Klenitise™

DEFINITION OF TERMS

Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, EtO gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health-care facilities. Sterilization is intended to convey an absolute meaning; unfortunately, however, some health professionals and the technical and commercial literature refer to "disinfection" as "sterilization" and items as "partially sterile." When chemicals are used to destroy all forms of microbiologic life, they can be called chemical sterilants. These same germicides used for shorter exposure periods also can be part of the disinfection process (i.e., high-level disinfection).

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects (Tables 1 and 2). In health-care settings, objects usually are disinfected by liquid chemicals or wet pasteurization. Each of the various factors that affect the efficacy of disinfection can nullify or limit the efficacy of the process. Factors that affect the efficacy of both disinfection and sterilization include prior cleaning of the object; organic and inorganic load present; type and level of microbial contamination; concentration of and exposure time to the germicide; physical nature of the object (e.g., crevices, hinges, and lumens); presence of biofilms; temperature and pH of the disinfection process; and in some cases, relative humidity of the sterilization process (e.g., ethylene oxide).

Unlike sterilization, disinfection is not sporicidal. A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called *chemical sterilants.* At similar concentrations but with shorter exposure periods (e.g., 20 minutes for 2% glutaraldehyde), these same disinfectants will kill all microorganisms except large numbers of bacterial spores; they are called *high-level disinfectants. Low- level disinfectants* can kill most vegetative bacteria, some fungi, and some viruses in a practical period of time (<10 minutes). *Intermediate-level disinfectants* might be cidal for mycobacteria, vegetative bacteria, most viruses, and most fungi but do not necessarily kill bacterial spores. Germicides differ markedly, primarily in their antimicrobial spectrum and rapidity of action.

Cleaning is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. *Decontamination* removes pathogenic microorganisms from objects so they are safe to handle, use, or discard.

Terms with the suffix ***cide*** or ***cidal*** for killing action also are commonly used. For example, a germicide is an agent that can kill microorganisms, particularly pathogenic

organisms ("germs"). The term ***germicide*** includes both antiseptics and disinfectants. *Antiseptics* are germicides applied to living tissue and skin; ***disinfectants*** are antimicrobials applied only to inanimate objects. In general, antiseptics are used only on the skin and not for surface disinfection, and disinfectants are not used for skin antisepsis because they can injure skin and other tissues. Virucide, fungicide, bactericide, sporicide, and tuberculocide can kill the type of microorganism identified by the prefix. For example, a bactericide is an agent that kills bacteria.

What is Terminal Cleaning?

Terminal cleaning methods vary, but usually include removing all detachable objects in the room, cleaning lighting and air duct surfaces in the ceiling, and cleaning everything downward to the floor. Items removed from the room are disinfected or sanitized before being returned to the room. Terminal cleaning of patient rooms should include the following steps:

• Using an EPA-approved, hospital-grade disinfectant, the following items should be cleaned:

> Top, front and sides of the bed's headboard, mattress, bedframe, footboard and side rails, and between side rails

> TV remote

> Nurse-call device and cord

> All high-touch areas in the room including tabletops, bedside tabletop and inner drawer, phone and cradle, armchairs, door and cabinet handles, light switches, closet handles, etc.

• In the bathroom, start with the highest surface and clean the toilet last; clean the sink and counter area, including sink fixtures, and if there is a shower, the support bars and shower fixtures and surfaces
• Privacy curtains should be removed, placed in a plastic bag in the room and double bagged into a laundry bag with the assistance of another member of the ES staff standing at the door outside the room. The person outside the door should wear gloves. After completing the task this person should remove gloves, wash hands with an antimicrobial soap and water or apply an alcohol rub to their hands.
• Cleaning of window curtains, ceiling or walls is not necessary unless visibly soiled.
• Following patient discharge, clinical equipment must be cleaned and disinfected, moved to the door of the room for removal to central supply or to the sterile processing department.
• Following the terminal cleaning of a patient room, gloves should be removed so as to avoid touching the outside of the gloves. Hands should be washed with an antimicrobial soap and water or an alcohol rub applied to the hands prior to donning a new set of gloves.

GLOSSARY

Action level: concentration of a regulated substance (e.g., ethylene oxide, formaldehyde) within the employee breathing zone, above which OSHA requirements apply.

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). Sodium hypochlorite products that make pesticidal claims, such as sanitization or disinfection, must be registered by EPA and be labeled with an EPA Registration Number.

Bleach Solution	Dilution	Chlorine (ppm)
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 pre-vacuum 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.

Centigrade or **Celsius:** a temperature scale (0oC = freezing point of water; 100oC = boiling point of water at sea level). Equivalents mentioned in the guideline are as follows: 20oC = 68oF; 25oC = 77oF; 121oC = 250oF; 132oC = 270oF; 134oC = 273oF. For other temperatures the formula is: Fo = (Co x 9/5) + 32 *or* Co = (Fo –32) x 5/9.

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, that is 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: 8 fluid ounces.

Decontamination: according to OSHA, "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal" [29 CFR 1910.1030]. 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 lipohilic 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. EPA groups disinfectants by product label claims of "limited," "general," or "hospital" disinfection.

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).

EPA Registration Number or **EPA Reg. No.:** a hyphenated, two- or three-part number assigned by EPA to identify each germicidal product registered within the United States. The first number is the company identification number, the second is the specific product number, and the third (when present) is the company identification number for a supplemental registrant.

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.

General disinfectant: EPA-registered disinfectant labeled for use against both gram-negative and gram- positive bacteria. Efficacy is demonstrated against both *Salmonella choleraesuis* and *Staphylococcus aureus.* Also called *broad-spectrum disinfectant.*

Germicide: agent that destroys microorganisms, especially pathogenic organisms.

Germicidal detergent: detergent that also is EPA-registered as a disinfectant.

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.

Huck towel: all-cotton surgical towel with a honey-comb weave; both warp and fill

yarns are tightly twisted. Huck towels can be used to prepare biologic indicator challenge test packs.

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

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; diagnosis, monitoring, treatment, or alleviation of or compensation for an injury or handicap;
- Investigation, replacement, or modification of the anatomy or of a physiologic process; or
- Control of conception and that does not achieve its primary intended action in or on the human body by pharmacologic, immunologic, or metabolic means but

might be assisted in its function by such means.

- **Microbicide:** any substance or mixture of substances that effectively kills microorganisms.

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.*

Muslin: loosely woven (by convention, 140 threads per square inch), 100% cotton cloth. Formerly used as a wrap for sterile packs or a surgical drape. Fabric wraps used currently consist of a cotton-polyester blend.

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 65–77oC (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.

Penicylinder: carriers inoculated with the test bacteria for in vitro tests of germicides. Can be constructed of stainless steel, porcelain, glass, or other materials and are approximately 8 x 10 mm in diameter.

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 = µg/mL or 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.

QUAT: abbreviation for *quaternary ammonium compound,* a surface-active, water-soluble disinfecting 100 substance that has four carbon atoms linked to a nitrogen atom through covalent bonds.

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.

Sanitizer: agent that reduces the number of bacterial contaminants to safe levels as judged by public health requirements. Commonly used with substances applied to inanimate objects. According to the protocol for the official sanitizer test, a sanitizer is a chemical that kills 99.999% of the specific test bacteria in 30 seconds under the conditions of the test.

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, semicritical, or noncritical 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, semicritical, and noncritical).

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 <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 121–123oC (250–254oF) and 132–135oC (270–275oF).

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 (132–135oC [270–275oF]; 141– 144oC [285–291oF]). 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 121–123oC (250–254oF), 132–135oC (270–275oF), and 141–144oC (285–291oF).

Surfactant: agent that reduces the surface tension of water or the tension at the interface between water and another liquid; a wetting agent found in many sterilants and disinfectants.

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.

Time-weighted average (TWA): an average of all the concentrations of a chemical to which a worker has been exposed during a specific sampling time, reported as an average over the sampling time. For example, the permissible exposure limit for ethylene oxide is 1 ppm as an 8-hour TWA. Exposures above the ppm limit are permitted if they are compensated for by equal or longer exposures below the limit during the 8-hour workday as long as they do not exceed the ceiling limit; short-term exposure limit; or, in the case of ethylene oxide, excursion limit of 5 ppm averaged over a 15-minute sampling period.

Tuberculocide: an EPA-classified hospital disinfectant that also kills *Mycobacterium tuberculosis* (tubercle bacilli). EPA has registered approximately 200 tuberculocides. Such agents also are called *mycobactericides.*

Use-life: the length of time a diluted product can remain active and effective. The stability of the chemical and the storage conditions (e.g., temperature and presence of air, light, organic matter, or metals) determine the use-life of antimicrobial products.

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

Virucide: an agent that kills viruses to make them noninfective. Adapted from Association for the Advancement of Medical Instrumentation; Association of peri-Operating Registered Nurses (AORN), American Hospital Association, and Block.

Source: Center for Diseases Control, Atlanta, GA - Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008