



American National Standard

ANSI/AAMI ST58:2024

Chemical sterilization and high-level
disinfection in health care facilities

Chemical sterilization and high-level disinfection in health care facilities

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AAMI

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Abstract: This recommended practice provides guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the U.S. Food and Drug Administration for use in hospitals and other health care facilities. Included within the scope of this recommended practice are functional and physical design criteria for chemical sterilization and high-level disinfection processing areas; staff qualifications, education, and other personnel considerations; criteria for selecting LCSs/HLDs and gaseous chemical sterilizers; safety and efficacy considerations in the use of LCSs/HLDs and gaseous chemical sterilizers; preparation of devices for processing by chemical sterilization or high-level disinfection; quality control methods; and quality process improvement. Definitions of terms and informative annexes are also provided.

Keywords: chemical sterilization, chemical sterilizers, chemical vapor, ethylene oxide, ethylene oxide emission control, ethylene oxide monitoring, formaldehyde, gaseous chemical sterilants, glutaraldehyde, high-level disinfectants, high-level disinfection, hydrogen peroxide, hydrogen peroxide gas plasma, liquid chemical sterilants, materials compatibility, ortho-phthalaldehyde, ozone, peracetic acid, sodium hypochlorite

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Foreword

This standard was developed by the AAMI Chemical Sterilants Hospital Practices Working Group under the auspices of the AAMI Sterilization Standards Committee.

The first edition of ANSI/AAMI ST58, *Safe use and handling of glutaraldehyde-based products in health care facilities*, was published in 1996. The second edition incorporated AAMI TIR7, *Chemical sterilants and high-level disinfectants: A guide to selection and use*, and was published in 2005. Key updates to the third edition included additional and current workplace safety information; new and updated annexes specific to vapor monitoring; expansion of the types of sterilization processes described to address new systems available to the health care user; improved guidance for workplace design; alignment of recommendations to companion health care facility documents, including ANSI/AAMI ST79 and ANSI/AAMI ST41; a revised product testing selection to simplify recommendations; expanded recommendations for personnel training; and updated quality process recommendations. This fourth edition includes chemical sterilants both liquid chemical and gaseous. ANSI/AAMI ST41, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness* has been withdrawn and is now updated and included in this standard.

In a 2017 multi-disciplinary stakeholders meeting hosted by AAMI, high-level disinfection practices were reviewed. Based on recent research that show some pathogens are resistant to high-level disinfectants (HLD), medical devices and instructions for use (IFU) are becoming more complex, and the introduction of new low temperature sterilization modalities that in many instances are the same amount of time as HLD or less. The output of the 2017 meeting included a recommendation that endoscopes used as semi-critical devices be sterilized.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;.

The provisions of this standard should be reviewed by department managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with the appropriate hospital committees (e.g., safety and hazardous materials).

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 901 N. Glebe Rd., Suite 300, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities* (ANSI/AAMI ST58:2024), but it does provide important information about the development and intended use of the document.

Chemical sterilization and high-level disinfection in health care facilities

1 Scope

1.1 General

This standard provides guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for use in hospitals and other health care facilities.¹ These guidelines are intended to assist health care personnel in the safe and effective use of gaseous chemical sterilizing systems, LCSs/HLDs, and associated equipment.

Chemical sterilants can be classified into three basic categories:

- a) LCSs/HLDs in which the items to be processed are immersed manually or processed in an automated system under defined conditions; and
- b) gaseous chemical sterilants that are used in a sterilizer under defined cycle conditions;
- c) foam or gel in which the items to be processed are manually or in an automated system coated with foam under defined conditions.

Processes that use liquid chemical sterilization/high-level disinfection and gaseous chemical sterilization are validated by different methods. Although each method achieves acceptable microbial lethality, some methods have limitations. Devices processed with liquid chemical sterilization/high-level disinfection are not packaged. LCSs/HLDs are most often used for high-level disinfection of semicritical medical devices or for sterilization of critical or semicritical medical devices that are not amenable to physical sterilization processes (e.g., steam, dry heat, radiation) or gaseous chemical sterilization processes (e.g., ethylene oxide [EO], hydrogen peroxide, hydrogen peroxide-ozone).

NOTE 1 The information provided in this standard was accurate at the time the document was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and written instructions for use (IFU) change accordingly. Therefore, it is essential that health care personnel obtain up-to-date information for the products that they use—or are considering using—and refer to manufacturers' current label directions and written IFU.

NOTE 2 The information provided in this standard and its annexes is for general reference and is not intended to imply endorsement of individual products.

¹ This standard covers LCSs/HLDs and gaseous chemical sterilization systems known to be commercially available at the time of this writing. For up-to-date information on gaseous chemical sterilization systems and LCSs/HLDs cleared by FDA, check the Center for Devices and Radiological Health (CDRH), FDA's web site at <http://www.fda.gov/cdrh>; or contact the Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection, DHT4B: Division of Infection Control and Plastic Surgery Devices, OHT4: Office of Surgical and Infection Control Devices, Office of Product Evaluation and Quality (OPEQ). FDA-Cleared Sterilants and High-level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices are provided at the FDA website. The list identifies the products cleared by FDA in a 510(k) with general claims for processing reusable medical and dental devices. This list does not include preamendment products (products that were on the market before 1976 and that have not been modified since that time); FDA-cleared germicides dedicated to specific devices, such as hemodialyzers or hemodialysis machines; or gaseous chemical sterilization systems.

1.2 Inclusions

This standard specifically addresses

- work area design considerations for processing areas in which liquid chemical sterilization/high-level disinfection and gaseous chemical sterilization systems are used;
- staff qualifications, education, and other personnel considerations;
- criteria for selecting liquid chemical sterilization/high-level disinfection and gaseous chemical sterilization systems;
- processing recommendations;
- safety and efficacy considerations in the use of liquid chemical sterilization/high-level disinfection and gaseous chemical sterilization systems;
- storage and transport of sterilized or disinfected devices;
- quality control methods; and
- quality process improvement.

This standard also includes definitions of terms and informative annexes on Microbial Lethality, Materials Compatibility, and Toxicity (Annex A); Considerations for the Selection of Liquid and Gaseous Chemical Sterilants/High-level Disinfectants (Annex B); Glutaraldehyde Solutions (Annex C); Hydrogen Peroxide Solutions (Annex D) ; Ortho-phthalaldehyde Solutions (Annex E); Peracetic Acid–Hydrogen Peroxide Solutions (Annex F); Sodium Hypochlorite Solutions (Annex G); Chemical Vapor Sterilants Using Alcohol and Formaldehyde (Annex H); Vaporized Hydrogen Peroxide Sterilization (Annex I); Hydrogen Peroxide-Ozone Sterilization (Annex J); Sonicated Hydrogen Peroxide Mist (Annex K); Government Regulation (Annex L); Development of a Prepurchase Evaluation Protocol or Rigid Sterilization Container Systems (Annex M); User Verification of Cleaning Processes (Annex N); Example of Documentation of Premature Resale of Implants (Annex O); Gas and Vapor Monitoring (Annex P); Infection Transmission and Standard Precautions (Annex Q); General Considerations for Cleaning and Disinfection (Annex R); Special Considerations for Ethylene Oxide Gas Sterilization (Annex S) and Relevant Literature (Bibliography).

NOTE For information regarding cleaning, disinfection and sterilization of flexible and semi-rigid endoscopes, see AAMI/ANSI ST91.

1.3 Exclusions

This standard does not cover

- steam sterilization (see ANSI/AAMI ST79 and ANSI/AAMI ST8);
- gaseous chemical sterilization systems and liquid chemical sterilization/high-level disinfection systems not cleared by the FDA at the time this document was published;
- the processing of medical devices intended for single use (see FDA [2000c]);
- the processing of devices that might have been exposed to prions, such as the prion that causes Creutzfeldt-Jakob disease (CJD).

NOTE—For information about processing devices exposed to prions, see AORN (2010a), Favero and Bond (2001), Rutala and Weber (2010), ANSI/AAMI ST79, and the recommendations of the Centers for Disease Control and Prevention (CDC) (<http://www.cdc.gov>) and the Healthcare Sterile Processing Association (<http://www.myhspa.org>) or

- the reprocessing of medical devices that require only terminal cleaning, low-level disinfection, or intermediate-level disinfection.

2 Definitions and abbreviations

2.1

absorb

take up or receive a vapor or liquid into a solid material

2.2

ACGIH®

American Conference of Governmental Industrial Hygienists

2.3

action level

- 1) For certain chemicals, the airborne concentration of an air contaminant, calculated as an 8-hour time-weighted average (TWA), above which particular monitoring, medical surveillance, or other stated OSHA requirements apply
- 2) Concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels.

2.4

adsorb

collect (a gas, liquid, or dissolved substance) in condensed form on a surface

2.5

air flow

air movement as measured in volume of air per unit time (e.g., cubic feet per minute or liters per second)

2.6

air velocity

airflow rate as measured by the average distance that air travels per unit time (e.g., feet per second)

2.7

ambulatory care

short-term treatment of medical, dental, or surgical needs within 24 hours in a medical office or clinic

2.8

asepsis

prevention of contact with microorganisms

2.9

bacterial count

method of estimating the number of bacteria per unit sample

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

2.10

bioburden

population of viable microorganisms on or in a product and/or a sterile barrier system

Note to entry: When measured, bioburden is expressed as the total count of bacterial and fungal CFUs per single item.

2.11

biofilm

accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily (Donlan, 2002)

Note to entry: Some microscopic organisms have the ability, when growing in water or water solutions or *in vivo* (e.g., the bloodstream), to adhere to a surface and then exude over themselves a polysaccharide matrix. The matrix contains cells, living and dead, as well as polysaccharide (sometimes referred to as "glycocalyx") and can prevent antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching the microbial cells.

2.12

biological indicator (BI)

test system containing viable microorganisms providing a defined resistance to a specified sterilization process

Note 1 to entry: According to the *Code of Federal Regulations*, “a biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization.” [21 CFR 880.2800(a)(1)]

Note 2 to entry: Biological indicators are intended to demonstrate whether or not the conditions were adequate to achieve sterilization. A negative BI does not prove that all items in the load are sterile or that all were exposed to adequate sterilization conditions.

Note 3 to entry: See ANSI/AAMI/ISO 11138-7 for information on the selection, use and interpretation of biological indicators.

2.13

calibration

set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards

2.14

ceiling limit

according to *the Code of Federal Regulations*, “the employee’s exposure [to an air contaminant] which shall not be exceeded during any part of the work day. If instantaneous monitoring is not feasible, then the ceiling shall be assessed as a 15-minute time weighted average exposure which shall not be exceeded at any time over a working day” (29 CFR 1910.1000)

Note to entry: See also **threshold limit value (TLV®)**.

2.15

challenge test pack

pack used in qualification testing of hospital sterilizers

2.16

chemical indicators (CIs)

test system that reveals change in one or more pre-specified process variables based on a chemical or physical change resulting from exposure to a process

2.17

chemical sterilant

chemical agent capable of rendering a product free of viable microorganisms

Note to entry: In this document, “chemical sterilant” includes both liquid and gaseous chemical sterilants unless otherwise noted.

2.18

chemical sterilization

process, using a chemical sterilant, designed to render a product free of viable microorganisms

2.19

chemical vapor sterilization

specific sterilization process that uses a solution of alcohol, water, and inert ingredients, with trace formaldehyde (less than 0.25%), which is heated to produce an unsaturated vapor with temperature, pressure, and exposure time within specified limits

Note to entry: Although “chemical vapor” can be taken to refer to gaseous chemical sterilants in general, the term is used here, as it is commonly used in the health care community, to refer to a specific process.

2.20

cleaning

removal of contamination from an item to the extent necessary for further processing or for the intended use

2.21

contaminated

presence of potentially infectious, pathogenic organisms (e.g., found in blood or other potential infectious material) in or on an object

2.22

critical devices

medical devices that are introduced into or have contact with the bloodstream or normally sterile areas of the body

Note to entry: Examples include, but are not limited to, implants and surgical instruments.

2.23

critical water

water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, deionization [DI], and reverse osmosis [RO] or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process

Note 1 to entry: This water is mainly used for the final rinse or for steam generation.

Note 2 to entry: See ANSI/AAMI ST108:2023 for specifications

2.24

culture

growth of microorganisms in or on a nutrient medium that supports their multiplication

2.25

culture medium

substance or preparation used to grow and cultivate microorganisms

2.26

cycle time

total elapsed time of a sterilization cycle from the time the sterilizer door is closed and the process is initiated until the cycle is completed and the door is opened

2.27

cycle, sterilization

defined sequence of operational steps that are designed to achieve sterilization and are carried out in a sealed chamber

Note to entry: See also **cycle time**.

2.28

decontamination

removal of contaminants to a specified level

Note to entry: A decontamination process can include a cleaning (physical removal) and/or an antimicrobial (e.g., disinfection) process, depending on the defined level previously specified as being appropriate for a defined purpose, and is often a combination of these processes [McDonnell et. al, 2021]

2.29

decontamination room

room designated for collection, retention, and cleaning of soiled and/or contaminated items

2.30

dedicated exhaust line

ductwork or tubing that leads from an interior building site to the exhaust termination or exhaust source and that is used solely to provide an exhaust path for the subject source

2.31

diffusion restricter

device or material that by its composition or geometry impedes the movement of gases (e.g., ethylene oxide, air)

2.32

disinfectant

chemical or combination of chemicals used for disinfection

2.33

disinfection

process that kills pathogenic and other microorganisms by physical or chemical means

Note to entry: Disinfection destroys most recognized pathogenic microorganisms but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes.

2.34

door capture zone

position of the door defined by the manufacturer to be within the influence of the gas-scavenging door hood vented to the dedicated exhaust system

2.36

employee breathing zone

sphere approximately 2 feet in diameter surrounding the head (OSHA, 1984)

Note to entry: The term is commonly used by industrial hygienists and safety professionals to refer to the air around a worker's nose. Air samples collected from the shoulder or lapel are assumed to assess a worker's breathing zone exposure to air contaminants.

2.37

engineering controls

According to the *Code of Federal Regulations*, "controls (e.g., sharps disposal containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace" (29 CFR 1910.1030). Engineering controls also can include equipment that helps to reduce occupational exposure to LCSs/HLDs or gaseous chemical sterilants (e.g., tamper-resistant sterilant delivery systems, sealed chambers, local exhaust hoods, and increased ventilation).

2.38

enhanced visualization

tools for inspection such as lighted magnification and video borescopes to aid visualization

2.39

EPA

U.S. Environmental Protection Agency

2.40

excursion limit

EL

maximum concentration of a chemical to which workers can be exposed over a short time period

Note to entry: "Excursion limit" (EL) is a term adopted by OSHA specifically for defining a short-term exposure limit.

2.41

exhaust duct

pipe, tubing, or duct leading from the area of generation of airborne pollutants and eventually discharging the pollutants to the outdoors

Note to entry: Air is moved through the exhaust duct by the exhaust source.

2.42

exhaust source

motor and fan or other means of providing air movement that are placed downstream of all the sources of airborne pollutants to be expelled from the building

Note to entry: The exhaust source creates negative pressure, thereby drawing contaminated air into ducts or hoods and propelling it outdoors.

2.43

expiration date

date that is calculated by adding a specific period of time to the date of manufacture or sterilization of a medical device or component and that defines its estimated useful life

2.44

expiration statement

statement, also known as a day-to-day expiration date, indicating that the contents of a package are sterile indefinitely unless the integrity of the package is compromised

2.45

exposure time

period for which the process parameters are maintained within their specified tolerances

2.46

face velocity

average rate of movement of air, in feet per minute, into a local exhaust ventilation system as measured at the opening of the hood

2.47

FDA

U.S. Food and Drug Administration

2.48

gaseous chemical sterilization (GCS)

validated process employing gaseous and/or vapor chemical sterilants (e.g., vaporized hydrogen peroxide, hydrogen peroxide-ozone, and ethylene oxide)

2.49

General Duty Clause

section 5(a)(1) of the Occupational Safety and Health Act of 1970, which provides that each employer “shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.”

2.50

Gram’s method of staining

method of differential staining used in microbiological identification. See also Stanier, Adelberg, and Ingraham (1976)

2.51

gram-negative bacteria

bacteria that are decolorized when stained by Gram’s method but take on the RED color of the counterstain

[SOURCE: ANSI/AAMI ST79:2017, 2.41]

2.52

gram-positive bacteria

bacteria that are not decolorized by Gram’s method but retain the original violet color

2.53

gross soil

Obvious tissue and blood that can be removed by flushing and wiping during or immediately following the procedure. It is not a term that implies that all blood or tissue will be removed as this is done during manual or automated cleaning in the appropriate environment according to manufacturer's instructions for use.

2.54

health care facility

hospital, nursing home, extended-care facility, freestanding surgical center, clinic, medical office, or dental office

2.55

health care–associated infections (HAIs)

infections that patients acquire during the course of receiving treatment for other conditions in a health care facility or that health care workers acquire while performing their duties within a health care setting (See <https://www.cdc.gov/hai/index.html>)

2.56

high-level disinfectant (HLD)

a chemical that inactivates all microbial pathogens except for bacterial endospores when they are present in large numbers, when used according to labeling (Rutala, 1990)

Note to entry: According to the FDA, an HLD is a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass the AOAC International sporicidal activity test as a sterilant. See Annex A

2.57

high-level disinfection

process that kills all microbial organisms but not necessarily large numbers of bacterial spore

Note to entry: For a process that can be used for both liquid chemical sterilization and high-level disinfection, the contact time for high-level disinfection is shorter than that necessary for sterilization, under otherwise identical conditions.

2.58

huck towel

all-cotton surgical towel with a tight-knit weave to limit linting

2.59

industrial hygienist

professional trained to anticipate, recognize, measure, evaluate, and control health hazards in the workplace

2.60

installation qualification (IQ)

process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: ISO 11139:2018, 3.220.2]

2.61

instructions for use (IFU)

see **manufacturer's written instructions for use (IFU)**

2.62

instrument air

medical gas that falls under the general requirements for medical gases as defined by NFPA 99 (Health care facilities code), is not respired, is compliant with the ANSI/ISA 7.0.01 (Quality standard for instrument air), and is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40°C (-40°F)

[SOURCE: ANSI/AAMI ST79:2017, 2.56]

2.63

intermediate-level disinfection

process that kills most viruses, mycobacteria, most fungi, and vegetative bacteria, but not necessarily bacterial spores

Note to entry: See also TIR68:2018.

2.64

labeling

any legend, work, or mark attached to, included in, belonging to, or accompanying any medical device or product

2.65

liquid chemical sterilant (LCS)

solution of a chemical that has been validated to provide microbial kill adequate to obtain FDA clearance for a sterilization label claim

Note to entry: According to the FDA, an HLD is a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass the AOAC International sporicidal activity test as a sterilant. See Annex A.

2.66

local exhaust hood

<venting hood>

system designed to capture contaminated air and conduct it into an exhaust duct

2.67

lot control number

<load control number>

numbers, letters, or a combination of both by which a particular group of products can be traced to a particular manufacturing or sterilization operation

2.68

low-level disinfection

process that kills most vegetative bacteria, some viruses, and some fungi, but not mycobacteria or bacterial spores

Note to entry: See also TIR68:2018.

2.69

manufacturer's written instructions for use

IFU

written recommendations provided by the manufacturer of a device that provide instructions for operation and safe and effective use

2.70

mechanical cleaning

documented, reproducible, automated, or semi-automated (partially manual) cleaning process that is validated for use with specific medical devices and yields a device(s) that is safe to handle for subsequent processing, as defined by its Spaulding classification and intended use

2.71

microbicidal process

process designed to provide a particular level of microbial lethality (kill)

Note to entry: Depending on the level of decontamination needed, this process could be a disinfection process or a sterilization process. The type and level of microbial kill achieved depends on factors such as the type and population of microorganisms present, the type of antimicrobial agent, the concentration of the antimicrobial agent, the exposure time, and the exposure temperature. When used for decontamination purposes, a microbicidal process does not necessarily yield an item that is safe for patient use.

2.72

microorganism

entity, encompassing bacteria, fungi, protozoa, and viruses, of microscopic size

2.73

minimum effective concentration

MEC

minimum concentration of a liquid chemical sterilant/high-level disinfectant that achieves the claimed microbicidal activity

Note 1 to entry: The MEC is determined by dose response testing (FDA, 2000a).

Note 2 to entry: The term “minimum recommended concentration” (MRC) is sometimes used interchangeably with “minimum effective concentration.” The MRC is not necessarily an MEC as determined by dose response testing.

2.74

minimum recommended concentration

MRC

minimum concentration at which the manufacturer tested the product and validated its performance

Note to entry: The term “minimum effective concentration” (MEC) is sometimes used interchangeably with “minimum recommended concentration.” The MRC is not necessarily an MEC as determined by dose response testing.

2.75

muslin

broad term describing a wide variety of plain-weave cotton or cotton-polyester fabrics having approximately 140 threads per square inch

2.76

NFPA

National Fire Protection Association

2.77

non-critical devices

medical devices that only contact intact patient skin or which have no direct patient contact but may become contaminated in a clinical setting

Note to entry: Examples include, but are not limited to, bedpans, reusable anesthesia masks, and blood pressure cuffs.

2.78

OQ

operational qualification

process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[SOURCE: ISO 11139:2018, 3.220.3]

2.79

OSHA

Occupational Safety and Health Administration

2.80

permissible exposure limits

PELs

according to the *Code of Federal Regulations*, “limits developed by OSHA to indicate the maximum airborne concentration of a contaminant to which an employee may be exposed over the duration specified by the type of PEL assigned to that contaminant” (29 CFR 1910.1000)

Note to entry: See also **threshold limit value (TLV®)**.

2.81

personal protective equipment

PPE

According to the *Code of Federal Regulations*, "specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment" (29 CFR 1910.1030).

2.82

point of use treatment

the collective activities that the user of a medical device performs at the point of use (where the procedure using the device was performed) immediately after patient use to prepare it for processing, including precleaning (to prevent biofilm formation and drying of soil), disconnecting accessories and/or disassembling items, preparing handoff communication, and preparing the device for transport to the decontamination

2.83

ppmv

parts per million volume

Note 1 to entry: Concentrations of gas vapor in air are commonly measured in parts of gas vapor per million parts of air by volume: 1 ppmv equals 1 volume of gas vapor per 1,000,000 volumes of air.

Note 2 to entry: Concentrations in gases are typically expressed as parts per million by volume (ppmv) or percent by volume, whereas in liquids concentrations are expressed as parts per million by weight or percent by weight. In both cases, common usage often is to refer to the concentration as ppm or percent.

2.84

PQ

performance qualification

process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements

[SOURCE: ISO 11139:2018, 3.220.4]

2.85

process challenge device

PCD

item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process

Note to entry: For purpose of this standard, a PCD is test pack containing a BI or a BI and a CI. See AAMI TIR31.

2.86

processing area

area of a health care facility in which decontaminated, clean medical devices and other medical and surgical supplies are inspected, assembled into sets and trays, and wrapped, packaged, or placed into rigid sterilization container systems for subsequent sterilization

Note to entry: This area is commonly referred to as the "preparation and packaging area" if it is part of sterile processing and as a "pack room" if textile packs are assembled there.

2.87

pyrogen

fever-producing substance

Note to entry: Debris (usually consisting of cell wall material) from killed microorganisms can be pyrogenic; limiting the bioburden before sterilization minimizes this debris.

2.88**qualification**

activities undertaken to demonstrate that utilities, equipment, and methods or modes are suitable for their intended use and perform properly

2.89**qualification test**

a challenge test of the sterilizer performed by the sterilizer manufacturer or other service provider, in cooperation with personnel, after (a) installation, relocation, and any major redesign of the sterilizer, and (b) sterilizer malfunctions and major repairs

2.90**qualified**

as the term is used with respect to personnel, prepared by training and experience to perform a specified task following verification of competency

2.91**quality assurance test**

periodic test conducted by qualified personnel as part of an ongoing quality assurance program and designed to provide a substantial challenge to the sterilizer under actual use conditions

2.92**restricted area**

area where access and traffic are limited to authorized personnel and where special attire is required

2.93**reusable medical device**

device intended for repeated use on different patients, with appropriate decontamination and other processing between uses

2.94**reuse life**

period of time that an LCS/HLD solution can be used following activation or dilution, if appropriate, provided that the concentration of the active ingredient remains at or above the manufacturer's specified MRC or MEC

Note to entry: The reuse life of most LCS/HLD products is 14, 21, 28, or 30 days.

2.95**SCBA**

self-contained breathing apparatus

2.96**SDS**

Safety Data Sheet

Note to entry: As of March 2012, Material Safety Data Sheets (MSDSs) are known as Safety Data Sheets (SDSs).

2.97**semicritical devices**

medical devices that contact intact mucous membranes or nonintact skin, but that do not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body

Note 1 to entry: Examples include, but are not limited to, intubation using a non-channelled endoscope and respiratory therapy equipment.

Note 2 to entry: A device that is normally classified as semicritical could also be a critical device when used in procedures where contact with the bloodstream or sterile areas of the body occurs.

2.97

shelf life

when the term is used with respect to a high-level disinfected medical device, the period of time during which the item is considered safe to use

[SOURCE: ANSI/AAMI ST79:2017, 2.104 – modified.]

2.99

short-term exposure limit

STEL

According to the *Code of Federal Regulations*, "...the employee's 15-minute time weighted average exposure which shall not be exceeded at any time during a work day unless another time period is specified [by OSHA]. If another time period is specified, the time weighted average exposure over that time period shall not be exceeded at any time during the working day" (29 CFR 1910.1000).

Note to entry: See also **threshold limit value (TLV®)**.

2.100

solution test strip

device used to monitor whether the concentration of the active ingredient(s) in a chemical disinfectant or sterilant solution is above or below the MRC or MEC for effective high-level disinfection or sterilization

2.101

spore test strip

test system containing a known number of bacterial spores (at least 10^5 per strip) of known resistance to a LCS/HLD and used in a defined liquid chemical sterilant processing system

2.102

sterilant/sterilizing agent

physical or chemical entity, or combination of entities, having sufficient microbicidal activity to achieve sterility under specified conditions

[SOURCE: ISO 11139:2018, 3.288]

2.103

sterile

free from viable microorganisms

2.104

sterile processing department /area

area within a health care facility that processes and controls medical supplies, devices, and equipment, sterile and not sterile, for some or all patient care areas of the facility

2.105

sterile storage area

room designed to store clean and sterile items and protect them from contamination

2.106

sterility assurance level (SAL)

probability of a single viable microorganism occurring on an item after sterilization

Note 1 to entry: SAL is usually expressed as 10^{-n} .

Note 2 to entry: An SAL of 10^{-6} means that there is less than or equal to one chance in a million that a single, viable microorganism is present on a sterilized item. It is generally accepted that a sterility assurance level of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers).

Note 3 to entry: SAL cannot be directly measured by a sterilization indicator.

2.107

sterilization

validated process used to render a product free from viable microorganisms

Note to entry: In a sterilization process, the nature of microbiological inactivation is described by an exponential function. Therefore, the presence of a viable microorganism on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero. See also **sterility assurance level**.

2.108

sterilization area

area of a health care facility designated to house sterilization equipment such as steam, ethylene oxide (EO), and vaporized hydrogen peroxide sterilizers

2.109

sterilizer

apparatus used to sterilize medical devices, equipment, and supplies by direct exposure to the sterilizing agent

Note to entry: In practice, no such absolute statement regarding the absence of microorganisms can be proven. See **sterilization**.

2.110

sterilizer qualification

assessment of sterilizer performance in the environment in which it will be used

Note to entry: See also **AAMI ST90**.

2.111

threshold limit value (TLV®)

According to ACGIH®, "Threshold Limit Values (TLVs®) refer to airborne concentrations of substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects" (ACGIH, 2013). Three categories of TLVs® are specified by ACGIH®: TLV®-TWA, TLV®-STEL, and TLV®-ceiling (TLV-C).

TLV®-TWA: According to ACGIH®, "the time-weighted average concentration for a normal 8-hour workday and a 40-hour workweek, to which nearly all workers may be repeatedly exposed, day after day, without adverse effect."

TLV®-STEL: According to ACGIH®, "a 15-minute TWA exposure which should not be exceeded at any time during a workday even if the 8-hour TWA is within the TLV®-TWA. Exposure above the TLV®-TWA up to the STEL should not be longer than 15 minutes and should not occur more than four times per day. There should be at least 60 minutes between successive exposures in this range."

TLV®-C: According to ACGIH®, "the concentration that should not be exceeded during any part of the working exposure. In conventional industrial hygiene practice if instantaneous monitoring is not feasible, then the TLV®-C can be assessed by sampling over a 15-minute period except for those substances that may cause immediate irritation when exposures are short."

2.112

time-weighted average (TWA)

According to the *Code of Federal Regulations*, "the employee's average airborne exposure in any 8-hour work shift of a 40-hour work week which shall not be exceeded" (29 CFR 1910.1000). See also **threshold limit value (TLV®)**.

2.113

transmission-based precautions

Precautions designed for patients documented or suspected to be infected with highly transmissible or epidemiologically important pathogens for which additional precautions are used to interrupt transmission in health care facilities. There are three types of transmission-based precautions: airborne precautions, droplet precautions, and contact precautions.

2.114

use life

period of time that an opened container of ready-to-use LCS/HLD product or of activated LCS/HLD product with no reuse claim can be stored and the contents used

2.115

user verification

documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met

2.116

validation

Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications. Validation is performed by the device manufacturer.

Note 1 to entry: Validation of equipment covers three activities: installation qualification, operational qualification, and performance qualification.

2.117

venting

collecting or capturing an air contaminant in order to discharge it through a pipe or duct to an area where human exposure can be minimized

3 Work area design considerations

3.1 General considerations

This section provides guidance for the design and maintenance of the workplace to facilitate effective and efficient processing, promote personal safety and standardization of procedures, minimize environmental contamination and maintain integrity of processed items.

Traffic control; engineering controls (adequate ventilation and hazard containment); ergonomics; and proper equipment installation, operation, and maintenance can reduce unnecessary or inadvertent exposure of personnel, patients, and visitors to chemical sterilants/high-level disinfectants.

This section includes information for:

- work area design;
- traffic control;
- ventilation and containment of chemical sterilants/high-level disinfectants in areas which chemical sterilization or high-level disinfection is performed; and
- considerations for storage and disposal of chemical solutions and containers.

3.2 Processing area

Designated areas for chemical sterilization and high-level disinfection are strongly encouraged. Chemical sterilization/high-level disinfection should:

- a) occur in a centralized department or area;
- b) occur in a clean environment to prevent recontamination of the medical device as it is removed from the process;
- c) provide space for cleaning/decontamination separate from the space used for chemical sterilization or high-level disinfection of medical devices;
- d) be separate from patient procedure areas and personnel support areas;
- e) allow material to flow in a one-way direction from the cleaning area to the chemical sterilization/high-level disinfection area and then on to storage or distribution;
- f) provide solid walls or barriers to separate the cleaning area from the chemical sterilization/high-level disinfection area:
 1. at a minimum, a partial barrier or marking should be present to designate the two areas with at least a 4 ft space from the edge of the cleaning sink to the high-level disinfection or sterilization processing equipment or soaking basin/container; and
 2. if a solid cleanable barrier is used, it should extend a minimum of 4 feet above the sink rim (Facilities Guidelines Institute, 2018);
- g) have floors, walls, and ceiling surfaces that are constructed of non-porous materials that will withstand frequent cleaning and disinfection and consistently wet conditions;
- h) have standardized policies and procedures throughout the health care facility, with emphasis on necessary engineering controls, appropriate personal protective equipment (PPE), hygiene, and safe work practices;

- i) provide adequate space for device or set preparation, quality monitors, chemicals, record-keeping supplies, and hand-hygiene facilities;
- j) be located in a restricted-access area;
- k) not be performed in high-traffic areas;
- l) be segregated from any potential sources of contamination, such as hoppers or other soiled containers for the disposal of linen and trash;
- m) have sufficient space for device inspection, drying and packaging;
- n) have instrument air available to aid drying of lumened devices and constricted spaces, e.g., camera head or endoscopic device handle; and
- o) provide sinks dedicated to hand hygiene.

Sinks of adequate size for the disposal of the LCS/HLD should be available close to the chemical sterilization/high-level disinfection processing area. The rinse sink should be equipped with critical water or other water quality recommended by the manufacturer of the devices being processed. Post HLD or LCS rinsing should occur in a separate sink or container from cleaning.

Consideration of the design of the processing area should be given to the recommended and safe disposal of LCS/HLD. Adequate space should be provided for LCS/HLD containers and rinsing containers. The containers used for LCS/HLD soaking must have lids that remain closed to minimize exposure to chemical vapor. The container must be labeled with the chemical name, use life, and health and physical hazard risks. Labelling for secondary chemical containers must follow OSHA guidelines (see OSHA standard 1910-1200).

In ambulatory surgery and office-based surgical facilities where separate processing rooms might not be possible, the decontamination sink should be separated from the clean work area by either a 4-foot distance from the edge of the sink or a separating wall or screen. If a screen is used, it should extend a minimum of 4 feet above the sink rim. (Facilities Guidelines Institute, 2018).

Rationale: LCS/HLD can be used in many areas of a health care facility (e.g., the operating room [OR], endoscopic procedure area, respiratory therapy area, radiology department). Designating specific areas for the use of LCS/HLD products helps minimize potential personnel exposure by ensuring that proper engineering controls are in place, that knowledgeable and competent personnel trained in sterilization and high-level disinfection are performing those tasks, and that transport of solutions can be minimized. Separating the decontamination area from the preparation, high-level disinfection, and sterilization areas will limit the possibility of cross-contamination. Separating processing areas from patient procedure areas reduces the potential for cross-contamination and for adverse health effects on patients, as could occur if the sterilant is accidentally released into the environment or if there is accidental contact between the sterilant chemicals and a patient. In addition, engineering controls such as local exhaust systems and increased ventilation might not be appropriate for patient procedure areas, because they can adversely affect negative-pressure air circulation systems and room temperature.

3.2.1 Environmental cleaning

3.2.1.1 Area design

The physical design and functional workflows of the sterile processing area should support safe and effective processing, workplace safety, and security. The healthcare organization should create a multidisciplinary team responsible for the oversight of any sterile processing area for such activities as construction and /or renovation and for the development of policies and procedures that outline hygiene practices.

For hygiene practices, a policy and procedure should outline restrictions related to food and beverages and provide recommendations for alternate locations for such items. Food and drink should be strictly prohibited in all areas where medical devices are processed and stored.

Rationale: A multidisciplinary team can provide expertise in the areas of functional design, the functional needs of the users, personnel safety, infection prevention, sustainability, and regulatory requirements from complementary perspectives. Dust and debris are environmental contaminants in the sterile processing area and can result in increasing the risk to employees and patients through contamination of sterilized items. Good hygiene practices include the restriction of food and beverages from the area. Food and beverages may attract insects and vermin. Controlling items permitted in areas that process medical devices is a method of helping to ensure a clean and safe environment. OSHA regulations “prohibits the consumption of food and drink in areas in which work involving exposure or potential exposure to blood or other potentially infectious material exists, or where the potential for contamination of work surfaces exists” as would be the case in Sterile Processing decontamination room/area. In addition to contamination of the food itself, one must consider that food and beverage containers may also become contaminated, resulting in unsuspected contamination of the hands.” “The employer must evaluate the workplace to determine in which locations food or beverages may potentially become contaminated and must prohibit employees from eating or drinking in those areas.” [29 CFR 1910.1030]

3.2.1.2 Housekeeping

Housekeeping procedures in areas used for any aspect of decontamination, preparation, or sterilization should be the same as those used to clean operating and delivery rooms and should ensure a high-level of cleanliness at all times. Floors and horizontal work surfaces should be cleaned at least daily. Other surfaces, such as walls, storage shelves, and air intake and return ducts, should be cleaned on a regularly scheduled basis as established by the facility policy and procedures and more often if needed. Stained ceiling tiles should be replaced, and any leaks causing the stains should be repaired. Lighting fixtures or covers should be cleaned at least once every six months or based on the facility policy and procedure. Care should be taken to avoid compromising the integrity of packaging during cleaning. Special attention should be paid to the sequence of cleaning to avoid transferring contaminants from “dirty” to “clean” areas and surfaces. It is good practice to provide separate housekeeping facilities for the decontamination and clean areas. If cleaning is contracted, appropriate written instructions that reflect these guidelines should be given to the contractor. Areas of attention include: High surface cleaning e.g. ceiling vents, tops of equipment and workstation lights, and low surface dusting e.g. base boards, sterilizer base and bottom of carts.

3.2.1.3 Cleaning schedule

A cleaning schedule and cleaning checklist may be used to demonstrate compliance with the cleaning schedule.

Cleaning verification tools such as ultraviolet visible markers and ATP bioluminescence may be used to measure the adequacy of environmental cleaning on work surfaces.

Rationale: Cleaning removes soil and reduces environmental contaminants, thus reducing the risk of transmission of microorganisms. Measurement provides feedback to improve the thoroughness of cleaning.

Areas of attention include: High-level surface cleaning (e.g. ceiling vents, tops of equipment and workstation lights), and low-level surface cleaning (e.g. base boards, sterilizer base and bottom of carts).

A cleaning schedule and cleaning checklist may be used to demonstrate compliance with the cleaning schedule.

Rationale: Cleaning removes soil and reduces environmental contaminants, thus reducing the risk of transmission of microorganisms. Measurement provides feedback to improve the thoroughness of cleaning and disinfection.

3.2.2 Storage of chemical sterilants/high-level disinfectants

A storage location for LCD/HLD should be designed and located to meet the requirements found in the product IFU, the SDS and product label. In general, however, unused chemical solutions should be stored in tightly closed containers in a cool, secure, properly marked, well-ventilated area; they should not be stored under sinks. Some chemicals used in processing have unique fire safety storage requirements, e.g., chemicals requiring flammable storage cabinets.

The area under sinks is an uncontrolled environment and is not suitable for storage.

Rationale: Secure and properly marked storage locations will prevent accidental damage to the containers. Tightly closed containers in cool storage will prevent spills and contamination and will enhance shelf life. For example, evaporation and exposure to high temperatures can result in polymerization of glutaraldehyde. Although the polymerization is not hazardous, it can negatively affect the biocidal efficacy of the product.

3.2.3 Disposal of chemical sterilant/high-level disinfectant

Chemical sterilant/high-level disinfectant solutions should be disposed of in accordance with the manufacturer's written IFU and with federal, state, and local ordinances. The health care facility must check with the local publicly owned treatment works (POTW) to determine whether the disposal of chemical solutions into the sewer system is permitted. If there are no disposal restrictions, solutions may be discarded, along with copious amounts of cold water, into a drain connected to a sanitary sewer; care should be taken to ensure that adequate ventilation is provided to prevent inhalation of sterilant chemical vapors during disposal. If this release cannot be managed safely, then alternative methods of disposal must be used. Chemical sterilant/high-level disinfectant solutions should not be discarded into septic systems.

Rationale: Pouring chemicals down a sink can often cause release of high concentrations of chemical vapors. Compliance with state and local regulatory requirements is mandatory. Chemical sterilants/high-level disinfectants can disrupt the biodegradation process in a septic system by killing off beneficial microorganisms. The environmental impact of each chemical sterilant/high-level disinfectant solution needs to be considered separately. Refer to the appropriate annex for the chemical in question.

3.2.4 Disposal of chemical solution containers

Empty containers should be disposed of in accordance with the disposal instructions given on the product label.

Rationale: Disposing of empty containers in an appropriate manner will prevent accidental chemical exposure or improper reuse of containers.

3.3 Traffic control

Traffic in all areas in which decontamination, preparation and packaging, high-level disinfection and sterilization, sterile storage, and distribution are carried out should be controlled and restricted to authorized personnel.

- Personnel with access to these areas should be knowledgeable about potential hazards and aware of appropriate precautions when working around chemical sterilants/high-level disinfectants.
- Criteria for authorized entry, movement within processing areas, and attire should be specified in written policies and procedures.
- The responsibility and authority for enforcing traffic control policies and procedures should be specified, as should methods of compliance. It is sometimes necessary for visitors to enter restricted areas; visitors should comply with the established dress code, as stated in the policies and procedures.

Rationale: Personnel and visitors can carry microorganisms into processing areas, thus increasing the potential for environmental contaminants. It is also important to protect personnel and visitors from the microorganisms that can be found on the items being processed. This can be prevented by wearing the appropriate PPE and having awareness of potential hazards and safe handling technique. Good traffic control practices also minimize the potential for contamination of unpackaged items processed by liquid chemical sterilization/high-level disinfection during transfer of the items to the point of use.

3.4 Utilities

3.4.1 Mechanical systems

A multidisciplinary team should review equipment manufacturer's recommendations for mechanical systems and collaborate to determine the specific facility needs, including:

- a) pressurized systems such as instrument air;

- b) vacuum systems; and
- c) treatment systems to the appropriate water quality (see ANSI/AAMI ST108:2023).

Rationale: Because of the increased sophistication of today's medical technology, complex equipment and systems might be needed to inspect, maintain, or verify device performance.

3.4.2 Electrical systems

Electrical engineers and facility operations managers should review equipment manufacturer's recommendations for electrical system requirements and collaborate to design electrical systems that include:

- a) allow for the safe and effective operation of the equipment (e.g., cleaning equipment, sterilization equipment, computers, telephones, lighting) used in the sterile processing department;
- b) allow for the emergency power service of the facility to be extended to include processing equipment; and
- c) provide uninterrupted power sources to all identified equipment.

Rationale: The complexity of processing and sterilization technologies, as well as patient and employee safety require adequate, safe and reliable electrical service.

3.4.3 Water

Water used during processing should be of specific quality that will reduce the chances for recontamination while preparing the medical device for, and without negatively impacting, subsequent processing. During washing the water utilized should be Utility Water and the final rinse should be Critical Water as defined per ANSI/AAMI ST108:2023.

3.4.4 Heating, ventilation, and air conditioning (HVAC) operating parameters

The health care organization should identify which version of ANSI/ASHRAE/ASHE 170 will be used based on when the HVAC system was initially installed or last upgraded. The health care facility should establish and implement systematic processes for monitoring HVAC performance parameters and a mechanism for identifying and resolving variances within the rooms throughout the facility where sterile processing occurs. The ventilation system should be designed so that airflow patterns will not allow air contaminants to enter clean areas. Air should flow from areas of positive pressure to areas of negative pressure. Air from rooms or areas under negative pressure should be exhausted to the outside via a nonrecirculating system. The soiled and decontamination area should be designed so that air flows into the area (negative pressure).

Down-draft-type air circulation systems limit contamination by carrying contaminants toward the floor and away from work surfaces.

Except for exhaust fans on ventilation systems and properly installed and operated fume control hoods, neither fixed nor portable fans should be permitted in any area sterile processing where medical devices are processed. Windows and doors that affect the ventilation and airflow should be kept closed.

Facility engineering personnel or designated responsible personnel should establish policies and procedures for monitoring and maintaining HVAC parameters within the sterile processing areas. Procedures should include maintaining records of monitoring results that are retrievable either from a central system or a local log.

If a variance in the HVAC parameters occurs, sterile processing personnel in combination with a multidisciplinary team (e.g., facility engineer, infection preventionist, risk manager, sterile processing manager or other designated personnel) should conduct a risk assessment. The sterile processing department is defined by ANSI/ASHRAE/ASHE 170 as a critical area.

Rationale: The effect of the HVAC system parameters falling out of range is variable. A small variance for a short period of time might not be of clinical concern, whereas a large variance for a longer period could have clinical significance. A risk assessment provides necessary information to guide appropriate response measures. Ventilation patterns, and

other environmental controls affect the proliferation and spread of potentially dangerous microorganisms and toxic chemicals if used. Control of bioburden and environmental contaminants is essential to ensure that the subsequent sterilization process is effective. Fixed or portable fans should not be permitted in any sterile processing area because they create highly turbulent air flow, which recirculates dust and microorganisms from the floor and work surfaces and thus interferes with designed airflow characteristics.

3.4.5 Lighting

Adequate lighting of work surfaces should be provided in accordance with the recommendations of the Illuminating Engineering Society of North America (IES) for minimum levels of illuminance for various categories of work environments (see Table 1) (Rea, 1993).

The three levels of lighting for each category were calculated on the basis of the following factors:

- a) the age of the workers (persons under 40 years of age require the least amount of illuminance, persons 40 to 55 years of age require an average amount of illuminance, and persons more than 55 years of age require the highest amount of illuminance).
- b) the importance of speed or accuracy of the work done in the area (the greater the importance of speed or accuracy, the more illuminance needed).
- c) the amount of light reflection in the work area (lighter colors reflect light; darker colors absorb light; the greater the reflectance, the less illuminance required).

An illumination engineer, in consultation with the department manager, should determine the appropriate illuminance for each work area within the processing area. Generally, all functions performed within a processing area require detailed inspection and accuracy. Ancillary lighting should be considered for areas where medical devices are manually cleaned and inspected. Lighting fixtures should be selected and mounted in positions that focus the light in front of the employee so that they are not working in their own shadows. The design of lighting fixtures should minimize the accumulation of dust.

NOTE Large areas of stainless steel surfaces found in sterile processing areas can affect lighting. The amount of stainless steel typically used in a processing area is enough to turn a warm color cool; therefore, the lighting should consider the types of materials in the area.

Table 1—IES-recommended illuminance levels for work environments

Work area/function	Least illuminance	Average illuminance	Highest illuminance
General inspection	500 lux (50 foot-candles)	750 lux (75 foot-candles)	1,000 lux (100 foot-candles)
Detailed inspection	1,000 lux (100 foot-candles)	1,500 lux (150 foot-candles)	2,000 lux (200 foot-candles)
Sink areas	500 lux (50 foot-candles)	750 lux (75 foot-candles)	1,000 lux (100 foot-candles)
General work areas	200 lux (20 foot-candles)	300 lux (30 foot-candles)	500 lux (50 foot-candles)
Processed storage	200 lux (20 foot-candles)	300 lux (30 foot-candles)	500 lux (50 foot-candles)

Rationale: Adequate lighting is essential to the proper performance of decontamination, preparation, inspection, and other processing tasks.

3.4.6 Hand hygiene

Sinks for hand hygiene should be designated for and separate from those used for processing of medical devices. Hand hygiene sinks should:

- a) be located in or near all areas in which medical devices and other devices are decontaminated and prepared for sterilization, as well as in all personnel support areas (e.g., toilets, lounges);
- b) be considered in the design or renovation of a sterile processing area;
- c) have a backup system for operation during power outages if electronic sensors are used; and
- d) include the use of disposable towels.

Space should be allocated for placement of alcohol-based hand rubs.

NOTE Alcohols are flammable. Flash points of alcohol-based hand rubs range from 21°C to 24°C (70°F to 75°F), depending on the type and concentration of alcohol present. Alcohol-based hand hygiene agents must have an alcohol concentration of 60% to 95% to be effective. State regulations might dictate when, where and how much such agents may be used and placed within the facility.

NOTE Automatic hot air hand dryers should not be used since can deposit microorganism on environmental surfaces (Glowicz, 2022).

Rationale: Contaminated instruments and other medical devices are sources of microorganisms to which personnel could be exposed through nicks, cuts, or abrasions in skin or through contact with the mucous membranes of the eyes, nose, or mouth. Washing hands in a sink separate from where contaminated instruments are processed will minimize potential exposures.

3.4.7 Emergency eyewash/shower equipment

According to ANSI/ISEA document Z358.1 (2014) "There are several factors that might influence the location of emergency facilities. It is recognized that the average person covers a distance of approximately 55 ft. (16.8 m) in 10 seconds when walking at a normal pace. The physical and emotional state of a potential victim (visually impaired, with some level of discomfort/pain, and possibly in a state of panic) should be considered along with the likelihood of personnel in the immediate area to assist. The installer should also consider other potential hazards that may be adjacent to the path of travel that might cause further injury. A single step up into an enclosure where the equipment can be accessed is not considered to be an obstruction. Additionally, installers should allow for adequate overhead clearance to accommodate the presence of cabinets over counter- or faucet- mounted emergency eyewashes, so as not to create an additional hazard that could be encountered when using the device.

A door is considered to be an obstruction. Where the hazard is not corrosive, one intervening door can be present so long as it opens in the same direction of travel as the person attempting to reach the emergency eyewash and shower equipment and the door is equipped with a closing mechanism that cannot be locked to impede access to the equipment.

Eyewash stations should not be in a location that requires flushing of the eyes in a decontamination sink. Plumbed eyewashes/facewashes and showers should be activated weekly for a period long enough to verify operation and ensure that the flushing solution is available. When activating plumbed eyewashes, eye/face washes, and showers, personnel should also verify that they are providing lukewarm, tepid water (between 15°C and 43°C [60°F and 100°F]) (ANSI/ISEA Z358.1). Routine testing should be documented.

Rationale: Emergency eyewash and shower equipment should be readily accessible in order to provide first aid to employees exposed to injurious chemicals and materials. The availability of eyewash units for immediate emergency use is required by OSHA. Proper maintenance of eyewash units is necessary to ensure adequate performance and to prevent contamination. See also OSHA's Eye and Face Protection Standard (29 CFR 1910.133), OSHA's Medical and First Aid Standard (29 CFR 1910.151), and ANSI/ISEA Z358.1.

3.4.8 Spill kit

A spill kit should be available in the area where the chemical is used. It should be appropriate for the chemical (e.g., a spill kit for peracetic acid might not be suitable for glutaraldehyde) and should be suitable for the maximum volume that may be spilled (See AAMI TIR67). See Annexes C-K for general information on spill requirements by chemical type.

3.4.9 Ventilation systems

3.4.9.1 General considerations

Proper ventilation will help ensure an irritation-free, safe, and comfortable work environment. Chemical odors could be the first indication that the ventilation might not be adequate.² However, the sharp, pungent odors of chemical sterilants/high-level disinfectants could be masked if a perfume scent is included in the formulation. Therefore, the ventilation system should be designed to control potential airborne concentrations of chemical sterilants, and measures should be taken to ensure that it is operational at all times.

Smell is an unreliable indicator of gas leaks, because the ability to smell an odor varies from person to person, and from day to day, and continued exposure can cause olfactory fatigue. For those chemicals that do have odor thresholds below recognized exposure limits, most individuals are not able to relate smell to vapor concentration. Additionally, many chemical sterilants and high-level disinfectants have no perceptible odor until well above dangerous levels. Each facility should assess whether to install a monitor or not as part of its overall safety-risk analysis for the department.

3.4.9.2 Room ventilation

Chemical sterilants/high-level disinfectants should be used in an area that is properly ventilated. Rooms in which chemical disinfection and sterilization are performed should be large enough to ensure adequate dilution of vapor and should have a minimum air exchange rate of 10 air exchanges per hour (local regulations might require a higher minimum exchange rate). Ideally, local exhaust ventilation should be located at the level of the point of discharge of the vapors (see Figure 1) and pull vapors away from the work area, not toward personnel in the room.

CAUTION—Fans and open windows will interfere with the proper function of the ventilation system and should not be permitted.

Rationale: The appropriate air exchange rate for a particular area depends on a number of variables, including:

- a) the volume of the room;
- b) asepsis considerations;
- c) the need to dilute chemical vapors; and
- d) requirements defined by the manufacturer of the equipment intended to operate in the area or room.

It is recommended that an air exchange rate of 10 air exchanges per hour be provided in areas where chemical sterilization/ high-level disinfection is performed and the chemicals are stored.

An air exchange rate of 10 air exchanges per hour is consistent with that generally recommended for dilution of vapors of major chemical sterilant/high-level disinfectant, EO, and with the FGI recommendations for sterilization areas.

The Facility Guidelines Institute (FGI) publishes guidelines for general ventilation of areas in health care facilities that can serve as reference. These guidelines, though widely recognized in the health care community and referenced in

² For glutaraldehyde, a study with a volunteer panel has shown that for human eyes, the threshold for sensory irritation by vapor exposure is 0.3 ppmv. Data from another study indicate that the odor threshold for glutaraldehyde is less than a part per billion (Cain, et al., 2003) and is more than 100 times lower than the ceiling limit of 0.05 ppmv recommended by ACGIH®. Thus, because human beings perceive glutaraldehyde in air well below the air concentration that causes irritation to mucous membranes, the smell of glutaraldehyde might have no health significance. If, however, the odor of glutaraldehyde is accompanied by irritation to the nose and eyes, then the ceiling limit could have been exceeded, and improved ventilation or respiratory protection could be required.

the accreditation manual of the Joint Commission, are based mainly on considerations of odor control, asepsis, and personnel comfort.

It should be noted that increasing the general room ventilation is usually not a cost-effective way to reduce hazardous vapor exposure levels because of the large amount of air that must be moved, heated, and cooled. Local exhaust ventilation located at the level of the point of vapor discharge prevents the vapor from escaping into the workplace and is the preferred method of reducing chemical vapor concentrations.

The Safety Data Sheet (SDS) for each specific chemical sterilant/high-level disinfectant being used should be consulted for ventilation requirements. The need for local exhaust ventilation can be assessed through environmental monitoring during manipulation and use of chemical sterilants/high-level disinfectants (including dispensing, pouring, and disposal).

If the observed levels in the air exceed the recommended limits, then local exhaust ventilation or other engineering controls should be employed.

3.4.10 Local exhaust ventilation

When general room ventilation is not adequate, a self-contained, freestanding system or a local exhaust hood should be installed to capture chemical vapor during processing.

- a) The local exhaust system should be designed to maintain adequate air movement to capture vapor from the top of the container and thereby minimize personnel exposure.
- b) The American Industrial Hygiene Association (AIHA) recommends an average face velocity of 0.4 to 0.6 meters per second (80 to 120 feet per minute) (AIHA, 2003).
- c) A ducted fume hood should be connected to a nonrecirculating exhaust system that goes to the outside atmosphere at a location away from people and air intake ducts.
- d) Alternatively, when an outside exhaust vent is not available, a ductless fume hood system can be used to deliver vapor to a filter system that chemically inactivates the vapor (Figure 2); clean, filtered air is returned to the room.
- e) All fume hood systems should be monitored regularly for proper performance. The effectiveness of the filter bed on a ductless fume hood should be monitored, and the filters should be replaced as indicated by the manufacturer.

Rationale: Exposures to chemical vapor can occur when the chemical is poured into or out of a container, when the container is opened for use, when the solution is agitated during use, and when medical devices are removed and rinsed or chemical is spilled. Local exhaust ventilation systems (exhaust hood, associated ductwork, exhaust fan) capture or control vapor at the source before the vapor can escape into the general work environment. The vapor is collected in a suitable hood and is either exhausted to the outside through a fan and duct system (ducted fume hood) or delivered to a filter system that captures or chemically inactivates the chemical (ductless fume hood). Local exhaust ventilation is an accepted and effective industrial hygiene method to control the workplace hazards of airborne chemicals.

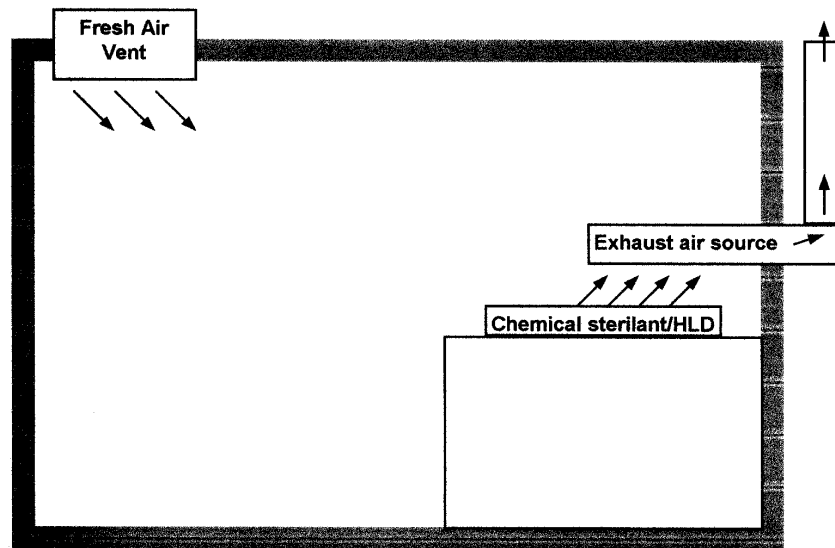


Figure 1—Recommended ventilation for areas in which chemical sterilants/high-level disinfectants are used. Fresh air should enter on one side of the room. Local exhaust ventilation should be placed across the room from the fresh-air return at the level of vapor discharge.

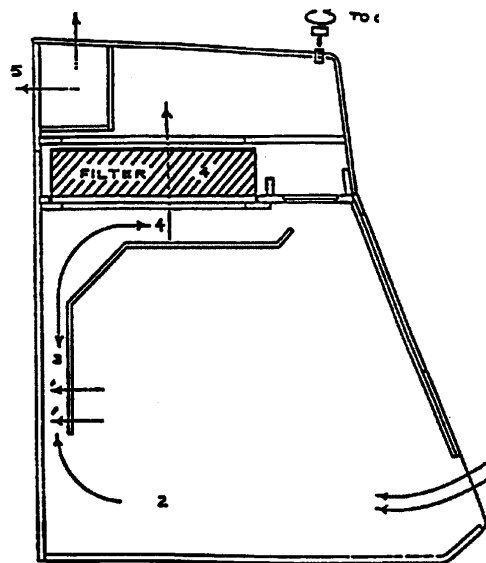


Figure 2—A ductless fume hood showing the airflow pattern. As air is drawn into the hood from the room (1), a horizontal air stream (2) removes contaminants from the work surface to the rear (3) of the fume hood. The air is channeled up and into the filter beds (4). Clean, filtered air is exhausted for recirculation (5).

3.5 Automated processing equipment for liquid chemical sterilants/high-level disinfectants

3.5.1 Selection of equipment

Before automated processing equipment is installed, consideration should be given to:

- a) space requirements;
- b) accessibility for use and servicing;
- c) safety features;
- d) mid-cycle inspection capability;
- e) any special plumbing requirements (e.g., measurement or control of water pressure or water temperature);
- f) water quality requirements;
- g) filter requirements;
- h) the heating system;
- i) the capabilities of the cycle (e.g., prewashing, post-disinfection air- and alcohol-purge features);
- j) load capacity;
- k) capacity for accessory processing;
- l) the means of changing and disposing of chemical solutions;
- m) requirements for proper ventilation that include ventilation requirements when LCS/HLDs are activated or processing equipment reservoir is filled;
- n) ventilation requirements for user to open the equipment mid-cycle in the case of equipment malfunction and troubleshooting;
- o) digital recording of physical parameters (recommended);
- p) storage for supplies and chemicals utilized in the processing;
- q) plumbing drainage; and
- r) are the devices intended to be used in automated processing equipment validated for LCS/HLD processes.

The equipment manufacturer should provide data verifying any claims regarding vapor reduction.

Automated processing systems are those that utilize LS/HLD for liquid chemical sterilization or high-level disinfection of medical devices. These systems are commonly used for processing flexible endoscopes but are indicated for other types of devices as described by the device manufacturer. They are designed to ensure the processing conditions to achieve sterilization or disinfection are met by controlling the physical parameters. The systems are designed also to reduce exposure of personnel to the chemical and chemical vapor of the LCS/HLD. These systems can also help improve department efficiency and increase compliance through digital recordkeeping.

Automated processing equipment can be semiautomatic or fully automatic. Automatic equipment with computer-generated records facilitates documentation.

Rationale: Although most types of automated processing equipment perform the same functions, the particular model specific capabilities, operational modes, safety features, and ability to meet the user's needs are considered.

3.5.2 Equipment location

Selecting an appropriate location for the equipment should be a joint decision by the health care facility engineer, the department manager, the primary users of the equipment, and the infection preventionist, based on recommendations from the manufacturer's representative and an engineering or industrial hygiene consultant when appropriate and available. Selection of the equipment location should take into account the manufacturer's site planning and installation information and any local codes. Equipment should be placed in a properly ventilated area.

Rationale: The health care facility is principally responsible for ensuring a safe work environment, but the manufacturer's advice will help ensure proper functionality of the equipment and utilities and provide ease of servicing. Industrial hygienists and certain engineering consultants have special expertise in the design of safe workplaces, and their advice also could be helpful.

3.5.3 Installation

The equipment manufacturer's written site and installation planning guide and operators/user manual (written instructions for use (IFU)) for installation should be followed. The equipment should not be operated until the equipment is properly installed and its performance has been verified according to the manufacturer's written IFU.

NOTE The health care facility has the responsibility to ensure not only the correct functioning of automated processing equipment but also the safety of the work environment. If indicated by the SDS and regulatory requirements, vapor monitoring should be conducted to ensure that the equipment minimizes employee exposure levels. (See Annexes C–K and AAMI TIR67 for information on monitoring chemical sterilant/high-level disinfectant vapors.)

Rationale: The equipment manufacturer is responsible for advising the user regarding proper equipment installation and safe operation. Verification of equipment performance before use is needed to ensure that the equipment can be operated safely and effectively and that vapor levels in the work environment are at or below the levels required by law or recommended by appropriate government agencies (e.g., NIOSH, EPA), ACGIH, or other competent organizations.

3.6 Gaseous chemical sterilizer equipment

Gaseous chemical sterilizer systems are those that utilize gaseous chemical sterilants for terminal sterilization of medical devices. These systems are commonly used for processing flexible endoscopes but are indicated for other types of devices as described by the device manufacturer. They are designed to ensure the processing conditions to achieve sterilization are met by controlling the physical parameters. These systems can also help improve department efficiency and increase compliance through digital recordkeeping.

3.6.1 Selection of equipment

Before sterilization equipment is installed, consideration should be given to:

- a) space requirements;
- b) accessibility for use and servicing;
- c) safety features;
- d) load capacity;
- e) capacity for accessory processing;
- f) the means of changing and disposing of chemicals/cartridges;
- g) ventilation requirements;
- h) digital recording of physical parameters (recommended);
- i) storage for supplies and chemicals utilized in the processing; and

- j) are the devices intended to be used in gaseous chemical sterilizer equipment.

The equipment manufacturer should provide data verifying any claims regarding vapor reduction.

Rationale: Although most types of gaseous chemical sterilizer equipment perform the same functions, the particular model specific capabilities, operational modes, safety features, and ability to meet the user's needs are considered.

3.6.2 Installation

3.6.2.1 Regulatory requirements

The health care facility is responsible for thoroughly investigating and complying with federal, state, and local regulatory codes, including but not limited to electrical, plumbing, fire prevention, safety, and ventilation codes. The health care facility is also responsible for obtaining any necessary permits for the use of gaseous chemical sterilants and for complying with state or local requirements pertaining to sterilant emissions or disposal. Voluntary guidelines should also be considered.

Rationale: Compliance with federal, state, and local regulations is mandatory.

3.6.2.2 Manufacturer's instructions

The purchaser should require that sterilizer, and emission control equipment manufacturers supply comprehensive instruction manuals. The manufacturers' installation instructions should be followed.

Rationale: The manufacturer is best able to advise the health care facility concerning proper equipment installation. It is necessary to verify the correct functioning of newly installed or reinstalled equipment before use to ensure that the equipment can be operated safely and effectively and that residual chemical levels in the work environment meet the OSHA standard.

3.6.2.3 Equipment location

Selecting an appropriate location for sterilization equipment should be a joint decision between the hospital engineer and the department manager, with advice from the manufacturer's representative. Sterilization equipment should be placed in a well-ventilated area. The equipment manufacturer's site planning information should be consulted.

Rationale: The health care facility is principally responsible for ensuring a safe work environment, but the manufacturer's advice will help ensure equipment effectiveness and ease of servicing. The importance of adequate ventilation is discussed in 3.4, but see also ACGIH® (2007b), Roy (1981), and Samuels and Eastin (1980).

3.6.3 Installation testing

3.6.3.1 Sterilizers

After the sterilizer is installed and before the health care facility either takes possession of the sterilizer or puts it into routine service, installation and acceptance testing must be completed.

Rationale: Proper performance of a sterilizer is a function not only of its design, but also of the electrical system and other utilities specific to the health care facility. The effectiveness of the sterilizer can be verified only in the actual hospital environment in which it will be used.

3.6.3.2 Emission control and ventilation systems

Emission control, if used, and ventilation systems should be tested for performance efficacy and the results documented and retained in accordance with applicable ordinances and regulations. Where state or local emission control regulations apply, operating permits must be obtained before the sterilizer is put into routine service.

4 Personnel considerations

4.1 General considerations

This section provides guidelines for personnel qualifications, education, and training as well as personnel health considerations. The decontamination and subsequent chemical sterilization or high-level disinfection of reusable medical devices is a complex process and requires the knowledge and competency of trained and qualified personnel.

4.2 Qualifications

4.2.1 Supervisory personnel

All preparation, high-level disinfection, and sterilization activities, including decontamination, inspection, preparation, packaging (for terminal sterilization), high-level disinfection, sterilization, storage, and distribution, should be supervised by competent, qualified personnel. Personnel assigned to supervisory functions should be prepared for this responsibility by education, training, and experience. Minimum recommended qualifications include:

- a) successful completion of documented specialized training, such as a sterile processing management certification examination;

NOTE Information concerning certification of sterile processing managers and technicians can be obtained from the Certification Board for Sterile Processing and Distribution (CBSPD) (148 Main St., Suite B-1, Lebanon, New Jersey 08833; 800-555-9765; <http://www.sterileprocessing.org>); the Healthcare Sterile Processing Association (<http://www.myhspa.org>); or the National Health Information Center (P.O. Box 1133, Washington, DC 20013; <http://www.health.gov/nhic/>).

- b) demonstration of current knowledge and adequate relevant experience in health care or hospital-related work;
- c) participation in continuing education programs and courses, including programs on federal and local regulations; personnel and material management programs; programs on financial management and leadership skills; and courses directly related to the management position, with special emphasis on infection prevention and control, safety, and the principles and methods of sterile processing; and
- d) demonstration of comprehensive knowledge of pertinent state and federal regulations, particularly OSHA regulations related to occupational exposure to bloodborne pathogens (29 CFR 1910.1030), including the specified methods of compliance, such as an exposure control plan, the use of standard and transmission-based precautions, and engineering and work-practice controls.

Supervisory personnel should maintain competency throughout their tenure. In addition to participating in continuing education programs and courses, personnel should

- a) participate in facility and departmental in-service and training programs; and
- b) demonstrate and improve their expertise through participation (as a member or resource person) in committees within the health care facility (e.g., risk management, hazardous materials, quality improvement, infection prevention and control, safety, standardization, product evaluation, policies and procedures) and in quality improvement activities.

Rationale: The decontamination and subsequent high-level disinfection or sterilization of reusable medical devices is a complex process requiring supervision by competent personnel with relevant health care experience, especially in cleaning methods and products, containment of contaminated items, sterilization and high-level disinfection methods, infection prevention and control, and standard and transmission-based precautions. Standard and transmission-based precautions prevent the transmission of airborne, droplet, and contact pathogens. Compliance with OSHA regulations will lower the incidence of occupational exposure to bloodborne and other pathogens as well as chemical risks. Participation in the product evaluation committee can help avoid purchases of items that cannot be reprocessed by equipment currently available in the processing department. Certification is a recognized method of initially determining competency.

4.2.2 Processing personnel

The responsibility for performing chemical high-level disinfection and sterilization processes should be assigned to qualified individuals who have demonstrated competence in decontamination, preparation, packaging for terminal sterilization, high-level disinfection, sterilization, storage, and distribution of sterile medical devices. Qualifications include:

- a) demonstrated knowledge of and documented competence in all aspects of decontamination, including sorting, disassembly/reassembly, manual and mechanical cleaning methods, microbicidal processes, equipment operation, standard and transmission-based precautions, and engineering and work-practice controls;
- b) demonstrated knowledge of and documented competence in the operation of the specific high-level disinfection or chemical sterilization system used by the processing department;
- c) demonstrated knowledge of and documented competence in principles of sterilization and infectious disease transmission; infection prevention and control; and all aspects of liquid and gaseous chemical sterilization and high-level disinfection (including decontamination, inspection, and packaging of items to be sterilized; sterilization procedures; equipment operation; and safety precautions);
- d) demonstrated knowledge of and documented competence in worker safety as it related to medical device processing and sterilization;
- e) demonstrated knowledge of and documented competence in worker safety and the use of PPE with respect to high-level disinfectants and chemical sterilants/high-level disinfectants;
- f) participation in in-service programs designed specifically for the personnel performing chemical sterilization and disinfection processes; and
- g) participation in in-service programs and training on automated and manual equipment used with LCSs/HLDs.

Competency shall be assessed for all processing personnel performing these activities upon orientation and whenever there are new products, processes have changed, are high-risk, low frequency or are problematic and recommended annually.

It is recommended that all personnel performing chemical sterilization or high-level disinfection activities receive documented specialized training and competency validation.

Further, it is recommended that such sterile processing personnel should successfully complete a central service certification examination within two years of employment and should maintain that certification throughout their employment.

Rationale: Safe handling of chemical sterilants/high-level disinfectants and use of appropriate work practices will reduce occupational and patient exposure to chemical sterilants/high-level disinfectants. Therefore, to ensure their safety and the safety of others, personnel engaged in processing activities should receive special training and their competency should be verified. Advances in medical and information technology, the emergence of new diseases and microorganisms, and the increased responsibility for all aspects of device processing have brought into focus how important it is for processing personnel to be knowledgeable and competent.

4.3 Training and continuing education

4.3.1 Processing personnel

Personnel engaged in processing and chemical high-level disinfection should receive both an initial orientation, on-the-job training and continuing education. This program should include:

- a) an initial orientation program;
- b) competency-based knowledge and skills in all tasks performed in the sterile processing department and in all decentralized areas responsible for chemical high-level disinfection and chemical sterilization; and

- c) orientation in facility and department policies and procedures regarding infection prevention and control, safety, attire, personal hygiene, and compliance with state and federal regulations.

Personnel should receive in-service training from the manufacturer for all new instrumentation, devices, and equipment. All orientation, on-the-job, and in-service training and competencies should be documented in personnel files.

Continuing education is necessary at regular intervals to review and update worker knowledge and skills and to maintain worker competency and certification. Education and training materials and information are available from AAMI, OSHA, sterile processing vendors, associations, and journals.

A training manual should be established that:

- a) documents all aspects of training related to the on-site approved protocols;
- b) includes checklists to document that training was performed and when initial competency was achieved;
- c) references guidance documents and/or training modules;
- d) is based on the facility's policies and procedures, accepted standards of practice, and manufacturers' recommendations; and
- e) is readily available for reference by users.

Rationale: Orientation training and on-the-job training establish the worker's base of knowledge. Whereas continuing education increases knowledge and skills, training can decrease the possibility of operator error during preparation and sterilization processing and help ensure that personnel are conversant with the latest data and techniques. Also, education and training are the most important aspects of any program intended to protect employees from a potential safety hazard. Without it, the employee might not recognize unsafe conditions or work practices and might not know how, when, or why to employ protective measures. Health care facility policies and procedures are a necessary part of any education and training program, and all personnel should be familiar with and adhere to these policies and procedures. Documentation of training and continuing education is required by accrediting agencies such as the Joint Commission (Joint Commission, 2012). Initial competency must be completed. It is recommended that such personnel should successfully complete a central service certification examination within two years of employment and should maintain that certification throughout their employment. It is necessary to provide instructions to decontamination personnel regarding the processing recommendations of specific device and equipment manufacturers. Advances in chemical sterilization and high-level disinfection, the emergence and re-emergence of new diseases and microorganisms respectively, the increasing complexity of medical devices, and the increased responsibility for all aspects of device processing have brought into focus how important it is for personnel using these products and systems to be knowledgeable and competent. Protection of patients, employees, and other individuals in the health care facility environment depends on the implementation of procedures designed to reduce the risk of exposure to potentially pathogenic microorganisms. Orientation, training, and continuing education reduce the possibility of errors during chemical high-level disinfection and sterilization processing and help ensure that personnel are conversant with the latest data and techniques. Knowledge of the health risks associated with exposure to chemical sterilants/high-level disinfectants will help ensure that potentially exposed personnel will adhere to established procedures. Documentation of competence provides verification of qualifications and training in the workplace, as required by regulatory and accrediting agencies.

4.3.2 Equipment Service personnel

Education and training programs for service personnel should be required, as service personnel must be knowledgeable of facility policy and safety requirements. The training program should include information on the hazards associated with bloodborne pathogens, the requirements of the OSHA standard on occupational exposure to bloodborne pathogens (29 CFR 1910.1030), the importance of vaccinations as protective measures, standard and transmission-based precautions, protective work practices, the use of PPE, emergency procedures, and procedures to follow if a chemical or biological exposure occurs.

Rationale: Education and training are the most important aspects of a program intended to protect employees, users and service personnel from a potential health hazard.

4.3.2.1 Equipment service personnel working with ethylene oxide

Personnel who are not assigned to the sterilization department but who have responsibility for maintaining EO sterilizers, ventilation systems, or emission control systems should be trained in safe work practices and engineering controls and should demonstrate competence. This training is typically completed either by factory service training by the sterilizer manufacturer or by service personnel employer.

Rationale: Maintenance personnel are especially at risk of exposure to high concentrations of EO and also could be at risk of exposure to toxic chemical agents (e.g., catalysts, acids, bases) used in emission control systems. Consequently, it is particularly important that they be well versed in the work practices and engineering controls that will ensure their safety. Such training is required by OSHA (29 CFR 1910.1047) and by the Joint Commission (Joint Commission, 2008), the Healthcare Facilities Accreditation Program (HFAP, 2005), and other organizations recognized by the U.S. Centers for Medicare and Medicaid Services as deemed accrediting organizations.

4.3.3 Other personnel

Personnel who are not assigned to the processing area but who have access to the sterile storage area should receive initial orientation and on-the-job training on proper attire and on the proper care, handling, and transport of sterile and high-level disinfected items and the importance of clean to dirty traffic flow.

Rationale: In some health care facilities, the sterile storage area is not attended by sterile processing personnel 24 hours a day, so it might be necessary for personnel from other departments to have access to sterile items. To protect the integrity of sterile items, it is important that these personnel comply with the same attire and supply-handling procedures as do personnel regularly assigned to the sterile processing department.

4.4 Personal protective equipment

The PPE required in the decontamination room is protect the employee from bloodborne pathogens.

4.4.1 General considerations

When processing medical devices with chemical solutions, personnel should wear appropriate PPE designed to protect their skin, eyes, mucous membranes, and clothing from splashes when there is risk of exposure. The health care facility should develop a written policy and procedure for the PPE, including its correct use. The health care facility must comply with OSHA's Medical and First Aid Standard (29 CFR 1910.151), which requires suitable facilities for eye washing. Personnel should also be familiar with OSHA's standards for employer and employee PPE responsibilities (29 CFR 1910.132), eye and face protection (29 CFR 1910.133), respiratory protection (29 CFR 1910.134), and hand protection (29 CFR 1910.138).

On April 6, 1994, OSHA expanded the requirements of the Personal Protective Equipment Standard, which specifies that an employer must conduct a hazard assessment to determine the hazards that necessitate use of PPE (29 CFR 1910.132[d]). The employer must certify in writing that the required workplace hazard assessment has been performed. The written certification must identify the workplace evaluated, the person certifying that the evaluation has been performed, and the dates of the hazard assessment; the document must be identified as a certification of hazard assessment.

The employer must provide specific training to each employee required to wear appropriate PPE. The employer must certify in writing that each employee has received and understood the required training. The written certification must identify each employee trained, the dates of training, and the subject of the certification.

Rationale: Chemical sterilants/high-level disinfectants present possible risks to employees, such as splashing on the face or skin or respiratory exposure. Compliance with all OSHA standards will help ensure employee safety and minimize possible exposures.

4.4.2 Eye protection for chemical safety (liquid)

Eyes must be protected against contact with chemical solutions. To prevent eye irritation, vapor levels must be kept below any applicable OSHA permissible exposure limit (PEL). In the absence of an OSHA limit, refer to the ACGIH

TLV®s (ACGIH, 2013). The manufacturer's SDS and product literature should be consulted for specific eye protection and first-aid guidance. See Annexes C–K for eye protection and first-aid recommendations specific to particular chemical solutions.

Suitable eyewash units must be available for immediate emergency use in all places where chemicals are used.

Rationale: Many chemicals are classified as eye irritants. Eye contact with such chemicals can cause moderate to severe irritation, experienced as discomfort or pain, excessive blinking, and tear production, with marked redness and swelling of the conjunctiva. (See also Annexes C–K.)

The availability of eyewash units for immediate emergency use is required by OSHA. Proper maintenance of eyewash units is necessary to ensure adequate performance and to prevent contamination.

See also OSHA's Eye and Face Protection Standard (29 CFR 1910.133), OSHA's Medical and First Aid Standard (29 CFR 1910.151), and ANSI Z358.1.

4.4.3 Skin protection (liquid)

Skin should be protected against contact with chemical solutions.

- a) Gloves impervious to the chemical should always be worn if there is any possibility of contact with a chemical solution, including the handling of the LCS/HLD solution containers, bottles, or cassettes.
- b) The forearms should be protected by elbow-length gloves or by protective sleeves made of a material impervious to the chemical.
- c) Fluid-resistant gowns or aprons plus sleeve protectors that are made of appropriate protective materials provide full body protection.
- d) The manufacturer's SDS and written IFU should be consulted for specific glove usage and protective clothing recommendations.
- e) See Annexes C–K for skin protection recommendations specific to particular chemical solutions.
- f) Protective clothing should be removed quickly if it becomes saturated, and it should be laundered before reuse.
- g) If any skin contact with a chemical solution should inadvertently occur, the skin should be washed thoroughly with soap and water and should be flushed with water for at least 15 minutes.

Rationale: OSHA's expanded Personal Protective Equipment Standard (29 CFR 1910.132) requires that employers conduct a hazard assessment and "select, and have each affected employee use, the type of PPE that will protect the affected employee from the hazard identified in the hazard assessment." OSHA's Hand Protection Standard (29 CFR 1910.138) states the following: "Before purchasing gloves, the employer should request documentation from the manufacturer that the gloves meet the appropriate test standard(s) for the hazard(s) anticipated." The referenced ASTM permeation protocol (ASTM F739) is the test method commonly used to evaluate the permeability of materials to various chemicals.

4.4.4 Respiratory protection

Standards set by OSHA for respiratory protection and hazard communication (29 CFR 1910.134 and 29 CFR 1910.1200, respectively) require the use of appropriate respirators by all employees who could be overexposed to chemical vapor during routine or emergency work procedures.

All personnel required by organization's hazard assessment must be trained in the care, correct application, and use of respirators. Routine respirator use is not a substitute for appropriate engineering, administrative, and work-practice controls. Regular respirator use should only be a temporary measure until chemical vapor exposure is reduced by other means.

The respirators used must be approved by the National Institute for Occupational Safety and Health (NIOSH) and must be appropriate for the specific chemical being used.

- a) NIOSH recommends the use of organic vapor cartridges with air-purifying respirators and respirator selection must be based on the ambient exposure situation.
- b) Appropriate engineering controls must be put into place to reduce exposure to chemical vapor.
- c) If temporary respiratory protection is necessary, only a full-face respirator (air-purifying or fresh air) or a self-contained breathing apparatus (SCBA) is acceptable (29 CFR 1910.134).
- d) The use of N95 and other similar respirators requires the user to be fit tested annually or more frequently as needed.

Vapor monitoring can be helpful in determining those operations likely to cause an overexposure (see Annex P and the appropriate annex for recommendations regarding vapor monitoring of particular chemical sterilants/high-level disinfectants).

Spill situations generally require a high-level of respiratory protection. See Annexes C-K. When the air concentration of the chemical vapor is unknown, the only acceptable respiratory protective equipment is an SCBA. However, if information is available about the amount and composition of the chemical spilled and the characteristics of the room ventilation, lower levels of respiratory protection could be adequate.

All personnel who might be required to wear a respirator for routine or emergency use must be included in a respiratory protection program that meets the requirements of OSHA's Respiratory Protection Standard (29 CFR 1910.134). An acceptable respiratory protection program must include written operating procedures covering all aspects of the program, including:

- a) workplace surveillance;
- b) respirator selection;
- c) employee medical evaluation and surveillance;
- d) procedures for periodic inspection, cleaning, and storage of respirators;
- e) employee training;
- f) qualitative or quantitative respirator fit testing; and
- g) program evaluation periodically (e.g., annually).

See AAMI TIR67 for additional information.

Rationale: The OSHA requirements for respirator use are very specific. They do not allow permanent or continued use of respirators as a means of employee protection. For routine operations, respirators can be used only until engineering, administrative, and work-practice controls are adequate to prevent overexposures.

4.5 Health and personal hygiene

Written policies on personal hygiene should be developed and communicated to employees. Such policies should be approved by the infection preventionist, the safety manager/director, and/or the designated person in charge of occupational health. Hand hygiene procedures should be specified. Hair, body, and nails should be kept clean at all times. Nail polish and/or artificial nails should not be worn. Fingernails should be kept short and clean and should not extend beyond the fingertips (AORN, 2023; CDC, 2020).

Uniforms or other garments that become soiled or wet during wear should be changed immediately. In collaboration with the institution's infection prevention and control committee, the department should establish a written policy on the reporting, treatment, and disposition of employees who are at risk of acquiring or transmitting infections. Exposures to

bloodborne diseases should be handled in accordance with OSHA regulations and current CDC recommendations.³ Personnel who could come into contact with items contaminated with blood or other potentially infectious materials should be encouraged to accept hepatitis B immunization. Any employee who declines immunization should sign the vaccine declination statement required by OSHA.

Personnel must be informed of the potential health effects of overexposure to chemical sterilants/high-level disinfectants and should be familiar with the information contained in the SDS. The SDS should be included in the safety manual and/or the safety section of the departmental policy and procedure manual. See Annexes C–K for information regarding the health effects of specific chemical sterilants/high-level disinfectants.

Rationale: Careful attention to occupational health, safety, and personal hygiene will minimize the potential for acquiring or transmitting disease. Nail polish can flake off, and the flakes can get into items being prepared; artificial nails can promote the growth of fungus under the nails (Baumgardner, et al., 1993; CDC, 2002; Jeanes and Green, 2001; Porteous, 2002; Salman, et al., 2002). Vaccinations are an important aspect of occupational health and also provide protection when there has been a failure in work practices or when an unexpected event occurs. Vaccination against hepatitis B will protect personnel from this serious disease, and OSHA requires that hepatitis B vaccination be offered to all personnel who could come into contact with blood or other body fluids when performing their jobs (29 CFR 1910.1030). Other immunizations could become appropriate and/or mandatory in the future.

Information about the potential health effects of overexposure to chemical sterilants/high-level disinfectants will encourage compliance with safety procedures. OSHA requires that an SDS be available to all employees for each type of chemical sterilant/high-level disinfectant with which they work. ANSI Z400.1 provides guidance to manufacturers on the preparation of SDSs.

5 Decontamination and preparation of medical devices

5.1 General considerations

This section covers transport of contaminated items, receiving of purchased items, cleaning and other decontamination processes, and packaging. Sterility assurance "begins at the loading dock," i.e., at the point at which the health care facility assumes responsibility for the incoming medical equipment, devices, and supplies. Therefore, sterility assurance measures should be used from the time that items are received into the health care facility until they are used.

5.2 Receiving

5.2.1 Receiving of purchased, repaired and loaned items

5.2.1.1 General considerations

Policies and procedures for the receipt of purchased, repaired and loaned items should be developed, implemented, and audited. Audits should be scheduled and documented. Clean or sterile items should be handled separately from foodstuffs, waste material, contaminated instrumentation, soiled laundry, and other potential sources of contamination. So that individual items are protected, bulk items may be stored in shipping cartons in the central receiving area. Items to be transported to sterile processing, endoscopy, surgery, or other clean/sterile areas within the facility should be removed from their external shipping containers before they enter the sterile storage area of the department. Any written IFU accompanying the items should be kept with the items. When loaned items are delivered to the receiving area, personnel should document that according to the packing slip, the correct number of packages have been received. The packaged items, along with any written IFU, should be delivered to sterile processing, endoscopy, surgery, or other clean storage areas within the facility as soon as possible.

³ Information on CDC recommendations regarding the prevention of exposures to bloodborne diseases and the post-exposure treatment of bloodborne disease can be obtained by checking the CDC website at <http://www.cdc.gov/HAI/organisms/organisms.html> or by calling the CDC at 1-800-311-3435.

Rationale: External shipping containers have been exposed to unknown and potentially high microbial contamination. Shipping cartons can serve as generators of and reservoirs for dust as well as harbor bugs from the environment.

5.2.1.2 Newly purchased reusable items and repaired and loaned reusable items

New and repaired reusable medical devices should be cleaned before they are processed by chemical sterilization or high-level disinfection. After they have been removed from their external shipping containers, such items should be inspected to ensure that they meet the required specifications and then should be transported directly to the decontamination area. The manufacturer's processing IFU should be followed.

Rationale: Many reusable medical devices are manufactured in an environment in which bioburden is not rigorously controlled, and some are handled extensively during the manufacturing process. Consequently, bioburden should be reduced by cleaning before the device is high-level disinfected or sterilized. Also, anticorrosive agents such as oils or greases might be left on the device by the manufacturer to protect it during shipping, and such agents will interfere with sterilization or high-level disinfection if not removed. It is necessary to inspect new or repaired items before decontamination so that if they do not meet the required specifications, they can be returned to the vendor in the condition and packaging in which they were received.

5.2.2 Disposition of sterile items

5.2.2.1 Items issued but not used

Unopened items that previously have been packaged, sterilized, and issued to a controlled environment such as the OR may be returned to the sterile storage area if the integrity of the packaging has not been compromised and there is no evidence of contamination; such items should be the first to be dispensed when needed.

Unopened items returned from the OR or other areas with controlled environments should be transported on a clean closed or covered cart and should not enter the decontamination area.

Rationale: Many of the packaging materials used today are extremely durable. Unnecessary costs may accrue from the indiscriminate discarding of expensive, disposable medical supplies that are unopened and returned in acceptable condition. The recommendations of 5.2.2 are based on the assumptions that an appropriate packaging material has protected unopened sterile items unless the package has been damaged and that the packaged items have been properly handled. Consequently, the retrieval and reissue of unopened sterile items are recommended only if the environment is controlled and if personnel are knowledgeable about the proper handling of sterile items. The more frequently sterile items are handled, the greater is the risk of contamination; therefore, reissued items should be used as promptly as possible.

5.2.2.2 Items opened but not used

Reusable items that have been opened or that have damaged packaging should be considered contaminated whether they have been used or not and should be unwrapped and reprocessed through decontamination in accordance with departmental policies and procedures.

Disposable items that have been opened or that have damaged packaging should be discarded; such items should not be reprocessed by the health care facility unless the manufacturer provides written IFU for processing and all FDA requirements for the processing of single-use items are met. (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-about-reprocessing-and-reuse-single-use-devices-third-party-and-hospital-0>)

Rationale: Opened items are no longer considered sterile and level of contamination is unknown so complete processing for reusable items is needed.

5.3 Handling, collection, and transport of contaminated items

5.3.1 General considerations

This section provides guidelines for segregating and handling contaminated items at the point of use and for the transport of contaminated items from the point of use to the decontamination area. The possibility of items being contaminated with infectious material is greatest at the point of use, where they have been in patient contact. Procedures for safely transporting contaminated items are important because many people—workers, patients, and visitors—can be exposed to potentially disease-producing microorganisms during transport. In addition, the general environment of a health care facility is not controlled, and persons encountered during transport will not be wearing PPE. Used medical devices should be kept moist and transported to the decontamination room preventing soils from drying or exposing them to unfavorable environmental conditions.

Procedures must be developed, with support from the infection prevention and control and hazardous materials personnel, to protect personnel, patients, and the environment from contamination and to comply with OSHA regulations limiting occupational exposure to blood-borne pathogens (29 CFR Part 1910.1030).

The health care facility should:

- a) perform a risk analysis to ensure that the procedures are being followed;
- b) develop action plans to address problems noted during the analysis; and
- c) schedule a follow-up analysis to verify that the problems have been corrected.

5.3.2 Separation of waste and reusable items at point of use

At the point of use,

- a) items should be separated into reusable items, single-use disposable items, and waste categories;
- b) disposable items should be separated by waste categories and disposed of in accordance with all federal, state, and local regulations; and
- c) sharps must be placed in puncture-resistant sharps containers that are OSHA compliant.

Contaminated items should be handled as little as possible. Contaminated reusable items should be contained

- a) in such a way that the contents of the containers are readily identifiable as contaminated by everyone who subsequently handles the items; and
- b) in a containment device that complies with the health care facility's established infection prevention and control and hazardous waste management procedures.

Health care facilities should develop and follow procedures that reduce the potential for contamination of personnel, their clothing, and the environment, including the following:

- a) When the outside of a transport container or cart is visibly soiled, it should be decontaminated, before transport, with an EPA-registered, intermediate-level disinfectant using manual or mechanical cleaning and disinfection methods (see Annex R).
- b) Handling of waste might require PPE.
- c) Other measures might also be adopted for infection prevention and control purposes or as part of hazardous waste management.

Rationale: Used, soiled, contaminated instruments, devices, and supplies are sources of microorganisms that could cause infections in personnel or patients. The infection hazard to personnel is greatest during the handling and segregation of soiled, contaminated items. All medical devices are considered to be soiled and contaminated after each use and to be potential sources of infection caused by hepatitis C virus (HCV), hepatitis B virus (HBV), human

immunodeficiency virus (HIV), and/or other pathogens. Segregation of soiled items and waste into separate streams of dispatch at the point of use will help minimize handling and therefore minimize the possibility of subsequent personnel exposure to potentially pathogenic organisms.

Separation is best done at the point of use by persons aware of the potential for injury from sharps and the potential infection hazards of the contaminated items.

Contaminated reusable items, contaminated disposable items and waste, and tissue specimens are placed into specifically labeled containers to prevent exposure of personnel to potentially infectious materials and to prevent contamination of the environment. Disposable items must be placed in an OSHA or EPA compliant biohazard container.

5.3.3 Point-of-use treatment of contaminated reusable items

5.3.3.1 General handling of medical devices during and after surgical procedure

After the surgical or invasive procedure, to remove residual gross soil, reusable medical devices should be wiped externally, and any lumens should be flushed – following the device manufacturer IFUs. Saline solution should not be used. Medical Devices should be kept in a moist condition to prevent residual soil from drying.

Rationale: Blood, other bodily fluids, and saline are highly corrosive and can cause pitting of instruments. If left to dry, they can be difficult to remove and can prevent sterilization. Cannulated medical devices or medical devices with lumens can become obstructed with organic material. Flushing these medical devices helps remove residue. Allowing soil to dry on the medical device can affect the cleaning process efficacy due to soil solubility changes (Kremer et al. 2023).

Preparation for decontamination of medical devices should begin at the point of use. To prevent the formation of biofilm and to reduce the risk of corrosion, cleaning and decontamination should occur as soon as possible after medical devices and equipment are used.

NOTE 1 Some microorganisms have the ability to adhere to a surface and then exude over themselves a polysaccharide matrix. Biofilm consists of an accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily. Biofilm has the effect of protecting microorganisms from attempts to remove them by ordinary cleaning methods used in the sterile processing area and of preventing antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching the microbial cells. Biofilm can form on many surfaces but is particularly problematic in devices with lumens. Once biofilm forms, direct friction and/or oxidizing chemicals are needed to remove it. Prompt cleaning reduces the population of microorganisms and thus helps to prevent the formation of biofilm.

NOTE 2 If performed in a sterile field, the sponge or lint-free cloth should be radiopaque, and the water and sponge/cloth must be sterile.

5.3.3.2 Removal of gross soil at point-of-use

Remove gross soil as soon as possible to:

- a) reduce the number of microorganisms on the item;
- b) reduce the nutrient material that supports microbial growth;
- c) prevent it from drying on;
- d) reduce the potential for environmental contamination by aerosolization or spillage; and
- e) minimize corrosion risk and damage to devices from such substances as blood, saline, iodine, and radiological dyes or from the subsequent vigorous cleaning processes needed to remove encrusted material.

Rationale: Treatment at the point of use, including removal of gross soil and the moistening of soil to prevent it from drying out, will help prevent items from becoming harder to clean. This improves the efficiency of decontamination and might extend the life of the instrument.