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American National Standard

ANSI/AAMI ST40:1992/(R)1998

Table-top dry heat (heated air) sterilization and sterility assurance in dental and medical facilities

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

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ST40 Table-Top Dry Heat Sterilization and Sterility Assurance

American National Standard

ANSI/AAMI ST40—1992

Table-top dry heat (heated air) sterilization and sterility assurance in dental and medical facilities

Developed by
Association for the Advancement of Medical Instrumentation

Approved 17 December 1992 and Reaffirmed 7 October 1998 by
American National Standards Institute, Inc.

Abstract:

This recommended practice provides guidelines for dry heat sterilization in dental and medical facilities. The recommended practice covers functional and physical design criteria for work areas; staff qualifications, education, and other personnel considerations; sterilization processing procedures; installation, care, and maintenance of table-top dry heat sterilizers; and quality control. Definitions, a bibliography, and annexes providing supplementary information are also included.

Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

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

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

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Foreword

This recommended practice was developed by the Dry Heat Sterilization Working Group of the AAMI Sterilization Standards Committee. This document provides guidelines for dry heat sterilization in dentists' and physicians' offices, laboratories, and ambulatory-care facilities. These guidelines are intended to promote sterility assurance and assist health care personnel in the proper use of dry heat sterilization processing equipment.

This recommended practice reflects the conscientious efforts of health care professionals, in cooperation with sterilizer manufacturers, to develop recommendations for optimum performance in the processing of medical and dental devices to be dry heat sterilized. It is not intended that these recommendations be construed as universally applicable to all circumstances. It is also recognized that, in many cases, these recommendations may not be immediately achievable. Therefore, the document should guide health care personnel toward desirable performance objectives, and all of the document's provisions should be considered and applied using professional judgment and experience. The term "should," as used in this document, reflects the committee's intent to define goals, not requirements. The term "must," as used here, denotes recommendations that the committee wishes to emphasize or that are mandated by federal regulation.

The concepts incorporated herein are not inflexible or static. The recommendations must be 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 five years.

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

NOTE—This foreword does not contain provisions of the American National Standard, *Table-top dry heat (heated air) sterilization and sterility assurance in dental and medical facilities* (ANSI/AAMI ST40—1992), but it does provide important information about the development and intended use of the document.

Table-top dry heat (heated air) sterilization and sterility assurance in dental and medical facilities

Introduction: Need for the recommended practice

The prevention of infection in persons undergoing dental, medical, or surgical treatment is important in avoiding human suffering and lessening health care costs. One aspect of the prevention of infection in health care facilities is the effective reprocessing and/or sterilization of reusable dental and medical devices by dry heat sterilization.

In dry heat sterilization, the energy of heated air is transferred to objects, and this energy kills microorganisms. Typically, devices to be sterilized are placed in a chamber that uses electrical elements as the heat source; hot dry air at a specified temperature is circulated around the devices for a specified time.

Advances in dry heat sterilization technology have led to the increased use of this mode of sterilization in dental and medical offices and in ambulatory-care clinics. As many as 40,000 medical and dental facilities currently use dry heat sterilizers. Dental and medical offices and ambulatory-care clinics may differ greatly from hospitals in their physical design and in the training level of personnel. Consequently, guidelines are needed for good processing practices, facility design, and personnel considerations that take into account the specific characteristics and needs of this segment of the health care community.

For any sterilization method, sterility assurance depends not only on the process itself but also on the minimization of bioburden before sterilization and the prevention of contamination after sterilization. Consequently, in addition to processing recommendations, this recommended practice covers facility design considerations, personnel considerations, work practices, and other variables that affect the achievement and maintenance of sterility.

Although these guidelines are intended to help health care personnel accomplish dry heat sterilization safely and effectively, they are not intended to be a substitute for office procedures or professional judgment.

NOTE—The term "should," as used in this recommended practice, reflects the committee's intent to define goals, not requirements, for performance. The term "must," as used here, denotes procedures the committee particularly wishes to emphasize or that are required by federal regulation.

1 Scope

1.1 General

This recommended practice provides guidelines for dry heat sterilization used in dentists' and physicians' offices, laboratories, ambulatory-care clinics, and other health care facilities. These guidelines are intended to increase the assurance of sterility by identifying the special considerations that apply to this method of sterilization and by providing recommendations on the proper use of table-top dry heat sterilization

processing equipment. This recommended practice also covers design considerations, personnel considerations, work practices, and other variables that affect sterility assurance.

1.2 Inclusions

This recommended practice specifically addresses

a) functional and physical design criteria for work areas;

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

c) preparation and packaging of devices (wrapped and unwrapped methods);

d) sterilization procedures;

e) sterile storage and distribution;

f) installation, care, and maintenance of table-top dry heat sterilizers;

g) quality control.

Definitions, a bibliography, and annexes providing supplementary information about dry heat sterilization are also included.

1.3 Exclusions

This recommended practice does not cover

a) construction and performance criteria for table-top dry heat sterilizers;

b) the use of conduction-type or radiation-type dry heat sterilization processes;

c) the use of table-top sterilization processes that employ sterilizing agents other than dry heat (such as ethylene oxide, steam, unsaturated chemical vapor, or peracetic acid).

2 Definitions

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

2.1 ambulatory care: The short-term treatment of medical, dental, or surgical needs within 24 hours in an office or clinic type of environment.

2.2 bioburden: The number and types of viable microorganisms with which an item is contaminated; also known as *bioload* or *microbial load*. When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item.

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

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

2.5 cleaning: The removal, usually with detergent and water, of adherent visible soil (e.g., blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or

further decontamination.

2.6 contaminated: The state of having been actually or potentially in contact with microorganisms. As used in health care, the term generally refers to the presence of microorganisms that may be capable of producing disease or infection.

2.7 culture: (a) A growth of microorganisms in or on a nutrient medium. (b) To grow microorganisms in or on such a medium.

2.8 culture medium: A substance or preparation used to grow and cultivate microorganisms.

2.9 cycle time: The total elapsed time of a sterilization cycle from the time the sterilizer door is closed and the cycle is initiated until the cycle is completed and the door opened. Cycle time may include come-up or heat-up time, exposure time, come-down time, and cooling time.

2.10 decontamination: The process of rendering contaminated items safe for handling by personnel who are not wearing protective attire.

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

2.12 dry heat sterilization: A sterilization process that utilizes dry heated air as the sterilizing agent.

2.13 exposure time: The period of time during a sterilization process in which items are exposed to the sterilant at the specified sterilization parameters. In a dry heat sterilization process, exposure time is the period during which items are heated at a particular temperature or temperature range.

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

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

2.16 Gram's method of staining: A method of differential staining used in microbiological identification. Gram's method of staining is also simply called *Gram staining*.

2.17 heat sink: A heat-absorbent material; a mass that readily absorbs heat.

2.18 heat-up time: As the term is used in relation to dry heat sterilization, the time required for the entire load to reach the exposure temperature or temperature range.

2.19 microorganisms: Animals or plants of microscopic size. As used in health care, the term generally refers to bacteria, fungi, viruses, and bacterial spores.

2.20 office-based health care facility: A health care facility designed for short-term treatment of ambulatory patients; for example, free-standing surgical centers, clinics, and medical and dental offices.

2.21 positive control: As the term is used in routine sterilization process monitoring, a biological indicator, from the same lot as a test biological indicator, that is left unexposed to the sterilization cycle and then incubated to verify the viability of the biological indicator.

2.22 process time: See **cycle time**.

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

2.24 sterility assurance level (SAL): The probability of survival of microorganisms after a terminal sterilization process and a predictor of the efficacy of the process. For example, a probability of microorganism survival of 10^{-6} means that there is less than or equal to one chance in a million that a

particular item is contaminated or nonsterile. It is generally accepted that a sterility assurance level of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (that is, tissue that has lost the integrity of the natural body barriers). A sterility assurance level of 10^{-3} (a one in a thousand chance of a surviving microorganism) is considered acceptable for items not intended to come into contact with compromised tissue.

2.25 sterilization: A process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level.

2.26 table-top dry heat sterilizer: A compact dry heat sterilizer that has a chamber volume of 2 cubic feet or less and that utilizes electrically heated hot air as the sterilizing agent.

3 Facility design considerations

3.1 General rationale

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

3.2 Work area design and functional work flow

3.2.1 Definitions of work areas

a) *Decasing/breakout area or space:* The unpacking area or space where products are removed from their external shipping containers before being taken into the preparation and packaging area or the sterile storage area.

b) *Receiving, cleaning, and decontamination area:* The area where reusable instruments, supplies, and equipment are received, sorted, cleaned, and decontaminated.

c) *Preparation and packaging area or space:* The area or space where decontaminated, clean instruments and supplies are inspected, prepared, and packaged for sterilization.

d) *Sterilization area or space:* The area or space where sterilization equipment is located.

e) *Sterile storage area or space:* The area or space where sterile and clean supplies are stored before being selected and distributed for procedures.

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

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

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

Figure B.1 in annex B illustrates these functional work areas.

3.2.2 Design criteria

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

a) where reusable patient care supplies and equipment will be cleaned and decontaminated, inspected,

assembled, sterilized, stored, and reissued;

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

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

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

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

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

g) where disposable items will be stored before use;

h) which items will be disposable and which will be reusable, and where these items will be processed and stored;

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

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

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

l) whether an area for processing reusable linen will be required.

Individual facilities may need to consider additional design requirements.

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

3.2.3 Functional work flow patterns

Workplace design should allow adequate space for all functions and should promote efficiency by minimizing distances between related areas. Functional work areas should be physically separated by walls, partitions, or space to maintain good traffic flow and to contain contaminants generated during the phases of reprocessing. Work flow patterns should be designed to flow from soiled to clean. Annex B provides an example of work area design and work flow patterns.

Rationale: Separating clean and "dirty" areas limits environmental contamination and, therefore, the bioburden on items to be sterilized.

3.2.4 Traffic control

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

Rationale: Good traffic control practices protect personnel, patients, and supplies from potential sources of cross-contamination.

3.3 Physical facilities

3.3.1 Space requirements

Numerous factors affect space allocation. Considerations should include the operational work flow patterns, the amount of equipment, the workload, and the desired staffing.

Rationale: Space requirements may vary significantly, depending on the specific activities and processing needs of the practice. In general, the space needed to perform routine maintenance activities, such as the reprocessing of reusable supplies tends to be underestimated during the planning phase.

3.3.2 Mechanical and electrical systems

Sources of compressed air and/or nitrogen may be needed. In addition to the routine electrical systems, an adequate number of suitable electrical outlets and "fault-grounded" wall plugs and adaptors should be provided.

Rationale: Because of the increasing sophistication of today's medical technology, complex equipment and systems may be needed to inspect, maintain, or verify equipment and device performance and to ensure the safety of employees. Compressed gas sources may be needed for such purposes as lubricating or drying drills after cleaning.

3.3.3 General area requirements

All work areas should conform with the following recommendations.

3.3.3.1 Floors and walls

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

Rationale: All surfaces in work areas are subject to spills and splashing and must be regularly and thoroughly cleaned (see 3.4) to control microbial contamination and to eliminate accumulated dust, which may act as a carrier for microorganisms. Accordingly, the materials of construction of floors and walls must not interfere with adequate cleaning or be adversely affected by frequent cleaning or the chemical agents typically used for cleaning.

3.3.3.2 Ceilings

Work area ceilings should have a flush, smooth, nonporous surface with recessed, enclosed fixtures. Pipes and other fixtures above work areas should also be enclosed.

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

3.3.3.3 Ventilation

The general ventilation system should be designed so that air flows into relatively soiled areas from clean adjoining spaces (via negative pressure) and is exhausted to the outside or to a filtered partial recirculating system. There should be no fewer than 10 air exchanges per hour. If possible, the air circulation system should be of a down-draft type. The ventilation system filtration should comply with the recommendations of American Institute of Architects (1993). Portable fans should not be used in any work area.

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

flow characteristics.

3.3.3.4 Temperature and humidity

All work areas should have a temperature controlled between 18°C and 22°C (64°F and 72°F) and a relative humidity controlled between 35 and 70 percent.

Rationale: The work environment should be comfortable for properly attired personnel. Worker productivity, electronic equipment, and the shelf life of sterile items are adversely affected by both high and low temperatures and humidities. Temperatures and humidities higher than those recommended can promote microbial growth and thus increase bioburden. Temperatures and humidities lower than those recommended may cause static electricity. The recommended humidity range was derived from American Institute of Architects (1993).

3.3.3.5 Lighting

Adequate ambient lighting at work surfaces should be provided in accordance with the engineering practices outlined by the Illuminating Engineering Society of North America (1987), which recommends illuminance levels for various categories of work environments. For general inspection functions, the specified illuminance is 500-750-1,000 lux (50-75-100 footcandles); for detailed inspection, 1,000-1,500-2,000 lux (100-150-200 footcandles); for sink areas, 500-750-1,000 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. If the adequacy of lighting is in doubt, a survey should be requested.

Rationale: Adequate lighting is essential to properly perform decontamination, preparation, and other processing tasks. See also Beck (1981) and Illuminating Engineering Society of North America (1987), which provide further recommendations for illumination.

3.3.3.6 Handwashing facilities

Handwashing facilities should be conveniently located and allow for good handwashing practices. Handwashing sinks should not be used for cleaning instruments or supplies.

Rationale: Handwashing is the single most important procedure for preventing infections in patients and staff. Personnel should wash their hands after handling items contaminated or likely to be contaminated with blood, other body fluids, excretions, or secretions; any time that soiled items are handled; after removing gloves before leaving the cleanup area; after removing masks or touching the face; and in other cases as dictated by good personal hygiene. Handwashing will minimize the transfer of organisms between and among patients, personnel, and inanimate objects.

3.3.4 Special area considerations

3.3.4.1 Decontamination

Ideally, the decontamination area should be a separate work area. However, the area where items are cleaned is sometimes the same area used for assembly, packaging, and sterilization of instruments and supplies. In this circumstance, "practical barriers" emphasizing good work practices and suitable signs to designate soiled and clean work spaces must be used to limit the possibility of cross-contamination into clean work areas.

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

3.3.4.2 Preparation and assembly

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

Rationale: A clean, dust-free, and moisture-free environment is essential to limiting the amount of bioburden on devices prior to sterilization.

3.3.4.3 Sterilization

Sterilizers should not be located near any potential sources of contamination, such as cleaning/ handwashing sinks or containers for the disposal of linen and trash.

Rationale: It is important to minimize bioburden on items before sterilization and to prevent contamination of sterile items after sterilization.

3.3.4.4 Sterile storage

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

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

3.4 Housekeeping

Housekeeping procedures in areas used for any aspect of the decontamination, preparation, or sterilization process should ensure a high level of cleanliness at all times. There should be at least daily cleaning of floors and horizontal work surfaces. Other surfaces, such as walls and storage shelves, should be cleaned on a regularly scheduled basis and more often if needed. Care should be taken to avoid compromising the integrity of packaging of clean and sterilized items during cleaning procedures. It is good practice to provide separate housekeeping equipment and supplies for decontamination and clean areas. If separate areas are not available, special attention should be paid to the sequence of cleaning to avoid transferring contaminants from "dirty" areas or surfaces to clean areas or surfaces. For example, clean areas should be cleaned before the decontamination area, and relatively clean surfaces, such as counters, should be cleaned before floors.

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

4 Personnel considerations

4.1 General rationale

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

knowledgeable personnel.

4.2 Qualifications

The responsibility for dry heat sterilization should be assigned to a qualified individual. Suggested minimum qualifications include:

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

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

c) demonstrated competence in all aspects of sterility maintenance.

Rationale: A dry heat sterilizer can present safety problems for both the patient (nonsterile items) and the operator (burns). Dry heat sterilization should be performed by persons knowledgeable in sterilization processing and the concepts of infection control.

4.3 Training and continuing education

Personnel engaged in dry heat sterilization processing should receive orientation and on-the-job training. They should attend seminars and/or formal courses on sterilization that cover sterilizer operation, parameters of dry heat sterilization, basic microbiological and infection control principles, and monitoring of sterilization cycles. It is recognized that personnel not normally involved with sterilization processing may be assigned related responsibilities. Such personnel should receive instruction on the proper preparation, care, handling, storage, and maintenance of sterile items.

Rationale: Adequate training and continuing education decrease the possibility of operator error during preparation and sterilization processing and help ensure that personnel are knowledgeable about the latest data and techniques.

4.4 Health and personal hygiene

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

Rationale: Careful attention to personal hygiene will minimize the potential for acquiring or transmitting disease. The hepatitis virus may be found in blood or other body fluids on contaminated instrumentation and can enter through small cuts or abrasions on the skin. Vaccination will protect personnel from this serious disease. OSHA (1991) requires that hepatitis B vaccination be offered to personnel who come into contact with blood or other body fluids. Other immunizations may become appropriate and/or mandatory in the future. See also American Dental Association (1988).

4.5 Attire

4.5.1 General

All personnel involved in sterile processing should wear a clean uniform or laboratory coat. Attire should be changed daily or more often as needed (that is, when wet or grossly soiled). Jewelry should be kept to a minimum. Employees should change into street clothes whenever they leave the health care facility.

Rationale: Appropriate attire protects personnel from the microorganisms on contaminated items. Changing soiled attire limits transfer of microorganisms to other personnel, patients, medical devices, and work areas.

4.5.2 Decontamination

In addition to the attire recommended in 4.5.1, personnel who clean and decontaminate items to be sterilized should wear heavy-duty rubber or plastic gloves, a fluid-resistant apron, protective eyewear, and a high-filtration-efficiency face mask. Employees should change into street clothes whenever they leave the health care facility.

Rationale: Contaminated instruments and other medical devices are a source of microorganisms that could invade personnel through nicks or cuts on the hands or through contact with the mucous membranes of the eyes, nose, or mouth. When contaminated items are being cleaned, the splashing or splattering of blood and other body fluids is probable. Wearing protective attire minimizes the risk.

5 Processing recommendations

5.1 General rationale

Contaminated instruments and other dental or medical devices are sources of microorganisms that could cause infections in personnel or patients. This section provides guidelines for the processing of devices before, during, and after sterilization. Proper work practices in preparing items for sterilization, implementing sterilization cycles, and handling, storing, and distributing sterilized items are essential to effective sterilization processing and to maintaining device sterility until use. The guidelines in this section apply solely to the reprocessing of items intended for reuse. Devices labeled for single use only should not be reprocessed or reused, because it may not be possible to adequately clean or disinfect/sterilize them, or they may be damaged by the cleaning or disinfection/sterilizing processes. In addition, the health care facility's liability may be affected if the device manufacturer's written instructions for use of a device are not followed.

5.2 Receiving

Sterility assurance measures should be employed from the time items are received until they are used. Newly purchased items should be removed from their external shipping containers before they are transported to processing or storage areas.

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

5.2.1 Contaminated items

5.2.1.1 Items previously used in patient care

Reusable items should be separated from waste and soiled material. Reusable items must be cleaned and decontaminated before they are prepared and packaged for resterilization.

Rationale: Cleaning and decontamination of items used in patient care render them safe for handling by personnel who are not wearing protective attire. Cleaning and decontamination also reduce bioburden, which is necessary to achieve sterilization.

5.2.1.2 Newly purchased reusable items

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

Rationale: Many reusable medical and dental devices are manufactured in an environment where bioburden is not rigorously controlled, and some are handled extensively during the manufacturing process. Consequently, to ensure that sterility can be achieved, the bioburden should be reduced by cleaning before the device is packaged for sterilization. Also, anticorrosive agents such as oils or greases may be left on the device by the manufacturer to protect it during shipping; such agents will interfere with sterilization if not removed.

5.2.2 Clean, nonsterile disposable items

Clean, nonsterile disposable items, such as prepackaged disposables, may be received directly into preparation areas without further cleaning.

Rationale: Nonsterile disposable items received from manufacturers are usually individually packaged for patient dispensing or sterilization, or they have been otherwise protected from contamination during transport. Also, such items are generally manufactured and packaged in an environment where the bioburden is controlled, so further cleaning is unnecessary.

5.2.3 Sterile items

Items that have been packaged, sterilized, and issued may be returned unopened to the sterile storage area if the packaging is intact. Before such items are received into either the sterile storage area or the reprocessing area, the integrity of the package must be assessed.

Rationale: This recommendation assumes that appropriate packaging material has protected unused sterile items, unless the package has been opened or damaged, and that the items have been properly handled. The environment should be controlled, and personnel should be knowledgeable about the proper handling of sterile items.

5.3 Cleaning and decontamination

Cleaning and decontamination, in an area provided for the handling of soiled items, should begin as soon as possible after items have been used.

Rationale: Cleaning and decontamination are more difficult if soil has dried on device surfaces.

5.3.1 Instruments

The instrument manufacturer's instructions should be consulted for specific guidance on cleaning and decontamination. In general, though, instruments should be maintained as free of gross soil as possible during the procedure. Before cleaning, all instruments should be sorted to separate general operating instruments and utensils from delicate instruments or devices requiring special handling. An initial cold water rinse will help remove visible soil. Instruments may be processed mechanically or washed by hand. Warm water and a detergent appropriate for the particular device or instrument being cleaned should be used, and the item should then be thoroughly rinsed. Instruments should be carefully inspected for flaws or damage and dried before packaging or sterilization.

Rationale: Because the degree of sterility assurance depends on the amount of contamination of items to be sterilized, thorough cleaning procedures are essential during presterilization processing. Not all cleaning and decontamination procedures and agents are appropriate for all types of instruments. Following the manufacturer's instructions for detergents and other aspects of the cleaning and decontamination process will avoid damage to instruments and prolong their useful lives.

5.3.2 Utensils

Soiled utensils, such as basins and trays, can be processed by hand using warm water and an appropriate detergent. Sterilization container systems should be disassembled and cleaned after each use in accordance

with the manufacturer's instructions.

Rationale: See the rationale statement for 5.3.1.

5.4 Packaging

Packaging material designed for dry heat sterilization processing should:

a) allow easy heat penetration;

b) provide an adequate barrier to microorganisms after sterilization;

c) resist tearing or puncture before and after sterilization;

d) have proven seal integrity (if self-sealed or heat-sealed);

e) allow for ease of aseptic presentation;

f) be free of toxic ingredients and nonfast dyes;

g) be low-linting;

h) be cost-effective and readily available.

Before a packaging material is selected, the manufacturer of the packaging material should be consulted to confirm compatibility of the packaging material with sterilizer temperatures.

Rationale: The prime functions of a package containing a sterile item are to allow the sterilization of the contents, to maintain the sterility of the contents until the package is opened, and to provide for removal of the contents without contamination. A packaging material not designed for dry heat sterilization temperatures may melt or burn, damaging instruments or presenting a fire hazard.

5.5 Sterilization of packaged items

5.5.1 Preparation of items to be sterilized

Where practical, small containers should be used, and the package density should be as low as possible. Instruments can be packaged in pouches of appropriate size and material. Only pouches designed to withstand dry heat temperatures should be used. Pouches made from nylon films are available in individually formed pouches or in roll stock (the user cuts the desired length from a roll and either tapes or heat-seals both ends to form an envelope or pouch). Pouches made of papers specially formulated to withstand high temperatures are also available. Rubber bands, tape (other than package sealing tape designed for dry heat sterilization), safety pins, paper clips, staples, and similar items should not be used to secure packages or organize package contents.

If a sterilization container or cassette is used, the container/cassette manufacturer's written recommendations should be followed. Scientific data in support of these recommendations should be provided by the manufacturer. Use of other types of closed containers must be based upon the results of biological monitoring of such containers in the type of sterilizer being used.

Rationale: If not formulated to withstand the high temperatures of dry heat sterilization, pouches may melt or be damaged, compromising the aseptic presentation of sterilized items; also, packaging material that melts onto the items being processed may be difficult to remove.

The design of sterilization container/cassette systems varies widely, so the container/cassette manufacturer's instructions are the best guide to preparation and processing. Closed containers may extend the time needed to achieve sterilization; therefore, use of such containers must be based upon biological monitoring results.

Rubber bands and most types of tape are not designed for the high temperatures involved in dry heat sterilization. Most types of tape will degrade, leaving baked-on tape residue on the items or losing adhesion

completely. Rubber bands become brittle and may produce undesirable particulates. Sharp pins, paper clips, and staples can puncture the packaging material and thus compromise the sterile barrier.

5.5.2 Loading the sterilizer

Devices and containers for dry heat sterilization should be clean and dry before they are placed in the sterilizer. The items must be loaded into the sterilizer with proper spacing in accordance with the loading configurations recommended by the sterilizer manufacturer or specified in office operating procedures (which must be based on the manufacturer's recommendations or on scientific data).

Rationale: Load configuration can affect air flow rate and distribution in the sterilizer. If the devices to be sterilized are loaded too tightly, air may not contact each item and, consequently, sterilization may not be accomplished.

5.5.3 Equipment operation

Some types of dry heat sterilizers are operated manually; for others, the cycle is controlled automatically or semiautomatically. The manufacturer's instructions should be included in the office operating procedures.

A simple batch cycle consists of loading the chamber, heating the chamber, holding the chamber at a specified temperature for a specified time, cooling the chamber to ambient temperature, and unloading the chamber. The manufacturer usually recommends that the sterilizer be preheated.

Another type of batch sterilizer operates at very high temperatures (up to 210°C [410°F]) with forced air convective heating. A preheating cycle is not required. The load is placed in the chamber, the door is closed, and the cycle is started. The sterilizer automatically heats to the specified temperature, exposes the load for a preset period of time, and then cools the load while it remains inside the chamber.

A third type of dry heat sterilizer (continuous cycle) maintains a constant preset temperature. The load is placed in the chamber, and an exposure period is selected. The load is exposed for the selected period of time and then removed to cool outside of the sterilizer.

The operator must become totally familiar with the manufacturer's operating instructions as well as the facility's specific procedures, which specify temperature and time set points, loading patterns, and other detailed operating parameters. The operator must also check and recheck the sterilizer operation to ensure that all parameters are being met. After the cycle is complete, the operator must prepare and assemble the proper documentation for the load and provide the documentation to the person responsible for office infection control.

5.5.4 Sterilization cycle parameters

The sterilizer manufacturer's written instructions for cycle parameters should be followed. If a sterilization container/cassette system is used as packaging, the container/cassette manufacturer's written recommendations regarding exposure time and temperature should be consulted and reconciled with those of the sterilizer manufacturer. In addition, certain types of dental and medical equipment may require prolonged exposure times; the recommendations of the sterilizer manufacturer, cassette/container manufacturer, and device manufacturer should be consulted and reconciled.

Rationale: Sterilizers vary in design and performance characteristics, so cycle parameters should always be verified against the sterilizer manufacturer's instructions for the specific sterilizer and load configuration being used. The use of container or cassette systems may affect the required exposure time. The design of some devices may itself affect the conditions necessary for dry heat sterilization.

5.5.5 Unloading the sterilizer

5.5.5.1 Removing items from the sterilizer

Personnel should use insulated handles or heavy gloves when removing items and packs from the sterilizer.

Rationale: Metal items retain heat and can cause burns.

5.5.5.2 Cooling

Items being cooled after removal from the sterilizer must remain untouched during the cooling period. Sterilizer trays with cooling items should be placed in a low-traffic area where there is no turbulent air. The time allowed for cooling must be based on professional judgment and experience and on the environmental conditions of the area. Instruments and other items should not be cooled by means of forced air outside of the sterilizing chamber.

Rationale: The type of sterilizer used can affect cooling time, based on how hot items are when they leave the sterilizer. (In some sterilizers, items are cooled to a safe temperature as part of the cycle.) Consequently, the time allowed for cooling must be based on professional judgment and experience. Placing the sterilizer tray in a low-traffic area decreases exposure of the items to particulates settling from the environment and minimizes the possibility of inadvertent personnel contact with the sterilized items.

5.5.5.3 Handling and inspection

All sterile items should be handled as little as possible. All packages should be visually inspected for integrity. Any items with torn or punctured packaging or with packaging that appears to have been opened or to have breached seals should not be used. Such items should be repackaged and reprocessed.

Rationale: Packages that are torn, punctured, or have defective seals must be considered contaminated.

5.5.6 Safety factors

The most common safety hazard associated with dry heat sterilization is injury received from burns resulting from the operator touching hot sterilizer surfaces or hot items. The operator must be constantly aware of this hazard and use protective clothing and equipment, such as insulated handles or heavy gloves, when handling hot items. Other, less likely safety hazards include electric shock and fire. Although fire is unlikely to occur under controlled operating conditions, the operator should follow specific office procedures in the event of a fire. Care must be taken by the operator to avoid circumstances that could lead to unsafe conditions.

Additional guidelines should be presented to the operator during a comprehensive safety program.

5.5.7 Common operator errors

Operator errors that can adversely affect the dry heat sterilization process include:

a) failure to understand and observe the sterilizer operating procedures;

b) incorrect preparation and packaging of items to be sterilized;

c) improper loading of the sterilizer with disregard for air circulation across the product;

d) incorrect setting of the exposure time and temperature;

e) failure to report possible maintenance problems to the responsible person(s);

f) failure to make proper cycle selection;

g) attempting to sterilize new items that have not been checked for compatibility with the sterilizer and sterilization process;

h) failure to properly document the sterilizer parameters;

i) improper handling of the item to be sterilized or the sterilizer equipment.

The operator must be trained to recognize the importance of these factors to proper sterilizer operation.

5.6 Sterilization of unwrapped items

5.6.1 General considerations

In general, it is preferable to package items for sterilization to prevent contamination prior to use. However, instruments and other items intended for immediate use, except for implantable devices, may be sterilized unwrapped if appropriate precautions are taken. The physical layout must ensure direct delivery of the sterilized items to the point of use. Work practices must ensure proper cleaning, decontamination, inspection, and arrangement of instruments prior to sterilization. Special care must be taken in the handling of items after sterilization. In general, the recommendations of 5.5 apply, except as noted in the following paragraphs.

5.6.2 Preparation of unwrapped items

Unwrapped items may be placed in open trays or on racks.

5.6.3 Cycle parameters for unwrapped items

Cycle parameters should be verified against the sterilizer manufacturer's instructions. The cycle parameters should not be adjusted below the minimum time and temperature recommended by the manufacturer. Most metal instruments require surface sterilization only. The addition of porous items appropriate for this type of sterilization process (e.g., gauze pads, cotton balls, dental rolls) will necessitate a longer exposure time to ensure adequate heat penetration; the recommendations of the sterilizer manufacturer and the device manufacturer should be consulted and reconciled.

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

5.6.4 Unloading the sterilizer

Special care must be taken when removing items from the sterilizer because they are vulnerable to contamination. The trays or items must be handled in a way that will prevent contamination en route to the point of use. Any items that are contaminated during handling must be cleaned and reprocessed.

5.7 Sterile storage of packaged items

5.7.1 Dust covers

Nonsterile plastic protective overwraps may be used to protect and extend the shelf life of properly packaged, sterilized, and cooled items that may be subjected to multiple handling prior to use. The cover should be clearly labeled as a dust cover to prevent its being mistaken for a sterile wrap.

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

5.7.1.1 Application of dust covers

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

Rationale: Dust covers should be applied as soon after sterilization as possible to enhance maintenance of sterility. However, placing a dust cover on a package that is not cool may cause the dust cover to melt, which may compromise the primary package and cause contamination of the package contents. Gloves prevent contamination of the package by perspiration from workers' hands.

5.7.1.2 Labeling

The lot or load control number and expiration date or statement must be visible through the dust cover, or an additional label must be affixed to the dust cover.

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

5.7.2 Storage environment

Packaged sterile items should be positioned so that they are not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised. Medical and dental supplies must not be stored under sinks, near water or sewer pipes, or in any location where they can become wet. Storage of supplies on floors, window sills, and in areas other than designated shelving should be avoided.

Rationale: Compression of packages can force air and microorganisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces. Sterile items should not be stored anywhere but on or in designated shelving, counters, or containers, because other areas may not be sufficiently clean, and window sills collect condensate that forms because of differences in temperature inside and outside.

5.7.3 Storage shelving

Closed or covered cabinets are recommended for the storage of packaged sterile items. Open shelving may be used but requires special attention to good housekeeping. Shelving or carts used for sterile storage must be maintained in a clean and dry condition. Outside shipping containers and corrugated cartons should not be used as containers in sterile storage areas.

Rationale: Closed cabinets limit dust accumulation, discourage handling, and minimize inadvertent contamination of sterile items. Shipping containers have been exposed to unknown and potentially high microbial contamination, and those that are corrugated serve as generators of and reservoirs for dust; hence, shipping containers should never be allowed in the sterile storage area.

5.7.4 Shelf life

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

Rationale: The contamination of a sterile item is event-related, not solely a function of time. However, the probability of occurrence of a contaminating event increases over time and with handling.

5.8 Distribution

5.8.1 Handling and inspection

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

Rationale: See the rationale statement for 5.8.2.

5.8.2 Distribution containers and cassettes

Sterile supplies should be transported in a covered or enclosed cart or other clean protective equipment. If items are placed inside plastic or paper bags or boxes for transport, the items must be arranged within the

containers so as to prevent them from being crushed or otherwise damaged or contaminated. Surfaces in direct contact with sterile packaging should be clean.

Rationale: Covered or enclosed carts or trays protect sterile items from inadvertent contact with personnel and other sources of contamination, and from environmental challenges that may exist along the transportation route. Surfaces in direct contact with sterile packaging should have minimum bioburden to decrease the risk of microbial penetration of the sterile barrier of the packaged items.

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

6.1 General rationale

This section broadly covers care and maintenance procedures applicable to table-top dry heat 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, at a minimum, all information necessary to carry out the procedures recommended in 6.4 and 6.6 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 must be retained by the user for as long as the sterilizer is in service.

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

6.3 Installation

Dry heat sterilizers must be installed in accordance with the manufacturer's written instructions. Particular care should be taken never to install a table-top dry heat sterilizer in an area where explosive or flammable materials or anesthetics are used or stored. The sterilizer should not be connected to an electrical circuit with other appliances or equipment unless the circuit is rated for the additional load. The sterilizer must be placed on a heat-resistant surface. If the sterilizer is mounted on a counter beneath a cabinet or other overhang, sufficient clearance must be available for adequate ventilation and access to the sterilizer for cleaning. The area in front of the sterilizer should be clear of any obstruction so that an operator can safely remove hot items or sterilizer trays.

Before the sterilizer is operated, a complete check of all systems and components, including the electrical and air flow systems, fans, instrumentation, and filters, must be conducted and necessary corrections made. Maintenance programs, instrument calibration, and operating procedures must be established before the equipment is placed into service.

Rationale: Dry heat sterilizers are electrically heated units, and some have a mechanical air flow system. Appropriate installation is necessary for proper function and use.

6.4 Routine care and maintenance

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

Rationale: Periodic inspection, cleaning, and preventive maintenance reduce the incidence of equipment

malfunctions that could cause sterilization failures. Cleanliness also reduces the risk of accidental contamination of sterile material.

6.5 Repair and Component Replacement

Certain repair or component replacement tasks requiring special tools (e.g., microcomputer controls) should be performed by the manufacturer or another qualified service facility. Potential problem areas include burned-out electrical elements, leaking door gaskets, improperly positioned dampers, malfunctioning fans, improperly set or loose baffles, and malfunctioning door interlocks.

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

6.6 Calibration

Periodic calibration should be performed as specified in the manufacturer's written instructions. Critical instrumentation, particularly the temperature monitoring equipment, should be calibrated on a regularly scheduled basis to ensure accuracy and reliability. All calibration activities should be documented. In the event of a sterilizer malfunction or the repair or replacement of any component affecting sterilizer performance, appropriate recalibration must be performed. Those performing calibration must have sufficient training and skills to understand the operation and calibration of the particular sterilizer type.

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

6.7 Record-keeping

A maintenance record must be kept for each sterilizer. This record should be maintained by the person responsible for the sterilizer. The maintenance record should include sufficient information to identify the sterilizer and to establish a continuous history of all scheduled and unscheduled service. At 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 (if appropriate);

d) the name of the individual requesting and authorizing service;

e) the reason(s) for the service request;

f) a description of the service performed;

g) the types and number of parts replaced;

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

i) the date the work was completed;

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

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

7 Quality control

7.1 General rationale

This section covers product identification and traceability; mechanical, chemical, and biological monitoring

of dry heat sterilization cycles; product recalls; and related quality-control measures. Assurance of sterility requires continuous attention to all aspects of sterilizer performance and the dry heat sterilization process.

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

7.2 Product identification and traceability

7.2.1 Lot control number (packaged items)

Each pack to be stored before use should be labeled with a lot control number. The lot control number should designate the sterilizer (if there is more than one), the date of sterilization, and the cycle number (cycle run of the sterilizer). If packages are to be labeled prior to sterilization, the labeling should be done immediately before the load is processed. If it is office policy to label packages after sterilization, care should be taken to avoid compromising the sterility of the packaged items, and the labeling should not be done until the packages are cool and dry.

Rationale: Lot identification enables retrieval of items in the event of a recall and the tracing of problems (e.g., temperature not in calibration) to their source. To ensure that unprocessed items are not mistakenly thought to be sterile, presterilization labeling should be done after sterilizer and cycle assignment is determined and as the tray is loaded. For poststerilization labeling, the packages must be cool and dry to prevent contamination.

7.2.2 Load records (nonpackaged items)

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

a) the date and time of the cycle;

b) a general description of the lot or load contents (e.g., linen packs, instrument packs);

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

d) the name or initials of the operator;

e) biological indicator results, if applicable;

f) chemical-indicator results.

The time and temperature recording chart or tape, if available, should also be dated and maintained, and each cycle on the chart should be initialed by the operator. As recommended in 6.7, a record of repair and preventive maintenance must also be kept for each sterilizer. All of the foregoing information may be incorporated into a sterilizer log system or filed as individual documentation records. All sterilizer records must be retained in a designated record storage area for a period of time not less than that specified by state or local statutes or by the infection control policies of the health care facility.

Rationale: Documentation ensures monitoring of the process as it is occurring, ensures that the cycle parameters have been met, establishes accountability, and affords legal protection.

In addition, documentation helps personnel determine whether recalls are necessary and the extent of recalls should evidence subsequent to lot release, such as a positive biological indicator, suggest sterility problems. Knowing the contents of the lot or load enables personnel to decide how critical a recall may be.

7.3 Physical monitoring

7.3.1 Use of physical monitors

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

Rationale: Physical monitors provide real-time assessment of the sterilization cycle conditions and, in some cases, provide permanent records by means of chart recordings or computer-driven printouts. Monitoring is needed to detect malfunctions as soon as possible, so that alternative procedures can be used in the event of failures.

NOTE—Most temperature sensors are located along a chamber wall, at the opening of the exhaust vent, or in the moving air stream and therefore do not reflect the temperature at the center of packs. Improper load configuration or package composition can interfere with heated air flow or convective air currents, conditions that will not be revealed in the temperature recordings or on temperature gauges. Therefore, physical monitors and other indicators must not be considered a substitute for careful adherence to prescribed packaging and loading procedures.

7.3.2 Sterilizer malfunctions

If a physical monitor indicates any malfunction or suspicious operation, the person responsible for the health care facility must be notified. After examination, if the malfunction cannot be corrected immediately, the cycle must be terminated in accordance with the manufacturer's instructions. The load must be considered nonsterile, and the sterilizer must be removed from service. Maintenance personnel or the contract maintenance service should be notified and the malfunction corrected. A faulty sterilizer cannot be made operational without identifying and correcting the underlying problem; merely extending the cycle exposure time or increasing the cycle temperature is not an acceptable corrective measure.

Rationale: Simply altering the cycle parameters of a malfunctioning sterilizer will not correct a problem but only mask it; the sterility of future loads will be jeopardized if the sterilizer continues to be used without repair. Common problems detected by recordings and gauges include inadequate temperature and exposure time. To restore a sterilizer to proper operation, the exact cause of the malfunction must be identified.

7.4 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 problems associated with incorrect packaging, incorrect loading of the sterilizer, or malfunction of the sterilizer. Because the nature and properties of the materials and items to be sterilized differ greatly in their thermal characteristics, it is essential to select the best indicator available for the temperature to be used and the material to be sterilized. The "pass" response of a chemical indicator does not prove that the item accompanied by the indicator is sterile.

7.4.1 Selecting 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 reliability of the indicator in maintaining end-point color change (if applicable) during storage of sterilized items, the sterilization conditions that the indicator will detect, and the storage requirements for and shelf life of the indicator itself. Additional guidelines on the selection of chemical indicators are provided in annex C.

Rationale: Various types of external and internal indicators are available, each with different response characteristics; that is, they differ in the sterilization conditions they will detect and verify. At present, there are no consensus standards to assist health care personnel in selecting specific products, so only broad criteria can be defined here. The degree of quality assurance needed is a judgment based on risk/benefit assessment, and the choice of chemical indicator depends upon the specific needs, resources, and sterilization equipment of the individual health care facility.

7.4.2 Types of chemical indicators and their use

7.4.2.1 External chemical indicators

External chemical indicators are available in several forms, such as indicator tape, labels, and crayons; some are preprinted on sterilizable packages. These devices are usually temperature-sensitive only. Except for packages that allow visual inspection of the internal indicator, such as nylon film pouches, an external indicator should be used on every package. A chemical indicator or an indicating printed legend should be affixed to or printed on all packages assembled in the health care facility and intended for sterilization. The external chemical indicator must visually denote that the package has been exposed to the physical conditions inside a dry heat sterilizer. In the case of unwrapped instruments, one or more chemical indicators must be placed among the instruments to be sterilized. The tape, label, or legend must be examined after sterilization and also before use to make sure that it indicates that the item has been exposed to a sterilization process.

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

7.4.2.2 Internal chemical indicators (wrapped items)

7.4.2.2(a) Placement and frequency of use

An internal chemical indicator should be used within each package, tray, container, or cassette being processed. The chemical indicator must be placed in that area of the package, tray, container, or cassette considered to be the least accessible to heat penetration; this may or may not be at the center.

Rationale: A chemical indicator should be used in each package, tray, container, or cassette, because variations in position or contents may affect heat penetration and, therefore, the time needed to attain the desired temperature.

7.4.2.2(b) Retrieval and interpretation

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

7.4.2.2(c) Nonresponsive or inconclusive chemical indicators

If the interpretation of the chemical indicator suggests inadequate dry heat processing, the item must not be used. Appropriate follow-up includes lot identification and a review of the physical monitoring information for the sterilization cycle, the results of chemical indicators elsewhere in the load, and, if applicable, the results of biological monitoring. This review will enable the person responsible for sterilization procedures to decide whether or not to recall the load.

Rationale: If a chemical indicator is nonresponsive or inconclusive, it is possible that the entire load is nonsterile; that is, the sterilization process failed. Using chemical indicators is only one way to verify sterilizer and cycle performance, however, and chemical indicators vary widely in their response characteristics. It is also possible that errors in loading or packaging have resulted in sterilization failures in

some, but not all, items in the load. Therefore, a single nonresponsive or inconclusive chemical indicator should not be considered *prima facie* evidence that the load is nonsterile. Professional judgment must be exercised in determining whether or not to recall the entire load, taking into account all factors having a bearing on the efficacy of the cycle and all performance indicators.

7.5 Biological indicators

A biological indicator is a sterilization process monitoring device consisting of a standardized, viable population of microorganisms known to be resistant to the mode of sterilization being monitored (in this case, dry heat). Biological indicators are intended to demonstrate whether the conditions in the sterilizing chamber were adequate to achieve sterilization in the location of the chamber where they were placed. 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. Where possible, biological indicators should be placed inside the package or article to be sterilized and positioned in the most difficult-to-sterilize location in the chamber.

7.5.1 Selecting biological indicators

Health care personnel should select biological indicators, consisting of spores of *Bacillus subtilis* var. *niger*, that comply with MIL-S-36586A (U.S. Department of Defense, 1976) and the suggested performance criteria published in the *United States Pharmacopeia*, Volume XXII (or equivalent). In addition, data should be obtained from manufacturers on the reliability, safety, and performance characteristics of their products. Manufacturers of biological indicators should also be required to provide written instructions on the storage, handling, use, and microbiological testing of their products. Additional guidelines on the selection of biological indicators are provided in annex D.

NOTE—At temperature higher than 218°C (425°F), the use of paper spore carriers becomes a concern. At these temperatures, paper begins to char.

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 upon the specific needs, resources, and sterilization equipment of the individual health care facility.

7.5.2 Frequency of use of biological indicators

The type and number of biological indicators used, and the frequency with which they are used, will depend on the cycle parameters, the information that is desired, and the type of sterilizer being used. Table-top gravity convection sterilizers produce greater temperature variations within the chamber than do mechanical convection (forced air) dry heat sterilizers. Whether of the static air-convection or forced-air type, table-top dry heat sterilizers should be biologically monitored during initial installation and after any major repairs (see 7.6). In addition, sterilization loads should be biologically monitored at least once a week (see 7.6). Each load containing implantable devices should be monitored and, whenever possible, the implantable devices should be quarantined until the results of the biological indicator testing are available. Biological indicators should also be used for periodic quality assurance testing of representative samples of actual product being sterilized (see 7.7).

Rationale: The condition of the sterilization equipment, the expertise of the sterilizer operator, and other factors determining the success or failure of a dry heat sterilization cycle may vary from one cycle to another. The less frequently the sterilizer is used, the greater the opportunity for the occurrence of an unnoticed event that could affect sterilization. The use of biological indicators provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores.

Because of the potential consequences to the patient of the implantation of a nonsterile device, the sterilization of implantables must be closely monitored. Ideally, for maximum sterility assurance, each load of implantables should be quarantined until it is verified that biological indicator testing has yielded negative

results. It is recognized, however, that in emergency situations it may not be possible to maintain the quarantine of implantables for which there is an immediate need. Therefore, the recommendation concerning quarantine of implantables, pending the outcome of biological indicator testing, is qualified by the words "whenever possible".

7.6 Sterilizer efficacy testing

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

Routine biological monitoring: All dry heat sterilizers should also be monitored routinely. If the sterilizer is designed to be used for multiple types of cycles, then each sterilization mode should be tested.

7.6.1 Biological-indicator test pack

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

Rationale: There are no universally accepted standardized challenge test packs for dry heat sterilizers. Therefore, it is recommended that a representative package or tray that is to be routinely processed through the sterilizer be used as the test pack. The products used as test packs will vary from office to office, depending on the types of items routinely sterilized.

There are no data to support the need for more than one test biological indicator. There are, however, several considerations in using more than one biological indicator:

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

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

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

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

7.6.2 Test pack placement

All biological monitoring is conducted in the most full or dense load. The biological indicator test pack of 7.6.1 should be placed in the coolest portion of the chamber, as identified by the sterilizer manufacturer.

Rationale: The denser the load, the greater the challenge presented to the sterilization process. Placing the test pack in the coolest area of the chamber likewise maximizes the challenge. The location of the coolest area of the chamber varies with the design of the sterilizer, so the manufacturer is the best source of information concerning the placement of the test pack.

7.6.3 Test procedure

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

a) Before being exposed to the sterilization cycle, the biological indicator test pack must be labeled with appropriate sterilizer information;

b) The test pack is positioned in the chamber according to 7.6.2;

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

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

NOTE—One additional biological indicator from the lot used for testing should be left unexposed to the sterilant, incubated, and treated as a control to verify the presterilization viability of the test spores. If the control from a lot fails to grow, it must be assumed that the test biological indicators from that lot are nonviable or that improper incubation occurred; therefore, the test results must be considered invalid and the test repeated.

7.6.4 Acceptance criteria

For *installation testing*, three consecutive test runs with negative results from the test biological indicators verify that the sterilizer has arrived in good working condition from the manufacturer and will function effectively in the facility in which it is installed.

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

7.6.5 Positive biological indicator results

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

a) Positive biological indicator results (other than viability controls) must be immediately reported by phone or messenger to the appropriate supervisor. This notification should be followed by a written report. The report and notification should include the time and date of the questionable sterilization cycle; a description of the sterilizer and load, with reference to the appropriate lot control number; the results of physical monitoring and of chemical-indicator tests; and any other information that may be useful in determining whether the report is valid or is questionable because of human error.

b) The microbiology laboratory should perform a presumptive identification of the microorganisms present on the positive biological indicator (see 7.6.6) and, if applicable, review the biological indicator transfer technique.

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

d) Because a sterilization failure has occurred, materials processed in that sterilizer, dating from the sterilization cycle having the last negative biological indicator to the next cycle showing satisfactory biological indicator results, must be considered nonsterile; they must be retrieved, if possible, and reprocessed.

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

7.6.6 Culturing of positive biological indicators

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

Rationale: Presumptive identification distinguishes accidental laboratory contamination from sterilization

failure. In the latter case, there would be incomplete destruction of the test microorganisms.

7.6.6.1 Presumptive identification test procedure

A subculture in soybean casein digest medium or nutrient broth is made from the recovered culture and is incubated at 35°C to 37°C (95°F to 98°F) for 24 to 48 hours. Smears of the incubated subculture are prepared, stained by Gram's method, and microscopically examined.

7.6.6.2 Interpretation of results

Presumptive identification should be considered positive for *Bacillus subtilis* var. *niger* if microscopic examination reveals gram-positive, spore-bearing rods and if growth occurs in the culture with a ring or possible pellicle at the air/media surface (orange pigment may be present).

7.7 Periodic product monitoring

A program should be established to monitor the sterilization process periodically by placing biological indicators in various types of packs. Such monitoring should also be performed whenever major changes are made in packaging, product or load configuration, or materials.

Rationale: Because routine biological testing is done on the product most frequently processed, it is important to check the effectiveness of the sterilizer by monitoring other items, packaging materials, and load configurations that may be processed from time to time.

7.8 Product recalls

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

Rationale: To ensure patient safety, the health care facility must establish recall procedures to expedite the retrieval of processed items that are suspected to be nonsterile and to ensure adequate follow-up actions, such as quarantine of the sterilizer, notification of physicians or dentists, and surveillance of patients.

7.8.1 Recall procedure

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

7.8.2 Recall order

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

7.8.3 Recall report

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

Annex A
(informative)
The science of dry heat sterilization

A.1 An historical perspective on dry heat sterilization

Starting with Robert Koch in 1881, dry heat sterilization was branded with the twin epithet, "slow and problematic" (Koch and Wolffhuegel, 1881). Indeed, penetration of dry heat through coverings, such as paper, is much slower than is penetration of moist heat. The application of dry heat in an oven is difficult to control, because the density of the air decreases rapidly as it is heated, promoting stratification. Even if a fan is used to mix cold and warm air, load temperature in ovens is likely to vary because the specific heat of air is low (Hailer and Heicken, 1929). Not surprisingly, a marked aversion developed against this agent, as expressed by one prominent authority (Walter, 1948): "The use of dry heat is limited to the sterilization of articles which do not withstand the corrosive action of steam, anhydrous objects which are spoiled by moist heat, and anhydrous substances which prevent the bactericidal action of moist heat. Cutting edge instruments, surgical gut, ground glass, and dry chemicals such as greases, oils, and glycerine are examples."

Early in this century, health care workers were confronted with a need for dry heat specifications, particularly temperature and time. Around 1930, an upper limit of 160°C (320°F) or thereabouts was set on the basis of metallurgy. Surgical instruments heated much beyond that value could lose their temper (Jeffries and Archer, 1924). In regard to exposure time, quantitative experiments with dry spores in sand heated to 135°C to 145°C (275°F to 293°F) demonstrated a requirement of 15 minutes or less to destroy some 10^6 colony-forming units (Murray and Headlee, 1931; Murray, 1931; Headlee, 1931). In a 1940 study, Oag reported a thermal death time of 9 minutes, when spores of *Bacillus anthracis* dried onto glass were heated at 160°C (320°F). These studies all point out that dry heat can be an efficient means of sterilization if the conditions of exposure are diligently controlled.

Unfortunately, this line of quantitative research never progressed to table-top ovens. In the absence of hard facts, especially data concerning heat transfer within different kinds of loads, the widely accepted standard that did evolve seems most reasonable: 1 hour at 160°C (320°F). So popular was this formulation that it gained equal status with the conditions of steam sterilization most often cited: "In dry heat sterilization an exposure time of 60 minutes at 160°C is approximately the equivalent of 15 minutes at 121°C in moist heat" (McCulloch, 1945). Not to be outdone, the *United States Pharmacopeia*, Volume XV, recommended 170°C (338°F) for 120 minutes (USP, 1955). Similarly, the American Dental Association to this day recommends 160°C (320°F) for 120 minutes (ADA, 1984).

Modern table-top dry heat sterilizers (those manufactured since 1987) have incorporated improved heat transfer techniques using mechanical air circulation, high-speed laminar flow, and higher process temperatures. These improvements, coupled with extensive validation testing required by regulatory agencies, allow the use of fixed exposure cycles and shorter exposure and overall process times.

A.2 How dry heat (heated air) sterilization is accomplished

Dry heated air sterilization is accomplished through the transfer of heat energy to objects upon contact. Microbial destruction results from dehydration, which prevents the cell from reproducing, either by direct effects on the genetic system or by disrupting the metabolic systems that provide the required stimulation and nutrient environment for reproduction.

A.3 Types of dry heat sterilizers

Some types of dry heat sterilizers work by convection heating, others by conduction heating, and still others by radiation heating. Conduction- and radiation-type dry heat sterilizers are not covered in this recommended practice.

There are two basic methods of convective dry heat sterilization: batch and continuous. A *batch process* is one in which a predetermined quantity of items is simultaneously subjected to a convective dry heat sterilization cycle. A *continuous process* is one in which a predetermined quantity of items is processed at a

predetermined rate through a convection cycle. An example of this type would be a conveyorized dry heat process.

All known table-top dry heat sterilizers are of the batch type, because they are simpler to manufacture, install, and operate. Practically all of the batch designs in use today use electrical heating elements as the energy source for heating air. A typical batch cycle is usually made up of three phases: (a) heat-up, (b) exposure and hold, (c) cool-down.

The simplest batch-type dry heat sterilizer is the *static air type*, in which heating is by natural convection (gravity). This type of sterilizer is usually preheated to the desired temperature, the load is placed into the heated chamber, the load is heated for an established period, and the load is then removed and allowed to cool naturally (figure A.1, p. 18).

Other batch-type dry heat sterilizers operate by *forced air*; some of these sterilizers use *continuous heating*, and some use *heating from ambient temperature*. In the continuous-heating type, continuous, high-velocity, heated air is circulated through the chamber. A load is placed into the continuously heated chamber, and an exposure time is selected. The cool load causes the chamber temperature to decrease. The load and chamber are heated to the pre-established temperature, and the selected exposure time commences once the chamber temperature recovers to its pre-established level. At the end of the exposure period, the load is removed from the chamber and allowed to cool. (See figure A.2.)

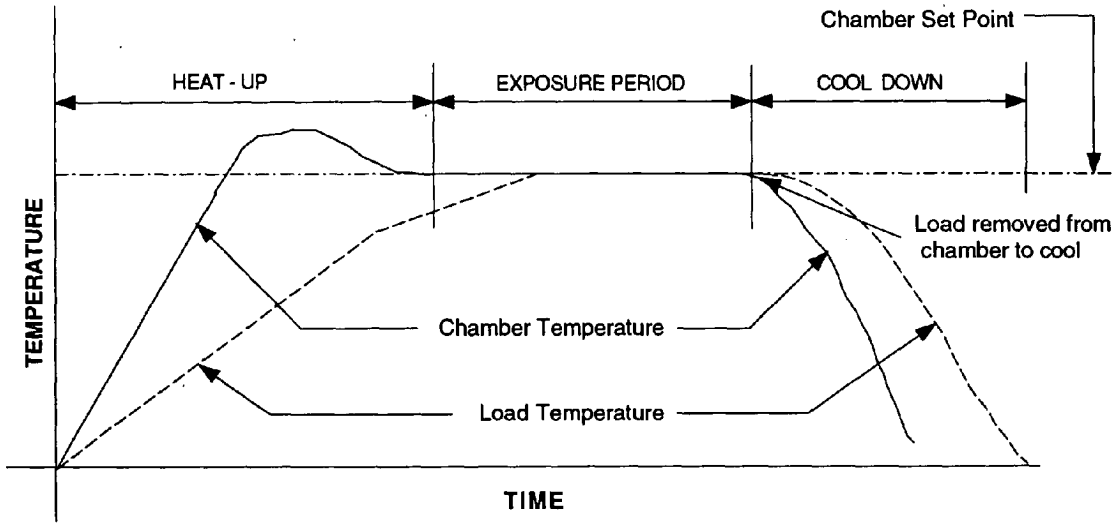

Figure A.1—Batch cycle: convective dry heat (static air)

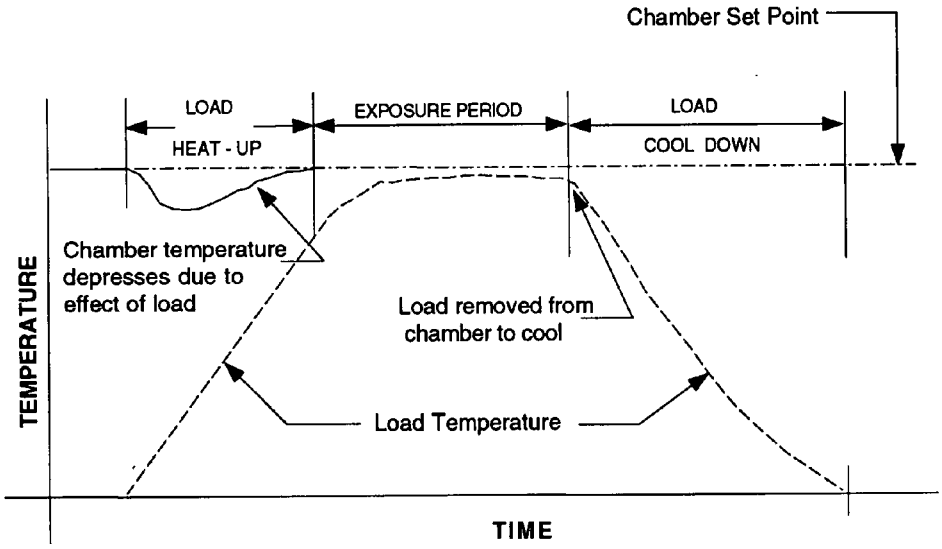

Figure A.2—Batch cycle: convective dry heat (forced air) with chamber heat continuously maintained

In sterilizers using heating from ambient temperature, a load is placed in an otherwise cold (room temperature) sterilizer chamber, the processing conditions are selected, and the cycle is started. The chamber and load are simultaneously heated by high-velocity heated air. Exposure time commences when a pre-established chamber temperature is achieved. At the end of the exposure period, the load is allowed to cool in the chamber until safe to handle. (See figure A.3, p. 19.)

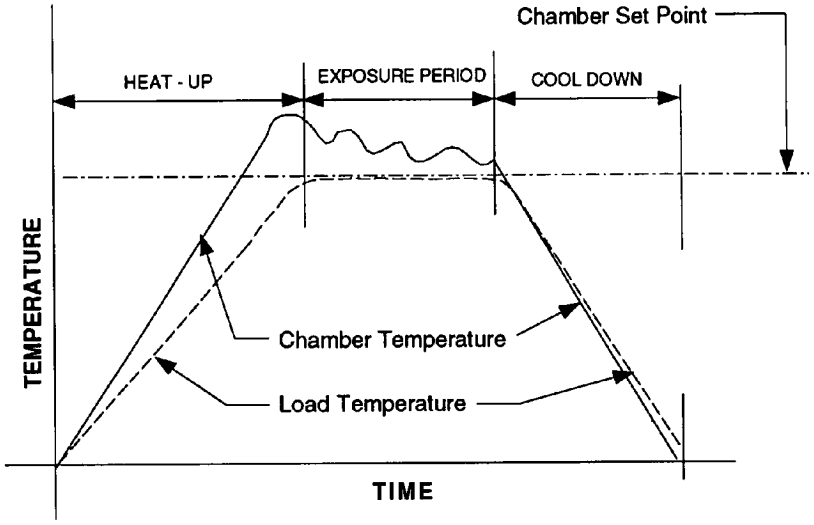

Figure A.3—Batch cycle: convective dry heat (forced air); load remains in chamber during cool-down

A.4 Variables associated with the dry heat sterilization process

The major process variables associated with dry heat sterilization are as follows:

a) *Temperature:* The most important variable in dry heat sterilization is temperature. It is the measure of heat energy level(s) available during the sterilization process. The effect of heat energy is a function of time. As the temperature is increased, the necessary exposure time is reduced.

b) *Time:* Sterilization science has defined time as the cumulative interval over which microbial destruction takes place. This is also referred to as integrational lethality. To simplify this concept and

also to provide a margin of safety, sterilization engineers use the term "exposure time" to mean the time at which a load has been exposed to a predetermined temperature profile or a specified temperature designed to achieve sterilization.

c) *Air flow rate and distribution:* Air flow, whether by convection or by mechanical means, and air distribution are factors affecting heat energy transfer efficiency. The heated air must be distributed uniformly within the load. Optimal air velocity reduces microorganism resistance via dehydration, resulting in reduced sterilization times.

d) *Load configuration/distribution:* The size and density of the load, as well as the number and shapes of instruments contained in the load, can affect air flow rate and distribution in the sterilizer.

The lethality of the dry heat sterilization process is also affected by the water content of the microorganisms, the physical and chemical properties of the microorganisms and adjacent support, the extent to which the microorganisms are protected from the sterilizing agent, and the gas atmosphere.

A.5 How dry heat sterilization is measured

As a load contaminated with microorganisms is heated, microbial destruction ensues at some minimum temperature and increases in rate as heating proceeds.

A.5.1 Indirect measurement

The most common technique is to maintain a specified temperature for a prescribed time. This heat dosage is called "exposure time," which is an indirect measurement of microbial destruction.

A.5.2 Direct measurement

In some dry heat sterilizers, microbial destruction can be tracked as it occurs if the killing power (lethal rate) is known for the temperatures to which the load is exposed and if this information is programmed into the device. In practice, a load signals its temperature to a time-keeping microprocessor, which converts that temperature to a lethal rate and integrates that rate over the time held into quantitative lethality. As exposure continues, the cumulative sum of these incremental lethalities converges on sterilization.

A.6 Typical items sterilized by dry heat

Dry heat sterilization is commonly used for items that can withstand the high temperatures of this process, such as dental instruments, burrs, reusable needles, glass syringes and medical instruments, glassware, heat-stable powders, and heat-stable oils. For any given item, the manufacturer's written instructions should be consulted to verify that dry heat sterilization is appropriate.

Annex B
(informative)
Examples of workplace design

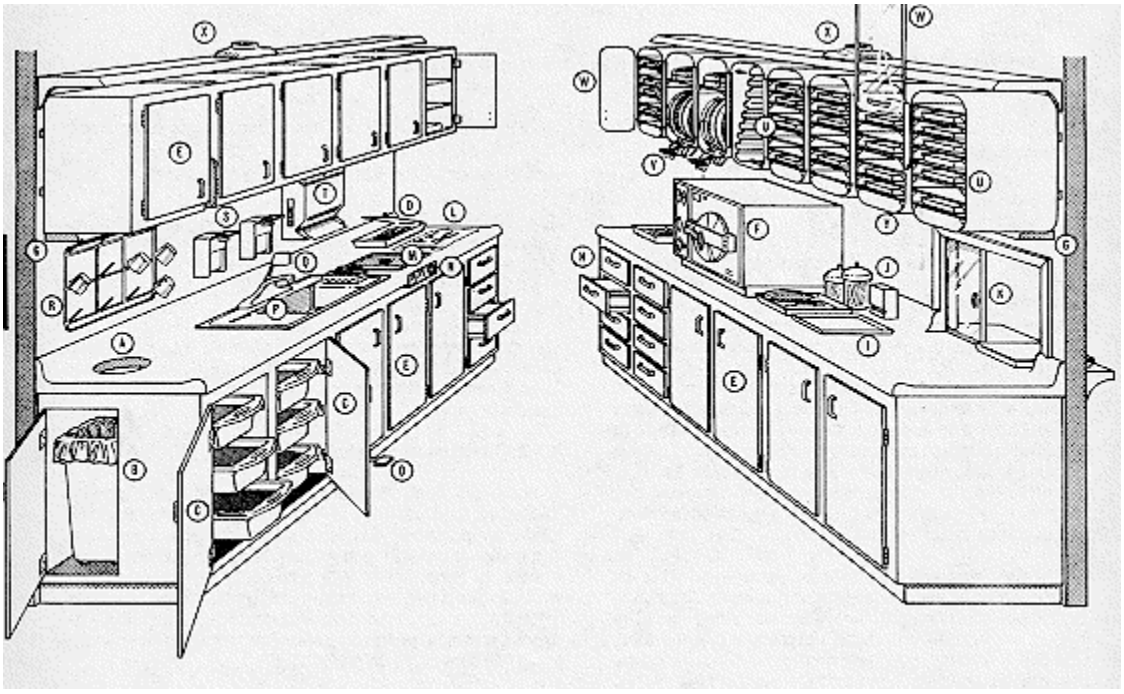

Figure B.1—Example of a double-wall instrument recirculation center (Reproduced, with permission of the publisher, from Runnells, R. [1987].)

Legend for figure B.1:

A = Large-capacity, surface-flush waste disposal

B = Waste disposal cabinet door in rear of cabinetry to utilize space

C = Storage space for holding contaminated instruments in covered container immersed in disinfectant until ready for cleaning

D = Foot control for sink faucet

E = Bulk supply storage

F =Sterilizer, cabinet-top or recessed on reinforced mobile glides

G = Lights

H = Drawers for process indicators, monitors, transfer forceps, and similar items

I = Clean surface for final sterile tray preparation

J = Containers for presterilized or industrially clean disposable items

K = Pass-through window to treatment area

L = Drying surface for items to be sterilized

M = Recessed ultrasonic cleaner

N = Ultrasonic cleaner controls

O = Disinfectant for temperature-sensitive items

P = Stainless steel sink with sloping drain to contain contaminated drain water

Q = Arm-actuated water temperature mixture control

R = Glassware drying rack

S = Arm-actuated soap and lotion dispenser

T = "No touch" paper towel dispenser

U = Sterile tray storage cabinets with removable, disinfectable slides

V = Packaging supplies and "cut to size" see-through bags

W = Glass or solid doors

X = Low-volume air evacuation system with microbial filter

Y = Air movement space between cabinets

Annex C
(informative)
Guidelines for the selection of chemical indicators

C.1 Introduction

The dry heat sterilization process and its outcome must be frequently monitored to ensure that all items have received a lethal dose and that the equipment is functioning effectively. Proper sterilization of devices and materials is an important aspect of the modern health care delivery system, whether it be in private dental or medical offices, in hospitals or clinics, or in industry.

Experienced practitioners use chemical indicators as an adjunct to mechanical monitors and biological indicators in an effort to achieve a system of "checks and balances." It should be understood that chemical indicators are not sterility indicators. They merely indicate that a device or material has been subjected to some parameter(s) of the sterilization process.

C.2 External chemical indicators

At the present time, the only external chemical indicators available for use in dry heat sterilization are pressure-sensitive labels and tape impregnated with temperature-sensitive indicator inks.

Advantages

a) Can be used over a wide temperature range;

b) Can be placed on each package to be sterilized;

c) Inexpensive.

Disadvantages

a) The surface to which the indicator is applied must be clean or the label will fall off during sterilization;

b) When applied to paper surfaces, the label will lose its adhesive qualities at temperatures above 375°F;

c) The label cannot be used at temperatures above 400° F, as it will char;

d) The label can lose its adhesive qualities if stored under adverse conditions;

e) "Baked-on" adhesive residues may remain on instruments or containers.

C.3 Internal chemical indicators

C.3.1 Time-temperature integrating color-change inks on strips or labels

Advantages

a) Can be used over a wide time and temperature range;

b) Can be placed inside the package to be sterilized;

c) Inexpensive.

Disadvantages

a) Will not be visible in all paper packaging.

C.3.2 Time-temperature integrating indicators with color-change liquids sealed in glass ampules

Advantages

a) Accurate to within ± 2°F at stated temperature or temperature range;

b) Can be placed inside of packages;

c) Easily interpreted.

Disadvantages

a) More expensive than indicator labels;

b) Must be cooled before they can be safely handled;

c) Potential breakage of ampule.

C.3.3 Temperature-sensitive pellets in glass ampules

Advantages

a) Accurate to within ± 2°F at stated temperature or temperature range;

b) Can be placed inside of packages;

c) Easily interpreted.

Disadvantages

a) More expensive than indicator labels;

b) Must be cooled before they can be safely handled;

c) Indication is temperature-sensitive *only;* cannot determine whether temperature was achieved for the desired time;

d) Potential breakage of ampule.

C.3.4 Time-temperature integrating pellets in glass ampules

Advantages

a) Accurate to within ± 2°F at stated temperature or temperature range;

b) Can be placed inside of packages;

c) Easily interpreted.

Disadvantages

a) More expensive than indicator labels;

b) Must be cooled before they can be safely handled;

c) Potential breakage of ampule.

Annex D
(informative)
Characteristics of biological indicators used to monitor dry heat sterilization

D.1 Introduction

Biological indicators used to monitor sterilization processes in health care facilities represent a worst-case microbial load challenge to the sterilization process. Because the resistance of naturally occurring microorganisms varies according to species, environment, and protection, it is necessary to use a biological indicator with a population of high resistance to the specific sterilization process being monitored. *A biological indicator can only demonstrate that the conditions necessary for sterilization were met; it cannot by itself validate that device sterility was actually achieved.*

"Sterility" has been defined as an absolute condition referring to the absence of living organisms. Populations of microorganisms are considered to die in a logarithmic fashion; that is, the same percentage of microorganisms dies during every minute of exposure to the sterilant. Consequently, in practice, it is necessary to define the sterility of an item in terms of a "probability of survivors." Theoretically, absolute sterility is never achieved; some fraction of the original microbial population remains viable. When an estimated number of survivors becomes small, fraction-negative results are observed; that is, a portion of the processed biological indicators will be nonviable. This portion of the survival curve is known as the area of probability of survivors. The fractional values refer to the probability that a survivor could be found from the original population. Therefore, it can be seen that not all biological indicators will be killed at the same exposure time.

Sterilization scientists have developed a mathematical description of this biological phenomenon: the decimal reduction time or D-value. The D-value is defined as the time necessary to reduce a given microbial population by 90 percent (one logarithm). The D-value permits scientists to estimate the probability of a nonsterile item (figure D.1).

D.2 Types of biological indicators

Only one type of biological indicator is commercially available for use in dry heat sterilization: filter paper strips impregnated with *Bacillus subtilis* var. *niger* or with a combination of *B. subtilis* var. *niger* and *B. stearothermophilus*. Spore strips with both spores present may be used to monitor most sterilization processes, including dry heat, ethylene oxide, saturated steam, and unsaturated chemical vapor sterilization processes. The strips are usually packaged individually in glassine envelopes.

Advantages

a) Causes little or no interference with heat penetration;

b) Allows detection of slow-growing and debilitated organisms;

c) Spore population can be carefully controlled;

d) Can detect laboratory contamination;

e) Reflects lethal process occurring in the sterilizer.

Disadvantages

a) Use becomes marginal at temperatures above 400°F;

b) Requires aseptic culturing techniques;

c) Relatively long period of time before results obtained.

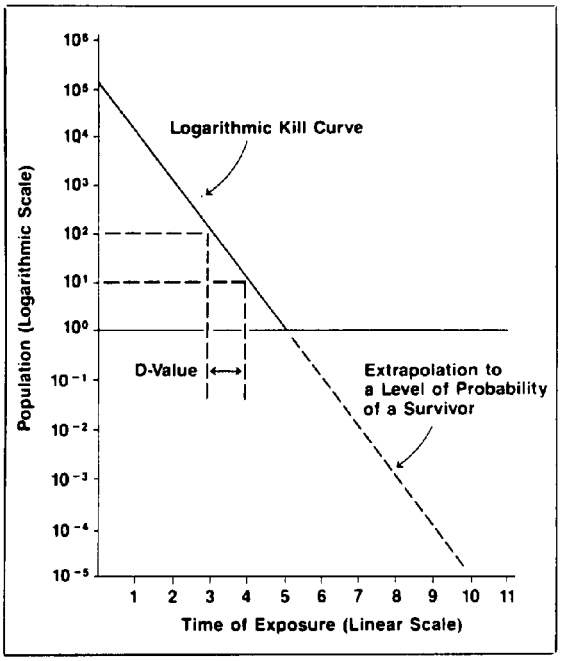

Figure D.1—Kill kinetics of microorganisms (Reproduced from AAMI [1991].)

Annex E
(informative)
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