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# Technical Information Report

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# Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers

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**Technical Information Report No. 12**

# Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A guide for device manufacturers

(AAMI TIR12—1994)

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

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# Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers

### 1 Introduction and scope

Scientific advances in diagnostic and therapeutic medicine have led to the development of new and

sophisticated reusable medical devices and instruments for use by health care practitioners. These devices vary in size, complexity, fragility, immersibility, and sensitivity to cleaning, disinfecting, and sterilization agents and processes. Manufacturers of reusable medical devices have the responsibility to support product label claims of reusability by providing complete and comprehensive written instructions for the handling, cleaning, disinfection, packaging, sterilization, and, if applicable, aeration of their products. Manufacturers also have the responsibility to conduct and document any testing necessary to support these instructions. Health care personnel, on the other hand, have the responsibility to review manufacturers' data and recommendations and to ensure that they have the necessary resources to follow manufacturers' instructions scrupulously.

All too often, health care professionals responsible for the reprocessing of reusable medical devices are frustrated by the lack of adequate cleaning and disinfection/resterilization instructions from device manufacturers. For their part, device manufacturers may not appreciate the need for this type of information or may find it difficult, in many instances, to anticipate the conditions under which their products will be reprocessed, complicating their efforts to develop cleaning instructions and disinfection/sterilization parameters which will assure that disinfection or sterility can be attained without compromising functionality.

This technical information report (TIR) is intended to assist medical device manufacturers in the design, testing, and labeling of devices intended for reuse and reprocessing in health care facilities. Device manufacturers may wish to reassess the labeling of existing products in the light of the recommendations of the TIR.

Secondarily, the TIR can also be a resource in identifying the questions health care professionals should ask manufacturers when considering a product for purchase or when devising a reprocessing protocol for a product already being used.

The scope of this report includes:

- *Design considerations:* Assurance that a device can be safely and effectively reprocessed begins with the design of the device. Chapter 3 of the TIR describes the materials and other design characteristics that affect the ability of health care personnel to adequately clean, disinfect, and/or resterilize devices;
- *Decontamination:* A device cannot be disinfected adequately or sterilized to an adequate sterility assurance level if it cannot be cleaned thoroughly. Chapter 4 addresses variables associated with cleaning and other decontamination processes used in health care facilities, as well as the minimum information that should be supplied to health care personnel by the device manufacturer;
- *Disinfection:* Chapter 5 describes the levels of disinfection, criteria for selecting chemical disinfectants, and the testing that should be performed by device manufacturers to establish the effectiveness of the disinfection processes recommended for their products;
- *Sterilization:* Chapter 6 describes sterilization processes commonly used in health care facilities, the minimum information that device manufacturers should provide with their products, and the procedures that device manufacturers may use to qualify the sterilization parameters that they recommend for their products;
- *Device/sterilant/equipment compatibility:* Chapter 7 addresses special considerations related to the interaction of medical devices with cleaning and sterilizing agents or equipment, and the need to harmonize the recommendations of the device manufacturer, the cleaning/sterilizing agent manufacturer, and the equipment manufacturer;
- *Regulatory considerations:* Chapter 8 provides an overview of Food and Drug Administration (FDA) regulation of medical devices.

The TIR also provides definitions of terms, a list of references, and annexes supplying supplementary information.

NOTE—This TIR does not cover the design, testing, and labeling of reusable textiles.

NOTE—The term "should," as used in this TIR, reflects the committee's recommendations. The term "must," as used here, denotes provisions that the committee particularly wishes to emphasize.

## 2 Definitions of terms

**aerator, ethylene oxide:** machine designed to speed the removal of ethylene oxide residuals from sterilized items by subjecting sterilized items to warm, circulating air.

**antigen:** according to Dorland (1982), "any substance capable, under appropriate conditions, of inducing a specific immune response and of reacting with the products of that response . . . Antigens may be soluble substances, such as toxins and foreign proteins, or particulate, such as bacteria and tissue cells . . ."

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

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

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

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

**chemical germicide:** disinfectant/sterilant which is labeled to disinfect or sterilize a medical device.

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

NOTE—Chemical indicators are intended to detect potential sterilization failures that 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.

**cleaning:** 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.

**D value:** exposure time required under a defined set of conditions to cause a 1-logarithm or 90% reduction in the population of a particular microorganism.

NOTE—The larger the D value, the more resistant the microorganism is to destruction. The value can be derived by plotting the logarithm of the number of microbial survivors against sterilization exposure time; the time corresponding to a 1-logarithm reduction in numbers may then be directly measured.

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

NOTE—In common usage, "decontamination" generally refers to all pathogens (microorganisms capable of producing disease or infection), not just those transmitted by human blood.

**device:** according to the Federal Food, Drug and Cosmetic Act, "an instrument, apparatus, implement,

machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official *National Formulary*, or the *U.S. Pharmacopeia*, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals . . . ." [21 CFR 201(h)]

**disinfection:** destruction of pathogenic and other microorganisms by thermal or chemical means. Disinfection is a less lethal process than sterilization, since it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes.

**endotoxin:** high-molecular-weight complex associated with the outer membrane of gram-negative bacteria. Endotoxins are pyrogenic and increase capillary permeability regardless of the species of bacteria.

NOTE—The biological effects of endotoxin have been demonstrated experimentally to produce the same symptoms as those seen in humans with gram-negative sepsis (e.g., fever, leukopenia, capillary hemorrhage, hypotension, and circulatory collapse).

**ethylene oxide sterilization:** sterilization process that utilizes ethylene oxide (EO) gas under defined conditions of gas concentration (milligrams EO per liter), temperature, and relative humidity.

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

**health care facility:** hospital, nursing home, extended care facility, free-standing surgical center, clinic, medical office, or dental office.

NOTE—For convenience, the term *hospital* is sometimes used in this TIR. In all instances, this term should be taken to encompass all other health care facilities.

**pasteurization:** intermediate-level disinfection process using hot water at temperatures of 65°C to 77°C (150°F to 170°F) for a contact time of at least 30 minutes.

**pyrogen:** fever-producing substance.

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

**reusable medical device:** device intended for repeated use on different patients, with appropriate decontamination and other processing between uses. Examples include surgical instruments, endoscopes, basins, and electromedical equipment.

**sanitization:** according to Block (1991), "the act of reducing the number of bacterial contaminants in the environment to a safe or relatively safe level as may be judged by public health requirements or at least to a significant degree where public health standards have not been established. Block (1983) qualifies the definition of a sanitizer in that such an agent is ordinarily used on an inanimate surface."

NOTE—There are currently no standards in the medical device industry or health care community defining "sanitization" in terms of time/temperature relationships or a specific reduction in the number of microorganisms. Mechanical sanitization equipment in health care facilities generally operates at 49°C to 79°C (120°F to 175°F) for exposure times of 2 to 10 minutes, and it is typically used to reprocess items of simple design that will only be in contact with intact skin.

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

**sterile/sterility:** state of being free from all living microorganisms; in practice, usually described as a

probability function, e.g., the probability of a surviving microorganism being one in a million.

**sterility assurance level:** probability of survival of microorganisms after a terminal sterilization process, and a predictor of the efficacy of the process.

NOTE—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 (e.g., 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.

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

## 3 Design considerations

A medical device intended for reuse must be designed to assure that it will perform safely and effectively throughout its useful life if reprocessed according to the device manufacturer's instructions, and must be designed to assure that health care personnel will be able to thoroughly clean and effectively disinfect/sterilize the device repeatedly throughout its useful life.

Four major design aspects of devices intended for reuse should be considered during the design process:

- physical design considerations;
- material design considerations;
- total system design considerations;
- user design considerations.

In addressing each of these aspects, the design process should take into account the function of the end product. The function of the end product is affected by the definition of the user (who uses it), the conditions of use (where it is used), the function of the device (what it does), the operation of the device (how it works), and the need for the device (why it is used).

These issues will be most effectively addressed if design development is conducted in consultation with the manufacturer, users, and professional organizations. Product consultation among the affected parties will help manufacturers provide health care personnel with the necessary information and criteria for reprocessing, and will assist health care personnel in determining whether the device can be reprocessed and maintained with the equipment and packaging methodologies available to them.

### Physical design considerations

Device manufacturers must establish whether the size, shape, or configuration of their devices imposes any constraints on the ability of health care personnel to clean, disinfect, or sterilize the device. Device manufacturers must avoid designs that create areas inaccessible to adequate cleaning but accessible to bacteria, patient fluids, patient tissue, and/or materials supportive of microbial growth. Designs that could result in retention of toxic cleaning/sterilizing agents must also be avoided.

It is also important to establish that the device can be disassembled for sterilization, if necessary, and safely reassembled for use under aseptic conditions. The ease of disassembly and reassembly, including such factors as the number and sizes of parts, should be considered, as well as the vulnerability of the design to incorrect assembly. The manufacturer should attempt in the design to limit or avoid the use of additional agents in reassembly, or should establish the safety of any such additives; these agents may include adhesives,

chemicals, or lubricants.

A device must be designed so that its size and configuration do not present any difficulties relating to presentation to the sterile field.

In the design process, device manufacturers should develop criteria for selecting packaging for reprocessing. Consideration should be given to:

- the compatibility of the packaging with device materials;
- the use of packaging materials commercially available to health care facilities;
- the compatibility of a wrapped device with the planned sterilization process;
- the need for effective air removal, moisture removal, and sterilant penetration and/or aeration in commonly used steam, EO, or other sterilization processes;
- whether packaging, containment, and/or placement criteria are required for other sterilization cycles (e.g., flash sterilization, dry heat sterilization, chemical vapor sterilization, liquid chemical sterilization);
- the ability of a packaged device, considering size, weight, and configuration, to be aseptically presented to a sterile field;
- the need for a protective organizing container system to protect or hold a device in place during sterilization, and the impact of such a system and any system accessories on sterilant contact and moisture removal.

Devices must be evaluated for any internal stresses built into them by their design and/or manufacture; for potential external stresses, such as bending, flexing, twisting, or pressing; and for the effects of cleaning/resterilization procedures in combination with such stresses. Designs with small, narrow openings should be avoided, as these openings could provide sites for corrosion if the materials are susceptible to corrosion by cleaning or sterilizing agents. (See also the next section.)

## Material design considerations

It must be established that the materials used in the construction of devices will be stable in the presence of recommended chemical agents and under expected environmental conditions (temperature, pressure, humidity). Manufacturers must also demonstrate that these materials will not release any toxic breakdown products as a result of the recommended cleaning, disinfection, and/or sterilization procedures. Where there is the potential for toxic breakdown products, manufacturers of "critical" or "semicritical" devices must follow the principles of biocompatibility testing outlined in AAMI (1994a), as appropriate for the intended use of the device.

If any materials in a device are adversely affected by the recommended cleaning, disinfection, or sterilization procedures, the limits of reuse must be determined. The impact of the cleaning, disinfection, and/or resterilization process on a device's materials degradation must also be evaluated. When storage conditions could affect the safety and functionality of the device, the device manufacturer should recommend optimum storage conditions.

### *Polymeric materials*

Many polymeric materials will not withstand saturated steam or dry heat sterilization. Such materials can also be susceptible to damage by certain chemical cleaning agents, disinfectants, or sterilants. Materials incompatibility could be manifested by the polymer crazing (thin silver streaks appear), cracking, swelling, dissolving, softening, or becoming brittle. Any one of these changes in the polymer could lead, in time, to poor device performance or even failure.

Many factors affect the chemical interaction between polymeric materials and disinfectants/sterilants. The major factors of concern are:

- the chemical nature of the disinfectant or sterilant (including inert ingredients);
- the type(s) of plastic involved;
- the conditions of use, such as the disinfectant/sterilant concentration, temperature, and contact time;
- the internal stresses built into the device by its design and/or manufacture;
- the external stresses on the device, such as bending, flexing, twisting, or pressing.

There are over 20 generic families of polymeric materials used in the manufacture of medical devices. These polymer families vary greatly in chemical formulation and will react differently to various chemicals, disinfectants, and sterilizing agents. While one type of sterilant or sterilization process might be compatible with a particular polymer, another could attack the polymer.

The conditions of use are significant in determining materials compatibility. In general, the probability of damage to a polymeric material increases with higher disinfectant/sterilant concentrations, higher temperatures, and longer exposure times.

A poorly designed device is more likely to be damaged by a chemical than is a well-designed product. A device with sharp corners, for example, is more likely to fail because of high internal stresses due to the part design.

Exposure of a device to a critical stress or load combined with exposure to a chemical disinfectant or sterilant can accelerate device or component degradation. While the polymeric material may be able to hold up to the stresses and chemical exposure separately, exposure to both at the same time could cause failure. This phenomenon is known as environmental stress cracking (ESC). Eliminating or decreasing the stress or changing the type of disinfection or sterilization process will help to alleviate the problem.

***Metals***

Devices manufactured from metal or containing metal components are susceptible to corrosion by cleaning, disinfecting, or sterilizing agents. The most common type of metal used in the manufacture of reusable medical devices is stainless steel. The classes of stainless steels and their various alloy compositions have a wide range of performance properties and corrosion resistance. While relatively impervious to organic solvents, stainless steels can be affected by exposure to certain inorganic solutions and acids. The two classes of stainless steel most commonly used in the medical device industry are austenitic stainless steel, known for its superior corrosion resistance, and martensitic stainless steel, also known as "hardened" stainless steel.

Stainless steel corrosion generally manifests itself as surface blemishes such as roughness and rust. These surface imperfections can lead to difficulties in cleaning or sterilization and may indicate sites at which future device failure may occur. Stainless steels corrode via a number of different mechanisms. The three most frequently encountered failure mechanisms are: (1) pitting; (2) crevice corrosion; and (3) stress corrosion cracking (SCC) or hydrogen cracking.

Pitting of stainless steel instruments, caused by exposure to chloride- or bromide-containing solutions, is a highly localized corrosion of the steel, resulting in shallow-to-deep penetrations. Chloride pitting is the downfall of typically corrosion-resistant austenitic stainless steel and is most commonly caused by exposure to sodium chloride (i.e., saline) used to moisten sponges for irrigation. Exposure to high chloride concentrations, elevated temperatures, and stagnant solutions increases the likelihood and severity of pitting.

Crevice corrosion is another localized form of corrosion that can occur whenever a shielded crevice allows an aggressive solution to stagnate. Red rust found in small, narrow openings indicates crevice corrosion. Small crevices such as joint sites, corners, port connections, and gasket areas are likely places for crevice corrosion to occur. Designing the device to minimize crevices and/or assuring that the cleaning process can remove stagnant solutions from crevices decreases the likelihood of crevice corrosion.

Hydrogen cracking and stress corrosion cracking are similar to the ESC phenomenon that occurs in polymeric materials. The corrosion cracks that propagate through stainless steel result from residual or applied stress on the steel in conjunction with exposure to an aqueous corrosive environment. Elevated temperatures increase the amount of corrosion cracking.

In the early stages of corrosion, the effects on stainless steel are primarily aesthetic. However, if the corrosion is allowed to continue, device failure may eventually occur. Corrosion may also interfere with proper cleaning and, as a consequence, inhibit effective disinfection or sterilization. Minimizing the concentration of the corrosive agent, the temperature, and/or the exposure time decreases the likelihood of failure due to corrosion (but may reduce the effectiveness of the disinfectant or sterilant).

### Total system design considerations

The design elements (components, subassemblies, and/or complete device) must be evaluated for the stresses imposed by cleaning, disinfection, and/or sterilization procedures in combination with all other expected stresses on the device system (e.g., mechanical, electrical, environmental).

The stresses of the cleaning/disinfection/sterilization procedure should be evaluated in terms of any effect on the device's compatibility with other devices in the intended operating system.

Device design must also incorporate features to ensure that the device or the cleaning, disinfection, and/or sterilizing agents that will be used to reprocess it can be discarded in an environmentally safe manner. The potential for recycling should also be considered.

### Use-related design considerations

The design process should include a risk assessment to identify the potential for device damage if inappropriate cleaning, disinfection, and/or sterilization processes are used. It might be desirable for the manufacturer to permanently attach a warning to the device and/or provide a warning in the information manual if serious damage could occur (e.g., the immersion of powered equipment).

## 4 Decontamination

Decontamination of reusable medical devices is a multistep process that includes preparation at point of use, thorough cleaning and rinsing, and, when necessary to ensure employee safety, an additional microbicidal process.

Thorough cleaning and rinsing are the first and most important steps in the reprocessing of any reusable medical device. Without thorough cleaning and rinsing, it might not be possible to achieve high-level disinfection or sterilization of the device. The purpose of cleaning and rinsing is to remove all adherent visible soil (e.g., blood, protein), to reduce the number of particulates and microorganisms, and to reduce the amount of pyrogenic and antigenic material. Any organic material or residual cleaning agents remaining on a device can inactivate liquid chemical disinfectants/sterilants as well as protect microorganisms from destruction.

The second step in decontamination is the microbicidal process, which has been defined by AAMI (1991) as "a process designed to provide a particular level of microbial lethality (kill). Depending on the level of decontamination needed, this process could be a sanitization process, a disinfection process, or a sterilization process. The type and level of microbial kill achieved depends on factors such as the type and population of microorganisms present, the type of antimicrobial agent, the concentration of the antimicrobial agent, the

exposure time, and the exposure temperature. When used for decontamination purposes, a microbicidal process does not necessarily yield an item that is safe for patient use."

To assure users that the product can be successfully decontaminated, device manufacturers should develop decontamination recommendations that:

- provide for thorough cleaning and defined microbial lethality;
- can be performed in the hospital using commonly available supplies and equipment;
- can be duplicated by hospital personnel;
- are in alignment with professional recommendations and with OSHA regulations for minimizing occupational exposure to bloodborne pathogens.

This chapter discusses cleaning agents, supplies, equipment, and procedures commonly used in health care facilities and the cleaning-related information that device manufacturers should develop and disclose to prospective users to assure that their products can be decontaminated. AAMI (1991) provides further guidance on decontamination procedures used in health care facilities.

## Common hospital cleaning/decontamination agents and procedures

Familiarity with common hospital processing procedures and with recommended practices published by professional organizations is needed if the information developed by device manufacturers is to be relevant.

As noted previously, cleaning is the first step in the decontamination process and is defined by AAMI (1991) as "the removal, usually with detergent and water, of all 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."

A variety of cleaning products, supplies, equipment, and procedures are used to decontaminate reusable medical devices. Not all cleaning and decontamination procedures are appropriate for all types of instruments and devices. The device manufacturer should specify, in written instructions, the specific cleaning agents and procedures that should be used to avoid damaging the device. It is recommended that the device manufacturer consult with manufacturers of cleaning products and equipment to develop these instructions.

### *Preparation at point of use*

In health care facilities, the cleaning of reusable devices usually begins soon after use. At the point of use, personnel wearing gloves and other protective attire separate disposable items or components from reusable devices and discard them in appropriate receptacles. Soil is wiped from device surfaces with a moist sponge or towel. The soiled/contaminated items are then contained in a manner that will reduce the risk of employee exposure to pathogens. Instruments or devices that have been used in a surgical procedure are usually placed in an instrument basket and covered with a towel that has been moistened with distilled water to prevent the blood and body fluids from drying. The basket or tray of instruments is then placed in an impervious bag or rigid container for transportation to the processing area. If the instrument has any sharp edges or can cause a puncture or abrasion during handling, a puncture-resistant container should be used, as prescribed by OSHA. Contaminated or soiled items are usually transported in or on a cart, as hand-carrying of soiled items is discouraged.

### *Cleaning agents*

To be effective, cleaning agents must assist in the removal of residual organic soil without damaging the device or the interior surfaces of cleaning equipment. No single cleaning agent removes all types of soil or is safe to use with every type of reusable device and cleaning equipment. Certain cleaning agents may damage metal or other device materials. Cleaning agents should be used in the correct dilution/concentration and at the

correct temperature in accordance with the cleaning agent manufacturer's directions. It is ultimately the user's responsibility to choose the correct cleaning agent, based on the instructions of the device manufacturer and any recommendations of the cleaning equipment manufacturer.

*Enzyme products* are commonly used in the processing of difficult-to-clean instruments such as vascular instruments, microinstruments, and instruments with lumens. Most major product lines of instrument cleaners include an enzymatic product. These various enzymatic formulations contain different types of enzymes (e.g., protease, lipase, amylase) and differing amounts of enzymes and other ingredients (e.g., wetting agents, surfactants). An enzyme is not a cleaner. An enzyme is intended to break down blood and body fluids (i.e., protein) and thus facilitate cleaning. Enzymes are themselves protein substances and must be thoroughly removed with a detergent. Some products are combinations of enzymes and detergents.

*Detergents* are generally recommended and used for cleaning medical devices and instruments. Detergents are any of a group of synthetic, organic, liquid, or water-soluble powders that contain wetting and emulsifying agents that suspend soil and prevent the formation of insoluble compounds or scum on the device or on the surface of the cleaning solution.

Detergents of neutral pH (7) are usually recommended for cleaning surgical instruments because metal surfaces can be damaged by harsher detergents. However, a neutral-pH detergent does not necessarily provide good cleaning. Some types of automatic washer-decontamination equipment use a detergent of higher pH (8 to 11), followed by rinsing with a neutralizing agent. There are also detergents in the acidic range that are used for manual cleaning. Thorough rinsing with water is necessary to protect instrument surfaces from damage.

*Detergent disinfectants* combine detergent-type cleaning agents with a chemical disinfectant. The use of detergent disinfectants usually involves a multistep process. Like all disinfectant solutions, a detergent disinfectant must be in contact with the microorganisms for sufficient time to achieve microbial kill; however, the exposure time required is not always specified on the product label.

Rinsing is necessary to remove all traces of detergents and extraneous debris. Water quality should be considered when developing and testing decontamination procedures. Some hospitals use filtered water systems in central service; however, tap water is the most common rinsing agent. Water hardness, temperature, and the type of soil affect the effectiveness of detergents and, consequently, the effectiveness of the cleaning process. Water particulate varies from one area to another and from season to season within the same area. If an analysis of the water used in the testing was performed, the results should be available for review by the prospective device user.

After devices are rinsed, they are visually inspected for cleanliness and working condition and then dried. Water droplets remaining on a device provide favorable conditions for microbial growth and survival, inhibit ethylene oxide and other sterilization processes, dilute liquid chemical disinfectants/sterilants, and can cause rusting or spotting of device surfaces. Surgical instruments with moving parts, hinges, and box locks can require lubrication. If lubrication is necessary, it is common practice to either immerse instruments for a few moments in a water-soluble lubricant solution or spray them with a water-soluble lubricant solution. After removal from the lubricant, instruments are allowed to air-dry or are dried by hand or by forced air. Silicone- or oil-based lubricants are not recommended for use because sterilants cannot penetrate the oil, which coats the microorganisms and thus inhibits sterilization.

*Cleaning supplies* are very basic, usually consisting of a surgical scrub brush, chenille pipe cleaners, cotton-tip applicators, several sizes and lengths of brushes, and a soft cloth. AAMI (1991) recommends that brushes and other cleaning implements be cleaned and disinfected or sterilized daily.

### *Cleaning methods and equipment*

Cleaning can be accomplished by hand, by one of several types of mechanical equipment available for health care processing procedures, or by a combination of manual and mechanical methods.

*Manual cleaning* is the most universal method of cleaning used by health care facilities. In many facilities, washing by hand is the only method available for the cleaning of reusable devices, instruments, and equipment. Manual cleaning may be required for certain delicate or complex medical devices, such as microsurgical instruments, lensed instruments, and air-powered drills. It is generally recommended that immersible devices be cleaned under water to prevent aerosolization of microorganisms. For devices that cannot be immersed, it is important that manufacturers provide instructions on how to clean and rinse such devices without creating aerosols. Cool-to-lukewarm water/detergent solutions (at temperatures below 43°C [110°F]) are recommended to prevent coagulation and thus facilitate the removal of protein substances. Instruments with small lumens or holes are typically cleaned with brushes and rinsed by irrigating clean water through the lumens with a syringe. Device manufacturers should provide any specialized implements or equipment that will be needed or direct the user to sources of such implements/equipment.

*Mechanical cleaning methods* are generally used because they minimize personnel exposure to harmful microorganisms, improve cleaning effectiveness, and increase productivity. Each type or model of mechanical cleaning equipment is designed to (1) lower bioburden by removing debris and microorganisms through the cleaning and rinsing action of the equipment, and (2) destroy particular types of microorganisms by thermal or chemical means. Mechanical equipment has been designed to clean and sanitize, clean and pasteurize, clean and thermally or chemically disinfect, and clean and sterilize. No one model or type of mechanical equipment will decontaminate all types of medical devices that must be reprocessed in health care facilities. Device manufacturers should evaluate the various cleaning methods that might be used and advise users on those which are appropriate or inappropriate for cleaning their devices. This evaluation may include validation studies by the device manufacturer, verification by the device manufacturer of data generated by equipment manufacturers which supports processing of a particular device, and/or collaborative efforts by both the device and equipment manufacturers.

*Ultrasonic cleaning equipment* converts ultra-high-frequency sound waves into mechanical vibrations that move through the water in the cleaner tank, creating microscopic bubbles. The bubbles attach to device surfaces and implode (burst inward), resulting in a vacuum action that pulls soil and debris off of the items being cleaned. Low-level ultrasonic energy has little or no destructive effect on microorganisms and is therefore considered to be only a cleaning/sanitizing process, not a disinfecting or sterilizing process. Ultrasonic cleaners are typically used only after gross soil has been rinsed or wiped from the items to be cleaned. The water/detergent solution must be changed before it becomes heavily soiled as soil will inhibit the cleaning action of the equipment. If the ultrasonic cleaner does not have a rinse cycle, the instruments must be manually rinsed to remove the soil particles that are deposited on the instruments as the basket is being removed from the cleaning solution.

Ultrasonic cleaners are useful in cleaning devices with joints or lumens that are difficult to reach manually (e.g., needles, stopcocks, and connectors). Because ultrasonic energy can loosen the fine screws of delicate instruments and can destroy the glues or amalgam used in certain complex instruments, the device manufacturer should warn the user if an ultrasonic cleaner will damage the device.

*Washer-sanitizers*, of varying size and load capacity, subject soiled items to wash/rinse cycles and a hot-water bath. This equipment generally operates at temperatures of 49°C to 79°C (120°F to 175°F) and requires 2 to 10 minutes of contact time to reduce/destroy some types of microorganisms. Some models of washer-sanitizers may provide a final rinse using a dilute concentration of a liquid chemical disinfectant. Dishwashers, of the type used in hospital dietary departments, may be used for cleaning and sanitizing instruments and utensils. Tunnel washers can also be used for this purpose. Cart washers are used to sanitize carts, mobile equipment, utensils, tote boxes, and various types of containers. Steam guns, which provide a spray of a water/detergent solution followed by rinsing, are also used for cleaning and sanitizing carts and other mobile equipment.

*Washer-pasteurizers* are commonly used to clean reusable anesthesia and respiratory tubings, masks, bags, and similar items. The system usually consists of two separate units, one for cleaning and one for disinfection. The

cleaning unit rotates specially designed baskets in a clockwise motion to allow the detergent solution to flow in and around the items. The baskets of cleaned items are manually transferred to the second unit, where they are immersed in a water bath for at least 30 minutes at a temperature of 66°C to 77°C (150°F to 170°F). Some types of washer-pasteurizers provide a final bath in a cold chemical disinfection solution (usually glutaraldehyde); items must be immersed in this bath for the period of time necessary to achieve high-level disinfection. The items must be rinsed thoroughly to remove residues of the chemical disinfectant, which may be toxic.

*Washer-disinfection/washer-decontamination equipment* cleans and thermally or chemically disinfects a wide assortment of medical devices. Each of the several commercially available models cleans/washes to remove soil, but the method and level of disinfection vary from one manufacturer to another and from one model to another. A *washer-sterilizer* is a mechanical apparatus in which heat-tolerant instruments, utensils, and medical devices are washed, rinsed, and subjected to steam sterilizing conditions: saturated steam at 121°C to 140°C (250°F to 285°F) and pressures of 16 to 35 pounds per square inch (gauge) (psig). It is important to note that all applicable recommended practices of professional organizations include the precaution that devices to be subjected to the cleaning/sterilizing cycles of washer-sterilizers should first be rinsed with cold tap water and/or precleaned in ultrasonic cleaners to avoid debris being cooked or baked onto instrument surfaces.

*Endoscope washers* are specially designed to clean and chemically disinfect flexible fiberoptic endoscopes and accessories.

## Manufacturers' responsibilities

Reusable medical devices vary in size, complexity, fragility, immersibility, sensitivity to cleaning agents and water temperatures, and other properties that affect "cleanability." Device manufacturers have the responsibility to support label claims of reusability by providing complete and comprehensive written instructions for the cleaning of their products. Manufacturers also have the responsibility to provide users with a summary and interpretation of the test results verifying that their products can be safely and effectively cleaned. Health care personnel are responsible for ensuring that the cleaning methods recommended by a manufacturer can be duplicated in their environment and that the manufacturer's instructions are followed correctly.

Effective cleaning is a multistep process that relies on several interdependent factors. Manufacturers of devices intended for reuse should provide appropriate information regarding:

- the quality of the water (e.g., distilled, deionized, hard or soft tap water);
- the type and quality of cleaning agents and cleaning accessories;
- the handling and preparation of devices for cleaning;
- the manual or mechanical method used for cleaning, rinsing, and drying;
- time-at-temperature parameters for mechanical cleaning equipment;
- the positioning of the device and load configuration for mechanical equipment cycles;
- any necessary functional testing that should be performed after cleaning;
- any necessary additives to be used in reassembly, such as lubricants.

Device manufacturers, especially manufacturers of complex medical devices, should also consider providing training programs to help assure that health care personnel will be able to comply to the fullest extent with the manufacturers' instructions.

### *Water quality*

Device manufacturers should consider the following questions and, based on appropriate test data or other

information, advise prospective users in the labeling instructions: Is tap water acceptable for use in cleaning, or is deionized or distilled water required to protect the device or its components from scaling, corrosion, and other types of deterioration? Is the hardness or softness of the water important? What should the water temperature be for soaking, cleaning, and rinsing? (It is common practice to initially soak devices or to rinse them in tap water at 22°C to 43°C [72°F to 110°F] to prevent the coagulation of blood and proteins onto the device and thus facilitate the removal of debris.)

***Cleaning agents***

Based on appropriate test data or other information, device manufacturers should specify in the labeling instructions the types of cleaning agents that should be used (and any acceptable alternatives), and how the cleaning agents should be used (e.g., concentration). A device manufacturer should also advise the user concerning any recommended agents for soaking the device before cleaning (e.g., protein enzyme-dissolving agents) and procedures for using them (e.g., how long the device must be soaked in an enzyme product to ensure that the enzyme reacts with protein). The device manufacturer should also warn the user against any cleaning agents known to be harmful to the device, its components, or its accessories. Users should be referred to manufacturers of recommended cleaning agents for specific information concerning the dispensing, concentration, or storage of the cleaning agents and for information concerning potential health hazards to personnel.

***Cleaning procedures***

If a device must be partially or completely disassembled for cleaning, the device manufacturer should provide detailed instructions for disassembly and reassembly. Advice should also be provided concerning any special tools needed to assure adequate cleaning or rinsing of a device (e.g., special brushes, irrigation adaptors). Spray attachments or compressed air guns should only be considered when they are essential to the cleaning process. Because of the aerosolization created by spray or compressed-air methods, recommendations for employee protection must also be provided.

It is also important for the user to know whether or not the device can be submerged in water/detergent solutions. If a component of the device will be damaged by contact with water, the user should be instructed regarding how to clean the component while protecting it from moisture.

Specific directions for manual cleaning should include:

- the temperature of water to be used (e.g., hot, cold, lukewarm, a specific temperature range);
- the correct amount of detergent to be used per volume of water;
- the amount/volume of water to be used for rinsing to remove detergent residuals or debris from the device;
- procedures to ensure that all surfaces, lumens, and components of the device are in contact with the soaking/cleaning solution.

If mechanical cleaning is recommended (i.e., cleaning by sanitizing equipment, ultrasonic cleaners, washer-disinfection equipment, washer-sterilizers), the device manufacturer should advise users on the type(s) of equipment to be used and (if significant) how the device should be positioned in the load. The device manufacturer should also provide warnings against the use of any method known by the manufacturer that would damage the device.

***Test data and user verification***

The device manufacturer should be prepared to provide users with a summary and interpretation of test data or other information that verifies the efficacy of the manufacturer's recommendations for cleaning agents and cleaning procedures. Any test procedures that can be easily replicated in a health care facility and that can help

users recognize whether or not cleaning was effective for all device surfaces should also be provided. Such tests are particularly important for devices with components that cannot be readily inspected for cleanliness (e.g., spring hinges, lumens, porous materials, crevices). For example, a 2% hydrogen peroxide solution has been used to verify the removal of protein from the lumens of instruments such as needles and tracheostomy tubes; the solution bubbles if it comes into contact with blood or protein substances. When appropriate, the device manufacturer should also provide instructions for any functional testing that should be done to assure that the device has not been damaged (e.g., tests for the electrical connections of reprocessed electrosurgical pencils).

The decontamination procedure developed by the manufacturer must, of course, be repeatable in health care facilities. The procedure should be based on the type and quantity of contamination expected to be on the device, the design of the device, the materials used in the construction of the device, and the potential for employee or patient exposure to pathogens. For example, a device that is soiled with internal body tissues, blood, or body fluids presents a greater risk of transmitting infectious microorganisms than an instrument/device that has only been in contact with unbroken skin. Instruments/devices that have been contaminated with blood or body fluids and that have sharp points or edges capable of penetrating the skin present the greatest risk to health care personnel and should be designed to withstand all of the cleaning, decontamination, and sterilization processes recommended by the instrument/device manufacturer.

Simulated soiling is generally performed in laboratory testing. The soil selected should be that which most closely simulates the contamination in actual clinical use. Hucker's soil, for example, which consists of the substances listed in table 1, simulates fecal matter. Other artificial soils include a mixture of 10 milliliters (ml) fetal calf serum and 6 grams (g) of dry milk powder and a 1:1 rabbit blood/saline mixture (Miles, 1991).

One method of evaluating the effectiveness of a cleaning process is to inoculate the artificial soil with nonpathogenic spores, such as *Bacillus stearothermophilus*, in a concentration of $10^4$ to $10^5$ colony-forming units (cfus) per milliliter of artificial soil. The spores in this testing are used as "tags." The instrument/device is soiled in a manner that simulates actual clinical use, and it is then prepared as it would be immediately after use and as stated in the manufacturer's instructions. The soiled device is then cleaned according to the instructions developed by the manufacturer, and the spores are recovered and counted. The efficacy of the cleaning process is described as a log reduction. The log reduction is calculated by subtracting the number of "tag spores" recovered from the device after cleaning from the number of "tag spores" recovered from a control device. Currently, there is no specific log reduction which is commonly accepted as a standard measure of adequate cleanliness, so manufacturers must necessarily make judgments based on relevant literature, the characteristics of a device, and other factors.

| Table 1—Composition of Hucker's soil* | |
|---|---|
| *Amount* | *Substance* |
| 10 g | Peanut butter |
| 10 g | Butter |
| 10 g | Flour |
| 10 g | Lard |
| 10 g | Dehydrated egg yolk (or 2 fresh eggs) |
| 15 ml | Evaporated milk |
| 50 ml | Distilled water |
| 4 ml | Higgins India ink |
| 20 gtts (drops) | International Printers Ink solution (A646 diluted one to one with 10 gtts boiled Linseed oil) |
| 3 ml | Normal saline solution |
| 1 g | Dehydrated blood |

* Other formulations of Hucker's soil have been reported, with slight variations in the amount or type of ingredients. In one formulation, for example, 10 drops of International Printers Ink solution is used instead of 20 drops, and 0.1 N sodium hydroxide is used instead of normal saline.

Using the bacterial spore inoculum method or other scientifically valid methods (e.g., methods using chemical or fluorescent tags), the manufacturer must show that the recommended cleaning process is effective in removing the simulated soil from all surfaces of the device that could come into contact with the patient or are accessible to tissue, blood, body fluids, and other organic material. Testing should be adequate to ensure that the process can be successfully duplicated in the hospital environment.

The primary means by which hospital personnel can verify cleanliness is visual inspection; that is, the hospital employee visually inspects a device, under normal lighting, to verify that the soil has been removed. If all surfaces of the device cannot be visually inspected (as in the case of some devices with lumens and some hinged instruments), "go/no go" inspection criteria should be included in the processing instructions.

## 5 Disinfection with liquid chemicals

Chemical disinfection is usually performed by soaking an item in a basin of solution, but it may also be accomplished by manually applying a disinfectant solution with a clean cloth or by means of automated equipment (e.g., automatic processors for flexible endoscopes). Many chemical disinfectant formulations are available for use in disinfecting medical devices. Manufacturers selecting disinfectant products to be used with their devices must know the spectrum or range of antimicrobial activity of the disinfectant formulation, the interaction of the disinfectant agent with the materials used in device construction, and the ability of the disinfectant to contact all device surfaces that will be contaminated during normal use. This chapter addresses the factors involved in selecting a disinfectant for a specific medical device. Annex A describes classes of disinfectants commonly used in health care facilities.

### Categories of medical devices

Spaulding (1972) suggested that the selection of a disinfection or sterilization process for a medical device should be based on the degree of risk associated with the use of the device. He described three broad categories of medical devices: critical, semicritical, and noncritical. The Centers for Disease Control and Prevention (CDC) subsequently used the same basic classification system in its guidelines for infection control (CDC, 1985):

*Critical items:* "Critical items are instruments or objects that are introduced directly into the bloodstream or into other normally sterile areas of the body. Examples of critical items are surgical instruments, cardiac catheters, implants, pertinent components of the heart-lung oxygenator, and the blood compartment of a hemodialyzer. Sterility at the time of use is required for these items; consequently, one of several accepted sterilization procedures is generally recommended."

NOTE—Hemodialyzers are provided sterile by manufacturers. In health care facilities where reuse of hemodialyzers is practiced, reprocessing is accomplished by high-level disinfection. High-level disinfection is considered adequate in this instance because hemodialyzers are reused for the same patient.

*Semicritical items:* "Items in the second category are classified as semicritical in terms of the degree of risk of infection. Examples are noninvasive, flexible and rigid fiberoptic endoscopes, endotracheal tubes, anesthesia breathing circuits and cystoscopes. Although these items come in contact with intact mucous membranes, they do not ordinarily penetrate body surfaces. If steam sterilization can be used, it is often cheaper to sterilize many of these items, but sterilization is not absolutely essential; at a minimum, a high-level disinfection procedure that can be expected to destroy vegetative microorganisms, most fungal spores, tubercle bacilli, and small nonlipid viruses is recommended. In most cases, meticulous physical cleaning followed by an appropriate high-level disinfection treatment gives the user a reasonable degree of assurance that the items are free of pathogens."

*Noncritical items:* "Noncritical items are those that either do not ordinarily touch the patient or touch only intact skin. Such devices include crutches, bed boards, blood pressure cuffs, and a variety of other medical accessories. These items rarely, if ever, transmit disease. Consequently, depending on the particular piece of equipment or item, washing with a detergent may be sufficient."

**Levels of disinfectant activity**

Disinfection processes offer varying degrees of microbial destruction or reduction. They are commonly divided into three levels of effectiveness (CDC, 1985):

- Low-level disinfection reduces the overall number of vegetative microorganisms, but it cannot be relied upon to destroy tubercle bacilli, bacterial endospores, or small nonlipid viruses.
- Intermediate-level disinfection will kill tubercle bacilli and most viruses.
- High-level disinfection will kill most forms of microbial life, including some bacterial endospores; the same chemical agent can also produce a sterile product, depending on variables such as bioload, concentration, temperature, and contact time.

These categories of disinfectant activity are based on the fact that microorganisms can be categorized into several general groups according to their innate resistance to chemical sterilant/disinfectant agents. These groups are listed in broad descending order of resistance in table 2; the examples of microorganisms given include some of the test organisms used to qualify products for registration by the Environmental Protection Agency (EPA) (see chapter 8). The relationship of these general levels of microbial resistance to the levels of disinfectant activity is shown in table 3.

***High-level disinfection***

Many reusable critical devices are heat-stable and are not adversely affected by repeated steam sterilization. However, some critical devices intended for reuse cannot be steam-sterilized—e.g., rigid telescopes, flexible fiberoptic endoscopes, and other items made—in whole or in part—of heat-sensitive plastic. Such devices must be reprocessed by "cold" methods such as ethylene oxide gas or liquid chemical sterilants.

High-level disinfection is the minimum treatment recommended by CDC for semicritical items. It is required

by law that, prior to marketing, agents intended for use in high-level disinfection must be cleared by FDA and registered by EPA as chemical sterilants. The logarithmic reduction of microorganisms is time-related; in the case of one particular agent, for example, soaking a device for 20 minutes results in high-level disinfection, while extending the time to approximately 10 hours results in sterilization. The process is usually performed manually, so the effectiveness of the process depends not only on the chemical agent itself but also on the quality control measures established for the procedure.

| **Table 2—Microorganisms listed in descending order of resistance to chemical sterilants/disinfectants** |
|---|
| ***Bacterial Spores*** |
| *Bacillus stearothermophilus* |
| *Bacillus subtilis* |
| *Clostridium sporogenes* |
| ***Mycobacteria*** |
| *Mycobacterium tuberculosis var. bovis* |
| ***Nonlipid or Small Viruses*** |
| Poliovirus |
| Coxsackie virus |
| Rhinovirus |
| ***Fungi*** |
| *Trichophyton* spp |
| *Cryptococcus* spp |
| *Candida* spp |
| ***Vegetative Bacteria*** |
| *Pseudomonas aeruginosa* |
| *Staphylococcus aureus* |
| *Salmonella choleraesuis* |
| ***Lipid or Medium-Sized Viruses*** |
| Herpes simplex virus |
| Cytomegalovirus |
| Respiratory syncytial virus |
| Hepatitis B virus |
| Human immunodeficiency virus |

**Table 3—Levels of disinfection according to type of microorganism**

| | Bacteria | | | Fungi[1] | Viruses | |
|---|---|---|---|---|---|---|
| **Levels** | ***Vege-tative*** | ***Tubercle Bacillus*** | ***Spores*** | | ***Lipid (Medium)*** | ***Nonlipid (Small)*** |
| High | +[2] | + | +[3] | + | + | + |
| Intermediate | + | + | ±[4] | + | + | +[5] |
| Low | + | – | – | +[6] | + | – |

[1] Includes asexual spores but not necessarily chlamydospores or sexual spores.
[2] Plus sign (+) indicates that a killing effect can be expected when the normal use concentrations of chemical disinfectants or pasteurization are properly employed; a negative sign (-) indicates little or no killing effect.
[3] Only with extended exposure times are high-level disinfectant chemicals capable of actual sterilization.
[4] Certain intermediate-level disinfectants can be expected to exhibit some sporicidal action.
[5] Some intermediate-level disinfectants may have limited virucidal activity.
[6] Some low-level disinfectants may have limited fungicidal activity.

***Intermediate-level disinfection***

Certain medical equipment surfaces, such as adjustment knobs, handles, buttons, or levers on hemodialysis machines, x-ray equipment, instrument trays and carts, and dental units, almost never come into direct contact with the patient. Due to the nature of the treatment or to equipment design, however, such surfaces may frequently become contaminated with patient blood or body fluids and are touched repeatedly by health care personnel during procedures involving parenteral or mucous membrane contact. These surfaces present the potential for secondary transmission of microorganisms from patient to patient or from patient to health care worker. For example, a dentist performing a surgical procedure may intermittently adjust the dental unit light; the light handle will likely become contaminated with blood and oral secretions and, if not adequately cleaned and disinfected after the procedure, may allow cross-contamination in subsequent procedures. Such equipment surfaces should at least be cleaned of visible material using soap and water; it may also be considered prudent to disinfect them with an intermediate-level disinfectant.

***Low-level disinfection***

Noncritical items ordinarily contact only the intact skin of patients during routine use and seldom, if ever, become contaminated with bloodborne pathogens. These items generally present little risk of transmitting infectious agents. Consequently, they are usually reprocessed by cleaning alone or in combination with a low-level disinfectant.

## Criteria for selecting an appropriate chemical disinfectant

As previously discussed, chemical disinfectants vary in their ability to kill specific types and numbers of microorganisms. To choose the appropriate chemical disinfectant for a particular application, it is necessary to determine the antimicrobial activity required (both in terms of types of organisms to be killed and reduction levels) and to examine the disinfectant manufacturer's label claims and technical information regarding antimicrobial activity. Annex A describes chemical disinfectants commonly used in health care facilities in the United States.

The EPA and/or the FDA require manufacturers of disinfectants to perform certain standardized tests to

demonstrate the effectiveness of their products (see chapter 8). These tests may not take into account the design complexity or materials of construction of each medical device, which will influence the choice of disinfectant.

In addition to the intended use of a device (critical, semicritical, noncritical), device design is an important variable. Smooth, nonporous surfaces are the easiest to clean and to disinfect or sterilize chemically. Crevices, joints, and pores make cleaning more difficult and present barriers to the penetration of liquid disinfectants; additional preparation may be required (e.g., irrigating the solution through channels), and prolonged contact times may be necessary for adequate disinfection. The size of a device also affects the types of disinfectants or sterilants that can be used. An instrument that is too large to be immersed in solution or placed in a sterilization chamber can only be disinfected by manual cleaning and repeated wipe-downs with a liquid disinfectant.

Device manufacturers should also be aware of normal factors related to the clinical use of the disinfectant which can alter its effectiveness and, consequently, the safety of the device.

*Use pattern.* Only those disinfectants labeled for reuse should be reused. A reuse claim on the disinfectant label indicates that the manufacturer has documented that, following a simulated reusing of the disinfectant for a specified period, the disinfectant was effective in killing microorganism types shown on the label. Use pattern is event-related, not time-related. For a disinfectant which is to be reused, there should be a test system for the user to verify that the minimum effective concentration of the agent is maintained throughout the reuse period.

*Use life.* The use life stated on the label must not be exceeded.

*Bioburden.* The disinfectant has been tested against a known number of microorganisms; therefore, the efficacy of the process depends upon the cleanliness of the items to be processed (i.e., the bioload on the device is less in numbers and resistance than that which has been tested).

*Water and extraneous materials.* Organic matter in the form of serum, blood, pus, or fecal material may protect microorganisms and may consume or inactivate the active chemical agent in the disinfectant. Materials such as soaps, detergents, cork, cotton, lint, cotton wool, cellulose sponges, and the minerals found in hard water may also interfere with the effectiveness of the disinfectant.

*Dilution.* The disinfectant is diluted by water remaining on surfaces and in the lumens of devices immersed in the disinfectant. Dilution can be very significant in long-term use and reuse and can potentially reduce the concentration of the chemical agent to a level too low to be effective in killing a sufficient number of certain microorganisms in the recommended exposure time. To avoid dilution of the disinfectant, water droplets are dried or wiped from items after cleaning. (However, it is generally recommended that items not be dried by forced air, because desiccation can interfere with the disinfection process.)

*Temperature and time.* The antimicrobial claims stated on the disinfectant label are determined according to exposure time and temperature. These claims should be fully documented.

*Evaporation and light.* If the solution is in an uncovered container, evaporation can occur. Generally, evaporation is not as critical as dilution. However, if the disinfectant agent is more volatile than the diluent (a gas dissolved in water is more volatile than water), then loss of the agent by evaporation can be very important. Chlorine products are especially susceptible to evaporation effects. Exposure to light may also affect chlorine products and disinfectants.

*pH.* Disinfectants may be formulated over a range of pH values, depending on the chemical agent used. Some agents are more effective in killing microorganisms under alkaline conditions (a pH higher than 7), while others work best under acidic conditions (a pH lower than 7). The introduction of detergents to the disinfectant solution, which might occur if the device is inadequately rinsed after cleaning, can alter the pH of the solution and reduce its effectiveness.

### Toxicity

Any chemical disinfectant must, of course, be toxic to some degree; otherwise, it would not be effective in killing microorganisms. To the extent possible, health care personnel must be protected from health hazards associated with occupational exposure to chemical sterilants, and patients must be protected from the potentially harmful effects of exposure to disinfectant residues remaining on the device.

Chemical disinfectants vary in their toxicity and, therefore, in the potential health hazards they pose to humans. Many chemical disinfectants can cause short-term health problems, such as sensitization and irritation to the eyes, skin, and respiratory passages. Some disinfectants, with enough exposure (concentration, time, or both), can pose serious long-term health hazards. Precautionary practices should be stated on the disinfectant label.

### Materials compatibility

Another important aspect of a chemical disinfectant's safety and performance is its compatibility with the materials used in the construction of the device. The disinfectant should not alter the material of the device in such a way that the device will not be safe or will not function as intended. Many materials, such as plastics and other polymers, can be adversely affected by exposure to certain chemicals and stresses. Some materials may become brittle and crack. Others, such as certain polymeric adhesives, may dissolve. Still others may swell or become distorted. (See chapter 3.)

Device manufacturers should conduct tests to determine the effects of the disinfectant they recommend for use with their products. Product compatibility testing should be completed to simulate the amount of time the device will be in contact with the disinfecting agent during repeated processing for the specified life of the device.

### Efficacy of the process

Device manufacturers must perform product testing to validate the ability of a device to be successfully disinfected by a particular process. Disinfection is a multiphase process, the efficacy of which is contingent upon the effectiveness of the cleaning process, the concentration of the active biocidal agent in the disinfecting solution, and the exposure or immersion time.

Device manufacturers must show that recommended disinfection procedures ensure that all device surfaces (including internal channels) that will either come in direct contact with the patient or physician or be soiled with blood, body fluids, and other organic material will be in contact with the solution. Testing should be adequate to ensure that the process can be successfully duplicated in the hospital environment.

### Test data and user verification

Device manufacturers should provide test data and other information supporting the efficacy of the recommended disinfectant products and procedures, including any test procedures that can be easily replicated in the health care facility and that can help users recognize whether the disinfecting process was effective in rendering the device safe for patient use. Disinfecting procedures developed by manufacturers must, of course, be repeatable in health care facilities.

## 6 Sterilization

This chapter outlines general concepts and procedures for use by manufacturers of medical devices in assuring that their devices can be sterilized by a specified sterilization method.

Device manufacturers are responsible for demonstrating that their devices are suitable for sterilization by a specified process. Health care personnel are responsible for assuring that they are capable of adhering to the process and maintaining process control. Health care personnel should demonstrate temperature uniformity throughout the sterilization chamber, generate process specifications, which may include loading patterns validated by the health care facility, and follow regular and documented preventive maintenance and

calibration programs. It is the responsibility of the device manufacturer to qualify the sterilization process for the device, and it is the responsibility of health care personnel to show that they can replicate this process exactly and reproducibly.

This chapter describes for device manufacturers:

- sterilization processes available to health care personnel;
- considerations in designing devices for sterilizability;
- procedures that may be used for sterilization process qualification.

## Sterilization processes available for use in health care facilities

The sterilization processes predominantly used in health care facilities are steam sterilization (AAMI, 1992b, 1993b, 1994b) and ethylene oxide (EO) sterilization (AAMI, 1992a). These processes can be controlled and monitored physically and microbiologically, and devices can be packaged to provide a microbial barrier for sterility maintenance until use. Other processes include sterilization by liquid chemicals (such as glutaraldehyde, peroxyacetic acid, hydrogen peroxide, sodium hypochlorite), chemical sterilant gases (such as formaldehyde, alcohol, ozone, vapor-phase chemicals), and dry heat. Chemical sterilization is covered in detail in AAMI (1990), dry heat sterilization in AAMI (1993c). Annex B describes typical hospital sterilization cycle parameters for these processes.

NOTE—Steam sterilization is the preferred sterilization process in health care facilities because it is cost-effective and poses no concerns about exposure of personnel or patients to toxic sterilant residuals. Other methods are used for devices that cannot withstand steam sterilization.

## Device design considerations for sterilization

During the design of a device intended to be repeatedly sterilized and reused, attention should be directed to functionality, product configuration, and materials composition.

In the case of steam sterilization and ethylene oxide sterilization, product configuration is important in two respects. Fitments (e.g., ports and vents) must be designed so that product integrity and functionality are maintained following sterilization and so that the rate and volume of steam access or sterilant gas transmission are adequate to assure product sterility.

Device materials selected should be compatible with the specific conditions or potential effects of the process:

*Steam sterilization:* Materials should be resistant to heat, distortion, warpage, and corrosion.

*Gas sterilization:* Materials should be resistant to chemical and physical changes due to repeated exposure to the gas or its diluents at sterilization conditions.

*Liquid chemical sterilization:* Materials should be resistant to chemical and physical changes due to repeated exposure to the sterilants, which can be highly acidic or alkaline.

It is important to consider the challenges that long lumens, areas of high material density, mated surfaces, and dead space create for the sterilization process.

Device manufacturers may wish to consider performing prequalification screening tests to assess material compatibility and sterilization efficacy. Testing for toxic residues from chemical sterilants and disinfectants may be performed during the material compatibility evaluation to eliminate later-stage changes in a device.

The sterilizer manufacturer may be able to assist in device testing and process qualification.

## Packaging considerations for steam and gas sterilization methods

The packaging material used by the manufacturer during qualification should be of a type that is readily

available to health care personnel. Considerations for selecting a packaging method to be used in the sterilization qualification include:

- suitability of the packaging material for the cycle and method (e.g., permeability to positive and negative steam pulses, moisture retention, susceptibility to gas degradation effects);
- strength of the package;
- type of packaging (e.g., reusable woven or single-use nonwoven textile wrapper, paper/plastic pouch, rigid container);
- package integrity properties as required by the device design.

**Device equivalence**

Device manufacturers may forego sterilization efficacy testing if they can show that a device being considered represents no greater challenge to the sterilization process than another device that has been qualified. For example, a pair of hand-held surgical forceps that has no mated surfaces or lumens would represent less of a challenge to the sterilization process than an endoscope with a long, narrow lumen. This type of analysis should be performed by an individual who is knowledgeable in sterilization science, and it should be based on an acceptable, documented rationale. Similar devices may be grouped into families.

**Sterilization efficacy testing**

Sterilization efficacy testing must be performed by the device manufacturer. The objective is for the manufacturer to show that recommended cycle parameters are capable of producing a sterility assurance level for the device of at least $10^{-6}$. It is recommended that the manufacturer attempt to qualify the cycle parameters of a process listed in annex B before considering other cycle parameters. If it is not possible to qualify a sterilization cycle using parameters given in annex B, it is recommended that the manufacturer adjust those parameters that health care personnel can control. An example would be lengthening the exposure time.

To qualify sterilization cycle parameters, it is necessary for the manufacturer to show that the cycle imparts sufficient lethality to produce a minimum sterility assurance level of $10^{-6}$ for the device. The overkill sterilization method, which is based on the concept that the sterilization process will be able to inactivate a resistant microbial challenge plus an additional safety factor, can be used to demonstrate this sterility assurance level. An example of cycle overkill is a 6-log reduction in one-half of the cycle exposure time of a microbial challenge having a heat or chemical resistance greater than typical naturally occurring organisms. A full cycle would produce sufficient lethality to effect at least a 12-log reduction and provide a $10^{-6}$ probability of microbial survival.

The microbiological challenge used to evaluate/qualify steam sterilization processes should contain a $10^6$ population of *Bacillus stearothermophilus* spores with a minimum D value of 1.0 minute, a $10^4$ population with a minimum D value of 1.5 minutes, or other bacterial populations and D values if they constitute an equivalent microbiological challenge to the sterilization process. AAMI (1987) states that an overkill cycle will inactivate 12 logs of an organism with a $D_{250}$ value of approximately 1.0 minute. Compliance with this recommendation can be shown by performing a one-half cycle and achieving a 6-log reduction of an organism with an initial population of $10^6$ and a $D_{250}$ value of 1.0 minute:

log (initial population) x D value

log $10^6$ x 1.0

6 x 1 = 6

Compliance with this recommendation can also be shown by performing a one-half cycle with an initial population of $10^4$ and a $D_{250}$ value of 1.5 minutes:

log (initial population) x D value

log $10^4$ x 1.5

4 x 1.5 = 6

These calculations show that the challenge characteristics of a $10^6$ population with a D value of 1.0 minute and a $10^4$ population with a D value of 1.5 minutes are equivalent. Other populations and D values may also constitute equivalent microbiological challenges to the sterilization process, such as a $10^3$ population with a D value of 2.0 minutes and a $10^5$ population with a D value of 1.2 minutes.

The biological indicators used to evaluate ethylene oxide gas sterilization processes should contain a minimum population of $10^6$ *Bacillus subtilis* spores (AAMI, 1986a). For new sterilization processes, biological indicators should be specified by the sterilizer manufacturer. The culturing and incubation conditions should comply with the instructions supplied by the manufacturer of the biological indicator.

Microbiological challenges should be placed in the most difficult-to-sterilize, accessible locations of the device. If it is not possible to reach these areas of the device with a spore strip, then the device may be inoculated with the specified microbial challenge by using a liquid suspension. Caution should be taken with this approach, since direct inoculation of a product can sometimes result in unreliable resistance (AAMI, 1988a).

Device manufacturers can demonstrate cycle lethality by utilizing the microbial challenges described and performing three sterilization cycles at one-half the exposure time, or by developing a death rate curve (D value) using fractional exposures and a minimum of three data points (including the initial microbial challenge as a data point). If a death-rate curve is used to demonstrate that a full-cycle exposure time imparts a $10^{-6}$ sterility assurance level, one additional half-time exposure cycle should be performed. It is recommended that a minimum of three samples of the device be included in each run.

In all sterilization qualification runs, the device should be packaged (if applicable) in a manner determined by the manufacturer to be appropriate for the device and available to health care personnel.

**Device and sterilization compatibility**

Device manufacturers should demonstrate the physical and functional compatibility of their devices with the sterilization processes being qualified. This evaluation may be based upon historical information for similar devices or upon data generated using the device being qualified. The evaluation should take into account a device's intended use and the effects of repeated sterilization on the intended use. Material properties such as physical strength, physical dimensions, resilience, and permeability (for gas sterilization) should be evaluated after multiple sterilization cycles to assure that they are still acceptable. Degradation effects that might be expected for each specified material in the device should be determined; for example, crazing, cracking, embrittlement, and phase separation would be potential degradation effects on polymeric materials. Discoloration, staining, and other negative aesthetic effects should also be determined. Materials should retain biocompatibility after sterilization. Any labeling associated with the product should be evaluated for legibility and adherence to product poststerilization.

**Evaluation of sterilant residues and aeration/rinsing parameters**

Reusable medical devices which are made in whole or in part of polymeric or rubber materials may absorb or have a surface reaction with various chemical sterilants and disinfectants, resulting in the formation of toxic residues. In some cases, such as ethylene oxide, methods of quantifying the residues are well characterized. This is not true for all chemical disinfectants and sterilants, and each must be evaluated.

***Ethylene oxide (EO)***

Residuals of EO and EO byproducts in a reusable medical device can be determined using the same procedure as that used for residual determination in single-use devices (AAMI, 1988b, 1989). For reusable devices, however, there are some additional considerations:

1) Because reusable devices are reprocessed many times, they must be evaluated to determine if a buildup of residues occurs. Factors to be considered include:
   - If buildup occurs, does it continuously increase with each sterilization cycle, or does it begin to plateau as more cycles are conducted?
   - What effect does aeration have? Will longer aeration reduce the residuals to very low or undetectable levels?
   - Does washing have an effect? (It may aid in the removal of low residual levels between resterilizations.)
2) What method of residue extraction is required? Simulated use is appropriate in those cases where all of the residue in the device will not be seen by the patient. However, if this level continues to rise with repeated sterilizations, the recommendations for aeration should take this into account.
3) Residue buildup with repeated sterilization may ultimately affect workplace exposure. If a large number of devices or large devices with a high total EO content are stored, especially in a confined area, the permissible exposure limit (PEL) mandated by OSHA may be exceeded.

***Other sterilant residues***

Chemical residues of other sterilants/disinfectants should be considered. Aqueous agents such as glutaraldehyde will generally have partition coefficients which preclude or significantly reduce any absorption by polymeric or other porous materials, thereby preventing residue buildup. Hydrogen peroxide and peroxyacetic acid are among those sterilant/disinfectant agents which quickly break down to nonharmful compounds that have no toxic residue potential.

Residues resulting from device or material interactions with sterilant/disinfectant systems that have not previously been characterized must be shown to be nontoxic at the levels present on the device. Alternatively, analytical methods may be developed which are capable of determining that the residue has been eliminated by aeration or rinsing.

***Rinsing parameters***

Procedures for rinsing reusable devices after cleaning or liquid sterilant/disinfectant treatment should be evaluated to ensure that any toxic chemical agent has been removed. Devices that have lumens, interfacing parts, or hinged areas may require special attention to ensure that the chemical is completely rinsed. Failure to properly rinse a device may result in the retention of potentially hazardous residues.

**Documentation of qualification**

Studies performed by manufacturers to qualify sterilization cycle lethality should be properly documented. A documentation package should include:

1) the protocol;
2) a description of the device and, if applicable, the packaging tested:
   - number of devices;
   - whether the device was disassembled;
   - weight of the device (if relevant to the process);

- type of packaging material (if applicable);
- dimensions of device and (if applicable) package;
- load configuration (if applicable) (e.g., distribution on carts, in trays, or within the sterilization chamber);
- location of microbial challenge;
- location of chemical indicators (if used);

  NOTE—See AAMI (1988c) for information on how chemical indicators are used in health care facilities.

3) an analysis of the data collected:

- a review of biological and chemical indicator results and a determination of the minimum lethality delivered to the device;
- a review of the data from each sterilization cycle to show conformance to specified parameters including, where applicable, recorder/data logger charts, exposure time, sterilant concentration, humidity, temperature, pressure gauge readings, and so forth;

  NOTE—If a liquid chemical sterilant is used, the formulation must be qualified to be efficacious for its specified use life.

- a determination of pack weight gain due to moisture absorption, if applicable;

  NOTE—Any absorbent materials used (surgical towels, tray liners, wrapping materials) should be removed and weighed, and the post-processing weight compared with the pre-processing weight. The difference in weight should not exceed 3%, and there should be no evidence of moisture on or within the sterilized package, container, or tray. This information can be used to develop drying times.

- a determination that the devices processed retained their identity, functionality, strength, quality, or other defined attributes after repeated sterilization cycles;
- if the device is fabricated from plastic and processed by EO gas, a determination of the EO residuals remaining in a specified number of devices after the recommended aeration procedure (see AAMI, 1988b, 1989);
- if the device is fabricated from plastic and processed by a liquid chemical sterilant, a determination of the toxic residues remaining in a specified number of devices after the recommended aeration/rinsing procedure.

**Information supplied to health care personnel**

Manufacturers should provide to health care personnel at least one method of sterilization that has been qualified. The information supplied should include the following:

- sterilization cycle parameters that have been shown by the manufacturer to provide a $10^{-6}$ sterility assurance level;

  NOTE—Manufacturers may wish to instruct health care personnel that the recommended sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.

- a description of the packaging used by the manufacturer in the study;

- if applicable, disassembly and reassembly instructions;
- cleaning instructions, including a statement to the effect that failure to properly clean the device may lead to inadequate sterilization;
- if applicable, a description of the process and the parameters of the process for removing toxic chemical residues.

### Device requalification

There should be a written specification defining the circumstances that necessitate requalification of cycle lethality by the device manufacturer. Cycle requalification might be necessary, for example, if the device is modified.

## 7 Device/sterilant/equipment compatibility

Medical devices are designed, manufactured, and labeled to perform a specific function. Manufacturers of reusable devices should include, in the written instructions for use, recommended methods and procedures to clean and, if necessary, disinfect or sterilize their devices. Instructions for use are also provided by manufacturers of cleaning/disinfection/ sterilization agents and equipment. This chapter addresses the difficulties that may arise in the interaction of the various products, the relative order of importance to users of the information available from the manufacturers, and the specific labeling instructions that ought to be provided by the various manufacturers in order to help prevent potential incompatibilities between products.

### Compatibility issues

Manufacturers of reusable devices may design, manufacture, and market equipment to simplify the cleaning and disinfection or sterilization of their devices. In some cases, such equipment might be manufactured and marketed by a second manufacturer, who might be operating independently of the original device manufacturer. The original device manufacturer could intend the device to be reprocessed in generic sterilizing equipment (e.g., a steam sterilizer or ethylene oxide sterilizer). Additionally, a third manufacturer might formulate and distribute solutions for cleaning and disinfecting/sterilizing the medical device. These solutions could be of a generic type and not specifically formulated for the purpose recommended by the original device manufacturer or the manufacturer of cleaning, disinfection, or sterilization equipment.

Problems could arise in the interaction of the medical device, the cleaning/disinfection/ sterilization equipment, and/or the cleaner/disinfectant/sterilant. These problems can be compounded when there is little communication among the various manufacturers.

Health care personnel must review and assess the information presented by the various manufacturers and be aware of the order of importance of the information provided. The original device manufacturer, of course, has the most knowledge about the medical device itself—the manufacturer designed and produced it. However, certain aspects of the device may not have been investigated by the manufacturer. For example, the manufacturer may not know whether or not a new sterilizing agent is compatible with the device. The device manufacturer may choose to support the new sterilizing agent by performing the necessary testing or to tell the user that the device manufacturer has no information on compatibility.

Should the original device manufacturer not choose to support cleaning, disinfection, or sterilization solutions or equipment marketed by other manufacturers, it will be necessary for users to find another source of compatibility and efficacy data or perform their own testing, in which case it becomes the responsibility of the user to assure the effectiveness of reprocessing.

### Order of support

In most cases, information from the original device manufacturer should take precedence over any other manufacturer's recommendations. If the device manufacturer does not support particular cleaning/disinfecting/sterilizing agents or equipment made by other manufacturers, those manufacturers must provide the necessary data to demonstrate that the device, after reprocessing, is safe and effective for its intended use.

If the data provided by the various manufacturers conflict, it will be necessary for the user to evaluate the data more closely. The user should question any differences between the recommendations of the original device manufacturer and those of other manufacturers making claims. For example, the manufacturer of a chlorine-based cleaning agent recommends that a device be exposed for 10 minutes to a 1% concentration of the cleaning agent. However, the original device manufacturer states that the device should not be exposed to chlorine. In questioning the device manufacturer, the user learns that the manufacturer's testing was performed using an 8% chlorine concentration for 12 hours and that lower concentrations for shorter exposure periods were not investigated. Testing by the manufacturer of the cleaning agent shows that the 1% concentration and comparatively short exposure time are adequate to effectively clean the device without damaging it. The data supplied by the manufacturer of the cleaning agent should be relied upon unless the original manufacturer provides further information substantiating concern. If testing by the device manufacturer shows that the device is damaged by the concentration and exposure time recommended by the cleaning-agent manufacturer, the user should be more cautious and should probably not use the cleaning agent.

## Recommended labeling

It is recommended that the various manufacturers provide the information listed in this section in order to help prevent potential incompatibilities between products. The information should be incorporated into the directions for use or other product literature.

The generic type of chemical disinfectant/sterilant, the appropriate concentration, and the appropriate exposure time are all pertinent and interrelated considerations, but they are currently among the most confusing choices to be made by health care personnel. A wide variety of brand-name products promoted for use in reprocessing medical devices is available. Some have the same basic active ingredient but contain different additives, ostensibly to increase the efficiency or stability of the product. Unclear label claims or instructions for use, as well as the advertising for many products, can add to user confusion.

### *Original device manufacturers*

Device manufacturers should provide complete directions for reprocessing their devices, including cleaning and disinfection/sterilization instructions. A device manufacturer should also list all products known to the manufacturer to be incompatible with the device, list all cautions and warnings that should be observed when the device is cleaned or sterilized, and list any recommended cleaning, disinfection, or sterilization equipment or agents.

### *Manufacturers of cleaning, disinfection, or sterilization equipment*

Manufacturers of cleaning, disinfection, or sterilization equipment should list the devices with which their products have been tested, be prepared to provide the test data demonstrating claims of efficacy and compatibility, and identify recommended cleaning/disinfecting/sterilizing agents.

### *Manufacturers of cleaning agents, disinfectants, sterilants*

Manufacturers of cleaning agents, disinfectants, and sterilants should identify any types of devices with which their products are not compatible, list the devices with which their products have been tested, specify the effective dilution ratio, provide any special instructions for use of their products, and list special warnings and cautions.

## 8 Regulatory considerations

Protection of the public health necessitates that reusable devices be designed so that they can be adequately cleaned and disinfected or sterilized between uses according to validated, documented procedures and retain their performance characteristics. The Food and Drug Administration (FDA) has labeling, premarket clearance, and good manufacturing practice (GMP) regulations applicable to these concerns.

Under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device Amendments of May 28, 1976, and by the Safe Medical Devices Act of 1990, the FDA regulates medical devices. For FDA purposes, there are three categories of medical devices: Class I, Class II, and Class III. Each class is associated with a particular degree of risk to patients and a corresponding level of regulation. The higher the level of risk to patients posed by a device, the higher its class and the more requirements with which it must comply. Many medical devices must be cleared by FDA before they can be marketed. Depending on a device's regulatory class and other factors, premarket clearance of a new medical device is accomplished by FDA review of either a 510(k) notification or a premarket approval application (PMA).

### FDA regulatory classification of medical devices

Class I devices are judged by FDA to present a relatively low risk to patients. The safety and effectiveness of such devices can be adequately assured by the "general controls" provisions of the Act. These requirements represent the least stringent level of regulation (see the next section), and many Class I devices may be marketed without advance clearance by FDA. Ultrasonic cleaners and most hand-held surgical instruments are examples of Class I devices.

Class II devices, because of the potential risks they pose to patients, are subject to special controls to assure their safety and effectiveness, as well as to the "general controls" provisions of the Act. Virtually all new or significantly modified Class II devices are subject to premarket clearance by FDA. Class II devices include ethylene oxide sterilizers, ethylene oxide aerators, steam sterilizers, biological indicators, chemical indicators, and sterilization wraps.

Class III devices are subject to premarket approval, which represents the most stringent level of regulation. Manufacturers of Class III devices, which include life-supporting devices and implants, are required to submit premarket approval applications to FDA, demonstrating safety and effectiveness by extensive scientific data, before they can market their products. Examples of Class III devices are heart valves, infant radiant warmers, and pacemakers.

### FDA requirements

#### *General controls*

Certain "baseline" requirements apply to all medical devices, regardless of classification, unless a device is specifically exempted by FDA from a particular requirement. These are the "general controls." Under general controls, manufacturers are required, among other things, to register with FDA, list their products with FDA, and produce their products in accordance with GMP regulations (21 CFR 820). In addition, all medical devices must be properly labeled in accordance with FDA's general labeling regulations (21 CFR 801), which require that product labeling include identification of the manufacturer, a description of the intended uses of the product, adequate directions for use, and other information. Labeling and GMP requirements are discussed in more detail in the next section.

Under FDA's medical device reporting (MDR) regulations, all manufacturers of medical devices are also required to report to FDA any device-related patient injuries or deaths and any device malfunctions that could cause a patient injury or death. Medical device users are also required to report such events to FDA and/or the device manufacturer. There is also a voluntary Medical Device and Laboratory Product Problem Reporting

Program, administered by the *U.S. Pharmacopeia* (USP), under which users can report device or sterilant-related problems.

***Special controls***

The FDA may impose special controls, which can include performance standards, on Class II devices to ensure their safety and effectiveness. Except for a laser safety standard, FDA has not yet promulgated a performance standard for any medical device or sterilant. For all practical purposes, then, Class II devices are regulated by general controls and by the premarket clearance requirements of the medical device law. (It should be noted that standards published by such organizations as the International Organization for Standardization, the American National Standards Institute, the American Society for Testing and Materials, and the Association for the Advancement of Medical Instrumentation are *voluntary* standards; that is, manufacturers are not legally obligated to comply with them unless they claim to do so.)

***Premarket clearance requirements***

As noted earlier, there are two types of premarket clearance processes: premarket or 510(k) notification and premarket approval. Manufacturers must notify FDA at least 90 days before a new or modified device is introduced to the market. The application the manufacturer uses for this purpose is called a 510(k) notification, because FDA's requirements are based on Section 510(k) of the medical device law. In this notification, the manufacturer must supply information and proposed labeling to demonstrate that the device is "substantially equivalent" to a "preenactment" device (a device that was on the market prior to May 28, 1976). Some Class I devices are specifically exempt from 510(k) requirements.

If FDA determines that the new or modified device is indeed "substantially equivalent" to a preenactment device, then the new device will be regulated in the same way as the preenactment device. For example, a new device found to be substantially equivalent to a Class II device is also considered a Class II device. When FDA has made its determination of substantial equivalency, the manufacturer receives a letter from FDA noting the determination.

If a new device is determined to be "not substantially equivalent," it is automatically classified as Class III and must undergo premarket approval or be formally reclassified as Class I or Class II before it can be marketed. Premarket approval entails a much lengthier and more detailed review by FDA than does clearance via a 510(k) notification. A premarket approval application must include extensive scientific evidence of the device's safety and effectiveness and, as part of the review process, FDA must obtain from an expert advisory panel a recommendation on whether the PMA should be approved.

With the exception of certain proprietary information, all data provided in a 510(k) notification or PMA are subject to disclosure under the Freedom of Information Act once the device is marketed.

## Labeling and GMP requirements

Existing FDA medical device regulations for labeling and good manufacturing practices cover, among other subjects, directions for use and simulated-use testing, respectively. The Safe Medical Devices Act of 1990 directs FDA to incorporate design qualification testing into GMP regulations.

***Labeling***

General labeling requirements for adequate directions for use are provided in 21 CFR 801, Subpart A, and include the following:

> Statements of all . . . uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising . . . [801.5(a)].
>
> Preparation for use, i.e., . . . manipulation or process [801.5(g)].

Detailed instructions for processing of a device prior to intended reuse are an essential part of adequate directions for use.

In Subpart D, "Exemptions from Adequate Directions for Use," labeling requirements for prescription devices include the following:

> . . any relevant hazards, contraindications . . . and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended . . . [801.809(c)].

In order to be used safely, a device must be labeled with essential precautions, including the specifications necessary for processing of the reused device to prevent transmission of infection between patients. Although this section also provides for the omission of the information "commonly known" to the practitioner, it is apparent from the inquiries received by FDA that knowledge of adequate processing methods for reused devices is incomplete in the health care community. The increasing complexity of devices and seriousness of health hazards necessitates more detailed labeling in this regard.

***Good manufacturing practices***

The GMP regulation, 21 CFR 820, states in its scope that:

> . . . the regulation is intended to assure that . . . devices will be safe and effective [820.1].

Subpart F, "Production and Process Controls," states that:

> Procedures for specification control measures shall be established to assure that the design basis for the device . . . is correctly translated into approved specifications [820.11(a)(1)].

In the case of a reusable device, specifications must be developed to assure that the design of the device as a reusable one is adequately considered. This includes assuring that the manufacturing process will result in a device that can be cleaned and disinfected and/or sterilized repeatedly for the defined period of reuse.

In Subpart I, "Device Evaluation," finished device inspection requirements include the following:

> There shall be written procedures for finished device inspections to assure that device specifications are met . . . . Where practical, a device shall be selected from a production run, lot or batch and tested under simulated use conditions [820.160].

Assurance that specifications are met for a reused device includes simulated use testing of cleaning and disinfection and/or sterilization conditions included in the labeling. This testing should include determination of the validity of cleaning, disinfecting, or sterilizing agents of defined chemical compositions and concentration under the extreme specified testing to assure that performance specifications are met. The residue levels left on the devices from these agents and their potential toxicity to patients must also be assessed. Adverse effects on device materials having an impact on their biocompatibility must also be tested. When multiple reuse is intended, repeated testing must incorporate or simulate the maximum anticipated number of reuses.

## FDA regulation of liquid chemical disinfectants/sterilants

Both FDA and the Environmental Protection Agency (EPA) have statutory authority to regulate liquid chemical disinfectants/sterilants for medical devices. The FDA regulates chemical disinfectants/sterilants labeled for use with devices as accessories to devices. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is responsible for registering pesticides before they are sold and for ensuring that, when used according to label directions, they are effective and do not present unreasonable risks to human health or the environment. Microorganisms are considered "pests" under FIFRA, so EPA's regulatory authority includes liquid chemical disinfectants and sterilants. Detailed information on EPA requirements for chemical

germicides is provided in AAMI (1990).

The statutory authorities of the two agencies have resulted in some duplicative regulation of chemical disinfectants and sterilants. On June 4, 1993, FDA and EPA signed a Memorandum of Understanding (MOU), "Notice Regarding Matters of Mutual Responsibility—Regulation of Liquid Chemical Germicides Intended for Use on Medical Devices." This MOU established agreement of the two agencies to undertake certain rulemakings in order to eliminate duplicative regulation of chemical disinfectants and sterilants. The agencies have also agreed to simplify and coordinate regulation of these germicides in the interim period before completion of rulemaking.

Under the MOU, FDA will be primarily responsible for the premarket clearance of liquid chemical sterilants intended for use on critical or semicritical devices. The EPA is primarily responsible for premarket review of general-purpose liquid disinfectants intended for use on noncritical devices. Critical, semicritical, and noncritical devices are defined according to the guidelines of the Centers for Disease Control and Prevention (CDC, 1985). The CDC guidelines define devices intended for topical contact as noncritical, intact mucous membrane contact as semicritical, and normally sterile body area contact as critical.

For further information on the implementation of the interim provisions of the MOU and/or other aspects of the MOU, the appropriate agency should be contacted at the following address: Chief, Antimicrobial Program Branch, Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460; Sterilization and Toxicology Project Officer, Office of Compliance, Food and Drug Administration, 2098 Gaither Road, Rockville, MD 20850.

**Reprocessing requirements for a specific reusable device**

The FDA's reprocessing requirements for specific reusable devices are related to the intended body contact of the device and follow CDC (1985):

*Noncritical reusable devices:* Adequate low-level disinfection of the device must be demonstrated using a disinfectant registered by EPA or using disinfectant equipment cleared by FDA for low-level disinfection.

*Semicritical reusable devices:* Adequate repeated high-level disinfection of the device must be demonstrated using a liquid chemical product cleared by FDA or using equipment performing high-level disinfection which is preenactment or cleared by FDA.

*Critical reusable devices:* Adequate repeated sterilization of the device must be demonstrated using a liquid chemical sterilant cleared by FDA or using sterilization equipment available to health care facilities which is either preenactment or cleared by FDA.

Further information regarding FDA requirements for liquid chemical sterilants and for sterilization equipment can be found in FDA (1992) and FDA (1993), respectively.

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## Annex A
## Liquid chemical disinfectants available in health care facilities

This annex describes classes of disinfectants commonly used in health care facilities.

### Phenolics

Phenol compounds, usually referred to as phenolics, are primarily used for the disinfection of environmental surfaces and noncritical medical devices. They are considered to be intermediate- to low-level disinfectants. Phenolics are not generally used to disinfect critical or semicritical medical devices because they are not sporicidal and because phenol residues, which are irritating to mucous membranes and skin, are difficult to remove.

### Quaternary ammonium compounds

Quaternary ammonium compounds, or "quats," are low-level disinfectants used primarily for general cleaning and housekeeping purposes. Most concentrated quaternary ammonium compounds must be mixed with distilled water, because they can be inactivated by the minerals in tap water. "Quats" can be corrosive to metals.

### Chlorine

Inorganic chlorine solutions are generally considered to be intermediate-level disinfectants, although sodium hypochlorite (bleach) is sometimes used for high-level disinfection or sterilization. Chlorine solutions are effective against a wide range of microorganisms, including vegetative bacteria, tubercle bacilli, fungi, some viruses, and some bacterial spores. The free chlorine in sodium hypochlorite or calcium hypochlorite has limited application in the disinfection of medical devices because it is corrosive. It is sometimes used to disinfect hydrotherapy baths and hemodialysis equipment but must be rinsed thoroughly.

### Iodophors

Iodophors, which consist of iodine and a solubilizing agent or carrier, are used as both antiseptics and as low-

or intermediate-level disinfectants. Iodophors can be corrosive to metal instruments and can stain nonmetallic items.

### Alcohols

Ethyl alcohol and isopropyl alcohol are classified as intermediate-level disinfectants. They are rapidly effective against vegetative bacteria, the tubercle bacillus, and fungi. Because alcohols evaporate quickly, they are primarily used to dry lumens of devices such as flexible endoscopes. Alcohols may adversely affect certain plastics. Also, rubber absorbs alcohol, which can cause irritation of skin or mucous membranes.

### Formaldehyde

Depending on concentration, formaldehyde may be a high-level disinfectant (8% formaldehyde/70% alcohol) or intermediate- to high-level disinfectant (4 to 8% formaldehyde in water). Sterility can be achieved with aqueous formaldehyde/alcohol formulations, but the required contact time may be 18 hours or longer. Formaldehyde produces irritating fumes and is potentially carcinogenic. It is commonly used, in a concentration of 4%, to disinfect hemodialysis systems and hemodialyzers but must be thoroughly rinsed to avoid tissue toxicity.

### Glutaraldehyde

A large number of glutaraldehyde-based formulations are commercially available for use as disinfectants or sterilants. The level of disinfection and the ability to sterilize depend on the concentration of glutaraldehyde and the contact time. Glutaraldehyde products are widely used in health care facilities, especially for the disinfection of endoscopic and respiratory therapy instruments. Safeguards are necessary to prevent excessive exposure of health care personnel and patients to irritating and toxic glutaraldehyde residuals.

### Hydrogen peroxide

Hydrogen peroxide is active against vegetative bacteria and viruses and, in high concentration, spores. Several EPA-registered formulations contain both hydrogen peroxide and peroxyacetic acid.

## Annex B
## Sterilization cycles available in health care facilities

This annex describes sterilization cycles that are currently available for use in health care facilities or that are expected to be available for hospital applications by the end of 1994. Not all of the processes listed are in wide use at the time of publication of this report, and not all of them are suitable for any given medical device. It is important for medical device manufacturers to consult with appropriate sterilizer manufacturers for further information on the characteristics of new processes and their suitability for particular devices. It should be noted that pressure parameters are not given here for the various processes, some of which operate under significant positive or negative pressure. The processes and cycle parameters are listed for information only, and their inclusion here does not imply endorsement by AAMI.

### Steam sterilization

Due to increasing cost constraints and, especially, to concerns about occupational exposure to toxic residuals of some gaseous and liquid chemical sterilization processes, sterilization by saturated steam is the preferred reprocessing method in health care facilities. Metal surgical instruments and other heat-stable medical devices are commonly sterilized by this method. Typical parameters for the generic cycles available for use in health care facilities are as follows:

***Gravity-displacement steam sterilization***

Wrapped items:

*Temperature:* 270°F to 275°F (132°C to 135°C)

*Exposure time:* 10 to 15 minutes

*Temperature:* 250°F to 254°F (121°C to 123°C)

*Exposure time:* 15 to 30 minutes

Unwrapped items ("flash" sterilization):

*Temperature:* 270°F (132°C)

*Exposure time:* 3 minutes (metal instruments only)

10 minutes (mixed porous, nonporous items)

***Prevacuum steam sterilization***

Wrapped items:

*Temperature:* 270°F to 275°F (132°C to 135°C)

*Exposure time:* 3 to 4 minutes

Unwrapped items ("flash" sterilization):

*Temperature:* 270°F (132°C)

*Exposure time:* 3 minutes (metal instruments only)

4 minutes (mixed porous, nonporous items)

***Steam-flush pressure-pulse steam sterilization***

Wrapped items:

*Temperature:* 250°F to 254°F (121°C to 123°C)

*Exposure time:* 20 minutes

Unwrapped items:

*Temperature:* 270°F to 275°F (132°C to 135°C)

*Exposure time:* 3 to 4 minutes

**Ethylene oxide sterilization**

Ethylene oxide (EO) sterilization is commonly used to sterilize items that cannot withstand high temperatures, such as medical devices composed entirely or in part of plastic. Currently, health care facilities generally use either 100% ethylene oxide or a sterilant mixture consisting of 12% ethylene oxide and 88% chlorofluorocarbon-12 (CFC-12); CFC-12 is used as a diluent to reduce the flammability of ethylene oxide. Because of concerns about the harmful effects of CFCs on the ozone layer of the earth's atmosphere, alternative EO sterilant mixtures are under development and some have begun to be introduced in health care facilities. Such mixtures are not in wide use at present, but will become more prevalent in the future as regulatory constraints reduce the production and use of CFC-12. Typical sterilization cycle parameters for the commonly used 100% EO and 12/88 EO/CFC-12 methods are given below, along with the parameters for two of the newer mixtures:

***100% EO***

*Concentration EO:* 883 milligrams per liter (mg/L)
*Temperature*: 131°F (55°C) or 99°F (37°C)
*Exposure time:* 60 to 250 minutes (depending on temperature)
*Humidity:* 70% RH minimum

*Concentration EO:* 725 mg/L
*Temperature:* 131°F (55°C) or 99°F (37°C)
*Exposure time:* 60 to 180 minutes (depending on temperature)
*Humidity:* 70% RH minimum

***12/88 EO/CFC-12***

*Concentration EO:* approximately 600 mg/L
*Temperature:* 130°F (55°C)
*Exposure time:* 105 to 120 minutes
*Humidity:* 30 to 80% RH

***EO/Carbon dioxide***

*Concentration EO:* approximately 450 mg/L
*Temperature:* 130°F (55°C) or 100°F (38°C)
*Exposure time:* 3 hours or 7.5 hours (depending on temperature)
*Humidity:* 30 to 80% RH

***EO/HCFC***

*Concentration EO:* approximately 600 mg/L
*Temperature:* 130°F (55°C) or 100°F (38°C)
*Exposure time:* 2 hours or 5 hours (depending on temperature)
*Humidity:* 30 to 80% RH

**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. 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. Typical cycle parameters are:

*Temperature:* 338°F (170°C)
*Exposure time:* 60 minutes

*Temperature:* 375°F (190°C)
*Exposure time:* 6 minutes (unwrapped items) or 12 minutes (wrapped items)

**Liquid chemical sterilants**

Liquid chemical sterilant formulations contain one or more sporicidal agents designated as "active" ingredients on EPA-approved labels and one or more ingredients designated as "inert." The inert ingredients can be important to the sterilizing process; they may include anticorrosive agents to improve the materials compatibility of the sterilant, detergents to increase wettability and soil removal, and buffers or activating agents to adjust the pH of the solution and assure the potency of the active agent.

Typically, an item must be totally immersed in the liquid sterilant for a defined period of time at a set temperature; these parameters are determined by the sterilant manufacturer and indicated in the product

labeling. Liquid chemical sterilant formulations were originally designed to be used manually; that is, the activated solution is poured into a large basin and the device is completely immersed. The user is responsible for ensuring that the concentration is adequate, the time-at-temperature is correct, and that all internal and external surfaces are in contact with the solution. In addition, the user must manually rinse the device to remove toxic chemical residues. Automated systems have been introduced, primarily for flexible endoscopes. In these systems, the sterilant is circulated around and through the items being sterilized. Automated systems control the sterilization parameters and, in some cases, provide sterile rinsing. Such systems are currently available for surgical instruments, flexible endoscopes, and hemodialyzers.

Common cycle parameters for various types of liquid sterilants are given below:

***Glutaraldehyde formulations***

| | |
|---|---|
| *Concentration of glutaraldehyde:* | 2 to 3.5% |
| *Temperature:* | 77°F (25°C) |
| *Exposure time:* | 10 hours |

NOTE—It cannot be assumed that any 2 to 3.5% glutaraldehyde formulation is a sterilant. The efficacy of glutaraldehyde sterilants depends on other active ingredients, the inactive ingredients, and the pH.

***Peroxyacetic acid formulations***

| | |
|---|---|
| *Concentration of peroxyacetic acid:* | 0.2% |
| *Temperature:* | 122°F to 132°F (50°C to 55.5°C) |
| *Exposure time:* | 12 minutes |

**Chemical sterilant gases**

The most widely used chemical sterilant gas is ethylene oxide. Ethylene oxide gas is an effective sterilant, but concerns about the toxicity of ethylene oxide and the impact of certain EO diluents on the ozone layer have led to regulatory constraints on its production and use and have spurred interest in alternative sterilant gases. Formaldehyde/alcohol combinations have been in use for some time. Also, new gaseous sterilization systems utilizing hydrogen peroxide and peroxyacetic acid are being developed and introduced for hospital applications. All chemical sterilant gases are intended to be used in enclosed sterilization chambers under cycle conditions designed and specified by the manufacturer. Cycle parameters for some chemical sterilant gas processes are as follows:

***Formaldehyde/alcohol***

| | |
|---|---|
| *Concentration of formaldehyde:* | 0.23% |
| *Temperature:* | 270°F (132°C) |
| *Exposure time:* | 20 minutes |

***Low-temperature hydrogen peroxide plasma***

| | |
|---|---|
| *Concentration of hydrogen peroxide:* | 6 mg/L |
| *Temperature:* | 76°F to 122°F (24°C to 50°C) |
| *Exposure time:* | 65 minutes |

***Low-temperature peroxyacetic acid/plasma***

| | |
|---|---|
| *Concentration of peroxyacetic acid:* | 2 mg/L (initial vapor phase) |
| *Temperature:* | < 113°F (45°C) |
| *Exposure time:* | 3 hours |

***Vapor-phase hydrogen peroxide***

| | |
|---|---|
| *Concentration of hydrogen peroxide:* | 35% (initial) |

| | |
|---|---|
| *Temperature:* | 100°F to 102°F (38°C to 39°C) |
| *Exposure time:* | 30 to 55 minutes |