List of Titles

American National Standard

ANSI/AAMI ST46:2002

Steam sterilization and sterility assurance in health care facilities

AAMI Association for the Advancement of Medical Instrumentation

The Objectives and Uses of AAMI Standards and Recommended Practices

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

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

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

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

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

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

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List of Titles

American National Standard

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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Association for the Advancement of Medical Instrumentation

AAMI Sterilization Standards Committee

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

Acknowledgments

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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.

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.

American National Standard ANSI/AAMI ST46:2002

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.

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.

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.

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.

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.

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.

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.

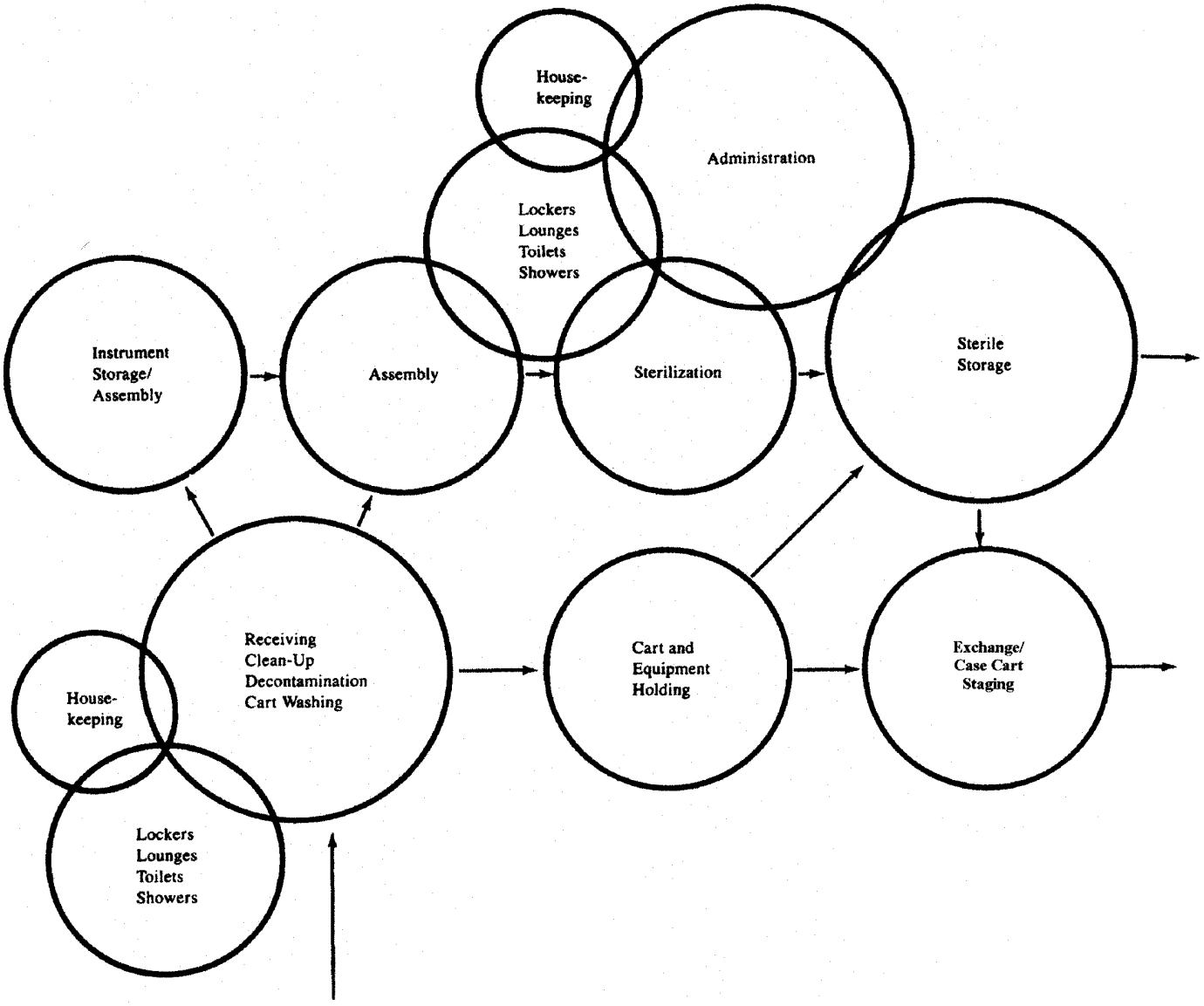


Figure 1—Functional work areas of a sterile processing department

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.

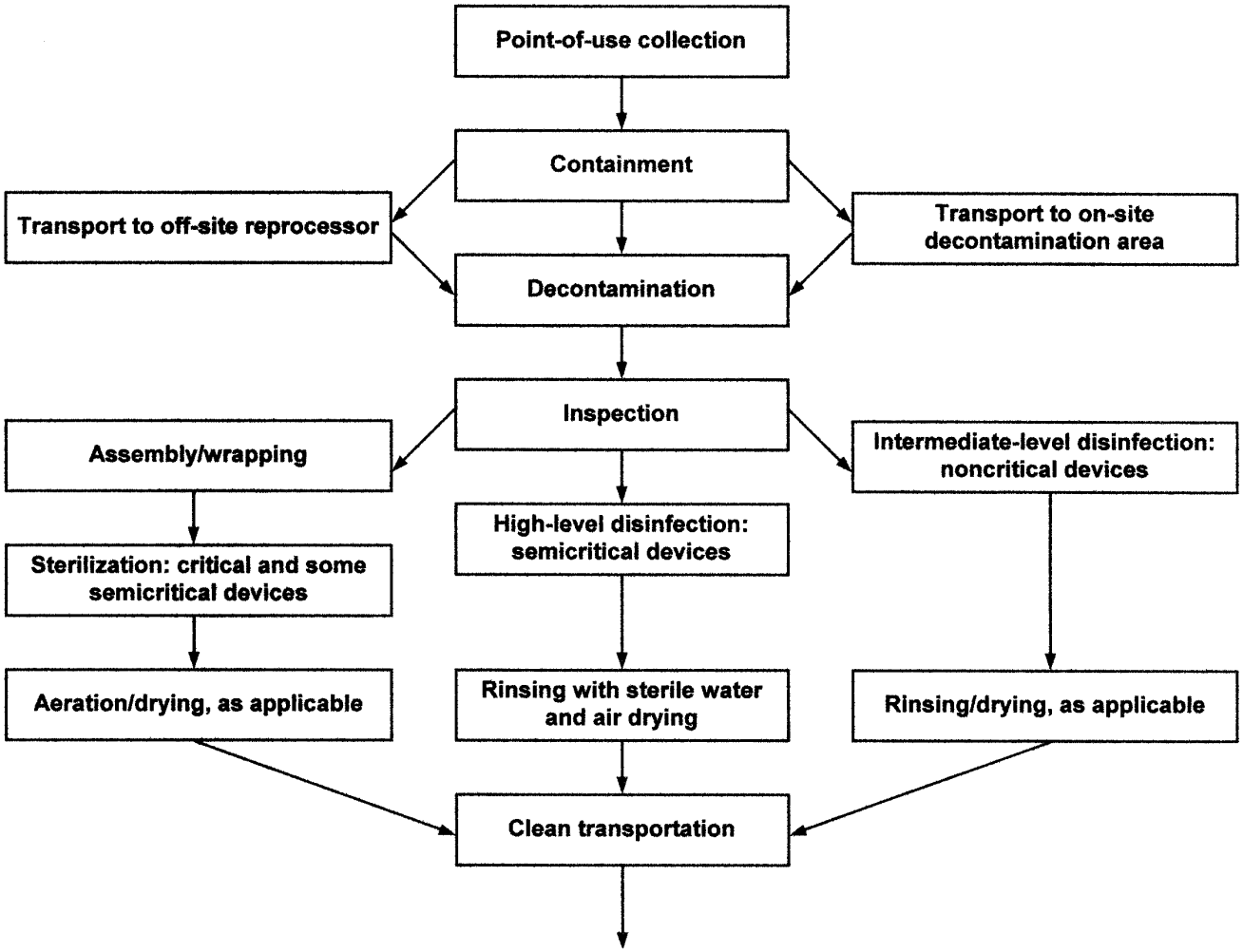


Figure 2—Work flow in a sterile processing department

With the permission of CSA International, this material (Figure 2) is reproduced from CSA Z314.8-00, *Decontamination of Reusable Medical Devices*, which is copyrighted by CSA International, 5060 Spectrum Way, Mississauga, Ontario, L4W 5N6, Canada. While use of this material has been authorized, CSA International shall not be responsible for the manner in which the information is presented, nor for any interpretations thereof.

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.

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.

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.

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.

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).

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

touching faucet handles, soap dispensers, or towel dispensers with their hands, thus minimizing microorganism transfer among patients, personnel, and inanimate objects.

3.3.6 Special area requirements and restrictions

3.3.6.1 Decontamination area

The decontamination area should be physically separate from all other areas of the processing department and accessible from a service corridor. The floor, walls, ceiling, and work surfaces should be constructed of nonporous materials that will withstand frequent cleaning and wet conditions (see 3.4). All air from the decontamination area should be exhausted to the outdoors without recirculation (see 3.3.5.3 and AIA, 2001).

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

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

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

c) soiled linen hampers;

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

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

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

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

h) handwashing facilities.

The decontamination area should have an emergency eyewash/shower station (3.3.7). A door should provide access to the preparation area; a pass-through window is also convenient for delicate instrumentation and water-sensitive equipment that have been manually cleaned.

An ideal decontamination sink is approximately 36 inches (in) (91 cm) from the floor and 8 in to 10 in (20 cm to 25 cm) deep, enabling a person of average size to work comfortably without undue strain on his or her back; foot stools should be kept on hand to accommodate shorter employees. The sink also should be of a width and length to allow a tray or container basket of instruments to be placed flat for pretreatment or manual cleaning. The sink should be constructed with three sections (for soaking, washing, and rinsing) and should have water ports to facilitate the flushing of instruments with lumens.

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

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

Designing the area to facilitate proper workflow and provide adequate space for necessary equipment reduces the potential for cross-contamination and enhances efficiency. For the rationale for the emergency eyewash/shower station, see 3.3.7.

The design and location of sinks can facilitate proper cleaning and employee safety. Sinks located too high or too low increase the risk of back injury or strain. Sinks that are too deep may present the risk of a sharps injury. However, sinks should be deep enough to allow items to be cleaned beneath the surface of the water.

3.3.6.2 Preparation area

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

Preparation of textile packs and individual wrapped textiles, when performed in the preparation area, should be carried out in an enclosed space separate from the remainder of the preparation area. The air flow should be of a downdraft type, and the number of air exchanges per hour should be sufficient to minimize lint particles in the air (3.3.5.3). There should be sufficient space for clean textile storage (both before and after assembly into packs), an illuminated inspection table, and patching equipment. For additional information, see ANSI/AAMI ST65.

If uncased bulk supplies for processing trays, sets, and single items are maintained in a separate, enclosed area, this area also should conform to the recommendations of 3.3.5.3.

The preparation area should include space for

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

b) computers, if used;

c) incubators for BIs;

d) magnifying lights;

e) heat sealers;

f) instrument storage and repair boxes;

g) transfer carts;

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

i) a station for instrument lubrication.

Rationale: Lint and airborne particles can carry microorganisms. A relatively lint-free environment is also important to the comfort and safety of employees. Because bulk supplies will be used to prepare items for sterilization, they should be stored in an environment that limits potential contamination. Providing adequate space for supplies and equipment and designing the layout to facilitate the flow of work through the various steps of preparation contributes to the efficiency and accuracy of the sterile processing staff. See also 3.3.5.3.

3.3.6.3 Sterilization area

The sterilization area should be adjacent to the preparation and packaging area. Material should flow from the preparation and packaging area to the sterilization area and then on to storage or distribution. The floors, walls, and ceiling surfaces should be constructed of nonporous material that will withstand frequent cleaning and wet conditions (see also 3.3.5.1 and 3.3.5.2). Adequate space should be allowed for sterilizers and aerators; the staging and loading of sterilizer carts; the storage of long, heat-resistant gloves, sterilizer cleaning supplies, and record-keeping supplies; and handwashing facilities.

All air from the sterilizer access area should be exhausted to the outdoors (3.3.5.3). Air intake or return ducts should not be located in the area designated for cool-down.

NOTE—If EO sterilizers and other chemical sterilants are used in the same area as steam sterilizers, the area must be designed and engineering controls 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 and balanced to provide controlled, directional air flow from the sterilization area to the access area, both to remove EO and other air contaminants and to minimize contaminants in the area (AIA, 2001). The air exhausted from EO sterilizers could expose personnel to excessive levels of EO. See also ANSI/AAMI ST41.

3.3.6.4 Sterile storage

The sterile storage area should be located adjacent to the sterilization area, preferably in a separate, enclosed, limited-access area, the only function of which is to store sterile and clean supplies. The storage system (e.g., open wire shelves, open solid shelves, or closed cabinets) should be selected based on 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. The ventilation system should be designed so that air flows out of the sterile storage area via positive pressure. Other aspects of ventilation should comply with the guidelines set forth in AIA (2001) for OR environments.

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

3.3.7 Emergency eyewash/shower equipment

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

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

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

3.4 Housekeeping procedures

Housekeeping procedures in areas used for any aspect of decontamination, preparation, or sterilization should be the same as those used to clean operating and delivery rooms. At least daily, floors and horizontal work surfaces should be cleaned. Other surfaces, such as walls, storage shelves, and air intake and return ducts, should be cleaned on a regularly scheduled basis and more often if needed. Care should be taken to avoid compromising the integrity of packaging during cleaning procedures. Special attention should be paid to the sequence of cleaning, to avoid transferring contaminants from “dirty” to “clean” areas and surfaces. It is good practice to provide separate housekeeping facilities for the decontamination and clean areas.

Rationale: Cleaning reduces microbial growth and thus reduces potential transmission of microorganisms.

4 Personnel considerations

4.1 General rationale

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

4.2 Qualifications

4.2.1 Supervisory personnel

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

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

NOTE—Information concerning certification of central service processing managers and technicians can be obtained from the National Institute for the Certification of Healthcare Sterile Processing and Distribution Personnel (P.O. Box 558, Annandale, NJ 08801; 800-555-9765; www.sterileprocessing.org); the International Association of Healthcare Central Service Materiel Management (213 Institute Place, Suite 307, Chicago, IL 60610; 312-440-0078; www.iahcsmm.com); or the National Health Information Center (P.O. Box 1133, Washington, DC 20013; www.health.gov/nhic/).

b) adequate relevant experience; and

c) participation in continuing education programs and courses, including programs on federal and local regulations, personnel and material management programs, and courses directly related to the central service management position with special emphasis on infection control, safety, and the principles and methods of decontamination, preparation, sterilization, sterile storage, and distribution of sterile medical devices.

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

a) participate in facility and departmental inservice and training programs; and

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

Rationale: Steam sterilization is a complex process that should be supervised by knowledgeable personnel with relevant hospital experience, especially in sterilization processing and infection control.

4.2.2 Sterilization processing personnel

The responsibility for steam sterilization should be assigned to one or more qualified individuals on each shift. Among the qualifications for assuming this responsibility are

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

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

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

NOTE—It is recommended that all personnel performing steam sterilization activities be certified as a condition of employment. As a minimum, all such personnel should successfully complete a central service certification examination within 2 years of employment.

Rationale: Sterilization processing personnel are responsible for sterilization of items used in hospitals. These responsibilities could include, but are not limited to, decontamination, preparation, packaging, inspection, sterilization, and the handling of items after sterilization. Also, sterilizers present potential hazards to personnel. Therefore, to ensure both effective processing and their own safety, personnel should be knowledgeable about and competent in related principles and practices.

4.3 Training and continuing education

4.3.1 Central service personnel

Personnel engaged in steam sterilization processing and operators of steam sterilizers should receive both an initial orientation and on-the-job training. This training should include instruction on sterilizer operation and the parameters of steam sterilization, basic microbiological principles, and the institution's infection control policies and procedures. In addition, there should be ongoing continuing education at regular intervals to review and update worker knowledge and skills and maintain their competency and certification. Personnel training and continuing education should be documented.

Rationale: Orientation training, on-the-job training, and continuing education decrease the possibility of operator error during preparation and sterilization processing and help ensure that personnel are conversant with the latest data and techniques. Also, such training is required by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO, 2001).

4.3.2 Other personnel

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

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

4.4 Health and personal hygiene

Written policies on personal hygiene should be developed and communicated to employees. Handwashing procedures should be specified. Hair, body, and nails should be clean at all times. The use of nail polish or artificial nails should be avoided. Uniforms or other garments that become soiled or wet during wear should be changed immediately. In collaboration with the institution's infection control committee, the department should establish a written policy on the reporting, treatment, and disposition of employees who are at risk of acquiring or transmitting infections.

Rationale: Careful attention to personal hygiene will minimize the potential for acquiring or transmitting disease. Nail polish can flake off, and the flakes can get into items being prepared. Artificial nails can promote the growth of fungus under the nails.

4.5 Attire

4.5.1 General

All personnel working in the decontamination, preparation, sterilization, and sterile storage areas should wear clean, facility-provided uniforms that are donned at the facility. Attire should be changed daily or more often as needed (i.e., when wet, grossly soiled, or visibly contaminated with blood or body fluids). If reusable, uniforms visibly contaminated by blood or body fluids must be laundered in the laundry facility/area designated by the health care facility for the decontamination of reusable surgical textiles (see ANSI/AAMI ST65). Reusable uniforms that are not visibly contaminated by blood or body fluids should be laundered in accordance with facility policy.

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

Rationale: Appropriate, clean attire minimizes the introduction of microorganisms and lint from personnel to items being processed and 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. The question of where nongrossly contaminated garments should be laundered is currently unresolved; there is no scientific data supporting a mandate for either facility or home laundering. Thus, it is necessary for each health care facility to establish its own policy. When deciding whether to allow home laundering, the facility should carefully consider the degree to which the requirements for clean attire can be met by workers and policed by managers. Minimum criteria for home laundering (Garcia, 2001) include:

— As required by OSHA, uniforms with visible blood or body fluids must be laundered by the health care facility, not at home.

— Home laundering should utilize an automatic washer and hot-air dryer.

— While not absolutely necessary, the use of hot water (110 °F to 125 °F) is recommended in order to assist in the inactivation of microorganisms.

— Chlorine bleach should be used unless the manufacturer specifically recommends against it on the garment label. If chlorine bleach is contraindicated, then oxidizing bleaches such as those containing hydrogen peroxide should be used.

— As a matter of good personal hygiene, hands should be washed after placing laundry in the washer.

— Detergent should be used according to the manufacturer's recommendations.

— Uniforms should not be laundered with underwear, since underwear is a significant source of microorganisms.

— To facilitate removal of soil and microorganisms, uniforms should be completely submerged in the washer throughout the wash and rinse cycles.

— The door/lid of the washing machine should be kept clean and sanitary in order to reduce the possibility that laundered clothing will be contaminated upon removal from the washer.

Jewelry should not be worn because it is not easily or routinely cleaned daily, can harbor microorganisms, and can become dislodged and fall into processed items. Wristwatches and rings on fingers, in particular, can catch on equipment or instrumentation, causing personal injury or damage to the item or packaging.

4.5.2 Decontamination area

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

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

NOTE—The protective clothing should be made of liquid-proof materials if there is a possibility that attire can become soaked with blood or other potentially infectious material (as when items are being washed by hand).

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

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

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

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

5 Processing recommendations

5.1 General rationale

This section covers guidelines for processing medical devices before, during, and after sterilization. These guidelines apply to the reprocessing and resterilization of items intended for reuse. Work practices related to

preparing items for sterilization and selecting sterilization cycles should be developed to ensure effective sterilization. Work practices related to the handling, storage, and distribution of sterilized items should be developed to help ensure the maintenance of sterility.

5.2 Receiving

5.2.1 General considerations

Policies and procedures for the receipt of purchased items should be developed, implemented, and audited. Audits should be scheduled and documented. Sterility assurance "begins at the loading dock," i.e., at the point at which the health care facility assumes responsibility for incoming medical equipment, devices, and supplies. Therefore, sterility assurance measures should be used from the time that items are received into the health care facility until they are used. In particular, clean or sterile items should be handled separately from foodstuffs, waste material, soiled laundry, and other potential sources of contamination. To protect individual items, bulk items may be stored in shipping cartons in the central receiving area. Items to be transported to central processing and storage areas within the facility should be removed from their external shipping containers before they enter the sterile storage area of the department.

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

5.2.2 Newly purchased reusable items and repaired reusable items

Reusable surgical instruments require decontamination prior to sterilization. After they have been removed from their external shipping containers, such items should be inspected to ensure that they meet the required specifications, then transported directly to the decontamination area. The manufacturer's processing instructions should be followed.

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

5.2.3 Disposable items

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

Rationale: Sterile disposable items received from manufacturers are usually individually packaged for dispensing. Clean, nonsterile disposable items are usually packaged for sterilization, or they have been otherwise protected from contamination during transport. Clean, nonsterile 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. Items that have been opened or have damaged packaging should either be disposed of or unwrapped and reprocessed through decontamination in accordance with departmental policies and procedures and/or manufacturers' written instructions (see FDA, 2000).

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

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

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

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

5.4 Handling, collection, and transport of items previously used in patient care

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

All soiled, contaminated, reusable supplies, instruments, and devices should be handled as little as possible. Preferably, soiled items should be immediately contained and transported to the decontamination area, where cleaning procedures can best be accomplished by personnel protected by appropriate attire and experienced in decontamination procedures. In many health care facilities, however, immediate containment, transportation, and cleaning are not feasible, so gross soil is removed at the point of use.

Reusable items should be separated from waste at the point of use by personnel wearing protective attire such as gloves and a protective apron or gown. Sharps should be removed and placed into an appropriate container. Devices that have been in contact with blood, tissue, or other body fluids and will be reprocessed should be cleaned of gross debris at the point of use. Soil should be removed by a method that does not promote cross-contamination; for example, personnel should avoid splashing water and thereby contaminating attire, the area near the sink, and other surfaces in the environment. A disposable sponge moistened with water (not saline) should be used to wipe gross soil from instruments and devices. Gauze sponges and similar items used in the cleaning process should be handled, contained, and discarded according to the health care facility's policy for infectious waste. Items should be kept moist to prevent the drying of soil onto device surfaces during transfer to the decontamination area and prior to the decontamination process. Items can be kept moist in the transport container by adding a moist towel or a foam, spray, or gel product specifically intended for this use. To prevent the formation of biofilms, definitive cleaning should occur as soon as possible. If processing is delayed, attention should be given to minimizing bacterial proliferation, including the use of certain inhibitory disinfectants. Even with this step, extremely long delays in processing, such as might occur over a weekend, can result in the formation of tenacious and difficult-to-remove biofilms that will shield microorganisms from routine cleaning procedures and possibly interfere with disinfection or sterilization.

Contaminated items should be confined during transport from the point of use to the decontamination area. Containment may be accomplished by any means that adequately prevents inadvertent personnel contact with or exposure to the contaminated items during transfer. Containers should be selected based on the characteristics of the items being transported; in particular, containers should prevent spillage of liquids, if applicable. Bins with lids, enclosed or covered carts, closed sterilization container systems, and impermeable bags are among the types of containers that may be used to transport contaminated items. Reusable collection containers for holding contaminated supplies should be made of materials that can be decontaminated effectively; containers designed for single use should be made of materials that can be disposed of easily following use. All materials returned to the decontamination area should be considered contaminated and reprocessed or disposed of as such. See also ANSI/AAMI ST35.

Rationale: Used, soiled, contaminated instruments, devices, and supplies are sources of microorganisms that could cause infections in personnel or patients. The infection hazard to personnel is greatest during the handling and segregation of soiled, contaminated items at the point of use. All medical devices are considered to be soiled and contaminated after each use, and potential sources of infection by hepatitis C virus (HCV), hepatitis B virus (HBV), human immunodeficiency virus (HIV), and/or other pathogens. Segregation of soiled items and waste into separate streams of dispatch at the point of use will minimize handling and therefore minimize the possibility of subsequent personnel exposure to potentially pathogenic organisms. Separation is best done at the point of use by persons aware of the potential infection hazards of the material. Containment minimizes airborne or contact spread of microorganisms and thus reduces the risk of cross-infection. Keeping items moist prevents the drying of soil on device surfaces and facilitates subsequent cleaning and decontamination. However, a moist towel, not water, should be used for this purpose, because adding water creates a spill hazard and promotes the proliferation of biofilms.

Biofilms are tenacious polysaccharide structures formed by some types of bacteria to allow them to cling to a surface and maximize efficiency in feeding and reproduction. They also have the effect of protecting the microorganisms from attempts to remove them by ordinary cleaning means used in the central service department. They can form on many surfaces but are particularly problematic in lumened devices. Once biofilms are formed, direct friction and/or oxidizing chemicals are needed to remove them. Prompt cleaning reduces or eliminates the population of biofilm-forming microorganisms and thus prevents the formation of biofilms. Only certain inhibitory disinfectants are appropriate for use in the event of processing delays, because some disinfectants will act as fixatives for debris and make cleaning more of a problem (Merritt, et al., 2000).

Documented process audits ensure that procedures are being followed and worker exposure to unsafe conditions is minimized.

5.5 Cleaning and other decontamination processes

5.5.1 General considerations

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

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

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

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

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

c) other characteristics of the device (for example, whether the materials from which the device is fabricated can tolerate high temperatures or mechanical cleaning).

Rationale: See ANSI/AAMI ST35.

5.5.2 Cleaning

5.5.2.1 Cleaning methods

The first and most important step in decontamination is thorough cleaning and rinsing. Items may be cleaned by hand, mechanical means, or a combination of the two methods. The written recommendations of the device manufacturer always should be followed (5.5.2.2). The use of mechanical equipment can increase productivity, improve cleaning effectiveness, and/or promote employee safety. Mechanical equipment is designed to remove microorganisms through mechanical cleaning and rinsing action and/or to destroy specific types of microorganisms through thermal or chemical means. Types of mechanical cleaning equipment include (a) ultrasonic cleaners; (b) washer-sanitizers, utensil washers, and cart washers; (c) pasteurization equipment; (d) washer-disinfectors; and (e) washer-sterilizers. No one model or type of mechanical equipment can be used to decontaminate all of the myriad types of reusable medical devices that must be processed. Thus, mechanical equipment should be chosen according to the health care facility's needs. The equipment manufacturer's directions for operation, use of cleaning agents, and maintenance should be followed. See ANSI/AAMI ST35 for additional guidelines on cleaning and decontamination.

Rationale: The purpose of cleaning and rinsing is to remove all adherent visible debris from an item and reduce the numbers of particulates, microorganisms, and pyrogens. Debris such as blood, mucus, oil, or other foreign matter interferes with the sterilization process by acting as a barrier to the sterilizing agent. Cleaning reduces the bioburden and enhances the probability of sterilization.

5.5.2.2 Manufacturers' instructions

The reusable medical device manufacturer is responsible for ensuring that the device can be effectively cleaned and sterilized. Sterilization qualification of a device requires microbiological, engineering, toxicological, and sometimes clinical evaluations of the device which are well beyond the abilities of most health care facilities. The device labeling

should identify a specific method of sterilization that has been validated by the manufacturer. If there are no specific instructions in labeling, then the manufacturer should be contacted directly to provide a documented method. See also AAMI TIR12 and FDA's *Labeling reusable medical devices for reprocessing in health care facilities* (FDA, 1996a).

Rationale: To ensure patient safety, a reusable device must be capable of being thoroughly cleaned and sterilized.

5.5.2.3 Instruments

Instruments should be maintained as free of gross soil as possible during the procedure. Cleaning and decontamination should begin as soon as possible after items have been used. Before they are cleaned, general operating instruments and utensils should be separated from delicate instruments or devices requiring special handling. The device manufacturer's instructions should be consulted for specific guidance on cleaning and decontamination and to determine whether the device will tolerate immersion or high heat (for example, air-powered instruments should not be immersed). To facilitate cleaning, all instruments or devices composed of more than one part should be disassembled, and all jointed instruments should be open to ensure that all surfaces are effectively cleaned. An initial cold water rinse with an abundant amount of running tap water or an initial soak in cool water and/or a blood-protein-dissolving enzymatic cleaner will help prevent coagulation of blood onto the device and help remove blood, tissue, and gross debris from device lumens, joints, and serrations. Hot water might be required for initial dissolving of protein enzyme substances; cool water may then be added to the dissolved enzymatic cleaner solution to fill the soaking pan or sink to an appropriate level for soaking of soiled items. (See the manufacturer's instructions for specific guidance on the use of enzymatic cleaner solutions.)

After pretreatment, instruments may then be either processed mechanically or washed by hand. To be effective, cleaning agents and methods must remove residual organic soil without damaging the device. Warm water and the appropriate cleaning agent or detergent (i.e., one that is compatible with the specific materials of which the device is composed and the cleaning/washing method selected) should be used in accordance with the instructions of the manufacturer of the cleaning agent. All instruments should then be thoroughly rinsed. Water-soluble instrument lubricants, specifically designed for compatibility with sterilization, may be used; the manufacturer's instructions for use should be followed. Instrument lubricants containing mineral oil or other oil bases should not be used, except to lubricate the internal mechanism of powered instruments as specified by the manufacturer. Instruments should be carefully inspected for flaws or damage and dried before packaging or sterilization.

NOTE—Lumened items that require moistening with distilled or demineralized water prior to sterilization should not be dried.

Rationale: Since effective sterilization depends on minimizing the amount of 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 instruments. Adherence to the manufacturer's instructions for the use of detergents and other aspects of the cleaning and decontamination process will avert damage to instruments, prolong their useful lives, and prevent the creation of crevices in which debris can collect. Oil-based instrument lubricants should not be used because the oil will coat bacteria and the instrument surface, interfering with steam contact during sterilization. Drying instruments before they are packaged reduces the chance of wet instrument packs after sterilization.

5.5.2.4 Utensils

Soiled utensils such as basins, bedpans, and trays, whether received from patient-care areas or surgical areas, should be processed through a mechanical washer, washer-sanitizer, washer-disinfector, or washer-sterilizer. Also, utensils may be washed by hand, although this is not usually cost-effective. In either case, warm water and an appropriate detergent should be used for cleaning. Sterilization container systems should be disassembled and cleaned after each use in accordance with the manufacturer's instructions.

Rationale: See the rationale for 5.5.2.3.

5.5.2.5 Reusable textiles

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

Rationale: See ANSI/AAMI ST65.

5.5.3 Microbicidal processes

See ANSI/AAMI ST35.

5.6 Packaging

5.6.1 Selection of packaging materials

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

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

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

c) resist tearing or puncture;

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

e) allow for ease of aseptic presentation;

f) be free of toxic ingredients and nonfast dyes;

g) be low-linting; and

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

When selecting a packaging system, personnel should obtain and keep on file the manufacturer's test data, instructions for use, and care and handling instructions. Packaging policies and procedures should be based on the manufacturer's instructions for use.

Rationale: The primary functions of a package containing a sterile medical item are to allow the sterilization of the contents, to maintain the sterility of the contents until the package is opened, and to provide for the removal of the contents without contamination. Documentation of the manufacturer's test data provides assurance that the packaging system selected meets the criteria required, such as linting level, barrier efficacy, puncture resistance, fluid resistance, and sterilant penetration and removal. Not all packaging systems are suitable for all types of sterilization methods. For example, some sterilization container systems can only be used in prevacuum steam sterilizers; and some types of packaging may require an increased drying time. Certain chemical cleaners may be needed for some types of packaging (e.g., sterilization container systems), or special storage conditions may be required (see 5.6.2.1 and 5.6.2.5).

5.6.2 Package configurations and preparation

5.6.2.1 General considerations

Prior to use, packaging materials should be held at room temperature (68 °F to 73 °F [20 °C to 23 °C]) and a relative humidity ranging from 30 % to 60 % for a minimum of 2 hours. All packaging materials, woven or nonwoven, should be examined regularly for defects and extraneous matter. Policies and procedures should be developed for packaging techniques and be consistent with the manufacturer's recommendations. Examples of sequential double-wrapping are provided in Figures 3 and 4. Examples of simultaneous double-wrapping are provided in Figures 5 and 6. Examples of single and double pouches are provided in Figure 7.

Wrappers should be kept snug to prevent low spots that could collect condensate on the exterior of the package; however, care should be taken not to wrap too tightly, because strike-through could occur. Sterilization container systems should be scientifically proven suitable for the specific sterilization cycle to be used; when items are being prepared for sterilization, the container system should be verified as the correct one for the cycle (ANSI/AAMI ST33).

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

Rationale: Temperature and humidity equilibration of packaging material and product is needed to permit adequate steam penetration and avoid superheating. Temperature affects relative humidity, so a preconditioning temperature range also is recommended. Experience has shown that if the packaging and product are too dry, problems such as superheating and positive BIs can result. The suggested humidity and temperature ranges were chosen for consistency with the conditions recommended for general environmental control in work areas of central service (see 3.3.5.4 and 3.3.5.5). The 2 hour preconditioning period is a minimum; some packaging materials might require a much longer equilibration time, depending on previous storage conditions. For sterility maintenance and aseptic presentation, certain items require double-wrapping. Container systems vary in their mechanics, specific performance characteristics, and suitability for particular sterilization cycles.

Adherence to established policies and procedures is important in ensuring proper sterilization and drying. Steam entering packages containing metal instruments immediately condenses as its latent heat is transferred to the metal items. Over the course of the exposure period, all of the condensate might not return to a vapor and can remain

trapped in the package in the form of water droplets. Elimination of the condensate is only possible with a sterilizer designed with heated drying capabilities. Inadequate drying could compromise the seal, integrity, or barrier protection ability of the package, and thus sterility might not be maintained.

5.6.2.2 Package labels

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

Rationale: Important identification information must not be lost during handling. Writing on the paper side of the pouch or on a textile wrapper (whether woven or nonwoven) could cause damage to the package (which might not be noticeable) and thus compromise the barrier protection.

5.6.2.3 Package closures

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

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

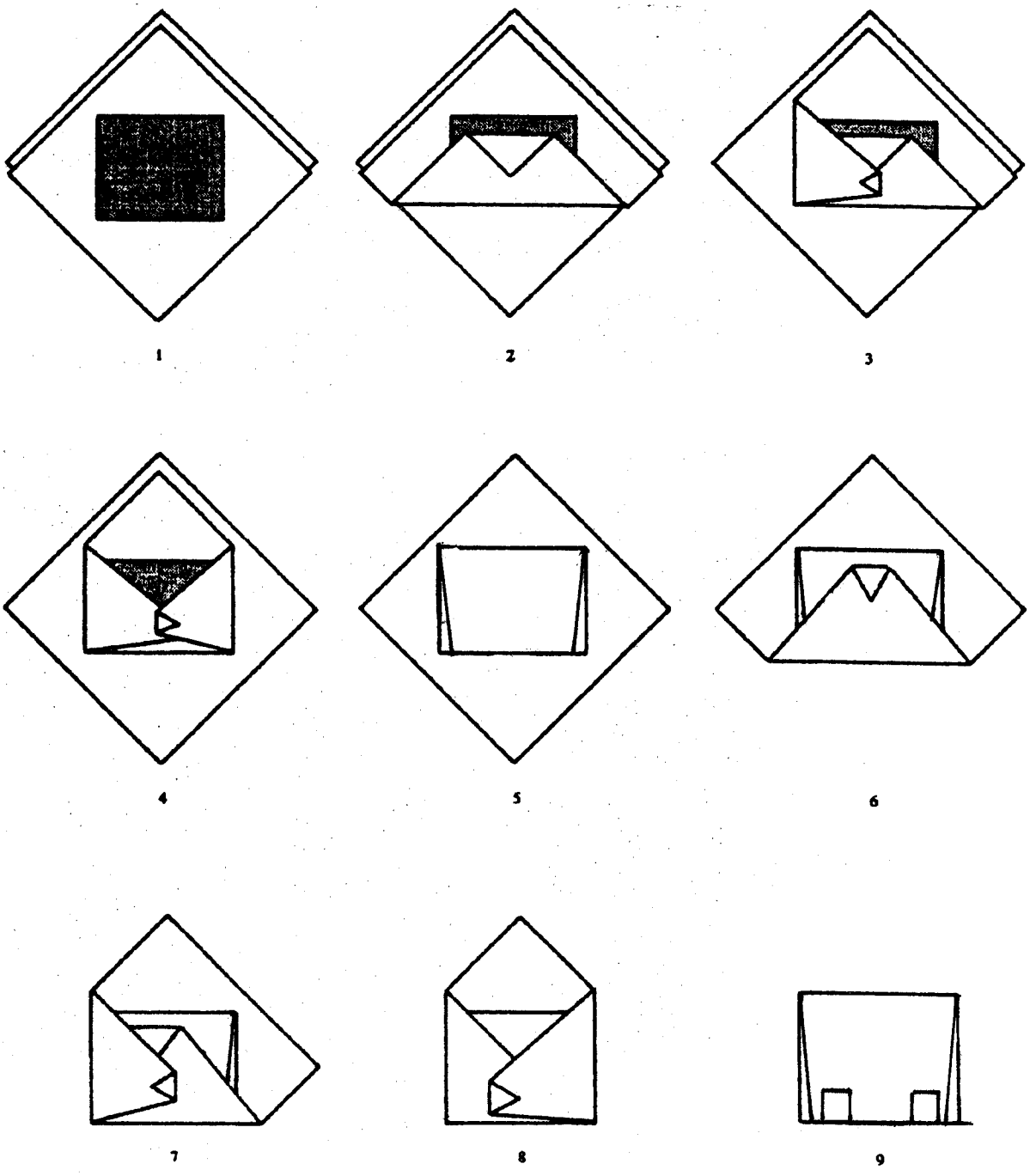


Figure 3—Sequential double-wrapping: Envelope fold

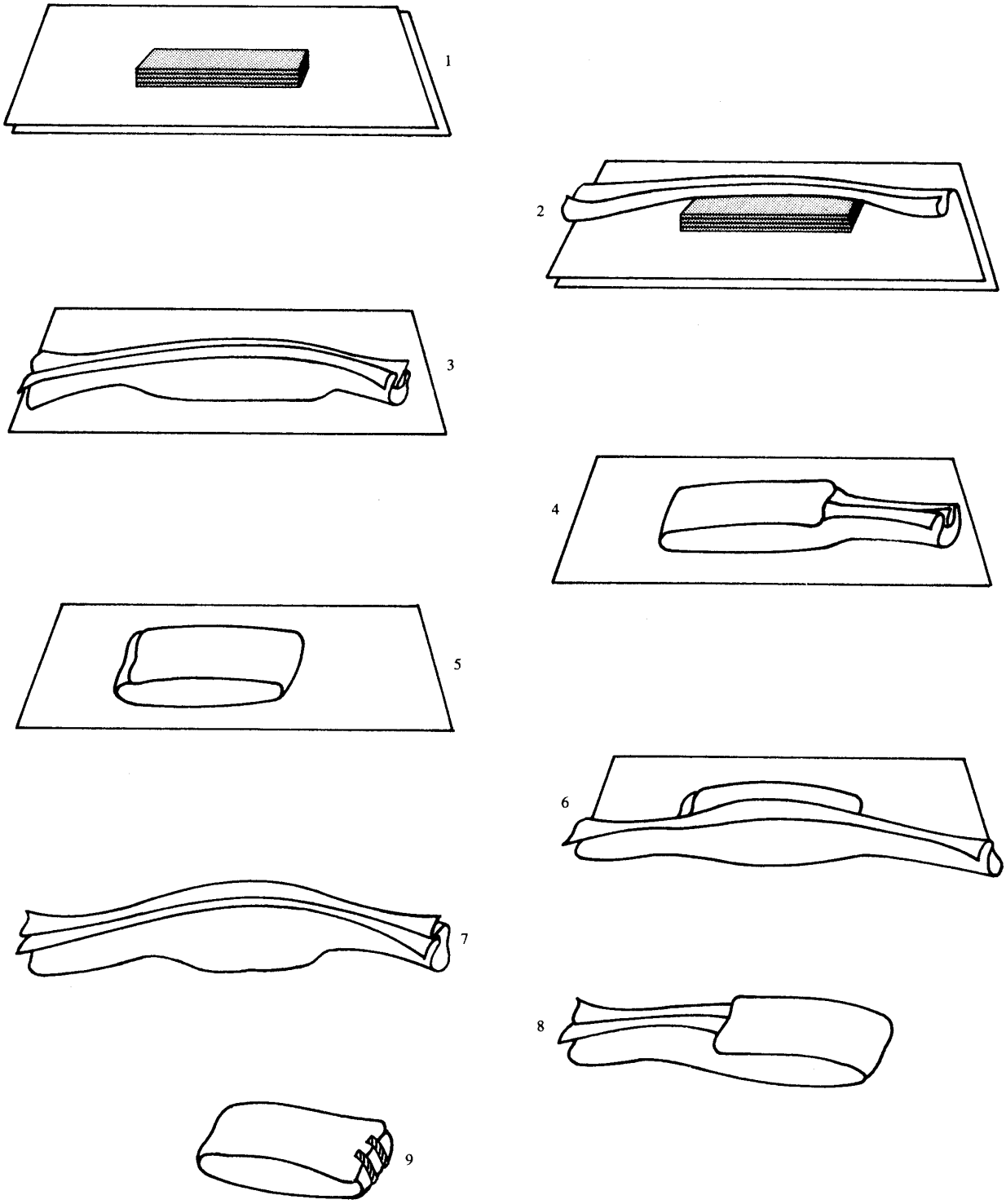


Figure 4—Sequential double-wrapping: Square fold

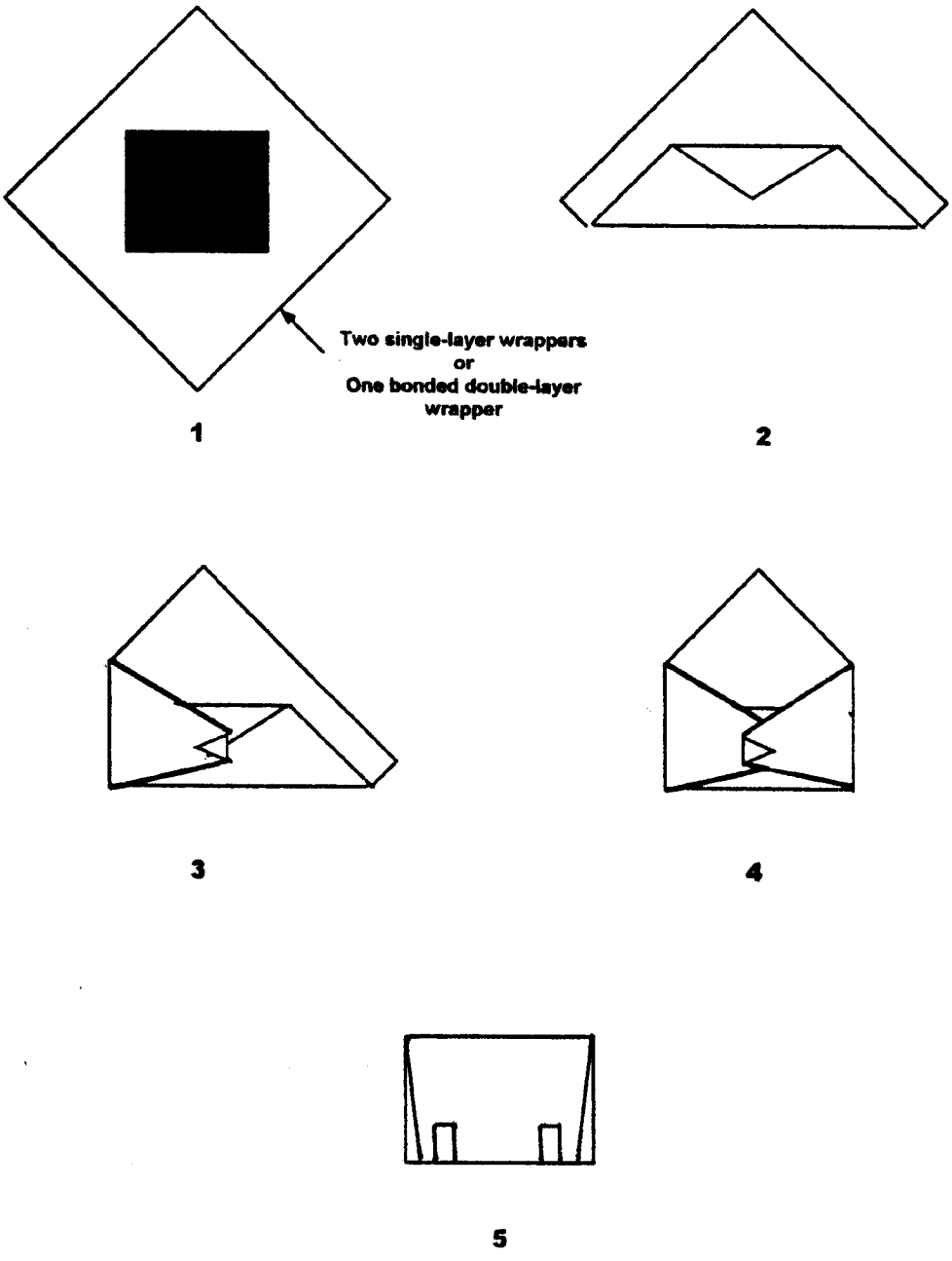


Figure 5—Simultaneous double-wrapping: Envelope fold

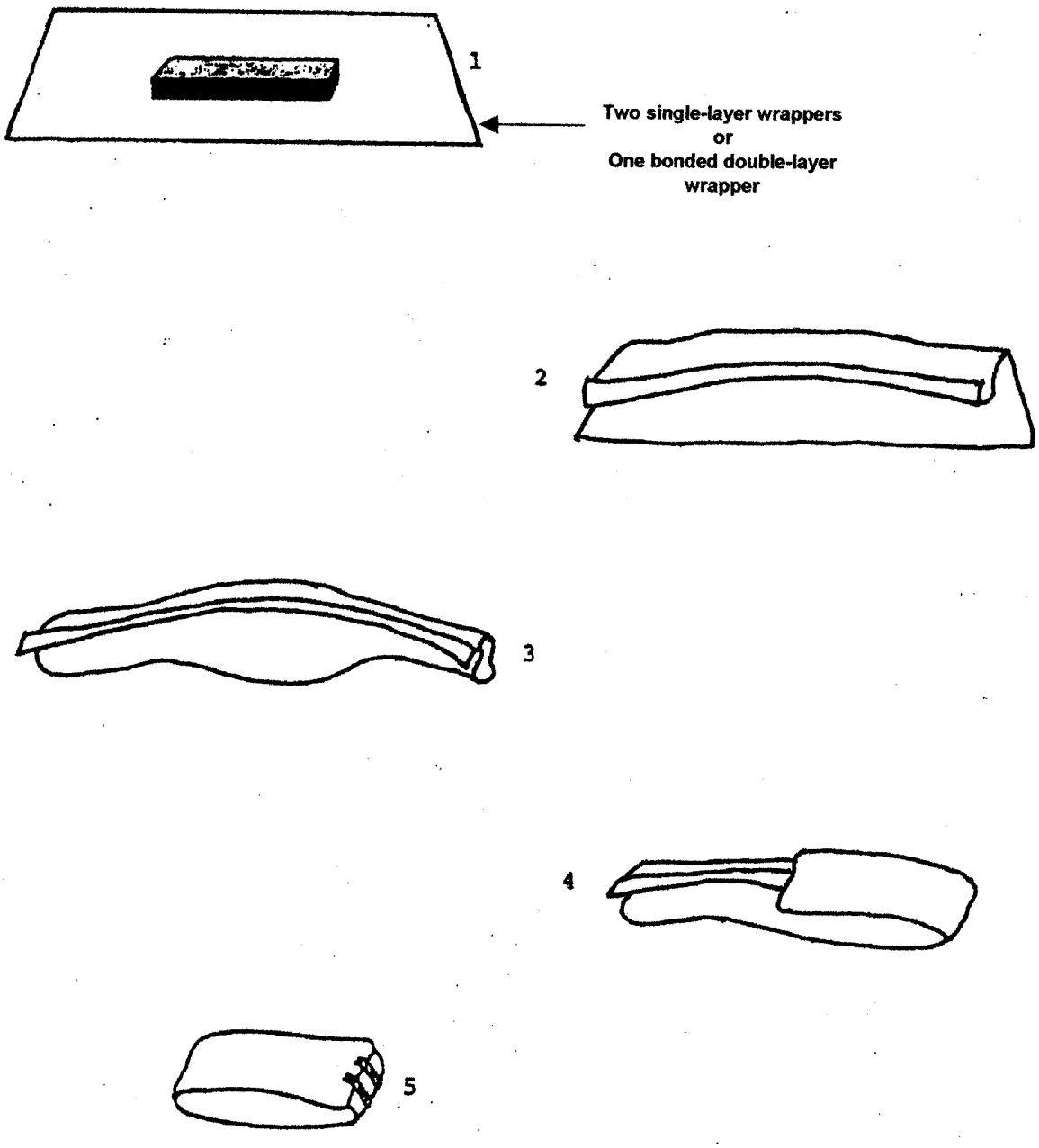


Figure 6—Simultaneous double-wrapping: Square fold

5.6.2.4 Paper/plastic pouches

Paper/plastic pouches should be used for small, lightweight, low-profile items (e.g., one or two clamps, microsurgical scissors) (see Figure 7). If the item is to be double-packaged, two sequentially sized pouches should be used (i.e., the sealed inner pouch will fit inside the other pouch without folding). The pouches should be positioned so that plastic faces plastic and paper faces paper. Paper/plastic pouches are not appropriate for use within wrapped sets or containers. See also 5.6.2.7.

NOTE—Small, perforated, mesh-bottom baskets with lids can be used instead of paper/plastic pouches to contain small items in sets. Small items or instruments also can be placed in an absorbent, single-layer, flat wrap or in an appropriate foam product (i.e., foam products labeled for this use). A chemical indicator should be placed inside these inner packages.

Rationale: The use of paper/plastic pouches with heavy metal instruments (e.g., orthopedic drills, retractors, weighted speculums, orthodontic pliers) could result in problems with sterility maintenance, such as inadequate drying of the package after sterilization (see also 5.6.2.1). Proper sizing and application of pouches allows for adequate air removal, steam penetration, and drying. It is inadvisable to use paper/plastic pouches within wrapped sets or containers because the pouches cannot be positioned to ensure adequate air removal, steam contact, and drying.

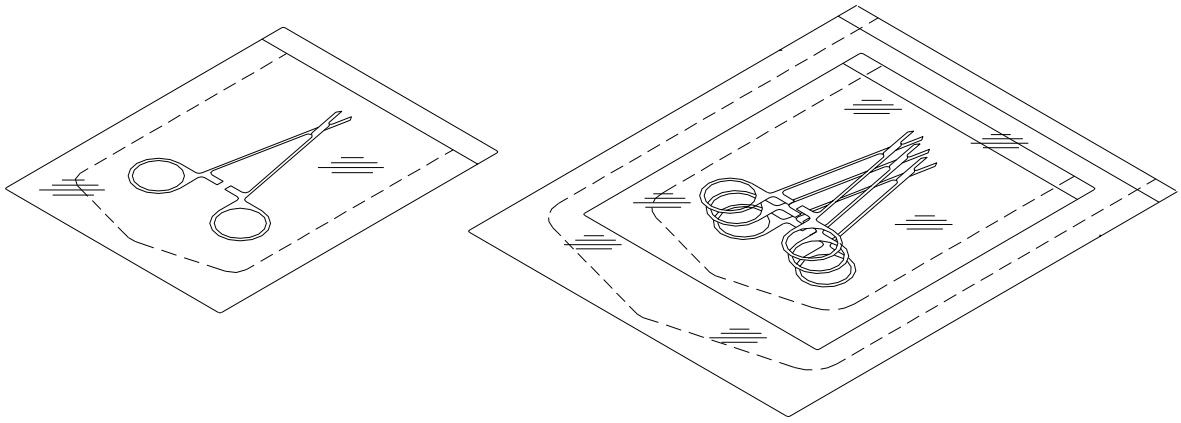


Figure 7—Example of single- and double-packaging with paper/plastic pouches

5.6.2.5 Textile packs

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

A pack should be prepared with clean, preconditioned textiles. It may be necessary to separate tightly-woven, liquid-resistant textile items in the pack with absorbent, less dense fabrics (e.g., surgical towels) in order to allow adequate air removal and steam penetration/evacuation. The wrapper should be securely applied but not pulled so that the contents are compressed. All textile packs should be temperature- and humidity-equilibrated, in accordance with 5.6.2.1, before sterilization.

The user should be knowledgeable regarding the effect that the materials and construction of the textiles used in pack preparation could have on the sterilization process, and evaluate each constructed pack for ease of air removal and steam penetration/evacuation. When textiles other than those known to be readily steam-permeable are used, be they woven or nonwoven (laminated) reusable materials, some simple tests should be conducted in the health care facility to demonstrate their compatibility with the sterilization process. These tests ensure that the wrapped packs indeed can be sterilized and thus that their specific configuration will be acceptable for steam sterilization. Textile packs should be evaluated for their suitability for particular sterilization cycles. Tests may include placing BIs in a sample pack to assess sterilant penetration (see 7.8), placing a Bowie-Dick test sheet in a sample pack to assess air removal, and measuring the weight of the pack before and after sterilization using a scale calibrated in ounces or grams to assess dryness. More sophisticated testing, such as the use of thermocouples to record real-

time and temperature profiles within the pack during sterilization, can be performed in cooperation with the sterilizer manufacturer and the manufacturer of the textile product.

Rationale: The term *pack density* refers to the ratio of weight to volume, and is affected by how textiles are arranged within a pack and how tightly that pack is wrapped prior to sterilization. Historically, professional guidelines have recommended that the maximum weight of a textile pack should not exceed 12 lb, and it should measure 12 in wide by 12 in high by 20 in long to achieve a pack density of 7.2 lb/ft^3. These recommendations were developed for muslin drapes and wrappers, products composed of materials very different from the fabrics used today. Temperature and humidity equilibration is especially important for textile packs because of their large volume. A desiccated pack can lead to superheating and, consequently, sterilization failure and decreased useful life of the materials. Because of the variety of textiles on the market, it is important for users to assess the various configurations of the pack.

5.6.2.6 Basins and basin sets

Graduated nested basins should differ in diameter by at least 1 in. Basin sets should be prepared so that all basins are placed in the same direction. Basin sets should be processed with nonlinting absorbent material between nested basins. Basins should be assembled to permit air removal, steam penetration, and steam removal during the sterilization and drying process. The weight of wrapped basin sets should not exceed 7 lb, and the total number of basin sets per load should be evaluated to ensure dry sets.

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

5.6.2.7 Instruments

Instrument sets should be sterilized in perforated or wire-mesh-bottom trays, or specially designed containers, with all instruments held open and unlocked. Multipart instruments should be disassembled for sterilization unless the device manufacturer has provided validated instructions to the contrary. If commercially customized organizing trays or cassettes are used, the health care facility should request scientific documentation from the device manufacturer that demonstrates the efficacy of the tray/cassette/instrumentation arrangement in the steam sterilization cycles available to the facility (see AAMI TIR12). Nonlinting absorbent material may be placed in the tray to facilitate drying. For adequate drying, it might also be necessary to wrap instruments of unusual design or high density with absorbent material. Individual instruments may be packaged in an acceptable packaging material, with the instrument held open, unlocked, or disassembled, and sterilized in a position that ensures adequate steam contact with all surfaces. See also 5.6.2.4.

The weight of an instrument set should be based on (a) whether personnel can use proper body mechanics in carrying the set, (b) the design and density of the individual instruments comprising the set, and (c) the distribution of mass (the density) in the set and sterilizer load. Instrument sets should be prepared in trays large enough to equally distribute the mass; set configuration should be evaluated to ensure dry sets. The total number of sets per load also should be evaluated to ensure dry sets; in hospitals in which steam quality is less than optimal, load size could adversely affect drying time. For instrument sterilization container systems, the user should consult the container manufacturer concerning the weight and density of instrument sets; however, it is the user’s responsibility to determine that the set can be effectively sterilized and dried. (See also ANSI/AAMI ST33.)

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

There is no magic number for instrument set weight. Preparation and assembly procedures should take into account the ratio between number of instruments and total set weight and density. This ratio is more important than an arbitrary weight limit. By considering the density of the individual instruments, the instrument set, and the sterilizer load, as well as the available steam quality, the user will be able to develop a total program that will yield sterile, dry instrument sets. The design of sterilization container systems varies widely, so the container manufacturer’s instructions are the best guide to instrument set weight, preparation, and processing.

5.6.2.8 Surgical supplies

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

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

5.6.2.9 Devices with lumens

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

Rationale: Moistening of lumens is required so that steam can be generated from within. Steam cannot penetrate from the outside of the catheter because the lumen is a diffusion restricter.

5.7 Loading the sterilizer

5.7.1 General considerations

Similar items requiring the same cycle parameters (i.e., sterilization exposure time/temperature, cycle drying and/or cool-down time) should be grouped together. Procedures describing load contents and placement configurations should be developed. If a cart shelf liner is used, it should be made of a nonlinting absorbent material that will dry in the drying time selected for the rest of the load. Load configurations should ensure adequate air removal, penetration of steam into each package, and steam evacuation. Items capable of holding water, such as solid-bottomed pans, basins, and trays, should be positioned so that they are oriented in the same direction and condensate can be eliminated, i.e., arranged in such a way (normally on their sides) that if water is present, it will drain out. (See Figure 8 for examples of proper loading.) Placing metal items above textile items should be avoided. In loading any sterilizer, the sterilizer manufacturer's written instructions should be followed; however, the recommendations of 5.7.2 to 5.7.4 address some specific aspects of sterilizer loading that have been perennial problems. Procedures for configuring mixed or heterogeneous loads should be developed, and process audits should be performed and documented to ensure compliance.

Rationale: Loading the sterilizer in this fashion allows adequate air elimination and drainage of condensate, which are needed to attain product sterility. Absorbent cart shelf liners can be helpful in drying a load; it is important that the material be nonlinting because lint can carry microorganisms into the surgical site and cause foreign body reactions.

Orienting items such as solid-bottomed pans in the same direction allows rapid, even distribution of steam throughout the load, with the least amount of interference. Placing metal items below textile items enables condensate to drain out without wetting other items in the load. Sterilizers differ in their design and operating characteristics, so it is important that the manufacturer's written instructions be carefully followed.

5.7.2 Paper/plastic pouches

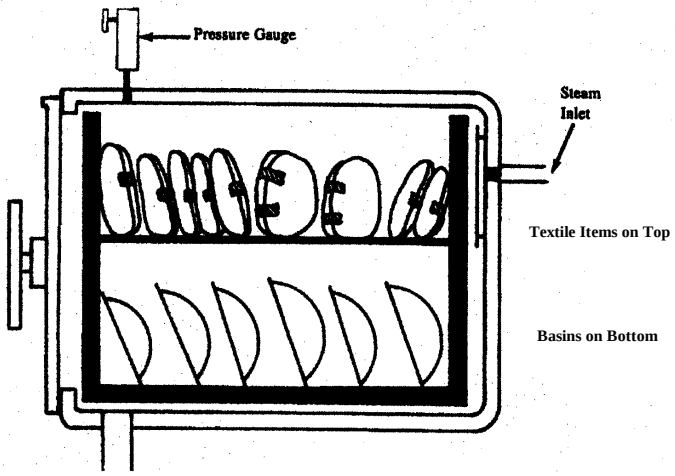
Paper/plastic pouches should stand on edge in relation to the cart; holding racks or baskets specifically designed for pouches can be used.

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

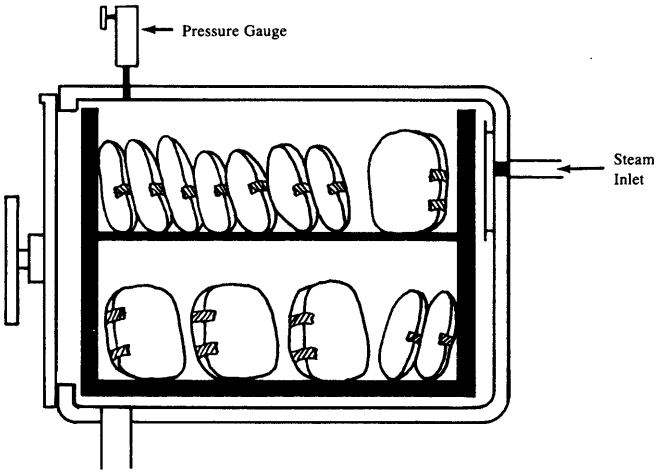
5.7.3 Instrument sets

Instrument sets should be placed on the sterilizer shelf or cart so that the bottom of the perforated tray is parallel to the shelf.

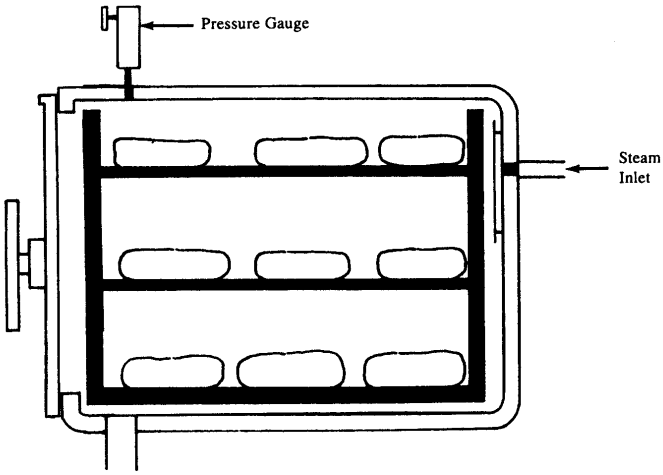
Rationale: This position maintains distribution of metal mass and allows air removal, sterilant penetration, condensate drainage, and drying. It also avoids instrument damage.



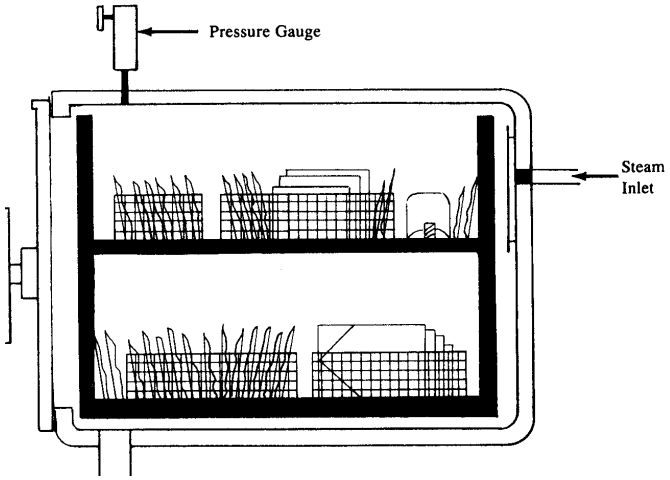
a) Mixed load



b) All-textile load



c) Wrapped instrument load:
Perforated or wire-mesh-bottom trays



d) Loading paper/plastic peel-down packaging, using wire-type baskets to keep the packages in position

Figure 8—Loading the sterilizer

5.7.4 Solutions

Primarily for personnel safety reasons, hospital preparation and sterilization of parenteral and irrigation liquids is discouraged. When solutions are processed in the hospital (i.e., in emergency situations or when sterile solutions not used as parenteral or irrigation liquids are needed), processing should be performed only by personnel familiar with the following guidelines:

a) Solutions should be sterilized separately from all other items (using the sterilizer cycle for liquid loads).

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

c) The sterilizer manufacturer's instructions for load configuration, exposure time, cycle setting, and post-sterilization handling should be followed.

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

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

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

5.8 Sterilization parameters

5.8.1 Sterilization parameters for wrapped or containerized items

The sterilizer manufacturer's written instructions for cycle parameters should be followed (see 5.5.2.2). Programmed cycle selections should be used. Any differences between the programmed cycle parameters and the cycle parameters recommended by the medical device manufacturer should be investigated and resolved before the items are sterilized. Tables 5 and 6 describe the most common temperature and time parameters for various types of loads. Procedures for correct cycle selection should be developed and implemented, and process audits should be conducted to ensure compliance.

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

If a sterilization container system is used as packaging, the container manufacturer's written recommendations regarding exposure time should be consulted and reconciled with those of the sterilizer manufacturer. The correct cycle parameters should be selected and verified based on the results of product testing (7.8). In addition, certain types of medical equipment (e.g., some air-powered instruments) might require prolonged exposure time.

Rationale: Sterilizers vary in design and performance characteristics, so cycle parameters should always be verified against the sterilizer manufacturer's instructions for the specific sterilizer and load configuration being used. The general parameters described in Tables 5 and 6 for gravity-displacement and dynamic-air-removal cycles are taken from Reichert and Young (1997). The use of rigid sterilization container systems could affect come-up and exposure times in steam sterilizers, depending on the efficiency of air removal from and steam penetration into the containers. Therefore, it is important to verify that containerized devices can be effectively sterilized by the cycle parameters selected. The design of some medical devices itself will hinder air removal and steam penetration, making sterilization more difficult. The device manufacturer is in the best position to specify the conditions necessary for steam sterilization of a particular device.

5.8.2 Monitoring

See section 7.

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

Item	Exposure time at 250 °F (121 °C)	Exposure time at 270 °F (132 °C)	Exposure time at 275 °F (135 °C)	Minimum drying time
Wrapped instruments	30 min	15 min		45 min
			10 min	30 min
Textile packs	30 min	25 min		30 min
			10 min	30 min
Wrapped utensils	30 min	15 min		30 min
			10 min	30 min

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

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

Item	Exposure time at 270 °F (132 °C)	Exposure time at 275 °F (135 °C)	Minimum drying time
Wrapped instruments	4 min		30 min
		3 min	16 min
Textile packs	4 min		5 min
		3 min	3 min
Wrapped utensils	4 min		20 min
		3 min	16 min

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

5.9 Sterility maintenance

5.9.1 Cooling

All items removed from the sterilizer after sterilization processing should remain on the sterilizer cart until adequately cooled. They should not be touched during the cooling process. The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used. A minimum cooling time of 30 min is recommended. During cooling, the sterilizer cart should be placed in a low-traffic area where there are no air-conditioning or other cold-air vents in close proximity. Warm items should never be transferred from the cart to cold metal racks or shelves for cooling or placed within dust covers before completion of the cooling process (see 5.9.3.1).

Rationale: Seasonal and geographic variations in ambient temperature and humidity affect cooling time, as do other factors unique to the individual facility. The type of sterilizer used also can affect cooling time, based on how hot items are when they leave the sterilizer. Consequently, the time allowed for cooling has to be based on professional judgment and experience. Although a minimum cooling time of 30 min is recommended, adequate cooling could require 2 hours or more. Packs should not be touched until they are cool because hot packs act as wicks, absorbing moisture and, hence, bacteria from hands. Placing the sterilizer cart in a low-traffic area decreases 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.

5.9.2 Handling and inspection

Written procedures should stress minimizing the handling of all sterile items. As items are removed from the sterilizer cart, they should be visually inspected. Any items with torn packaging or 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. It should be noted that wet packaging might indicate problems with package composition, loading procedures, sterilizer performance or operation, or the steam generation and distribution system. See American Society for Healthcare Central Service Professionals (1997) for further information.

5.9.3 Sterile storage

5.9.3.1 Sterility maintenance covers

Sterility maintenance covers (dust covers) may be used to protect properly packaged and sterilized items that could be subjected to environmental challenges or multiple handling before use, and thereby extend shelf life. Only products specifically labeled as sterility maintenance covers should be used for this purpose. A sterility maintenance cover or dust cover should be clearly designated as such to prevent its being mistaken for a sterile wrap. Sterility maintenance covers are designed to provide protection against outside elements (e.g., dust), not to provide a microbiological barrier.

If sterility maintenance covers are to be applied to sterilized packages, they should be applied as soon as possible after sterilization, but not before the items are thoroughly cool and dry.

The sterility maintenance cover is sealed using either a heat sealer designed to seal plastic to plastic or an alternative method that is similarly effective; a self-sealing cover may also be used. The lot or load control number and expiration statement should be visible through the sterility maintenance cover, or an additional label should be used on the sterility maintenance cover. (See also 7.2.1 and 7.2.3.)

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

Applying sterility maintenance covers soon after sterilization enhances sterility maintenance. However, placing a sterility maintenance cover on a package that is not cool and dry could result in condensation inside the sterility maintenance cover and, since the sterility maintenance cover is not sterile, cause contamination of 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.

5.9.3.2 Storage facilities

Sterile materials should be stored at least 8 in to 10 in above the floor, at least 18 in below the ceiling or the level of the sprinkler heads, and at least 2 in from outside walls. The items should be positioned so that packaging is not crushed, bent, compressed, or punctured, and their sterility is not otherwise compromised. Medical and surgical supplies should not be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they could become wet. Storage of supplies on floors, window sills, and areas other than designated shelving, counters, or carts should be avoided. (See also 3.3.6.2, 3.3.6.3, and 3.3.6.4.)

Closed or covered cabinets are recommended for the storage of seldom-used supplies. Open shelving may be used, but requires special attention to traffic control, area ventilation, and housekeeping. Shelving or carts used for sterile storage should be maintained in a clean and dry condition. Outside shipping containers and corrugated cartons should not be used as containers in sterile storage areas. (See also 5.2.1.)

Rationale: Adequate space is needed around sterile materials to allow for air circulation in the room, prevent contamination during cleaning of floors, and 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 in) to ensure the effectiveness of sprinkler systems. (See National Fire Protection Association (NFPA), 1999.) Compression of packages can force air and microorganisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces. Sterile items should not be stored anywhere but on or in designated shelving, counters, or containers, because other areas might not be sufficiently clean, and window sills collect condensate that forms due to differences in temperature between inside and outside air.

Closed cabinets limit dust accumulation, discourage handling, and minimize inadvertent contact with sterile items. Shipping containers have been exposed to unknown and potentially high microbial contamination, and those that are

corrugated serve as generators of and reservoirs for dust. Hence, shipping containers should never be allowed in the sterile storage area.

5.9.4 Shelf life

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

Rationale: The contamination of a sterile item is event-related, and the probability of its occurrence increases over time and with increased handling. See also JCAHO (2001) and AORN (2001b).

5.10 Distribution

5.10.1 Handling and inspection

Supplies should be handled carefully. Care should be taken to avoid 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: See the rationale for 5.10.2.

5.10.2 Distribution containers

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, the items should be arranged within the containers 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 have a reclosable opening. Carts should be decontaminated and dried before they are reused for transporting sterile supplies. For automated cart distribution systems and pneumatic systems, the manufacturer's instructions on distribution and decontamination procedures should be followed.

Rationale: Covered or enclosed carts protect sterile items from inadvertent contact with personnel and other sources of contamination, and environmental challenges that might exist along the transportation route. A solid bottom shelf on the cart prevents contamination via the so-called "rooster-tail effect," in which the wheels pick up contaminants from the floor and spin them upwards. Surfaces 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.

6 Installation, care, and maintenance of sterilizers

6.1 General rationale

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

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

6.2 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 6.3 and 6.4, and should specify the frequency with which these procedures should be performed. Specific rather than general information should be provided for each equipment model. The manufacturer's instructions should be kept by the user for as long as the equipment is in service.

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

6.3 Installation testing

After installation of the sterilizer and before the health care facility takes the sterilizer into possession or puts it into routine service, installation and acceptance testing should be carried out according to the procedures outlined in 7.5.3.

Rationale: 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 specific health care facility. The compatibility of the sterilizer with these systems, and thus its overall effectiveness, only can be verified in the actual hospital environment in which it will be used.

6.4 Routine care

Sterilizers should be inspected and cleaned daily according to the manufacturer's written instructions (see 6.2). Examples of items requiring daily care and/or cleaning are recording charts, printers, printer ribbons, marking pens and ink, door gaskets, the chamber drain screen, the internal chamber, and external surfaces. Weekly or other prescribed inspection and cleaning should be performed as specified in the manufacturer's written instructions.

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

6.5 Preventive maintenance

6.5.1 General

The manufacturer of the sterilizer should provide written instructions for preventive maintenance of the equipment. This maintenance should be carried out by a qualified individual. Particular attention should be given to the inspection, maintenance, and replacement of components subject to wear, such as recording devices (as applicable), filters, steam traps, drain pipes, valves, and door gaskets. Simple charts showing the locations and replacement dates of components will show trends in deterioration and provide the framework of a preventive maintenance program. The maintenance program may be in-house or contracted with the equipment manufacturer or other qualified service company. Preventive maintenance and repair records should be retained (see 6.7).

Rationale: Malfunction of critical components can cause sterilization failures or failures of the sterilization parameter recording system.

6.5.2 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 facility. The frequency of maintenance depends on how often the equipment is used and might vary from institution to institution; the manufacturer's instructions should be consulted for guidance.

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

6.6 Calibration

Periodic calibration should be performed as specified in the manufacturer's instruction manual (see 6.2), 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 engineering staff, or contract service personnel. Those performing this 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.

6.7 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, the hospital engineering staff, the service person/organization who performed the servicing, and/or whoever else is deemed appropriate by the health care

facility. Included in this maintenance record should be sufficient information to identify the equipment and establish a continuous history of all scheduled and unscheduled service. At least the following information should be recorded:

a) the date on which service was requested;

b) the model and serial number of the sterilizer;

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

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

e) the reason for the service request;

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

g) the types and quantities of parts replaced;

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

i) the date the work was completed; and

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

These records must be maintained for the length of time specified by regulatory agencies (e.g., state health departments) or, if unspecified by regulatory agencies, the length of time determined by the infection control committee of the individual health care facility.

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

7 Quality control

7.1 General rationale

This section covers product identification and traceability; mechanical, chemical, and biological monitoring of steam sterilization cycles; residual air (Bowie-Dick) testing of dynamic-air-removal sterilizers; product recalls; and related quality control measures. Sterility assurance requires continuous attention to all aspects of the steam sterilization process and the performance of the sterilizer.

NOTE—Quality control is usually thought of only as product and process monitoring, and section 7 is primarily concerned with those applications. In its broadest sense, however, quality control involves continuous supervision of personnel performance and work practices and ongoing verification of adherence to established policies and procedures.

7.2 Product identification and traceability

7.2.1 Lot control numbers

Each item or pack intended for use as a sterile product should be labeled with a lot control identifier. The lot control identifier should designate the sterilizer identification number or code, the date of sterilization, and the cycle number (cycle run of the sterilizer). The policy of the individual health care facility determines when the lot control label is affixed to the package. If packages are to be labeled before sterilization, the labeling should be done immediately before the load is processed. If it is the policy to label packages after sterilization, the labeling should not be done until the packages are cool and dry.

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

7.2.2 Sterilizer records

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

a) the lot number;

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

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

d) the name or initials of the operator;

e) the results of biological testing (if applicable);

f) the response of the CI placed in the BI test pack (if applicable); and

g) any reports of inconclusive or nonresponsive CIs found later in the load (see also 7.4.2.3[b][3]).

The time and temperature recording chart, printer, or tape (if applicable) should also be dated and maintained, and each cycle on the chart should be reviewed and signed by the operator. In addition, records should be kept of Bowie-Dick testing (if applicable). A record of repairs and preventive maintenance also should be kept for each sterilizer (see 6.7). All of the foregoing information may be incorporated into a sterilizer paper or electronic log system or filed as individual documentation records. All sterilizer records must be retained in the central service department or another designated storage area for a period of time not less than that specified by state or local statutes or, if statutes are nonspecific, by the infection control committee of the individual institution. Electronic records of the sterilization cycles, with item-specific identification, are recommended.

Rationale: Documentation ensures monitoring of the process as it is occurring, ensures that cycle parameters have been met, and establishes accountability. In addition, documentation helps personnel determine whether recalls are necessary and the extent of recalls, should evidence subsequent to lot release, such as a positive BI or nonresponsive CI, suggest sterility problems. Knowing the contents of the lot or load enables personnel to decide how critical a recall might be. Computerization of the process will make all data applicable to the cycle readily available, facilitating a quick response.

7.2.3 Expiration dating

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

Rationale: Labeling items with a lot control number and expiration statement or (when applicable) expiration date is necessary for proper stock rotation. See also 5.9.4.

7.3 Physical monitoring

7.3.1 Use of physical monitors

Physical monitors include time, temperature, and pressure recorders; displays; digital printouts; and gauges. The operator should ensure at the beginning of the cycle that the recording chart is marked with the correct date and the sterilizer and cycle identification number, and that the pen or printer is functioning properly on the chart. At the end of the cycle and before items are removed from the sterilizer, the operator should examine the record to verify that cycle parameters were met and mark it to allow later identification of the operator (7.2.2). Sterilizers that do not have recording devices should not be used.

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

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

7.3.2 Sterilizer malfunction

If the records indicate any malfunction or suspicious operation, the department head or designee should be notified. After examination, if the malfunction cannot be corrected immediately, the cycle should be terminated in accordance with the sterilizer manufacturer’s instructions. The load should be considered nonsterile, and the sterilizer should be removed from service. The hospital engineer or maintenance contract service should then be notified and the malfunction corrected. 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 to a dynamic-air-removal sterilizer, three consecutive Bowie-Dick test cycles should be run, one right after the other, and the test sheets examined. (See also 7.6.) For all types of steam sterilizers following major repair,

three consecutive test cycles with a BI test pack should be run, one right after the other, in an otherwise empty chamber. The test results should be obtained (i.e., the BI should be incubated according to the manufacturer's instructions for assessing spore growth after sterilization) and determined to be satisfactory before the sterilizer is returned to service. (See also 7.5.)

NOTE—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 or a major piping assembly, or rebuilds or upgrades of controls. Normal preventive maintenance, such as the rebuilding of solenoid valves, is not considered major repair. When repairs involve parts normally replaced under preventive maintenance procedures, three BI tests and three Bowie-Dick tests are not required before the sterilizer is returned to service. Verification of the sterilizer's operation to the manufacturer's specifications is sufficient.

Rationale: The load should be considered nonsterile under these conditions, not only because of sterilizer failure, but also because the contents become wet upon introduction of steam. Simply altering the cycle parameters of a malfunctioning sterilizer will not correct a problem; the sterility of future loads will be jeopardized if the sterilizer continues to be used without repair. To restore a sterilizer to proper performance, it is necessary to identify the exact cause of the malfunction. Common problems detected by mechanical monitoring include inadequate temperature, vacuum, exposure time, and drying time.

7.4 Sterilization process indicators

7.4.1 General considerations

As technology progresses, new sterilization process monitoring devices may become available. Health care facilities should rely on the knowledge and expertise of their infection control, central service, and surgical services professionals in the selection and use of process monitoring devices.

Rationale: The choices made in the selection and use of sterilization process monitoring devices play a large role in determining the level of quality of the sterile processing function, and thus should be made based on technical knowledge and expertise, not merely economics.

7.4.2 Chemical indicators

7.4.2.1 Definition

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

7.4.2.2 Selecting chemical indicators

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

> **Process indicators (Class 1)** are intended for use with individual units (e.g., packs, containers) to demonstrate that the unit has been exposed to the sterilization process and distinguish between processed and unprocessed units.
>
> **Indicators for use in specific tests (Class 2)** include Bowie-Dick-type indicators. (See 7.6 for recommendations concerning the use of these indicators. See also ANSI/AAMI ST66, *Sterilization of health care products—Chemical indicators—Part 2: Class 2 indicators for air removal test sheets and packs*.)
>
> **Single-parameter indicators (Class 3)** are designed to react to one of the critical parameters of sterilization and indicate exposure to a sterilization cycle at a stated value of the chosen parameter.
>
> **Multi-parameter indicators (Class 4)** are designed to react to two or more of the critical parameters of sterilization and indicate exposure to a sterilization cycle at stated values of the chosen parameters.
>
> **Integrating indicators (Class 5)** are designed to react to all critical parameters over a specified range of sterilization cycles, and their performance has been correlated to the performance of a BI under the labeled conditions of use.

Some CIs are sensitive to certain parameters (e.g., temperature); others are less sensitive to a specific sterilization parameter, but simultaneously test the overall sterilization process. Health care personnel should obtain data from manufacturers on the reliability, safety, and performance characteristics of their products (e.g., how to interpret indicator results, the reliability of the indicator in maintaining end-point response during storage of sterilized items,

the sterilization conditions that the indicator will detect, the shelf life of the indicator, and the storage requirements for the indicator itself before and after sterilization). See also ANSI/AAMI ST60.

Another indicator available for monitoring the effectiveness of the steam sterilization process is comprised of a multiple, interactive enzyme tablet of bacterial origin that does not contain spores. When this indicator is exposed to steam sterilization conditions, enzymatic activity is progressively lost over time, which correlates to the deactivation data for *Bacillus stearothermophilus* spores. The design and performance characteristics of this indicator are not adequately described in the performance standards for Class 5 integrating indicators (ANSI/AAMI ST60) or biological indicators (ANSI/AAMI ST19).

Rationale: Various types of external and internal CIs are available, each with different response characteristics; i.e., they differ in the sterilizing conditions that they will detect and verify.

7.4.2.3 Using chemical indicators

a) **External chemical indicators**

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

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

b) **Internal chemical indicators**

1) *Placement and frequency of use*

An internal CI should be used within each package to be sterilized. This internal CI may be a single-parameter indicator (Class 3), multi-parameter indicator (Class 4), or integrating indicator (Class 5), depending on the complexity of the pack and contents. The CI should be placed in that area of the package considered to be least accessible to steam penetration; this location might or might not be the center of the package. Internal indicators should be used in the routine monitoring of items sterilized.

Multi-parameter CIs and integrating CIs provide more information about the process than do single-parameter indicators. The results of Class 5 integrating indicators may serve as the basis for the release of processed items, excluding implants. These integrating indicators must be used within an appropriate challenge test pack. Using Class 5 integrating indicators for this purpose does not replace the use of BIs as described in 7.4.3.

Rationale: There are no practical means of verifying the sterility of individual items. Chemical indicators do not verify sterility, but they do allow detection of certain equipment malfunctions, and they may assist in the identification of certain procedural errors.

2) *Retrieval and interpretation*

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

Rationale: Internal CIs cannot be retrieved without compromising the sterile integrity of the packaging and thus must be retrieved and interpreted at the time of use.

3) *Nonresponsive or inconclusive chemical indicators*

If the interpretation of the CI suggests inadequate steam processing, the contents of the package should *not* be used. The interpreter should inform the appropriate supervisor, who should return the complete unused package, including load identification and the CI, for appropriate follow-up. The department head or designee in the sterilizing department should then decide whether to recall that sterilized load. This decision should be based on the results of physical monitoring (time and temperature recordings), the results of CIs elsewhere in the load, and, if applicable, the results of biological monitoring. If biological monitoring was performed but the results are not yet available, the

remaining packages from the same load should be quarantined and not used until the BI results are obtained.

Rationale: If a CI is nonresponsive or inconclusive, it is possible that the entire load is nonsterile; that is, the sterilization process failed. The use of CIs is only one way to verify sterilizer and cycle performance, however, and CIs vary widely in their response characteristics. It is also possible that errors in loading or packaging have resulted in sterilization failures in some (but not all) packages in the load. Therefore, a single nonresponsive or inconclusive CI should not be considered evidence that the entire load is nonsterile. The supervisor should exercise professional judgment in determining whether to recall the entire load, taking into account all factors having a bearing on the efficacy of the cycle and all performance indicators.

c) **Use of other indicators**

Indicators comprised of multiple, interactive enzyme tablets of bacterial origin, as described in 7.4.2.2, should be used in accordance with the manufacturer's written instructions in conjunction with a comprehensive quality control program.

7.4.3 Biological indicators

7.4.3.1 Definition

A biological indicator is a sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored. 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. A conventional BI requires incubation for an appropriate length of time to ensure that any surviving microorganisms will grow out.

7.4.3.2 Selecting biological indicators

Health care personnel should select BIs that consist of spores of *B. stearothermophilus* and comply with ANSI/AAMI ST19. In addition, data should be obtained from manufacturers on the reliability, safety, and performance characteristics of their products. Manufacturers of BIs also should be required to provide written instructions on the storage, handling, use, and microbiological testing of their products.

NOTE—Biological indicators with an enzyme-based early-readout capability are also available. This early readout may serve as the basis for release of processed items, including loads containing implantable devices. These BIs must be used within an appropriate challenge test pack (7.5.2) and must be cleared by the FDA.

Rationale: Various types of BIs are available, each with different response characteristics. The degree of quality control needed is a value judgment based on risks and benefits, and the choice of BI depends highly on the specific needs, resources, and sterilization equipment of the individual health care facility.

7.4.3.3 Frequency of use of biological indicators

Biological indicator challenge test packs (7.5.2) should be used during initial installation testing of steam sterilizers (7.5.3), after relocation (7.5.3), after sterilizer malfunction (7.3.2), after sterilization process failures (7.5.4.4), after any major repairs of the sterilizer (7.5.3), and for periodic quality assurance testing of representative samples of actual products being sterilized (7.8). Biological indicator test packs also should be used routinely in sterilization loads at least weekly, but preferably every day that the sterilizer is in use (7.5.4). If a sterilizer is designed to be used for multiple types of cycles (gravity-displacement, dynamic-air-removal, "flash"), then each sterilization mode should be tested.

Each load containing wrapped/packaged implantable devices should be monitored with a BI challenge test pack and, whenever possible, quarantined until the results of the BI testing (early readout or spore growth) are available. When documented medical exceptions dictate (e.g., the need for trauma-related orthopedic screw/plate sets), it may be necessary to release an implantable device before the BI results (early readout or spore growth) are known. As with all cycles, the sterilizer operator should review the sterilizer chart/printout and the results of other indicators that have been used to monitor the sterilization process (7.7). It should be documented that the device was released without the results of the BI being known. See annex C for examples of an implant log and exception form.

Rationale: The condition of the sterilizer equipment, the expertise of the sterilizer operator, and other factors determining 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 opportunity for the occurrence of an unnoticed event that could affect sterilization. Because of the potential consequences to the patient of the implantation of a nonsterile device, the sterilization of implantables should be closely monitored. Ideally, for maximum sterility assurance, each load of implantables should be quarantined until it is verified that BI testing has yielded negative results. It is recognized,

however, that in emergency situations, it might not be possible to maintain the quarantine of implantables for which there is an immediate need. Therefore, the recommendation concerning quarantine of implantables pending the outcome of BI testing states that implantables should be quarantined "whenever possible."

7.4.3.4 Biological indicators with enzyme-based early-readout capability

Biological indicators with enzyme-based early-readout capability may be used in the routine monitoring of items sterilized. The indicator outcome may serve as the basis for release of those items for use (7.7) when the indicator is used within an appropriate challenge test pack (7.5.2) and when all other aspects of the sterilization cycle, including loading, cycle selection, and physical monitoring, have been demonstrated to be adequate. Used properly, these indicators provide an early indication of the adequacy of the sterilization process. The manufacturer is responsible for providing written guidelines for interpretation of results. The user is ultimately responsible for the interpretation of indicator results, and should document acceptance criteria and procedures for indicator use.

Proper application of these devices requires that the performance of the sterilization process be periodically verified by either (a) allowing continued incubation in accordance with the manufacturer's instructions for a period of time sufficient to ensure that any surviving microorganisms will grow out or (b) using conventional BIs as indicated in 7.4.3.1 and 7.4.3.3. This periodic verification should be performed at least weekly, but preferably every day that the sterilizer is in use.

In the event of a sterilization process failure, no matter how detected, use of the sterilizer should be discontinued until a cause has been identified and the proper functioning of the sterilizer confirmed with a BI challenge test pack, as indicated in 7.3.2 and 7.4.3.3.

Indicators fully complying with the requirements for a conventional BI (as described in 7.4.3.1) should be used during initial installation testing of steam sterilizers (7.5.3); after relocation (7.5.3); after sterilizer malfunction (7.3.2); after sterilization process failures, no matter how detected (7.5.4.4); after any major repairs of the sterilizer (7.5.3); and for periodic quality assurance testing of representative samples of actual products being sterilized (7.8). Early-readout capabilities should not be relied upon for these critical assessments.

Rationale: Biological indicators provide the best means of confirming the ability of a sterilization process to inactivate a large population of viable microorganisms resistant to the sterilization process. Due to the retrospective nature of BI testing, however, test results are not always available on a timely basis. Biological indicators with enzyme-based early-readout capability can provide timely feedback on the efficacy of a sterilization cycle if quarantine of the sterilization load (until the outgrowth of spores can be assessed) is not feasible in a given situation. Under these circumstances, the routine use of these indicators with periodic verification by conventional BI testing, with the growth of both test and control BIs as the criteria, in conjunction with the implementation of an effective quality control system, provides an effective means of monitoring sterilization processes.

7.5 Sterilizer efficacy testing

7.5.1 General considerations

All steam sterilizers should be tested using BIs upon installation and routinely thereafter to ensure their effectiveness in sterilizing medical and surgical items. All steam sterilizers also should be tested using BIs after relocation, sterilizer malfunctions, major repairs, and sterilization process failures. Dynamic-air-removal sterilizers should be tested upon installation and periodically thereafter to ensure that the air removal system adequately removes air during the sterilization cycle. In addition, the air removal system should be tested after sterilizer relocation, sterilizer malfunctions, major repairs, and sterilization process failures. If a sterilizer is designed and used for multiple types of cycles (gravity-displacement, prevacuum, steam-flush pressure-pulse, "flash"), then each sterilization mode should be tested. This section covers the routine biological monitoring of sterilization cycles and the testing of sterilizers after installation, relocation, malfunctions, major repairs, and sterilization process failures. When any variable of a sterilization process is outside of its acceptable limits, a sterilization cycle always should be regarded as unsatisfactory, irrespective of the results obtained from BIs. Routine Bowie-Dick testing of dynamic-air-removal sterilizers is addressed in 7.6. The routine monitoring of "flash" sterilization cycles is covered in ANSI/AAMI ST37.

Rationale: The use of BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. See also the rationale for 7.5.3.1.

7.5.2 Challenge test pack

For the routine biological monitoring of gravity-displacement and dynamic-air-removal sterilizers and the testing of sterilizers after installation, relocation, malfunctions, major repairs, and sterilization process failures, the BI test pack should consist of 16 clean, preconditioned, reusable huck or absorbent surgical towels, in good condition, each approximately 16 in × 26 in (41 cm × 66 cm). Each towel is folded lengthwise into thirds and then folded widthwise in the middle (see Figure 9). 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 in wide, 9 in long, and 6 in high (23 cm × 23 cm × 15 cm). One or

more BIs are placed between the eighth and ninth towels in the approximate geometric center of the pack. If CIs are used, they should be placed adjacent to the BI(s). The pack is then taped in a manner that will yield the approximately 6 in (15 cm) height. The pack should weigh approximately 3 lb and should have a density of approximately 11.3 lb/ft^3. (See Figure 9 and annex B.)

NOTE—A wrapper should not be used for this test pack.

Commercially available disposable test packs may be used only if they are shown to be equivalent in scientific experiments. Manufacturers of disposable test packs should provide written information regarding the instructions for use, storage, handling, and testing of their products.

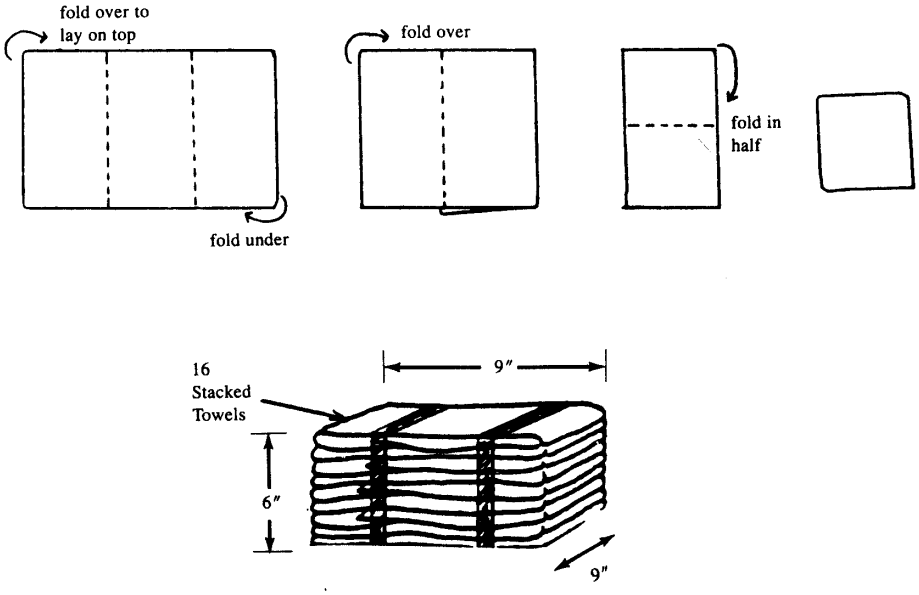


Figure 9—Preparation of the 16-towel BI test pack

Rationale: The 16-towel test pack provides a sterilization challenge for air removal and steam penetration to the BI and CI within the test pack. Use of the test pack provides evidence of the efficacy of the process with regard to microbial kill. The 16-towel pack is not wrapped, since the test pack is intended to provide a reproducible, well defined, easily constructed, standardized challenge to test sterilizer performance. Also, experience with the original, wrapped test pack has shown that the wrapper adds another difficult-to-control variable.

Only one BI need be used for the test in order to achieve a microbial challenge. There is no data to support the need for more than one BI. However, there are several considerations in using more than one BI:

a) They may provide additional information for a marginal cycle.

b) They may provide information on differences in sterility assurance at various locations.

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

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

See annex B for information on the development and qualification of the 16-towel test pack.

7.5.3 Installation testing

7.5.3.1 General considerations

The testing of a sterilizer after installation, relocation, and major repairs should be conducted in the health care facility by health care personnel in cooperation with the manufacturer. The testing should be performed between the time the steam sterilizer is installed, relocated, or repaired and the time it is released for use in the health care

facility. For gravity-displacement and dynamic-air-removal sterilizers, three consecutive cycles should be run, one right after the other, with a BI test pack (7.5.2), yielding negative results from all test BIs. The test may be performed in an otherwise empty chamber, because it is recognized that there might be insufficient material for a full load. For dynamic-air-removal sterilizers, three additional consecutive cycles should be run, one right after the other, with the Bowie-Dick test pack (7.6.1), with each test result demonstrating adequate air removal; as in routine Bowie-Dick testing, an empty chamber should be used for the tests.

Rationale: The purpose of testing 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 is intended to ensure that the sterilizer performs to specifications after the correction of a malfunction. The size and density of the BI test pack of 7.5.2 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.

7.5.3.2 Test pack placement

The BI test pack of 7.5.2 should be placed *flat* (layers of towels horizontal) on a rack or shelf in an otherwise empty sterilizer 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 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 10.)

Rationale: In the qualification testing that compared the performance of the 16-towel test pack to that of the original, 12 in $\times$ 12 in $\times$ 20 in pack (see annex B), the 16-towel test pack was positioned flat in the chamber. Placing the pack 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 in $\times$ 12 in $\times$ 20 in heterogeneous pack. Placement near the drain generally ensures that the pack is in the coolest portion of the chamber, but the sterilizer manufacturer is best able to advise the user on the “cold point.”

7.5.3.3 Test procedure

The test procedure is as follows:

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

b) The pack should be positioned in the chamber according to 7.5.3.2.

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

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

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

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

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

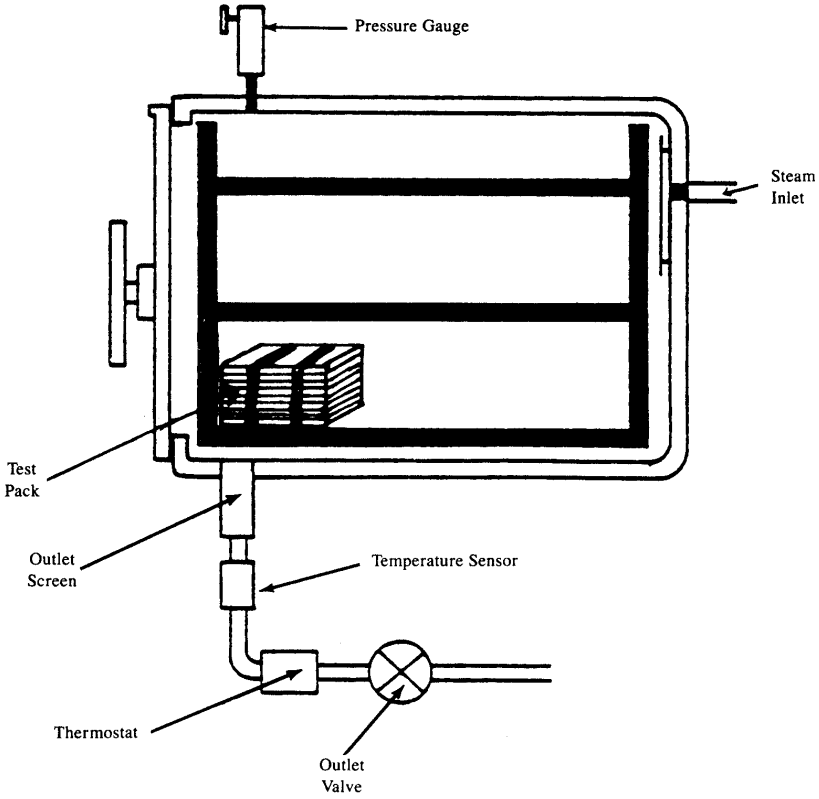


Figure 10—Placement of the 16-towel BI test pack for installation testing

7.5.3.4 Acceptance criteria

Three consecutive test runs with negative results from the test BIs, along with cycle printout records demonstrating correct and complete sterilization cycles, provide verification that the sterilizer has been properly installed (or reinstalled after relocation) or repaired to the manufacturer's specifications and will function effectively in the facility in which it is installed.

7.5.4 Routine biological monitoring

7.5.4.1 Test pack placement

Routine biological monitoring is performed in a fully loaded chamber. The 16-towel BI test pack of 7.5.2 should be placed flat (layers of towels horizontal) in the area of the sterilizer chamber and load that is least favorable to sterilization (i.e., the area representing the greatest challenge to the BI). The sterilizer manufacturer should identify the exact location of this area (the "cold point") in the instruction manual, and instruct users to place the test pack at this location. This area varies with sterilizer design, but is normally in the front, bottom section of the sterilizer, near the drain. (See Figure 11.)

Rationale: See the rationale for 7.5.3.2.

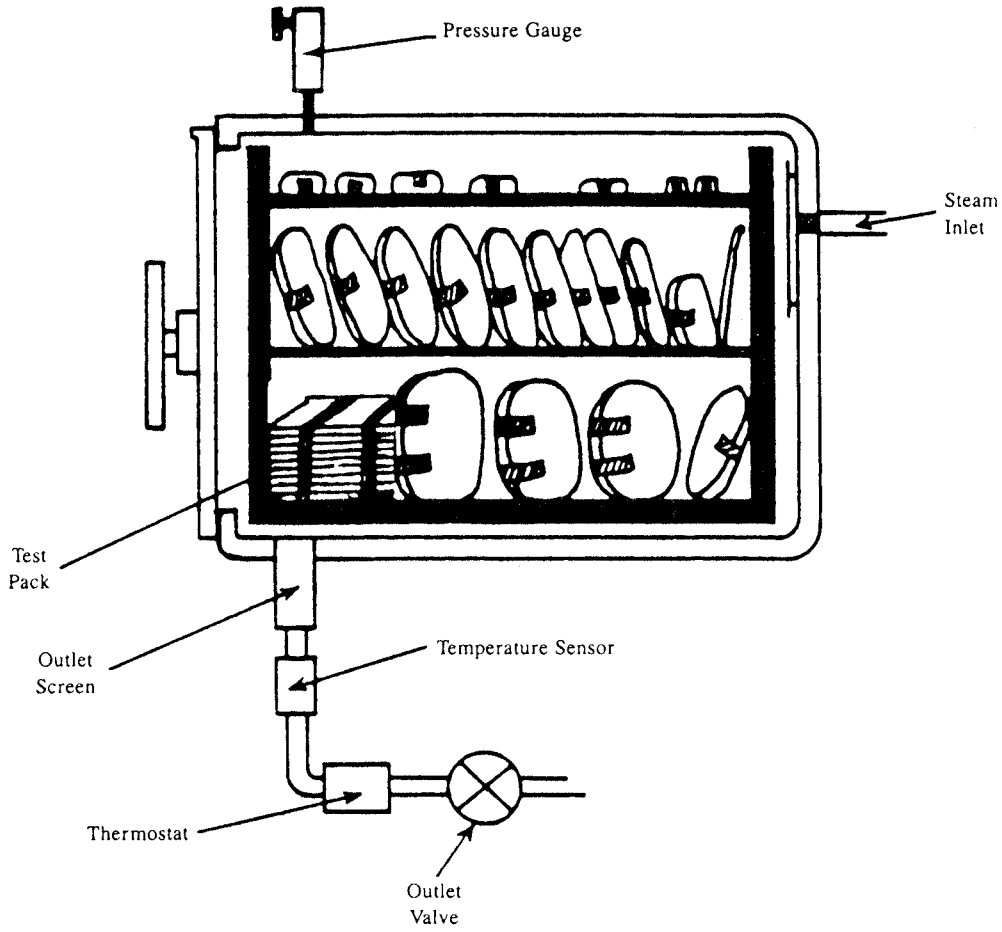


Figure 11—Placement of the 16-towel BI test pack for routine biological monitoring

7.5.4.2 Test procedure

The test procedure is as follows:

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

b) The pack should be positioned in the load according to 7.5.4.1.

c) A normal cycle should be run, according to the sterilizer manufacturer's instructions.

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

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

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

7.5.4.3 Acceptance criteria

An acceptable process is evidenced by negative results from all BIs in the test pack 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.

7.5.4.4 Positive biological indicator results

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

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

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

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

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

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

b) Because a sterilization failure has occurred, items processed in that sterilizer, dating from the sterilization cycle having the last negative BI to the next cycle showing satisfactory BI challenge results, should be considered nonsterile. They should be retrieved, if possible, and reprocessed. (See 7.9.)

c) The microbiology laboratory should perform a presumptive identification of the microorganisms present on the positive BI in accordance with the BI manufacturer's instructions and (if applicable) review the BI transfer technique. (See 7.5.5.)

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

e) After the cause of the sterilization failure has been determined and corrected, the sterilizer in question should be immediately rechallenged with a BI test pack (7.5.2) in three consecutive empty-chamber cycles. For dynamic-air-removal sterilizers, a Bowie-Dick test pack (7.6.3.1) also should be run in three consecutive empty-chamber cycles. Until the results of retesting are satisfactory (three cycles with negative BIs and three cycles with acceptable color change in the Bowie-Dick indicator), the performance of the sterilizer should be considered in question.

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

7.5.5 Microbiological testing

For positive BIs, the microbiology laboratory should perform a presumptive identification according to the BI manufacturer's instructions to determine whether the recovered microorganism is indeed the test microorganism that was on the BI spore strip or a laboratory contaminant.

Two subcultures are made from the recovered culture (the manufacturer should be consulted for the culturing procedure). One subculture is incubated at 95 °F to 99 °F (35 °C to 37 °C), and the other at 131 °F to 140 °F (55 °C to 60 °C), for 24 to 48 hours. Smears of the incubated subcultures are prepared, stained by Gram's method, and microscopically examined. Presumptive identification should be considered positive for *B. stearothermophilus* if microscopic examination reveals gram-positive/gram-variable, spore-bearing rods, and if the results of the incubation studies demonstrate growth at 131 °F to 140 °F (55 °C to 60 °C) but no growth at 95 °F to 99 °F (35 °C to 37 °C).

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

7.6 Dynamic-air-removal sterilizer residual air test

7.6.1 Purpose

This test, generally referred to as the Bowie-Dick test, is used to evaluate the efficacy of air removal in dynamic-air-removal steam sterilizers. It is *not* a sterility assurance test.

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

Rationale: Dynamic-air-removal sterilizers utilize preconditioning techniques to remove air from the sterilizing chamber and the load prior to pressurization with steam to a sterilizing 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 evaluate the ability of prevacuum sterilizers to reduce air residuals in the chamber space sufficiently to prevent air compaction by reentrainment into a load (the "small-load effect") as steam is introduced after evacuation. It was later found that the same test could provide evidence of air leaks and ineffective air removal with other air removal techniques that do not utilize a deep vacuum. 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.

7.6.2 Frequency of use

The Bowie-Dick test should be carried out each day the sterilizer is used, before the first processed load. A Class 2 CI is used in conducting this test (see ANSI/AAMI ST66). A shortened cycle (i.e., a cycle omitting the drying phase) should be run first to properly heat the sterilizer. If the sterilizer is used continuously, the test may be performed at any time, but should be performed at the same time every day. The Bowie-Dick test also should be carried out during initial installation (7.5) and after relocation (7.5), sterilizer malfunction (7.3.2), sterilization process failures (7.5.4.4), and major repairs (7.5).

Rationale: A Bowie-Dick test is conducted every day, before the first processed load, because it is a sensitive and rapid means of detecting air leaks and inadequate air removal. Insufficient air removal in a dynamic-air-removal sterilizer or air leaks in a prevacuum sterilizer can defeat dynamic-air-removal steam sterilization and result in a large volume of nonsterile supplies if undetected. See also 7.6.1.

7.6.3 Test pack composition

7.6.3.1 Towel packs constructed in the hospital

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

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

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

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

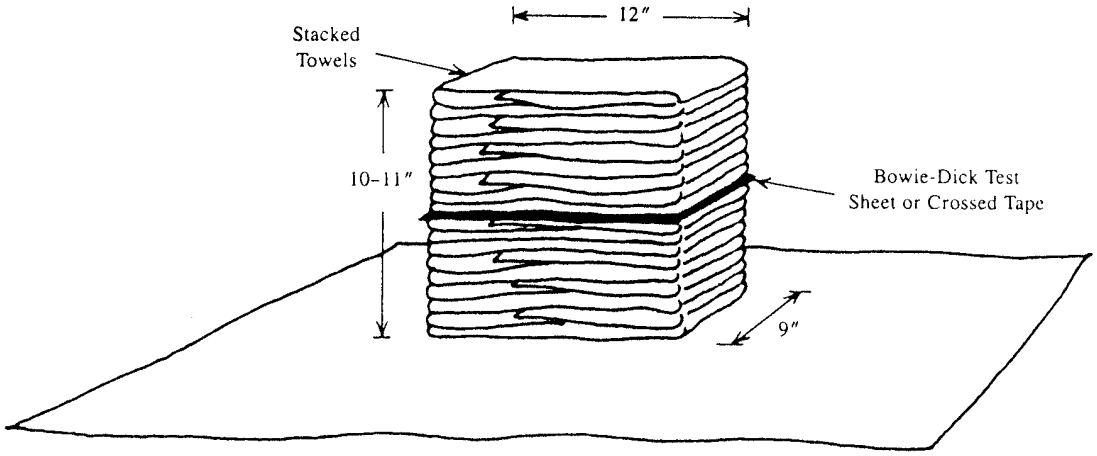


Figure 12—Composition of the Bowie-Dick test pack

7.6.3.2 Other test packs and test devices

Test packs or devices other than that described in 7.6.3.1, such as disposable Bowie-Dick-type test packs, may be used only if in scientific experiments they have been proven to be equivalent.

Rationale: See the rationale for 7.6.3.1.

7.6.4 Test pack placement

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

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

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

7.6.5 Test procedure

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

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

7.6.6 Acceptance criteria

Any unexpected color change, such as the center of the test sheet being paler or a different color than the edges (i.e., there is a nonuniform color change) indicates that there was an air pocket present during the cycle due to sterilizer malfunction. Any test results that do not conform to the recommended color standards provided by the manufacturer of the test sheet should be reported to the supervisor on duty, who will determine the disposition of the sterilizer (i.e., whether it should be retested, serviced, or remain in use).

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

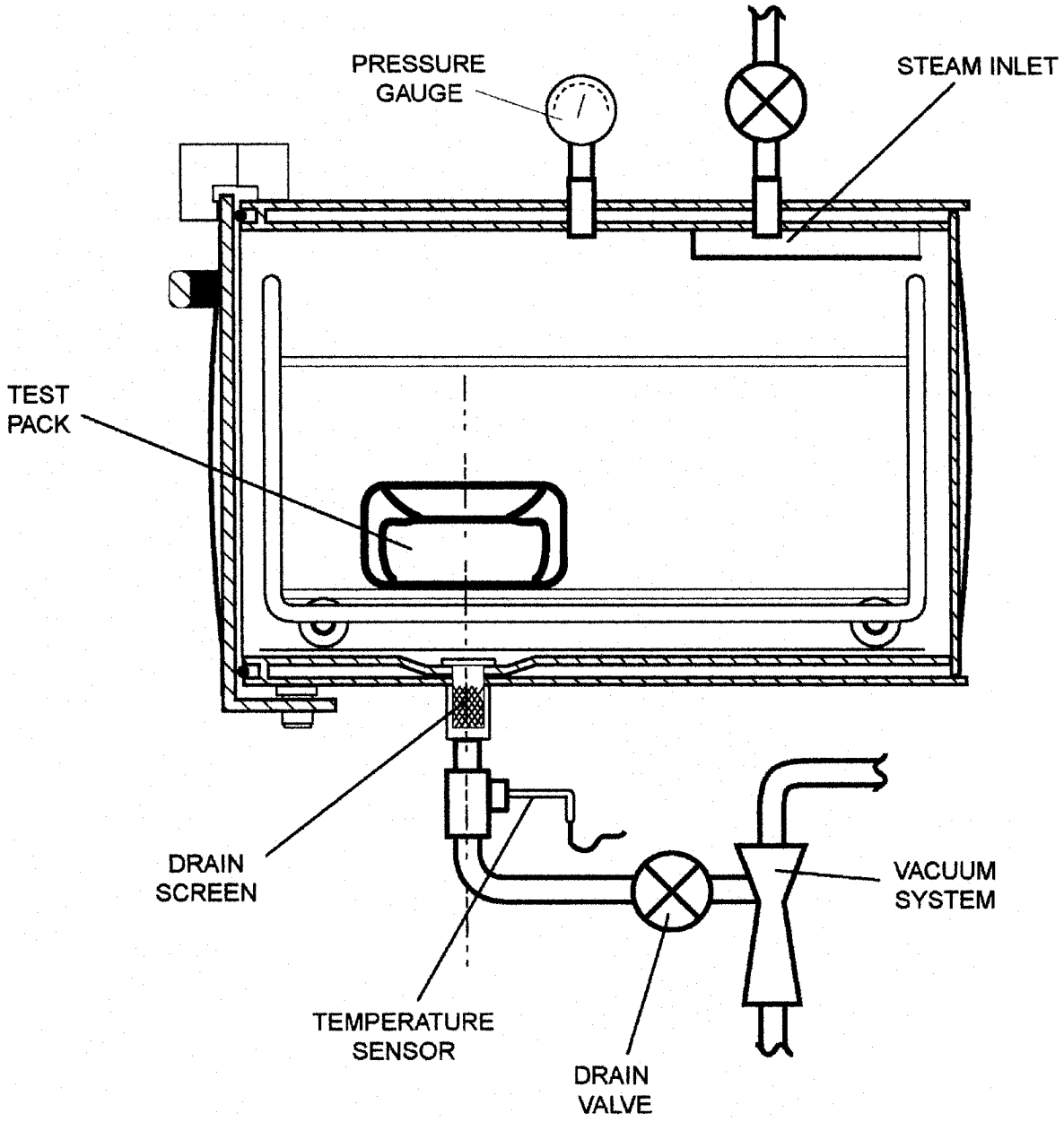


Figure 13—Placement of the Bowie-Dick test pack

7.7 Product release

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

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

7.8 Product testing

Quality assurance testing of routinely processed items should be performed on an ongoing basis. A program should be established to periodically test products routinely sterilized. Product testing always should be performed when major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper used. The test program should include BI testing and an evaluation of poststerilization moisture content (i.e., the occurrence of "wet packs").

Biological indicators, as described in 7.4.3.2, should be placed within the product test samples; CIs of Class 3, 4, and/or 5 also may be used. The number of BIs and CIs used within each product test sample will depend on the size and configuration of the pack being tested. Product test samples should be properly identified and placed among other products in a routine sterilizer load. The product test samples should be placed strategically throughout the load at the points most difficult to sterilize (i.e., the most resistant to steam penetration). After inspection and retrieval of the BIs and CIs, sample packs used in product testing should be disassembled and the contents either reprocessed or discarded, as appropriate. Examples of product testing are:

a) For textile packs wrapped in woven or nonwoven materials, the BIs and, if used, 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, if used, 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 may be appropriate to use BIs contained in glassine envelopes rather than BIs in rigid containers, since the latter could separate the basins (permitting more steam contact) and the ampules could break.

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

d) For containers, the BIs and, if used, CIs should be placed in each corner, the center, and any other areas recommended by the container manufacturer. (See ANSI/AAMI ST33.)

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

Moisture content can be checked by weighing product test samples before sterilization and after sterilization and cooling. Product test samples also should be examined for water droplets and water stains when they are removed from the sterilizer, cooled, and opened. There should be no more than a 3 % increase in the weight of absorbent material used in the pack or tray, and no evidence of excessive moisture if the sterilizer is performing properly and 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). See also Reichert and Young (1997).

Any test results that indicate a problem, such as positive BIs or wet packs, should be thoroughly investigated. It might be necessary to change the configuration of the load and/or items within the package, or to service the sterilizer. Product use should be discontinued until the problem is resolved. (See also 5.6, 5.7, Lee [1997] and ISO 13683.) The test protocol, test results, and any corrective actions taken should be documented and maintained as part of the sterilization log or quality assurance program data.

Rationale: The standardized BI test pack of 7.5.2 presents a known challenge to the sterilization process. However, this pack does not reflect 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 avoid wet packs. The products to be tested will vary from institution to institution, depending on the types of products routinely sterilized. The contents of the sample packs are exposed to a greater population of bacterial spores than are other products, and therefore should not be used in patient care unless reprocessed. Also, inspecting the pack and retrieving the BIs and CIs contaminates the contents.

7.9 Product recalls

7.9.1 General considerations

Written policies and procedures for the recall of items from issued or stored loads should be developed in cooperation with the infection control committee and risk management of the individual institution. These policies and procedures should be documented, and records should be maintained. Recall of processed supplies is at the discretion of the department head or designee. Whenever there is evidence of a sterilization failure, the infection control officer should be notified so that follow-up surveillance of patients can be conducted. Written policies and procedures should be developed for compliance with the Safe Medical Devices Act of 1990 as it pertains to failures of reusable medical devices (i.e., the Medical Device Reporting [MDR] regulations of 21 CFR 803). For additional information on user facility MDR requirements, see FDA (1996b).

Rationale: To ensure patient safety and compliance with the user facility reporting requirements of the Safe Medical Devices Act of 1990, the health care facility should establish recall procedures to expedite the retrieval of processed items that are suspected to be nonsterile and to ensure adequate follow-up actions such as quarantine of the sterilizer, notification of physicians and affected clinical departments, and surveillance of patients.

7.9.2 Recall procedure

A recall procedure should

a) be written;

b) outline the circumstances for issuing a recall order;

c) designate the person(s) authorized to issue a recall order; and

d) designate the person(s) responsible for reporting on the execution of a recall order.

7.9.3 Recall order

A recall order should

a) be immediately communicated to affected departments and followed by a written order;

b) identify by sterilization lot number the products to be recalled;

c) identify the persons or departments to whom the order is addressed;

d) require the recording, in terms of kind and quantity, of the products obtained in the recall; and

e) specify the action to be taken by the persons receiving the order (e.g., destruction or return of product).

7.9.4 Recall report

A report of a recall order should

a) identify the circumstances that prompted the recall order;

b) specify the corrective action(s) taken to prevent a recurrence;

c) state, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall; and

d) provide verification that the recalled items were reprocessed or destroyed, as appropriate.

8 Quality process improvement

8.1 General rationale

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

8.2 Quality process

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, health care facility policies and procedures for the handling of unfavorable/unplanned events, and the type of process variable.

A problem analysis should be completed for any problem relating to any aspect of steam sterilization processing that could pose a risk to personnel or patients. The problem analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected.

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

According to the 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 make improvements in performance.

8.3 Functional areas for product and process improvements

8.3.1 Workplace design

Optimization of product and process performance relies on efficient workplace design. Problems such as cross-contamination, excessive processing costs, product failures, inefficient time usage, and so on can be created or aggravated by poor workplace design. Workplace design encompasses the physical layout of the reprocessing area, functional work flow patterns, physical facilities (e.g., mechanical and electrical systems, lighting, plumbing, ventilation, environmental controls), and types and locations of processing equipment and supplies. The adequacy of the workplace design should be assessed by such means as employee input, accident records, and evaluation of the workplace in terms of the recommendations of section 3.

8.3.2 Processing policies and procedures

Evaluating and monitoring the effectiveness of the process should be an ongoing effort and is critical to maintaining control over and determining methods for improvement of the product and process. The review of records and documented quality control procedures that have been implemented should serve as the basis for monitoring and evaluating the process. Written procedures should be reviewed, and current practices audited for compliance in the areas included in the CQI program, for example:

a) training and continuing education (see 4.3);

b) medical device processing protocols (see section 5);

c) maintenance of sterilizers (see section 6);

d) product identification and traceability (i.e., lot control numbers [7.2.1] and load records [7.2.2]);

e) sterilizer physical monitoring records (see 7.3);

f) sterilization process indicator records (see 7.4);

g) sterilizer efficacy testing records (see 7.5 and 7.6); and

h) product testing records (see 7.8).

8.3.3 Product use

Evaluating the performance of products that have been or will be used can offer important feedback on the effectiveness of the process and/or the appropriateness of the products selected. Performance measures can come from internal evaluations, end-user feedback, and/or supplier testing.

a) **Internal evaluations.** Internal evaluations can be used to audit the quality of finished products. For example, instrument packs can be evaluated by observing the number, type, and configuration of their components. Preprocessing decontamination can be evaluated by visually examining instruments for contamination. Product recalls can be evaluated by reviewing records of actions following documented sterilization cycle failures. Periodic product monitoring can be evaluated based on the appropriateness of the loads tested and the actions taken as a result of failures.

b) **End-user feedback.** A formal documented system to log, investigate, and resolve complaints and/or product failures should be established. Issues such as patient infections, protective attire failures, inoperative instruments and equipment, incorrect pack configurations, and dispensing of incorrect products should be documented, monitored, and tracked over time. A procedure should be established for investigation and remediation of serious and repeat problems.

c) **Supplier testing.** Concerns relative to the performance of products and/or supplies should be evaluated by the manufacturer through testing. There should be a written request to and response from any vendor

whose products, supplies, or services are in question. All correspondence should be filed with the corresponding complaint, including details of the investigation, findings, and any actions taken by the vendor for resolution of the problem.

8.4 Implementing product and process improvements

There is no single right way to implement a CQI program. The program should be customized to the individual facility. However, a team approach has been proven to be successful because it allows direct input from multiple employees and results in a superior program.

Employees who are actively involved in and responsible for the day-to-day functions outlined in the plan should be members of the team. This approach generates input from those most knowledgeable in methods of effectively improving the program. Additionally, such involvement promotes in those individuals a sense of ownership and tends to lead to a higher degree of commitment on the part of the employees implementing the program.

The single most important issue for those charged with implementing a CQI program is the accurate collection of data using the facility plan for documenting process monitoring and product performance (developed as part of the CQI program). The frequency and type of information generated will vary based on the level of control established in the documentation plan. Facilities with processes that are uncontrolled or highly variable will require increased process monitoring and documentation, which can be reduced over time as the program brings these processes under improved control.

The CQI program should assess all components of the sterilization process for the ongoing ability to achieve the desired outcome of consistently delivering a sterile product to the user. Performance improvement plans, when needed, should be implemented to enhance the sterilization process based on this assessment. Trending data for the number of BI tests, number of BI failures for each sterilizer, education compliance (percentage attending or percentage passing tests or competency measures), time and completeness of sterilizer preventive maintenance, ability to locate all items during recalls, and completeness of test records are examples of measures to be considered when assessing the process.

Annex A
(informative)

Examples of workplace design

NOTE—All figures 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.

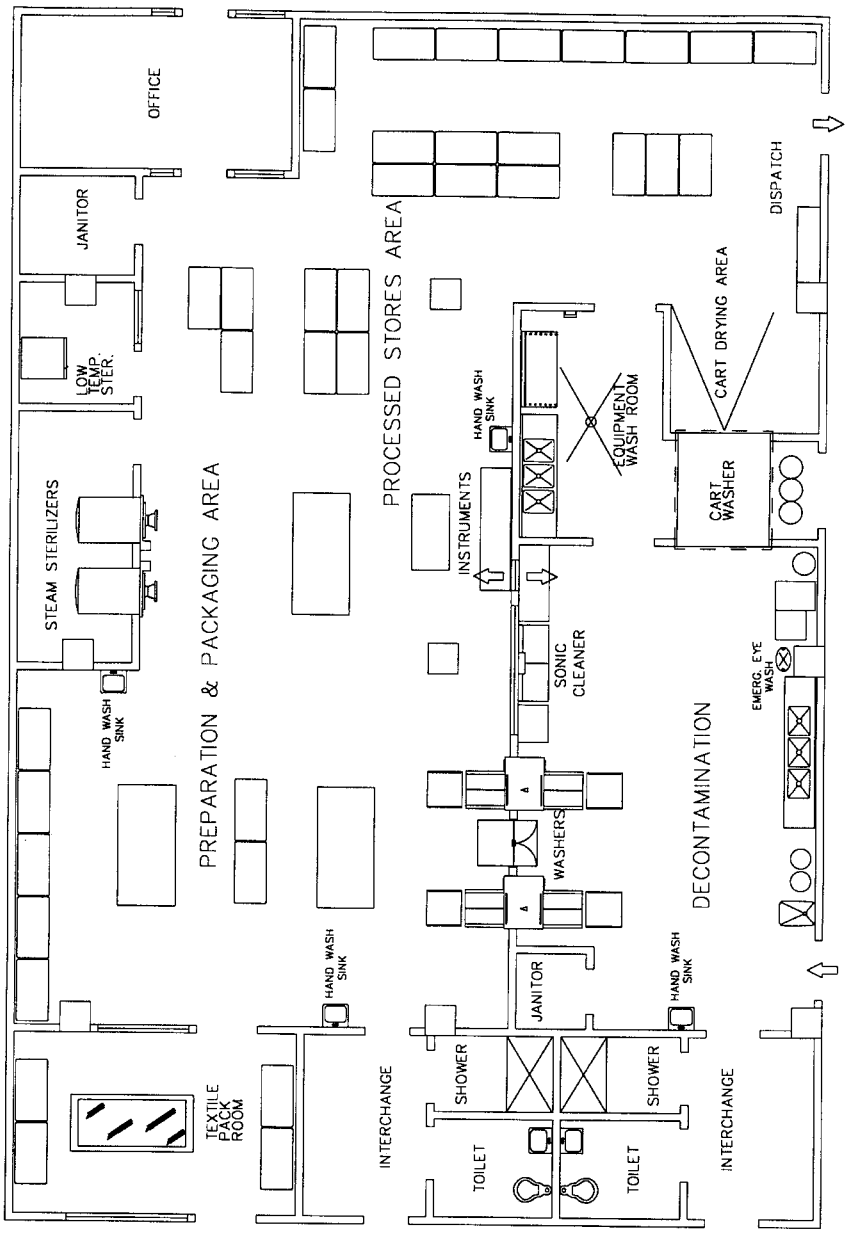


Figure A.1—Example of a work area design and work flow pattern for a sterile processing department in a typical small hospital

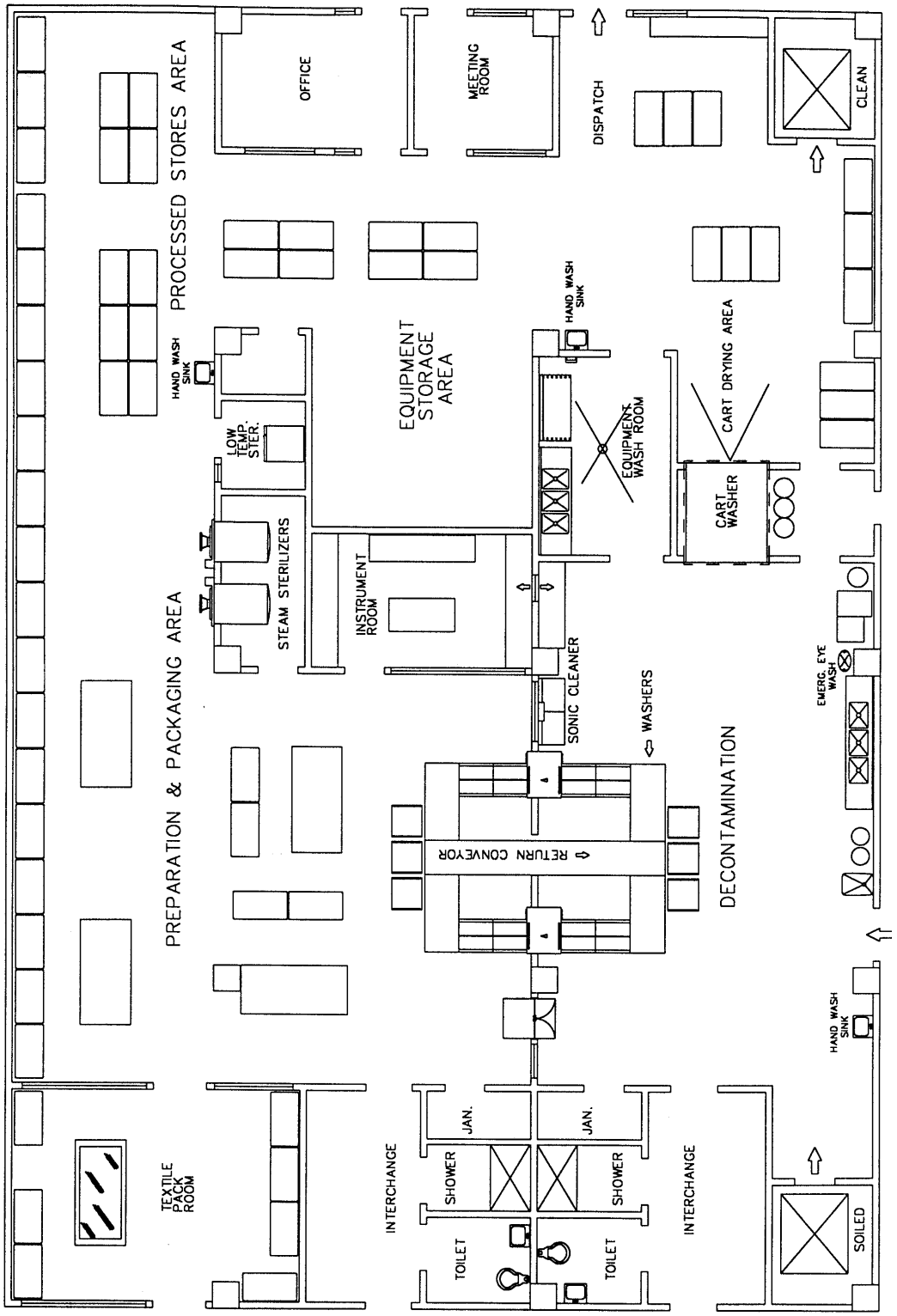


Figure A.2—Example of a work area design and work flow pattern for a sterile processing department in a typical medium-sized hospital

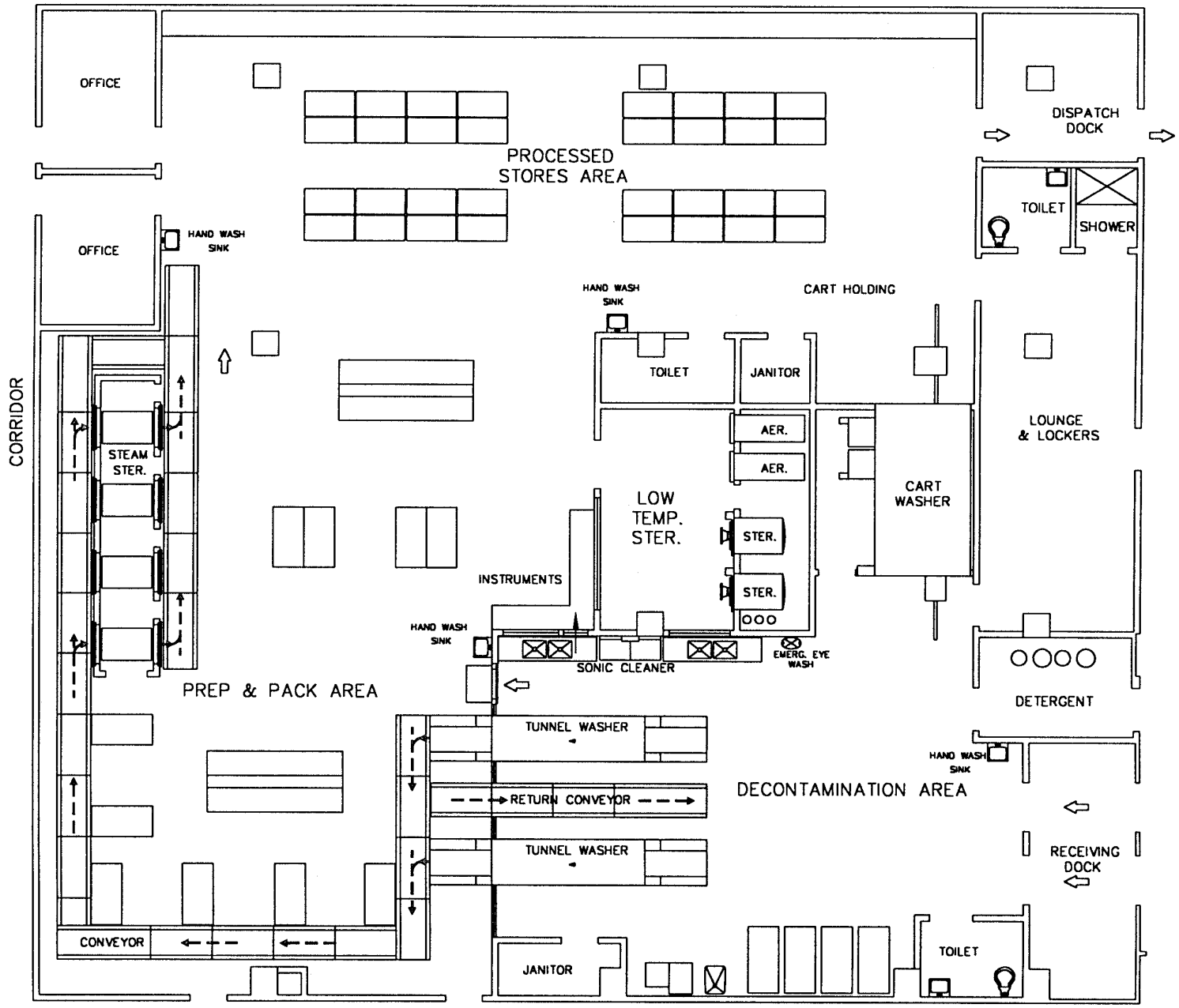


Figure A.3—Example of a work area design and work flow pattern for a sterile processing department in a typical regional processing center

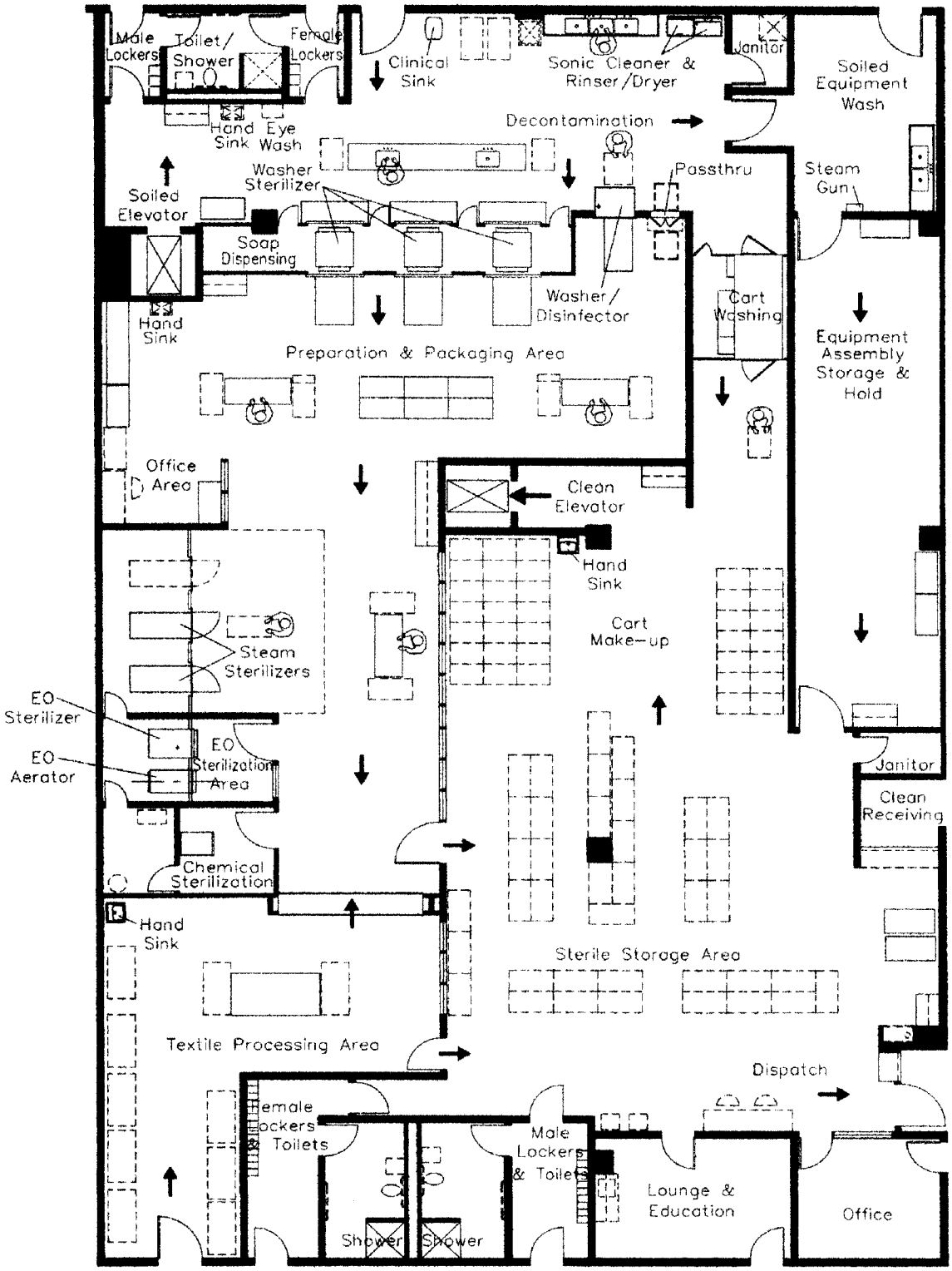


Figure A.4—Example of a work area design and work flow pattern for a sterile processing department

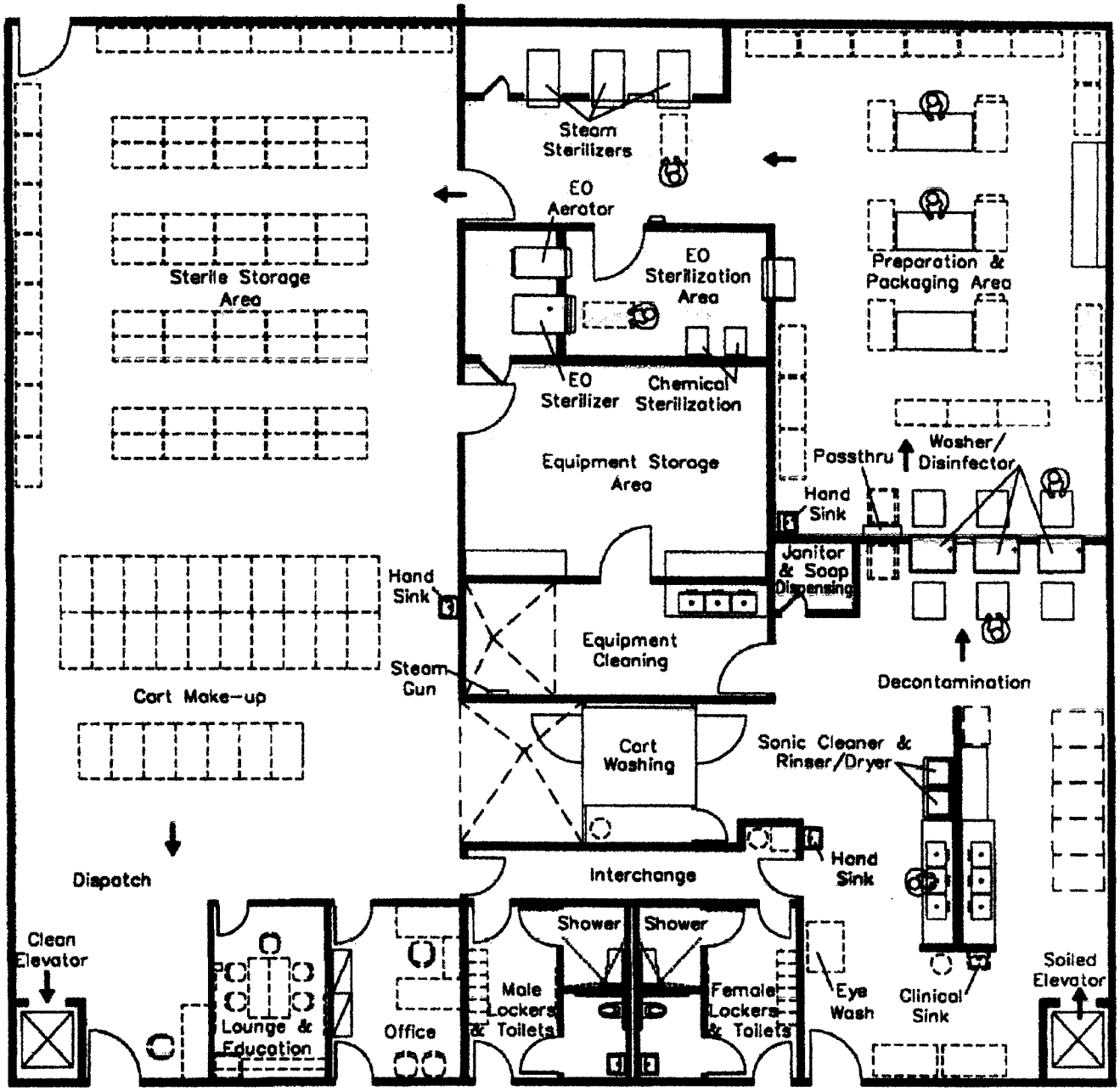


Figure A.5—Example of a work area design and work flow pattern for a sterile processing department

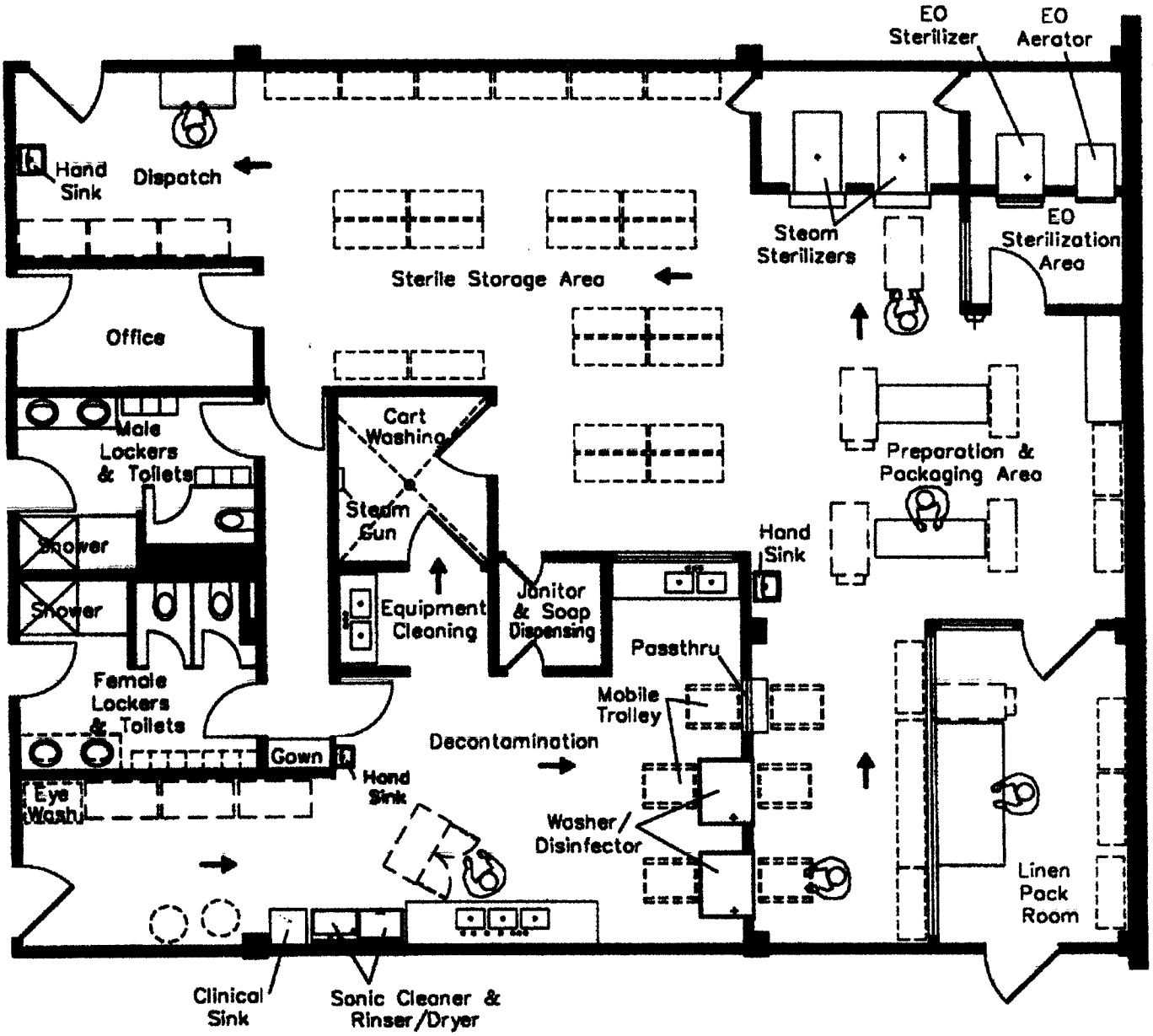


Figure A.6—Example of a work area design and work flow pattern for a sterile processing department

Annex B
(informative)

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

B.1 Introduction

The first edition of this recommended practice (AAMI, 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, sequentially wrapped with 2 muslin wrappers. The test pack was recommended to be approximately 12 in × 12 in × 20 in and weigh 10 lb to 12 lb, for a resulting pack density of 7.2 lb/ft^3. 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 (AORN, 1982; General Services Administration, 1975) and individual health care facilities and became a hospital standard for biological monitoring.

In the years following adoption of the 12 in × 12 in × 20 in test pack, numerous comments were raised concerning difficulties in obtaining items to make up the pack, the placement of biological indicators within the pack, the appropriateness of the muslin wrapper, and the rationale for the pack contents. The Hospital Practices Working Group of the AAMI Steam Sterilization Subcommittee formed a task force to investigate these issues. The results of a survey of hospital personnel revealed a need for a simpler steam BI test pack with more readily available contents. Respondents to the survey recommended that (a) the new pack consist of materials whose properties could be specified so that critical parameters affecting steam penetration and air removal are controlled; (b) rationale and documentation be developed to specify BI placement within the pack; and (c) the pack exhibit performance characteristics essentially equivalent to the current test pack.

Through a cooperative effort among hospital personnel, industrial representatives, and independent consultants, testing was conducted to develop a new BI test pack for evaluation of steam sterilizers within health care facilities. The new pack was to have performance characteristics similar to the old pack and consist of materials readily available to hospital personnel. This annex summarizes the testing that resulted in the new 16-towel test pack recommended as an alternative to the original pack in the second edition of the recommended practice (AAMI, 1988), and recommended here as the sole challenge pack.

B.2 Survey and preliminary testing

Before any laboratory testing, a questionnaire was distributed to health care personnel to solicit their thoughts on the original 12 in × 12 in × 20 in pack and ideas concerning a new test pack. Results of the questionnaire confirmed that most hospitals did not have available all of the materials to make the 12 in × 12 in × 20 in pack, since they were purchasing such items as lap sponges as sterile, single-use items. The majority of the respondents indicated that they 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. Since surgical towels also were used in the Bowie-Dick test pack and recommended for use in EO test packs (AAMI, 1985), it was decided to investigate the use of surgical towels for the BI test pack.

Questions arose about the variability of surgical towels used by health care facilities and how this might affect test pack performance. More than 20 test packs were obtained from health care facilities throughout the country. All towels had been washed and were in routine use at the various institutions. Average surgical towel dimensions were 16.5 in by 26.3 in.

In considering the characteristics of the 12 in × 12 in × 20 in heterogeneous pack, it was noted that 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 250 °F gravity cycle to determine the number of towels and size of test pack needed to yield performance characteristics similar to those of the 12 in × 12 in × 20 in pack.

Figure B.1 shows temperature profiles from 12 in × 12 in × 20 in 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 12 in × 12 in × 20 in pack.

It was agreed that the performance of the new towel pack should approximate that of the slower-to-heat 12 in × 12 in × 20 in pack illustrated in Figure B.1. The preliminary testing indicated that 16 surgical towels folded to produce a pack with overall pack dimensions of 9 in × 9 in × 6 in yielded thermal come-up profiles and BI results comparable to the 12 in × 12 in × 20 in pack with the slowest heat-up time.

Tests were run to compare horizontal (flat) versus vertical (on edge) placement of the towel pack. As expected, horizontal placement provided more of a challenge to sterilization in a gravity cycle, as indicated by a longer come-up time (1 min to 2 min) and 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, since 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 B.1 summarizes characteristics of the 16-towel packs that were tested. The average pack dimensions were 9.4 in × 8.9 in × 6.1 in. The average weight and density of the packs were 3.3 lb and 11.3 lb/ft^3, respectively. Questions arose concerning the differences between huck and absorbent surgical towels used to make up a 16-towel pack. Figure B.2 shows the average temperature profiles in a gravity cycle for the two types of packs. No significant differences were observed.

Table B.1—16-towel pack survey

Towel size		Average pack size			Average pack weight (lb)	Average pack density (lb/ft^3)
Length (in)	Width (in)	Length (in)	Width (in)	Height (in)		
26.3 ± 2.1*	16.5 ± 1.3*	9.4	8.9	6.1	3.3**	11.3

* Average ± one standard deviation.

** Pack weights ranged from 2.6 lb to 3.7 lb.

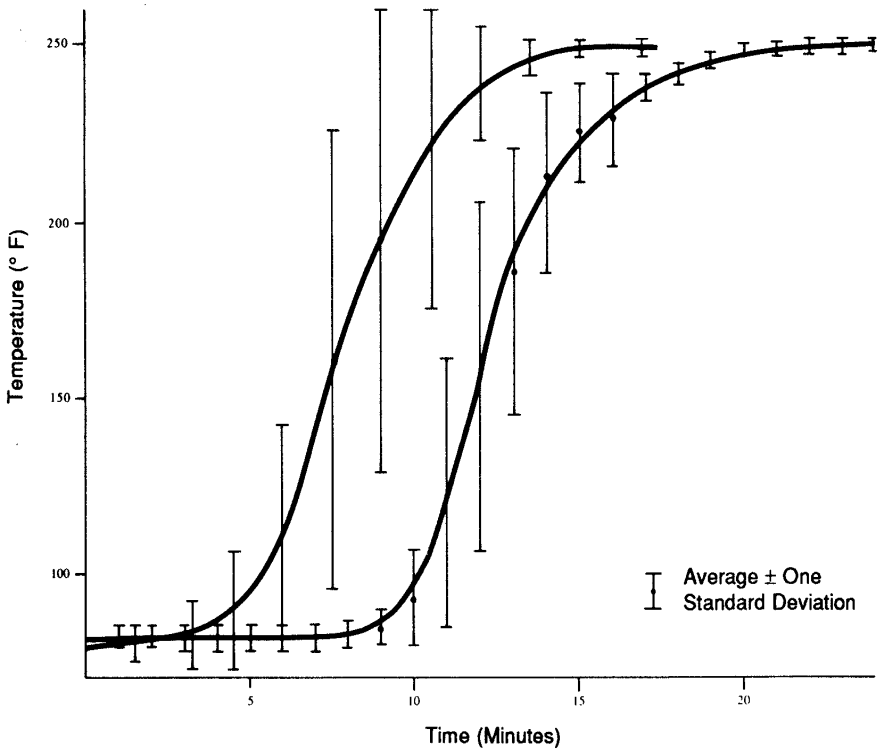


Figure B.1—Temperature profiles for two different configurations of 12 in × 12 in × 20 in packs in a 250 °F gravity cycle

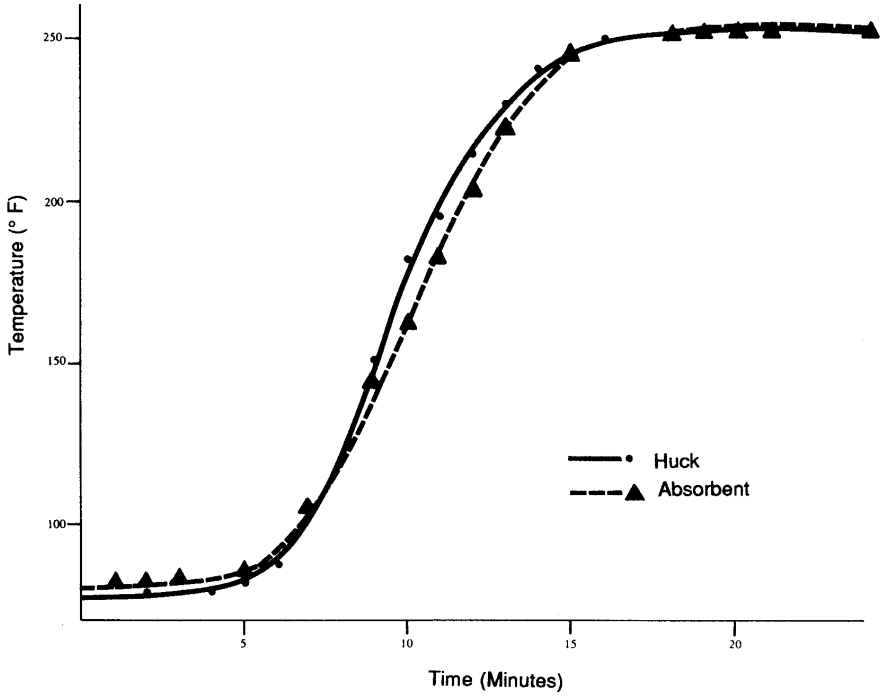


Figure B.2—Temperature profiles for huck and absorbent 16-towel packs in a 250 °F gravity cycle

B.3 Validation testing in gravity cycles

The 16-towel test packs were processed in 250 °F gravity cycles. Thermocouples and BIs were placed in the center of each pack. The 12 in × 12 in × 20 in packs were similarly instrumented to permit a direct comparison of the two types of packs. The 12 in × 12 in × 20 in 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 B.3 shows the average temperature profile for the 16-towel pack, which is very similar to the profile shown in Figure B.1 for the slowest-to-heat 12 in × 12 in × 20 in pack. The pack-to-pack variation for the 16-towel pack was significantly less than for the 12 in × 12 in × 20 in pack, as evidenced by the standard deviations. Table B.2 shows the BI results; the 16-towel pack was less resistant than the 12 in × 12 in × 20 in pack in a 250 °F gravity cycle.

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

Exposure time (minutes)	Biological indicator response*			
	12 in × 12 in × 20 in pack		16-towel pack	
	Spore strips			
16	nt**		4/4	(100 %)
18	2/2	(100 %)	1/4	(25 %)
20	5/12	(42 %)	8/16	(50 %)
22	3/4	(75 %)	nt**	
25	0/12	(0 %)	0/10	(0 %)
	Self-contained			
16	nt**		5/8	(63 %)
18	4/4	(100 %)	2/8	(25 %)
20	11/16	(69 %)	7/24	(29 %)
22	4/8	(50 %)	nt**	
25	0/16	(0 %)	0/12	(0 %)

* Number positive/number exposed (% positive).

** Not tested.

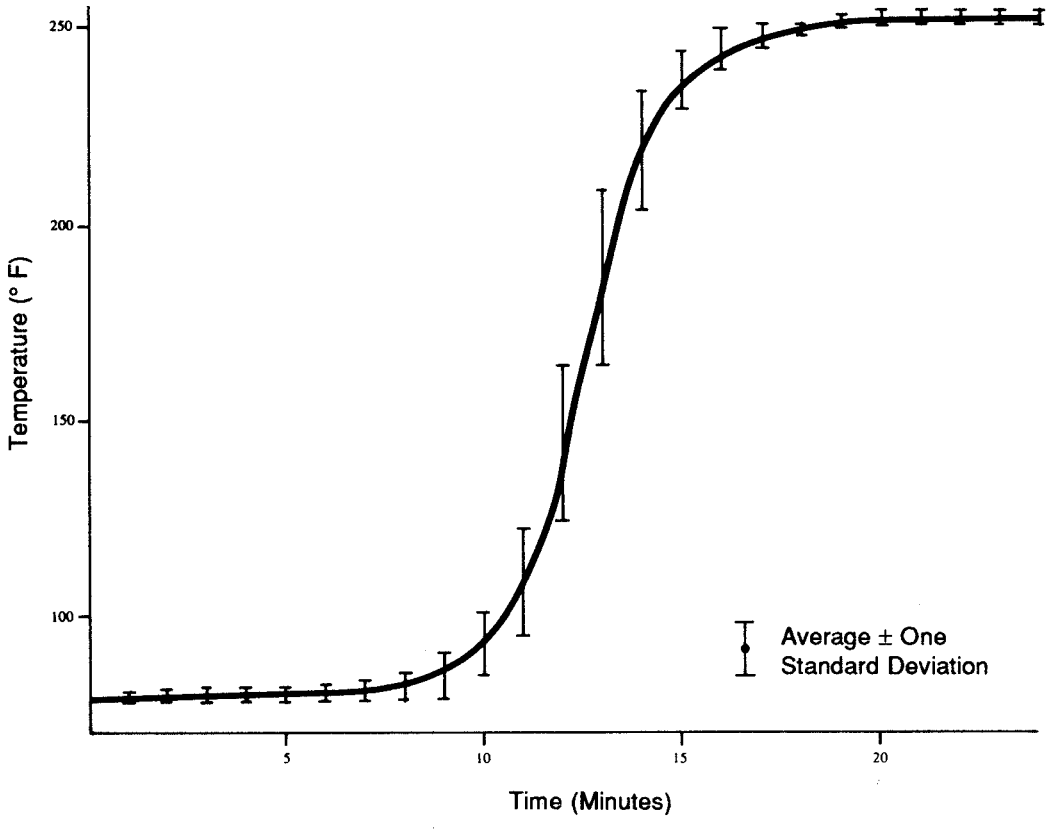


Figure B.3—Average temperature profile for the 16-towel pack in a 250 °F gravity cycle

B.4 Validation testing in prevacuum cycles

Both deep-vacuum and pulsing prevacuum sterilizers were used for the evaluations. In general, the center-of-pack temperatures closely followed the sterilizer drainline temperature. The temperature profiles of the 12 in × 12 in × 20 in pack and the 16-towel pack were identical, or the 16-towel pack lagged behind the 12 in × 12 in × 20 in pack by a maximum of 30 seconds. Table B.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 min to 4 min. The data indicates that in prevacuum cycles, the 16-towel pack is slightly more resistant than the 12 in × 12 in × 20 in pack. Table B.4 summarizes the BI results when test packs were run in a pulsing vacuum cycle at 270 °F. As with the deep-vacuum cycle, the 16-towel pack was slightly more resistant.

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

Exposure time (minutes)	Biological indicator response*			
	12 in × 12 in × 20 in pack		16-towel pack	
	Spore strips			
0	3/4	(75 %)	4/4	(100 %)
0.5	5/14	(36 %)	4/18	(22 %)
2	0/18	(0 %)	0/18	(0 %)
3	0/16	(0 %)	0/16	(0 %)
4**	0/16	(0 %)	0/16	(0 %)
	Self-contained			
0	8/8	(100 %)	8/8	(100 %)
0.5	20/28	(71 %)	26/28	(93 %)
2	4/28	(14 %)	14/28	(50 %)
3	5/32	(16 %)	11/32	(34 %)
4**	0/32	(0 %)	0/32	(0 %)

* Number positive/number exposed (% positive).

** Recommended exposure.

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

Exposure time (minutes)	Biological indicator response*			
	12 in × 12 in × 20 in 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 %)

* Number positive/number exposed (% positive).

B.5 Direct comparison of the 12 in × 12 in × 20 in 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 in × 12 in × 20 in 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 chemical indicators were scored on a ranking scale. The ranking scale was 0 to 13, with 13 equal to a complete change of the chemical indicator. A thermocouple was located approximately 2 in from the chamber drain, and temperature readings were taken at 1 min intervals to calculate an F_o value for each cycle.

The results of the first and second series of tests are shown in Table B.5 and Table B.6, respectively. The data shown in Table B.6 was evaluated statistically to determine if performance between the two packs differed significantly. An F-test showed homogenicity of variance for both the fraction-value and chemical-indicator data. A series of paired or unpaired t-tests, using data with F_o values in the range of 18 min to 27 min or 26 ± 1 min, showed no significant differences between the 16-towel pack and the 12 in × 12 in × 20 in pack (t = 0.124 to 0.402, p 0.05, 4 or 5 d.f.). The Mann-Whitney U-test also showed no significant differences between the two types of pack (p 0.35, $n_1 = n_2 = 5$, U = 10). There was minimal correlation between the independent variables (steam exposure time or F_o value) and the dependent variables (fraction-value or chemical-indicator results), with t-values in the range of 0.176 to 0.834 (p 0.5 to 0.1, 3 d.f.).

Overall, this data provides little or no support for a rejection of the null hypothesis of no difference between the 16-towel test pack and the 12 in × 12 in × 20 in test pack at the p = 0.1 level; that is, no statistically significant differences were found in the performance of the two packs.

B.6 Summary of round-robin testing

The results of testing showed significant variation in the performance of the 12 in × 12 in × 20 in 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 in × 12 in × 20 in 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 in × 12 in × 20 in pack.

Table 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)*

Exposure time (at 250 °F)	Most Probable Number assessment			Sterility assessment (survivors/no. tested)
	Spore strip	Suspending fluid	MPN value	
14 minutes				
16-towel pack	#1	+	800	3/3
	#2	+	460	
12 in × 12 in × 20 in pack**	#1	+	460	3/3
	#2	+	3,000	
15 minutes				
16-towel pack	#1	+	460	1/3
	#2	+	< 460	
12 in × 12 in × 20 in pack**	#1	+	460	2/3
	#2	+	460	
16 minutes				
16-towel pack	#1	+	460	nt***
	#2	+	< 460	
12 in × 12 in × 20 in pack**	#1	+	460	nt***
	#2	+	460	

* Noncollaborative data gathered by Sterilization Technical Services.

** 52 in × 52 in wrap.

*** Not tested.

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

F_o value	Intended exposure time at 250 °F (min)	16-towel pack				12 in × 12 in × 20 in pack**			
		Spore strip	Chemical indicator***			Spore strip	Chemical indicator***		
			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		

* Noncollaborative data gathered by Sterilization Technical Services.

** 50 in × 64 in wrap.

*** Scale of chemical indicator response:
0 = no evidence of sterilization
13 = complete response, indicating sterilization conditions met.

B.7 Supplemental data for steam-flush pressure-pulsing cycles

Subsequent to the round-robin testing to qualify the 16-towel test pack, noncollaborative data was collected to compare the 16-towel test pack and 12 in × 12 in × 20 in test pack in steam-flush pressure-pulse cycles. The two types of test packs were processed in 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, since all of the BIs were killed in the test exposure times (see Table B.7). Similar testing was performed for 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 (see Table B.8).

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

Exposure time (min)	Biological indicator response**			
	12 in × 12 in × 20 in pack		16-towel pack	
	Spore strips			
8	17/18	(94.4 %)	18/18	(100 %)
10	0/18	(0 %)	0/18	(0 %)
12	0/18	(0 %)	0/18	(0 %)
14	0/18	(0 %)	0/18	(0 %)
	Self-contained			
8	18/18	(100 %)	18/18	(100 %)
10	3/18	(16.6 %)	6/18	(33.3 %)
12	0/18	(0 %)	0/18	(0 %)
14	0/18	(0 %)	0/18	(0 %)

* Noncollaborative data gathered by Joslyn Sterilizer Company.

** Number positive/number exposed (% positive).

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

Exposure time (min)	Biological indicator response**			
	12 in × 12 in × 20 in pack		16-towel pack	
	Spore strips			
0.5	0/18	(0 %)	0/18	(0 %)
2	0/18	(0 %)	0/18	(0 %)
3	0/18	(0 %)	0/18	(0 %)
4	0/18	(0 %)	0/18	(0 %)
	Self-contained			
0.5	18/18	(100 %)	18/18	(100 %)
2	0/18	(0 %)	0/18	(0 %)
3	0/18	(0 %)	0/18	(0 %)
4	0/18	(0 %)	0/18	(0 %)

* Noncollaborative data gathered by Joslyn Sterilizer Company.

** Number positive/number exposed (% positive).

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Annex C
(informative)

Example of documentation of premature release of implants

This annex provides an Implantable Devices Load Record and an Exception Form for Premature Release of Implantable Device/Tray, as examples of the forms recommended in 7.4.3.3.

IMPLANTABLE DEVICES LOAD RECORD

Date	Description of Implants(s)	DEPT.	Time Sterilized (Specify AM/PM)	Ster. #	Load #	Date/Time BI in Incubator	Date/Time and BI Result	EARLY RELEASE?	Date/Time Released to OR	Released by (Full Name)

Figure C.1—Implantable devices load record

EXCEPTION FORM FOR PREMATURE RELEASE OF IMPLANTABLE DEVICE/TRAY

NOTE—In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form MUST accompany the implant to the Operating Room. OR personnel MUST complete this form and return to Central Service within 24 hours.

PLEASE COMPLETE ALL INFORMATION:

DATE: _____ SHIFT: _____ TIME: _____ AM PM

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: _____

THE FOLLOWING IMPLANTABLE DEVICES/TRAYS WERE PREMATURELY RELEASED TO THE OR:

_____

_____

_____

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES:

_____

OPERATING ROOM REPORT:

PATIENT NAME: _____

SURGEON NAME: _____

TIME OF PROCEDURE: _____ AM PM DATE: _____

REASON PREMATURE RELEASE WAS NEEDED: _____

_____

_____

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS (THESE) DEVICE(S)? TRAY(S)?

_____

_____

NAME OF OR PERSON COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____

DATE FORM RETURNED TO CENTRAL SERVICE: _____

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

Annex D
(informative)

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