List of Titles

American National Standard

ANSI/AAMI ST:42:1998

Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care, medical, surgical, and dental facilities

AAMI Association for the Advancement of Medical Instrumentation

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American National Standard

ANSI/AAMI ST42—1998
(Revision of ANSI/AAMI ST42—1992)

Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities

Developed by
Association for the Advancement of Medical Instrumentation

Approved 9 January 1998 by
American National Standards Institute, Inc.

Abstract: This recommended practice provides guidelines for steam sterilization, by either the wrapped or unwrapped method, in ambulatory-care clinics, office-based surgical practices, dental offices, and similar health care facilities. The recommended practice covers functional and physical design criteria for work areas; staff qualifications, education, and other personnel considerations; sterilization processing procedures; installation, care, and maintenance of table-top steam sterilizers; quality control; and continuous quality improvement (process performance). Definitions of terms, a bibliography, and annexes providing supplementary information are also provided.

List of Titles

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Association for the Advancement of Medical Instrumentation

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This recommended practice was developed by the Ambulatory-Care and Office-Based Steam Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Committee approval of the recommended practice does not necessarily imply that all committee and 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.

Foreword

This recommended practice was developed by the AAMI Ambulatory-Care and Office-Based Steam Sterilization Working Group, under the auspices of the AAMI Sterilization Standards Committee. This document provides guidelines for steam sterilization in ambulatory-care clinics; office-based medical, surgical, and dental practices; and similar health care facilities. These guidelines are intended to promote sterility assurance and assist health care personnel in the proper use of steam sterilization processing equipment.

This recommended practice is the second edition of the American National Standard, *Steam sterilization and sterility assurance in office-based, ambulatory-care medical and dental facilities* (ANSI/AAMI ST42—1992), which was first published in early 1993. AAMI procedures require that standards and recommended practices be reviewed and, if necessary, revised at least once every 5 years. Accordingly, the AAMI Ambulatory-Care and Office-Based Steam Sterilization Working Group undertook a revision effort in mid-1996.

The new edition reflects the following changes and additions:

a) Certain recommendations have been editorially revised for clarity.

b) In section 3, the recommended temperature and humidity ranges for work areas have been revised for consistency with the latest edition of *Guidelines for design and construction of hospital and health care fa*cilities (American Institute of Architects 1996).

c) A new section, "Product and process improvements," has been added to address continuous quality improvement.

This recommended practice reflects the conscientious efforts of health care professionals, in cooperation with sterilizer manufacturers, to develop recommendations for optimum performance in the processing of medical, surgical, and dental devices to be steam sterilized. It is not intended that these recommendations be construed as universally applicable to all circumstances. It is also recognized that, in many cases, these recommendations might not be immediately achievable. Therefore, the document should be used to guide health care personnel toward desirable performance objectives, and all of the document's provisions should be considered and applied using professional judgment and experience.

As used in 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 concepts incorporated herein are not inflexible or static. The recommendations are reviewed periodically to assimilate new data and advancements in technology. As noted above, AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every 5 years.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword does not contain provisions of the AAMI recommended practice, Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities (ANSI/AAMI ST42—1998), but it does provide important information about the development and intended use of the document.

Introduction: Need for the recommended practice

The prevention of nosocomial infections in persons undergoing medical, surgical, or dental treatment is important in avoiding human suffering and lessening health care costs. One aspect of the prevention of infections in health care facilities is the effective reprocessing and/or sterilization of medical, surgical, and dental devices by saturated steam under pressure. Saturated steam under pressure is the oldest effective means and the most common agent used in health care facilities for the sterilization of medical, surgical, and dental instruments, devices, and supplies. However, steam sterilization is not a simple process. Providing a sterile product depends on proper cleaning to lower the bioburden prior to sterilization, using an effective sterilization cycle, and preventing recontamination of sterilized items through good handling and storage techniques prior to delivery to the point of use. These three phases are interrelated, and each must be accomplished to produce and maintain a sterile product.

The principles of and guidelines for effective steam sterilization and sterility assurance in health care facilities are addressed in two other recommended practices developed by the Association for the Advancement of Medical Instrumentation (AAMI): *Good hospital practice: Steam sterilization and sterility assurance* (AAMI, 1994a) and *Flash sterilization: Steam sterilization of patient care items for immediate use* (AAMI 1996a). The principles and guidelines provided in these documents are generally applicable to all health care facilities, but they focus primarily on sterilization activities in health care facilities using large steam sterilizers (steam sterilizers having a chamber volume of greater than 2 cubic feet).

Advances in medical, surgical, and dental practice have led to the increased use of alternative health care sites, such as offices, ambulatory-care clinics, and similar clinical settings; many such facilities use small table-top steam sterilizers. Office-based practices may differ greatly from hospitals in their physical design and in the training level of personnel. Consequently, additional guidelines are needed that take into account the specific characteristics and needs of office-based, ambulatory-care medical, surgical, and dental facilities.

This recommended practice sets forth guidelines for facility design and work practices to assist health care personnel in office-based practices in the development of procedures to achieve and maintain acceptable sterility assurance levels for devices sterilized in table-top steam sterilizers.

Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities

1 Scope

1.1 General

This recommended practice provides guidelines for steam sterilization in ambulatory-care clinics, office-based medical/surgical practices, dental offices, and similar health care facilities. The guidelines provided here are intended to assist personnel in the proper use of table-top steam sterilization processing equipment (see 2.23) in order to promote sterility assurance.

1.2 Inclusions

This recommended practice specifically addresses

a) functional and physical design criteria for work areas;

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

c) sterilization processing procedures for both wrapped items and unwrapped items;

d) installation, care, and maintenance of table-top steam sterilizers;

e) quality control;

f) process performance (continuous quality improvement).

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

1.3 Exclusions

This recommended practice does not cover construction and performance criteria for table-top steam sterilizers (see AAMI [1997]), nor does it address the use of any table-top sterilization processes other than saturated steam under pressure. Although the principles of steam sterilization and sterility assurance apply equally to the use of both table-top sterilizers and large steam sterilizers (that is, sterilizers having a chamber volume of greater than 2 cubic feet), the user of the latter type of equipment should refer to AAMI (1994a) for guidance.

The reprocessing or reuse of items labeled as single-use by the original manufacturer also is not covered in this recommended practice. The issues surrounding such reuse are complex and include the ability to adequately clean or resterilize such devices, the effect of such practices on liability exposure, and other legal and ethical concerns. For more information, see Canadian Healthcare Association (1996) and ECRI (1996).

2 Definitions

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

2.1 ambulatory care: Short-term treatment of medical, dental, or surgical needs within less than 24 hours in a medical office or clinic.

2.2 bioburden: Number and types of viable microorganisms with which an item is contaminated; also known as bioload or microbial load.

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

2.3 biological indicator: 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.

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

2.4 chemical indicator: Sterilization process monitoring device designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber.

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.

2.5 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.

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

2.7 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 just those transmitted by blood.

2.8 drying time (cycle): As used in relation to table-top steam sterilizers, the time that the sterilizer door is left ajar to complete the drying of sterilized items.

2.9 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.

2.10 housekeeping equipment storage area or space: Area or space where housekeeping items are stored.

2.11 microbicidal process: As used in relation to decontamination, a process designed to provide some level of microbial lethality (kill).

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

2.12 office-based health care facility: Health care facility designed for short-term treatment of ambulatory patients, e.g., free-standing surgical centers, clinics, and medical and dental offices.

2.13 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).

2.14 preparation and packaging area or space: Area or space where clean/decontaminated instruments and supplies are inspected, prepared, and packaged for sterilization.

2.15 pyrogen: Fever-producing substance.

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

2.16 receiving, cleaning, and decontamination area: Area or space where reusable instruments, supplies, and equipment are received, sorted, cleaned, and decontaminated.

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

2.18 sterile storage area or space: Area or space where sterile and clean supplies are stored prior to being selected and distributed for procedures.

2.19 sterility assurance level (SAL): Probability of a viable microorganism being present on a product unit after sterilization.

NOTES—

1) SAL is normally expressed as $10^{[-]}$.

2) A SAL of 10^{-6} means that there is less than or equal to one chance in a million that a viable microorganism is present on a sterilized item. It is generally accepted that an assurance level of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (that is, tissue that has lost the integrity of the natural body barriers). The sterilizer manufacturer is responsible for ensuring that the sterilizer is capable of achieving the desired SAL. The user is responsible for monitoring the performance of the sterilizer to ensure that it is operating in conformance to the manufacturer's recommendations.

2.20 sterilization: Validated process used to render a product free of all forms of 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 may be reduced to a very low number, it can never be reduced to zero.

2.21 sterilization area or space: Area or space where sterilization equipment is located.

2.22 support area or space: Area or space providing toilet, locker, and lounge facilities for personnel.

NOTE—This area should be restricted to facility personnel only.

2.23 table-top steam 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.

2.24 textile processing area or space: Area or space where clean reusable textiles received from contracted or on-site laundry facilities are inspected for defects and extraneous material (e.g., lint, soil), folded, and assembled into packs.

2.25 universal precautions: An approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for human immunodeficiency (HIV), hepatitis B virus (HBV), and other bloodborne pathogens. It is assumed that every direct contact with such fluids may result in infection, and it is required that every employee having such exposure be protected by appropriate personal protective attire and observe appropriate work practices. Universal precautions are intended to prevent transmission to health care workers of bloodborne pathogens that may be present in parenteral fluids, mucous membranes, and nonintact skin.

NOTE—The term "standard precautions" also is sometimes used as well as the terms "body substance isolation" and "transmission-based precautions." (See, for example, Centers for Disease Control and Prevention [CDC, 1996]).

3 Workplace design considerations

3.1 General considerations

This section provides guidelines for the design and maintenance of the workplace to facilitate effective and efficient processing, minimize environmental contamination, and prevent the contamination of clean or sterile instruments, devices, and supplies.

NOTE—Office-based facilities that are planning or currently have free-standing, centralized sterilization processing departments should refer to AAMI (1994a).

3.2 Work area design and functional work flow

3.2.1 Functional work areas:

a) **decasing/breakout area or space:** unpacking area or space where products are removed from their external shipping containers prior to being taken into the preparation and packaging area or the sterile storage area;

b) **receiving, cleaning, and decontamination area:** area or space where reusable instruments, supplies, and equipment are received, sorted, cleaned, and decontaminated;

c) **preparation and packaging area or space:** area or space where clean/decontaminated instruments and supplies are inspected, prepared, and packaged for sterilization;

d) **sterilization area or space:** area or space where sterilization equipment is located;

e) **sterile storage area or space:** area or space where sterile and clean supplies are stored prior to being selected and distributed for procedures;

f) **textile processing area or space:** area or space where clean reusable textiles received from contracted or on-site laundry facilities are inspected for defects and extraneous material (e.g., lint, soil), folded, and assembled into packs;

g) **support area or space:** area or space providing toilet, locker, and lounge facilities for personnel. This area should be restricted to facility personnel only;

h) **housekeeping equipment storage area or space:** area or space where housekeeping items are stored.

3.2.2 Design criteria

During the initial design stage, basic concepts of operation should be defined. The inventory of clean and sterile supplies (including disposables) should be projected, the method and type of distribution system selected, and the functional work areas designed to accommodate the projected inventory. The following examples illustrate some of the specific decisions that need to be made:

a) where reusable patient-care supplies and equipment will be cleaned/decontaminated, inspected, assembled, sterilized, stored, and reissued;

b) whether cleaning and decontamination procedures will be accomplished manually, mechanically (e.g., by ultrasonic cleaners or washer/decontaminators), or by a combination of these methods;

c) how much space will be required for preparation and packaging procedures and for storage of packaging materials;

d) the types of sterilization equipment and accessories that will be used and where the equipment will be installed;

e) how much space will be needed for storage of clean and sterilized items, including disposables;

f) the inventory of clean and sterile items that will be maintained in the sterile storage area;

g) where disposable items will be stored before use;

h) which items will be disposable and which will be reusable (e.g., anesthesia and inhalation therapy items), and where these items will be processed and stored;

i) what type of materials handling will be required to transport clean and sterile items from storage areas to areas of use and to retrieve and transport used/soiled items from areas of use to the receiving/decontamination area;

j) where disposable items, infectious waste, hazardous waste, and recyclable trash will be collected, sorted, and/or compacted;

k) where soiled reusable textiles will be collected for reprocessing;

l) whether an area for processing reusable textiles will be required;

m) what method will be used for record retention and how much space will be needed.

Rationale: Sterility assurance and product quality control depend not only on the sterilization process itself but also on pre- and poststerilization processing functions and controls. Consequently, all of the factors listed ought to be considered in the design of the workplace.

3.2.3 Functional workflow patterns

Functional work areas should be physically separated by walls or partitions to control contaminants generated during the phases of reprocessing. Work flow and traffic patterns should be designed to flow from clean to soiled areas. Workplace

design should allow adequate space for all functions and should promote efficiency by minimizing distances between related areas. Annex A provides examples of work area designs.

NOTE—While physical separation of functional work areas (e.g., the decontamination and clean/sterile areas) is desirable, spatial separation may be satisfactory if accompanied by good work flow patterns, air-flow characteristics, and work practices.

Rationale: Separating clean and "dirty" areas limits environmental contamination and, therefore, the bioburden on items to be sterilized. It is recognized that in existing facilities, it may not be feasible to fully comply with the recommendations for physical separation of functional work areas; however, compliance is practical and desirable during new construction and major modifications.

3.2.4 Traffic control

Traffic in all areas in which decontamination, preparation and packaging, sterilization processing, and sterile storage and distribution are performed should be restricted to facility personnel. Criteria for authorized entry, movement within processing areas, and attire should be specified in written policies and procedures.

Rationale: Well-designed traffic control patterns protect personnel, patients, and supplies from potential sources of cross-contamination.

3.3 Physical facilities

3.3.1 Space requirements

Numerous factors affect space allocation. Considerations should include the operational work flow patterns; clean and sterile storage space requirements; the need for separate rooms/areas for decontamination, preparation/assembly, and sterilization; the types and amount of equipment; the installation requirements for equipment; the workload; and the desired staffing.

Rationale: Space requirements may vary significantly, depending on the specific activities and processing needs of the practice. The space needed to perform routine maintenance activities, such as the reprocessing of reusable supplies, is frequently underestimated during initial facility planning.

3.3.2 Mechanical and electrical systems

In addition to the routine electrical and plumbing systems, the processing area may need pressurized gases and a vacuum system. An adequate number of suitable electrical outlets and "fault-grounded" wall plugs and adaptors should be provided. A source of distilled or deionized water might also be needed.

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

3.3.3 General area requirements

All work areas should conform to the following recommendations.

3.3.3.1 Floors and walls

Floors should be constructed of materials capable of withstanding daily or more frequent wet vacuuming or washing and the application of chemical cleaning agents; the use of carpet in work areas is not recommended. Walls should be constructed of materials capable of withstanding frequent cleaning.

Rationale: All surfaces in work areas are subject to spills and splashing and must be regularly and thoroughly cleaned to control microbial contamination and to remove or minimize accumulated dust, which may act as a carrier for microorganisms. Accordingly, the materials used for floors and walls must be able to withstand frequent cleaning with chemical agents typically recommended for environmental cleaning.

3.3.3.2 Ceilings

Work area ceilings should have flush, smooth, nonporous surface with recessed, enclosed light fixtures.

Rationale: A finished ceiling with enclosed light fixtures minimizes the formation of condensation and the accumulation of dust, which are possible sources of contamination.

3.3.3.3 Ventilation

The ventilation system should be designed so that air flows into relatively soiled areas from clean adjoining spaces (via negative pressure) and is exhausted to the outside or to a filtered partial recirculating system. There should be no fewer than 10 air exchanges per hour. If possible, the air circulation system should be of a down-draft type. The ventilation system should

comply with the recommendations of the American Institute of Architects (AIA 1996). Except for exhaust fans, neither fixed nor portable fans should be used in any work area.

Rationale: Control of bioburden and environmental contamination is essential to the sterilization process. Ventilation patterns affect the proliferation and spread of potentially pathogenic microorganisms. Down-draft-type air circulation systems limit contamination by carrying contaminants toward the floor and away from work surfaces. The recommended number of air exchanges per hour reflects the committee's consensus on the minimum air exchange rate necessary to reduce environmental contamination effectively by air dilution. Fans should not be used because they create highly turbulent airflow, which recirculates dust and microorganisms from the floor and work surfaces and thus interferes with designed air flow characteristics.

3.3.3.4 Temperature and humidity

All work areas should have a temperature controlled between 20° C and 23° C (68° F and 73° F). Relative humidity should be controlled to a range of 30 to 60 percent.

Rationale: The work environment should be comfortable for properly attired personnel. Worker productivity, electronic equipment, and the shelf life of sterile items are adversely affected by both high and low temperatures and humidities. Temperatures and humidities higher than those recommended can promote microbial growth and thus increase bioburden. Temperatures and humidities lower than those recommended can cause static electricity and adversely affect certain sterilization parameters (such as steam penetration). The specific temperature and humidity ranges recommended are based on AIA (1996).

3.3.3.5 Lighting

Adequate lighting at work surfaces should be provided in accordance with the engineering practices described by Rea (1995), which recommends illuminance levels for various categories of work environments. For general inspection functions the specified illuminance is 500 to 1000 LUX (50 to 100 footcandles); for detailed inspection, 1000 to 2000 LUX (100 to 200 footcandles); for sink areas, 500 to 1000 LUX (50 to 100 footcandles); for general work areas, 200 to 500 LUX (20 to 50 footcandles); and for processed storage, 200 to 500 LUX (20 to 50 footcandles). The specific value selected for each area depends on several factors. These factors should be evaluated, and the appropriate illuminance value selected by a qualified illumination engineer. If the adequacy of lighting is in doubt, a survey should be requested.

Rationale: Adequate lighting is essential to the proper performance of decontamination, preparation, and other processing tasks. See also Beck (1981), which provides additional recommendations for operating room illumination.

3.3.3.6 Handwashing facilities

Handwashing facilities should be conveniently located in or near the decontamination and preparation areas. Handwashing sinks are not appropriate receptacles for the collection of soiled items. Sinks should be equipped for hands-free operation (either with foot controls or electric sensors) so that personnel need not touch the faucet handles with their hands. Handwashing facilities should also be located in all personnel support areas (e.g., toilets, lounges). Appropriate antimicrobial handwashing agents or products should be supplied. Personnel should receive instructions regarding handwashing technique.

Rationale: Handwashing is the single most important procedure for preventing infections in patients and staff. Adequate handwashing facilities will encourage the practice of good handwashing technique. The transfer of microorganisms between and among patients, personnel, and inanimate objects will be minimized by appropriate sink design and handwashing practices (e.g., washing the hands after masks are changed, after gloves are removed, any time soiled items are handled without gloves, and otherwise in accordance with the facility's policy). See also OSHA regulations for the prevention of occupational exposure to bloodborne pathogens (29 CFR 1910.1030).

3.3.3.7 Emergency eyewash/shower equipment

Emergency eyewash/shower equipment should be accessible within 10 seconds and 30 meters of potential chemical exposure (American National Standards Institute [ANSI] 1990). The equipment should be selected, installed, and maintained to meet the performance standards described in ANSI (1990). Procedures for testing and documenting the performance of the equipment should be developed and followed. Employees should be instructed in the proper use and maintenance of the emergency equipment. After the emergency treatment, employees should seek medical attention.

Rationale: Emergency eyewash and shower equipment should be readily accessible in order to provide first aid to employees exposed to injurious chemicals and materials. Immediate flushing of exposed tissue is recommended to reduce the risk of serious injury.

3.3.4 Special area considerations

3.3.4.1 Decontamination

Ideally, the decontamination area should be physically separate from the clean/sterile processing and storage areas. However, the area where items are cleaned is sometimes the same one used for assembly, packaging, and sterilization of instruments and supplies. In the absence of physical barriers, good work practices and suitable signs to designate soiled and clean work spaces should be used to limit the possibility of cross-contamination into clean work areas. See also 3.2.3.

Rationale: Separation of work areas for the various processing tasks reduces the risk of cross-contamination. When contaminated instruments and supplies are washed, fluids can be splashed or aerosols created. Cross-contamination can also occur when personnel with soiled, gloved hands touch environmental surfaces, clean items, or other personnel. Regular cleaning, decontamination, and drying of the work area is essential for controlling environmental contaminants.

3.3.4.2 Preparation and assembly

The area used for the preparation and assembly of instruments and other items to be sterilized should be physically separate from the decontamination area. If physical separation of these areas is not possible, the preparation area should be thoroughly cleaned and decontaminated before it is used for clean preparation and assembly tasks.

Rationale: A clean, dry environment is essential to limiting the amount of bioburden on devices prior to sterilization. Therefore, decontamination of soiled areas is necessary.

3.3.4.3 Sterilization

Sterilizers should not be located in high-traffic areas or near any potential sources of contamination, such as cleaning/handwashing sinks or containers for the disposal of linen and trash. Preferably, sterilizers should be located in a restricted-access area. Sterilizers to be used for sterilization of unwrapped items for immediate use should be located near the treatment site.

Rationale: It is important to minimize bioburden on items before sterilization and to prevent contamination of sterile items after sterilization. It is particularly important that sterilization of unwrapped items for immediate use be carried out in a clean environment and that devices processed by this method be transported as short a distance as possible. Because these items are not protected by packaging, they are extremely vulnerable to contamination en route to the point of use. See also AAMI (1996a).

3.3.4.4 Sterile storage

The area for storage of sterile items should be a limited-access area that is clean, dry, and properly ventilated to limit the accumulation of dust and potential contaminants. Closed or covered cabinets are preferable for high-traffic areas. Open or wire shelving is suitable for confined storage areas, provided that proper attention is given to traffic control, area ventilation, and housekeeping. Storage areas should be designed for safe storage of sterile items, protecting them and their packaging from damage.

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Rationale: Most packaging materials do not provide an absolute microbial barrier. Therefore, it is important that the storage area be designed to minimize the potential for events that could compromise sterility.

3.4 Housekeeping

Housekeeping procedures in areas used for any aspect of the decontamination, preparation, or sterilization process should ensure a high level of cleanliness at all times. There should be at least daily cleaning of floors and horizontal work surfaces. Other surfaces, such as walls and storage shelves, should be cleaned on a regularly scheduled basis and more often if needed. (For specific guidance on cleaning methods, see AORN [1998a].) Care should be taken to avoid compromising the package integrity of clean and sterilized items during cleaning procedures. Special attention should be paid to the sequence of cleaning to avoid transferring contaminants from "dirty" areas to clean areas or surfaces. It is good practice to provide separate housekeeping equipment and supplies for the decontamination and clean areas. If cleaning is contracted, appropriate instructions that reflect these guidelines should be given to the contractor.

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

4 Personnel considerations

4.1 General considerations

This section provides guidelines for personnel qualifications, training, and education as well as minimum criteria for personnel health and personal hygiene. It is important that all aspects of processing (decontamination, preparation, packaging, and sterilization) be performed correctly and be supervised by knowledgeable personnel.

4.2 Qualifications

The responsibility for steam sterilization processing should be assigned to a qualified individual. Suggested minimum qualifications include the following:

a) demonstrated competence in steam sterilizer operation and maintenance, according to a comprehensive operator's manual and/or the manufacturer's instructions, including safety precautions and process monitoring techniques;

b) demonstrated competence in all aspects of steam sterilization, including cleaning, preparation, and packaging of items to be sterilized;

c) demonstrated competence in all aspects of sterility maintenance;

d) demonstrated competence in and knowledge of OSHA regulations for the prevention of occupational exposure to bloodborne pathogens (29 CFR 1910.1030), other regulatory requirements, and current Centers for Disease Control and Prevention (CDC) infection control guidelines.

Rationale: Steam sterilization is a complex process that should be performed by persons knowledgeable in sterilization processing and infection control concepts.

4.3 Training and continuing education

Personnel engaged in steam sterilization processing should receive orientation and on-the-job training. They should attend seminars and/or formal courses on sterilization that cover sterilizer operation, parameters of steam sterilization, basic microbiological principles, monitoring of sterilization cycles, and other aspects of sterility assurance. Familiarity with current steam sterilization guidelines, such as AAMI (1994a), AAMI (1996a), and AORN (1998b), is beneficial. It is recognized that personnel not normally involved with sterilization processing may be assigned related responsibilities. Such personnel should receive instruction on the proper preparation, care, handling, storage, and maintenance of sterile items.

Rationale: Adequate training and continuing education reduce the potential for employee injury and the possibility of operator error during preparation, sterilization processing, and handling and storage of sterilized items. Training and continuing education also help ensure that personnel are knowledgeable about the latest data and techniques.

4.4 Health and personal hygiene

Good personal hygiene is essential for the protection of both personnel and patients. Good handwashing procedures should be employed. Attire should be protected and should be changed whenever it is wet or soiled/contaminated. Criteria for wearing gloves and other protective attire must be specified and must comply with OSHA (1991). A written policy should be established for the reporting, treatment, and disposition of employees who are at risk of acquiring or transmitting infections. Personnel involved in the processing of instruments must be offered hepatitis B vaccination.

Rationale: Careful attention to personal hygiene will minimize the potential for acquiring or transmitting disease. The hepatitis virus may be found in blood or other body fluids on contaminated instrumentation and can enter through small cuts or abrasions on the skin. Vaccination will protect personnel from this serious disease, and OSHA (1991) requires that hepatitis B vaccination be offered to personnel who come into contact with blood or other body fluids. Other immunizations may become appropriate and/or mandatory in the future. See also American Dental Association (1992).

4.5 Attire

4.5.1 General

All personnel involved in sterile processing should wear a clean uniform or laboratory coat. Attire should be changed daily or more often as needed (that is, when wet or grossly soiled). Jewelry should be kept to a minimum.

Rationale: Wearing clean uniforms or laboratory coats and changing soiled attire limits transfer of microorganisms to other personnel, patients, medical devices, and work areas. Jewelry can harbor microorganisms and can pose a work hazard to personnel.

4.5.2 Decontamination

In addition to the attire recommended in 4.5.1, personnel who clean and decontaminate items to be sterilized should wear heavy-duty rubber or utility gloves, a fluid-resistant gown, protective eyewear, a high-efficiency-filtration face mask, and (at their option) shoe covers. Protective attire must provide suitable protection for the task being performed and must comply with OSHA regulations for the prevention of occupational exposure to bloodborne pathogens (29 CFR 1910.1030).

Rationale: Contaminated instruments and other medical devices are a source of microorganisms that could invade personnel through nicks or cuts on the hands or through contact with the mucous membranes of the eyes, nose, or mouth.

When contaminated items are being cleaned, the splashing or splattering of blood and other body fluids is probable. Wearing protective attire minimizes this risk.

5 Processing recommendations

5.1 General considerations

Contaminated instruments and other medical, surgical, and dental devices are sources of microorganisms that could cause infections in personnel or patients. This section covers guidelines for the processing and handling of devices before, during, and after sterilization. Proper work practices in preparing items for sterilization, implementing sterilization cycles, and handling, storing, and distributing sterilized items are essential to effective sterilization processing and to maintaining device sterility until use.

The guidelines in this section apply solely to the reprocessing of items intended for reuse. Devices labeled for single use only should not be reprocessed or reused, because it might not be possible to clean or sterilize them adequately, they could be damaged by the sterilization process, or they could retain toxic residues. In addition, the health care facility's liability could be affected if the device manufacturer's written instructions for use are not followed.

5.2 Receiving of purchased items

5.2.1 Sterile disposable items

Sterility assurance measures should be used from the time sterile disposable items are received into the health care facility until they are used. In particular, all items should be removed from their external shipping containers before they are transported to processing or storage areas; care should be taken not to contaminate the individual packages.

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

5.2.2 Nonsterile reusable items

Some items, such as surgical instruments, are received nonsterile from the manufacturer and require cleaning prior to sterilization. (The manufacturer should provide cleaning instructions.)

Rationale: Many reusable medical devices are manufactured in an environment where bioburden is not rigorously controlled, and some manufacturing processes require extensive handling of the item. In addition, anticorrosive agents, such as oils or greases, may be used to protect the device during shipping, and such agents will interfere with sterilization if not removed.

5.2.3 Clean, nonsterile, disposable items

Clean, nonsterile, bulk disposable items, such as 4 x 4 gauze sponges or packaging materials used in the preparation of procedure trays, may be taken to the preparation area after they have been removed from the external shipping container.

Rationale: Nonsterile disposable items received from manufacturers are usually either provided in bulk or individually packaged for patient dispensing or sterilization, or they have been otherwise protected from contamination during transport. Such items are generally manufactured and packaged in an environment where the bioburden is controlled. The external shipping containers, however, are a reservoir of environmental contaminants.

5.3 Cleaning and other decontamination process

5.3.1 General considerations

After patient use, reusable items should be separated from waste and soiled linen. Then, reusable items must be decontaminated before they are prepared and packaged for resterilization. The first and most important step in decontamination is thorough cleaning and rinsing. For many items, cleaning constitutes the entire decontamination process. Cleaning primarily removes rather than kills microorganisms, and a subsequent microbicidal process could be necessary to render an item safe for handling. Cleaning alone may not adequately decontaminate items that, by their design, the nature of their contamination, and/or their intended use, may present a high risk of disease transmission to workers or patients. Such items include devices that have been in contact with blood or other body fluids (such as surgical instruments), devices that have been contaminated with very large populations of microorganisms, and devices that could cause cuts or puncture wounds (such as reusable needles and sharp-edged devices). After such items have been cleaned, they must be subjected to a subsequent microbicidal process. Microbicidal processes include disinfection and sterilization by thermal or chemical processes. See AAMI (1996b).

NOTE—Items that previously have been packaged, sterilized, and issued but are not used may be returned to the sterile storage area if the integrity of the packaging has not been compromised (i.e., contaminated or damaged).

Rationale: The purpose of cleaning and rinsing is to remove all visible debris from an item and to reduce the number of particulates, microorganisms, and potential pyrogens. Thorough cleaning and rinsing are vital to the effectiveness of the subsequent microbicidal processes used for decontamination and/or terminal sterilization. Any organic material and/or residues of cleaning agents remaining on an item may inactivate chemical disinfectants or sterilants as well as protect microorganisms from destruction. Microbicidal processes provide a greater margin of safety than cleaning alone when personnel must handle items that pose a high risk of disease transmission.

5.3.2 Instruments

Gross soil should be removed from the instrument(s) throughout the patient care procedure. The cleaning/decontamination process should begin as soon as possible after the items have been used and delivered to the decontamination area. Before cleaning, all instruments should be sorted to separate general instruments and utensils from delicate instruments or devices requiring special handling. An initial cold water rinse should be used to remove the visible soil. A subsequent enzyme presoak also may be helpful. Instruments may be cleaned manually or mechanically. Warm water and the detergent appropriate for the particular item being cleaned should be used, and the item should then be thoroughly rinsed.

Rationale: Cleaning and decontamination will be more difficult if soil has dried on device surfaces. Thorough cleaning and rinsing procedures are essential. Remaining lubricants, oils, blood, tissue, or residues of cleaning agents can inactivate chemical disinfectants or sterilants. Not all detergents are appropriate for all devices and instruments. The use of an appropriate, product-specific detergent will avoid damage to items and prolong their useful lives.

5.3.3 Utensils

Soiled utensils, such as basins and trays, can be cleaned using warm water and an appropriate detergent. Sterilization container systems should be disassembled and cleaned after each use in accordance with the manufacturer's instructions.

Rationale: See the rationale statement for 5.3.2.

5.4 Packaging and preparation

5.4.1 Selection of packaging materials

Typical packaging materials for items to be sterilized in table-top steam sterilizers include woven textile wrappers, nonwoven disposable wrappers, wrapped or unwrapped cassettes or other rigid sterilization container systems, and paper/plastic pouches. At a minimum, packaging material for steam sterilization processing should have the following characteristics:

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

b) allow for proper drying of the packaging and package contents;

c) provide an adequate barrier to microorganisms;

d) resist tearing or puncture;

e) have proven seal integrity;

f) allow for ease of aseptic presentation;

g) be free of toxic ingredients and nonfast dyes;

h) be low-linting;

i) be demonstrated by the manufacturer, by appropriate testing, to be suitable for use in table-top steam sterilizers;

j) be cost-effective and readily available.

Rationale: The primary functions of packaging materials and systems 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.

5.4.2 Preparation

5.4.2.1 General considerations

Successful sterilization of any item depends not only on proper cleaning but also on proper preparation, packaging, and positioning in the load. These elements are as critical as choosing the correct exposure time and temperature. It is important that each item be prepared in a manner that will facilitate air removal, steam penetration, and steam contact with all surfaces

of the device that are intended to be sterilized. In addition, efficient steam removal is necessary for proper drying and the prevention of wet packages at the end of the sterilization cycle.

5.4.2.2 Packaging accessories

Tape (other than sterilization indicator tape) should not be used to secure packages, nor should safety pins, paper clips, staples, or other sharp objects be used. 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. Rubber bands or tape used to hold instruments together in a group could interfere with steam contact of the surfaces beneath them. If tip protectors are fabricated from inappropriate materials or if they fit too tightly, they could also interfere with steam contact. Sharp objects, such as pins, paper clips, and staples, could puncture the packaging material and thus compromise the sterile barrier.

5.4.2.3 Paper/plastic pouches

If one paper/plastic pouch is placed inside another pouch, care should be taken to select the appropriate sequential sizing to avoid folding the inside pouch over onto itself so that it can fit into the outer package. Paper/plastic pouches should only be labeled on the plastic side, by means of a proper marking pen.

Paper/plastic pouches were designed for use with small, lightweight medical devices and porous items. The use of these pouches with heavy metal instruments (e.g., orthodontic pliers, scissors, scalers) in table-top steam sterilizers without a heated drying phase could result in inadequate drying of the package after sterilization.

Rationale: Pouches must be sized and applied properly to allow for adequate air removal, steam penetration, and drying. Writing on the paper side of the pouch could cause damage to the package (which may or may not be noticeable) and thus compromise the barrier protection. Steam entering a paper/plastic pouch containing a metal instrument immediately condenses as its latent heat is transferred to the metal item. Over the course of the exposure period, all of the condensate may not return to a vapor and could remain trapped in the pouch in the form of water droplets. Elimination of this condensate is only possible with sterilizers designed with heated drying capabilities. Inadequate drying could compromise the seal, the integrity, or the barrier protection ability of the paper/plastic pouch, and thus sterility may not be maintained.

5.4.2.4 Textile packs

The sterilizer manufacturer's recommendations for size, weight, and density of textile packs should be followed. Before sterilization, all textiles should be temperature- and humidity-equilibrated for at least 2 hours at room temperature (20° C to 23° C [68° F to 73° F]) and at a relative humidity in the range of 30 to 60 percent. Using textiles designed for steam sterilization processing, small, lightweight packs (e.g., surgical gowns or towels) should be assembled in a manner that will enhance steam penetration, air removal, and drying; laying the textiles so that the folds lie in alternating directions is helpful. Packs should be small enough that they will not touch the chamber walls. For guidelines for wrapping packs, see annex B.

Rationale: Temperature and humidity equilibration is especially important for textile packs. A dessicated pack can lead to superheating and, consequently, sterilization failure and decreased useful life of the materials. Tightly wrapped packs inhibit air removal, steam penetration, and steam evacuation and thus interfere with sterilization and drying. Packs that touch the chamber wall can become scorched and/or wet.

5.4.2.5 Basins and other metal items

Nested basins should differ in diameter. Basin sets should be processed with absorbent towels or other absorbent material between nested basins of similar size. Metal items should be assembled so as to permit air removal, steam penetration, and condensate drainage (necessary for adequate drying) during the sterilization process.

Rationale: Separating basins with absorbent towels enhances adequate air removal and passage of steam to all surfaces and facilitates drying. Proper alignment of basins, to prevent them from acting as reservoirs for air or moisture, is essential to achieve sterility and a dry pack.

5.4.2.6 Instruments

Instruments should be carefully inspected for cleanliness and flaws or damage and then dried before packaging. Instrument sets should be sterilized in perforated or wire-mesh-bottom trays or in specially designed containers or cassettes. Single, light weight instruments can be sterilized in paper/plastic pouches or in wrappers. All instruments should be held open and in the unlocked position. Tip protectors, if used, should be steam-permeable and fit loosely. Instruments that can be disassembled should be processed as separate components. If a sterilization container system is used, the container manufacturer's written recommendations for maximum weight, set preparation, sterilizer loading procedure, exposure times, and drying should be followed. Scientific data in support of these recommendations should be provided by the manufacturer.

Rationale: Preparing instruments in this manner helps ensure that there will be adequate steam contact with all surfaces and reduces the potential for wet packs. The design of sterilization container systems varies widely, so the container manufacturer's instructions are the best guide to preparation and processing.

5.4.2.7 Supplies

Supplies such as reusable syringes, reusable needles, dressings, cotton balls, and similar items should be individually packaged. 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. Because it is necessary to remove the canister lid for the sterilization cycle, the sterility of items in the canister is compromised as soon as the sterilizer door is opened and the canister contents are exposed to the environment. Also, canisters with solid bottoms will not allow adequate air displacement. Syringes should be disassembled to ensure adequate steam contact with all surfaces.

5.4.2.8 Reusable devices with lumens

Devices with stylets or plugs (e.g., suction tips) should be disassembled prior to steam sterilization. Devices with lumens (e.g., catheters, needles, and tubing) should be flushed with distilled, demineralized, or deionized water (as recommended by the manufacturer for use with the sterilizer) immediately before sterilization. If sterilization is delayed, the devices should be unwrapped, the lumens flushed, and the devices repackaged. Devices with lumens should be positioned on the shelf in the chamber so that the lumen is horizontal to the shelf.

Rationale: Air, which is a barrier to steam penetration, is entrapped in devices with lumens. When the lumen is flushed with water before sterilization, the water within the lumen is converted to steam, which displaces the air out of the lumen.

5.5 Loading the sterilizer

5.5.1 General considerations

Supplies requiring a common exposure cycle may be safely and economically sterilized in the same load. Loading procedures should allow for free circulation of steam around and within each packaged item. The sterilizer manufacturer's instructions for loading and for the sterilization process should be followed.

Rationale: Adequate air removal and steam circulation are essential to sterilization. It is necessary for steam to contact all surfaces intended to be sterilized. Sterilizers differ in their design and operating characteristics, so it is important that the manufacturer's written instructions be followed carefully.

5.5.2 Instrument sets

Instrument sets in standard perforated or mesh-bottom trays should be placed flat on the sterilizer shelf. Metal items should be placed below textile packages (on a separate shelf). If a sterilization container or cassette system is used, the manufacturer's recommendations for loading should be followed.

Rationale: Adequate condensate drainage is important to the sterilization and drying process. Placing metal items below textile items allows condensate to drain out without wetting other items in the load. The design of sterilization container and cassette systems varies widely, so the manufacturer's instructions are the best guide to sterilizer loading.

5.5.3 Textile packs

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

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

5.5.4 Utensils and glassware

Materials capable of holding water, such as solid-bottom pans, bowls, and trays, should be positioned tilted on edge and oriented in the same direction.

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

5.5.5 Paper/plastic pouches

Paper/plastic pouches and similar packages should be positioned standing on edge, with the paper side of one pouch next to the plastic side of the other pouch (see annex C). Loading racks or baskets specifically designed for these types of packages, or other means of holding them on edge and properly spaced, should be used. Lining the tray or basket with a reusable or disposable surgical towel will wick condensate and aid in drying.

Rationale: Positioning paper/plastic pouches in the manner recommended helps ensure adequate air removal, steam penetration, and drying.

5.5.6 Solutions

Solutions (e.g., saline, water) should not be processed in health care facilities, including office-based, ambulatory-care medical, surgical and dental facilities.

Rationale: Health care facilities are not equipped to perform the quality control procedures necessary for processing solutions. In addition, there is a great potential for serious injury in unloading sterilized bottles of fluids. Special flasks and closures are needed to maintain sterility without creating an explosion hazard.

5.6 Sterilization procedures

5.6.1 Steam generation

Table-top steam sterilizers generate their own steam. The user should carefully follow the sterilizer manufacturer's instructions regarding water purity requirements, filling, draining, and general maintenance of the system.

NOTE—Because table-top steam sterilizers generate their own steam, come-up time (achieving sterilization temperature) takes longer than for large hospital steam sterilizers; hence, the total cycle time is also longer.

Rationale: Distilled or deionized water is generally recommended to help prevent the buildup of minerals in the sterilizing system and to ensure the purity of the steam generated for sterilization.

5.6.2 Sterilization cycle parameters for wrapped or containerized items

The sterilizer manufacturer's written instructions for cycle parameters should be followed. 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. In addition, certain types of medical equipment (e.g., some air-powered instruments) may require prolonged exposure times; the device manufacturer's written recommendations should be followed.

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 use of rigid sterilization container systems may affect come-up and exposure times in steam sterilizers, depending on the efficiency of air removal from and steam penetration into the containers. The design of some medical devices will itself hinder air removal and steam penetration, making sterilization more difficult. The device manufacturer is in the best position to specify the conditions necessary for steam sterilization of a particular device.

5.6.3 Sterilization cycle parameters for unwrapped items

NOTE—The sterilization of unwrapped items is sometimes referred to as "flash sterilization."

Cycle parameters should be verified against the sterilizer manufacturer's instructions. The cycle parameters should not be adjusted below the minimum time and temperature recommended by the manufacturer. Most metal instruments require surface sterilization only. The addition of porous items (e.g., towels, rubber or plastic items) or items with lumens necessitates a longer exposure time to ensure adequate steam penetration.

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

Rationale: Sterilizers vary in design and performance characteristics, so the manufacturer's instructions should always be followed.

5.6.4 Drying

Not all table-top sterilizers provide a drying phase. When the cycle does include a drying phase, drying time should be programmed into the sterilization cycle to follow the exposure time in accordance with the manufacturer's instructions. The usual technique for drying is to open the door approximately 1/2 inch (or per the manufacturer's instructions) at the end of the cycle to allow moisture to escape, then initiate the drying cycle, which generally operates with the door open. For table-top sterilizers without a drying phase, the manufacturer should be consulted concerning recommendations for drying the load.

Rationale: In a table-top sterilizer, residual moisture is trapped in the chamber; to achieve drying, it is necessary to vent this moisture to the atmosphere. Drying time varies depending on the sterilizer and load configuration.

5.7 Unloading the sterilizer

5.7.1 Removing wrapped items from the sterilizer

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

Rationale: Moisture will wick contaminants into package contents (see also the rationale statement for 5.7.4). Metal items retain heat and can cause burns.

5.7.2 Cooling

Wrapped items being cooled after removal from the sterilizer should remain in the loading tray, untouched, during the cooling period. Warm items should not be transferred from the sterilizer to cold surfaces. The tray of sterile items should be placed on a clean rack (raised 3 to 4 inches above the counter or other surface) in a low-traffic area where there are no air-conditioning or other cold-air vents nearby. The time allowed for cooling should be based on professional judgment, experience, and the environmental conditions of the area.

Rationale: Seasonal and geographic variations in ambient temperature and humidity affect cooling time, as do other factors unique to individual medical devices. The type of sterilizer used can also 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. Packs should not be touched until they are cool, because hot packs act as wicks, absorbing moisture and, hence, bacteria from hands. Placing the cooling rack 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.

5.7.3 Handling and inspection

Sterile items should never be handled before they are cool, and they should be handled as little as possible thereafter. All packages should be visually inspected for integrity and dryness. Any items with torn, compressed, wet, or punctured packaging or with packaging that appears to have been opened or to have breached seals should not be used. Any items dropped on the floor should not be used. All such items should be reprocessed.

Rationale: Packages that are dropped on the floor, compressed, torn, or wet should be considered contaminated. Wet packaging could indicate problems with package composition, loading procedures, or sterilizer performance or operation. When a pack is wet, a pathway could be created by which microorganisms can enter the just-sterilized contents and contaminate them.

5.7.4 Removing unwrapped items from the sterilizer

Aseptic transfer procedures should be used to deliver the hot and possibly wet items from the sterilizer to the point of use. Special care should be taken to avoid sources of contamination. The tray should not be placed on anything except a sterile, impervious, draped surface. Items sterilized by the unwrapped method are intended for immediate use and cannot be stored.

Rationale: Unwrapped items are vulnerable to contamination. Sterile items are contaminated when they come into contact with a nonsterile surface. See also the rationale for 3.3.4.3.

5.8 Sterile storage

5.8.1 Dust covers

5.8.1.1 Purpose of dust covers

Nonsterile plastic protective overwraps (dust covers) may be used to protect and extend the shelf life of properly wrapped and sterilized items that might be subjected to contamination from environmental challenges or multiple handling before use. The outside cover should be clearly labeled as a dust cover to prevent its being mistaken for a sterile wrap.

Rationale: Plastic provides a barrier to moisture and dust; this barrier can help to preserve the sterile integrity of the package, especially one that is not going to be used immediately or that will be transported long distances. Because a dust cover is applied after sterilization, the outer layer of actual packaging material should be considered clean (not sterile) for purposes of sterile presentation.

5.8.1.2 Application of dust covers

If dust covers are to be applied to sterilized packages, they should be applied only to thoroughly cooled, dry items. Clean plastic or rubber gloves should be worn when applying the dust cover.

Rationale: Dust covers should be applied as soon after sterilization as possible to enhance maintenance of sterility. However, placing a dust cover on a package that is not cool and dry could result in condensation inside the dust cover and, because the dust cover is not sterile, could cause contamination of the package contents. Gloves should be worn to prevent contamination of the package by perspiration from workers' hands.

5.8.1.3 Sealing of dust covers

Dust covers should be applied using either a heat sealer designed to seal plastic to plastic or an alternative method that is similarly effective, such as a self-sealing pouch or tape.

Rationale: To be an effective barrier to moisture, the cover must be sealed.

5.8.1.4 Labeling

The lot or load control number and expiration statement should be visible through the dust cover, or an additional label should be used on the dust cover. (See also 7.2.1 and 7.2.3.)

Rationale: The dust cover is only a protective device; the identity and traceability of the package within has to be maintained.

5.8.2 Storage environment

Sterile items should be stored in clean, dry, easily accessible areas. They should be positioned so that their packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised. Medical, surgical, and dental supplies should not be stored under sinks, near water or sewer pipes, or in any location where they can become wet. Supplies should not be stored on floors, window sills, and in areas other than on or in designated shelving, counters, or containers.

Rationale: 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 may not be sufficiently clean, and because window sills collect condensate resulting from differences in inside and outside temperature.

5.8.3 Storage shelving

Closed or covered cabinets are recommended for the storage of sterile items. Open shelving may be used but requires that special attention be given to good housekeeping. Open shelves should be at least 2 inches from external walls. The bottom shelf should be 8 to 10 inches from the floor, and items stored on the top shelf should be at least 18 inches below sprinkler heads. 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 clean or sterile storage areas.

Rationale: Closed cabinets limit dust accumulation, discourage handling, and minimize inadvertent contamination of sterile items. Adequate space is needed around storage shelves to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between clean/sterile items and the condensation that may form on the interior surfaces of outside walls. State and local safety regulations, such as fire codes, also affect the placement of storage shelves. Shipping containers have been exposed to unknown and potentially high microbial contamination; those that are corrugated serve as generators of and reservoirs for dust. Hence, shipping containers should never be allowed in clean or sterile storage areas.

5.8.4 Shelf life

The shelf life of a packaged sterile item is event-related and depends on the quality of the wrapper material, the storage conditions, the conditions during transport, and the amount of handling. Shelf life is not simply a matter of sterility maintenance but is also a function of materials life and inventory control. In general, stock rotation according to the "first in, first out" principle 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. A "first in, first out" stock rotation system facilitates stock turnover.

5.9 Distribution

5.9.1 Handling and inspection

Supplies should be handled and carried carefully to avoid crushing, bending, compressing, or puncturing the packaging or otherwise compromising the sterility of the contents. Before a sterile item is issued, its packaging should be thoroughly inspected visually for integrity and labeling.

Rationale: Careful and limited handling of sterile supplies during distribution is important in maintaining the integrity of the product. See also the rationale statement for 5.9.2.

5.9.2 Distribution containers

Items should be protected from contamination during transport. Surfaces in direct contact with sterile packaging should be clean. Sterile supplies should be covered when being transported. Closed carts, bins, plastic or paper bags, boxes, or other clean protective equipment may be used. Items placed inside plastic bags, paper bags, or boxes for transport should be arranged within the containers so as to prevent them from being crushed or otherwise damaged.

Rationale: Covered or enclosed carts protect sterile items from inadvertent contact with personnel and other sources of contamination and from environmental challenges that exist along the transportation route. 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.

6 Installation, care, and maintenance of table-top sterilizers

6.1 General considerations

This section broadly covers care and maintenance procedures applicable to table-top steam sterilizers. Proper attention to equipment maintenance will minimize sterilizer "down time" and help prevent sterilizer malfunctions.

6.2 Instruction manuals

The purchaser should require the sterilizer manufacturer to 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 6.4 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 instruction manual should be retained by the user for as long as the sterilizer is in service.

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

6.3 Installation

Sterilizers should be installed in accordance with the manufacturer's written instructions (see 6.2). Particular care should be taken never to install a table-top sterilizer in areas where explosive or flammable materials or anesthetics are used or stored. The sterilizer should not be connected to an electrical circuit with other appliances or equipment unless the circuit is rated for the additional load. The sterilizer should be placed on a level, heat-resistant surface. If the sterilizer is mounted on a counter beneath a cabinet or other overhang, there should be sufficient clearance for adequate access to the sterilizer. The area in front of the sterilizer should be clear of any obstruction.
Rationale: Proper installation is necessary to ensure that the sterilizer will perform correctly. The recommendations for placement of the sterilizer are intended to help ensure that (a) explosion and fire hazards are minimized, (b) there is proper water distribution in the chamber, (c) cleaning and water replenishment can be accomplished readily, and (d) the operator can step away from the unit, when opening the sterilizer door, if a puff of steam is emitted.

6.4 Routine care and maintenance

The manufacturer of the sterilizer should provide written instructions for the routine care and preventive maintenance of the equipment and its components. Sterilizers should be inspected and cleaned in accordance with the manufacturer's written instructions. Examples of items requiring periodic care and cleaning are recording charts and pens, printers (paper and ribbons), door gaskets, chamber vents or drain screens, the internal chamber, and the external surfaces. The manufacturer should clearly specify the frequency with which such tasks are to be performed (see 6.2).

Rationale: Periodic inspection, cleaning, and preventive maintenance reduce the incidence of equipment malfunctions that could cause sterilization failures. Cleanliness also reduces the risk of accidental contamination of sterile material.

6.5 Repairs

Repairs should be performed by the manufacturer's service representative or by another qualified service technician.

Rationale: Repair or component replacement by properly trained service representatives having appropriate tools and metering devices helps ensure the proper functioning of the sterilizer after service.

6.6 Calibration

Periodic calibration should be performed as specified in the manufacturer's written instructions (see 6.2). Calibration should be documented. Examples of items requiring calibration are pressure and temperature gauges, timers, controls, and recording devices. In the event of a sterilizer malfunction or the repair or replacement of any component affecting sterilizer performance, appropriate recalibration should be performed. Those performing this task should have sufficient training and skills to understand the operation and calibration of the particular sterilizer type.

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

6.7 Recordkeeping

A maintenance record should be kept for each sterilizer. This record should be maintained by the person responsible for the sterilizer. The maintenance record should include sufficient information to identify the sterilizer and to establish a continuous history of all scheduled and unscheduled service. At a minimum, the following information should be recorded:

a) the date on which service was requested;

b) the model number and serial number of the sterilizer;

c) the location of the sterilizer (if appropriate);

d) the name of the individual who requested and authorized service;

e) the reason for the service request;

f) a description of the service performed;

g) the types and number of parts replaced;

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

i) the date the work was completed;

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

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

7 Quality control

7.1 General considerations

This section covers product identification and traceability; mechanical, chemical, and biological monitoring of steam sterilization cycles; product recalls; and related quality control measures. Assurance of sterility requires continuous attention to all aspects of sterilizer performance and the steam sterilization process.

NOTE—Quality control is usually thought of only as process and product monitoring, and section 7 is primarily concerned with these applications. More generally, though, quality control also involves continuous compliance with established policies and procedures as well as ongoing quality assessment and improvement of process performance (see section 8).

7.2 Product identification and traceability

7.2.1 Lot control number (wrapped items)

A lot control number can be used for wrapped items that are to be stored before use. The lot control number should contain the date of processing, the cycle number, and the sterilizer number (if there is more than one sterilizer). If packages are to be labeled prior to 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, and the method of labeling should not compromise the sterility of the package contents by puncturing the package or by ink strike-through.

Rationale: Lot identification enables the tracing of problems to their source and, if necessary, the retrieval of items processed in a particular load. To ensure that unprocessed items are not mistakenly thought to be sterile, presterilization labeling should be done as the sterilizer is being loaded. For poststerilization labeling, the packages must be cool and dry to prevent contamination.

7.2.2 Load records

The following information should be recorded and maintained:

a) the date and time of the cycle;

b) a general description of the contents of the load;

c) the exposure time and temperature;

d) the name or initials of the operator;

e) the results of biological indicators, whenever used;

f) chemical-indicator results.

The time and temperature recording chart or parameter printout, if available, should be dated and maintained. Each cycle tracing or printout should be reviewed by the operator, who should verify that it indicates that appropriate parameters were maintained. As recommended in 6.7, a record of repair and preventive maintenance should also be kept for each sterilizer. All the foregoing information may be incorporated into a single system or filed as individual documents. All sterilizer records must be filed in a designated record storage area for a period of time not less than that specified by state or local statutes.

Rationale: Documentation encourages monitoring of the process as it is occurring, helps ensure that cycle parameters have been met, and establishes accountability.

7.2.3 Expiration dating (wrapped items)

If expiration dates are employed by the facility, each wrapped item intended for use as a sterile product should be labeled with an expiration date or statement (e.g., "contents sterile unless package is damaged or opened"). This information may be incorporated into the lot identification on the label or imprinted or affixed separately on the outside of the package.

Rationale: Sterility is event-related; however, labeling items with expiration dates or statements facilitates proper stock rotation. Expiration dates facilitate use of the "oldest" item first (that is, the item processed first) unless the integrity of the packaging material has been compromised. See also 5.8.4.

7.3 Physical monitoring

7.3.1 Use of physical monitors

Physical monitors include time-, temperature-, and pressure-recording devices and gauges. When time- and temperature-recording charts are provided, the record should be marked with the date and the sterilizer number (if there is more than one sterilizer). At the end of each cycle, and before items are removed from the sterilizer, the operator should examine the record to verify that cycle parameters were met. If recording devices are unavailable, the operator should monitor the time- and temperature-indicating gauges at periodic intervals during the cycle, document at the end of the cycle that cycle parameters were met, and identify himself or herself on the documentation.

NOTE—Physical monitoring and other indicators of sterilizer performance should never be considered a guarantee of sterilization. Improper load configuration or package composition can interfere with air evacuation and steam penetration. These conditions will not be revealed in the temperature recording because most temperature sensors indicate temperature at the exhaust line of the sterilizer, not at the center of packs.

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 alternate procedures can be used in the event of failures.

7.3.2 Sterilizer malfunctions

If physical monitoring indicates any malfunction or suspicious operation, the appropriate person should be notified. The load should be considered nonsterile, and the sterilizer should not be used until the reason for the malfunction is identified and the problem is corrected.

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. Common problems detected by physical monitoring include inadequate or excessive temperature and inadequate pressure, exposure time, or drying time.

7.4 Chemical indicators

7.4.1 General considerations

Chemical indicators are physical or chemical devices employed to monitor one or more sterilization process parameters for the purpose of detecting failures in packaging, loading, or sterilizer function. The use of chemical indicators is part of an effective quality assurance program. Chemical indicators enable the user to verify that products have been subjected to certain processing conditions. No chemical indicator verifies that an item is actually sterile.

7.4.2 Selecting chemical indicators

Health care personnel should select chemical indicators that comply with AAMI (1996c) and should obtain data from manufacturers on the reliability, safety, and performance characteristics of their products. In addition, manufacturers of chemical indicators should be required to provide written information on how to interpret indicator results, the reliability of the indicator in maintaining end-point color change (if applicable) during storage of sterilized items, the sterilization conditions that the indicator will detect, and the storage requirements for and shelf life of the indicator. Indicators should be selected that do not bleed, flake, or otherwise adulterate the devices being sterilized. For additional information, refer to AAMI (1988).

Rationale: Various types of external and internal chemical indicators are available, each with different response characteristics, that is, they differ in the sterilizing conditions they will detect and verify. The choice of chemical indicator depends on the specific needs, resources, and sterilization equipment of the individual health care facility.

7.4.3 Using chemical indicators

7.4.3.1 External chemical indicators

Steam sterilizer indicator tape, indicating labels, or an indicating printed legend should be affixed to or printed on all packages assembled in the health care facility and intended for sterilization; the indicator should be readily visible after the package is assembled. An indicator sensitive to steam should be attached to or printed on all commercially acquired packages if sterilization is to be performed by the health care facility. Except for packages that allow visual inspection of an internal indicator, such as paper/plastic packaging, an external indicator should be used on every package. The external chemical indicator should visually denote that the package has been exposed to physical conditions present in the steam sterilizer. This tape, label, or legend should be examined after sterilization and also before use to make sure that it indicates that the item has been exposed to a sterilization process.

Rationale: The purpose of an external chemical indicator is to differentiate between processed and unprocessed products, not to establish whether the parameters for adequate sterilization were met.

7.4.3.2 Internal chemical indicators

7.4.3.2.1 Placement and frequency of use

An internal chemical indicator sensitive to steam should be used within each package, tray, or container being processed. The chemical indicator should be placed in that area of the package, tray, or container considered to be least accessible to steam penetration; this area might or might not be at the center. For unwrapped loads, at least one internal indicator should be placed in the tray with the items to be sterilized.

Rationale: A chemical indicator should be used in each package, tray, or container, because variations in position or contents may affect steam contact of all surfaces and the time needed to attain the required temperature.

7.4.3.2.2 Retrieval and interpretation

For packaged items, the chemical indicator is retrieved at the time of use and interpreted by the user. For unpackaged items, the chemical indicator is examined at the end of the sterilization cycle. The user should be adequately trained and knowledgeable about the performance characteristics of the particular type of chemical indicator being used.

7.4.3.2.3 Nonresponsive or inconclusive chemical indicators

If the interpretation of the chemical indicator suggests inadequate steam processing, the packaged product should not be used. Appropriate follow-up includes lot identification, review of the physical monitoring information for the sterilization cycle, the results of chemical indicators elsewhere in the load, and (if applicable) the results of biological monitoring of the sterilizer. This review will enable the person responsible for sterilization procedures to decide whether to recall the load.

Rationale: If a chemical indicator is nonresponsive or inconclusive, it is possible that the entire load is nonsterile; that is, the sterilization process failed. Using chemical indicators is only one way to verify sterilizer and cycle performance, however, and chemical indicators 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, items in the load. Therefore, a single nonresponsive or inconclusive chemical indicator should not be considered conclusive evidence that the load is nonsterile. Professional judgment should be exercised in determining whether or not to recall the entire load, taking into account all factors having a bearing on the efficacy of the cycle and all performance indicators.

7.5 Biological indicators

7.5.1 General considerations

A biological indicator is a sterilization process monitoring device consisting of a standardized, viable population of microorganisms known to be resistant to the mode of sterilization being monitored (in this case, steam). Biological indicators

are intended to demonstrate whether or not the conditions in the sterilizing chamber were adequate to achieve sterilization. A negative biological indicator does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

7.5.2 Selecting biological indicators

Health care personnel should select biological indicators, consisting of spores of *Bacillus stearothermophilus*, that comply with AAMI (1986). In addition, data should be obtained from manufacturers on the reliability, safety, and performance characteristics of their products. Manufacturers of biological indicators should also be required to provide written instructions on the storage, handling, use, and microbiological testing of their products.

Rationale: Various types of biological indicators and combined biological and chemical indicators 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 biological indicator depends on the specific needs, resources, and sterilization equipment of the particular health care facility.

7.5.3 Frequency of use of biological indicators

Table-top steam sterilizers should be biologically monitored during initial installation and after any major repairs (see 7.6). In addition, sterilization loads should be biologically monitored at least once a week but preferably daily (see 7.6). Each load containing implantable devices should be monitored and, whenever possible, the implantable devices should be quarantined until the results of the biological indicator testing are available. Biological indicators should also be used for periodic monitoring of all types of packages and trays processed (see 7.7).

Rationale: The condition of the sterilization equipment, the expertise of the sterilizer operator, and other factors determining the success or failure of a steam sterilization cycle can 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. The use of biological indicators provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. (See also the rationale for 7.7.)

Because of the potential consequences to the patient of the implantation of a nonsterile device, it is necessary to closely monitor the sterilization of implantables. Ideally, for maximum sterility assurance, each load of implantables should be quarantined until it is verified that biological indicator 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 biological indicator testing, is qualified by the words "whenever possible."

7.6 Sterilizer efficacy testing

7.6.1 Types of testing

7.6.1.1 Installation testing

All table-top steam sterilizers should be biologically monitored upon installation and after any major repairs. The purpose of installation testing is to assess sterilizer performance in the environment in which it will be used. This testing should be conducted by health care personnel in cooperation with the manufacturer.

7.6.1.2 Routine biological monitoring

All table-top steam sterilizers should also be monitored routinely. If a sterilizer is designed to be used for multiple types of cycles (e.g., wrapped items and flash-sterilized items), then each sterilization mode should be tested.

7.6.2 Biological indicator test pack

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

Only one biological indicator need be used inside a test pack to achieve a microbial challenge. One additional biological indicator from the lot used for testing should be left unexposed to the sterilant, incubated, and treated as a control.

Rationale: Large hospital sterilizers are routinely tested using standardized challenge test packs containing biological indicators. There are no universally accepted standardized challenge test packs for table-top, gravity-type steam sterilizers. Therefore, this recommended practice suggests that a representative package or tray that is to be routinely processed through the sterilizer be used as the test pack. The packages or trays used as test packs will vary from office to office, depending on the types of items routinely sterilized. There are no data to support the need for more than one biological indicator. There are, however, several considerations in using more than one biological indicator: (a) they may provide

additional information about a marginal cycle; (b) they may provide information on differences in sterility assurance at various locations; (c) they may help minimize the effects of errors in laboratory culturing; (d) they may help increase the confidence level for a quicker readout and therefore a shorter turnaround time on biological indicator results (check the indicator manufacturer's instructions).

A control biological indicator is needed to verify the presterilization viability of the test spores. If the control from a lot fails to grow, it must be assumed that the test biological indicators from that lot are nonviable or that improper incubation occurred; therefore, the test results must be considered invalid and the test repeated.

7.6.3 Test pack placement

All biological monitoring is conducted in a fully loaded chamber. The biological indicator test pack of 7.6.1 should be placed on its edge if it is a small pack or flat if it is a tray or large pack. It should be positioned in the area of the sterilizer chamber and load that is least favorable to sterilization. This area, the "cold point," varies with sterilizer design but is normally in the center of the load towards the front of the chamber.

Rationale: Small packs are routinely placed on edge to allow adequate steam exposure. Larger packs or trays are routinely placed flat on the shelf because their size will not permit any other orientation in the relatively small chambers of table-top steam sterilizers. Placing the test in the coolest portion of the chamber presents the most severe challenge.

7.6.4 Test procedure

The test procedure for both installation testing and routine monitoring is as follows:

a) Before being exposed to the sterilization cycle, the biological indicator test pack is labeled with appropriate sterilizer information.

b) The test pack is positioned in the chamber according to 7.6.3.

c) The appropriate cycle is run according to the sterilizer manufacturer's instructions.

d) After being exposed to the sterilization cycle, the biological indicators are removed from the test pack and their identification noted. All biological indicators used in challenging the sterilization cycle and as controls should be accounted for. The biological indicators should be handled and incubated according to the biological indicator manufacturer's instructions.

CAUTION—*Bacillus stearothermophilus* does not grow at 35° C to 37° C (95° F to 99° F), the temperature of standard bacteriology laboratory incubators. A temperature of 55° C to 60° C (131° F to 140° F) is required; therefore, a special incubator must be used.

7.6.5 Acceptance criteria

7.6.5.1 Installation testing

For installation testing, three consecutive test runs with negative results from the test biological indicators verify that the sterilizer has arrived in good working condition from the manufacturer and will function effectively at the facility in which it is installed. All packages or trays processed during installation testing should be quarantined until the results of the biological indicator testing of all three test runs are available.

7.6.5.2 Routine biological monitoring

For routine biological monitoring, the sterility of the load is evidenced by the killing (failure to recover) of all spores on the test biological indicators (spore strips). All biological indicator results, including result from controls, should be interpreted by a qualified individual and included in the sterilizer records.

7.6.6 Positive biological indicator results

The following actions should be taken if a biological indicator tests positive:

a) Because a sterilization failure has occurred, materials processed in that sterilizer since the last cycle showing satisfactory biological indicator results should be considered nonsterile; they must be retrieved, if possible, and reprocessed (see also 7.8).

b) Positive biological indicator results (other than viability controls) should be immediately reported by phone or messenger to the appropriate supervisor. This notification should be followed by a written report. The notification and report should include the time and date of the questionable sterilization cycle; a description of the sterilizer and load, with reference to the appropriate lot control number; the results of physical monitoring and of chemical indicator tests;

and any other information that will be useful in determining whether the report is valid or is questionable because of human error.

c) The attending practitioner or infection control officer should also be notified of the positive biological indicator, so that follow-up surveillance of patients can be conducted if needed.

d) The microbiology laboratory should perform a presumptive identification of the microorganisms present on the positive biological indicator (see 7.6.7) and, if applicable, review the biological indicator transfer technique.

e) The appropriate supervisor should attempt to determine the cause of the sterilization failure and arrange for corrective action.

f) After the cause of the sterilization failure is determined and corrected, the sterilizer in question should be immediately rechallenged with biological indicators. Until the results of retesting are satisfactory, the performance of the sterilizer should be considered to be questionable.

Rationale: Positive biological indicators require immediate action to determine the cause of the problem and to establish appropriate follow-up steps (e.g., quarantine of the sterilizer, follow-up surveillance of patients, notification of practitioners). Therefore, a carefully defined procedure should be established to evaluate all possible causes of the positive biological indicators. This procedure should include a thorough evaluation and retesting of the sterilizer, a review of quality assurance records, a review of culturing techniques, and an evaluation of the biological indicators used. See also the rationale statement for 7.8.1.

7.6.7 Microbiological testing

7.6.7.1 General

For positive biological indicators, the microbiology laboratory should do a presumptive identification to determine whether the recovered microorganism is indeed the test microorganism that was on the biological indicator or is an external contaminant.

NOTE—For self-contained biological indicators, consult the manufacturer's instructions for the procedure by which to retrieve positive biological indicators for presumptive identification.

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

7.6.7.2 Test procedure

Two subcultures are made from the recovered culture; one is incubated at 35° C to 37° C (95° F to 99° F) and the other at 55° C to 60° C (131° F to 140° F) for 24 to 48 hours. Smears of the incubated subcultures are prepared, stained by Gram's method, and microscopically examined.

7.6.7.3 Interpretation of results

Presumptive identification should be considered positive for *Bacillus stearothermophilus* if microscopic examination reveals gram-positive, spore-bearing rods and if the results of the incubation studies demonstrate growth at 55° C to 60° C (131° F to 140° F) but no growth at 35° C to 37° C (95° F to 99° F).

7.7 Periodic product monitoring

A program should be established to monitor the sterilization process periodically by placing biological indicators in various types of packages and trays. Because routine biological testing is done on the packages or trays most frequently processed, it is important to check the effectiveness of the sterilizer by monitoring other items, packaging materials, and load configurations that are processed from time to time. Such monitoring should also be performed whenever major changes are made in packaging, product or load configuration, or materials.

Rationale: Table-top steam sterilizers are electrically heated sterilizers that produce steam from a predetermined volume of distilled or deionized water. The water is first heated to create saturated steam (i.e., steam containing the maximum amount of water possible at a given temperature). That steam then condenses on the load, giving up vaporization heat, which thermally sterilizes the load. If porous items in the load absorb the steam, there might not be sufficient heat transfer to kill microorganisms. Similarly, if the load is too large, the load will absorb heat energy at a rate that will not permit saturated steam conditions to exist with the fixed amount of water available to make steam. To avoid potential sterilization failures due to such causes, it is important to conduct periodic biological monitoring of items less frequently processed as well as routine biological testing of typical loads.

7.8 Product recalls

7.8.1 Written policies and procedures

Written policies and procedures for the recall of items from issued or stored loads should be developed by the person(s) responsible for the operation of the health care facility. These policies and procedures should be documented and records maintained. The recall of processed items is at the discretion of the person(s) responsible for the operation of the health care facility. Whenever there is evidence of sterilization failure, follow-up surveillance of patients should be conducted.

Rationale: To ensure patient safety, 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 surveillance of patients.

7.8.2 Recall procedure

A recall procedure should be written, outlining the circumstances for issuing a recall order; designating the person(s) authorized to issue a recall order; and designating the person(s) responsible for reporting on the execution of a recall order.

7.8.3 Recall order

A recall order should be written, identifying by sterilization lot number the items to be recalled; identifying the persons or departments to whom the order is addressed; requiring the recording, in terms of kind and quantity, of the items obtained in the recall; and specifying the action to be taken by the person(s) receiving the order (e.g., the destruction or return of the item).

7.8.4 Recall report

A report of a recall order should identify the circumstances that prompted the recall order; specify the corrective actions taken to prevent a recurrence: and state, in terms of total number of items intended to be recalled, the percentage of items actually located in the recall.

8 Product and process improvements

8.1 General considerations

This section of the recommended practice identifies performance measures and process monitors that can be used for quality assurance (QA) and 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 and sterility assurance in office-based, ambulatory-care medical, surgical, and dental facilities, a CQI program encompasses the entire process of decontamination, sterilization, and aseptic transfer.

8.2 Functional areas for product and process improvements

8.2.1 Scope of QA and CQI programs for table-top steam sterilization

The effectiveness of QA and/or CQI programs is enhanced when they address all aspects of the process they evaluate. For this reason, QA and/or CQI programs for steam sterilization and sterility assurance in office-based, ambulatory-care medical, surgical, and dental facilities should interface product and process performance in relation to workplace design, processing policies and procedures, and product use. The overall performance of processes and products should be evaluated and improvements implemented based on the results of systematic documentation and evaluation of each of these aspects over time.

8.2.2 Workplace design

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

8.2.3 Processing policies and procedures

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

a) functionality of the workplace design, work flow patterns, and equipment (see section 3) through such means as employee input, accident records, and so forth;

b) training and continuing education (see 4.3);.

c) instrument processing protocols (see 5.2 through 5.9);

d) maintenance of sterilizers (see 6.2 through 6.7);

e) product identification and traceability, that is, lot control numbers (7.2.1) and load records (7.2.2);

f) sterilizer physical monitoring records (7.3);

g) biological indicator records (7.5);

h) chemical indicator records (7.4);

i) sterilizer efficacy testing records (7.6);

j) periodic product monitoring records (7.7).

8.2.4 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. Periodical 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 verified 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.

8.3 Implementing product and process improvements

There is no single right way to implement a QA or 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 QA or CQI program is the accurate collection of data using the facility plan for documenting process monitoring and product performance (developed as part of the QA or 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.

Annex A
(informative)

Examples of workplace design

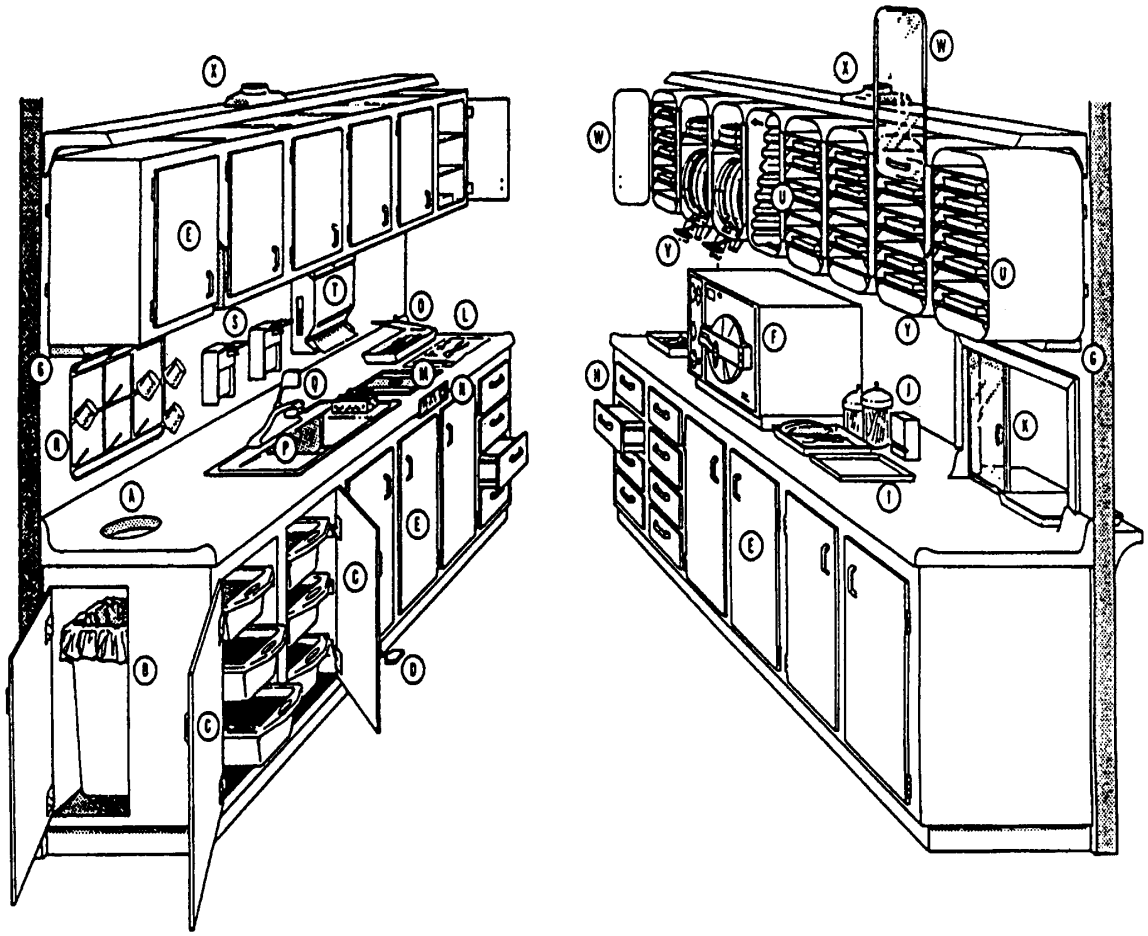


Figure A.1—Example of a double-wall instrument recirculation center
(Reproduced, with permission of the publisher, from Runnells [1987])

Legend for figure A.1:

A = Large-capacity, surface-flush waste disposal
B = Waste disposable cabinet door in rear of cabinetry to utilize space
C = Storage space for holding contaminated instruments in covered container immersed in disinfectant until ready for cleaning
D = Foot control for sink faucet
E = Bulk supply storage
F = Sterilizer, cabinet-top or recessed on reinforced mobile glides
G = Lights
H = Drawers for process indicators, monitors, transfer forceps, and similar items
I = Clean surface for final sterile tray preparation
J = Containers for presterilized or industrially clean disposable items
K = Pass-through window to treatment area
L = Drying surface for items to be sterilized
M = Recessed ultrasonic cleaner
N = Ultrasonic cleaner controls
O = Disinfectant for temperature-sensitive items
P = Stainless steel sink with sloping drain to contain contaminated drain water
Q = Arm-actuated water temperature mixture control
R = Glassware drying rack
S = Arm-actuated soap and lotion dispenser
T = "No touch" paper towel dispenser
U = Sterile tray storage cabinets with removable, disinfectable slides
V = Packaging supplies and "cut to size" see-through bags
W = Glass or solid doors
X = Low-volume air evacuation system with microbial filter
Y = Air movement space between cabinets

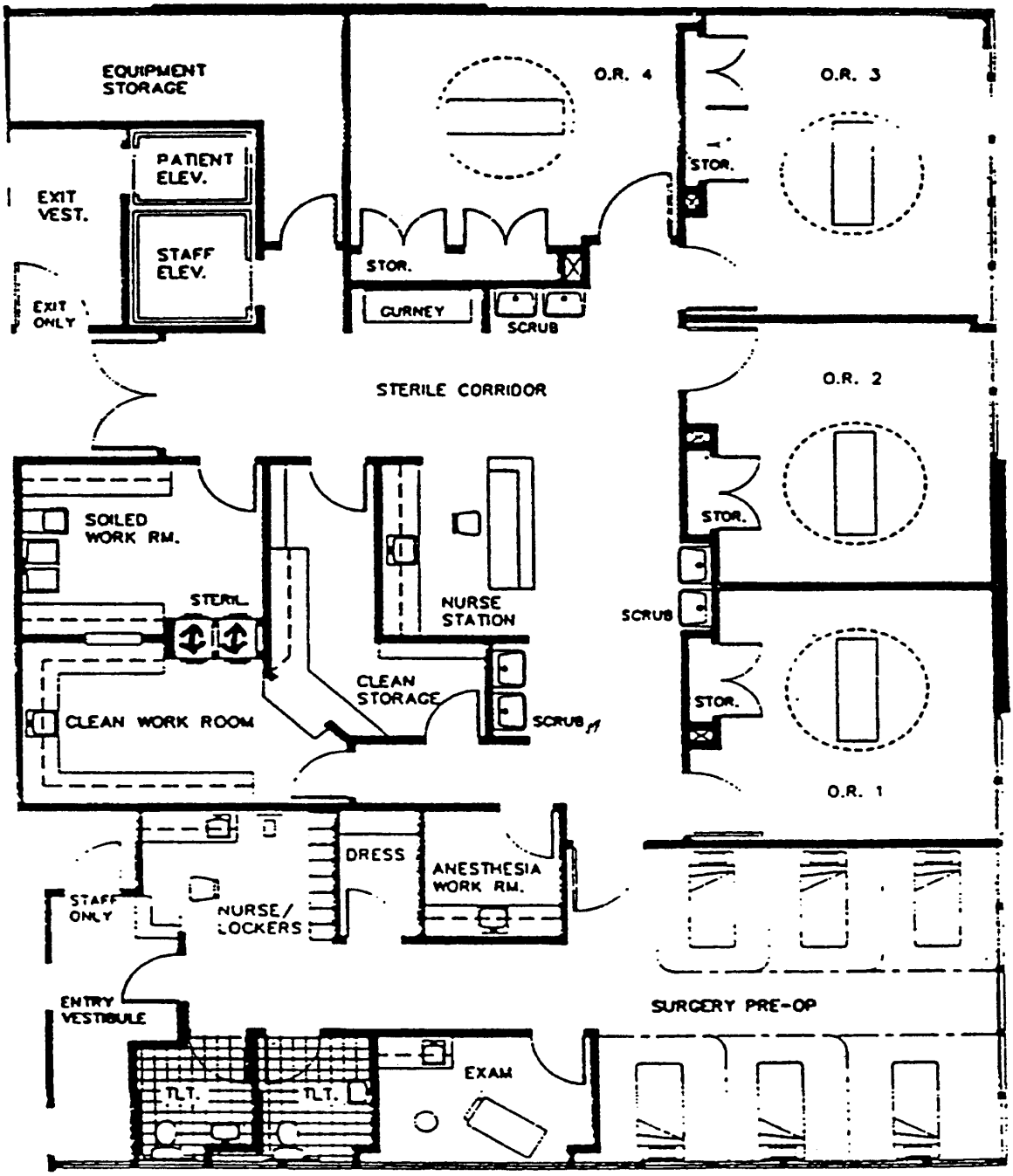


Figure A.2—Example of an ambulatory surgery facility
(Reproduced, with permission of the publisher, from Malkin [1989])

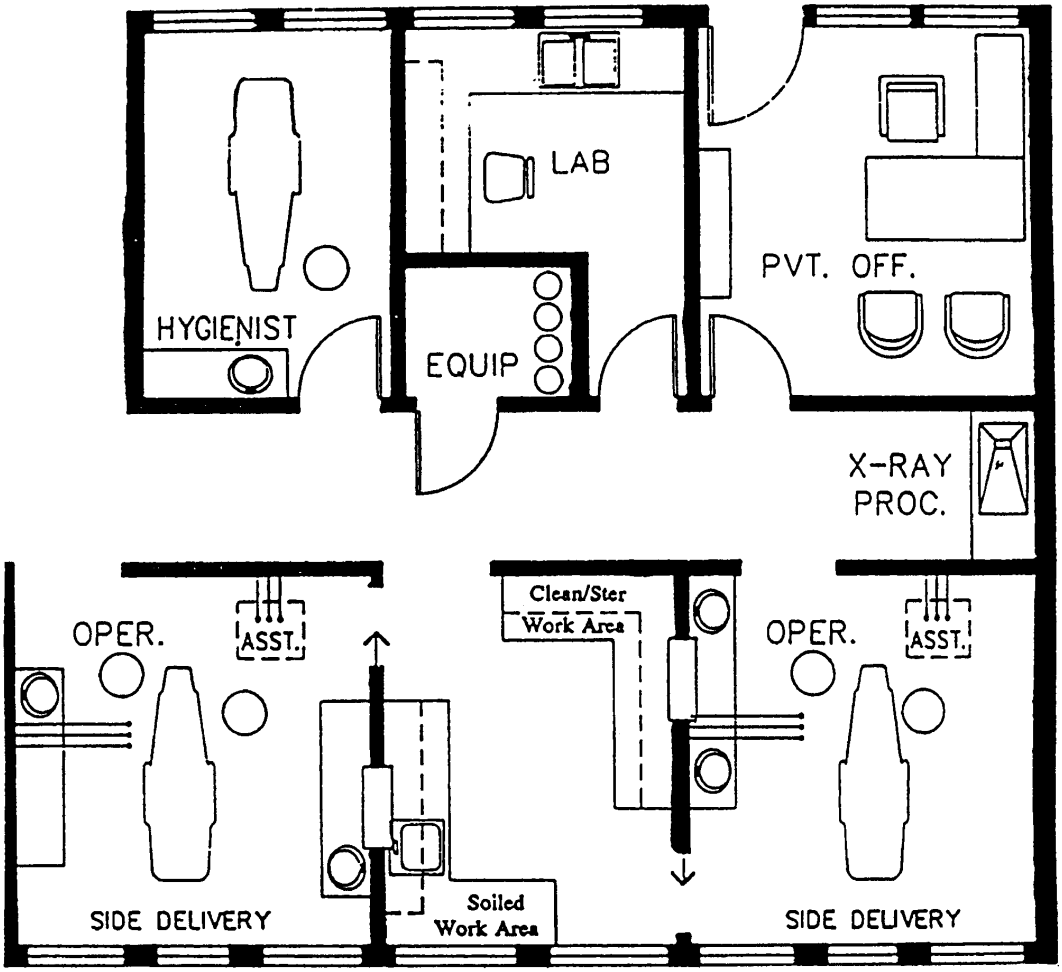


Figure A.3—Example of a dental facility
(Reproduced, with permission of the publisher, from Malkin [1989])

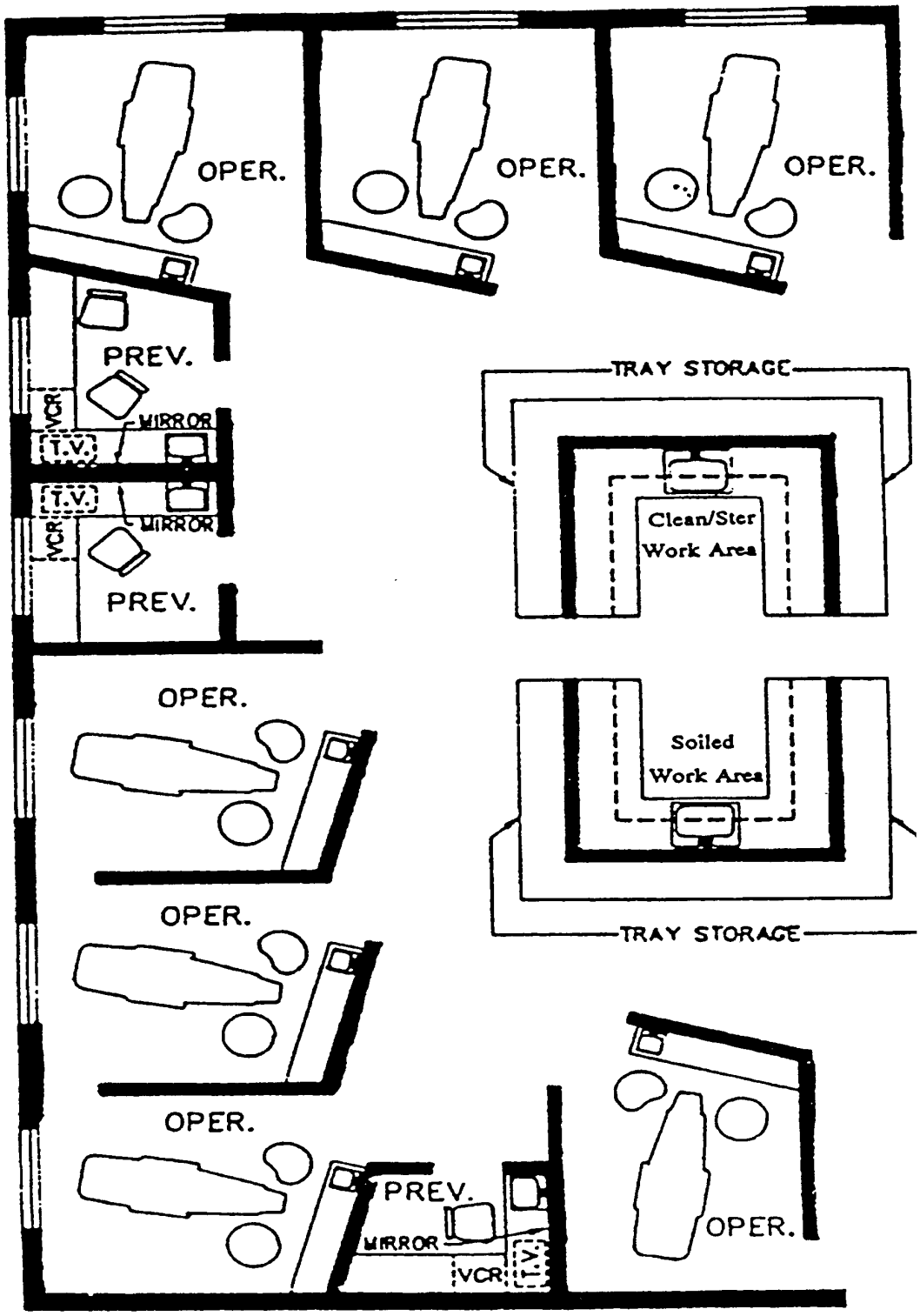


Figure A.4—Example of a dental facility
(Reproduced, with permission of the publisher, from Malkin [1989])

Annex B
(informative)

Wrapping techniques

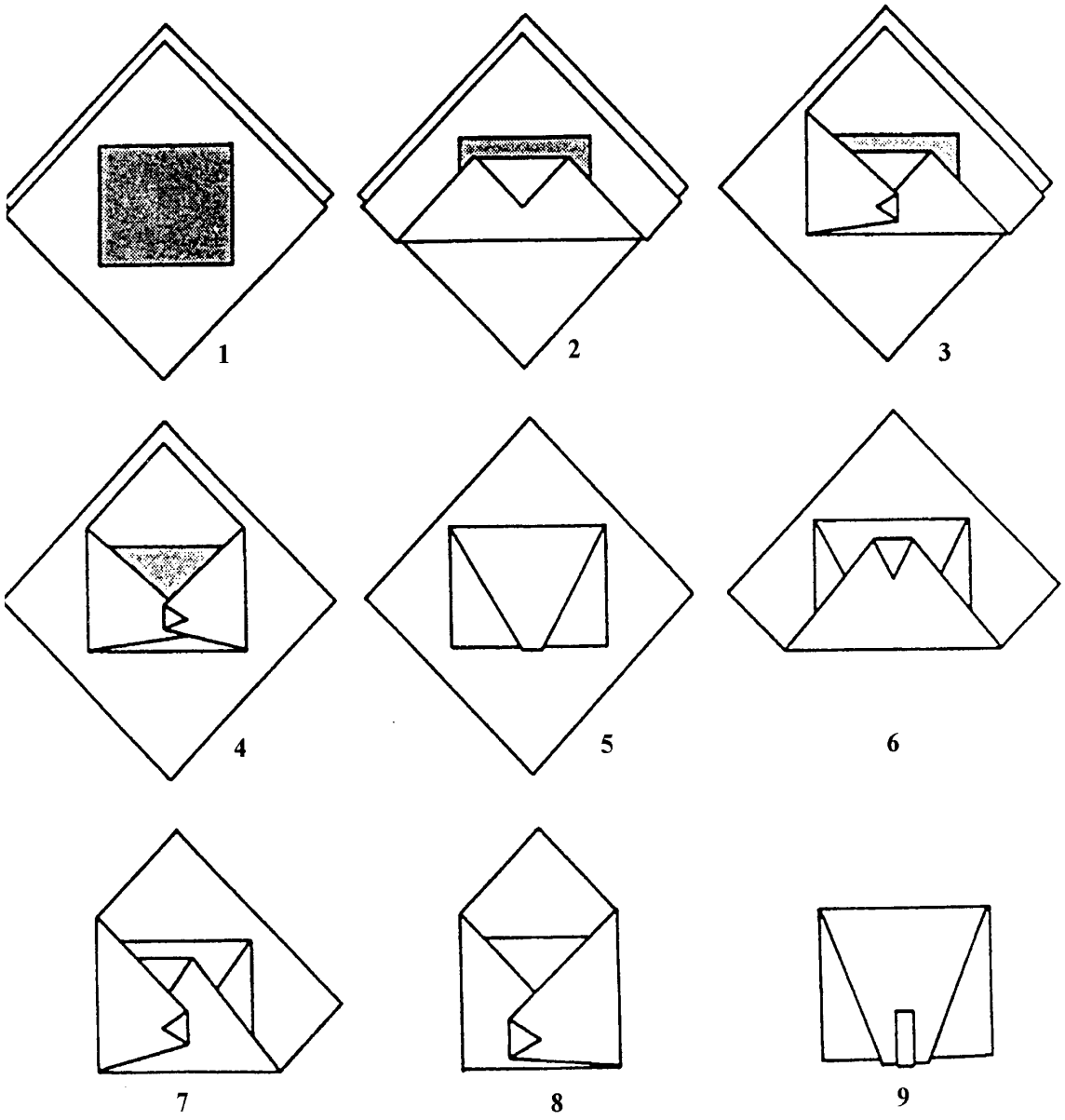


Figure B.1—Envelope wrap
(Reproduced from AAMI [1994a]).

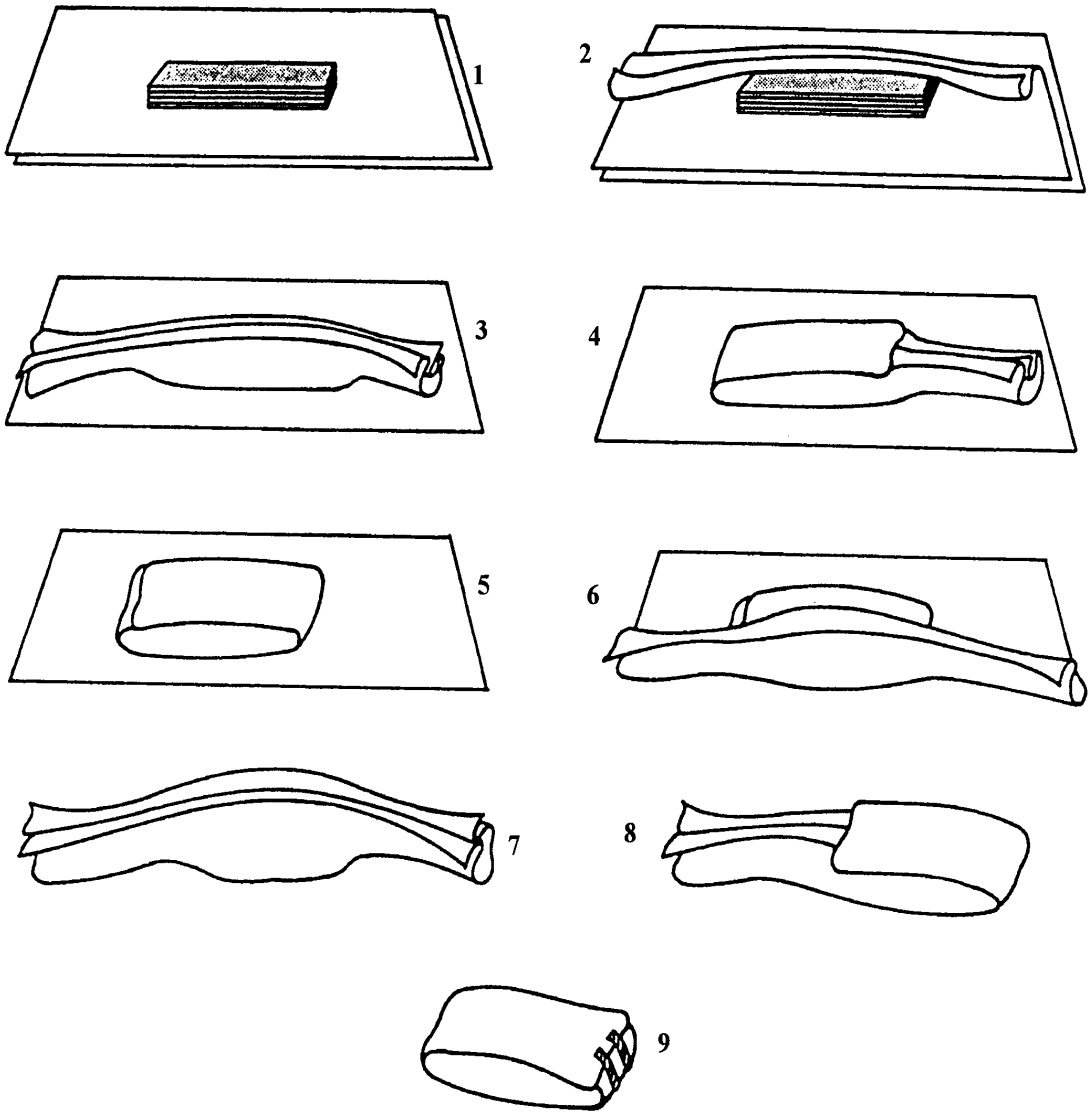


Figure B.2—Square wrap
(Reproduced from AAMI [1994a])

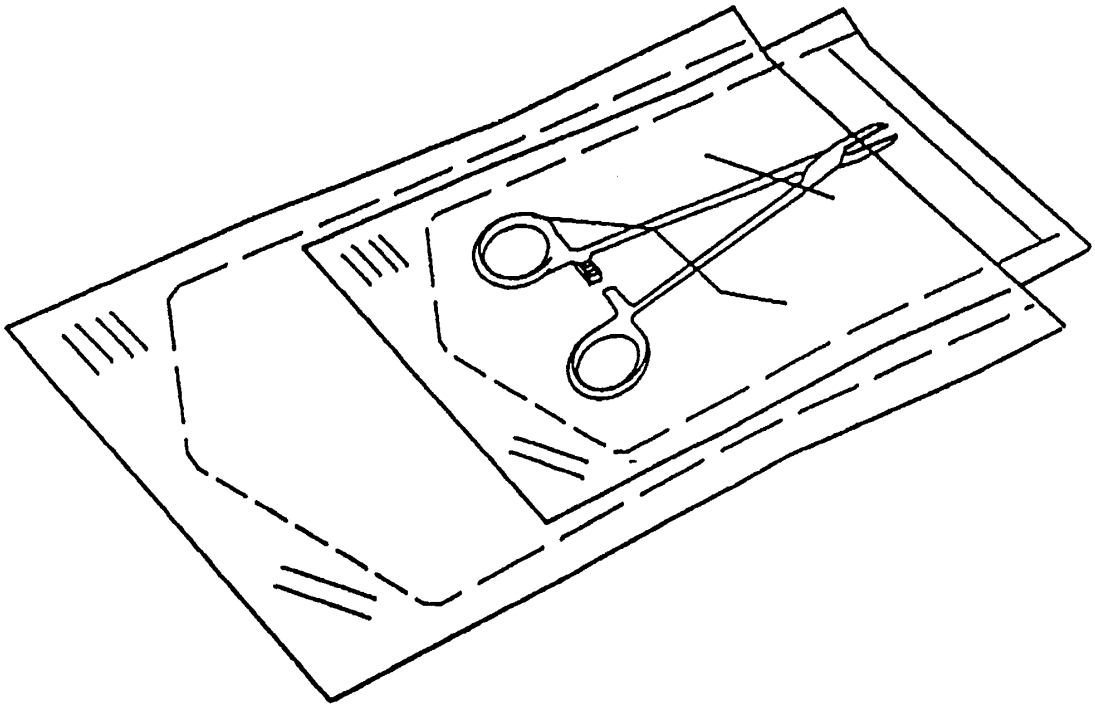
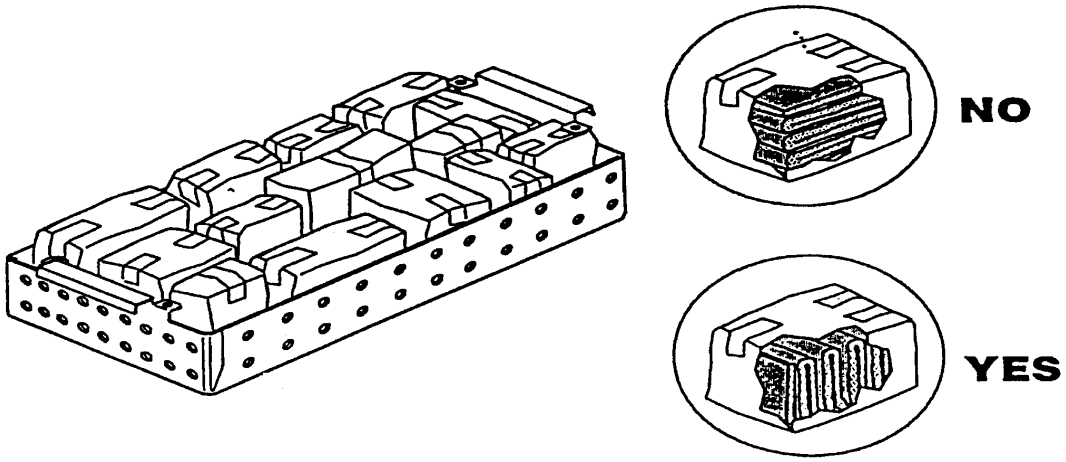


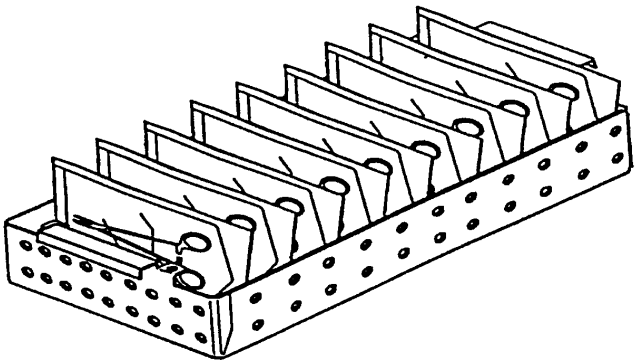
Figure B.3—Paper/plastic pouches

Annex C
(informative)

Loading the sterilizer



WRAPPED PACKS
(Placed on Edge)



PAPER/PLASTIC PEEL POUCHES
(Placed on Edge)

Figure C.1—Loading table-top steam sterilizers

Annex D

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