American National Standard

ANSI/AAMI ST46:2002

Steam sterilization and sterility assurance in health care facilities

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ANSI/AAMI ST46:2002
(Revision of ANSI/AAMI ST46:1993)

Steam sterilization and sterility assurance in health care facilities

Developed by
Association for the Advancement of Medical Instrumentation

Approved 14 November 2002 by
American National Standards Institute, Inc.

Abstract: This recommended practice covers steam sterilization in health care facilities. The recommendations are intended to promote assurance of sterility and 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: moist heat sterilization, quality system, saturated steam

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Contents

Page

Committee representation vii

Acknowledgments ix

Foreword x

Introduction: Need for the recommended practice xi

1 Scope 1

1.1 General 1
1.2 Inclusions 1
1.3 Exclusions 1

2 Definitions, symbols, and abbreviations 1

3 Design considerations 6

3.1 General rationale 6
3.2 Work area design and functional work flow 6
3.2.1 Definitions of work areas 6
3.2.2 Design criteria 8
3.2.3 Functional work flow patterns 8
3.2.4 Traffic control 8
3.3 Physical facilities 9
3.3.1 Space requirements 9
3.3.2 Mechanical systems 10
3.3.3 Electrical systems 10
3.3.4 Steam for sterile processing 10
3.3.5 General area requirements 11
3.3.6 Special area requirements and restrictions 15
3.3.7 Emergency eyewash/shower equipment 17
3.4 Housekeeping procedures 17

4 Personnel considerations 17

4.1 General rationale 17
4.2 Qualifications 17
4.2.1 Supervisory personnel 17
4.2.2 Sterilization processing personnel 18
4.3 Training and continuing education 18
4.3.1 Central service personnel 18
4.3.2 Other personnel 18
4.4 Health and personal hygiene 19
4.5 Attire 19
4.5.1 General 19
4.5.2 Decontamination area 20

5 Processing recommendations 20

5.1 General rationale 20
5.2 Receiving 21
5.2.1 General considerations 21
5.2.2 Newly purchased reusable items and repaired reusable items 21
5.2.3 Disposable items 21
5.3 Disposition of sterile items (issued but not used) 21
5.4 Handling, collection, and transport of items previously used in patient care 22

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST46:2002, Steam sterilization and sterility assurance in health care facilities

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5.5 Cleaning and other decontamination processes 23
5.5.1 General considerations 23
5.5.2 Cleaning 23
5.5.3 Microbicidal processes 24
5.6 Packaging 25
5.6.1 Selection of packaging materials 25
5.6.2 Package configurations and preparation 25
5.7 Loading the sterilizer 33
5.7.1 General considerations 33
5.7.2 Paper/plastic pouches 33
5.7.3 Instrument sets 33
5.7.4 Solutions 35
5.8 Sterilization parameters 35
5.8.1 Sterilization parameters for wrapped or containerized items 35
5.8.2 Monitoring 35
5.9 Sterility maintenance 36
5.9.1 Cooling 36
5.9.2 Handling and inspection 36
5.9.3 Sterile storage 37
5.9.4 Shelf life 38
5.10 Distribution 38
5.10.1 Handling and inspection 38
5.10.2 Distribution containers 38

6 Installation, care, and maintenance of sterilizers 38

6.1 General rationale 38
6.2 Instruction manuals 38
6.3 Installation testing 39
6.4 Routine care 39
6.5 Preventive maintenance 39
6.5.1 General 39
6.5.2 Scheduled maintenance 39
6.6 Calibration 39
6.7 Record-keeping 39

7 Quality control 40

7.1 General rationale 40
7.2 Product identification and traceability 40
7.2.1 Lot control numbers 40
7.2.2 Sterilizer records 40
7.2.3 Expiration dating 41
7.3 Physical monitoring 41
7.3.1 Use of physical monitors 41
7.3.2 Sterilizer malfunction 41
7.4 Sterilization process indicators 42
7.4.1 General considerations 42
7.4.2 Chemical indicators 42
7.4.3 Biological indicators 44
7.5 Sterilizer efficacy testing 45
7.5.1 General considerations 45
7.5.2 Challenge test pack 45
7.5.3 Installation testing 46
7.5.4 Routine biological monitoring 48
7.5.5 Microbiological testing 50
7.6 Dynamic-air-removal sterilizer residual air test 51
7.6.1 Purpose 51
7.6.2 Frequency of use 51
7.6.3 Test pack composition 51
7.6.4 Test pack placement 52
7.6.5 Test procedure 52
7.6.6 Acceptance criteria 52
7.7 Product release 53
7.8 Product testing 54

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST46:2002, Steam sterilization and sterility assurance in health care facilities
Single user licence only. Copying, networking and distribution prohibited.

7.9 Product recalls 54
7.9.1 General considerations 54
7.9.2 Recall procedure 55
7.9.3 Recall order 55
7.9.4 Recall report 55

8 Quality process improvement 55

8.1 General rationale 55
8.2 Quality process 55
8.3 Functional areas for product and process improvements 56
8.3.1 Workplace design 56
8.3.2 Processing policies and procedures 56
8.3.3 Product use 56
8.4 Implementing product and process improvements 57

Annexes

A Examples of workplace design 58

B Development and qualification of the 16-towel biological indicator challenge test pack 64

C Example of documentation of premature release of implants 73

D Bibliography 75

Tables

1 Saturated steam pressure conversion units at sea level 5

2 Typical limiting values of contaminants of steam and/or water in contact with product and/or product packaging* 11

3 Ventilation requirements for functional areas 12

4 IES-recommended illuminance levels for work environments 14

5 Minimum cycle times for gravity-displacement steam sterilization cycles* 36

6 Minimum cycle times for dynamic-air-removal steam sterilization cycles* 36

B.1 16-towel pack survey 65

B.2 Biological indicator results from 250 °F gravity cycle 67

B.3 Biological indicator results from 270 °F deep-vacuum cycle 68

B.4 Biological indicator results from 270 °F pulsing vacuum cycle 68

B.5 Comparison of the 16-towel pack with the 12 in × 12 in × 20 in pack by Most Probable Number and sterility assessment of spore strips (250 °F gravity cycle)* 70

B.6 Fraction-negative results in a 250 °F gravity cycle* 70

B.7 Biological indicator results from 250 °F steam-flush pressure-pulse cycle* 71

B.8 Biological indicator results from 270 °F steam-flush pressure-pulse cycle* 71

Figures

1 Functional work areas of a sterile processing department 7

2 Work flow in a sterile processing department 9

3 Sequential double-wrapping: Envelope fold 27

4 Sequential double-wrapping: Square fold 28

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST46:2002, Steam sterilization and sterility assurance in health care facilities

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5 Simultaneous double-wrapping: Envelope fold 29

6 Simultaneous double-wrapping: Square fold 30

7 Example of single- and double-packaging with paper/plastic pouches 31

8 Loading the sterilizer 34

9 Preparation of the 16-towel BI test pack 46

10 Placement of the 16-towel BI test pack for installation testing 48

11 Placement of the 16-towel BI test pack for routine biological monitoring 49

12 Composition of the Bowie-Dick test pack 52

13 Placement of the Bowie-Dick test pack 53

A.1 Example of a work area design and work flow pattern for a sterile processing department in a typical small hospital 58

A.2 Example of a work area design and work flow pattern for a sterile processing department in a typical medium-sized hospital 59

A.3 Example of a work area design and work flow pattern for a sterile processing department in a typical regional processing center 60

A.4 Example of a work area design and work flow pattern for a sterile processing department 61

A.5 Example of a work area design and work flow pattern for a sterile processing department 62

A.6 Example of a work area design and work flow pattern for a sterile processing department 63

B.1 Temperature profiles for two different configurations of 12 in × 12 in × 20 in packs in a 250 °F gravity cycle 65

B.2 Temperature profiles for huck and absorbent 16-towel packs in a 250 °F gravity cycle 66

B.3 Average temperature profile for the 16-towel pack in a 250 °F gravity cycle 67

C.1 Implantable devices load record 73

C.2 Exception form for premature release of implantable device/tray 74

Documents
Document Sharing Hub

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

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Foreword

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

The first edition of this document, then titled *Good hospital practice: Steam sterilization and sterility assurance*, was approved and published in January 1980 under the designation "AAMI ST1—1980." The second edition, designated AAMI SSSA—1988, was published in 1988; the third, "ANSI/AAMI ST46," in 1993. The current (fourth) edition of the recommended practice reflects new technical data that has come to light since the third edition was published.

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 toward desirable performance objectives, and all of its provisions should be considered and applied in the light of professional judgment and experience.

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

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

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 1110 North Glebe Road, Suite 220, Arlington, VA 22201-5762.

NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST46:2002), but it does provide important information about the development and intended use of the document.

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Introduction: Need for the recommended practice

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

The delivery of sterile health care products for use in patient care depends not only on the efficacy of the sterilization process itself, but also on efficient facility design, proper training of personnel, good infection control practices designed to prevent health care-associated infections, and effective quality control and process improvement systems that encompass all aspects of device reprocessing from point of use through sterilization to reuse.

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. In addition, this recommended practice introduces the concepts of quality systems and process validation, but is not intended to provide comprehensive guidance on these subjects.

NOTE—Quality systems and parametric release of sterilized items are addressed in detail by ISO 13683 and other international standards.

Many activities that affect sterilization processing take place outside of the central service department. Therefore, the policies and procedures governing sterilization processing should be developed in consultation with the managers of departments that use medical devices and with appropriate hospital committees (e.g., safety, hazardous materials, risk management, infection control). In addition, the support of the hospital administration is vital, especially in those facilities where the establishment of a quality system to implement steam sterilization process validation and parametric release is being considered.

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

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Steam sterilization and sterility assurance in health care facilities

1 Scope

1.1 General

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

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

1.2 Inclusions

This recommended practice specifically addresses

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

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

c) processing recommendations;

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

e) quality control; and

f) quality process improvement.

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

1.3 Exclusions

This recommended practice does not cover

a) specific construction and performance criteria for steam sterilizers (see ANSI/AAMI ST8 and ANSI/AAMI ST55);

b) the use of table-top steam sterilizers (see ANSI/AAMI ST42);

c) steam sterilization processing by the "flash" method (see ANSI/AAMI ST37);

d) the laundering of reusable surgical textiles (see ANSI/AAMI ST65); or

e) the reprocessing of devices labeled for single use only (see FDA 2000).

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

2 Definitions, symbols, and abbreviations

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

2.2 asepsis: Absence of pathogenic microorganisms.

2.3 bioburden (bioload or microbial load): Population of viable microorganisms on a raw material, component, finished product, and/or package.

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

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

2.5 biological indicator (BI): Inoculated carrier contained within its primary pack ready for use and providing a defined resistance to the specified sterilization process.

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

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

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

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

2.8 challenge test pack: Pack used in qualification, installation, and routine quality assurance testing of hospital sterilizers.

2.9 chemical indicator (CI): System that reveals a change in one or more predefined process parameters based on a chemical or physical change resulting from exposure to a process.

NOTE—Chemical indicators are intended to detect potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a chemical indicator does not prove that the item accompanied by the indicator is sterile.

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

> **Class 1 (process indicator):** Chemical indicator intended for use with individual units (e.g., packs, containers) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.
>
> **Class 2 (Bowie-Dick test indicator):** Chemical indicator designed for use in a specific test procedure (e.g., the Bowie-Dick test).
>
> **Class 3 (single-parameter indicator):** Chemical indicator designed to react to one of the critical parameters of sterilization and to indicate exposure to a sterilization cycle at a stated value of the chosen parameter.
>
> **Class 4 (multi-parameter indicator):** Chemical indicator designed to react to two or more of the critical parameters of sterilization and to indicate exposure to a sterilization cycle at stated values of the chosen parameters.
>
> **Class 5 (integrating indicator):** Chemical indicator designed to react to all critical parameters over a specified range of sterilization cycles and whose performance has been correlated to the performance of the stated test organism under the labeled conditions of use.

See also 7.4.2.2.

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

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

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

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

2.13 cycle, steam sterilization, dynamic-air-removal type: Type of sterilization cycle in which air is removed from the chamber and the load by means of pressure and vacuum excursions or by means of steam flushes and pressure pulses.

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NOTE 1—In prevacuum steam sterilizers, the dynamic-air-removal cycle depends on one or more pressure and vacuum excursions at the beginning of the cycle to remove air. This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system and because of the usually higher operating temperatures (270 °F to 275 °F [132 °C to 135 °C]). This type of cycle generally provides for shorter exposure times and accelerated drying of fabric loads by pulling a further vacuum at the end of the sterilizing cycle.

NOTE 2—In steam-flush pressure-pulse steam sterilizers, the dynamic-air-removal cycle depends on a repeated sequence consisting of a steam flush and a pressure pulse to remove air from the sterilizing chamber and processed materials. As is the case with prevacuum sterilizers, the dynamic-air-removal cycle of a steam-flush pressure-pulse sterilizer rapidly removes air from the sterilizing chamber and wrapped items. Air removal is achieved with the sterilizing chamber pressure at above atmospheric pressure (no vacuum is required to remove air for sterilization). Typical operating temperatures are 250 °F to 254 °F (121 °C to 123 °C) and 270 °F to 275 °F (132 °C to 135 °C).

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

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

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

2.16 cycle time: Total elapsed time of a sterilization cycle from the time the process is initiated until the cycle is completed. Cycle time may include heat-up time, exposure time, come-down time, cooling or drying time, and, on appropriate equipment, pre- and postvacuum time.

2.17 decontamination: According to the Occupational Safety and Health Administration (OSHA), "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal." [29 CFR 1910.1030]

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

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

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

2.20 dust cover: Protective plastic bag used to maintain the sterility of an item by protecting it from the environment; also known as a sterility maintenance cover. Usually made of polyethylene in 2 mil to 3 mil thickness, the dust cover protects the item from being exposed to moisture, dust, lint, and other contaminants.

2.21 entrainment: Collecting or transporting of solid particles or a second fluid or vapor by the flow of the primary fluid or vapor at high velocity.

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

2.22 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.

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

2.24 exposure time: Period of time during a sterilization process in which items are exposed to the sterilant at the specified sterilization parameters.

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

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

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

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

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

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

2.30 health care products: Medical devices, medicinal products (pharmaceuticals and biologics), and *in vitro* diagnostics.

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

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

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

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

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

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

NOTE—According to the U.S. Food and Drug Administration, labeling includes any literature provided with a device, as well as all advertising claims published by the manufacturer.

2.36 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.

2.37 lux: One-tenth of a footcandle.

2.38 medical device: Instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is

1) recognized in the official *National Formulary*, or the *United States Pharmacopeia*, or any supplement to them;

2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or

3) intended to affect the structure or any function of the body of man or other animals; and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. (21 U.S.C. 321[h])

2.39 medium: See **culture medium**.

2.40 microorganisms: Animals or plants of microscopic size.

NOTE—As used in health care, the term generally refers to bacteria, fungi, viruses, and bacterial spores.

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

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

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

2.44 OSHA: Occupational Safety and Health Administration.

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

2.46 parametric release: Declaring a product is sterile, based on physical and/or chemical process data rather than on the basis of sample testing or BI results.

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NOTE—Use of this term is generally restricted to sterilization processes that have gone through a complete validation process (installation qualification, operational qualification, and performance qualification, with appropriate documentation and review).

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

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

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

2.49 preconditioned: Held at room temperature (68 °F to 73 °F [20 °C to 23 °C]) and at a relative humidity ranging from 30 % to 60 % for a minimum of 2 hours.

2.50 processing area: Area of a health care facility in which decontaminated, clean instruments and other medical and surgical supplies are inspected, assembled into sets and trays, and wrapped, packaged, or placed into container systems for subsequent sterilization. This area is commonly referred to as the "preparation and packaging area" if it is part of central service and as a "pack room" if textile packs are assembled there.

2.51 pounds per square inch absolute (psia): Other units of saturated pressure are pounds per square inch gauge (psig) and kiloPascals (kPa). Typical values of saturated pressure for steam sterilization are given in Table 1.

Table 1—Saturated steam pressure conversion units at sea level

psia	psig	kPa
29.8	15.1	205.8
41.9	27.2	288.6
45.4	30.7	313.2
53.3	38.6	367.6

2.52 pyrogen: Fever-producing substance.

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

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

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

2.55 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.

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

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

2.58 steam quality: Weight of dry steam present in a mixture of dry saturated steam and entrained water.

NOTE—The dryness fraction should not fall below 97 %.

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

2.60 sterile: State of being free from all living microorganisms.

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

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

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2.62 sterilization: Process used to render a product free from viable microorganisms.

NOTE—In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

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

2.64 sterilization cycle: See **cycle**, **sterilization**.

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

2.66 sterilizer, steam: Sterilizing apparatus that uses saturated steam under pressure as the sterilant.

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

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

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

3 Design considerations

3.1 General rationale

This section provides guidelines for the design and maintenance of the workplace to facilitate effective and efficient processing and personnel safety, minimize environmental contamination, and maintain the sterility of processed items. Whenever possible, centralized sterilization processing (i.e., sterilization processing in one department) is encouraged. Sterilization is a complex process requiring sophisticated equipment, adequate space, qualified personnel who are provided with ongoing training, and continuous 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 may 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.

3.2 Work area design and functional work flow

3.2.1 Definitions of work areas

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

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

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

c) **Decasing/breakout area:** The area where products are removed from their external shipping containers prior to entry into the preparation and packaging area or sterile storage area.

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

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

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

g) **Sterilization area(s):** The area(s) where sterilizers (steam, EO, and/or low-temperature gas plasma) are located, including the space for loading, unloading, and lining up carts and for cool-down.

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

h) **Sterile storage areas:** The areas of the health care facility designed to store clean and sterile items.

i) **Equipment and cart holding area:** The holding area for clean medical equipment and carts prior to storage or issue.

j) **Equipment storage area:** The area located within central service or elsewhere in the distribution system where clean medical equipment is stored until issued.

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

l) **Housekeeping equipment storage area:** The area where housekeeping items are stored. The decontamination area and "clean" areas should each have dedicated housekeeping storage areas.

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

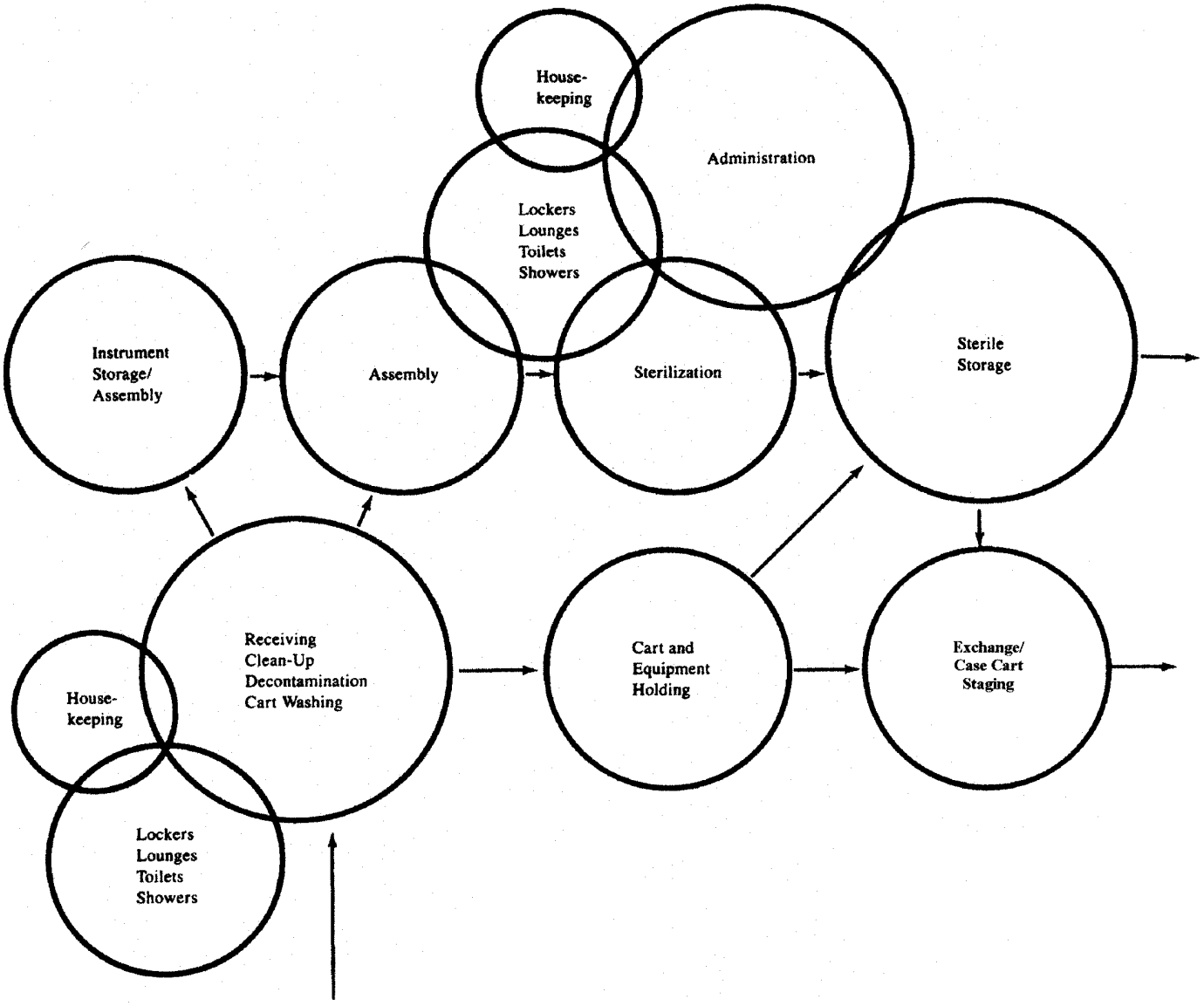


Figure 1—Functional work areas of a sterile processing department

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3.2.2 Design criteria

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

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

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

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

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

e) the anticipated inventory storage;

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

g) the method of requisition/dispatch to be used;

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

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

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

k) the amount of space needed for infectious waste management;

l) the type of documentation system to be used (manual versus computerized); and

m) electronic and communication needs.

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

3.2.3 Functional work flow patterns

The central processing department should be designed to separate areas in which contaminated items are received and processed from areas in which clean items are packaged, sterilized, and stored. Work area design also should allow adequate space for all functions, and should promote efficiency by minimizing distances between related areas. Figure 2 is a general schematic of appropriate work flow. Annex A provides examples of work area design and work flow patterns in central service departments 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. These figures relate to hospital workplaces. For examples of workplace designs for ambulatory-care and office-based facilities, see ANSI/AAMI ST42.

Rationale: Separating “clean” and “dirty” areas limits environmental contamination and, therefore, the potential for bioburden on devices to be sterilized.

3.2.4 Traffic control

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

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

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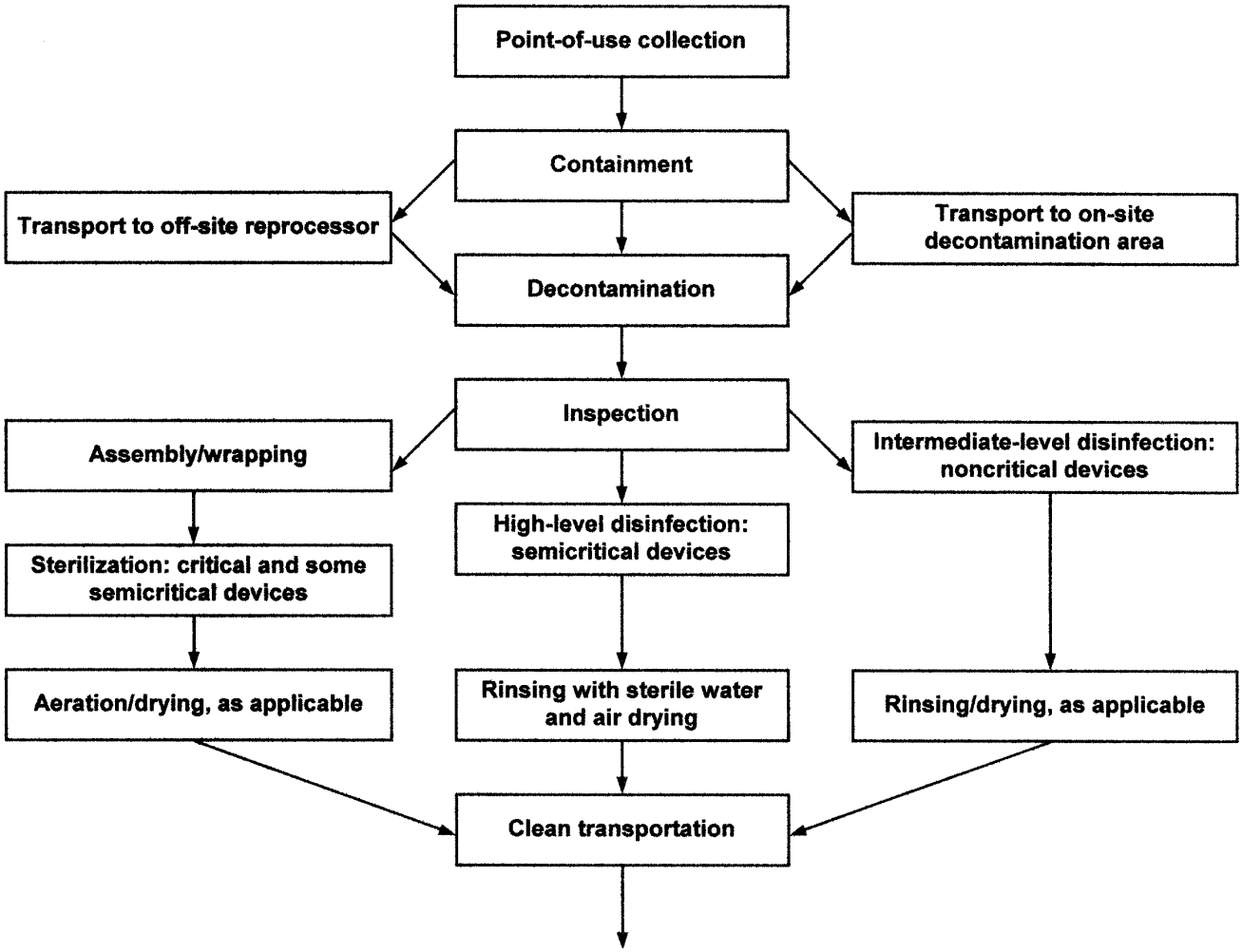


Figure 2—Work flow in a sterile processing department

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3.3 Physical facilities

3.3.1 Space requirements

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

Rationale: Space requirements may vary significantly, depending on the specific processing needs of the health care facility, and often are underestimated during the planning process.

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3.3.2 Mechanical systems

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

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

3.3.3 Electrical systems

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

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

3.3.4 Steam for sterile processing

3.3.4.1 General

There are two common sources for steam used for sterile processing: hospital steam boiler systems and self-contained packaged steam generators. Each system should be designed, monitored, and maintained to ensure that the quality, purity, and quantity of the steam provided is appropriate for effective sterile processing. In certain circumstances, "house" steam from hospital steam boiler systems might not be acceptable for sterile processing due to the design of the overall system and the type and method of use of boiler feedwater treatment chemicals.

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

3.3.4.2 Steam quality

Steam systems should be designed to ensure that the steam delivered to the sterilizer is saturated steam having a steam quality of 97 % to 100 %. These conditions require an adequate steam capability, appropriately placed steam traps, and insulated steam lines, especially in situations where the steam is generated in a location remotely located from the sterilizer. 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 and boilers/generators in good working order, and periodically assessing products for the presence of "wet packs." In some circumstances, a steam separator may be used to remove entrained water and increase the degree of steam saturation. If used, such a separator should be placed in the steam supply piping as close as possible to the sterilizer.

Rationale: Steam of poor quality can contribute to wet packs and suboptimal steam sterilization cycles that might not be identified by biological monitoring.

3.3.4.3 Steam purity

The boiler feedwater source, treatment chemicals used, and design/maintenance of the steam supply system should minimize the presence of potential contaminants in the steam. The feedwater should be treated so that its condition and/or chemistry does not damage the boiler or steam lines. Boiler additives and feedwater conditioners should be monitored. The use of such compounds on a batch basis is not recommended for sterile processing applications. It is recommended that only additives and conditioners approved for use in the food industry be used (21 CFR 173.310). Steam lines should be designed to eliminate the presence of "dead legs," which can harbor/propagate contaminants, including microorganisms. Procedures to monitor steam purity and, when necessary, provide corrective action should be established and performed on a regular basis. If necessary, there are in-line filters that can be used to remove particulate matter such as scaling that may occur as systems age. When used, they should be installed as close to the sterilizer as possible. The purity of the steam should meet or exceed the recommendations in ISO 13683 (see Table 2).

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

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Table 2—Typical limiting values of contaminants of steam and/or water in contact with product and/or product packaging*

evaporate residue	≤ 15 milligrams/liter (mg/L)
silica	≤ 2 mg/L
iron	≤ 0.2 mg/L
cadmium	≤ 0.005 mg/L
lead	≤ 0.05 mg/L
rest of heavy metals	≤ 0.1 mg/L
chloride	≤ 3 mg/L
phosphate	≤ 0.5 mg/L
conductivity	≤ 50 microsiemens/centimeter
pH	6.5 to 8
appearance	colorless, clean, without sediment
hardness	≤ 0.1 mmol/L

* Reproduced from Table A.1 of ISO 13683.

3.3.4.4 Steam quantity

Steam demand requirements and the corresponding necessary capacity should be determined in order to design and build a system to meet peak demands of the facility. This information should be used to ensure that the minimum pressure required to properly operate the sterilizer(s) is available at all times and under all conditions of steam demand.

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

3.3.4.5 Monitoring steam systems

Procedures to maintain (preventive maintenance and repair), monitor, and document corrective action should be in place to ensure correct operation of the boilers and/or steam generators used for sterile processing. The monitoring/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.

3.3.5 General area requirements

NOTE—Unless otherwise stated in 3.3.6, all processing work areas should conform to the following recommendations.

3.3.5.1 Floors and walls

Floors and walls should be constructed of materials that will withstand wet cleaning. These materials should not be of a particulate- or fiber-shedding composition.

Rationale: All processing areas should be cleaned periodically (see 3.4) to control microbial contamination and eliminate accumulated dust, which may act as a carrier for microorganisms. Accordingly, the materials of construction of floors and walls should be able to withstand frequent cleaning and should not be adversely affected by the chemical agents typically used for cleaning.

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3.3.5.2 Ceilings

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

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

3.3.5.3 Ventilation

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

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

Table 3—Ventilation requirements for functional areas

Functional area	Air flow	Minimum number of air exchanges per hour (ANSI/AAMI ST46)	Minimum number of air exchanges per hour (AIA 2001)	All air exhausted directly to the outdoors?
Soiled/decontamination	Negative (in)	10	6	Yes
Sterilizer equipment access	Negative (in)	10	10	Yes
Sterilizer loading/unloading	Positive (out)	10	–	Yes
Restrooms/housekeeping	Negative (in)	10	10	Yes
Preparation and packaging	Positive (out)	10, downdraft type	4	No
Textile pack room	Positive (out)	10, downdraft type	–	No
Clean/sterile storage	Positive (out)	4, downdraft type	4	No

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

Except for exhaust fans on ventilation systems and properly installed and operated fume control hoods, neither fixed nor portable fans should be permitted in any area of central service. Other aspects of ventilation should comply with the guidelines set forth by the American Institute of Architects (AIA, 2001). See also American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) (1989) and ASHRAE (1995).

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

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

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

3.3.5.4 Temperature

General work areas should have a temperature controlled between 68 °F and 73 °F (20 °C and 23 °C). The decontamination area should have a temperature controlled between 60 °F and 65 °F (16 °C and 18 °C). The temperature in sterilization equipment access rooms should be controlled between 75 °F and 85 °F (24 °C and 29 °C) or as recommended by the equipment manufacturer. The temperature in sterile storage and personnel support areas (e.g., toilets, showers, locker rooms) may be as high as 75 °F (24 °C).

Rationale: Work areas should be comfortable for properly attired personnel. Comfort is a particular consideration in the decontamination area, where personal protective equipment (PPE) is worn for long periods of time and where temperatures suitable for general work areas may be uncomfortably hot. Although AIA allows the temperature in clean work areas to be as high as 75 °F (24 °C) (AIA, 2001), the consensus of the AAMI committee was to recommend consistent temperature ranges for all general work areas. Relative humidities higher than those recommended can promote microbial growth, especially molds, on environmental surfaces and thus increase bioburden. Controlling the temperature in sterilization equipment access rooms promotes higher efficiency of the equipment contained within the enclosures. For additional information on temperature control, refer to AIA (2001).

3.3.5.5 Relative humidity

Relative humidity should be controlled between 30 % and 60 % in all work areas except the sterile storage area, where the relative humidity should not exceed 70 %.

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

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

Rationale: Relative humidities higher than those recommended can promote microbial growth and thus increase bioburden. Relative humidity lower than 30 % will permit absorbent materials to become excessively dry, which can adversely affect certain sterilization parameters (such as steam penetration) and the performance of some products (such as BIs and CIs). Thus, for best results, the committee recommends an ideal relative humidity level of 50 % and a minimum level of 35 %. The recommended range for relative humidity was largely based on AIA (2001).

3.3.5.6 Lighting

Adequate lighting at work surfaces should be provided in accordance with the engineering practices outlined in Rea (1993), which describes the recommendations of the Illuminating Engineering Society of North America (IES) for minimum levels of illuminance for various categories of work environments (see Table 4).

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Table 4—IES-recommended illuminance levels for work environments

Work area/function	Least illuminance	Average illuminance	Highest illuminance
General inspection	500 lux (50 footcandles)	750 lux (75 footcandles)	1000 lux (100 footcandles)
Detailed inspection	1000 lux (100 footcandles)	1500 lux (150 footcandles)	2000 lux (200 footcandles)
Sink areas	500 lux (50 footcandles)	750 lux (75 footcandles)	1000 lux (100 footcandles)
General work areas	200 lux (20 footcandles)	300 lux (30 footcandles)	500 lux (50 footcandles)
Processed storage	200 lux (20 footcandles)	300 lux (30 footcandles)	500 lux (50 footcandles)

The three levels of lighting for each category were calculated based on:

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

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

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

Not mentioned in the IES recommendations, but factors of importance when considering the lighting in the central service department, are the large areas of stainless steel surfaces found in sterile processing areas. The amount of stainless steel that one expects to find in a processing area is great enough to turn a warm color cool. Therefore, the type of fluorescent lighting (cool or warm), the color of the walls (white, light warm colors, or dark colors), and the type and color of work surfaces (stainless steel, shiny formica-type, matte formica-type) will affect the type and amount of illuminance required.

A qualified illumination engineer, in consultation with the department manager, should determine the appropriate illuminance for each functional area within the processing department. Generally, all functions performed within a processing department require detailed inspection and accuracy. Ancillary lighting should be considered for manual cleaning and instrument inspection areas.

Lighting fixtures should be selected and mounted in positions that will ensure that the light is focused in front of the employee, thereby eliminating the possibility that employees are working in their own shadows.

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

3.3.5.7 Handwashing facilities

Handwashing facilities should be conveniently located and designed to allow good handwashing practices. They should be located in or near all areas in which instruments and other devices are decontaminated and prepared for sterilization, as well as in all personnel support areas. The installation of hands-free-operated equipment (e.g., foot controls, electronic sensors) for use with sinks, soap dispensers, and towel dispensers should be considered during the design of new facilities. If hands are not visibly soiled, hands may be decontaminated with alcohol-based, waterless, hand hygiene agents, which should be made available to health care personnel.

Rationale: Adequate handwashing facilities will facilitate hand decontamination by appropriate handwashing. Hands should be washed when visibly soiled. The use of alcohol-based, waterless agents is an effective means of hand decontamination when hands are not visibly soiled. Such agents have been shown to decrease dryness and irritation associated with traditional handwashing. Additionally, increased availability of these agents in the work area can contribute to increased compliance with hand decontamination. Therefore, both traditional handwashing and hand hygiene should be encouraged to reduce the risk of transmission of microorganisms via the hands. Hands should be decontaminated after gloves are removed for any reason, after the removal of other PPE, and in accordance with good personal hygiene practices and departmental policy. Hands-free-operated equipment helps personnel avoid

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