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American National Standard

ANSI/AAMI ST33:1996

Guidelines for the selection and use of reusable rigid container systems for ethylene oxide sterilization and steam sterilization in health care facilities

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

Association for the Advancement
of Medical Instrumentation
1110 N. Glebe Rd., Suite 220
Arlington, VA 22201-4795

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ST33 Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities

(Revision of ANSI/AAMI ST33—1990)

American National Standard

Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities

Developed by
Association for the Advancement of Medical Instrumentation
Approved 15 July 1996 by
American National Standards Institute, Inc.

Abstract:

This recommended practice covers the selection and use of reusable rigid sterilization container systems as packaging for items to be ethylene oxide sterilized or steam sterilized. Guidelines are provided for cleaning and decontamination, preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic presentation. The recommended practice also includes definitions of terms, a bibliography, and annexes providing supplementary information.

Keywords

Containerized, packaging, sterile storage, sterility assurance

Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

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

The **Sterilization Standards Committee** has the following members:

Cochairs: Carl W. Bruch, PhD
Virginia C. Chamberlain, PhD

Members: Carl W. Bruch, PhD, Consultant, Hudson, WI
Virginia C. Chamberlain, PhD,* BRI, Bethesda, MD
Neal E. Danielson, D's Enterprise, Wichita, KS
Judith Dowler, Medical Devices Bureau, Health Canada, Ottawa, ON
Frank B. Engley, Jr., PhD, University of Missouri, Columbia, MO

Collette P. Keyser, RN, Colonel, U.S. Army (Retired), Alexandria, VA
Robert Morrissey, PhD, Johnson & Johnson
Barry F.J. Page, Consultant, Garner, NC
Marimargaret Reichert, RN, Reichert Consulting, Olmsted Falls, OH
Janet K. Schultz, RN,** Jan Schultz and Associates, Allison Park, PA
James Whitbourne, Sterilization Technical Services
James L. Whitby, MA, MB, FRCP, University of Western Ontario, London, Ontario

The **Steam Sterilization Hospital Practices Working Group** has the following members:

Cochairs: Barbara J. Goodman, RN
Charles O. Hancock

Members: Zoe Z. Aler, RN,*** Consultant, Timonium, MD
Thomas A. Augurt, PhD, Propper Manufacturing Company
Diane Brown, Baylor University Medical Center, Dallas, TX
Ross A. Caputo, PhD, Abtox
Nancy Chobin, American Society for Healthcare Central Service Personnel
Anne Cofiell, International Association of Healthcare Central Service Materiel Management
Neal E. Danielson, D's Enterprise, Wichita, KS
Gerald B. Goethals, RN, Colonel, U.S. Army (Retired), VA Medical Center, Houston, TX
Barbara J. Goodman, RN, James Lawrence Kernan Hospital, Baltimore, MD
Joel R. Gorski, PhD, North American Science Associates
Charles O. Hancock, MDT Corporation
Paul A. Honan, Getinge International
Collette P. Keyser, RN, Colonel, U.S. Army (Retired), Alexandria, VA
Carol Kiep, RN, Consultant, Fort Wayne, IN
Lee Kulle, J&J Medical
Sandra A. Lee, RN, Steris Corporation
Charles D. Paige, U.S. Department of Veterans Affairs
Marimargaret Reichert, RN, Reichert Consulting, Olmsted Falls, OH
Richard J. Rosen, Sisters of Providence Health System, Seattle, WA
Peggy Ryan, RN, Ryan Associates, Boulder, CO
Janet K. Schultz, RN,** Jan Schultz and Associates, Allison Park, PA
Retta C. Sengstock, RN, Medical Sterilization
Mark A. Seybold, Baxter Healthcare Corporation
Linda A. Slone, RN, Sibley Memorial Hospital, Washington, DC
Frank W. Stout, DDS, University of Florida College of Dentistry, Gainesville, FL
Betty Strickland, Memorial Hospital System, Stafford, TX
Susan Thomaschefsky, Kimberly-Clark Corporation
Julie Thompson, RN, Association of Operating Room Nurses
Timothy Ulatowski, Center for Devices and Radiological Health, U.S. Food and Drug Administration
James Whitbourne, Sterilization Technical Services
Kathleen E. Wolf, RN, Cottrell, Ltd.

Alternates: Ruth Anne Brooks, International Association of Healthcare Central Service Materiel Management
Jacqueline Daly, RN, MSN, Advanced Sterilization Products
Jack Scoville, Cottrell, Ltd.

James Weber, Kimberly-Clark Corporation

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

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Foreword

This recommended practice was developed by the AAMI Steam Sterilization Hospital Practices Working Group under the auspices of the AAMI Sterilization Standards Committee. The guidelines contained in this document are intended to assist health care personnel in the selection and effective use of reusable rigid sterilization container systems.

This is the second edition of *Good Hospital Practice: Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems* (ANSI/AAMI ST33), which is now entitled *Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities*. The first edition was published in 1990. Under AAMI standards- development procedures, all standards and recommended practices must be reviewed and either revised or reaffirmed within 5 years of issue. Consequently, the review and revision of this recommended practice was undertaken in 1994.

The new edition reflects the following changes and additions:

- revisions to address the use of reusable rigid sterilization container systems in steam-flush pressure-pulse steam sterilizers;
- revisions of the recommendations concerning temperature and air exchange rate in storage areas to take into account the current *Guidelines for Design and Construction of Hospital and Health Care Facilities* (American Institute of Architects, 1996);
- a new section entitled *Process Performance* to address quality assessment;
- expanded recommendations concerning prepurchase evaluation to take into account the variety of container systems now in use.

This recommended practice reflects the conscientious efforts of health care professionals, in cooperation with representatives of medical device manufacturers, regulatory agencies, accrediting agencies, and professional organizations, to develop recommendations for the optimum use of container systems. It is not intended for these recommendations to be construed as universally applicable to all circumstances. It is also recognized that, in many cases, these recommendations may not be immediately achievable. Therefore, the document should 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 within the context of this document, "shall" indicates requirements strictly to be followed in order to conform to the recommended practice; "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; "may" is used to indicate that a course of action is permissible within the limits of the recommended practice; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

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

The concepts incorporated herein should not be considered inflexible or static. The recommendations must be reviewed periodically to assimilate new data and advancements in technology. As noted previously, 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, *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities* (ANSI/AAMI ST33—1996), but it does provide important information about the development and intended use of the document.

Introduction: Need for the recommended practice

Reusable rigid sterilization container systems serve as packaging for items prior to, during, and after sterilization. These systems also can be used to contain and transport contaminated items after use. Container systems are made from a variety of metal, plastic, and composite materials.

Such systems have been used in Europe and other parts of the world for many years. Since the early 1980s, rigid sterilization container systems have been purchased and used by many U.S. health care facilities as an alternative to the traditional woven or nonwoven wrapping materials used as packaging systems for the sterilization of instruments, metal devices, and other supplies. Through the years of use, a great deal of scientific evidence, as well as user clinical evidence, has been developed and published as validation that container systems are an effective sterilization packaging method.

Whenever a new packaging configuration or technology for sterilization is introduced in a health care facility, all procedures associated with its use should be carefully evaluated and adapted to maintain the effectiveness of the total sterilization and sterility maintenance system.

This document discusses the factors that should be considered in the selection and use of reusable rigid sterilization container systems in health care facilities. The provisions should be reviewed by departmental managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with appropriate hospital committees (e.g., safety, infection control, hazardous materials).

Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities

1 Scope

1.1 General

This recommended practice provides guidelines for the selection and use of reusable rigid sterilization container systems in hospitals and other health care facilities. These guidelines are intended to increase assurance of sterility by identifying the special considerations that apply to this packaging method and by providing recommendations on the proper use of the container system.

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

1.2 Inclusions

This recommended practice specifically addresses

a) cleaning and decontamination of container systems;

b) preparation and assembly of container systems with instruments;

c) loading container systems into the sterilizer and unloading them from the sterilizer;

d) matching the container system to the appropriate sterilization method and cycle (gravity-displacement steam sterilization, dynamic-air-removal steam sterilization, ethylene oxide [EO] sterilization);

e) quality assurance;

f) sterile storage;

g) transport of container systems within and between health care facilities;

h) aseptic presentation of container systems;

i) process performance.

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

1.3 Exclusions

This recommended practice does not cover a) labeling or design criteria for container systems or the quality and performance capabilities of the filters; b) the use of container systems for packaging items other than instrument sets or procedural trays; c) ongoing sterility assurance programs; d) rigid, protective organizing cases that require wrapping prior to sterilization; e) flash sterilization; f) any other method of sterilization not noted in 1.2.

NOTE—For guidelines on steam sterilization, see AAMI (1994b) ANSI/AAMI ST8-1993 and AAMI (1996a) ANSI/AAMI ST37-1996. For guidelines on EO sterilization, see AAMI (1992) ANSI/AAMI ST41-1992. For safety and performance criteria for steam sterilizers and ethylene oxide sterilizers, see AAMI (1994b) ANSI/AAMI ST8-1993 and AAMI (1993) ANSI/AAMI ST24-1992, respectively. For information on the use of a container system with sterilization technologies other than ethylene oxide and saturated steam, consult the container manufacturer.

2 Definitions

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

2.1 absorbent towel: All-cotton towel having a plain weave with only the warp yarns tightly twisted.

2.2 aerator, ethylene oxide: Machine designed to speed up the removal of ethylene oxide residuals from sterilized items by subjecting them to warm, circulating air.

2.3 biological indicator (BI): 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 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 can 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 container, rigid sterilization: Packaging system designed to contain items for sterilization, storage, transportation, aseptic presentation of contents, and return of contaminated items to the decontamination area.

NOTE—The system generally consists of a bottom or base with carrying handles and a lid that is secured to the base by means of a latching mechanism. A basket or tray to hold instruments or other items to be sterilized is placed inside. A filter or valve system is incorporated into the lid and/or base to provide for air evacuation and sterilant penetration during the sterilization cycle and to act as a barrier to microorganisms during storage.

2.6 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 are capable of producing disease or infection.

2.7 cycle time: Total elapsed time of a sterilization cycle from the time the sterilizer door is closed and the cycle is activated until the time the cycle is completed and the door is opened.

NOTE—Cycle time can include come-up or heat-up time, exposure time, come-down time, and cooling or drying time. For appropriate equipment, cycle time also can include prehumidification time, pre- and post-vacuum time, and aeration time.

2.8 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 generally is used in health care facilities with reference to all pathogenic organisms, not just those transmitted by blood.

2.9 density: Mass per unit of volume.

2.10 filter: Device secured to the rigid container lid and/or bottom that serves to allow passage of air and sterilants yet provides a microbial barrier.

NOTE—The filter media may be reusable, disposable, or permanently affixed to the container.

2.11 filter retention system: Mechanism that secures disposable filters in place.

NOTE—The filter retention system may be a retention plate or a retaining ring. It is disengaged to release used filters for disposal and reengaged to secure new filters.

2.12 gasket: Pliable strip that serves as a seal between the lid and the container to prevent entry of microorganisms.

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

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

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

2.15 huck towel: All-cotton surgical towel with a honeycomb-effect weave.

NOTE—Both warp and fill yarns are tightly twisted.

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

2.17 latching mechanism: Mechanical device that secures the container lid to the container bottom.

2.18 performance qualification: Element of the sterilization validation program consisting of selected engineering and microbiological demonstrations that are performed according to a predefined protocol to show process reproducibility and product acceptability.

2.19 steam quality: Ratio of the weight of dry steam to the weight of dry saturated steam and entrained water.

NOTE—For example, if the quality of steam has been determined to be 95%, the wet-steam mixture delivered from the boiler is composed of 5 parts by weight of water, usually in the form of a fine mist, and 95 parts by weight of dry saturated steam. Likewise, if the quality of the steam has been determined to be 100%, the boiler has delivered no wet steam; 100% of the steam delivered is dry saturated steam.

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

2.21 sterile/sterility: State of being free from viable microorganisms.

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

2.22 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 can be reduced to a very low number, it can never be reduced to zero.

2.23 sterilizer, ethylene oxide: Sterilizer that utilizes ethylene oxide under defined conditions of gas concentration, temperature, and percent relative humidity.

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

NOTES—

1) *Prevacuum steam sterilizers* depend upon one or more pressure and vacuum excursions at the beginning of the cycle to remove air. This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system and because of the usually higher operating temperature (132° C–135° C [270° F–275° F]; 141° C–144° C [285° F–291° F]). This type of sterilizer generally provides for shorter exposure times and accelerated drying of fabric loads by pulling an additional vacuum at the end of the sterilizing cycle.

2) *Steam-flush pressure-pulse steam sterilizers* depend upon a repeated sequence consisting of a steam flush and a pressure pulse to remove air from the sterilizing chamber and processed materials using steam at above atmospheric pressure (no vacuum is required). Like a prevacuum sterilizer, a steam-flush pressure-pulse sterilizer rapidly removes air from the sterilizing chamber and wrapped items; however, the system is not susceptible to air leaks, because air removal is achieved with the sterilizing chamber pressure at above atmospheric pressure. Typical operating temperatures are 121° C–123° C (250° F–254° F), 132° C–135° C (270° F–275° F), and 141° C –144° C (285° F–291° F).

2.25 sterilizer, steam, gravity-displacement type: Type of steam sterilizer in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber. Typical operating temperatures are 121° C–123° C (250° F–254° F) and 132° C–135° C (270° F–275° F).

2.26 tamper-evident device: Seal or disposable "lock" generally secured on the container-latching mechanism.

NOTE—The device is designed so that it cannot be resealed after opening. It is intended to indicate that the container has not been opened intentionally or accidentally and therefore exposed to potential contamination prior to use.

2.27 terminal sterilization: Process whereby a product is sterilized in its final container and permits the measurement and evaluation of quantifiable microbial lethality.

2.28 treated water: Water that has been processed to reduce impurities.

NOTE—Typical water treatment can employ filtration, deionization, distillation, or reverse osmosis, singly or in combination.

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

NOTE—Validation covers three activities: commissioning, verification of process specification, and performance qualification.

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

3 Cleaning and decontamination

3.1 General rationale

Reduction of bioburden is essential for sterilization. The cleaning and decontamination of rigid sterilization container systems is as important as the cleaning and decontamination of the soiled/ contaminated contents.

3.2 Transfer of contaminated items to the decontamination area

If the manufacturer's written instructions permit, closed sterilization container systems (with solid bottoms or with filters in place, if applicable) can be used for containment and transport of contaminated instruments and medical devices to a decontamination area, where cleaning procedures can best be performed. Contaminated items should be handled as little as possible. Gloves should be worn when placing the contaminated items into the container. Care should be taken to avoid touching the outer surfaces of the container with gloved, soiled hands.

Rationale: Some manufacturers instruct users not to use the same container system for transport of contaminated items as for sterilization, so it is important to consult the labeling. Contaminated items harbor microorganisms that can cause infection in susceptible individuals; gloves provide a barrier to direct contact with contaminated items. If the outer surfaces of the container are touched with gloved, soiled hands, then the entire container is considered contaminated.

3.3 Disassembly

3.3.1 Removable filters

When using container systems with removable filters, the filter protectors or holders (retention plates) should be removed or released to disengage the filter media. If disposable, the entire filter should be disposed of according to the policies and procedures of the health care institution. Removable, reusable filters should be disassembled, cleaned, and replaced according to the manufacturer's instructions.

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

3.3.2 Valves

If the container system is provided with valve-type closures, the manufacturer's instructions for frequency and method of removal, disassembly, and cleaning should be followed.

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

3.3.3 Interior baskets

The interior basket always should be removed from the container for decontamination. Depending on the type of basket and instrument set, the user might need to remove the instruments from the basket before proceeding with the cleaning and decontamination process. In most cases, the interior basket can be processed with the instruments in the basket according to the institution's usual routine.

Rationale: Separation of the basket from the container allows for effective decontamination. The interior basket functions as a tray, much like the mesh-bottomed pan used in a conventionally wrapped set.

3.3.4 Labeling

Reusable identification labels may be affixed to container systems. Depending on the institution's procedure, the user might need to remove the labeling prior to further processing. If a particular container always is used for the same set of instruments, it could be important to keep the label with the container.

Rationale: Labeling enables the identification of container contents.

3.3.5 Process indicators, disposable labels, and disposable locks

Process indicators, disposable labels, and disposable locks should be removed prior to any cleaning of the container system.

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

3.3.6 Dividers and sorting pins

It might be necessary to dismantle dividers and sorting pins that are part of instrument baskets if the dividers and pins will interfere with the proper cleaning of the basket.

Rationale: If the position of the dividers and pins interferes with adequate cleaning, there might not be adequate penetration of the sterilant to these areas.

3.4 Cleaning methods

Reusable sterilization containers should be cleaned carefully prior to sterilization even if they are to be returned immediately to use. The cleaning method generally used should comply with the institution's procedures prior to acquiring container systems. Container systems can be cleaned by either manual or mechanical means.

3.4.1 Manual cleaning

The container manufacturer's instructions for cleaning and rinsing procedures should be followed, as should accepted practices for decontamination and employee safety. Personnel who clean and decontaminate containers and contaminated contents of containers must wear appropriate personal protective attire for the tasks they are performing.

Rationale: Adequate cleaning is the first step in the decontamination and reuse process. Protective attire is necessary for avoiding infection and for complying with OSHA regulations (29 CFR 1910.1030). See also the rationale statement for 3.5.

3.4.2 Mechanical cleaning

Most container systems can be cleaned and decontaminated in mechanical equipment. The selection of method depends on the container manufacturer's instructions. When positioning the outer container in a mechanical washer, care should be taken to avoid the accumulation and subsequent retention of very hot water.

Rationale: It is important to consult the manufacturer's instructions, because some container systems are not compatible with all mechanical cleaning methods. Very hot water can cause burns; spilled water can cause personnel to slip and fall. See also 3.4.1.

3.5 Cleaning agents

The container manufacturer's instructions for choice of detergent should be followed, and the container should be rinsed thoroughly after cleaning.

Rationale: Certain cleaning agents can cause corrosion or deterioration of container surfaces, such as discoloration or stress cracking; for example, detergents that do not have a neutral or near-neutral pH can corrode metal, and specific additives can affect adversely some plastics. Therefore, the manufacturer's instructions should be consulted. Thorough rinsing is essential for removal of the cleaning agents.

3.6 Inspection

Nuts, bolts, screws, rivets, filter retention mechanisms, and permanent filters should be inspected for cleanliness and damage.

Rationale: Hidden surfaces and crevices can make thorough cleaning difficult. Residual organic matter can reduce significantly the efficacy of the decontamination process. Damaged components of containers could interfere with the sterilization process or allow contamination of the contents.

4 Preparation and assembly

4.1 General rationale

This section provides recommendations for the preparation and assembly of instrument sets when sterilization container systems are used as the packaging method. In general, these recommendations are not unique to containerized packaging, because the same basic considerations apply to all packaging methods or systems.

4.2 Inspection of container system

Before each use, the container system should be inspected. The sealing or mating surfaces or edges of the container and lid should be checked to ensure that they are not dented or chipped. Filter retention mechanisms and fasteners such as screws and rivets should be secure and should not be distorted or burred; the securing mechanism should function properly, and the filter media should be examined for integrity. The gaskets should be pliable, securely fastened, and without breaks or cuts. The valves should work freely and should be without breaks, cuts, chips, or dents.

Rationale: To assure the container system's operating efficiency, a thorough and clearly delineated inspection procedure is necessary. All of the container's components (top, bottom, valve or filter mechanisms, securing or latching mechanisms) must function effectively as a unit. It is vital to the maintenance of sterility that these components work together to allow air removal, to facilitate sterilant penetration and removal, and to inhibit microbial migration and contamination.

4.3 Configuration of instrument sets

4.3.1 Weight and density of sets

Regardless of the packaging method used, the weight of any instrument set should be based on whether personnel can use proper body mechanics in carrying the set, on the design and density of individual instruments comprising the set, and on the distribution of mass (density) in the set and sterilizer load. The mass of instruments should be distributed as uniformly as possible throughout the tray. The user should consult the container manufacturer concerning weight and density of instrument sets; however, it is the user's responsibility to determine that the set can be sterilized and dried effectively. In addition, consideration should be given to load size as it affects drying. In hospitals in which steam quality is less than optimal, load size can adversely affect drying time.

Rationale: There is no magic number for instrument set weight. Preparation and assembly procedures should take into account the number of instruments, the size of the instrument tray, and total set weight and density. By considering the density of the individual instruments, the instrument set, and the sterilizer load, as well as the available steam quality, the user will be able to develop a total program that will yield sterile, dry instrument sets. (See also annex B.)

4.3.2 Instrument placement

As with any other packaging method, the principles of instrument preparation should be followed. Items to be sterilized should be arranged in containers according to the following guidelines:

a) The basket(s) placed in the container should be large enough to allow the metal mass of instruments and devices to be distributed equally in the basket(s). Woven mesh-bottomed trays or baskets generally are acceptable for use.

NOTE—The use of some nonabsorbent tray liners (e.g., plastic/silicone-fingered organizing mats) can cause condensate to pool. See also 4.3.3.

b) Instruments should be positioned to allow the sterilant to come into contact with all surfaces.

c) All jointed instruments should be in the open or unlocked position with ratchets not engaged. Racks, pins, stringers, or other specifically designed devices can be used to hold the instruments in the open position.

d) Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled unless the device manufacturer provides specific instructions, supported by test data, to the contrary.

e) Instruments should not be held together with rubber bands.

f) Care should be taken in evaluating the placement of items made of glass, rubber, or, in the case of surgical instruments, dissimilar metals.

g) For steam sterilization, items with lumens should first be moistened with treated water. For EO sterilization, items with lumens should be dried thoroughly.

h) Items with concave surfaces and/or broad, flat surfaces that will retain water should be placed on edge so that these surfaces will drain water or condensate.

i) Heavy instruments should be placed in such a way that they will not damage more delicate items. Lighter instruments should be positioned to protect tips and to prevent damage from changes in position.

j) Complex instruments (e.g., air-powered instruments, endoscopes, and instruments with lumens or channels) should be prepared and sterilized according to the device manufacturer's written instructions. When combining complex instruments in a set, the user might have to test and evaluate the effectiveness of sterilization and drying.

k) Small, basket-type accessory containers with covers or lids (e.g., nail or bone screw holders), protective organizing baskets, trays, or cases (e.g., microsurgery instrument cases, air-powered equipment sets, orthopedic instrument organizing sets) should be placed into sterilization containers only if the sterilization containers have been specifically designed and tested for this purpose. Collaborative testing should be performed by the device manufacturer, the manufacturer of the protective organizing case, and the container manufacturer. The user has the responsibility to test and evaluate the effectiveness of sterilization and drying of protective organizing cases during the specific sterilizer cycles to be used for sterilization processing. Prior to preparation and sterilization of multipart sets or complex instruments, processing personnel should review the specific written instructions that are applicable.

l) Plastic/paper pouches may be used to package specific instruments (e.g., small parts and pieces) only if they can be placed on edge and held on edge during the sterilization cycle. Plastic/paper pouches should not be folded.

The manufacturer of the container system being used should be consulted for product-specific information regarding set preparation and assembly.

Rationale: Sterilization depends on contact of the sterilizing agent with all surfaces for the prescribed time. Improper positioning or abrupt changes in positioning can result in damage to the instrument or the container system and could prevent adequate sterilant penetration and contact during processing. Devices made of glass can be damaged if positioned incorrectly; rubber can become tacky due to the heat generated by hot metal instruments; and devices made of dissimilar metals can be damaged because of material interactions.

For items to be steam sterilized, lumens are moistened with treated water so that air can be more easily displaced and steam can contact all inner surfaces. It is necessary to dry thoroughly the lumens of items to be EO sterilized, because water droplets protect microorganisms from ethylene oxide and can therefore inhibit sterilization; excessive moisture also increases the possibility of formation of ethylene glycol, which is not removed by aeration.

Instruments with concave and/or broad, flat surfaces that are not placed standing on edge during processing can create moisture problems, because condensate pools beneath the lowest part of the instrument and might not revaporize completely at the end of the cycle.

For complex instruments, the device manufacturer is best able to specify packaging requirements and sterilization methods, including the cycle times that are required because of instrument configuration. As with any other packaging method, protective organizing baskets, trays, or cases should not be used without consulting the container manufacturer or conducting specific testing, because these devices can affect the dynamics of the sterilization and drying process. Protective organizing baskets, trays, or cases can impede air removal and sterilant penetration and thus prevent sterilization from being accomplished in the specified cycle time.

It is essential that plastic/paper pouches remain securely in place during the sterilization cycle to ensure adequate air removal, sterilant penetration, and sterilant removal.

4.3.3 Use of tray liners or organizing devices

The judicious use of tray liners or other absorbent material can alleviate drying problems. Absorbent inner wraps can also assist in the aseptic presentation of the contents of the container. Organizing devices can help keep items in place to ensure adequate sterilant contact. However, the specific recommendations of the container manufacturer concerning the use of organizing devices or inner absorbent material should be consulted, and the user should evaluate the effectiveness of the sterilization and drying process when such devices or materials are used.

Rationale: Absorbent material wicks condensate away from instruments and disperses it over a greater surface area for more efficient drying. However, an excessive amount of absorbent material or the incorrect type of absorbent material can impede air removal and sterilant penetration and interfere with proper drying. Organizing devices could also impede sterilant penetration and the drying process. As is always the case in the sterilization process, a delicate balance is necessary.

5 Sterilizer loading and unloading

5.1 General rationale

Although the principles of loading and unloading sterilization containers into and out of the sterilizer are the same as for any other product to be sterilized, sterilization containers require special considerations related to employee safety, adequate sterilant penetration, and cooling.

5.2 Loading the sterilizer

5.2.1 Placement

Regardless of the method of sterilization used, container systems should be placed flat on the sterilizer shelves.

Rationale: Flat placement helps ensure adequate air evacuation, adequate sterilant penetration, and efficient drying or aeration.

5.2.2 Mixed loads

Items packaged in container systems can be sterilized safely and economically in the same load with other supplies that require a common exposure cycle. Container systems should be placed on shelves below absorbent items.

Rationale: Placing container systems below absorbent items prevents the wetting of the absorbent items by condensate from the container systems.

5.2.3 Stacking

Before stacking container systems for sterilization, the user should consult the manufacturer's recommendations and documentation. The user also should conduct verification testing in the sterilizers to be used. (See also section 6.)

NOTE—Users are cautioned that stacking container systems of differing manufacture is not advisable because the configurations might not be compatible. Recommendations from both manufacturers should be obtained, and verification testing should be conducted in the sterilizers to be used.

Rationale: Stacking container systems in the sterilizer could interfere with air evacuation, sterilant penetration, and drying or aeration. The appropriateness of stacking container systems in the sterilizer depends on the design of the container system as well as on the method of sterilization.

5.3 Unloading the sterilizer

Containers should remain on the sterilizer cart until container surfaces are cool to the touch and can be handled safely by the operator with bare hands. The cool-down period begins within the sterilizer chamber. The door may be opened slightly at the end of the cycle and the items left inside for a period of time in order to reduce the potential for condensation formation. After the containers are removed from the sterilizer, they should be placed in a draft-free area that is not near cooling or air-conditioning vents.

Rationale: If containers are not properly cooled prior to their removal from the sterilizer cart, recondensation of steam vapor can occur. Because the materials used for containers are not absorbent, condensate can appear as small droplets on or within the container system. Condensate on the outside of a container system could flow downward toward the filter of another container and contaminate it. Condensate can also run down the sides and onto noncontainerized packages below, contaminating them if the packaging is not impervious to moisture. Condensate within any container system can compromise the sterility of the contents if the condensate is able to come into contact with outside contaminants. The potential for outside contamination depends on several factors, such as the type of filter media and the seal of the filter or valve. The potential for outside contamination also depends on the construction of the container system, e.g., whether the container system has a solid bottom or feet to raise it above contaminated surfaces. Because some of the materials used in rigid container systems can burn the operator when hot, care should be exercised in handling them. Opening the door for a period of time at the end of the sterilization cycle and before the containers are removed from the chamber reduces the temperature differential between the inside and outside of the chamber and thus helps prevent the formation of condensate.

6 Matching the container system and sterilization cycle

6.1 General rationale

Container systems vary widely in design, mechanics, and materials of construction. Work practices, sterilizer performance characteristics, and the function of the hospital utilities supplying the sterilizer can also affect the dynamics of the sterilization process. (See AAMI 1992, ANSI/AAMI ST41-1992; AAMI 1993, ANSI/AAMI ST24-1992; AAMI 1994a, ANSI/AAMI ST46-1993; and AAMI 1994b, ANSI/AAMI ST8-1993.) These factors can affect markedly the specific performance characteristics of container systems and their suitability for particular sterilization methods and cycles. This section covers the responsibilities of manufacturers and users in matching container systems and sterilization cycles.

6.2 Responsibilities of the manufacturer

6.2.1 General

The manufacturer of a container system should demonstrate by scientific evidence that the system is suitable for the specific sterilization methods and cycles for which it is designed and recommended. The manufacturer should provide the user with complete instructions for use and inservice education, as well as documentation of the methodology and results of performance testing of the container system. This documentation should cover the following aspects of performance: sterilization (6.2.2), drying (if applicable) (6.2.3), ethylene oxide residual removal (if applicable) (6.2.4), and sterility maintenance (6.2.5).

Rationale: Ongoing instruction and inservice education help assure the effective use of the container system. Documentation of test methodology and results enables users to compare the performance of various container systems and verify that a particular container system is suitable for the applications of the health care facility.

6.2.2 Sterilization

Documentation of the manufacturer's test methodology and results should include information verifying that the sterilization efficacy of the container system has been qualified in standard hospital sterilization cycles and has passed standard AAMI challenge tests for each method of sterilization for which the container system is labeled. At least the following information should be made available to the user:

a) the methods of sterilization and types of cycles (e.g., gravity-displacement steam sterilization, dynamic-air-removal steam sterilization, ethylene oxide sterilization);

b) the test equipment nomenclature and equipment cycle performance verification test data, including the manufacturers, types, model numbers, chamber sizes, cycle sequence, and parameters (e.g., pressures, temperatures, number of pulses, time intervals) of the sterilizers used;

c) the types, sizes, and placement of filters or valve assemblies in the container system;

d) the weight, density, and distribution of the contents of the container system (e.g., the separation of the contents into layered baskets or other accessories);

e) the type, placement, and rationale for the use of any inner wrapping or absorbent materials included in the contents that could affect sterilization and, if applicable, drying or ethylene oxide aeration;

f) the types, number, placement sites, and performance characteristics (e.g., D value) of the biological indicators (BIs) and, if applicable, chemical indicators used for validation of cycle processing;

g) the methodology used for retrieving and culturing BIs and the results;

h) if applicable, the results of chemical monitoring;

i) the sterilizer load configuration, including the recommended container stacking pattern if stacking has been validated;

j) load preheating time prior to cycle start (if the load was preheated during testing and if preheating is recommended to diminish the formation of condensate during the sterilization cycle);

k) the methodology used for obtaining time-at-temperature profiles of the container system and contents during the sterilization cycle (e.g., use and placement of thermocouples inside containers);

l) the rationale for the recommended sterilization exposure time;

m) any other factors that influence the sterilization time required for each type of sterilization cycle for which the container system is recommended.

6.2.3 Drying (if applicable)

Documentation of the test methodology and results should include at least the following information:

a) if applicable, the level of pressure attained during the drying phase of the cycle, including the multiple excursions used in a pulsing cycle;

b) the time of the drying phase;

c) the factors that can influence the drying time of the container system and its contents, such as the following:

- the materials of construction of the container system;
- the size and contents of the container system;
- the number of container systems in the load;
- the temperature of the container system and contents at the beginning of each test;
- whether the load was preheated and to what temperature;
- the steam quality;
- whether the sterilizer door was "cracked" after the drying phase of the cycle (to allow slower cooling of the container systems and to minimize condensate formation) and for how long;
- the environmental conditions (temperature, relative humidity, air exchange rate) of the cool-down area;
- the duration of cool-down between the time the container system was removed from the sterilizer and the time it was opened to determine the dryness of the contents and inner container surfaces;
- the use of any inner wrapping or absorbent materials within the contents;

d) the methodology used to test and validate the conditions necessary to ensure consistent and effective drying of the container system and its contents.

6.2.4 Ethylene oxide residual removal (if applicable)

Documentation of the test methodology and results should include at least the following information:

a) the EO residual removal times for container components such as gaskets and filters and for the container system contents;

b) the methodology and results of testing conducted to determine the potential for the retention or buildup of EO residuals within the construction materials of the container system after repeated EO cycles (which could markedly affect the safe removal of EO residuals from the container system and its contents as well as the necessary time for EO residual removal).

6.2.5 Sterility maintenance

Maintenance of sterility is event-related, and the probability of occurrence of a contaminating event increases over time and with handling, whether woven or nonwoven materials, pouches, or container systems are used as the packaging method. Manufacturers of container systems should provide test data that support the ability of the correctly assembled system to inhibit microbial migration. Documentation of the test methodology and results should include at least the following information:

a) the design characteristics of the container system that limit microbial migration and penetration of contaminants to the contents (e.g., the tortuous pathways afforded by the filter system or valves);

b) the factors that limit or minimize the potential for contamination of the inside of the container system and its contents;

c) the potential causes of contamination of the inside of the container system and its contents (e.g., filter puncture or dislodgment, inadvertent opening of the container, or any other conditions that compromise the integrity of the packaging);

d) the environmental conditions that affect recondensation on inner surfaces of the container system or the contents;

e) a statement with supporting documentation that explains whether moisture within the container system, after sterilization, will compromise the sterility of the contents;

f) test documentation demonstrating sterility maintenance, such as real-time shelf-life studies, physical whole-package challenge studies, or microbial whole-package challenge studies.

6.3 User responsibilities

6.3.1 General

Health care personnel bear the ultimate responsibility for ensuring that <u>any</u> packaging method or material, including a reusable rigid sterilization container system, is suitable for use in sterilization processing and sterility maintenance. Before purchasing any packaging system, the user should gather information and perform testing to ensure that items to be packaged can be sterilized by the specific sterilizers and/or sterilization methods to be used within the facility. The interaction of container and sterilizer technologies is complex. A container system to be used for steam sterilization needs to allow complete air removal, adequate steam penetration, and drying. A container system to be used for ethylene oxide sterilization needs to allow penetration of water vapor and the sterilant and permit adequate removal of EO residuals from container components and contents.

The specific design of the container needs to be compatible with the design and performance characteristics of the sterilizer(s) in which it is used. Prepurchase evaluation assures that the particular container system being considered will be acceptable to all prospective users in the facility and that it will perform properly in the health care facility's sterilizing equipment. The testing that should be performed by users, which is described in 6.3.2 and 6.3.3, is not a substitute for the more extensive validation testing conducted by manufacturers to qualify their products.

Rationale: Manufacturers of container systems can only test properly designed and operating sterilization equipment. Various sizes of sterilizers having the same sterilization cycle could have different air-removal efficiencies. Manufacturers cannot possibly test all combinations of sterilizer sizes, cycles, and process efficiencies. Health care personnel need to perform testing to verify that there are no problems or to identify technical problems to be resolved in consultation with the container manufacturer, the sterilizer manufacturer, and consultants.

6.3.2 Prepurchase evaluation

6.3.2.1 General

Users should conduct a prepurchase product evaluation of any container system being considered for use in sterilization processing. It should be determined, before purchase, whether or not the health care facility can verify the manufacturer's test results. If not, it is necessary to seek advice from the manufacturer concerning instructions and guidelines for use of the system.

Testing should be conducted in the health care facility to assure that the conditions essential to sterilization can be achieved and that the specific configuration of the container contents is acceptable for the sterilization process and for the requirements at the point of use. The instructions for use, test methodology, and test data supplied by the manufacturer should be assessed in relation to the environment in which the container system will be used and in relation to the sterilizer to be used for the processing of containerized instruments and procedural trays. Paragraphs 6.3.2.2, 6.3.2.3, and 6.3.2.4 describe the aspects of sterilization efficacy that should be investigated. Section 6.3.3 outlines recommended test protocols, which are summarized in table 1 .

Rationale: See 6.3.1.

6.3.2.2 Sterilization process conditions

Sterilization process conditions such as exposure time should be evaluated by mechanical, biological, and chemical monitoring. In each container to be tested, biological and chemical indicators should be placed strategically alongside each other at locations that present the greatest challenge to air evacuation and sterilant penetration. Particularly in gravity-displacement steam sterilizers, the corners of the container and the underside of the lid, away from the filters, are the likeliest locations for air pockets. Therefore, for steam sterilization, the biological and chemical indicators should be placed in a lower corner, the diagonally opposite upper corner, and the underside of the lid to maximize the challenge of the test. The BIs should be secured in such a way that they do not directly contact metal surfaces; for example, the BI placed at the underside of the lid may be suspended by tape. Suspending the BI prevents direct conduction of heat to the indicator.

After the sterilization cycle, the user should retrieve and incubate the BIs according to the BI manufacturer's written instructions. The test container and instruments should be reprocessed before use in patient care. Positive BIs can indicate a sterilization process failure and should be thoroughly investigated.

See also 6.3.3 and its subparagraphs.

Rationale: This testing helps ensure adequate sterilant penetration and demonstrates that items processed in containers can be sterilized reliably. The testing is <u>not</u> a substitute for routine monitoring (see 7.7.1) or for the container manufacturer's validation testing.

6.3.2.3 Evaluation of minimum drying times in steam sterilization

The use of container systems occasionally requires extending the drying times normally used for wrapped items. Steam quality, the design and composition of the container system, the type, number, and configuration of instruments, and the ways that excess water vapor can escape are all factors that have to be considered in the evaluation or selection of drying time. In addition, for each location within the institution, it could be important to evaluate the following factors: distance from the steam source, effectiveness of moisture removal from the incoming steam, and the potential difference between sterilizers.

For container systems with valves, water vapor can only escape and the contents dry if the valves are open. The valves are designed to close when pressure equalization occurs within the container during the drying/cooling phase. All moisture might not be eliminated before the valves close. Moisture or water droplets might be seen within the container and its contents when it is opened for use.

Rationale: The combined metal mass of instruments and metal container systems could cause excessive condensation formation during the heat-up phase of the cycle. The metal mass also can cause a slower temperature come-up time and the need for a longer drying time. Metal acts as a heat sink, taking heat from the saturated steam as it enters the sterilizer and causing the steam to collapse (turn into liquid water). The steam supply system, delivery lines, steam traps, sterilizer location, and other factors affect steam quality and the amount of moisture transported in the steam. Plastic and metal do not wick moisture as an absorbent wrapper does; consequently, it might be necessary to extend the drying time. The design of a container system, especially the routes by which water vapor escapes, also can affect drying time.

6.3.2.4 Other considerations (steam sterilization)

It also could be desirable or necessary to:

a) evaluate whether preheating the load helps diminish the formation of condensate during the prevacuum pulsing and load-heating phases of the cycle;

b) evaluate the weight and density of instrument sets;

c) evaluate the use of optional absorbent materials (e.g., cotton towels, instrument tray liners, inner wraps) to aid in the drying of inner container surfaces and contents;

NOTE—Absorbent materials sometimes hinder the drying process by precluding the escape of condensate from the container system and its contents. Moisture retained in the materials might not be easily detectable.

d) develop a policy and procedure regarding the sterility and use of the contents of container systems that appear to have retained moisture. Containers can prevent contact contamination, but internal condensate can damage instrumentation if contact with moisture is prolonged, and the acceptability of the item could be questioned by the practitioner who opens the set for use.

6.3.3 Prepurchase evaluation test protocols

6.3.3.1 General

The following paragraphs (summarized in table 1) describe recommended test protocols for prepurchase evaluation of container systems intended for use in dynamic-air-removal steam sterilization processes (6.3.3.2), gravity-displacement steam sterilization processes (6.3.3.3), and/or EO chemical sterilization processes (6.3.3.4). Containers should only be evaluated and used in cycles recommended by the container manufacturer.

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

Rationale: Most container systems are designed for use in prevacuum steam sterilizers. The container manufacturer might or might not recommend use in other sterilization processes.

6.3.3.2 Dynamic-air-removal steam sterilizers

6.3.3.2.1 Intent

The testing recommended here is intended to enable the user to assess four fundamentally essential aspects of the use of containers in dynamic-air-removal steam sterilization: 1) Will the container design permit adequate air removal from the container when the sterilizer chamber has reached the point of maximum air removal? 2)

Does the container design allow adequate steam penetration to reach equilibrium between the sterilizer chamber and the interior and contents of the container? 3) Will the combination of sterilizer and container design achieve sterilization conditions? 4) Will the combination of sterilizer and container design permit adequate drying and thus help promote sterility maintenance?

6.3.3.2.2 Test container (test configuration A)

For evaluation of container performance in dynamic-air-removal steam sterilizers, containers are prepared with the largest instrument sets (including any optional absorbent material) that will be processed in containers and with biological and chemical indicators placed as described in 6.3.2.2. The containers should represent the sizes that are available in the system being evaluated and that will be used for routine processing in the health care facility.

Rationale: The sterilant enters through discrete portals in a container and then must diffuse throughout the inside of the container and finally to the items being sterilized. Thus, there are two barriers to be overcome before the inside of the container reaches equilibrium with the sterilizer chamber. In this respect, container systems are very different from flexible wraps in which the entire barrier is permeable. In a sense, flexible wraps are more forgiving, because the tendency to retain air is lessened due to displacement or removal across the entire barrier surface and throughout the duration of the sterilization cycle. In a container, entrained or retained air not completely removed by vacuum or displacement will interfere with steam contact and thus with sterilization. In other words, the container can be viewed as a chamber within a chamber, and both chambers have to be tested.

6.3.3.2.3 Procedure

A maximum-load test and a small-load test should be run for representative sterilizers; for the remaining sterilizers, it is necessary only to run the small-load test. For the maximumload test, the user places two test containers on the bottom shelf over the drain and two test containers on each of the other sterilizer shelves (if space permits). (For example, to test a sterilizer having three shelves, six containers will be needed.) The chamber otherwise is fully loaded with conventionally packaged items.

In the small-load test, one test container is placed on the bottom shelf over the drain in an otherwise empty chamber.

A sterilization cycle is run with an exposure time of at least 3 minutes (or longer, if recommended by the container manufacturer). Upon completion of the cycle, the chemical indicators are checked, and the BIs are retrieved and incubated.

Rationale: In general, the recommended number of test containers is sufficient to evaluate sterilizer/container compatibility. A maximum load is tested to ensure that the large volume of air in this type of load is removed adequately and that the steam supply is sufficient to achieve sterilization in a load in which the considerable mass results in significant condensation. Maximum-load testing also permits the user to determine if additional steps are necessary to achieve adequate drying. The small-load test identifies any problems associated with the small-load effect, a phenomenon in sterilizers having dynamic air removal in which residual air in the chamber can become entrained in packaged items as steam enters the chamber.

6.3.3.2.4 Interpretation of results

To qualify the container/sterilizer combination, all BIs should be negative and all chemical indicators should show complete endpoint responses. In the maximum-load test, positive BIs or incompletely responding chemical indicators suggest that the sterilization process is inadequate; there could be a problem with the sterilizer itself, the container, or the sterilizer/container combination. In the small-load test, failures indicate insufficient steam penetration or air removal, which could be due to the sterilizer, the container, or the sterilizer/container combination.

To investigate any apparent sterilization failures, the first step is to check the mechanical monitors to ensure that the cycle parameters were correct. If the cycle parameters were correct, then the sterilizer should be evaluated with biological-indicator test packs and Bowie-Dick test packs to identify any equipment malfunction. Containers should not be used in this evaluation. See AAMI (1988), AAMI TIR No. 3-1988 and AAMI (1994a), ANSI/AAMI ST46-1993 for guidelines on sterilizer testing and interpretation of positive biological and chemical monitoring results.

The sterilizer manufacturer should be consulted if the performance of the sterilizer is questionable. If the sterilizer appears to be functioning properly, the container manufacturer should be consulted for assistance in resolving the problem.

Table 1—Summary of test configurations for prepurchase evaluation of rigid sterilization containers

Sterilizer Type	Cycle Type	Number of Containers Tested	Test Configuration
Dynamic-air-removal steam	Wrapped	Maximum load	A
		Small load	A
Dynamic-air-removal steam	Unwrapped	Small load	A
Gravity-displacement steam	Wrapped	Maximum load	A
		Small load	A
Ethylene oxide		Maximum load	B

NOTES—

Dynamic-air-removal steam sterilizers: The maximum-load test is conducted by placing two test configuration A containers on the bottom shelf over the drain and two on each of the other sterilizer shelves. (For example, to test a sterilizer having three shelves, six test containers will be needed.) The chamber otherwise is fully loaded with conventionally packaged items. The small-load test is conducted with one test configuration A container, placed on the bottom shelf over the drain in an otherwise empty chamber.

Gravity-displacement steam sterilizers: The maximum-load test is conducted by placing two test configuration A containers on the bottom shelf over the drain and two on each of the other sterilizer shelves. The chamber otherwise is fully loaded with conventionally packaged items. In the small-load test, only one test container is used, and it is placed on the bottom shelf over the drain in an otherwise empty chamber.

Ethylene oxide sterilizers: The maximum-load test is conducted by placing one test configuration B container in the center of the chamber and one on each of the other sterilizer shelves. The chamber otherwise is fully loaded with conventionally packaged items.

Test configuration A: A container is prepared with the largest instrument set (including any optional absorbent material) that will be processed in containers. Biological and chemical indicators should be placed as described in 6.3.2.2.

Test configuration B: A container is prepared with an EO challenge test pack (AAMI, 1992) ANSI/AAMI ST41-1992. Care should be taken not to compress the contents of the pack.

6.3.3.3 Gravity-displacement steam sterilizers

6.3.3.3.1 Intent

The testing recommended here is intended to enable the user to assess the same aspects of the gravity-displacement steam sterilization process as are important in dynamic-air-removal steam sterilization: adequate air removal from the container, adequate steam penetration into the contents of the container, adequate sterilization cycle conditions, and adequate drying and sterility maintenance. However, the evaluation of the container/sterilizer combination is especially important in gravity-displacement steam sterilization because of the relative inefficiency of air removal in this sterilization process. In particular, the user should review the data upon which the container manufacturer bases the recommended cycle time and verify those results in the hospital's sterilizers.

NOTE—Many newer gravity-displacement steam sterilizers now employ a slight prevacuum and/or a timed flush to remove air more effectively. These more efficient systems should be evaluated according to the same procedures as conventional gravity-displacement steam sterilizers.

6.3.3.3.2 Test container (test configuration A)

To evaluate container performance in gravity-displacement steam sterilizers, containers are prepared with the largest instrument sets (including any optional absorbent material) that will be processed in containers and with biological and chemical indicators placed as described in 6.3.2.2. Where specified in the test procedure, the test containers should be of the size and design representing the smallest sterilant penetration area relative to container volume. The container to choose can be determined by calculating the ratio between the number of holes in the filter area of the lid and the volume of the container. For example, a container that is 6 inches deep, 11 inches wide, and 17 inches long has a volume of 1122 cubic inches (6 times 11 times 17). If the container has 420 holes in the filter area, the ratio of sterilant penetration area to volume would be 0.37 (420 divided by 1122). For a container having the same dimensions but fewer holes, the ratio would be smaller. For a container having the same dimensions but more holes, the ratio would be larger. If containers of different sizes have the same sterilant penetration area to volume ratio, the container having the largest total volume should be chosen for test purposes.

NOTE—The formula described above is based on the assumption that all holes are the same size in all containers of a given manufacturer's product line; therefore, it is not necessary to measure the holes to determine the sterilant penetration area. If the holes are not all the same size, the manufacturer should be consulted to determine which container size or design configuration has the smallest ratio of sterilant penetration area to volume.

Rationale: The rationale for using test configuration A containers is described in 6.3.3.2.2. A container with the smallest ratio of sterilant penetration area to volume represents a worst-case challenge to the sterilization process. Thus, the container will help detect any problems associated with the relative inefficiency of air removal in a gravity-displacement steam sterilizer.

6.3.3.3.3 Procedure

A maximum-load test and a small-load test should be run for each gravity-displacement steam sterilizer in which container systems will be used. The maximum-load test is conducted by placing two test containers on the bottom shelf over the drain and two test containers on each of the other sterilizer shelves (if space permits). The containers placed on the bottom shelf should be of the size and design determined to have the lowest ratio of sterilant penetration area to volume (6.3.3.3.2). The remaining containers should be chosen from the other sizes available in the system being evaluated. The chamber is otherwise fully loaded with conventionally packaged items.

In the small-load test, one test container is used. It is placed on the bottom shelf over the drain in an otherwise empty chamber. The container should be of the size and design determined to have the smallest ratio of sterilant penetration area to volume.

A gravity-displacement cycle is run according to the container manufacturer's recommendations. Upon completion of the cycle, the chemical indicators are checked, and the biological indicators are retrieved and incubated.

Rationale: Extensive testing of all gravity-displacement steam sterilizers is recommended because of the potential problem with air removal from containers in gravity-displacement steam sterilization (see annex B). The maximum-load test is designed to challenge the steam supply, ensure that a full-load configuration permits adequate steam diffusion, and detect pockets of residual air that would defeat sterilization. The test also challenges the container design to ensure that steam diffusion into the container is sufficient to remove enough air to permit steam contact with the container contents. The small-load test demonstrates that air evacuation and load heat-up occur nearly simultaneously in the load and container. A significant lag in container heat-up or air evacuation can result in sterilization failure. Such a lag can occur if the thermostatic chamber drain closes and the exposure time begins before the container contents have reached process temperature.

6.3.3.3.4 Interpretation of results

To qualify the container/sterilizer combination, all BIs should be negative, and all chemical indicators should show complete endpoint responses. A positive biological or chemical indicator could mean that there is a problem with the sterilizer, the container, or the sterilizer/container combination.

To investigate any apparent sterilization failures, the first step is to check the mechanical monitors to ensure that the cycle parameters were correct. If the cycle parameters were correct, then the sterilizer should be evaluated with biological-indicator test packs (not in containers) to identify any equipment malfunction. See AAMI (1988) AAMI TIR No. 3-1988 and AAMI (1994a) ANSI/AAMI ST46-1993 for guidelines on sterilizer testing and interpretation of positive biological and chemical monitoring results.

The sterilizer manufacturer should be consulted if the performance of the sterilizer is questionable. If the sterilizer appears to be functioning properly, the container manufacturer should be consulted for assistance in resolving the problem.

6.3.3.4 Ethylene oxide sterilizers

6.3.3.4.1 Intent

The testing recommended here is intended to demonstrate that the use of containers will not decrease the effectiveness of the sterilization phase of the EO process. There is no practical method by which health care personnel can verify EO residual removal capabilities. Therefore, the container manufacturer's data and labeling claims concerning EO residual removal should be carefully examined. (Verification of EO residual removal capabilities requires sophisticated testing. See AAMI [1995] ANSI/AAMI/ISO 10993-7.)

6.3.3.4.2 Test container (test configuration b)

To evaluate container performance in EO sterilizers, containers are prepared with EO challenge test packs (AAMI, 1992) ANSI/AAMI ST41-1992. Care should be taken not to compress the contents of the packs. The test containers should represent the sizes that are available in the system being evaluated and that will be used in routine processing in the health care facility.

Rationale: The AAMI EO biological-indicator challenge test pack is recommended for the evaluation because it was designed to serve as a challenge to penetration of moisture, heat, and EO. The test pack is used with a wrapper, because a wrapper is specified in AAMI (1992) ANSI/AAMI ST41-1992. The wrapper does not create an excessive challenge, even though the pack is inside the container, because flexible packaging does not further inhibit or impede EO penetration and removal.

6.3.3.4.3 Procedure

A maximum-load test should be run for each type of EO sterilizer in which container systems will be used. This test is conducted by placing one test container in the center of the chamber and one on each of the other sterilizer shelves. The chamber otherwise is fully loaded with conventionally packaged items. An EO sterilization cycle is run according to the sterilizer manufacturer's recommendations or, if provided, the instructions of the container manufacturer. Upon completion of the cycle, the BIs are retrieved and incubated.

NOTE—Manufacturers and scientists differ in their recommendations on the need to aerate EO test packs prior to removal of BIs. Aeration of the test pack before removing the biological indicators prolongs the BIs' exposure to ethylene oxide. Nevertheless, worker safety should be given primary consideration. The amount of residual EO left in the pack will vary from sterilizer to sterilizer as a result of differences in EO exposure conditions and in end-of-cycle vacuum and air-purge parameters. Because of these differences, it is strongly recommended that the sterilizer manufacturer be consulted about the need for aeration of test packs prior to BI removal.

Rationale: Only a maximum-load test is necessary for evaluating the use of containers in an EO sterilization process, because this load configuration represents the worst-case challenge, serving as a significant heat sink, moisture barrier, and sterilant barrier. The test containers are placed as recommended because the center of the chamber is the most difficult location to sterilize in an EO chamber.

6.3.3.4.4 Interpretation of results

To qualify the container/sterilizer combination, all BIs should be negative. A positive BI could mean that there is a problem with the sterilizer, the container, or the sterilizer/container combination.

To investigate any apparent sterilization failures, the first step is to check the mechanical monitors to ensure that the cycle parameters were correct. If the cycle parameters were correct, then the sterilizer should be evaluated with biological-indicator test packs (not in containers) to identify any equipment malfunction. See AAMI (1992), ANSI/AAMI ST41-1992 for guidelines on sterilizer testing.

The sterilizer manufacturer should be consulted if the performance of the sterilizer is questionable. If the sterilizer appears to be functioning properly, the container manufacturer should be consulted for assistance in resolving the problem.

7 Quality assurance

7.1 General rationale

This section covers recommended quality assurance procedures for sterilization container systems. Abuse or misuse of containers or lack of a standardized inspection and monitoring program can lead to problems that can compromise the quality of the sterilization program.

7.2 Receiving inspection

Each container should be thoroughly inspected upon receipt to verify that it is in proper working order:

a) All gaskets should be free of breaks, cracks, or cuts. Each gasket should be properly secured and should mate evenly at joining surfaces.

b) All filter material should cover completely the perforated area, and the device holding the filter in place should provide a tight, uniform seal that keeps the filter from dislodging.

c) The latching mechanism should secure the lid so that it cannot move when locked. A method of demonstrating that the latching mechanism has not been opened after sterilization and before use is preferred.

d) Mechanical valves should function properly; they should move freely with no sign of damage.

e) Rivets and screws should be secure and show no evidence of damage or corrosion.

7.3 Quality assurance audit

7.3.1 Routine inspection

During routine cleaning, the container should be inspected for mechanical wear and stress. Section 4.2 describes the procedure to be employed and the items to be checked.

Rationale: Frequent inspection will reveal system problems at an early stage.

7.3.2 Annual audit

At least annually, all containers should be inspected in the same manner as they were during receiving inspection.

Rationale: An in-depth inspection will uncover problems that might not be apparent during routine inspection.

7.3.3 Review of policies and procedures

At least annually, policies and procedures related to container systems should be reviewed in consultation with the container manufacturer. Inservice education sessions on these policies and procedures should be held at least annually for all involved staff members.

Rationale: During periodic review, policies and procedures can be updated with new knowledge and adapted to new conditions. Inservice education provides personnel with the knowledge and skills they need to work with container systems.

7.4 Cycle verification

Personnel should understand how the sterilization method and the items being sterilized affect the selection of the appropriate packaging method. Whenever items are prepared for sterilization, the user should verify that the container system has been tested for the type of cycle being used and that the container system is the correct one for the cycle. The design, density, and weight distribution of the contents also should be considered when selecting the cycle. Sterilization cycles not specifically recommended by the container manufacturer should not be used. If there is any doubt about the appropriateness of any container for a specific sterilization cycle, the container manufacturer should be consulted.

Rationale: Selecting the appropriate cycle for a specific container system design is critical to achieving sterilization. Not all containers have been validated for every cycle.

7.5 Filter material quality assurance

Only filter materials that have been tested and documented to be efficacious in the specific container system should be used. Before use, filters should be inspected for visible holes.

Rationale: A change in the filter material (e.g., a change in brand) can affect air removal or sterilant penetration and evacuation in a container system. Filter material cannot be tested easily by health care personnel. There is no nationally recognized referee test for microbial barrier performance. However, as with any packaging system, inspection for integrity is part of a good quality assurance program.

7.6 Chemical monitoring

7.6.1 External chemical indicators

An external chemical indicator should be affixed to each container. The chemical indicator should denote visually that the package has been exposed to physical conditions present in the sterilizer. The indicator should be examined after sterilization and also before use to make sure that the container and its contents were exposed to a sterilization process.

Rationale: The purpose of an external chemical indicator is to differentiate between processed and nonprocessed containers, not to verify that the parameters for adequate sterilization of the contents were met.

7.6.2 Internal chemical indicators

An internal chemical indicator should be used within each container. It should be placed in the area of the container considered to be least accessible to sterilant penetration. The chemical indicator is retrieved at the time of use and interpreted by the user, who should be adequately trained and knowledgeable about the performance characteristics of that particular type of indicator. See also AAMI (1988) AAMI TIR No. 3-1988 and AAMI (1994a) ANSI/AAMI ST46-1993.

Rationale: There are no practical means of verifying the sterility of individual items. Chemical indicators do not verify sterility, but they do allow detection of certain procedural errors and equipment malfunctions. Internal chemical indicators cannot be retrieved without compromising the sterile integrity of the container and its contents. Thus, internal chemical indicators must be retrieved and interpreted at the time of use.

7.7 Biological monitoring

7.7.1 Routine monitoring

To monitor steam sterilization loads, a biological-indicator challenge test pack (not in a container) should be used at least weekly, but preferably daily. To monitor EO sterilization loads, a routine test pack should be used in every sterilization load. The composition and placement of the test pack, the test procedure, the acceptance criteria, and the investigation of positive BI results should conform to the recommendations of AAMI (1994a) ANSI/AAMI ST46-1993 or AAMI (1992) ANSI/AAMI ST41-1992, as applicable.

Rationale: Routine use of BI test packs provides evidence that the sterilizer is capable of producing sterilization conditions. Such testing does not guarantee that all items in the load are sterile.

7.7.2 Periodic product monitoring

A program should be established to monitor periodically the sterilization process by placing BIs in randomly selected instrument sets. Such monitoring should be performed at least annually, whenever new sterilizers or new instrument sets are introduced; when major maintenance is performed on an existing sterilizer; and whenever major changes are made in the design or contents of instrument sets to be containerized. For dynamic-air-removal steam sterilizers, the maximum-load testing of 6.3.3.2 should be performed; for gravity-displacement steam sterilizers, the maximum-load testing of 6.3.3.3 ; for EO sterilizers, the test procedure of 6.3.3.4. See also AAMI (1994a) ANSI/AAMI ST46-1993.

Rationale: The standardized test packs used in routine monitoring (7.7.1) present known challenges to the sterilization process. However, these packs do not reflect the items usually processed in container systems, and the challenge presented by containerized items can vary with the design of container system and the type and number of items being processed. Therefore, periodic product monitoring is recommended as part of a complete quality assurance program to ensure the effectiveness of the sterilization process for items packaged in container systems.

8 Sterile storage

8.1 General rationale

The criteria for the storage of a sterile container are the same as those for the storage of any other type of sterile packaged item. The objective is to preserve the sterile integrity of the contents until the time of use. The contamination of sterile items is event-related, and the probability of occurrence of a contaminating event increases over time and with handling.

8.2 Area requirements

Container systems should be stored in a manner that reduces the potential for contamination. In general, the temperature in storage areas should be approximately 75° F (24° C). There should be at least 4 air exchanges per hour, and relative humidity should be controlled so that it does not exceed 70% (American Institute for Architects, 1996). Traffic should be controlled to limit access to containers to those individuals who know how to handle them properly.

Rationale: As with all packaging systems, safe handling and clean storage are essential to maintaining the sterility of an item to the point of use.

8.3 Storage considerations for container systems

As with any sterile item, sterile container systems should be stored far enough away from the floor, the ceiling, and outside walls to allow for adequate air circulation, ease of cleaning, and compliance with local fire codes. Sterile container systems should not be stored under sinks, near exposed water or sewer pipes, or in any location where the containers can become wet.

Closed or covered cabinets are preferred for the storage of seldom used sterile supplies. Open shelving designed for container systems may be used, provided that proper traffic control is observed and the area is designed to prevent dust or lint from accumulating on the container systems. Proper stock rotation procedures should be used.

Shelving or racks used for the storage of container systems should be designed for the weight and configuration of the containers. The racks or shelves should be kept clean and dry in a controlled environment.

When stacking container systems, the user should take care to ensure that they are firmly seated one upon another and that they can be removed easily.

Written policies and procedures for the storage, handling, rotation, and labeling of container systems should be developed and enforced.

Rationale: Container systems must be stored to prevent damage and avoid compromising the sterility of the contents. Adequate space is needed around sterile materials to allow for air circulation in the room, to prevent contamination during floor cleaning, and to prevent contact between sterile items and the condensation that can form on the interior surfaces of outside walls. Fire codes specify minimum ceiling distances (usually 18 inches) to assure the effectiveness of sprinkler systems. Sterile items should be stored only on or in designated shelving, counters, or containers; other areas might not be sufficiently clean. Closed cabinets limit dust accumulation, discourage handling, and minimize any inadvertent personnel contact with sterile items. No type of packaging can provide an absolute microbial barrier, so it is important that environmental contamination be minimized to avoid compromising the sterility of the contents during storage.

9 Transport and aseptic presentation

9.1 General rationale

Reusable rigid sterilization container systems are one of the many types of packaging materials available. The purpose of any packaging is to contain items for sterilization, storage, transport, and aseptic presentation. The package should ensure that the sterility of the contents is maintained until the package is opened intentionally. The package also should allow the contents to be removed without contamination. The following guidelines apply to the transport and aseptic presentation of reusable rigid sterilization containers.

9.2 Transport of sterile container systems

Sterilized items packaged in rigid container systems should be transported in a manner that will protect the items from contamination by moisture, excessive humidity, condensation caused by exposure to temperature extremes, insects, vermin, dust and dirt, excessive air pressures, and microbial contaminants.

Rationale: Just as with all sterilized instruments and supplies, adequate protection during transport minimizes the potential for damage and helps prevent compromise of their sterility. This rationale also holds for paragraphs 9.2.1 through 9.2.5.

9.2.1 Tables and carts (open or closed)

Transport carts and tables should be large enough for all of the container systems to be placed securely in the appropriate position (flat) without extending beyond the edge of the cart shelf or table surface. See also 9.4.1.

9.2.2 Hand transport

A container system transported by hand should be maintained in a position parallel with the floor. The carrier should exercise good body mechanics.

9.2.3 Dedicated lifts

If a container system is transported directly from the point of processing to the point of use by means of a dedicated lift (i.e., one used only for clean or sterile items), the lift may be considered equivalent to a closed cart. The lift should be large enough to allow the container systems to be securely placed flat on the shelves.

9.2.4 Off-site transportation

Vehicles used for transporting container systems between health care facilities should provide for the complete separation of clean and sterile items from contaminated items. Container systems or carts housing container systems should be secured within the vehicle to prevent damage or contamination. Transport vehicles and handling practices should allow for ease of loading and unloading.

NOTE—For the purposes of this paragraph, all external shipping cartons (corrugated or otherwise) are considered contaminated, even if they contain packaged sterile goods.

When motor vehicles are used, environmental conditions should be assessed while the vehicle is in motion, as well as when it is not in motion. Additionally, in geographical areas where high humidity is the norm, actual testing should be performed to determine the potential for contamination of absorbent items and/or the contents of the containers becoming wet due to the condensate that can occur on metal or plastic surfaces of containers that are moved from air-conditioned environments within the processing facility to the non-air-conditioned environment of transport vehicles to the air-conditioned storage area of the using facility. The design and materials used in the construction of all transport vehicles (motorized or manual) should allow for appropriate decontamination processes, especially if the vehicles are to be used alternately for the transport of sterile/clean items and soiled items. Transport vehicles (motorized or manual) that are loaded and ready for transport should not be left unattended in unsecured areas.

9.2.5 Policies and procedures

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

9.3 Aseptic presentation

9.3.1 Opening the container system

The following guidelines should be observed when opening a container system:

1) The container system should be positioned on a separate dry, flat surface at or above the level of the sterile field and at the edge of the surface nearest to the scrub person.

2) Before it is opened, the container should be inspected for the appropriate appearance of the filters or valves and the external chemical indicator(s) and the physical integrity of the outer container and tamper-evident devices. (The external chemical indicator may be located on the identification card, the tamper-proof lock, the filter, or elsewhere according to the policy of the health care facility or the design of the container system.)

3) The tamper-evident devices should be disengaged in accordance with the manufacturer's instructions. The external lid latches should be positioned as far away from the container rim (seal) as possible.

4) The manufacturer's recommendations for lid removal should be followed and care should be taken to

ensure that there is no contact between the lid and the inner rim, the sterile contents, or any part of the inside of the container.

5) The lid should be inspected for the integrity of the filter or valve and the gasket, and the internal chemical indicator should be checked to confirm the appropriate endpoint response.

Rationale: Positioning the container system as recommended facilitates aseptic removal of the instrument basket. External chemical indicators are used to demonstrate that items have been exposed to a sterilization process. Internal chemical indicators demonstrate that some or all of the conditions necessary for sterilization have been reached within the package. Sterility assurance is event-related and depends upon maintenance of package integrity up to the time the package is opened intentionally. The exterior of the lid is not sterile; if it comes into contact with the interior of the container or its sterile contents, the contents could be contaminated.

9.3.2 Removing the instrument set and transferring it to the sterile field

The following guidelines should be observed when removing the contents from the container system and transferring the contents to the sterile field:

1) Before removing the instrument basket, the surgically attired scrub person should check the internal chemical indicator for the appropriate endpoint response.

2) The inner instrument basket (tray) should be removed by the scrub person, who should grasp the inner basket handles with both hands and lift the basket well above the container bottom. The scrub person should avoid all contact with the table, external surfaces of the container, and the upper rim of the container.

NOTE—If multiple instrument baskets are stacked inside the container, they should be removed individually to the sterile field.

3) Before the instrument basket is placed on the sterile field, the container bottom should be inspected visually for the proper appearance of the filter or valve assembly; and the instruments, basket, and container bottom should be inspected for moisture.

4) The instrument basket should be aseptically transported to the sterile field.

5) In addition to the scrub person, the circulator should inspect thoroughly the integrity and proper alignment of the plate and filter or valve in accordance with the manufacturer's instructions, and the container bottom should again be inspected for moisture.

Rationale: Basic aseptic techniques and principles of sterilization are the same for rigid container sterilization systems as for any sterile wrapped package.

9.4 Transport of contaminated items in containers

A container system that has been reassembled and that has closed valves or intact, dry filters can be used to contain contaminated items for transport with no further covering, provided that the external surfaces of the container have not been contaminated by blood or body fluids. Such contamination should be presumed to have occurred if the external surfaces of the container have been touched by persons or items that might have contacted blood or body fluids. Examples include the scrub person in the operating room who is still wearing gown and gloves or the circulating nurse assisting with procedure cleanup who might have donned gloves to handle sponges or specimens and has not removed them before touching the container. If such external contamination is present, the reassembled container system should be further enclosed for transport by placing it in a plastic bag, a bin with a lid, or a closed or covered cart.

Rationale: Materials contaminated with blood or body fluids can serve as sources of infection to personnel unless the materials are properly contained. The recommendations of paragraphs 9.4.1 through 9.4.4 are intended to help ensure that containers are not damaged during transport and that personnel and the environment are not exposed to contaminated items. See also AAMI (1996b) ANSI/AAMI ST35-1996.

9.4.1 Table and carts (opened or closed)

Tables and carts used to transport contaminated containers and their contents should be able to be decontaminated properly. There should be an acceptable method of covering tables and open carts. Transport carts and tables should be large enough for containers and their contents to be placed securely flat (parallel to the floor). The containers should not extend beyond the edge of the cart shelf or table surface.

9.4.2 Hand transport

A contaminated container system transported by hand should be maintained in a position parallel to the floor. The carrier should exercise good body mechanics.

9.4.3 Dedicated lifts

If a contaminated container system is transported directly from the point of use to the point of reprocessing by means of a dedicated, soiled lift, the lift may be considered equivalent to a closed cart. If the external surfaces of the container are contaminated (see 9.4), the container should be placed in a plastic bag or a bin with lid before being placed in the lift. The lift should be large enough to allow the container system to be placed securely in the appropriate position.

9.4.4 Off-site transportation

Vehicles used for transporting container systems between health care facilities should provide for the complete separation of contaminated items from clean and sterile items. Carts housing contaminated container systems and the container systems themselves should be secured within the vehicle to prevent damage. Transport vehicles and handling practices should allow for ease of loading and unloading.

The design and materials used in the construction of all transport vehicles (motorized or manual) should allow for appropriate decontamination after use. Transport vehicles (motorized or manual) that are loaded and ready for transport should not be left unattended in unsecured areas.

10 Process performance

10.1 General rationale

To assure a sterile product for the patient, continuous quality improvement is recognized as imperative for the use of reusable rigid sterilization container systems. To assure that the container system serves as an effective sterilization packaging method, inspection and monitoring of the container system is an integral part of the total process.

10.2 Quality process

Procedures for the use of reusable rigid sterilization container systems should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with the appropriate departments and should be integrated into the overall quality process in the health care facility. Monitoring frequency will vary depending on the quality improvement goals, the number of containers used, the frequency of use, and the type of performance measure.

a) *Transfer of contaminated items to the decontamination area* (3.2). Performance measures should include but are not limited to the container's ability to secure contaminated instruments and medical devices, the labeling of contaminated items, placement of the container on the transportation cart, and proper protective attire.

b) *Decontamination processes* (3.3, 3.4 , 3.5, 3.6). Performance measures should include but are not limited to compliance with the manufacturer's recommendations in all aspects of the decontamination process, including removal of filters, selection and use of cleaning agents, manual cleaning and rinsing, preparation of containers for mechanical cleaning and disinfection, correct loading of containers into decontamination equipment, and selection of appropriate cycle parameters.

c) *Inspection of container systems* (4.2). Performance measures should include but are not limited to checking the sealing, mating surfaces, and edges of the container and lid to ensure that they are not dented or chipped; checking that filter retention mechanisms and fasteners, such as screws and rivets, are secure and not distorted or burred; checking that securing mechanisms are functioning properly; checking that the integrity of the filter media is not compromised; checking that gaskets are pliable, securely fastened, and without breaks or cuts; and checking that valves work freely.

d) *Configuration of instrument sets* (4.3). Performance measures should include but are not limited to monitoring to ensure that the weight and density of instrument sets allow for effective sterilization and drying; placement of basket(s) in the container to allow even distribution of instruments and devices; positioning of instruments so that sterilant comes in contact with all surfaces; opening or unlocking jointed instruments; disassembly of multiple-part instruments; correct placement of instruments made of glass, rubber, or dissimilar metals; treatment of lumens; protection of delicate and light instruments; and compliance with the manufacturer's instructions for complex instruments and specialized instrument containers.

e) *Sterilizer loading and unloading* (5.2, 5.3). Performance measures should include but are not limited to correct number of containers in the sterilizer load, correct placement of containers on the sterilizer rack and in mixed loads (containers are placed below absorbent towels), stacking of containers (done only after reviewing the manufacturer's instructions and documentation followed by verification testing in the sterilizer to be used), and cooling time before containers are handled.

f) *Matching the container system and sterilization cycle* (6.2, 6.3). Performance measures should include but are not limited to the methods of sterilization and types of cycles and the equipment cycle performance verification test data.

g) *Sterility maintenance* (6.2.5). Performance measures should include but are not limited to container storage conditions (designed to minimize the potential for contamination of contents) and test documentation demonstrating sterility maintenance (such as real-time shelf-life studies or aerosol-challenge evaluators).

Annex A
(Informative)

Development of a prepurchase evaluation protocol

A.1 Introduction

A.1.1 A variety of sterilization container systems have become commercially available. They are being implemented into processing systems in health care facilities for a number of reasons:

a) reduction of certain types of operating expenses;

b) environmental issues associated with reusable and disposable packaging materials;

c) improvement of sterility assurance and better protection of sterile items afforded by the rigid design of container systems;

d) standardization and organization of surgical instrument sets and equipment;

e) improvement of storage space utilization;

f) reduction of space needed to store wrappers;

g) utilization of container systems for containment of contaminated instruments.

A.1.2 The decision to evaluate the use of rigid sterilization containers should be followed by the development of a specific protocol or plan by the health care facility. The answers to the following questions will assist in the development of an evaluation protocol:

a) What are the reasons for considering reusable rigid container systems? Can these reasons be quantified?

b) How much time will be necessary to evaluate each container system?

c) Who will be involved in the evaluation process? Infection control, operating room, central processing, other user departments, purchasing? (Generally, it will be appropriate to include all departments that would be handling or using the product.)

d) What are the comparative costs of all the packaging methods under consideration (disposable wrapping material, reusable wrapping material, container systems)? How does the current cost/benefit ratio compare with the projected cost/benefit ratio of a new system?

e) If one type of container system currently is in use, what will be the impact of a second type of container system (i.e., one of different manufacture)?

f) What key points will be critical in the evaluation?

g) How many of each type of container system will be needed for the evaluation?

h) What information will be needed from whom to prepare the assessment?

The evaluation protocol should include specific questionnaires concerning product needs or problems in each use and handling area. Additionally, a detailed plan regarding the actual evaluation process in each area of use or handling should be included.

The following text presents a number of questions and statements that might be used as guidelines when developing a health care facility's prepurchase evaluation protocol for reusable rigid sterilization container systems.

A.2 General considerations

a) Have the scientific data to support label claims (e.g., specific sterilization methods and cycle parameters) been provided by the container manufacturer?

b) Was the testing performed with biological spore strips or inoculated devices?

c) Does the documentation address sufficiently all performance elements in sterilization (via steam or ethylene oxide, including aeration), drying, and sterility maintenance?

d) Was the testing representative of the types of items that will be sterilized routinely?

e) Is the container suitable for use in the sterilizers available in the health care facility (gravity-displacement, prevacuum, steam-flush pressure-pulse, ethylene oxide)?

f) Have complete instructions been provided? Are they illustrated and easy to follow?

g) Will knowledgeable and qualified assistance (technical support) be readily available during the evaluation process; for employee education; during implementation; and for follow-up, troubleshooting, and problem solving? What is the scope of service after the sale?

h) Are containers available in appropriate sizes for the items to be sterilized? Is it important that one container system meet everyone's needs? (Be certain that the container systems are acceptable to all users.)

i) What is the estimated or expected life of the container system and its parts? What kinds of warranties, preventive maintenance assistance, replacement parts, and refurbishment services are available from the manufacturer?

j) Is the total system cost-effective for the health care facility?

A.3 Instruments and devices to be containerized

a) Will all surgical instruments/equipment be containerized or only delicate instruments (e.g., microsurgical or plastic instruments) or certain specialty items (e.g., powered instruments, orthopedic instruments, cardiac instruments, neurosurgical instruments)?

b) Will holders, clips, or other retaining/protective devices be needed to customize trays for specialty instruments?

c) Will all the instruments being used in one room be prepared in containers?

d) Will emergency room, obstetrical, ambulatory surgery, respiratory therapy, or radiology instrumentation be containerized?

e) What is the maximum number of instrument sets arriving from the operating room or other user departments within 30 minutes?

f) Will containers be used as procedural trays (e.g., for cut-down, lumbar puncture, chest tube insertion, or cardiac catheter procedures)? That is, can the inner container be used as a sterile field?

g) Will instruments be organized into standard sets that travel through the system as complete units with their assigned containers?

A.4 Cleaning and decontamination considerations

a) Can the container be disassembled easily for cleaning? Will any parts interfere with adequate cleaning?

b) Can the container, interior baskets, and accessories be processed manually or in a cartwasher, washer/decontaminator, or washer/sterilizer? Will the design of the container, baskets, or accessories create a barrier to effective cleaning by any of these methods when using the generic recommendations for cycle times?

c) Will it be necessary to change the detergents or disinfectants that are used currently in order to avoid harming the container? Is special handling necessary?

d) Is there adequate work space in decontamination areas to break down and queue containers for processing?

e) Will the addition of containers have an impact on the decontamination work load? Are there sufficient processing equipment, utilization time, and personnel available to accommodate an additional work load using manual or mechanical cleaning or decontamination methods?

f) Is the processing equipment adequate to handle the containers? Will special holders for containers be required? Is there adequate equipment cycle time for processing the containers?

g) Can the container be used to confine and transport contaminated items?

A.5 Preparation and assembly considerations

a) Is the container easy to assemble? Are the lid and bottom interchangeable or easily identifiable? Are the top and bottom filter-retaining plates interchangeable or easily identifiable for proper placement? Are parts interchangeable among the various sizes of containers?

b) Can damage to parts such as gaskets, sealing edges, filter-retention plates, filter-holding rings, valves, and locking mechanisms be easily recognized?

c) Are accessories available to organize and secure instruments in the proper position for sterilization and for the protection of the instruments? Has testing been performed to assure that these accessories will not impede contact with the sterilant?

d) Is there a maximum weight recommended by the manufacturer, with supporting documentation, for the amount of instrumentation that can be placed into a container for sterilization and drying or aeration? Does the recommended weight refer only to the instruments or to the combined weight of the instruments and the container system? Does the recommended weight relate to sterilization and drying, personnel safety when lifting, or both?

e) Are there any special instructions regarding the distribution of dense masses of metal/equipment (e.g., orthopedic instruments) when assembling the instrument set in the basket?

f) Can instrument trays or baskets other than those designed for the system be used if they fit the container? What is the impact on sterilization and drying? On aeration?

g) Can specialty instrument organizing/protecting trays (e.g., orthopedic implant sets) be used with the container system if they fit? What is the impact on sterilization and drying? On aeration?

h) What is the manufacturer's advice concerning the use of absorbent material (e.g., surgical towels) within the set to facilitate drying? If the use of absorbent material is recommended, where should it be placed (e.g., in the basket, in the tray, in the bottom of the container)?

i) Are there any special recommendations regarding the placement of internal chemical indicators and biological indicators?

j) Can the container be easily closed, secured, and labeled?

k) Do the external label and chemical indicator meet the requirements established within the health care facility?

A.6 Matching the container system and sterilization cycle

NOTE—See section A.2 of this annex and section 6 of the main text.

a) What sterilization processes are compatible with the container system? Are there any special considerations for each process?

b) Has container compatibility been tested with biological monitors in each type of sterilizer in the facility and in each appropriate sterilization cycle?

A.7 Loading the sterilizer

a) Can the containers be positioned <u>flat</u> on sterilizer loading shelves without touching chamber walls?

b) Does the size of the container optimize the available shelf space on the sterilizer loading cart?

c) Will the placement allow personnel to utilize good body mechanics when loading and unloading the containers from the cart?

d) Are there any special considerations related to dedicated loads, mixed loads, the positioning of containers on shelves, or other aspects of sterilizer loading? For example, will a mixed load tend to produce wet packs or drying difficulties?

e) In general, is there a maximum number of containers per usable sterilizer volume or load? Is there a maximum weight per load?

f) Does the manufacturer recommend the use of absorbent sterilizer shelf covers to facilitate drying? Are there shelf liner materials that are contraindicated?

g) Can the containers be stacked? If so, in which type of sterilization process (gravity-displacement steam sterilization, dynamic-air-removal steam sterilization, ethylene oxide sterilization including aeration)? In what configuration ("one over one" or "offset, straddling two")? How many can be stacked? Can two different types of containers be stacked?

h) Has product testing demonstrated effective sterilization and drying or aeration when containers are stacked? Were the items used in the testing representative of the items that will be processed in the container system?

A.8 Choosing the appropriate exposure and drying times

NOTE—See A.2 of this annex and section 6 of the main text.

a) Can routine sterilization cycles recommended for wrapped packs by the sterilizer manufacturer be used?

b) Does the container manufacturer provide a method of testing the efficacy of the sterilizer in which the containers will be processed?

c) According to the container manufacturer's studies, is it necessary to extend exposure or drying time to accomplish sterilization and drying? Is documentation available of the testing done to determine appropriate parameters? Has the documentation been reviewed?

d) To produce a dry set at the end of the cycle, is it recommended or necessary that the load be preheated prior to initiation of the cycle? Is it recommended or necessary that the load be dried by leaving the containers in the sterilizer chamber for a specified period of time before they are unloaded? Are test data available?

e) Does the manufacturer provide a method of determining and verifying the effectiveness of the drying process?

f) Are special modifications necessary before the container can be used for ethylene oxide sterilization? (Review the scientific test data and documentation supplied by the manufacturer. Then test compatibility with the sterilizer/aerator to be used.)

g) Does the container create a barrier to air flow during aeration? Has the manufacturer tested the container and compared the results to the test results for a traditional wrapped tray?

h) Is extra time needed to aerate such components as gaskets and filters? Is extended aeration time necessary for the contents because of the container's design configuration?

i) Can plastic containers be used in ethylene oxide processing? If so, is more time needed to aerate the container itself or the contents?

j) Has the compatibility of the container with the chosen sterilization process/cycle been verified by testing at the health care facility?

A.9 Unloading the sterilizer and cooling the load

a) Are there any special instructions regarding how soon containers can be touched once the cycle has been completed or the loading cart has been removed from the sterilizer? How should the containers be handled?

b) What are the manufacturer's recommendations for cool-down? Do the recommendations pertain to personnel safety (i.e., the avoidance of thermal burns from touching metal that is too hot), condensation, or both? Are there recommendations regarding the environment in which an instrument container should be cooled?

A.10 Sterility maintenance

a) Can the manufacturer produce test data that support the effectiveness of the system as a microbial barrier? Do the test results demonstrate satisfactorily the container system's ability to prevent contamination during normal handling and storage? Do the test methods used by the manufacturer simulate the environment and activities within the health care facility?

b) What are the potential causes of barrier failure (e.g., slipped filter, failure of the gasket to seal, failure of the locking mechanism, loosened screws or rivets)? Has the manufacturer provided inspection criteria to assure that the system is functioning effectively?

c) Is moisture within the container after sterilization considered a potential source of contamination? Or is the set to be considered sterile? Are data and documentation available to support the claim?

A.11 Sterile storage

a) Are there any special requirements for the storage area?

b) Are special storage systems necessary? Are special carts/racks available for storage of sterilized containers? Will they minimize handling?

c) Will existing storage shelving and space in all areas of use or handling accommodate the container systems?

d) Will the added weight of the containers require reinforcement of the existing storage system?

e) Can personnel easily place the containers into storage units and remove them using good body mechanics and infection prevention practices? Can the containers be stacked? Are there any limitations?

f) Will the containers fit into case carts?

A.12 Transportation

a) Are there any special recommendations or requirements for handling transportation?

b) Are special transportation vehicles/carts necessary for on-site or off-site delivery? Would the vehicles differ from those used for packaged items?

A.13 Aseptic presentation

a) Is the container easy for personnel to handle?

b) Are the container locks/handles easy to remove/open?

c) Are the labeling and external indicator located in a place that is convenient for the user to check?

d) Is the lid easy to remove without contaminating the contents or the scrub person's hands?

e) Can the instrument baskets be removed easily without contaminating the contents or the scrub person's hands?

f) Can filters, retaining mechanisms, and valves be easily identified and inspected for security?

g) If an internal wrap is used, can it be opened easily without contaminating the contents or the scrub person?

A.14 Conclusion

You have a choice. Make one that clearly will satisfy your needs.

Annex B
(informative)

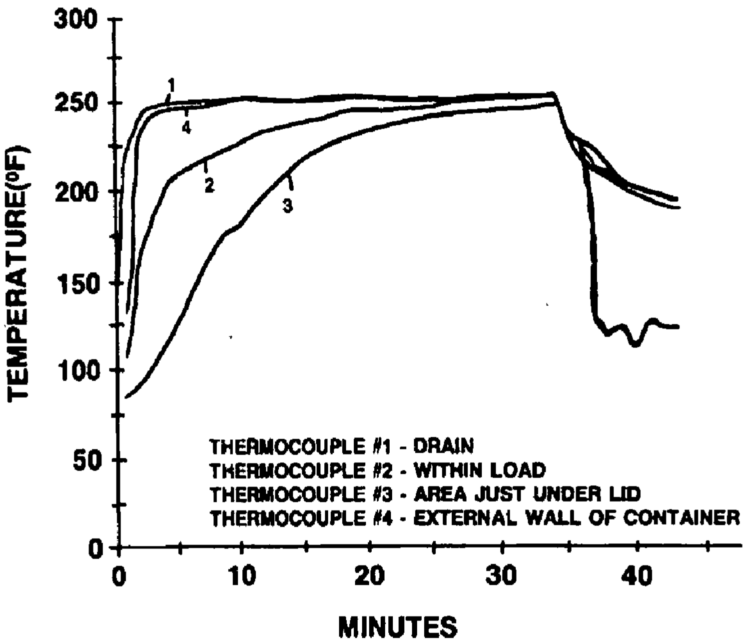

Figure B.1—Typical sterilization container system processed in a gravity-displacement cycle at 250° F

Effect of containerized packaging on load heat-up time

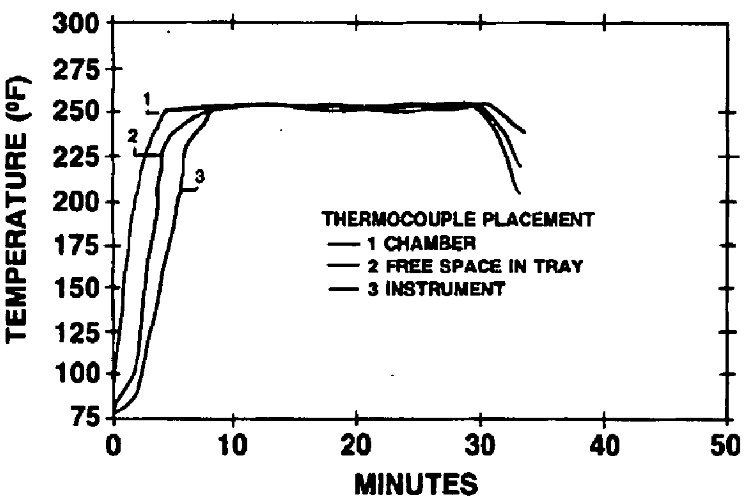

Figure B.2—Muslin-wrapped, 16-pound instrument set processed in a gravity-displacement cycle at 250° F

The use of sterilization container systems has become a common practice in the United States. For most applications, both the method of use and the mode of sterilization are similar to those used for wrapped instrument sets. However, one significant difference has to be accounted for in gravity-displacement steam sterilization. More air is trapped within a container system than in a conventional wrapped set. In gravity-displacement steam sterilization, it takes longer to remove this air. Thus, the temperature within the container rises more slowly than that in a wrapped set. This difference holds true for all containers that use nonwoven filters or do not provide a means of rapid air removal during the air-displacement phase of the steam sterilization process. Figure B.1, figure B.2 and figure B.3 illustrate this phenomenon.

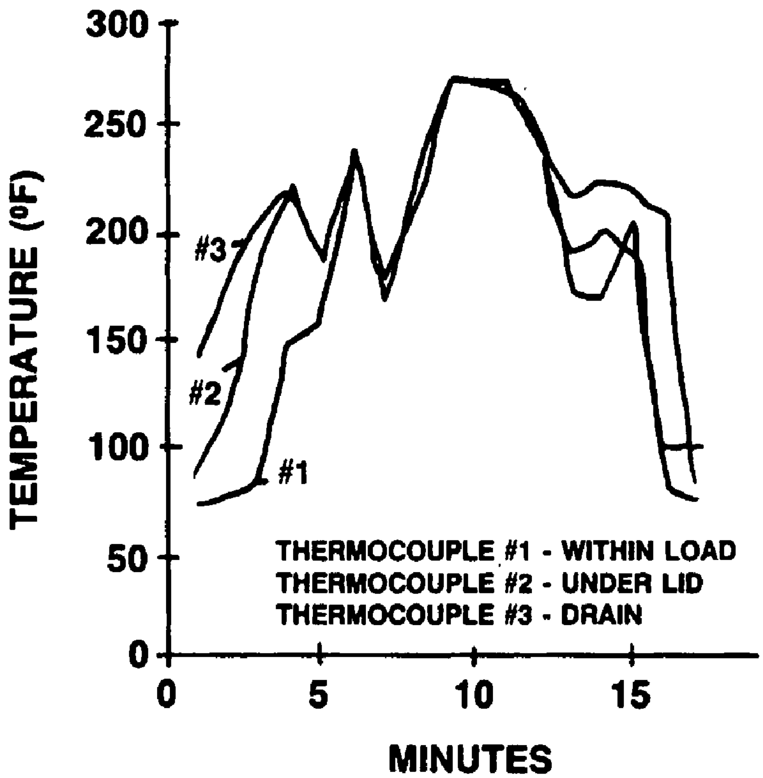

Figure B.3—Typical sterilization container system processed in a prevacuum cycle at 270° F

Figure B.1 and figure B.2, respectively, contrast the temperature profiles of containerized versus wrapped instrument sets in a gravity-displacement cycle at 250° F (121° C). There is a delay in the heat-up time for the containerized load. For this reason, the container manufacturer should be consulted for a documented recommendation as to the time and temperature cycle to be used. While it is preferable to operate at the highest practical temperature available, each cycle should be verified by appropriate tests conducted in each sterilizer in which the use of container systems is anticipated.

A delay in heat-up time is not seen in container systems processed in a prevacuum sterilization cycle (figure B.3). Therefore, it is usually unnecessary to extend the cycle time in prevacuum sterilizers. Container systems designed with perforations in both the top and bottom, as well as those with perforations only in the top, can be used safely in conventional prevacuum cycles. Similarly, exposure time in ethylene oxide sterilization cycles need not be extended for containerized loads, provided that the EO process employs a vacuum.

Annex C
(informative)

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Annotations from ST33.pdf

Page 3

Annotation 1; Label: AAMI; Date: 10/03/2000 3:03:18 PM
* At the time this document was balloted, Dr. Chamberlain represented the Center for Devices and Radiological Health, U.S. Food and Drug Administration.

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Annotation 1; Label: AAMI; Date: 10/03/2000 3:03:50 PM
** At the time this document was balloted, Ms. Schultz represented AMSCO International.

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*** At the time this document was balloted, Ms. Aler represented the American Society for Healthcare Central Service Personnel.

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