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American National Standard

ANSI/AAMI ST37:1996

# Flash sterilization—Steam sterilization of patient care items for immediate use

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

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# ST37 Flash sterilization: Steam sterilization of patient care items for immediate use

American National Standard

ANSI/AAMI ST37—1996 (Revision of ANSI/AAMI ST37—1992)

# Flash sterilization: Steam sterilization of patient care items for immediate use

Developed by
**Association for the Advancement of Medical Instrumentation**
Approved 12 January 1996 by
**American National Standards Institute, Inc.**

**Abstract:**

This recommended practice covers flash sterilization in health care facilities. Guidelines are provided for: the functional and physical design of areas in health care facilities where flash sterilization is carried out; staff qualifications, education, and other personnel considerations; sterilization processing procedures; the use and maintenance of *sterilizer*s designed for flash sterilization; and quality control. The recommended practice also includes definitions of terms and a bibliography.

## 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.

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

## Acknowledgment

The Steam sterilization Hospital Practices Working Group gratefully acknowledges the contributions of Ann E. J. Kobs, MS, RN, Joint Commission on Accreditation of Healthcare Organizations, and of former Working Group member, Lillian H. Nicolette, RN, Association of Operating Room Nurses.

## 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: assuring the *sterility* of devices and materials processed by "flash" steam sterilization; maintaining the *sterility* of processed items until the point of use; and promoting good infection control and safe handling practices.

This is the third edition of *Flash sterilization: Steam sterilization of patient care items for immediate use,* which was first published in June 1986 as *Good Hospital Practice: Steam sterilization using the unwrapped method (flash sterilization)* (AAMI SSUM–9/85). The second edition (ANSI/ AAMI ST37–1992) was published in March 1992 as *Good Hospital Practice: Flash sterilization¾steam sterilization of patient care items for immediate use.* Under AAMI standards-development procedures, the second edition would not have been due for reaffirmation or revision until 1997. In recent years, however, the practice of steam sterilization of unwrapped items ("flash" sterilization) has come under increased scrutiny, and in late 1993, numerous reports and inquiries indicated that many in the health care community desired clarification of AAMI's recommendations regarding flash sterilization. Therefore, the preparation of a revised edition was undertaken in June 1994.

Unlike previous editions, this edition does not attempt to define the circumstances under which flash sterilization is appropriate. Instead, the recommended practice focuses on what is needed to ensure that flash sterilization is safe and effective: work practices for the complete process of sterilization, the physical layout of the facility, and procedures to ensure aseptic transfer of sterilized items to the sterile field. The document also incorporates additional text, taking into account a new technology, steam-flush pressure- pulse steam sterilization, and it addresses continuous quality improvement in a new section entitled "Process performance." Finally, the recommendations concerning temperature and humidity in processing areas have been updated to reflect current guidelines.

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 optimum performance in the processing of medical devices to be steam sterilized by the flash method. It is not intended that these recommendations be construed as universally applicable to all circumstances. It is also recognized that, in many cases, these recommendations might not be immediately achievable. Therefore, the document should be utilized to guide health care personnel towards 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 standard; “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 standard; 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 are reviewed periodically to assimilate new data and advancements in technology. 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.

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NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Flash sterilization: Steam sterilization of patient care items for immediate use* (ANSI/AAMI ST37—1996), but it does provide important information about the development and intended use of the document.

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## Introduction: Need for the recommended practice

The delivery of sterile products for use in patient care depends not only on the efficacy of the sterilization process itself, but also on efficient facility design, infection prevention practices, effective quality control, and other aspects of device processing prior to, during, and after sterilization.

A flash sterilization cycle is one that has been designed to meet the following criteria:

a) The cycle is preprogrammed to a specific time/temperature setting established by the manufacturer based on the type of sterilizer control (i.e., gravity-displacement, prevacuum, or steam- flush pressure-pulse) and selected by the user based on the configuration of the load (i.e., the presence or absence of porous materials). For other types of hospital steam sterilization cycles, it is assumed that porous materials (e.g., packaging) will be present in the load.

b) The items to be processed are usually unwrapped, although a single wrapper may be used in certain circumstances if the sterilizer manufacturer's instructions permit. Some rigid, reusable sterilization container systems have been designed and validated by the container manufacturer for use with flash cycles.

c) Since drying time is not usually part of a preprogrammed flash cycle, the items processed are assumed to be wet at the conclusion of the cycle.

d) The processed item(s) must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use, usually the sterile field in an ongoing surgical procedure. Regardless of whether or not the items are wrapped, there is NO storage or shelf life of flash-sterilized items because of the probability of contamination after the sterilizer door is opened and the items are removed.

It is essential for health care personnel to properly carry out the complete multistep process (including *decontamination* and preparation) when flash sterilization is used, just as is the case for items to be processed using wrapped-goods sterilization cycles. In any method of sterilization, it is important to adhere to good processing practices. This is particularly important in flash sterilization because of the difficulties associated with the aseptic delivery of devices sterilized by this method to the point of use. When performed correctly, flash sterilization is safe and effective for the sterilization of medical devices intended for use in contact with compromised tissue or the vascular system, as might occur during surgery or obstetrical delivery. The exposure times used in flash sterilization cycles are capable of producing appropriate lethality, as compared to the exposure times used to sterilize wrapped items.

Several concerns stimulated the development of this recommended practice. First, the committee was aware of inadequate cleaning and *decontamination* practices in flash sterilization. Reduction of bioburden and removal of gross soil are essential steps in preparing an item for sterilization by any method. Decontamination procedures are also designed to protect the worker.

Second, documentation of the flash sterilization process is necessary and should be consistent with the

requirements applicable to and the practices used in documenting the routine processing of wrapped loads.

Third, flash-sterilized items should be transported to the point of use in such a way that the potential for contamination is minimized. In deciding on techniques for a particular situation, consideration should be given to the possible ways in which the items could become contaminated and to the safety of workers handling the hot and possibly heavy trays. Contamination is an event-related process, with the probability of an event that could result in contamination increasing over time. When opened to the air, all sterile items will eventually become contaminated unless opened and kept within a true HEPA-filtered, laminar- air-flow unit. Thus, any item that is opened and left on the back table of a surgical setup can become contaminated by particles settling on it. The longer an item is open, the greater the number of particles, with their accompanying microbiological flora.

The risk of contamination of flash-sterilized items increases if they are transported through areas where personnel are scrubbing or washing their hands, creating splashing or aerosolization. Transport through areas where air flow is not filtered to the degree present in the operating room can also increase the rate of contamination. Practitioners should examine their own situations and develop practices to minimize contamination. Some methods are: placing flash sterilizers as close to the intended point of use as can be reasonably accomplished; using rigid, reusable sterilization container systems that have been specifically validated and labeled for use in flash sterilization; using the single-wrapper technique in appropriate cycles; aseptically placing a sterile covering over the sterilized item as it is removed from the sterilizer.

Finally, flash sterilization of instrumentation should be considered only if all of the following conditions are met:

a) Work practices ensure proper cleaning and decontamination, inspection, and arrangement of instruments into the recommended sterilizing trays or containers prior to sterilization.

b) The physical layout of the department or work area ensures direct delivery of sterilized items to the point of use (e.g., the sterilizer opens into the procedure area).

c) Procedures are developed, followed, and audited to assure aseptic handling and personnel safety during transfer of the sterilized items from the sterilizer to the using area.

Implantables should not be flash-sterilized (CDC, 1985). The possible consequences to the patient from even a minimally contaminated device placed in an essentially avascular environment and left there at the conclusion of the procedure are potentially severe. Although the risk of an unrecognized sterilization failure can be minimized if the physical parameters of time, temperature, and pressure are monitored, recorded, and examined for each cycle, it is recommended that health care personnel quarantine implantable devices and await the outcome of biological monitoring of the cycle before releasing these items for use. However, because flash-sterilized items are intended for immediate use, they cannot be held or stored pending the results of biological monitoring. Careful planning, appropriate packaging (e.g., packaging that allows the user to see the device for sizing and verification of features), and inventory management in cooperation with suppliers can eliminate the need to flash sterilize implantable items. This is a goal that all institutions should strive to achieve.

Health care facilities differ in their physical design, the type and quantity of equipment, and the training level of personnel involved in sterilization processing. This recommended practice sets forth guidelines for facility design and work practices to assist health care personnel in the development of procedures to achieve and maintain the *sterility* of devices that are flash-sterilized. Many of the recommendations provided here apply to all steam sterilization processes, not just flash sterilization. For the convenience of the reader, these recommendations cover the entire process in a logical sequence, from considerations of facility design to quality control.

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). These policies and procedures should be followed consistently wherever flash sterilization is performed in the health care facility.

# Flash sterilization: Steam sterilization of patient care items for immediate use

## 1 Scope

### 1.1 General

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

NOTES—

1) 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" is sometimes used; in all instances, the term encompasses all other health care facilities.

2) Flash sterilization can be performed in various areas of the health care facility, including the operating room, labor/delivery room, emergency/trauma room, and other areas where steam sterilizers are located. The term "department," as used here, refers to the administrative unit responsible for the area in which the sterilizer is located.

### 1.2 Inclusions

This recommended practice specifically addresses

a) functional and physical design criteria for areas of health care facilities where flash sterilization is carried out;

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

c) sterilization processing procedures;

d) the use and maintenance of sterilizers used for flash sterilization;

e) quality control;

f) process performance.

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

### 1.3 Exclusions

Specific construction and performance criteria for steam sterilizers are *not* covered by this recommended practice, nor are guidelines for steam sterilization of wrapped items.

NOTE—For safety and performance criteria for steam sterilizers, see AAMI (1994b). For guidelines on steam sterilization of wrapped items, see AAMI (1994a).

## 2 Definitions

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

**2.1 asepsis:** prevention of contact with microorganisms.

**2.2 bacterial count:** method of estimating the number of bacteria per unit sample.

NOTE—The term also refers to the estimated number of bacteria per unit sample, usually expressed as number of colony-forming units (CFUs).

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

**2.4 biological indicator:** sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored.

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

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

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

**2.6 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 could be capable of producing disease or infection.

**2.7 control, positive:** biological indicator, from the same lot as a test biological indicator, which is left unexposed to the sterilization cycle and then incubated to verify the viability of the test biological indicator.

**2.8 culture:** growth of microorganisms in or on a nutrient medium; to grow microorganisms in or on such a medium.

**2.9 culture medium:** substance or preparation used to grow and cultivate microorganisms.

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

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

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

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

**2.12 flash sterilization:** process designed for the steam sterilization of patient care items for immediate use.

NOTE—See also "Introduction: Need for the recommended practice."

**2.13 implantable device:** according to the Food and Drug Administration (FDA), "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more" [21 CFR 812.3(d)].

**2.14 incubator:** apparatus for maintaining a constant and suitable temperature for the growth and cultivation of microorganisms.

**2.15 infectious microorganisms:** microorganisms capable of producing disease in appropriate hosts.

**2.16 microorganisms:** animals or plants of microscopic size.

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

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

**2.18 sterile/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**).

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

NOTES—

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

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

**2.20 sterilization:** validated process used to render a product free of all forms of viable microorganisms.

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

**2.21 sterilization area:** area of a health care facility designed to house sterilization equipment, usually steam or ethylene oxide sterilizers, or both.

**2.22 sterilizer:** apparatus used to sterilize medical devices, equipment, and supplies by direct exposure to the sterilizing agent.

**2.23 sterilizer, 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.

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

**2.24 sterilizer, prevacuum type:** type of steam sterilizer that depends upon one or more pressure and vacuum excursions at the beginning of the cycle to remove air.

NOTE—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 to 135° C [270° F to 275° F]; 141° C to 144° C [285° F to 291° F]). This type of sterilizer generally provides for shorter exposure time and accelerated drying of fabric loads by pulling a further vacuum at the end of the sterilizing cycle.

**2.25 sterilizer, steam-flush pressure-pulse type:** type of sterilizer in which a repeated sequence consisting of a steam flush and a pressure pulse removes air from the sterilizing chamber and processed materials using steam at above atmospheric pressure (no vacuum is required).

NOTE—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 to 123° C (250° F to 254° F), 132° C to 135° C (270° F to 275° F), and 141° C to 144° C (285° F to 291° F).

## 3 Design considerations

### 3.1 General rationale

This section provides guidelines for the design and maintenance of the workplace to minimize bioburden, facilitate effective and efficient processing, and prevent contamination of items that are flash-sterilized.

### 3.2 Traffic control

Traffic in areas in which flash sterilization is carried out should be restricted to authorized personnel. There should be controlled access. The decontamination, preparation, and sterilization areas should be located away from patients and from personnel not involved in the sterilization process. Written policies and procedures should be developed and communicated to all involved personnel. The responsibility and authority for enforcing these policies should be specified, as should methods of compliance.

*Rationale:* Controlled access to the decontamination, preparation, and sterilization areas minimizes the transfer of microorganisms from contaminated items to patients and personnel. These practices also minimize the potential for contamination of flash-sterilized items during removal from the sterilizer and transfer to the point of use. Recommendations for traffic patterns in the operating room have been provided by the Association of Operating Room Nurses (AORN, 1994c)

### 3.3 Physical facilities

#### 3.3.1 Decontamination area

##### 3.3.1.1 Location

The area in which instruments and other devices are decontaminated should be physically separated from the area where items are inspected and reassembled for sterilization (i.e., the preparation area), from the sterilization area, and from areas in which clean or sterile patient care procedures are carried out. Doors separating the decontamination area from adjoining clean spaces should remain closed.

NOTE—While physical separation of decontamination and clean/sterile areas in operating room suites is desirable, spatial separation may be satisfactory if accompanied by good work flow patterns, air-flow characteristics, and work practices.

*Rationale:* In the process of washing or cleaning contaminated items, fluids can be splashed or aerosols created. These fluids and aerosols are laden with microbial flora from the contaminated devices. Contamination can also be spread by personnel who indiscriminately touch environmental surfaces, other devices, or other personnel with soiled hands. Physical enclosure of the decontamination area and appropriate ventilation controls are necessary, because contaminated aerosols, droplet nuclei, and dust particles can be carried from "dirty" to clean areas by air currents.

##### 3.3.1.2 Ceilings, floors, and walls

Materials that will withstand daily or more frequent wet vacuuming or washing should be used in the

construction or covering of wall surfaces and floors. Materials used for wall surfaces and ceilings should not be of a particulate- or fiber-shedding type.

*Rationale:* The floor and walls of the decontamination area are subject to spills and splashing and need to be regularly cleaned to control microbial contamination. Accordingly, it is necessary that the materials used in constructing or covering these surfaces be capable of withstanding frequent cleaning and not be adversely affected by the chemical agents typically used for cleaning. Ceilings and wall surfaces should be constructed of nonshedding materials to minimize the potential for airborne particulates, which can carry disease-producing microorganisms.

### 3.3.1.3 Temperature and humidity

The temperature in the decontamination area should be controlled to between 20° C and 23° C (68° F to 73° F). Relative humidity should be controlled to a range of 30-60 %.

*Rationale:* The work area should be warm enough and humid enough to be comfortable for properly attired personnel. Temperatures and humidities higher than those recommended can produce an environment conducive to microbial growth and thus increase the overall bioburden. The specific temperature and humidity ranges are recommended by the American Institute of Architects (AIA, 1996).

### 3.3.1.4 Lighting

Adequate lighting at work surfaces should be provided in accordance with the engineering practices outlined by the Illuminating Engineers Society (IES, 1987), which recommends illuminance levels for various categories of work environments. For general inspection functions, the specified illuminance is 500-750-1000 LUX (50-75-100 footcandles); for detailed inspection, 1000-1500-2000 LUX (100-150-200 footcandles); for sink areas, 500-750-1000 LUX (50-75-100 footcandles); for general work areas, 200-300-500 LUX (20-30-50 footcandles); and for processed storage, 200-300-500 LUX (20-30-50 footcandles). The value selected for each area depends on the combined effect of: (a) the age of the workers (persons under 40 years of age require the lowest area illuminance, persons between 40 and 55 years of age require moderate area illuminance, and persons over 55 years of age require the highest area illuminance); (b) the importance of speed or accuracy to the work done in the area (the greater the importance, the more illuminance required); and (c) the reflectance of the task (the higher the reflectance, the lower the illuminance required). The evaluation of these three factors and the selection of the appropriate illuminance value should be performed by a qualified illumination engineer, in consultation with the department supervisor. If there is any doubt that there is adequate illumination in existing decontamination areas, the department supervisor should request a survey of area illumination and compare the measured values with the acceptable ranges described above.

*Rationale:* Adequate lighting is essential to the proper performance of decontamination procedures. See also Beck (1981) and IES (1987).

### 3.3.1.5 Ventilation

The ventilation system should be designed so that air flows into the decontamination area, which is under negative pressure, from adjoining clean spaces and is exhausted to the outside or to a filtered partial recirculating system. There should be no fewer than 10 air exchanges per hour. Other aspects of ventilation should comply with the guidelines set forth by the American Institute of Architects (AIA, 1996) for the particular department in which the areas are located.

*Rationale:* Ventilation patterns affect the spread of potentially dangerous microorganisms. Control of environmental contaminants and product bioburden is essential to ensure the effectiveness of the subsequent sterilization process. The recommended air flow pattern (i.e., air flowing out of clean areas into "dirty" areas) contains the contaminants within the decontamination area and minimizes the possibility of air currents carrying contaminants from the decontamination area to clean areas. The recommended number of hourly air exchanges was judged by committee consensus to be the minimum air exchange rate necessary to effectively reduce

environmental contamination by means of air dilution.

### 3.3.2 Sterilization area

#### 3.3.2.1 Location

The steam sterilizer used for flash sterilization should be located in a restricted-access area where personnel are required to wear hair coverings, masks, and complete surgical attire. The sterilization area should be immediately adjacent to, or part of, the area where the sterilized items will be used in patient care (e.g., the operating room). The sterilizer should *not* be located near any potential sources of contamination, such as scrub sinks, clinical sinks or hoppers, wash sinks, or linen or trash disposal areas. See also 3.3.1.1.

*Rationale:* It is particularly important that the flash sterilization method of steam sterilization processing be carried out in a clean environment and that devices processed by this method be transferred and handled as little as possible, since the items might not be protected by packaging before or after the sterilization process.

#### 3.3.2.2 Temperature and humidity

See 3.3.1.3.

#### 3.3.2.3 Lighting

See 3.3.1.4.

#### 3.3.2.4 Ventilation

There should be no fewer than 10 air exchanges per hour. Other aspects of ventilation should comply with the guidelines set forth by the American Institute of Architects (AIA, 1996) for the area in which the sterilizer is located.

*Rationale:* Ventilation patterns affect the spread of potentially dangerous microorganisms. Control of environmental contaminants and product bioburden is essential to the sterilization process. The safe delivery of flash-sterilized devices to the point of use requires that the devices be protected from microorganisms.

### 3.3.3 Handwashing facilities

Handwashing facilities should be convenient and designed to allow good handwashing practices. They should be located in or near all areas in which instruments and other devices are decontaminated and prepared for sterilization.

*Rationale:* Appropriate handwashing practices (e.g., washing the hands after changing gloves, after changing or removing shoe covers or masks, or any time soiled items are handled without gloves) will minimize the transfer of microorganisms between and among patients, personnel, and inanimate objects.

## 3.4 Housekeeping

Housekeeping procedures in areas used for the decontamination, preparation, or sterilization of medical devices should be the same as those used to clean the operating and/or delivery rooms. There should be at least daily cleaning of floors and horizontal work surfaces. Other surfaces, such as walls and ceilings, should be cleaned on a regularly scheduled basis. To avoid transferring contaminants from "dirty" to clean areas or surfaces, clean areas and surfaces should always be cleaned first, then dirty areas and surfaces.

*Rationale:* Cleaning reduces microbial buildup and thus the risk of transmission of microorganisms.

# 4 Personnel considerations

## 4.1 General rationale

Flash sterilization is often performed by personnel who are involved in the actual use of the device being sterilized (e.g., the surgical procedure). It is important that anyone who operates sterilization equipment has

demonstrated expertise in the use and application of the steam sterilization process. Control of bioburden and containment of contamination are essential to the sterilization process. Therefore, it is important that attention be given to such considerations as the health, hygiene, and attire of personnel, as well as personnel qualifications, training, and continuing education.

### 4.2 Qualifications

#### 4.2.1 Supervision

The preparation and sterilization of items by the flash sterilization method shall be performed under competent supervision. Personnel shall be prepared for supervisory responsibility by education, training, and experience. Suggested minimum qualifications include:

a) adequate relevant experience in health care or hospital-related work;

b) participation in the health care facility's formal orientation and training programs (e.g., educational seminars; personnel and material management programs; and courses directly related to the position, with special emphasis on decontamination and steam sterilization processing);

c) participation in inservice programs designed specifically by the department responsible for flash sterilization;

d) demonstration and improvement of expertise through participation in committees within the health care facility (e.g., standardization, nursing practices, infection control, safety, hazardous materials, pharmacy and therapeutics, and quality assurance committees).

*Rationale:* Direct supervision of any highly technical task or process requires basic knowledge of the task as well as skill in basic management. Decontamination, preparation, and sterilization are evolving technologies. Staying abreast of current developments requires continuous updating through formal and informal learning opportunities.

#### 4.2.2 Sterilization processing personnel

The responsibility for preparation and flash sterilization of items should be assigned to a qualified individual(s), who has demonstrated competence in all aspects of steam sterilization, including cleaning, decontamination, inspection, preparation, sterilization procedures, equipment operation, safety precautions, and aseptic techniques. The competence of individuals to perform assigned tasks should be verified and documented.

*Rationale:* Sterilization processing personnel are responsible for preparing the items to be sterilized, for loading the sterilizer, and for selecting the appropriate cycle. They are also responsible for verifying exposure time and temper-ature and for aseptically transferring the sterilized items to the point of use. Individuals from more than one depart-ment or area of assignment may be involved in different stages of sterilization processing, but all personnel should be familiar with all aspects of the process. Documentation of competence provides verification of qualifications and training in the workplace, as required by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO, 1994).

### 4.3 Training and continuing education

Personnel engaged in flash sterilization shall receive initial orientation and on-the-job training, including instruction in sterilizer operation, the parameters of steam sterilization, basic microbiological principles, and the institution's infection control policies and procedures. In addition, continuing education should be provided at regular intervals so that workers can review and update their knowledge and skills. On-the-job training and continuing education shall be documented.

*Rationale:* Orientation training and on-the-job training help ensure that personnel are conversant with the latest data and techniques and reduce the possibility of operator errors during preparation and sterilization processing. This training is required by JCAHO (1994).

### 4.4 Health and personal hygiene

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

*Rationale:* Careful attention to personal hygiene and health will minimize the potential for employees to acquire or transmit disease.

### 4.5 Attire

#### 4.5.1 General

All personnel working in the decontamination/preparation and sterilization areas should wear surgical attire consisting of pants and a tucked-in shirt or close-fitting tunic. Attire should be changed daily or more often as needed (i.e., when it is wet, grossly soiled, or contaminated). Reusable attire should be laundered by the laundry facilities used by the health care institution for other surgical textiles. Shoes should be clean, have nonskid soles, and be durable enough to prevent injury if an item drops on the foot. All head and facial hair (except for eyebrows and eyelashes) should be completely covered with a surgical-type hair covering or hood. Jewelry should not be worn. The attire to be worn when the employee leaves the department to travel to other areas of the facility and the required attire for reentry into the sterilization area should be defined in policies and procedures developed by the department supervisor in consultation with the infection control professionals.

*Rationale:* Appropriate attire will minimize the transfer of microorganisms from personnel to items being processed. Controlled laundering of garments can reduce the risk of transferring microorganisms from the health care facility to home and family.

#### 4.5.2 Decontamination and preparation

In addition to the attire recommended in 4.5.1, personnel who clean and decontaminate items must wear appropriate personal protective attire for the tasks they are performing. If splashing can occur, such attire should include liquid-resistant (preferably heavy-duty) protective gloves, a long-sleeved, liquid-resistant covering (e.g., a jumpsuit or gown), a liquid-resistant face mask, and eye protection (splash-proof goggles and/or a full face shield). Torn gloves should be replaced immediately after appropriate handwashing. After completion of the cleaning and decontamination of the items, and before proceeding with further preparation for sterilization, employees should remove gloves, liquid-resistant coverings, hair coverings, masks, eye protection, and shoe coverings (if worn), and should wash their hands. Items worn or used in the decontamination area should themselves be regarded as contaminated. Reusable gloves, aprons, and eye protection devices should be cleaned at least daily. Appropriate areas should be provided for the donning and removal of protective attire.

NOTE—Protective attire should be liquid-proof if clothing can become soaked with blood or other potentially infectious material, as when items are being washed by hand. If there is excessive pooling of water on the floor, liquid-proof shoe covers or boots should be worn.

*Rationale:* Appropriate attire will minimize the transfer of microorganisms from items being processed to personnel and the environment. Contaminated instruments and other medical devices are sources of microorganisms that could invade personnel through nicks or cuts on hands or through contact with the mucous membranes of the eyes, nose, or mouth. The practice of wearing gloves while handling soiled material and removing the gloves afterwards also limits the microbial burden on hands and decreases the risk of cross-contamination. Face masks limit the transfer of microorganisms to and from the respiratory tracts of personnel involved in cleaning contaminated items. Eye protection reduces the risk of pathogenic microorganisms entering the eyes. Since water acts as a vehicle for the transfer of microorganisms, both from

soiled materials and from the skin of personnel, wet surgical attire should be considered contaminated. See also 3.3.1.1 and the OSHA standard, "Occupational Exposure to Blood-Borne Pathogens" (29 CFR 1910.1030).

### 4.5.3 Sterilization

In addition to the attire recommended in 4.5.1, personnel working in the sterilization area should wear a liquid-resistant face mask. Other protective and/or sterile attire might also be necessary, depending on the method by which items are transferred from the sterilizer to the point of use (see 5.4.5 and 5.5.4).

*Rationale:* Respiratory droplets can contaminate unprotected sterile items.

## 5 Processing recommendations

### 5.1 General rationale

Producing sterile items by means of the flash sterilization method is a multistep process. Correctly completing each step of this process is critical to achieving and maintaining sterility. These steps include: handling of contaminated items at the point of use, decontamination, preparation, loading the sterilizer, selecting the appropriate cycle, and the aseptic transfer of items to the point of use.

### 5.2 Transfer of contaminated items to the decontamination area

Contaminated items should be handled as little as possible. Gloves should be worn when handling such items. Contaminated items should be contained and then transported to an area specifically designed for the decontamination of medical devices, where cleaning procedures can best be performed. Containment may be accomplished by any means that adequately prevents personnel contact with the contaminated items during transfer. For example, items can be contained in bins with lids, enclosed or covered carts, closed sterilization container systems (with filters in place, if applicable), or plastic bags.

There can be circumstances in which it is not possible to transfer a contaminated item to an area specifically designed for decontamination, as when an item is dropped or contaminated in the operating room and is needed immediately. In such circumstances, the item may be decontaminated in the substerile area adjacent to the operating room or next to the sterilizer. As is the case whenever contaminated items are handled, personnel must wear protective attire (see 4.5.2) and use good work practices to avoid contaminating surfaces beyond the sink.

*Rationale:* Contaminated items harbor microorganisms that can cause infection in susceptible individuals. Gloves provide a barrier to direct contact with contaminated items. Transferring items to an area specifically designed for decontamination is ideal because such areas have ventilation controls and air-flow patterns that will help minimize cross-contamination; also, the personnel working there routinely perform cleaning and other decontamination processes and thus might have a higher skill level than the personnel at the point of use. Containment for transport minimizes airborne or contact spread of microorganisms to workers and the environment.

### 5.3 Decontamination

### 5.3.1 Cleaning

Any contaminated instruments or the reusable containers used to transport them to the decontamination area should be carefully cleaned prior to sterilization even if they are to be immediately returned to use. Items composed of more than one removable part or piece should be disassembled; care should be taken to ensure that all parts are retained together so that reassembly can be accomplished efficiently. Before they are cleaned, general operating instruments should be separated from delicate instruments or devices requiring special handling. An initial cold water rinse will help remove blood, tissue, and gross soil. Warm water and a detergent appropriate for the items being cleaned should be used, whether cleaning is accomplished mechanically or by hand. For additional information concerning manual and mechanical cleaning, see AAMI

(1996a).

NOTE—Processing soiled items through a single cycle of a washer/sterilizer should not be considered a terminal sterilization process. These items should be considered decontaminated but not ready for use in surgery, because of (a) the need to inspect the items for cleanliness and function and (b) the need to sort and arrange instruments prior to terminal sterilization.

*Rationale:* The purpose of cleaning and rinsing is to remove visible soil and particulate matter and to reduce the number of microorganisms and the potential for pyrogens.

### 5.3.2 Microbicidal processes

Even after thorough cleaning and rinsing, a subsequent microbicidal process could be necessary for personnel safety (AAMI, 1996a). If a subsequent microbicidal process cannot be performed, personnel should change to clean gloves to prepare items for sterilization.

*Rationale:* Cleaning alone might not adequately reduce microorganisms to a safe level. A subsequent microbicidal process could be necessary for items that by their design, the nature of their contamination, and/or their intended use can present a high risk of disease transmission to workers. Such items include devices that have been in contact with blood or other body fluids (such as surgical instruments), devices that have been contaminated with very large populations of microorganisms, and devices that can cause cuts or puncture wounds (such as reusable needles and sharp-edged devices). Microbicidal processes include disinfection and sterilization by thermal or chemical processes. Due to time constraints or other considerations in flash sterilization, it might not always be possible to use a microbicidal process to assure personnel safety; in such cases, protective attire will be required.

## 5.4 Open-tray sterilization of routine porous and nonporous loads

### 5.4.1 Preparation

Sterilizer manufacturers generally recommend that open perforated or mesh-bottomed trays or baskets be used for preparation and sterilization of instruments and devices. Trays or baskets with covers or lids should not be used unless the tray/basket manufacturer can demonstrate that items can be effectively sterilized by flash sterilization.

Items to be sterilized should be arranged in instrument trays/baskets according to the following guidelines:

a) Instruments and devices with concave surfaces should be positioned to facilitate drainage of water.

b) All hinged instruments should be opened, without engaging the ratchet, and should be placed on instrument racks, pins, or stringers as needed.

c) Items with removable parts should be disassembled unless the device manufacturer provides specific instructions, supported by test data, to the contrary.

d) Heavy items should be placed in such a way that they will not damage more delicate items.

e) Complex instruments (e.g., air-powered instruments, instruments with lumens or channels) should be prepared and sterilized according to the device manufacturer's written instructions.

f) The weight of the instrument set should be based on the design and density of the individual instruments, the distribution of the metal mass in the tray, and on whether personnel can carry it using proper body mechanics and maintaining aseptic technique as needed. The tray should be large enough so that the metal mass is equally distributed in the tray.

Cases for organizing, holding, or protecting instruments (e.g., microsurgery instrument cases, air-powered equipment sets, orthopedic instrument organizing sets) should be used only if they have been specifically designed and tested for this purpose. Collaborative testing should be performed by both the device

manufacturer and the manufacturer of the protective organizing case. Recommendations should include instructions on the preparation of specific instruments prior to sterilization.

*Rationale:* To achieve sterility, high-temperature saturated steam must come into direct contact with all surfaces of all items. Air-removal, steam penetration, and drainage of condensate are enhanced by proper positioning and by the use of perforated or mesh-bottomed trays or baskets. Provision for the drainage of condensate from the tray and/or tray cover should be made, since flash sterilization cycles do not provide for drying the items and visible moisture (condensation) is normally found on the items following the process.

For complex, multiple-part instruments, it might be necessary to extend the exposure time, to disassemble them to ensure sterilant contact, and/or to flush channels with distilled water. The device manufacturer's recommendations for specialized instruments such as air-powered drills should be supported by test data from the device manufacturer.

Protective organizing cases can impede air removal and steam penetration and thus prevent sterilization from being accomplished in the specified cycle time.

There is no magic number for instrument set weight. The preparation and assembly procedures should take into account the number of instruments, the weight and density of the set, and the size of the tray.

### 5.4.2 Loading the sterilizer

The perforated or mesh-bottomed instrument tray or basket or the protective organizing case should be placed flat on the sterilizer shelf.

*Rationale:* Placing trays flat will help keep instruments in orderly arrangement, prevent instrument damage, and ensure access to the tray for removal from the sterilizer. Flat placement of trays also facilitates air removal and the elimination of surface condensation.

### 5.4.3 Sterilization cycle parameters

NOTE—The flash method of steam sterilization of instruments and other selected devices must not be used to sterilize wrapped items (except as indicated in 5.5). See AAMI (1994a) for procedures and cycle parameters applicable to steam sterilization of wrapped items.

#### 5.4.3.1 Gravity-displacement cycles for porous and nonporous items

The minimum exposure time and temperature for nonporous items (e.g., routine metal instruments) is 3 min at 132° C (270° F). When nonporous and porous items are sterilized together, the minimum exposure time and temperature is 10 min at 132° C (270° F).

*Rationale:* Forceps, needle holders, scissors, and other routine metal instruments require surface sterilization only, and the specified exposure time and temperature have been found to be adequate for this purpose. The addition of porous items (e.g., towels, rubber or plastic items, items with lumens, items with sliding parts that prevent sterilant contact with surfaces) requires a longer exposure time to ensure adequate steam penetration (see also Perkins, 1969).

NOTE—Chemical indicators are not considered porous items, for purposes of determining cycle parameters as per 5.4.3.1, 5.4.3.2, and 5.4.3.3.

#### 5.4.3.2 Prevacuum cycles for porous and nonporous items

The minimum exposure time and temperature for nonporous items (e.g., routine metal instruments) is 3 minutes at 132° C (270° F). When nonporous and porous items are sterilized together, the minimum exposure time and temperature is generally 4 min at 132° C (270° F). However, the sterilizer manufacturer's written instructions should be consulted for specific recommendations.

NOTE—These are minimum exposure times that may be exceeded if necessary. Some prevacuum sterilizers have preset timers that fix exposure times at more than 3 min.

*Rationale:* As noted in 5.4.3.1, forceps, needle holders, scissors, and other routine metal instruments require surface sterilization only, and the specified exposure time and temperature have been found to be adequate for this purpose. As in the case of gravity-displacement cycles, the addition of porous items (e.g., towels, rubber or plastic items, items with lumens, items with sliding parts that prevent sterilant contact with surfaces) can necessitate a longer exposure time to ensure adequate steam penetration. However, a prevacuum sterilizer facilitates air removal and aids steam penetration, so the required exposure time can be minimized.

**5.4.3.3 Steam-flush pressure-pulse cycles for porous and nonporous items**

The minimum exposure time and temperature for either nonporous items or mixed nonporous/porous items is 3 min at 132° C to 135° C (270° F to 275° F) or 2 min at 141° C to 144° C (285° F to 291° F). However, the sterilizer manufacturer's written instructions should be consulted for specific recommendations.

*Rationale:* The steam-flush pressure-pulse process facilitates air removal and steam penetration and provides sufficient lethality to flash-sterilize either nonporous or porous items in the recommended exposure times.

**5.4.4 Monitoring**

See section 7.

**5.4.5 Unloading the sterilizer**

Flash-sterilized items are to be used immediately, not stored for later use. Procedures for transferring the items from the sterilizer to the point of use should be based on the assumption that condensate will be present within the tray so care should be taken to avoid contamination of the sterilized items. The tray and the items within will also be hot, so care should be taken to avoid thermal injury. Personnel should wear sterile gloves and may use sterile towels as "potholders" when removing items from the sterilizer. The tray should never be placed on a nonsterile surface. These procedures should be developed in consultation with the supervisor of the department and the infection control professional, with the objective of assuring the best practice possible for aseptic transfer within the physical constraints of the facility.

*Rationale:* See 3.3.2.1.

**5.5 Flash cycles with single wrappers**

Some prevacuum and pulsing gravity-displacement steam sterilizers provide a cycle designed to permit flash sterilization using a *single* wrapper (nonwoven or textile) on the instrument tray. The sterilizer manufacturer's written directions and guidelines for use shall be followed. Only general surgical instrumentation should be processed using this cycle. Instruments with lumens (e.g., needles for injection and diagnostics or metal suction cannulae) should not be processed by this method. Except for the wrapper, no porous items (e.g., towels) should be placed in the tray. *Wrappers should not be used in flash sterilization cycles unless the sterilizer is specifically designed and labeled for this use.*

*Rationale:* The single wrapper is intended to confine the sterilized items and protect them from environmental contaminants that might be encountered en route from the sterilizer to the point of use. The abbreviated prevacuum cycle has fewer prevacuum pulses so air removal and subsequent steam contact within lumens could be difficult to achieve. See also the rationale for 5.4.3.2.

**5.5.1 Preparation of items to be sterilized**

Surgical instruments are decontaminated as described in 5.3 and then prepared in a perforated or mesh-bottomed instrument tray or basket as described in 5.4.1.

*Rationale:* See the rationale statements for 5.3 and 5.4.1.

### 5.5.2 Sterilization cycle parameters

The parameters for sterilization are established and/or preset by the sterilizer manufacturer. The sterilizer manufacturer shall supply written recommendations, with supporting scientific data, for the use of a single wrapper in flash processing.

*Rationale:* Cycle parameters vary depending on the design of the sterilizer. Only the sterilizer manufacturer is able to establish appropriate parameters.

### 5.5.3 Monitoring

See section 7.

### 5.5.4 Unloading the sterilizer

Flash-sterilized items are to be used immediately, not stored for later use. Special precautions should be taken to ensure that these wrapped trays are differentiated from wrapped trays processed conventionally. Procedures for transferring the items from the sterilizer to the point of use should be based on the assumption that condensate will be present within the tray (as is typical of flash sterilization). Moisture can strike through the wrapper, so care shall be taken to avoid contamination by contact with nonsterile surfaces. The wrapper and the item within will also be hot. Personnel should wear sterile gloves and may use sterile towels as "potholders" when removing items from the sterilizer. The wrapped tray should never be placed on a nonsterile surface. A sterile, impervious drape, placed on a surface separate from the sterile field, should be used so that the wrapped tray can be placed there and then opened by the circulator. The sterile items may then be removed from the tray by the scrub person and taken to the sterile field. These procedures should be developed in consultation with the supervisor of the department and the infection control professional, with the objective of assuring the best practice possible for aseptic transfer within the physical constraints of the facility.

*Rationale:* This type of flash cycle includes a very brief drying time. At the end of the cycle, however, the wrapper could be wet on the bottom, depending on the amount of condensation created by the types and number of instruments within the tray. Also, even if the wrapper appears dry when the sterilizer is opened, handling of the wrapped item can cause the wrapper to become wet in spots. Therefore, the precautions recommended above should be taken.

## 5.6 Sterilization container systems

Some rigid sterilization container systems might be suitable for use in flash sterilization. Manufacturers making claims that such systems can be used shall supply scientific evidence that the product is suitable for this method of sterilization. This scientific evidence shall include but is not limited to

a) demonstration of kill of appropriate test biological indicators;

b) temperature profiles demonstrating adequate steam penetration throughout the container;

c) test data substantiating the recommended process time;

d) instructions regarding loading and/or the types of materials that can be processed;

e) instructions regarding the use of filters or the positioning of valves, ports, the container, and its lid.

In general, items are prepared as indicated in 5.4.1.

For specific recommendations on validation (by both the manufacturer and the health care facility), preparation, and use of rigid container systems, see AAMI (1996b).

*Rationale:* Container systems should be specifically designed and tested for use in flash sterilization to ensure that sterilization can be achieved in this abbreviated cycle.

### 5.7 Specialty instruments

Sterilization of specialty instruments and devices, such as drills, could require extended exposure times. Certain manufacturers of such devices do not recommend flash sterilization. The device manufacturer's instructions should be followed. See also AORN (1994a).

NOTE—For specialty instruments and devices, a drying time might be recommended by the device manufacturer, even though an unwrapped technique is used.

*Rationale:* The instrument or device manufacturer is best able to determine the required sterilization parameters. Drying is necessary for some devices in order to ensure longevity and proper performance.

## 6 Care and maintenance of sterilizers

### 6.1 General rationale

This section provides an overview of care and maintenance procedures applicable to steam sterilizers. Proper attention to equipment maintenance will minimize sterilizer "down time" and help prevent sterilizer malfunctions.

### 6.2 Instruction manuals

The purchaser should require that the sterilizer manufacturer supply a comprehensive instruction manual. The care and maintenance section of the manual should include, as a minimum, all information necessary to carry out the procedures recommended in 6.3, 6.4, and 6.5, and should specify the frequency with which these procedures should be performed. Specific rather than general information should be provided for each equipment model. The manufacturer's instruction manual shall be retained by the user as long as the sterilizer is in service.

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

### 6.3 Routine care

Sterilizers shall be inspected and cleaned in accordance with the manufacturer's written instructions (see 6.2). Examples of items requiring daily care and cleaning are recording charts and pens, door gaskets, the chamber drain screen, the internal chamber, and external surfaces.

*Rationale:* Periodic inspection and cleaning reduce the occurrence of sterilizer malfunctions. Cleanliness also reduces the risk of accidental contamination of sterile material.

### 6.4 Preventive maintenance

#### 6.4.1 General

The manufacturer of the sterilizer shall provide written instructions for preventive maintenance of the equipment, which shall be carried out by qualified personnel. Particular attention shall be given to inspection, maintenance, and replacement of components (e.g., recording devices [if applicable], filters, steam traps, drain pipes, valves, and door gaskets). The maintenance program may be conducted inhouse or by contract with the sterilizer manufacturer or a qualified service company. Preventive maintenance and repair records should be retained as long as the equipment is in service and according to hospital policy (see also 6.6).

NOTE—AAMI (1993) provides general recommendations for establishing and evaluating maintenance programs for medical equipment.

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

### 6.4.2 Scheduled maintenance

Lubrication of appropriate parts and replacement of expendable parts (e.g., steam traps) should be performed, as needed, by qualified personnel. Certain maintenance tasks requiring special tools or calibration equipment unavailable in the health care facility should be performed by the manufacturer, the manufacturer's representative, or another qualified service company. The frequency with which this maintenance is performed depends on how frequently the equipment is used and can vary from institution to institution.

*Rationale:* It might not be economical for health care facilities to acquire expensive, rarely used special tools or calibration equipment. The normal service life of some mechanical components depends solely on how frequently or infrequently they are used. Others simply wear out over time. For some mechanical components, both age and frequency of use affect their service life.

### 6.5 Calibration

Periodic calibration shall be performed as specified in the manufacturer's instruction manual (see 6.2) and documented. Examples of items requiring calibration are: pressure and temperature gauges, timers, controls, and recording devices. In the event of a sterilizer malfunction or the repair or replacement of any component affecting sterilizer performance, appropriate recalibration shall be performed. Calibration may be performed by the manufacturer, the manufacturer's representative, the health care facility's engineering staff, or contract service personnel. Those performing this service shall have sufficient training to understand the operation and calibration of the particular sterilizer type.

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

### 6.6 Maintenance records

A maintenance record shall be kept for each sterilizer. This record should be maintained by the supervisor at the health care facility who has responsibility for the sterilizer, the health care facility's engineer, and/or by the service person who has performed the servicing, and by whoever else is deemed appropriate by the institution. Included in this maintenance record should be sufficient information to identify the sterilizer and to establish a continuous history of all scheduled and unscheduled service. At least the following information should be recorded:

a) the date on which service was requested;

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

c) the location of the sterilizer (hospital identification, if appropriate);

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

e) the reason for the service request;

f) a description of the service performed;

g) the types and number of parts replaced;

h) the results of any post-maintenance testing performed, if needed, before the sterilizer was returned to service;

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

j) the date the work was completed;

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

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

analysis.

## 7 Quality control

### 7.1 General rationale

The purpose of a quality control program is to ensure that materials processed through the steam sterilizer by the flash sterilization method have been exposed to the prescribed sterilization process. This section of the recommended practice covers the quality control measures that should be taken and the documentation that should be maintained.

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

### 7.2 Policies and procedures

The policies and procedures developed for flash sterilization should be followed consistently wherever flash sterilization is performed in the health care facility.

*Rationale:* Policies and procedures should be consistent for the quality of patient care and to enhance the performance of personnel who are transferred from one area to another.

### 7.3 Record-keeping

#### 7.3.1 Load records

For each sterilizer load, the following information should be documented:

a) the general contents of the load;

b) the duration and temperature of the exposure phase of the cycle;

c) the initials or other identification of the operator;

d) the number or other identification of the sterilizer;

e) the date and time of the cycle.

Flash sterilization of implantable devices is not recommended; however, if it is unavoidable, full traceability to the patient shall be maintained.

*Rationale:* Certain quality control measures (e.g., the use of biological indicators [BIs]) do not yield final results until after the sterilizer load has been used. In addition, sterilization quality control relies heavily on historical data, especially where quality control measures yield conflicting evidence. Record-keeping is needed both for epidemiological tracking and for ongoing assessment of the reliability of the sterilization process. Accountability to the patient and surgeon for sterility of an implantable item requires documentation of biological monitoring results that can be directly traced to the patient.

#### 7.3.2 Sterilizer records

For each sterilizer, the results of biological monitoring and any necessary follow-up actions should be documented, as well as the results of Bowie-Dick-type testing (if applicable). As recommended in 6.6, a record of repair and preventive maintenance should also be kept for each sterilizer.

*Rationale:* See 7.3.1.

### 7.4 Physical monitoring

#### 7.4.1 Use of electronic or mechanical monitors

Physical monitors include time, temperature, and pressure recorders; displays; computer printouts; and gauges. When time/temperature recordings are provided, the operator shall ensure, at the beginning of the day, that the recording device is ready for use (i.e., that the recording chart is aligned properly, the pen is functional, the correct date is indicated, and computer printouts are legible). Before starting each cycle, the operator shall review the recording of the previous cycle to see if it was completed satisfactorily. At the end of each cycle, the operator shall examine the recording document (chart or printout) to verify that the correct temperature was attained and maintained for the correct exposure time. The recording document is then signed by the operator before items are removed from the sterilizer. If a recording device is not available, the operator shall monitor the time- and temperature-indicating gauges during the cycle and, at the end of the cycle, record the following information: sterilization date, sterilization temperature, actual length of sterilization cycle at exposure temperature, remarks (if appropriate), and the signature (not initials) of the operator.

NOTE—Sterilizer temperature recordings indicate chamber drainline temperatures, not the temperature attained by the devices being sterilized.

*Rationale:* Physical monitoring provides real-time assessment of the sterilization cycle conditions and, in some cases, provides permanent records by means of chart recordings or computer-driven printouts. Physical monitoring is necessary for the earliest possible detection of malfunctions, so that alternative procedures can be used in the event of failures. See also 7.3.1.

### 7.4.2 Record-keeping

After the sterilizer operator has verified the proper functioning of the sterilizer, the charts shall be maintained with other sterilizer records in the department using the sterilizer or in another designated filing area. These records shall be maintained for as long as is required by state or local statutes and by the policies of the individual institution.

*Rationale:* See 7.3.1 and 7.4.1.

### 7.4.3 Sterilizer malfunctions

If the time/temperature recordings indicate any malfunction or suspicious operation, the department manager or his/her designee shall be notified. If the malfunction cannot be corrected immediately after examination, the sterilizer shall be removed from service, the hospital engineer or preventive maintenance contract service notified, and the malfunction corrected. Written policies and procedures shall be developed, in cooperation with the infection control professional, concerning the notification of the infection control professional following discovery of a malfunction. Sterilizer malfunctions and follow-up actions shall be documented and records maintained. The contents of the load processed in the malfunctioning sterilizer are considered nonsterile and shall not be used. See also AAMI (1994a).

*Rationale:* See 7.3.1 and 7.4.1.

## 7.5 Chemical indicators

### 7.5.1 Characteristics of chemical indicators

Chemical indicators are sterilization process monitoring devices designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators are intended to detect potential sterilization failures that could result from personnel errors or sterilizer malfunctions. The "pass" response of a chemical indicator does not prove that the item accompanied by the indicator is sterile.

### 7.5.2 Selection of chemical indicators

Health care personnel should obtain data from manufacturers on the reliability, safety, and performance characteristics of their products. In addition, manufacturers of chemical indicators should be required to provide

written information on how to interpret indicator results, the sterilization conditions that the indicator will detect, and the storage requirements for and shelf life of the indicator. Indicators should be selected that do not bleed, flake, or otherwise adulterate the devices being sterilized.

NOTE—General guidelines for the selection and use of chemical indicators in steam sterilization process monitoring are provided in AAMI (1988).

*Rationale:* Various types of chemical indicators are available, each with different response characteristics; that is, they differ in the sterilizing conditions they will detect and verify. At present, there are no consensus standards available to assist health care personnel in selecting specific products, so only broad criteria can be defined here. The choice of chemical indicator depends highly on the specific needs, resources, and sterilization equipment of the individual health care facility.

### 7.5.3 Guidelines for chemical monitoring

A chemical indicator should be used in each tray or container being processed. After the sterilization cycle has been completed, the chemical indicator should be interpreted in accordance with the written instructions of the manufacturer.

*Rationale:* The purpose of chemical indicators is to detect sterilizer malfunctions or possible operator errors in the steam sterilization process.

## 7.6 Biological indicators

### 7.6.1 Characteristics of biological indicators

Biological indicators are sterilization process monitoring devices consisting of a standardized, viable population of microorganisms (bacterial spores) known to be resistant to the mode of sterilization being monitored. Biological indicators are intended to demonstrate whether or not the conditions were adequate to achieve sterilization. A negative biological indicator does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

### 7.6.2 Selection of biological indicators

Health care personnel should select biological indicators, consisting of spores of *Bacillus stearothermophilus*, that comply with AAMI (1986). *Only biological indicators that have been specifically validated and are recommended for use in monitoring flash sterilization cycles should be selected for this purpose.* In addition, data should be obtained from manufacturers on the reliability, safety, and performance characteristics of their products. Manufacturers of biological indicators should also be required to provide written instructions on the storage, handling, use, incubation, interpretation, and disposal of their products.

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

### 7.6.3 Frequency of use of biological indicators

Biological-indicator tests should be run during initial installation testing of steam sterilizers and after any major repairs (see 7.7.2). Biological indicators should also be used to check each sterilizer at least once a week, but preferably daily. Any load containing implantable devices shall be biologically monitored; the surgeon and the infection control professional shall be notified of the event and the outcome of the biological monitor according to hospital policy. Each type of tray configuration (e.g., open surgical tray, single-wrapped surgical tray, protective organizing case, rigid sterilization container) and each type of cycle (e.g., gravity-displacement, prevacuum, steam-flush pressure-pulse, flash cycle with single wrapper) in routine use for flash sterilization should be tested separately.

*Rationale:* The condition of the sterilizer, the expertise of the sterilizer operator, and other factors determining the success or failure of a steam sterilization cycle can vary from one cycle to another. The less frequently the sterilizer is used, the greater the opportunity for the occurrence of an unnoticed event that could affect sterilization. If, on the other hand, the sterilizer is used very frequently, daily use of biological indicators allows earlier discovery of equipment malfunctions and thus minimizes the extent of patient surveillance needed in the event of a positive biological indicator. Because of the potential consequences to the patient of the implantation of a nonsterile device, the sterilization of implantables ought to be closely monitored even though it will not be possible to quarantine the load pending the biological indicator results.

### 7.7 Sterilizer efficacy testing

#### 7.7.1 Requirements for efficacy testing

All steam sterilizers shall be biologically tested upon installation and routinely thereafter to assure their effectiveness in sterilizing medical and surgical items. The use of biological indicators provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. In addition, prevacuum sterilizers shall be tested upon installation and routinely thereafter to assure that the vacuum system adequately removes air during the sterilization process. This section (7.7) covers installation testing and routine biological monitoring. Bowie-Dick testing of prevacuum sterilizers is addressed in 7.8.

#### 7.7.2 Installation testing

Installation testing should be conducted in the health care facility by health care personnel in cooperation with the manufacturer. Testing should be performed between the time the steam sterilizer is installed and the time it is released for use in the health care facility. Three consecutive cycles should be run with a biological indicator and test tray (as described in 7.6.2 and 7.7.3.1, respectively). Each of these test runs shall yield negative BI results and have satisfactory physical monitoring results before the sterilizer is placed in service. Each type of cycle used for flash sterilization should be tested separately (see 7.6.3).

*Rationale:* Installation testing assesses sterilizer performance in the environment in which the sterilizer is to be used. Satisfactory test runs verify that the sterilizer has arrived in good working condition and has been properly connected to local utility services (e.g., power, steam, water).

#### 7.7.3 Routine biological monitoring

##### 7.7.3.1 Composition and placement of test tray

One or more biological indicators and a chemical indicator should be placed in the tray configuration to be tested: a perforated, mesh-bottomed, open surgical tray; a rigid sterilization container; a protective organizing case; or a single-wrapped surgical tray. The test surgical tray, protective organizing case, or rigid container should be of appropriate size for the sterilizer being tested and should be placed on the bottom shelf of an otherwise empty sterilizer. The biological indicator(s) and chemical indicator should be located in the most difficult-to-sterilize portion of the surgical tray, protective organizing case, or rigid container. For open surgical trays, single-wrapped surgical trays, and protective organizing cases, the most difficult-to-sterilize area is the area nearest the sterilizer drain. For rigid sterilization container systems, the biological indicator(s) should be placed in accordance with AAMI (1996b).

NOTE—One additional biological indicator from the lot used for testing should be left unexposed to the sterilant, incubated, and treated as a positive control. After use, the positive control should be disposed of according to the manufacturer's instructions.

*Rationale:* The BI test is conducted in an otherwise empty sterilizer, rather than in one containing patient care items, because for flash sterilization this configuration is a more rigorous biological challenge to sterilizer performance than is a filled tray. Performing the test in an empty chamber minimizes heat-up time (because there is little metal mass to absorb the heat) and, therefore, minimizes the lethality of the process and creates a

greater challenge to the biological indicator. Only one biological indicator need be used for the test in order to achieve a microbial challenge. There are no data to support the need for more than one biological indicator. There are, however, several considerations in using more than one biological indicator: they might provide additional information in the event of a marginal cycle; they could provide information on differences in sterility assurance at various locations; they can help minimize the effects of errors in laboratory culturing; and they could help increase the confidence level for a quicker readout and therefore a shorter turnaround time on BI results. (Check the BI manufacturer's instructions.) The biological indicator used as a positive control could contain a high population of living microorganisms. Although *B. stearothermophilus* is not a human pathogen, some local jurisdictions could require that the positive control be treated as infectious waste. It is recommended that a chemical indicator be placed in the test surgical tray, protective organizing case, or rigid container, because chemical indicators give immediate information regarding sterilization process efficacy. Also, some chemical indicators can detect marginal malfunctions that might not be detected by the biological indicator(s). The area near the drain is usually the coolest portion of the sterilizer and therefore presents the greatest challenge.

**7.7.3.2 Test procedure**

A nonporous load cycle is run in accordance with the instructions of the sterilizer manufacturer (see also 5.4.3). The sterilizer manufacturer's recommended sterilization temperature, exposure time, and, if applicable, drying time should be used. The instructions of the BI manufacturer should also be observed.

*Rationale:* Since this is a challenge test, the operating conditions should be the same as those for normal use of the sterilizer.

**7.7.3.3 Acceptance criteria**

All results of biological indicators, including those biological indicators used as positive controls, should be interpreted by qualified personnel and should be included in the sterilizer records. The test is satisfactory if the test biological indicator is reported negative (no microbial growth) and the control biological indicator is reported positive (microbial growth). If a positive culture is obtained from the test biological indicator, a presumptive identification should be performed to determine whether the recovered microorganism is indeed the test microorganism from the biological indicator or is a laboratory contaminant (see also 7.7.3.5).

*Rationale:* If a positive BI culture is obtained, it should be assumed to be a "true" positive until proven otherwise. False positives are possible, however, as a result of accidental contamination during poststerilization handling of the biological indicators. False positives can sometimes be identified by presumptive identification.

**7.7.3.4 Reporting of positive BI results**

When positive BI results (other than viability controls) are confirmed by presumptive identification, the appropriate supervisor should be immediately notified by phone or messenger, and the notification should be followed by a written report. The notification and report should include identification of the sterilizer, the time and date of the questionable sterilization cycle, the time and date of notification of positive results, and any information that will help the supervisor determine whether the results could be attributable to human error.

NOTE—Positive biological indicators should be disposed of according to the manufacturer's instructions.

*Rationale:* To prevent continued use of a possibly malfunctioning sterilizer, immediate notification of the appropriate supervisor is essential. Full, written documentation is needed for possible future examination.

**7.7.3.5 Follow-up actions for positive biological indicators**

Positive biological indicators, if identified as *Bacillus stearothermophilus*, could indicate inadequate sterilization conditions. Therefore, the following steps are recommended:

a) The department supervisor, with appropriate health care facility maintenance staff and sterilizer service

personnel, should attempt to determine the cause of sterilization failure and arrange for corrective action.

b) The sterilizer in question should be immediately retested with biological indicators. All quality control information available concerning the sterilization cycle in question (e.g., physical monitoring records), as well as other historical data on sterilizer performance, should be reexamined and a decision made on whether to quarantine the sterilizer until satisfactory BI results are achieved.

c) The infection control professional should be notified of the positive biological indicator, so that follow-up surveillance of patients can be conducted.

*Rationale:* Positive biological indicators require immediate action to determine the cause of the problem and to establish appropriate follow-up steps (e.g., quarantine of the sterilizer, follow-up surveillance of patients, notification of physicians). Therefore, it is important to establish a carefully defined procedure to evaluate all possible causes of the positive biological indicators. This procedure should include a thorough evaluation and retesting of the sterilizer, a review of quality assurance records, a review of culturing techniques, and an evaluation of the biological indicators used. See also the rationale statement for 7.7.3.1.

### 7.8 Prevacuum sterilizer air leak test

This test, generally referred to as the Bowie-Dick test, is used to detect air leaks in prevacuum sterilizers. It is not a sterility assurance test. The test pack and test procedure to be used are described in AAMI (1994a).

### 7.9 Product testing

Quality assurance testing of routinely processed supplies should be performed on an ongoing basis. A program should be established to periodically test products routinely sterilized. See AAMI (1994a) for guidelines.

## 8 Process performance

### 8.1 General rationale

Continuous quality improvement is recognized as imperative to the flash sterilization process in order to minimize risk and assure a sterile product for the patient. Decontamination and aseptic transfer are as important as the sterilization cycle itself and should be an integral part of total process performance measurement. This section of the recommended practice identifies performance measures that are recommended as part of the continuous quality improvement process.

### 8.2 Quality process

Procedures for flash sterilization shall be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with the appropriate using 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, on hospital policy and procedures for the handling of untoward events, and on the type of performance measure.

a) ***Decontamination area*** (3.3.1). Performance measures should include, but are not limited to, traffic control; condition of floors, walls, and ceilings; temperature and humidity readings; lighting; and ventilation, including air exchanges per hour and air flow pattern.

b) ***Containment of contaminated items*** (5.2). Performance measures should include, but are not limited to, placement of contaminated items within the containment system, security of the containment system, labeling of contaminated items, placement on the transport cart, security of items on the transport cart, and condition of items upon receipt in the decontamination area.

c) ***Work practices*** (4.5, 5.3, 5.4). Performance measures should include, but are not limited to, selection and use of appropriate protective attire; soiled to clean work flow during instrument disassembly; manual cleaning and rinsing; prepararation of items for automated cleaning; instrument reassembly, inspection,

and preparation of items for flash sterilization (including positioning of instruments in the basket or tray); and compliance with the manufacturer's recommendations for complex instruments.

d) ***Installation, care, and maintenance of sterilizers*** (section 6). Performance measures should include, but are not limited to, accessibility of the manufacturer's instruction manual, verification of installation testing and acceptance, verification of routine inspection and cleaning, verification of routine replacement of parts as recommended by the sterilizer manufacturer, and verification of routine maintenance (such as lubrication and calibration) as recommended by the manufacturer.

e) ***Sterilization process*** (sections 3 through 7). Performance measures should include, but are not limited to, verification of training and continuing education, correct loading of items into the sterilizer chamber, accurate load records, selection of appropriate sterilization cycle parameters (time and temperature), selection and use of chemical or biological indicators, and documentation of physical, chemical, and biological monitoring.

f) ***Aseptic handling and transfer*** (5.4.5). Performance measures should include, but are not limited to, selection and use of proper attire and correct techniques for unloading the sterilizer and transferring sterilized items to the point of use.

A problem analysis should be completed for any problem with any aspect of flash sterilization that could pose a risk to patients. The problem analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected. There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Auditing results should be routinely summarized and submitted to Infection Control for review.

*Rationale:* Variables in the system must be controlled to assure quality and process efficacy. Assurance that sterility has been achieved will minimize the potential risk to patients. Measurements of process performance allow the system to be monitored and the results compared to a predetermined level of quality. Analysis of this information provides a method of identifying problems or shifts in activities and making improvements in the system.

**Annex A**
**(informative)**

**References**

AMERICAN HOSPITAL ASSOCIATION. *Steam and its use in sterilization: resolving observed problems with the purity of steam.* Chicago: AHA, 1985.

AMERICAN INSTITUTE OF ARCHITECTS ACADEMY OF ARCHITECTURE FOR HEALTH. *Guidelines for design and construction of hospital and health care facilities.* Washington, D.C.: American Institute of Architects Press, 1996 (in press).

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Biological indicators for saturated steam sterilization processes in health care facilities*. AAMI ST19—1985 . Arlington (Vir.): AAMI, 1986. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Good hospital practice: Steam sterilization and sterility assurance.* ANSI/AAMI ST46—1993. Arlington (Vir.): AAMI, 1994a. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Guideline for establishing and administering medical instrumentation maintenance programs.* AAMI MIR2. Arlington (Vir.): AAMI, 1993. AAMI Management Information Report.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Hospital steam*

*sterilizers*. ANSI/ AAMI ST8—1993. Arlington (Vir.): AAMI, 1994b. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings*. ANSI/AAMI ST35—1996. Arlington (Vir.): AAMI, 1996a. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities.* ANSI/AAMI ST33—1996. Arlington (Vir.): AAMI, 1996b (in press). American National Standard (proposed).

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Selection and use of chemical indicators for steam sterilization monitoring in health care facilities.* AAMI TIR No. 3—1988. Arlington (Vir.): AAMI, 1988. AAMI Technical Information Report.

ASSOCIATION OF OPERATING ROOM NURSES. Recommended practices for care of instruments, scopes, and powered surgical instruments. In: *AORN standards and recommended practices for perioperative nursing.* Denver: AORN, 1994a.

ASSOCIATION OF OPERATING ROOM NURSES. Recommended practices for operating room attire. In: *AORN standards and recommended practices for perioperative nursing.* Denver: AORN, 1994b.

ASSOCIATION OF OPERATING ROOM NURSES. Recommended practices for traffic patterns in surgical suites. In: *AORN standards and recommended practices for perioperative nursing.* Denver: AORN, 1994c.

BAUMEISTER, T., ed. *Standard handbook for mechanical engineers.* 8th ed. New York: McGraw-Hill, 1977.

BECK, WC. Operating room illumination: the current state of the art. *Hospital Topics*, May/June 1982, pp. 20-25. (Reprinted from *Bull Amer Coll Surgeons*, May 1981.)

BLOCK, SS. *Disinfection, sterilization, and preservation.* 4th ed. Philadelphia: Lea and Febiger, 1991.

CENTERS FOR DISEASE CONTROL. *Guidelines for handwashing and hospital environmental control, section 2: Cleaning, disinfecting and sterilizing patient care equipment.* Atlanta: CDC, 1985.

ILLUMINATING ENGINEERS SOCIETY. *IES lighting handbook.* New York: IES, 1987.

JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS. *Accreditation manual for hospitals, 1995.* Chicago: JCAHO, 1994.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Occupational exposure to blood-borne pathogens: Final rule. *Federal Register*, vol. 56, no. 235, pp. 64003-64182, December 6, 1991. *Code of Federal Regulations*, Title 29, Part 1910.1030.

PERKINS, JJ. *Principles and methods of sterilization in health sciences.* 2nd ed. Springfield (Ill.): Charles C Thomas, 1969.

REICHERT, M., and YOUNG, J. *Sterilization technology in the healthcare facility.* Gaithersburg (Md.): Aspen, 1993.

**Annotations from ST37.pdf**

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*Annotation 1; Label: AAMI; Date: 10/3/2000 11:21:04 AM*
*At the time this recommended practice was balloted, Dr. Chamberlain represented the Center for Devices and Radiological Health, Food and Drug Administration.

*Annotation 2; Label: AAMI; Date: 10/3/2000 11:22:03 AM*
**At the time this recommended practice was balloted, Mr. Danielson represented HCA Wesley Medical Center, Wichita, Kansas.

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*Annotation 1; Label: AAMI; Date: 10/3/2000 11:22:45 AM*
**At the time this recommended practice was balloted, Mr. Danielson represented HCA Wesley Medical Center, Wichita, Kansas.