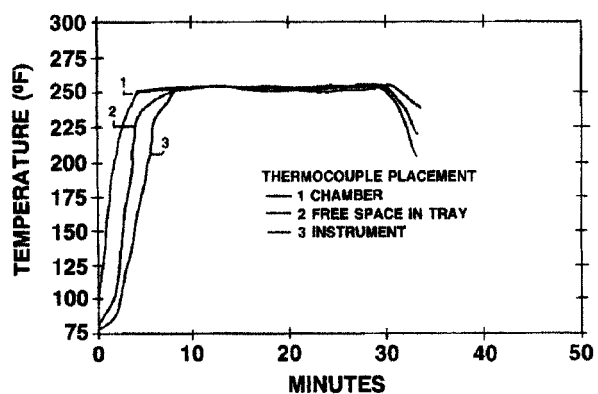


Figure I.2—Muslin-wrapped, 16 pound instrument set processed in a gravity-displacement cycle at 121°C (250°F)

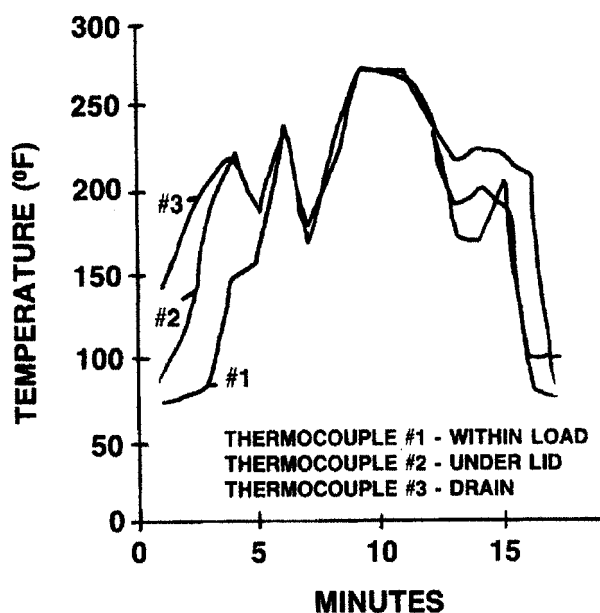


Figure I.3—Typical rigid sterilization container system processed in a prevacuum cycle at 132°C (270°F)

Annex J (informative)

Development and qualification of the 16 towel PCD (biological-indicator challenge test pack)

J.1 Introduction

The first edition of this recommended practice (AAMI ST1:1980) recommended the use of a heterogeneous challenge test pack consisting of 3 muslin surgical gowns, 12 huck or absorbent surgical towels, 30 gauze sponges, 5 lap sponges, and 1 muslin surgical drape, and sequentially wrapped with 2 muslin wrappers. The test pack was recommended to be approximately 12 × 12 × 20 inches in size and to weigh 10 to 12 pounds, for a resulting pack density of 7.2 pounds per cubic foot. The pack specifications were based on Perkin's work to restrict the size and density of processed packs so that standard sterilization cycle parameters would have an adequate margin of safety (Perkins, 1969). This pack was adopted by various other organizations (e.g., AORN, 1982) and by individual health care facilities and became a hospital standard for biological monitoring.

In the years following adoption of the 12 × 12 × 20 inch test pack, numerous comments were raised concerning difficulties in obtaining items to make up the pack, the placement of BIs within the pack, the appropriateness of the muslin wrapper, and the rationale for the pack contents. The Hospital Practices Working Group of the AAMI Steam Sterilization Subcommittee formed a task force to investigate these issues. The results of a survey of hospital personnel revealed the need for a simpler steam BI test pack with more readily available contents. Respondents to the survey recommended that (a) the new pack consist of materials whose properties could be specified so that critical parameters affecting steam penetration and air removal are controlled; (b) rationale and documentation be developed to specify BI placement within the pack; and (c) the pack exhibit performance characteristics essentially equivalent to the current test pack.

Through a cooperative effort among hospital personnel, industrial representatives, and independent consultants, testing was conducted to develop a new BI test pack for evaluation of steam sterilizers within health care facilities. The new pack was to have performance characteristics similar to the old pack and consist of materials readily available to hospital personnel. This Annex summarizes the testing that resulted in the new 16 towel PCD (BI challenge test pack) recommended as an alternative to the original pack in the second edition of the recommended practice (AAMI SSSA:1988) and recommended in subsequent editions as the sole PCD.

J.2 Survey and preliminary testing

Before any laboratory testing was performed, a questionnaire was distributed to health care personnel to solicit their thoughts on the original 12 × 12 × 20 inch pack and their ideas concerning a new test pack. The questionnaire results confirmed that all of the materials needed for the 12 × 12 × 20 inch pack were not available in most hospitals, in part because such items as lap sponges were being purchased as sterile, single-use items. The majority of respondents wanted a test pack that was well defined in terms of content, size, and BI placement. Surgical towels were identified as the material most readily available within health care facilities for making a test pack. Because surgical towels also were used in the Bowie-Dick test pack and recommended for use in EO test packs (AAMI EOTP:1985), the Working Group decided to investigate the use of surgical towels for the BI test pack.

Questions arose about the variability of surgical towels used by health care facilities and how this could affect test pack performance. More than 20 test packs were obtained from health care facilities throughout the country. All towels had been washed and were in routine use at the various institutions. Average surgical towel dimensions were 16.5 by 26.3 inches.

In the 12 × 12 × 20 inch heterogeneous pack, the materials were arranged in two stacks with a space between. The two stacks act as virtually independent challenges to air evacuation and steam penetration, as measured by temperature profiles, even though they are contained in the same wrapper. Preliminary testing was conducted in a 121°C (250°F) gravity-displacement cycle to determine the number of towels and the size of test pack needed to yield performance characteristics similar to those of the 12 × 12 × 20 inch pack.

Figure J.1 shows temperature profiles from 12 × 12 × 20 inch packs prepared and run at two different test laboratories. Significantly different profiles were observed, even though both laboratories prepared their packs in accordance with the 1980 AAMI recommendations. The packs differed in size of wrapper used, method of folding towels, and type of surgical gowns used. None of these parameters were specified in descriptions of the 12 × 12 × 20 inch pack.

It was agreed that the performance of the new towel pack should approximate that of the slower-to-heat 12 × 12 × 20 inch pack illustrated in Figure J.1. The preliminary testing indicated that 16 surgical towels folded to produce a pack with overall pack dimensions of 9 by 9 by 6 inches yielded thermal come-up profiles and BI results comparable to the 12 × 12 × 20 inch pack with the slowest come-up time.

Tests were run to compare horizontal (flat) vs. vertical (on edge) placement of the towel pack. As expected, horizontal placement provided more of a challenge to sterilization in a gravity-displacement cycle, as indicated by a longer come-up time (1 to 2 minutes [min]) and by the BI results. Tests also were run with the towel pack in a fully loaded chamber and with the towel pack in an otherwise empty chamber. The use of a single pack was more of a challenge to the sterilizer, because the chamber reached temperature faster, thereby activating the exposure timer sooner. The center of the pack, on the other hand, took the same time to reach temperature whether the chamber contained one pack or was fully loaded.

Table J.1 summarizes characteristics of the 16 towel packs that were tested. The average pack dimensions were 9.4 by 8.9 by 6.1 inches. The average weight and density of the packs were 3.3 pounds and 11.3 pounds per cubic foot, respectively. Questions arose concerning the differences between huck and absorbent surgical towels used to make up a 16 towel pack. Figure J.2 shows the average temperature profiles in a gravity-displacement cycle for the two types of packs. No significant differences were observed.

Table J.1—16 towel pack survey

Towel size		Average pack size			Average pack weight (lbs)	Average pack density (lbs/ft ³)
Length (inches)	Width (inches)	Length (inches)	Width (inches)	Height (inches)		
26.3 ± 2.1 ¹⁾	16.5 ± 1.3 ¹⁾	9.4	8.9	6.1	3.3 ²⁾	11.3

NOTE 1—Average ± one standard deviation.

NOTE 2—Pack weights ranged from 2.6 to 3.7 lbs.

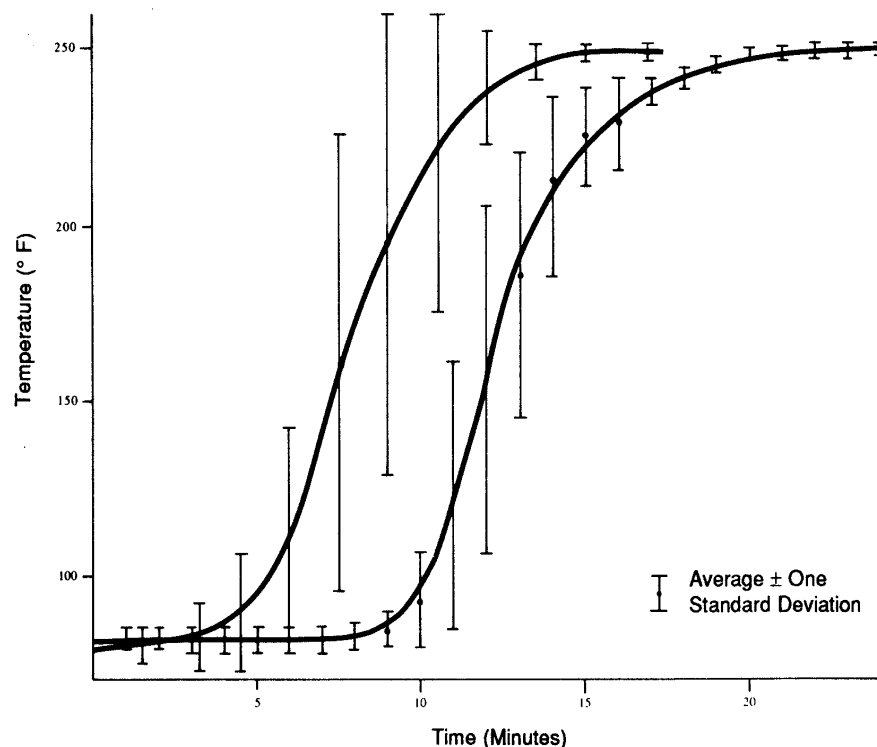


Figure J.1—Temperature profiles for two different configurations of 12 × 12 × 20 inch packs in a 121°C (250°F) gravity-displacement cycle

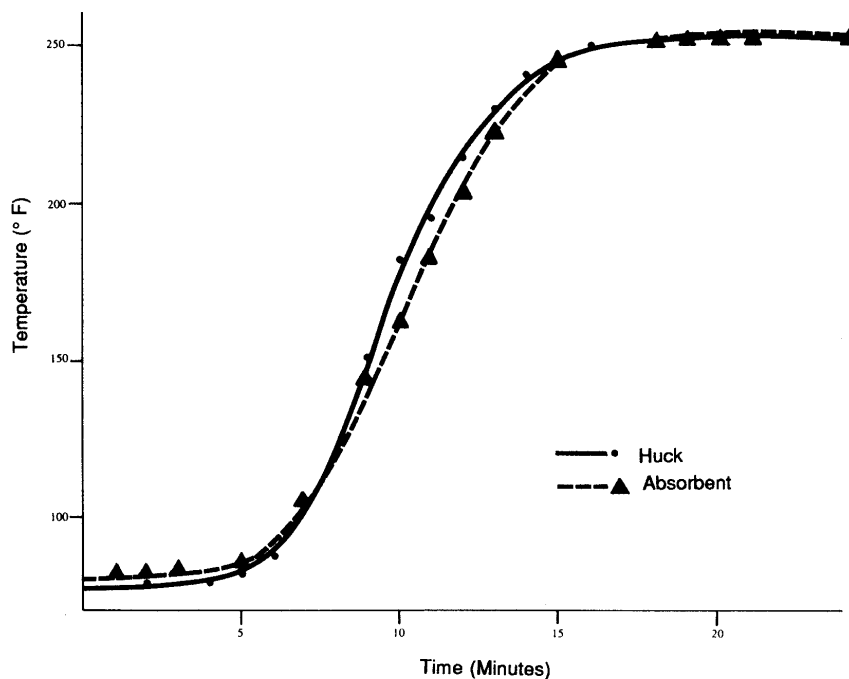


Figure J.2—Temperature profiles for huck and absorbent 16 towel packs in a 121°C (250°F) gravity-displacement cycle

J.3 Validation testing in gravity-displacement cycles

The 16 towel test packs were processed in 121°C (250°F) gravity-displacement cycles. Thermocouples and BIs were placed in the center of each pack. The 12 × 12 × 20 inch packs were similarly instrumented to permit a direct comparison of the two types of packs. The 12 × 12 × 20 inch packs were placed vertically (on edge) in the sterilizer,

and the 16 towel packs were placed horizontally (flat). The packs were evaluated at three different laboratories. Figure J.3 shows the average temperature profile for the 16 towel pack, which is very similar to the profile shown in Figure J.1 for the slowest-to-heat $12 \times 12 \times 20$ inch pack. The pack-to-pack variation for the 16 towel pack was significantly less than for the $12 \times 12 \times 20$ inch pack, as evidenced by the standard deviations. Table J.2 shows the BI results; the 16 towel pack was less resistant than the $12 \times 12 \times 20$ inch pack in a 121°C (250°F) gravity-displacement cycle.

Table J.2—Biological-indicator results from 121°C (250°F) gravity-displacement cycle

Exposure time (minutes)	Biological-indicator response ¹⁾			
	12 × 12 × by 20 inch pack		16 towel pack	
16 18 20 22 25	Spore strips			
	nt ²⁾		4/4	(100%)
	2/2	(100%)	1/4	(25%)
	5/12	(42%)	8/16	(50%)
	3/4	(75%)	nt ²⁾	
	0/12	(0%)	0/10	(0%)
16 18 20 22 25	Self-contained			
	nt ²⁾		5/8	(63%)
	4/4	(100%)	2/8	(25%)
	11/16	(69%)	7/24	(29%)
	4/8	(50%)	nt ²⁾	
	0/16	(0%)	0/12	(0%)

NOTE 1—Number positive per number exposed (% positive).

NOTE 2—Not tested.

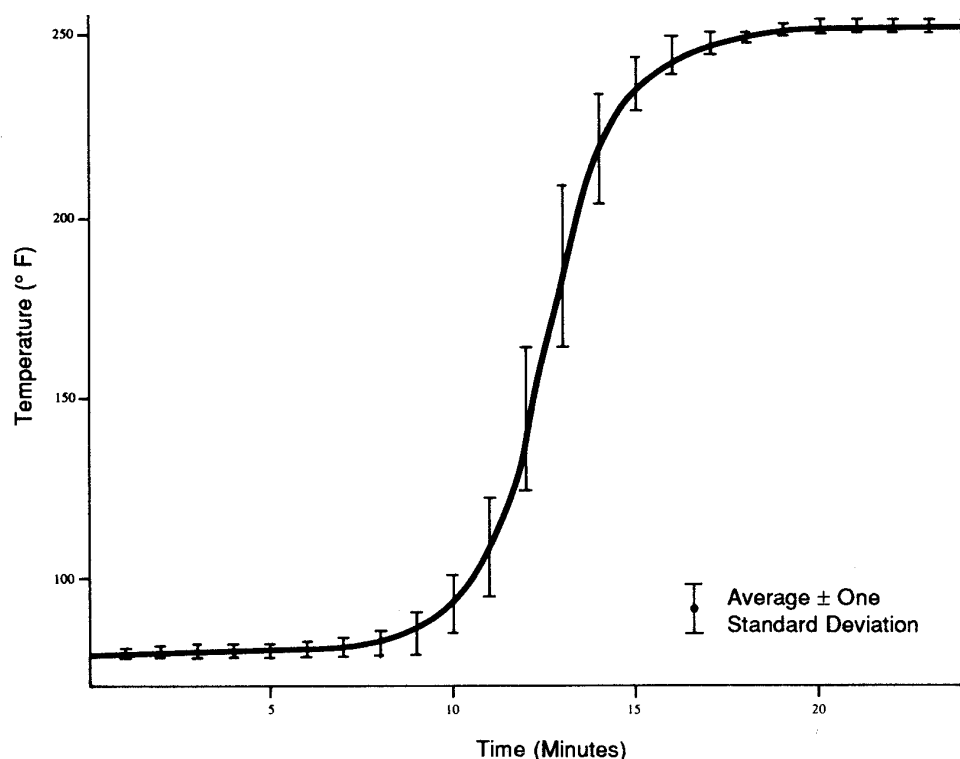


Figure J.3—Average temperature profile for the 16 towel pack in a 121°C (250°F) gravity-displacement cycle

J.4 Validation testing in prevacuum cycles

Both deep-vacuum and pulsing prevacuum sterilizers were used for the evaluations. In general, the center-of-pack temperatures closely followed the sterilizer drain-line temperature. The temperature profiles of the $12 \times 12 \times 20$ inch pack and the 16 towel pack were identical, or the 16 towel pack lagged behind the $12 \times 12 \times 20$ inch pack by a maximum of 30 seconds. Table J.3 summarizes the BI results from a deep-vacuum sterilizer. Spore strips were

sterile with exposure times of 2 min or less, and self-contained indicators were killed with exposure times of 3 to 4 min. Table J.4 summarizes the BI results when test packs were run in a pulsing vacuum cycle at 132°C (270°F).

Table J.3—Biological-indicator results from 132°C (270°F) deep-vacuum cycle

Exposure time (minutes)	Biological-indicator response ¹⁾			
	12 × 12 × 20 inch pack		16 towel pack	
0	Spore strips			
	3/4	(75%)	4/4	(100%)
0.5	5/14	(36%)	4/18	(22%)
2	0/18	(0%)	0/18	(0%)
3	0/16	(0%)	0/16	(0%)
4 ²⁾	0/16	(0%)	0/16	(0%)
0	Self-contained			
	8/8	(100%)	8/8	(100%)
0.5	20/28	(71%)	26/28	(93%)
2	4/28	(14%)	14/28	(50%)
3	5/32	(16%)	11/32	(34%)
4 ²⁾	0/32	(0%)	0/32	(0%)

NOTE 1—Number positive per number exposed (% positive).

NOTE 2—Recommended exposure.

Table J.4—Biological-indicator results from 132°C (270°F) pulsing vacuum cycle

Exposure time (minutes)	Biological-indicator response ¹⁾			
	12 × 12 × 20 inch pack		16 towel pack	
	Spore strips			
1	1/9	(11%)	0/17	(0%)
2	0/3	(0%)	1/16	(6%)
3	0/4	(0%)	0/14	(0%)
	Self-contained			
1	3/17	(18%)	7/28	(25%)
2	0/11	(0%)	5/31	(16%)
3	0/8	(0%)	0/22	(0%)

NOTE 1—Number positive per number exposed (% positive).

J.5 Direct comparison of the 12 × 12 × 20 inch and 16 towel test packs

In noncollaborative testing, the foregoing BI and thermocouple testing was conducted with each test pack placed individually in an otherwise empty chamber. To reduce some of the cycle-to-cycle variation inherent in the testing, a final series of test cycles was run with both a 16 towel pack and a 12 × 12 × 20 inch pack present in the chamber at the same time.

In one test series, five BIs were used per test pack. After exposure to the sterilization cycle, two of the five BIs were cultured for sterility and three were assessed by the Most Probable Number (MPN) technique, as described in United States Pharmacopeia (1984).

In the second test series, all five BIs were cultured for sterility after exposure, and three CIs were scored on a ranking scale. The ranking scale was 0 to 13, with 13 equal to a complete change of the CI. A thermocouple was located approximately 2 inches from the chamber drain, and temperature readings were taken at 1 min intervals to calculate an F_0 value for each cycle.

The results of the first and second series of tests are shown in Table J.5 and Table J.6. The data shown in Table J.6 were evaluated statistically to determine if performance between the two packs differed significantly. An F-test showed homogeneity of variance for both the fraction-value and CI data. A series of paired or unpaired t-tests, using data with F_0 values in the range of 18 to 27 min or 26 ± 1 min, showed no significant differences between the 16 towel pack and the 12 × 12 × 20 inch pack ($t = 0.124$ to 0.402 , $p > 0.05$, 4 or 5 d.f.). The Mann-Whitney U-test also showed no significant differences between the two types of pack ($p > 0.35$, $n_1 = n_2 = 5$, $U = 10$). There was minimal correlation between the independent variables (steam exposure time or F_0 value) and the dependent variables (fraction-value or CI results), with t-values in the range of 0.176 to 0.834 ($p > 0.5$ to 0.1, 3 d.f.).

Overall, these data provide little or no support for a rejection of the null hypothesis of no difference between the 16 towel test pack and the 12 × 12 × 20 inch test pack at the $p = 0.1$ level; that is, no statistically significant differences were found in the performance of the two packs.

Table J.5—Comparison of the 16 towel pack with the 12 × 12 × 20 inch pack by Most Probable Number and sterility assessment of spore strips (121°C [250°F] gravity-displacement cycle)¹⁾

Exposure time at 121°C (250°F)	Most Probable Number assessment			Sterility assessment (survivors per number tested)
	Spore strip	Suspending fluid	MPN value	
14 minutes				
16 towel pack	#1	+	800	3/3
	#2	+	460	
12 × 12 × 20 inch pack ²⁾	#1	+	460	3/3
	#2	+	3,000	
15 minutes				
16 towel pack	#1	+	460	1/3
	#2	+	< 460	
12 × 12 × 20 inch pack ²⁾	#1	+	460	2/3
	#2	+	460	
16 minutes				
16 towel pack	#1	+	460	nt ³⁾
	#2	+	< 460	
12 × 12 × 20 inch pack ²⁾	#1	+	460	nt ³⁾
	#2	+	460	

NOTE 1—Noncollaborative data gathered by Sterilization Technical Services.

NOTE 2—52- by 52-inch wrap.

NOTE 3—Not tested.

Table J.6—Fraction-negative results in a 121°C (250°F) gravity-displacement cycle¹⁾

F ₀ value	Intended exposure time at 250°F (minutes)	16 towel pack				12 × 12 × 20 inch pack ²⁾			
		Spore strip	Chemical indicator ³⁾			Spore strip	Chemical indicator ³⁾		
			1	2	3		1	2	3
18.8	16	4/5	0	0	0	5/5	1	9	2
25.7	15	3/5	4.5	5	4	1/5	11	9.5	8
26.2	18	4/5	12	9	8.5	5/5	7	6	12
26.4	17	5/5	4	4	11	3/5	2	2	3
26.8	19	2/5	13	12	9	2/5	7	4	6
Total		18/25	96.5			16/25	89.5		

NOTE 1—Noncollaborative data gathered by Sterilization Technical Services.

NOTE 2—50- by 64-inch wrap.

NOTE 3—Scale of CI response: 0 = no evidence of sterilization; 13 = complete response, indicating sterilization conditions met.

J.6 Summary of round-robin testing

The results of testing showed significant variation in the performance of the 12 × 12 × 20 inch pack, depending on how the pack was constructed. Overall, the 16 towel pack performed similarly to one of the more difficult configurations of the 12 × 12 × 20 inch pack. Although the two types of packs differed somewhat in specific types of sterilization cycles, the 16 towel pack showed less run-to-run variation. The committee decided to recommend the 16 towel pack for use in biological monitoring, because the 16 towel pack gives more reproducible results and can be more easily constructed than the 12 × 12 × 20 inch pack.

J.7 Supplemental data for steam-flush pressure-pulsing cycles

Subsequent to the round-robin testing to qualify the 16 towel test pack, noncollaborative data were collected to compare the 16 towel test pack and the 12 × 12 × 20 inch test pack in steam-flush pressure-pulse cycles. The two types of test packs were processed in 121°C (250°F) cycles. Biological indicators were placed in the center of each pack. The two packs were placed horizontally (flat) in the sterilizer. There was no discernible difference between the two packs in BI results—all of the BIs were killed in the test exposure times (Table J.7). Similar testing was performed for 132°C (270°F) cycles. Spore strips were found to be sterile after exposure times of 0.5 min or more. Self-contained BIs were killed with exposure times of 2 min or more. There was no discernible difference between the two packs in microbial kill (Table J.8).

Table J.7—Biological-indicator results from 121°C (250°F) steam-flush pressure-pulse cycle¹⁾

Exposure time (minutes)	Biological-indicator response ²⁾			
	12 × 12 × 20 inch pack		16 towel pack	
8	Spore strips			
	17/18	(94.4%)	18/18	(100%)
10	0/18	(0%)	0/18	(0%)
12	0/18	(0%)	0/18	(0%)
14	0/18	(0%)	0/18	(0%)
8	Self-contained			
	18/18	(100%)	18/18	(100%)
10	3/18	(16.6%)	6/18	(33.3%)
12	0/18	(0%)	0/18	(0%)
14	0/18	(0%)	0/18	(0%)

NOTE 1—Noncollaborative data gathered by Joslyn Sterilizer Company.

NOTE 2—Number positive per number exposed (% positive).

Table J.8—Biological-indicator results from 132°C (270°F) steam-flush pressure-pulse cycle¹⁾

Exposure time (minutes)	Biological-indicator response ²⁾			
	12 × 12 × 20 inch pack		16 towel pack	
0.5	Spore strips			
	0/18	(0%)	0/18	(0%)
2	0/18	(0%)	0/18	(0%)
3	0/18	(0%)	0/18	(0%)
4	0/18	(0%)	0/18	(0%)
0.5	Self-contained			
	18/18	(100%)	18/18	(100%)
2	0/18	(0%)	0/18	(0%)
3	0/18	(0%)	0/18	(0%)
4	0/18	(0%)	0/18	(0%)

NOTE 1—Noncollaborative data gathered by Joslyn Sterilizer Company.

NOTE 2—Number positive per number exposed (% positive).

Annex K (informative)

Documentation of emergency release of sterilizer loads

This Annex provides an Exception Form template for emergency release of sterilizer loads, as referenced in 13.6.3. Emergency situations should be defined in written guidance developed in consultation with infection prevention and control, the surgeon, and risk management.

NOTE—In a documented emergency situation, implantable devices may be released from quarantine in sterile processing without the biological monitor result. It is recommended that this form be adapted to support the health care facility's corrective action/risk management process.

Example of an Exception Form for emergency release of sterilizer load

PLEASE COMPLETE ALL INFORMATION:

DATE: _____ **SHIFT:** _____ **TIME:** _____ **AM PM**

STERILIZER #

LOAD #

PERSON COMPLETING THIS REPORT IN STERILE PROCESSING: _____

The following devices were released because of a documented emergency:

INDIVIDUAL REQUESTING EMERGENCY RELEASE OF DEVICES:

OPERATING ROOM REPORT:

PATIENT NAME: _____

SURGEON NAME: _____

TIME OF PROCEDURE: _____ **AM PM** **DATE:** _____

REASON EMERGENCY RELEASE WAS NEEDED: _____

WHAT COULD HAVE PREVENTED EMERGENCY RELEASE OF THIS DEVICE/TRAY? _____

NAME OF INDIVIDUAL COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____ **FORM RETURNED TO STERILE PROCESSING ON:** _____

Figure K.1—Exception form for emergency release of sterilizer load

Annex L (informative)

Steam quality

L.1 Introduction

This Annex provides guidelines on how to achieve and maintain adequate steam quality for steam sterilization processes.

L.2 General considerations

As recommended in 3.3.3 of the main text, steam systems should be designed to ensure that a continuous and adequate supply of saturated steam is available to the sterilizer. The critical variables are the dryness of the steam, expressed as a dryness fraction, and the level of noncondensable gas (such as air), expressed as a fraction by volume. Steam dryness should be at a value between 97% and 100%, and the level of noncondensable gas should be at a level at which it will not impair steam penetration into sterilization loads.

Steam pipework should be insulated, and it should be designed so that any condensate flows by gravity in the same direction as the steam, except for vertical rises between floors. This general principle applies equally to steam mains, branch connections, and pipework on the sterilizer itself, especially in situations where the steam is generated in a location remotely located from the sterilizer. Air vents and steam traps should be fitted at each vertical rise. Care should be taken to trap, drain, and return any condensate that could be collected in pockets in the pipework. Dead legs should be avoided. (A "dead leg" is a section of pipe that leads nowhere and does not form part of a constant circulation system; in a steam line, condensate can form in a dead leg and become stagnant.) Branch steam lines should exist from the top of the main lines to reduce condensate carryover. The accumulation of condensate during the periods when the sterilizer is not in operation should be avoided, particularly in any part of the pipework and fittings between the take-off from the manifold and the sterilizer chamber. This can be achieved by the correct declination of each portion of pipework and by adequate trapping throughout the steam distribution system.

At installation, an assessment of the steam quality should be made and documented. Steam quality should be maintained by monitoring and controlling the process of generating steam; maintaining steam traps, boilers, and generators in good working order; and periodically assessing sterilization loads for wet packs. In some circumstances, a steam separator may be used to remove entrained water and increase the degree of steam saturation. If used, the separator should be placed in the steam supply piping as close as possible to the sterilizer.

L.3 Steam dryness

The dryness of the steam is of vital importance to the performance of any steam sterilizer. Excess moisture can cause damp loads in porous materials and uneven temperature distribution in nonporous materials, particularly those containing a large number of small items. Sterilizing conditions might not be attained if the moisture contained in the steam supply is insufficient to prevent the steam from becoming superheated when it expands into the chamber. Significant deviations in steam dryness are likely to cause the following problems:

- a) Wet loads, resulting from a dryness value that is too low
- b) Superheating, resulting from either a dryness value that is too high before the pressure-reducing system or from excessive pressure reduction through the valve (superheating can be severe if both conditions are present simultaneously)
- c) Difficulties with operation of the pressure-reducing system, resulting from a low pressure-reduction ratio, water hammer, water logging, and/or dirt and other carryover.

If wet steam continues to be a problem, "priming" could be occurring in the boiler, causing water droplets to be delivered in the steam. Modern compact, high-rated boilers and steam generators are particularly sensitive to the quality of feedwater and are much more likely to prime than boilers of traditional design. Priming or foaming (which results in carryover of boiler water) can result from

- d) treating feedwater incorrectly;
- e) setting the boiler water level too high;

- f) forcing a boiler that needs internal cleaning;
- g) violent boiling under fluctuating load conditions; and/or
- h) a high level of total dissolved solids (typically 2,000 ppm).

Superheated steam is an unsuitable medium for steam sterilization and can cause failure to sterilize, scorching of textiles and paper, and rapid deterioration of rubber. Superheat conditions within the load and chamber could result from adiabatic expansion, exothermic reaction, or both. Superheating caused by *adiabatic expansion* (high-pressure steam entering a low-pressure chamber) is usually the result of an excessive reduction in pressure through a throttling device, such as a pressure-reducing system or a partially closed main steam valve. It is unlikely to be of significance in the circumstances normally encountered in hospital steam distribution systems, but superheating can arise if the main steam supply is dry or the pressure is unusually high before the throttling device. Superheating arising from *exothermic reaction* (rise in temperature from absorption of moisture) can occur during sterilization as a result of rehydration of exceptionally dry hygroscopic material.

L.4 Noncondensable gases

Noncondensable gases (NCGs) are defined as gases that cannot be liquefied by compression under the conditions of temperature and pressure used during the sterilization process. They can be simplistically described as air in a steam supply. Low levels of NCGs contained in steam supplied to sterilizers can markedly affect the performance of the sterilizer and the efficacy of the process and lead to inconsistencies in the performance of the sterilizer and in Bowie-Dick test results.

The main source of NCGs in the steam supply is the boiler feedwater, and the level will be greatly influenced by the water treatment used. In some cases, a study by a water-treatment specialist will be necessary. The study should cover analysis of the water, the venting characteristics, and the blow-down regime required to ensure protection of the boiler against corrosion while minimizing the entrainment of NCGs in the steam supply. If anti-foaming agents and oxygen-scavenging agents (such as sodium sulfite) are used, it is essential to ensure that the dosages are accurate.

Water-softening treatment is required to prevent the formation of scale. Except in hard-water areas, a simple base-exchange system, in which bicarbonate ions are effectively converted into sludge-forming carbonates, is usually adequate. This process releases carbon dioxide into the water. A properly managed blow-down regime is essential to remove the accumulated sludge. The most effective way of driving off dissolved air, carbon dioxide, and other NCGs is to degas the boiler feedwater before use by heating it in a vented tank (a hot well). This process will also break down bicarbonate ions, driving off more carbon dioxide. For the degassing to be effective, it is important that the temperature of the feedwater remain high.

Annex M (informative)

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

M.1 Introduction

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

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

Outbreaks of TASS have often been linked to the failure to follow the processing procedures recommended by the instrument manufacturer and by organizations such as AAMI (ANSI/AAMI ST79), the Association of periOperative Registered Nurses (AORN, 2017a), the Centers for Disease Control and Prevention (CDC, 2008), and the International Association of Healthcare Central Service Material Management (IAHCSMM, 2007). Specific instrument cleaning and sterilization recommendations intended to diminish the risk of TASS associated with intraocular surgical instruments have been compiled by a multidisciplinary panel and published by the American Society of Cataract and Refractive Surgery (ASCRS) and the American Society of Ophthalmic Registered Nurses (ASORN). See ASCRS and ASORN (2007) for additional details.

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

M.2 Processing recommendations

M.2.1 General considerations

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

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

M.2.2.1 Instrument inventory

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

M.2.2.2 Designated cleaning area and equipment

A designated cleaning area and equipment dedicated to the cleaning of intraocular surgical instruments should be identified. Intraocular surgical instruments should be processed separately from general surgical instruments and equipment to reduce the potential for cross-contamination by material or residue from general surgical instruments.

The recommendations provided in ANSI/AAMI ST79 for work area design, work flow, physical facilities, housekeeping, and personnel should be followed, because the same considerations apply to the processing of

M.2.2.3 Manufacturer's instructions

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

M.2.2.4 Precleaning

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

M.2.2.5 Transport of instruments to the decontamination area

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

M.2.2.6 Personal protective equipment

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

M.2.2.7 Cleaning agents

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

M.2.2.8 Sterilization

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

M.2.2.9 Maintenance of processing equipment

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

M.3 Resources and training

Facility-specific written policies and procedures that are both general and instrument-specific should clearly outline the important steps in instrument cleaning and sterilization. Processing personnel should not only follow the appropriate processing procedures, but also maintain knowledge of those factors and practices that could have an impact on the efficacy of cleaning and sterilization. At each surgical center or other health care facility, at least one individual should be responsible for remaining current with recommendations for processing intraocular surgical instruments. Responsibility should also be designated for monitoring the continued competency of those who clean and sterilize surgical instruments. Useful sources of information on the processing of surgical instruments and the implementation of training programs include the following:

- a) Recommended practices, guidelines, procedures, and notifications published by government agencies and professional associations, e.g.:
 - American Society for Cataract Refractive Surgery (<http://www.ascrs.org>)
 - American Society of Ophthalmic Registered Nurses (<http://www.ASORN.org>)
 - Association for the Advancement of Medical Instrumentation (<http://www.aami.org>)
 - Association of periOperative Registered Nurses (<http://www.aorn.org>)
 - Centers for Disease Control and Prevention (<http://www.cdc.gov>)
 - Food and Drug Administration (<http://www.fda.gov>)
 - International Association of Healthcare Central Service Materiel Management (<http://iahcsmm.org>)
- b) Scientific publications and trade journals
- c) Manufacturers of surgical instruments and processing equipment
- d) Discussions with professional peers and associates

Training programs should include the means of verifying the efficacy of training and continued competency in instrument processing procedures; written examinations specific to intraocular surgical instrument processing procedures can be useful for documentation purposes. Periodic observation of cleaning and sterilization practices by training personnel and periodic audits of the cleanliness of processed instruments are essential. Section 13 and Annex D include information on quality control and user verification of the cleaning process.

M.4 Summary

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

Annex N (informative)

Comparison of the differences between AAMI and FDA classifications of chemical indicators

N.1 Introduction

The purpose of this Annex is to explain the meaning of the FDA's recognition of a consensus standard and to clarify the similarities and differences between the chemical indicator classifications and requirements defined by ANSI/AAMI/ISO and FDA. The documents that describe the two positions are ANSI/AAMI/ISO 11140-1, *Sterilization of health care products—Chemical indicators—Part 1: General requirements* and FDA's *Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators* (FDA, 2003).

There has been considerable confusion on the part of users of chemical indicators because of the differences between the ANSI/AAMI/ISO standard and the FDA guidance document. Manufacturers of chemical indicators for sale in the United States need to follow FDA recommendations and yet also need to meet the performance requirements provided by the international consensus standard. The two documents have similar classifications and requirements for process indicators and air-removal indicators (e.g., Bowie Dick test indicators), but the differences in terminology and specifications for the other types of indicators have caused confusion.

N.2 History

The first international chemical indicator standard, promulgated by the International Organization for Standardization (ISO), was ISO 11140-1:1995, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*. This standard categorized indicators into six classes. AAMI assessed ISO 11140-1:1995, but adopted ANSI/AAMI ST60:1996, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, which differed from the ISO standard in several ways, including the deletion of Class 6 emulating indicators. ANSI/AAMI ST60 has since been withdrawn.

FDA began clearing chemical indicators as medical devices for use in health care facilities via the 510(k) process in 1976. FDA issued its first guidance document for chemical indicators on December 19, 2003.

Various standards organizations such as AAMI and ISO publish consensus standards that might or might not be recognized by FDA. If FDA recognizes a standard, medical device manufacturers can more easily use conformance to that standard as part of the route to obtaining marketing clearance, via a 510(k) premarket submission, of their products. FDA classifies indicators as either "process indicators," "air removal indicators," or "chemical integrators." FDA's definition of a "chemical integrator" differs from that of the ANSI/AAMI/ISO 11140-1:2014 term "integrating indicator," which is also known as a Type 5 integrating indicator. The AAMI performance requirements and FDA's recommendations were rather similar when ANSI/AAMI ST60 was issued in 1996 and FDA released its guidance document in 2003.

N.3 FDA recognition of a consensus standard

An FDA "recognized consensus standard" is a consensus standard that FDA has evaluated and recognized for use in satisfying a regulatory requirement and for which FDA has published a notice in the *Federal Register*. Conformance to consensus standards can be used as part of the 510(k) submission to FDA, and it might help to reduce the volume of information that must be submitted to FDA. Use of a consensus standard within a product registration process is voluntary. A manufacturer may choose to provide all necessary information to meet the requirements for registration without relying on a consensus standard. Chemical indicators that have not been cleared by FDA are not permitted to be sold in the United States.

NOTE—Detailed information on FDA-recognized consensus standards is provided in FDA's guidance document on this subject, which can be accessed at: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm074973.htm.

The extent of FDA recognition of ANSI/AAMI/ISO 11140-1:2014 is currently limited to the following sections of the standard: Type 1 process indicators, Type 2 indicators for use in specific tests, and Type 6 emulating indicators. FDA's recognition of these three classes from ANSI/AAMI/ISO 11140-1 does not limit a manufacturer from filing for 510(k) clearance of a chemical integrator that also meets the performance requirements of Type 4 or Type 5 indicators. For each of the FDA-recognized categories, in order for manufacturers to obtain 510(k) clearance, FDA recommends additional testing not specified in ANSI/AAMI/ISO 11140-1. For example, to obtain FDA clearance,

manufacturers of chemical indicators should evaluate their products for performance in an ANSI/AAMI/ISO compliant resistometer (see ANSI/AAMI/ISO 18472), test their products in an actual sterilizer used in a health care facility, and submit data showing that the endpoint specifications for their products are appropriate for standard sterilization cycles used in health care facilities. Shelf-life testing and stability testing of endpoint color reaction for all chemical indicators is also recommended by FDA.

N.4 Types of chemical indicators defined in ANSI/AAMI/ISO 11140-1 vs. the FDA guidance document

The six types of chemical indicators described in ANSI/AAMI/ISO 11140-1 are

- a) Type 1 process indicators;
- b) Type 2 indicators for use in specific tests;
- c) Type 3 single critical process variable indicators;
- d) Type 4 multicritical process variable indicators;
- e) Type 5 integrating indicators; and
- f) Type 6 emulating indicators.

FDA does not support the use of numerical type designations. FDA uses text descriptions.

Chemical indicator classes defined in FDA's *Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators* (FDA, 2003) are

- a) process indicators;
- b) chemical integrators; and
- c) air removal indicators.

The relationship between ANSI/AAMI/ISO and FDA categories of chemical indicators is as follows:

Type 1 process indicators: From a technical perspective, ANSI/AAMI/ISO 11140-1 Type 1 process indicators and FDA-defined process indicators may be considered equivalent.

Type 2 indicators for use in specific tests: The most commonly accepted type of Indicator for use in specific tests is known as a Bowie-Dick test indicator. This type of indicator is defined within ANSI/AAMI/ISO 11140-1, but specified in more detail in separate parts of the ANSI/AAMI ISO 11140 series. ANSI/AAMI/ISO 11140-5 is recognized by FDA.

Type 3 single critical process variable indicators: The ANSI/AAMI/ISO 11140-1 defines a single critical process variable indicator as a chemical indicator 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. This section of the consensus standard is not recognized by FDA.

Type 4 multicritical process variable indicators: The ANSI/AAMI/ISO 11140-1 defines a multicritical process variable indicator as a chemical indicator designed to react to two or more of the critical variables of the sterilization process and intended to indicate exposure to a sterilization process at specific stated values of the chosen variables. For the steam sterilization process, there are three critical variables (or parameters), so it is conceivable that the ANSI/AAMI/ISO 11140-1 Type 4 indicator could react to all parameters specified by the FDA requirements for an integrator. This section of the consensus standard is not recognized by FDA.

If a product that is currently marketed outside the United States as an ANSI/AAMI/ISO 11140-1 Type 4 multicritical process variable indicator were to be tested and validated to show that it meets all FDA performance specifications for a chemical integrator, such a product could be considered for clearance by FDA as a chemical integrator.

Type 5 integrating indicators: The ANSI/AAMI/ISO 11140-1 definition of an Integrating indicator is as follows: "An integrating indicator shall be designed to react to all critical variables. The [stated values] are generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for BIs." It was recognized that the manufacturer of an integrating indicator should be required to demonstrate to the user how the product actually integrates time and temperature over the sterilization range of temperatures. A requirement was added that the manufacturer must provide at least three stated values for time at three stated value temperatures (121°C [250°F], 135°C [275°F], and one or more temperatures in between).

The Type 5 section of ANSI/AAMI/ISO 11140-1 is not recognized by FDA. Both FDA and ANSI/AAMI/ISO 11140-1 define an integrating indicator as a chemical indicator designed to react to all critical parameters over a specified range of sterilization cycles. The stated values represent the critical parameters at which the indicator is designed to reach its endpoint, which is a Pass result. For the FDA-defined chemical integrator, a Fail result must be attained with 15% or less than the stated value for time and 1°C below the stated value for temperature. ANSI/AAMI/ISO 11140-1 requires that integrating indicators for steam have SVs at 121°C (250°F) and 135°C (275°F) and at one or more equally spaced temperature points in the range of 121°C to 135°C (250°F to 275°F). The ANSI/AAMI/ISO standard further requires that the SVs for time at 121°C (250°F) and 135°C (275°F) be specified, that those SVs not be less than 16.5 min at 121°C (250°F) and 1.2 min at 135°C (275°F), and that integrating indicators not reach their endpoint at any of the SVs minus 1°C and minus 15% time (Fail condition).

For the manufacturer to obtain FDA clearance for a product as a chemical integrator, a Type 5 integrating indicator should be evaluated for performance in an ANSI/AAMI/ISO compliant resistometer, should be tested side-by-side with appropriate biological indicators, should be characterized for performance by varying only one parameter at a time, and should be tested in an actual sterilizer used in a health care facility. If a product that is currently marketed outside the United States as an ANSI/AAMI/ISO Type 5 integrating indicator were to be tested and validated to show that it meets all FDA performance specification recommendations for a chemical integrator, such a product could still be considered an ANSI/AAMI/ISO Type 5 integrating indicator. The FDA guidance document states that chemical integrators need only be tested for performance at a single time and temperature point. As noted previously, the ANSI/AAMI/ISO 11140-1 Type 5 integrating indicator must be tested at three temperature points over the steam sterilization range to demonstrate that the product actually integrates.

Type 6 emulating indicators: Type 6 emulating indicators are defined in ANSI/AAMI/ISO 11140-1 as “cycle verification indicators” designed to react to all critical variables of specified sterilization processes.

The Type 6 section of ANSI/AAMI/ISO 11140-1 is recognized by FDA. In addition to meeting the performance specifications for Type 6 emulating indicators in ANSI/AAMI/ISO 11140-1 (if the manufacturer claims conformance), manufacturers seeking to obtain FDA clearance of a Type 6 emulating indicator as a chemical integrator should evaluate the performance of the product in an ANSI/AAMI/ISO compliant resistometer (see ANSI/AAMI/ISO 18472), should test the product side-by-side with appropriate biological indicators, should characterize the product's performance by varying only one parameter at a time, and should test the product in an actual sterilizer used in a health care facility. FDA may recognize Type 6 emulating indicators but apply its own chemical integrator performance standards to that class.

Table N.1 summarizes the differences between ANSI/AAMI/ISO 11140-1 types of chemical indicators and the categories of chemical indicators defined in the FDA guidance document (FDA, 2003).

Table N.1—Comparison of terminology and differences between performance requirements of ANSI/AAMI/ISO 11140-1 and FDA (2003) guidance recommendations

ANSI/AAMI/ISO 11140-1	FDA Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators (FDA, 2003)	FDA Consensus Standard Recognition	Comments
Type 1 process indicators	Process indicators	Process indicators	Considered equivalent
Type 2 indicators for use in specific tests	Air removal indicators	Indicators for use in specific tests	No differences
Type 3 single critical process variable indicators	Not included	Type 3 not part of consensus standard recognition by FDA	N/A
Type 4 multicritical process variable indicators	Process indicators or chemical integrators	Type 4 not part of consensus standard recognition by FDA	Some Type 4 devices that can meet the recommended performance standards of FDA for chemical integrators and demonstrate substantial equivalence to a legally marketed chemical indicator might also be able to meet the performance requirements for a Type 4 multicritical process variable indicator as defined in ANSI/AAMI/ISO 11140-1.
Type 5 integrating indicators	Chemical integrators	Type 5 not part of consensus standard recognition by FDA	Some Type 5 devices that can meet the recommended performance standards of FDA for chemical integrators and demonstrate substantial equivalence to a legally marketed chemical indicator might also be able to meet the performance requirements for a Type 5 integrating indicator as defined in ANSI/AAMI/ISO 11140-1.
Type 6 emulating indicators	Chemical integrators	Emulating indicators	Some Type 6 devices that can meet the recommended performance standards of FDA for chemical integrators and demonstrate substantial equivalence to a legally marketed chemical indicator might also be able to meet the performance requirements of a Type 6 emulating indicator as defined in ANSI/AAMI/ISO 11140-1.

Annex O (informative)

Moisture assessment

If visible moisture is left in (interior) or on (exterior) a package after sterilization and the proper cooling period, the package should be considered a wet pack. If moisture is present on or in two or more packages, the load should be considered a wet load. The moisture may be in the form of visible dampness, droplets, or puddles of water on or within a pack. If wet packs are observed in the processing area, they should not be released. If wet packs are observed in the user area (e.g., in the operating room), they should not be used. Any wet packs should be reprocessed after measures are taken to help ensure that excess moisture/condensation does not occur.

Moisture found on the outside of a package can be caused by condensate dripping from the sterilizer cart railings or shelves, the collection of condensation in improperly trapped steam lines, or condensation dripping from metal items on a shelf above other items. Moisture found on the inside of a package can be caused by positioning items in a way that will trap moisture or by other pack preparation errors, including but not limited to

- a) preparing instrument sets that are too heavy or too dense;
- b) failing to use absorbent material to wick moisture between basin sets;
- c) wrapping textile packs too densely; or
- d) wrapping items that are not dry.

In addition, the composition materials (e.g., plastic) of containment devices can cause wet items.

Wet packs are a concern because the moisture on or within a package can create a pathway for microorganisms to migrate from the outside to the inside of a package. Investigation should be conducted to discover and diagnose the problem.

The occurrence of wet packs should be documented. Finding the cause and cure of wet packs and/or wet loads is not always easy. Many factors need to be taken into consideration. A team should be formed to help solve the wetness problems because of the complexity of the issue. This team can be made up of sterile processing technicians and managers, infection preventionists, health care technologists, facilities managers, and equipment repair personnel.

The investigation process is a multiple-step process. It should start with a series of questions related to the occurrence of wetness. Some of the questions that need to be asked are as follows:

- a) Did the wet packs/pouches happen at a certain time of day?
- b) Did they happen on a certain shift?
- c) Are the wet packs/pouches happening at a certain time of the year or with the change of seasons?
- d) Are the wet packs/pouches happening only with certain trays? Orthopedic trays? Basins? Certain containers? Wrapped trays?
- e) Is the wetness concern taking place in a specific sterilizer?
- f) Is the wetness appearing at a certain level or location of the sterilizer cart?
- g) Is the wetness appearing in a certain location of the sterilizer chamber?
- h) If textiles are being used, do the trays appear to be wrapped too tightly?
- i) Are trays produced by a specific employee experiencing a higher incidence of wet packs?
- j) What is the humidity in the area where wrapping and assembly take place?
- k) Is the wetness appearing on the outside of the item? Inside? Or inside and outside at the same time?
- l) Is water draining from lumens?

The next step in the investigation process is to use the moisture assessment check list of Table O.1. This list helps in identifying many of the causes of wet packs in relation to the location of the wetness (interior or exterior). The flow chart of Figure O.1 is another investigational tool that can be used to review various points within the process.

Table O.1—Moisture assessment check list

Processing		
Clinical Practice	Interior	Exterior
Major changes in packaging, wraps, or load configuration	X	
Wrapper too tight or too loose		X
Manufacturer's packaging IFU not followed	X	X
Rigid organizing trays or rigid sterilization container systems not used according to the manufacturer's written IFU	X	
Flat trays not placed on the sterilizer cart at an angle	X	
Solid-bottomed trays placed incorrectly	X	
Absorbent material not used in heavy trays	X	
Multiple-part instruments requiring disassembly not disassembled	X	
Incorrect use or placement of liners and other protective devices	X	
Wrappers not allowed to come to room temperature/humidity levels before use	X	
Sterilizer load not at room temperature	X	
Transportation without protection from moisture or excessive heating and/or cooling		X
Instruments or containment devices not dry before packaging	X	X
Set and Load Content and Configuration	Interior	Exterior
Instrument set too heavy or dense	X	
Instruments not dry before packaging	X	
Inadequate steam contact with all surfaces	X	
Trays or contents not designed to allow proper drainage and drying	X	
Tray too small for amount of instruments	X	
Package too dense	X	X
Use of nonabsorbent tray liners	X	
Items that are not steam permeable placed in loads/packs	X	X
Metal mass not evenly distributed or excessive	X	X
Placement of concave surfaces that does not allow for drainage	X	X
Incorrect packaging or containment device for the cycle parameters	X	X
Incorrect preparation of containment device for use (e.g., incorrect filters, valves, or bottom tray)	X	X
Use of any device not cleared for the sterilization method and parameters used, which could result in inadequate air removal or steam penetration	X	
Inadequate preconditioning of packaging materials (i.e., not holding package materials at 68°F to 73°F [20°C to 23°C] for two hours before use)	X	
Double-pouching when not indicated in manufacturer's written IFU.	X	X
Manufacturer's written IFU not followed when double-pouching.	X	X

Sterilization Process	Interior	Exterior
Inadequate drying time per the medical device manufacturer's written IFU	X	X
Items in the load that have dissimilar sterilization or drying requirements	X	
Sterilizer cart shelf lined with nonabsorbent material	X	X
Sterilizer not loaded according to the manufacturer's written IFU	X	X
Solid-bottomed pans, basins, or trays positioned so that they do not drain adequately	X	
Solid-bottomed pans, basins, or trays not oriented in the same direction	X	
Incorrect placement of textile packs (i.e., not placing them on edge)	X	
Metal items placed above textile items	X	X
Paper-plastic pouches not properly placed on edge	X	X
Rigid containers placed above absorbent items	X	X
Loading that does not allow adequate air elimination and drainage of condensate	X	X
Inappropriate stacking of trays or rigid containers	X	X
Cooling vents located directly over cooling loads	X	X
Temperature of area designated for cooling sterilized loads too cool	X	X
Manufacturer's prescribed cool-down procedure not followed	X	X
Sterilizer or Utility Malfunctions		
Boiler System	Interior	Exterior
Steam dryness not between 97% and 100% (i.e., too much water in the steam)	X	X
Boiler feedwater that contains too many noncondensable gases (such as air)	X	X
Water treatment affecting the level of noncondensable gases	X	X
Changed (e.g., seasonal), unusual, or increased demands placed on the steam system	X	X
Boiler not properly maintained	X	X
Improper insulation of steam lines	X	X
Malfunction of trap in steam line or no trap in steam line	X	X
Malfunction of drain check valve or no drain check valve	X	X
Steam Delivery System (Piping)	Interior	Exterior
Improper or insufficient insulation of steam lines	X	X
Blocked or partially blocked steam lines	X	X
Blocked or partially blocked chamber drain line	X	X
Steam pipework designed so condensate cannot flow properly	X	X
Condensate not appropriately trapped and drained	X	X
Air vents and steam trap not fitted at each vertical rise	X	X
Dead legs in the steam piping	X	X
No steam lines from the top of the main lines, resulting in condensate carryover	X	X
Accumulation of condensate when the sterilizer is not in operation	X	X

Sterilizer Performance	Interior	Exterior
Malfunction of drain check valve or no drain check valve	X	X
Malfunction of trap in steam line or no trap in steam line	X	X
Out-of-calibration pressure gauges and controllers	X	X
Clogged steam supply strainer	X	X
Clogged strainer	X	X
Clogged drain screen	X	X
Malfunction of valves	X	X
Non-intact gasket	X	X
Environmental Issues	Interior	Exterior
High humidity because of geographic area where health care facility is located (actual testing should be performed to determine the potential for absorbent items to become contaminated)	X	
Moving packages from air-conditioned environments within the processing facility to the non-air-conditioned environment of transport vehicles to the air-conditioned storage area of the using facility	X	
Design and materials used in the construction of transport vehicles (motorized or manual) does not allow for appropriate decontamination processes, particularly if vehicles are used alternately for sterile/clean and soiled items.	X	
Humidity too high in sterile storage area	X	X

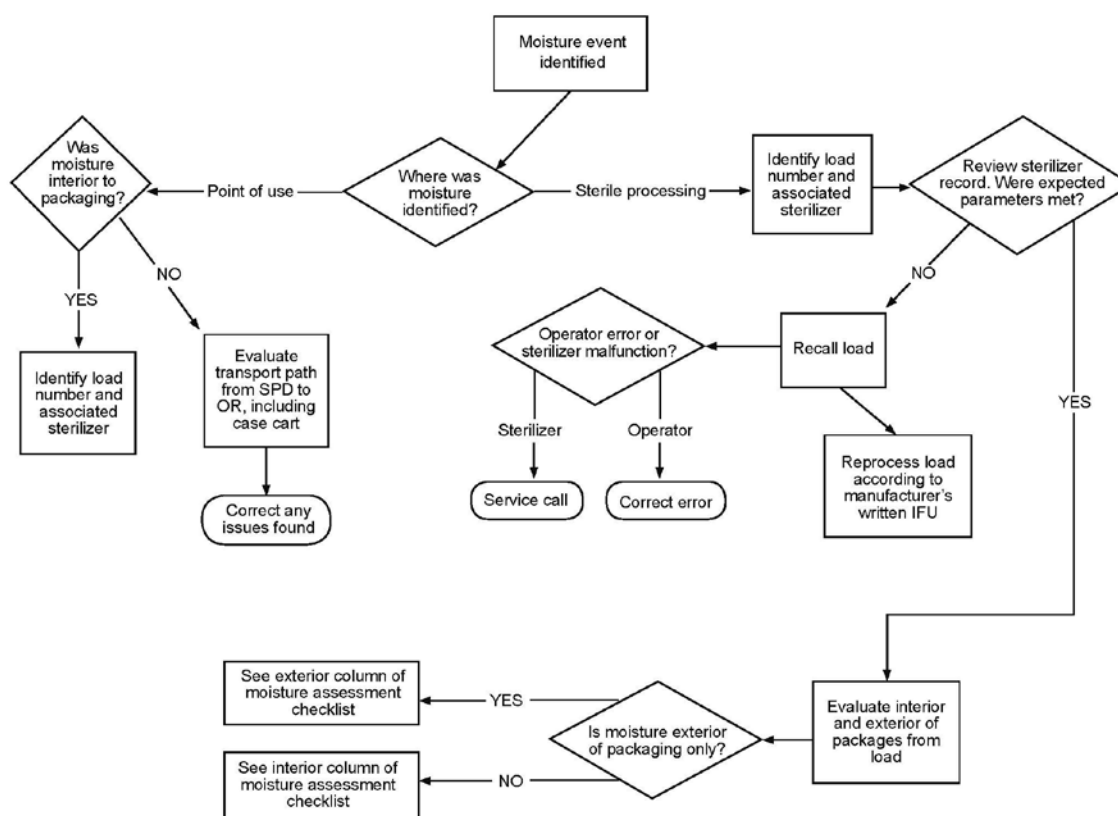


Figure O.1—Moisture assessment flow chart

Combining information from the initial questions, the checklist, and the flow chart will help identify the source of the wetness issue and possible solutions. Some solutions might be equipment- or utility-oriented. Others might relate to clinical practice. Or, a combination of solutions might be needed to resolve wet pack issues.

Annex P (informative)

General considerations for cleaning and disinfection

P.1 Introduction

The FDA defines reprocessing as a “validated process used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection and sterilization.” (FDA, 2015) Reprocessing involves the following sequential steps: 1) point-of-use processing, 2) thorough cleaning, and 3) disinfection and sterilization.

The CDC *Guideline for Disinfection and Sterilization in Healthcare Facilities* describes the proper level of processing between patient uses for critical, semicritical, and noncritical items (CDC, 2008). Thermal disinfection is usually an intermediate step in the processing of medical devices; that is, it is intended to render the items safe to handle by personnel not wearing protective attire, not to process them fully for reuse in patient care. Critical items should be subjected to a sterilization process after decontamination is complete. Semicritical items should be subjected to either sterilization or, at a minimum, high-level disinfection. See CDC (2003) and CDC (2008) for additional information.

Although the characteristics of pasteurization do not support a claim of high-level disinfection, many semicritical items such as respiratory therapy and anesthesia devices are ready for patient use after cleaning and pasteurization. High numbers of bacterial spores are not generally found on these devices after use; cleaning before pasteurization reduces the biobload substantially.

For noncritical items, processing through a washer–disinfector provides more than adequate disinfection of precleaned devices. Performance monitoring each day that a washer–disinfector is used, in accordance with manufacturer-recommended equipment maintenance schedules, helps ensure that the equipment is performing as designed. Verifying that spray arms achieve full rotation and that filters, nozzles and other critical parts of the equipment are clean and well maintained will help ensure an effective cleaning process.

Effective cleaning is a multistep process that relies on several interdependent factors: the quality of the water; the quality, concentration, and type of detergent or enzymatic cleaner; the washing method; rinsing and drying; preparation of items to be processed by cleaning equipment; the time and temperature parameters and load capacity of the equipment; and operator and equipment performance.

Many types of soil could be present on reusable medical devices. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a challenge to cleaning. However, other body fluids, fats, carbohydrates, and, in particular, prion-contaminated tissue might be equally or significantly more challenging. Non-patient-sourced contaminants (e.g., cements, oils) used during a procedure also can be a significant challenge to cleaning.

The amount of residue that remains on an instrument will vary depending on the conditions of use of the cleaning agents, the specific component materials of the reprocessed devices, and the methods used to reduce residuals before reuse. Any organic material or residual cleaning agents remaining on an item can inactivate chemical disinfectants or sterilants as well as protect microorganisms from destruction. In addition, debris could become dislodged and could cause potential health risks, such as a foreign-body reaction or a breeding place for infection.

P.2 Mechanical (automated) cleaning and disinfection

P.2.1 General considerations

Each type or model of mechanical cleaning equipment is designed to significantly reduce the viable number of microorganisms on medical devices through the detergent washing, rinsing, flushing, and draining action of the equipment. Some types of mechanical cleaning equipment are also designed to destroy vegetative or pathogenic microorganisms by means of moist-heat thermal disinfection or chemical disinfection. Such equipment can be labeled as providing low-, intermediate-, or high-level disinfection.

P.2.2 Ultrasonic cleaning equipment

P.2.2.1 Overview

Ultrasonic cleaners typically consist of an electronic ultrasound generator and numerous ultrasound transducers bonded to the sides or the underside of a stainless steel tank filled with a cleaning solution. Five types are available, each with specific features intended for a specific purpose.

Some are intended for very specific types of devices, such as those with lumens or minimally invasive instrumentation. Several include a disinfection process in addition to ultrasonic cleaning. The generator supplies an electrical signal that causes the transducers to oscillate, producing high-frequency sound waves. This ultrasonic energy (at a frequency higher than 20,000 cycles per second, or 20 kHz) is transmitted into the tank, producing sound waves that compress and decompress molecules in the solution to produce alternate zones of high and low pressure. The low pressure creates microscopic bubbles that implode during the high-pressure cycle, causing cavitation. Cavitation creates mechanical scrubbing action everywhere water contacts the surfaces of the object in the tank, dislodging the debris.

Cavitation provides an effective means of mechanically removing bioburden from joints, box locks, crevices, channels, serrated tips, and other areas that are difficult to clean by other methods. A compatible detergent containing enzymes is commonly used for suspending loose bioburden in the tank solution. Basic ultrasonic cleaners are not designed or intended to provide microbial lethality for disinfection or sterilization. However, some newer models provide the option for mechanical detergent washing and rinsing, as well as thermal disinfection.

The ability to clean medical devices mechanically and to fine-clean by the ultrasonic process is of great value, considering the complexity of many devices and the heavy workload of the average sterile processing area. The variety of equipment available and the intricacy of many medical devices make it essential that manufacturers be consulted and their written IFU followed to maximize effectiveness and avoid expensive and unnecessary damage. The device manufacturer's written IFU will indicate whether the device can be safely cleaned using ultrasonic equipment.

Trapped air inside the cleaning solution needs to be released by the running of a degassing cycle. Sources of trapped air includes the water itself, the cleaning agent that is added and the addition of air to the bath during filling. If the ultrasonic cleaner does not have a preprogrammed degas cycle, then an ultrasonic cleaning cycle in an empty bath must be run before the ultrasonic is used for cleaning.

Testing the equipment upon installation, daily during routine use, and after repairs allows the user to verify its continued effectiveness. The tank solution should be changed after every use. The health care facility should define "use" in their policies and procedures. Tanks should be cleaned and disinfected at least daily in order to reduce the possibility of cross-contamination.

P.2.2.2 Basic ultrasonic washers

The basic ultrasonic washer is the simplest configuration: a tank that is surrounded by transducers (below and/or around the external sides of the tank) or that contains a transducing rod inside the bath area. Typically, the frequency used in basic ultrasonic washers for medical device cleaning is 38 kHz or greater. Some models have automated processes consisting of several phases: filling with water, adding a cleaning agent, degassing, rinsing, and draining. Simpler models are completely manual, with the user performing all the functions of filling, rinsing, draining, and so on.

P.2.2.3 Ultrasonic irrigators

Some ultrasonic cleaner models are designed specifically to clean minimally invasive surgical (MIS) devices with lumens, flushing the inside of instruments as well as exterior surfaces. These models feature the same cavitation process with the addition of flushing and irrigation in order to remove the bioburden from lumens, channels, box locks, and other crevices. These types of ultrasonic cleaners contain water ports with hoses and special adapters to connect to various devices such as laparoscopic, robotic, and other instrumentation. Rinsing the exterior and interior of lumened devices following ultrasonic treatment is recommended.

P.2.2.4 Ultrasonic irrigator washers

Ultrasonic irrigator-washers ultrasonically clean external surfaces and interior lumen channels with rapid-flow, high-pressure irrigation. In addition, this equipment provides programmable wash cycles. It contains a tank that fills with solution and replaces the solution several times during the process. Cycles include pre-rinse, enzyme flush, specific sonic, wash, and several rinse cycles, with the final rinse usually consisting of water treated by reverse osmosis or deionization.

P.2.2.5 Ultrasonic irrigator washer–disinfectors

This equipment provides programmable automated ultrasonic cleaning processes. It cleans internal lumens and channels through high-pressure irrigation, detergent solution washing, optional lubrication, and thermal disinfection. Items are safe for staff to handle once this process is complete.

P.2.3 Washer–pasteurizers

Pasteurization is not a sterilization process; its purpose is to destroy all pathogenic microorganisms except bacterial spores. Pasteurization of respiratory therapy and anesthesia equipment is an alternative to chemical disinfection.

P.2.4 Washer–disinfectors

P.2.4.1 Overview

Washer–disinfectors provide automated processes that combine mechanical cleaning technologies, application of cleaning chemistries, treated water in critical phases, a microbicidal process, and drying to produce clean medical devices.

A programmable controller enables users to select standard cycle parameters from a menu or to set up custom validated cycles. The controller automatically runs the machine through the pre-programmed cycle and monitors transition and performance.

Finished loads are clean, disinfected, and safe to handle for further processing. Depending on the intended use and the manufacturer's IFU, some items could be ready for immediate use.

Some washer–disinfectors are designed with doors on the front and rear for pass-through operations between the soiled receiving area and the clean preparation and packaging area. Washer–disinfectors have various chamber sizes and load carriers, depending on the type of washer–disinfector and the design of the devices to be processed.

One example of a validated programmable cleaning process is as follows:

- *Pre-Rinse:* A cold-water rinse to rehydrate bioburden and remove gross soil.
- *Detergent Wash Phase 1:* Washing with a solution of an enzyme detergent or a high-alkaline detergent in heated water to remove bioburden and break down organic soils.
- *Rinse 1:* Flushing of chemical residues and retained bioburden from the chamber and load before a new chemical is introduced.
- *Detergent Wash Phase 2:* In the case of an enzyme detergent in phase 1, a heated detergent wash with chelating agents (the detergent typically has a neutral pH or is mildly alkaline); in the case of a high-alkaline detergent in phase 1, a neutralizing detergent with an acidic pH. The chemical is automatically dispensed and circulated.
- *Wash 2:* an optional second wash with detergent.
- *Rinse 2:* A clean hot-water rinse to flush chemical and bioburden residue from the chamber and load. The rinse temperature is typically 82°C (180°F) or greater for 1 minute or longer for thermal disinfection and microbial reduction, making instrumentation safe to handle. This process is usually performed using critical water (see AAMI TIR 34).
- *Multiple Additional Rinses:* Additional rinses used to continually reduce residual chemical and bioburden levels in the chamber and on medical devices.
- *Lubrication:* Application of lubricant in the final rinse, using high-purity water preferably at disinfecting temperatures.
- *Hot Air Drying:* Circulation of hot air (usually HEPA filtered air pulled into a heating unit) by high pressure within the chamber in order to effectively dry the items being processed. Items should show no signs of moisture at the end of the cycle.

Three main types of washer–disinfectors are commonly used in today's health care settings:

- a) Single-chamber washer–disinfectors
- b) Multi-chamber washer–disinfectors
- c) Cart washer–disinfectors (also validated for Instruments)

P.2.4.2 Single-chamber washer–disinfectors

Single-chamber washer–disinfectors are designed to clean and disinfect small to medium size items such as surgical instruments, MIS devices, utensils such as OR bowls and basins, and disassembled rigid sterilization containers. All single-chamber washer–disinfectors have shelf racks or removable wash carts designed for specific devices such as trays of general instruments, instruments with lumens, orthopedic instruments, MIS instruments, and other surgical items. Chambers are designed with rotating spray arms attached to the chamber or on the carts, multiple feedwater valves, multiple chemical injectors, recirculation tanks with a water heater and pumps, external boilers, high-pressure manifold port connections, ultrasonic systems, air inlets for hot-air drying, and exhaust and filtration systems.

Single-chamber washer–disinfectors are variously designed with powered sliding doors, fold-down doors, or fully automated feeder configurations that load and unload the chamber. Trolleys and wash carts are usually specific to the instrumentation being cleaned.

For manual loading, the trolley is loaded with the wash cart and locked into position on the cart. The cart is then docked to the washer–disinfector on the decontamination side of the department. The door is opened and the wash cart is pushed into the chamber. The door is closed and a cycle is selected. Unloading is done in the reverse order.

P.2.4.3 Multi-chamber washer–disinfectors

Multi-chamber washer–disinfectors are indexing tunnel washers. These machines connect three to five single-chamber washer–disinfectors together in a system that transports wash carts through each chamber of the process. This washer delivers the same critical cleaning, rinsing, washing, sonic, rinse, thermal or chemical disinfection, and drying processes.

P.2.4.4 Cart washers

Cart washers are designed to clean and provide low- to intermediate-level thermal disinfection of such items as stainless steel case carts, wire supply carts, tote bins, basins, and rigid sterilization containers. Some cart washers are validated to wash and disinfect surgical instruments. If the cart washer has an instrument cycle, the washer should be tested at least weekly, preferably daily, on the instrument cycle program. The manufacturer's IFU should be followed for processing the medical devices that can be cleaned with that specific model/type of cart washer.

Annex Q (informative)

Alternatives for keeping cool in the sterile processing environment

Q.1 Introduction

The healthy human body maintains a core temperature of about 98.6°F (37°C). Core body temperature will stay basically the same no matter what the temperature of the surrounding area might be or what the activity level of the person might be. A healthy safe core temperature is between 98°F and 100°F for most people. Some individuals might naturally have a core temperature that is slightly lower or higher than 98.6°F. If a person is exposed to an environment that is very warm or very cool the body will take steps to bring the core temperature back to the healthy range. The process of regulating core temperature is called thermoregulation.

The hypothalamus controls thermoregulation. When core temperature becomes too high or too low, the hypothalamus issues instructions to muscles, organs, glands, and the nervous system. If the body needs to cool down, the instructions will cause sweating and vasodilation to occur. As sweat evaporates, it will cool the skin, which will help lower core temperature. The central nervous system can cause the capillaries under the skin to open or dilate, which increases blood flow to the skin surface and allows the body to release heat.

There are steps that can be taken to heat or cool the body as needed. In winter, people wear additional layers of clothing, and in summer people wear lighter-weight clothing. In addition, eating cool foods like ice cream or iced drinks and cooling the pulse points of the body can help to cool the body. The opposite is also true. Eating warm foods and warming the body's pulse points will help to warm the body.

The American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) has a standard on thermal comfort, ANSI/ASHRAE 55-2013, *Thermal environmental conditions for human occupancy*. This standard provides information on working in various environmental conditions and what most people would consider to be comfortable. The University of California Berkeley Center for the Built Environment has developed a tool to assist companies in determining whether the environment in a particular room meets this standard. This tool can be found at no cost on the Internet at <http://cbe.berkeley.edu/comforttool/>.¹ The tool measures thermal comfort based on sustained activity for one hour. Functionality to evaluate comparisons of different variables is available. Several variables can be addressed in the tool. Detailed help information on how to use the thermal comfort tool is available through a help link, which will take one to: <http://comfort.cbe.berkeley.edu/static/html/help.html>. Information on determining the metabolic rate to be used can be found in ISO 8996, *Ergonomics of the thermal environment—Determination of metabolic rate*. Information regarding the impact of clothing can be found at ISO 9920, *Ergonomics of the thermal environment—Estimation of thermal insulation and water vapour resistance of a clothing ensemble*.

It is possible that the protective attire worn in the decontamination area could cause workers to feel overheated and to perspire. Lowering the ambient temperature might not be an efficient mechanism for reducing body temperature. This Annex discusses alternatives for how personnel can keep cool in the sterile processing environment.

Q.2 Decontamination environment

The temperature and relative humidity of the decontamination area/room of the sterile processing department is controlled to minimize potential growth of bacteria, fungi, and molds and to provide a comfortable working environment. The personal protective equipment (PPE) required to be worn when working in the decontamination area/room can be uncomfortable even when the temperature of the decontamination area is within the recommended range. Some individuals might feel overheated when working in this area and wearing PPE. Lowering the room temperature is not effective in lowering the body temperature of individuals wearing PPE because not enough skin is exposed to the air for perspiration to evaporate and cool the body. More effective alternative measures can be taken to make workers comfortable.

Q.3 Protective attire

Protective attire worn in the decontamination area might be uncomfortable because it doesn't allow the body to disperse heat that is generated while working. Many of the protective gowns and aprons used in the decontamination area are made of plastic or other fluid-resistant materials. The plastic or other fluid-resistant material provides an

¹ Hoyt Tyler, Schiavon Stefano, Piccioli Alberto, Moon Dustin, and Steinfeld Kyle, 2013, CBE Thermal Comfort Tool. Center for the Built Environment, University of California Berkeley, <http://cbe.berkeley.edu/comforttool/>

excellent barrier to blood-borne pathogens, but it does not allow for the body to disperse any excess heat that might build up. This heat can cause employees to sweat, which can be uncomfortable.

Q.4 Alternative cooling methods for personnel working in the decontamination area/room

Rather than being exposed to heat for extended periods of time during the course of the job, workers should, wherever possible, be permitted to distribute the workload evenly over the day and incorporate work/rest cycles. Work/rest cycles give the body an opportunity to get rid of excess heat, slow down the production of internal body heat, slow down the heart rate, and provide greater blood flow to the skin. In the evaluation of an appropriate work/rest schedule, shorter work periods and more frequent rest periods should be considered

- a) as temperature rises;
- b) as humidity increases;
- c) when there is no air movement;
- d) when protective clothing or gear is worn; and
- e) for heavier work.

In general, more frequent, shorter periods of exposure to heat are better than fewer longer exposures. Individual requirements can vary greatly.¹

It is important that a person is well hydrated before donning PPE. Hydration will help to keep the body cool. Employees can take breaks to maintain hydration.

Cooling devices worn under PPE could provide additional comfort. Cooling devices can be reusable or single-use and include

- a) cooling bandanas, skull caps, or head bands;
- b) cooling neck scarfs or towels; and
- c) cooling vests.

Frequent breaks might also be needed so that cooling devices or cool water can be applied to body pulse points. Pulse points include the back of the neck, the inside of the wrists, the inside of the elbows, the back of the knees, the inside groin area, and the head, between the temple and ear. Applying cool water or ice to these areas can help to cool the body.

Because no two facilities or individuals are the same, it is important to establish policies and procedures to provide for the comfort and safety of the personnel working in the SPD decontamination area/room environment. The plan should address the preferences of the individual worker in relation to environmental temperature and humidity and the design and capacity of the HVAC system. A multidisciplinary team that includes at least representatives from infection prevention and control, facilities management, risk management, human resources, and SPD should establish the policies and procedures. All staff working in the decontamination area/room should receive education and training in the dynamics of cooling the body and measures that can be taken to work comfortably while wearing PPE in the decontamination area/room.

¹ Occupational Safety and Health Administration. About Work/Rest Schedules. Available at: https://www.osha.gov/SLTC/heatillness/heat_index/work_rest_schedules.html. Accessed June 26, 2017.

Bibliography

Alfa MJ, Olson N, DeGagne P, and Jackson M. Evaluation of rapid readout biological indicators for 132 °C vacuum-assisted steam sterilization cycles using a new automated fluorescent reader. *Infect Control Hosp Epidemiol*, 23(7):388–392, 2002.

Alfa MJ, and Nemes R. Manual versus automated methods for cleaning reusable accessory devices used for minimally invasive surgical procedures. *J Hosp Infect*, 58(1):50–58, 2004.

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

Alfa M, Fatima I, Olson N. Validation of adenosine triphosphate to audit manual cleaning of flexible endoscope channels. *Am J Infec Control*, 40:860–865, 2012a.

Alfa M, Sepehri S, Olson N, et al. Establishing a clinically relevant bioburden benchmark: a quality indicator for adequate reprocessing and storage of flexible gastrointestinal endoscopes. *Am J Infec Control*, 40(3):233–236, 2012b.

Alfa M, Iram f, Olson N. The adenosine triphosphate test is a rapid and reliable audit tool to assess manual cleaning adequacy of flexible endoscope channels. *Am J Infec Control*, 41(3):249–253, March 2013.

Alvarado CJ, and Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. *Amer J Infec Control*, 28(2):138–155, 2000.

American Conference of Governmental Industrial Hygienists. 2017 TLVs® and BEIs®: Threshold limit values for chemical substances and physical agents & biological exposure indices. Cincinnati: ACGIH®, 2017.

American National Standards Institute. *Emergency eyewash and shower equipment*. ANSI/ISEA Z358.1:2014. 3rd ed. New York: ANSI, 2014.

American Society for Gastrointestinal Endoscopy. Multisociety guideline for reprocessing flexible GI endoscopes: 2016 update. *Gastrointest Endosc*, 85(2):282–294.e1, 2017. Available at: https://www.sgna.org/Portals/0/MS_guideline_reprocessing_GI_endoscopes.pdf. Accessed August 18, 2017.

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

American Society of Heating, Refrigeration, and Air Conditioning Engineers. *Ventilation for acceptable indoor air quality*. Standard 62.1-2016. Atlanta: ASHRAE, 2016.

American Society of Heating, Refrigeration, and Air Conditioning Engineers. 2015 ASHRAE Handbook—HVAC Applications. Atlanta: ASHRAE, 2015.

American Society of Heating, Refrigeration, and Air Conditioning Engineers. *Thermal environmental conditions for human occupancy*. ANSI/ASHRAE 55-2013. Atlanta: ASHRAE, 2013a.

American Society of Heating, Refrigeration, and Air Conditioning Engineers. *Ventilation of health care facilities*. ANSI/ASHRAE/ASHE Standard 170-2013. Atlanta: ASHRAE, 2013b.

American Society of Heating, Refrigeration, and Air Conditioning Engineers. Room design. In: *HVAC Design Manual for Hospitals and Clinics*. 2nd ed. Atlanta, GA: ASHRAE; 2014, pp. 151–202.

AOAC International. *Official Methods of Analysis of AOAC International*. 20th ed. Washington (DC): AOAC International, 2016.

Association for the Advancement of Medical Instrumentation. *Good hospital practice: Performance evaluation of ethylene oxide sterilizers—ethylene oxide test packs*. AAMI EOTP:1985. Arlington (VA): AAMI, 1985. AAMI Recommended Practice.

Association for the Advancement of Medical Instrumentation. *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*. ANSI/AAMI PB70:2012. Arlington (VA): AAMI, 2012. American National Standard.

Association for the Advancement of Medical Instrumentation. *Reprocessing of hemodialyzers*. ANSI/AAMI RD47:2008/(R)2013. Arlington (VA): AAMI, 2008. American National Standard.

Association for the Advancement of Medical Instrumentation. *Hospital steam sterilizers*. ANSI/AAMI ST8:2013. Arlington (VA): AAMI, 2013. American National Standard.

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

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

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

Association for the Advancement of Medical Instrumentation. *Table-top dry heat (heated air) sterilization and sterility assurance in dental and medical facilities*. ANSI/AAMI ST40:2004/(R)2010. Arlington (VA): AAMI, 2004. American National Standard.

Association for the Advancement of Medical Instrumentation. *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*. ANSI/AAMI ST41:2008/(R)2012. Arlington (VA): AAMI, 2008. American National Standard.

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

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

Association for the Advancement of Medical Instrumentation. *Table-top steam sterilizers*. ANSI/AAMI ST55:2016. Arlington (VA): AAMI, 2016. American National Standard.

Association for the Advancement of Medical Instrumentation. *Chemical sterilization and high-level disinfection in health care facilities*. ANSI/AAMI ST58:2013. Arlington (VA): AAMI, 2013. American National Standard.

Association for the Advancement of Medical Instrumentation. *Processing of reusable surgical textiles for use in health care facilities*. ANSI/AAMI ST65:2008/(R)2013. Arlington (VA): AAMI, 2008. American National Standard.

Association for the Advancement of Medical Instrumentation. *Containment devices for reusable medical device sterilization*. ANSI/AAMI ST77:2013. Arlington (VA): AAMI, 2013. American National Standard.

Association for the Advancement of Medical Instrumentation. *Flexible and semi-rigid endoscope processing in health care facilities*. ANSI/AAMI ST91:2015. Arlington (VA): AAMI, 2015. American National Standard.

Association for the Advancement of Medical Instrumentation. *Medical electrical equipment—Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment*. ANSI/AAMI/IEC 60601-2-16:2012. Arlington (VA): AAMI, 2012.

Association for the Advancement of Medical Instrumentation. *Cardiovascular implants and artificial organs—Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters*. ANSI/AAMI/ISO 8638:2010/(R)2015. Arlington (VA): AAMI, 2010. American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes*. ANSI/AAMI/ISO 11138-3:2006/(R)2010. Arlington (VA): AAMI, 2006. American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Chemical indicators—Part 1: General requirements*. ANSI/AAMI/ISO 11140-1:2014. Arlington (VA): AAMI, 2014. American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs*. ANSI/AAMI/ISO 11140-5:2007/(R)2015. Arlington (VA): AAMI, 2007. American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Biological indicators—Guidance for the selection, use, and interpretation of results*. ANSI/AAMI/ISO 14161:2009/(R)2014. Arlington (VA): AAMI, 2009. American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Biological and chemical indicators—Test equipment*. ANSI/AAMI/ISO 18472:2006/(R)2015. Arlington (VA): AAMI, 2006.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Chemical indicators—Guidance on the selection, use, and interpretation of results*. ANSI/AAMI/ISO 15882:2008/(R)2013. Arlington (VA): AAMI, 2008. American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Vocabulary*. ANSI/AAMI/ISO TIR11139:2006. Arlington (VA): AAMI, 2006. ANSI/AAMI/ISO Technical Information Report.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Moist heat—Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-2*. ANSI/AAMI/ISO TIR17665-2:2009/(R)2016. Arlington (VA): AAMI, 2009. ANSI/AAMI/ISO Technical Information Report.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Moist heat—Part 3: Guidance on the designation of a medical product to a product family and processing category for steam sterilization*. ANSI/AAMI/ISO TIR17665-3:2014. Arlington (VA): AAMI, 2014. ANSI/AAMI/ISO Technical Information Report.

Association for the Advancement of Medical Instrumentation. *Selection and use of protective apparel and drapes in health care facilities*. AAMI TIR11:2005/(R)2015. Arlington (VA): AAMI, 2005. AAMI Technical Information Report.

Association for the Advancement of Medical Instrumentation. *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities*. AAMI TIR12:2010. Arlington (VA): AAMI, 2010. AAMI Technical Information Report.

Association for the Advancement of Medical Instrumentation. *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*. AAMI TIR30:2011. Arlington (VA): AAMI, 2011. AAMI Technical Information Report.

Association for the Advancement of Medical Instrumentation. *Water for the reprocessing of medical devices*. AAMI TIR34:2014. Arlington (VA): AAMI, 2014. AAMI Technical Information Report.

Association of periOperative Registered Nurses. Guideline for cleaning and care of surgical instruments. In: *Guidelines for perioperative practice*. Denver: AORN, 2017a.

Association of periOperative Registered Nurses. Guideline for environmental cleaning. In: *Guidelines for perioperative practice*. Denver: AORN, 2017b.

Association of periOperative Registered Nurses. Guideline for product selection. In: *Guidelines for perioperative practice*. Denver: AORN, 2017c.

Association of periOperative Registered Nurses. Guideline for selection and use of packaging systems for sterilization. In: *Guidelines for perioperative practice*. Denver: AORN, 2017d.

Association of periOperative Registered Nurses. Guideline for sterilization. In: *Guidelines for perioperative practice*. Denver: AORN, 2017e.

Association of periOperative Registered Nurses. Guideline for surgical attire. In: *Guidelines for perioperative practice*. Denver: AORN, 2017f.

Association of periOperative Registered Nurses. Guideline for a safe environment of care. In: *Guidelines for perioperative practice*. Denver: AORN, 2017g.

Aycliffe GAJ. Equipment-related infection risks. *J Hosp Infect*, 11 (Suppl. A):279–284, 1988.

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

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

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

Baxter HC, Campbell GA, Whittaker AG, et al. Elimination of transmissible spongiform encephalopathy infectivity and decontamination of surgical instruments by using radio-frequency gas-plasma treatment *J Gen Virol*, 86:2393–2399, 2005.

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

Bernoulli C, Siegfried J, Baumgartner G, et al. Danger of accidental person-to-person transmission of Creutzfeldt-Jakob disease by surgery. *Lancet*, I (8009):478–479, 1977.

Block SS. *Disinfection, Sterilization, and Preservation*. 5th ed. Philadelphia: Lea and Febiger, 2001.

Bongers CC, Thijssen DH, Veltmeijer MT, Hopman MT, and Eijsvogels TM. Precooling and percooling (cooling during exercise) both improve performance in the heat: a meta-analytical review. *Brit J Sports Med*, 49(6):377–386, 2015.

Bowie H, Kelsey JC, and Thompson GR. The Bowie and Dick autoclave tape test. *Lancet*, I:586–587, 1963a.

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

Bradley DW. Transmission, etiology, and pathogenesis of viral hepatitis non-A, non-B, in nonhuman primates. In: Chisari F (Ed.). *Advances in Hepatitis Research*. New York: Masson Publishing, USA, Inc., 1984, pp. 268–280.

Brown P. Environmental causes of human spongiform encephalopathy. In: Baker H, and Ridley RM (Eds.). *Methods in Molecular Medicine: Prion Diseases*. Totowa (NJ): Humana Press, 1996, pp. 139–154.

Brown P, Preece M, Brandel J-P, et al. Iatrogenic Creutzfeldt-Jakob disease at the millennium. *Neurol*, 5:1075–1081, 2000.

Brown S, Merritt K, Woods T, and Busick D. Effects on instruments of the World Health Organization-recommended protocols for decontamination after possible exposure to transmissible spongiform encephalopathy-contaminated tissue. *J Biomed Materials Research, Part B: Applied Biomaterials*, September 24, 2004. Available at: <https://www.cdc.gov/prions/cjd/pdfs/effects-instruments-who-protocol-508.pdf>. Accessed August 18, 2017.

Burlew J. *Care and Handling of Ophthalmic Microsurgical Instruments*. 2nd ed. San Francisco (CA): American Society of Ophthalmic Registered Nurses, 2006.

Canadian Standards Association. *Decontamination of reusable medical devices*: CSA Z314.8-14. Ontario, Canada: CSA, 2014.

Canadian Standards Association. *Effective sterilization in health care facilities by the steam process*. CSA Z314.3-14. Ontario, Canada: CSA, 2014.

Canadian Standards Association. *Selection and use of packaging (sterile barrier systems) in healthcare settings*. CSA Z314.14-15. Ontario, Canada: CSA, 2015.

Centers for Disease Control. Creutzfeldt-Jakob Disease, Classic (CJD). Available at: <https://www.cdc.gov/prions/cjd/occurrence-transmission.html>. Accessed August 17, 2017.

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

Centers for Disease Control and Prevention. Guideline for hand hygiene in health-care settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *Morbidity and Mortality Weekly Report (MMWR)*, 51(RR-16):1–45, 2002a. Available at: <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>. Accessed June 26, 2017.

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

Centers for Disease Control and Prevention. Guidelines for infection control in dental health-care settings. *Morbidity and Mortality Weekly Report (MMWR)*, 52(RR-17):1–66, 2003. Available at: <http://www.cdc.gov/mmwr/PDF/rr/rr5217.pdf>. Accessed June 26, 2017.

Centers for Disease Control and Prevention. *Guidelines for isolation precautions: Preventing transmission of infectious agents in healthcare settings*. Atlanta (GA): CDC, 2007. Available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>. Accessed June 26, 2017.

Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *Guideline for disinfection and sterilization in healthcare facilities, 2008*. Atlanta (GA): CDC, 2008. Available at: http://www.cdc.gov/hai/pdfs/disinfection_nov_2008.pdf. Accessed June 26, 2017.

Chan-Myers H, McAlister D, and Antonoplos P. Natural bioburden levels detected on rigid lumened medical devices before and after cleaning. *Amer J Infect Control*, 25:471–476, 1997.

Cole EC, Rutala WA, Nessen L, Wannamaker NS, and Weber DJ. Effects of methodology, dilution, and exposure time on the tuberculocidal activity of glutaraldehyde-based disinfectants. *Appl Envir Microbiol*, 56(6):11813–11817, 1990.

Committee for European Standardization. *Packaging materials for terminally sterilized medical devices—Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285. Requirements and test methods*. EN 868–8:2009. Brussels (Belgium): CEN, 2009.

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

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

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

Donlan RM. Biofilms: Microbial life on surfaces. *Emerging Infectious Diseases*, 8(9):881–890, 2002.

Facility Guidelines Institute. *Guidelines for Design and Construction of Health Care Facilities*. Chicago: FGI, 2014.

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

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

Fernie K, Steele PJ, Taylor DM, Somerville RA. Comparative studies on the thermostability of five strains of transmissible-spongiform-encephalopathy agent. *Biotechnol Appl Biochem*, 47(Pt 4):175–183, 2007.

Fichet G, Comoy E, Duval C, Antlogo K, Dehen C, Charbonnier A, McDonnell G, and Brown P. Novel methods for disinfection of prion-contaminated medical devices. *Lancet*, 364:521–526, 2004.

Fichet G, Comey E, et al. Investigations of a prion infectivity assay to evaluate methods of decontamination. *J Microbiol Methods*, 70(3):511–518, 2007a.

Fichet G, Antlogo K, et al. Prion inactivation using a new gaseous hydrogen peroxide sterilization process. *J Hosp Infect*, 67(3):278–286, 2007b.

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

Hewitt PE, Llewelyn CA, Mackenzie J, and Will RG. Creutzfeldt-Jacob disease and blood transfusion: results of the UK Transfusion Medicine Epidemiological Review study. *Vox Sanguinis*, 91:221–230, 2006.

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

Ho DD, Moudgil T, and Alam M. Quantitation of human immunodeficiency virus type 1 in the blood of infected persons. *N Eng J Med*, 321(24):1621–1625, December 1989.

Instrument Society of America. *Quality standard for instrument air*. ANSI/ISA 7-0-01-1996. New York: ISA, 1996.

International Association of Healthcare Central Service Materiel Management. *Central Service Technical Manual*. 7th ed. Chicago: IAHCMM, 2007.

International Organization for Standardization. *Compressed air—Part 1: Contaminants and purity classes*. ISO 8573-1:2010. Geneva (Switzerland): ISO, 2010.

International Organization for Standardization. *Ergonomics of the thermal environment—Determination of metabolic rate*. ISO 8996:2004. Geneva (Switzerland): ISO, 2004.

International Organization for Standardization. *Ergonomics of the thermal environment—Estimation of thermal insulation and water vapour resistance of a clothing ensemble*. ISO 9920:2007. Geneva (Switzerland): ISO, 2007.

Ironside JW. Variant Creutzfeldt-Jakob disease: An update. *Folia Neuropathol*, 50(1):50–56, 2012.

Jackson GS, McKintosh E, Flechsig E, et al. An enzyme-detergent method for effective prion decontamination of surgical steel. *J Gen Virol*, 86: 869–878, 2005.

Joint Commission. *2017 Comprehensive accreditation manual for hospitals: The official handbook (CAMH)*. Chicago: Joint Commission, 2016.

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

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

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

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

Kirk B. Noncondensable gases (NCG) in the steam supply of a sterilizer. *Zentral Sterilisation*, 9(5): 317–334, 2001.

Klug GM, Boyd A, Zhao T, Stehmann C, Simpson M, McLean CA, Masters CL, and Collins SJ. Surveillance for Creutzfeldt-Jakob disease in Australia: Update to December 2012. *Commun Dis Intell Q Rep*, 37(2):E115–20, June 2013.

Knieler R. Manual cleaning and disinfection of flexible endoscopes—an approach to evaluating a combined procedure. *J Hosp Infect*, 48(suppl):S84–S87, 2001. Jeanes A, and Green J. Nail art: A review of current infection control issues. *J Hosp Infect*, 249:139–142, 2001.

Kovach, S. Understanding the sonic cleaning process. *Managing infect control*, June 2011.

Kruger S. Testing the cleaning efficacy in decontamination equipment. *Zentr. Steril.*, 5:332–344, 1997.

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

Lee S. Steam sterilization: Troubleshooting wet pack problems. In: Reichert M and Young JH (Eds.). *Sterilization Technology for the Health Care Facility*. 2nd ed. Gaithersburg (MD): Aspen Publications, 1997, Chapter 18.

Lemmer K, Mielke M, et al. Decontamination of surgical instruments from prion proteins: In vitro studies on the detachment, destabilization, and degradation of PrP^{Sc} bound to steel surfaces. *J Gen Virol*, 85:3805–3816, 2004.

Llewelyn CA, Hewitt PE, Knight RS, et al. Possible transmission of variant Creutzfeldt-Jakob disease by blood transfusion. *Lancet*, 363:417–421, 2004.

Malkin J. *Medical and Dental Ppace Planning: A Comprehensive Guide to Design, Equipment and Clinical Procedures*. 3rd ed. New York: John Wiley & Sons, 2002.

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

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

McDonnell G. Prion disease transmission: can we apply standard precautions to prevent or reduce risks? *J Perioper Pract*, 18(7):298–304, 2008.

McDonnell G, and Sheard D. *A Practical Guide to Decontamination in Healthcare*. Hoboken (NJ): Wiley-Blackwell, 2012.

McDonnell G, and Burke P. The challenge of prion decontamination. *Clin Infect Dis*, 36:1152–1154, 2003.

Merritt K, Hitchins VM, and Brown SA. Safety and cleaning of medical materials and devices. *J Biomed Material Research (Applied Biomaterials)*, 53:131–136, 2000.

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

National Fire Protection Association. *Health care facilities code*. NFPA 99. Quincy (MA): NFPA, 2012.

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

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

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

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

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

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

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

Occupational Safety and Health Administration. Hospital eTool, Central Supply. Available at: <http://osha.gov/SLTC/etools/hospital/central/central.html>. Accessed June 27, 2017.

Peretz D, Supattapone S, Giles K, et al. Inactivation of prions by acidic sodium dodecyl sulfate. *J Virol*. 80:322–331, 2006.

Perkins JJ. *Principles and Methods of Sterilization in Health Sciences*. 2nd ed. Springfield (IL): Charles C Thomas, 1969.

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

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

Rea MS (Ed.). *Lighting Handbook: Reference and Application*. 8th ed. New York: Illuminating Engineering Society of North America, 1993.

Reichert M, and Young JH. *Sterilization Technology for the Health Care Facility*. 2nd ed. Gaithersburg (MD): Aspen Publishing, 1997.

Rogez-Kreuz C, Yousfi R, et al. Inactivation of animal and human prions by hydrogen peroxide gas plasma sterilization. *Infect Control Hosp Epidemiol*, 30(8):769–777, 2009.

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

Rutala WA. Disinfection, sterilization, and waste disposal. In: Wenzel RP (Ed.). *Prevention and Control of Nosocomial Infections*. Baltimore: Williams and Wilkins, 1987.

Rutala WA. APIC guideline for selection and use of disinfectants. *Amer J Infec Control*, 24:313–342, 1996.

Rutala WA, and Weber DJ. Creutzfeldt-Jakob disease: Recommendations for disinfection and sterilization. *Clin Infect Diseases*, 32:1348–1356, 2001.

Rutala WA, and Weber DJ. Guideline for disinfection and sterilization of prion-contaminated medical instruments, a SHEA guideline. *Infect Control Hosp Epidemiol*, 31(2):107–117, 2010.

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

Rutala WA, Clontz EP, Weber DJ, and Hoffman KK. Disinfection practices for endoscopes and other semicritical items. *Infect Control and Hosp Epidemiol*, 12:282–288, 1991b.

Rutala WA, Gergen MF, and Weber DJ. Evaluation of a rapid readout biological indicator for flash sterilization with three biological indicators and three chemical indicators. *Infect Control and Hosp Epidemiol*, 14(7):390–393, 1993.

Rutala WA, Jones SM, and Weber DJ. Comparison of a rapid readout biological indicator for steam sterilization with four conventional biological indicators and five chemical indicators. *Infect Control and Hosp Epidemiol*, 17(7):423–482, 1996.

Rutala WA, Stiegel MM, Sarubbi FA, and Weber DJ. Susceptibility of antibiotic-susceptible and antibiotic-resistant hospital bacteria to disinfectants. *Infect Control and Hosp Epidemiol*, 18:417–421, 1997.

Salman L, et al. Banning artificial nails from health care settings. *Amer J Infect Control*, 30:252–254, 2002.

Schmid-Hempel P, and Frank SA. Pathogenesis, virulence, and infective dose. *PLoS Pathog*, 3(1): e147, 2007.

Shikata T, et al. Hepatitis B antigen and infectivity of hepatitis B virus. *J Infect Diseases*, 136(4):571–576, 1977.

Society of Gastroenterology Nurses and Associates. *Standards of infection control in reprocessing of flexible gastrointestinal endoscopes*. Washington (DC): SGNA, 2012.

Soule BM (Ed.). *The APIC Curriculum for Infection Control Practice*. Vol. 1. Washington (DC): Association for Professionals in Infection Control and Epidemiology, 1983.

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

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

Taylor DM. Inactivation of transmissible degenerative encephalopathy agents: A review. *Vet J*, 159(1):10–17, 2000.

U.S. Department of Transportation. Class 6, Division 6.2—Definitions and exceptions. *Code of Federal Regulations*, Title 49, Part 173.134.

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

U.S. Food and Drug Administration. *Medical device reporting for user facilities*. Rockville (MD): FDA, 1996. FDA Guidance. Available at: <https://www.fda.gov/downloads/MedicalDevices/.../UCM095266.pdf>. Accessed June 27, 2017.

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

U.S. Food and Drug Administration. *Guidance for industry and FDA reviewers: Content and format of premarket notification [510(k)] submissions for liquid chemical sterilants/high level disinfectants*. January 3, 2000. Rockville (MD): FDA, 2000b. Available at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm073773.htm>. Accessed June 27, 2017.

U.S. Food and Drug Administration. *Guidance on enforcement priorities for single-use devices reprocessed by third parties and hospitals*. FDA, August 14, 2000c. FDA Guidance. Available at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm107164.htm>. Accessed June 27, 2017.

U.S. Food and Drug Administration. *Guidance for industry and FDA staff: Premarket notification [510(k)] submissions for chemical indicators*. Rockville (MD): FDA, 2003.

U.S. Food and Drug Administration. *Guidance for industry and FDA staff: Medical glove guidance manual*. Rockville (MD): FDA, 22 January 2008. Available at: <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm428191.pdf>. Accessed July 27, 2017.

U.S. Food and Drug Administration. *Reprocessing medical devices in health care settings: Validation methods and labeling. Guidance for industry and Food and Drug Administration staff*. Rockville (MD): FDA, March 2015. FDA Guidance. Available at: <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf>. Accessed August 17, 2017.

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

U.S. Food and Drug Administration. Use of octadecylamine in steam lines of drug establishments. *Code of Federal Regulations*, Title 21, Part 200.11.

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

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

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

U.S. Food and Drug Administration. Investigational device exemptions. *Code of Federal Regulations*, Title 21, Part 812.3.

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

U.S. Food and Drug Administration. Sterilization process indicator. *Code of Federal Regulations*, Title 21, Part 880.2800.

U.S. Food and Drug Administration. Medical washer. *Code of Federal Regulations*, Title 21, Part 880.6991.

U.S. Pharmacopeial Convention. *United States Pharmacopeia 1984*. Vol. 21. Easton (PA): Mack Publishing Co., 1984.

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

Verjat D, Prognon P, and Darbord JC. Fluorescence-assay on traces of protein on reusable medical devices: cleaning efficiency. *Internat J Pharmaceutics*, 179:267–271, 1999.

Vesley D, Langholz AC, Rohlfing SR, and Foltz WE. Fluorimetric detection of a *Bacillus stearothermophilus* spore-bound enzyme, alpha-D-glucosidase, for rapid indicator of flash sterilization failure. *Applied & Environ Microbiol*, 58(2):717–719, 1992.

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

Wadsworth JD, Dalmau-Mena I, et al. Effect of fixation on brain and lymphoreticular vCJD prions and bioassay of key positive specimens from a retrospective vCJD prevalence study. *J Pathol*, 223(4):511–518, 2011.

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

World Health Organization. WHO Tables on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies. Updated 2010. Available at: <http://www.who.int/bloodproducts/tablestissueinfectivity.pdf>. Accessed August 27, 2017.

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

Zuhlsdorf B, Emmrich M, Floss H, and Martiny H. Cleaning efficacy of nine different cleaners in a washer-disinfector designed for flexible endoscopes. *J Hosp Infect*, 52:206–211, 2002.

ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

AMENDMENT 1: Environmental services/fans/food and drink

Approved 17 September 2020 by
AAMI

Approved 26 October 2020 by
American National Standards Institute, Inc.

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

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

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Contents	Page
Committee representation	iv
Foreword	viii
1 Revise content in 3.2.1.1	1
2 Revise content in 3.3.5.5	3
Figure	
Figure 1—Example of environmental cleaning checklist	2

Committee representation

Association for the Advancement of Medical Instrumentation

Steam Sterilization Hospital Practices Working Group

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

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Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
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- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall.”

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

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

ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

AMENDMENT 1: Environmental services/fans/food and drink

1 Revise content in 3.2.1.1

1.1 General considerations: change header, revise 1st paragraph: Add NOTE and Rationale.

3.2.1.1 General considerations for environmental cleaning

The physical design and functional workflows of the sterile processing department/area should support safe and effective processing, workplace safety, and security. The healthcare organization should create a multidisciplinary team responsible for the oversight of any sterile processing area for such activities as construction and /or renovation and for the development of policies and procedures that outline hygiene practices.

For hygiene practices, a policy and procedure should outline restrictions related to food and beverages and provide recommendations for alternate locations for such items. Food and drink should be strictly prohibited in all areas where medical devices are processed.

NOTE-Section 4.5.1 g) discusses prohibiting personal electronic devices in processing areas and exceptions should be noted in the organization's policies.

Rationale: A multidisciplinary team can provide expertise in the areas of functional design, the functional needs of the users, personnel safety, infection prevention, sustainability, and regulatory requirements from complementary perspectives. Dust and debris are environmental contaminants in the sterile processing department/area and can result in increasing the risk to employees and patients through contamination of sterilized items. Good hygiene practices include the restriction of food and beverages from the area. Food and beverage may attract insects and vermin. Controlling items permitted in areas that process medical devices is a method of helping to ensure a clean and safe environment. OSHA regulations "prohibits the consumption of food and drink in areas in which work involving exposure or potential exposure to blood or other potentially infectious material exists, or where the potential for contamination of work surfaces exists" as would be the case in Sterile Processing decontamination room/area. In addition to contamination of the food itself, one must consider that food and beverage containers may also become contaminated, resulting in unsuspected contamination of the hands." "The employer must evaluate the workplace to determine in which locations food or beverages may potentially become contaminated and must prohibit employees from eating or drinking in those areas." [29 CFR 1910.1030]

3.4 Environmental services

Environmental cleaning procedures in all sterile processing areas (i.e., decontamination, preparation, packaging, sterilization, sterile storage) should be established and followed. These procedures should be determined by a multidisciplinary team as defined by the facility and to include the personnel responsible for infection prevention and control and environmental cleaning. Environmental cleaning procedures should be based on an assessment of risk in each sterile processing area. This team should define the type of cleaning, the surfaces to be cleaned, the disinfectant to be used, and the frequency cleaning will be performed. Terminal environmental cleaning is thorough environmental cleaning that is performed each day the area is being used, or when an event necessitates more frequent cleaning.

Areas for environmental cleaning can include walls, floors, high contact surface areas, movable equipment including any wheels, non-movable equipment, utility sinks, hand-hygiene sinks, air vents, storage cabinets, and racks, as defined in the facility's policy. See Figure 1.

3.4.1 Environmental Cleaning – All Areas of Sterile Processing

Upon entering each area, proper attire must be donned and doffed according to facility policy. Products used for cleaning and disinfection should be determined and approved by the facility. Workflow begins in the clean areas (e.g., sterile storage, packaging, sterilization) and progresses to soiled areas (e.g., decontamination area). All equipment and supplies used for environmental cleaning of the decontamination area should not be utilized in any other area of the facility. **The person who completes these tasks should initial the chart upon completion.**

Daily:

- Remove all general trash and soiled linens (pulled not dumped); clean and disinfect receptacles when soiled and replace liners/bags with new ones;
- Check and replace receptacles (e.g., biohazardous waste, sharps, recycling);
- Check hand hygiene supplies and refill or replace where needed; do not "top off" soaps and hand sanitizers;
- Clean and disinfect all sinks;
- Clean and disinfect workstations and work surfaces;
- Clean and disinfect additional surfaces in the **decontamination area**;
 - Walls and surfaces that are visibly soiled;
 - Equipment exterior surfaces (e.g., ultrasonic cleaner, washer-disinfector);
- Clean and disinfect floors including corners and edges.

		Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Week 1	Date							
	Initials							
Week 2	Date							
	Initials							
Week 3	Date							
	Initials							
Week 4	Date							
	Initials							
Week 5	Date							
	Initials							

Weekly:

- Damp dust in high and low areas (e.g., tops of cabinets, tops of sterilizers, under racks, cabinets).

	Week 1	Week 2	Week 3	Week 4	Week 5
Date:					
Initials:					

Monthly:

- Clean and disinfect air vents and sprinklers;
- Clean and disinfect inside cabinets and storage bins;
- Clean and disinfect under and behind movable storage cabinets, cart, and equipment (i.e., move these to reach those areas).

Monthly
Date:
Initials:

Figure 1—Example of environmental cleaning checklist

NOTE The areas to be considered in environmental cleaning procedures include but are not limited to walls, floors, ceilings, horizontal work surfaces, storage shelves, air intake, return ducts, light fixtures, and equipment.

Floors should be cleaned at least daily. High contact surface areas as defined by facility policy should be cleaned at least daily when in use. Follow the facility's infection prevention and control policies.

Dust mops and brooms should not be used in any area of Sterile Processing. Floors should be cleaned using a damp mop. Only clean, non-linting cloths should be used to clean high contact surface areas.

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

Areas of attention should include but not be limited to ceiling intake and exhaust vents, tops, behind and sides of equipment, workstation lights, baseboards/cove bases, sterilizer base and bottom of carts.

A cleaning schedule along with a complementary checklist should be used to demonstrate compliance and areas of focus.

Cleaning verification tools such as ultraviolet light visible markers, protein tests and ATP bioluminescence may be used to measure the adequacy of environmental cleaning.

NOTE Cleaning verification can also include direct observation of employees performing environmental cleaning.

Trash should be emptied at least daily when area in use and as needed.

Rationale: Cleaning removes soil and reduces environmental contaminants, thus reducing the risk of transmission of microorganisms. Measurement with cleaning verification tools provides a mechanism for feedback to improve the thoroughness of cleaning. Dust mops and brooms enable dust to move throughout the room being carried by air currents.

2 Revise content in 3.3.5.5

2.1 Heating, ventilation, and air conditioning (HVAC) operating parameters: Add a new 2nd paragraph and additional content for the Rationale

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

Except for exhaust fans on ventilation systems and properly installed and operated fume control hoods, neither fixed nor portable fans should be permitted in any area of Sterile Processing. All windows and doors that affect the ventilation and airflow (positive to negative) should be kept closed when not in use.

Rationale: Ventilation patterns, and other environmental controls affect the proliferation and spread of potentially pathogenic microorganisms. Control of bioburden and environmental contaminants is essential to ensure that the subsequent sterilization process is effective. Down-draft-type air circulation systems limit contamination by carrying contaminants toward the floor and away from work surfaces. Fans are not permitted in any sterile processing area as they may create highly turbulent air flow, causing disturbance of dust and microorganisms from the floor and work surfaces and thus interfere with airflow balance characteristics.

ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

AMENDMENT 2: Inspection of insulated instruments

Approved 17 September 2020 by
AAMI

Approved 26 October 2020 by
American National Standards Institute, Inc.

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

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

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Contents

Page

Committee representation	iv
Foreword	viii
1 Add new sections 8.2 and 8.2.1	1
2 Add to Bibliography	5

Figures

Figure 1—Laparoscopic instrumentation: examples of collar not flush against distal working mechanism.....	3
Figure 2—Laparoscopic instrumentation: examples of shaft and handle nicks, cracks, lacerations, gouges, and microscopic pin holes	3
Figure 3—Insulated forceps: examples of frays at distal tip, lacerations, housing cracks	4
Figure 4—Cables/cords: examples of separation of the cord at the proximal end, nicks, lacerations, pin holes....	4
Figure 5—LEEP and miscellaneous insulated coated instruments/devices: examples of nicks, lacerations, gouges, pin holes.....	5

Table

Table 1—Inspection points and possible damage for various instruments/devices	2
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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:

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The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall.”

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

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

ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

AMENDMENT 2: Inspection of insulated instruments

1 Add new sections 8.2 and 8.2.1

1.1 Change the subsequent numbering of this section; add new related references to Bibliography.

8.2 Inspection of instruments

Each time a medical device is processed, it should be visually inspected for cleanliness and integrity. Enhanced inspection with magnification, borescopes, or other inspection methods to verify cleanliness and integrity may be used. Borescopes or other methods may be used to check internal channels of instrumentation for cleanliness and integrity unless otherwise recommended in the instrument manufacturer's written IFU and the borescope manufacturer's written IFU. When recommended in the instrument manufacturer's written IFU, enhanced inspection should be used and the enhanced visualization tool manufacturer's written IFU should be followed. Health care facilities should have a method of ensuring the cleanliness and integrity of every instrument and medical device used in every procedure. Upon inspection, medical devices with retained soil or residue should be subjected to repeated cleaning and decontamination processes until the device is completely clean. Damaged instruments should be removed from service; damage is addressed according to organizational policy and procedure (e.g., evaluation, repair).

Altering instruments from their original state can cause fractures or surface damage and can affect the device's ability to perform as intended.

When an instrument is purchased, all inspection equipment should be present and available prior to first use of equipment.

Rationale: Proper inspection prevents instruments with bioburden, foreign material, or damage from going unnoticed and being distributed. Inadequately cleaned instruments can interfere with the sterilization process. Damaged instruments or incomplete instrument sets/trays may cause a delay or cancellation of a surgical procedure and/or increase risk of patient harm related to instrument malfunction.

8.2.1 Inspection of instruments intended to be used with electric current

Damage to insulated instruments including cords can occur during normal use, processing, contact with sharp instruments, and use of high voltage. Instruments should be organized and protected from damage. Repeated use/processing of these instruments and cords can cause damage to the insulation.

The following steps should be taken:

- a) Instrumentation intended for use with electric current should be tested for integrity each time it is processed in accordance with the instrument manufacturer's written IFUs for inspection.

NOTE Any damage to the coating can compromise the safety of the device.

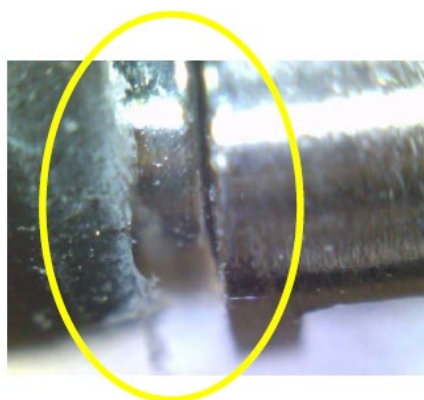
- b) Unless otherwise directed, the insulation should first be inspected using lighted magnification.
- c) Insulation material should be free of defects as defined by the manufacturer's written IFU.

- d) Insulation testing should be performed following instrument manufacturers' instructions for use. Testing devices should be used following the testing device manufacturer's IFU.
- e) The insulation should be checked at appropriate inspection points for the instrument (see Table 1 and Figure 1 through Figure 5).
- f) Cables/cords are also a source of concern and need to be inspected and checked for integrity and continuity. When indicated, testing devices should be used following testing device manufacturer's IFU.
- g) When damage is noted, the device should be removed from service following facility policy and procedure (e.g., evaluation, repair).

Table 1—Inspection points and possible damage for various instruments/devices

Instrument/Device	Inspection Points	Possible damage	Methods to assist with inspection/testing
Laparoscopic including robotic instrumentation	<ul style="list-style-type: none"> — shaft — handles if applicable 	<ul style="list-style-type: none"> — distal tip collar not flush against distal working mechanism — frays at the distal tip of insulation — shaft and handle nicks, cracks, lacerations, gouges, and microscopic pin holes 	<ul style="list-style-type: none"> — insulation tester — lighted magnification — enhanced magnification (microscope) — visual inspection — tactile inspection
Insulated forceps e.g., bipolar forceps	<ul style="list-style-type: none"> — forceps shaft sides — forceps base housing 	<ul style="list-style-type: none"> — frays at the distal tip of insulation — shaft nicks, cracks, lacerations, gouges, and microscopic pin holes — housing cracks and separation 	<ul style="list-style-type: none"> — insulation tester — lighted magnification — enhanced magnification (microscope) — visual inspection — tactile inspection
Insulated scissors	<ul style="list-style-type: none"> — shafts — handle — blades 	<ul style="list-style-type: none"> — shaft nicks, cracks, lacerations, gouges, and microscopic pin holes — shaft nicks, cracks, lacerations, gouges, and microscopic pin holes — frays at the distal blades 	<ul style="list-style-type: none"> — insulation tester — lighted magnification — enhanced magnification (microscope) — visual inspection — tactile inspection
Cables/cords	<ul style="list-style-type: none"> — distal (plugs into instrument) — proximal (plugs into electrosurgical unit) — full length of the cord 	<ul style="list-style-type: none"> — separation of the cord to the distal tip — separation of the cord at the proximal end — shaft nicks, cracks, lacerations, gouges, and microscopic pin holes 	<ul style="list-style-type: none"> — insulation tester — lighted magnification — enhanced magnification (microscope) — visual inspection — tactile inspection

Instrument/Device	Inspection Points	Possible damage	Methods to assist with inspection/testing
LEEP/misc. coated instruments and devices	— full insulation coating	— shaft nicks, cracks, lacerations, gouges, and microscopic pin holes	— insulation tester — lighted magnification — enhanced magnification (microscope) — visual inspection — tactile inspection

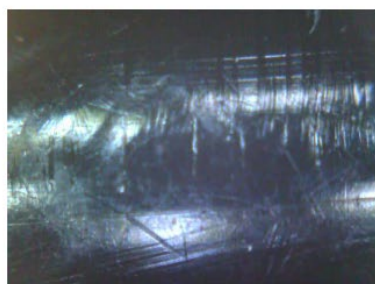


Gap in insulation collar



Gap in insulation collar

Figure 1—Laparoscopic instrumentation: examples of collar not flush against distal working mechanism



Nicks, lacerations, gouges on shaft



Pin hole on shaft



Pin hole on handle

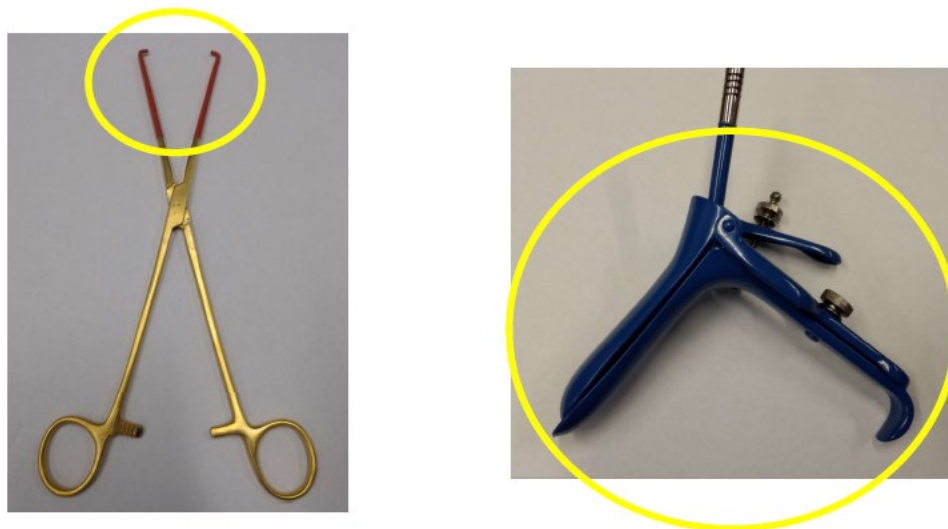
Figure 2—Laparoscopic instrumentation: examples of shaft and handle nicks, cracks, lacerations, gouges, and microscopic pin holes



Figure 3—Insulated forceps: examples of frays at distal tip, lacerations, housing cracks



Figure 4—Cables/cords: examples of separation of the cord at the proximal end, nicks, lacerations, pin holes



**Figure 5—LEEP and miscellaneous insulated coated instruments/devices:
examples of nicks, lacerations, gouges, pin holes**

Personnel responsible for processing these instruments should receive education in the use of all testing equipment used before using the equipment. Competency should be verified and documented before first assignment to use the equipment (see Section 4).

Insulation testing methods vary with insulation tester type. Each insulation tester may be supplied with a variety of accessories to test specific instrumentation and cables/cords based on their design and may require additional training and in-services. Refer to the instrument and insulation tester manufacturers' written IFUs for their recommended procedures. Tabletop and handheld are available. Each is designed to detect small current leaks that can place the patient at risk for significant harm. Any time instrument insulation does not pass inspection, the device should be removed from service; damage should be addressed according to organizational policy and procedure (e.g., evaluation, repair, replacement). If any of these conditions occur, it shows that the instrument has been compromised and should be taken out of service.

Rationale: Insulated electrical current instruments are susceptible to physical and mechanical damage and degradation related to repeat use. Defects in insulation are not always visually detectable; some are only detectable through use of insulation and continuity testing devices. The use of malfunctioning insulated instrumentation places the patient at risk for significant harm (burns) from electrical current escape. Electrical current escape can go undetected during the surgical procedure if they occur outside the view of the surgical team, which is often the case. Smaller defects are particularly problematic because they can concentrate the escaped energy and cause more serious tissue injury. In a 2014 review of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, reported surgical energy-based device injuries and deaths were reviewed for from January 1994 to December 2013 (Overbey et al, 2015). Among these reports, 178 deaths and 3,553 injuries were attributed to electrosurgical complications. Of these, 324 injuries and 14 patient deaths were attributed to insulation failure.

2 Add to Bibliography

- [1] U.S. FDA. *Recommendations to Reduce Surgical Fires and Related Patient Injury: FDA Safety Communication*. <https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm608637.htm>
- [2] *Frequency and Severity of Stray Energy Burns*. https://www.encision.com/wp-content/uploads/2018/04/Frequency_and_Severity_of_Stray_Energy_Burns_MAR00032.pdf
- [3] Martin, Moore, Tucker, Fuchshuber, Robinson., Quantifying Inadvertent Thermal Bowel Injury from the Monopolar Instrument. *The Journal of Surgical Endoscopy*. November 2016, Volume 30, Issue 11, pp 4776–4784.

- [4] Nduka CC, Super PA, Monson JR, Darzi AW., *Cause and prevention of electrosurgical injuries in laparoscopy*. J Am Coll Surg. 1994;179(2):161-170.
- [5] Reprocessing of Instruments to Retain Value, 11th edition 2017, www.a-k-i.org. *Working Group Instrument Reprocessing*
- [6] Overbey DM, Townsend NT, Chapman BC, et al. Surgical energy-based device injuries and fatalities reported to the food and drug administration. *Journal of the American College of Surgeons*. 2015;221(1):197-205.e1.

ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

AMENDMENT 3: Modification of content pertaining to frequency of cleaning for routine care of sterilizers for sterile processing areas in health care facilities

Approved 17 September 2020 by
AAMI

Approved 18 December 2020 by
American National Standards Institute, Inc.

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

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Contents

Committee representation iv

Foreword viii

1 Revise section 12.4 1

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Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

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

ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

AMENDMENT 3: Modification of content pertaining to frequency of cleaning for routine care of sterilizers for sterile processing areas in health care facilities

1 Revise section 12.4

1.1 Eliminate daily cleaning recommendation.

12.4 Routine care

Sterilizers should be visually inspected according to the manufacturer's written IFU. Examples of items that might require daily care include recording charts, printers, printer ribbons, marking pens and ink. Weekly or other prescribed inspection and cleaning should be performed as specified in the manufacturer's written IFU and should be documented per internal procedures. Examples of items to be observed are excessive staining and discoloration of the internal chamber. If staining or discoloration is noted, then follow the process for cleaning the internal surfaces of the sterilizer as outlined in the manufacturers' written IFU. If anything, out of the ordinary is noted during daily or weekly inspection, refer to the manufacturer's written IFU for steps to follow.

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

ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

AMENDMENT 4: Content addressing recording BI lot numbers in sterilizer records for sterile processing in health care facilities

Approved 17 September 2020 by
AAMI

Approved 26 October 2020 by
American National Standards Institute, Inc.

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

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

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Contents	Page
Committee representation	iv
Foreword	viii
1 Revise section 13.3.3	1
1.1 Add content pertaining to lot numbers	1
2 Revise section 13.8.2.3 6) to read:	1
3 Revise section 13.8.3.3 6) to read:	1
4 Revise section 13.8.4.3 e) to read:	2

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:

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AMENDMENT 4: Content addressing recording BI lot numbers in sterilizer records for sterile processing in health care facilities

1 Revise section 13.3.3

1.1 Add content pertaining to lot numbers.

13.3.3 Sterilizer records

The critical parameters of a sterilization process (time and temperature) provided on the recording chart, printer, tape or electronic record should be reviewed, signed and dated (hard copy or electronically) by the operator to indicate an acceptable cycle. For each sterilization cycle, the following information should be documented:

- a) the load number;
- b) sterilizer identification number or code;
- c) the specific contents of the lot or load, including quantity, department, and a specific description of the items (e.g., towel packs, type/name of instrument sets);
- d) the exposure time and temperature, if not provided on the sterilizer recording chart;
- e) operator identification;
- f) the lot numbers and results of biological testing (test BI(s) and control BI(s), see 13.8.2.3, 13.8.3.3 and 13.8.4.3), if applicable;
- g) the results of Bowie-Dick testing, if applicable;
- h) the response of the CI placed in the PCD, if applicable; and
- i) any reports of inconclusive or nonresponsive CIs found later in the processed devices (see also 13.5.2.2).

2 Revise section 13.8.2.3 6) to read:

- 6) The lot number of both test BIs and control BIs should be documented.

3 Revise section 13.8.3.3 6) to read:

- 6) The lot number of both test BIs and control BIs should be documented.

4 Revise section 13.8.4.3 e) to read:

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