



**ASIA PACIFIC SOCIETY OF  
INFECTION CONTROL**

**THE ASEAN GUIDELINES  
FOR DISINFECTION AND STERILIZATION OF INSTRUMENTS IN  
HEALTH CARE FACILITIES**

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## Glossary

**Action level:** concentration of a regulated substance (e.g., ethylene oxide, formaldehyde) within the employee breathing zone

**Activation of a sterilant:** process of mixing the contents of a chemical sterilant that come in two containers (small vial with the activator solution; container of the chemical); keeping the two chemicals separate until use extends the shelf life of the chemicals.

**Aeration:** method by which ethylene oxide (EtO) is removed from EtO-sterilized items by warm air circulation in an enclosed cabinet specifically designed for this purpose.

**Antimicrobial agent:** any agent that kills or suppresses the growth of microorganisms.

**Antiseptic:** substance that prevents or arrests the growth or action of microorganisms by inhibiting their activity or by destroying them. The term is used especially for preparations applied topically to living tissue.

**Asepsis:** prevention of contact with microorganisms.

**Autoclave:** device that sterilizes instruments or other objects using steam under pressure. The length of time required for sterilization depends on temperature, vacuum, and pressure.

**Bacterial count:** method of estimating the number of bacteria per unit sample. The term also refers to the estimated number of bacteria per unit sample, usually expressed as number of colony-forming units.

**Bactericide:** agent that kills bacteria.

**Bioburden:** number and types of viable microorganisms with which an item is contaminated; also called *bioload* or *microbial load*.

**Biofilm:** accumulated mass of bacteria and extracellular material that is tightly adhered to a surface and cannot be easily removed.

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

**Bleach:** Household bleach (5.25% or 6.00%–6.15% sodium hypochlorite depending on manufacturer) usually diluted in water at 1:10 or 1:100. Approximate dilutions are 1.5 cups of bleach in a gallon of water for a 1:10 dilution (~6,000 ppm) and 0.25 cup of bleach in a gallon of water for a 1:100 dilution (~600 ppm).

<b>Bleach Solution</b>	<b>Dilution</b>	<b>Chlorine (ppm)</b>
5.25-6.15%	None	52,500-61,500
	1:10	5,250-6,150
	1:100	525-615
	1:1000	53-62

**Bowie-Dick test:** diagnostic test of a sterilizer’s ability to remove air from the chamber of a prevacuum steam sterilizer. The air-removal or Bowie-Dick test is not a test for sterilization.

**Ceiling limit:** concentration of an airborne chemical contaminant that should not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling must be assessed as a 15-minute time-weighted average exposure.

**Central processing or Central service department:** the department within a health-care facility that processes, issues, and controls professional supplies and equipment, both sterile and non-sterile, for some or all patient-care areas of the facility.

**Challenge test pack:** pack used in installation, qualification, and ongoing quality assurance testing of health-care facility sterilizers.

**Chemical indicator:** device for monitoring a sterilization process. The device is designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators are intended to detect potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The “pass” response of a chemical indicator does not prove the item accompanied by the indicator is necessarily sterile. The Association for the Advancement of Medical Instrumentation has defined five classes of chemical indicators: Class 1 (process indicator); Class 2 (Bowie-Dick test indicator); Class 3 (single-parameter indicator); Class 4 (multi-parameter indicator); and Class 5 (integrating indicator).

**Contact time:** time a disinfectant is in direct contact with the surface or item to be disinfected. For surface disinfection, this period is framed by the application to the surface until complete drying has occurred.

**Container system, rigid container:** sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents.

**Contaminated:** state of having actual or potential contact with microorganisms. As used in health care, the term generally refers to the presence of microorganisms that could produce disease or infection.

**Control, positive:** biologic indicator, from the same lot as a test biologic indicator, i.e. left unexposed to the sterilization cycle and then incubated to verify the viability of the test biologic indicator.

**Cleaning:** removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms 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.

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

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

**Cup:** 250 mls

**Decontamination:** “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” In health-care facilities, the term generally refers to all pathogenic organisms.

**Decontamination area:** area of a health-care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

**Detergent:** cleaning agent that makes no antimicrobial claims on the label. They comprise a hydrophilic component and a lipo-philic component and can be divided into four types: anionic, cationic, amphoteric, and non-ionic detergents.

**Disinfectant:** usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects.

**Disinfection:** thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

**D value:** time or radiation dose required to inactivate 90% of a population of the test microorganism under stated exposure conditions.

**Endoscope:** an instrument that allows examination and treatment of the interior of the body canals and hollow organs.

**Enzyme cleaner:** a solution used before disinfecting instruments to improve removal of organic material (e.g., proteases to assist in removing protein).

**Exposure time:** period in a sterilization process during which items are exposed to the sterilant at the specified sterilization parameters. For example, in a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

**Flash sterilization:** process designed for the steam sterilization of unwrapped patient-care items for immediate use (or placed in a specially designed, covered, rigid container to allow for rapid penetration of steam).

**Fungicide:** agent that destroys fungi (including yeasts) and/or fungal spores pathogenic to humans or other animals in the inanimate environment.

**Germicide:** agent that destroys microorganisms, especially pathogenic organisms.

**High-level disinfectant:** agent capable of killing bacterial spores when used in sufficient concentration under suitable conditions. It therefore is expected to kill all other microorganisms.

**Hospital disinfectant:** disinfectant registered for use in hospitals, clinics, dental offices, and any other medical-related facility. Efficacy is demonstrated against *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*. EPA has registered approximately 1,200 hospital disinfectants.

**Implantable device:** “device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more”

**Inanimate surface:** nonliving surface (e.g., floors, walls, furniture).

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

**Infectious microorganisms:** microorganisms capable of producing disease in appropriate hosts.

**Inorganic and organic load:** naturally occurring or artificially placed inorganic (e.g., metal salts) or organic (e.g., proteins) contaminants on a medical device before exposure to a microbicidal process.

**Intermediate-level disinfectant:** agent that destroys all vegetative bacteria, including tubercle bacilli, lipid and some nonlipid viruses, and fungi, but not bacterial spores.

**Limited disinfectant:** disinfectant registered for use against a specific major group of organisms (gram-negative or gram-positive bacteria). Efficacy has been demonstrated in laboratory tests against either *Salmonella choleraesuis* or *Staphylococcus aureus* bacteria.

**Lipid virus:** virus surrounded by an envelope of lipoprotein in addition to the usual core of nucleic acid surrounded by a coat of protein. This type of virus (e.g., HIV) is generally easily inactivated by many types of disinfectants. Also called *enveloped* or *lipophilic virus*.

**Low-level disinfectant:** agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores.

**Mechanical indicator:** devices that monitor the sterilization process (e.g., graphs, gauges, printouts).

**Medical device:** instrument, apparatus, material, or other article, whether used alone or in combination, including software necessary for its application, intended by the manufacturer to be used for human beings for diagnosis, prevention, monitoring treatment, or alleviation of disease.

**Microorganisms:** animals or plants of microscopic size. As used in health care, generally refers to bacteria, fungi, viruses, and bacterial spores.

**Minimum effective concentration (MEC):** the minimum concentration of a liquid chemical germicide needed to achieve the claimed microbicidal activity as determined by dose-response testing. Sometimes used interchangeably with *minimum recommended concentration*.



**Mycobacteria:** bacteria with a thick, waxy coat that makes them more resistant to chemical germicides than other types of vegetative bacteria.

**Nonlipid viruses:** generally considered more resistant to inactivation than lipid viruses. Also called nonenveloped or hydrophilic viruses.

**One-step disinfection process:** simultaneous cleaning and disinfection of a noncritical surface or item.

**Pasteurization:** process developed by Louis Pasteur of heating milk, wine, or other liquids to 65–77°C (or the equivalent) for approximately 30 minutes to kill or markedly reduce the number of pathogenic and spoilage organisms other than bacterial spores.

**Parametric release:** declaration that a product is sterile on the basis of physical and/or chemical process data rather than on sample testing or biologic indicator results.

**Permissible exposure limit (PEL):** time-weighted average maximum concentration of an air contaminant to which a worker can be exposed, according to OSHA standards. Usually calculated over 8 hours, with exposure considered over a 40-hour work week.

**Personal protective equipment (PPE):** specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts) not intended to function as protection against a hazard are not considered to be PPE.

**Parts per million (ppm):** common measurement for concentrations by volume of trace contaminant gases in the air (or chemicals in a liquid); 1 volume of contaminated gas per 1 million volumes of contaminated air or 1¢ in \$10,000 both equal 1 ppm. Parts per million =  $\mu\text{g/mL}$  or  $\text{mg/L}$ .

**Prions:** transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including sheep and goats, bovine spongiform encephalopathy in cattle, and Creutzfeldt-Jakob disease in humans. They are unlike any other infectious pathogens because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (PrP). Prions are extremely resistant to inactivation by sterilization processes and disinfecting agents.

**Process challenge device (PCD):** item designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process and used to assess the effective performance of the process. A PCD is a challenge test pack or test tray that contains a biologic indicator, a Class 5 integrating indicator, or an enzyme-only indicator.

**Recommended exposure limit (REL):** occupational exposure limit recommended by NIOSH as being protective of worker health and safety over a working lifetime. Frequently expressed as a 40-hour time-weighted-average exposure for up to 10 hours per day during a 40-work week.

**Reprocess:** method to ensure proper disinfection or sterilization; can include: cleaning, inspection, wrapping, sterilizing, and storing.

**Shelf life:** length of time an undiluted or use dilution of a product can remain active and effective. Also refers to the length of time a sterilized product (e.g., sterile instrument set) is expected to remain sterile.

**Spaulding classification:** strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semi-critical, or non-critical on the basis of risk to patient safety from contamination on a device. The system also established three levels of germicidal activity (sterilization, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semi-critical, and non-critical).

**Spore:** relatively water-poor round or elliptical resting cell consisting of condensed cytoplasm and nucleus surrounded by an impervious cell wall or coat. Spores are relatively resistant to disinfectant and sterilant activity and drying conditions (specifically in the genera *Bacillus* and *Clostridium*).

**Spore strip:** paper strip impregnated with a known population of spores that meets the definition of biological indicators.

**Steam quality:** steam characteristic reflecting the dryness fraction (weight of dry steam in a mixture of dry saturated steam and entrained water) and the level of noncondensable gas (air or other gas that will not condense under the conditions of temperature and pressure used during the sterilization process). The dryness fraction (i.e., the proportion of completely dry steam in the steam being considered) should not fall below 97%.

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

**Steam sterilization, dynamic air removal type:** one of two types of sterilization cycles in which air is removed from the chamber and the load by a series of pressure and vacuum excursions (prevacuum cycle) or by a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush-pressure-pulse cycle).

**Sterile** or **Sterility:** state of being free from all living microorganisms. In practice, usually described as a probability function, e.g., as the probability of a microorganism surviving sterilization being one in one million.

**Sterility assurance level (SAL):** probability of a viable microorganism being present on a product unit after sterilization. Usually expressed as  $10^{-6}$ ; a SAL of  $10^{-6}$  means  $\leq 1/1$  million chance that a single viable microorganism is present on a sterilized item. A SAL of  $10^{-6}$  generally is accepted as appropriate for items intended to contact compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers). The sterilizer manufacturer is responsible for ensuring the sterilizer can achieve the desired SAL. The user is responsible for monitoring the performance of the sterilizer to ensure it is operating in conformance to the manufacturer's recommendations.

**Sterilization:** validated process used to render a product free of all forms of viable microorganisms. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

**Sterilization area:** area of a health-care facility designed to house sterilization equipment, such as steam ethylene oxide, hydrogen peroxide gas plasma, or ozone sterilizers.

**Sterilizer:** apparatus used to sterilize medical devices, equipment, or supplies by direct exposure to the sterilizing agent.

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

**Sterilizer, prevacuum type:** type of steam sterilizer that depends on one or more pressure and vacuum excursions at the beginning of the cycle to remove air. This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system and because of the usually higher operating temperature (132–135°C; 141–144°C). This type of sterilizer generally provides for shorter exposure time and accelerated drying of fabric loads by pulling a further vacuum at the end of the sterilizing cycle.

**Sterilizer, steam-flush pressure-pulse type:** type of sterilizer in which a repeated sequence consisting of a steam flush and a pressure pulse removes air from the sterilizing chamber and processed materials using steam at above atmospheric pressure (no vacuum is required). Like a prevacuum sterilizer, a steam-flush pressure-pulse sterilizer rapidly removes air from the sterilizing chamber and wrapped items; however, the system is not susceptible to air leaks because air is removed with the sterilizing chamber pressure at above atmospheric pressure. Typical operating temperatures are 121–123°C, 132–135°C, and 141–144°C).

**Tabletop steam sterilizer:** a compact gravity-displacement steam sterilizer that has a chamber volume of not more than 2 cubic feet and that generates its own steam when distilled or deionized water is added.

**Vegetative bacteria:** bacteria that are devoid of spores and usually can be readily inactivated by many types of germicides.

(Reference: CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 )

## General Principles

The goals of safe reprocessing of medical equipment/devices include:

- a) preventing transmission of microorganisms to personnel and clients/patients/residents; and
- b) minimizing damage to medical equipment/devices from foreign material (e.g., blood, body fluids, saline and medications) or inappropriate handling.

Best practices in reprocessing medical equipment/devices must include the following:

- a) adequate review by all parties whenever new equipment/devices are being considered for purchase (e.g., reprocessing committee);
- b) a centralized area for reprocessing or an area that complies with the requirements for reprocessing;
- c) written policies and procedures for reprocessing each type of medical equipment/device;
- d) training of all staff who performs reprocessing;
- e) validation of cleanliness, sterility and function of the reprocessed equipment/device;
- f) continual monitoring of reprocessing procedures to ensure their quality;
- g) a corporate strategy for dealing with single-use medical equipment/devices;
- h) management and reporting of medical incidents;
- i) management and reporting of safety-related accidents;
- j) recall of improperly reprocessed devices; and
- k) procedures to be followed in emergency situations (e.g., utilities shutdowns, compromised packaging, biological indicator (BI) testing failures).

### ***Recommendation 1***

***It is strongly recommended that, wherever possible, reprocessing should be performed in a centralized area that complies with the physical and human resource requirements for reprocessing.***

Decisions related to reprocessing medical equipment/devices should be made by a multi-disciplinary Infection Control Committee that includes the individuals responsible for purchasing the equipment/device, reprocessing the equipment/device, maintaining the equipment/device, infection prevention and control, occupational health and safety, and the end-user of the equipment/device.

It is strongly recommended that, wherever possible, reprocessing should be performed in a centralized area that complies with the physical and human resource requirements for reprocessing.

When formulating written policies and procedures, the following steps in reprocessing must be included:

- a) collection at point-of-use, containment and transport;
- b) disassembly (if required);
- c) inspection;
- d) cleaning;
- e) disinfection/sterilization (including establishment of the level of reprocessing required for items, based on Spaulding's Classification and manufacturer's instructions);
- f) rinsing (following disinfection);
- g) drying/aeration;
- h) reassembly and functional testing;
- k) clean transportation; and
- l) storage.

It is essential that an overall inventory of all reprocessing practices within the healthcare setting is done, including documentation as to where, how and by whom all equipment/devices are being reprocessed and whether current standards are being met, as set out in this document. All processes must continue to be audited on a regular basis (e.g., annually), with clear and known consequences resulting from non-compliance.

As new reprocessing technologies and processes become available, they must be evaluated against the same criteria as current methodologies. Verify that:

- a) the process is compatible with the equipment/device being reprocessed;
- b) the process is compatible with the cleaning products being used;
- c) environmental issues with the process have been considered (e.g., odors, toxic waste products, toxic vapors);
- d) occupational health issues with the process have been considered (e.g., is PPE or special ventilation required);
- e) staff education and training is available (provided by the manufacturer);
- f) the facility is able to provide the required preventive maintenance;
- g) the process can be monitored (e.g., there are physical, chemical and biologic monitors and indicators available);
- h) quarantine of non-implantable items in processed loads pending results of biological indicator (BI) testing (if load quarantine is not possible, evaluation of a Class 5 or 6 chemical indicator (CI) and specific cycle physical parameters may be used to justify the release of loads);
- i) quarantine of each load containing implantable devices pending results of BI testing.

## **Factors Affecting the Efficacy of the Reprocessing Procedure**

Policies and procedures for disinfection and sterilization must include statements and information relating to factors that might affect the effectiveness of reprocessing. These procedures must be readily accessible to staff doing the reprocessing.

Many factors affect the efficacy of reprocessing, particularly when chemical reprocessing is used. These factors include:

### **a) Cleanliness of the surface of the equipment/device:**

- i) many chemical disinfectants/sterilants are inactivated by organic material; cleaning must always precede decontamination;
- ii) the greater the bioburden, the more difficult it is to disinfect or sterilize the equipment/device.

### **b) Characteristics of equipment/device:**

- i) long, narrow lumens and channels are difficult to clean;
- ii) materials such as rubber and plastic may require special treatment;
- iii) rough or porous surfaces may trap microorganisms (e.g., ridges, ribbing, grooves, and articulations);
- iv) hinges, cracks, coils, valves, joints, clamps, crevices on the equipment/device may impede successful disinfection/sterilization.

### **c) Type and concentration of the product:**

- i) products used for disinfection and/or sterilization must be mixed according to the manufacturer's recommendations in order to achieve the correct dilution; if the concentration of the disinfectant is too low, the efficacy will be decreased; if the concentration is too high, the risk of damage to the instrument or toxic effects on the user increases;
- ii) dry equipment/devices after cleaning, before immersing in disinfectant, to prevent dilution of the disinfectant;
- iii) discard solutions on or before expiry date; diluted products are inherently unstable once mixed and the manufacturer's directions as to duration of use must be followed;
- iv) use chemical test strips for all high-level liquid disinfectants to assess their efficacy; during reuse, the concentration of active ingredients may decrease as dilution of the product occurs and organic impurities accumulate;
- v) use the appropriate disinfectant/sporicide for the task; infection prevention and control must approve disinfectants and their application; and

vi) some microorganisms are more resistant to disinfectants/sporicides, and this must be taken into consideration when choosing the product/process.

**d) Duration and temperature of exposure to the product:**

i) use Spaulding's Classification (see Table 1) for the level of disinfection/sterilization required for the intended use of the equipment/device and minimum exposure time to disinfectants/sterilants to achieve this level ;

ii) use manufacturer's recommendations for temperature and for exposure time required to achieve the desired level of disinfection/sterilization; do not exceed the manufacturer's maximum exposure time, as some chemicals may cause damage to the medical equipment/device if used for extended periods of time;

iii) all surfaces of the article must be in direct contact with the disinfectant/sterilant; and

iv) contact may be compromised by the complexity of the article and the ability of the disinfectant to penetrate lumens etc.

**e) Physical and chemical properties of the reprocessing environment:**

i) water hardness can affect some disinfectants;

ii) excessive humidity may compromise sterile wrappings and

iii) the pH of the solution may be an important consideration, as extremes of acidity or alkalinity affect growth of microorganisms or alter the activity of disinfectants and sterilants.

***Recommendation 2***

***Procedures for disinfection and sterilization must include statements and information regarding the type, concentration and testing of chemical products; duration and temperature of exposure; and physical and chemical properties that might have an impact on the efficacy of the process. These procedures must be readily accessible to staff performing the function.***

**Figure 1**

**Decreasing order of resistance of microorganisms to disinfection and sterilization and the level of disinfection or sterilization (Reference: CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008)**

<b>Resistant Level</b>	<b>Level / method of disinfection &amp; sterilization</b>
<b>Resistant</b>	
Prions (Creutzfeldt-Jakob Disease)	Prion reprocessing
Bacterial spores ( <i>Bacillus atrophaeus</i> )	Sterilization
Coccidia ( <i>Cryptosporidium</i> )	
Mycobacteria ( <i>M. tuberculosis</i> , <i>M. terrae</i> )	High
Nonlipid or small viruses (polio, coxsackie)	Intermediate
Fungi (Aspergillus, Candida)	
Vegetative bacteria ( <i>S. aureus</i> , <i>P. aeruginosa</i> )	Low
↓ Lipid or medium-sized viruses (HIV, herpes, hepatitis B)	
<b>Susceptible</b>	

**Disassembly, Inspection and Cleaning of Reusable Medical Equipment/Devices**

Reusable medical equipment/devices must be thoroughly cleaned before disinfection or sterilization. The process of cleaning physically removes contaminants from the equipment/device, rather than killing microorganisms. If an item is not cleaned, soil (e.g., blood, body fluids, dirt) can protect the microorganisms from the action of the disinfection or sterilization process making it ineffective, as well as inactivate the disinfectant or sterilant so that it does not work. Disinfectants that become overloaded with soil can become contaminated and may become a source for transmission of microorganisms. Cleaning is always essential prior to disinfection or sterilization. An item that has not been cleaned cannot be adequately disinfected or sterilized.

**A. Pre-Cleaning**

Gross soil (e.g., faeces, sputum, blood) shall be removed immediately at point-of-use. If cleaning cannot be done immediately, the medical equipment/device must be submerged in tepid water and detergent or enzymatic cleaner to prevent organic matter from drying on it. This does not eliminate the chance of transmission of infectious agents to healthcare workers. Personnel who perform such task should wear appropriate protective equipment and follow safe work practice according to Standard Precautions.



Factors that affect the ability to effectively clean medical equipment/devices must be considered prior to cleaning. Policies and procedures for cleaning medical equipment/devices shall be based on the manufacturer's instructions and must be developed in consultation with Infection Prevention and Control, Occupational Health and Safety, Biomedical Engineering and Environmental Services. Full PPE shall be worn for handling and cleaning contaminated equipment/devices. Once medical equipment/devices have been received in the reprocessing area/department, they must be disassembled, sorted and soaked:

a) **Disassembly** – facilitates access of the cleaning agent, disinfectant and/or sterilant to device surfaces:

- i) equipment/devices shall be disassembled prior to cleaning if there is one or more removable part, unless otherwise recommended by the manufacturer; and
- ii) follow the manufacturer's recommendations when disassembling medical equipment/devices prior to washing.

b) **Sorting** – keeps medical equipment/devices that belong to a set together and streamlines the cleaning process:

- i) sort equipment/devices into groups of like products requiring the same processes;
- ii) segregate sharps and/or delicate equipment/devices to prevent injury to personnel and damage to the equipment/device.

c) **Soaking** – prevents soil from drying on equipment/devices and makes them easier to clean:

- i) soak equipment/device in a hospital approved instrument soaking solution;
- ii) do not use saline as a soaking solution as it damages some medical equipment/devices;
- iii) use detergent-based products, including those containing enzymes, as part of the soaking process;
- iv) ensure that detergents (including enzymatic cleaners) are appropriate to the equipment/device being cleaned (products used must be approved by the equipment/device manufacturer); and
- v) avoid prolonged soaking (e.g., overnight) of equipment/devices.

## **B. Cleaning**

Cleaning may be done manually or using mechanical cleaning machines (e.g., washer-disinfector, ultrasonic washer, washer-sterilizer) after gross soil has been removed. Automated machines may increase productivity, improve cleaning effectiveness and decrease staff exposure to blood and body fluids. Manual cleaning may be required for delicate or intricate items. The equipment/device

manufacturer's cleaning instructions shall be followed, including specifications for detergent type, water temperature and cleaning methods. The following procedures are included in the cleaning process:

**a) Physical Removal of Organic Materials**

- i) completely submerge immersible items during the cleaning process to minimize aerosolization of microorganisms and assist in cleaning;
- ii) minimize the production of aerosols when cleaning non-immersible equipment/devices;
- iii) remove gross soil using tools such as brushes and cloths;

**b) Manual Cleaning**

- i) any brushing required should be done under water
- ii) clean equipment/devices that have lumens with a brush, according to the manufacturer's instructions, then manually or mechanically flush with a detergent solution and rinse;
- iii) check equipment/devices with lumens for obstructions and leakage;

**c) Mechanical Cleaning**

Whenever possible, clean equipment/devices by mechanical means:

- i) any brushing required should be done underwater;
- ii) use mechanical washers in accordance with the manufacturer's instructions;
- iii) manually clean heavily soiled equipment/devices before mechanical cleaning;
- iv) ensure that the equipment/device to be cleaned is compatible with the mechanical cleaning equipment and chemical solutions that are being used;
- v) ultrasonic washers are strongly recommended for any semi-critical or critical medical equipment/device that has joints, crevices, lumens or other areas that are difficult to clean:

- the manufacturer's instructions must be followed for use and routine cleaning and maintenance of the ultrasonic washer
- equipment/devices shall be completely immersed in the washing solution
- after cleaning, equipment/devices shall be rinsed thoroughly prior to further reprocessing
- the ultrasonic washing solution should be changed at least daily or more frequently if it becomes visibly soiled or if the manufacturer's instructions specify more frequent changes

- v) washer-disinfectors are strongly recommended for medical equipment/devices that can withstand mechanical cleaning, to achieve the required exposure for cleaning and to

reduce potential risk to personnel:

- the manufacturer's instructions must be followed for the use and routine maintenance, cleaning and calibration of the washer-disinfector
- washer-disinfectors may be used for low-level disinfection
- washer-disinfectors are not to be used for high-level disinfection

#### **d) Care of Cleaning Tools**

- i) inspect brushes and other cleaning equipment for damage after each use, and discard if necessary;
- ii) clean, disinfect, dry and store tools used to assist in cleaning (e.g., brushes, cloths).

#### **e) Rinsing**

Rinsing following cleaning is necessary, as residual detergent may neutralize the disinfectant:

- i) rinse all equipment/devices thoroughly after cleaning with water to remove residues which might react with the disinfectant/sterilant;
- ii) perform the final rinse for equipment/devices containing lumens with commercially prepared sterile, pyrogen-free water (note: distilled water is not necessarily sterile or pyrogen-free).

#### **f) Drying**

Drying is an important step that prevents dilution of chemical disinfectants which may render them ineffective and prevents microbial growth:

- i) follow the manufacturer's instructions for drying of the equipment/device;
- ii) equipment/devices may be air-dried or dried by hand with a clean, lint-free towel;
- iii) dry lumens with compressed air that has been filtered and dried;
- iv) dry stainless steel equipment/devices immediately after rinsing to prevent spotting.

### **C. Post-Cleaning**

Once medical equipment/devices have been reprocessed, there must be a process to ensure that they can be differentiated from equipment/devices which have not been reprocessed. Sterilized items may be identified using external chemical indicators (CIs), such as autoclave tape, which changes color during sterilization. Equipment/devices which receive high-level disinfection should also be labeled, tagged or color-coded to indicate that they have been reprocessed.

The following procedures must be included following the cleaning process:

**a) Reassembly and Inspection**

- i) visually inspect all equipment/devices once the cleaning process has been completed and prior to terminal disinfection/sterilization to ensure cleanliness and integrity of the equipment/device (e.g., cracks, defects, adhesive failures, missing parts);
- ii) repeat the cleaning on any item that is not clean;
- iii) do not reassemble equipment/device prior to disinfection/sterilization; if the equipment/device manufacturer's instructions specify reassembly at this stage in the reprocessing, it shall take place in a clean area and be performed in accordance with the manufacturer's instructions.

**b) Lubrication**

- i) follow the manufacturer's guidelines for lubrication;
- ii) equipment/devices requiring lubrication shall be lubricated prior to sterilization;
- iii) lubricants shall be compatible with the device and with the sterilization process;
- iv) discard lubricants on expiry date or when visibly soiled or contaminated.

**c) Wrapping**

- i) equipment/devices that are to be sterilized require wrapping prior to sterilization (except for flash sterilization);
- ii) container and materials used for wrapping shall be prepared in a manner that will allow adequate air removal, steam penetration and evacuation to all surfaces.

**d) Practice audits**

- i) cleaning processes must be audited on a regular basis;
- ii) a quality improvement process must be in place to deal with any irregularities/concerns resulting from the audit.

***Recommendation 3***

***Reusable medical equipment/devices must be thoroughly cleaned before disinfection or sterilization.***

***Recommendation 4***

***If cleaning cannot be done immediately, the medical equipment/device must be submerged in tepid water and detergent or enzymatic cleaner to prevent organic matter from drying on it.***

***Recommendation 5***

***Factors that affect the ability to effectively clean medical equipment/devices must be considered prior to cleaning.***

***Recommendation 6***

***The process for cleaning should include written protocols for disassembly, sorting, soaking, physical removal of organic material, rinsing, drying, physical inspection, lubrication and wrapping.***

***Recommendation 7***

***Audits of the cleaning process must be done on a regular basis.***

## **Policies and Procedures**

Policies and procedures must be established to ensure that the disinfection processes follow the principles of infection prevention as set out by CDC, WHO or the country Ministry of Health. Completed policies and procedures should be reviewed by an individual with infection prevention and control expertise (e.g., facility's infection prevention and control professionals, public health staff with certification in infection prevention and control). Review of reprocessing policies and procedures must take place at least annually.

Reprocessing policies and procedures shall include the following:

- a) responsibilities of management and staff;
- b) qualifications, education and training for staff involved in reprocessing;
- c) infection prevention and control activities;
- d) worker health and safety activities;
- e) preventive maintenance requirements with documentation of actions;
- f) written protocols for each component of the cleaning, disinfection and/or sterilization processes that are based on the manufacturer's recommendations and established guidelines for the intended use of the product;
- g) provision for annual review of policies and procedures with updating as required;
- h) documentation and maintenance of records for each process;
- i) ongoing audits of competency and procedures (who, when, how);
- j) management and reporting to administration or appropriate regulatory body of incidents where healthcare workers and patient safety may have been compromised;
- k) procedures for the recall and reprocessing of improperly reprocessed medical requirements for

internal or external subcontractors, if applicable written a protocol that prevents the release of loads containing implantable devices pending results of BI testing equipment/devices; and

***Recommendation 8***

*The health care setting will, as a minimum, have policies and procedures for all aspects of reprocessing that are based on current recognized standards/recommendations and that are reviewed at least annually.*

***Recommendation 9***

*All policies and procedures for reprocessing medical equipment/devices require review by an individual with infection prevention and control expertise.*

***Recommendation 10***

*A procedure should be established for the recall of improperly reprocessed medical equipment/devices.*

**Education and Training**

The manager and all supervisors involved in reprocessing must, as a minimum, have completed a recognized qualification/certification course in reprocessing practices. A plan must be in place for each person involved in reprocessing to obtain this qualification.

It is the supervisor's responsibility to ensure that:

- a) any individual involved in the cleaning, disinfection and/or sterilization of medical equipment/devices is properly trained and their practice audited on a regular basis to verify that standards are met;
- b) training includes information on cleaning, disinfection and sterilization, occupational health and safety issues, and infection prevention and control;
- c) orientation and continuing education is provided and documented for all personnel involved in reprocessing of medical equipment/devices; and
- d) feedback is provided to reprocessing staff in a timely manner.

The policies of the health care setting specify the requirements for, and frequency of, education and training as well as competency assessment for all personnel involved in the reprocessing of medical equipment/devices and will ensure that:

- a) all staffs who are primarily involved in reprocessing obtain and maintain certification;
- b) any individual involved in any aspect of reprocessing obtains education, orientation and training

specific to the medical equipment/device to be reprocessed (e.g., dental hygienists, radiation technologists, nurses in long- term care, nurses in physician offices);

- c) there is a process in place to ensure continued competency, including continuing education;
- d) supervisory staff must be competent through education, training and experience in the reprocessing of reusable medical equipment/devices.

All staff involved in reprocessing of medical equipment/devices must be supervised and shall be qualified through education in a formally recognized course for sterilization technology, training and experience in the functions they perform shall be provided at regular intervals and periodic competency assessment all orientation, training and continuing education is documented.

***Recommendation 11***

***The policies of the healthcare setting shall specify the requirements for, and frequency of, education and training as well as competency assessment for all personnel involved in the reprocessing of medical equipment/devices.***

***Recommendation 12***

***All aspects of reprocessing shall be supervised and shall be performed by knowledgeable, trained personnel.***

***Recommendation 13***

***Managers, supervisors and staff involved in reprocessing have completed a recognized qualification/certification course in reprocessing practices.***

***Recommendation 14***

***A plan must be in place for each person involved in reprocessing to obtain certification qualification.***

## **Environmental Requirements for Reprocessing Areas**

### **A. Physical Space**

There must be a centralized area for reprocessing medical equipment/devices. Reprocessing performed outside the centralized area must be kept to a minimum and must be approved by the Infection Control Committee or those accountable for safe reprocessing practices and must conform to the requirements for reprocessing space. In smaller settings, such as clinics or offices in the community, this refers to any segregated area where reprocessing of equipment/devices takes place, away from clients/patients/residents and clean areas.

The central processing area(s) ideally should be divided into at least three areas: decontamination, packaging, and sterilization and storage. Physical barriers should separate the decontamination area from the other sections to contain contamination on used items.

In the decontamination area, reusable contaminated supplies (and possibly disposable items that are reused) are received, sorted, and decontaminated. The recommended airflow pattern should contain contaminants within the decontamination area and minimize the flow of contaminants to the clean areas.

The American Institute of Architects recommends negative pressure and no fewer than six air exchanges per hour in the decontamination area (AAMI recommends 10 air changes per hour) and 10 air changes per hour with positive pressure in the sterilizer equipment room.

The environment where cleaning/decontamination is performed must:

- a) have adequate space for the cleaning process and storage of necessary equipment and supplies;
- b) be distinctly separate from areas where clean/disinfected/sterile equipment/devices are handled or stored;
- c) have easy access to hand hygiene facilities;
- d) have surfaces that can be easily cleaned and disinfected;
- e) have slip-proof flooring that can withstand wet mopping and hospital-grade cleaning and disinfecting products;
- f) have restricted access from other areas in the setting and ensure one-way movement by staff.

Decontamination work areas shall be physically separated from clean and other work areas by walls or partitions to control traffic flow and to contain contaminants generated during the stages of cleaning. Walls or partitions should be cleaned regularly and be constructed of materials that can withstand cleaning and disinfection.

Decontamination sinks:

- a) shall be designed and arranged to facilitate soaking, washing and rinsing of equipment/devices with minimal movement or delay between steps;
- b) should be adjacent to waterproof counter tops and a backsplash;
- c) shall not have an overflow;
- d) should be at a height that allows workers to use them without bending or straining;
- e) should be large enough to accommodate trays or baskets of instruments;
- f) should be deep enough to allow complete immersion of larger devices and instruments so that aerosols are not generated during cleaning; and



g) should be equipped with water ports for the flushing of instruments with lumens, if appropriate.

The packaging area is for inspecting, assembling, and packaging clean, but not sterile, material.

The sterile storage area should be a limited access area with a controlled temperature (may be as high as 24°C) and relative humidity (30-60% in all works areas except sterile storage, where the relative humidity should not exceed 70%).

The floors and walls should be constructed of materials capable of withstanding chemical agents used for cleaning or disinfecting. Ceilings and wall surfaces should be constructed of non-shedding materials.

Hand hygiene facilities should be located in all personnel support areas and at all entrances to, and exits from, the decontamination area. Hand hygiene facilities should include:

- a) accessible hand washing sinks with hands-free controls, soap dispensers and paper towels; and/or
- b) alcohol-based hand-rub (ABHR).

See Table 3 in Appendix for recommended design parameters.

***Recommendation 15***

***Reprocessing performed outside the centralized area must be kept to a minimum and must be approved by the Infection Control Committee or those accountable for safe reprocessing practices and must conform to the requirements for reprocessing space.***

**B. Air Quality**

Occupational exposure limits such as ceiling exposure value (CEV) for chemical agents (e.g., glutaraldehyde, ethylene oxide) are to be complied with in accordance to local environmental law. A CEV is the maximum airborne concentration of a chemical agent to which a worker is exposed at any time. If control measures are not available during reprocessing involving a chemical agent, air sampling may be required to ensure that the regulated limit has not been exceeded for the chemical being used. (Reference: CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008)

The health care setting must have air changes; temperature and humidity appropriate to the

process/product being used. In health care settings where there are dedicated central reprocessing areas, negative pressure airflow must be maintained in soiled areas and positive pressure airflow must be maintained in clean areas and be monitored.

### **C. Water Quality**

The health care setting should be aware of the quality of its water supply and develop policies to address known problems. There should be written reprocessing contingency plans in place that address loss of potable water, boil water advisories and other situations where the water supply becomes compromised.

### **D. Environmental Cleaning in Sterile Processing Departments**

The housekeeping department should consult with the management of the sterile processing department and infection prevention and control to establish policies and procedures for cleaning practices and cleaning frequency. As a minimum:

- a) the facility shall have written cleaning procedures with clearly defined responsibilities for all areas in the facility where decontamination is performed;
- b) all work areas, stands, tables, countertops, sinks and equipment surfaces shall be cleaned with hospital approved agents and disinfected at least daily;
- c) floors shall be cleaned at least daily;
- d) if a spill occurs, the affected area shall be cleaned immediately;
- e) sinks shall be cleaned each shift at a minimum and more frequently as necessary;
- f) sinks used for cleaning endoscopes and respiratory equipment shall be cleaned between each use;
- g) the sequence of cleaning shall be from clean areas to soiled areas, from high areas to low areas (i.e., top of walls to floor) and from least contaminated to most contaminated;
- h) cleaning staff shall not move back and forth between clean and soiled areas; and
- i) cleaning equipment used in the decontamination area shall not be used in any other area.

#### ***Recommendation 16***

***The decontamination work area shall be physically separated from clean areas by walls or partitions.***

#### ***Recommendation 17***

***Wherever chemical disinfection/sterilization is performed, air quality must be monitored when using products that produce toxic vapors and mists.***

***Recommendation 18***

***There must be a regular schedule for environmental cleaning in the Sterile Processing Department that includes written procedures and clearly defined responsibilities***

**Occupational Health and Safety for Reprocessing**

An Occupational Health and Safety review is recommended for all protocols for reprocessing medical equipment/devices to verify that staff safety measures are followed and are in compliance with the local Occupational Health and Safety Act. This review will verify that:

- a) sharps are handled appropriately
- b) local exhaust ventilation systems adequately protect staff from toxic vapors
- c) chemicals are labeled, stored and handled appropriately, and Material Safety Data Sheets (MSDS) are readily available
- d) an eyewash fountain is installed to prevent a potential hazard to the eye due to contact with a biological or chemical agent; and
- e) personal protective equipment such as elbow length impervious gloves (insulated if using a steam autoclave) for unloading the autoclave is present and complies with regulatory requirements. Procedures must be in place for immediate response to staff exposure to blood and body fluids or injury from sharp objects. All staff working in reprocessing must be immune to Hepatitis B or receive Hepatitis B immunization.

**A. Routine Practices**

Routine practices must be part of all staff education and training to prevent exposure to body substances. Routine practices in reprocessing areas include:

- a) a policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics or and handling contact lenses in the reprocessing area;
- b) no storage of personal effects, including food and drink, in the reprocessing area;
- c) hand hygiene facilities located at all entrances to, and exits from, reprocessing areas and faucets;
- d) should be supplied with foot-, wrist- or knee-operated handles or electronic sensors
- e) hands are cleaned before beginning work, before breaks and upon completion of work; after removing gloves; and whenever hands are contaminated with body substances if there is visible soil on the hands, hand hygiene is performed with soap and water; if there is no visible soil on the hands, staff may use either soap and water or an alcohol-

based hand rub (ABHR)

- f) hand and arm jewelry or artificial nails are not worn; and
- g) provision for, and wearing of, appropriate PPE for all reprocessing activities;
- h) dedicated staff for the decontamination area.

## **B. Personal Protective Equipment (PPE)**

Standard precautions are to be complied by all staffs. Staff involved in reprocessing must be trained in the correct use, wearing, limitations and indications for PPE:

- a) PPE worn for cleaning and handling contaminated equipment/devices includes gloves appropriate to the task, face protection (full face shield OR fluid-impervious face mask and protective eyewear) and impermeable gown or waterproof apron;
- b) when choosing gloves, the following points need to be considered:
  - i) gloves must be long enough to cover wrists and forearms;
  - ii) gloves must be of sufficient weight to be highly tear-resistant;
  - iii) gloves must allow adequate dexterity of the fingers;
  - iv) disposable gloves are recommended; if reusable gloves are used, they must be decontaminated daily, inspected for tears and holes.
- c) PPE is removed on completion of the task for which it was indicated and before leaving the reprocessing area;
- d) staff must be trained in management of a blood or body fluid spill and
- e) where there is the risk of exposure to biological and/or chemical agents, eye wash stations must be provided and staff must be trained in their use.

## **C. Safe Handling of Sharps**

Procedures shall be in place to prevent injuries from sharp objects. When working with sharps, staff in the decontamination area shall:

- a) place disposable sharp objects in puncture-resistant containers;
- b) take care when handling glass and other fragile objects;
- c) discard chipped or broken glass devices or arrange to have them repaired;
- d) not recap used needles or other sharps unless using a recapping device; and
- e) not manually bend or break needles.

## **D. Work Restrictions**

Reprocessing staff are subject to some work restrictions:

- a) staff who have respiratory problems (e.g., asthma) should be assessed by Occupational Health

- and Safety staff prior to working with chemical disinfectants or cleaning agents; and
- b) staffs who have exudative lesions or weeping dermatitis shall refrain from handling client/patient/resident care equipment until the condition is resolved.

***Recommendation 19***

*Occupational Health and Safety for the healthcare setting will review all protocols for reprocessing medical equipment/devices to verify that worker safety measures and procedures to eliminate or minimize the risk of exposure are followed and are in compliance with the Occupational Health and Safety Act of the country.*

***Recommendation 20***

*There is a policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics or/and handling contact lenses in the reprocessing area.*

***Recommendation 21***

*Appropriate personal protective equipment (PPE) should be worn for all reprocessing activities.*

***Recommendation 22***

*All staff working in reprocessing shall be offered Hepatitis B immunization unless they have documented immunity to Hepatitis B.*

***Recommendation 23***

*Measures and procedures shall be written to prevent and manage injuries from sharp objects.*

***Recommendation 24***

*Measures and procedures shall be in place for immediate response to worker exposure to blood and body fluids.*

### **Transportation and Handling of Contaminated Medical Equipment / Devices**

Soiled medical equipment/devices must be handled in a manner that reduces the risk of exposure and/or injury to personnel and clients/patients/residents, or contamination of environmental surfaces:

- a) closed carts or covered containers designed to prevent the spill of liquids, with easily cleanable surfaces, shall be used for handling and transporting soiled medical equipment/devices;

- b) soiled equipment/devices shall be transported by direct routes, that avoid high-traffic, clean/sterile storage and client/patient/resident care areas, to areas where cleaning will be done;
- c) containers or carts used to transport soiled medical equipment/devices shall be cleaned after each use; and
- d) disposable sharps shall be disposed of in an appropriate puncture-resistant sharps container at point-of-use, prior to transportation.

***Recommendation 25***

***Disposable sharps shall be disposed of in an appropriate puncture-resistant sharps container at point-of-use, prior to transportation.***

***Recommendation 26***

***Soiled medical equipment/devices must be handled in a manner that reduces the risk of exposure and/or injury to personnel and clients/patients/residents, or contamination of environmental surfaces.***

***Recommendation 27***

***A process shall be in place that will ensure that medical equipment/devices which have been reprocessed can be differentiated from equipment/devices which have not been reprocessed (e.g., color coding).***

***Recommendation 28***

***Contaminated equipment/devices shall not be transported through areas designated for storage of clean or sterile supplies, client/patient/resident care areas or high-traffic areas.***

***Recommendation 29***

***Sterile and soiled equipment/devices shall not be transported together.***

## **Disinfection of Reusable Medical Equipment/Devices**

Disinfection is the inactivation of disease-producing microorganisms. Disinfection does not destroy bacterial spores or prions. Disinfection of medical equipment/devices falls into two major categories – low-level disinfection and high-level disinfection.

### **A. Low-Level Disinfection (LLD)**

Low-level disinfection eliminates vegetative ('live') bacteria, some fungi and enveloped viruses. LLD is used for non-critical medical equipment/devices and some environmental surfaces. Low-level disinfectants include 3% hydrogen peroxide, 0.5% accelerated hydrogen peroxide, some quaternary ammonium compounds (QUATS), phenolics and diluted sodium hypochlorite (e.g., bleach) solutions.

LLD is performed after the equipment/device is thoroughly cleaned; rinsed and excess rinse water is removed. The container used for disinfection must be washed, rinsed and dried when the solution is changed. Non-critical medical equipment/devices require decontamination using a low-level disinfectant.

### **B. High-Level Disinfection (HLD)**

High-level disinfection eliminates vegetative bacteria, enveloped viruses, fungi, mycobacteria (e.g., Tuberculosis) and non-enveloped viruses. HLD is used for semi-critical medical equipment/devices. High level disinfectants include 2% glutaraldehyde, 6% hydrogen peroxide, 0.2% peracetic acid, 7% accelerated hydrogen peroxide and 0.55% ortho-phthalaldehyde (OPA). Refer to Table 4 in Appendix for contact time required for high level disinfection. Pasteurization also achieves high-level disinfection. HLD is performed after the equipment/device is thoroughly cleaned, rinsed and excess rinse water is removed. Semi-critical medical equipment/devices require decontamination using, at a minimum, high-level disinfection. Sterilization is preferred.

### **C. Methods of Disinfection for Semi-critical Medical Equipment/Devices**

There are two major methods of disinfection used in health care settings – liquid chemicals and pasteurization.

#### **1. Liquid Chemical Disinfection**

When selecting a disinfectant for reprocessing medical equipment/devices in the health care setting, consider:

- a) efficacy for the intended use;
- b) compatibility with the equipment/device and surfaces to be disinfected;
- c) compatibility with detergents, cleaning agents and disinfection and/or sterilization processes;
- d) the intended end use of the equipment/devices to be disinfected;
- e) the method for monitoring the product concentration;
- f) recommendations for rinsing (e.g., water quality, volume, time);
- g) safety for use, with minimal toxic and irritating effects to/for staff; and

- i) environmental safety and biodegradability.

The manufacturer's recommendations for chemical disinfectants must be followed pertaining to:

- a) usage - disinfectant manufacturers must supply recommended usage for the disinfectant to ensure that it is compatible with the medical equipment/devices on which it will be used;
- b) contact time (NOTE: where the manufacturer recommends a shorter contact time with a particular product than is required to achieve the desired level of disinfection/sterilization, an infection prevention and control professional must be consulted for advice);
- c) shelf life;
- d) storage;
- e) appropriate dilution; and
- f) required PPE.

The process of high-level disinfection requires monitoring and auditing:

- a) chemical test strips should be used to determine whether an effective concentration of active ingredients is present, despite repeated use and dilution:

- i) the frequency of testing should be based on how frequently the solutions are used (i.e., test daily if used daily);
- ii) chemical test strips must be checked each time a new package/bottle is opened to verify they are accurate, using positive (e.g., full strength disinfectant solution) and negative (e.g., tap water) controls; see manufacturer's recommendations for appropriate controls;
- iii) test strips must not be considered a way of extending the use of a disinfectant solution beyond the expiration date;

- b) a permanent record of processing shall be completed and retained according to the policy of the facility; this record shall include, but not be limited to:

- i) the identification of the equipment/device to be disinfected;
- ii) date and time of the clinical procedure;
- iii) concentration and contact time of the disinfectant used in each process;
- iv) results of each inspection (and, for endoscopes, each leak test);
- v) result of each testing of the disinfectant; and
- vi) the name of the person completing the reprocessing.

- c) disinfection practices shall be audited on a regular basis and a quality improvement process must be in place to deal with any irregularities/concerns resulting from the audit;

- d) prepared solutions shall not be topped up with fresh solution;

- e) if manual disinfection is performed, the container used for disinfection shall be kept covered during use and washed, rinsed and dried when the solution is changed; and



f) rinsing of medical equipment/devices following chemical disinfection requires three separate rinses, using sterile water, and the rinse solutions must be changed after each process.

## **2. Pasteurization**

Pasteurization is a process of hot water disinfection (minimum 71°C for 30 minutes), which is accomplished through the use of automated pasteurizers or washer disinfectors. Semi-critical medical equipment/devices suitable for pasteurization include equipment for respiratory therapy and anesthesia.

Advantages of pasteurization include:

- a) no toxicity;
- b) rapid disinfection cycle; and
- c) moderate cost of machinery and upkeep.

Disadvantages of pasteurization include:

- a) may cause splash burns;
- b) difficulty validating the effectiveness of the process; and
- c) pasteurizers and related equipment can become contaminated without a good preventive maintenance program and careful monitoring of processes.

The manufacturer's instructions for installation, operation and ongoing maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated:

- a) the process must be monitored with mechanical temperature gauges and timing mechanisms for each load, with a paper printout record; pasteurizing equipment must have, or be retrofitted for, mechanical paper printout;
- b) water temperature within the pasteurizer should be verified weekly by manually measuring the cycle water temperature;
- c) cycle time should be verified manually and recorded daily;
- d) calibration of pasteurization equipment will be performed according to the manufacturer's recommendations;
- e) daily cleaning of pasteurizing equipment is required following the manufacturer's recommendations; and
- f) following pasteurization, medical equipment/devices should be inspected for wear, cracks or soil:
  - i) damaged equipment/devices shall be handled according to facility procedures; and
  - ii) soiled equipment/devices shall be reprocessed.

Following pasteurization, medical equipment/devices shall be handled in a manner that prevents contamination. Equipment/devices shall be transported directly from the pasteurizer to a clean area for drying, assembly and packaging. Medical equipment/devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and is used exclusively for the drying of pasteurized equipment/devices. A preventive maintenance program for drying cabinets must be implemented and documented. Printed records of each cycle (i.e., temperature, time) shall be retained in accordance with the health care setting's requirements.

***Recommendation 30***

***Non-critical medical equipment/devices are to be decontaminated using a low-level disinfectant.***

***Recommendation 31***

***Semi-critical medical equipment/devices must be decontaminated using, at a minimum, high-level disinfection. Sterilization is preferred.***

***Recommendation 32***

***The chemical disinfectant used for disinfecting medical equipment/devices must be compatible with both the equipment/device manufacturer's instructions for disinfection and the cleaning products involved in the reprocessing of the equipment/device.***

***Recommendation 33***

***Disinfectant manufacturers must supply recommended usage for the disinfectant to ensure that it is compatible with the medical equipment/devices on which it will be used.***

***Recommendation 34***

***The process of high-level disinfection requires monitoring and auditing. If a chemical product is used, the concentration of the active ingredient(s) must be verified and a logbook of daily concentration test results is to be maintained.***

***Recommendation 35***

***Manufacturer's instructions for installation, operation and ongoing maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated.***

***Recommendation 36***

***A preventive maintenance program for pasteurizing equipment must be implemented and documented.***

***Recommendation 37***

*Following the pasteurizing cycle, medical equipment/devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and that is used exclusively for the drying of pasteurized equipment/devices.*

***Recommendation 38***

*A log of contents, temperature and time is to be maintained for each pasteurizer cycle.*

**Selection of Product/Process for Reprocessing**

The reprocessing method and products required for medical equipment/devices will depend on the intended use of the equipment/device and the potential risk of infection involved in the use of the equipment/device. The process and products used for cleaning, disinfection and/or sterilization of medical equipment/devices must be compatible with the equipment/devices:

- a) compatibility of the equipment/device to be reprocessed to detergents, cleaning agents and disinfection/sterilization processes is determined by the manufacturer of the equipment/device; and
- b) the manufacturer must provide written information regarding the safe and appropriate reprocessing of the medical equipment/device.

**A. Reprocessing Process**

The classification system developed by Spaulding divides medical equipment/devices into three categories, based on the potential risk of infection involved in their use:

**Table 1: Spaulding's Classification of Medical Equipment/Devices and Required Level of Processing/Reprocessing**

<b>Classification</b>	<b>Definition</b>	<b>Level of Processing/ Reprocessing</b>	<b>Examples</b>
Critical	Equipment/device that enters sterile tissues, including vascular	Cleaning followed by sterilization	Surgical instruments, biopsy instruments

<b>Classification</b>	<b>Definition</b>	<b>Level of Processing/ Reprocessing</b>	<b>Examples</b>
	system		
Semi-critical	Equipment/device that comes into contact with non-intact skin or mucous membranes but do not penetrate them	Cleaning followed by high-level disinfection (as a minimum). Sterilization is preferred	Respiratory therapy equipment, anesthesia equipment, tonometer
Non-critical	Equipment/device that touches only intact skin and not mucous membranes, or does not directly touch the patient	Cleaning followed by low-level disinfection	ECG machines, oximeter, bedpans, urinals, commodes, blood pressure cuffs, crutches, computers, bed rails, bedside tables, patient furniture and floors

All medical equipment/devices that will be purchased and will be reprocessed must have written device specific manufacturer's cleaning, disinfection and sterilization instruction. If disassembly or reassembly is required, detailed instructions with pictures must be included. Staff training must be provided on these processes before the medical equipment/device is placed into circulation.

## **B. Reprocessing Products**

Products used for any/all stages in reprocessing (i.e., cleaning, disinfection, sterilization) must be:

- a) appropriate to the level of reprocessing that is required for the use of the medical equipment/device;
- b) approved by the committee responsible for product selection, by an individual with reprocessing expertise and by an individual with infection prevention and control expertise (e.g., facility's infection prevention and control professionals, public health staff with training in infection prevention and control, regional infection control network).

### ***Recommendation 39***

***Products used for any/all stages in reprocessing (i.e., cleaning, disinfection, sterilization) must be approved by the committee responsible for product selection, by an individual with reprocessing expertise and by an individual with infection prevention and control expertise.***

### ***Recommendation 40***

***The reprocessing method and products required for medical equipment/devices will depend on the intended use of the equipment/device and the potential risk of infection involved in the use of the equipment/device.***

***Recommendation 41***

***Products used for decontamination must be appropriate to the level of reprocessing that is required for the use of the medical equipment/device.***

***Recommendation 42***

***The process and products used for cleaning, disinfection and/or sterilization of medical equipment/devices must be compatible with the equipment/devices.***

***Recommendation 43***

***All medical equipment/devices that will be purchased and will be reprocessed must have written device-specific manufacturer's cleaning, disinfection and sterilization instruction. If disassembly or reassembly is required, detailed instructions with pictures are highly recommended. Staff training must be provided on these processes before the medical equipment/device is placed into circulation.***

## **Reprocessing Endoscopy Equipment/Devices**

For the purposes of this document, endoscopes will be considered to be of two types:

Due to the complexity of their design, flexible fibreoptic and video endoscopes ('semi-critical endoscopes') require special cleaning and handling.

**Critical Endoscope:** Endoscopes used in the examination of critical spaces, such as joints and sterile cavities. Many of these endoscopes are rigid with no lumen. Examples of critical endoscopes are arthroscopes and laparoscopes.

***Recommendation 44***

***Critical endoscopes shall be sterilized prior to use.***

**Semi-critical Endoscope:** Fibreoptic or video endoscopes used in the examination of the hollow viscera. These endoscopes generally invade only semi-critical spaces, although some of their components might enter tissues or other critical spaces. Examples of semi-critical endoscopes are

laryngoscopes, nasopharyngeal endoscopes, transesophageal probes, colonoscopes, gastroscopes, duodenoscopes, sigmoidoscopes and enteroscopes.

***Recommendation 45***

***Semi-critical endoscopes require a minimum of high-level disinfection prior to use.***

***Recommendation 46***

***Since flexible bronchoscopes and cystoscopes are entering a sterile cavity, it is highly recommended that these be sterilized; however, if they are not compatible with sterilization, high-level disinfection is the minimum requirement.***

**A. Education and Training**

Individuals responsible for reprocessing endoscopes require training and must meet the health care setting's written endoscope processing competency requirements, which include ongoing education and training:

- a) staff assigned to reprocess endoscopes must receive device-specific reprocessing instructions to ensure proper cleaning and high-level disinfection or sterilization;
- b) competency testing of personnel reprocessing endoscopes shall be performed at least annually and
- c) temporary personnel shall not be allowed to reprocess endoscopes until competency has been established.

**B. Physical Space**

The area used to reprocess endoscopes must include:

- a) adequate space for the storage and holding of clean and soiled materials that is separate from other activities and controlled to prohibit public contact;
- b) dedicated processing room(s) for cleaning and decontaminating instruments that are physically separated from clean areas, client/patient/resident care areas and procedure rooms;
- c) within processing/decontamination rooms, utility sink(s) appropriate to the volume of work and method of decontamination;
- d) dedicated hand hygiene sink(s);
- e) eye-washing facilities;
- f) sufficient cleanable counter space to handle the volume of work;
- g) space and utility connections for automatic endoscope reprocessor(s) (AER), if used;
- h) ventilation system that will remove toxic vapors generated by, or emitted from, cleaning or disinfecting agents;

- i) the vapor concentration of the chemical disinfectant used shall not exceed allowable limits (e.g., 0.05 ppm for glutaraldehyde);
  - ii) air-exchange equipment (e.g., ventilation system, exhaust hoods) should be used to minimize the exposure of all persons to potentially toxic vapors;
  - iii) in-use disinfectant solutions must be maintained in closed, covered, labeled containers at all times; and
  - iv) air quality should be monitored on a scheduled basis to ensure control of vapors; and
- i) clean equipment room(s), including storage, should protect the clean equipment from contamination.

### **C. Cleaning Procedures**

Each health care setting in which endoscopic procedures are performed shall have written detailed procedures for the cleaning and handling of endoscopes. Endoscopic cleaning shall take place immediately following completion of the clinical procedure, as soil residue in endoscope lumens dries rapidly, becoming very difficult to remove.

Immediately following completion of the endoscopy procedure:

- a) flush and wipe the endoscope at point-of-use;
- b) use a freshly prepared enzymatic cleaning solution; and
- c) place the endoscope and accessories in a covered, leak proof container and transport to the designated decontamination area.

The following steps must be included in the cleaning procedure:

- a) follow the manufacturer's recommendations for cleaning and cleaning products;
- b) perform leak testing after each use, prior to cleaning:
  - i) verify the potency and integrity of the endoscope sheath through leak testing, performed prior to, and during, immersion of the endoscope;
  - ii) perform the leak test according to the manufacturer's instructions;
  - iii) an endoscope that fails the dry leak test should not undergo the immersion leak test;
- c) soak and manually clean all immersible endoscope components with water and a recommended cleaning agent prior to automated or further manual disinfection or sterilization;
- d) disconnect and disassemble endoscope components (e.g., air/water and suction valves) as far as possible and completely immerse the endoscope and components in enzymatic cleaner;
- e) flush and brush all channels and lumens of the endoscope while submerged to remove debris and minimize aerosols;
- f) ensure that brushes used for cleaning lumens are of an appropriate size, inspected before and after use, and discarded or cleaned, high-level disinfected and dried following use;

- g) consider irrigation adaptors or manifolds that may be recommended by the manufacturer to facilitate cleaning;
- h) thoroughly rinse endoscope and all components with clean filtered water prior to disinfection/sterilization and remove excess rinse water;
- i) identify damaged endoscopes and immediately remove from service;
- j) discard enzymatic cleaner after each use; and
- k) discard disposable cleaning items or thoroughly clean and high-level disinfect/sterilize non-disposable items between uses.

#### **D. Endoscope Disinfection and Sterilization**

Procedures for disinfection and sterilization of endoscopes must ensure that a minimum of high-level disinfection is used for all endoscopes and their accessories, excluding biopsy forceps and brushes (which require sterilization). The following steps must be included in the disinfection/sterilization procedure:

- a) choose a disinfectant that is compatible with the endoscope;
- b) monitor the efficacy of the disinfectant before each use with test strips available from the product manufacturer;
- c) maintain a written log of monitoring test results;
- d) do not use disinfectants past their expiry date;
- e) carefully follow the manufacturer's directions regarding the ambient temperature and duration of contact for the disinfectant (e.g., 2% glutaraldehyde for 20 minutes at 20°C);
- f) completely immerse the endoscope and endoscope components in the high-level disinfectant/sterilant and ensure all channels are perfused; and
- g) following disinfection, rinse the endoscope and flush the channels with bacteria-free or sterile water.

#### ***Recommendation 47***

***Disposable sheaths/condoms placed over the endoscope reduce the numbers of microorganisms on the scope but do not eliminate the need for cleaning/disinfection/sterilization between uses.***

#### **E. Drying and Storage of Endoscopes**

Steps in the final drying of semi-critical endoscopes include:

- a) initial flushing of all channels with medical or filtered air;
- b) flushing all channels with 70% isopropyl alcohol to aid in the drying process; and
- c) second flushing of the channels with medical or filtered air.



Storage procedures must include the following:

- a) remove caps, valves and other detachable components during storage and reassemble just before use; store close to the endoscope in a manner that minimizes contamination;
- b) store semi-critical endoscopes by hanging vertically in a well-ventilated area in a manner that minimizes contamination or damage;
- c) store endoscopes that have been sterilized in their sterilization containers;
- d) do not allow endoscopes to coil, touch the floor or bottom of the cabinet while handling, or be stored in their cases;
- e) ensure that endoscope storage cabinets are constructed of non-porous material that can be cleaned;
- f) clean and disinfect endoscope storage cabinets at least weekly.

Colonoscopes have a maximum shelf life of 7 days, if stored dry. There are no recommendations regarding shelf life of other types of endoscopes.

#### **F. Accessories**

Endoscopic accessories (e.g., biopsy forceps and brushes) that break the mucosal barrier must be sterilized after each use:

- a) because of the difficulty cleaning biopsy forceps/brushes, it is strongly recommended that disposable items be used; and
- b) if reusable biopsy forceps/brushes are used, they must be meticulously cleaned prior to sterilization.

#### **G. Automated Endoscope Reprocessor (AER)**

To achieve consistency in endoscope reprocessing, it is recommended that automated endoscope reprocessor (AER) be used. The following must be included in the procedure:

- a) follow the manufacturer's instructions for use of the AER;
- b) ensure that the endoscope and endoscope components to be reprocessed are compatible with the AER used;
- c) ensure that channel connectors and caps for both the AER and the endoscope are compatible;
- d) place brushes and instruments used to clean the endoscope in the AER for disinfection;
- e) do not open or stop the AER once started; if an AER cycle is interrupted, high-level disinfection cannot be assured;
- f) implement and document preventive maintenance program(s) for the AER(s).

## **H. Equipment Used for Cleaning**

The water bottle and its connecting tube, used for cleaning the endoscope lens and irrigation during the procedure, should receive high-level disinfection or sterilization at least daily. Sterile water shall be used to fill the water bottle.

### ***I. Record-keeping***

An accurate, permanent record of endoscope use and reprocessing will assist in tracking endoscopes and clients/patients/residents in the event of a recall or follow-up:

- a) for each procedure, document the client/patient/resident's name and record number, the date and time of the procedure, the type of procedure, the endoscopist, and the serial number or other identifier of both the endoscope and the AER (if used) to assist in outbreak investigation;
- b) record the endoscope number in the patient record; and
- c) retain records according to the policy of the facility.

#### ***Recommendation 48***

*Individuals responsible for reprocessing endoscopes shall be specially trained and shall meet the facility's written endoscope processing competency requirements, including ongoing education and training and annual competency testing.*

#### ***Recommendation 49***

*Each health care setting in which endoscopic procedures are performed shall have written, detailed procedures for the cleaning and handling of endoscopes.*

#### ***Recommendation 50***

*Ventilation shall be such as to remove toxic vapors generated by, or emitted from, cleaning or disinfecting agents.*

#### ***Recommendation 51***

*Endoscope cleaning shall commence immediately following completion of the clinical procedure.*

#### ***Recommendation 52***

*Patency and integrity of the endoscope sheath should be verified through leak testing, performed after each use.*

#### ***Recommendation 53***

*Endoscopic equipment/devices shall be rinsed and dried prior to disinfection or sterilization.*

***Recommendation 54***

***Critical endoscopes shall be sterilized.***

***Recommendation 55***

***Semi-critical endoscopes and accessories (excluding biopsy forceps and brushes) must receive at least high-level disinfection after each use.***

***Recommendation 56***

***Endoscopic accessories (e.g., biopsy forceps and brushes) that break the mucosal barrier must be disposable or sterilized after each use.***

***Recommendation 57***

***If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components are compatible with the AER.***

***Recommendation 58***

***Final drying of semi-critical endoscopes shall be facilitated by flushing all channels with 70-90% ethyl or isopropyl alcohol, followed by forced air purging of the channels.***

***Recommendation 59***

***Semi-critical endoscopes shall be stored hanging vertically in a well-ventilated area in a manner that minimizes contamination or damage. Endoscopes shall not be coiled, allowed to touch the floor or bottom of the cabinet while hanging, or stored in their cases.***

***Recommendation 60***

***The water bottle and its connecting tube, used for cleaning the endoscope lens and irrigation during the procedure, should receive high-level disinfection or sterilization at least daily.***

***Recommendation 61***

***A preventive maintenance program for automated endoscope reprocessor (AER) must be implemented and documented.***

***Recommendation 62***

***Healthcare settings shall have policies in place providing a permanent record of endoscope use and reprocessing, as well as a system to track endoscopes and patients that includes recording the endoscope number in the patient record.***

**Sterilization of Reusable Medical Equipment/Devices**

Sterilization is the elimination of all disease-producing microorganisms, including spores (e.g. *Clostridium* and *Bacillus* species) and prions. The latter is not susceptible to routine sterilization. Sterilization is used on critical medical equipment/devices and, whenever possible, semi-critical medical equipment/devices.

***Recommendation 63***

***The preferred method for sterilization of heat-resistant equipment/devices is steam. (pre-vacuum sterilizers are preferred). The preferred sterilization method for heat sensitive instruments would be low temperature sterilization.***

For equipment/devices that cannot withstand heat sterilization, some examples of sterilants include:

- a) 6% hydrogen peroxide;
- b) 2% glutaraldehyde (> 10 hours);
- c) hydrogen peroxide gas plasma;
- d) 0.2% peracetic acid;
- e) 7% accelerated hydrogen peroxide; and
- f) 100% ethylene oxide.

Refer to Table 4 in Appendix for contact time for sterilization.

**A. Sterilization Process**

Medical equipment/devices that have contact with sterile body tissues or fluids are considered critical items. All critical medical equipment/devices must be sterilized, because microbial contamination could result in disease transmission. Critical items include surgical instruments, implants, foot care equipment, endoscopes that enter sterile cavities and spaces, colposcopy equipment, biopsy forceps and brushes, eye equipment and dental equipment.

Semi-critical medical equipment/devices have contact with non-intact skin or mucous membranes but do not penetrate them. Whenever possible, semi-critical medical equipment/devices should be sterilized. When sterilization is not possible, semi-critical equipment/devices shall be cleaned, followed by high-level disinfection. Health care settings shall have written policies and procedures for sterilization of medical equipment/devices processes that:

- a) ensure that the sterilization processes follow the principles of infection prevention and control;
- b) ensure that manufacturer's instructions for installation, operation, cleaning and preventive maintenance of the equipment are followed;
- c) include clearly defined responsibilities;
- d) include cleaning, decontamination, drying, inspection, lubrication, disassembly, wrapping, sealing and labeling;
- e) include a thorough evaluation of all sterilization processes before being put into service, and at regular intervals thereafter.

The floors and walls should be constructed of materials capable of withstanding chemical agents used for cleaning or disinfecting. Ceilings and wall surfaces should be constructed of non-shedding materials. Physical arrangements of processing areas are presented schematically in four references.

(Reference: CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008)

## **B. New Sterilizers**

Input from a professional with infection prevention and control expertise must be obtained prior to the purchase of a new sterilizer. There must be good communication between the health care setting and the manufacturer of the sterilizer to ensure that:

- a) manufacturers of sterilizers provide specific, written instructions on installation and use of their equipment;
- b) storage and transportation practices maintain sterility to the point of use; and
- c) manufacturers of sterilizers are specific as to which medical equipment/devices can be sterilized in their machines and the recommended sterilization methods.

Sterilizers must be subjected to rigorous testing and monitoring on installation and following disruptions to their normal activity:

- a) autoclaves must be installed according to the manufacturer's instructions;
- b) tabletop steam sterilizers are recommended for office settings;

- c) following installation of a new sterilizer, the sterilizer must pass at least three consecutive cycles with the appropriate challenges (i.e., biological, chemical) placed in an empty sterilizer, as well as at least one cycle challenged with a full test load, before the sterilizer can be put into routine service;
- d) for sterilizers of the dynamic air removal type (vacuum), three consecutive air removal tests shall be conducted in an empty sterilizer with the air detection test pack (e.g., Bowie-Dick)
- e) a sterilizer shall not be approved for use if the biological indicator (BI) yields a positive result on any of the tests;
- f) sterilizers must be monitored with a test load and be fully re-qualified in the following circumstances:
  - i) after major repairs to an existing sterilizer;
  - ii) when there has been construction, relocation or other environmental changes in the area;
  - iii) after unexplained sterility failures;
  - iv) after changes in steam and/or ethylene oxide supply or delivery; and
  - v) after repairs or modification to the emission control system.

## **C. Monitors and Indicators**

Physical, biological and chemical monitoring is done to verify the effectiveness of sterilizers and the sterilization process. Monitoring is done when a sterilizer is first installed before it is put into general use and to assess routine performance thereafter. Performance monitoring using all three types of indicators/monitors must be completed in all sterilizers to ensure that effective sterilization has been achieved.

### **1. Physical Monitors**

A physical monitor is a device that monitors the physical parameters of a sterilizer, such as time, temperature and pressure that are measured during the sterilization cycle and recorded (as a printout or electronic record) on completion of each cycle.

### **2. Biological Indicators (BI)**

A biological indicator is a test system containing viable microorganisms (e.g., spore-laden strips or vials) providing a defined resistance to a specified sterilization process. The BI is generally contained inside a process challenge device (PCD) that simulates the in-use challenges presented by packaged devices. Once sterilized, a BI is incubated to see if the microorganism will grow, which indicates a failure of the sterilizer.

The manufacturer's instructions regarding the type of BI to be used in a particular sterilizer should be followed. The recommended test microorganisms generally used as BIs are:

a) *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*) spores for sterilizers that use steam, hydrogen peroxide gas plasma or peracetic acid, as well as flash sterilizers; and

b) *Bacillus atrophaeus* (formerly *Bacillus subtilis*) spores for sterilizers that use dry heat or ethylene oxide.

The BI is incubated according to the manufacturer’s instructions. Most BIs require up to 48 hours of incubation before the test is complete. Recently, however, rapid readout biological indicators have become available that provide BI results in one hour. These indicators detect enzymes of *Geobacillus stearothermophilus* (the test organism for steam sterilizers) by reading a fluorescent product produced by the enzymatic breakdown of a non-fluorescent substrate. Studies have shown that the sensitivity of rapid-readout tests for steam sterilization (1 hour for 132°C gravity sterilizers, 3 hours for 121°C gravity and 132°C vacuum sterilizers) parallels that of the conventional sterilization-specific BIs.

### 3. Chemical Indicators (CI)

A chemical indicator is a system that responds to a change in one or more predefined process variables with a chemical or physical change. There are six classes of chemical indicators (see Table 2, ‘International Classes of Steam Chemical Indicators’).

***Recommendation 64***

***All sterilizers must be tested for performance using physical, chemical and biological monitors and indicators. Chemical indicators do not replace the need to use a biological indicator.***

**Table 2: International Classes of Steam Chemical Indicators**

Class	Definition type	Use	Examples
I	Process indicator to differentiate processed from non-processed items	To indicate that item has been directly exposed to sterilization process, usually applied outside of packages	Indicator tapes, indicator labels, load cards
II	Indicator for use in specific tests	To evaluate sterilizer performance	Bowie-Dick test
III	Single variable indicator to indicate	For pack control monitoring but not as	Temperature tubes

Class	Definition type	Use	Examples
	when a stated value has been reached e.g. temperature at specific location in chamber	useful as Class IV or V indicators; for exposure control monitoring	
IV	Multi-variable indicator that reacts to 2 or more critical variables in sterilization cycle	For pack control	Paper strips
V	Integrating indicator that reacts to all critical variables in the sterilization process (time, temperature, presence of steam) and has stated values that correlate to a BI at 3 time/temperature relationships	For pack control or as additional monitoring tool to release loads that do not contain implants	
VI	Emulating indicator that reacts to all critical variables (time, temperature, presence of steam) for specified sterilization cycle (e.g. 10 min, 18 min, 40 min)	As internal CI pack control	

#### 4. Process Challenge Device (PCD)

A process challenge device is a test device intended to provide a challenge to the sterilization process that is equal to, or greater than, the challenge posed by the most difficult item routinely processed. Examples include BI test packs which also contain a chemical indicator, or CI test packs which contain a Class 5 integrating indicator or an enzyme-only indicator. During routine monitoring of sterilizers, the BI and/or CI is usually placed within a PCD and placed in the sterilizer. A PCD can be commercially manufactured or prepared in-house.



#### **D. Routine Monitoring of Sterilizers**

Routine monitoring verifies that the sterilization process is working as expected and that medical equipment/devices achieve sterility. Routine monitoring of sterilizers involves the assessment of physical parameters of the sterilizer cycle, chemical indicators and biological indicators. All monitoring must comply with the manufacturer's instructions.

The following are included in routine monitoring:

- a) record and initial results of physical, chemical and biological parameters;
- b) document daily operation of the sterilizer:
  - i) review physical monitoring parameters for each operation (e.g., printed or electronic records);
  - ii) note any malfunction and take appropriate action to ensure that the product either has been properly treated or is returned for reprocessing;
- c) test filter systems for leakage;
- d) validate gas sterilization units for such factors as gas concentration, temperature, and relative humidity;
- e) conduct three consecutive tests with the air detection test pack (Bowie-Dick) for sterilizers of the dynamic air removal type; and
- f) monitor dry heat sterilization with each cycle due to differences in penetration with different items.

When using sterilization indicators:

- a) indicator shall be used according to the indicator manufacturer's instructions;
- b) indicator shall be used only for the sterilizer type and cycle for which it was designed and validated;
- c) indicator shall be interpreted only by qualified staff who have been trained to do so;
- d) indicator shall not be used beyond the expiration date; and
- e) indicator shall be stored in accordance with the manufacturer's instructions.

The following requirements apply to chemical monitoring:

- a) an internal chemical indicator shall be placed inside each package, container or bundle that is undergoing sterilization in the area judged to be least accessible to steam penetration or to the sterilizing agent; this may not necessarily be at the centre of the package; the class of indicator chosen is based on the parameters being measured and the degree of precision that is needed;
- b) each package or container to be sterilized shall have an externally visible Class I chemical indicator, which is examined immediately after sterilization to make sure that the item has been exposed to the sterilization process; and
- c) for dynamic air removal-type sterilizers, an air removal test with a Class II chemical indicator shall be performed every day the sterilizer is used.

The following requirements apply to biological monitoring:

- a) a biological indicator shall be used to test the sterilizer each day that it is used and with each type of cycle that is used that day; except for steam sterilizer which should be done weekly;
- b) a biological indicator shall be included in every load that is to be sterilized with ethylene oxide;
- c) a biological indicator shall be included in every load containing implantable devices;
- d) items in the processed load should not be released until the results of the BI test are available; if quarantine pending BI results is not possible, evaluation of a Class 5 or 6 chemical indicator and the specific cycle physical parameters may be used to justify the release of routine loads; and
- e) implantable devices should be quarantined until the results of the BI test are available.

### **Flash Sterilization**

Flash sterilization shall only be used in emergency situations and shall not be used for implantable equipment/devices or on complete sets or trays of instruments. Sterilization is a process, not an event. Operative scheduling and lack of instrumentation do not qualify as reasons to use flash sterilization. Effective sterilization is impaired if all the necessary parameters of the process are not met. These include, but are not limited to, the following:

- a) decontamination and sterilization areas must meet the requirements for processing space and shall not be located in the operative procedure room or near any potential source of contamination, such as sinks, hoppers, linen or trash disposal areas;
- b) a record for each piece of equipment/device being subjected to flash sterilization that includes the name of the client/patient/resident, procedure, physician/practitioner and equipment/device used; the client/patient/resident record should also reflect this information;
- c) if, in an emergency situation, a flash sterilizer is used, a biological monitor must be included at least once daily and with each type of cycle and every load configuration (i.e., open tray, rigid flash container, single wrapper) that will be used that day;
- d) the load printout must be signed to verify that the required time, temperature and pressure have been achieved;
- e) records must be retained according to the facility's policy;
- f) there must be a procedure for notification of the client/patient/resident in the event of a recall (e.g., positive biological indicator); and
- g) records should be reviewed on a regular basis to correct issues relating to overuse of flash sterilization.

#### ***Recommendation 65***

***Flash sterilization shall only be used in emergency situations and must never be used for implantable equipment/devices.***

## ***Unacceptable Methods of Disinfection/Sterilization***

The following methods of disinfection/sterilization are **NOT** recommended.

### ***A. Boiling***

The use of boiling water to clean instruments and utensils is not an effective means of sterilization. Boiling water is inadequate for the destruction of bacterial spores and some viruses.

### ***B. Ultraviolet Irradiation***

The germicidal effectiveness of ultraviolet (UV) radiation is influenced by organic matter, wavelength, type of suspension, temperature, type of microorganism and UV intensity, which is affected by distance and dirty tubes. The application of UV light in the health care setting is limited to the destruction of airborne organisms (e.g., ventilation ducts) or inactivation of microorganisms located on surfaces (e.g., laboratory hoods). It is not an acceptable method of disinfection/sterilization for medical equipment/devices.

### ***C. Glass Bead Sterilization***

Glass bead sterilizers use small glass beads and high temperature for brief exposure times to inactivate microorganisms. Glass bead sterilizers are difficult to monitor for effectiveness, have inconsistent heating resulting in cold spots, and often have trapped air which affects the sterilization process. The U.S. Food and Drug Administration has determined that a risk of infection exists with this equipment because of their potential failure to sterilize dental instruments and has required their commercial distribution cease until the device has received FDA clearance. Glass bead sterilization is not an acceptable method of sterilization for medical equipment/devices.

### ***D. Chemiclave***

Unsaturated chemical-vapor sterilization ('chemiclave') involves heating a chemical solution of primarily alcohol with 0.23% formaldehyde in a closed pressurized chamber. Because of the environmental risks associated with formaldehyde, this method of sterilization is discouraged. If used, it must be closely monitored and local regulations for hazardous waste disposal must be followed and air sampling for toxic vapors may be indicated.

### ***E. Microwave Oven Sterilization***

Microwave ovens are unreliable and difficult to monitor for effective sterilization. Home microwaves have been shown to inactivate bacteria, viruses, mycobacteria and some spores, however there may not be even distribution of microwave energy over the entire device. More research and testing is required to validate the use of microwave ovens for sterilization. The use of microwave ovens for sterilization of medical equipment/devices is not currently acceptable.

***Recommendation 66***

***Boiling is not an acceptable method of sterilization.***

***Recommendation 67***

***The use of ultraviolet light is not an acceptable method of disinfection/sterilization.***

***Recommendation 68***

***Glass bead sterilization is not an acceptable method of sterilization.***

***Recommendation 69***

***The use of a chemiclave for sterilization poses an environmental risk and must be closely monitored.***

***Recommendation 70***

***The use of microwave ovens for sterilization is not acceptable.***

### **Continued Monitoring and System Failures Recalls**

Improper reprocessing includes, but is not limited to, the following situations:

- a) the load contains a positive BI;
- b) an incorrect reprocessing method was used on the equipment/device;
- c) print-outs on reprocessing equipment indicate failure to reach correct parameters (e.g., temperature, pressure, exposure time);
- d) CI or monitoring tape has not changed colour; and
- e) there is doubt about the sterility of medical equipment/devices.

A written procedure must be established for the recall and reprocessing of improperly reprocessed medical equipment/devices. All equipment/devices in each processed load must be recorded to enable tracking in the event of a recall. The recall procedure should include:

- a) designation of department and staff responsible for executing the recall;
- b) identification of the medical equipment/devices to be recalled<sup>1</sup>; if recall is due to a failed BI, the recall shall include the medical devices in the failed load as well as all other devices processed in the sterilizer since the last successfully sterilized load;

- c) assessment of client/patient/resident risk;
- d) procedure for subsequent notification of physicians, patients, other facilities and/or regulatory bodies, if indicated; and
- e) involvement of the facility's risk manager, if applicable.

Health care settings shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies.

***Recommendation 71***

***If a failed chemical indicator is found, the contents of the package shall be reprocessed before use.***

***Recommendation 72***

***A procedure must be established for the recall of improperly reprocessed medical equipment/devices.***

***Recommendation 73***

***The recall procedure should include assessment of client/patient/resident risk and a procedure for subsequent notification of physicians, clients/patients/residents, other facilities and/or regulatory bodies if indicated.***

***Recommendation 74***

***Health care settings shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies.***

### **Single-Use Medical Equipment/Devices**

Health care settings must have written policies regarding single-use medical equipment and devices. Critical and semi-critical medical equipment/devices labeled as single-use must not be reprocessed and re-used unless the reprocessing is done according to institutional policy.

Health care settings that wish to have their single-use medical equipment/devices reprocessed should ensure that the facilities and procedures have been certified by a regulatory authority or an accredited quality system auditor to ensure the cleanliness, sterility, safety and functionality of the reprocessed

equipment/devices. In order to have critical or semi-critical medical equipment/devices reprocessed by one of these facilities, there must be processes for:

- a) tracking and labeling equipment/devices;
- b) recalling improperly reprocessed medical equipment/devices;
- c) assuring proof of sterility or high-level disinfection;
- d) testing for pyrogens;
- e) maintenance of equipment/device functionality and integrity;
- f) quality assurance and quality control;
- g) reporting adverse events; and
- h) provision of good manufacturing procedures.

Whereas reusable medical equipment/devices are sold with instructions for proper cleaning and sterilization, no such instructions exist for single-use medical equipment/devices. Furthermore, manufacturers often have not provided data to determine whether the equipment/device can be thoroughly cleaned, whether the materials can withstand heat or chemical sterilization, or whether delicate mechanical and electrical components will continue to function after one or more reprocessing cycles. In circumstances where the manufacturer does not approve of reuse, the facility will bear the brunt of legal responsibility in establishing when and under what conditions reuse of medical equipment/devices presents no increased risk to patients and that a reasonable standard of care was adhered to in the reuse of the equipment/device. This would involve written policies, extensive testing of reprocessing protocols and strict adherence to quality assurance investigations. This is a detailed and expensive process and should only be undertaken if there is a compelling reason to do so.

### **A. Sharps**

Sharps are devices that can cause occupational injury to a worker. Some examples of sharps which cannot be safely cleaned include needles, lancets, blades and glass. Reprocessing needles is an occupational health hazard. Further, reprocessing needles is a patient safety issue as there is no guarantee that the lumen is clean and that the reprocessing is effective. Needles must be single-use and must not be reprocessed. When purchasing sharps or devices with sharp components that cannot be safely cleaned, single-use devices or components shall be considered.

### **B. Equipment/Devices with Small Lumens**

Reusable equipment/devices with small lumens or other characteristics that make them difficult to clean effectively can put patients at risk, as they cannot be cleaned effectively or be adequately

checked for cleanliness during reprocessing. This includes items, such as catheters, drains, fine cannulae (excluding endoscopy equipment). These items should be designated single-use and not be reprocessed and re-used, even if designated as reusable by the manufacturer.

***Recommendation 75***

***The health care setting must have written policies regarding single-use medical equipment/devices.***

***Recommendation 76***

***Critical and semi-critical medical equipment/devices labeled as single-use must not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor.***

***Recommendation 77***

***Needles must be single-use and must not be reprocessed.***

***Recommendation 78***

***It is strongly recommended that catheters, drains and other medical equipment/devices with small lumens (excluding endoscopy equipment) be designated single-use and not be reprocessed and re-used, even if designated as reusable by the manufacturer.***

## **Storage and Use of Reprocessed Medical Equipment/Devices**

The shelf life of a sterile package is event-related rather than time-related. Event-related shelf life is based on the concept that items that have been properly decontaminated, wrapped, sterilized, stored and handled will remain sterile indefinitely, unless the integrity of the package is compromised (i.e., open, wet, dirty).

### **A. Sterile Storage Areas**

The sterile storage area should be located adjacent to the sterilization area, preferably in a separate, enclosed, limited-access area. See Table 3 in Appendix for recommended design parameters. Requirements for this area include:

- a) containers used for storage of clean equipment/devices should be moisture-resistant and cleanable (i.e., cardboard boxes must not be used);
- b) equipment/devices are stored in a clean, dry, dust-free area (closed shelves), not at floor level, and at least one meter away from debris, drains, moisture and vermin to prevent contamination;

- c) equipment/devices are stored in an area where they are not subject to tampering by unauthorized persons;
- d) equipment/devices are transported in a manner that avoids contamination or damage to the equipment/device; and
- e) supplies and materials not used for reprocessing will not be stored in sterile processing areas.

## **B. Maintaining Sterility**

Health care settings must have procedures for storage and handling of clean and sterile medical equipment/devices that include:

- a) medical equipment/devices purchased as sterile must be used before the expiration date, if one is given;
- b) reprocessed medical equipment/devices shall be stored in a clean, dry location in a manner that minimizes contamination or damage;
- c) sterility must be maintained until used;
- d) sterile packages that lose their integrity shall be re-sterilized prior to use; and
- e) equipment/devices must be handled in a manner that prevents recontamination of the item.

## **C. Using Sterile Equipment/Devices**

At point-of-use, upon opening the reprocessed medical equipment/device, a check must be made for integrity of the packaging and the equipment/device. Those performing this inspection must be provided with education that includes:

- a) validating results of chemical tape and internal monitors, if present;
- b) visually inspecting the equipment/device for discoloration or soil; if present, the item is removed from service and reprocessed;
- c) checking for defective equipment/devices and removing them from use;
- d) checking for dampness or wetness (e.g., high humidity); if present, reprocessing may be required;
- e) reassembly of equipment/device if required.

### ***Recommendation 79***

***Sterility of sterile items must be maintained until used.***

### ***Recommendation 80***

***Reprocessed medical equipment/devices shall be stored in a clean, dry location in a manner that minimizes contamination or damage.***



***Recommendation 81***

***At point-of-use, upon opening the reprocessed medical equipment/device, check for integrity of the packaging and the equipment/device; validate results of chemical monitors if present; and reassemble equipment/device if required.***

## Recommendations

### *Recommendation 1*

*It is strongly recommended that, wherever possible, reprocessing should be performed in a centralized area that complies with the physical and human resource requirements for reprocessing.*

### *Recommendation 2*

*Procedures for disinfection and sterilization must include statements and information regarding the type, concentration and testing of chemical products; duration and temperature of exposure; and physical and chemical properties that might have an impact on the efficacy of the process. These procedures must be readily accessible to staff performing the function.*

### *Recommendation 3*

*Reusable medical equipment/devices must be thoroughly cleaned before disinfection or sterilization.*

### *Recommendation 4*

*If cleaning cannot be done immediately, the medical equipment/device must be submerged in tepid water and detergent or enzymatic cleaner to prevent organic matter from drying on it.*

### *Recommendation 5*

*Factors that affect the ability to effectively clean medical equipment/devices must be considered prior to cleaning.*

### *Recommendation 6*

*The process for cleaning should include written protocols for disassembly, sorting, soaking, physical removal of organic material, rinsing, drying, physical inspection, lubrication and wrapping.*

### *Recommendation 7*

*Audits of the cleaning process must be done on a regular basis.*

### *Recommendation 8*

*The health care setting will, as a minimum, have policies and procedures for all aspects of reprocessing that are based on current recognized standards/recommendations and that are*

*reviewed at least annually.*

***Recommendation 9***

*All policies and procedures for reprocessing medical equipment/devices require review by an individual with infection prevention and control expertise.*

***Recommendation 10***

*A procedure should be established for the recall of improperly reprocessed medical equipment/devices.*

***Recommendation 11***

*The policies of the healthcare setting shall specify the requirements for, and frequency of, education and training as well as competency assessment for all personnel involved in the reprocessing of medical equipment/devices.*

***Recommendation 12***

*All aspects of reprocessing shall be supervised and shall be performed by knowledgeable, trained personnel.*

***Recommendation 13***

*Managers, supervisors and staff involved in reprocessing have completed a recognized qualification/certification course in reprocessing practices.*

***Recommendation 14***

*A plan must be in place for each person involved in reprocessing to obtain certification qualification.*

***Recommendation 15***

*Reprocessing performed outside the centralized area must be kept to a minimum and must be approved by the Infection Control Committee or those accountable for safe reprocessing practices and must conform to the requirements for reprocessing space.*

***Recommendation 16***

*The decontamination work area shall be physically separated from clean areas by walls or partitions.*

***Recommendation 17***

*Wherever chemical disinfection/sterilization is performed, air quality must be monitored when using products that produce toxic vapors and mists.*

***Recommendation 18***

*There must be a regular schedule for environmental cleaning in the Sterile Processing Department that includes written procedures and clearly defined responsibilities.*

***Recommendation 19***

*Occupational Health and Safety for the healthcare setting will review all protocols for reprocessing medical equipment/devices to verify that worker safety measures and procedures to eliminate or minimize the risk of exposure are followed and are in compliance with the Occupational Health and Safety Act of the country.*

***Recommendation 20***

*There is a policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics or/and handling contact lenses in the reprocessing area.*

***Recommendation 21***

*Appropriate personal protective equipment (PPE) should be worn for all reprocessing activities.*

***Recommendation 22***

*All staff working in reprocessing shall be offered Hepatitis B immunization unless they have documented immunity to Hepatitis B.*

***Recommendation 23***

*Measures and procedures shall be written to prevent and manage injuries from sharp objects.*

***Recommendation 24***

*Measures and procedures shall be in place for immediate response to worker exposure to blood and body fluids.*

***Recommendation 25***

*Disposable sharps shall be disposed of in an appropriate puncture-resistant sharps container at point-of-use, prior to transportation.*

***Recommendation 26***

*Soiled medical equipment/devices must be handled in a manner that reduces the risk of exposure and/or injury to personnel and clients/patients/residents, or contamination of environmental surfaces.*

***Recommendation 27***

*A process shall be in place that will ensure that medical equipment/devices which have been reprocessed can be differentiated from equipment/devices which have not been reprocessed (e.g., color coding).*

***Recommendation 28***

*Contaminated equipment/devices shall not be transported through areas designated for storage of clean or sterile supplies, client/patient/resident care areas or high-traffic areas.*

***Recommendation 29***

*Sterile and soiled equipment/devices shall not be transported together.*

***Recommendation 31***

*Semi-critical medical equipment/devices must be decontaminated using, at a minimum, high-level disinfection. Sterilization is preferred.*

***Recommendation 32***

*The chemical disinfectant used for disinfecting medical equipment/devices must be compatible with both the equipment/device manufacturer's instructions for disinfection and the cleaning products involved in the reprocessing of the equipment/device.*

***Recommendation 33***

*Disinfectant manufacturers must supply recommended usage for the disinfectant to ensure that it is compatible with the medical equipment/devices on which it will be used.*

***Recommendation 34***

*The process of high-level disinfection requires monitoring and auditing. If a chemical product is used, the concentration of the active ingredient(s) must be verified and a logbook of daily concentration test results is to be maintained.*

***Recommendation 35***

***Manufacturer's instructions for installation, operation and ongoing maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated.***

***Recommendation 36***

***A preventive maintenance program for pasteurizing equipment must be implemented and documented.***

***Recommendation 37***

***Following the pasteurizing cycle, medical equipment/devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and that is used exclusively for the drying of pasteurized equipment/devices.***

***Recommendation 38***

***A log of contents, temperature and time is to be maintained for each pasteurizer cycle.***

***Recommendation 39***

***Products used for any/all stages in reprocessing (i.e., cleaning, disinfection, sterilization) must be approved by the committee responsible for product selection, by an individual with reprocessing expertise and by an individual with infection prevention and control expertise.***

***Recommendation 40***

***The reprocessing method and products required for medical equipment/devices will depend on the intended use of the equipment/device and the potential risk of infection involved in the use of the equipment/device.***

***Recommendation 41***

***Products used for decontamination must be appropriate to the level of reprocessing that is required for the use of the medical equipment/device.***

***Recommendation 42***

***The process and products used for cleaning, disinfection and/or sterilization of medical equipment/devices must be compatible with the equipment/devices.***

***Recommendation 43***

***All medical equipment/devices that will be purchased and will be reprocessed must have written device-specific manufacturer's cleaning, disinfection and sterilization instruction. If disassembly or***

*reassembly is required, detailed instructions with pictures must be included. Staff training must be provided on these processes before the medical equipment/device is placed into circulation.*

***Recommendation 44***

*Critical endoscopes shall be sterilized prior to use.*

***Recommendation 45***

*Semi-critical endoscopes require a minimum of high-level disinfection prior to use.*

***Recommendation 46***

*Since flexible bronchoscopes and cystoscopes are entering a sterile cavity, it is highly recommended that these be sterilized; however, if they are not compatible with sterilization, high-level disinfection is the minimum requirement.*

***Recommendation 47***

*Disposable sheaths/condoms placed over the endoscope reduce the numbers of microorganisms on the scope but do not eliminate the need for cleaning/disinfection/sterilization between uses.*

***Recommendation 48***

*Individuals responsible for reprocessing endoscopes shall be specially trained and shall meet the facility's written endoscope processing competency requirements, including ongoing education and training and annual competency testing.*

***Recommendation 49***

*Each health care setting in which endoscopic procedures are performed shall have written, detailed procedures for the cleaning and handling of endoscopes.*

***Recommendation 50***

*Ventilation shall be such as to remove toxic vapors generated by, or emitted from, cleaning or disinfecting agents.*

***Recommendation 51***

*Endoscope cleaning shall commence immediately following completion of the clinical procedure.*

**Recommendation 52**

*Patency and integrity of the endoscope sheath should be verified through leak testing, performed after each use.*

**Recommendation 53**

*Endoscopic equipment/devices shall be rinsed and dried prior to disinfection or sterilization.*

**Recommendation 54**

*Critical endoscopes shall be sterilized.*

**Recommendation 55**

*Semi-critical endoscopes and accessories (excluding biopsy forceps and brushes) must receive at least high-level disinfection after each use.*

**Recommendation 56**

*Endoscopic accessories (e.g., biopsy forceps and brushes) that break the mucosal barrier must be disposable or sterilized after each use.*

**Recommendation 57**

*If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components are compatible with the AER.*

**Recommendation 58**

*Final drying of semi-critical endoscopes shall be facilitated by flushing all channels with 70% ethyl or isopropyl alcohol, followed by forced air purging of the channels.*

**Recommendation 59**

*Semi-critical endoscopes shall be stored hanging vertically in a well-ventilated area in a manner that minimizes contamination or damage. Endoscopes shall not be coiled, allowed to touch the floor or bottom of the cabinet while hanging, or stored in their cases.*

**Recommendation 60**

*The water bottle and its connecting tube, used for cleaning the endoscope lens and irrigation during the procedure, should receive high-level disinfection or sterilization at least daily.*

**Recommendation 61**

*A preventive maintenance program for automated endoscope reprocessor (AER) must be*



*implemented and documented.*

***Recommendation 62***

*Healthcare settings shall have policies in place providing a permanent record of endoscope use and reprocessing, as well as a system to track endoscopes and patients/residents that includes recording the endoscope number in the patient/resident record.*

***Recommendation 63***

*The preferred method for sterilization of heat-resistant equipment/devices is steam. (pre-vacuum sterilizers are preferred). The preferred sterilization method for heat sensitive instruments would be low temperature sterilization.*

***Recommendation 64***

*All sterilizers must be tested for performance using physical, chemical and biological monitors and indicators. Chemical indicators do not replace the need to use a biological indicator.*

***Recommendation 65***

*Flash sterilization shall only be used in emergency situations and must never be used for implantable equipment/devices.*

***Recommendation 66***

*Boiling is not an acceptable method of sterilization.*

***Recommendation 67***

*The use of ultraviolet light is not an acceptable method of disinfection/sterilization.*

***Recommendation 68***

*Glass bead sterilization is not an acceptable method of sterilization.*

***Recommendation 69***

*The use of a chemiclave for sterilization poses an environmental risk and must be closely monitored.*

***Recommendation 70***

*The use of microwave ovens for sterilization is not acceptable.*

***Recommendation 71***

*If a failed chemical indicator is found, the contents of the package shall be reprocessed before use.*

***Recommendation 72***

*A procedure must be established for the recall of improperly reprocessed medical equipment/devices.*

***Recommendation 73***

*The recall procedure should include assessment of client/patient/resident risk and a procedure for subsequent notification of physicians, clients/patients/residents, other facilities and/or regulatory bodies if indicated.*

***Recommendation 74***

*Health care settings shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies.*

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*Needles must be single-use and must not be reprocessed.*

***Recommendation 78***

*It is strongly recommended that catheters, drains and other medical equipment/devices with small lumens (excluding endoscopy equipment) be designated single-use and not be reprocessed and re-used, even if designated as reusable by the manufacturer.*

***Recommendation 79***

*Sterility of sterile items must be maintained until used.*

***Recommendation 80***

*Reprocessed medical equipment/devices shall be stored in a clean, dry location in a manner that minimizes contamination or damage.*

***Recommendation 81***

***At point-of-use, upon opening the reprocessed medical equipment/device, check for integrity of the packaging and the equipment/device; validate results of chemical monitors if present; and reassemble equipment/device if required.***

## Appendix

**Table 3      Design parameters (ANSI/ASHRAE/ASHE standard 170-2008)**

Location	Pressure relationship to adjacent areas	Minimum outdoor ACH	Minimum total ACH	All room air exhausted directly to outdoors	Air recirculated by means of room units	Relative humidity (%)	Temperature (°C)
Decontamination room	Negative	2	6	Yes	No	No requirement	22-26
Clean workroom	Positive	2	4	No requirement	No	No requirement	22-26
Sterile storage	Positive	2	4	No requirement	No requirement	Maximum 60	22-26
Sterilizer equipment room	Negative	No requirement	10	Yes	No	No requirement	No requirement

**Table 4      High-level chemical disinfectants or sterilants (Reference: CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008)**

	High level disinfection claim	Sterilization claim
Hydrogen peroxide 7.5%	30 mins at 20°C	6 hours at 20°C
Peracetic acid 0.2%	NA	12 mins at 50-56°C
Glutaraldehyde ≥2%	20-90 mins at 20-25°C	10 hours at 20-25°C
Ortho-phthalaldehyde 0.55% (OPA)	5 mins at 20°C, 5 mins at 25°C in AER	None
Hydrogen peroxide / peracetic acid (7.35% / 0.23%)	15 mins at 20°C	3 hours at 20°C