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ANSI/AAMI ST58:2024

Chemical sterilization and high-level disinfection in health care facilities

AAMI
Advancing Safety in Health Technology

American National Standard

ANSI/AAMI ST58:2024
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Chemical sterilization and high-level disinfection in health care facilities

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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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Association for the Advancement of Medical Instrumentation

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This standard was developed by the AAMI Chemical Sterilants Hospital Practices Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval.

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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 -40ºC (-40ºF)

[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 sterilze 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

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[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.

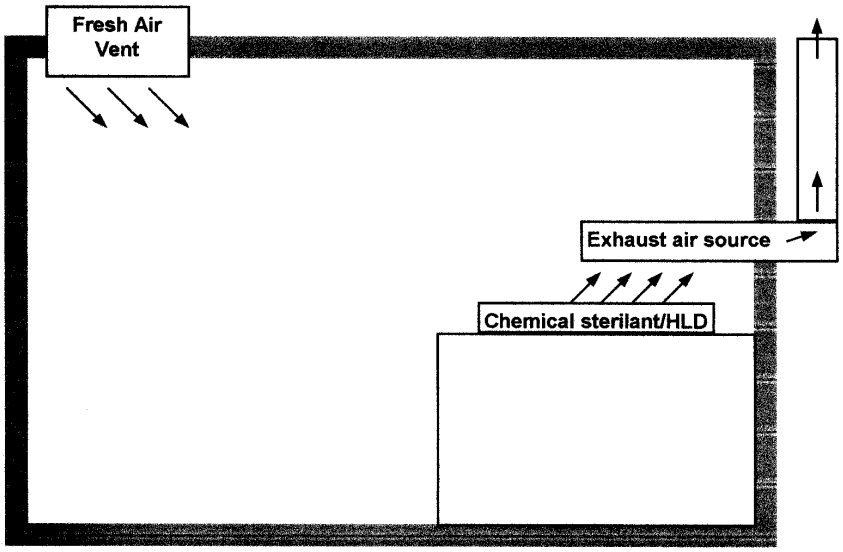

Figure 1—Recommended ventilation for areas in which chemical sterilants/high-level disinfectants are used. Fresh air should enter on one side of the room. Local exhaust ventilation should be placed across the room from the fresh-air return at the level of vapor discharge.

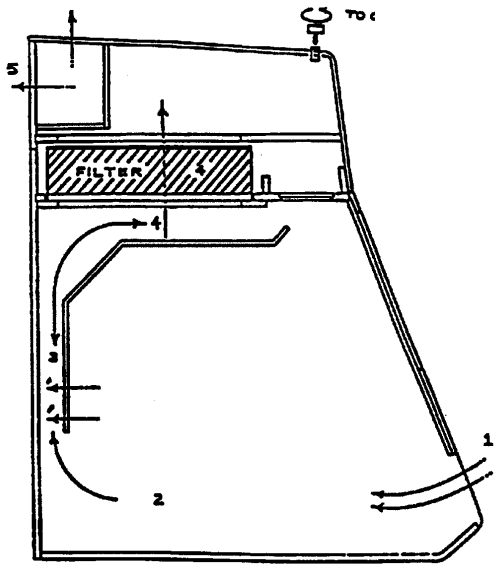

Figure 2—A ductless fume hood showing the airflow pattern. As air is drawn into the hood from the room (1), a horizontal air stream (2) removes contaminants from the work surface to the rear (3) of the fume hood. The air is channeled up and into the filter beds (4). Clean, filtered air is exhausted for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

5.3.3.3 Disassembly of instruments

When medical devices are composed of more than one piece, they should be opened, disassembled according to the manufacturer's written IFU, and arranged in an orderly fashion.

Rationale: Disassembling and opening of medical devices followed by their placement into the original set configuration minimizes the risk of medical device displacement and improves the efficiency of processing.

5.3.3.4 Prevention of medical device damage and contamination

After pre-treatment at the point of use, personnel should:

a) place medical devices into their respective containers, medical device pans, or other transportation pans so as to prevent damage to the instrumentation;

b) have a process in place to identify medical devices in need of repair/maintenance and removal from service (e.g., a tag);

c) protect delicate medical devices from damage (e.g., microsurgical medical devices and endoscopes);

d) segregate reusable sharp medical devices inside the container;

e) place heavy instrumentation on the bottom and lighter, delicate medical devices on top; and

f) dispose of single-use items.

Rationale: Medical device damage is often due to care and handling issues. Proper preparation at the point of use reduces medical device damage. Medical devices can shift during transport. Keeping the instrumentation in an orderly fashion will help prevent medical device damage.

Contaminated items should always be handled in a manner that reduces the potential exposure of workers to disease-producing organisms and contamination of the environment. When handling contaminated items, personnel should:

a) wear appropriate PPE;

b) use work-practice controls and engineering controls to minimize the risk of injury;

c) remove soil by a method that does not promote cross-contamination (e.g., personnel should avoid splashing water and thereby contaminating attire, the area near the sink, and other surfaces in the environment); and

d) contain and discard gauze sponges and similar items used in the cleaning process according to the health care facility’s policy for infectious wastes.

Prior to transport, medical devices should be prepared in such a way as to prevent organic soils from drying by:

a) place a towel moistened with water (not saline) over the instrument;

b) place items inside a package designed to maintain humid conditions; or

c) apply a product designed for pretreatment.

Rationale: Immediate containment and transport to a designated area minimizes the risk of employee contact with contaminants and allows the cleaning process to be performed in a controlled environment by personnel who are protected by PPE. Saline can be corrosive to instruments. Long delays in transporting soiled medical devices to the decontamination room can result in the formation of tenacious and difficult-to-remove biofilm that will shield microorganisms from routine cleaning procedures and possibly interfere with disinfection or sterilization.

5.3.4 Containment

Contaminated items should be contained during transport from the point of use to the decontamination area. Containment may be accomplished by any means that prevents personnel contact with the contaminated items during transfer.

NOTE The type of container used depends on the items being transported. Bins with lids, enclosed or covered carts, rigid sterilization container systems, and impermeable bags are among the types of containers that may be used alone or in combination to transport contaminated items.

OSHA requires that

a) all containers, devices, or carts used for containing contaminated items be marked with a biohazard label, a red bag, or other means of identifying contaminated contents; and

b) puncture-resistant, leak-proof on the sides and bottom, closable, and labeled containers must be used for devices with edges or points capable of penetrating container or skin.

Contaminated items should be kept moist in the transport container by adding a towel moistened with water (not saline) or a pretreatment product specifically intended for this use, or by placing items inside a package that can maintain moist conditions.

Containers used for holding contaminated items should be

a) made of material that can be effectively decontaminated; or

b) designated for single use and made of material that can be incinerated or otherwise disposed of following use.

Environmental issues and hazardous waste policies should be considered before single-use containers are selected as a containment method.

If the container manufacturer's written IFU permit, rigid sterilization container systems with closed valves or intact, dry filters may be used to contain contaminated items for transport with no further coverings, and have a label indicating biohazardous material provided that the external surfaces of the container have not been contaminated by blood or body fluids. Such contamination should be presumed to have occurred if the external surfaces of the container have been touched by persons or items that could have contacted blood or other bodily fluids.

If such external contamination is present, the reassembled container system should be further enclosed for transport by placing it in a plastic bag, a bin with a lid, or a closed or covered cart labeled as biohazardous (29 CFR 1910.1030).

Rationale: Materials contaminated with blood or other bodily fluids can serve as sources of infection to personnel unless the materials are completely contained. Containment minimizes the possibility of airborne or contact spread of microorganisms. Keeping items moist prevents soil from drying on device surfaces and facilitates the decontamination process.

5.3.5 Communication

Communication from point of use to the decontamination area may include the patient identifier, date of procedure, and time of point of use treatment was completed. Other information that may be helpful is the completed procedure time, location of the procedure, and employee contact.

Any concerns with the device performance should be communicated.

5.3.6 Transport

5.3.6.1 Segregation of clean/sterile items

During transport, clean/sterile items should be contained and segregated from contaminated items, trash, and food.

Rationale: Transporting clean/sterile items in proximity to contaminated items, trash, or food could contaminate the clean/sterile items.

5.3.6.2 Transportation scheduling and routes

The amount of time between use and decontamination should be minimized because the soil on items provides an ideal medium for microbial reproduction and increases the risk of corrosion. Biofilm can begin to form within minutes and is difficult to remove. In addition, soil can dry on the medical device if left standing, making it difficult to remove. Personnel should schedule the pickup and transport of soiled items from each area so that the items are transported and cleaned as soon as possible after becoming soiled. Transport routes should:

a) be designed to facilitate efficient pickup and delivery to the decontamination area; and

b) avoid areas of high traffic.

Rationale: Cleaning items as soon as possible helps prevent the formation of biofilm and the drying of blood, tissue, and mucus on the items, which can increase the risk of corrosion and make cleaning even more difficult to perform.

5.3.6.3 Transportation equipment

To help prevent damage to reusable items and avoid contamination of the environment, transport carts or other system should:

a) be designed to prevent items from falling over or off during transport;

b) be large enough to maintain the security and package integrity of the items being transported;

c) be covered or closed;

d) be decontaminated after each use; and

e) have wheels that turn easily and are routinely cleaned.

Rationale: Decontamination of transportation equipment after each use helps prevent cross-contamination of items transported at a later time. The wheels of a transport cart should turn easily to help prevent items from falling off the cart. Routine cleaning of the wheels removes debris that can interfere with the wheels' movement.

5.3.6.4 Hand transport

Prior to transportation, items contaminated with blood and other potentially infectious materials should be placed in a container that is puncture-resistant, leak-proof on the bottom and sides, labeled as biohazardous, and sealed. Containers used to transport contaminated items by hand should be carried in a position parallel to the floor. The carrier should exercise good body mechanics (e.g., bend at the knees when lifting an item, hold the item close to the body).

Rationale: Keeping containers parallel to the floor prevents the dislodging of or potential damage to the items within them. Good body mechanics promote worker safety.

5.3.6.5 Dedicated lifts

Dedicated, soiled lifts should:

— be located in the decontamination area;

— be large enough to allow the containers to be positioned securely;

— be cleaned on a routine basis, according to the organization's policy, to remove gross contamination that could build up over time and use; and

— not be used to distribute clean or sterile items.

If containers of contaminated items are transported directly from the point of use to the point of decontamination by means of a dedicated, soiled lift, the lift may be considered equivalent to a closed cart.

Rationale: Using dedicated lifts and equipment as described in this subsection helps prevent damage to reusable items and avoid contamination of the environment. General cleanliness is maintained by periodic and spot cleaning.

5.3.6.6 Transport between buildings

When contaminated items are transported outside the controlled environment of the health care facility consideration should be given to

a) the containment or packaging of the items;

b) loading procedures;

c) temperature control in transportation vehicles;

d) temperature changes that could enhance microbial growth or impact subsequent processing or use; and

e) separation of clean and contaminated items.

The transportation system should be enclosed and designed to minimize

a) the risk of personnel exposure to blood-borne pathogens and other disease-producing organisms; and

b) the possibility of damage to the medical devices and other items being transported.

Vehicles used for transporting contaminated items between buildings should provide for the complete separation of contaminated items from clean and sterile items. Because contamination of the vehicle could have occurred, transportation vehicles should be decontaminated between trips and after any spill.

Transportation personnel should receive training in basic infection prevention and control principles related to their responsibilities. PPE and a biohazardous spill kit should be available in transportation vehicles.

Devices may need to be conditioned to department temperature before processing or use.

Rationale: Separation of clean and contaminated items helps to prevent cross-contamination during transport. Training is needed to help reduce the risk that transportation personnel will be exposed to blood-borne and other pathogens. The effect of transport on device temperature should be considered as a very hot or very cold device may not be within the temperature range of decontamination and sterilization processes or for its intended use.

5.3.6.7 Off-site transportation

The procedures for packaging and transporting contaminated items off-site for processing must comply with applicable Department of Transportation (DOT) and state regulations. See also Annex L.

Certain contaminated, “nonwaste” products are considered to be “infectious substances” under DOT regulations. The DOT defines an infectious substance as a “material known or reasonably expected to contain a pathogen. A pathogen is a microorganism . . . that can cause disease in humans or animals” (49 CFR 173.134 [a][1]). Such products qualify as Class 6, Division 6.2, hazardous materials and thus fall under DOT’s regulations for “Infectious Substances (Etiologic Agents).” Certain states also have regulations that can affect the transport of contaminated items.

Clean and contaminated items should be separated to prevent cross-contamination during transport.

Vehicles (motorized or manual) used for transporting contaminated items between health care facilities should:

a) provide for the complete separation of contaminated items from clean and sterile items;

b) be secured within the vehicle to prevent damage to contents and to prevent contamination by spills;

c) allow for ease of loading and unloading;

d) allow for decontamination after use;

e) remain closed at all times except during loading and unloading;

f) be completely enclosed to prevent leaks; and

g) be checked periodically to ensure that there are no leaks.

Transport vehicles that are loaded and ready for transport should not be left unattended in unsecured areas.

5.4 Cleaning and other decontamination processes

5.4.1 General considerations

All microorganisms in health care facilities should be considered potentially pathogenic. Their ability to cause an infection or disease depends on several factors, including the number and virulence of infectious organisms, the presence of a portal of entry, and the susceptibility of the host (see Annex A). Medical devices, instruments, and equipment used in patient care become contaminated with microorganisms and should be decontaminated. Decontamination is the removal of contaminates to specified levels and can include the physical removal of contaminants through cleaning or an antimicrobial process designed to reduce and/or inactivate microorganisms (e.g., disinfection, sterilization). This section provides guidance for the decontamination steps for medical device processing.

Infection prevention and control is enhanced when soiled supplies and equipment are correctly and safely handled, and when reusable medical items are thoroughly decontaminated. The first and most important step in decontamination is thorough cleaning. Cleaning is the removal of organic and inorganic materials. Cleaning can reduce microorganisms through removal but does not inactivate them. The microbicidal process might not be effective if soil has not been first removed by cleaning. Devices should be thoroughly rinsed to remove detergent and processing residues that might interfere with subsequent processes.

Some devices can be prepared for patient reuse following cleaning and disinfection, whereas others should be prepared and subjected to further disinfection process or sterilization (e.g., sterilization of surgical instruments). The extent of decontamination required for a particular contaminated device depends on the biohazard that the device presents. The cleaning and/or microbicidal processes appropriate for a particular device depend on

— the intended use of the device;

— the necessary level of microbial lethality based on use of the device according to Spaulding Classification (CDC, 2008), for example, a higher assurance of lethality is needed for items that have been in contact with body tissues, blood, or other bodily fluids than for items that have only been in contact with unbroken skin;

— the device manufacturer’s written IFU;

— the design of the device; and

— the materials from which the device is fabricated (e.g., whether the device can tolerate high temperatures, whether the device is fully immersible).

Adherence to the principles of infection prevention and control will help prevent the spread of potentially infectious or disease-producing microorganisms from one person to another and will help ensure that all items are safe for handling during inspection, assembly, preparation, and packaging. In addition, adherence to these principles is one of the essential factors in achieving effective sterilization for a reusable medical device. The selection of a decontamination method is complex because of the huge variety of reusable items and the wide range of processes for achieving various levels of decontamination. The health care organization, including representatives of sterile processing and of infection prevention and control, should purchase only those devices that can be decontaminated appropriately by a method available in the health care facility. Personnel performing decontamination tasks must wear PPE and be trained to safely perform decontamination-related tasks. (See 29 CFR 1910.1030.)

A microbicidal process used after cleaning and prior to final disinfection or sterilization is intended to render a device safe for handling and subsequent processing, as determined by the intended use (as in the case of surgical medical devices needed for sterile procedures).

5.4.2 Policies and procedures

Policies and procedures for point-of-use treatment, soiled transport, decontamination, chemical high-level disinfection or sterilization, rinsing or residue removal according manufacturer's instructions for use, drying, and storage should be developed. The policies and procedures should be in-serviced and audited. Staff competencies in decontamination, high-level disinfection, and sterilization processes should be established and verified annually.

Rationale: Policies and procedures provide guidelines for maintaining process control and for determining methods of improving processes and products.

5.4.3 Manufacturer's written IFU

The device manufacturer's current written IFU should be accessible, reviewed, and followed. If there are no specific written IFU in the labeling, then the manufacturer should be contacted and requested to provide a documented method of cleaning, disinfection and/or sterilization.

For sterilization or disinfection, the sterilizer/LCS/HLD manufacturers' FDA cleared instructions for use and labelling should also be considered.

Rationale: The device manufacturer is responsible for ensuring that the device can be effectively cleaned and disinfected and/or sterilized with the means and methods available in health care facilities. Sterilization and disinfection validation of a device requires microbiological, engineering, toxicological, and sometimes clinical evaluations of the device, which are beyond the abilities of most health care facilities. For patient safety, a reusable device needs to be capable of being thoroughly cleaned and disinfected and/or sterilized. The device labeling describes specific methods of cleaning and disinfection and/or sterilization that have been validated by the manufacturer.

5.4.4 Decontamination

General considerations for all devices.

To help ensure effective decontamination of devices, sterile processing personnel should:

a) follow the device manufacturer's written IFU to ensure proper cleaning / disinfection of device;

b) collaborate with clinical personnel to help ensure that medical devices are kept as free of gross soil as possible during the surgical or other procedure;

c) begin decontamination as soon as possible after the items have been used or as directed by the medical device manufacturer;

d) separate general operating medical devices and utensils from delicate medical devices or devices that require special handling;

e) disassemble all medical devices or devices comprising more than one part according to manufacturers' written IFU;

f) open all jointed instruments;

g) pretreat the device according to the manufacturer's written IFU;

h) use a cleaning solution that is compatible with the device and follow the cleaning product manufacturer's written IFU for proper dilution, concentration, temperature, and contact time;

NOTE—Using a concentration higher than recommended may result in inefficient rinsing leaving residual cleaning agent on the device, whereas using a concentration that is too low can result in ineffective cleaning, either of which could interfere with subsequent processing stages and/or create risk for the patient.

i) verify visually that the cleaning solution is clean before manual cleaning and prepare fresh when it appears soiled, which could be after one use; and

NOTE—For manual cleaning of flexible endoscopes, cleaning solution is prepared fresh for each endoscope.

j) rinse with water of the quality specified by the device manufacturer. When the water quality is not specified by the device manufacturer, refer to ANSI/AAMI ST108:2023.

Medical devices should not be treated with any additional chemical (e.g., alcohol, disinfectant wipes) unless such treatment is specifically recommended in the manufacturer's written IFU.

Cloths used in decontamination should be clean and non-linting and should be changed frequently. Brushes should be clean and of the appropriate size and bristle type. Worn brushes should be discarded. Reusable brushes should be cleaned after each use and disinfected or sterilized at least once a day or otherwise specified by the manufacturer's IFU. Single-use cleaning implements (e.g., single-use wipes) should be discarded after each use.

Medical devices should be carefully inspected for flaws, damage, debris, detergent residue, and completeness, then dried. Medical device tape and plastic dipping material, when used properly, are ways of identifying specific instruments. These types of marking products wear out over time and staff need to inspect them each time the medical device is processed, check them for wear according to the IFU of the product used, and replace them as often as needed.

Rationale: Because effective disinfection and sterilization depends on minimizing the contamination present on items before the disinfection or sterilization cycle, thorough cleaning procedures are essential. Not all decontamination procedures and agents are appropriate for all types of devices. Adherence to the manufacturer's written IFU for detergents and other aspects of the decontamination process can help avert damage to instruments, prolong their use life, and prevent the creation of crevices in which debris can collect. Ensuring the completeness of instrumentation helps reduce the number of lost medical devices and medical device parts. Drying medical devices before they are packaged can reduce the occurrence of cycle aborts due to moisture. Cloths with lint can leave lint on instrumentation. Using cleaning implements that are free from contamination reduces the risk of contamination during cleaning. If a brush is too large, it will not fit into the lumen; if it is too small, it will not have complete contact with the lumen walls and, consequently, will not clean them thoroughly. Brushes that show wear will not clean thoroughly. Prompt cleaning of brushes and other cleaning implements reduces or eliminates the microorganisms that can cause biofilm formation.

5.4.4.1 Special Considerations

5.4.4.1.1 Reusable textiles

Used textiles should be placed in a laundry bag that prevents leakage for transport to the laundry for processing. For guidelines on handling and processing of reusable surgical textiles, see ANSI/AAMI ST65.

5.4.4.1.2 Medical device lubricants

Medical device lubricants should be specifically designed for their intended use and compatible with the processing method being used. The lubricant manufacturer should provide evidence to support material compatibility and biocompatibility (e.g., lack of cytotoxicity) of the lubricant for its intended use (e.g., following sterilization). Lubricants should be used according to the device manufacturer's instructions.

5.4.5 Preparation for cleaning

5.4.5.1 Presoaking

Following point-of-use treatment, medical devices should be presoaked as soon as possible after use with a product intended to loosen soil. Medical devices should only be presoaked if indicated in the medical device manufacturer's written IFU.

The presoak solution manufacturer’s written IFU should be reviewed and followed for the correct dilution, temperature, and contact time. Saline and other solutions that might cause corrosion should not be used in the presoaking process. Some disinfectant chemicals may fixate soil to surfaces and should not be used in the presoaking process.

Medical devices should be thoroughly rinsed after presoaking.

Rationale: Presoaking medical devices moistens and loosens the soil, thus making the cleaning step more effective and efficient. Thorough rinsing removes potentially harmful residues and blood and other potentially infectious material. Alcohol and other disinfectants might affix biofilm to surfaces and make it difficult to remove.

5.4.5.2 Sorting and disassembly

5.4.5.2.1 General considerations

Following transport to the decontamination area, contaminated items should be handled as follows:

a) Contaminated items should be removed from their transport containers.

b) Contaminated items should be sorted. General operating medical devices should be segregated from delicate items that require special handling, sharp items, and those identified for repair. Repair tags that are designed for surgical instrumentation should remain on the instrumentation throughout the cleaning process.

c) All disposable products (e.g., tip protectors and CIs) should be removed.

d) Unless otherwise directed by the manufacturer, medical devices should be disassembled in preparation for cleaning according to the manufacturer’s written IFU.

- Device and medical device manufacturers’ written IFU for disassembly and reassembly of all processed items should be reviewed and followed.
- Protective devices (e.g., silicone mats, dividers) should be removed, as appropriate.
- All small parts (e.g., screws, nuts, and washers) should be contained to prevent loss.
- Non-interchangeable components, such as parts of a metal stopcock, should be kept together to ensure correct reassembly.
- Procedures should be established and followed to ensure that personnel do not reach by hand into the container to retrieve reusable sharps as this will pose a risk for occupational injury.

Rationale: Differentiating medical devices identified for repair from functional medical devices during the cleaning process can reduce the risk of defective medical devices being returned to the user before repairs have been made. Disassembly of medical devices and other items composed of more than one part or piece (e.g., metal tracheostomy tubes, procedure needles, dental handpieces, laparoscopic instrumentation, trumpet valves) exposes surfaces to the cleaning process. Hidden surfaces and crevices can prevent thorough cleaning. Residual organic matter or large numbers of microorganisms can significantly reduce the effectiveness of the subsequent microbicidal process. The recommended procedures for disassembly and reassembly are intended to help ensure that reassembly can be accomplished without damage to the device. The recommendation concerning reusable sharps is based on OSHA regulations (29 CFR 1910.1030).

5.4.5.2.2 Rigid sterilization container systems

5.4.5.2.2.1 General considerations

Before acquiring rigid sterilization container systems, the health care facility (or organization) should confirm that the facility has the capability to follow the manufacturer's validated decontamination methods. Container shall also be compatible with the proposed sterilization system, for example Low Temperature Vaporized Hydrogen Peroxide, EO, etc.

The method selected should be guided by the container system manufacturer's written IFU in conjunction with the mechanical cleaning equipment manufacturer's written IFU.

Rigid sterilization container systems should be cleaned and thoroughly dried

a) before sterilization, either manually or mechanically;

b) according to the container system manufacturer's written IFU; and

c) by personnel following accepted practices for decontamination and employee safety, including PPE.

Only cleaning agents intended for cleaning rigid sterilization containers and not contraindicated in the device manufacturer's validated IFU should be used.

After the cleaning process is completed, nuts, bolts, screws, rivets, filter retention mechanisms, gaskets, and permanent filters should be inspected for cleanliness and damage. The container should be thoroughly dried paying particular attention to areas around the gasket and any constrained spaces.

Rationale: Certain cleaning methods or cleaning agents might not be compatible with a particular rigid sterilization container system. Some cleaning agents can cause corrosion or deterioration of container surfaces, such as discoloration or stress cracking; for example, some detergents that do not have a neutral or near-neutral pH might corrode more sensitive metals, and specific additives can adversely affect some plastics and gasket materials. Thorough rinsing is essential for removal of detergent and other residues. Hidden surfaces and crevices can make thorough cleaning difficult. Residual organic matter can significantly reduce the efficacy of the decontamination process. Damaged components of container systems could interfere with the sterilization process or allow contamination of the contents.

5.4.5.2.2.2 Removable filters

Removable filters and filter protectors or holders (retention plates) should be removed or released to disengage the filter media to allow for cleaning.

Disposable filters should be discarded.

Rationale: Filters can be reservoirs of contamination, especially when the container system is used to collect or transport used instruments. A disposable filter might not maintain its barrier effectiveness for more than one cycle, and reuse could result in improper sterilization or contamination of the container system contents.

5.4.5.2.2.3 Interior baskets

The interior basket should be removed from the external container.

The container manufacturer's written IFU should be followed to determine whether medical devices can be decontaminated in the basket or should be removed.

Rationale: Separation of the internal basket from the external container allows for effective decontamination.

5.4.5.2.2.4 Process indicators, disposable labels, and disposable locks

Process indicators, disposable labels, and disposable locks should be removed and discarded.

Rationale: The presence of process indicators or fragments of disposable labels or locking mechanisms on the surface of the container system impedes decontamination and the proper functioning of mechanical processing equipment.

5.4.5.2.2.5 Container accessories

Protective mats, dividers, and sorting pins that are not affixed to the tray should be disassembled or removed according to the manufacturer's written IFU.

Rationale: If the position of the dividers and pins interferes with cleaning of the baskets, the effectiveness of sterilization could be compromised.

5.4.6 Cleaning

5.4.6.1 General considerations

Effective disinfection / sterilization depends on minimizing the contamination, including detergent and water residues present on items. Not all decontamination procedures and agents are appropriate for all types of devices. Adherence to the manufacturer's written IFU for detergents and other aspects of the decontamination process can help avert damage to devices, prolong their use life, and prevent the creation of crevices in which debris can collect.

a) Items should be presoaked.

b) After presoaking, devices should be cleaned according to the manufacturers' IFU.

c) Devices should be thoroughly rinsed. If a basin is used, the rinse water should be changed after each use. The final rinse (mechanical or manual) should be with Critical Water. See TIR34 for recommendations on the use of Critical Water.

d) Cloths and towels used in cleaning and drying should be clean and nonlinting (e.g., microfiber cloth or cellulose sponge) and should be changed at regular established intervals and when they are soiled or wet.

e) Brushes should be clean and of the appropriate size and bristle type. Worn brushes should be discarded. Reusable brushes should be cleaned after each use and disinfected or sterilized at least once a day unless otherwise specified by manufacturer IFU.

f) Single-use cleaning implements (e.g., single-use wipes or brushes) should be discarded after use.

g) Devices should be inspected for flaws, damage, debris, detergent residue, and completeness, then dried.

h) Brushing is a cleaning function and should only be done in the decontamination area and not in the clean (preparation and assembly) area. If a medical device is found to be dirty upon inspection in the assembly area, it should be returned to the decontamination area for recleaning.

Rationale: A cold water rinse and the use of a presoaking product will help prevent coagulation of blood onto the device and help remove blood, tissue, and gross debris from device lumens, joints, and serrations. Precleaning solutions can interfere with subsequent cleaning steps.

Cloths with lint can leave lint on instrumentation. Using cleaning implements that are clean reduces bioburden. Reusable brushes used for decontamination should be cleaned after each use and disinfected or sterilized at least daily. Single use brushes should be used once and discarded. Brushes that show wear will not clean thoroughly. Prompt cleaning of brushes and other cleaning implements reduces or eliminates biofilm-forming microorganisms and thus minimizes the risk of formation of biofilm.

When decontaminating devices with lumens, personnel should:

a) soak and flush the lumen according to the manufacturer's written IFU;

b) brush the lumen with a brush that is of the correct size (diameter and length) and bristle type and material for the lumen, then rinse it;

c) if using a pressurized lumen-flushing device, verify that it is connected correctly and follow manufacturer's written IFU; and

d) prior to LCS/HLD, remove gross residual liquid that would dilute the high-level disinfectant or liquid chemical sterilant with a purge of instrument air. Instrument air should be used to remove water from lumens or constricted areas also in preparation for borescopic inspection or sterilization. Consult the device manufacturer's written IFU for maximum pressure (psi).

Rationale: Thoroughly flushing lumens helps ensure complete surface contact with the solution. If a brush is too large, it will not fit into the lumen; if it is too small, it will not have complete contact with the lumen walls and, consequently, will not clean them thoroughly.

5.4.6.2 Cleaning agents

Cleaning agents recommended in the device manufacturer's written IFU should be used. The cleaning agent should:

a) be compatible with the medical device or container system to be cleaned as well as with the materials used in the cleaning equipment itself;

b) be efficacious on the types of clinical soil typically found on medical devices after clinical use;

c) be nonabrasive;

d) be low-foaming;

e) be free-rinsing (i.e., easily removed from the medical device);

f) be biodegradable;

g) rapidly dissolve/disperse soil;

h) be nontoxic; and

i) have a shelf life and use-life consistent with the anticipated clinical use.

The volume and temperature of water used in the cleaning sink or other cleaning container is very important for the efficacy of the process. The appropriate dilution should be calculated according to the volume of the water used to ensure consistent and accurate cleaning solution concentration.

The PPE requirements and safe work practices should be reviewed and revised as necessary whenever a new cleaning agent is introduced into the cleaning process.

When using an automated chemical delivery system/device or sink proportioner, personnel should routinely verify or calibrate the automated doser. Calculation of sink volume might or might not be necessary.

Rationale: The characteristics of a cleaning product, as outlined above, contribute to the removal of clinically relevant soils and the rinsing of residual chemicals, soils or bioburden that can be harmful to patients or damage the device.

5.4.6.3 Methods of cleaning

5.4.6.3.1 Selection of an appropriate method

Personnel should use the cleaning method or methods (manual, mechanical, or a combination) specified in the device manufacturer's written IFU.

Prior to acquisition of a device, the device manufacturer's written IFU should be reviewed to confirm the availability of the mechanical cleaning equipment, cleaning devices, and methods required to safely reprocess the device.

Before personnel elect to use alternative equipment and/or cleaning agents, they should consult the device manufacturer, the manufacturer of the cleaning equipment, and the manufacturer of the cleaning agent.

Rationale: Medical devices vary in size, complexity, fragility, sensitivity to cleaning agents, immersibility, and other properties that affect the choice of cleaning method.

5.4.6.3.2 Manual cleaning

Manual cleaning should be performed on all medical devices if specified by the medical device's written IFU in addition to mechanical methods or if automatic cleaning equipment is not available.

When manually cleaning devices, personnel should:

a) wear appropriate PPE;

b) follow the detergent manufacturer's written IFU for water hardness, pH, temperature, and the type(s) of soil the detergent is suitable for removing;

c) clean lumened items with a brush of the recommended type, size (diameter and length), and bristle type and material, flush the lumen with the recommended cleaning solution, and then rinse the lumen, preferably with utility water (unless otherwise specified in the manufacturer's written IFU);

d) clean immersible devices under water to minimize aerosolization;

e) clean devices that cannot be immersed in a manner that will not produce aerosols;

f) use brushes and other cleaning implements intended for use on medical devices; brushes should be checked for visible soil and damage following each use and should be frequently cleaned and disinfected. If the device manufacturer specifies a specific brush or cleaning implement, the brush or an equivalent should be used;

g) avoid abrasive cleaning compounds and implements such as metal scouring pads, unless specified in the device manufacturer's written IFU;

h) thoroughly performed final rinse using cirtical water and dry devices following the decontamination process using a nonlinting cloth or instrument air;

   Rationale: Thorough rinsing removes residual cleaning agent. Residual cleaning agent might affect the efficacy of the LCS/HLD or the gaseous chemical sterilant. Proper drying of devices prior to gaseous sterilization prevents cycle abortion and potential exposure to sterilant post-cycle

i) monitor the water temperature as required in the manufacturer's written IFU; and

   NOTE—Optimal temperature ranges for use of the detergents should follow detergent manufacturer's recommendations and IFU of device manufacturer, as outside of the recommended temperature range (high or low), the detergents might be less effective.

j) change the solution after every use (a "use" should be defined in the health care facility's policies and procedures).

Rationale: Microorganisms, patient tissue, blood, and lubricants in the cleaning solution on brushes and other cleaning implements could be transmitted from one device to the next during cleaning. In addition, accumulated microorganisms, patient blood, and patient tissue on cleaning implements could pose potential health risks to personnel. Adequate rinsing removes residual cleaning agent which might affect the efficacy of the LCS/HLD or the gaseous chemical sterilant. Proper drying of devices prior to gaseous sterilization prevents cycle abortion and potential exposure to sterilant post-cycle.

5.4.6.3.3 Mechanical cleaning

5.4.6.3.3.1 General considerations

Mechanical cleaning is a 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

with documentation. Mechanical cleaning equipment often includes a disinfection cycle to make the item safe to handle by processing staff.

The equipment manufacturer's written IFU should be reviewed and followed for indications for use and operation, including loading practices, use of accessories, and cycle selection.

Rationale: Mechanical cleaning methods minimize personnel risk of cross-contamination, improve cleaning effectiveness, increase productivity, and are more easily monitored for quality performance. Additional information is in Annex R.

5.4.6.3.3.2 Maintenance of mechanical cleaning and disinfection equipment

Mechanical cleaning equipment should be used, cleaned, disinfected, and maintained according to the manufacturer’s written IFU. Personnel should:

a) verify that the equipment is functioning according to the manufacturer’s written specifications;

b) check the spray arms (if applicable) at least daily to ensure that the arms are completely free-turning and that spray nozzles are not clogged;

c) clean strainers (if applicable) at least daily or when there is visible debris;

d) ensure that regular preventive maintenance is performed;

e) clean external surfaces when soiled and at least daily; and

f) verify that settings are held constant and have not been changed after repair or maintenance by manufacturers, users, or technicians unless there was an identified need that was recorded.

Rationale: Maintaining the equipment according to the manufacturer's written IFU will help ensure optimal performance.

5.4.6.3.3.3 Selection of mechanical cleaning and disinfection equipment

Selection of mechanical cleaning equipment should be based on the requirements for cleaning of the devices to be processed. The mechanical cleaning equipment currently available for processing medical devices that are moisture-, detergent-, and temperature-stable include the following:

a) ultrasonic cleaning equipment

b) irrigator cleaners

c) ultrasonic irrigators

d) ultrasonic irrigator washers

e) ultrasonic irrigator washer–disinfectors

f) floor-mounted cart washer–disinfectors

g) single-chamber washer–disinfectors

h) multi-chamber washer–disinfectors

i) medical washers (including Automated Endoscope Reprocessors/AERs)

5.4.6.3.3.4 Loading mechanical cleaning and disinfection equipment

When loading mechanical cleaning and disinfection equipment, personnel should do the following:

a) Remove gross debris.

b) Remove all presoak chemicals, either manually or mechanically.

c) Follow the loading procedure described in the manufacturer's written IFU.

d) To facilitate cleaning, disassemble all devices composed of more than one part according to the device manufacturer's written IFU.

e) Connect lumened medical devices to irrigation ports, if available.

f) Open all hinged surgical medical devices with handles, such as scissors, hemostats, and forceps, to full extension unless contraindicated by the manufacturers' written IFU.

g) Position devices to prevent damage. Heavy devices should be placed on the bottom. Position items such as rigid sterilization container and basins to avoid the accumulation and retention of water.

h) Develop a mechanism to verify the dosing of the detergent in consultation with the equipment manufacturer.

i) Check that the spinning arms are unobstructed.

j) Place delicate devices in a perforated basket and secure them to prevent them from moving around.

k) Position items so they do not protrude from the washer baskets.

l) Use hold-down screens or other retaining systems to prevent dislodging and improper movement of devices during the process.

m) Separate multi-level sets so that all surfaces are exposed to impingement action.

n) Open trays with lids/covers so that the contents are exposed and water can drain freely.

o) Remove silicone and rubber mats from the set to permit full impingement action.

p) Load utensils so that the spray can easily reach all surfaces and so that water can drain out.

q) Remove disposable items such as filters and chemical indicators.

r) Verify that the correct cycle and dry time are selected for the load.

s) Avoid mixed loads (e.g., medical devices and utensils) to ensure that the correct wash cycle parameters are applied to each device.

t) Remove debris from the bottom of the washer and clean the filter at least daily when there is visible debris present.

Rationale: Gross debris left on devices will circulate through the washer and be deposited onto the other devices, impeding the cleaning action. For washing to be effective, all surfaces of the device should have contact with the cleaning solutions. Devices are loaded to prevent medical device damage. Disposable items placed into the washer can clog the washer and become debris, preventing full impingement action. Hold-down screens prevent items from tipping over during the wash cycle. Shortened cycles can negatively affect cleaning outcomes.

5.4.6.3.3.5 Unloading mechanical cleaning and disinfection equipment

If the cleaning equipment provides cycle verification, the cycle selection should be checked, before the devices are unloaded, to ensure that the correct cycle was used. The printout should be saved for the period of time specified by the facility or by state and/or local regulations. As devices are unloaded, they should be inspected for debris and wetness.

The drain strainer should be checked for debris and cleaned if debris is present.

After the wash cycle, devices are hot and might be wet. They should be removed carefully to prevent worker thermal injury. Items should be dry before loading into a gaseous chemical sterilizer.

5.4.6.3.4 Ultrasonic cleaning equipment

5.4.6.3.4.1 General considerations

Ultrasonic cleaning equipment designed for cleaning medical devices is used for fine cleaning to remove soil from joints, crevices, lumens, and other areas that are difficult to clean by other methods.

Ultrasonic cleaning should be:

a) used only for those devices for which ultrasonic cleaning has been indicated in the device manufacturer's written IFU;

b) used only after gross soil and detergents have been removed from items;

c) performed using cleaning solutions labeled for use in ultrasonic cleaning equipment;

d) performed with fresh cleaning solution; solution should be changed after each use (a “use” should be defined in the health care facility’s policies and procedures); and

e) followed by thorough clean water rinsing or detergent washing to remove ultrasonic cleaning equipment bath residues and contaminants.

Ultrasonic cleaning equipment should be cleaned every day that it is used according to the manufacturer’s written IFU.

In addition to following the manufacturer’s written IFU, the following actions should be taken:

a) Request performance verification test methods from the ultrasonic equipment manufacturer.

b) Perform cavitation testing daily whenever the equipment is in use.

c) Prior to using it, degas the solution in accordance with the ultrasonic equipment manufacturer’s IFU.

d) Avoid placing plastics and soft metal (e.g., lead hands) in the ultrasonic cleaner.

e) Keep the lid closed when the ultrasonic cleaner is in use unless otherwise directed by the device manufacturer’s written IFU.

Rationale: The ability to clean medical devices mechanically and to fine-clean by the ultrasonic cleaning process is beneficial because of the complexity of many devices. The variety of equipment available and the intricacy of many medical devices make it essential that manufacturers be consulted and their written IFU reviewed and followed for maximum effectiveness and to avoid expensive and unnecessary damage. Changing the cleaning solution after each use will minimize cross-contamination of instrumentation. The cavitation process has a tendency to create aerosols (particles of cleaning solution released into the air). To contain these aerosols and other contaminants, the ultrasonic cleaner should have a lid and the lid should remain closed during the cleaning process. Degassing the cleaning solution in the ultrasonic cleaner will remove gases from utility water that can interfere with the cavitation process. Plastic materials can absorb the sound waves interfering with cleaning.

5.4.6.3.4.2 Loading ultrasonic cleaning equipment

When loading an ultrasonic cleaning equipment, personnel should:

a) place devices in open-weave or perforated metal baskets below the water level;

b) place devices in an open position;

c) place heavy items on the bottom;

d) remove rubber or silicone mats;

e) when required, connect lumen devices to flushing ports by tubing and adapters, and follow the device manufacturer's written IFU for mechanical cleaning using ultrasonic equipment with pressurized lumen irrigation or disinfection parameters; and

NOTE This step also applies to mechanical irrigation cleaners that do not include an ultrasonic function.

f) follow the ultrasonic cleaner manufacturer's instructions for loading and placement of devices in the cleaner.

Rationale: Long, hollow, small-lumen, and ported devices are generally difficult to clean. Specific validated IFU should be followed in order to thoroughly clean these complicated and advanced devices thoroughly.

5.4.6.3.4.3 Unloading ultrasonic cleaning equipment

When unloading medical devices from ultrasonic cleaning equipment, personnel should carefully remove devices from the ultrasonic cleaner:

a) If the device is connected to any flushing ports, disconnect it first before removing it from the ultrasonic cleaner;

b) If the ultrasonic cleaning equipment does not have a rinse cycle, rinse the devices before inspecting them for cleanliness;

c) After ensuring that the devices have been thoroughly rinsed, inspect them for cleanliness according to the medical device manufacturer's written IFU.

5.4.7 Inspection and verification of the cleaning process

Cleaning verification and inspection includes visual inspection and cleaning verification testing. It can also include borescopic examination. Cleaning verification of manually cleaned items should be performed periodically. After completing the cleaning process, personnel should visually inspect each item carefully, preferably with lighted magnification, to detect any visible soil. Cleaning verification of the mechanical cleaning equipment performance should be tested at a minimum each day the equipment it is used and more frequently if the equipment is routinely malfunctioning or items do not appear clean. All results should be recorded.

Users should ask device manufacturers to provide test procedures that can be easily replicated and that can assist users in recognizing whether cleaning was effective for all device areas. Such tests are particularly important for devices with components that cannot be readily inspected for cleanliness (e.g., spring hinges, lumens, porous material, crevices). If the medical devices are deemed clean, they can now proceed to the next step in their processing cycle.

Rationale: High-level disinfection or sterilization cannot be assured unless proper cleaning of the device and reduced bioburden and soil was achieved. Verification and documentation of automated cleaning processes through objective means is an important aspect of quality control. Cleaning encompasses the removal of organic residues (e.g., blood, tissues, bone fragments, secretions and excretions) and microorganisms from the patient, from handling, or from water exposure during processing. Inspection using enhanced visualization tools such as lighted magnification and video borescopes might identify residues not observable by the unaided eye. Visual inspection alone might not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure or detect organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures Appropriate testing is based on the type of equipment. See Annex N for guidance on available methods including testing ultrasonic cleaners.

5.4.8 Excess Moisture

For most gaseous sterilization processes and liquid chemical sterilization/high-level disinfection processes, it is also necessary to remove excess moisture from items being processed. The LCS/HLD manufacturer's written IFU should be consulted for guidance regarding whether moisture removal is essential. LCSs/HLDs can be diluted by water remaining on the surfaces and in the lumens of items, and the concentration of the HLD active ingredient can be reduced to a level that is too low to be effective in killing certain microorganisms within the recommended exposure time. If there has been significant dilution of the LCS/HLD, as determined by minimum effectiveness concentration (MEC) monitoring, the solution should be discarded even if it has not yet reached the manufacturer's stated reuse time,

number of reuses, or expiration date. Solution test strips or chemical monitoring devices that are recommended by the LCS/HLD manufacturer are available to monitor the active ingredient concentration during the use-life of the product.

Excess moisture can also impact the effectiveness of some gaseous chemical sterilants because the system may rely on the absence or control of moisture. In some gaseous chemical sterilization methods, excess moisture can cause cycle cancellation. Evaporation of excessive moisture during the air removal stage in some gaseous sterilization systems may cause localized cold spots in the load which may result in condensation of the gaseous sterilant resulting in cancelled cycles and failed monitoring products. Further, residual water droplets have the potential to cause residual chemicals to be present in a liquid form at the conclusion of the sterilization cycle, which may cause exposure to the chemical.

6 Safe and effective use of liquid chemical sterilants/high-level disinfectants and equipment

6.1 General considerations

The safety and performance characteristics of a LCS/HLD can be categorized in terms of its:

a) effectiveness in killing microorganisms under the prescribed conditions of use;

b) effects on the materials and devices it is intended to sterilize or disinfect; and

c) toxicity and potential to harm personnel, patients and the environment.

Microbial lethality, materials compatibility, and toxicity of LCS/HLD are discussed in general terms in Annex A.

NOTE More detail information on the characteristics, safety requirements, and use of specific liquid chemical sterilants/high-level disinfectants is provided in Annexes C-G and K.

Certain general principles apply to the safe and effective use of any LCS/HLD product . This section covers general safety and efficacy considerations in the use of chemical sterilants/high-level disinfectants. More detail information on the characteristics, safety requirements, and use of specific chemical sterilants/high-level disinfectants is provided in Annexes C-G.

6.1.1 Safety considerations

6.1.1.1 General considerations

All personnel must be advised of the hazards associated with the chemicals they work with, and they should be thoroughly trained in appropriate safety procedures, both general safety procedures and, where applicable, those that pertain to specific hazards that could be encountered. OSHA requires that SDSs for all hazardous chemicals be maintained on site and be readily accessible during each work shift to employees when they are in the work areas. Both employee and employer compliance with the OSHA Hazard Communication Standard (29 CFR 1910.1200) must be ensured. In particular, compliance with OSHA’s Enforcement Procedure for Occupational Exposure to Formaldehyde (OSHA, 1990) must be enforced.

In general, personnel should avoid direct contact with chemical sterilants/high-level disinfectants. When using LCSs/HLDs, personnel should wear PPE, as appropriate, to prevent skin and eye contact with the solution, and solutions should always be kept covered to prevent inhalation exposure to the fumes. LCSs/HLDs should always be used in a well-ventilated area; in some cases, a hood and local exhaust ventilation system will be needed as well.

Some chemical sterilants/high-level disinfectants are explosive and/or flammable. Special storage conditions and use precautions are required for such products and must be specified in the SDS. Use of such chemicals in patient treatment rooms is not recommended. To prevent patient exposure to chemical sterilant residues, personnel should carefully follow any aeration or rinsing or residue removal procedures specified by the manufacturer.

Specific safety considerations applying to particular chemical sterilants/high-level disinfectants are discussed in Annexes D-H.

6.1.1.2 Emergency procedures

6.1.1.2.1 Spill containment team

An LCS/HLD spill containment “response team” should be established. The response team should include a representative from the safety committee, a physician (ideally an occupational health physician), the unit supervisor, and any other personnel deemed appropriate. This response team should be responsible for developing and executing procedures for LCS/HLD spills in accordance with the LCS/HLD manufacturer’s written IFU and facility requirements.

Rationale: For rapid, efficient, and effective response to LCS/HLD spills, it is important that specific individuals be assigned responsibility for developing and implementing procedures for handling the spills. The composition of the response team should reflect all expertise relevant to the control of spills and the resulting vapor.

6.1.1.2.2 Spill containment plan

The response team should prepare a written plan for containment of LCS/HLD spills. The team should consider the concentration of chemical in the solutions and the design of the facility (such as the type of ventilation, the air turnover rate, and the size and temperature of the room) before defining those spills that personnel can safely clean up. The procedures should specify (a) cleanup equipment, (b) placement of cleanup equipment for easy access, (c) a plan for alerting personnel, (d) recommendations for avoiding contact with the chemical solution, and (e) evacuation of nonessential personnel, if necessary. The plan should include:

a) the procedures for evacuating personnel in the event of a spill;

   NOTE—Spills have the potential to cause the ambient concentrations of chemicals such as glutaraldehyde to exceed the TLV®-C.

b) the procedures for medically treating persons who might have come into contact with an LCS/HLD or who are overcome by vapor;

c) the procedures for reporting an emergency to appropriate authorities (e.g., the safety officer or health and safety personnel);

d) the procedures for material cleanup, which should specify ready access to cleanup equipment and the appropriate PPE (see Annexes C–G);

   NOTE—An SDS must be accessible to all personnel and must be appropriately filed to maintain OSHA compliance. If an SDS is not currently on file, it can be obtained from the chemical sterilant/high-level disinfectant manufacturer or supplier and is often available on the manufacturer's website.

e) a description of the employee training program and of the method used to verify competency;

f) the recommended and known rates of air exchanges;

g) the potential for the general ventilation system to carry chemical vapor from the site of the spill to other areas in the health care facility, a prescribed course of action to prevent the dispersal of vapor into other areas, and a means of determining the extent to which the vapor has dispersed and when the vapor has cleared sufficiently that personnel can return to the affected area;

h) the recommendations of the chemical sterilant/high-level disinfectant manufacturer for emergency procedures, as found in the SDS or manufacturer's written IFU, or obtained by calling the manufacturer's emergency phone number;

i) a description of the respiratory protection program that outlines the safe use, location, storage, fit-testing, and periodic inspection of emergency-use respirators and the procedures to be used for medical assessment of staff required to use the apparatus; and

NOTE—Personnel entering a spill area for corrective action may need respiratory protection with NIOSH and Mine Safety and Health Administration (MSHA) approved respirators recommended for the specific chemical. Respirators and protective attire such as gloves and aprons must be readily accessible.

j) designation of the persons responsible for supervising the handling of LCS/HLD spills.

Rationale: A well-designed plan of action, with which personnel are thoroughly familiar, will help reduce the potential adverse effects of an LCS/HLD spill.

6.1.2 Liquid chemical sterilants/high-level disinfectant selection and use

The label sterilization claims for most LCSs/HLDs represent the contact conditions necessary for the product to pass the AOAC Sporicidal Activity Test (Horwitz and Latimer, 2010) as a sterilant (i.e., to pass the test with no failures), not necessarily the contact conditions needed to sterilize medical devices (see Annex A). Liquid chemical sterilants/high-level disinfectant are most often used for high-level disinfection of semi critical medical devices or for sterilization of critical or semi critical medical devices that are not amenable to physical sterilization processes (e.g., steam, dry heat, radiation) or gaseous chemical sterilization processes (e.g., EO, hydrogen peroxide, hydrogen peroxide-ozone). An LCS used for high-level disinfection has a shorter contact time than when used for liquid chemical sterilization. Many LCSs and high-level disinfectants (HLD) cleared by the FDA are labelled for use in both liquid processes. However, some HLD solutions require an extended time (e.g., 22–32 hours) to pass the AOAC Sporicidal Test as a sterilant and therefore are labelled only for high-level disinfection and are not indicated for device liquid chemical sterilization.

6.1.2.1 General considerations

Many LCSs/HLDs cleared by the FDA are labeled for use in both sterilization and high-level disinfection, with sterilization requiring a longer contact time than high-level disinfection, but are most often used for high-level disinfection. The appropriate conditions for use of each product are given on the product label for high-level disinfection or sterilization and are determined by the manufacturer. The labeled conditions for high-level disinfection are the time and temperature required to achieve a six-log reduction of an appropriate *Mycobacterium species*, such as *M. bovis* BCG or *M. terrae*, that has resistance characteristics similar to those of the human strain of *M. tuberculosis* on devices, such as endoscopes, under the conditions specified by the manufacturer (See Annex B).

High-level disinfection and liquid chemical sterilization can be achieved with manual or automated processes. Manual high-level disinfection and liquid chemical sterilization is subject to variability and inconsistency. The automated processes utilize Automated Endoscope Reprocessors (AER) or endoscope washer-disinfectors which is equipment designed to deliver the LCS/HLD solution to all parts of the endoscope to achieve effective liquid chemical sterilization/high-level disinfection.

Whether sterilization or high-level disinfection through manual or mechanical process, items processed by liquid chemicals are not packaged. Therefore, processed items should be used promptly and should be handled with special care to avoid contamination before patient use. Alternatively, high-level disinfected items can be stored in a manner that prevents recontamination according to device manufacturer's written IFU and facility policy.

For most FDA-cleared LCSs/HLDs, the labeled contact conditions for sterilization are the contact conditions required to pass the AOAC Sporicidal Activity Test (Horwitz and Latimer, 2010) as a sterilant (i.e., to pass the test with no failures). Some LCS/HLD products have label claims for device sterilization for which the contact conditions are based on simulated-use testing with medical devices such as endoscopes. The list of FDA-cleared LCS/HLD products provides information on how the sterilization and high-level disinfection contact conditions were determined (see FDA website). Due to the inherent limitations of using liquid chemical germicides for sterilizing medical devices, the FDA recommends that processing with LCSs/HLDs be limited to devices that are heat-sensitive and incompatible with other sterilization methods (FDA, 2000b).

6.1.2.1.1 Single-use solutions vs. reusable solutions

Some LCS/HLD products are designed for single use; others are designed for reuse. The user should read the labeling to determine how to use the product correctly. Only those LCSs/HLDs labeled for reuse should be reused; the specified use-life and expiration date must not be exceeded. A reuse claim on the product label indicates that the manufacturer has documented that, after simulated reuse of the LCS/HLD for the period of time specified, the concentration of the

product active ingredient(s) remains above the MRC or MEC that has been shown to be effective against bacterial spores and mycobacteria. However, LCS/HLD solutions should not be used if the concentration of active ingredient falls below the product's MRC or MEC, regardless of the number of days that the solution has been in use.

6.1.3 Consideration for selection

6.1.3.1 General considerations

LCSs/HLDs are commonly provided as formulations containing one or more microbicidal agents designated as active ingredients and other ingredients designated as inert. Although inert ingredients are not considered to have a microbicidal function, they can affect the sterilization or disinfection process. Inert ingredients include anticorrosive agents to improve the materials compatibility of the sterilant, detergents to increase wettability and soil removal, and buffers or activating agents to adjust the pH of the solution and ensure the potency of the active ingredient. Many products must be activated by combining the active and inert ingredients at the time of use. The user must ensure that the active and inert ingredients are thoroughly mixed. Some products are available as ready-to-use solutions; others are available as concentrates that must be diluted to the proper use concentration.

6.1.3.2 Process parameters

Typically, after being thoroughly cleaned, an item is immersed in the LCS/HLD for a defined period of time at a set temperature; these parameters are determined by the manufacturer and indicated within the manufacturer's written IFU. Some products are intended for manual use in trays or other containers; it is necessary for the user to ensure that the sterilant concentration, exposure time, and exposure temperature are correct and to remove residue from the sterilized or high-level disinfected items using an aseptic rinse or undergoing a thorough residue removal process.

Some LCSs/HLDs are provided for use in automated systems that circulate the chemical around and through the items to be processed. An automated reprocessor may control the contact time, but it is not necessarily capable of maintaining the specified solution temperature of the processing chamber during the disinfection period. Some systems also provide rinsing with filtered water. Many different automated systems are currently on the market and a thorough review of their advantages and limitations should be performed by the user when selecting processing equipment. The user may want to consider this information in selecting process equipment.

6.1.3.3 Water quality for dilution and rinsing

When preparing use solutions (i.e., activated, diluted, or ready-to-use), the user should follow the LCS/HLD manufacturer's written IFU concerning the quality of the water to be used in the formulation. For some LCSs/HLDs, it might be acceptable to use utility water; for other solutions, softened water or other treated water may be needed. If a water treatment process is used, it should be monitored to ensure that the appropriate water quality is achieved.

All items processed with LCSs/HLDs should be thoroughly rinsed, using fresh water with each rinse, with strict adherence to the manufacturer's written IFU regarding the quantity of rinsing solution needed to reduce chemical residues. The microbial quality of the solution used to rinse items processed with LCSs/HLDs is an important aspect of the sterilization or high-level disinfection process. Users should follow the recommendations of the device manufacturer and the sterilant manufacturer for the microbial quality of the solution to be used for rinsing (see ANSI/AAMI ST108:2023). If the device is not rinsed with sterile water, the sterility of the device will be compromised. For rinsing post high-level disinfection, the water quality should be of a level to not reintroduce microorganisms to the device. For example, sterilized Critical Water (see TIR34) may be required to prevent re-contamination. For further information pertaining to the microbial quality of rinse water: see ANSI/AAMI ST108:2023, ASTM D1193, Block and Schwartzbrod (1989); Blosse, Boulter, and Sundaram (1998); Cooke, et al. (1998); Eaton, et al. (2012); EPA (2012); Floyd and Sharp (1977); HIMA (1982), Howard and Duberstein (1980); Humphreys and Lee (1999); Hurst (1991); Levy (2001); Muscarella (2002b); Parnell and Wilcox (2001); Richards, et al. (2002); and USP (2012).

6.1.3.4 Containers used for solution storage

The user should follow the LCS/HLD manufacturer's written IFU concerning the type of container (i.e., materials composition) that should be used in preparing the solution to ensure that there is no interaction between the container and the active or inert ingredients of the LCS/HLD. In addition, the container used to store the solution of an LCS/HLD should not interact with its active or inert ingredients. Containers of LCS/HLD use solutions should be covered to

prevent personnel exposure to fumes, evaporation (and thus a change in concentration) of the LCS/HLD, and environmental fallout (e.g., lint, dust) into the solution. The container must be labeled with the contents description and expiration date.

6.1.3.5 Monitoring of LCS/HLD

The concentration of the active ingredient in solutions should be monitored (ASGE and SHEA, 2011). The LCS/HLD manufacturer's written IFU should be followed. Most manufacturers of LCSs/HLDs provide solution test strips or chemical monitoring devices for use with their products. Biological indicators and traditional chemical indicators (e.g., CIs as defined in ANSI/AAMI/ISO 11140) are generally not available or labeled for use to monitor the effectiveness of LCSs/HLDs; however, a spore test strip has been labeled for use in one commercially available LCS processing system. Users should follow the manufacturer's written IFU for all FDA-cleared indicators recommended by the LCS/HLD manufacturer—or cleared by the FDA as substantially equivalent—for use with the LCS/HLD. The results of monitoring should be documented.

6.2 LCS/HLD types

Products containing the following active ingredients are marketed under various brand names and in various concentrations:

a) glutaraldehyde;

b) glutaraldehyde with phenol-phenate;

c) hydrogen peroxide;

d) ortho-phthalaldehyde (high-level disinfection only);

e) combinations of peracetic acid and hydrogen peroxide;

f) sodium hypochlorite–hypochlorous acid (high-level disinfection only);

g) sonicated hydrogen peroxide mist (high-level disinfection only); and

h) chlorine dioxide foam (high-level disinfection only)

A few LCS/HLD products have label claims for device sterilization with contact conditions that are based on simulated-use testing with medical devices such as endoscopes, in addition to passing the AOAC Sporicidal Test. The LCS/HLD products that have been cleared for market by the FDA are listed at https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and.

6.3 Manufacturer’s instructions/IFU

6.3.1 LCS/HLD manufacturer’s written IFU

Personnel should follow the LCS/HLD manufacturer’s written IFU, which should include:

a) instructions for the safe and effective use of the LCS/HLD;

b) identification of materials, devices, or soaking or storage trays known to be incompatible with the LCS/HLD;

c) notification of any changes in the LCS/HLD that could affect its compatibility with device materials; and

d) instructions for spill containment and clean up.

Rationale: LCSs/HLDs vary in their conditions for use, mode of action, and potential toxicity. The LCS/HLD manufacturer's written IFU describe the processing procedures and parameters that have been validated by the manufacturer and explain important safety precautions. In addition, labeling instructions for some products identify specific items or device materials that can be effectively sterilized or high-level disinfected and/or items for which the processing method is not suitable. Using nonvalidated processing conditions can jeopardize the effectiveness of the liquid chemical sterilization or high-level disinfection process or the performance of the medical device. For example, a sterilant concentration lower than that recommended by the manufacturer could result in process failures, whereas a concentration higher than that recommended could damage the item being processed.

An important aspect of the safety and performance of an LCS/HLD is its compatibility with the materials and devices that it is intended to sterilize or disinfect. The LCS/HLD should not alter the material composition in such a way that the device will not be safe or will not function as intended. Materials such as metals, alloys, and plastics and their polymers can be adversely affected by exposure to certain chemicals and stresses. Some materials might become brittle and crack. Others, such as certain polymeric adhesives, might dissolve. Still others might swell or become distorted. Any of those effects can cause the device to malfunction or even fail.

6.3.2 Automated processing equipment manufacturer's written IFU

Personnel should follow the LCS/HLD equipment manufacturer's written IFU, which should include:

a) information on a cleaning cycle including the type of detergent that should be used, if present, and whether or not the cleaning cycle is intended to supplement manual cleaning or to replace all or part of the device manufacturer's written procedures for manual cleaning;

b) instruction on how to load or unload the equipment properly, a description of the cycle(s) including how to use specific adaptors for various endoscopes or other lumened devices, if needed, information on how these adaptors can be differentiated and processed, and information on how to identify whether the adaptors are working properly;

c) a description of the water quality necessary for dilution of cleaning agents and LCS/HLD processes;

d) the required water temperature range;

e) utility requirements for routine use;

f) a description of the water quality necessary for rinsing of devices after processing;

g) instructions for filter replacement (if applicable);

h) instructions for alcohol rinse (if applicable);

i) instructions for cleaning and maintaining the equipment; and

j) instructions for spill containment and clean up.

6.4 Maintenance

The equipment manufacturer must provide written instructions for routine care and preventive maintenance. These instructions should provide all information necessary to carry out the procedures recommended and should specify the frequency with which these procedures should be performed. Specific rather than general information should be provided for each equipment model. The manufacturer's instructions must be kept by the user for as long as the equipment is in service.

The equipment should be cleaned and inspected daily according to the manufacturer's written instructions. Weekly or other prescribed inspection and cleaning should be performed as specified in the manufacturer's written instructions.

Maintenance should be carried out by a qualified individual. Particular attention should be given to the inspection, maintenance, and replacement of components subject to wear. Simple charts showing the locations and replacement dates of components will show trends in deterioration and provide the framework of a preventive maintenance program.

The maintenance program may be in-house or contracted with the equipment manufacturer or other qualified service company. Preventive maintenance and repair records should be retained.

Follow the sterilizer manufacturers' instructions for scheduled maintenance. Certain maintenance tasks that require special tools or calibration equipment not available in the health care facility should be performed by the manufacturer, the manufacturer's representative, or another qualified service facility.

A maintenance record should be kept for each equipment. This record should be maintained by the supervisor responsible for the equipment, by the hospital engineering staff, by the service person or organization that performed the servicing, and by whomever else is deemed appropriate by the health care facility. Included in this maintenance record should be sufficient information to identify the equipment and to establish a continuous history of all scheduled and unscheduled service. At least the following information should be recorded:

a) the date of service;

b) the model and serial number;

c) the location of the equipment (hospital identification, if applicable);

d) the name of the individual from the health care facility who requested and authorized the service;

e) the reason for the service request;

f) a description of the service performed;

g) the types and quantities of parts replaced;

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

i) the date the work was completed; and

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

These records must be maintained for the length of time specified by regulatory agencies (e.g., state health departments).

6.5 Processing and post-processing considerations after liquid chemical disinfection or high-level disinfection

6.5.1 Manual high-level disinfection and liquid chemical sterilization processes

Consult the instrument manufacturer's written IFU to determine the compatibility of the device with the selected LCS/HLD solution. To ensure safety and efficacy, the user should observe the following:

a) use only those LCS/HLD solutions recommended by the instrument manufacturer or that have been validated for use for both efficacy and compatibility and cleared by the FDA;

b) use a timing device to assure correct exposure time (AORN, 2022). Use a clean, dry container;

c) while wearing PPE recommended in the manufacturer's written IFU, prepare the LCS/HLD product according to the manufacturer's written IFU;

d) if an immersion system is used, devices should be thoroughly cleaned, rinsed and excess moisture should be removed before they are immersed in the solution to avoid adding debris to the solution or diluting the solution, both of which can shorten the efficacy period;

e) before immersion, check the expiration date of the solution. Completely immerse the device in the LCS/HLD solution to ensure that all surfaces are covered by the solution and that all appropriate lumens have been filled

with the LCS/HLD, as recommended. A channel irrigation device or syringe might be needed to fill all lumens with the LCS/HLD;

f) for immersion processes, use a solution test strip or chemical monitoring device to test the concentration of the active ingredients before each use. Only those solution test strips or chemical monitoring devices that have been cleared by the FDA for that LCS/HLD should be used. Quality control checks of the solution test strips, or chemical monitoring devices should be performed according to the manufacturer's written IFU;

g) when the concentration of the active ingredients falls below the MRC or MEC, discontinue use of the solution;

h) ensure that the solution is at the minimum required temperature, as specified in the solution manufacturer's IFU. Document the temperature. Do not use a solution that is above or below the required temperature range. Use a calibrated thermometer to ensure that the soaking temperature meets that specified on the HLD label (AORN, 2022);

i) ensure that exposure to chemical solutions and vapors is kept to a minimum, and below OSHA and ACGIH® occupational exposure limits;

j) keep solutions covered to prevent evaporation;

k) solutions that evaporate or drain below the soak level may require additional solution to facilitate complete immersion of the device. Before adding solution, first consult the LCS/HLD manufacturer's IFU to ensure that adding solution is permitted. The solution cannot be used beyond the original soaking solution expiration date (use life). Before being used, the solution must be tested for MRC or MEC;

l) do not use solutions beyond the reuse period indicated on the label even if the concentration of the active ingredients is at or above the MRC or MEC. An LCS/HLD product might be labeled for multiple-day use or (if it is a concentrate) for one-time use;

m) do not use LCS/HLD solutions beyond their shelf life;

n) store unopened solutions in a cool, well ventilated area at the temperature recommended by the manufacturer; and

o) dispose of LCS/HLD solutions and their containers in accordance with state and local regulations (e.g., neutralization of the product prior to disposal in the sewer system).

Items that have completed manual high-level disinfection or liquid chemical sterilization and are intended for use in a semi-critical application are not packaged and are to be thoroughly rinsed or to undergo a thorough residue removal process, dried internally and externally, and stored in accordance with Section 11.

6.5.1.1 Manual rinsing

Follow the endoscope and LCS/HLD solution manufacturers' written IFU on the quantity and quality of rinse water as well as the number of rinses and the time required for each rinse to reduce chemical residues to a safe level. Each rinse should be performed using fresh water. To prevent recontamination of the item, the container or sink used to perform the rinse should be clean and should not be the same container or sink that was used to clean or disinfect the endoscope. The microbial quality of the water used to rinse endoscopes is important (see ANSI/AAMI ST108:2023). Users should follow the endoscope and LCS/HLD solution manufacturers' written IFU for the required microbial quality of the water to be used for rinsing (also see ANSI/AAMI ST108:2023). The specific procedure for rinsing is as follows:

a) Don fresh PPE, including gloves, skin and eye protection, fluid-resistant masks, and fluid-resistant shoe covers.

b) Thoroughly rinse all surfaces and channels of the endoscope and its removed components according to the endoscope and LCS/HLD solution manufacturers' written IFU in order to remove all traces of the disinfectant.

c) Use critical water for the final rinse (see ANSI/AAMI ST108:2023) unless sterile water is specified by the manufacturer's written IFU. Follow the device manufacturer's written IFU for the specified rinse water quality.

Rationale: Following manufacturer's rinsing instructions prevents potential patient exposure and skin and mucous membrane injury from chemical residues. Use of sterile or critical water for the final rinse reduces the risk of contamination by waterborne microorganisms.

6.5.2 Considerations after processing

6.5.2.1 Removing devices from HLD equipment and delivery to point of use

High-level disinfected items should be protected from contamination until the item is delivered to the point of use. Disinfected items should be removed from the HLD equipment in a manner that protects the disinfected item from recontamination. The equipment manufacturer's written IFU should be followed. High-level disinfected items should be transported to the point of use using a technique that does not result in recontamination of the medical device (e.g., aseptic technique). Containerized items intended for use on a sterile field should never be placed on a nonsterile surface. The high-level disinfected items should be removed from the containment device at the point of use by a trained person.

It is recommended that high-level disinfected devices be used as soon as possible or be stored in a manner that prevents recontamination according to device manufacturer's written IFU and facility policy. If storage is recommended under some conditions, the device manufacturer's written IFU should be strictly followed. See AAMI ST91 for detailed information on storage of high-level disinfected flexible or semi-rigid endoscopes.

6.5.2.2 Drying after liquid chemical sterilization or high-level disinfection

Effective drying of items can reduce the risk of increasing (or accelerating) proliferation following liquid chemical sterilization/high-level disinfection (e.g., recontamination of the device after liquid chemical sterilization or high-level disinfection) (Kovaleva, 2017; Ofstead, 2016; Ofstead, 2018; Perumpail, 2019; Saliou, 2015). Certain waterborne microorganisms, such as Pseudomonas aeruginosa, can pose an infection risk to a portion of the endoscopy patient population, especially those undergoing a bronchoscopy procedure or endoscopic retrograde cholangiopancreatography (ERCP) procedure (Kovaleva, 2013). Further, the presence of such microorganisms in conjunction with retained moisture can lead to the development of biofilms and further patient risk. This is a particular risk when tap water is used to rinse the endoscope following the antimicrobial process. As part of the facility water management plan, periodic microbial assessment of the AER and processing equipment should be considered to identify water contaminants or contaminated equipment which may contribute to recontamination of the device after high-level disinfection (Ofstead, 2016). Periodic microbial assessment of the water used for final rinse should be considered to identify any contaminants which can contribute to recontamination of the device after liquid chemical sterilization or high-level disinfection (Ofstead, 2018; Seidelman, 2019; Ofstead, 2016).

Rationale: In studies where endoscopes harbored bacteria, including waterborne pathogens, following high-level disinfection despite adherence to processing guidelines, water used to rinse disinfected endoscopes was implicated (Ofstead, 2018; Seidelman, 2019; Ofstead, 2016). Similar rationale also applies to devices processed by liquid chemical sterilization.

Unless otherwise directed by the instrument manufacturer, drying of lumens is accomplished by flowing instrument air or HEPA-filtered air through the lumens for a specified period of time and pressure according to the instruments manufacturer's written IFU. Research has demonstrated that a minimum 10-minute dry time is effective in drying the channels of flexible endoscopes and should be implemented (Alfa, 1991; Ofstead, 2018; Barakat, 2019) (see ST91:2021). The exterior and removable parts may be dried using unused, clean, or sterile non-linting cloths. Complete drying to thoroughly remove all residual fluid after high-level disinfection is necessary to prevent the growth of gram-negative bacteria and other potential pathogens.

Use pressure-regulated instrument air or HEPA-filtered air to dry the channels in accordance with the manufacturer's written IFU (Ofstead, 2018; Barakat, 2019). An assortment of adapters can be needed to accommodate various size lumens, depending on the configuration of the drying device. The use of syringes or a handheld compressed air gun to dry the channels is not recommended.

1) Refer to the instrument's manufacturer's written IFU for guidance on correlating the force of air pressure to lumen size and select the air pressure accordingly.

2) Use the instrument air until no visible signs of moisture remain (or as recommended by the endoscope manufacturer).

Ensure that crevices are dry. Pressure-regulated instrument air or HEPA-filtered air may be directed at crevices to facilitate drying of these hard to reach areas. To reduce the risk of trapping liquid inside the endoscope, do not attach accessories to the endoscope during storage.

Instruments should be dried promptly after every reprocessing cycle. This means that a device should be dried whether it is intended for immediate patient use or for storage (Rutala and Weber, 2016; Petersen et al., 2017), with the exception of liquid chemically sterilized items such as endoscopes that are used immediately.

6.5.2.3 Labelling of LCS/HLD items after processing

Identification of patient-ready devices is important because it distinguishes disinfected/sterilized devices from non-patient ready medical devices.

6.5.2.4 Storage post Liquid chemical sterilization or high-level disinfection

After items have gone through liquid chemical sterilization/high-level disinfection and are thoroughly dried, they should be placed in a clean container, package or if a large item such as a flexible endoscope in a clean storage cabinet (See ANSI/AAMI ST91 for storage of endoscopes).

Items that have undergone liquid chemical sterilization/high-level disinfection are to be stored dry in an area that is clean, well-ventilated, and dust-free in order to keep the item dry and prevent exposure to potentially hazardous microbial contamination. They should be stored in a manner that will protect them from damage or contamination and in accordance with the item and storage cabinet manufacturers' written IFU.

Before storage, the lumens of the liquid chemical sterilization/high-level disinfection item should be dry to help prevent bacterial growth and the formation of biofilm. If a drying cabinet is not used, dryness can be checked by using dryness indicators. For endoscope storage see ANSI/AAMI ST91.

All critical devices (e.g., ureteroscopes) not used immediately should be processed again before use. Items should not be left in an automatic processor for extended amounts of time (e.g., more than one hour), otherwise the item should be reprocessed through high level disinfection/liquid chemical sterilization process prior to storage or immediate clinical use.

Storage should be situated in a secure location such as in the clean workroom or sterile storage. Locating the storage cabinet in the clean workroom or in a sterile storage room helps prevent contamination of processed items. Storage cabinets should have doors and be located at least 3 ft (0.9 m) from any sink. Ensuring that storage cabinets have doors and are separated from sinks by at least 3 ft (0.9 m) provides protection and reduces the potential for processed items to be contaminated by water droplets (AORN, 2018e). Cabinets should remain closed to protect the integrity of the disinfected endoscope.

The storage area and storage containers shall be visually inspected to ensure cleanliness when the item is placed into storage and also when the item is removed for patient use. An item that is removed from a visibly dirty cabinet or container or is not dry shall be processed before use (SGNA, 2018). Storage cabinets and containers should be cleaned in accordance with the manufacturer's IFU, or at least weekly and when visibly soiled.

7 Safe and effective use of gaseous chemical sterilizers

7.1 General considerations

All chemical sterilants have in common the ability to kill bacterial spores, but gaseous chemical sterilization processes and processes that use LCSs/HLDs are validated by different methods.

Gaseous/vaporized chemical sterilants are used in a sterilizer under defined cycle conditions. Medical devices undergoing gaseous chemical sterilization can be packaged in a sterile barrier to maintain product sterility. Refer to the packaging system IFU for the validated duration of sterility maintenance.

All chemical sterilants have in common the ability to kill bacterial spores.

7.1.1 Safety considerations

The safety and performance characteristics of a gaseous chemical sterilant can be categorized in terms of its (a) effectiveness in killing microorganisms under the prescribed conditions of use, (b) effects on the materials and devices it is intended to sterilize or disinfect, and (c) toxicity and potential to harm personnel, patients and the environment.

NOTE The FDA clearance process for gaseous chemical sterilization systems addresses all these issues

Certain general principles apply to the safe and effective use of any gaseous chemical sterilization process. This section covers general safety and efficacy considerations in the use of chemical sterilants. More detail information on the characteristics, safety requirements, and use of specific chemical sterilants is provided in Annexes H–J, and S.

7.1.1.1 General considerations

All personnel must be advised of the hazards associated with the chemicals they work with by their employer, and they should be thoroughly trained in appropriate safety procedures, both general safety procedures and, where applicable, those that pertain to specific hazards that could be encountered. OSHA requires that SDSs for all hazardous chemicals be maintained on site and be readily accessible during each work shift to employees when they are in the work areas. Both employee and employer compliance with the OSHA Hazard Communication Standard (29 CFR 1910.1200) must be ensured. In particular, compliance with OSHA's Enforcement Procedure for Occupational Exposure to Formaldehyde (OSHA, 1990) must be enforced.

In general, personnel should avoid direct contact with chemical sterilants. When using chemical sterilant, personnel should wear PPE, as appropriate, to prevent skin and eye contact with the sterilant. Some chemical sterilants are explosive and/or flammable. Special storage conditions and use precautions are required for such products and must be specified in the SDS. To prevent patient exposure to chemical sterilant residues, personnel should carefully follow manufacturer's instructions for use. Specific safety considerations applying to particular chemical sterilants are discussed in Annexes H–J, and S.

7.1.1.2 Emergency procedures

7.1.1.2.1 Spill containment team

A chemical sterilant spill containment "response team" should be established. The response team should include a representative from the safety committee, a physician (ideally an occupational health physician), the unit supervisor, and any other personnel deemed appropriate. This response team should be responsible for developing and executing procedures for chemical sterilant spills in accordance with the sterilant manufacturer's written IFU and facility requirements.

Rationale: For rapid, efficient, and effective response to chemical sterilant spills, it is important that specific individuals be assigned responsibility for developing and implementing procedures for handling the spills. The composition of the response team should reflect all expertise relevant to the control of spills and the resulting vapor.

7.1.1.2.2 Spill containment plan

The response team should prepare a written plan for containment of chemical sterilant spills. The team should consider the concentration of the chemical and the design of the facility (such as the type of ventilation, the air turnover rate, and the size and temperature of the room) before defining those spills that personnel can safely clean up. The plan should include:

a) the procedures for evacuating personnel in the event of a spill and recommendations for avoiding contact with the chemical;

   NOTE—Spills have the potential to cause the ambient concentrations of chemicals to exceed the TLV®-C.

b) the procedures for medically treating persons who might have come into contact with an chemical sterilant or who are overcome by vapor;

c) the procedures for reporting an emergency to appropriate authorities (e.g., the safety officer or health and safety personnel);

d) the procedures for material cleanup, which should specify ready access to cleanup equipment and the appropriate PPE (see Annexes H–J, and S);

NOTE—An SDS must be accessible to all personnel and must be appropriately filed to maintain OSHA compliance. If an SDS is not currently on file, it can be obtained from the chemical sterilant manufacturer or supplier and is often available on the manufacturer's website.

e) a description of the employee training program and of the method used to verify competency;

f) the recommended and known rates of air exchanges;

g) the potential for the general ventilation system to carry chemical vapor from the site of the spill to other areas in the health care facility, a prescribed course of action to prevent the dispersal of vapor into other areas, and a means of determining the extent to which the vapor has dispersed and when the vapor has cleared sufficiently that personnel can return to the affected area;

h) the recommendations of the chemical sterilant manufacturer for emergency procedures, as found in the SDS or manufacturer's written IFU, or obtained by calling the manufacturer's emergency phone number;

i) a description of the respiratory protection program that outlines the safe use, location, storage, fit-testing, and periodic inspection of emergency-use respirators and the procedures to be used for medical assessment of staff required to use the apparatus; and

NOTE—Personnel entering a spill area for corrective action may need respiratory protection with NIOSH and Mine Safety and Health Administration (MSHA) approved respirators recommended for the specific chemical. Respirators and protective attire such as gloves and aprons must be readily accessible.

j) designation of the persons responsible for supervising the handling of chemical sterilant spills.

Rationale: A well-designed plan of action, with which personnel are thoroughly familiar, will help reduce the potential adverse effects of an chemical sterilant spill.

7.2 Gaseous chemical sterilization types

Chemical sterilants utilizing the following active ingredients are marketed under various brand names and in various sterilization systems:

a) low termperature vaporized hydrogen peroxide;

b) ethylene oxide;

c) chemical vapor sterilant using alcohol and formaldehyde; and

d) hydrogen peroxide-ozone.

The gaseous chemical sterilization processes and the corresponding sterilant for that system have been cleared for market by the FDA. Annexes H, I, J, and S provide specific information on the safe and effective use of currently available gaseous chemical sterilization processes and corresponding sterilants.

7.3 Manufacturer’s Instructions/IFU

Personnel should follow the gaseous chemical sterilization equipment manufacturer’s written IFU, which should include:

a) complete information for site and installation planning, including required building system utilities, service area requirements, and types of materials required;

b) comprehensive information to ensure safe and effective operation of the equipment, including recommended sterilizer settings, cycle selection, safety precautions to be taken during routine use, and directions for safely terminating a cycle in progress;

c) instructions for cleaning and maintaining the sterilizer;

d) instructions on how to load and unload the equipment properly, including;

e) limitations on acceptable load temperature;

f) instructions for spill containment and cleanup;

g) methods to monitor the efficacy of the process (e.g., chemical and biological monitoring indicators); and

NOTE—The sterilizer equipment manufacturer is only required to describe one method for monitoring in the IFU. Other FDA cleared monitoring products may be commercially available and are accepted methods for monitoring gaseous chemical sterilization equipment.

h) maximum weight limit for each load for each cycle type.

7.4 Sterilizer Maintenance

7.4.1 Manufacturer's instructions

The equipment manufacturer must provide written instructions for routine care and preventive maintenance. These instructions should provide all information necessary to carry out the procedures and should specify the frequency with which these procedures should be performed. Specific rather than general information should be provided for each equipment model. The manufacturer's instructions must be kept by the user for as long as the equipment is in service.

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

7.4.2 Routine care of sterilizers

Sterilizers should be cleaned and inspected daily according to the manufacturer's written instructions. Examples of items requiring daily care and cleaning are recording charts and pens, door gaskets, the chamber drain screen, the internal chamber, and external surfaces. Before each load, the gasket seals of sterilizer should be inspected for cracks, tears, debris, and other foreign substances. Weekly or other prescribed inspection and cleaning should be performed as specified in the manufacturer's written instructions.

Rationale: Periodic inspection and cleaning reduce the frequency of equipment malfunction and the risk of accidental contamination of sterile items. Gaseous sterilants can escape from the equipment into the workplace through faulty or poorly maintained gaskets, valves, and fittings.

7.4.3 Preventive maintenance

7.4.3.1 General considerations

Maintenance should be carried out by a qualified individual. Particular attention should be given to the inspection, maintenance, and replacement of components subject to wear, such as recording devices (as applicable), filters, drain pipes, valves, and door gaskets. Simple charts showing the locations and replacement dates of components will show trends in deterioration and provide the framework of a preventive maintenance program. The maintenance program may be in-house or contracted with the equipment manufacturer or other qualified service company. Preventive maintenance and repair records should be retained.

Rationale: Malfunction of critical components can cause sterilization failures or failures of the sterilization parameter recording system.

7.4.3.2 Scheduled maintenance

Follow the sterilizer manufacturers' instructions for scheduled maintenance, e.g., for lubricating and replacing expandable parts and inspection of valves. Certain maintenance tasks that require special tools or calibration equipment not available in the health care facility should be performed by the manufacturer, the manufacturer's representative, or another qualified service facility. The manufacturer's instructions should be followed.

Rationale: Gaseous sterilant can escape from the equipment into the work area through faulty or poorly maintained gaskets, valves, and fittings. Proper operation of vent hood (e.g. with EO gas) helps ensure adequate ventilation.

7.4.3.3 Calibration

Periodic calibration should be performed as specified in the manufacturer's instruction manual, and the results should be documented. Examples of items requiring calibration are pressure and temperature gauges, humidity control apparatus (if applicable), timers, controls, and recording devices. The instruments used for calibration should be traceable to the primary standards of the National Institute for Standards and Technology. In the event of a sterilizer malfunction or the repair or replacement of any component affecting sterilizer performance, appropriate recalibration should be performed. Calibration may be performed by the manufacturer, the manufacturer's representative, the health care facility engineering staff, or contract service personnel. Those performing this service should have sufficient training to understand the operation and calibration of the specific sterilizer type.

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

7.4.3.4 Emission control systems

The reactive components of emission control systems (e.g., catalytic cells, acid baths) should be replaced or replenished regularly, depending on the results of periodic monitoring of emission control efficiency.

Rationale: The effective life of the chemical components of emission control systems is finite; other ambient chemicals can also react with the active elements. Therefore, it is important to monitor emission control efficiency over time to maintain the expected performance. Catastrophic failure of emission control systems is unlikely, but because performance efficiency degrades over time, the planned replenishment (or replacement) of the active components is required.

7.4.3.5 Record keeping

A maintenance record should be kept for each sterilizer, and emission control system if used. This record should be available to the Sterile Processing leadership team responsible for the equipment and records maintained by the health care facility engineering staff, by the service person or organization that performed the servicing, and by whomever else is deemed appropriate by the health care facility. Included in this maintenance record should be sufficient information to identify the equipment and to establish a continuous history of all scheduled and unscheduled service. At least the following information should be recorded:

a) the date of service;

b) the model and serial number of the sterilizer, and emission control system (if applicable);

c) the name of the individual from the health care facility who requested and authorized the service;

d) the reason for the service request;

e) a description of the service performed (e.g., calibration, repair);

f) the types and quantities of parts replaced;

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

h) the date the work was completed; and

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

These records must be maintained for the length of time specified by regulatory agencies (e.g., state health departments).

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

7.5 Packaging, preparation and sterilization

7.5.1 Selection of sterile barrier systems

When selecting a sterile barrier system, personnel should obtain the current written IFU and have it readily accessible. Sterile barrier systems used in health care facilities are medical devices that require FDA clearance The sterilization method and cycle shall be documented in the indications for use of the sterile barrier system.

A sterile barrier system should:

a) allow air removal to permit sterilant penetration of the package contents;

b) provide a barrier to microorganisms during sterilization processing, handling, distribution, transport, and storage;

c) resist tearing or puncture;

d) allow a method of sealing that results in a complete seal that is tamper-evident and provides seal integrity;

e) maintain protection for the sterile contents during storage and transportation to the point of use;

f) allow for aseptic presentation;

g) be free of toxic components and nonfast dyes;

h) be nonlinting; and

i) be compatible with the intended methods of sterilization, sterilization parameters, and the devices to be sterilized.

Packaging policy and procedures and packaging techniques should be based on the sterile barrier system's written IFU and on facility policy. See Table 2 for typically compatible packaging by low temperature sterilization method.

Table 2—Packaging for gaseous sterilization

Sterilization method	Packaging
Ethylene oxide	Textiles, nonwovens, polypropylene wraps, paper–plastic pouches and rolls, Tyvek® (all-plastic) pouches, polyethylene, most rigid sterilization containers
Hydrogen peroxide–ozone	Sterilization pouches made of nonwoven polyethylene with polyester/low-density polyethylene and transparent film, aluminum containers using disposable polypropylene filters recommended for use with vaporized hydrogen peroxide sterilization processes, nonwoven polypropylene wraps, Tyvek® (all-plastic) pouches and metal and plastic trays
Vaporized hydrogen peroxide	Sterilization pouches made of nonwoven polyethylene with polyester/low-density polyethylene and transparent film, aluminum containers using disposable polypropylene filters recommended for use with vaporized hydrogen peroxide sterilization processes, nonwoven polypropylene wraps, Tyvek® (all-plastic) pouches and metal and plastic trays

NOTE Cellulosic materials (e.g., paper, cotton) should not be used in in hydrogen peroxide based sterilizers

7.5.2 Rigid container inspection

A rigid sterilization container system should be inspected before use to ensure that:

a) the latching mechanism or closure will remain secure during the sterilization process;

b) the sealing or mating surfaces or edges of the container system and lid are not dented or chipped;

c) filter retention mechanisms and fasteners such as screws and rivets are secure and are not distorted or burred, the securing mechanism functions properly, and the filter medium is not damaged;

d) the gaskets are pliable, securely fastened, and without breaks or cuts; and

e) the valves work freely and are not broken, cut, chipped, or dented.

Only filters recommended by the rigid sterilization container manufacturer should be used.

The rigid container system should be cleaned after each use in accordance with ANSI/AAMI ST79:2017, 7.5.2.2.

Rationale: To ensure the operating efficiency of a rigid sterilization container system, a thorough and clearly delineated inspection procedure is necessary. Rigid sterilization container systems vary in their mechanics, their specific performance characteristics, and their suitability for particular sterilization cycles. A change in the filter material (e.g., a change in brand) can affect air removal or sterilant penetration and evacuation in a container system. Filter material cannot be tested easily by personnel. There is no nationally recognized referee test for the microbial barrier performance of filters. However, as with any sterile barrier or packaging system, inspection for integrity is part of a good quality assurance program.

7.5.3 Post-process handling of devices processed with gaseous chemical sterilants

Packaged medical devices should be handled carefully. Care should be taken to avoid dragging, sliding, crushing, bending, compressing, or puncturing the packaging or otherwise compromising the sterility of the contents during handling and storage. Packaging should be thoroughly inspected visually for integrity and labeling before an item is issued. Sterile items should be transported in a covered or enclosed cart with a solid bottom shelf. Basic aseptic techniques should be used when delivering the medical device to the sterile field.

Rationale: Maintaining package sterility is event-related so packages should be handled carefully to ensure that they are delivered sterile to the patient.

8 Quality control

8.1 General considerations

This section covers product identification and traceability, documentation and record-keeping, monitoring of chemical sterilization and high-level disinfection processes, product testing, product recalls, and quality process improvement.

NOTE Quality control is not limited to product and process monitoring. It includes supervision of personnel performance and work practices and ongoing verification of adherence to established policies and procedures.

8.2 Monitoring of mechanical cleaning equipment

This section addresses washer–disinfectors, automated endoscope reprocessor (AERs), ultrasonic cleaners, and other mechanical cleaning equipment. Personnel should perform verification testing on all mechanical cleaning equipment as part of the overall quality assurance program. Methods of verification include:

a) directly testing individual medical devices for residual soils (e.g., adenosine triphosphate [ATP], protein, hemoglobin) after cleaning;

b) employing a cleaning verification test device that is a consistent and repeatable challenge to the cleaning effectiveness of the equipment; and

c) monitoring critical parameters to evaluate the performance of the mechanical cleaning equipment.

Mechanical cleaning equipment should be tested upon installation, each day that it is used, and after major repairs.

When evaluating or changing to a new type of cleaning solution and after all major repairs, all cycles used should be tested to ensure that the cleaning solution and cleaning action are effective. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment. Examples include a software upgrade or the replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, ultrasonic generators, or computer controls.

Monitoring and verification of cleaning processes should be documented. Some mechanical washers have digital readouts and cycle printouts that should be reviewed for each cycle and initialed by the operator to indicate an acceptable cycle. Cycle printouts or cycle recording devices should be located on the clean side of pass-through mechanical washers.

Key performance outcomes include clean surfaces and adequate fluid flow in equipment that has adaptors for lumened devices.

Rationale: To ensure that mechanical cleaning equipment is working properly and according to the manufacturer's specifications, routine monitoring is required. Testing the equipment upon installation, during routine use, and after repairs allow the user to verify its continued effectiveness (AORN, 2017a). Reviewing and initialing the readouts and cycle printouts confirms that the mechanical equipment completed all the required phases of the cycle. Directly testing individual items provides valuable information on the effectiveness of the manual or mechanical cleaning processes, especially on difficult or challenging to clean items and may help to identify degradation of the device.

8.3 Verification and monitoring of the cleaning process

8.3.1 General considerations

Satisfactory cleaning processes should reduce clinical soil to a level that allows the subsequent disinfection or sterilization process to be effective. Verification involves both visual inspection and the use of rapid cleaning verification indicators. Both are important as part of a comprehensive quality control program.

Visual inspection is greatly enhanced with the use of magnification and illumination. Visual inspection can include the use of borescopes to inspect the inner channels / lumens present in many flexible endoscopes (see Annex E of AAMI ST91:2021)

Visual inspection alone is not able to determine if the reduction in clinical soil is sufficient for an effective cleaning result but is critical to determine any defects or potential damage to the device.

Cleaning verification indicators provide an independent, objective assessment of the cleaning process. Benchmarks can be determined by the facility based on guidelines, independent research or information provided by the product manufacturer. Cleaning verification is also used for surgical instruments and environmental surfaces to assess the cleanliness of the item.

Proper rinsing in accordance with the manufacturers written IFU can help avoid potential residual detergent/ disinfectant interference.

There are various markers that can be detected in clinical soil that can provide important information to the user, identify inadequate cleaning processes, and serve as a quality control tool.

Cleaning verification tests are performed following cleaning and are used to verify the effectiveness of a cleaning process in removing or reducing to an acceptable level the clinical soil that occurs during the use. These types of indicators do not measure microbial contamination.

It is not recommended to perform a cleaning monitor test after the AER cycle as these tests are meant to verify cleaning efficacy and do not measure microbial contamination.

Rationale: Visual inspection alone is not sufficient for assessing the efficacy of the cleaning process. The use of methods that are to identify organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures.

NOTE See Annex N for more information on about the user verification of cleaning processes. For additional information about monitoring of endoscope manual cleaning, consult AAMI ST91:2021.

8.3.2 Visual inspection after manual cleaning

Cleaning verification of devices by users should include the following:

a) Visual inspection combined with other verification methods that allow the assessment of both external surfaces and lumens (see Annex N).

b) Testing of the cleaning efficacy of mechanical equipment.

c) Monitoring of key cleaning parameters (e.g., cleaning agent dose, temperature).

The device should be visually inspected. If any damage is observed during or after the cleaning process, the device should be removed from service and evaluated for repair.

Tools such as video borescopes of an appropriate dimension (i.e., length and diameter) can be used to visually inspect accessible internal lumens and spaces and document their condition.

Several methods can be used to evaluate the results of the cleaning process. The most common is visual inspection. Careful visual inspection should be conducted to detect the presence of any residual soil. Inspection using magnification and additional illumination will identify residues and/or damage more readily than the unaided eye. Direct visual inspection is not possible for all inner components of medical devices that have lumens or that are of nonsealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices, and biopsy forceps) without the use of special equipment (e.g., borescope). Not all residual contamination can be detected by visual inspection as they are not accessible to visual inspection. Further, residual organic soil and microbial contamination may be present on an accessible surface even though the device looks clean (Visrodia et al., 2014 [369]).

8.3.3 Cleaning verification test for users

Cleaning verification tests are performed following cleaning and before disinfection or sterilization and are used to verify the effectiveness of a cleaning process to remove or reduce to an acceptable level the clinical soil that occurs during the use of a device.

Methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be implemented.

ST91 Annex N provides information related to user verification of cleaning procedures and cleaning equipment, including the currently available test methods that apply to in-use evaluation of, respectively, efficacy of cleaning of medical devices and efficacy of washer-disinfectors used for flexible and semi-rigid endoscope processing. An example of a cleaning verification program is also provided.

Several technologies are available that can be used to measure the levels of organic soil and microbial contamination on the cleaned device. The published studies that have evaluated the specific markers that can be used to determine

cleaning efficacy have indicated that the following markers are useful for benchmarking purposes by the user: protein, carbohydrate, hemoglobin (blood), adenosine triphosphate (ATP), and an enzyme that detects specific bacteria (Alfa et al., 2012 [6]; Alfa et al., 2013 [3]; Alfa et al., 2014 [5]; Visrodia et al., 2014 [290]; Alfa, 2020 [7]).

Two basic components of user verification of cleaning efficacy are as follows:

a) establishing a reasonable benchmark; this is the level of cleaning that can be achieved consistently using specific soil markers relevant to devices used for patients; and

b) using rapid, easy-to-perform methods that reliably demonstrate that the cleaning benchmarks have been achieved.

Facilities should establish benchmarks based on their facility practices, types of devices, types of equipment, training available, and cleaning verification test used. Realistic benchmarks depend on what can be achieved by routine cleaning and the limit of detection of the method used. Check with specific cleaning verification test manufacturers' written IFU for their recommended benchmark or pass/fail threshold value. See Annex N.2.

The benchmarks for residual soil and bioburden levels after cleaning might become more definitive as more data become available and/or more efficient cleaning methods are developed. Users should review current literature along with the manufacturer's data to formulate policies and procedures for verification of cleaning efficacy. A study has shown that some benchmarks can be significantly lowered due to the increase in cleaning efficacy achieved by automated pump-assisted cleaning (Alfa et al., 2014 [5]).

Some cleaning verification systems provide quantitative results that can be tracked and trended over time. Some systems additionally have record-keeping or data capture systems that can aid in identifying endoscopes with repeated failed cleaning results.

Rationale: Visual inspection alone is not sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures.

8.3.4 Testing cleaning efficacy

The facility's quality assurance program should include ways to verify that the cleaning equipment is working and that the cleaning process is effective. Automated cleaning equipment should be tested upon installation, during routine use, and on all cycles used after repairs, and when changing to a new type of cleaning solution. The automated cleaning efficacy test and equipment manufacturer's written IFU should be followed.

When developing a user verification procedure for the cleaning process (see Annex N), processing personnel should ensure the following:

a) The device manufacturer has provided a written IFU detailing the recommended cleaning process.

b) The facility has established, clarified, and documented a standard cleaning process for the device.

c) Cleaning verification results are documented.

d) The facility has established, clarified, and documented a process to address cleaning verification failures and trends.

e) The facility has established an education, training, and competency assessment program that verifies that personnel are consistently achieving the expected level of cleaning.

Rationale: Meticulous manual cleaning is essential for the removal of organic contamination that can interfere with the subsequent disinfection or sterilization process. The manual cleaning step is prone to error (Dirlam-Langley, 2013 [96]; Ofstead, 2010 [193]; ASGE, 2017 [17]; Ofstead, 2015 [191]; Ofstead, 2016 [192]) and therefore should be monitored on a routine basis at least as frequently as is recommended for the cleaning equipment. Testing the equipment upon

installation, during routine use and on all cycles used, after repairs, and when changing to a new type of cleaning solution allows the user to verify its continued effectiveness (AORN, 2018 [268]).

8.3.5 Product identification and traceability

8.3.5.1 Lot control numbers

Each item or pack intended for use as a sterile product should be labeled with a lot control identifier. The lot control identifier should designate:

a) the identification number or code of the sterilizer, processor, or soaking container;

b) the date of chemical sterilization or high-level disinfection; and

c) the sterilization or high-level disinfection cycle number or the patient identifier.

The policy of the health care facility determines when the lot control information is affixed to the package or correlated to the device (e.g., a flexible endoscope).

Items that are processed for immediate use by means of an LCS/HLD soaking system do not require lot numbers; however, a means of identification of the items processed and date processed should be assigned to each load of a cycle, chamber, or soaking tray.

Full traceability to the patient should be maintained by recording the load identifier on the patient chart or by recording the patient name or other identifier on the load record.

Rationale: Lot identification enables personnel to retrieve items in the event of a recall and to trace problems to their source. Quality control measures (e.g., the use of conventional BIs) might not yield results until after the processed load has been used. Quality control record-keeping is critical and relies heavily on historical data, especially where quality control measures yield conflicting evidence. Record-keeping is needed both for epidemiological tracking and for ongoing assessment of the reliability of chemical sterilization and high-level disinfection processes.

8.3.6 Cycle documentation and record-keeping

8.3.6.1 High-level disinfection cycle

For each high-level disinfection cycle, the following information should be recorded and maintained:

a) the assigned lot number, including processor or soaking container identification, cycle number, date and time of the cycle;

b) the specific contents of the lot or load, including quantity, department, and a description of the items;

c) if applicable, the serial number or other identification of the item;

d) the shelf-life date, if applicable, the lot number, and the date that the original container of LCS/HLD was opened; the use-life of the open container; the date that the product was activated or diluted; the date that the activated, diluted, or ready-to-use solution was poured into a secondary container; and the reuse-life of the solution;

e) the exposure time and temperature, if not provided on the physical monitors;

f) the name or initials of the operator;

g) the results of spore strip testing for liquid chemical sterilization system, if used;

h) the results of solution test strip testing or MRC or MEC testing, if applicable; and

i) any reports of low MRC or MEC testing results (as indicated by solution test strips).

The recording chart, printer, or tape, if applicable, should also be dated and maintained, and the operator should review and sign each cycle on the recorder. A record of repairs and preventive maintenance should also be kept for each sterilizer, processor, and soaking container. Data on personnel exposure testing should also be recorded. All of the foregoing information may be incorporated into a paper log or, preferably, an electronic record-keeping system or may be filed as individual documentation records. All records must be retained in the sterile processing area or another designated storage area for a period of time not less than that specified by state or local statutes, legal considerations (e.g., statutes of limitations for lawsuits), and individual situation. If statutes are not specific, record retention should be determined in conjunction with the facility's risk management department (or legal counsel) and infection prevention and control committee.

Rationale: Documentation ensures monitoring of the process as it is occurring, ensures that cycle parameters have been met, and establishes accountability. In addition, documentation helps personnel determine whether recalls are necessary and the extent of recalls, if evidence subsequent to lot release, such as a positive BI, nonresponsive CI, solution test strip, or chemical monitoring device, suggests sterility or processing problems. Knowing the contents of the lot or load enables personnel to decide how critical a recall might be. Digitization of the process will allow quick access to load information, thus facilitating a quick response. In addition, this documentation provides evidence of a department's quality control program. Electronic records of process monitoring results, including specific load item identification, are recommended because of their better legibility, accuracy, traceability, security, and data integrity. The length of time to retain sterilization records depends on many different factors and may vary from facility to facility depending on policy and applicable regulations.

8.3.6.2 Gaseous chemical sterilization cycle

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

a) the assigned lot number, including chemical sterilizer id, cycle number; date and time of the cycle;

b) the specific contents of the lot or load, including quantity, department, and a description of the items;

c) the lot number of the chemical sterilant used for the cycle;

d) the physical monitoring results on a print-out or electronic record. Parameters should be checked and the record initialled.

e) the name or initials of the operator;

f) the results BI; and

g) the results of CI if used in a process challenge device as a load monitor.

8.3.7 Expiration dating

Each packaged item in a load should be labeled with a control date for stock rotation and the following statement (or its equivalent): "Contents sterile unless package is opened or damaged. Please check before using." This information can be incorporated into the lot identification on the label or imprinted or affixed separately on the outside of the package. If the product contains material that degrades over time (e.g., latex), the product package should be labeled with a clearly identifiable expiration date that takes this degradation into account or is based on the device manufacturer's written IFU. If a time-related shelf-life system is used, the product package should be labeled with an expiration date.

Rationale: Labeling items with a lot control number and an expiration statement or (when applicable) expiration date is necessary for proper stock rotation.

8.4 Monitoring manual processes that use LCSs/HLDs

8.4.1 General considerations

BIs and CIs are not available for monitoring processes that use LCSs/HLDs. Solution test strips and chemical monitoring devices, which are used to determine whether the concentration of the active ingredient in an LCS/HLD solution is adequate, are typically required per LCS/HLD manufacturer's written IFU. However, these solution test strips and chemical monitoring devices are not the same as CIs used to monitor gaseous or other sterilization processes.

8.4.2 Use of physical monitors

Physical monitoring of manual LCS/HLD processes should be performed for each cycle with an accurate thermometer (temperature critical parameter) and timer (time critical parameter). The user should document the results of temperature and time monitoring. Physical monitoring of automated LCS/HLD processes is described in 8.5.2. The results of physical monitoring should be documented 9.3.2.

The solution should be visually inspected before each use and discarded if precipitates are observed, even if the solution is within its use-life. Visual inspection should also ensure that the solution container is covered to prevent evaporation of the solution and exposure to light, both of which can affect the efficacy of the chemical agent. Visual observations should be documented.

If the interpretation of the physical monitors or visual inspection of the solution suggests inadequate processing, the items should not be dispensed or used. The interpreter should inform the appropriate supervisor, who should initiate appropriate follow-up measures.

Rationale: Physical monitoring is needed to help ensure that the parameters are correct for every cycle and to detect malfunctions as soon as possible so that appropriate corrective action can be taken.

8.4.3 Solution test strips and chemical monitoring devices

8.4.3.1 General considerations

Solution test strips and chemical monitoring devices are designed to determine whether the concentration of the active ingredient in the LCS/HLD solution is above or below the MRC or MEC for the LCS/HLD. These solution test strips and chemical monitoring devices assist the user in determining when the solution should no longer be used. All solution test strips and chemical monitoring devices should be used according to the manufacturer's written IFU.

8.4.3.2 Using solution test strips and chemical monitoring devices

Personnel should use the FDA-cleared solution test strip or chemical monitoring device recommended by the LCS/HLD manufacturer or a solution test strip or chemical monitoring device cleared by the FDA as substantially equivalent. The manufacturer's written IFU should provide information on the reliability, safety, and performance characteristics of the product, including the interpretation of the solution test strip or chemical monitoring device reaction, the MRC or MEC that the solution test strip or chemical monitoring device is designed to detect, and the shelf life and storage requirements. Any necessary efficacy testing of the solution test strip or chemical monitoring device should be performed according to the manufacturer's written IFU.

NOTE Solution test strips and chemical monitoring devices for LCS/HLD solutions are medical devices that require FDA premarket clearance. The intended-use statement in the labeling of the solution test strip or chemical monitoring device should specify the LCS/HLD products with which it can be used.

Rationale: Solution test strips or chemical monitoring devices are needed to detect inadequate concentration of the active ingredient of the LCS/HLD.

8.4.3.3 Frequency of use

Personnel should use the appropriate solution test strip or chemical monitoring device to test the LCS/HLD solution. The solution should be tested before each use (ASGE and SHEA, 2011). If the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate, the solution should not be used. The solution test strip or chemical monitoring device manufacturer's written IFU for testing, storage of the strips and reagents, interpretation of results, and expiration should be followed.

Rationale: The purpose of the solution test strip or chemical monitoring device is to ensure that the concentration of the active ingredient in the LCS/HLD solution is at or above the product's MRC or MEC and to provide an indication of the solution's continued effectiveness. The concentration of an active ingredient in the LCS/HLD solution will decrease with dilution by water, the presence of organic or other extraneous materials, evaporation of the solution, and exposure

of the solution to light. Checking the concentration of the active ingredient before use can reduce the risk associated with use of an ineffective LCS/HLD solution.

8.4.3.4 Interpretation

The solution test strip or chemical monitoring device should be read before the LCS/HLD solution is used. The user should be appropriately trained and knowledgeable about the performance characteristics of the solution test strip or chemical monitoring device and the interpretation of results. The user's competency should be assessed.

If the interpretation of the solution test strip or chemical monitoring device, performed in accordance with the manufacturer's written IFU, suggests that the concentration of the active ingredient is inadequate, the solution should be discarded even if it is within its use life. Suppliers of solution test strips and chemical monitoring devices that change color often provide visual color interpretation reference charts. If available, these charts should be obtained and used for user training and routine reference.

If the chemical monitoring device indicates that the concentration of the active ingredient was inadequate during processing or after, those items should be considered inadequately processed and they should not be used until processed with a solution with adequate concentration of active ingredient. These items should not be used until they are reprocessed.

Rationale: The solution test strip or chemical monitoring device provides the only indication that the LCS/HLD solution is at or above its proper MRC or MEC. If the solution test strip (utilized prior to processing) indicates that the concentration of the active ingredient of the LCS/HLD is inadequate, the solution should not be used to process devices.

8.4.3.5 Inadequate concentration level

If the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate and if items have been processed in this ineffective solution, the following actions should be taken to identify these items:

a) The appropriate supervisor and the infection prevention and control professional should be notified immediately by phone or messenger, and this notification should be followed by a written report. The report and notification should include:

   1) the time and date of the questionable processing cycles;

   2) a description of the soaking or processing container and the load, including appropriate lot control numbers, product and patient names, and other identifying information;

   3) the results of physical monitoring and the solution test strip or chemical monitoring device as obtained from the user department; and

   4) any other information that could be useful in determining whether the report is valid or is questionable because of human error.

b) Because a processing failure has occurred, items processed since the last cycle for which the solution test strip or chemical monitoring device indicated an adequate concentration should be considered unprocessed. They should be retrieved, if possible, and reprocessed. The LCS/HLD solution in question should not be used but a sample should be retained for testing.

c) After the cause of the processing failure has been determined and corrected, the LCS/HLD solution should be tested with a solution test strip or chemical monitoring device. If the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate, the solution should be discarded and replaced with freshly prepared solution.

Rationale: A continuous quality improvement (CQI) process is important to ensure that patient care products are safe and effective. Conducting the recommended protocol when the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate will provide valuable data in support of corrective actions and will aid in identifying potential improvements in work practices.

8.5 Monitoring automated processes that use LCSs/HLDs

8.5.1 General considerations

Chemical process monitoring devices (such as spore test strips, solution test strips, and chemical monitoring devices) should always be used to monitor the effectiveness of automated processing equipment that uses LCSs/HLDs. The devices should be selected based on the IFU, because not all chemical process monitoring devices are commercially available for all automated processes. Furthermore, solution test strips and chemical monitoring devices are not the same as CIs used to monitor gaseous or other sterilization processes.

FDA-cleared spore test strips should be used and interpreted according to the manufacturer's written IFU. Solution test strips and chemical monitoring devices should be used to test automated equipment at the same frequency as for manual processes. The use and interpretation of solution test strips and chemical monitoring devices used to monitor the concentration of active ingredients in LCS/HLD solutions are described in 9.4.3.

8.5.2 Physical monitors

Physical monitors should be used to monitor automated processor performance. These typically include time, temperature, pressure, and flow rate. Some automated processes include LCS/HLD concentration monitors. The output of these monitors may be recorded by way of charts, printouts, or digital data. The operator should:

a) verify that the recording device is functioning properly; and

b) examine and interpret the chart, printout, or data to verify that all cycle parameters were met.

Confirmation that the cycle parameters were met should be documented by the operator signing the chart or printout or by suitable electronic means for data.

NOTE It is important that the chart or printout is readable.

Rationale: Physical monitors and associated recording devices provide real-time assessment of the sterilization cycle conditions and a permanent record by means of charts, printouts, or digital data. Physical monitoring is needed to detect malfunctions as soon as possible, so that appropriate corrective actions can be taken.

8.5.3 Use of physical monitors and process monitoring devices

Physical monitors reflect the parameters of the automated processing equipment and include displays, digital printouts, and gauges. The user should obtain information from the manufacturer of the monitoring device certifying the accuracy and precision of the monitor, what parameters are measured, and describing any maintenance required to ensure the continued adequate performance of the equipment.

The automated processing equipment printout should be checked at the beginning of the cycle to verify that the cycle identification number has been recorded and that the printer is functioning properly. At the end of the cycle and before items are removed from the processing equipment, the operator should examine and interpret the printout to verify that cycle parameters were met and should initial it to allow later identification of the operator.

Automated processing equipment that does not have physical-monitor recording devices should not be used.

Electronic software programs are also available that provide a real-time, paperless, permanent recording of physical parameters. Automated processing equipment without electronic data transfer, recording, or printing capabilities should not be used.

NOTE It is important that any chart or printout is readable.

If the interpretation of the physical monitors or process monitoring devices (such as spore test strips, solution test strips, and chemical monitoring devices) or visual inspection of the chemical solution, as defined by the manufacturer,

suggests inadequate processing, the items should not be dispensed or used. The interpreter should inform the appropriate supervisor, who should initiate appropriate follow-up measures.

One proprietary automated processing system that uses peracetic acid can be monitored with a spore test strip FDA cleared for that system and should be used and interpreted according to the manufacturer's written IFU.

Rationale: Physical monitoring provides real-time assessment of the automated processing equipment cycle conditions and provides permanent records by means of chart recordings, digital printouts, or electronic records. Physical monitoring is needed to detect malfunctions as soon as possible so that appropriate corrective actions can be taken in the event of failures. Process monitoring devices (such as BIs, spore test strips, CIs, solution test strips, and chemical monitoring devices) provide additional information about the effectiveness of the process and assist in determining the reasons for a process failure.

8.5.4 Automated processing equipment malfunction

If the physical-monitoring records or process monitoring devices (such as spore test strips, solution test strips, and chemical monitoring devices) indicate any malfunction or suspicious operation, the cycle load should be considered inadequately processed and should not be used. The department head or designee should be notified.

The automated processing equipment manufacturer’s written IFU should be reviewed for troubleshooting information. After examination, if the malfunction cannot be corrected immediately, the cycle should be terminated according to the manufacturer’s written IFU and the processing equipment should be removed from service. All items in the terminated cycle should be reprocessed, if appropriate. The health care facility engineer or maintenance contract service should then be notified and the malfunction should be corrected. Faulty processing equipment cannot be made operational without identifying and correcting the underlying problem; merely extending the cycle time, for example, is not appropriate.

Many LCS/HLD automated processing equipment computer programs are designed to detect inadequate cycle conditions. Computer-controlled equipment will often abort the cycle when the required parameters for the process have not been met. Some automated equipment will also provide various types of alerts regarding equipment performance. Users of the equipment should be adequately trained to distinguish between alerts that represent failure conditions and those that do not.

A major repair is a repair outside the scope of normal maintenance, such as rebuilding or upgrading controls. When repairs involve parts that are usually replaced under preventive maintenance procedures, verification of the processing equipment’s operation to the manufacturer’s specifications is sufficient to return the processing equipment to service. After a major repair, follow the manufacturer's written IFU for verification testing before the processing equipment is returned to service.

Rationale: When automated processing equipment malfunctions, the load should be considered inadequately processed. Simply altering the cycle parameters of malfunctioning processing equipment will not correct a problem. Adequate processing of future loads will be jeopardized if the processing equipment continues to be used without repair and requalification. To restore processing equipment to proper performance, it is necessary to identify the exact cause of the malfunction.

8.5.5 Inadequate processing

If any process monitoring devices (such as spore test strips, solution test strips, and chemical monitoring devices) defined for use with the LCD/HLD indicate that the concentration of the active ingredient or other parameters are inadequate and if items have been processed in this ineffective solution or inadequate process, the actions described below should be taken to identify those items:

a) Follow the manufacturer's written IFU to troubleshoot the problem.

b) If troubleshooting was not successful, a description of the processing equipment should be included in a written report and notification.

c) Any automated processing equipment in question should be removed from service.

d) The head of the microbiology department (or designee), the head of the sterilizing or using department (or designee), and appropriate facility maintenance and equipment service personnel should attempt to determine the cause of the processing failure.

e) After the cause of the processing failure has been determined and corrected, the LCS/HLD should be tested according to the manufacturer's written IFU, including any associated diagnostic cycles and/or testing with process monitoring devices (such as spore test strips, solution test strips, and chemical monitoring devices). If the physical-monitoring results and the process monitoring devices for the cycle are satisfactory, the processing equipment can be returned to service.

Rationale: A CQI process is important to ensure that patient care products are safe and effective. Conducting the above protocol when process monitoring devices (such as spore test strips, solution test strips, and chemical monitoring devices) indicate that the concentration of the active ingredient or other parameters are inadequate and provide valuable data in support of any corrective action required and potential improvements in work practices.

8.6 Monitoring gaseous chemical sterilization processes

8.6.1 General Considerations

An essential element of sterility assurance gaseous chemical sterilization is process monitoring, which consists of

a) monitoring of every package and sterilization load (see Table 3);

b) routine monitoring of sterilizer efficacy (see Table 3);

c) sterilizer testing after sterilization process failures (see Table 3);

d) qualification testing of the sterilizer after installation, relocation, sterilizer malfunction, and major repairs (see Table 3); and

e) periodic product quality assurance testing (see Table 3).

Table 3—Gaseous chemical sterilization process monitoring recommendations

Routine load release		**Routine sterilizer efficacy monitoring**	**Sterilizer qualification testing**	**Periodic product quality assurance testing**
Nonimplants	**Implants**			
Perform for every load Physical monitoring of cycle External and internal CI monitoring packages Optional monitoring of the load with a PCD containing a BI or FDA-cleared BI-containing quality monitoring device. EO processes are monitored for every load.	Perform for every load Physical monitoring of cycle External and internal CI monitoring packages Monitoring of the load with a PCD containing a BI or FDA-cleared BI-containing quality monitoring device Load should be quarantined until result of BI is known.	Should be performed at least daily (each day the sterilizer is used), preferably with each load. Sterilizer efficacy testing is not performed in an empty chamber. EO processes are monitored for every load. Physical monitoring of cycle External and internal CI monitoring packages	Perform according to manufacturer's IFUs after installation, relocation, malfunctions, major repairs, sterilization process failures that were not resolved successfully. Physical monitoring of cycle External and internal CI monitoring packages, if applicable PCD containing a BI or FDA-cleared BI-containing quality monitoring device	Perform periodically or when major changes are made to a product design or IFU, the load composition, the packaging or when a new sterilizer or processing equipment is purchased. Physical monitoring of cycle Placement of BIs and CIs within the product test samples.

		PCD containing a BI or FDA-cleared BI-containing quality monitoring device		
NOTE The purpose of qualification testing of a sterilizer after installation or relocation is to assess sterilizer performance in the environment in which it will be used.				

Sterilization process monitoring devices include physical monitors, chemical indicators, and biological indicators. Each of these devices plays a distinct and specific role in sterilization process monitoring, and each is indispensable to sterility assurance. Physical monitors verify that the parameters of the sterilization cycle have been met. Chemical indicators verify that one or more conditions necessary for sterilization have been achieved within the package and/or at a specific location within the load. Biological indicators verify that the conditions at a location within the load were adequate to kill a population of microorganisms resistant to the sterilization process and demonstrate lethality of the sterilization cycle. Biological indicators and chemical indicators are used within a process challenge device, an item that is designed to constitute a defined resistance to a sterilization process and used to assess the performance of the process. PCDs are commonly known as test packs, challenge packs, or load packs.

As technology progresses, new sterilization process monitoring devices may be cleared by FDA and become available for use in health care facilities. Health care facilities should rely on the knowledge and expertise of their infection prevention and control, sterile processing, and surgical services professionals in the selection and use of process monitoring devices. The choices made in the selection and use of sterilization process monitoring devices play a large role in determining the level of quality of the sterile processing function and thus should be made on the basis of product performance characteristics and scientific data reviewed by those with technical knowledge and expertise, not merely on the basis of economics.

8.6.2 Use of physical monitors

Physical monitors include time, temperature, and pressure recorders; displays; digital printouts; and gauges. The user should obtain information from the manufacturer of the monitoring device certifying the accuracy and precision of the monitor and describing any maintenance required to ensure the continued adequate performance of the equipment.

For sterilizers with recording charts, the operator should ensure at the beginning of the cycle that the recording chart is marked with the correct date and the sterilizer number. For sterilizers with printouts, the printout should be checked to verify that the cycle identification number has been recorded and that the pen or printer is functioning properly. At the end of the cycle and before items are removed from sterilizer, the operator should examine and interpret the chart or printout to verify that cycle parameters were met and initial it to allow later identification of the operator. Sterilizers without recording charts or printouts should not be used.

NOTE It is important that the chart or printout is readable.

Data from physical monitors contained in the sterilizer cycle report has limitations. Improper load configurations, overweight loads, using packaging types not labelled for the process, improper materials or package compositions, can interfere with air evacuation, warming of the load, and sterilant penetration, conditions that will not be revealed in the sterilizer cycle report. Therefore, physical monitoring and other indicators of sterilizer performance should never be considered a substitute for careful adherence to prescribed packaging and loading procedures and the results from chemical indicators and biological indicators.

If the interpretation of the physical monitors suggests inadequate processing, the items should not be dispensed or used. The interpreter should inform the appropriate supervisor, who should initiate appropriate follow-up measures.

Rationale: Physical monitoring provides real-time assessment of the sterilization cycle conditions and provides permanent records by means of chart recordings or digital printouts. Physical monitoring is needed to detect malfunctions as soon as possible, so that appropriate corrective actions can be taken in the event of failures.

8.6.3 Gaseous chemical sterilizer malfunction

If the interpretation of the physical monitors suggests inadequate processing, the contents of the load should not be released or used. The operator should inform the appropriate supervisor, who should initiate appropriate follow-up measures as dictated by the health care facility policy and procedure.

Removing a load from a cancelled cycle can present a risk of exposure of workers to residual sterilant. The sterilizer manufacturer's written IFU should be followed, appropriate safety precautions should be observed, and personnel should wear appropriate PPE. Items from cancelled cycles should be removed from packaging while wearing PPE, cleaned if needed to remove residual chemicals, repackaged with new monitoring products and the load reprocessed.

If the sterilizer requires a major repair, the sterilizer should be requalified per 8.6.5.5. A major repair is a repair outside the scope of normal maintenance, such as rebuilding or upgrading controls. When repairs involve parts that are usually replaced under preventive maintenance procedures, the sterilizer is returned to service after verification of the sterilizer's operation to the manufacturer's specifications is sufficient.

8.6.4 Chemical indicators

8.6.4.1 General considerations

Chemical indicators are sterilization process monitoring devices that are designed to respond with a chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile. The use of CIs is part of an effective quality assurance program; CIs should be used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process. All CIs should be used according to the CI manufacturer's written IFU.

Rationale: When a sterilizer malfunctions, the load should be considered nonsterile. Conducting the above protocol whenever sterilization process failure is indicated by physical monitor will provide data useful in the sterilization process failure investigation and subsequent corrective action.

ANSI/AAMI/ISO 11140-1:2014, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, defines six types of CIs and specifies performance requirements for them:

Type 1 (process indicators): chemical indicators intended for use with individual units (e.g., packs, containers) to indicate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.

Type 2 (Bowie-Dick test indicators): chemical indicators intended for use in a specific test procedure (e.g., the Bowie-Dick test used to determine if air removal has been adequate in a steam sterilization process).

Type 3 (single critical process variable indicators): chemical indicators designed to react to one of the critical variables and intended to indicate exposure to a sterilization process at a stated value of the chosen variable.

Type 4 (multicritical process variable indicators): chemical indicators designed to react to two or more of the critical variables and intended to indicate exposure to a sterilization process at stated values of the chosen variables.

Type 5 (integrating indicators): chemical indicators designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for BIs.

Type 6 (emulating indicators): chemical indicators designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specified sterilization process. ANSI/AAMI/ISO 11140-1 refers to these indicators as a cycle verification indicators.

NOTE 1 CIs assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or sterilizer malfunctions. The “pass” response of a CI does not prove that the item monitored by the indicator is sterile.

NOTE 2 See ANSI/AAMI/ISO 11138-7 for information on the selection, use and interpretation of biological indictors.

8.6.4.2 Using chemical indicators

Chemical indicators used in health care facilities are medical devices that require FDA clearance. Personnel should use FDA-cleared CI. The intended use statement in the labeling of the CI specifies the sterilization methods and systems with which it can be used. The CI manufacturer indications for use of the CI should be consulted for information on the specific cycles FDA cleared for use with the respective CI.

A CI should be used on the outside of each package unless the internal indicator is visible. The CI is examined after sterilization and also before use of the item to verify that the item has been exposed to the sterilization process.

An internal CI should be used inside each package, tray, containment device (rigid sterilization container system, medical device case, cassette, or organizing tray) to be sterilized. The CI should be placed in that area of the package, tray, or containment device that creates the greatest challenge to sterilant penetration or as specified by the IFU of the chemical indicator or the IFU of the sterile barrier system. The CI should be retrieved at the time of use and interpreted by the user.

The user should be appropriately trained and knowledgeable about the performance characteristics of the CI and the interpretation of the results. The user’s competency should be assessed.

For general information about CIs, see ANSI/AAMI/ISO 11140-1 and ANSI/AAMI/ISO 15882.

8.6.4.3 Nonresponsive or inconclusive chemical indicators

If the interpretation of the CI suggests inadequate processing, the contents of the package should not be used. The interpreter should inform the appropriate supervisor, who should return the complete unused package, including load identification and the CI, for appropriate follow-up. The department head or designee in the sterilizing department should then decide whether to recall that sterilized load. This decision should be based on the results of physical monitoring, and—if applicable and visible—the results of CIs elsewhere in the load, and—if applicable—the results of biological monitoring. If biological monitoring was performed but the results are not yet available, the remaining packages from the same load should be quarantined and should not be used until the BI results are obtained.

Rationale: If a CI is nonresponsive or inconclusive, it is possible that the entire load is nonsterile (i.e., the sterilization process failed). It is also possible that errors in loading or packaging have resulted in sterilization failures in some, but not all, packages in the load. Therefore, a single nonresponsive or inconclusive CI should not be considered definitive evidence that the entire load is nonsterile. The supervisor should exercise professional judgment in determining whether to recall the entire load, taking into account all factors having a bearing on the efficacy of the cycle and all performance indicators.

8.6.5 Biological indicators and process challenge devices

8.6.5.1 General considerations

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

Process challenge devices (PCDs) are challenge test packs containing a BI or a BI and a CI. A PCD is a device used to assess the effective performance of a sterilization process.

8.6.5.2 Using biological indicators and process challenge devices

BIs used in health care facilities are medical devices that require FDA clearance. Personnel should use BIs cleared by the FDA for use with that sterilization system. The intended-use statement in the labeling of the BI specifies the sterilization methods and systems with which it can be used. Information should be obtained from the BI manufacturers on the specific cycles FDA cleared for use with the respective BI.

The user should be appropriately trained and knowledgeable about the interpretation of the results. The user's competency should be assessed.

For general information about BIs, see ANSI/AAMI/ISO 11138-1 and ISO 11138-7.

Commercially available PCDs used in health care facilities are medical devices that require FDA premarket clearance. The intended-use statement in the labeling of the PCD should specify the sterilization methods and systems with which it can be used. At this time, there are no guidelines on how personnel can create a user-assembled PCD for gaseous sterilization processes, with the exception of EO.

For general information on PCDs, see AAMI TIR31.

Rationale: The condition of the sterilizer equipment, the expertise of the sterilizer operator, and other factors that determine the success or failure of a sterilization cycle could vary from one cycle to another. The less frequently the sterilizer is used, the greater the chance that an unnoticed event could affect sterilization. Therefore, it is necessary to regularly challenge the sterilizer and the sterilization process with a PCD or an FDA-cleared BI-containing quality monitoring device.

8.6.5.3 Frequency of use of biological indicators and process challenge devices

Biological indicators should be used within PCDs or an FDA-cleared BI-containing quality monitoring device for routine sterilizer efficacy monitoring for each cycle type every day the sterilizer is in use, but preferably in every load. EO processes should be monitored for each load. Sterilizer efficacy testing is not performed in an empty chamber.

Biological indicators within a PCD or an FDA-cleared BI-containing quality monitoring device may be used as part of the criteria for release of loads. Additionally, BIs within PCDs or an FDA-cleared BI-containing quality monitoring device should be used to monitor every load containing implants that have been cleared for low temperature sterilization. Implants should be quarantined until the results of the BI testing are available (CDC, 2008).

Rationale: BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Biological monitoring provides the only direct measure of the lethality of a sterilization cycle. Sterilizer manufacturers utilize BIs as part of the validation of their sterilization cycles during the half-cycle validation testing; therefore, routine sterilizer efficacy monitoring in health care facilities should also be conducted using BIs.

8.6.5.4 Routine efficacy testing

8.6.5.4.1 Routine efficacy test procedure with BIs

The test procedure is as follows:

a) Should be performed at least daily in each cycle type (each day the sterilizer and cycle are used), preferably with each load. EO processes should be monitored for each load.

b) Sterilizer efficacy testing is not performed in an empty chamber.

c) Before being exposed to the sterilization cycle, the PCD containing a BI or FDA-cleared BI-containing quality monitoring device should be labelled with sterilizer lot and load information. Refer to the sterilizer manufacturer's IFU for details about the location in the sterilizer chamber to place the BI PCD or FDA-cleared BI-containing quality monitoring device. The BI manufacturer's IFU can provide details about how the BI should be placed in the sterilizer (e.g., in a pouch, in a tray, or naked) and orientation of the BI within the sterilizer chamber.

d) Upon completion of the sterilization cycle, the BI(s) and CI(s) (if CI's are used) should be removed from the PCD or FDA-cleared BI-containing quality monitoring device and their identification recorded. The CI manufacturer's written IFU for interpretation of CI results should be followed (if CI's used). The BI(s) should be handled and incubated according to the BI manufacturer's written IFU.

e) Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control to verify the presterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the proper incubation temperature. Test and lot control numbers should be recorded. Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are not viable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the test should be repeated.

NOTE If several test BIs from the same lot are run on the same day, only one control BI from that lot needs be used.

8.6.5.4.2 Acceptance criteria

An acceptable process is evidenced by negative results from all test BIs in the BI PCD or FDA-cleared BI-containing quality monitoring device, positive results from control BIs, and appropriate readings from physical monitors and CIs showing that the sterilization cycle was correct and complete. All monitoring results, including results from BI controls, should be interpreted by a qualified individual and should be included in the sterilizer records; see Table 3.

8.6.5.5 Sterilizer qualification testing

8.6.5.5.1 General considerations

All gaseous chemical sterilizers should be tested using BI PCDs upon installation, relocation, sterilizer malfunctions, major repairs, and after sterilization process failures that were not resolved successfully. Sterilizer testing after installation, relocation, and major repairs should be conducted by the Sterilizer Service Technician providing guidance in collaboration with the healthcare facility. The testing should be performed between the time the sterilizer is installed, relocated, or repaired and the time it is released for use or returned to service in the health care facility. Personnel should follow the sterilizer manufacturer's written IFU, which should include recommendations for use of an FDA-cleared BI and PCD, the location and method of placement of the BI PCD in the chamber, number of cycles to run and which cycle(s) should be tested. Testing should be performed in an empty chamber except for the BI PCD.

Rationale: The purpose of testing a sterilizer after installation or relocation is to assess the efficacy of the sterilizer performance in the environment in which it will be used. Satisfactory test runs verify that the sterilizer is in working condition after shipment from the manufacturer or relocation from its previous site and that the sterilizer can provide direct lethality of a large number of highly resistant bacterial spores. Sterilizer testing after major repairs is also intended to ensure that the sterilizer can provide direct lethality of a large number of highly resistant bacterial spores after the correction of a malfunction or unresolved sterilization process failure. Testing is performed in an empty chamber to reduce the negative impact of the load and the expertise of the sterilizer operator on the test results and provides one assessment of sterilizer performance with minimal outside influences on the sterilizer.

8.6.5.5.2 Sterilizer qualification test procedure with BIs

The test procedure is as follows:

a) Before being exposed to the sterilization cycle, the BI PCD should be labeled with appropriate sterilizer lot and load information.

b) The BI manufacturer's IFU can provide details about how the BI should be placed in the sterilizer (e.g., in a pouch, in a tray, or naked) and orientation of the BI within the sterilizer chamber. Refer to the sterilizer manufacturer's IFU for details about the location in the sterilizer chamber to place the BI PCD.

c) A normal cycle with an empty chamber should be run, according to the sterilizer and/or BI/PCD manufacturer's written IFU.

d) Upon completion of the sterilization cycle, the BI(s) and CI(s) (if CIs are used) should be removed from the PCD and their identification recorded. The CI manufacturer's written IFU for interpretation of CI results should be followed (if CIs are used). The BI(s) should be handled and incubated according to the BI manufacturer's written IFU.

e) Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control to verify the presterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the proper incubation temperature. Test and control lot numbers should be recorded. Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are not viable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the control and test BIs should be repeated.

NOTE If several test BIs from the same lot are run on the same day, only one control BI from that lot need be used.

8.6.5.5.3 Acceptance criteria

Negative results from the test BIs, positive results from control BIs, and cycle printout records demonstrating correct and complete sterilization cycles provide verification that the sterilizer has been properly installed or repaired and that it will function effectively in the facility in which it is installed. All monitoring results, including results from BI controls, should be interpreted by a qualified individual and should be included in the sterilizer records.

8.6.5.6 Actions to take when BIs, CIs, or physical monitors/indicators indicate a sterilization process failure

The following actions should be taken if a BI tests positive:

a) A processed PCD with a positive BI, a failed CI or a failed physical monitor should be immediately reported in accordance with facility policy. The following information should be included in the initial notification (generally verbal) and subsequent written documentation:
   1) the time and date of the incident, including the sterilizer identification number and load control number;
   2) a description of the incident, including any information about patient(s) potentially affected (see ANSI/AAMI ST79:2017 Table 4);
   3) the results of physical monitoring and of internal CIs (if applicable); and
   4) additional relevant information (e.g., evidence of operator error).

b) The gaseous processes in the scope of this document can be technique sensitive, where the expertise or variability introduced by the user can have a significant impact on the outcome of the process. If the cause of failure is immediately identified (or resolved) and confined to one load or one item in the load (e.g., an item with a nonresponsive internal CI), the cause of the failure should be corrected, and the load or item should be reprocessed. Requalification of the sterilizer is not required.

c) If the cause of the failure is not immediately identified (or resolved), the load should be quarantined, and all loads back to the last negative BI should be recalled. Items in these loads should be retrieved, if possible, and reprocessed. The sterilizer in question should be taken out of service until the cause of the failure is corrected.

d) A multidisciplinary team should work to determine the root cause of the sterilization process failure and implement corrective action.

e) If the root cause of the sterilization process failure has been determined to be a sterilizer malfunction and a major repair is required for correction, the sterilizer in question should be immediately requalified with a BI PCD.

Rationale: A CQI process is important to ensure that patient care products are safe and effective. Conducting the recommended protocol when positive BI results occur will provide valuable data in support of corrective actions and aid in identifying potential improvements in work practices.

8.6.6 Process challenge devices

Process challenge devices (PCDs) are challenge test packs containing a BI or a BI and a CI. A PCD is a device used to assess the effective performance of a sterilization process.

NOTE Commercially available PCDs used in health care facilities are medical devices that require FDA premarket clearance. The intended-use statement in the labeling of the PCD should specify the sterilization methods and systems with which it can be used. At this time, there are no guidelines on how personnel can create a user- assembled PCD for gaseous sterilization processes.

The user should be appropriately trained and knowledgeable about the interpretation of the results. The user's competency should be assessed.

For general information on PCDs, see AAMI TIR31.

See Annex S for specific information on user assembled EO PCD for routine testing.

Rationale: The condition of the sterilizer equipment, the expertise of the sterilizer operator, and other factors that determine the success or failure of a sterilization cycle could vary from one cycle to another. The less frequently the sterilizer is used, the greater the chance that an unnoticed event could affect sterilization. Therefore, it is necessary to regularly challenge the sterilizer and the sterilization process with a PCD or an FDA-cleared BI-containing quality monitoring device.

8.7 Product release

Product release should be an active decision based on evaluation of all available data from the sterilization or high-level disinfection process for the particular load. The decision to release product should be made by an experienced, knowledgeable person at the conclusion of the chemical sterilization or high-level disinfection cycle. Loads that do not meet the criteria for release should be clearly identified so that they are not mistakenly distributed.

Rationale: Releasing processed devices based on all quality control measures is critical in providing safe and effective products for the care and treatment of patients.

8.8 Product testing

8.8.1 General considerations

Product testing consists of a series of procedures used to verify that manufacturer's written IFU can be successfully performed in the user facility. Chemical high-level disinfection and sterilization processes generally provide restrictive requirements for the types of devices and loads that can be reprocessed in the manufacturer's written IFU. It is not necessary to conduct product testing of medical devices on an ongoing basis, unless recommended by the applicable manufacturer. The following guidelines are given where product testing is conducted.

Product testing is not a substitute for the more extensive validation testing conducted by manufacturers to qualify their products. Product testing does not allow a health care facility to validate a change in the medical device manufacturer's written IFU for packaging, loading, type of process, or critical process parameters. Product testing can only be used to verify the information provided in the manufacturer's written, validated IFU.

Not all medical devices processed need to be product tested. Instead medical devices are typically placed into product families. The most challenging device to process from each family can be identified as the master product, which represents the entire family of devices during testing. A product family can be based on the manufacturer's defined product family. For example, surgical powered equipment and batteries from vendor A could be a family of products and surgical powered equipment and batteries from vendor B could be another family of products that require gaseous chemical sterilization. For LCS/HLD processing a family of products could be specifically related flexible endoscopes from vendor A and another family of products could be specifically related flexible endoscopes from vendor B.

Consideration should also be given to the load requirements specified by the manufacturer (e.g., number or devices, load weight).

The following product characteristics can be considered when evaluating new medical devices to determine whether they belong to an existing product family or can be safely reprocessed under the device manufacturer's instructions:

a) design configuration;

b) number of components;

c) materials of construction;

d) size and/or surface area;

e) need for disassembly;

f) surface finish or texture;

g) presence of cannulations, lumens, or mated surfaces;

h) written processing instructions provided by the manufacturers.

Some products may not have an easily identified product family and the user will need to work with the device manufacturer to identify the appropriate family of products and master product using the characteristics listed above. If the new medical device does not fit with an existing product family, then a new product family may need to be established, with the new medical device becoming the master product for that family. Product testing should be done initially on all the master products designed for each identified family of products processed within the health care facility.

Before newly purchased medical devices are placed into routine use, the user should determine which existing family of products they belong to and if the existing product testing is applicable to these devices. If this newly purchased medical device is less of a challenge than the master product previously tested for the designated family for a specific process and parameters, then product testing does not need to be performed. If this newly purchased medical device is a greater challenge than the master product previous tested for the designated family then product testing should be performed before the product is placed into routine use.

Product testing could be repeated whenever changes are made to a product family's composition, designated master product or written IFU or if a new sterilizer or other piece of processing equipment is purchased.

A limited program should be established to periodically test products that are routinely processed to ensure that the process and related factors have not changed since the initial product testing. For example, a program could be established to test one master product of one family each month.

For gaseous chemical sterilization, product testing may be considered when major changes are made in packaging or load configuration, such as dimensional changes, weight changes, or changes in the type of packaging material used. Changes that would require product testing include changing brands or types of peel-pouches, wrappers, or rigid sterilization container systems. Load configuration changes may occur when a sterilizer with a different size chamber is purchased. This may create a greater challenge to sterilant penetration.

For LCS/HLD processes, product testing may be considered when major changes are made in the type of automated processing equipment, LCS/HLD solution, or critical parameters.

8.8.2 Product testing for gaseous chemical sterilization processes

For product testing devices that use gaseous chemical sterilization processes, BIs and CIs should be placed within the product test samples. The number of BIs and CIs used within each product test sample will depend on the size and configuration of the package being tested. Medical device manufacturers can assist in identifying where to place BIs and CIs. Document the placement of the BIs and CIs (e.g., digital photo) and label each to determine where the positive BIs and/or unresponsive CIs were located to assist in a thorough investigation to determine the reasons for the failures.

Examples of placement of BIs and CIs for product testing are as follows:

a) For an medical device set, the BIs and CIs should be placed at each end of the tray and among the medical devices that are placed in stringers.

b) For rigid sterilization container systems and other containment devices, the BIs and CIs should be placed in areas recommended by the containment device manufacturer.

c) For multilayered medical devices sets in containment devices, the BIs and CIs should be placed in the location determined by the device manufacturer to create the greatest challenge to the sterilization process. It might be necessary to use BIs contained in glassine envelopes rather than self-contained BIs if test areas cannot accommodate the BI ampoules (e.g., inside multilayered trays with sliding lids).

d) For other types of items, the BIs and CIs should be placed in the area of the product test samples representing the greatest resistance to sterilant penetration.

The product test samples should be placed strategically throughout the load at the point most difficult to sterilize (i.e., the greatest resistant to sterilant penetration). After inspection and retrieval of the BIs and CIs, sample packs used in product testing should be disassembled and the contents either reprocessed or discarded, as appropriate.

If positive BIs and/or unresponsive CIs indicate the product testing samples were not properly sterilized, perform a thorough investigation to determine the reasons for the failure. It might be necessary to change the configuration of the load or the items within the package, check the sterilizer critical parameters, or assess the sterilizer performance. Product use should be discontinued until the problem is resolved. The test protocol, test results, and any corrective actions taken should be documented and maintained as part of the sterilization log or quality assurance program data. Documentation of product testing activities should be maintained, including the date the testing was performed, the name of the master product, product family name, identification of the locations of BIs and CIs within the master product, and test results.

Rationale: Process challenge devices used for sterilizer efficacy and routine testing present a known challenge to the sterilization process. However, PCDs do not reflect the items routinely processed in a health care facility. Therefore, product testing is recommended as part of a complete quality assurance program to ensure the effectiveness of the sterilization process. The products to be tested will vary from facility to facility, depending on the types of products routinely sterilized. The contents of the master products are exposed to a greater population of bacterial spores than are other products and therefore should not be used in patient care unless reprocessed. In addition, inspecting the pack and retrieving the BIs and CIs contaminates the contents.

8.8.3 Product testing for LCS/HLD automated processes

For product testing devices using LCS/HLD automated processing equipment, the master product should be placed into the automated processing equipment chamber according to the equipment and device manufacturers' written IFU. The solution should be tested before each use with the appropriate solution test strip or chemical monitoring device. If the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate, the solution should not be used. When the solution test strip shows the concentration of the solution to be at or above the product’s MRC or MEC, continue with the product testing for processes that have available spore test strips and/or CIs.

The automated processing equipment manufacturer should provide information on periodic calibration and on methods that can be used to verify that the correct temperature and the LCS/HLD solution volume and concentration are being achieved.

If positive spore test strips and/or unresponsive CIs indicate the product testing samples were not properly high-level disinfected, perform a thorough investigation to determine the reasons for the failure. It might be necessary to change the configuration of the load or to assess the processor performance. Product use should be discontinued until the problem is resolved. The test protocol, test results, and any corrective actions taken should be documented and maintained as part of the sterilization log or quality assurance program data. Documentation of product testing activities should be maintained, including the date the testing was performed, the name of the medical device (master product), product family name, identification of the locations of spore test strips and CIs within the master product, and test results.

Rationale: Product testing is recommended as part of a complete quality assurance program to ensure the effectiveness of the LCS/HLD automated processing equipment, LCS/HLD solution, and critical LSC/HLD parameters. The products to be tested will vary from facility to facility, depending on the types of products routinely high-level disinfected. The contents of the master products may be exposed to a greater population of bacterial spores than other products and therefore should not be used in patient care unless reprocessed. In addition, retrieving and inspecting the load and retrieving the spore test strips and CIs contaminate the contents.

8.9 Product recalls

8.9.1 General considerations

Written policies and procedures for the recall of issued or stored packaged items that have been processed with a chemical sterilant/high-level disinfectant should be developed in cooperation with the infection prevention and control committee and the risk management committee of the individual institution or integrated health care network, as appropriate. Written policies and procedures for the identification of items not packaged or stored but immediately used should also be developed. Policies and procedures should be documented, and records should be maintained. The department head or designee should decide, on the basis of the health care facility's policies and procedures, when a recall of processed supplies should be implemented. Whenever there is evidence of a sterilization or high-level disinfection process failure, the infection prevention and control professional and the director of the department in which the suspect items were used should be notified so that follow-up surveillance of patients can be conducted. Written policies and procedures should be developed for compliance with the Safe Medical Devices Act of 1990 as it pertains to failures of reusable medical devices (i.e., FDA's Medical Device Reporting [MDR] regulations of 21 CFR 803). For additional information on user facility MDR requirements, see FDA (1996b).

Rationale: To ensure patient safety and compliance with the user facility reporting requirements of the FDA's MDR regulations, the health care facility should establish recall procedures to expedite the retrieval of processed items and the identification of items immediately used that are suspected to be nonsterile or incorrectly high-level disinfected, thus helping to ensure adequate follow-up actions (e.g., quarantine of the sterilizer or automated processing equipment, notification of physicians and affected clinical departments, and surveillance of patients).

8.9.2 Recall procedure

A recall procedure should:

a) be written;

b) outline the circumstances for issuing a recall order;

c) designate the person or people authorized to issue a recall order; and

d) designate the person or people responsible for reporting on the execution of a recall order.

8.9.3 Recall order

A recall order should:

a) include all items processed back to the last negative BI (if applicable);

b) be immediately communicated to affected departments and followed by a written order;

c) identify products to be recalled by lot number (if applicable), product or patient name, or other information;

d) identify the people or departments to whom the order is addressed;

e) require the recording, in terms of kind and quantity, of the products obtained in the recall; and

f) specify the action to be taken by the people receiving the order (e.g., destruction or return of product).

8.9.4 Recall summary report

A summary report of a recall order should:

a) identify the circumstances that prompted the recall order;

b) specify the corrective actions taken to prevent a recurrence;

c) state, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall; and

d) provide verification that the recalled items were reprocessed or destroyed, as appropriate.

8.9.5 Outbreak report

The people responsible for the health care facility's infection prevention and control function and risk management function should report any outbreaks associated with chemical sterilization or high-disinfection processes to the FDA, the State Board of Health, the CDC, the medical device manufacturer, and the manufacturer of the chemical sterilant/high-level disinfectant or chemical sterilization system (ASGE and SHEA, 2011).

9 Quality process improvement

9.1 General rationale

This section identifies performance measures and process monitors that can be used for CQI programs. Continuous quality improvement programs are recognized as an effective means of improving the performance of any process. For chemical sterilization and high-level disinfection, a CQI program encompasses the entire process: point-of-use treatment, decontamination, preparation, packaging (if applicable), chemical sterilization or high-level disinfection, quality control, sterile storage (if applicable), and product distribution.

9.2 Quality process

9.2.1 General considerations

Procedures for chemical sterilization and high-level disinfection should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with appropriate departments and integrated into the overall quality process in the health care facility. Variables in the system can be controlled to achieve assurance of product quality and process efficacy. Monitoring frequency will vary, depending on the quality improvement goals, on health care facility policies and procedures for the handling of unfavorable or unplanned events, and on the type of process variable.

A root cause analysis should be completed for any problem relating to any aspect of chemical sterilization or high-level disinfection processing that could pose a risk to personnel or patients. The root cause analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected.

There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Quality processes can be enhanced by audits that are conducted on a regular basis. The information from these activities should be summarized and made available to appropriate individuals or groups.

According to the FDA, a quality audit is defined as "a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives." (21 CFR 820.3[t]).

Rationale: Measurements of process performance allow chemical sterilization and high-level disinfection processes to be monitored against a predetermined level of quality. Evaluation of findings provides a method of identifying problems or shifts in activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data essential to assessing the effectiveness of the processes and making improvements in performance.

9.2.2 Risk analysis

High-level disinfection is not sporicidal; therefore, a high-level disinfected device is one that is free of viable microorganisms except for small numbers of bacterial spores. The Spaulding classification of the device will determine the level of disinfection required (Spaulding, 1972). Devices that require at a minimum high-level disinfection with a chemical disinfectant are usually classified as semicritical devices because they are in contact with mucous membranes or non-intact skin. As with sterilization, it is recognized that the effectiveness of these processes cannot be fully verified by subsequent inspection and testing of the product. For this reason, high-level disinfection processes are validated for use, the performance of the process is monitored routinely, and the equipment is maintained.

The quality system model used for processing medical devices in health care facilities is a validated system in which

a) the reprocessing equipment manufacturer and appropriate representatives of the health care facility conduct installation qualification and operational qualification; and

b) the individual medical device manufacturer and the reprocessing equipment manufacturer recommend validated means of disinfecting the specific devices to be reprocessed, in lieu of a formal performance qualification.

NOTE The “validated cycle” provided by the medical device manufacturer is often based on the assumption that the device is to be processed alone.

In health care facilities, a high-level disinfection risk analysis, in its broadest sense, includes risk assessment, risk management, and risk communication:

- **Risk assessment** involves identifying the source of a manual or automated processing failure, estimating the likelihood that such a failure will occur, assessing the consequences if that failure does occur, and assessing how prepared the facility is to manage the failure. It should be assumed that at some time a failure will occur.
- **Risk management** entails determining which of the failures identified in the risk assessment process require management and selecting and implementing the plans or actions that are needed to ensure that those high-level disinfection failures are controlled. This document describes the accepted means of managing these risks.
- **Risk communication** involves an interactive dialogue between processing personnel, operating room or procedure area personnel, and infection prevention and control professionals (infection preventionists) that actively informs the other concerned parties (patients). This process is the facility’s recall procedure.

The high-level disinfection risk analysis should be part of the health care facility’s overall infection prevention and control risk analysis in accordance with accreditation agency requirements. It should be performed at least annually and should be reevaluated whenever significant changes occur.

Risk analysis = risk assessment + risk management + risk communication

9.2.3 Decontamination

Procedures for decontamination should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with the appropriate departments and should be integrated into the overall quality process in the health care facility. Written policies and procedures should take into account federal, state, and local regulations, CDC recommendations, national voluntary standards and standards, and the recommendations of medical device and processing equipment manufacturers. Variables in the system should be controlled to achieve assurance of quality and process efficacy. Performance measures should be developed to monitor environmental, performance, and process factors, including tests for monitoring and verifying the parameters of the cleaning process. Monitoring frequency will vary, depending on the quality improvement goals, on the health care facility’s policy and procedures for the handling of untoward events, and on the type of performance measure.

a) **Design of the work area (Section 3)**. Performance measures should include, but are not limited to, ventilation, including air exchanges per hour and airflow pattern for general room ventilation and local exhaust ventilation; installation of automated processing equipment; location of manual high-level disinfection; storage and disposal of LCSs/HLDs; and traffic control.

b) **Personnel (Section 4)**. Performance measures should include, but are not limited to, staff education, development, training, and continuing education; verification of competency of personnel; health and personal hygiene; and proper attire, including appropriate PPE.

c) **Decontamination and preparation (Section 5)**. Performance measures should include, but are not limited to, selection and use of appropriate PPE; sorting and disassembly of instruments; selection and use of cleaning agents, implements and accessories; manual cleaning; mechanical cleaning; rinsing procedures; water quality; and cleaning verification documentation.

A root cause analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The root cause analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected. There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Auditing results should be routinely summarized and submitted to the infection prevention and control department for review.

Rationale: Measurements of process performance allow the system to be monitored and the results compared with a predetermined level of quality. Evaluation of the findings provides a method of identifying problems or shifts in activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data that can be used to assess the effectiveness of the process and make ongoing improvements in performance.

9.2.4 Liquid chemical sterilization, high-level disinfection, and gaseous chemical sterilization

Procedures for liquid chemical sterilization, high-level disinfection, and gaseous chemical sterilization should be based on a documented quality process that measures objective performance criteria. The quality process should be developed in conjunction with the appropriate departments and integrated into the overall quality process in the health care facility. Monitoring frequency will vary depending on the quality improvement goals, on the health care facility's policy and procedures for the handling of untoward events, and on the type of performance measure.

a) **Use of LCSs/HLDs.** Performance measures should include, but are not limited to, verification of training and continuing education; correct choice of and use of LCSs/HLDs and appropriate PPE; correct loading of items into the solution container or automated processing equipment; selection of appropriate LCS/HLD cycle parameters; selection and use of spore test strips, and solution test strips or chemical monitoring devices; accurate load records; documentation of physical and chemical monitoring; and adherence to device, LCS/HLD, and automated processing equipment manufacturers' written IFU.

b) **Gaseous chemical sterilization processes.** Performance measures should include, but are not limited to, verification of training and continuing education; correct loading of items into the sterilizer chamber; selection of appropriate chemical sterilization cycle; selection and use of CIs and BIs with PCD; accurate load records; documentation of physical, chemical, and biological monitoring; and adherence to device and sterilizer manufacturers' written IFU.

c) **Aseptic handling and transfer.** Performance measures should include, but are not limited to, selection and use of proper attire; correct techniques for unloading the sterilizer, automated processing equipment, or solution container; and correct techniques for transferring items to the point of use.

A root cause analysis should be completed for any problem with any aspect of liquid chemical sterilization, high-level disinfection, gaseous chemical sterilization, or aseptic transfer that could pose a risk to patients. The root cause analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected. There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Auditing results should be routinely summarized and submitted to the infection prevention and control department for review.

Rationale: Variables in the system must be controlled to ensure quality and process efficacy. Ensuring that liquid chemical sterilization, high-level disinfection, or gaseous chemical sterilization has been achieved will minimize the potential risk to patients. Measurements of process performance allow the system to be monitored and the results compared with a predetermined level of quality. Analysis of this information provides a method of identifying problems or shifts in activities and making improvements in the system.

9.3 Functional areas for product and process improvement

9.3.1 Workplace design

Optimization of product and process performance relies on efficient workplace design. Problems such as cross-contamination, excessive processing costs, product failures, inefficient time usage, and so on can be created or exacerbated by poor workplace design. Workplace design encompasses the physical layout of the processing area; the one-way functional work flow patterns; the physical facilities (e.g., the mechanical and electrical systems, lighting, plumbing, ventilation, environmental controls); and the types and locations of processing equipment and supplies. The adequacy of the workplace design should be assessed by such means as employee input, accident records, and evaluation of the workplace in terms of the recommendations of Section 3.

9.3.2 Processing policies and procedures

Evaluating and monitoring the effectiveness of the process should be an ongoing effort and is critical to maintaining control over and determining methods for improvement of the product and process. The review of records and of documented quality control procedures that have been implemented should serve as the basis for monitoring and evaluating the process. Written procedures should be reviewed, and current practices should be audited for compliance in the areas included in the CQI program. Examples of CQI program areas include:

a) Training, continuing education, and competency assessments (4.3);

b) Product identification and traceability (i.e., lot control numbers [9.3.1] and load records [9.3.2]);

c) Monitoring manual processes that use LCSs/HLDs (9.4);

d) Monitoring automated processes that use LCSs/HLDs (9.5);

e) Monitoring gaseous chemical sterilization processes (9.6);

f) Product testing (9.8); and

g) Product recalls (9.9).

9.3.3 Product use

Evaluating the performance of products that have been or will be used can offer important feedback on the effectiveness of the process and the appropriateness of the products selected. Performance measures can come from internal evaluations, end-user feedback, supplier testing, and repair records:

a) **Internal evaluations**. Internal evaluations can be used to audit the quality of finished products. For example, medical devices can be checked for functionality, appropriate packaging, and correct delivery. Processing decontamination can be evaluated by visually examining medical devices for contamination. Product recalls can be evaluated by reviewing records of actions following documented chemical sterilization or high-level disinfection process failures. Periodic product monitoring can be evaluated on the basis of the appropriateness of the loads or cycles tested and the actions taken as a result of failures.

b) **End-user feedback**. A formal documented system to log, investigate, and resolve complaints and product failures should be established. Issues such as patient infections, PPE failures, malfunctioning medical devices and equipment, and dispensing of incorrect products should be documented, monitored, and tracked over time. A procedure should be established for investigation and remediation of serious and repeat problems.

c) **Supplier testing**. The manufacturer should thoroughly analyze concerns relative to the performance of products or supplies through testing or other means. Personnel should make a written request to and receive a response from any vendor whose products, supplies, or services are in question. All correspondence should be filed with the corresponding complaint, including details of the investigation, the findings, and any actions taken by the vendor to resolve the problem.

d) **Repair records.** Review of medical device repair records might show a pattern. Once identified, the cause for the repair can be reviewed, corrected, and then monitored to ensure the problem has been resolved.

9.4 Implementation of product and process improvements

There is no single right way to implement a CQI program. The program should be customized to the individual facility. However, a team approach has been proven to be successful, because it allows direct input from multiple employees and results in a superior program.

Employees who are actively involved in and responsible for the day-to-day functions outlined in the plan should be members of the team. This approach generates input from those most knowledgeable in methods of effectively improving the program. Additionally, such involvement promotes a sense of ownership in those individuals and tends to lead to a higher degree of commitment on the part of the employees implementing the program.

The single most important issue for those charged with implementing a CQI program is the accurate collection of data using the facility plan for documenting process monitoring and product performance (developed as part of the CQI program). The frequency and type of information generated will vary depending on the level of control established in the documentation plan. Facilities with processes that are uncontrolled or highly variable will require increased process monitoring and documentation, which can be reduced over time as the program brings these processes under improved control.

The CQI program should assess all components of chemical sterilization and high-level disinfection processes for the ongoing ability to achieve the desired outcome of consistently delivering an efficacious product to the user. Performance improvement plans, when needed, should be implemented to enhance chemical sterilization and high-level disinfection processes on the basis of this assessment. Examples of measures to be considered when assessing chemical sterilization and high-level disinfection processes include trending data over a defined time period related to:

a) the number of items processed;

b) the number of BI tests, if applicable;

c) the number of BI failures for each chemical sterilization process, if applicable;

d) the number of physical parameter failures;

e) the number of failed CIs, if applicable;

f) the number of spore test strips, if applicable;

g) the number of spore test strip failures, if applicable;

h) the number of solution test strip or chemical monitoring device failures for processes that use LCSs/HLDs;

i) education compliance (the percentage of employees attending or percentage passing tests or competency measures);

j) timing and completeness of preventive maintenance of gaseous chemical sterilizers and automated processing equipment;

k) ability to locate all items during recalls; and

l) completeness of test records.

Annex A
(informative)
Microbial lethality, materials compatibility, and toxicity

A.1 Introduction

This Annex provides a general discussion of microbial lethality, materials compatibility, and toxicity in relation to chemical sterilants/high-level disinfectant.

A.2 Microbial lethality

Both physical sterilization processes (e.g., steam) and chemical sterilization processes are defined by their effectiveness against a range of microorganisms, including bacterial spores, vegetative bacteria, mycobacteria, and viruses. However, the methods used to validate physical sterilization processes, gaseous chemical sterilization processes, and liquid chemicals intended for use in sterilization differ from those used to validate liquid chemicals intended for use in high-level disinfection. Because bacterial spores have the greatest resistance to most sterilization processes (Table A.1), the effectiveness of a chemical sterilant/high-level disinfectant is determined by its ability, under specified conditions, to kill bacterial spores.

“Sterilization” and “sterile” refer to absolute states. “Sterilization” is often defined as a validated process used to render a product free from viable microorganisms. It is extremely difficult, however, to prove the absence of viable microorganisms. Consequently, in practice, sterility is usually described in terms of the probability of a surviving microorganism, and the nature of microbiological death in a sterilization process is described by an exponential function if the death curve exhibits log linear kinetics. Although the probability of a surviving microorganism can be reduced to a very low number, it can never be reduced to zero. This probability is referred to as the sterility assurance level (SAL). It is generally accepted that an SAL of 10^{-6}—which 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—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). The SAL concept is based on the ability to extrapolate probabilities of survivors remaining on devices after exposure to a sterilization process. For example, if a sterilization process demonstrates log linear kill kinetics, then the process exposure time is determined by linear extrapolation to a log population of 10^{-6} (SAL). Because even traditional sterilization methods, including steam and EO, might not demonstrate complete log linear kinetics, mathematical models are built that yield a conservative calculation of the exposure time necessary to achieve a SAL of 10^{-6} (Favero and Bond, 2001).

Methods have been developed to determine the probability of a surviving microorganism, making it possible to demonstrate the effectiveness of a sterilization process—its microbial lethality. The survival kinetics for thermal sterilization methods, such as steam and dry heat, and for chemical sterilization with EO have been studied and characterized extensively; similar studies have been conducted with some other chemical sterilization processes. Thermal or physical sterilization processes are generally preferred to chemical sterilization processes. The kinetics for sterilization with chemical-based processes are often less well understood or described. The information that is available in the literature suggests that LCSs/HLDs, depending on their formulation or use in a process, may not convey the same SAL as sterilization by thermal or physical methods (Spaulding, 1971; Favero, 1995; Justi et al, 2000). The data indicate that the survival curves for LCSs/HLDs might not exhibit log linear kinetics and that the shape of the survivor curve can vary depending on the formulation, chemical nature, and stability of the LCS/HLD. In addition, the design of the AOAC Sporicidal Activity Test (Horwitz and Latimer, 2010) does not provide for quantification of the microbial challenge.

Because log linear kinetics have not been demonstrated for most liquid chemicals, other methods are used to evaluate the efficacy of those products. Typically, these methods are qualitative and are based on demonstration of total kill endpoints. Examples of such test methods include the AOAC Sporicidal Activity Test, the AOAC Use-Dilution Test, and the AOAC Fungicidal Test (Horwitz and Latimer, 2010). As the AOAC Sporicidal Activity Test is now performed, the probability of a survivor cannot be accurately estimated. In other words, because the AOAC Sporicidal Activity Test is an endpoint test (total exposure time), it does not permit the accurate calculation of a SAL or a determination of whether log linear kinetics are present. In the absence of constant kill rates, one cannot necessarily predict very low risks of

sterilization failures, as with traditional sterilization processes. Therefore, for a device processed by a method validated with endpoint measures alone, the probability that it is sterile cannot be calculated. Tests of LCSs against spores in suspension can be used to obtain quantitative data on the rate of kill. However, spores on device surfaces could provide a different challenge to LCSs than spores in suspension.

Table A.1—Microorganisms listed in descending order of resistance to chemical sterilants/high-level disinfectants[1]

Bacterial spores
Geobacillus stearothermophilus[2]
Bacillus subtilis
Bacillus atrophaeus[3]
Clostridium sporogenes
Protozoa - cyst forms of parasites
Cryptosporidium oocysts
Mycobacteria
Mycobacterium tuberculosis var. *bovis*
Nontuberculous mycobacteria[4]
Nonlipid or small viruses
Poliovirus
Coxsackie virus
Rhinovirus
Fungi
Trichophyton spp.
Cryptococcus spp.
Candida spp.
Protozoa (non-cyst forms of parasites)
Trichomonas vaginalis
Vegetative bacteria
Pseudomonas aeruginosa
Staphylococcus aureus
Salmonella choleraesuis
Enterococci
Lipid or medium-sized viruses
Herpes simplex virus
Cytomegalovirus
Respiratory syncytial virus
Hepatitis B virus
Hepatitis C virus
Human immunodeficiency virus

NOTE 1 The order of resistance is given as a guide and can vary depending on the microorganism and the chemical sterilant/high-level disinfectant.

NOTE 2 Formerly *Bacillus stearothermophilus* (see Nazina, et al., 2001).

NOTE 3 Strains now designated *Bacillus atrophaeus* were formerly classified as *Bacillus subtilis* (see Fritze and Pukall, 2001).

NOTE 4 Some strains of nontuberculous mycobacteria and *Pseudomonas* have shown unique resistance to glutaraldehyde and OPA (Duarte, et al., 2009; Griffiths, et al., 1997; Svetlikova, et al., 2009; Tschudin-Sutter, et al., 2011).

NOTE 5 Prions, the causative agents of transmissible spongiform encephalopathies, present a unique resistance challenge to germicidal chemicals. Prions have been shown to have unusually high resistance to heat and chemicals, in some cases demonstrating greater resistance than bacterial spores. Special consideration should be given to prion decontamination in suspected or confirmed cases. For information regarding the processing of devices exposed to prions, see AORN (2010a), Favero and Bond (2001), Rutala and Weber (2001a), and the recommendations of CDC (http://www.cdc.gov) and HSPA (http://www.myhspa.org).

NOTE 6 Some cyst forms of parasites have shown high-level resistance to glutaraldehyde and OPA (Barbee, et al., 1999; Coulon, et al., 2010).

One of the primary differences between thermal and chemical processes for sterilization of medical devices is the accessibility of microorganisms to the sterilant. Heat can penetrate barriers, such as biofilm, tissue, and blood, to kill organisms, whereas chemicals might not adequately penetrate these barriers. In addition, gaseous chemical sterilants, depending on the process used, might not be able to penetrate the narrow lumens and mated surfaces of some devices, and the viscosity of some LCSs/HLDs may impede their access to organisms in these areas. A specific limitation of liquid chemicals in the sterilization of devices is the post-processing environment of the device. During processing with a liquid chemical, devices may not be wrapped or adequately contained to maintain sterility after processing and during storage. In addition, the process monitors for liquid chemical sterilization or high-level disinfection differ from the BIs and CIs used for thermal and gaseous processes. The process monitor used during sterilization or high-level disinfection with an LCS/HLD might not be present with the device processed. Furthermore, after exposure to the LCS/HLD, the devices may be rinsed with water that may not be sterile, which may allow recontamination after processing and during storage. Due to the inherent limitations of using liquid chemical germicides for sterilizing medical devices, the FDA recommends that processing with LCSs/HLDs be limited to devices that are heat-sensitive and incompatible with other sterilization methods (FDA, 2000b).

For a manufacturer to obtain FDA clearance for marketing a chemical sterilant/high-level disinfectant, the FDA recommends that the manufacturer conduct certain tests to demonstrate that the product is effective when used as directed. Manufacturers must base their labeling claims and recommendations for use on the outcome of those tests.

Additional technical information on methods used to determine microbial lethality can be found in the bibliography (Beloian and Stuart, 1968; Block, 2001b; Cremieux, et al., 2001; Horwitz and Latimer, 2010; Miner, et al., 1995; Pflug, et al., 2001; Stonehill, Krop, and Borick, 1963). Information on FDA regulatory recommendations can be found in the FDA guidance document on LCSs/HLDs (FDA, 2000b), which is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073773.htm, or from the Center for Devices and Radiological Health (CDRH) through the Division of Industry and Consumer Eduction (DICE), at (800) 638-2041 or (301) 796-7100.

A.3 Materials compatibility

A.3.1 General considerations

Another important aspect of the safety and performance of an LCS/HLD or gaseous chemical sterilant is its compatibility with the materials and devices that it is intended to sterilize or disinfect. That is, the chemical sterilant/high-level disinfectant should not alter the material of a device in such a way that the device will not be safe or will not function as intended. Many materials, such as metals, alloys, and plastics and their polymers, can be adversely affected by exposure to certain chemicals and stresses. Some materials might become brittle and crack. Others, such as certain polymeric adhesives, might dissolve. Still others might swell or become distorted. Some materials absorb certain chemicals that could later be released during use. Any of these effects can cause the device to malfunction or even fail.

When selecting a chemical sterilant/high-level disinfectant, the prospective user should weigh materials compatibility as heavily as efficacy. The interaction of a chemical sterilant/high-level disinfectant with device materials can adversely affect device safety and effectiveness in various ways. The extent of the reactivity depends on many factors:

a) **The chemical nature of the chemical sterilant/high-level disinfectant, including inert ingredients.** The mode of microbicidal action of most chemical sterilants/high-level disinfectants is either alkylation or oxidation. Alkylating agents (such as glutaraldehyde, formaldehyde, and ortho-phthalaldehyde [OPA]) and oxidizing agents (such as hydrogen peroxide and peracetic acid) not only alkylate or oxidize microorganisms and organic matter, but also might react with the device materials and alter the physical integrity and function of the device. Variations in the formulation of “inert” ingredients in the chemical sterilant/high-level disinfectant

also might affect materials compatibility. Additives that are considered inert in terms of microbial kill might not be inert in terms of materials compatibility.

b) **The types of polymeric materials or metals involved.** Many types of polymeric materials and metals are used in the manufacture of medical devices (see A.3.2 and A.3.3). Some materials are resistant to reaction with chemical sterilants/high-level disinfectants, whereas others undergo reaction but are functionally unaffected by the changes. Some materials, however, undergo chemical reactions that adversely affect the properties and function of the material. Ideally, if a device is heat-sensitive, it will be manufactured with materials that are compatible with chemical sterilants/high-level disinfectants.

c) **The conditions of use (e.g., chemical sterilant concentration, temperature, contact time, repeated exposure of the device to the chemical sterilant/high-level disinfectant).** Chemical changes can be additive, so the conditions of use of a chemical sterilant/high-level disinfectant play a role in materials compatibility. In general, for a given chemical sterilant/high-level disinfectant, the likelihood of chemical attack on materials increases with higher concentration, higher temperature, and longer exposure time. Repeated exposure of a device to a chemical sterilant/high-level disinfectant also might have an impact on materials compatibility. Device manufacturers conduct tests to determine the effects of common chemical sterilants/high-level disinfectants on their products under expected use conditions. Therefore, when one is using a chemical sterilant/high-level disinfectant, it is best to follow the written IFU of both the chemical sterilant/high-level disinfectant manufacturer and the device manufacturer to minimize adverse effects.

d) **The internal stresses built into the device by its design or manufacture.** Some device designs are more susceptible to damage by a chemical sterilant/high-level disinfectant than others. For example, a device with sharp corners is more likely to fail because of high internal stresses, fatigue, or stress corrosion.

e) **The external stresses on the device (e.g., bending, flexing, twisting, or pressing during use).** Exposure of a device to a critical stress or load combined with exposure to a chemical sterilant/high-level disinfectant can lead to premature device or component failure. The stresses from repeated use of the device might fatigue the materials so that they show the effects of chemical reaction sooner.

Medical device manufacturers should conduct tests to determine the effects of the LCSs/HLDs or gaseous chemical sterilants that they recommend for use on their products. The FDA recommends that manufacturers of LCSs/HLDs and gaseous chemical sterilization systems provide test data on materials compatibility and device functionality after repeated exposures for generic types of medical devices (see Annex L). Because the materials compatibility testing submitted to the FDA during a 510(k) review process might not apply to all devices within a generic group, personnel should check with the reusable device manufacturer and/or the sterilizer/LCS/HLD manufacturer for specific information regarding the compatibility of a particular device with the chemical sterilant/high-level disinfectant. It is important that personnel use an LCS/HLD or gaseous chemical sterilization system under the conditions and according to the written IFU specified in the manufacturer's labeling, because product compatibility has been demonstrated for those conditions and cannot be ensured under other conditions.

A.3.2 Effects on polymeric materials

The interaction between chemical sterilants/high-level disinfectants and polymers can range from no interaction at all to chemical attack that breaks the chemical bonds of the polymer chain. Incompatibility can manifest itself in crazing (thin streaks appear), cracking, swelling, dissolution, softening, or embrittlement. Any one of these changes in the polymer could lead, in time, to poor device performance or even to failure; difficulty in cleaning, high-level disinfection, or sterilization could also result. Among the types of polymers used in device manufacture are thermosets, thermoplastics, elastomers or rubbers (including thermoplastic elastomers), plastisols, molding compounds, copolymers, and polymer alloys. Applications of these polymers include knobs, housings, and structural parts (e.g., castings and injection moldings); tubing; rods (extrusions); films (blown or extruded); and coatings. Fabricated components frequently are complex systems that contain modifiers such as colorants, antioxidants, lubricants, plasticizers, fillers, and other additives.

These polymer families and systems vary greatly in terms of their chemical makeup and their compatibility with various chemical sterilants/high-level disinfectants. Although one type of chemical sterilant/high-level disinfectant might be compatible with a particular polymer, another could attack the polymer. Also, a polymer might be compatible as a heat resin, but the same polymer with additives might be vulnerable to change or deterioration.

Although a polymeric material might be able to hold up to stresses and chemical exposure separately, exposure to both at the same time could cause failure. This phenomenon is known as environmental stress cracking (ESC). Eliminating or decreasing the stress through process modifications (e.g., thermal annealing) or changing the type of chemical sterilant/high-level disinfectant could alleviate the problem. The device manufacturer might be able to offer assistance as well.

A.3.3 Effects on metals

Metals, although not necessarily heat-sensitive, might be exposed to chemical sterilants/high-level disinfectants as components of reusable, heat-sensitive devices. Exposure of metals to incompatible solutions can cause chemical and electrochemical attack called corrosion. Stainless steel is the most common type of metal used in the manufacture of reusable medical devices. Liquid solutions, especially those containing chlorides, are of concern for certain stainless steels. Some other nonferrous metals and alloys—including solders, brazes, brasses, Monel® (an alloy of nickel, copper, iron, and manganese), nickel, chrome plating, and anodized aluminum—are also found in certain medical devices and show a variety of effects when exposed to chemical sterilants/high-level disinfectants.

The classes of stainless steels and their various alloys demonstrate a wide range of performance properties and corrosion resistance. Although relatively impervious to organic solvents, stainless steels can be affected by exposure to certain inorganic solutions and acids. The two classes of stainless steel most commonly used in the medical device industry are austenitic stainless steel, which is known for its superior corrosion resistance, and martensitic stainless steel, which is also called “hardened” stainless steel.

Stainless steel corrosion generally manifests itself as surface blemishes such as roughness and rust. These surface imperfections can lead to difficulties in sterilization or disinfection and can indicate sites at which future device failure could occur. Stainless steels corrode by several different mechanisms, including pitting, crevice corrosion, and stress corrosion cracking (SCC) or hydrogen cracking.

Pitting, caused by exposure to chloride- or bromide-containing solutions, is highly localized corrosion that results in shallow to deep penetrations. Chloride pitting is the downfall of typically corrosion-resistant austenitic stainless steel. Exposure to a high chloride concentration, elevated temperatures, and stagnant solutions increases the likelihood and severity of pitting. The addition of molybdenum to some stainless steel alloys, such as 316 and 317, enhances the resistance of the material to pitting.

Crevice corrosion occurs in small, shielded crevices such as joint sites, corners, port connections, and gasket areas; it is evident as red rust. These areas are prone to corrosion when devices are immersed in aggressive solutions that are stagnant. Removing stagnant solutions from these crevices decreases the likelihood of crevice corrosion.

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

In the early stages of corrosion, the effects on stainless steel are primarily aesthetic. However, if the corrosion is allowed to continue, device failure can eventually occur. Corrosion can also interfere with proper cleaning and, consequently, can inhibit the disinfection or sterilization process. Minimizing the concentration of the corrosive agent, the temperature, or the exposure time decreases the likelihood of failure caused by corrosion (but might reduce the effectiveness of the chemical sterilant/high-level disinfectant).

The compatibility of nonferrous metals with chemical sterilants/high-level disinfectants and the resistance of such metals to corrosion depend on the nature of the alloy and the chemical environment. These alloys are more susceptible to corrosion when immersed in strongly acidic solutions than when exposed to a gaseous sterilant. Also, plating and coatings can be affected by chemical attack, even if the plating or coating itself is actually inert. A gap in the film (such as a pinhole, crack, or scratch) exposes a substrate that is subject to corrosion, undercutting, or interfacial attack, which can, in turn, lead to peeling and debonding. Strong oxidizing chemical sterilants, such as those containing chlorine, hydrogen peroxide, or peracetic acid, cause fading of nonferrous metals such as anodized aluminum. Fading of a dyed anodized coating from black or colored to an almost clear color occurs when the organic dye that is trapped in the

anodization layer is bleached. This effect does not typically affect functionality, because the oxide layer remains undamaged, but the dye contained inside the pores in the film is bleached.

A.3.4 Conclusion

When selecting a chemical sterilant/high-level disinfectant for use with a particular device, the user should consider not only the possible interactions between the chemical sterilant/high-level disinfectant and the device materials, but also the conditions of use of the chemical sterilant/high-level disinfectant. For further information, see AAMI TIR12; American Society for Metals (1988); Baijal (1982); Bland, et al. (1988); Boyer and Gall (1985); Sedricks (1979); and Uhlig and Revie (1985).

A.4 Toxicity

Personnel must be protected from hazards associated with occupational exposure to LCSs/HLDs and gaseous chemical sterilants. Patients must be protected from the potentially harmful effects of exposure to LCS/HLD residues and gaseous chemical sterilant residues remaining on medical devices. Before clearing an LCS/HLD or gaseous chemical sterilization system for marketing, the FDA evaluates information provided by the manufacturer on the safety of the product. The FDA must also clear the manufacturer's labeling for the product, which includes written IFU with adequate warnings and precautions.

Because LCSs/HLDs and gaseous chemical sterilants vary in their toxicity, they also vary in the potential health hazards to humans. Many LCSs/HLDs and gaseous chemical sterilants cause short-term health problems, such as irritation to the eyes, skin, and respiratory passages. Others—depending on exposure concentration, exposure time, or both—can pose serious long-term health hazards. The SDS and other relevant manufacturer's or public literature on the specific product should be consulted. OSHA imposes limits on occupational exposure to various chemicals used in high-level disinfection, but not all such compounds have OSHA limits. For those compounds without OSHA limits, employers are still under a duty to provide a safe work environment (OSH Act (1970), sec. 5) and employers must provide adequate engineering controls, work practices, exposure monitors, and appropriate PPE to protect workers as determined by the hazardous properties of the compound. Employers should consult the manufacturer for information regarding the hazards and the means of employee protection. OSHA requires manufacturers and importers to provide SDSs with their products. The SDSs must be readily accessible at all times to employees using the chemicals, and it must provide pertinent information regarding toxicity, reactivity, appropriate PPE, storage, and disposal (see Annex L).

Annex B
(informative)
Selection of liquid and gaseous chemical sterilants/ high-level disinfectants

B.1 Introduction

This Annex describes factors to consider in the selection of liquid and gaseous chemical steriliants/ disinfectant for a particular application.

Various formulations of LCSs/HLDs are commercially available, This section provides factors to consider when choosing disinfecting and sterilizing agents and equipment. It also provides suggestions about information that users should obtain from the manufacturers of LCS/HLD products and automated processing equipment, the manufacturers of gaseous chemical sterilization systems, and the manufacturers of medical devices to be processed.

When any product is being considered for use within a facility, it is the responsibility of the intended users to evaluate the product using a systematic process of product evaluation and to establish policies and procedures that reflect this process and that are appropriate to the health care organization. Periodically, new products enter the market for which AAMI does not offer guidance for application. The selection criteria provided in this section may be used regardless of whether AAMI or similar professional organizations provide guidelines on the new product being considered by the health care organization.

NOTE Users are cautioned to request that manufacturers substantiate, in written documentation, the answers to all questions that apply to the selection process.

B.2 Categories of items to be disinfected or sterilized

Surgical medical devices and other medical devices and equipment could pose a significant risk of transmitting infection to patients or personnel if they are not properly decontaminated and then disinfected or sterilized. Spaulding divided medical medical devices and equipment into three categories (critical, semicritical, and non-critical) on the basis of the risk of infection from contamination on the item (Spaulding, 1972). The Centers for Disease Control and Prevention (CDC) has described the level of disinfection or sterilization needed after decontamination and before patient use for the three Spaulding categories (Garner and Favero, 1985; CDC, 2003, 2008), as well as a fourth category, environment surfaces (Favero and Bond, 2001).

a) **Critical devices** are medical devices or objects that are introduced directly into the human body, either into or in contact with the bloodstream or other normally sterile areas of the body, and products with sterile fluid pathways. Examples of critical items include surgical instruments, needles, transfer forceps, cardiac catheters, implants, inner surface components of extracorporeal blood-flow devices such as heart–lung machines and blood oxygenators, and the blood compartments of hemodialyzers. Critical items present a high degree of risk of transmission of infection if contaminated and, therefore, must be sterile at the time of use.

b) **Semicritical devices** are medical devices or objects that contact intact mucous membranes or nonintact skin of the patient during use, but do not usually penetrate the blood barrier or other normally sterile areas of the body. Examples include noninvasive flexible and rigid fiberoptic endoscopes, endotracheal and aspirator tubes, bronchoscopes, laryngoscopes, respiratory therapy equipment, cystoscopes, vaginal specula, and urinary catheters. Semicritical devices should be sterilized, if possible. However, if sterilization is not feasible, the device, at a minimum, must be subjected to a high-level disinfection process that would be expected to destroy all microorganisms except for large numbers of bacterial spores. In most cases, meticulous physical cleaning followed by high-level disinfection provides reasonable assurance that the items are free of pathogenic microorganisms.

c) **Critical items** confer a high risk for infection if they are contaminated with any microorganism. Thus, objects that enter sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease. This category includes surgical instruments, cardiac and urinary catheters, implants, and

ultrasound probes used in sterile body cavities. Most of the items in this category should be purchased as sterile or be sterilized with steam if possible. Heat-sensitive objects can be treated with EO, low temperature vaporized hydrogen peroxide; or if other methods are unsuitable, by liquid chemical sterilants. Liquid chemical sterilants reliably produce sterility only if cleaning precedes treatment and if proper guidelines are followed regarding concentration, contact time, temperature, and pH.

The CDC (Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008; Update: May 2019, Table 1) recognized three levels of disinfection: three levels of disinfection: High- level disinfection, Intermediate-level disinfection and low-level disinfection. If sterilization cannot be performed, the CDC recommends high-level disinfection of semicritical patient care items (items that will be in contact with intact mucous membranes and do not normally penetrate body surfaces). Intermediate- or low-level disinfection is considered suitable for non-critical items that come into direct contact with the patient but normally only touch intact skin.

This categorization of patient care items and knowledge of the antimicrobial activity of various types of disinfectants facilitate the selection of an appropriate chemical disinfectant. The method should be chosen on the basis of the device manufacturer's written IFU, how the device will contact the next patient, the physical configuration (cleanability) of the device, the type and degree of contamination after use, the physical and chemical stability of the device, and the ease or difficulty in removing (rinsing, aerating) the chemical agent after the necessary exposure time. As part of the quality assurance program, users should periodically reassess the intended use and appropriate category of patient care items. For EPA registered disinfectants utilized for low and intermidate disinfectants see AAMI TIR68.

B.3 LCS/HLD types

Products containing the following active ingredients are marketed under various brand names and in various concentrations:

- glutaraldehyde;
- glutaraldehyde with phenol-phenate;
- hydrogen peroxide;
- ortho-phthalaldehyde (high-level disinfection only);
- combinations of peracetic acid and hydrogen peroxide. sodium hypochlorite–hypochlorous acid (high-level disinfection only);
- sonicated hydrogen peroxide mist (high-level disinfection only); and
- chlorine dioxide foam (high-level disinfection only)

A few LCS/HLD products have label claims for device sterilization with contact conditions that are based on simulated-use testing with medical devices such as endoscopes, in addition to passing the AOAC Sporicidal Test. The LCS/HLD products that have been cleared for market by the FDA are listed at https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and. This list is updated as new products are cleared and includes the concentration of active ingredients, the sterilization or high-level disinfection contact time and temperatures, and the maximum reuse time period for each product. This website identifies the LCSs/HLDs cleared by the FDA in a 510(k) with claims for processing reusable medical and dental devices. It does not include preamendment products (marketed prior to 1976), FDA-cleared LCSs/HLDs dedicated to specific devices such as hemodialyzers or hemodialysis machines, or gaseous chemical sterilization systems. Annexes C–G and K provide more specific information on the effective use of currently available LCSs/HLDs. See Table B.1.

B.4 Gaseous chemical sterilization types

Chemical sterilants utilizing the following active ingredients are marketed under various brand names and in various sterilization systems:

— low temperature vaporized hydrogen peroxide;

— ethylene oxide;

— chemical vapor sterilant using alcohol and formaldehyde; and

— hydrogen peroxide-ozone

The gaseous chemical sterilization processes and the corresponding sterilant for that system have been cleared for market by the FDA. Annexes H-J and S provide specific information on the safe and effective use of currently available gaseous chemical sterilization processes and corresponding sterilants. See Table B.1.

Table B.1—LCS/HLD and gaseous chemical sterilant annexes

Annex	Description	Type	Page
C	Glutaraldehyde solutions	LCS/HLD	113
D	Hydrogen peroxide solutions	LCS/HLD	122
E	Ortho-phthalaldehyde solutions	LCS/HLD	127
F	Peracetic acid–hydrogen peroxide solutions	LCS/HLD	132
G	Sodium hypochlorite solutions	LCS/HLD	139
H	Chemical vapor sterilants using alcohol and formaldehyde	GCS	144
I	Vaporized Hydrogen peroxide	GCS	147
J	Hydrogen peroxide-ozone	GCS	151
K	Sonicated hydrogen peroxide mist	HLD	155
S	Special considerations for Ethylene Oxide	GCS	199

B.5 Activity levels of disinfectants

Disinfectants can be classified as high-, intermediate-, or low-level disinfectants based on their ability to kill various microorganisms, including vegetative bacteria, mycobacteria, bacterial spores, fungi, and viruses.

When choosing a disinfectant for a particular application, the user might find the published descriptions of the effectiveness of various chemical agents (active ingredients) in disinfectants quite confusing. The ability of a specific chemical agent to kill or inactivate microorganisms is affected by factors such as the concentration of the chemical in the disinfectant, the contact temperature, and the exposure time. For example, a very low concentration of a particular agent might inactivate viruses, whereas a higher concentration, higher temperature, and/or longer exposure time could be required to inactivate other types of microorganisms, such as mycobacteria or bacterial spores. Also, some chemical agents are not capable of killing certain microorganisms under practical conditions, that is, at reasonable temperatures, concentrations, and exposure times.

The biocidal effectiveness of chemical agents can be described in several ways:

a) as data on the chemical agent with no mention of brand names or specific product formulations;

b) as label claims supported by technical data for a particular product formulation that contains the chemical agent; and

c) as the results of controlled studies by independent parties.

The first type of information is a guide to the expected efficacy of the active ingredient shown on the product label. To determine if the chemical agent in a product formulation will provide the level of decontamination required, the user should consult both the label claims and the current, relevant professional literature.

B.6 Labeling of disinfectant products

The labeling of LCSs/HLDs that are intended to be used as the terminal step in processing reusable critical and semicritical medical devices is regulated by FDA. The labeling of these devices provides a guide for users in evaluating the activity levels of disinfectant products. Under FDA regulation, the labeling for a LCS/HLD must provide information relating to the safe and effective use of the product. The labeling should identify the lot number, the expiration date, the active ingredients and their concentrations, any dilution or activation required before use, and the required contact time and temperature. The labeling should also provide information on material and device compatibility, necessary PPE, and, for products that can be reused, the reuse life and instructions for determining whether the concentration of the active ingredient is at or above the minimum recommended concentration (MRC) or minimum effective recommendation (MEC). The labeling includes the bottle label and any package insert, which may contain all of the above information as well as any supplemental information for the user. Labeling for FDA-regulated products uses disinfection terms defined by Spaulding (1972), such as “high-level-disinfection,” to indicate product effectiveness. Terms previously allowed by EPA, such as “virucidal,” “fungicidal,” “bactericidal,” and “tuberculocidal,” have been phased out. In addition, FDA labeling policy does not permit references to specific diseases, such as AIDS and tuberculosis, unless effectiveness has been shown in clinical trials. Guidance on FDA regulation of disinfectants, including labeling requirements, is provided in FDA (2000b).

B.7 Criteria for selecting LCS/HLD and gaseous chemical sterilants

As noted in B.2, the choice of disinfecting method should be based on the device manufacturer’s written processing instructions, how the device will contact the next patient, the physical configuration (cleanability) of the device, the type and degree of contamination after use, the physical and chemical stability of the device, and the ease or difficulty of removing (rinsing, aerating) the chemical agent after the necessary exposure time.

The product label should be examined for information on the use pattern, reuse life, and storage life of the product. It is important to distinguish between the reuse life of a disinfectant and its use pattern. The reuse life of a disinfectant is the period of time after required activation or dilution of the product or, for ready-to-use products, the day the bottle is opened, for which the disinfectant solution can be used, provided that the concentration of active ingredients remains above the MRC or MEC. The reuse life can be 1 day, 14 days, 28 days, or whatever period is indicated on the label. The actual reuse life could be shorter than stated on the label because dilution, the presence of organic material, or residual detergent could alter the effectiveness of the solution as it is being used (see E.7). For this reason, a disinfectant solution should be monitored with an appropriate solution test strip every time it is used throughout the reuse period. If the test strip shows that the active ingredient is below the MRC or MEC, the solution should be discarded regardless of the number of days it has been in use.

The use pattern refers to how many times the solution can be used; it might be used one time only, or it might be reused for the period of its reuse life. The use pattern also can be expressed in terms of the number of disinfection cycles. The storage life, which is determined by the expiration date and which could be a year or more if the product is stored according to the manufacturer’s written IFU, is the time period after which the unused, unopened product is no longer deemed effective.

Both the manufacturer of the disinfectant and the manufacturer of the device to be decontaminated should provide information on materials compatibility. The data should support the safety of a solution with respect to the materials from which a particular device is constructed (e.g., metal, alloys, plated metals, plastics, and combinations thereof). The information should state whether materials compatibility is affected by exposure time, exposure temperature, or concentration. Certain chemicals, especially when dissolved in water, are capable of corroding metals; this is particularly true of strong oxidizing agents, such as products that contain chlorine. Certain metals in contact with one another tend to corrode more rapidly than each metal alone. Certain plastics can become brittle if exposed to particular chemical agents. Some items requiring decontamination are very expensive (e.g., endoscopes), so the user should contact the manufacturer of the device to determine if the materials in the device have been tested and found to be compatible with the disinfectant product.

The selection of a product or process to render a medical device safe for patient use should be determined by how the device will be used. The Spaulding classification provides the bases of this decision, it is based on three categories critical, semicritical, and non-critical.

Critical devices are devices that are introduced directly into the bloodstream or which contact a normally sterile tissue or body space during use and for which sterilization is required. Semi-critical devices come in contact with mucous membranes or non-intact skin. These items should be sterilized prior to use, and if sterilization is not possible, high-level disinfection is the minimum advised processing method (Spaulding, 1972; FDA, 2015; AORN, 2018).

High-level disinfection does not provide a margin of safety that sterilization does. Sterilization provides an increased safety margin of approximately 6 logs. The selection process should include a review of the medical devices IFU. If a sterilization method is listed as a method, it should be the primary consideration.

B.8 Factors to consider in chemical disinfection and gaseous chemical sterilization

The user should be aware of factors that can alter the effectiveness of a chemical disinfectant:

a) **Use pattern:** Only those disinfectants labeled for reuse should be reused. A reuse claim on the product label indicates that the manufacturer has documented that, after a simulated reusing of the disinfectant for the period of time specified in the manufacturer's study, the disinfectant was effective in killing the microorganism types shown on the label. Use-pattern is event-related, not time-related.

b) **Reuse life:** The reuse life stated on the label must not be exceeded. Reuse life is event-related as well as time-related. The reuse life could be shorter than what is stated on the label because of events that alter the concentration of the liquid chemical germicide.

c) **Bioburden:** The process has been tested against a known number of microorganisms, and its success depends on the cleanliness of the items to be processed.

d) **Water and extraneous materials:** Organic matter in the form of serum, blood, pus, or fecal material can protect microorganisms and consume or inactivate the active chemical agent in the disinfectant. Soaps, detergents, cork, cotton, lint, cotton wool, cellulose sponges, and the minerals found in hard water can also interfere with the effectiveness of the disinfectant. The manufacturer of the disinfectant should be consulted for information on the appropriate water, soaps, and detergents to be used in conjunction with the disinfectant.

   NOTE The disinfectant manufacturer might not have included organic matter or extraneous materials in challenge tests of antimicrobial efficacy. Even if simulated soil was used to challenge the disinfectant (see AAMI TIR12 and AAMI TIR30), the amount of organic or foreign material used in the testing might not be comparable to that encountered in actual use conditions.

e) **Dilution and MEC/MRC monitoring:** The disinfectant is diluted by water remaining on surfaces and in the lumens of devices immersed in the disinfectant. Dilution can be very significant in the long-term use and reuse of a chemical disinfectant and can potentially reduce the concentration of the chemical agent to a level too low to be effective in killing a sufficient number of certain microorganisms in the recommended exposure time. To avoid dilution of the disinfectant, excess moisture should be removed after cleaning. Disinfectant solutions must not be used at concentrations below the MEC or MRC stated on the label. An MEC or MRC statement is required by FDA. As part of a health care facility's quality control program, LCS/HLD solutions such as glutaraldehyde should be monitored upon activation and before each use in order to detect unexpected dilution of the solution.

f) **Temperature:** The antimicrobial claims stated on the product label are determined according to exposure time and temperature. For example, the label might state: "To kill *M. tuberculosis*, immerse the device for 1 hour at 25°C (77°F)." This label claim will have been fully documented. If the temperature of the solution is at any time lower than the temperature indicated on the product label, then complete disinfection might not be achieved during the prescribed time period. On the other hand, the temperature should not be high enough for the active ingredients to evaporate appreciably. A thermometer should be used to monitor the solution temperature.

g) **Evaporation and light:** Evaporation can occur from a solution in an uncovered container. If the chemical agent is more volatile than the diluent (a gas dissolved in water is more volatile than water), then loss of the agent by evaporation can be very important. Chlorine products are especially susceptible to evaporation effects. Exposure to light can also affect chlorine products and disinfectants.

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

i) **Device characteristics:** A disinfectant solution is only effective if it can contact all surfaces of the item to be disinfected. The FDA recommends that medical device manufacturers perform testing that assesses the compatibility of the device with cleaning and defoaming agents and materials, including in-use testing of devices with complex design configurations that could impede penetration by cleaning and disinfectant agents.

j) **Rinsing:** Inadequate quality of the rinse water used could result in recontamination of the medical device. If the medical device is required to be sterile and undergoes liquid chemical sterilization, then it should be rinsed with sterile water (0.2 µm filtered water is acceptable, provided that the filtration systems are adequately maintained).

The user should be aware of factors that can alter the effectiveness of a gaseous sterilant:

a) **Bioburden:** The process has been tested against a known number of microorganisms, and its success depends on the cleanliness of the items to be processed.

b) **Water and extraneous materials:** Water or organic matter in the form of serum, blood, pus, or fecal material can protect microorganisms and consume or inactivate the active chemical agent. Soaps, detergents, and the minerals found in hard water or water systems, if not rinsed away thoroughly, can interfere with the sterilization effectiveness. Failure to thoroughly clean, rinse and dry devices could result in an ineffective sterilization cycle.

c) **Venting or immersion caps:** Use of venting, ethylene oxide, or immersion caps per manufactures instructions is required to ensure sterilization and prevent device damage.

d) **Device characteristics:** Device design characteristics should align with sterilizer cycle claims. Materials identified by the sterilizer manufacturer as non-compatible should not be processed in the sterilizer.

B.9 General considerations and selection criteria

Personnel should take into account some general considerations when selecting a chemical sterilant/high-level disinfectant, including, but not limited to the following:

a) Can the medical device undergo sterilization?

b) Has the liquid chemical sterilant/high-level disinfectant or gaseous chemical sterilization system been cleared by the FDA?

c) When should chemical sterilization/high-level disinfection be selected?

d) What types of medical devices are suitable for sterilization or high-level disinfection by this product or process? What criteria were used to determine the suitability of a device for chemical sterilization or high-level disinfection?

e) How is sterilization or high-level disinfection accomplished? (What is the process, and how is it used?)

f) Is a dedicated container or other equipment needed in order to use the LCS/HLD? If so, does the LCS/HLD manufacturer have material requirements for the container?

g) How can the efficacy of the product be measured? How can the user determine whether the product is effective, initially and after several uses? (For example, is there a test to determine the concentration or strength of the active chemical?)

h) How can the efficacy of the process be measured? Can the process be monitored with physical, chemical, and biological indicators? What kind of qualification, routine, and product testing is required for the process?

1) Is a BI PCD available?

i) How is the device handled after processing to prevent recontamination?

j) What are the limitations of the product or process?

k) Before exposing a device to the product or process, how should it be cleaned?

l) If the chemical sterilant is gaseous, is emission control technology required? Is a dedicated exhaust system needed? Is a continuous gas monitoring system necessary?

m) What types of utilities and room requirements are required to install and run the equipment?

n) How much time is required for the sterilization or high-level disinfection process? That is, how much time is needed to ready the liquid chemical sterilization/high-level disinfection or gaseous chemical sterilization process and to prepare and process an item so that it is ready for reuse?

o) What packaging materials and systems are compatible with the process?

p) Will the gaseous chemical sterilant adequately penetrate currently used types of packaging, including rigid sterilization container systems?

q) Is the system user friendly? For example, how many steps are involved in the process? Do the sterilization or high-level disinfection parameters, such as time, temperature, and concentration or dose, have to be selected by the user, or are they preset? How much in-service training is required? What is required to ensure operator competency?

r) Has the medical device to be sterilized or high-level disinfected been validated for efficacy and verified for compatibility with the process? Is any special preparation needed for the device before processing (e.g., disassembly)?

s) Is control of water quality critical to the process? If so, what water quality is necessary? What water control steps are necessary?

t) What are the requirements for record-keeping?

u) If lumened medical devices are to be proceesed, are devices within the system's validated claims (e.g., lumen length and diameter)?

v) What type of quality control monitor will be used?

w) What are the time and temperature requirements for HLDs?

In addition, when selecting a new chemical sterilant/high-level disinfectant, the health care facility should establish a multidisciplinary committee with representation from those who will be affected by the new product. For a product related to chemical sterilization, representation could include, but not necessarily be limited to, infection prevention and control, operating room, sterile processing, risk management, health care technology management, and staff development/education. Relevant research articles published in peer-reviewed journals should also be reviewed.

B.9.1 Health and safety considerations

Personnel should take into account some health and safety considerations when selecting a chemical sterilant/high-level disinfectant, including, but not limited to the following:

a) To what extent has toxicity testing been performed?

b) Has a copy of the SDS been provided?

c) What are the potential short- and long-term adverse health effects of overexposure to the chemical sterilant/high-level disinfectant?

d) Is the chemical sterilant/high-level disinfectant potentially toxic to personnel? In what way? Are there toxic vapors or toxic byproducts? Does the chemical sterilant/high-level disinfectant react with certain materials (e.g., cleaning agents, adhesives) to form toxic products?

e) At what level of exposure is the chemical sterilant/high-level disinfectant toxic to humans? By what route of exposure is it toxic (skin contact, inhalation)? Is there an applicable OSHA regulation for occupational exposure? If so, what is the PEL established by OSHA for the active ingredient?

f) What are the occupational exposure limits from the ACGIH, NIOSH or Cal-OSHA that may provide more current criteria for determining safe exposure limits?

g) How would the user measure what the gas or vapor concentration is, and what are the symptoms of over exposure and what adverse health effects may result?

h) What PPE is required? Do the chemical sterilant/high-level disinfectant manufacturer's written IFU indicate that special types of gloves are required when working with the product?

i) Is environmental or personnel monitoring required by OSHA, recommended by ACGIH®, or necessitated by the potentially hazardous nature of the sterilant? If so, which methods are appropriate?

j) Are there specific IFU that explain how toxic conditions or reactions can be avoided during use? For example, must time, temperature, or humidity be controlled? Should a local exhaust hood be used?

k) Are special storage conditions necessary for the chemical sterilant/high-level disinfectant or processed items?

l) Does the chemical sterilant/high-level disinfectant leave residues on processed items that could be toxic to patients or personnel? Is there a method of reducing residues on processed items to nontoxic levels? If it is necessary to aerate processed items, what are the time and temperature parameters? How can adequate aeration be monitored and ensured? If rinsing is necessary, what tests have been performed by the manufacturer to document that the recommended rinse process will adequately remove residues?

m) Is contact (allergic) sensitization or tissue irritation a potential health effect?

n) Are there physical hazards such as fire or explosion?

o) Can heat or other environmental conditions cause chemical changes in the chemical sterilant/high-level disinfectant that would result in other hazards?

p) What precautions should be taken in the disposal of the LCS/HLD? Even if the product itself is not toxic when discarded, can it react with other substances (in the sewer, for example) to form new volatile or toxic products? Are there applicable federal, state, or local regulations?

q) What level of in-service instruction or other personnel training in the safe use of the chemical sterilization system does the manufacturer provide?

r) What level of testing has been done to determine that processed devices remain safe for patient use after repeated processing?

s) Is it necessary to retain occupational health records? If so, for how long?

t) Where will the eyewash station be located? Are existing eyewash stations placed appropriately, and are they adequate for the chemical sterilant/high-level disinfectant?

B.9.2 Effectiveness

Personnel should take into account some effectiveness considerations when selecting a chemical sterilant/high-level disinfectant, including, but not limited to the following:

a) Are test results available to indicate what types of materials and devices can be sterilized or high-level disinfected without adverse effects on the items? On the patient? On the effectiveness of the chemical

sterilant/high-level disinfectant? Are data available to demonstrate the effectiveness of the product in sterilizing or high-level disinfecting specific types of devices?

b) What types of materials or devices can and cannot be sterilized or high-level disinfected effectively? Are there any restrictions on the types of devices that can be sterilized or high-level disinfected (e.g., devices with particular lumen diameters, devices with hinges, devices of specified length)? Is an itemized list of the types of devices that were tested available?

c) Must items be partially or completely disassembled before exposure to the chemical sterilization or high-level disinfection process?

d) Are test results available demonstrating how the presence of organic material, inorganic material, and residual detergent affect the effectiveness of the sterilization or high-level disinfection process? Did the manufacturer challenge sterilization using organic and inorganic substances?

e) For LCS/HLD products, what are the manufacturer's recommended contact conditions (i.e., temperature and time)? Does the LCS/HLD product require activation or dilution before use, or is the product ready-to-use? If dilution is required, what quality of water (see ANSI/AAMI ST108:2023) should be used? For how long can the use solution (activated or diluted, if appropriate) be reused? Is there a solution test strip or chemical monitoring device available to determine whether the concentration of the active ingredient in the solution is adequate? Does the LCS/HLD manufacturer specify the solution test strip or chemical monitoring device to be used with its LCS/HLD product? Does the manufacturer provide recommendations about how the accuracy of the solution test strip or chemical monitoring device can be verified? Is an equivalent FDA-cleared solution test strip or chemical monitoring device commercially available from another manufacturer?

NOTE The manufacturer of an LCS/HLD product should provide or recommend an appropriate FDA-cleared solution test strip or chemical monitoring device to be used with its product to determine whether the concentration of the active ingredient in the LCS/HLD use solution is higher than the product's minimum recommended concentration (MRC) or minimum effective concentration (MEC). Solution test strips or chemical monitoring devices determined by the FDA to be substantially equivalent to the FDA-cleared solution test strip or chemical monitoring device recommended by the LCS/HLD manufacturer may also be used. The labeling of the solution test strip or chemical monitoring device should specify the LCS/HLD products with which it can be used. All solution test strips or chemical monitoring devices should be used in accordance with the manufacturer's written IFU.

f) Is the positioning of the device in the chemical sterilant/high-level disinfectant or sterilizer critical?

g) If applicable, what are the manufacturer's recommendations for the packaging that should be used?

h) Are test results available to demonstrate that the effectiveness of the process can be measured or monitored? How can the effectiveness of the process be ensured or documented? What controls are in place to alert the user if the process fails?

i) What are the important factors in the reuse of the LCS/HLD (e.g., dilution, time, temperature, organic and inorganic soils, bioburden)?

j) Does the chemical sterilant/high-level disinfectant manufacturer have data demonstrating microbial kill on and within the devices processed? Were the test organisms inoculated into the areas of the device that are most difficult for the chemical agent to reach? Were worst-case sterilizing conditions evaluated (e.g., half cycles for gaseous chemical sterilization systems)?

k) Is the manufacturer aware of instances of failure of the LCS/HLD product or gaseous chemical sterilizer, even when the product was properly used according to the manufacturer's directions?

l) Are accessories to process certain devices (e.g., connectors) required? If so, are they available from the chemical sterilant/high-level disinfectant manufacturer, and does the manufacturer provide explicit written IFU and replacement criteria?

m) Has the manufacturer of the medical device to be sterilized or high-level disinfected validated the process for efficacy and verified for compatibility with the process?

n) Has the LCS/HLD along with the cleared AER been listed on the FDA website identifying products that have demonstrated acceptable performance processing duodenoscopes?

NOTE The device manufacturer's written IFU should be followed.

B.9.3 Materials compatibility

Personnel should take into account some materials compatibility considerations when selecting a chemical sterilant/high-level disinfectant, including, but not limited to the following:

a) What testing has the manufacturer performed to demonstrate the compatibility of the chemical sterilant/high-level disinfectant with medical device materials? Which materials have been shown to be incompatible?

b) Have the devices listed on the label for use with this product been adequately evaluated for degradation of functionality after prolonged, repeated use of the chemical sterilant/high-level disinfectant? Have the device manufacturers evaluated the compatibility of their products with the chemical sterilant/high-level disinfectant?

c) Has the sterilizer/LCS/high-level disinfectant manufacturer established the device material is compatible in their FDA cleared labelling?

d) Will use of the chemical sterilant/high-level disinfectant affect the ultimate use-life of the processed items? If so, will all the materials in the device be affected or only certain components? Do devices composed of multiple materials pose more compatibility problems than devices composed of a single material?

e) Are there test data establishing a limit, because of materials compatibility, on the number of times that the chemical sterilant/high-level disinfectant can be used for certain materials?

f) Does the manufacturer recommend additional inspection to ensure device functionality? If so, will special instrumentation be needed to perform inspections or tests?

g) Will residuals of previously used chemicals interfere or react with product materials?

h) Is the process compatible with the packaging (if applicable)?

i) What products or chemicals does the device manufacturer recommend or not recommend for processing the device?

NOTE The device manufacturer's written IFU should be followed.

B.9.4 Cost-effectiveness

Personnel should take into account, but not base the decision solely on, cost-effectiveness considerations when selecting a chemical sterilant/high-level disinfectant.

Evaluation of cost effectiveness should assess the impact of space, turnaround time and resulting equipment inventory requirements for:

a) use;

b) storage;

c) special equipment required;

d) disposal considerations;

e) cost per use/cycle; and

f) productivity.

B.9.5 Rigid sterilization container systems

Is the rigid sterilization container system selected suitable for the proposed sterilization use and is compatible with the devices and sterilizers in use?

Annex C
(normative)
Glutaraldehyde solutions

NOTE The information provided in this Annex was accurate at the time the standard was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and written IFU change accordingly. Therefore, it is essential that 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.

C.1 Introduction

Glutaraldehyde-based products are effective sterilants and disinfectants used primarily for medical devices that cannot be steam sterilized, particularly heat-sensitive, lensed medical devices that are commonly subjected to high-level disinfection between patient uses. If used properly, glutaraldehyde-based products can be used without tissue irritation or other adverse health effects.[4] However, dermatologic and respiratory effects on overexposed personnel have been reported as well as eye irritation and, in some individuals, skin sensitization to glutaraldehyde; therefore, adequate precautions should be taken when using glutaraldehyde-based products (Ballantyne, 1995).

This Annex covers the properties and applications of glutaraldehyde; occupational exposure considerations specific to glutaraldehyde, including vapor monitoring and procedures for handling spills; and the disposal of glutaraldehyde solutions.

NOTE Glutaraldehyde is a major component of many LCS/HLD products. Chemical and toxicological properties are unique to any given chemical, so the properties of glutaraldehyde discussed here should not be generalized to other components that a formulation might contain. The product manufacturer should be consulted for further details on the formulation and for an SDS.

C.2 Properties and applications of glutaraldehyde

The biocidal properties of 2% glutaraldehyde in alkaline aqueous solution were discovered in the early 1960s (Borick, Dondershine, and Chandler, 1964). This basic formulation was later refined to include, when appropriate, corrosion inhibitors, wetting agents, and buffers to control the pH of the solution. Other formulations with higher sterilant concentrations (e.g., 3.4%) also have been developed.

Several companies now produce glutaraldehyde-based liquid sterilants and high-level disinfectants. These products are sometimes referred to as either "acid glutaraldehyde" or "alkaline glutaraldehyde." Products designated as "alkaline" are usually supplied in two parts (active glutaraldehyde solution and activator buffer), which require mixing before use to impart an alkaline pH to the solution (a pH of approximately 8). Those designated as "acid" usually do not require an activator.

Glutaraldehyde-based sterilants usually are used as HLDs for semicritical devices. Conditions for high-level disinfection generally range from 5 minutes to 90 minutes at 20ºC to 35ºC (68ºF to 95ºF), depending on the product formulation and glutaraldehyde concentration (Table D.1). For currently available products, the contact time for sterilization is 10 hours at temperatures ranging from 20ºC to 25ºC (68ºF to 77ºF) or 7 hours and 40 minutes at 35ºC (95ºF), depending on the product formulation and glutaraldehyde concentration. Depending on the product, the device sterilization contact conditions indicated in the labeling of a cleared LCS/HLD could be based only on the AOAC Sporicidal Activity Test or on additional simulated-use testing with devices.

Because the health care industry has used glutaraldehyde for many decades to disinfect and sterilize medical devices, there is a large amount of information in the literature regarding its mechanism of action, the role of pH control, its compatibility with the various materials used to manufacture medical devices, the effect of temperature on the rate of

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[4] The Australian government's 1994 assessment report, *Glutaraldehyde: Priority existing chemical no. 3,* concludes that "glutaraldehyde can be used safely... if the proper control measures are in place. The main health effects of glutaraldehyde are irritation of the skin, eyes and respiratory system."

microbial kill, and the procedures that should be used for the safe handling of glutaraldehyde solutions (Alvarado, et al., 2000; Chervenak, 2002, 2003; Jordan, 1995; Rubbo, Gardner, and Webb, 1967; Russell, 1994; Stonehill, Krop, and Borick, 1963). Despite this, recent evidence has suggested that some types of microorganisms demonstrate resistance to the antimicrobial effects of glutaraldehyde and may not be inactivated by such disinfectants. Strains of nontuberculous mycobacteria and *Pseudomonas* have shown unique resistance to glutaraldehyde, some of which has been associated with infection outbreaks (Duarte, et al., 2009; Griffiths, et al., 1997; Svetlikova, et al., 2009; Tschudin-Sutter et al., 2011). Some cyst and even vegetative forms of protozoa also demonstrate resistance to the effects of glutaraldehyde (Barbee, et al., 1999; Coulon, et al., 2010). To ensure the safe and effective use of a particular product, users should consult the labeling, because the directions vary according to the manufacturer's formulation.

Table C.1—Examples of labeled contact conditions for high-level disinfection for FDA-cleared glutaraldehyde products[1]

Glutaraldehyde solution	Contact conditions
1.12% glutaraldehyde, 1.93% phenol–phenate solution	25ºC (77ºF), 20 minutes
2.4% to 2.6% glutaraldehyde solutions without surfactants	20ºC to 25ºC (68ºF to 77ºF), 45 minutes
2.4% to 2.5% glutaraldehyde solutions with surfactants	20ºC to 25ºC (68ºF to 77ºF), 45 to 90 minutes
2.5% glutaraldehyde solution with surfactants[2]	35ºC (95oF), 5 minutes
3.0% to 4.0% glutaraldehyde solutions with surfactants	20ºC to 25ºC (68ºF to 77ºF), 20 to 90 minutes
3.4% glutaraldehyde, 20.1% isopropanol	20ºC (68ºF), 10 minutes

NOTE 1 A complete list of FDA-cleared HLDs and LCSs can be found at https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and.

NOTE 2 This solution must be used in an AER with the FDA-cleared capability of maintaining the solution at 35ºC.

Glutaraldehyde-based products can be used in automated or manual high-level disinfection processes. Many automated reprocessors are equipped with temperature-control devices, computerized processing cycles, and bacteria-retentive filters for rinse water, as well as filters for removing suspended materials from the reused disinfectant solution. Although automated reprocessors might control the temperature of the solution in the reservoir, they might not be capable of maintaining the temperature of the solution in the processing chamber during high-level disinfection; the user should check with the manufacturer of the automated reprocessor. It should be noted that formulations containing surfactants might not be suitable for automated systems because of the potential for foaming.

Glutaraldehyde is compatible with most device materials used today and can be used to process medical devices containing heat-sensitive materials. Most glutaraldehyde-based chemical sterilants are labeled for reuse for 14 to 28 days. During the recommended reuse period, the concentration of the active ingredients in the solution should be tested with the solution test strips or chemical monitoring devices recommended by the manufacturer, and the testing should be performed according to the label instructions. If the concentration of the active ingredients in the solution falls below the MRC or MEC, the solution should be discarded regardless of how many days it has been in use.

C.3 Effective use of glutaraldehyde

To ensure efficacy, the user should observe the following guidelines:

a) The medical device manufacturer's written IFU should be consulted to determine the compatibility of the device with the selected glutaraldehyde solution.

b) Flexible endoscopes should be processed according to ANSI/AAMI ST91 Flexible and semi-rigid endoscope processing in health care facilities.

c) If an automated reprocessor is to be used, the device manufacturer and automated reprocessor manufacturer should be consulted to determine the advisability of using glutaraldehyde products containing a surfactant (which might not be suitable for automated systems because of the potential for foaming).

d) The glutaraldehyde product should be mixed according to the label instructions.

e) Devices should be thoroughly cleaned and dried before they are immersed in the solution to avoid adding debris to the solution or diluting the solution, both of which can shorten the efficacy period.

f) Devices should be thoroughly and completely immersed in the HLD solution to ensure that all surfaces are covered by the solution and that all appropriate lumens have been filled with the HLD, as recommended.

g) A solution test strip or chemical monitoring device should be used to test the concentration of the active ingredients before each use. Only those solution test strips or chemical monitoring devices recommended by the glutaraldehyde product manufacturer should be used. Quality control checks of the solution test strips or chemical monitoring devices should be performed according to the manufacturer's written IFU.

h) When the concentration of the active ingredients falls below the MRC or MEC, the solution should no longer be used.

i) Solutions should be kept covered to prevent evaporation.

j) Solutions that evaporate or drain below the soak level may require additional solution to facilitate complete immersion of the device. Before adding solution, the user must first consult the high-level disinfectant IFU to ensure that the manufacturer permits the adding of solution. The solution cannot be used beyond the original soaking solution expiration date (use life). Before being used, the solution must be tested for MEC.

k) Solutions should not be used beyond the reuse period indicated on the label even if the concentration of the active ingredients is at or above the MRC or MEC. A glutaraldehyde product might be labeled for 14-day use, for 28-day use, or (if it is a concentrate) for one-time use.

l) Glutaraldehyde solutions should not be used beyond their shelf life.

m) Unopened solutions should be stored in a cool, well-ventilated area at the temperature recommended by the manufacturer.

C.4 Safe use of glutaraldehyde

C.4.1 Occupational exposure

C.4.1.1 General considerations

Procedures should be developed that will prevent contact with glutaraldehyde solution; identify appropriate methods for determining the glutaraldehyde vapor concentration to ensure that the exposure to glutaraldehyde vapor is at the lowest reasonably obtainable level below the occupational exposure limit. Personnel should always wear appropriate PPE when using glutaraldehyde solutions (see D.4.1.4).

Rationale: Exposure to glutaraldehyde vapor, even at levels below the TLV®-C, can cause symptoms such as headaches and irritation of eyes, nose, and throat. These symptoms should disappear when the individual leaves the area of glutaraldehyde use. Exposure to glutaraldehyde vapor can also cause asthma-like symptoms in some individuals. See also D.4.1.2.

C.4.1.2 Health effects of glutaraldehyde

C.4.1.2.1 Potential health effects of short-term exposure

Glutaraldehyde is an irritant to the skin, eyes, and respiratory system. Skin contact can cause minor irritation with itching and slight local redness. Prolonged skin contact causes mild to moderate local redness and swelling. Even in low concentrations, there is a potential for liquid glutaraldehyde to be a contact sensitizer, through the dermal route of exposure, in a small percentage of exposed individuals. Glutaraldehyde in concentrations of less than 10% is not known to be absorbed through the skin in harmful amounts. Glutaraldehyde is a protein cross-linking agent, and its reactivity with skin proteins is a major factor in limiting percutaneous absorption.

Glutaraldehyde in concentrations of more than 0.1% is considered to be irritating to the eyes. Eye contact causes moderate to severe irritation, experienced as discomfort or pain, excessive blinking, and tear production, with marked redness and swelling of the conjunctiva. Ocular contact with aqueous solutions containing 2% or higher concentrations of glutaraldehyde can cause severe eye irritation and damage, including minor to moderate corneal injury that can persist and, if not adequately and promptly treated, result in permanent impairment of vision.

If swallowed, glutaraldehyde in concentrations of less than 5% can be mildly to moderately irritating to the mouth, throat, and stomach. There could be abdominal discomfort or pain, nausea, vomiting, diarrhea, dizziness, and weakness.

Nose and throat irritation and general tightness of the chest have been reported by workers exposed to glutaraldehyde vapor.[5] Vapors generated from glutaraldehyde can be irritating to the respiratory tract, and current information suggests that inhalation of the vapor can cause asthma-like symptoms as well as aggravate pre-existing asthma and inflammatory or fibrotic pulmonary disease. Nosebleeds have also been reported in workers exposed to glutaraldehyde but are rare. For these reasons, all glutaraldehyde solutions should be used in well-ventilated areas or in freestanding or vented chemical fume hoods.

These symptoms are generally temporary and should subside when the individual leaves the area of glutaraldehyde exposure. Evidence indicates that skin and respiratory irritant effects are exacerbated on repeated exposure to glutaraldehyde.

The information in this section is based on Ballantyne (1995), Ballantyne and Jordan (2001), and—in the case of the information on skin effects of prolonged contact with glutaraldehyde—Fowler (1989).

C.4.1.2.2 Potential health effects of long-term exposure

Respiratory irritation and skin-sensitizing effects of glutaraldehyde have been confirmed (Beauchamp et al., 1992). There is no evidence that exposure to glutaraldehyde causes adverse reproductive health effects, and a mortality study did not reveal an increased incidence of cancer deaths. Animal studies have shown no evidence of any target organ toxicity. Case reports have suggested an association between glutaraldehyde and asthma-like symptoms (Chan-Yeung, et al., 1993; Stenton, et al., 1994; Gannon, et al., 1995; Di Stefano, et al., 1999). To date, only a very small number of cases have been diagnosed as asthma on the basis of both clinical features and appropriate investigational procedures.

Glutaraldehyde is listed as a Group 3 carcinogen (“unclassifiable as to carcinogenicity to humans”) by the International Agency for Research on Cancer (IARC) and as “not classifiable as a human carcinogen” by ACGIH®.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010). For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2013).

C.4.1.3 Occupational exposure limits

Currently, ACGIH® recommends a ceiling threshold limit value (TLV®-C) for glutaraldehyde of 0.05 parts per million volume (ppmv) (ACGIH®, 2013). A threshold limit value is the airborne concentration of a substance to which "it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects. Because of wide variation in individual susceptibility, however, a small percentage of workers may experience discomfort from some substances at concentrations at or below the threshold limit; a smaller percentage may be affected more seriously by aggravation of a pre-existing condition, or by development of an occupational illness” (ACGIH®, 2013). However, federal OSHA can enforce exposure limits, including the currently ACGIH®-recommended TLV®-C for glutaraldehyde, by means of its General Duty Clause, which is designed to ensure that each employer provides a workplace for employees that is free from recognized hazards. Additionally, states with federally approved state OSHA programs can opt to enforce exposure limits as originally promulgated in the Air Contaminants Standard or their own stricter standards.

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[5] Reports describing asthma-like symptoms resulting from overexposure to high vapor concentrations have been published. It is unknown whether these symptoms are associated with an immune-mediated mechanism or are provoked by irritating concentrations, because the current body of evidence is inconclusive.

NOTE The occupational exposure limits discussed above were current at the time this document was published. However, it is essential that personnel keep informed of the status of federal, state, and local regulations applicable to glutaraldehyde, as well as with professional guidelines published by such organizations as ACGIH®.[6]

Certain Environmental Protection Agency (EPA) regulations also apply to glutaraldehyde. Users should contact the federal EPA office or their state EPA offices for information on EPA requirements.[7] Additional regulatory information can be obtained from the manufacturer's SDS.

C.4.1.4 Personal protective equipment and first aid

C.4.1.4.1 Eye protection

Splashproof goggles or both safety glasses with side shields and a wraparound full-face shield should always be worn when working around glutaraldehyde-based LCSs/HLDs. For eye protection, both safety glasses and face shields are needed, because many face shields alone do not offer total protection against eye contamination, and their use should be considered an adjunct to safety glasses in order to protect facial skin.

If any eye contact should occur, the eye should be washed immediately and continuously with flowing water for at least 30 minutes. (Flushing with water dilutes and removes the glutaraldehyde.) Contact lenses should be removed after the first 5 minutes and the washing continued. The employee should then receive prompt medical attention, preferably from an ophthalmologist.

C.4.1.4.2 Skin protection

For glutaraldehyde, nitrile and butyl rubber are the most impervious materials; gloves made of polyethylene and certain man-made copolymers give protection for several hours (Jordan, et al., 1996). The permeability of gloves varies considerably, depending on the manufacturer; therefore, the recommendations of the glove manufacturer and the LCS/HLD manufacturer should be consulted. Polyvinyl chloride and neoprene gloves do not give adequate protection from glutaraldehyde and can actually absorb the chemical; therefore, the use of these types of gloves is not recommended. The use of latex gloves also is not recommended, because they are not designed to protect against chemical exposures.

Personnel who have come into contact with liquid glutaraldehyde should immediately remove contaminated clothing and shoes and thoroughly wash contaminated skin with flowing water for 15 to 20 minutes. Exposed personnel should receive prompt medical attention from a physician—ideally an occupational health physician—immediately after these emergency measures. Contaminated reusable clothing should be laundered before it is worn again, and rubber goods should be rinsed thoroughly before use. Any heavily contaminated clothing, shoes, or equipment that cannot be thoroughly washed and decontaminated should be discarded.

C.4.2 Ventilation

Glutaraldehyde solutions should be prepared and used in a well-ventilated area or in freestanding or vented chemical fume hoods.

C.4.3 Preparing activated solutions

Glutaraldehyde solutions should be prepared and activated according to the manufacturer's written IFU. Appropriate PPE should be worn, and every effort should be made to minimize splashing, spilling, and personnel exposure. Preparation of activated solutions should be performed only in a properly ventilated area. The date of activation (mixing

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[6] Information on current OSHA regulations can be obtained at OSHA's web site, http://www.osha.gov; see also Annex J. Information on current ACGIH guidelines can be obtained at ACGIH's web site, http://www.acgih.org, or by contacting the American Conference of Governmental Industrial Hygienists, Technical Affairs Office, Kemper Woods Center, 1330 Kemper Meadow Drive, Cincinnati, OH 45240, (513) 742-2020, fax (513) 742-3355.

[7] Information on current EPA regulations can be obtained at EPA's web site, http://www.epa.gov, or by contacting the U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 272-0167.

date) and the expiration date should be recorded on the activated solution container and documented according to facility policies and procedures.

Rationale: The recommended ventilation, spill prevention procedures, and appropriate PPE are intended to protect the worker from the irritating and sensitizing effects of glutaraldehyde. The activation and expiration dates should be recorded to ensure that the solution will not be used longer than its effective use life.

C.4.4 Pouring activated solutions

The solution should be poured from the original container to a clean, dry immersion container by a method that will prevent employee contact with the chemical solution and reduce exposure to glutaraldehyde vapor to the lowest reasonably obtainable level below the TLV®-C. Agitation and splashing during transfer should be minimized. Examples of methods of minimizing contact with the solution or vapor include the use of closed transfer devices, local exhaust hoods, and/or ductless fume hoods and strict adherence to the use of appropriate PPE.

Rationale: Avoiding contact with glutaraldehyde-based products prevents skin and eye injury and minimizes the potential for skin sensitization, which has been reported in a small proportion of users. Minimizing agitation and splashing during transfer also minimizes the potential for increased vapor. See also C.4.1.2.

C.4.5 Transporting solutions

Transport of glutaraldehyde solutions in secondary containers such as trays or buckets should be avoided. If it is absolutely necessary to transport an activated solution to another area, that area should be properly ventilated, and a transport method should be selected that will minimize the potential for spills and the possibility of personnel exposure to the solution or vapor.

Rationale: Transporting solutions in secondary containers increases the risk of spills. Spills increase the surface area of the solution and thus increase the potential for vapor to raise the air concentration above the TLV®-C. Spills also increase the potential for skin and eye contact and irritation, as described in C.4.1.2.

C.4.6 Storing activated and unused solutions

Glutaraldehyde should be stored in a closed container or system in a well-ventilated area. Soaking containers should always be covered and clearly labeled, in accordance with the OSHA Hazard Communication Standard (21 CFR 1910.1200[f][5]), with appropriate warnings, precautionary statements, and first-aid instructions. The surface area of the containers should be as small as possible; containers should be narrow and deep rather than large, long, and shallow. The lid should be kept on the soaking container at all times except when items are being placed into or taken out of the solution. Automated systems should be designed to prevent the escape of glutaraldehyde vapor and liquid.

Rationale: A closed system will minimize evaporation of the glutaraldehyde and subsequent personnel exposure to vapor.

C.4.7 Immersing items to be high-level disinfected or sterilized

Personnel should wear appropriate PPE when placing medical devices or other items into the activated solution; this activity should take place in a properly ventilated area. The worker should gently place clean, dry items into the activated solution, taking care to disturb and agitate the surface of the solution as little as possible.

NOTE Ensure that there are no air bubbles remaining on the surface of the device during the exposure time.

When manually irrigating or flushing the solution through internal channels or lumens of an instrument, personnel should be careful to avoid being splashed or sprayed with the solution. The syringe should be carefully filled with the solution and securely attached to the channel opening or all-channel irrigator. The solution in the syringe should be slowly pushed into the channel; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator. A new syringe should be used each time.

Gloved hands should be rinsed thoroughly with water before the cover is replaced on the solution container to avoid contaminating the surface of the container with solution. The medical devices or other items should be allowed to soak for the amount of time and at the temperature specified by the manufacturer to achieve high-level disinfection or

sterilization. (See the device manufacturer's written IFU for additional recommendations on high-level disinfection and sterilization.)

Rationale: These procedures will help prevent worker exposure to glutaraldehyde and help ensure the effectiveness of the high-level disinfection or sterilization process. Reusing syringes for irrigation or flushing could lead to contamination of the solution.

C.4.8 Rinsing high-level-disinfected or sterile items

Personnel should wear appropriate PPE when removing items from the activated solution; this activity should take place in a properly ventilated area.

Before removing the device from the solution, personnel should remove the solution from the internal channels or lumens of the device by flushing each channel several times with a syringe filled with air. Personnel should be careful to avoid being splashed with the solution. The device should be totally immersed in the solution, and the syringe should be securely attached to the channel opening or all-channel irrigator. The plunger should be pushed slowly; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator or cause the solution to squirt from the channel opening.

The medical devices should be gently removed from the solution and rinsed thoroughly with water of the quality specified by the device to be processed manufacturer's and/or chemical manufacturer's IFU. (Personnel should rinse their gloved hands with water and then replace the cover on the solution container.) To remove all residual solution, personnel should rinse the external surfaces of the items and any removable parts with copious amounts of critical running water; should immerse them in successive containers of critical water (the rinse solution should be discarded after each use, not reused); or should otherwise rinse the device in accordance with the manufacturer's written IFU. For medical devices with interior channels, each channel or the all-channel irrigator should be flushed several times with critical water until all residual solution is removed from the channels (at least 500 milliliters [mL] of water during each separate rinse, unless the device manufacturer instructs otherwise). The flushing procedure should be repeated using flowing instrument air or HEPA-filtered air. For medical devices with interior channels, drying of lumens is accomplished by flowing instrument air or HEPA-filtered air through the lumens for a specified period of time and pressure according to the instrument manufacturer's written IFU.

NOTE Some manufacturers may have drying processes included in their IFUs.

Additional care should be taken to ensure that the recommended number of fresh water rinses are performed to ensure that residual levels of glutaraldehyde are removed, due to toxicity concerns. The external surfaces of medical devices should be thoroughly wiped dry with a sterile, lint-free cloth.

Rationale: Proper procedures for rinsing, flushing, drying, and storing medical devices will help prevent worker exposure to glutaraldehyde and help ensure that residual glutaraldehyde is not introduced into patient tissue. Running water or successive immersions in water is recommended for rinsing in order to further dilute the solution and to prevent the retention of solution that could occur in standing water (Durante, et al., 1992).

C.5 Procedures for cleaning up glutaraldehyde spills

NOTE Glutaraldehyde spills need not be reported to regulatory authorities responsible for air quality (e.g., state health or environmental authorities such as a state Air Control Board, OSHA, or EPA). Glutaraldehyde does not have a reportable quantity (RQ) established by EPA under the Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA), nor is it on the toxic release inventory (TRI) list established under the Superfund Amendments and Reauthorization Act of 1986 (SARA), Title III. Glutaraldehyde concentrations of 1% or more are listed in some states' right-to-know regulations. Because glutaraldehyde contains no levels of listed substances that California has found to cause cancer, birth defects, or other reproductive harm, it is not listed under Proposition 65.

C.5.1 General considerations

All spills, no matter how small, should be cleaned up immediately. The glutaraldehyde concentration, the volume of the spill, the temperature of the room and the solution, and the type of ventilation in the area of the spill will affect whether it can be cleaned up safely without the use of inactivating chemicals and respiratory equipment. The committee judged

it safer not to use a volume measurement to differentiate between a drip, a splash, a small spill, and a large spill but instead to provide recommendations based on the assumption that anything larger than a drip or splash might need to be inactivated. Personnel might need to wear respirators, depending on the volume of the spill and the area ventilation. Use of a respirator is required for any spill with unknown vapor concentrations (see 4.4.4).

C.5.2 Deactivating chemicals

Several chemicals can be used to reduce the glutaraldehyde concentration in solutions and reduce ambient vapor levels in spill situations; there are also a number of commercially available products designed for this purpose. Such chemicals have varying degrees of activity; some are used to deal with the solution, some with vapor. Before using a glutaraldehyde-based product, personnel should be familiar with the manufacturer's specific written recommendations and supporting technical data for chemicals to be used to clean up spills.

C.5.3 Drips and splashes

It is important that all spills, including drips and splashes, be cleaned up immediately. All necessary cleanup equipment, including a mop and bucket, plastic dustpans, plastic trash bags, and sponges and towels, should be readily available. All appropriate PPE should be worn (see C.4.1.4).

Drips and splashes can be wiped up quickly with a sponge, towel, or mop. Alternatively, the glutaraldehyde solution can be neutralized with an appropriate chemical agent (see C.5.2) and then wiped up with a sponge, towel, or mop. The sponge, towel, or mop should be thoroughly rinsed with large amounts of water, and the water should be discarded down the drain. After being rinsed, reusable sponges, towels, or mop heads should be placed in the appropriate container to be laundered before reuse. After being rinsed, disposable sponges, towels, or mop heads should be disposed of according to the procedures designated by the glutaraldehyde spill containment response team.

Rationale: The most important thing is to clean up the glutaraldehyde solution quickly to control vapor and prevent contact with skin or eyes. For small drips and splashes, it is not necessary to neutralize the glutaraldehyde, because the amount being rinsed down the drain will not exceed 5 ppm by the time it reaches a sewage treatment plant, nor is it likely to cause the room vapor to exceed the TLV®-C. However, there is no harm in neutralizing the glutaraldehyde, regardless of the amount.

C.5.4 Large spills

Any glutaraldehyde spill larger than a small drip or splash can cause vapor levels to increase above the TLV®-C. The spill should be cleaned up by a team equipped with the appropriate respiratory equipment for the ambient air concentration of glutaraldehyde vapor; the appropriate PPE (including rubber boots or shoe protection); and the necessary cleanup tools: mop, sponges, towels, squeegee, plastic dust pan, plastic scoop, and a chemical for deactivating the glutaraldehyde (see C.5.2).

Large spills should be contained and neutralized or contained and collected for disposal. When spills are contained, it might be possible to neutralize the spilled solution with an appropriate chemical agent (see D.5.2). Depending on the amount of solution and the environmental conditions, some heat and fumes could be liberated by the reaction. When large spills are collected using an absorbent, the absorbed medium can be disposed of or incinerated according to appropriate federal, state, and local regulations. See also C.6.

After the glutaraldehyde solution is collected and disposed of, the area where the glutaraldehyde solution was collected should be thoroughly rinsed. The cleanup tools should be rinsed with large amounts of water, and the water should be discarded down the drain. Reusable cleanup tools, such as sponges, towels, or mop heads, should be placed in an appropriate container to be laundered before reuse. After being rinsed, disposable sponges, towels, or mop heads should be disposed of according to the procedures designated by the glutaraldehyde spill containment response team.

Rationale: Immediate neutralization and cleanup of spills minimizes the potential for chemical exposure. Spills increase the surface area of the glutaraldehyde solution and, if left unattended, will increase the air concentration of glutaraldehyde. Larger spills present increased risk because the TLV®-C could be exceeded; also, additional considerations are necessary for disposal of contaminated equipment and the neutralized solution. Proper respirators, appropriate PPE, and training are essential to preventing overexposure of workers and others in the area (see also C.4.1.4).

C.6 Disposal of glutaraldehyde solutions

Five-day biological demand and aquatic metabolism studies indicate that glutaraldehyde degrades readily. Also, glutaraldehyde does not inhibit the growth of unacclimated sewage microorganisms at concentrations less than 5 milligrams/liter (mg/L) or 5 ppm.[8]

Because glutaraldehyde is diluted by other waste streams in a municipal sewage system and because it is deactivated by proteinaceous components of sewage effluent, some authorities have concluded that the disposal of spent glutaraldehyde will have no adverse effects on the sewage treatment plant.[9]

[8] Bio-oxidation studies were conducted by Union Carbide Corporation according to APHA (1976). For additional information, see Dow Chemical Company (2003).

[9] The Australian government's 1994 assessment report, *Glutaraldehyde: Priority existing chemical no. 3,* estimated "that concentrations of glutaraldehyde in sewage treatment plants will remain below 200 mg/L. Such levels do not constitute a significant environmental hazard, and will be reduced further by biodegradation during sewage treatment."

Annex D
(normative)
Hydrogen peroxide solutions

NOTE The information provided in this Annex was accurate at the time the standard was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and IFU change accordingly. Therefore, it is essential that 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.

D.1 Introduction

Hydrogen peroxide-based products have been cleared by the FDA for use as HLDs and LCSs used primarily for heat-sensitive medical devices (e.g., flexible endoscopes). This Annex covers the properties and applications of hydrogen peroxide solutions; the occupational exposure considerations specific to hydrogen peroxide, including vapor monitoring and procedures for handling spills; and the disposal of hydrogen peroxide solutions.

D.2 Properties and applications of hydrogen peroxide

Hydrogen peroxide-based products are generally used as HLDs for heat-sensitive and submersible medical devices such as flexible or rigid endoscopes. Hydrogen peroxide products do not require activation, being formulated as ready-to-use liquid chemical germicides. They are generally odorless, reusable, and can be used in manual soak applications or automated endoscope processing systems.

For example, one product contains 2% hydrogen peroxide, buffers, chelating agents, and a corrosion inhibitor. The labeled contact conditions are 8 minutes at 20ºC (68ºF). The product has a reuse life of 21 days at or above its MRC/MEC of 1.5% hydrogen peroxide.

For example, a second product contains 7.5% hydrogen peroxide, 0.85% phosphoric acid, and 91.65% inert ingredients. The labeled contact conditions for HLD are 30 minutes at 20ºC (68ºF); for sterilization, the labeled contact conditions are 6 hours at 20ºC (68ºF). The product has a reuse life of 21 days at or above its MRC/MEC of 6% hydrogen peroxide.This hydrogen peroxide product might cause cosmetic damage (e.g., discoloration) to a device. As in all cases, it is recommended that before using a disinfectant, users should consult with the device and disinfectant manufacturers to ensure device compatibility.

Before each processing cycle, both products should be checked to verify that the concentration of the active ingredient (hydrogen peroxide) is at or above the MRC/MEC with the appropriate solution test strips or chemical monitoring devices recommended by the manufacturer.

D.3 Effective use of hydrogen peroxide solutions

To ensure efficacy, the user should observe the following guidelines:

a) The medical device manufacturer's written IFU should be consulted to determine the compatibility of the device with hydrogen peroxide. If the IFU does not specifically reference hydrogen peroxide, it is recommended that before using the solution, users should consult with the device manufacturer to ensure device compatibility.

b) Flexible endoscopes should be processed according to ANSI/AAMI ST91 Flexible and semi-rigid endoscope processing in health care facilities.

c) If an automated reprocessor is to be used, the manufacturer should be consulted to determine the compatibility of the equipment with the specific hydrogen peroxide product.

d) Devices should be disassembled and thoroughly cleaned and dried before they are immersed in the solution in order to avoid adding debris to the solution or diluting the solution, both of which can shorten the efficacy period.

e) Devices should be thoroughly and completely immersed in the hydrogen peroxide solution to ensure that all surfaces are covered by the solution and that all appropriate lumens have been filled with hydrogen peroxide, as recommended.

f) A solution test strip or chemical monitoring device should be used to test the concentration of hydrogen peroxide before each processing cycle. Only those solution test strips or chemical monitoring devices recommended by the hydrogen peroxide product manufacturer should be used. Quality control checks of the solution test strips or chemical monitoring devices should be performed according to the manufacturer's written IFU.

g) When the concentration of hydrogen peroxide falls below the MRC/MEC, the solution should no longer be used.

h) Solutions should be kept covered to prevent evaporation.

i) Solutions that evaporate below the level that permits immersion of the device should not be topped off. Instead, the entire solution should be discarded and a fresh solution prepared.

j) Solutions should not be used beyond the reuse period indicated on the label even if the concentration of hydrogen peroxide is at or above the MRC/MEC.

k) Solutions should not be used beyond their shelf life. Manufacturer's written IFU should be consulted to determine the unopened-container and opened-container shelf life of the product.

l) Unopened solutions should be stored in a cool, well-ventilated area at the temperature recommended by the manufacturer.

D.4 Safe use of hydrogen peroxide solutions

D.4.1 Occupational exposure

D.4.1.1 General considerations

Procedures should be developed that will prevent contact with hydrogen peroxide; identify appropriate methods for determining the hydrogen peroxide vapor concentration and reduce exposure to hydrogen peroxide vapor to the lowest reasonably obtainable level below the OSHA recommended PEL of 1 ppm. Personnel should always wear appropriate PPE when using hydrogen peroxide solutions (see D.4.1.4).

D.4.1.2 Health effects of hydrogen peroxide

D.4.1.2.1 Potential health effects of short-term exposure

The manufacturer's SDS should be consulted regarding potential health effects from exposure to hydrogen peroxide. The effects of exposure can vary from product to product and manufacturer to manufacturer.

The 7.5% hydrogen peroxide solution is severely irritating and corrosive to the eyes, skin, and gastrointestinal tract. Excessive exposure could cause irreversible tissue damage to the eyes, including blindness. Inhalation of vapors can be severely irritating to the nose, throat, and lungs.

The 2% hydrogen peroxide solution is a mild irritant to the eyes and a slight irritant to the skin. Any tissues that come in contact with the 2% hydrogen peroxide solution should be rinsed immediately. Inhalation of hydrogen peroxide vapors can be irritating to the nose, throat, and lungs.

D.4.1.2.2 Potential health effects of long-term exposure

IARC, NTP, and OSHA do not list hydrogen peroxide as a carcinogen. ACGIH® lists hydrogen peroxide as an A3 animal carcinogen.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010). For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2013).

D.4.1.3 Occupational exposure limits

The OSHA PEL for hydrogen peroxide is 1 ppm, calculated as an 8 hour time weighted average. The ACGIG TLV for hydrogen peroxide is the same as the OSHA PEL. Some states have issued short term exposure limits (e.g. Hawaii and Washington STEL = 3 ppm).

D.4.1.4 Personal protective equipment and first aid

D.4.1.4.1 Eye protection

For the 2% hydrogen peroxide solution, safety glasses or goggles should be worn. For the 7.5% hydrogen peroxide solution, cup-type chemical goggles, a full-face shield, or both should be worn. If any eye contact should occur, the eye should be flushed immediately with plenty of water for at least 15 minutes. Medical advice should be sought.

D.4.1.4.2 Skin protection

Rubber, neoprene, vinyl, or nitrile gloves should be worn to protect hands. Other appropriate protective clothing, including long sleeves, should be worn to minimize exposure to the skin. If any skin contact should occur, the affected area of the skin should be thoroughly washed and rinsed according to the manufacturer's written IFU and the SDS.

D.4.2 Ventilation

Hydrogen peroxide solutions should be used in a well-ventilated area.

D.4.3 Pouring solutions

The solution should be poured from the original container into a clean, dry immersion container by a method that will prevent employee contact with the chemical solution and reduce exposure to hydrogen peroxide to the lowest reasonably obtainable level below the OSHA recommended PEL. Agitation and splashing during transfer should be minimized. Examples of methods for minimizing contact with the solution or vapor, where necessary, include the use of closed transfer devices, local exhaust hoods, and/or ductless fume hoods and strict adherence to the use of appropriate PPE.

Rationale: Avoiding contact with hydrogen peroxide products prevents skin and eye injury. Minimizing agitation and splashing during transfer also minimizes the potential for increased vapor. See also D.4.1.2.

D.4.4 Transporting solutions

Transport of hydrogen peroxide solutions in secondary containers such as trays or buckets should be avoided. If it is absolutely necessary to transport a solution to another area, that area should be properly ventilated, and a method of transport should be selected that will minimize the potential for spills and the possibility of personnel exposure to the solution or vapor.

The risks associated with spills occurring during transportation of hydrogen peroxide solution and appropriate remedial action should be considered during the hazard evaluation for the department.

Rationale: Transporting solutions in secondary containers increases the risk of spills. Spills increase the surface area and thus increase the potential for vapor to raise the air concentration above the TLV®. Spills also increase the potential for skin and eye contact and irritation, as described in D.4.1.2.

D.4.5 Storing unused solutions

Hydrogen peroxide solutions should be stored in vented, closed containers or systems in a well-ventilated area. Soaking containers should always be covered and clearly labeled, in accordance with the OSHA Hazard Communication Standard (21 CFR 1910.1200[f][5][i]), with appropriate warnings, precautionary statements, and first-aid instructions.

The surface area of the containers should be as small as possible; containers should be narrow and deep rather than large, long, and shallow. The lid should be kept on the soaking container at all times except when items are being placed into or taken out of the solution. Automated systems should be designed to prevent the escape of hydrogen peroxide vapor and liquid.

Rationale: A closed system will minimize evaporation of the hydrogen peroxide solution and subsequent personnel exposure to vapor.

D.4.6 Immersing items to be high-level disinfected or sterilized

Personnel should wear appropriate PPE when placing medical devices or other items into the solution; this activity should take place in a properly ventilated area. Personnel should gently place clean, dry items into the solution, taking care to minimize splashing.

When the solution must be manually irrigated or flushed through internal channels or lumens of an instrument, personnel should take care to avoid being splashed or sprayed with the solution. The syringe should be carefully filled with the solution and securely attached to the channel opening or all-channel irrigator. The solution in the syringe should be slowly pushed into the channel; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator. A new syringe should be used each time.

Gloved hands should be rinsed thoroughly with water before the cover is replaced on the solution container to avoid contaminating the surface of the container with solution. The medical devices or other items should be allowed to soak for the amount of time and at the temperature specified by the manufacturer to achieve high-level disinfection or sterilization. (See the device manufacturer's written IFU for additional recommendations on high-level disinfection and sterilization.)

Rationale: These procedures will help prevent worker exposure to hydrogen peroxide and help ensure the effectiveness of the high-level disinfection or sterilization process. Reuse of syringes for irrigation or flushing could lead to contamination of the solution.

D.4.7 Rinsing disinfected or sterile items

Personnel should wear appropriate PPE when removing items from the solution; this activity should take place in a properly ventilated area.

Before removing the device from the solution, personnel should remove the solution from the internal channels or lumens of the device by flushing each channel with instrument air or HEPA filtered air according to manufacturer’s IFU. Personnel should be careful to avoid being splashed with the solution. The device should be totally immersed in the solution, and the syringe should be securely attached to the channel opening or all-channel irrigator. The plunger should be pushed slowly; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator or cause the solution to squirt from the channel opening.

The medical devices should be gently removed from the solution and rinsed thorougly with critical water of the quality specified by the device to be processed manufacturer’s and/or chemical manufacturer’s IFU. Personnel should rinse their gloved hands with critical water and then replace the cover on the solution container. The product-specific rinsing instructions should be followed to ensure that all external surfaces of the items and any removable parts are free of all residual solution. The rinse solution should be discarded after each use. For medical devices with interior channels, each channel or the all-channel irrigator should be flushed according to the manufacturer's written IFU with fresh critical water until all residual solution is removed from the channels. The flushing procedure should be repeated using instrument air or HEPA-filtered air through the lumens for a specified period of time and pressure according to the instruments manufacturer’s written IFU. Some manufacturers may have drying included processes inclluded n thier IFUs. The external surfaces of medical devices should be thoroughly wiped dry with a sterile, lint-free cloth.

NOTE Some manufacturers may have drying included processes included in thier IFUs.

Rationale: Proper procedures for rinsing, flushing, drying, and storing medical devices will help prevent worker exposure to hydrogen peroxide and help ensure that residual hydrogen peroxide is not introduced into patient tissue. Complete immersion in water ensures that all external surfaces of the device come into contact with the rinse water.

D.5 Hydrogen peroxide spills

Spilled hydrogen peroxide solutions should be collected or confined immediately and then diluted with a large volume of water. The diluted solution should then be disposed of in accordance with federal, state, and local regulations. Personnel should wear appropriate PPE when cleaning up spills.

D.6 Disposal of hydrogen peroxide solutions

Hydrogen peroxide solutions should be diluted with a large amount of water, and the hydrogen peroxide should be allowed to decompose. Higher concentrations of hydrogen peroxide should be allowed to decompose. The diluted solution may then be discharged into a suitable treatment system in accordance with federal, state, and local regulations.

D.7 Vapor monitoring

Gas and vapor emissions can occur from even the best made equipment and odor is an unreliable indicator of the presence and concentration of hydrogen peroxide below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release and provide record keeping. Review the SDS and consult the suppliers of the hydrogen peroxide, and the manufacturers of the sterilizer and the gas monitoring equipment for more information.

Annex E
(normative)
Ortho-phthalaldehyde solutions

NOTE The information provided in this Annex was accurate at the time the standard was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and IFU change accordingly. Therefore, it is essential that 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.

E.1 Introduction

Ortho-phthalaldehyde (OPA) based products have been cleared by the FDA for use as an HLD for processing heat-sensitive medical devices. This Annex covers the properties and applications of OPA; occupational exposure considerations specific to OPA, including vapor monitoring and procedures for handling spills; and the disposal of OPA.

E.2 Properties and applications of OPA

Ortho-phthalaldehyde solution is an HLD intended for use in processing heat-sensitive devices. It is particularly active against certain strains of mycobacteria, but some strains show high-level resistance to OPA (Svetlikova, et al., 2009; McDonnell, et al., 2007). Some cyst and even vegetative forms of protozoa also demonstrate resistance to OPA (Barbee, et al., 1999; Coulon, et al., 2010). Ortho-phthalaldehyde solutions do not require activation. These solutions have no odor to mild odor. Several OPA products contain 0.55% to 0.60% OPA, corrosion inhibitors, chelating agents, and a dye in phosphate buffer. They have been cleared for use as an HLD for manual processing (12 minutes at 20ºC [68ºF]) and for processing in automated endoscope reprocessors (5 minutes at 25ºC [77ºF]) that have FDA-cleared capability to maintain solution temperature at 25ºC (77ºF). If the solution temperature cannot be maintained at 25ºC (77ºF) in an AER, the device should be processed using the parameters for manual processing. In both applications, the products have a reuse life of 14 days.

Another OPA formulation is designed for single use in an automated system. In this system, concentrated (5.75%) OPA is diluted with buffers, chelating agents, corrosion inhibitors, and a dye to its 0.05% "in-use" solution. The labeled contact conditions for high-level disinfection are 10 minutes at 50ºC to 55ºC (122ºF to 131ºF). Although OPA products—and all FDA-cleared HLDs—must pass the AOAC Sporicidal Test (Horowitz and Latimer, 2010), there is no sterilization claim for them.

Ortho-phthalaldehyde solution should not be used to process any urological instrumentation used to treat patients with a history of bladder cancer. In rare instances, OPA solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies (Joshi and Rosenfeld, 2004; Sokol, 2004a, 2004b). As in all cases, it is recommended that before using a disinfectant, users should consult with the device and disinfectant manufacturers to ensure device compatibility.

For additional information on OPA as a high-level disinfectant, see Alfa and Sitter (1994), Rutala and Weber (2001b), Gregory, et al. (1999), and Walsh, et al. (1999).

E.3 Effective use of OPA

To ensure efficacy, the user should observe the following guidelines:

a) The medical device manufacturer's written IFU should be consulted to determine and provide in writing the compatibility of the device with the selected OPA solution.

b) Flexible endoscopes should be processed according to ANSI/AAMI ST91, *Flexible and semi-rigid endoscope processing in health care facilities*

c) If an automated reprocessor is to be used, the manufacturer should be consulted to determine the compatibility of the equipment with OPA solution.

d) Blood, other body fluids, and lubricants must be thoroughly cleaned from the surfaces and lumens of medical devices before the devices are reprocessed in the disinfectant. Blood and other body fluids should be disposed of according to all applicable regulations for infectious waste disposal. The medical device manufacturer's written IFU for device disassembly, decontamination, and leak testing should be followed.

e) All surfaces and lumens of cleaned devices should be thoroughly rinsed and rough-dried.

f) The date that the OPA container was opened should be recorded on the container label and in a logbook.

g) The reusable solution in the secondary container can be used for a period of up to 14 days. The solution should be discarded after 14 days even if the OPA solution test strip or chemical monitoring device indicates a concentration at or above the MRC or MEC.

h) The device should be completely immersed in the OPA solution, filling all lumens and eliminating air pockets, for at least 12 minutes at a minimum temperature of 20ºC (68ºF).

i) After manual high-level disinfection, the lumens and all device surfaces should be thoroughly flushed and rinsed with fresh critical water at least 3 times according to the OPA solution manufacturer's instructions to remove toxic OPA residuals.

j) A solution test strip or chemical monitoring device should be used to test the concentration of OPA before each processing cycle per timeframe specified by manufacturer's IFUs. During the recommended reuse period, the concentration of the active ingredients in the solution should be tested.Only those solution test strips or chemical monitoring devices recommended by the OPA product manufacturer should be used. Quality control checks of the tests strips or chemical monitoring devices should be performed according to the manufacturer's written IFU.

k) Solutions should be kept covered to prevent evaporation.

l) Solutions that evaporate below the level that permits immersion of the device should not be topped off. Instead, the entire solution should be discarded and a fresh solution prepared.

m) Ortho-phthalaldehyde solutions should not be used beyond their shelf life.

n) Unopened solutions should be stored in a cool, well-ventilated area at the temperature recommended by the manufacturer.

E.4 Safe use of OPA

E.4.1 Occupational exposure

E.4.1.1 General considerations

Procedures should be developed that will prevent contact with OPA solutions. Personnel should always wear appropriate PPE, including gloves, long sleeves, and splashproof monogoggles, when using OPA solutions (see F.4.1.4).

E.4.1.2 Health effects of OPA

E.4.1.2.1 Potential health effects of short-term exposure

Breathing OPA vapors may be irritating to the nose, throat, or respiratory system and may cause coughing, chest discomfort and tightness, difficulty with breathing, or headache. Preexisting bronchitis or asthma conditions can be aggravated by exposure to OPA solutions, as can skin conditions such as dermatitis. Ocular contact with dilute solutions of OPA can cause eye irritation and damage. OPA can also stain skin and, if processed medical devices are not rinsed properly, patient tissue.

At use concentrations, OPA can be a contact sensitizer through the dermal route of exposure. OPA is a potent sensitizer that, in susceptible individuals, might induce anaphylaxis (Joshi and Rosenfeld, 2004; Sokol, 2004a, 2004b).

E.4.1.2.2 Potential health effects of long-term exposure

Neither IARC nor ACGIH® has established carcinogen classifications for OPA.

E.4.1.3 Occupational exposure limits

Currently, there is no OSHA PEL for OPA, nor is there an ACGIH®-recommended TLV®.

NOTE The lack of an OSHA PEL does not mean that a chemical is safe, OPA can be anticipated to have similar toxicity to other dialdehydes such as glutaraldehyde.

E.4.1.4 Personal protective equipment and first aid

E.4.1.4.1 Eye protection

Splashproof monogoggles should be worn. If any eye contact should occur, the eye should be rinsed immediately with plenty of water for at least 15 minutes. Medical advice should be sought.

E.4.1.4.2 Skin protection

Polyvinylchloride and nitrile or butyl rubber gloves are suitable for routine use. The permeability of gloves varies considerably, depending on the manufacturer; therefore, the written recommendations of the glove manufacturer and the LCS/HLD manufacturer should be consulted. If any skin contact should occur, the affected area should be washed immediately with soap and water and rinsed for at least 15 minutes. If a skin reaction occurs, medical advice should be sought.

E.4.2 Ventilation

Solutions containing OPA should be used in a well-ventilated area.

E.4.3 Pouring solutions

The solution should be poured from the original container into a clean, dry disinfection container by a method that will prevent personnel contact with the chemical solution and reduce exposure to OPA. Agitation and splashing during transfer should be minimized. Examples of methods for minimizing contact with the solution or vapor include the use of closed transfer devices, local exhaust hoods, and/or ductless fume hoods and strict adherence to the use of appropriate PPE.

Rationale: Avoiding contact with OPA prevents skin and eye injury and protects the worker from the sensitizing effects of OPA. Minimizing agitation and splashing during transfer also minimizes the potential for increased vapor. Avoiding contact with OPA solution prevents staining of the skin. See also E.4.1.2.

E.4.4 Transporting solutions

Transport of OPA solutions in secondary containers such as trays or buckets should be avoided. If it is absolutely necessary to transport a solution to another area, that area should be properly ventilated, and a method of transport should be selected that will minimize the potential for spills and the possibility of personnel exposure to the solution or vapor.

Rationale: Transporting solutions in secondary containers increases the risk of spills. Spills increase the surface area and thus increase the potential for vapor to raise the air concentration of OPA. Spills also increase the potential for skin and eye contact and irritation, as described in E.4.1.2.

E.4.5 Storing opened solutions

Solutions containing OPA should be stored in closed containers or systems in a well-ventilated area. Soaking containers should always be covered and clearly labeled, in accordance with the OSHA Hazard Communication Standard (21 CFR 1910.1200[f][5]), with appropriate warnings, precautionary statements, and first-aid instructions. The surface area of the containers should be as small as possible; containers should be narrow and deep rather than large, long, and

shallow. The lid should be kept on the soaking container at all times except when items are being placed into or taken out of the solution. Automated systems should be designed to prevent the escape of OPA vapor and liquid.

Rationale: A closed system will minimize evaporation of OPA and subsequent personnel exposure to vapor.

E.4.6 Immersing items to be high-level disinfected

Personnel should wear appropriate PPE when placing medical devices or other items into the solution; this activity should take place in a properly ventilated area. The worker should gently place clean, dry items into the solution, taking care to disturb and agitate the surface of the solution as little as possible.

When manually irrigating or flushing the solution through internal channels or lumens of an instrument, personnel should be careful to avoid being splashed or sprayed with the solution. The syringe should be carefully filled with the solution and securely attached to the channel opening or all-channel irrigator. The solution in the syringe should be slowly pushed into the channel; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator. A new syringe should be used each time.

Gloved hands should be rinsed thoroughly with water before the cover is replaced on the solution container to avoid contaminating the surface of the container with solution. The medical devices or other items should be allowed to soak for the amount of time and at the temperature specified by the manufacturer to achieve disinfection. (See the device manufacturer's written IFU for additional recommendations on disinfection.)

Rationale: These procedures will help prevent worker exposure to OPA and help ensure the effectiveness of the disinfection process. Reuse of syringes for irrigation or flushing could lead to contamination of the solution.

E.4.7 Rinsing disinfected items

Personnel should wear appropriate PPE when removing items from the solution; this activity should take place in a properly ventilated area.

Before removing the device from the disinfecting solution, personnel should remove the solution from the internal channels or lumens of the device by flushing each channel several times with a syringe filled with air. Personnel should be careful to avoid being splashed with the solution. The device should be totally immersed in the solution, and the syringe should be securely attached to the channel opening or all-channel irrigator. The plunger should be pushed slowly; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator or cause the solution to squirt from the channel opening.

The medical devices should be gently removed from the solution and rinsed thoroughly with water of the quality specified by the device to be processed manufacturer's and/or chemical manufacturer's IFU. (Workers should rinse their gloved hands with water and then replace the cover on the solution container.) To remove all residual solution, personnel should rinse the external surfaces of the items and any removable parts with copious amounts of critical running water; should immerse them in successive containers of critical water (the rinse solution should be discarded after each use, not reused); or should otherwise rinse the device in accordance with the manufacturer's written IFU. For medical devices with interior channels, each channel or the all-channel irrigator should be flushed several times with critical water until all residual solution is removed from the channels (at least 500 mL of water during each separate rinse, unless the medical device manufacturer instructs otherwise). The flushing procedure should be repeated using instrument air or HEPA-filtered air through the lumens for a specified period of time and pressure according to the instruments manufacturer's written IFU. (However, see the device manufacturer's written IFU.) Additional care should be taken to ensure that the recommended number of critical water rinses are performed to ensure that residual levels of OPA are removed, due to toxicity concerns. The external surfaces of medical devices should be thoroughly wiped dry with a sterile, lint-free cloth.

Rationale: Proper procedures for rinsing, flushing, drying, and storing medical devices will help prevent worker exposure to OPA and help ensure that residual OPA is not introduced into patient tissue. Running water or successive immersions in water is recommended for rinsing in order to further dilute the solution, to prevent the retention of solution that could occur in standing water (Durante, et al., 1992), and to prevent staining of patient tissue. The flushing of channels with alcohol followed by air greatly reduces the possibility of recontamination of medical devices by waterborne microorganisms. See also ASGE and SHEA (2011).

E.5 OPA spills

Personnel responsible for cleanup of OPA spills should have demonstrated competency in hazardous material spill cleanup procedures and should wear appropriate PPE, which should include at least:

a) splashproof monogoggles;

b) polyvinylchloride, nitrile, or butyl rubber gloves;

c) rubber boots or other shoe protection; and

d) for spills larger than one gallon, an OSHA/NIOSH-approved reusable or disposable breathing mask equipped with an organic vapor cartridge filter.

For spill neutralization, there are several commercial products available to neutralize OPA. Alternatively, the following procedure should be followed:

a) The spilled liquid should be collected with sponges, mopped into a plastic container suitable for the size of the spill, or both.

b) Approximately 25 grams of glycine (free base) powder per gallon of estimated OPA volume should be sprinkled on the spill. The glycine should be thoroughly blended into the spill with a mop or other tool and allowed to neutralize the OPA for one hour.

c) The spill area should be mopped down with soap and water and then rinsed with water. All liquid should be flushed down the drain, followed by large amounts of water.

d) The cleanup tools should be rinsed with soap and water and then rinsed with large amounts of water. The rinse water should be discarded down the drain, followed by large amounts of water.

e) The neutralized OPA solution should be poured down the drain, followed by large amounts of water.

E.6 Disposal of OPA solutions

Spent OPA solutions should be disposed of in accordance with federal, state, and local regulations. Some spent OPA solutions need to be neutralized before discarding down the drain, if applicable regulations require it.

E.7 Vapor monitoring

Gas, vapor, and droplet emissions can occur from manual use and even the best made equipment. Although the vapor pressure for OPA is low, OPA has potential health effects (see F.4.1.2) and odor is an unreliable indicator of the presence and concentration of OPA below hazardous concentrations. However, continuous gas/vapor monitoring systems are not currently available to detect potentially hazardous concentrations. Review the SDS and consult the suppliers of OPA-based disinfectants for advice on safe use.

Annex F
(normative)
Peracetic acid–hydrogen peroxide solutions

NOTE The information provided in this Annex was accurate at the time the standard was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and IFU change accordingly. Therefore, it is essential that 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.

F.1 Introduction

Peracetic acid solutions exist as equilibrated solutions of hydrogen peroxide, acetic acid, peracetic acid, and water. They typically have a vinegar-like odor, which can be strong depending on the concentration of acetic acid and peracetic acid.

The strong microbicidal effects and broad-spectrum activity of peracetic acid (also referred to as peroxyacetic acid) at relatively low concentrations have been known since the early 1900s (Freer and Novy, 1902; Block, 2001a). Peracetic acid alone is highly unstable and normally cannot exist without hydrogen peroxide and acetic acid. Therefore, all aqueous solutions of peracetic acid contain hydrogen peroxide. The relationship between the concentrations of peracetic acid, acetic acid, and hydrogen peroxide is determined by the composition of the mixture and the chemical equilibrium constant. Peracetic acid solutions can vary significantly, such as from 35% peracetic acid and 6% hydrogen peroxide to 5% peracetic acid and 26% hydrogen peroxide. Peracetic acid–hydrogen peroxide formulations can be formulated to include buffers, surfactants, and anticorrosives for specific applications. These will range in antimicrobial efficacy, safety considerations, and device compatibility. To ensure compatibility, users are advised to consult the medical device manufacturer's written IFU before using the product.

This Annex covers the properties and applications of peracetic acid–hydrogen peroxide solutions; occupational exposure considerations specific to peracetic acid and hydrogen peroxide, including vapor monitoring and procedures for handling spills; and the disposal of peracetic acid–hydrogen peroxide solutions.

F.2 Properties and applications of peracetic acid–hydrogen peroxide solutions

A variety of peracetic acid–hydrogen peroxide solutions are available for high-level disinfection and sterilant applications. They will vary considerably in their antimicrobial activity and instructions for use (including contact times, exposure temperatures, and reuse recommendations). They range in their peracetic acid and hydrogen peroxide concentrations, with typical high-level disinfectant claims ranging from 5 to 30 minutes and sterilant contact times of 6 minutes to 8 hours.

One peracetic acid formulation is designed for single use in an automated system. This sterilant formulation is FDA-cleared for the liquid chemical sterilization of manually cleaned, immersible, reusable critical and semicritical heat-sensitive medical devices, including endoscopes and their accessories. Devices processed in this system are chemically sterilized using a peracetic acid LCS and rinsed with extensively treated, potable water. In this system, concentrated (35%) liquid peracetic acid is diluted within a buffered system to its ~0.2% (~2,000 ppm) "use dilution." The labeled contact conditions for sterilization are 6 minutes at 46ºC to 60ºC (115°F to 140°F). During the sterilization cycle, time and temperature are automatically controlled and monitored. The cycle is completed by rinsing with extensively treated potable water to remove sterilant residues. The processor treats potable water using a three-stage process: pre-filtration, UV irradiation, and 0.1 micron (μ) filtration. The pre-filtration stage reduces particulates present in the potable water. The UV irradiation stage inactivates waterborne pathogenic viruses in the unlikely event that they are present in potable water. The dual membrane, 0.1 μ pharmaceutical sterilizing-grade filter effectively removes bacteria, fungi, and protozoa larger then 0.1 μ from the rinse water. The efficacy of this filtration process depends on the quality of the incoming tap water (EPA, 2012). The typical cycle time is about 23 minutes. Chemical indicators designed for this system are available from the manufacturer. A spore test strip has also been cleared for use in this system. U.S. Department of Transportation shipping restrictions apply to concentrated solutions of peracetic acid (including 35% to 43% solutions), which are categorized as organic peroxides and corrosive. Special handling procedures for the concentrated liquid are listed in the manufacturer's SDS . Unless otherwise noted, the SDS applies

only to the concentrate, not to the “use dilution” in the processor. Safety information about the diluted solution can be obtained from the manufacturer and other authoritative sources.

Prediluted and ready-to-use formulations are also available. These formulations are indicated use in liquid chemical sterilization and high-level disinfection of cleaned, immersible, reusable medical and surgical devices. For example, one formulation contains 1% hydrogen peroxide and 0.08% peracetic acid; the contact time for sterilization is 8 hours at 20ºC (68ºF), and the contact time for high-level disinfection is 25 minutes at 20ºC (68ºF). This formulation is reusable for up to 14 days. Another formulation contains 8.3% hydrogen peroxide and 7.0% peracetic acid; the contact time for sterilization is 5 hours at 25ºC (77ºF), and the contact time for high-level disinfection is 5 minutes at 25ºC (77ºF). This formulation is reusable for up to 5 days. Unlike the more concentrated solutions, the ready-to-use solutions may not be labeled as skin irritants and may not cause dermal sensitization. Toxic inhalation effects can vary depending on the formulation, but users should avoid breathing the vapors. Formulations are considered corrosive to ocular tissue.

Peracetic acid–hydrogen peroxide solutions are typically formulated to include buffers, surfactants, and anticorrosives. These formulations vary in their efficacy, stability, and materials compatibility. Peracetic acid can be directly corrosive to metals, including copper, brass, and stainless steel, although these effects are significantly reduced by buffers and anticorrosives in individual formulations. Cosmetic material effects can include discoloration of colored aluminum and removal of paint from surfaces. As in all cases, it is recommended that before using a disinfectant, users should consult with the device and disinfectant manufacturers to ensure device compatibility.

F.3 Effective use of peracetic acid–hydrogen peroxide solutions

To ensure efficacy when using the concentrated formulation, the user should observe the following guidelines:

a) The medical device manufacturer’s written IFU should be consulted to determine the compatibility of the device with peracetic acid–hydrogen peroxide solutions.

b) Flexible endoscopes should be processed according to ANSI/AAMI ST91, *Flexible and semi-rigid endoscope processing in health care facilities*

c) Devices should be disassembled and thoroughly cleaned. The reprocessor manufacturer’s written IFU should be consulted regarding whether it is essential that devices be dry before processing.

d) The device and reprocessor manufacturers’ written IFU for placing and connecting the device within the reprocessor should be followed.

e) The reprocessor manufacturer’s written IFU should be followed.

f) The process should be monitored with a CI and/or a spore test strip as recommended by the reprocessor manufacturer.

g) Solutions should not be used beyond their shelf life.

h) The concentrated peracetic acid should be stored in a well-ventilated area at the temperature recommended by the manufacturer.

To ensure efficacy when using the prediluted formulations, the user should observe the following guidelines:

a) The medical device manufacturer’s written IFU should be consulted to determine the compatibility of the device with peracetic acid–hydrogen peroxide solutions.

b) If an automated reprocessor is to be used, the manufacturer should be consulted to determine the compatibility of the equipment with the peracetic acid–hydrogen peroxide solution.

c) Devices should be disassembled and thoroughly cleaned and dried before they are immersed in order to prevent adding debris to the solution or diluting the solution, both of which can shorten the efficacy period.

d) Devices should be thoroughly and completely immersed in the solution to ensure that all surfaces are covered by the solution and that all appropriate lumens have been filled with the solution, as recommended.

e) A solution test strip or chemical monitoring device should be used to test the concentration of the active ingredients before each use. Only solution test strips or chemical monitoring devices recommended by the product manufacturer should be used. Quality control checks of the solution test strips or chemical monitoring devices should be performed according to the manufacturer's written IFU.

f) When the concentration of the active ingredients falls below the MRC or MEC, the solution should no longer be used.

g) Solutions should be kept covered to prevent evaporation or formation of precipitate from airborne contaminants.

h) Solutions that evaporate below the level that permits immersion of the device should not be topped off. Instead, the entire solution should be discarded and a fresh solution prepared.

i) Solutions should not be used beyond the reuse period indicated on the label even if the concentration of the active ingredients is at or above the MRC or MEC. (For the currently available products, the reuse period is 5 to 14 days.)

j) Solutions should not be used beyond their shelf life.

k) Unopened solutions should be stored in their original containers in a cool, well-ventilated area at the temperature recommended by the manufacturer.

l) Devices should be adequately rinsed in accordance with the manufacturer's written IFU prior to patient use.

F.4 Safe use of peracetic acid–hydrogen peroxide solutions

F.4.1 Occupational exposure

F.4.1.1 General considerations

Procedures should be developed that will prevent contact with peracetic acid–hydrogen peroxide solutions and reduce exposure to peracetic acid and hydrogen peroxide vapor. A means should be identified to determine the concentration of hazardous vapors and to ensure that the vapors are at the lowest reasonably obtainable levels below the occupational exposure limit.

NOTE For most peracetic acid, hydrogen peroxide, acetic acid formulations, a comparison of the respective vapor pressures and occupational exposure limits indicates that the peracetic acid vapor will be the most hazardous component of the vapor.

Personnel should always wear appropriate PPE when handling undiluted peracetic acid–hydrogen peroxide solutions (see G.4.1.4). The sterilant manufacturer's written IFU should be consulted regarding when personnel should wear appropriate PPE when using the diluted product.

F.4.1.2 Health effects of peracetic acid and hydrogen peroxide

F.4.1.2.1 Potential health effects of short-term exposure

The manufacturer's SDS and other authoritative sources such as National Research Council (2010) should be consulted regarding potential health effects from exposure to peracetic acid. The effects of exposure can vary from product to product and manufacturer to manufacturer, depending on the concentration and exposure time.

Eye contact with undiluted peracetic acid–hydrogen peroxide solutions is corrosive and can cause irreversible eye damage, including blindness. Skin contact with undiluted peracetic acid–hydrogen peroxide solutions can cause severe burns; hydrogen peroxide burns are indicated by a whitening of the skin.

Inhalation of vapors and mists will irritate the eyes, nose, throat, and lungs. Coughing and breathing difficulty can occur. Higher exposures can cause a buildup of fluid in the lungs (pulmonary edema), a medical emergency with shortness of breath (http://nj.gov/health/eoh/rtkweb/documents/fs/1482.pdf).

F.4.1.2.2 Potential health effects of long-term exposure

Long-term health effects vary with the concentration of the peracetic acid product and extent and duration of exposure. In addition to the short-term symptoms, high or repeated exposure can also affect the liver and kidneys (New Jersey Department of Health and Senior Services, 2004). The product SDS and other authoritative sources should be consulted to evaluate potential health hazards and any worker protection standards. Some peracetic acid–hydrogen peroxide solutions are considered sensitizing. Some formulations' ingredients, present at low concentrations, are listed by the IARC as ''possibly carcinogenic to humans."

Hydrogen peroxide is listed as a Group 3 carcinogen ("unclassifiable as to carcinogenicity to humans") by the IARC and as an animal carcinogen by ACGIH®.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010) or the IARC web site. For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2013).

F.4.1.3 Occupational exposure limits

There is no OSHA permissible exposure limit for peracetic acid, but there are recommended 8-hour TWA limits for hydrogen peroxide vapor (1 ppm) and acetic acid (10 ppm).

The NIOSH recommended exposure limit (REL) for acetic acid is 10 ppm TWA, STEL 15 ppm. There is currently no REL for peracetic acide. The hydrogen peroxide is 1 ppm as a time-weighted average for up to a 10-hour work day and a 40-hour work week.

The ACGIH®-recommended TLV® for hydrogen peroxide is 1 ppm as an 8-hour TWA (ACGIH®, 2013), for acetic acid the TW is 10 ppm, and the TWA STEL is 15 ppm (15 min TWA). For peracetic acid the ACGIH STEL is 0.4 ppm (15 min TWA). No limits have been established for peracetic acid; for acetic acid however, ACGIH® recommends a 10-ppm TWA and a 15-ppm short-term exposure limit (STEL).

The EPA has published Acute Exposure Guidelines for peracetic acid, with an 8-hour TWA of:

- EPA AEGL 1: 0.52 mg/m^3 (0.17 ppm)
- EPA AEGL 2: 6 mg/m^3 (0.51 ppm)
- EPA AEGL 3: 4.6 mg/m^3 (1.3 ppm)

See http://www.epa.gov/opptintr/aegl/pubs/results80.htm.

The AEGL limits are defined as follows (EPA, 2012b):

- AEGL-1 is the airborne concentration, expressed as parts per million or milligrams per cubic meter (ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.
- AEGL-2 is the airborne concentration (expressed as ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.
- AEGL-3 is the airborne concentration (expressed as ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

See http://www.epa.gov/opptintr/aegl/pubs/define.htm.

Peracetic acid can be detected by several methods, and monitors for continuously measuring the peracetic acid vapor concentrations in the workplace are also available.

F.4.1.4 Personal protective equipment and first aid

F.4.1.4.1 Eye protection

Personnel should wear safety glasses or goggles when handling peracetic acid–hydrogen peroxide solutions. If any eye contact should occur, the eye should be rinsed immediately with plenty of water for at least 15 minutes. Medical advice should be sought.

F.4.1.4.2 Skin protection

Rubber or neoprene gloves should be worn. If any skin contact should occur, the affected area should be washed with large amounts of water according to the manufacturer's written IFU and the SDS. If irritation occurs, medical advice should be sought.

F.4.2 Ventilation

Peracetic acid–hydrogen peroxide solutions should be used in a well-ventilated area. For specific ventilation requirements, the chemical manufacturer's written IFU should be consulted.

F.4.3 Pouring solutions

The solution should be poured from the original container into a clean, dry immersion container by a method that will prevent employee contact with the solution and reduce exposure to peracetic acid and hydrogen peroxide vapor. Agitation and splashing during transfer should be minimized. Examples of methods for minimizing contact with the solution or vapor include the use of closed transfer devices, local exhaust hoods, and/or ductless fume hoods and strict adherence to the use of appropriate PPE.

Rationale: Avoiding contact with peracetic acid–hydrogen peroxide products prevents skin and eye injury. Minimizing agitation and splashing during transfer also minimizes the potential for increased vapor. See also F.4.1.2.

F.4.4 Transporting solutions

Transport of peracetic acid–hydrogen peroxide solutions in secondary containers such as trays or buckets should be avoided. If it is absolutely necessary to transport a solution to another area, that area should be properly ventilated, and a method of transport should be selected that will minimize the potential for spills and the possibility of personnel exposure to the solution or vapor.

Rationale: Transporting solutions in secondary containers increases the risk of spills. Spills increase the surface area and thus increase the potential for vapor to raise the air concentration above the exposure limits in F.4.1.3. Spills also increase the potential for skin and eye contact and irritation, as described in F.4.1.2.

F.4.5 Storing solutions

Peracetic acid–hydrogen peroxide solutions should be stored in vented, closed containers or systems in a well-ventilated area. Soaking containers should always be covered and clearly labeled, in accordance with the OSHA Hazard Communication Standard (21 CFR 1910.1200[f][5][i]), with appropriate warnings, precautionary statements, and first-aid instructions. The surface area of the containers should be as small as possible; they should be narrow and deep rather than large, long, and shallow. The lid should be kept on the soaking container at all times except when items are being placed into or taken out of the solution. Automated systems should be designed to prevent the escape of vapor and liquid.

Unused peracetic acid–hydrogen peroxide solutions should be stored in a manner that allows for stock rotation. They should be disposed of after the labeled expiration date.

Rationale: A closed system will minimize evaporation of the peracetic acid–hydrogen peroxide solution and subsequent personnel exposure to vapor. The manufacturer's expiration date should not be exceeded because the solution will no longer be effective.

F.4.6 Immersing items to be high-level disinfected or sterilized

Personnel should wear appropriate PPE when placing medical devices or other items into the solution; this activity should take place in a properly ventilated area. The worker should gently place clean, dry items into the solution, taking care to disturb and agitate the surface of the solution as little as possible. Personnel should ensure that their exposure to peracetic acid vapor does not exceed safe limits.

When manually irrigating or flushing the solution through internal channels or lumens of an instrument, personnel should be careful to avoid being splashed or sprayed with the solution. The syringe should be carefully filled with the solution and securely attached to the channel opening or all-channel irrigator. The solution in the syringe should be slowly pushed into the channel; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator. A new syringe should be used each time.

Gloved hands should be rinsed thoroughly with water before the cover is replaced on the solution container to avoid contaminating the surface of the container with solution. The medical devices or other items should be allowed to soak for the amount of time and at the temperature designated by the manufacturer to achieve high-level disinfection or sterilization. (See the device manufacturer's written IFU for additional recommendations on high-level disinfection and sterilization.)

Devices to be sterilized or high-level disinfected in an automated reprocessor should be loaded in the reprocessor in accordance with the manufacturer’s written IFU.

Rationale: These procedures will help prevent worker exposure to peracetic acid and hydrogen peroxide and help ensure the effectiveness of the high-level disinfection or sterilization process. Reuse of syringes for irrigation or flushing could lead to contamination of the solution.

F.4.7 Rinsing disinfected or sterile items

Personnel should wear appropriate PPE when removing items from the solution or from a reprocessor that does not include rinsing in the cycle; this activity should take place in a properly ventilated area.

For devices that are processed manually or in a reprocessor that does not include rinsing in the cycle, personnel should remove the solution from the internal channels or lumens of the device before removing the device from the solution; this can be accomplished by flushing each channel several times with a syringe filled with air. Personnel should take care to avoid being splashed with the solution. The device should be totally immersed in the solution, and the syringe should be securely attached to the channel opening or all-channel irrigator. The plunger should be pushed slowly; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator or cause the solution to squirt from the channel opening.

The medical devices should be gently removed from the solution and rinsed thoroughly with fresh critical water of the quality specified by the device to be processed manufacturer’s and/or chemical manufacturer’s IFU. (Workers should rinse their gloved hands with water and then replace the cover on the solution container.) To remove all residual solution, personnel should rinse the external surfaces of the items and any removable parts with copious amounts of clean running water; should immerse them in successive containers of clean water (the rinse solution should be discarded after each use, not reused); or otherwise rinse the device in accordance with the manufacturer’s written IFU. For medical devices with interior channels, each channel or the all-channel irrigator should be flushed several times with fresh critical water until all residual solution is removed from the channels (at least 500 mL of water during each separate rinse, unless the medical device manufacturer instructs otherwise). The flushing procedure should be repeated using instrument air or HEPA-filtered air through the lumens for a specified period of time and pressure according to the instruments manufacturer’s written IFU. The external surfaces of medical devices should be thoroughly wiped dry with a sterile, lint-free cloth.

NOTE Some manufacturers may have drying included processes included in thier IFUs.

Some automated reprocessors include rinsing in the high-level disinfection or sterilization cycle.

Rationale: Proper procedures for rinsing, flushing, drying, and storing medical devices will help prevent worker exposure to peracetic acid and hydrogen peroxide and help ensure that residuals of these chemicals are not introduced into

patient tissue. Running water or successive immersions in water is recommended for rinsing in order to further dilute the solution and to prevent the retention of solution that could occur in standing water (Durante, et al., 1992).

F.4.8 Transport and storage of processed devices

After medical devices or other items are removed from the reprocessor, they should be aseptically transferred and presented at the point of use or stored between uses according to the device manufacturer's written IFU and health care facility protocol (ASGE and SHEA, 2011).

F.5 Peracetic acid–hydrogen peroxide spills

In the case of undiluted peracetic acid–hydrogen peroxide solutions, all sources of ignition should be removed, and the area should be ventilated. Personnel wearing appropriate PPE should flush the material with large quantities of water until all material is dissolved (diluted 1:20). Unopened containers should be placed in a sink of water and submerged, then opened and diluted.

In the case of ready-to-use peracetic acid–hydrogen peroxide solutions, see the manufacturer's written IFU.

F.6 Disposal of peracetic acid–hydrogen peroxide solutions

Peracetic acid–hydrogen peroxide solutions should be diluted with at least 20 parts of water and then disposed of in accordance with federal, state, and local regulations. Undiluted material should not be allowed to enter storm or sanitary sewer systems. Peracetic acid–hydrogen solutions should not be mixed with hypochlorite solutions.

F.7 Vapor monitoring

Gas and vapor emissions can occur from even the best made equipment and odor is an unreliable indicator of the presence and concentration of peracetic acid–hydrogen peroxide below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release and provide record keeping. Review the SDS and consult the suppliers of the peracetic acid–hydrogen peroxide, and the manufacturers of the sterilizer and the gas monitoring equipment for more information.

Annex G
(normative)
Sodium hypochlorite solutions

NOTE The information provided in this Annex was accurate at the time the standard was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and IFU change accordingly. Therefore, it is essential that 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.

G.1 Introduction

Chlorine and chlorine-releasing agents (CRAs) have a long history of use for antisepsis of the skin, hands, and wounds; disinfection in hospitals and other facilities; disinfection of water and sewage; and bleaching of textiles and other materials (Dychdala, 2001; Rutala and Weber, 1997). Sodium hypochlorite is the most commonly used CRA in health care facilities, where it is used primarily for environmental and hard-surface disinfection and for decontamination of blood spills and in other high-risk situations (Bloomfield, 1996). Commercial formulations of sodium hypochlorite are available in concentrations ranging from 1% to 14% (w/v) available chlorine, including household bleach, which contains approximately 5% available chlorine.

Chlorine compounds are oxidizing agents and are biocidal to a broad spectrum of microorganisms. However, most CRA preparations are not intended for use in sterilization or high-level disinfection of medical devices, primarily because these agents are highly corrosive to many materials used in devices, including metals, rubber, and fabrics.

A system that generates sodium hypochlorite–hypochlorous acid has been cleared by the FDA for use in high-level disinfection of heat-sensitive medical devices such as flexible endoscopes. This Annex covers the properties and applications of sodium hypochlorite solutions; occupational exposure considerations specific to sodium hypochlorite, including vapor monitoring and procedures for handling spills; and the disposal of sodium hypochlorite solutions.

G.2 Properties and applications of sodium hypochlorite solutions

The biocidal activity of CRAs is mediated by hypochlorous acid (HOCl), which forms in aqueous solutions of sodium hypochlorite (NaOCl) at a pH of 5 to 8 (Gardner and Peel, 1991). Strongly alkaline solutions, in which hypochlorite ions (OCl) predominate, have very little, if any, biocidal activity, but have greater stability during storage. Lower pH increases the quantity of hypochlorous acid in the solution and the biocidal activity of the solution. A pH of 6 to 8 is necessary for effective biocidal activity. At a pH of 4 or less, sodium hypochlorite–hypochlorous acid solutions decompose and form elemental chlorine (Cl_2). Sodium hypochlorite–hypochlorous acid solutions react with organic matter, such as blood, feces, and tissues, and rapidly lose effectiveness in the presence of these materials.

Strong sodium hypochlorite solutions have irritating and penetrating odors, attributable to the release of gaseous chlorine, and can be irritating to the eyes, skin, and respiratory system. These solutions can bleach most organic dyes and can damage some textiles and polymers. They are also extremely corrosive to metals. Silver and aluminum are the most susceptible to corrosion, but stainless steel is damaged by the concentrations needed for general health care facility disinfection (Gardner and Peel, 1991).

The FDA-cleared high-level disinfection system generates the active sodium hypochlorite–hypochlorous acid solution at the site of use by electrochemical activation of a dilute aqueous solution of sodium chloride. The active solution is generated for a single use at the MRC or MEC of 650 to 675 ppm available free chlorine. The system can be used in manual and automated processing procedures. High-level disinfection requires immersion for 10 minutes at 25ºC (77ºF). As in all cases, it is recommended that before using a disinfectant, users should consult with the device and disinfectant manufacturers to ensure device compatibility.

G.3 Effective use of sodium hypochlorite solutions

To ensure the efficacy of sodium hypochlorite solutions, the user should observe the following guidelines:

a) The medical device manufacturer's written IFU should be consulted to determine the compatibility of the device with sodium hypochlorite solutions.

b) Flexible endoscopes should be processed according to ANSI/AAMI ST91, *Flexible and semi-rigid endoscope processing in health care facilities*

c) If an automated reprocessor is to be used, the manufacturer's written IFU should be consulted to determine the compatibility of the equipment with sodium hypochlorite solutions.

d) Devices should be disassembled and thoroughly cleaned and dried before they are immersed in order to prevent adding debris to the solution or diluting the solution, both of which can reduce the solution's effectiveness. Cleaning procedures, including the selection of appropriate cleaning agents, should be developed according to the written IFU of the device manufacturer and the sodium hypochlorite solution manufacturer.

e) Devices should be thoroughly and completely immersed in the sodium hypochlorite solution to ensure that all surfaces are covered by the solution and that all appropriate lumens have been filled with sodium hypochlorite, as recommended.

f) Before each use, the concentration of active ingredient in the sodium hypochlorite solution should be verified to be at or above the solution's MRC or MEC, using the procedure recommended by the solution manufacturer. The FDA-cleared system incorporates a preprogrammed colorimeter for direct reading of chloride concentration.

g) When the concentration of the active ingredient is below the MRC or MEC, the solution should not be used.

h) Sodium hypochlorite solutions should not be used beyond their shelf life.

i) Unopened solutions should be stored in a cool, well-ventilated area at the temperature recommended by the manufacturer.

G.4 Safe use of sodium hypochlorite solutions

G.4.1 Occupational exposure

G.4.1.1 General considerations

Procedures should be developed that will prevent contact with sodium hypochlorite solutions and reduce exposure to vapors from the solution. A means should be identified to determine the concentration of chlorine gas and to ensure that the concentration is at the lowest reasonably obtainable levels below the occupational exposure limit. Personnel should always wear appropriate PPE when handling sodium hypochlorite solutions (see H.4.1.4) and should follow the sodium hypochlorite manufacturer's written IFU on appropriate PPE.

G.4.1.2 Health effects of sodium hypochlorite

G.4.1.2.1 Potential health effects of short-term exposure

Sodium hypochlorite can cause irritation and burning of the skin, eyes, respiratory system, and gastrointestinal tract. Exposure to high-levels or prolonged exposure may result in severe corrosive damage to the eyes, skin, respiratory system, and gastrointestinal tissues and can be fatal. Corrosive damage to eye tissue can result in blindness. Prolonged or repeated exposure to sodium hypochlorite vapors can cause coughing, shortness of breath, headaches, bronchopneumonia, and pulmonary edema (a medical emergency resulting from a buildup of fluid in the lungs).

G.4.1.2.2 Potential health effects of long-term health exposure

Hypochlorite salts are listed as Group 3 carcinogens ("unclassifiable as to carcinogenicity to humans") by the IARC.

NOTE IARC carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010) or the IARC web site.

G.4.1.3 Occupational exposure limits

While sodium hypochlorite is a significant hazard for skin and other contact, chlorine gas is the principle vapor hazard. OSHA has set a PEL for chlorine of a ceiling of 1 ppm [29 CFR 1910.1000, Table Z-1]. The ACGIH® TLV is 0.5 ppm calculated as an 8-hour TWA.

The American Industrial Hygiene Association has established a workplace environmental exposure limit (WEEL) for sodium hypochlorite: a STEL of 2 milligrams per cubic meter (mg/m^3) for a 15-minute exposure (AIHA, 2009).

G.4.1.4 Personal protective equipment and first aid

G.4.1.4.1 Eye protection

If there is a potential for the sodium hypochlorite solution to splash into the eyes, chemical safety goggles should be worn. A full-face mask might be necessary when working with highly concentrated solutions. If the solution contacts the eyes, the eyes should be rinsed slowly with water for 15 minutes. If irritation persists, medical attention should be sought.

G.4.1.4.2 Skin protection

Personnel should wear protective gloves and clothing. The appropriate glove and protective clothing materials should be selected according to the sodium hypochlorite manufacturer's written IFU. If the solution contacts the skin, clothing should be removed and the skin immediately rinsed with water for 15 minutes.

G.4.1.4.3 Respiratory protection

Sodium hypochlorite solutions should be used in a well-ventilated area, and personnel should avoid exposure to vapors. If exposure to vapor occurs, the patient should be removed to fresh air. If ill effects occur, medical attention should be sought. If the potential for high exposure exists, an approved respirator appropriate for chlorine gas might be necessary.

G.4.2 Ventilation

Sodium hypochlorite solutions should be used in a well-ventilated area.

G.4.3 Pouring solutions

The sodium hypochlorite solution should be poured from the original container into a clean, dry immersion container by a method that will prevent employee contact with the chemical solution and reduce respiratory exposure. Agitation and splashing during transfer should be minimized. Examples of methods for minimizing contact with the solution or vapor include the use of closed transfer devices, local exhaust hoods, and/or ductless fume hoods and strict adherence to the use of appropriate PPE.

Rationale: Avoiding contact with sodium hypochlorite solutions prevents skin and eye injury. Minimizing agitation and splashing during transfer also minimizes the potential for increased vapor. See also G.4.1.2.

G.4.4 Transporting solutions

Sodium hypochlorite solutions should not be transported in secondary containers such as trays or buckets. If it is absolutely necessary to transport a solution to another area, that area should be properly ventilated, and a method of transport should be selected that will minimize the potential for spills and the possibility of personnel exposure to the solution or vapor.

Rationale: Transporting solutions in secondary containers increases the risk of spills. Spills increase the surface area of the solution and thus increase the potential for exposure to vapors. Spills also increase the potential for skin and eye contact and irritation, as described in G.4.1.2.

G.4.5 Storing solutions

Sodium hypochlorite solutions should be stored in tightly closed, nonmetal containers in a cool, dry, ventilated area. The sodium hypochlorite manufacturer's written IFU regarding maximum storage times of use solutions should be followed.

Rationale: Sodium hypochlorite solution is corrosive to metals and can react strongly with many chemicals to produce hazardous materials such as chlorine gas. Commercial preparations of sodium hypochlorite are formulated to be stable under normal use and storage, but the maximum storage time can vary from one preparation to another.

G.4.6 Immersing items to be high-level disinfected or sterilized

Personnel should wear appropriate PPE when placing medical devices or other items into the solution; this activity should take place in a properly ventilated area. Personnel should gently place clean, dry items into the solution, taking care to disturb and agitate the surface of the solution as little as possible.

When the solution must be manually irrigated or flushed through internal channels or lumens of an instrument, care should be taken to ensure that the employee is not splashed or sprayed with the solution. The syringe should be carefully filled with the solution and securely attached to the channel opening or all-channel irrigator. The solution in the syringe should be slowly pushed into the channel; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator. A new syringe should be used each time.

Gloved hands should be rinsed thoroughly with water before the cover is replaced on the solution container to avoid contaminating the surface of the container with solution. The medical devices or other items should be allowed to soak for the amount of time and at the temperature designated by the manufacturer to achieve high-level disinfection or sterilization. (See the device manufacturer's written IFU for additional recommendations on high-level disinfection and sterilization.)

Devices to be processed in an automated reprocessor should be loaded in the reprocessor in accordance with the manufacturer's written IFU.

Rationale: These procedures will help prevent worker exposure to sodium hypochlorite and help ensure the effectiveness of the disinfection or sterilization process. Reuse of syringes for irrigation or flushing could lead to contamination of the solution.

G.4.7 Rinsing disinfected or sterile items

Personnel should wear appropriate PPE when removing items from the solution; this activity should take place in a properly ventilated area.

Before removing the device from the solution, personnel should remove the solution from the internal channels or lumens of the device by flushing each channel several times with a syringe filled with air. Personnel should be careful to avoid being splashed with the solution. The device should be totally immersed in the solution, and the syringe should be securely attached to the channel opening or all-channel irrigator. The plunger should be pushed slowly; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator or cause the solution to squirt from the channel opening.

The medical devices should be gently removed from the solution and rinsed thoroughly with water of the quality specified by the device to be processed manufacturer's and/or chemical manufacturer's IFU. (Personnel should rinse their gloved hands with water and then replace the cover on the solution container.) To remove all residual solution, personnel should rinse the external surfaces of the items and any removable parts with copious amounts of clean running water; immerse them in successive containers of clean water (the rinse solution should be discarded after each use, not reused); or otherwise rinse the device in accordance with the manufacturer's written IFU. For medical devices with interior channels, each channel or the all-channel irrigator should be flushed several times with clean water until all residual solution is removed from the channels (at least 500 mL of water during each separate rinse, unless the medical device manufacturer instructs otherwise), and the flushing procedure should be repeated with air. For medical devices with interior channels, the channels should be flushed with 70% to 90% ethyl or isopropyl alcohol, followed by

forced air, to facilitate drying. (However, see the device manufacturer's written IFU.) The external surfaces of medical devices should be thoroughly wiped dry with a sterile, lint-free cloth.

Automated reprocessors include rinsing in the processing cycle.

Rationale: Proper procedures for rinsing, flushing, drying, and storing medical devices will help prevent worker exposure to sodium hypochlorite and help ensure that residual sodium hypochlorite is not introduced into patient tissue. Running water or successive immersions in water is recommended for rinsing in order to further dilute the solution and to prevent the retention of solution that could occur in standing water (Durante, et al., 1992). The flushing of channels with alcohol followed by air greatly reduces the possibility of recontamination of medical devices by waterborne microorganisms. See also ASGE and SHEA (2011).

G.4.8 Transport and storage of processed devices

The manufacturer's recommendations for transportation and storage of processed devices should be followed.

G.5 Sodium hypochlorite spills

Spilled sodium hypochlorite solutions should be confined and collected immediately and be disposed of according to H.7. Personnel should wear appropriate PPE when cleaning up spills.

G.6 Disposal of sodium hypochlorite solutions

Sodium hypochlorite solutions should be diluted with a large amount of water. The diluted solution may then be discharged into a suitable treatment system in accordance with federal, state, and local regulations. Large-volume or high-concentration solutions might require absorption and transfer to a suitable container to be disposed of in accordance with federal, state, and local regulations.

G.7 Vapor monitoring

Gas and vapor emissions can occur from even the best made equipment and odor is an unreliable indicator of the presence and concentration of sodium hypochlorite below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release and provide record keeping. Review the SDS and consult the suppliers of the sodium hypochlorite, and the manufacturers of the sterilizer and the gas monitoring equipment for more information.

Annex H
(normative)
Chemical vapor sterilants using alcohol and formaldehyde

NOTE The information provided in this Annex was accurate at the time the standard was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and IFU change accordingly. Therefore, it is essential that 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.

H.1 Introduction

Small table-top sterilizers employing a sterilant mixture of alcohol with a trace amount (< 0.25%) of formaldehyde are used in dentistry and other health care applications for sterilizing dental medical devices and related devices. This Annex covers the properties and applications of chemical vapor sterilants; occupational exposure considerations specific to formaldehyde and alcohol, including vapor monitoring and procedures for handling spills; and the disposal of chemical vapor sterilants.

H.2 Properties and applications of chemical vapor sterilants

In this method, known as the unsaturated chemical vapor sterilization process, a sterilizing solution composed of various alcohols, water, and a trace amount (< 0.25%) of formaldehyde is introduced into a heated chamber, where it is vaporized. The vapors initially condense as the items reach processing temperature (vaporization phase). Nominal cycle parameters are 20 minutes at a temperature of 132ºC (270ºF) and a pressure of 20 pounds per square inch gauge (psig). A shorter flash cycle for a single nonlumened device is available on some units. A post-process purge (of approximately 7 minutes) and an emission filter are recommended to reduce residual vapors and limit environmental exposure.

This process will not corrode metal medical devices or dull cutting edges, and no drying phase is necessary. The process is not recommended for liquids or agars, textiles, items contained in dense packs, nylon tubing or sealed containers, or items that cannot withstand elevated temperatures. Both biological and chemical indicators are available for monitoring the process.

Items to be sterilized may be packaged in FDA cleared sterile barrier systems to maintain sterility after the sterilization process.

For further information about chemical vapor sterilization, see Lyon and Devine (1974), Miller and Sheldrake (1991), and Guggenheim (1995). As in all cases, it is recommended that before using a sterilant, users should consult with the device and sterilant manufacturers to ensure device compatibility.

H.3 Effective use of chemical vapor sterilizers

To ensure efficacy when using chemical vapor sterilizers, the user should observe the following guidelines:

a) The medical device and sterilizer manufacturers' written IFU should be consulted to determine the compatibility of the device with chemical vapor sterilization.

b) Devices with lumens can be sterilized by the chemical vapor process. The sterilizer manufacturer's written IFU should be followed.

c) Devices should be thoroughly cleaned and dried before sterilization. Medical devices should be lubricated according to the manufacturer's written IFU using a lubricant that is compatible with the sterilant.

d) Any hinged medical devices should be opened.

e) To ensure adequate sterilant contact, the user should load the sterilizer in accordance with the sterilizer manufacturer's written IFU.

f) Biological indicators (containing *Geobacillus stearothermophilus* spores) and CIs should be used to monitor the process.

H.4 Safe use of chemical vapor sterilizers

H.4.1 Occupational exposure

H.4.1.1 General considerations

Procedures should be developed that will minimize exposure to formaldehyde. Personnel should always wear appropriate PPE when using chemical vapor sterilizers (see H.4.1.4).

H.4.1.2 Health effects of formaldehyde and alcohol

H.4.1.2.1 Potential health effects of short-term exposure

Exposure to formaldehyde–alcohol solutions or their vapors can cause eye damage and skin irritation.

H.4.1.2.2 Potential health effects of long-term health exposure

Formaldehyde is listed as a Group 1 carcinogen (“carcinogenic to humans”) by the IARC and as a suspect human carcinogen by ACGIH®.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010) or the IARC web site. For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2013).

H.4.1.3 Occupational exposure limits

The current OSHA occupational exposure limit for formaldehyde is 0.75 ppm as an 8-hour TWA and 2.0 ppm as a 15-minute STEL, with an action level of 0.5 ppm as an 8-hour TWA (29 CFR 1910.1048). ACGIH® recommends a ceiling limit of 0.3 ppm for formaldehyde. The exposure limit for alcohol varies with the particular types of alcohol. The user should consult the label to identify the constituent alcohols and should refer to OSHA for the applicable occupational exposure limits. The spent sterilant solution (condensate) should be disposed of in accordance with state and local regulations.

H.4.1.4 Personal protective equipment and first aid

H.4.1.4.1 Eye protection

Safety glasses, safety goggles, or a face shield should be worn. If any eye contact should occur, the eye should be rinsed immediately with plenty of water for at least 15 minutes. Medical advice should be sought.

H.4.1.4.2 Skin protection

Protective gloves should be worn (see the manufacturer’s written IFU). In case of skin contact, the skin should be washed with water for at least 15 minutes.

H.4.1.4.3 Respiratory protection

See 4.4.4.

H.4.2 Ventilation

Chemical vapor sterilizers should be used in a well-ventilated area. The standard air exchange rate for all sterilization areas, 10 air exchanges per hour, is recommended.

H.4.3 Safety guidelines

To ensure safe use of chemical vapor sterilizers, the user should observe the following guidelines:

a) The sterilizer door should not be opened until the cycle is complete.

b) To prevent exposure to chemical vapors, personnel should not operate the sterilizer without the emission filter in place.

c) After the sterilization cycle is complete, the sterilizer door should be opened and left ajar for 15 seconds before the load is removed.

d) Sterilized items will be hot. To prevent burns, personnel should wear heat-protective gloves when removing items from the sterilizer.

e) Door gaskets should be maintained properly in order to prevent personnel exposure to formaldehyde– alcohol vapors and ineffective sterilization cycles.

H.5 Chemical vapor spills

Personnel should wear appropriate PPE when wiping up spills. Alcohol is flammable; the materials used to wipe up spills should be disposed of properly.

H.6 Disposal of chemical vapor sterilants

Used liquid sterilant from the chemical vapor process should be disposed of in accordance with applicable state and local regulations.

H.7 Vapor monitoring

Gas and vapor emissions can occur from even the best made equipment and odor is an unreliable indicator of the presence and concentration of formaldehyde below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release and provide record keeping. Review the SDS and consult the suppliers of the formaldehyde, and the manufacturers of the sterilizer and the gas monitoring equipment for more information.

Annex I
(normative)
Vaporized hydrogen peroxide sterilization

NOTE The information provided in this Annex was accurate at the time the standard was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and IFU change accordingly. Therefore, it is essential that 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.

I.1 Introduction

Vaporized hydrogen peroxide sterilization processes are particularly suited for sterilizing heat-–sensitive materials because temperatures within the load currently do not exceed 55ºC (131ºF) and sterilization occurs in a low-moisture environment. Heat tolerant devices and materials can also be indicated for vaporized hydrogen peroxide sterilization processes. FDA-cleared vaporized hydrogen peroxide sterilizers, either with or without plasma, are currently available in the United States. This Annex covers the properties and applications of vaporized hydrogen peroxide sterilization; occupational exposure considerations, including vapor monitoring and procedures for handling spills; and sterilant disposal.

I.2 Properties and applications of vaporized hydrogen peroxide sterilization systems

The currently available vaporized hydrogen peroxide sterilization systems follow similar steps for their sterilization processes. It commonly involves the following sequential steps: items to be sterilized are placed into the sterilization chamber, the chamber is closed, and a vacuum is drawn. An aqueous solution of hydrogen peroxide is injected into the chamber, where it vaporizes and surrounds the items to be sterilized. Different technologies employ different cycle characteristics. All of the currently marketed vaporized hydrogen peroxide sterilizers evacuate the chamber to a specific pressure in preparation for one or more repeated injections of hydrogen peroxide, which may include up to four identical injections. After the last injection, the sterilizer will go into a programmed aeration or a plasma phase sequence to reduce the hydrogen peroxide residual associated with the processed medical device. At the end of the process, residues are reduced to a safe level and the remaining oxygen and water vapor are exhausted into the room as byproducts. Items inside the chamber are now ready for use. Chemical and biological indicators are available and cleared by the FDA for the specific sterilizer that they are designed to monitor.

As in all cases, it is recommended that before using any gaseous sterilizer, users should consult with the device and/or the gaseous sterilizer manufacturer to ensure device compatibility. The written IFU will specify any limitations, such as the maximum load weight per cycle, including the minimum internal diameter and length for any lumen-containing medical devices (such as rigid and flexible endoscopes). Liquids, powders, and items made from cellulose cannot be processed in these systems.

For additional information on vaporized hydrogen peroxide sterilization, see Block (2001b); Rutala, et al. (1998); and McDonnell (2007).

I.3 Effective use of vaporized hydrogen peroxide sterilizers

To ensure efficacy when using a vaporized hydrogen peroxide sterilizer, the user should observe the following guidelines:

a) The medical device and/or sterilizer manufacturers' written IFU should be consulted to determine the compatibility of the device with vaporized hydrogen peroxide sterilization.

b) Improper loading of the sterilizer chamber can result in cancelled cycles or failed monitoring products (e.g., positive BIs and incomplete CIs). Always understand and follow the maximum loading weight for each cycle type. Never exceed the maximum chamber loading weight for each cycle type. Ensure enough space between all items in the load to allow for adequate sterilant contact.

c) No cellulose-based products should be included inside or outside the package to be sterilized. (Cellulose-based products such as towels, gauze, or paper are absorptive and can interfere with the sterilization process. These types of materials can cause cycle cancellation.)

d) The only lumened items that should be sterilized are those with lumen sizes cleared by the FDA for the specific vaporized hydrogen peroxide sterilizer being used. FDA-cleared lumen internal diameter and length vary among manufacturers and sterilizer models. The cycles times and characteristics also vary among manufacturers.) The user should consult the sterilizer manufacturer's written IFU to identify specific items appropriate for sterilization in the specific sterilizer cycle.

e) Devices should be thoroughly cleaned and dried before sterilization because excessive moisture can cause cycle cancellation or can result in failed monitoring products (e.g., positive BIs and incomplete CIs).

f) Any hinged medical devices should be opened.

g) Devices should be packaged in Tyvek®-Mylar® pouches, polypropylene wrap, or reusable rigid sterilization container systems cleared by the FDA for use in the specific type of vaporized hydrogen peroxide sterilizer.

h) Only trays and mats recommended by the sterilizer manufacturer and cleared by the FDA for use in the specific sterilizer should be used.

i) To ensure adequate sterilant contact, personnel should load the sterilizer as recommended in the sterilizer manufacturer's written IFU. Do not stack items within the sterilizer. To prevent impeding plasma formation or arcing in those processes that employ a plasma phase, personnel should not allow items to contact the RF electrode when loading the sterilizer.

j) Chemical indicators cleared by the FDA for use in the specific vaporized hydrogen peroxide sterilizer should be used to monitor the process. A CI should be used on the outside of each package unless the internal indicator is visible. An internal pack CI should be used inside each package, tray, containment device (rigid sterilization container system, medical device case, cassette, or organizing tray) to be sterilized. The use of a multivariable chemical indicator as cleared by the FDA monitors two or more parameters of the chemical vapor sterilization process and provides more information about the process as compared to sterilization process indicators as cleared by the FDA and can provide additional quality assurance for the individual monitoring of such items as complex devices, surgical trays, and rigid sterilization container systems.

k) *Geobacillus stearothermophilus* BIs cleared by the FDA for use in the specific vaporized hydrogen peroxide sterilizer should be used to monitor the process.

NOTE ANSI/AAMI/ISO 11138-1 specifies general requirements for BIs. At the time of publication, there were no published ISO standards providing performance requirements for BIs used to monitor VH2O2 processes.

l) Stop or reduce the use of nonessential materials in the load that may increase the absorption of vaporized hydrogen peroxide (e.g. foam or sheet or bubble wrap tray liners, underneath guard liners, rubber corner protectors, foam pocketed medical device protectors, transport trays, oversized or highly dense disposable sterilization wraps).

m) Avoid overlapping indicator tape or placing adhesive labels on top of indicator tape on the outside of packages processed in VH202 to prevent an ambiguous change result for the indicator under the overlap.

n) The sterilization chamber should be kept in a clean state. Assure to clean the chamber per the sterilizer manufacturers user manual.

o) To reduce the risk of VH2O2 sterilization processes failures always clean and rinse metal trays and rigid containers according to manufacturer's instructions for use (e.g. the use of water and detergent solutions with the correct pH and the use of critical water for the final rinse).

I.4 Safe use of vaporized hydrogen peroxide sterilizers

The liquid hydrogen peroxide used for vaporized hydrogen peroxide sterilization is provided packaged by the manufacturer to minimize interaction of the user with the sterilant liquid.

I.4.1 Occupational exposure

I.4.1.1 General considerations

Procedures should be developed that will minimize exposure to hydrogen peroxide and hydrogen peroxide vapor (see J.7). Personnel should always wear appropriate PPE when using vaporized hydrogen peroxide sterilizers (see I.4.1.4).

I.4.1.2 Health effects of hydrogen peroxide

I.4.1.2.1 Potential health effects of short-term exposure

Contact with hydrogen peroxide solutions is corrosive and severely irritating to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Eye contact can cause irreversible eye damage, including blindness. Inhalation of vapors or mists can be severely irritating to the nose, throat, and lungs; in severe cases, it can result in pulmonary edema and permanent lung damage.

I.4.1.2.2 Potential health effects of long-term exposure

Hydrogen peroxide is listed as a Group 3 carcinogen (“unclassifiable as to carcinogenicity to humans”) by the IARC and as an animal carcinogen by ACGIH®.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010) or the IARC web site. For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2013).

I.4.1.3 Occupational exposure limits

The OSHA recommended PEL for hydrogen peroxide is 1 ppm as an 8-hour TWA (29 CFR 1910.1000, Table Z-1).

The ACGIH® recommended threshold limit value (TLV®) for hydrogen peroxide is 1 ppm as an 8-hour TWA (ACGIH®, 2013).

The NIOSH recommended exposure limit (REL) for hydrogen peroxide is 1 ppm as a time-weighted average for up to a 10-hour workday and a 40-hour workweek.

I.4.1.4 Personal protective equipment and first aid

I.4.1.4.1 Eye protection

Direct hydrogen peroxide contact with the eyes can cause irreversible tissue damage. For any necessary eye PPE, see the manufacturer’s written IFU. If eye contact occurs, the eyes should be immediately flushed with large amounts of water according to the manufacturer’s written IFU and the SDS , and a physician should be consulted immediately.

I.4.1.4.2 Skin protection

When items have been properly prepared (thoroughly cleaned, rinsed and dried prior to packaging) and the sterilization cycle successfully completes, the risk of hydrogen peroxide contact when removing the load from the sterilizer is negligible. However, as a precaution to protect users from potential hydrogen peroxide contact in the event that items have not been properly prepared, personnel should wear polyvinylchloride or nitrile gloves when removing items from the sterilizer after a cycle has canceled, or at any time the items in the load have any visible moisture or liquid. Moisture or liquid in the load could be present due to poor drying or the rupture of a biological indicator medial ampoule. If any skin contact with hydrogen peroxide should occur, the skin should be washed with large amounts of water according to the manufacturer’s written IFU and the SDS.

I.4.1.4.3 Respiratory protection

Respiratory protection is not usually required during normal operation of the sterilizer. The manufacturer's written IFU should be consulted for information on respiratory protection needed in the event of a sterilizer malfunction or aborted cycle.

NOTE Overexposure is unlikely to occur unless there is a cycle cancellation and the items in the load have visible moisture or liquid.

I.4.2 Ventilation

Hydrogen peroxide gas sterilizers should be used in a well-ventilated area.

I.4.3 Safety guidelines

To ensure safe use of the hydrogen peroxide gas sterilizer, the user should observe the following guidelines:

a) Sterilant cassettes/cartridges or cups should be checked for integrity before use. Cassettes/cartridges or cups that are leaking should not be opened.

b) Gloves should be worn when disposing of spent cassettes/cartridges or cups and when removing packages from a canceled cycle.

I.5 Spills

Personnel should wear eye protection and chemical-resistant gloves when cleaning up spills. Spills should be contained and absorbed with an inert absorbent material and then placed in a disposable container. Spilled hydrogen peroxide solution should be kept away from combustible material. Any liquid inside a gaseous hydrogen peroxide sterilizer should be considered to contain hydrogen peroxide and cleaned as described above.

I.6 Sterilant disposal

Hydrogen peroxide solutions must be disposed of in accordance with appropriate U.S. federal and state regulations and international regulations. If unaltered by use, hydrogen peroxide solutions may be disposed of by treatment at a permitted facility or as advised by the local hazardous waste regulatory authority.

I.7 Vapor monitoring

Vapor monitoring is recommended if there is the potential for the hydrogen peroxide vapor concentration to exceed the OSHA recommended permissible exposure limits. Emissions from properly operated and maintained chemical vapor sterilizers should be well below the OSHA PEL, but sterilizers and exhaust systems, as with any other complex equipment, can and sometimes do fail. If monitoring is deemed necessary, continuous personal and area monitors for hydrogen peroxide are commercially available.

Gas and vapor emissions can occur from even the best made equipment and odor is an unreliable indicator of the presence and concentration of hydrogen peroxide gas below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release and provide record keeping. Review the SDS and consult the suppliers of the hydrogen peroxide solutions and the manufacturers of the sterilizer and the gas monitoring equipment for more information.

Annex J
(normative)
Hydrogen peroxide-ozone sterilization

NOTE The information provided in this Annex was accurate at the time the recommended practice was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and IFU change accordingly. Therefore, it is essential that 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.

J.1 Introduction

Hydrogen peroxide-ozone sterilization processes are particularly suited for sterilizing heat-sensitive materials because temperatures within the load currently do not exceed 41°C (106°F) and sterilization occurs in a low-moisture environment. Heat tolerant devices and materials can also be indicated for hydrogen peroxide gas sterilization processes. One FDA-cleared hydrogen peroxide-ozone sterilizer is currently available in the United States. This Annex covers the properties and applications of hydrogen peroxide-ozone sterilization; occupational exposure considerations, including vapor monitoring and procedures for handling spills; and sterilant disposal.

J.2 Properties and applications of hydrogen peroxide-ozone gas sterilization systems

Hydrogen peroxide-ozone sterilization uses a single cycle for all types of load. It has been cleared by the FDA for the sterilization of general instruments, rigid endoscopes and flexible endoscopes including multichannel gastrointestinal endoscopes. The items to be sterilized should be thoroughly cleaned and dried before sterilization following the device manufacturer IFU. Chemical and biological indicators are available and cleared by the FDA for monitoring the sterilization process.

The currently available hydrogen peroxide-ozone sterilization process involves the following sequential steps:

a) cleaned and packaged items to be sterilized are placed on the loading rack and into the sterilization chamber;

b) the chamber is closed, the cycle is started and a vacuum is drawn;

c) an aqueous hydrogen peroxide solution is vaporized, injected in the chamber and surrounds the items to be sterilized, until a pre-set pressure differential is achieved;

d) ozone is injected into the chamber and surrounds the items to be sterilized. Ozone is generated from oxygen within the sterilizer's self-contained ozone generator.

e) exposure time;

f) the sterilizer evacuates the sterilants from the chamber;

g) a second sterilization phase is executed and included repetition of steps c) to f);

h) the sterilizer goes into a programmed aeration sequence to reduce the hydrogen peroxide and ozone residual associated with the processed medical device. At the end of the process, no toxic residues are left and the remaining oxygen and water vapor are exhausted into the room as by-products.

i) items inside the chamber are now ready for use.

As in all cases, it is recommended that before using a sterilant, users should consult with the device and/or sterilizer manufacturer to ensure device compatibility. The written IFU will specify any limitations, including the minimum internal diameter and length for any lumen-containing medical devices (such as rigid and flexible endoscopes). Liquids, powders, and items made from cellulose cannot be processed in this system.

J.3 Effective use of hydrogen peroxide-ozone gas sterilization

To ensure efficacy when using the hydrogen peroxide gas sterilizer, the user should observe the following guidelines:

a) The medical device and/or sterilizer manufacturers' written IFU should be consulted to determine the compatibility of the device the sterilizer system.

b) No cellulose-based products should be included inside or outside the package to be sterilized. (Cellulosebased products such as towels, gauze, or paper are absorptive and can interfere with the sterilization process. These types of materials can cause cycle cancellation.)

c) The only lumened items that should be sterilized are those with lumen sizes cleared by the FDA for the hydrogen peroxide-ozone sterilizer being used. FDA-cleared lumen internal diameter and length vary among manufacturers and sterilizer models. The user should consult the sterilizer manufacturer's written IFU to identify specific items appropriate for sterilization.

d) Devices should be thoroughly cleaned and dried before sterilization because excessive moisture can cause cycle cancellation.

e) Any hinged medical devices should be opened.

f) Devices should be packaged in Tyvek® pouches, polypropylene wrap, or reusable rigid sterilization container systems cleared by the FDA for use in the specific type of hydrogen peroxide-ozone sterilizer.

g) Only trays and mats recommended by the sterilizer manufacturer and cleared by the FDA for use with the sterilizer should be used.

h) To ensure adequate sterilant contact, personnel should load the sterilizer as recommended in the sterilizer manufacturer's written IFU and respect the recommended load temperatures.

i) Chemical indicators and *Geobacillus stearothermophilus* BIs cleared by the FDA for use in the hydrogen peroxide-ozone sterilizer should be used to monitor the process.

J.4 Safe use of hydrogen peroxide-ozone gas sterilizer

J.4.1 Occupational exposure

J.4.1.1 General considerations

Procedures should be developed that will minimize exposure to hydrogen peroxide and ozone. Personnel should always wear appropriate PPE when using hydrogen peroxide-ozone sterilizers (see J.4.1.5).

J.4.1.2 Health effects of hydrogen peroxide

J.4.1.2.1 Potential health effects of short-term exposure

Contact with hydrogen peroxide solutions is corrosive and severely irritating to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Eye contact can cause irreversible eye damage, including blindness. Inhalation of vapors or mists can be severely irritating to the nose, throat, and lungs; in severe cases, it can result in pulmonary edema and permanent lung damage.

J.4.1.2.2 Potential health effect of long-term exposure

Hydrogen peroxide is listed as a Group 3 carcinogen ("unclassifiable as to carcinogenicity to humans") by the IARC and as an animal carcinogen by ACGIH®.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010) or the IARC web site. For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2013).

J.4.1.3 Health effects of ozone

J.4.1.3.1 Potential health effects of short-term exposure

Exposure to ozone causes dryness of the mouth, coughing, and eye, throat, nose, and chest irritation. Ozone exposure may cause breathing difficulties, headache, and fatigue, and it also may increase sensitivity to bronchoconstrictors, including allergens.

The sharp odor of ozone can be detected at low concentrations (0.01 to 0.05 ppm).

J.4.1.3.2 Potential health effects of long-term exposure

The effects of long-term exposure to ozone can include inflammation and permanent lung damage.

J.4.1.4 Occupational exposure limits

J.4.1.4.1 Hydrogen peroxide

The OSHA recommended PEL for hydrogen peroxide is 1 ppm as an 8-hour TWA (29 CFR 1910.1000, Table Z-1). The ACGIH® recommended threshold limit value (TLV®) for hydrogen peroxide is 1 ppm as an 8-hour TWA (ACGIH®, 2013).

The NIOSH recommended exposure limit (REL) for hydrogen peroxide is 1 ppm as a time-weighted average for up to a 10-hour workday and a 40-hour workweek.

J.4.1.4.2 Ozone

The OSHA PEL for ozone is 0.1 ppm (8 hr TWA), and OSHA recommends using a STEL of 0.3 ppm (15 min TWA), through the latter is not currently enforceable. The ACGIH®-recommended TLV®s for ozone range for 0.05 ppm TWA to 0.20 ppm TWA, depending on the conditions and duration exposure.

J.4.1.5 Personal protective equipment and first aid

J.4.1.5.1 Eye protection

Direct hydrogen peroxide contact with the eyes can cause irreversible tissue damage. For any necessary eye PPE, see the manufacturer’s written IFU. If eye contact occurs, the eyes should be immediately flushed with large amounts of water according to the manufacturer’s written IFU and the SDS, and a physician should be consulted immediately.

J.4.1.5.2 Skin protection

When items have been properly prepared (thoroughly cleaned, rinsed and dried prior to packaging) and the sterilization cycle successfully completes, the risk of hydrogen peroxide contact when removing the load from the sterilizer is negligible. However, as a precaution to protect users from potential hydrogen peroxide contact in the event that items have not been properly prepared, personnel should wear polyvinylchloride or nitrile gloves when removing items from the sterilizer after a cycle has canceled, or at any time the items in the load have any visible moisture or liquid, as hydrogen peroxide could be present. If any skin contact with hydrogen peroxide should occur, the skin should be washed with large amounts of water according to the manufacturer’s written IFU and the SDS.

J.4.1.5.3 Respiratory protection

Respiratory protection is not usually required during normal operation of the sterilizer. The manufacturer’s written IFU should be consulted for information on respiratory protection needed in the event of a sterilizer malfunction or aborted cycle.

NOTE Overexposure is unlikely to occur unless there is a cycle cancellation and the items in the load have visible moisture or liquid.

J.4.1.6 Ventilation

Hydrogen peroxide-ozone gas sterilizers should be used in a well-ventilated area.

J.4.1.7 Safety guidelines

To ensure safe use of the hydrogen peroxide-ozone gas sterilizer, the user should observe the following guidelines:

a) Sterilant solution bottles should be checked for integrity before use. Bottles that are leaking should not be used. Users should not attempt to open sterilant solution bottles as they are designed to be safely loaded closed into the sterilizer.

b) Gloves should be worn when disposing of spent bottles and when removing packages from a canceled cycle.

c) The user should verify that the sterilizer has been installed in accordance with the manufacturer written IFU and should follow the manufacturer's written IFU.

Users do not handle the ozone during the process and, by design, cannot be exposed to ozone.

J.5 Spills

Personnel should wear eye protection and chemical-resistant gloves when cleaning up hydrogen peroxide spills. Spills should be contained and absorbed with an inert absorbent material and then placed in a disposable container. Spilled hydrogen peroxide solution should be kept away from combustible material.

Ozone spills cannot occur because ozone is a gas that cannot be found in a liquid state at room temperature.

J.6 Sterilant disposal

Hydrogen peroxide solutions must be disposed of in accordance with appropriate U.S. federal and state regulations and international regulations. If unaltered by use, hydrogen peroxide solutions may be disposed of by treatment at a permitted facility or as advised by the local hazardous waste regulatory authority.

Ozone disposal is unnecessary for the currently available sterilization system. The sterilizer is designed so that all of the ozone produced is converted after use to oxygen by means of a catalytic converter.

J.7 Vapor monitoring

Vapor monitoring is recommended if there is the potential for the hydrogen peroxide vapor concentration to exceed the OSHA recommended permissible exposure limits. Gas and vapor emissions can occur from even the best made equipment and odor is an unreliable indicator of the presence and concentration of hydrogen peroxide or ozone gas below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release and provide record keeping. Review the SDS and consult the suppliers of the hydrogen peroxide solutions and the manufacturer of the sterilizer and the gas monitoring equipment for more information.

Annex K
(informative)
Sonicated hydrogen peroxide mist

NOTE The information provided in this Annex was accurate at the time the recommended practice was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and IFU change accordingly. Therefore, it is essential that 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.

K.1 Introduction

Sonicated hydrogen peroxide (35%) mist has been cleared by the FDA for use as an HLD for ultrasound transducers and is currently available in the United States. Sonicated hydrogen peroxide mist is not a liquid based HLD or LCS, rather it consists of very fine droplets of hydrogen peroxide suspended in a mist. As such, there are some unique considerations necessary for its use. This Annex covers the properties and occupational exposure considerations specific to sonicated hydrogen peroxide mist.

K.2 Properties and applications of sonicated hydrogen peroxide mist

The currently available sonicated hydrogen peroxide mist device follows the following sequential steps: the ultrasound transducer to undergo HLD is placed in the disinfection chamber and the chamber is sealed. An aqueous solution of 35% hydrogen peroxide is drawn from a replaceable cartridge that is locked in the automated delivery system. The solution is then sonicated inside the automated delivery system and injected into the disinfection chamber as a nebulized mist and surrounds the transducer. The cycle lasts 7 minutes with residual hydrogen peroxide being removed at the end of the process via catalytic destruction. The hydrogen peroxide mist is evacuated from the chamber and broken down into oxygen and water which is collected in a waste drawer for disposal. The transducer is removed from the disinfection chamber, wiped with a clean low-linting cloth and is ready for use. As in all cases, it is recommended that before using a disinfectant, users should consult with the transducer and disinfectant manufacturers' IFUs to ensure transducer compatibility.

For additional information on sonicated hydrogen peroxide mist HLD of ultrasound transducers, see Vickery (2013); Ngu (2014); and Meyers (2016).

K.3 Effective use of sonicated hydrogen peroxide mist

To ensure efficacy, the user should observe the following guidelines:

a) The ultrasound transducer manufacturer's written IFU should be consulted to determine the compatibility with sonicated hydrogen peroxide mist. If the IFU does not specifically reference sonicated hydrogen peroxide mist, it is recommended that users should consult with the ultrasound transducer manufacturer to ensure compatibility.

b) Ultrasound transducers should be thoroughly cleaned and dried before they are inserted into the chamber to ensure HLD is achieved.

c) Only the manufacturer supplied FDA cleared chemical indicator should be used to verify that each processing cycle achieved HLD. A new chemical indicator should be used for each cycle and according to the manufacturer's written IFU.

d) The aqueous solution of 35% hydrogen peroxide disinfectant is supplied in a sealed cartridge which is punctured after insertion and locking in the enclosed automated delivery system.

e) The sealed cartridge and the chemical indicators should not be used beyond their shelf life. Unopened solutions should be stored according to manufacturer instructions.

K.4 Safe use of sonicated hydrogen peroxide mist

K.4.1 Occupational exposure

K.4.1.1 General considerations

The hydrogen peroxide cartridge is supplied sealed and is punctured only after it is locked in the automated delivery system. During the disinfection cycle the transducer is completely sealed inside the chamber preventing user exposure to hydrogen peroxide liquid, mist or vapor. Personnel should always follow the manufacturer's IFU. Personnel should always wear gloves when handling the disinfectant cartridge, used chemical indicators or waste drawer according to the manufacturer's written IFU.

K.4.1.2 Health effects of sonicated hydrogen peroxide mist

K.4.1.2.1 Potential health effects of short-term exposure

The sealed cartridge and automated delivery system are designed to prevent the user coming into contact with hydrogen peroxide liquid, mist or vapor such that gloves are the only form of PPE required according to the manufacturer's IFU. The manufacturer's SDS should be consulted regarding potential health effects from exposure to hydrogen peroxide. Contact with hydrogen peroxide solutions is corrosive and severely irritating to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Eye contact can cause irreversible eye damage, including blindness. Inhalation of vapors or mists can be severely irritating to the nose, throat, and lungs; in severe cases, it can result in pulmonary edema and permanent lung damage.

K.4.1.2.2 Potential health effects of long-term exposure

Hydrogen peroxide is listed as a Group 3 carcinogen ("unclassifiable as to carcinogenicity to humans") by the IARC and as an animal carcinogen by ACGIH®.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010) or the IARC web site. For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2013).

K.4.1.3 Occupational exposure limits

The ACGIH® recommended threshold limit value (TLV®) for hydrogen peroxide is 1 ppm as an 8-hour TWA (ACGIH®, 2013). The NIOSH recommended exposure limit (REL) for hydrogen peroxide is 1 ppm as a time-weighted average for up to a 10-hour workday and a 40-hour workweek.

NOTE The currently available sonicated hydrogen peroxide mist device is designed to prevent the release of vapor through the sealed chamber design and catalytic destruct process. The device is designed to be used in the patient environment; ensure manufacturer IFU is consulted.

K.4.1.4 Personal protective equipment and first aid

K.4.1.4.1 Eye protection

Eye protection is not required during normal operation of the sonicated hydrogen peroxide mist device due to the enclosed nature of the device and consumable system. Direct hydrogen peroxide contact with the eyes can cause irreversible tissue damage. If eye contact occurs, the eyes should be immediately flushed with large amounts of water according to the manufacturer's written IFU and the SDS, and a physician should be consulted immediately.

K.4.1.4.2 Skin protection

Personnel should wear gloves when removing the transducer from the chamber and wipe the probe with a clean low lint cloth. Users should also wear gloves when handling the chemical indicator after the HLD cycle. If any skin contact with hydrogen peroxide should occur, the skin should be washed with large amounts of water in accordance with the manufacturer's written IFU and the SDS.

K.4.1.4.3 Respiratory protection

Respiratory protection is not usually required during normal operation. The manufacturer's written IFU should be consulted for information on respiratory protection needed in the event of a malfunction or aborted cycle. See also 4.4.4.

K.4.2 Ventilation

Sonicated hydrogen peroxide mist systems should be used in a well-ventilated area.

K.4.3 Safety guidelines

To ensure safe use of the Sonicated hydrogen peroxide mist system, the user should observe the following guidelines:

a) Disinfectant cassettes/cartridges or cups should be checked for integrity before use. Cassettes/cartridges or cups that are leaking should not be opened.
b) Gloves should be worn when disposing of spent cassettes/cartridges or cups and when removing packages from a canceled cycle.

K.5 Hydrogen peroxide spills and leaks

Hydrogen peroxide is sealed inside the cartridge which is punctured when locked in the automated delivery system to prevent spills and leaks. During the HLD cycle the chamber is sealed. Ensure the manufacturer IFU is consulted in the event of a spill or leaks.

Annex L
(informative)
Government regulation

L.1 Introduction

Chemical sterilants and disinfectants are regulated by the EPA, the FDA, OSHA, and state and local governments. The extent of regulation by each agency depends on the type and intended use of the chemical sterilant/high-level disinfectant.

Before passage of the Food Quality Protection Act of 1996 (FQPA), both the EPA and the FDA regulated LCSs/HLDs used on medical devices. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is responsible for registering pesticides before they are sold and for ensuring that, when used according to label directions, they are effective and do not present unreasonable risks to human health or the environment. The FQPA excluded LCSs/HLDs used to reprocess critical and semicritical medical devices from the FIFRA definition of pesticide. Consequently, the FDA now has *sole* regulatory jurisdiction over these LCSs/HLDs. The FQPA did not affect the regulation of general-purpose disinfectants.

Before an LCS/HLD product can be introduced into interstate commerce, the manufacturer must submit a premarket notification to the FDA in accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act (FD&C Act) and receive premarket clearance for the product. Although the FDA clears new products for marketing, it does not endorse any product or conduct independent testing of a product's safety and performance characteristics. The agency relies exclusively on the manufacturer's safety and efficacy data during product evaluation.

The FDA also regulates sterilization systems that are sold to health care facilities and that use gaseous chemical sterilants, including EO, chemical vapor, vaporized hydrogen peroxide, and hydrogen peroxide-ozone. The manufacturer of a gaseous chemical sterilizer intended for use by health care facilities must submit a premarket notification (510[k]) to the FDA and must receive market clearance before the sterilizer can be introduced into interstate commerce. The EPA regulates EO gas, but not the other gaseous agents used in sterilizers. More information on the FDA's premarket notification requirements for sterilizers can be found in FDA guidance documents (FDA, 1993, 2000b). These guidance documents are available on the FDA/CDRH website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationsandGuidance/GuidanceDocuments/UCM081341.pdf, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-premarket-notification-510k-sterilizers-intended-use-health-care-facilities and https://www.fda.gov/regulatory-information/search-fda-guidance-documents/addendum-guidance-premarket-notification-510k-submissions-sterilizers-intended-use-health-care.

The Occupational Safety and Health Administration regulates occupational exposure to toxic chemicals that might be present or used in the workplace. Consequently, this agency is empowered to establish limits on occupational exposure to chemical sterilants/high-level disinfectants and to impose labeling requirements on manufacturers.

State and local health agencies also regulate certain aspects of the use and disposal of chemical sterilants/high-level disinfectants. Such regulations must be at least as stringent as federal requirements; in some cases, state and local requirements are *more* stringent than federal requirements. Personnel should know their obligations under state laws and local ordinances.

L.2 FDA regulation of medical devices

The FDA regulates medical devices under the authority of the FD&C Act. Under the Medical Device Amendments of 1976, as amended by the Safe Medical Devices Act of 1990 and the Food and Drug Administration Modernization Act of 1997 (FDAMA), devices are to be classified into one of three regulatory classes, according to the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness: Class I (general controls), Class II (special controls), or Class III (premarket approval [PMA]).

L.3 History of FDA regulation of LCSs/HLDs

In 1980, when other general hospital and personal-use devices were classified (FDA, 1980), liquid chemical germicides were not included. In subsequent years, the FDA actively regulated only those liquid chemical germicides (sterilants and disinfectants) that were used as accessories to specific Class II devices, such as hemodialyzers. The FDA began actively regulating all liquid chemical germicides in the early 1990s, following publication in 1992 of an FDA guidance document for liquid chemical germicides.

If liquid chemical germicides were considered to be accessories to other medical devices, then they would be in the same regulatory class as the primary medical device. Thus, the same liquid chemical germicide product could be regulated as a Class I, Class II, or Class III device. To prevent the confusion that this system would create, the FDA determined that liquid chemical germicides were unclassified devices rather than accessory devices. The FDA also determined that two categories of liquid chemical germicides existed:

a) **Liquid chemical sterilants/high-level disinfectants,** which are intended for use as the terminal step in processing critical and semicritical medical devices before patient use; and

b) **General-purpose disinfectants,** which are intended to process non-critical medical devices and medical equipment surfaces and which can be used to preclean or decontaminate critical or semicritical devices before terminal sterilization or high-level disinfection.

NOTE—General-purpose disinfectants are used primarily for the final disinfection of non-critical medical devices and patient care equipment after these items have been cleaned. Some general-purpose disinfectants might also be labeled for use to preclean or decontaminate critical or semicritical medical devices before terminal sterilization or high-level disinfection of the device. The objective of using a general-purpose disinfectant for precleaning or decontamination is to reduce bioburden and to protect the employee during subsequent steps in the process. However, before using a general-purpose disinfectant for precleaning, the user must ensure that the disinfectant product is appropriate for use with the specific devices to be processed and must follow the manufacturer's IFU for precleaning or decontamination. After precleaning, the devices must be subjected to terminal sterilization or high-level disinfection, as appropriate, before patient use.

The FDA uses the Spaulding classification to determine whether a medical device is a critical, semicritical, or non-critical device. Spaulding divided medical medical devices and equipment into three categories that were based on the risk of infection from contamination on the device (Spaulding, 1972). *Critical devices* are those that are introduced directly into the human body, either into or in contact with the bloodstream or other normally sterile areas of the body. Critical devices present a high degree of risk of transmission of infection if contaminated and, therefore, must be sterile. *Semicritical devices* are those that contact intact mucous membranes or nonintact skin during use, but do not usually penetrate the blood barrier or other normally sterile areas. If a semicritical device cannot be sterilized, it must be subjected to a high-level disinfection process in which a sterilant is used but for a shorter exposure time than required to achieve sterilization. The FDA and CDC state that the use of sheaths does not replace the need for sterilization or high-level disinfection of critical and semi-critical ultrasound probes (the use of sheaths for endoscopes is addressed in ANSI/AAMI ST91) (FDA 2019, CDC 2008).[1,2] *Non-critical devices or instruments*, which pose the lowest risk of transmission of infection, are those that usually contact only intact skin; these devices must be thoroughly cleaned and might require intermediate or low-level disinfection.

In July 1995, the FDA General Hospital and Personal Use Devices Advisory Panel recommended the classification of liquid chemical germicides used on medical devices, and proposed classification rules were published in the *Federal Register* in November 1998 (FDA, 1998e). The final rule, published in the *Federal Register* in June 2000 (FDA, 2000a), classified LCSs/HLDs as Class II devices subject to special controls (21 CFR 880.6885) and general-purpose disinfectants as Class I devices subject to general controls and exempt from premarket notification requirements (21 CFR 880.6890). Special controls for LCSs/HLDs include the FDA guidance document (see L.4.1) and user information and training. Although general-purpose disinfectants are exempt from premarket notification, they are still subject to GMP requirements and are required by EPA to be registered as pesticides.

L.4 Current FDA regulation of LCSs/HLDs

L.4.1 Premarket notification submissions

Certain administrative information is required to be included in all premarket notification submissions. For LCSs/HLDs, manufacturers are also requested to provide information describing (a) the chemical and physical properties of the sterilant product and its active and inert ingredients, (b) the product containers and the compatibility of the sterilant and container materials, (c) any accessories or containers specified for use with the sterilant, (d) product stability, (e) microbicidal efficacy, (f) biocompatibility (residues and toxicity), (g) compatibility with materials and devices with which the product is to be used, and (h) the solution test strips or chemical monitoring devices to be used to monitor the concentration of the active ingredients of germicide products with reuse claims.

Personnel or manufacturers seeking additional information on premarket notification submissions for LCSs/HLDs should consult FDA's guidance document, *Guidance on the content and format of premarket notification [510(k)] submissions for liquid chemical sterilants and high-level disinfectants,* which was issued on January 3, 2000 (FDA, 2000b), and is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-and-format-premarket-notification-510k-submissions-liquid-chemical-sterilantshigh-level.

L.4.2 Labeling

As described in EPA PR Notice 98-2 (EPA, 1998), manufacturers of products with claims regulated only by the FDA (i.e., LCSs/HLDs labeled for use on critical and semicritical medical devices) are required to remove all EPA references from the labeling, including the EPA registration number and the EPA establishment number. Manufacturers are also required to remove all FDA references from the labeling of products regulated only by EPA.

All FDA-regulated products, including LCSs/HLDs, must be properly labeled in accordance with the FDA's general labeling regulation (21 CFR 801), including the specific requirements for adequate directions for use (21 CFR 801.5). Under FDA regulation, the labeling for LCSs/HLDs must provide information relating to safe and effective use. The labeling must identify the active ingredients and their concentrations and provide information on measuring the MRC or MEC before use, the required contact time and temperature, the reuse pattern, material and device compatibility, necessary PPE, stability, and shelf life. Labeling includes a package insert containing the above information and any supplemental information needed by the user for the safe and effective use of the product. The FDA-required labeling relies on the broader disinfection terms defined by Spaulding to indicate product effectiveness. It is FDA's policy that, unless proven by clinical trials, labeling should not contain references to specific diseases or specific microorganisms. The user should be able to infer the microbicidal efficacy of a sterilant product by examining the FDA-cleared claims for the product, such as sterilization or high-level disinfection.

Users can obtain information about labeling requirements and about 510(k) submissions for cleared chemical sterilant/high-level disinfectant products or sterilizing systems from the Center for Devices and Radiological Health (CDRH) website at http://www.fda.gov/cdrh; from CDRH Device Advice at https://www.fda.gov/MedicalDevices/default.htm; or from 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).

L.5 FDA medical device reporting (MDR) regulation

The medical device reporting (MDR) regulation (21 CFR 803) requires medical device manufacturers and importers to report to the FDA any deaths, serious injuries, and device malfunctions that could result in patient injury or death. The regulation also requires device user facilities (i.e., hospitals, nursing homes, ambulatory care facilities, and outpatient treatment and diagnostic facilities) to report deaths to both the FDA and the device manufacturer and to report serious injuries to the manufacturer. The MDR requirements are summarized in Table L.1.

Table L.1—Summary of MDR requirements

Reporter	Report what?	To whom?	When?
User facility	Deaths	FDA and manufacturer	Within 10 work days
	Serious injuries	Manufacturer; FDA only if manufacturer unknown	Within 10 work days
	Annual reports of deaths and serious injuries	FDA	January 1
Manufacturer	30-day reports of deaths, serious injuries, and malfunctions	FDA	30 days from becoming aware
	Baseline report to identify and provide basic data on each device that is subject of a report	FDA	With 30-day report when device is reported for first time
	5-day report on events that require immediate remedial action and on other types of events designated by FDA	FDA	Within 5 work days
Importer	30-day reports of deaths, serious injuries, and malfunctions	FDA	30 days from becoming aware
Distributor	No reporting requirements, but must maintain device complaint files for incident information		

If an MDR reportable event should occur in connection with an LCS/HLD or a gaseous chemical sterilization system, the user should report the event to the sterilant or sterilizer manufacturer as well as to the reusable device manufacturer. If the event does not qualify for reporting under the MDR regulation, it should be reported through FDA's voluntary MedWatch Reporting Program.

Additional information on MDR and MedWatch reporting can be found at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm and https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program, respectively.

L.6 OSHA regulation of chemical sterilants/high-level disinfectants

L.6.1 General

Under the Occupational Safety and Health Act, OSHA regulates occupational exposure to chemicals that are present or used in the workplace. Under its Hazard Communication Standard, OSHA also requires manufacturers of chemicals to provide users with SDSs . These regulations apply to chemical sterilants/high-level disinfectants.

L.6.2 Occupational exposure limits

Occupational exposure limits have been established for several agents used in LCS/HLD formulations and gaseous chemical sterilization systems. Employers are required by law to ensure compliance with these limits by implementing engineering controls, defining procedures for safe employee work practices, establishing medical surveillance programs, providing respiratory protection, and taking other measures to the extent specified by OSHA. In addition, product manufacturers might be subject to certain labeling requirements.

Limits established by OSHA for airborne contaminants, including some LCS/HLD and gaseous sterilant chemicals, are set forth in 29 CFR 1910.1000. Separate standards limiting occupational exposure to EO and formaldehyde are set forth in 29 CFR 1910.1047 and 29 CFR 1910.1048, respectively. In 1989, OSHA adopted a final rule for air contaminants in which PELs for hundreds of chemicals were revised or added to the Air Contaminants Standard in 29

CFR 1910.1000. In 1992, the 11th Circuit Court of Appeals ruled that OSHA did not sufficiently demonstrate that the new PELs were necessary or feasible. As a result of the court's decision to vacate the new limits, OSHA was forced to return to the original limits published in 1971. However, OSHA can invoke the General Duty Clause of the Occupational Safety and Health Act of 1970 to regulate employee exposure to hazardous chemicals for which OSHA-established limits do not exist. Before 1989, for example, the Air Contaminants Standard did not include exposure levels for glutaraldehyde, and there are no current OSHA-established exposure limits for glutaraldehyde. However, OSHA has invoked the General Duty Clause to regulate employee exposure and has recommended that exposures be controlled to the ACGIH®-recommended TLVs® for glutaraldehyde (Table L.2). Additionally, states with federally approved state OSHA programs may independently decide to enforce the PELs originally promulgated in the 1989 rule for air contaminants.

Table L.2—Occupational exposure limits for some chemical sterilants/high-level disinfectants

Chemical agent	OSHA PEL	ACGIH® TLV®
Alcohols	Various[1)]	Various[1)]
Ethylene oxide	1 ppm TWA 5 ppm STEL	1 ppm TWA
Formaldehyde	0.75 ppm TWA 2 ppm STEL 0.5 ppm AL	0.3 ppm ceiling
Glutaraldehyde	None[2)]	0.05 ppm ceiling
Hydrogen peroxide	1 ppm TWA 1.4 mg/m^3 TWA	1 ppm TWA
Ozone	0.1 ppm TWA 0.3 ppm STEL	0.05 ppm TWA to 0.20 ppm TWA (depending on conditions and duration of exposure)
Peracetic acid	None[3)]	0.4 ppm (15 min TWA) (Ref. ACGIH 2014).
Ortho-phthalaldehyde	None	None

NOTE 1 Various types of alcohol are used in sterilant formulations, and the occupational exposure limits vary. Refer to the product label for the active ingredients, and consult the latest ACGIH® recommendations and OSHA regulations.

NOTE 2 No exposure limits have been established by OSHA. However, OSHA can invoke the General Duty Clause of the Occupational Safety and Health Act of 1970 to regulate exposure to glutaraldehyde and has recommended that the ACGIH® TLVs® be followed.

NOTE 3 There is an OSHA PEL for acetic acid (a component of peracetic acid mixtures): 10 ppm TWA (25 mg/m3 TWA).

NOTE 4 However, there are ACGIH® TLVs® for acetic acid (a byproduct of peracetic acid): 10 ppm TWA; 15 ppm STEL.

Limits on occupational exposure to chemical agents are commonly defined in terms of the maximum amount of chemical to which an employee can be exposed over a specified period of time. For example, OSHA mandates PELs calculated as an 8-hour TWA exposure. For some chemicals, a STEL, which is based on a 15-minute exposure, has been established. For certain chemicals, including EO and formaldehyde, OSHA has established an "action level" (AL), which is the 8-hour TWA exposure level above which employers must initiate certain compliance activities, such as periodic employee exposure monitoring and medical surveillance. (The OSHA standard limiting occupational exposure to ethylene oxide can be found at 29 CFR 1910.1048. The OSHA standard for formaldehyde can be found at 29 CFR 1910.1047.) "Excursion limit" (EL) is a term adopted by OSHA specifically for defining a short-term exposure limit for EO. Like a STEL, an EL is the maximum 15-minute exposure to which a worker may be subjected. ACGIH®, a private professional organization, recommends TLVs®—defined in terms of 8-hour TWAs, 15-minute STELs, or ceiling limits—for a large number of chemical substances and physical agents.

Table L.2 lists chemical agents found in LCS/HLD formulations and gaseous chemical sterilization systems and the exposure limits currently mandated by OSHA and recommended by ACGIH®. Additional information on OSHA requirements can be found at http://www.osha.gov. Additional information on ACGIH® recommendations can be found in ACGIH® (2013) or at http://www.acgih.org.

L.6.3 Safety Data Sheets

The SDS for a chemical used in an LCS/HLD formulation or gaseous chemical sterilization system provides the user with valuable information about the toxicity of the product as well as other safety information, such as explosion hazards, required safety equipment, and safe exposure limits for individual chemicals. The following information must be included in the SDS:

a) the identity of the chemical or product;

b) the chemical name and common name of the substance;

c) the chemical name and common name of hazardous ingredients;

d) the physical and chemical characteristics;

e) the physical hazards, including the potential for fire, explosion, and reactivity;

f) the health hazards, including signs and symptoms of exposure;

g) the primary routes of exposure;

h) the OSHA-mandated PEL or the ACGIH®-recommended TLV®;

i) a statement on whether the chemical is listed as a carcinogen by the National Toxicology Program, the IARC, or OSHA;

j) precautions for safe handling, use, and disposal;

k) generally applicable control measures, including appropriate engineering controls and personal protective equipment;

l) emergency and first-aid procedures;

m) the latest findings in the published literature;

n) the date of preparation of the SDS or date of the most recent revision or update; and

o) the name, address, and telephone number of the manufacturer.

It is important that users of chemical sterilants/high-level disinfectants obtain and understand the contents of the SDS for the product that they are using. An SDS for each hazardous chemical must be maintained on site and be readily accessible, during each work shift, to employees when they are in their work areas. Users should be sure to obtain the latest revision of each SDS, because SDSs are frequently updated.

L.6.4 OSHA area offices, regional offices, state-plan offices, and consultation project state directory

Information on OSHA regulations, federal OSHA area offices, federal OSHA regional offices, OSHA state-plan offices, and the OSHA consultation project state directory can be obtained at http://www.osha.gov.

L.6.5 OSHA standard for occupational exposure to ethylene oxide

OSHA's occupational exposure to ethylene oxide standard (29 CFR 1910.1047) can be found at https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1047.

L.7 State and local regulations

Many states and local communities have safety, health, and community “right-to-know” regulations applicable to the use and disposal of chemical sterilants/high-level disinfectants. By law, such regulations may not be less stringent than the corresponding federal regulations. In some cases, however, state and local requirements are more stringent than those imposed at the federal level. Personnel should know their obligations under state laws and local ordinances.

Annex M
(informative)
Development of a prepurchase evaluation protocol for rigid sterilization container systems

M.1 Introduction

M.1.1

A variety of reusable rigid sterilization container systems have become commercially available. They are being implemented into processing systems in health care facilities for a number of reasons:

a) Reduction of certain types of operating expenses

b) Environmental issues associated with reusable and disposable packaging materials

c) Improvement of sterility assurance and better protection of sterile items afforded by the rigid design of container systems

d) Standardization and organization of surgical instrument sets and equipment

e) Improvement of storage space utilization

f) Reduction of space needed to store wrappers

g) Containment of contaminated instruments

M.1.2

The decision to evaluate the use of reusable rigid sterilization container systems should be followed by the development of a specific protocol or plan by the health care facility. The answers to the following questions will assist in the development of an evaluation protocol:

a) What are the reasons for considering reusable rigid sterilization container systems? Can these reasons be quantified?

b) How much time will be necessary to evaluate each container system?

c) Who will be involved in the evaluation process? Infection prevention and control, operating room, central processing, other user departments, purchasing? (Generally, it will be appropriate to include all departments that would be handling or using the product.)

d) What are the comparative costs of all the packaging methods under consideration (disposable wrapping material, reusable wrapping material, container systems)? How does the current cost–benefit ratio compare with the projected cost–benefit ratio of a new system?

e) If one type of container system currently is in use, what will be the impact of a second type of container system (i.e., one of different manufacture)?

f) What key points will be critical in the evaluation?

g) How many of each type of container system will be needed for the evaluation?

h) What information will be needed from whom to prepare the assessment?

The evaluation protocol should include specific questionnaires concerning product needs or problems in each use and handling area. Additionally, a detailed plan regarding the actual evaluation process in each area of use or handling should be included.

The following text presents a number of questions and statements that personnel can use as guidelines when developing a health care facility's prepurchase evaluation protocol for reusable rigid sterilization container systems.

M.2 General considerations

a) Has the container system been FDA-cleared for use in a sterilization process?

b) Have the scientific data to support label claims (e.g., specific sterilization methods and cycle parameters) been provided by the container system manufacturer?

c) Was the testing performed with biological spore strips or inoculated devices?

d) Does the documentation address sufficiently all performance elements in sterilization (via steam or EO, including aeration), drying, and sterility maintenance?

e) Was the testing representative of the types of items that will be sterilized routinely?

f) Is the container system suitable for use in the sterilization modality?

g) Have complete written IFU been provided? Are they illustrated and easy to follow?

h) Will knowledgeable and qualified assistance (technical support) be readily available during the evaluation process; for employee education; during implementation; and for follow-up, troubleshooting, and problem solving? What is the scope of service after the sale?

i) Are container systems available in appropriate sizes for the items to be sterilized? Is it important that one container system meet everyone's needs? (Be certain that the container systems are acceptable to all users.)

j) What is the estimated or expected life of the container system and its parts? What kinds of warranties, preventive maintenance assistance, replacement parts, and refurbishment services are available from the manufacturer?

k) Is the total system cost-effective for the health care facility?

M.3 Instruments and devices to be containerized

a) Will all surgical instruments and equipment be containerized or only delicate instruments (e.g., microsurgical or plastic instruments) or certain specialty items (e.g., powered instruments, orthopedic instruments, cardiac instruments, neurosurgical instruments)?

b) Will holders, clips, or other retaining or protective devices be needed to customize trays for specialty instruments?

c) Will all the instruments being used in one room be prepared in container systems?

d) Will emergency room, obstetrical, ambulatory surgery, respiratory therapy, or radiology instrumentation be containerized?

e) What is the maximum number of instrument sets arriving from the operating room or other user departments within 30 minutes?

f) Will container systems be used as procedural trays (e.g., for cut-down, lumbar puncture, chest tube insertion, or cardiac catheter procedures)? That is, can the inner container be used as a sterile field?

g) Will instruments be organized into standard sets that travel through the system as complete units with their assigned containers?

M.4 Cleaning and decontamination considerations

a) Can the container system be disassembled easily for cleaning? Will any parts interfere with adequate cleaning?

b) Can the container system, interior baskets, and accessories be processed manually or in a cart washer or washer–decontaminator? Will the design of the container system, baskets, or accessories create a barrier to effective cleaning by any of these methods when the generic recommendations for cycle times are used?

c) Will it be necessary to change the detergents or disinfectants that are used currently in order to avoid harming the container system? Is special handling necessary?

d) Is there adequate workspace in decontamination areas to break down and queue container systems for processing?

e) Will the addition of container systems have an impact on the decontamination workload? Are there sufficient processing equipment, utilization time, and personnel available to accommodate an additional workload using manual or mechanical cleaning or decontamination methods?

f) Is the processing equipment adequate to handle the container systems? Will special holders for container systems be required? Is there adequate equipment cycle time for processing the container systems?

g) Can the container system be used to confine and transport contaminated items?

M.5 Preparation and assembly considerations

a) Is the container system easy to assemble? Are the lid and bottom interchangeable or easily identifiable? Are the top and bottom filter-retaining plates interchangeable or easily identifiable for proper placement? Are parts interchangeable among the various sizes of container systems?

b) Can damage to parts such as gaskets, sealing edges, filter-retention plates, filter-holding rings, valves, and locking mechanisms be recognized easily?

c) Are accessories available to organize and secure instruments in the proper position for sterilization and for the protection of the instruments? Has testing been performed to ensure that these accessories will not impede contact with the sterilant?

d) Is there a maximum weight recommended by the manufacturer, with supporting documentation, for the amount of instrumentation that can be placed into a container system for sterilization and drying or aeration? Does the recommended weight refer only to the instruments or to the combined weight of the instruments and the container system? Does the recommended weight relate to sterilization and drying, personnel safety when lifting, or both?

e) Are there any special instructions regarding the distribution of dense masses of metal when assembling the instrument set in the basket?

f) Can instrument trays or baskets other than those designed for the container system be used if they fit the container system? What is the impact on sterilization and drying?

g) Can specialty instrument organizing or protecting trays be used with the container system if they fit? What is the impact on sterilization and drying?

h) Are there any special recommendations regarding the placement of internal CIs and BIs?

i) Can the container system be easily closed, secured, and labeled?

j) Do the external label and CI meet the requirements established within the health care facility?

M.6 Matching the rigid sterilization container system and sterilization cycle

NOTE See M.2.

a) What sterilization processes are compatible with the container system? Are there any special considerations for each process?

b) Has the compatibility of the container system been tested with BIs in each type of sterilizer in the facility and in each appropriate sterilization cycle?

M.7 Loading the sterilizer

a) Can the container systems be positioned flat on sterilizer loading shelves without touching chamber walls?

b) Does the size of the container system optimize the available shelf space on the sterilizer loading cart?

c) Will the placement allow personnel to use good body mechanics when loading and unloading the container systems from the cart?

d) Are there any special considerations related to dedicated loads, mixed loads, the positioning of container systems on shelves, or other aspects of sterilizer loading? For example, will a mixed load tend to produce wet packs or other drying difficulties?

e) In general, is there a maximum number of container systems per usable sterilizer volume or load? Is there a maximum weight per load?

f) Can the container systems be stacked? If so, in which type of sterilization process? In what configuration ("one over one" or "offset, straddling two")? How many can be stacked? Can two different types of container systems be stacked?

g) Has product testing demonstrated effective sterilization and drying or aeration when container systems are stacked? Were the items used in the testing representative of the items that will be processed in the container system?

M.8 Choosing the appropriate exposure and drying times

NOTE See M.2.

a) Can routine sterilization cycles recommended for wrapped packs by the sterilizer manufacturer be used?

b) Does the container system manufacturer provide a method of testing the efficacy of the sterilizer in which the container systems will be processed?

c) According to the container system manufacturer's studies, is it necessary to extend exposure or drying time to accomplish sterilization and drying? Is documentation available of the testing done to determine appropriate parameters? Has the documentation been reviewed?

d) Does the manufacturer provide a method of determining and verifying the effectiveness of the drying process?

e) Has the compatibility of the container system with the chosen sterilization process and cycle been verified by testing at the health care facility?

M.9 Unloading the sterilizer and cooling the load

a) Are there any special instructions regarding how soon container systems can be touched once the cycle has been completed or the loading cart has been removed from the sterilizer? How should the container systems be handled?

b) What are the manufacturer's recommendations for cool-down? Do the recommendations pertain to personnel safety (i.e., the avoidance of thermal burns from touching metal that is too hot), condensation, or both? Are there recommendations regarding the environment in which a container system should be cooled?

M.10 Sterility maintenance

a) Can the manufacturer produce test data that support the effectiveness of the container system as a microbial barrier? Do the test results demonstrate satisfactorily the container system's ability to prevent contamination during normal handling and storage? Do the test methods used by the manufacturer simulate the environment and activities within the health care facility?

b) What are the potential causes of barrier failure (e.g., slipped filter, failure of the gasket to seal, failure of the locking mechanism, loosened screws or rivets)? Has the manufacturer provided inspection criteria to ensure that the container system is functioning effectively?

c) Is moisture within the container system after sterilization considered a potential source of contamination? Or is the set to be considered sterile? Are data and documentation available to support the claim?

M.11 Sterile storage

a) Are there any special requirements for the storage area?

b) Are special storage systems necessary? Are special carts or racks available for storage of sterilized container systems? Will they minimize handling?

c) Will existing storage shelving and space in all areas of use or handling accommodate the container systems?

d) Will the added weight of the container systems require reinforcement of the existing storage system?

e) Can personnel easily place the container systems into storage units and remove them using good body mechanics and infection prevention and control practices? Can the container systems be stacked? Are there any limitations?

f) Will the container systems fit into case carts?

M.12 Transportation

a) Are there any special recommendations or requirements for handling transportation?

b) Are special transportation carts or other vehicles necessary for on-site or off-site delivery? Would the vehicles differ from those used for packaged items?

M.13 Aseptic presentation

a) Is the container system easy for personnel to handle?

b) Are the container system locks and handles easy to remove or open?

c) Are the labeling and external indicator located in a place that is convenient for the user to check?

d) Can the lid be removed easily without contaminating the contents or the scrub person’s hands?

e) Can the instrument baskets be removed easily without contaminating the contents or the scrub person’s hands?

f) Can filters, retaining mechanisms, and valves be easily identified and inspected for security?

g) If an internal wrap is used, can it be opened easily without contaminating the contents or the scrub person?

Annex N
(informative)
User verification of cleaning processes[10]

N.1 General considerations

Verification of a cleaning process consists of:

a) Defining a cleaning process that can be accomplished with comprehensive personnel training and verified through observation that it can be followed consistently; and

b) Implementing a testing system that verifies adequate, consistent results.

Two principles are involved in verifying a cleaning process. The first consists of establishing, clarifying, and documenting a standard cleaning process that is based on device manufacturers' written IFU and published recommended practices or guidelines. The second concerns measuring and evaluating residual contaminants on medical devices after applying the established cleaning process.

FDA has not reviewed the effectiveness of cleaning verification assays; rather, the manufacturers of cleaning verification assays develop their own methods and criteria for assessing the effectiveness of their products.

The medical device manufacturer must validate that the device can be cleaned and disinfected or sterilized adequately to allow the device to be reused and provide the information in the written instructions for the handling, cleaning, disinfection, packaging, and sterilization of medical devices in a health care facility. (ANSI/AAMI/ISO 17664, AAMI TIR12 and ANSI/AAMI ST98 address the issues related to manufacturers' validation testing for cleaning of medical devices.)

Medical device manufacturers should be familiar with cleaning, disinfection, and sterilization technologies used in health care facilities and with the kinds of soil and microbial contamination encountered as a result of patient use. Users establish an appropriate cleaning policy and procedures for the reusable medical devices they process. The procedures should be based on the validated recommendations of the device manufacturer and the cleaning solution manufacturer, published data on the cleaning efficacy for the medical devices (if available), and published recommended practices or guidelines.

Cleaning efficacy tests are used to verify the ability of a cleaning process to remove or reduce to an acceptable level the clinical soil so that the subsequent disinfection or sterilization process can be effective.

Ideally, cleaning verification should include:

a) visual inspection combined with other verification methods that allow the assessment of both external surfaces and the inner housing and channels of medical devices;

b) testing the cleaning efficacy of equipment and the cleaning process; and

c) monitoring key cleaning parameters (e.g., temperature). Manufacturers provide users with such tests so that medical devices can be tested directly after cleaning in a way that will not damage the device or require recleaning.

A more objective and sensitive method than visual inspection is to measure the levels of organic soil on the cleaned device. There are commercially available tests that allow users to rapidly verify that adequate cleaning has been performed.

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[10] Adapted from ANSI/AAMIST91, Annex F.

A facility's quality assurance program should include ways to verify that the cleaning equipment is working properly and that the cleaning process is effective. Automated cleaning equipment should be tested upon installation, per the manufacturer's written IFU or each day that it is used if frequency is not specified, on all cycles used after repairs, and when changing to a new type of cleaning solution. The automated cleaning efficacy test and equipment manufacturers' written IFU should be followed.

Simple monitoring tools that provide objective, real-time quality control checks can help to verify staff competency and compliance with cleaning guidelines.

Basic components of user verification of cleaning efficacy are:

a) select an appropriate rapid, easy-to-use test that represents a soil marker relevant to the devices used;

b) establish reasonable benchmarks for the level of cleaning that can be achieved; and

c) determine frequency of use based on facility factors (e.g., types and condition of devices, etc.).

N.2 Markers

Cleaning is the removal of organic material (e.g., patient secretions), inorganic material (e.g., salts), and microbial contamination (acquired from the patient procedure, the environment or during handling) to ensure that adequate disinfection or sterilization can be achieved, thereby making the device safe for subsequent use on patients. Published studies that have evaluated the specific markers that can be used to determine cleaning efficacy have indicated that one or more of the following markers are useful for benchmarking purposes:

a) protein;

NOTE 1 Protein detection by chemical reaction interpreted as a visible color change or a quantitative measure of residue (utilizing a color chart [semi-quantitative] or photometric device). Samples may be collected by swabbing, flushing, or direct application of reagent.

b) carbohydrate;

c) hemoglobin (blood); and

NOTE 2 Hemoglobin detection by chemical reaction. Interpreted as a visible color change or a quantitative measure of residues. Samples may be collected by swabbing or flushing.

d) adenosine triphosphate (ATP).

NOTE 3 Detection of ATP by chemical reaction. Measurement of fluorescent light reported as a numeric value. Samples can be collected by swabbing or flushing.

Different cleaning verification methods have benchmarks that have been established and, in some cases, validated by the cleaning indicator manufacturer or through independent studies. Facilities should determine whether the benchmarks pertain to the tests they intend to use based on the endoscope type, component tested, and whether the units or measurements are applicable.

Realistic benchmarks depend on what can be achieved by routine cleaning and the limit of detection of the method used. Data indicate that for flexible endoscopes that have been cleaned after use on patients, the average level of soil markers in the suction/biopsy channel are as follows:

a) protein, <6.4 µg/cm^2;

b) carbohydrate, <1.8 µg/cm^2;

c) hemoglobin, <2.2 µg/cm^2;

d) sodium ion, <1 µmole/cm^2;

e) endotoxin, <2.2 EU/cm^2;

f) bioburden, <4 log_{10} CFU/cm^2;

g) ATP, <22 femtomoles/cm2

(Alfa et al., 2002, 2012, 2013).

NOTE Research has found that reduced protein and bioburden cut offs can be achieved.

N.2.1 ATP

ATP has been validated against other common markers including protein, carbohydrate, and bioburden . (Alfa et al., 2002, 2012, 2013).

The unit of measure for ATP is femtomole (1 X 10^{-15} mole). An ATP monitoring system converts ATP to light, and the amount of femtomoles of ATP present in a sample is detected by a measuring device that can read the amount of light generated by the ATP. The measuring device gives a readout of that light value in Relative Light Units (RLUs), which is directly proportional to the amount of femtomoles of ATP present in the sample. As different systems are available with various measuring devices, a benchmark value of <22 femtomoles of ATP/cm^2, has been correlated to the equivalent values of other markers including the established protein benchmark of 6.4 µg/cm^2 (200 RLU converts to 22 femtomoles/cm^2 for the system cited in Alfa, 2013a; Alfa, 2014; Alfa, 2013b).

For the specific ATP system cited in the literature, 200 RLU was correlated to the equivalent values of other markers. For that system, the ATP values can be converted from 200 RLU to femtomoles/cm^2 by using the conversion factor of 9 RLUs/femtomole of ATP which provides a correlated value of 22 femtomoles of ATP/cm^2 (196 RLUs/cm^2 divided by 9 femtomoles of ATP/RLU). Other ATP systems might have different conversion factors.

NOTE ATP test manufacturers use varying scales. Check with the ATP test manufacturer for the recommended benchmark or the femtomole-to-RLU conversion factor.

N.2.2 Protein

A number of methods for protein detection and quantification have been developed and validated for a variety of purposes, including cleaning verification testing. These include:

a) Pyrogallol Red method (Fujita et al., 1983): This is a color reaction between Pyrogallol Red-molybdate complex and protein. The complex binds to basic amino acid groups of protein molecules. The increase in absorbance is directly proportional to protein concentration in the sample. Results can be read visually for color change (qualitative test) or using a color interpretation chart (semi-quantitative test), or with a spectrophotometer for quantitative results.

b) Bromophenol Blue method (Flores et al., 1978): Protein is detected using the pH indicator Bromophenol blue. At a low pH Bromophenol blue is yellow in the absence of protein. Presence of a protein slightly increases the pH of the solution. This increased pH causes Bromophenol blue to change its color from yellow to greenish blue. This color change can be read visually for color change (qualitative test), compared to a color chart (semi-quantitative) or with a spectrophotometer for quantitative results.

N.2.3 Hemoglobin

Peroxidase test method (Geissler et al., 1977; Liem et al., 1979): Relies on the peroxidase-like activity of hemoglobin in blood to catalyze the oxidation of some compounds in the presence of hydrogen peroxide to yield colored substances, which are easily detected. This reaction can show blood residues by a color change to blue. This color change can be read visually for color change (qualitative test), compared to a color chart (semi-quantitative) or with a spectrophotometer for quantitative results.

N.2.4 Carbohydrates

Glucose oxidase test method (Jakobsen, 1960): Specifically tests for glucose. This test is based on a sequential enzyme reaction. Glucose oxidase converts the glucose to gluconic acid and hydrogen peroxide. A second enzyme, peroxidase, catalyses the reaction of peroxides to produce a positive color change. This color change can be read visually (qualitative test), compared to a color chart (semi-quantitative) or with a spectrophotometer for quantitative results.

N.3 Cleaning verification tests for users

There are a number of commercially available validated test methods for rapid detection of organic residues on flexible endoscopes.

Ideally, cleaning tests for in-use verification of medical device processing should be:

a) rapid;

b) easy to perform;

c) sensitive (i.e., meet realistic benchmarks);

d) accurate;

e) repeatable;

f) free of interfering substances; and

g) robust (i.e., do not require exacting conditions or time constraints that cannot be achieved in routine processing areas).

To be of most utility to users, cleaning verification tests should enable users to quickly test medical devices directly after cleaning and in a way that will not damage the device or require recleaning. Moreover, easy-to-perform tests are also needed to verify the functionality of automated washers. Such tests should not lead to the introduction of interfering or extraneous materials that could remain on medical devices post-testing.

For verification of routine cleaning processes, users should incorporate test methods that verify the functionality of the mechanical cleaning equipment (if used) and the cleanliness of specific devices after manual or mechanical cleaning is completed. These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks once these benchmarks have been defined**.**

N.3.1 Verification tests for ultrasonic cleaners

a) **Test for cavitation in ultrasonic bath:** Indication can be physical measurement or visual assessment.

b) **Test for soil removal (external) in ultrasonic bath:** Indication is visual assessment or absence of marker on a coupon placed in the ultrasonic bath.

c) **Test for soil removal (internal within lumens) in ultrasonic bath:** Indication is visual assessment or absence of marker on a coupon placed in the ultrasonic bath.

N.3.2 Verification test for mechanical washers

a) **Test for soil removal:** Indication is visual assessment or absence of marker on a coupon placed in the washer.

N.4 A program for verification of the efficacy of the manual cleaning during endoscope processing: An example

The purpose of verifying manual cleaning efficacy is to ensure that the manual cleaning step performed during endoscope processing is consistently performed correctly according to established thresholds. Implementation of a cleaning verification program should be part of a complete endoscope processing quality control program.

A manual cleaning verification program has two goals.

1) **Quality control.** Is each endoscope effectively cleaned before HLD or sterilization? In this case, the efficacy of the manual cleaning process is verified for every endoscope after every use.

2) **Process control.** Is the manual cleaning process under control? This approach verifies the efficacy of manual cleaning for a percentage of endoscopes over a specified number of processing cycles to assess if the manual cleaning process is under control. This approach can highlight undesirable variability in the efficacy of the manual cleaning process. Verification data can be used to assess if changes or improvements in processing procedures are working as intended (e.g., reducing variability in the number and frequency of manual cleaning failures).

A comprehensive manual cleaning verification program is not a substitute for other quality control measures (e.g., culturing of endoscopes after processing by high-level disinfection or sterilization).

A complete cleaning verification program contains the following components:

1) Establish policies and procedures

Policies and procedures for a manual cleaning verification program should include the following:

a) Designation of a person or department responsible for defining, establishing, and implementing a routine manual cleaning verification program.

b) Designation of a person or department responsible for ensuring that all personnel implementing the cleaning verification program are adequately trained and that, at a minimum, annual competency verifications are performed.

c) A method for verification data capture and storage.

d) A process for routine review and analysis of verification data.

e) A process for addressing cleaning verification failures.

2) Identify which endoscope types will be routinely monitored

a) Identify high-risk endoscopes. Additional endoscope types may be added to the high-risk category depending on individual facility manual cleaning performance. Evidence of endoscope-associated infections due to cross-contamination or outbreak situations could result in the temporary addition of any endoscope type to the high-risk category.

b) Identify those endoscopes that are not high-risk.

c) Ideally, all endoscope types should be included in a cleaning verification program.

3) Determine test points for each type of endoscope

Test points should include at a minimum:

a) suction/biopsy (working) channel;

b) elevator mechanism if present;

c) elevator channel if present.

Consider periodic assessment of irrigation accessories, the external distal tip of the endoscope, the control handle, valve housings, the biopsy port, and reusable valves (buttons).

4) Determine pass/fail thresholds

a) Pass/fail thresholds should be pre-determined before verification testing begins.

b) Pass/fail thresholds vary depending on the cleaning verification technologies used. The manufacturer's written recommendations for pass/fail thresholds should be followed.

c) Pass/fail thresholds should be established related to the area of the endoscope sampled and should be validated for use with endoscopes.

d) Health care facilities may establish pass/fail thresholds for their unique facilities. These thresholds should be based on solid statistical methodology.

5) Frequency of testing

Cleaning verification should take place after manual cleaning and before high-level disinfection or sterilization. The frequency of verification testing depends on the type of endoscope:

a) High-risk endoscopes should be monitored after every use.

b) Those endoscopes that are determined NOT to be high-risk shall be verified:

— when new endoscopes are purchased;

— when loaned endoscopes are received for temporary use; and

— at established intervals (e.g., after each use, daily) or, at a minimum, at a statistically significant frequency based on the number of procedures.

Endoscopes should be randomly selected for verification testing to avoid repeated testing of the same endoscopes.

The frequency of testing should be increased if tests done as process controls identify cleaning failures for a substantial proportion of endoscopes. If the process is not under good control, then the tests should be done every time for quality control until cleaning consistently succeeds at removing soil.

6) Data analysis

Verification data should be reviewed on a regular basis so that adverse issues can be addressed in a timely manner. Examples of how cleaning verification data can be used include the following:

a) verification that education and training of personnel responsible for manual cleaning of endoscopes is effective;

b) verification of processing technician competency in manual cleaning procedures. Managers should review verification data for each processing technician at least quarterly;

c) identification of ongoing systematic errors in the manual cleaning process;

d) identification of aging or damaged endoscopes that are difficult to clean;

e) identification of other factors that may be contributing to problems with cleaning effectiveness, such as sitting used during lengthy procedures, substantial bleeding or secretions, a lack of adequate point-of-care treatment, necrosectomy, or delayed reprocessing;

f) verification that an endoscope has met a pre-determined threshold for cleanliness and is ready for high-level disinfection or sterilization (quality control);

g) verification that the manual cleaning process is under control (process control);

h) assessment of whether changes or improvements made to manual cleaning procedures are effective in reducing variability in the number and frequency of cleaning failures. Manual cleaning verification data cannot be used to verify that an endoscope has been adequately high-level disinfected or sterilized and is safe for use on a patient.

Annex O
(informative)
Example of documentation of premature release of implants

This Annex provides an Implantable Devices Load Record and an Exception Form for Premature Release of Implantable Device/Tray.

Date	Description of implants	Dept.	Time sterilized (specify AM/PM)	Sterilizer #	Load #	Date/time BI in incubator	Date/time and BI result	Early release?	Date/time released to OR	Released by (full name)

Figure O.1—Implantable devices load record

Exception Form for Premature Release of Implantable Device/Tray

NOTE In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form should accompany the implant to the Operating Room. OR personnel should complete this form and return it to Central Service within 24 hours.

PLEASE COMPLETE ALL INFORMATION:
DATE: _____ SHIFT: _____ TIME: _____ AM PM

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: _____

The following implantable devices/trays were prematurely released to the Operating Room:

_____
_____
_____

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES:

_____

OPERATING ROOM REPORT:

PATIENT NAME: _____

SURGEON NAME: _____

TIME OF PROCEDURE: _____ AM PM DATE: _____

REASON PREMATURE RELEASE WAS NEEDED: _____

_____

_____

_____

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS (THESE) DEVICE? TRAY? _____

_____

_____

_____

NAME OF OR PERSON COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____ FORM RETURNED TO CENTRAL SERVICE ON: _____

Figure O.2—Exception form for premature release of implantable device/tray

Annex P
(informative)
Gas and vapor monitoring

P.1 General considerations

To ensure a safe work environment and to establish compliance with regulatory limits and voluntary guidelines on occupational exposure to the gases and vapors of chemical sterilants/high-level disinfectants, several air sampling and monitoring techniques are currently in use. Information is available on the relative effectiveness of some of the methods and programs available for vapor monitoring in the health care facility work environment. The information contained in this section should be used as a guideline. Monitoring technology continues to evolve, and it is incumbent on personnel to keep abreast of the latest developments.

Many chemical and gaseous sterilants have different toxicological profiles than other gases currently monitored in health care facilities, such as EO and gluteraldehyde. Oxidizing chemistries like peracetic acid, hydrogen peroxide (gas or liquid), or hypochlorite do not have the same long-term toxicological concerns from the germicide or their breakdown products (unlike EO). The toxicological profile of the chemical to be monitored and its potential for long-term effects should be considered when evaluating whether monitoring is to be conducted or how often.

Chemical and gaseous sterilants are specially formulated to be used only within a certain processor, or under specified use conditions. The manufacturer of the chemical or gaseous sterilant should be consulted as to its safe and effective use. Manufacturers ensure the safety of their products through extensive testing and are the best source of information for the safety of their products.

OSHA has established PELs for many compounds. Even if the health care facilities are not specifically required by law to monitor the vapor concentration, OSHA can enforce PELs by means of its General Duty Clause, which is designed to ensure that each employer provides a workplace for employees that is free from recognized hazards that are causing or likely to cause death or serious physical harm to employees. OSHA will typically use commonly accepted standards, such as ACGIH® TLV® exposure limits to determine whether the exposures are deemed harmful levels. Monitoring may be used to demonstrate compliance with the accepted exposure standard.

NOTE 1 A vapor is a gaseous form of a compound that is a liquid at ambient temperature and pressure (i.e., its boiling point is above room temperature), whereas a gas is a compound whose boiling point is below room temperature. In this annex, the terms gas and vapor are used interchangeably.

NOTE 2 In this annex, the term "chemical" refers to chemicals used for sterilization or high-level disinfection.

NOTE 3 The term "monitor" has several meanings in common usage and refers more to the intent to provide ongoing exposure measurements rather than a single gas concentration measurement (sampling). The term monitor therefore includes methods such as exposure badges and diffusion tubes as well as continuous monitors. Most of these technologies provide one data point for the gas concentration collected over a sampling period (e.g., 8 hours) and often that result is only known after a subsequent laboratory analysis. The term "continuous monitor" refers to a medical device that measures the gas concentration in real time and provides the gas concentration continuously over time.

P.2 Instrumentation

P.2.1 Monitoring methods

In recent years, continuous personal and area monitors have become available for many vapors. Some traditional vapor monitoring methods should be performed or supervised by a technically qualified person trained in air-sampling strategies and monitoring techniques. Other monitoring methods are less complex and can be used reliably by personnel to monitor the workplace. The monitoring method chosen will depend on the type of chemical, the mode and frequency of use, and the evaluated risk of exposure. Another consideration is how monitoring data should be interpreted to assess worker safety. Because of these complexities, personnel may wish to seek the advice of an industrial hygienist or other qualified professional when designing a monitoring program.

Some continuous monitors may not be chemical specific and may respond to other chemicals present in the air, including perfumes and other personal scents. These continuous monitors may provide advantages over older methods in that they can offer ease of use, continuous and real-time measurements, and often automatic record-keeping.

Rationale: Health care facilities vary in financial and technical resources and in the volume of chemical high-level disinfection and sterilization processing performed. Some vapor-monitoring techniques involve considerable time, effort, cost, and data analysis. While the relationship between the costs and benefits of sampling should be carefully considered, the result must be a safe and healthful workplace for personnel.

Below is a list of common technologies for detecting the gases and vapors from high-level disinfectant and sterilization chemicals in the concentration range relevant to workplace safety monitoring. The chemical literature is full of novel sensors and detection methods, but the table below only includes those methods that are commercially available. This list is not exhaustive and other methods for detecting many of these compounds exist; inclusion in or exclusion from this list is not intended to be an endorsement or rejection of any particular method.

Table P.1—Technologies for the detection of gases and vapors of high-level disinfection and sterilization chemicals

Compound	Technology of continuous monitors available	Badges and other sampling methods available	OSHA and NIOSH analytical methods
Ethylene Oxide	Electrochemical sensors, GC	Diffusion badge monitors are available using chemistry similar to OSHA 1010.	OSHA 1010[11] and NIOSH 1614[12] Collect on HBr/charcoal tubes, desorbed with water/CH_3CN/toluene or DMF respectively, analysis by GC.
Formaldehyde	Electrochemical Sensors, GC	Available based on NIOSH 2016 OSHA ID 205[13] – Passive badge monitor containing bisulfite-impregnated paper. Sample filters are extracted with water, acidified, chromotropic acid is added, and analyzed by UV	NIOSH 2016[14] – Collected on silica gel coated with 2,4-dinitrophenylhydrazine, extracted with CH_3CN and analyzed by HPLC OSHA Method 52[15] – Air samples are collected with XAD-2 adsorbent, coated with 2-(hydroxymethyl)piperidine, desorbed with toluene and then analyzed by GC
Glutaraldehyde	Electrochemical	Available based on OSHA 64.	OSHA 64[16] – Sample collected on glass fiber filters, coated with 2,4-dinitrophenylhydrazine and phosphoric acid, extracted with acetonitrile and analyzed by HPLC

11 OSHA Method 1010 for ethylene oxide, https://www.osha.gov/sites/default/files/methods/osha-1010.pdf, retrieved 5/15/24.

12 NIOSH Method 1614 for ethylene oxide, https://www.cdc.gov/niosh/docs/2003-154/pdfs/1614.pdf, retrieved 5/15/24.

13 OSHA Method ID 205 for formaldehyde, http://www.osha.gov/dts/sltc/methods/inorganic/id205/id205.html, retrieved 6/11/12.

14 NIOSH Method 2016 for formaldehyde, http://www.cdc.gov/niosh/docs/2003-154/pdfs/2016.pdf, retrieved 6/11/12.

15 OSHA Method 52 for formaldehyde http://www.osha.gov/dts/sltc/methods/organic/org052/org052.html, retrieved 6/11/12.

16 OSHA Method 64 for glutaraldehyde, http://www.osha.gov/dts/sltc/methods/organic/org064/org064.html, retrieved 6/11/12.

Compound	Technology of continuous monitors available	Badges and other sampling methods available	OSHA and NIOSH analytical methods
Hydrogen peroxide	Electrochemical sensors	Available based on OSHA VI-6	OSHA VI-6[17] TiOSO4 reaction forming peroxide complex analyzed photometrically OSHA ID-126-SG,[18] similar to VI-6 but analysis by differential pulse polarography
o-phthalaldehyde	N/A	Available based on chemically activated adsorbent to form a derivative of o-phthalaldehyde	
Ozone	Electrochemical sensors	Available	OSHA ID-214[19] – Ozone collected with nitrite-impregnated glass fiber filters, extracted with water and analyzed by ion chromatography
Peracetic acid	Electrochemical sensors	N/A	
Sodium hypochlorite (as chlorine)	Electrochemical sensors	Available	NIOSH 6011[20] – Collect on silver membrane, extract with sodium thiosulfate and analyze by ion chromatography

P.2.2 Reliability and use of instrumentation

The manufacturer's written IFU provided by the vapor-monitoring equipment and sampling apparatus manufacturers should be followed. Data on the accuracy, reproducibility, and reliability of the instrumentation are also necessary. In particular, monitoring instrumentation and methods should be proven capable of accurately and reproducibly determining vapor concentrations in the range of (and below) the exposure limit. When considering the use of any equipment to monitor chemical vapors, the user should be aware that components and other characteristics of workplace air (e.g., inert diluents, water vapor, perfumes, solvent vapor, and temperature variations) may interfere with some instruments' ability to accurately measure the chemical vapor concentration; the health care facility should inform the supplier of the monitoring equipment or the service provider of other gases and vapors in the environment.

Rationale: The manufacturer is the best source of information on the performance characteristics of monitoring equipment, and the manufacturer's written IFU should be followed to ensure proper operation of the equipment and accurate results.

P.3 Procedures

P.3.1 Monitoring sites

If electing to perform monitoring, the monitoring should be conducted in all work areas where workers might be exposed to chemical vapor. The area in which chemicals are used should be monitored or the breathing zone of each employee

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17 OSHA Method VI-6 for hydrogen peroxide; http://www.osha.gov/dts/sltc/methods/inorganic/id006/hydrogen_peroxide.html, retrieved 6/11/12.

18 OSHA Method ID-214 for hydrogen peroxide, http://www.osha.gov/dts/sltc/methods/partial/t-id126sg-pv-01-0201-m/t-id126sg-pv-01-0201-m.html, retrieved 6/11/2012.

19 OSHA Method ID-214 for ozone, http://www.osha.gov/dts/sltc/methods/inorganic/id214/id214.html, retrieved 6/11/2012.

20 NIOSH method 6011, http://www.cdc.gov/niosh/docs/2003-154/pdfs/6011.pdf, retrieved 6/11/2012.

directly involved with any disinfection or sterilization process. Monitoring should be conducted during normal processing activities.

Rationale: Monitoring should yield a meaningful description of the vapor concentration in the workplace and, hence, the potential for occupational exposure exceeding the OSHA PELs or other recognized exposure limits

P.3.2 Frequency of monitoring

Baseline monitoring should be performed after initiating use of disinfection or sterilization processes or establishing a vapor-monitoring program. If a monitoring program is established, it is recommended that monitoring be conducted whenever there is a major change in protocol, workplace ventilation systems, or case load; after major repairs to an automated endoscope reprocessor or other automated equipment; and after changes in work practices. The frequency of routine monitoring depends on the amount of chemical used by the health care facility, on the frequency of chemical sterilization processing, on other facility-specific factors, and on the recommendations of an industrial hygienist.

Rationale: Regular monitoring will help ensure that ambient vapor concentrations are below the OSHA PEL or other recognized exposure limits and will help detect ventilation system inadequacies or other issues, such as poor work practices, that may result in employee exposure.

P.3.3 Time-weighted average and ceiling exposures

Personnel (e.g., safety manager/hygienist) responsible for workplace monitoring should determine the workplace vapor concentration during all parts of the working exposure period. If the OSHA PEL is a ceiling limit, then the vapor concentration must not exceed this value. If the OSHA PEL is a time-weighted average, then the concentration, calculated as a time-weighted average, must never exceed the PEL. The time-weighted average exposures are usually calculated for 15 minutes or 8 hours.

If there is no OSHA PEL, then health care facilities should use the ACGIH® TLV® limits or limits from other recognized authorities, such as the EPA Acute Exposure Guidelines. While the OSHA PELs are legal requirements, the ACGIH® TLV®, EPA AEGLs, etc., represent the customary standard of care and failure to meet these standards can be used by OSHA as evidence that the workplace is hazardous.

Special attention should be given to short periods of time when airborne concentrations of vapor might be particularly high (e.g., when the worker is pouring a spent solution down the drain or pouring fresh solution into the container or reservoir). For accurate assessment of a ceiling limit, exposure monitoring should be conducted for the shortest sampling time possible. OSHA states that "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). A 15-minute TWA sampling technique will usually understate exposure levels as they relate to a ceiling limit.

Rationale: Health care facilities should understand the nature and risk for chemical exposure to determine the monitoring program needed for a safe and healthful workplace.

P.3.4 Record-keeping

If performed, employee breathing zone (EBZ) monitoring should be documented, and records maintained in the department files or another designated location. If recorded manually, this documentation should include the name and qualifications of the person or organization that conducted the monitoring, the date the survey was made, a description of the task conducted, the sampling or analytical method used, the test protocol and instrumentation, the workplace ventilation system characteristics at the time of sampling, the results (locations and measured vapor concentrations), any PPE worn, and any recommendations for corrective actions. Many continuous area and personal gas monitors provide data logging capability and automatic record-keeping and reporting functions. If EBZ monitoring shows that vapor concentrations exceed the recognized exposure limit, corrective actions should be taken. It is recommended that the results of workplace monitoring be posted in an area that is readily accessible to employees.

Rationale: Good record-keeping enables the health care facility to establish a continuous history of the work environment. OSHA record-keeping requirements apply if monitoring is conducted (29 CFR 1910.1020). When vapor-monitoring results are posted, workers will know that potentially hazardous concentrations of vapors might exist in the

workplace, and the importance of good work practices will be reinforced. The importance of good work practices is also validated when vapor-monitoring results verify that vapor concentrations are below the recommended OSHA PEL or other recognized exposure limits.

P.4 Selecting vapor-monitoring equipment or services

P.4.1 General considerations

This section was developed to assist the appropriate, designated personnel in the selection of equipment or services to measure vapor concentrations in the workplace and in the assessment of worker exposure to chemical vapors. This section is intended to

a) assist users in understanding the conceptual approaches that can be used to monitor vapor concentrations or worker exposure to chemical vapors;

b) describe some of the chemical vapor exposure monitoring equipment and services currently available; and

c) summarize certain advantages and disadvantages of the available equipment and services.

Most experts would agree that an ideal vapor monitor would meet the following specifications:

a) It would accurately measure vapor in the range of 0.1 to 10 times the OSHA PEL or other recognized exposure limit. (For instance, for hydrogen peroxide vapor, the OSHA PEL is 1 ppm (8 hr TWA), then this range would be 0.1 to 10 ppm.)

b) It would be reliable.

c) It would be inexpensive.

d) It would be easy to use, requiring minimal technical ability on the part of the operator.

e) It would give a continuous and instantaneous reading.

f) It would be specific to the target chemical vapor, so there would be no cross-sensitivities to other gases or vapors in the environment.

g) It would automatically log the data so that the health care facility has records of exposure.

h) It would not require daily calibration.

For some chemical vapors, continuous monitors are available that meet essentially all the above requirements, but for other chemicals, fewer of the requirements are met. However, even for those vapors for which the ideal monitor is not available, its lack cannot be used as an excuse to avoid monitoring exposure levels. All managers of locations where chemicals are used have clearly defined responsibilities to monitor and minimize worker exposure to chemical vapors.

Before selecting a particular chemical vapor-monitoring product or service, personnel should analyze the specific needs and resources of their institution and consult appropriate experts in chemical monitoring, industrial hygiene, and regulatory requirements.

P.4.2 Personal and area monitoring

Chemical vapor monitoring falls into two main areas: personal monitoring and area monitoring. Both of these methods are widely used. Personal monitoring provides a measure of what an individual is exposed to, and so the result is directly related to the OSHA PELs. Area monitoring, as the name suggests, monitors an area and warns if the vapor concentration exceeds safe limits whether anyone is there or not. Area monitoring is applicable where the vapor source is a single or a few specific locations, which is normally the case in health care, and has the advantage that it is relatively unobtrusive. By placing the monitors near the sources, if the vapor concentrations in the area are shown to be low, then anyone working in the area should be safe. If the vapor concentration is too high, then remedial action can be taken without exposure to workers. Personal monitoring can be used both for localized vapor sources and more diffuse

sources but it requires a representative number of employees in all jobs with potential exposure to the chemical of concern to be monitored.

P.4.3 Personal monitoring

Personal monitoring is performed to determine the concentration of airborne contaminants in the EBZ; this measured concentration is assumed to be the amount actually inhaled by personnel. Personal monitoring devices are generally worn by the worker for a certain length of time; the vapor concentration in the EBZ is measured during the time the monitor is worn, and the results are expressed as a TWA concentration.

For chemicals with a ceiling exposure limit or a short-term exposure limit, the sampling time period should be as short as technically feasible, with a maximum sampling time of 15 minutes (29 CFR 1910.1000). To measure a ceiling limit reliably, a continuous monitor with a real-time display is needed; however, for those vapors where continuous monitors are not available, use of lab-analyzed sample methods can be applied to tasks where peak exposures are anticipated. A ceiling value is an exposure limit that must not be exceeded, even for a brief period of time, at any time during the work shift. A 15-minute TWA measurement will usually understate exposure levels as they relate to a ceiling limit and if taking spot measurements, there is the obvious risk of missing a short term exposure over the ceiling limit. Consequently, a measured 15-minute TWA concentration below the ceiling limit is not a guarantee that workers have not been overexposed at some time during the same period. Shorter sampling times might allow detection of brief, transient overexposures.

Electronic personal monitors are available for most of the chemicals used in sterilization and high-level disinfection and provide a continuous, real-time measurement of vapor concentration. They also provide instantaneous alarms if the alarm threshold concentration is exceeded, allowing remedial action to be taken immediately. These continuous monitors have significant advantages over older devices and methods in which the air concentration results cannot be acquired until sometime after the sampling period. With the older devices and methods, if a worker is exposed to a high concentration of chemical vapor (e.g., because of a failure in the ventilation system or poor work practices), the worker has no way of knowing about the exposure until the results are received from the monitor analyst. In some cases, the results might not be available until several days or weeks after the sampling period. For this reason, continuous monitors (area or personal) provide real-time measurement of chemical exposure levels when used according to the manufacturer's written IFU and are not affected by cross-sensitivity to other chemicals present in the workplace.

NOTE When considering a particular monitoring device, personnel should refer to the specified detection limit and range of the badge or instrument. Personnel exposures can be validated only within the detection limit and range of the monitoring method chosen.

P.4.4 Area monitoring

Area monitoring is performed to determine the general (i.e., environmental) concentration of airborne contaminants in a prescribed space or area. There could be personnel in the area monitored, and the measured concentration of airborne contaminant might not be the concentration of contaminant actually inhaled by personnel if they are present. In addition, if traditional sample-and-analyze monitors are used, vapor levels measured under static exposure conditions (when solutions are not being agitated) may be lower than under actual use conditions.

Most continuous area monitors are electronic devices or electronically controlled devices that measure, more or less instantaneously, the target vapor present at the sampling point of the device. Some active or passive sampling devices also can be used as area monitors. For example, if engineering controls (such as new ventilation equipment) have just been installed in an area where chemical vapor had been escaping into the workplace, personal monitoring devices can be used to measure ambient vapor concentrations in the area while employees are not present. The monitor should be placed near an open tray or AER or other automated equipment to represent actual use conditions more closely.

NOTE When considering a particular monitoring device, personnel should refer to the specified detection limit and range of the badge or instrument. Personnel exposures can be validated only to the detection limit and range of the monitoring method chosen.

P.4.5 Devices available for gas or vapor monitoring

P.4.5.1 Characteristics and ratings of air monitoring devices

Several types of devices are available for use in monitoring air concentrations of chemical vapors. For each type of device, the following characteristics should be considered:

a) **Principle of operation.** The manner in which the equipment detects or indicates the vapor concentration is briefly described.

b) **Portability.** A brief statement indicates whether the equipment can be routinely moved about the workplace.

c) **Ease of operation.** The ease with which the equipment can be used is characterized in two categories: —"preparation and use" and "data collection." "Preparation and use" describes the complexities involved in preparing the equipment for use (e.g., calibration, special training requirements, sampler conditioning) and in actually using it. "Data collection" describes the complexities involved in determining the test results (ppmv vapor).

In these two categories, each type of equipment can be rated as "simple," "moderate," or "difficult." *Simple:* The instructions provided by the equipment supplier are generally adequate for any user. *Moderate:* One or more aspects of the equipment require that the user receive in-service or other special training. *Difficult:* One or more aspects of the equipment require the skills of an individual with special expertise, such as a technician or industrial hygienist, who has been trained or has the qualifications to be trained in the proper use of the equipment.

For example, some passive sampling devices (PSDs) require little or no preparation to use, and their actual use involves nothing more than clipping the device in place. Determining the results of such monitoring, however, sometimes requires relatively complex extraction and analysis techniques. Hence, this type of device would be rated "simple" in the category of "preparation and use" and "difficult" in the category of "data collection."

d) **Accuracy and precision.** Accuracy is the difference between the measured concentration of the vapor and the true vapor concentration. Precision is the repeatability of measurements under unchanged conditions. Both are likely to vary among device types within a given generic category of measuring devices. Users should obtain information from the manufacturer regarding the accuracy and precision of the monitor in the range of concentration intended to be measured.

e) **Specificity.** Some equipment will measure the presence of air components other than the target vapor (i.e., it is not specific to that vapor). This criterion addresses the impact of unrelated air components on the measuring device.

f) **Lower detectable limit.** The lower detectable limit is the lowest measurable concentration of the target vapor claimed by the equipment manufacturer. The user should require the supplier to provide supportive documentation of claims regarding detection limits.

P.4.5.2 Diffusion and sample-draw continuous monitors

a) **Principle of operation.** There are two main types of continuous monitors, diffusion and sample draw. In a diffusion system, the sensor is placed into the environment to be sampled, so there are separate detector points at each location to be sampled.

For portable continuous monitors, each monitor may contain sensors for one or more vapors in a device that is small enough to be worn. The monitor will usually include a display showing the real-time vapor concentration and audible and visual alarms if the concentration exceeds alarm thresholds. Many models include data logging, allowing the exposure data to be downloaded to a computer at a later time.

Area monitors also usually include a display to continuously show the vapor concentration at that location and also include audible and visible alarms, but the detector points may be wired back to a central computer or other controller for automatic data logging and further data analysis.

Sample draw monitors include a pump that draws an air sample in and blows it past the sensor or detector. The sample draw system allows a central unit to sample from various locations via the sample tubes. The central unit will include alarm functions and data logging. Some multipoint sample draw systems do provide continuous monitoring, by having each sample line deliver to its own sensor. Others, such as multipoint gas

chromatographs, use a single detector, that sequentially draws from each sample line and thus there is a lag time between readings as the monitor goes through its sampling cycle.

b) **Portability.** Portable continuous monitors are portable, often wearable; fixed monitors are wall-mounted.

c) **Ease of operation.** In terms of preparation and use, ease of operation is simple to moderate depending on the design of the continuous monitor. Some monitors require manual calibration with compressed gases, whereas for other monitors the manufacturers either provide a calibration service or automatic calibration. In terms of data collection, operation is simple.

d) **Accuracy.** Users should obtain information from the manufacturer regarding the accuracy of the monitor in the range of concentration intended to be measured.

e) **Specificity.** The specificity varies greatly with the type of vapor being detected and the model of continuous monitored used. Refer to the manufacturer's written IFU.

f) **Lower detectable limit.** Refer to the manufacturer's written IFU.

P.4.5.3 Active sampling devices

a) **Principle of operation.** In this technique, a small, portable, battery-powered suction pump (usually clipped to the worker's belt) is connected by means of plastic tubing to a glass tube or filter containing an adsorbent or reactive material. The pump draws a known volume of air through the glass tube or filter, and the contaminants are adsorbed onto the surface of the material or chemically derivatized (i.e., converted to another stable chemical) by a reactive chemical on the filter. By means of the glass tube or filter clipped to the lapel of the worker's shirt, EBZ samples can be collected.

   At the end of the sampling period, the tubes or filters are sealed and sent to a laboratory for analysis. At the laboratory, the adsorbent or reactive material is removed from the glass tubes or filters and treated with a solvent that desorbs the absorbed or derivatized chemical(s). The solvent extract is then analyzed to determine the overall amount of target chemical adsorbed or chemically derivatized during the sampling period. Knowing the duration of the sampling period, the volume of air drawn through the tube or filter, and the amount of vapor adsorbed or derivitized enables one to calculate an 8-hour TWA or 15-minute TWA exposure.

   The desorption process and analytical technique are moderately complex and should be attempted only by laboratories with experienced analytical chemists or technicians. Sample tubes or filters collected for analysis by a service laboratory might require special shipping procedures. The service laboratory should be consulted for proper packaging and shipping procedures.

b) **Portability.** Completely portable.

c) **Ease of operation.** In terms of preparation and use, ease of operation is simple to moderate. In terms of data collection, operation is difficult.

d) **Accuracy** varies, depending mainly on the ability of the analyst and the accuracy of calibration.

e) **Other comments.** Portable pumps should have a feature that allows the user to detect whether the pump stopped functioning during the collection of the samples (as might occur, for instance, if the battery fails). Pumps should be calibrated before and after each use. (As batteries run down, airflow rate can change.) The pump supplier should be asked about the expected life of the pump and batteries; they all contain parts that eventually will wear out.

   Blank and control samples also should be collected. The analytical laboratory should be consulted about the proper techniques for blank and control sampling.

P.4.5.4 Passive sampling devices

a) **Principle of operation.** Like active sampling devices, PSDs are clipped to the worker's lapel. Passive sampling devices rely on the natural diffusion of vapor into a sorbent of reactant material and, hence, do not

require the use of a pump. These devices are normally worn throughout a full day or during short periods when the excursion level can be detected.

After the sampling has been completed, the PSD is either sealed and sent to a laboratory for analysis or, depending on the type of PSD, processed and read on-site.

Blank and control samples should also be collected. The PSD manufacturer or the analytical laboratory should be consulted about the proper techniques for blank and control sampling.

b) **Portability.** Completely portable.

c) **Ease of operation.** In terms of preparation and use, operation is simple. In terms of data collection, ease of operation is moderate to difficult.

d) **Accuracy.** Accuracy varies; refer to the manufacturer's written IFU.

e) **Specificity.** Refer to the manufacturer's written IFU.

f) **Lower detectable limit.** The manufacturer should state the lower detectable limit.

g) **Other comments.** PSDs are generally easier to use and lighter than active sampling devices because no pump is needed. However, PSDs are typically less precise thanactive sampling devices because of the better control of airflow with active sampling devices. Refer to the PSD manufacturer's instructions, and verify that the air flows in the area being monitored are within the maximum and minimum air flows for the specific PSD.

Passive sampling devices could be suitable for area monitoring if the minimum airflow across the face of the PSD is attained as specified by the PSD manufacturer.

Some users have found considerable variability among types of PSDs.

P.4.5.5 Questions that should be asked of monitoring device manufacturers

The prospective user should ask the manufacturer the following questions before purchasing a monitoring device:

a) What gases or contaminants will interfere with the performance of the device?

b) Does the device require calibration? How is the calibration performed?

NOTE 1—If a gas reference sample is required, the user should request a written statement from the gas supplier regarding the stability and availability of the gas mixture as well as any special handling instructions.

c) Is any special training required to use the device? If so, does the manufacturer provide this training?

d) What is the range of the monitor, i.e., the highest and lowest concentration of vapor that can be measured accurately by the device? What is its accuracy and repeatability?

e) What is the sensor or detection technology (e.g., electrochemical, infrared)? If the method involves sending a sample for laboratory analysis, what method is used to analyze samples (e.g., gas chromatography, high-performance liquid chromatography)?

f) Are the vapor concentrations available instantaneously and continuously or, if not, then how long does it take to receive the results of the sampling?

g) Is preventive maintenance of the device required? If so, who will perform the maintenance? Will it be necessary to return the device to the factory, or is field service available?

h) Are there any special handling, shipping, or storage requirements for the sampling device?

i) For active and passive sampling devices, does the manufacturer provide laboratory services for analysis? If not, who does the manufacturer recommend?

j) Are accessory devices available for use with the device (designed so it cannot provide a source of ignition, even upon failure, and so can be used in potentially flammable atmospheres) or explosion proof?

NOTE 2—An intrinsically safe product should have been tested and certified by an independent laboratory to the recognized standard (such as UL 60079-0 and UL 60079-11).

NOTE 3—If only intrinsically safe or explosion-proof equipment is permitted in a classified area of the facility, the manufacturer shall certify that the equipment meets this requirement.

k) Is there a single point of failure, or is there redundancy designed into the system?

l) Are other area health care facilities or organizations using this device? If so, which ones?

NOTE 4—The user might wish to contact the health care facilities or companies and ask them if they are satisfied with the device.

m) Are other monitoring services offered, such as a tracking system to provide at least an annual recapitulation of the results of periodic monitoring?

P.5 Contracted services

P.5.1 General considerations

Many companies or organizations offer services that include vapor monitoring services.

Among the industrial hygiene companies, the breadth of services available varies significantly from contractor to contractor. Some will perform only personnel monitoring; others will conduct a complete survey of the health care facility to identify sources of chemical vapors and provide recommendations for possible solutions to identified problems. Some of the advantages of using contract services are as follows:

a) Reputable contractors are familiar with the causes of potential chemical vapor overexposure, enabling them to save time at the outset in determining where the problems might be. Engineering or work-practice solutions can then be designed and implemented.

b) Contract services can be performed on a shared-services basis; that is, several health care facilities can jointly contract with the contractor. Discounts for services might be available under such circumstances.

c) The same contractor might be able to provide services to meet similar needs in other departments (e.g., monitoring waste anesthesia gases in the operating room).

A major consideration in relying on contract services is that the health care facility should implement some form of ongoing monitoring program, especially if consultant or contract services are intermittent. Contract services or other ongoing monitoring should take into account the amount of chemicals used, the location of the chemicals, the equipment used, the number of people normally present in the vicinity of chemical sterilization or high-level disinfection activities, and other factors.

P.5.2 Finding contract service organizations

Personnel can find contract service organizations through the local or state health department, occupational health consulting services, or worker compensation or other insurance carriers; universities can be approached to determine whether they provide consultant services and, if not, to secure their recommendations.

a) Nearby health care facilities can be approached to learn their experiences with consultants and to obtain their recommendations.

b) Chemical suppliers can usually provide suggestions.

c) The American Industrial Hygiene Association can provide a list of consultants and accredited laboratories in the region.

d) If a local consultant is not available, a cooperative effort (shared service) to bring in a reputable consultant can be considered.

P.5.3 Selection criteria

Once a list of possible service organizations is prepared, the following steps should be taken in selecting the one to hire:

a) References should be requested, preferably from nearby clients with similar operations.

b) The consultant should describe the specific qualifications and years of technical experience of the individuals who perform the work. (Certified industrial hygienist or professional engineer is usually a good credential. Certified safety professional or biomedical equipment technician, with appropriate experience, could also be a valid credential.)

c) Those who perform the work should be interviewed and asked the following questions. Not all the questions are appropriate to all situations.

— What is the relevant experience of the consultant with the chemicals being used?

— Is the person familiar with the clinical use of the respective chemicals? (Ask follow-up questions.)

— What kind of equipment will be used to perform the work? What interferences might affect the monitoring? Compare with other chemicals used in the work area.

— What areas of the facility will be examined?

d) The contractor should be asked if blank or control samples are collected and submitted.

e) The contractor should specify who performs the analysis of the absorbent and describe the level of experience of that individual.

f) The general operation, the number and types of sterilization areas clinical use areas, the work practices, the number of employees per shift, and the facility layout should be discussed. Agreement should be reached in advance about which activities will be monitored and what ancillary tests (e.g., verification tests) will be performed. Either personal monitoring or area monitoring can be considered. It should be specified that all work shifts during which the chemical of concern is used will be surveyed.

g) The contractor should be asked whether ventilation checks will be performed (e.g., local exhaust hoods, air exchange rate, location of building intake in relation to the building's exhaust points, positive- and negative-pressure areas).

h) The contractor should describe the report that will be issued upon completing the work and provide an example of the report format. The user and contractor should agree on the date that the report will be issued and who will receive a copy. The report should contain at least the following information:

— the date the monitoring was performed;

— a detailed description of the operations monitored;

— the names or identification numbers of the personnel monitored;

— the exact locations of the sampling devices (photographs or maps are very helpful);

— if applicable, the most recent date on which the monitoring devices were calibrated and the calibration technique that was used;

— the specific times that samples were collected, with notations concerning other pertinent activities (e.g., changing LCS/HLD solution);

- the vapor concentration in ppm at each sample location (measured as a 15-minute or 8-hour TWA or a maximum concentration using a discrete monitor);
- a description of the sampling, calibration, and analytical procedures used;
- the name of the contractor's organization;
- the names and qualifications of the survey personnel who did the work at the facility;
- a description of the PPE used;
- the temperature and relative humidity of the area surveyed; and
- an authorized signature with a title.

i) The contractor‘s fee should be discussed.

j) The possibility of follow-up visits should be discussed. How many visits will be made and when they will be scheduled should be determined.

k) Once the contractor has been selected, it is important to ensure that the contractor will provide ample advance notice before coming to the facility so that the appropriate supervisor can schedule time for the survey and so that actual normal operations (including chemical disinfection or sterilization processes and disposal of spent solutions) will occur during the survey. A "simulated load" outside of the normal routine should not be surveyed.

Annex Q
(informative)
Infection transmission and standard precautions

Q.1 Introduction

Properly performing decontamination is a critical component of public health. The purpose of the decontamination process in a health care facility is to prevent the transmission of disease. Health-care-associated infections can occur because of the presence of infectious agents, multiple modes of transmission, and a population of susceptible individuals. An understanding of the chain of infection enables health care professionals to develop and implement policies and procedures that will reduce the risk of infection transmission.

Health-care-associated infections are those that manifest themselves after a patient is admitted to the facility and that were not incubating at the time of admission. Such infections involve not only patients but also others present in the facility, principally health care workers.

There are six main factors in the chain of infection: the etiologic agent, a reservoir, the portal of exit, the mode of transmission, the portal of entry, and a susceptible host. (See Figure Q.1.) Each of these factors is vitally important and must be present for an infection to take place.

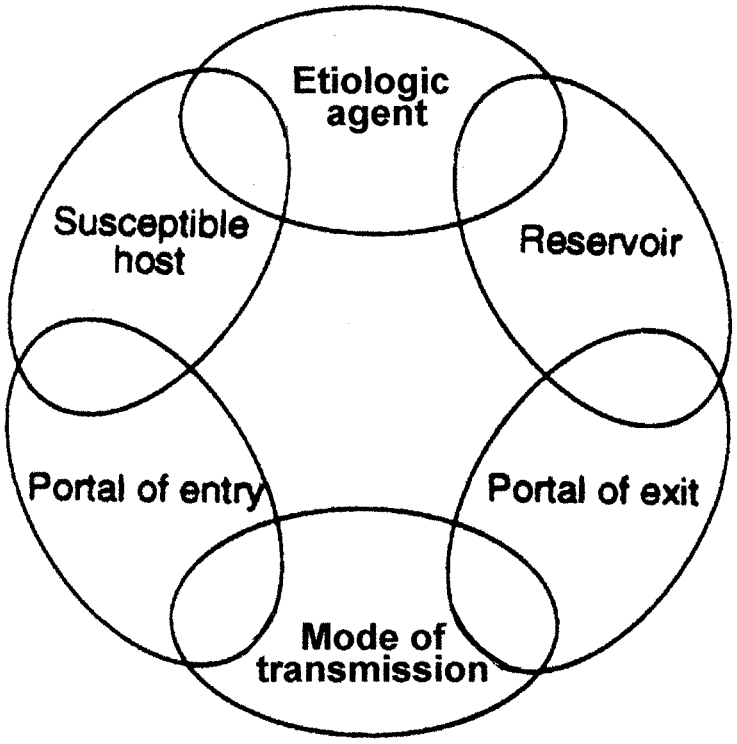

Figure Q.1—The chain of infection, components of the infectious disease process

(Adapted, with permission of the publisher, from: Soule BM, ed. *The APIC Curriculum for Infection Control Practice,* Vol. 1. Washington (DC): Association for Professionals in Infection Control and Epidemiology, Inc., 1983.)

Q.2 Chain of infection

Q.2.1 Etiologic agent

Q.2.1.1 General

The first link in the chain of infection is the etiologic agent itself: any bacterium, virus, fungus, or other microorganism. Most pathogenic microorganisms of concern with respect to patient care equipment are included in one of the following four classes: (a) spore-forming bacteria such as *Bacillus anthracis, Clostridium botulinum, Clostridium perfringens,* and *Clostridium tetani;* (b) vegetative bacteria such as *Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus,* and *Mycobacterium tuberculosis*; (c) viruses such as the human immunodeficiency virus (HIV) and the herpes simplex, polio, and hepatitis B viruses; and (d) fungi such as *Candida albicans, Coccidioides, Aspergillus,* and *Alternaria.* Also of importance are prions, small proteinaceous agents believed to be the smallest infectious particles. Prions are neither bacterial, fungal, nor viral and contain no genetic materials. They have been held responsible for a number of degenerative diseases involving the brain, including Creutzfeldt-Jakob disease, variant Creutzfeldt-Jakob disease (also known as bovine spongiform encephalopathy or “mad cow” disease), fatal familial insomonia, kuru, and an unusual form of heredity dementia known as Gertsmann-Straeussler Scheinkler disease.

Q.2.1.2 Pathogenicity

Not only must the infectious agent be present, it also must be pathogenic (capable of causing disease). The ability of a microorganism to cause disease depends upon its virulence and its invasiveness.

Virulence is the degree of pathogenicity of a given microorganism, as indicated by morbidity and mortality case rates. Invasiveness is the ability of a microorganism to invade tissues of the body. Organisms that can penetrate the body’s intact barriers are generally of more concern than those that cannot. However, some microorganisms need not directly attack intact body tissues in order to cause disease. For example, *Vibrio cholerae* is noninvasive in the gastrointestinal tract but produces toxins that react with the mucosa and cause diarrhea. In contrast, *Shigella* organisms cause disease by actually invading the gastrointestinal submucosa.

Q.2.1.3 Dose

A third factor critical to this particular link involves a phenomenon referred to as the “infectious dose.” The infectious dose is the minimum number of a given microorganism needed to cause infection. This number varies from organism to organism and from host to host. However, seldom has the transmission of disease resulted from the transfer of a single microorganism. It usually requires thousands to millions of these agents before infection can actually take place. However, some pathogens can begin an infection with only a small number of cells in the initial inoculums. Enterohemorraghic strains of *Escherichia coli* require an infective dose of only about ten cells, whereas other pathogens, including *Vibrio cholera,* require a large number of cells (10^3 to 10^8 cells) in the inoculums to successfully infect a host (Schmid-Hempel and Frank, 2007). Some viral diseases can be accompanied by extremely high viral concentrations in body fluids such as blood; consequently, a significant number of microorganisms can be carried in a very minute volume of liquid. (See Figure O.2.) The concept of infectious dose is particularly important to understand when considering the importance and efficacy of good hand hygiene practices. Although properly performed hand hygiene does not eliminate all organisms from the skin, it does reduce their numbers to a level far below the infectious dose needed for the transfer of most diseases.

Q.2.2 Reservoir

The second major link in the chain of infection involves the presence of a reservoir or source that will allow for microbial survival and, perhaps, even multiplication of a potential pathogen. Common reservoirs include the multitude of supplies and equipment used in patient care. However, the role played by food and drink, linen, and other inanimate objects is of comparatively minor significance when measured against that played by the main reservoir, man himself. Studies have shown that normal human skin harbors approximately 10,000 organisms per square inch, equivalent to nearly 20 million microorganisms over the surface of the entire body. The oral cavity is thought to harbor an additional 100 million organisms and the gastrointestinal tract to contain another 100 million in each gram of stool. Thus, on and within the human body, well over a trillion microorganisms can be found, and therein lies one of the main reasons for the use of gloves any time that contact with body fluids is anticipated. It is a well-documented fact that most health-care-associated

infections are indeed caused by the patient's own microbial flora. This is not to imply that such infections cannot be prevented, simply that they are usually the result of prior microbial colonization of the patient.

Q.2.3 Portal of exit

The third link requires the presence of a source from which the pathogen can emerge, a portal of exit. Obvious portals of exit include the respiratory tract, blood vascular system, skin, and mucous membranes, as well as the gastrointestinal and genitourinary tracts. In addition, contact of patient care supplies and equipment with any portal of exit will invariably result in potential contamination and the subsequent possibility of disease transfer.

Volume of strike-through[1] *Approximate size*	100 µL	10 µL	1 µL	0.1 µL
Number of bloodborne pathogens[2]				
HBV	10,000,000	1,000,000	100,000	10,000
HCV	100–100,000	10–100,000	1–1,000	0.1–100
HIV	6–700	0.6–70	0.06–7	0.006–0.7

NOTE 1 Volume of red 40 dyne/cm synthetic blood delivered to white blotter papers.
NOTE 2 Based on documented whole blood concentrations of infected patients.

Figure Q.2—Blood-borne pathogen strike-through conversion chart

Figure Q.2 converts the amount of strike-through to the amount of potential blood-borne pathogen contamination. The four spots at the top were formed from premeasured droplets of synthetic blood and are marked in microliters ranging from 100 microliters to 0.1 microliter. Listed on the left are the three primary blood-borne pathogens: HBV, HCV, and HIV. The approximate number of infectious units that could be present in each spot, on the basis of documented whole blood concentrations in infected patients, is shown for each type of virus. These data were derived from Bradley (1984), Ho et al. (1989), and Shikata et al. (1977). A study of transmission of blood-borne pathogens to health care workers found serum concentrations of HBV, HCV, and HIV to be as high as 10^8, 10^6, and 10^3 viral particles per milliliter, respectively (Lanphear, 1994). (Figure courtesy of W.L. Gore & Associates, Inc.)

Q.2.4 Mode of transmission

Although several potential mechanisms for transmission exist, the main mode of disease transfer involves contact transmission, either through direct or indirect contact with the patient or through droplet spread via contact with exhaled respiratory secretions. Direct-contact transmission primarily involves person-to-person spread such as contact with the unwashed hands of a health care worker. Indirect-contact transmission can be the result of contact with a contaminated intermediate object such as a catheter, dressing, or surgical instrument. Droplet spread occurs through contact of the conjunctivae or the mucous membranes of the nose or mouth with large (greater than 5 microns) droplets of respiratory secretions. Such droplets are generated primarily during coughing, sneezing, or talking. Typical examples of illnesses transmitted in this manner include streptococcal pharyngitis, mumps, and influenza.

Three additional means by which diseases can be transmitted are airborne, vehicular, and vector transmission. Airborne transmission occurs by means of the dissemination of either very small (less than 5 microns) droplet nuclei resulting

from respiratory secretions or dust particles containing the infectious agent. Typical diseases transmitted in this manner include tuberculosis, measles, and chicken pox.

Vehicular transmission involves the spread of disease-causing organisms through some secondary route, usually environmental objects such as contaminated medications or antiseptics (e.g., eyedrops, multidose vials), food (e.g., hepatitis A or staphylococcal food poisoning), or water (e.g., giardiasis). Such diseases are very rarely the result of health care delivery.

Vector transmission involves the spread of pathogenic agents through secondary, animate hosts, such as insects and rodents or other small animals. Typical examples of vector-borne diseases include malaria, rabies, plague, and Lyme disease. As with vehicular transmission of disease, vector transmission associated with the delivery of health care is extremely rare, if not nonexistent, in the United States.

Q.2.5 Portal of entry

The fifth link in the chain of infection is a suitable portal of entry. The avenues for gaining entry into the body are, in most instances, identical to the portals of exit. It is important to understand that each of these portals is usually peculiar to given diseases and that, for any given disease, there is usually a very specific portal of exit and entry. For example, tuberculosis and influenza involve only the respiratory tract and typhoid fever the gastrointestinal tract. Hepatitis B involves transmission by blood. Most infectious diseases and conditions require very specific portals of both entry and exit.

Q.2.6 Susceptible host

The last link is a susceptible host, someone who lacks effective resistance to a given pathogenic agent. A variety of host factors must be present before infection can occur. Very few organisms can gain entrance through normal intact skin. Most require some breach in skin integrity. Other less obvious lines of defense include tears, gastric acid, and the cilia of the nose and upper respiratory tract. One's ability to mount a local inflammatory response provides yet another nonspecific host defense mechanism. Patients who are immunocompromised (e.g., the very young, the elderly, those who are undergoing immunosuppressive therapy, those with disorders of the immune system) are susceptible hosts.

Q.3 Barrier protection and protective clothing

Protective clothing is often used to limit or prevent contact transmission of microorganisms. Strategies employed in the laboratory evaluation of protective clothing materials and the resulting understanding of performance expectations are very important when deciding which products are suitable for which applications. Such strategies need to consider both the modes of transmission (e.g., liquid-borne, aerosol-borne) and the perceived risk associated with varying types of microorganisms (e.g., viruses, bacteria, fungi). It is extremely difficult to duplicate the myriad of physical, chemical, and thermal stresses placed on protective clothing in an actual setting. Nonetheless, the goal of laboratory testing is to provide information that will allow a realistic estimation of the performance of protective clothing during actual use.

NOTE 1 The Food and Drug Administration maintains a list of recognized standards, including standards applicable to protective clothing and barrier integrity testing. This list can be accessed at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/results.cfm.

NOTE 2 ANSI/AAMI PB70 classifies surgical gowns, other protective attire, surgical drapes, and drape accessories according to barrier performance determined by specified laboratory test methods. This standard has been recognized by FDA.

Annex R
(informative)
General considerations for cleaning and disinfection

R.1 Introduction

The FDA defines reprocessing as a “validated process used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection and sterilization” (FDA, 2015). Reprocessing involves the following sequential steps: 1) point-of-use processing, 2) thorough cleaning, and 3) disinfection and sterilization.

The CDC *Guideline for Disinfection and Sterilization in Healthcare Facilities* describes the proper level of processing between patient uses for critical, semicritical, and non-critical items (CDC, 2008). Thermal disinfection is usually an intermediate step in the processing of medical devices; that is, it is intended to render the items safe to handle by personnel not wearing protective attire, not to process them fully for reuse in patient care. Critical items should be subjected to a sterilization process after decontamination is complete. Semicritical items should be subjected to either sterilization or, at a minimum, high-level disinfection. See CDC (2003) and CDC (2008) for additional information.

Although the characteristics of pasteurization do not support a claim of high-level disinfection, many semicritical items such as respiratory therapy and anesthesia devices are ready for patient use after cleaning and pasteurization. High numbers of bacterial spores are not generally found on these devices after use; cleaning before pasteurization reduces the bioload substantially.

For non-critical items, processing through a washer–disinfector provides more than adequate disinfection of precleaned devices. Performance monitoring each day that a washer–disinfector is used, in accordance with manufacturer-recommended equipment maintenance schedules, helps ensure that the equipment is performing as designed. Verifying that spray arms achieve full rotation and that filters, nozzles and other critical parts of the equipment are clean and well maintained will help ensure an effective cleaning process.

Effective cleaning is a multistep process that relies on several interdependent factors: the quality of the water; the quality, concentration, and type of detergent or enzymatic cleaner; the washing method; rinsing and drying; preparation of items to be processed by cleaning equipment; the time and temperature parameters and load capacity of the equipment; and operator and equipment performance.

Many types of soil could be present on reusable medical devices. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a challenge to cleaning. However, other body fluids, fats, carbohydrates, and, in particular, prion-contaminated tissue might be equally or significantly more challenging. Non-patient-sourced contaminants (e.g., cements, oils) used during a procedure also can be a significant challenge to cleaning.

The amount of residue that remains on an instrument will vary depending on the conditions of use of the cleaning agents, the specific component materials of the reprocessed devices, and the methods used to reduce residuals before reuse. Any organic material or residual cleaning agents remaining on an item can inactivate chemical disinfectants or sterilants as well as protect microorganisms from destruction. In addition, debris could become dislodged and could cause potential health risks, such as a foreign-body reaction or a breeding place for infection.

R.2 Mechanical (automated) cleaning and disinfection

R.2.1 General considerations

Each type or model of mechanical cleaning equipment is designed to significantly reduce the viable number of microorganisms on medical devices through the detergent washing, rinsing, flushing, and draining action of the equipment. Some types of mechanical cleaning equipment are also designed to destroy vegetative or pathogenic microorganisms by means of moist-heat thermal disinfection or chemical disinfection. Such equipment can be labeled as providing low-, intermediate-, or high-level disinfection.

R.2.2 Ultrasonic cleaning equipment

R.2.2.1 Overview

Ultrasonic cleaners typically consist of an electronic ultrasound generator and numerous ultrasound transducers bonded to the sides or the underside of a stainless steel tank filled with a cleaning solution. Five types are available, each with specific features intended for a specific purpose.

Some are intended for very specific types of devices, such as those with lumens or minimally invasive instrumentation. Several include a disinfection process in addition to ultrasonic cleaning. The generator supplies an electrical signal that causes the transducers to oscillate, producing high-frequency sound waves. This ultrasonic energy (at a frequency higher than 20,000 cycles per second, or 20 kHz) is transmitted into the tank, producing sound waves that compress and decompress molecules in the solution to produce alternate zones of high and low pressure. The low pressure creates microscopic bubbles that implode during the high-pressure cycle, causing cavitation. Cavitation creates mechanical scrubbing action everywhere water contacts the surfaces of the object in the tank, dislodging the debris.

Cavitation provides an effective means of mechanically removing clinical soil from joints, box locks, crevices, channels, serrated tips, and other areas that are difficult to clean by other methods. A compatible detergent containing enzymes is commonly used for suspending loose bioburden in the tank solution. Basic ultrasonic cleaners are not designed or intended to provide microbial lethality for disinfection or sterilization. However, some newer models provide the option for mechanical detergent washing and rinsing, as well as thermal disinfection.

The ability to clean medical devices mechanically and to fine-clean by the ultrasonic process is of great value, considering the complexity of many devices and the heavy workload of the average sterile processing area. The variety of equipment available and the intricacy of many medical devices make it essential that manufacturers be consulted and their written IFU followed to maximize effectiveness and avoid expensive and unnecessary damage. The device manufacturer’s written IFU will indicate whether the device can be safely cleaned using ultrasonic equipment.

Trapped air inside the cleaning solution needs to be released by the running of a degassing cycle. Sources of trapped air includes the water itself, the cleaning agent that is added and the addition of air to the bath during filling. If the ultrasonic cleaner does not have a preprogrammed degas cycle, then an ultrasonic cleaning cycle in an empty bath must be run before the ultrasonic is used for cleaning.

Testing the equipment upon installation, daily during routine use, and after repairs allows the user to verify its continued effectiveness. The tank solution should be changed after every use. The health care facility should define “use” in their policies and procedures. Tanks should be cleaned and disinfected at least daily in order to reduce the possibility of cross-contamination.

R.2.2.2 Basic ultrasonic washers

The basic ultrasonic washer is the simplest configuration: a tank that is surrounded by transducers (below and/or around the external sides of the tank) or that contains a transducing rod inside the bath area. Typically, the frequency used in basic ultrasonic washers for medical device cleaning is 38 kHz or greater. Some models have automated processes consisting of several phases: filling with water, adding a cleaning agent, degassing, rinsing, and draining. Simpler models are completely manual, with the user performing all the functions of filling, rinsing, draining, and so on.

R.2.2.3 Ultrasonic irrigators

Some ultrasonic cleaner models are designed specifically to clean minimally invasive surgical (MIS) devices with lumens, flushing the inside of instruments as well as exterior surfaces. These models feature the same cavitation process with the addition of flushing and irrigation in order to remove the bioburden from lumens, channels, box locks, and other crevices. These types of ultrasonic cleaners contain water ports with hoses and special adapters to connect to various devices such as laparoscopic, robotic, and other instrumentation. Rinsing the exterior and interior of lumened devices following ultrasonic treatment is recommended.

R.2.2.4 Ultrasonic irrigator washers

Ultrasonic irrigator–washers ultrasonically clean external surfaces and interior lumen channels with rapid-flow, high-pressure irrigation. In addition, this equipment provides programmable wash cycles. It contains a tank that fills with

solution and replaces the solution several times during the process. Cycles include pre-rinse, enzyme flush, specific sonic, wash, and several rinse cycles, with the final rinse usually consisting of water treated by reverse osmosis or deionization.

R.2.2.5 Ultrasonic irrigator washer–disinfectors

This equipment provides programmable automated ultrasonic cleaning processes. It cleans internal lumens and channels through high-pressure irrigation, detergent solution washing, optional lubrication, and thermal disinfection. Items are safe for staff to handle once this process is complete.

R.2.3 Washer–pasteurizers

Pasteurization is not a sterilization process; its purpose is to destroy all pathogenic microorganisms except bacterial spores. Pasteurization of respiratory therapy and anesthesia equipment is an alternative to chemical disinfection.

R.2.4 Washer–disinfectors

R.2.4.1 Overview

Washer–disinfectors provide automated processes that combine mechanical cleaning technologies, application of cleaning chemistries, treated water in critical phases, a microbicidal process, and drying to produce clean medical devices.

A programmable controller enables users to select standard cycle parameters from a menu or to set up custom validated cycles. The controller automatically runs the machine through the pre-programmed cycle and monitors transition and performance.

Finished loads are clean, disinfected, and safe to handle for further processing. Depending on the intended use and the manufacturer’s IFU, some items could be ready for immediate use.

Some washer–disinfectors are designed with doors on the front and rear for pass-through operations between the soiled receiving area and the clean preparation and packaging area. Washer–disinfectors have various chamber sizes and load carriers, depending on the type of washer–disinfector and the design of the devices to be processed.

One example of a validated programmable cleaning process is as follows:

a) *Pre-Rinse:* A cold-water rinse to rehydrate soil and remove gross soil.

b) *Detergent Wash Phase 1:* Washing with a solution of an enzyme detergent or a high-alkaline detergent in heated water to break down organic soils.

c) *Rinse 1:* Flushing of chemical residues and retained bioburden from the chamber and load before a new chemical is introduced.

d) *Detergent Wash Phase 2:* In the case of an enzyme detergent in phase 1, a heated detergent wash with chelating agents (the detergent typically has a neutral pH or is mildly alkaline); in the case of a high-alkaline detergent in phase 1, a neutralizing detergent with an acidic pH. The chemical is automatically dispensed and circulated.

e) *Wash 2:* an optional second wash with detergent.

f) *Rinse 2:* A clean hot-water rinse to flush chemical and soil residue from the chamber and load. The rinse temperature is typically 82°C (180°F) or greater for 1 minute or longer for thermal disinfection and microbial reduction, making instrumentation safe to handle. This process is usually performed using critical water (see AAMI TIR 34).

g) *Multiple Additional Rinses:* Additional rinses used to continually reduce residual chemical and bioburden levels in the chamber and on medical devices.

h) *Lubrication:* Application of lubricant in the final rinse, using high-purity water preferably at disinfecting temperatures.

i) *Hot Air Drying:* Circulation of hot air (usually HEPA filtered air pulled into a heating unit) by high pressure within the chamber in order to effectively dry the items being processed. Items should show no signs of moisture at the end of the cycle.

Three main types of washer–disinfectors are commonly used in today's health care settings:

a) Single-chamber washer–disinfectors

b) Multi-chamber washer–disinfectors

c) Cart washer–disinfectors (also validated for Instruments)

R.2.4.2 Single-chamber washer–disinfectors

Single-chamber washer–disinfectors are designed to clean and disinfect small to medium size items such as surgical instruments, MIS devices, utensils such as OR bowls and basins, and disassembled rigid sterilization containers. All single-chamber washer–disinfectors have shelf racks or removable wash carts designed for specific devices such as trays of general instruments, instruments with lumens, orthopedic instruments, MIS instruments, and other surgical items. Chambers are designed with rotating spray arms attached to the chamber or on the carts, multiple feedwater valves, multiple chemical injectors, recirculation tanks with a water heater and pumps, external boilers, high-pressure manifold port connections, ultrasonic systems, air inlets for hot-air drying, and exhaust and filtration systems.

Single-chamber washer–disinfectors are variously designed with powered sliding doors, fold-down doors, or fully automated feeder configurations that load and unload the chamber. Trolleys and wash carts are usually specific to the instrumentation being cleaned.

For manual loading, the trolley is loaded with the wash cart and locked into position on the cart. The cart is then docked to the washer–disinfector on the decontamination side of the department. The door is opened and the wash cart is pushed into the chamber. The door is closed and a cycle is selected. Unloading is done in the reverse order.

R.2.4.3 Multi-chamber washer–disinfectors

Multi-chamber washer–disinfectors are indexing tunnel washers. These machines connect three to five single-chamber washer–disinfectors together in a system that transports wash carts through each chamber of the process. This washer delivers the same critical cleaning, rinsing, washing, sonic, rinse, thermal or chemical disinfection, and drying processes.

R.2.4.4 Cart washers

Cart washers are designed to clean and provide low- to intermediate-level thermal disinfection of such items as stainless steel case carts, wire supply carts, tote bins, basins, and rigid sterilization containers. Some cart washers are validated to wash and disinfect surgical instruments. If the cart washer has an instrument cycle, the washer should be tested at least weekly, preferably daily, on the instrument cycle program. The manufacturer's IFU should be followed for processing the medical devices that can be cleaned with that specific model/type of cart washer.

Annex S
(normative)
Considerations for ethylene oxide gas sterilization

NOTE The information listed below was previously included in AAMI ST41: Ethylene oxide sterilization in healthcare facilities: Safety and effectiveness which is now obsolete with this version of ST58

58.

NOTE The information provided in this Annex was accurate at the time the standard was approved for publication. However, sterilization processes evolve over time, and FDA-cleared manufacturers' label claims and IFU change accordingly. Therefore, it is essential that 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.

S.1 Introducton

Ethylene Oxide gas sterilization processes are particularly suited for sterilizing heat-sensitive materials because temperatures within the load currently do not exceed 55ºC (131ºF) and sterilization occurs in a low-moisture environment. Heat tolerant devices and materials can also be indicated for ethylene oxide gas sterilization processes. FDA-cleared ethylene oxide gas sterilizer are currently available in the United States. This Annex covers the properties and applications of ethylene oxide gas sterilization; occupational exposure considerations, including vapor monitoring, ventiliation and procedures for handling spills; and sterilant disposal.

S.2 Properties and applications of ethylene oxide gas sterilization

Ethylene oxide (EO) gas and its mixtures are effective sterilants that are primarily used for heat- and moisture sensitive medical devices that cannot be processed through other sterilization methods. Only devices that have been validated by the manufacteurer for ethylene oxide and its gas mixtures should be processed by this method.

The delivery of sterile products for use in patient care depends not only on the efficacy of the sterilization process itself but also on efficient facility design, good infection prevention and control practices, effective quality control, and other aspects of device processing before, during, and after sterilization.

Ethylene oxide gas must be used with care because of its toxicity and (when used in its pure form) its flammability and explosiveness.

S.3 Design considerations

S.3.1 General rationale for EO sterilization

Proper design of EO sterilization areas will help minimize occupational exposure to EO as well as promote efficient work flow. This section describes design criteria specific to EO sterilization processing, including ventilation recommendations. The release of EO within health care facilities is a potentially serious problem. Centralization of EO sterilization processing, containment of EO sterilization areas, adequate ventilation and environmental discharge controls, proper storage of supplies, proper use of alarms, and traffic control can prevent unnecessary or inadvertent exposure of hospital personnel, visitors, and patients to EO.

NOTE Detailed guidance on the design of sterile processing departments is provided in ANSI/AAMI ST79

S.3.2 Centralization

Centralized EO processing, sterilization process in health care facilities is strongly encouraged. Consistent policies and procedures should be maintained throughout the health care system, with special emphasis on necessary engineering controls, safe work practices, and quality assurance.

Rationale: Ethylene oxide sterilization is a complex and potentially hazardous process requiring sophisticated equipment, adequate space, trained personnel, and exposure monitoring. Achieving and maintaining compliance with

federal, state and local environmental and occupational regulations restricting the emission of EO into the environment may be streamlined if EO processing is centralized. Thus, both safety and cost considerations support centralization of EO processing equipment and functions rather than replication in several areas of the health care facility or within several facilities within an integrated health network. See also Samuels (1978a), Samuels and Eastin (1980), Hancock (1993), Schneider (1997), and Danielson (1998).

S.3.3 Ethylene oxide containment areas

All EO sterilizers should be located in a containment area that is physically separate from all other work areas. The containment area should be large enough to ensure and to accommodate the loading, unloading, storage of supplies and maintenance of sterilizers. The temperature range and air-exchanges should comply with EO sterilizer manufacturers recommendations and should be actively ventilated to ensure that under normal conditions, the EO concentration does not exceed the permissible exposure. limit (PEL).

Adequate space to allow service access to the equipment shall be provided. Figure 1 provides an example of a layout for an EO sterilization area. Outside the EO containment area but in a readily accessible locker or cabinet, equipment must be stored for use in emergencies. Employee work stations, pack preparation areas, desks, washing areas, lounge areas, and other personnel support areas must be located so as to minimize EO exposure. The acceptability of these locations can be determined through environmental monitoring.

Signs demarcating regulated areas and entrances to regulated areas must be posted and maintained. Such signs must be legible and must bear the following legend:

DANGER
ETHYLENE OXIDE
MAY CAUSE CANCER
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS AREA
AUTHORIZED PERSONNEL ONLY

Rationale: Physical containment of the EO sterilization area can significantly reduce incidental personnel exposure to EO. Adequate dilution ventilation can reduce residual EO in the room that is not readily captured by local dedicated exhaust systems or that is released from minor sources. Personal protective equipment designated for use in emergencies must be readily available but not stored in an area likely to be affected by an EO spill or other emergency. Otherwise, personnel could be exposed to high-levels of EO when attempting to retrieve the equipment. “Safe” locations for employee work stations and other personnel support areas will depend largely on the specific characteristics of the ventilation system and thus can be determined only by environmental monitoring.

The signs and labeling described herein are required by OSHA’s Hazard Communication Standard (19 CFR 1910.1200) and Ethylene Oxide Standard (19 CFR 1910.1047).

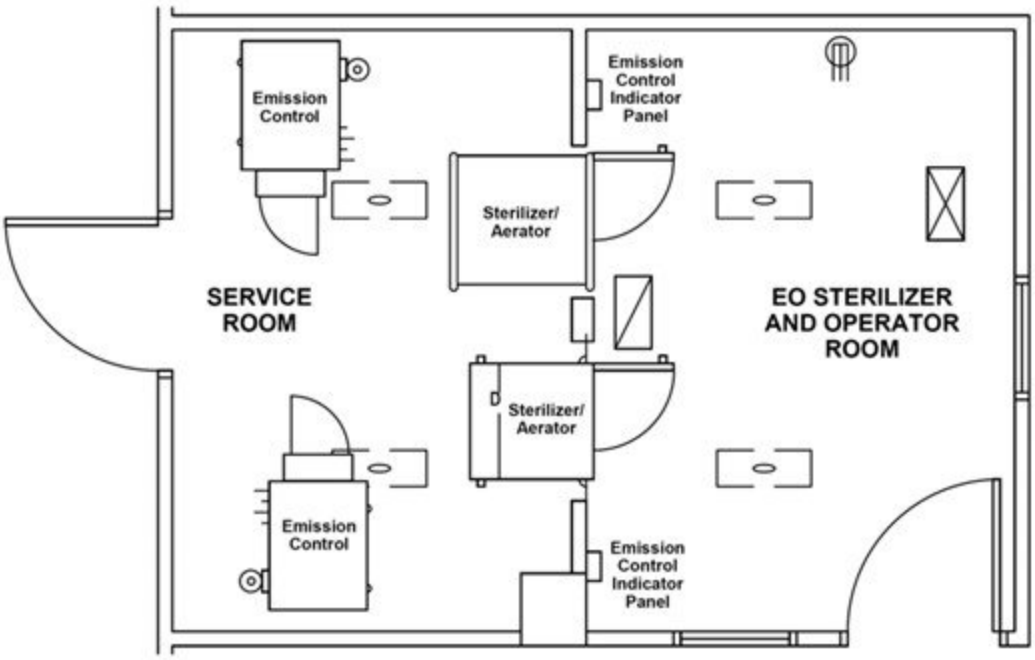

Figure S.1—Example of an EO sterilization containment area

S.3.4 Routing of traffic

Personnel not involved in sterilization processing should be routed around or away from all sterilization equipment. Such routing can be accomplished by signs and posters, floor paint or tape lines around the equipment area, or temporary or permanent partitions.

Rationale: Traffic control around EO sterilization equipment is an important aspect of infection prevention and control and occupational health and safety. Aseptic practice demands that sterilizers be operated, and sterile items handled, only by trained personnel directly responsible for sterilization. This principle is equally important for personnel safety, because under normal circumstances only those persons directly involved with EO sterilization will be familiar with safe handling techniques and potential hazards. Demarcating areas where the PEL for EO could be exceeded and limiting access to those areas should significantly reduce incidental personnel exposure to EO. Tape lines will serve as visual reminders to personnel.

S.3.5 EO Minimum room size

The room in which the sterilizer is located should be large enough to ensure adequate EO dilution and to accommodate the loading, unloading, and maintenance of the sterilizer.

Rationale: Dilution ventilation can reduce residual EO in the room that is not captured by local exhaust systems or that is released from minor sources. The committee decided that room size should be addressed here to discourage the use of closets as EO sterilization facilities, a practice that was revealed in the NIOSH study (Glaser, 1977) and other studies.

S.4 Ventilation recommendations for areas housing EO sterilization

S.4.1 General considerations for EO sterilization

Engineering controls, in the form of general room ventilation and local exhaust ventilation, play an important role in controlling personnel exposure to EO. Variables that should be considered in evaluating the overall effectiveness of the ventilation system include:

a) the total exhaust volumetric flow rate (i.e., cubic feet per minute) with respect to room size;

b) the ratio of makeup air to total exhaust volumetric flow rate;

c) the concentration of EO in the supply air; and

d) EO concentrations for an appropriate period of time in selected areas, which will indicate the potential for exposure.

The recommendations in the following paragraphs address ventilation needs for areas housing EO sterilization and aeration equipment, but adequate space for personnel to work and service equipment should also be provided. Refer to the EO sterilization equipment manufactures site planning, utilities, environmental condition including air exchanges and maintenance recommendations.

S.4.2 Local exhaust ventilation

S.4.2.1 Local exhaust ventilation systems

Local exhaust ventilation (LEV) systems, including the exhaust hood, associated ductwork, and exhaust fan, capture or control contaminants at their source before they can escape into the general work environment. The contaminant is collected in a suitable hood and is exhausted to the outside atmosphere through a fan and duct system. LEV is an accepted, effective industrial hygiene method of controlling the workplace hazards of airborne chemicals.

Rationale: Many studies have demonstrated the effectiveness of LEV systems in reducing EO diffusion and, hence, active and passive EO exposure (e.g., Samuels and Eastin, 1980; Roy, 1981).

S.4.2.2 Local exhaust ventilation parameters

Variables that can affect the efficacy of LEV in reducing EO exposure in the workplace include:

a) dimensions of the LEV hood in relation to the sources to be controlled;

b) hood design and location;

c) air-flow patterns between the hood and the sources to be controlled;

d) hood flow rate and velocity;

e) capture velocity and ambient air velocity around the sources to be controlled; and

f) system design specifications.

S.4.2.3 Sites for local exhaust ventilation

The following areas benefit from LEV:

a) the area immediately in front of the sterilizer door opening; and

b) the area near the EO sterilizer chamber pressure-relief valve, if applicable.

Rationale: These sites are the most common areas where EO concentrations could potentially occur.

S.4.2.4 Location of exhaust hoods

For sterilizers not factory equipped with integral capture devices, a local exhaust hood should be installed as close to the source of EO as possible. (For some sterilizers, it will be necessary to position the hood above the door; for others,

below or alongside the door. The manufacturer should be consulted for recommendations.) The face velocity of air entering the exhaust hood (i.e., the capture velocity) should be high enough to ensure the capture of most of the EO being released. The sterilizer manufacturer, the exhaust hood manufacturer, or a qualified industrial hygienist or engineer with expertise in EO ventilation should be consulted for specific recommendations.

Rationale: The closer the exhaust hood is to the EO source, the smaller the amount of EO that will escape to the workplace environment. Proper placement of the exhaust hood depends on the sterilizer design and on the air-flow patterns. Sterilizer manufacturers are best able to recommend the hood placement that will be most effective for their equipment.

NOTE This section maynot be applicable to new models of EO sterilizers.

S.4.2.5 Exhaust source

The health care facility should establish that the exhaust capacity of the system (expressed as cubic feet of air per minute) is sufficient to handle the output from all sterilizers and exhaust hoods connected to the dedicated exhaust system, while maintaining system operation at or above its nominal flow rate. The EO exhaust source (e.g., fan) should be of a nonsparking type, and the local exhaust hood should be electrically grounded to the Earth., For EO exhaust it might also be necessary for facility engineering to determne if NFPA 70 is applicable for electrical equipment.

All EO exhaust sources should be connected to a dedicated, non-recirculating system that is vented to the atmosphere.

Rationale: The importance of adequate air movement is described in 3.2. The provisions concerning nonsparking exhaust sources and electrical grounding are designed to reduce fire hazard. See also Glaser (1977) and 19 CFR 1910.1047.

S.4.2.6 Exhaust ducts

A separate exhaust duct to the outside is required. The exhaust duct should terminate away from areas where people walk or work. The duct should be located at least 7.6 meters (25 feet) away from the building air intake source and must be engineered according to existing codes. A longer distance might be needed in some situations, depending on the direction of prevailing winds and the location of buildings.

NOTE State or local EO emissions regulations might also dictate a longer distance or prohibit altogether the discharge of EO into the environment. Consult the manufacturer of the sterilizer before a local exhaust system is installed.

S.4.3 Ventilation system alarms

A system to detect ventilation system failures and to alert personnel with audible alarms, visual alarms, or both must be installed for personnel protection. Several suitable types of alarm systems are available. For example, a sail switch or differential pressure switch can be installed in the ductwork near the fan, or a static pressure gauge can be used.

NOTE Connecting the ventilation and alarm system to an emergency power distribution system should be considered during the design phase in case of main power failure.

Rationale: Ventilation failures, which could result from malfunctioning fans, obstructed ductwork, or power outages, could lead to excessive levels of EO in the workplace. See also 19 CFR 1910.1047. Ventilation system malfunctions can cause elevated ambient EO concentrations, and prompt corrective action will be required. Connecting to the health care facility emergency power source will aid in reducing unnecessary exposure to EO in case of a power failure.

S.4.4 General room ventilation

S.4.4.1 Ventilation parameters

Variables that can affect the efficacy of general room ventilation in reducing EO levels include:

a) the size and layout of the department;

b) the location of supply air inlets and exhaust outlets;

c) the air-flow rate at each inlet and outlet;

d) air-flow patterns within the room; and

e) system design specifications.

S.4.4.2 Air flow

Locating sterilization equipment in proper relationship to room air intakes and exhausts helps ensure adequate ventilation of the area housing the sterilizer. The direction of exhaust air flow in the immediate vicinity of sterilizers should be verified that there is air flow away from sterilizer operators and other personnel in the sterilization area and that air flows into the mechanical access area.

S.4.4.3 Air exchanges

A minimum of 10 total air exchanges per hour is recommended for areas housing sterilizers.

Rationale: The recommended number of air exchanges per hour was selected on the basis of the consensus of the committee regarding the minimum air exchange rate necessary to effectively reduce environmental microbial contamination by air dilution.

A well-ventilated EO sterilization area can also help reduce passive exposure to EO. General ventilation, however, should never be relied on as the only means of reducing EO concentrations to safe levels. Local exhaust ventilation and proper operating practices, in addition to the proper venting of EO sterilizers to the outside, are the most important methods of reducing EO concentrations, and thus EO exposure, in the workplace. See also Glaser (1977) and AIA (2006).

S.4.4.4 Ventilation monitoring

Because general ventilation is essential for EO sterilization areas, ventilation rates should be monitored and documented at least annually by the health care facility engineer, other qualified in-house personnel, or an outside contractor. One measure of general ventilation performance is the ratio of the total volumetric flow rate exhausted from the room to the room volume. Assessing general ventilation should take into account such factors as the floor plan; the dimensions of the EO sterilization area; supply air inlet and exhaust air outlet locations and volumetric flow rates; and the air flow between and around possible EO release points, work stations, and ventilation openings. If possible, the system design specifications for duct sizing, fan ratings, and makeup air or recirculation parameters should be obtained. The monitoring results should be compared to the system design specifications to determine if the system is functioning as designed.

S.4.5 Environmental discharge controls

S.4.5.1 Ethylene oxide

The EPA sterilization regulations for hospitals are at 40 CFR . 63 Subpart WWWWW—National Emission Standards for Hospital Ethylene Oxide Sterilizers.[7] The goal of the regulations is to reduce EtO emissions and the key provisions are summarized as follows:

a) Facilities must submit an Initial Notification of Compliance Status certifying that they are sterilizing full loads of items having a common aeration time except under medically necessary circumstances.

b) For each sterilization unit not equipped with an air pollution control device, the facilty must record the date and time of each sterilization cycle, whether each sterilization cycle contains a full load of items, and if not, a statement from a hospital sterile processing staff, a hospital administrator, or a physician that it was medically necessary.

c) If there are air pollution control devices on the sterilization unit(s) pursuant to a State or local regulation, facilitites must submit an Initial Notification of Compliance Status certifying that they are operating the sterilization unit in accordance with State or local regulations and following control device manufacturer’s recommended procedures.

d) If there are air pollution control devices on the sterilization unit(s) but they are not subject to any State or local regulation, then the facility must submit an Initial Notification of Compliance Status certifying that it is venting the ethylene oxide emissions from each sterilization unit to an add-on air pollution control device and that control device are used during all sterilization processes and in accordance with manufacturer's recommended procedures.

[Editorial note: The above language has been edited to simplify. The original language is at https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol15/pdf/CFR-2014-title40-vol15-part63-subpartWWWWW.pdf]

Several emission control technologies are available for use in health care facilities. All are based on the assumption that reducing toxic gas to an acceptable level will be accomplished before the sterilized materials are released from the system. Emission control devices should be approved by the EO sterilizer manufacturer before installation and use.That system removes the EO while the materials are enclosed in the sterilizing chamber. The concentration of EO in the exhaust stream strongly influences the applicability and efficiency of the various control technologies that are available. Sterilization-phase exhaust is typically a high-concentration, low-volume stream, whereas aeration-phase exhaust is typically a low-concentration, high-volume stream. Some control systems direct both high-concentration, sterilization-phase exhaust and low-concentration, aeration-phase exhaust to the same emission control device. Others separate the two, diverting the flow to an emission control device appropriate to the flow conditions and concentration. Ventilation ducting around the sterilizer is used to capture EO emissions in the event of equipment failure or to capture EO emissions from sterilizers that emit sterilant into the work environment when the sterilizer door is opened. These ventilation ducts can be routed to the aeration-phase emission control device or directly to the outside.

S.4.5.2 General rationale

This section covers the installation, venting, routine care, and maintenance of EO sterilizers, and EO abatement (emission control) and ventilation systems. All such equipment used in health care facilities should be evaluated and monitored to ensure that it has been designed, installed, or modified to help the health care facility meet the OSHA standard and to otherwise minimize personnel exposure. A safe work environment can be ensured with proper attention to EO sterilizer installation, venting, and emission control; appropriate equipment maintenance and record keeping; correct EO gas source storage and handling methods; and well-defined procedures for handling EO leaks and spills. Inadequate attention to venting of equipment and improper operating procedures have been shown to cause high ambient concentrations of EO (Glaser, 1977). In addition, proper equipment installation and maintenance will minimize equipment "down time," help prevent equipment malfunctions, and help ensure effective sterilization processing.

S.4.6 Venting of EO sterilizers

S.4.6.1 General considerations

All EO sterilizers should be vented out of the workplace to the outside atmosphere via an emission control system or a dedicated vent line. The sterilizer manufacturer's written instructions for venting should be followed.

Rationale: Failure to comply with the manufacturer's written instructions for venting could result in excessive personnel exposure to EO and, if applicable, the withdrawal of the sterilizer's warranty.

S.4.6.2 Sterilizers venting to the outside atmosphere

Sterilizers venting to the outside atmosphere should be vented by means of a dedicated vent line that is properly installed and that is constructed of EO-impervious material. The vent line should not terminate within 7.6 meters (25 feet) of any building air intake source; a longer distance might be needed in some situations, depending on the direction of prevailing winds and the location of buildings.

NOTE State or local EO emission regulations might also dictate a longer distance or prohibit altogether the discharge of EO into the environment.

Rationale: Compliance with the preceding recommendations not only helps ensure that occupational exposure to EO is minimized, but also helps prevent the passive exposure of patients, other hospital workers, visitors, and individuals in or near the health care facility. The specific recommendations for constructing the vent line are based on ACGIH® (2007b) and AIA (2006). These documents are regularly updated, and personnel should consult the latest editions.

S.5 Occupational health

S.5.1 Information concerning the potential hazards of exposure to EO

S.5.1.1 General considerations

Upon assignment to the EO sterilization department and at least annually thereafter, each worker must be informed of the possible health effects of exposure to EO. This information must include an explanation of OSHA requirements (29 CFR 1910.1047) and must identify the areas and tasks in which there is potential exposure to EO. Workers must also be notified if they have been exposed to EO at levels above the PEL.

NOTE Persons with occasional potential exposure to EO, such as maintenance personnel should receive the same information.

Rationale: Potential health hazards are associated with the use of EO. The OSHA standard mandates the dissemination of information on health risks to employees.

S.5.1.2 Health effects of short-term exposure to EO

Exposure to EO can cause acute reactions such as skin, eye, or mucous membrane irritation. Exposure to EO in liquid form can cause chemical burns or severe irritation of the skin if contact with EO is prolonged; frostbite-like symptoms can also occur, because of the rapid evaporation of EO from the skin surface. Liquid EO can also cause eye irritation and injury to the cornea. Ingesting EO can cause stomach irritation and liver damage. Acute effects of inhaling EO vapors include respiratory tract irritation and lung damage, headache, nausea, vomiting, diarrhea, shortness of breath, cyanosis, and even death.

S.5.1.3 Health effects of long-term exposure to EO

With respect to chronic, long-term exposure, there are concerns that EO could be mutagenic or carcinogenic or that it could adversely affect the reproductive system.

NOTE See Steenland et al. (1991) and the OSHA standard (29 CFR 1910.1047) for a more detailed summary of known potential health effects in humans of long-term exposure to EO.

S.5.1.4 Health effects of exposure to EO residuals

Excessive levels of residual EO or EO byproducts (ethylene glycol, ethylene chlorohydrin) on medical devices can be harmful. Anyone exposed to items such as prosthetic devices, instruments, or catheters that have been improperly aerated can experience serious chemical burns or tissue irritation.

S.5.2 Medical surveillance and treatment

S.5.2.1 Routine medical examinations

Employees who are exposed to EO at or above the action level (0.5 ppm) for at least 30 days per year, even if an approved respirator is used, must have medical examinations at least annually. All examinations and procedures must be performed or supervised by a licensed physician at a reasonable time and place and at no cost to the employee. Although broad latitude in prescribing specific tests to be included in the medical surveillance program is extended to the examining physician, OSHA requires that the following elements be included in the routine examination:

a) medical and work histories, with special emphasis on symptoms related to the respiratory, blood, nervous, and reproductive systems and the eyes and skin;

b) physical examination, with particular emphasis on the respiratory, blood, nervous, and reproductive systems and the eyes and skin;

c) complete blood count, including at least a white cell count (including differential cell count), red cell count, hematocrit, and hemoglobin measurement; and

d) any laboratory or other test that the examining physician deems necessary on the basis of sound medical practice.

At the employee's request, the medical examination must include pregnancy testing or a laboratory fertility evaluation as deemed appropriate by the physician.

In certain cases, to provide sound medical advice to the employer and the employee, the physician might find it necessary to evaluate situations not directly related to EO exposure. For example, employees with skin diseases might be unable to tolerate wearing protective clothing. In addition, those with chronic respiratory disease might not tolerate wearing negative-pressure (air-purifying) respirators. Additional tests and procedures that will help the physician determine which employees are medically unable to wear such respirators should include an evaluation of cardiovascular function, a baseline chest x-ray to be repeated every 5 years, and a pulmonary function test to be repeated every 3 years. Medical records are confidential; information discovered during the course of an examination not related to EO concerns must not be disclosed to anyone but the worker.

Rationale: Routine medical examinations of EO workers are necessary to detect adverse health effects and to comply with the OSHA standard.

S.5.2.2 Medical examinations for acute exposures

Accidental excessive exposure to EO by inhalation or skin contact (e.g., as a result of a leaking EO canister, a spill, a malfunctioning ventilation system) must be recorded. Inhalation levels higher than those specified by OSHA set in motion a variety of record-keeping, medical surveillance, and other requirements (29 CFR 1910.1047). In cases of accidental acute exposure, a medical examination is necessary. A physician examining personnel exposed to excessive EO must document the extent and degree of inflammatory changes in involved tissues. Inflammatory changes clear within several hours or within 2 to 3 days, depending on the severity of involvement. In severe instances, anti-inflammatory medications might be useful.

Rationale: Guidelines for medical examinations are provided here for general information in response to requests from reviewers. See the OSHA standard for more detailed information.

S.5.2.3 Record keeping

Medical records and records of employee exposures to EO must be maintained in accordance with local, state, and federal regulations. Health care facilities are required to provide an employee's exposure records to the employee's physician on written request.

Rationale: These record-keeping requirements are based in part on OSHA regulations (29 CFR 1910.20).

S.6 Packaging, preparation, and sterilization

S.6.1 EO General rationale

This section covers guidelines for processing medical devices before, during, and after sterilization. These guidelines apply mainly to reprocessing and resterilizing items intended for reuse. Proper work practices in preparing items for sterilization; implementing sterilization cycles; and handling, storing, and distributing sterilized items are essential to personnel safety, effective sterilization processing, and sterility maintenance.

S.6.1.1 Effective use of ethylene oxide sterilizers

To ensure efficacy when using an ethylene oxide gas sterilizer, the user should observe the following guidelines:

The medical device and sterilizer manufacturers' written IFU should be consulted to determine the compatibility of the device with ethylene oxide gas sterilization.

a) Devices should be thoroughly cleaned and dried before sterilization.

b) Any hinged instruments should be opened.

c) Devices should be packaged in Tyvek®-Mylar® pouches, polypropylene wrap, or reusable rigid sterilization container systems cleared by the FDA for use in ethylene oxide gas sterilizer.

d) To ensure adequate sterilant contact, personnel should load the sterilizer as recommended in the sterilizer manufacturer's written IFU.

e) Chemical indicators and *Bacillus atrophaeus* BIs cleared by the FDA for use in the ethylene oxide gas sterilizer should be used to monitor the process.

S.6.2 Items suitable for EO sterilization

Ethylene oxide sterilization processing should be limited to essential uses (i.e., the processing of heat- or moisture-sensitive items that are compatible with EO). For items that require EO sterilization, the device manufacturer's written instructions for cleaning, preparation, and sterilization parameters should be followed.

Liquids, oils, and powders (e.g., talc) should not be EO sterilized.

Rationale: Limiting EO sterilization processing to essential uses helps minimize occupational exposure to EO. Careful attention to the device manufacturer's instructions is necessary to ensure sterility and to prevent damage to the device. (For example, some endoscopes could be damaged if not properly vented.)

Ethylene oxide sterilization in combination with liquids could produce byproducts that are harmful and that are unlikely to be removed by aeration. It is difficult to achieve sterilization of oils and powders by EO. Oils and other petroleum products are not penetrable by EO and are generally sterilized by dry heat. Talc in volume is also a barrier to EO penetration and is generally sterilized by dry heat (see also *OR Manager*, 1992).

S.6.3 Preconditioning (humidification)

The moisture content of a device and its packaging material significantly affect the EO sterilization process. It is advisable to maintain relative humidity in the range of 35 % to 60 % throughout the preparation, processing, and storage areas. Drops of moisture should be dried or wiped from the device before packaging. Porous items should not be dried by heated forced air. Certain items might require special preconditioning procedures; the device manufacturer should be consulted for instructions.

NOTE Although the recommended humidity range for all work areas is 30 % to 60 %, ideal relative humidity in processing areas is 50 % and should not be less than 35 % for best results in achieving sterilization.

Rationale: Moisture hydrates microorganisms, making them more susceptible to destruction by EO. Drying porous items by heated forced air reduces the moisture content too much; the humidity could be insufficient to allow EO penetration of microbial cell walls. However, visible drops of water are undesirable. Water drops protect microorganisms from EO by inhibiting exposure of the microorganism to EO or by diluting the EO concentration to which the microorganism is exposed and can therefore inhibit sterilization. Excessive moisture also increases the possibility that ethylene glycol will be formed, and ethylene glycol is not removed by aeration.

S.6.4 Packaging

S.6.4.1 Selection of packaging materials

An effective packaging material for EO sterilization processing should, at a minimum:

a) allow adequate humidification and EO penetration of the package contents;

b) allow adequate aeration of the package contents;

c) provide an adequate barrier to microorganisms or their vehicles;

d) resist tearing or puncture;

e) have proven seal integrity (i.e., will neither delaminate on opening nor reseal after opening);

f) allow for ease of aseptic presentation;

g) be free of toxic ingredients and nonfast dyes;

h) be low linting;

i) be shown by value analysis to be cost-effective; and

j) be cleared by FDA for use with EO.

Many packaging materials and systems are appropriate for use in EO sterilization. See Table 1 for a list of materials considered to be acceptable or unacceptable for EO sterilization.

Rationale: The primary functions of any package containing a sterile medical item are to allow the sterilization of the contents, to maintain the sterility of the contents until the package is opened, and to allow removal of the contents without contamination. The packaging for items to be EO sterilized has to be gas permeable and allow for proper aeration. Extreme caution should be exercised in using any packaging material not specifically warranted by the manufacturer for use in EO sterilization.

Table S.1—EO packaging

Sterilization method	Packaging
Ethylene oxide	Textiles, nonwovens, polypropylene wraps, paper–plastic pouches and rolls, Tyvek® (all-plastic) pouches, polyethylene, most rigid sterilization containers

S.6.4.1.1 Periodic product quality assurance testing of rigid sterilization container systems

Refer to ST79 and Annex M.

S.6.4.1.2 Package configurations and preparation

S.6.4.1.2.1 Package closures

Accessories used to close or secure packages should be chosen to allow the EO sterilization process to occur, to avoid constriction of the package, and to maintain package integrity. Tape (other than EO sterilization indicator tape), should not be used to seal packages, nor should safety pins, paperclips, staples, or other sharp objects. Elastomer bands designed specifically for sterile packaging are acceptable as outside closures only if the wrapper manufacturer explicitly recommends their use and only if care is taken to choose the proper size (relative to the length and width of the package) so that the elastomer band fits snugly yet does not constrict the package (e.g., create an “hourglass” effect) or cause excessive wrinkles or folds in the package. Rubber bands or tape should not be used to hold instruments together in a group. Tip protectors, if used, should be permeable to the sterilant, validated for that sterilization modality, fit loosely, and be used according to the manufacturer’s instructions. The latching mechanism on rigid sterilization container systems should secure the lid so that it cannot move when locked.

Rationale: Unacceptable methods used to seal packages could compromise the integrity of the package. Rubber bands or tape used to hold instruments together in a group could interfere with EO contact of the surfaces beneath them. If tip protectors are fabricated from inappropriate materials or if they fit too tightly, they could also interfere with EO contact. Sharp objects, such as pins, paperclips, and staples, can puncture the packaging material and thus compromise the sterile barrier.

S.6.4.1.2.2 Package labels

Package labels (e.g., process indicators, labels for product identification and lot number, expiration statement labels) should be capable of remaining securely affixed to packages throughout the course of their handling, from sterilization to use. If a marking pen is used to label plastic-peel pouches, the labeling information should be written only on the plastic side of the pouch. If a marking pen is used to label wrapped packs, basins, instruments, or other surgical supplies, the ink should be nontoxic, and the labeling information should be written on the indicator tape or affixed labels.

Rationale: Important identification information must not be lost during handling. Writing on the paper side of the pouch or on a wrapper could cause damage to the package (which might not be noticeable) and thereby compromise the barrier protection. Use of permanent markers with nontoxic materials and ink is recommended to avoid toxins being deposited on packages or instruments.

S.6.4.1.2.3 Package configurations

Before peel pouches are sealed, excess air should be removed so that the sealed seams will not be blown out during the sterilization process or by subsequent handling. If one peel pouch is to be placed inside another pouch, the pouches should be of appropriate size to avoid folding the inner pouch over onto itself to fit the outer pouch. The pouches should be positioned so that plastic faces plastic and paper faces paper. The pouches should allow for adequate air removal, humidification, and EO penetration and aeration. Instruments that must be EO sterilized because they might be damaged by steam sterilization should be placed in perforated or wire-mesh-bottomed trays or in specially designed containers, with all instruments held open and unlocked. Instruments that can be easily disassembled into component parts may be disassembled for sterilization. Individual instruments may be packaged in an acceptable packaging material, with the instrument prepared and positioned to ensure adequate EO contact with all surfaces.

Rationale: It is necessary to package and position items to be sterilized so as to facilitate contact with the sterilant.

S.6.4.2 Loading the sterilizer

S.6.4.2.1 Load composition

To the extent practical, the operator should attempt to sterilize full loads of items having a common aeration time.

Rationale: As compared to sterilizing the same volume in partial loads, sterilizing full loads of items having a common aeration time is cost-effective and reduces the potential for occupational exposure and for environmental release of EO.

S.6.4.2.2 Load configuration

Items should be placed loosely and well within the confines of the basket, shelf, or cart. Packaged items should not touch chamber walls.

Rationale: Overloading impedes proper air removal, humidification of the load, and sterilant penetration and evacuation.

S.6.4.3 Sterilization parameters

S.6.4.3.1 General considerations

In general, the most common parameters are EO concentrations from 450 to 1200 milligrams per liter (mg/L), temperatures from 37 ^{o}C to 63 ^{o}C (99 ^{o}F to 145 ^{o}F), exposure times from 60 to 360 minutes, and chamber humidities from 40 % to 80 %. Other cycle parameters may be used if available on an FDA-cleared sterilizer. The manufacturer must supply scientific evidence to support the suitability of the process for its stated use. The manufacturer's operating manual should be consulted for specific exposure times and temperatures.

Rationale: These general guidelines are based on Burgess and Reich (1997).

S.6.4.3.2 Sterilizer manufacturer's instructions

The sterilizer manufacturer's written instructions for cycle parameters should be followed. Programmed cycle selections should be used. Any differences between the programmed cycle parameters and the cycle parameters recommended by the medical device manufacturer should be investigated and resolved before the items are sterilized.

Rationale: Sterilizers vary in design and performance characteristics, so the cycle parameters should always be verified and the sterilizer manufacturer's instructions followed.

S.6.4.3.3 Device and packaging manufacturers' instructions

The sterilization instructions provided by the device manufacturer and the manufacturer of the packaging system (e.g., rigid sterilization container) should be compared to those provided by the sterilizer manufacturer. Any differences should be resolved to ensure an appropriate sterilization process.

Rationale: The design of some instruments and certain types of packaging can affect EO penetration, temperature and moisture equilibration, and exposure time.

S.7 Safely Unloading the sterilizer

S.7.1 Sterilizers with integral aeration

Modern EO sterilizers combine sterilization and aeration in the same chamber as a continuous process.

Rationale: When sterilization and aeration occur as sequential processes in the same chamber without interruption, potential occupational exposure to EO during door opening and load transfer is minimized. The efficiency and effectiveness of aeration is affected by load characteristics, temperature, and air-flow patterns and velocity. Altering any of these variables can affect the amount of aeration time required.

S.7.2 Aeration times

The aeration time necessary for a particular material or device depends on many variables, including:

a) the composition, thickness, design configuration, and weight of the device and its wrapping material or sterilization container system;

b) the characteristics of the sterilization system used (i.e., the temperature, EO concentration, and duration of exposure);

c) the characteristics of the aeration system used (i.e., the temperature, rate of air exchange, and air-flow pattern);

d) the size and arrangement of packages in the sterilizer–aerator or aeration cabinet and the number of highly EO-absorptive materials being aerated; and

e) the intended application of the device (i.e., external or implantable use), which will influence the level of EO residuals permissible.

Personnel should obtain an IFU from the device manufacturers and packaging suppliers to recommend aeration times and conditions for their products. Because of the many aeration process variables, it is not practical to recommend specific minimum aeration times here. As a guideline, however, it has been determined that a typical polymer that is difficult to aerate, polyvinylchloride (PVC) tubing, could require approximately 12 hours to aerate in an aeration cabinet at 50 °C (122 °F) and 8 hours at 60 °C (140 °F). Some materials will require less time; others will require much more time. (See Danielson, 1998; Stetson, et al., 1976; Whitbourne and Page, 1993; and Whitbourne, et al., 1997.)

Rationale: Manufacturers of sterilizers provide cycles with general sterilization parameters. Medical device manufacturers are responsible for providing the specific sterilization parameters necessary for the devices to be processed. The user needs to determine if the parameters required by the device to be processed can be met by the sterilizer.

S.8 Storage and handling of EO gas sources

S.8.1 Storage of unit-dose containers of 100% EO

The health care facility should consult the unit-dose container manufacturer to determine how many unit doses may be stored in the sterilizer area. In general, however, if each dose contains 50 or more grams of EO, then only one day's supply of cartridges, up to a maximum of 12 cartridges, should be stored in the immediate area of the sterilizer. If more than 48 cartridges are to be stored in one place in inventory, the area should be suitable for flammable liquid storage and should conform to NFPA 30.

Rationale: The recommendations of NFPA 30, which is the applicable national code on the storage of flammable liquids, deal with the storage of Class I flammable liquids (such as 100 % EO) inside office, educational, and institutional occupancies. Subsection 6.5.2 states: "The combined volume of Class I and Class II liquids stored in a single fire area outside of a storage cabinet or an inside liquid storage area not stored in safety cans shall not exceed 38 L (10 gal)." The NFPA recommendation permitting 10 gallons (32.8 kilograms [kg] of 100 % EO) concerns bulk storage. The AAMI committee considered it prudent to recommend that if more than 48 cartridges of 100 % EO (maximum weight, 6.4 kgs) are held in inventory, they should be stored in an area suitable for flammable liquid storage. Because health care facilities do not require large quantities of EO, the AAMI committee judged that adopting more stringent recommendations would decrease the hazard without causing hardship.

S.8.2 Disposal of unit-dose containers of 100 % EO

Empty unit-dose containers should be disposed of along with normal nonincinerated waste. Unused, outdated, or underweight unit-dose containers should be returned or disposed of in accordance with the manufacturer's instructions. If such containers are not to be returned to the manufacturer, the health care facility should contract with a licensed hazardous waste disposal company to dispose of the containers. The disposal company must comply with EO health and safety requirements and with applicable local regulations.

Rationale: Disposing of empty unit-dose containers with nonincinerated waste will prevent the incineration of full containers that might accidentally be discarded along with spent containers. Incinerating full containers is an explosion hazard. Unused, outdated, or underweight unit-dose containers likewise present a fire and explosion hazard if not disposed of properly.

S.9 EO leaks and spills

S.9.1 General considerations

The OSHA standard requires that each facility in which EO is used have a written emergency plan. In an emergency, appropriate sections of the plan must be followed. The plan must include procedures for alerting personnel (e.g., an alarm system), avoiding EO contact, evacuating and accounting for personnel, and reentering the area after the spill or leak. An alarm system (e.g., a hospital switchboard or an intercom system) is required for areas with more than 10 employees; the system may be audible, visible, or both. OSHA has specific requirements for the installation, maintenance, and testing of alarms. Direct voice communications can be used in areas with 10 or fewer employees, provided that all employees can hear the alarm; such workplaces need not have a backup system. Personnel entering a spill or leak area for corrective action must wear self-contained breathing apparatus approved for EO by NIOSH.

S.9.2 Emergency team

The health care facility should appoint an emergency team responsible for developing and executing written emergency response procedures for EO leaks and spills. This emergency team should consist of a representative of the facility's safety committee, a physician, an engineer, the sterile processing supervisor, and any other personnel deemed appropriate (e.g., local fire officials). The emergency response team must meet the training requirements specified in the OSHA Hazardous Waste Operations and Emergency Response Standard (29 CFR 1910.120).

Rationale: For a rapid, efficient response to emergency situations, it is important that specific individuals be assigned responsibility for developing and implementing procedures for handling EO leaks and spills. The composition of the emergency team should reflect all expertise relevant to the control of EO.

S.9.3 Emergency plan

The emergency team should prepare a written emergency plan consisting of at least the following elements:

a) a description of the alarm system and the procedures for its use, maintenance, and testing;

b) the procedures for evacuating and accounting for personnel in the event of a spill or leak;

c) the procedures for medically treating persons who have come into contact with liquid EO or who are overcome by EO vapors;

d) the procedures for reporting an emergency to appropriate authorities (e.g., the safety officer; local fire, health, and safety personnel; or representatives of the gas supplier or sterilizer manufacturer);

e) the procedures for hazardous material cleanup;

NOTE—A Safety Data Sheet must be obtained from the gas manufacturer or supplier.

f) the procedures for determining whether it is safe to reenter a spill or leak area;

g) a description of the employee training program;

h) the amount and location of EO used and stored in the health care facility;

i) the known rate of air exchange;

j) the potential for the general ventilation system to carry EO from the site of the EO leak or spill to other areas in the hospital, and a prescribed course of action to prevent the dispersal of EO to other areas;

k) procedures for assessing the risks and benefits of evacuating other departments in the event that EO is dispersed throughout the facility;

l) the recommendations of the sterilizer manufacturer for emergency procedures;

m) a description of the respiratory protection program, outlining the safe use, location, storage, fit testing, and periodical inspection of self-contained breathing apparatus and the procedures to be used for medical assessment of staff members required to use the apparatus (respirators and protective attire such as gloves and aprons must be readily accessible but stored away from areas where EO leaks or spills could occur); and

n) designation of the persons responsible for supervising the handling of EO leaks or spills.

Rationale: A well-designed plan of action, with which personnel are thoroughly familiar, will help reduce the potential adverse effects of an EO leak or spill. The plan should include information concerning the ventilation system so that appropriate evacuation decisions can be made. For example, in the case of a dedicated exhaust ventilation system that carries EO directly to the outside, it might not be necessary to evacuate the entire hospital if an EO leak or spill occurs. It is important that personal protective equipment be stored away from the EO sterilization processing area so that workers can reach it without exposing themselves to high EO concentrations caused by the leak or spill.

S.9.4 First aid

S.9.4.1 Liquid EO

Personnel who have come into contact with liquid EO should immediately remove contaminated clothing and shoes and thoroughly wash contaminated skin. In the case of eye contact with liquid EO, the eyes should be flushed with copious amounts of water for at least 15 minutes. Exposed personnel should be evaluated by a physician immediately after these emergency measures. Contaminated reusable clothing should be aerated and laundered before it is worn again, and rubber goods should be aerated before use. Contaminated leather shoes should be removed immediately and safely discarded. Disposable garments should be aerated and then discarded.

Rationale: Exposure to liquid EO can cause chemical burns or severe skin irritation. Flushing with water dilutes and removes the EO. Frostbite-like symptoms can also occur because of the rapid evaporation of EO from the skin surface. Liquid EO can also cause eye irritation and injury to the cornea. Prolonged flushing with water can also damage the eyes, however, so caution should be exercised.

S.9.4.2 EO gas

Personnel who have inadvertently inhaled EO gas should be moved immediately to fresh air. If breathing is difficult, oxygen should be administered. Such personnel should see a physician as soon as possible. In severe cases, cardiopulmonary resuscitation could be necessary to restore breathing, after which oxygen should be administered.

S.10 Quality control

S.10.1 EO sterilization qualification testing

EO sterilizers are qualified prior to use. Follow the sterilizer manufacturers recommended procedures for qualification.

In the previous ST41 the construction and use of a EO challenge BI test pack was described and retained here for reference.

The PCD (challenge BI test pack) should contain the items described below (see also Figures S.2 and S.3). These materials are intended to challenge all of the parameters necessary for EO sterilization. The fact that these materials are recommended for use as test pack components does not mean that these types of materials, in themselves, should be sterilized by EO. Most of the recommended materials are heat stable and are steam sterilized for use in patient care. Some of the recommended components are disposable items and are not recommended for reprocessing and reuse in patient care.

The components of the challenge BI test pack are:

a) four clean, approximately 18-inch by 30-inch, reusable, freshly laundered, preconditioned surgical towels (woven, 100 % cotton absorbent), each folded in thirds and then in half to create six layers per towel and then stacked one on top of another (Figure S.4);

NOTE Before being assembled in the pack, the towels should not be ironed, and they should not have been taken directly from the dryer. See below for humidity recommendations.

b) two BIs, each of which is placed in a separate plastic syringe of sufficient size that the plunger diaphragm does not touch the biological indicator when the plunger is inserted into the barrel of the syringe (Figure S.2). The BIs should not be removed from the protective covering supplied by the manufacturer. The instructions of the BI manufacturer should be consulted to ensure that the BI selected is appropriate for use in the specific sterilizer being challenged. The correct orientation of the BI in the syringe ensures that any vent in the BI faces toward the needle end of the syringe. (Paper strip BIs may be used in any orientation.) The needle end of the syringe should be open (i.e., the tip guard should be removed);

NOTE Syringes to be used in patient care or laboratory applications are not customarily sterilized with the plunger inserted into the barrel.

c) one adult plastic airway (Figure S.3);

d) one 10-inch-long section of latex tubing with an internal diameter of 3/16 inch and a wall thickness of 1/16 inch (Figure S.3);

NOTE PVC tubing may be used if latex tubing is not available, because it provides an aeration challenge similar to that of latex tubing (World Health Organization, 1985; Nakata, et al., 2000).

e) a CI; and

f) two clean, approximately 24-inch by 24-inch wrappers, either woven or nonwoven (Figure S.3).

Before assembly, the test pack components should be held at room temperature (18 °C to 24 °C [65 °F to 75 °F]) and a relative humidity of at least 35 % for a minimum of 2 hours. If the towels are inadvertently ironed, stored in an area in which the relative humidity is lower than 30 %, or otherwise dried out, the minimum temperature and humidity equilibration time should be extended to 24 hours.

NOTE 1 Although the recommended humidity range for all work areas is 30 % to 60 %, the ideal relative humidity in processing areas is 50 % and should not be less than 35 % for best results in achieving sterilization.

For assembly of the test pack, the syringes, latex tubing, plastic airway, and CI are placed between the folded cotton towels in the center of the stack (Figure S.4). The stack is then double-wrapped and secured with tape.

NOTE 2 Commercially available test packs for routine biological monitoring should not be used for qualification testing unless the manufacturer's specifications indicate that the commercial test pack has been validated against the PCD (challenge BI test pack).

Rationale: This PCD (challenge BI test pack) is designed to challenge all of the parameters on which EO sterilization depends. The towels and wrappers act as moisture and EO absorbents and provide a barrier to heat transfer, as do the syringe bodies; the rubber and plastics act as EO absorbents; the plastic syringes with barrels are EO absorbents and penetration challenges; and the BIs are a microbial challenge. Placing the BIs in the center of the pack challenges the heating, humidification, and gas diffusion characteristics of the sterilizer.

The towels for the test pack, together with the other components, are intended to create a somewhat greater challenge to the sterilizer than does the load itself. The pack is intentionally composed of materials that are readily available to both manufacturers and health care facilities (e.g., absorbent towels, plastic devices). The use of items such as surgical towels to serve as heat sinks and moisture absorbers should not be construed as a recommendation that towels be routinely sterilized by EO. The same is true of the disposable materials, which are used only for test purposes. These items provide the challenges described, yet avoid the need to reserve expensive and limited inventory materials specifically for use in sterilization test packs.

NOTE 3 Under no circumstances should single-use items previously used in patient care be used as components of the test pack.

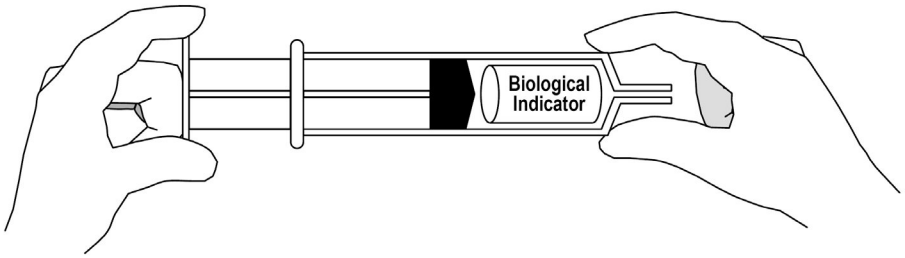

Figure S.2—Placement of BI in syringe

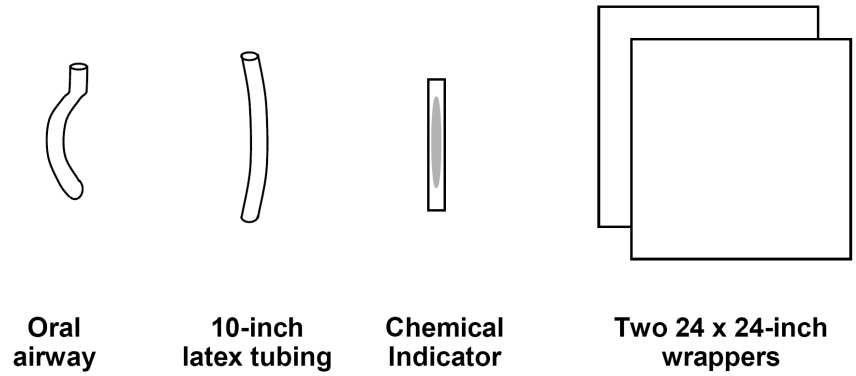

Figure S.3—Some components of the PCD (challenge BI test pack)

NOTE 4 PVC tubing may be used if latex tubing is not available, because it provides an aeration challenge similar to that of latex tubing (World Health Organization, 1985; Nakata, et al., 2000).

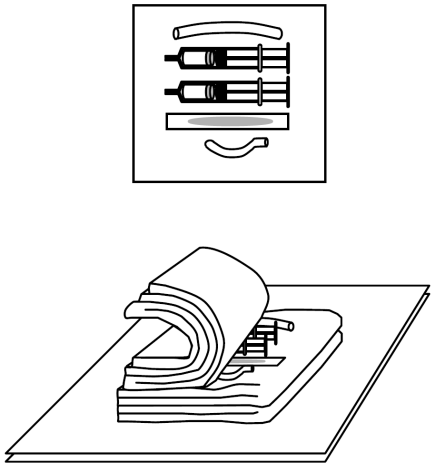

Figure S.4—Placement of components in PCD (challenge BI test pack)

S.10.2 Simulated load and placement of the PCDs (challenge BI test packs)

The test cycles are run in a simulated load which is made up of PCDs without BIs. Table 3 defines the number of PCDs to be used for simulated loads in various sizes of sterilizers. Each qualification load will contain one PCD that includes a BI and remainder of the PCD in the load do not contain a BI. The number of PCDs is based on the chamber volume as shown in Table S.2.

Table S.2—Simulated loads

Sterilizer volume (cubic feet)[1]	Number of PCDs containing BIs	Total number of PCDs (including those containing BIs)
4	1	4
5	1	5
8.8	1	7

NOTE 1 For any other sterilizer size, at least 10 % of its volume should be filled with PCDs to make up a simulated load.

NOTE 2 Chamber volume in cubic feet can be calculated by multiplying chamber height in inches by chamber length in inches by chamber width in inches and then dividing the resulting value by 1,728 (the number of cubic inches in a cubic foot). For example, a sterilizer having a 24- by 36- by 48-inch chamber has a chamber volume of 24 cubic feet.

For EO sterilizers with chamber volumes of less than 16 cubic feet, *one* PCD is used, and it is placed in the front of the chamber near the door (Figure 7d).

Rationale: These locations for the PCDs are likely to be the areas of the chamber where it is most difficult to sterilize products. The sterility of the load could be compromised by stratification of the sterilant gas and air and by variations in the temperature distribution throughout the load.

S.10.2.1 EO sterilization qualification testing

Table S.3 provides the number of qualification testing runs and simulated load information based on the reason for qualification.

Table S.3—Qualification testing

Qualification testing after malfunction / cycle failure resulting in major repair	Qualification test after installation, relocation, or facility major redesign
Physical monitoring of cycle	Physical monitoring of the cycles
Test three consecutive cycles with one or more PCDs containing a BI and a CI (the routine test pack of 8.3) in a load similar in composition and density to the load exhibiting the sterilization process failure. If items in the test load are to be used in patient care, the load should be quarantined until the BI results are known.	Test three consecutive cycles with one or more PCDs containing a BI and a CI (the challenge test pack of 8.3) in a simulated load2

S.10.3 Routine sterilizer efficacy monitoring

See section 8.6.1 and Table 3 for recommendations for routine sterilizer efficacy monitoring for EO processes.

S.10.3.1 Composition of an alternative(user assembled) EO PCD (routine BI test pack)

The PCD (routine BI test pack) should be made up as follows:

a) One BI should be placed in a plastic syringe of sufficient size that the plunger diaphragm does not touch the BI when the plunger is inserted into the barrel of the syringe (Figure S.2,S.3 and S.4). The BI should not be removed from the protective covering supplied by the manufacturer. The instructions of the BI manufacturer

should be consulted to ensure that the BI selected is appropriate for use in the specific sterilizer being monitored. The correct orientation of the BI in the syringe ensures that any vent in the BI faces toward the needle end of the syringe. (Paper strip BIs may be used in any orientation.) The needle end of the syringe should be open (i.e., the tip guard should be removed).

NOTE Syringes to be used in patient care or laboratory applications are not customarily sterilized with the plunger inserted in the barrel.

b) The syringe and a CI should be placed in the folds of a clean, freshly laundered, preconditioned surgical towel (woven, 100 % cotton huck, 18 inches by 30 inches, see ST65), which has been folded lengthwise into thirds and then in thirds again to create nine layers (Figure S.2,S.3 and S.4).

c) These items should be placed in one peel pouch or one woven or nonwoven wrapper large enough to contain the test pack components and typical of that customarily used in the health care facility (Figure S.2,S.3 and S.4).

d) Before assembly, the test pack components should be held at room temperature (18 °C to 24 °C [65 °F to 75 °F]) and at a relative humidity of at least 35 % for at least 2 hours. If the towel is inadvertently ironed, stored in an area in which the relative humidity is lower than 30 %, or otherwise dried out, the minimum temperature and humidity equilibration time should be extended to 24 hours.

Rationale: This routine BI PCD presents a validated challenge to an EO process. The plastic syringe acts as an EO absorbent and penetration challenge. The BI represents a microbial challenge to the sterilization process. The towel absorbs heat and moisture. Placing the syringe within the folds of the towel presents the greatest challenge. This PCD (routine BI test pack) is not designed to represent as severe a challenge as the PCD (challenge BI test pack) of 8.3. It is presented as a simplified, alternative test pack that will facilitate more frequent monitoring of sterilization loads. See also S.10.4, which describes the round-robin testing that was performed to quantify the resistance of the routine BI test pack.

S.10.3.2 Placement of the EO PCD (routine BI test pack)

Only one PCD is used, regardless of sterilizer chamber size, and it is placed in the area of the chamber and load that is considered to be least favorable to sterilization (usually the center of the load unless otherwise indicated by the sterilizer manufacturer).

NOTE 1 In small sterilizers, where load configuration does not permit placement of the routine BI test pack in the center of the load, the front portion of the sterilizer can be used.

Rationale: The center of the load is considered to be the most difficult to sterilize location in a (loaded) EO sterilizer because that location presents the greatest challenge to penetration of humidity and EO gas and because it generally takes the longest time to reach the desired temperature in that location.

NOTE 2 The BI is placed in the syringe according to the BI manufacturer's instructions. The correct orientation of the BI in the syringe ensures that any vent in the BI faces toward the needle end of the syringe. Paper strip BIs can be used in any orientation.

NOTE 3 CIs are placed in the folds of the towel.

S.10.3.3 Test procedure

The test procedure is as follows:

a) The PCD should be assembled at the same time as the load to be EO sterilized.

b) Before being exposed to the sterilization cycle, the PCD should be labeled with appropriate sterilizer lot and load information.

c) The sterilization cycle should be run according to the sterilizer manufacturer's instructions.

d) On completion of the cycle, the BI and other components of the pack should be handled according to the health care facility's protocol for minimizing worker exposure to EO.

e) For each test BI that is run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control to verify the presterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the proper incubation temperature. On completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are nonviable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the test repeated.

NOTE If several test BIs from the same lot are run on the same day, only one control BI from that lot need be used.

S.10.4 Round-robin study of the PCD (routine BI test pack)

S.10.4.1 Introduction

The PCDs (routine BI test packs and challenge BI test packs) of S.#.# was originally recommended in *Good Hospital Practice: Performance Evaluation of Ethylene Oxide Sterilizers—Ethylene Oxide Test Packs* (AAMI 1985). These packs were designed on the basis of the scientific experience and professional judgment of the members of the AAMI Ethylene Oxide Sterilization Hospital Practices Working Group.

In the course of preparing a revised and expanded edition of AAMI (1985), the Working Group decided to sponsor a round-robin study to evaluate the resistance of the test pack recommended for routine monitoring of EO sterilizer performance (S.#.#). Annex A of AAMI (1985) describes the methods used in the round-robin study and the test results. This work was also reported in Hart, et al. (1993).

Because of its makeup, the PCD (challenge BI test pack) of S.#.# offers substantially more resistance than the PCD (routine BI test pack) of S.#.#. However, the resistance of the PCD of S.#.# has not been quantified.

S.10.5 Materials and methods

S.10.5.1 Test strategy

The general test strategy of the round-robin study was to compare the resistance of the PCD (routine BI test pack) containing a BI to that of a BI *not* contained within a test pack. Three types of self-contained BIs were studied (Assert™ Biological Indicator No. 001500, Attest™ Biological Indicator No. 1264, and Proof Plus™ Biological/Chemical Indicator No. NA 052) and one type of spore strip (Castle® Tec-Test Biological Culturing System). All laboratories used BIs from the same lots.

S.10.5.2 Test laboratories

Five laboratories participated in the study: American Sterilizer Company, MDT Corporation, Sterilization Technical Services, 3M Health Care, and Weck Instruments.

S.10.5.3 Sterilization equipment

All laboratories used BIER (biological indicator-evaluator resistometer) EO exposure vessels complying with AAMI (1982) and providing the following constant sterilization cycle parameters: 600 ± 30 mg/L EO, 54 °C ± 1 °C, 60 % ± 10 % relative humidity. (A BIER EO gas vessel is a test chamber that, unlike a commercial sterilizer, allows control and monitoring of all critical cycle parameters during the exposure phase: gas concentration, temperature, relative humidity, and time.)

S.10.5.4 Test pack components and assembly

Each test pack used in the study consisted of a 20-ml plastic syringe with diaphragm and plunger (but no needle or needle guard), a 7-inch by 13-inch paper–plastic pouch, one 100 % cotton surgical towel (18 inches ± 1 inch × 30 inches ± 1 inch), and two BIs (one placed inside the syringe and the other attached with EO indicator tape to the outside of the test pack). Before the test pack was assembled, the test pack components were preconditioned at 18 °C to 24 °C (65 °F to 75 °F) and at a relative humidity of 60 % ± 15 % for 2 to 24 hours.

The test packs were assembled in accordance with 10.7.2. One BI was placed inside the syringe, and the syringe was placed in the center of the folds of the surgical towel. (The Assert™ and Proof Plus™ BIs were oriented so that their caps were next to the tip of the syringe. The spore strips in glassine envelopes were placed in the syringe.) The other

BI was attached with EO indicator tape to the upper corner of the test pack closest to the tip of the syringe, which was pointed toward the rear of the BIER vessel.

S.10.5.5 Exposure conditions

Each test cycle was run in the following manner:

a) A prevacuum was drawn to evacuate the vessel to 1.00 PSIA (pounds per square inch absolute).

b) The load was prehumidified to 60 % ± 10 % relative humidity for 30 minutes. The vacuum was increased to 2.11 to 2.55 PSIA.

c) The vessel was operated at 54 °C ± 1 °C.

d) The chamber fan was turned off during the cycle.

e) The chamber was charged with 12/88 sterilant by increasing the pressure differential by 19.7 ± 1.0 PSIA to provide a gas concentration of 600 ± 30 mg/L EO.

f) Each cycle was replicated three times for each of the following exposure times: 10, 20, 30, 40, 50, 70, and 80 minutes.

g) Six post vacuum pulses or a 5- to 10-minute post cycle vacuum were drawn.

S.10.5.6 Test procedure

The test procedure was as follows:

a) The test pack materials were preconditioned and assembled in accordance with H.2.4.

b) A “dummy” cycle was run as per H.2.5 except for a 5-minute prehumidification time and a 5-minute exposure time.

c) The chamber was loaded with four test packs, each containing a different type of BI. The packs were positioned vertically, with the outside-of-test-pack BIs located at the upper rear of the vessel. The pouch surfaces were oriented paper to paper.

d) At the end of the cycle, the test packs were removed from the chamber and placed in a chemical or laminar-flow hood. The BIs were immediately removed from the test packs and aerated at room temperature for 30 to 45 minutes.

e) Within 2 hours of the end of the aeration cycle, the BIs were activated and cultured in accordance with the manufacturers’ instructions at 36 °C ± 1 °C. The self-contained BIs were incubated for 48 hours, and the spore strips were incubated for 5 days.

S.10.5.7 Data collected

For each of the seven test cycles (each of which was replicated three times), the number of surviving BIs (positives) and the number of killed BIs (negatives) were recorded.

S.10.6 Results

The results of the study, summarized in Table S.4, show the mean kill time for each type of BI according to whether it was inside the test pack or outside the test pack. Statistical analysis of these data revealed that the mean kill time for the BIs inside the test pack was significantly greater than for BIs outside the test pack, demonstrating that the test pack indeed offers substantial resistance to the sterilization process.

Table S.4—Mean kill times (minutes) and standard deviations for BIs inside the test pack vs. outside the test pack

Biological indicator	Outside test pack	Inside test pack
1	19.0 ± 4.0	31.3 ± 9.7
2	26.7 ± 5.5	43.3 ± 9.9
3	26.0 ± 5.6	42.3 ± 9.0
4	26.7 ± 5.5	49.3 ± 11.4
Overall	24.6 ± 6.1	41.6 ± 11.9

S.11 Environmental and employee monitoring

S.11.1 General rationale

To ensure a safe work environment and to establish compliance with federally mandated limits and voluntary guidelines on occupational exposure to EO, actual EO concentrations must be measured in the workplace during and after the use of sterilization equipment. Determinations of 8-hour TWAs and of 15-minute excursion levels within the breathing zone of each employee are required to verify compliance with the OSHA standard. If EO levels in employee breathing zones (EBZs) are shown to be lower than the 0.5-ppm TWA "action level" defined by OSHA, some of the requirements of the OSHA standard do not apply to the health care facility. Many air sampling and monitoring techniques are currently in use. Data are available on the relative effectiveness and benefit–cost ratio of some of the methods and programs available for EO monitoring in the hospital work environment (see Annex J). However, the recommendations of this section are only guidelines; the health care facility must obtain from the manufacturer of the EO monitoring equipment a description of the sampling and monitoring methods as well as evidence that they comply with OSHA accuracy standards. Monitoring technology continues to evolve, and it is incumbent on personnel to keep abreast of the latest developments.

S.11.2 Instrumentation

S.11.2.1 Selection of monitoring methods

Some EO monitoring methods must be supervised by a technically qualified person trained in air sampling strategies and monitoring techniques. Other monitoring methods are less complex and, with instructions available from the manufacturer, personnel can reliably use them to monitor the workplace. The monitoring method chosen will depend on the frequency of EO use; the level of monitoring needed; the type of monitoring needed (e.g., employee monitoring with or without area monitoring); and the availability of sampling and analytical instrumentation, as well as on whether the health care facility chooses to initiate its own monitoring program or to use an outside service. Another consideration is the interpretation of monitoring data for assessment of worker safety. Because of these complexities, personnel should seek the advice of an industrial hygienist or other qualified professional when designing a monitoring program.

Rationale: Health care facilities vary in financial and technical resources and in the volume of EO sterilization processing; no single monitoring method is best for all facilities. Some EO monitoring techniques and procedures involve a considerable amount of time, effort, cost, and data analysis. The relationship between the costs and benefits of sampling should be carefully considered without losing sight of the ultimate goal: a safe and healthful workplace for sterilizer equipment operators and other personnel.

S.11.2.2 Reliability and use of instrumentation

The instructions for use provided by the monitoring equipment and sampling apparatus manufacturers should be followed. Information on the accuracy, reproducibility, and reliability of the instrumentation is also necessary. In particular, monitoring instrumentation and methods must be proven capable of accurately and reproducibly determining EO concentrations in the range of (and below) the OSHA limit on occupational exposure. When reviewing any EO monitoring equipment, the user should determine that components and other characteristics of workroom air (e.g., inert

diluents, water vapor, solvent vapors, and temperature variations) will not interfere with the instrument's ability to accurately measure the EO concentration.

Rationale: The OSHA standard requires that employee monitoring devices be accurate, with a confidence level of 95 %, to within 25 % for airborne concentration of EO at the 1-ppm TWA and to within 35 % at the 0.5-ppm TWA action level or the 5-ppm EL. The manufacturer is the best source of information on the performance characteristics of monitoring equipment, and the manufacturer's instructions for use should be followed to ensure proper operation of the equipment and accurate results.

S.11.3 Procedures

S.11.3.1 Monitoring sites

Sampling should be conducted in all work areas in which workers might be exposed to EO. The EO sterilizer area should be monitored, as well as the breathing zone of each employee directly involved in the sterilization process. Monitoring should be conducted during sterilizer operation and use, not during simulated sterilization runs with less-than-normal loads.

Rationale: Monitoring should yield a meaningful description of the EO concentration in the workplace. Although OSHA requires that at least representative monitoring (the monitoring of representatives of each job classification) be done, the AAMI committee judged that more rigorous sampling is necessary to define the exposure potential of the workplace and to ensure the protection of sterilizer operators and other employees at high risk of exposure.

S.11.3.2 Frequency of monitoring

Monitoring should be performed initially upon establishing the monitoring program and periodically thereafter. According to the OSHA standard, if the initial monitoring indicates employee exposures above the 1-ppm 8-hour TWA or the 5-ppm 15-minute EL, then each such employee should be monitored at least quarterly and more often, as needed. If the initial monitoring indicates employee exposures that are above the 0.5-ppm action level but below the 1-ppm 8-hour TWA, then each such employee should be monitored semiannually. Monitoring may be discontinued or the frequency of monitoring reduced if two consecutive measures, taken at least 7 days apart, indicate that employee exposures are below the 0.5-ppm action level and the 5-ppm EL. Monitoring must be resumed when there are changes to processes, equipment, employees, or work practices that might result in new EO exposures; monitoring may be discontinued when the employer can again document, twice consecutively 7 days apart, that employee exposures are less than the action level and the EL.

Monitoring should also be conducted on installation of new or replacement EO sterilizers or emission control systems and on major modifications of the ventilation system.

NOTE When a small quantity of EO is being used (less than 15 grams in any one day) and when a worst-case determination has been made that the OSHA standard will not be exceeded, consideration can be given to relaxing these monitoring frequency recommendations. This exception is based on the assumption that the room volume and room ventilation are sufficient to rapidly dissipate the EO released during processing by small sterilizers. If this is not the case, such sterilizers must be operated only inside functional exhaust ventilation hoods connected to the outside through either a dedicated or a nonrecirculating system.

Rationale: Initial monitoring to determine EO levels in the EBZ is required by OSHA unless monitoring after June 15, 1983, revealed EO levels below the action level of 0.5-ppm TWA. (OSHA exempts health care facilities from much of its standard if the action level and the EL are not exceeded in the work environment.) For sterilizing systems that use small quantities of EO, monitoring is not required by OSHA if data are available (e.g., from the manufacturer) demonstrating that the highest possible release of EO from the sterilizer and from EO storage areas would result in airborne concentrations lower than the action level. These and the other OSHA requirements described in this section are part of a minimum standard intended for all facilities in which EO is manufactured or used. Continued documentation of employee exposures may require more frequent routine monitoring. Frequent monitoring helps ensure that ambient EO concentrations are at or below the limits established by regulation and will help detect.

S.11.3.3 Short-term exposures

Personnel should determine exposure levels during short periods of time when airborne EO concentrations could be particularly high for example when the sterilizer door is open at the completion of the cycle. Short-term exposure levels

should be calculated when the sterilization equipment is installed, after any major repairs, after changes in the ventilation system, and after any changes in work practices (including the assignment of a new employee in a potential EO exposure area). Short-term exposure levels must not exceed the OSHA EL of 5 ppm, measured over a 15-minute exposure period.

Rationale: Calculating short-term exposure levels is useful for developing ventilation strategies and evaluating work practices and, hence, for preventing excessive employee exposure to EO. Since 1988, health care facilities have been required to comply with OSHA's EL.

S.11.4 Record keeping

Environmental and EBZ monitoring must be documented, and records maintained in the department files or another designated location. The documentation must include at least the following information:

a) the name and qualifications of the person or organization that conducted the monitoring;

b) the date the survey was made;

c) the sampling or analytical method used;

d) the test protocol and instrumentation, including evidence of method accuracy;

e) the ventilation system characteristics at the time of sampling;

f) the results (locations and measured EO concentrations); and

g) any recommendations for corrective actions.

See also the OSHA standard (29 CFR 1910.1047[k][2]).

Employees must be notified of their personal monitoring results within 15 days of when the monitoring report is available, and a copy of the monitoring records must be kept in each employee's file. In accordance with the OSHA standard, these records must be maintained by the health care facility for the duration of employment and for at least 30 years thereafter. If EBZ monitoring shows EO levels exceeding the PEL or EL, corrective actions must be taken and documented, as required by OSHA. The results of environmental monitoring should be posted in an area that is readily accessible to employees.

Rationale: Good record keeping enables the health care facility to establish a continuous history of the work environment. Records of monitoring results are also required by OSHA. If environmental monitoring results are posted, workers will know that potentially dangerous concentrations of EO could exist in the workplace, and the importance of proper work practices will be reinforced. If the posted results show that all areas and occupations are below the action level, employees will be encouraged to continue the safe practices that made this possible.

S.12 Selecting equipment or services for monitoring airborne ethylene oxide at an EO sterilization facility

S.12.1 Introduction

There are two applications for EO monitoring, with different requirements and equipment. The first application is for occupational safety, which is the focus of this Annex. The second is for emissions control, which will not be addressed here.

This annex was developed to assist personnel in selecting equipment or services for measuring airborne EO in the workplace and for assessing worker exposure to airborne EO. It is intended to (a) help users understand the conceptual approaches that can be used to monitor airborne EO concentrations or worker exposure to EO, (b) describe most of the kinds of EO monitoring equipment and services currently available, and (c) summarize the advantages and disadvantages of the available equipment and services.

Most experts would agree that an ideal EO monitor for a healthcare facility using EO sterilization would meet the following specifications:

a) It would accurately measure airborne EO with a precision of less than 0.17 ppm.

b) It would be specific for EO, with no response from other gases or vapors.

c) It will continuously monitor for EO and provide warnings in real time if the EO concentration exceeds alarm threshold limits.

d) It would be reliable and inexpensive to own and operate.

e) It could be used to detect leaks as well as to determine worker EO exposure levels.

f) It would be easy to use, requiring minimal technical ability on the part of the operator.

g) It will provide a record of past exposures.

There are many options available for monitoring EO. Facilities should review the specifications from the gas monitor manufacturers with the above list to find the product that best suits their requirements. All managers of locations in which EO is used have a clearly defined legal requirement to monitor and minimize worker exposure to EO.

S.12.2 General approaches to EO environmental and personnel monitoring

S.12.2.1 Personnel monitoring

Two general types of monitoring are performed in facilities in which EO is used: personnel monitoring and area monitoring. Personnel monitoring is performed to determine the concentration of airborne contaminants in the EBZ, providing a measure of the concentration of EO inhaled during that time. The results are expressed as a TWA concentration. The time periods selected are usually either the individual's full work shift, to measure an 8-hour TWA, or short intervals during process-related tasks, to measure EO excursion levels. The OSHA permissible exposure limits (PELs) are similarly expressed as TWAs, namely an Excursion Limit which is a 15 minutes TWA and an 8-hour TWA PEL based on personnel monitoring.

There are three main types of personal monitor. The first type is a passive device, such as a badge, which collects EO over the sampling period and then requires subsequent analysis to get the result. The second type, often employed by industrial hygienists is more accurate and comprises a sample collection using a pump which draws the EO through an absorbent medium for later analysis. The third type of personal monitor is an electronic instrument with an EO sensor which can give the EO concentration, and usually the TWA values update continuously in real time.

A significant disadvantage of the personnel sampling methods that require laboratory analysis is that the results of the sampling cannot be obtained until sometime after the sampling has been performed. For example, if a worker is exposed to a high concentration of EO (e.g., because of an unknown leak, a failure in the ventilation system, or poor work practices), the worker has no way of knowing about the high EO concentration until after the results are received from the analytical laboratory. This time delay could range from several days to several weeks after the sampling period. However, some passive personnel monitors can be developed on-site (e.g., in the health care facility) to provide more rapid test results.

Another limitation of non-instrumental personnel monitoring devices is that the results usually only indicate an average concentration over time and therefore do not yield information about concentration variations within specific segments of the sampling period. For example, a low TWA concentration could actually be the result of a very high short-term exposure with little or no exposure during the remainder of the sampling period. Electronic EO instruments provide a real time reading of the EO concentration and will typically give an alarm if the concentration gets too high enabling the user to avoid excessive exposure to EO.

S.12.2.2 Area monitoring

Area monitoring is performed to determine the general (i.e., environmental) concentration of airborne contaminants in a prescribed space or area. There might or might not be personnel in the area monitored, and the concentration of airborne contaminant measured might not be the concentration of contaminant actually inhaled by personnel if they are present. Some area monitors are electronic devices or electronically controlled devices that measure, more or less instantaneously, the EO present at the sampling points of the device. Such area monitors may also provide a continuous record of EO concentrations, thus enabling analysis of any change in concentration. In addition, records of

unacceptable area EO concentrations can be seen, thereby allowing remedial action before an employee returns to. For example, the EO release times may coincide with a particular stage during the sterilization cycle, facilitating fault identification and correction.

Area monitoring can also be performed using “grab sampling” techniques. In grab sampling, the air containing the suspected contaminant is sampled by rapidly pumping a representative portion of air into an EO impervious bag that contains a sealing valve. The air sample thus “grabbed” can be analyzed immediately to determine the concentration of impurity, or it can be sent to a laboratory for analysis.

Some area monitors use only a single sampling point; hence, the EO concentration will be measured at that point only, other are systems with multiple measuring/sampling points which connect back to a central computer/controller. Other devices incorporate a multipoint sampling apparatus that draws samples of air into the instrument successive times from several points, some multipoint samplers are able to collect samples from 20 or more points. For multipoint sampling systems with a single detector, there is a tradeoff between the number of sampling points and the time needed between readings at a particular location.

The price for such equipment usually increases as the sample point capability increases. Some area monitoring equipment can be used to measure more than one sterilant gas (e.g., hydrogen peroxide as well as EO on the same system), although not necessarily at the same time in the same place. Selecting this type of equipment could therefore satisfy two or more needs.

The disadvantage of area monitoring equipment is that the measured concentration does not necessarily represent personnel exposure and might not be a time-weighted average. However, the advantage of area monitors that provide real time readings is that they are normally placed close to potential leak locations, and so can provide a warning of high EO concentrations in the air before anyone is exposed, by for example providing an alert of a high EO concentration warning personnel not to enter that area until the concentration returns to safe levels.

S.12.3 Area and personnel monitoring devices

S.12.3.1 General considerations

The key technologies used for the detection of EO in healthcare are discussed below. For each type of equipment, the following topics are addressed:

a) *Principle of operation:* The manner in which the equipment detects or indicates EO concentration is briefly described.

b) *Portability and application:* A brief statement indicates whether the equipment can be routinely moved about the workplace or whether it needs to remain static in use.

c) *Ease of operation:* The ease with which the equipment can be used is characterized in two categories: “preparation and use” and “data collection.”

   — “Preparation and use” describes the complexities involved in preparing the equipment for use (e.g., calibration, special training requirements, sampler conditioning) and in actually using the device. “Data collection” describes the complexities involved in determining the test results (ppm EO).

   — In these two categories, each type of equipment is rated as simple, moderate, or difficult. *Simple:* The instructions provided by the equipment supplier are generally adequate for any user. *Moderate:* One or more aspects of the equipment require that the user receive in-service or other special training. *Difficult:* One or more aspects of the equipment require the skills of an individual with special expertise, such as a technician or scientist, who has been trained or has the qualifications to be trained in the proper use of the equipment.

   — As an example, some passive sampling devices require little or no preparation to use, and their actual use involves nothing more than clipping the device in place. Determining the results of such monitoring, however, sometimes requires relatively complex extraction and analysis techniques. Hence, this type of device would be rated simple in the category of preparation and use, but difficult in the category of data collection.

d) *Accuracy:* Accuracy (the difference between the measured concentration of EO and the true EO concentration) is likely to vary among device types within a given generic category of measuring device. The accuracy characterizations listed here are broad because they apply to generic categories.

e) *EO specificity:* Some equipment will measure the presence of air components other than EO; that is, it is not specific to EO. General comments are made for each type of monitor.

f) *Lower detectable limit for EO:* The lower detectable limit listed is the lowest measurable concentration of EO claimed by the equipment manufacturer. AAMI has not verified the validity of this information, nor does AAMI endorse such claims. The lower detectable limits are presented as a point of reference only, to aid the user in selecting equipment or methods of analysis. The user should require the supplier to document claims regarding detection limits.

The cost of various monitoring technologies is not addressed here because of the many variables involved, such as available options and accessories, degree of automation, and maintenance cost.

S.12.3.1.1 Applications

Some technologies are only suitable for use as area monitors, whereas others can be used for both area monitoring and personal monitoring. This typically depends on the size, weight of the detector and support apparatus needed. For example, if engineering controls have just been installed in an area where EO vapors had been escaping into the workplace, the use of a personnel monitoring device carefully placed near the new equipment could measure ambient EO concentrations in that area while employees are not present.

S.12.3.2 Detection technologies

Gas detection technologies fall into two groups. The first group are the more traditional chemical methods in which the EtO is collected and analyzed by a laboratory or by chemical reaction to give a color change. The second group are instrumental methods.

S.12.3.2.1 Chemical methods for the detection of EO

The key feature of these chemical methods for EO is that they are single use. The device may collect EO over time to give a time weighted average reading, but once the EO is collected the sample must be analyzed. Similarly, gas detection tubes are used once, and then must be replaced before another reading can be taken.

S.12.3.2.1.1 Activated carbon tubes

Principle of operation: In this technique, a small, portable, battery-powered suction pump (usually clipped to the worker's belt) is connected via plastic tubing to a glass tube packed with a special type of activated or hydrogen-bromide (HBR) treated carbon. The pump draws a known volume of air through the glass tube, and the contaminants (including EO) are adsorbed or chemically derivatized (i.e. converted to another stable chemical) by the activated carbon. By clipping the glass tube to the lapel of the worker's shirt or blouse, the user can collect EBZ samples.

The worker usually wears this equipment throughout the workday or during short-duration, process-related tasks when excursion levels warrant monitoring.

At the end of the sampling period, the tubes are sealed and sent to a laboratory for analysis. At the laboratory, the activated is removed from the glass tubes and treated with a solvent that desorbs the EO from the carbon. The EO-solvent mixture is then analyzed by gas chromatography to determine the overall amount of EO adsorbed or chemically derivatized during the sampling period. Knowing the duration of the sampling period, the volume of air drawn through the activated carbon tube, and the amount of EO adsorbed allows calculation of a TWA EO value.

The desorption process and analytical technique are complex and should be attempted only by laboratories with experienced analytical chemists or technicians.

Activated-carbon-type tubes to be analyzed by a service laboratory should be packed in dry ice and preferably shipped via overnight mail. These requirements obviously affect the overall cost of such a system. (Several days' worth of tubes can be collected, stored in a refrigerated environment, and shipped together. The service laboratory should be

consulted on this point.) Because of the expense, activated carbon tubes are rarely used by sterilizer operators, but are commonly used by industrial hygienists.

Portability: Completely portable, and so used for personal monitoring. Can be used for area monitoring for short term exposures (hours), but tube needs to be replaced after reach run, and so this method is not suitable for long-term area monitoring.

Ease of operation:

Preparation and use: moderate to difficult.

Data collection: difficult.

Accuracy: Variable, depending mainly on the ability of the analyst and the accuracy of calibration.

EO specificity: Specific to EO.

Lower detectable limit for EO: Levels as low as 0.1 ppm for activated carbon.

Other comments: Portable pumps should have a feature that allows the user to detect whether the pump stopped functioning during the collection of samples (as might occur, for instance, if the battery failed). Pumps must be calibrated before and after each use. (As batteries run down, the rate of air flow might change.) The pump supplier should be asked about the expected life of the pump and batteries; all types of pumps contain parts that will eventually wear out.

Blank and control samples must also be collected. The analytical laboratory should be consulted about the proper techniques for blank and control sampling.

The user should verify that the activated carbon has been treated such that it is intended for EO collection. (Most types of activated carbon are poor adsorbents for EO, especially in high humidity.) The tube supplier should also be required to provide written documentation of the requirements for activated carbon refrigeration and, for accurate results, the maximum length of time between sample collection and sample analysis.

Multiple activated carbon tubes might be necessary for 8-hour sampling.

S.12.3.2.1.2 Passive sampling devices

Principle of operation: Like activated carbon tubes, passive sampling devices (PSDs) are clipped to the worker's lapel. Passive sampling devices rely on the natural diffusion of EO into a sorbent or reactant material and, hence, do not require the use of a pump. These devices are normally worn throughout the full day or during short periods when the task-related excursion level is determined.

After the sampling has been completed, the PSD is either sealed and sent to a laboratory for analysis or, depending on the type of PSD, processed and read on-site. For PSDs requiring laboratory analysis, the analysis can be performed by a laboratory at the sampling site (if properly equipped), by a contract service laboratory, or by the PSD supplier (most suppliers offer analytical services for a fee). Some PSDs do not require laboratory analysis; they provide on-site exposure analysis and results within 10 minutes.

It might be necessary to collect blank and control samples. The PSD manufacturer or the analytical laboratory should be asked for recommendations.

Several companies currently market PSDs. One kind of PSD collects diffused EO onto specially treated charcoal that converts the EO to a stable derivative (2-bromoethanol). During the laboratory analysis, the 2-bromoethanol is extracted from the charcoal and analyzed by gas chromatography to determine the EO concentration.

One kind of PSD system designed to be directly read on-site produces an intermediary alkylation product as EO comes into contact with the badge substrate. This intermediary produces a colorimetric reaction when the badge is immersed in a developer solution and read directly in ppm EO via a small, compact reader.

Portability: Completely portable, so used for portable monitoring. At the end of the sample period (hours), the device is collected and sent to a lab, and so these devices are unsuitable for long term exposure monitoring.

Ease of operation:

Preparation and use: simple.

Data analysis: moderate to difficult.

Accuracy: Variable; the PSD supplier or contract analytical laboratory should be consulted. The manufacturer should be required to supply documentation to support accuracy claims for both the PEL and the excursion limit.

EO specificity: A few air contaminants can interfere. The PSD manufacturer should be asked to supply a written statement specifying which contaminants might interfere with the PSD materials.

Lower detectable limit for EO: Most PSDs are able to detect less than 0.1 ppm EO as an 8-hour TWA and less than 5 ppm as a 15-minute excursion level.

Other comments: In some cases, PSDs are easier to analyze than activated carbon tubes. The absence of the portable pump is an obvious advantage (no battery, no pump calibration, and lighter PSDs).

The following questions should be asked of the PSD supplier:

a) What gases will interfere with the performance of the PSD?

b) Can potential interferences be measured to obtain a true EO measurement?

c) What is the lower detectable EO limit for the PSD?

d) To perform the analysis in the hospital's own laboratory, what accessories will be needed and what do they cost?

e) Has the PSD been field-tested by independent laboratories? (A copy of the protocol and individual laboratory results should be provided.)

f) Does the PSD meet the accuracy criteria for sampling techniques, as specified by OSHA? (A copy of the protocol and individual laboratory results should be provided.)

g) Are other area health care facilities or organizations using this PSD? If so, which ones?

h) How long will it take to receive the results of the sampling if the PSDs are sent to the manufacturer's laboratory or a contract laboratory for analysis?

i) Are other benefits offered, such as a tracking system to provide at least an annual recapitulation of the results of periodic monitoring?

S.12.3.2.1.3 Gas detector tubes

Principle of operation: A hand pump draws air through a glass tube packed with a chemically treated substance that changes color on exposure to certain contaminants. The degree of color change is proportional to the concentration of the contaminant.

Portability: Excellent, but single use, so each tube represents the EO concentration at a point in time.

Ease of operation:

Preparation and use: simple.

Data collection: simple.

Accuracy: varies with manufacturer.

EO specificity: Fairly good, there are substances other than EO can react with the color-changing chemical, Formaldehyde shows a cross sensitivity on some brands of detector tube and alcohols produce a cross sensitivity on other brands.

Lower detectable limit for EO: At least one manufacturer claims a detection limit of 0.1 ppm.

Other comments: Tubes have a limited shelf life. Storage temperature limits should be verified with the supplier. Because tubes can generally be used only for a single air sample and are then discarded, they might not be suitable for TWA determinations.

S.12.3.2.1.4 Gas collection devices

The EO can be collected in a sealed system, such as a nonpermeable bag system using a portable pump (similar to that used with activated carbon tubes), which collects EBZ air and pumps it into a bag made of a material that is not permeable to EO (e.g., Tedlar® or Teflon®). At the conclusion of the sampling period, the bag is sent to a laboratory for gas chromatographic analysis. Overflow of EO vapors and leakage should be prevented. A similar alternative is to use a rigid container that has been evacuated to collect the sample, on opening the valve atmospheric pressure pushes the air sample into the container. The container is then sent to a laboratory for analysis.

S.12.3.2.1.5 Impingers

A traditional way to collect EO is by means of an impinger (bubbler). In impingers, air is drawn through a vial containing an acidic solution using a pump. The EO from the air is converted to a derivative (ethylene glycol), which is then analyzed with a gas chromatograph. Spillage or breakage of the vials should be prevented to avoid damage and chemical burns from the acid.

Table S.5—Summary of chemical EO detection technologies

Detection Technology	Activated Carbon tubes	Passive Badges	Gas Detection Tube	Gas Collection	Impinger
Portable	Yes	Yes	Yes	Yes	Yes
Use	Single use	Single use	Single use	Single use	Single Use
Instantaneous reading	No	No	Yes	No	No
TWA measurement	Yes	Yes	No	No	Yes
Selective to EO	Yes	Yes	Yes	Yes	Yes
Ease of Use	Easy	Easy	Moderate	Moderate	Moderate
Ease of Data Collection	Difficult	Difficult	Easy	Difficult	Difficult
Lower detection limit	0.1 ppm	0.1 ppm	0.1 to 1 ppm	0.1 ppm	<0.1 ppm

S.12.3.2.1.6 Instrumental methods for the detection of EO

There are a wide range of instruments available from the detection of EtO, ranging from fairly simple gross leak detectors to more advanced detectors with lower detection limits, time weighted average calculations and datalogging. Instrumental methods typically give a continuous readout reflecting the changing EO concentrations, or the device may take a sample, analyze it and then repeat. Some instruments also have outputs that can interface with external systems such as building controls, e.g. to automatically increase the ventilation in the event of a leak.

S.12.3.2.1.7 Metal oxide semiconductors

Principle of operation: Metal oxide semiconductors, is a type of solid-state device which changes electrical resistivity in the presence of EO. The greater the change in resistance, the higher the concentration of EO.

Portability: Both portable and stationary models are available.

Ease of operation:

Preparation and use: moderate.

Data collection: simple.

Accuracy: Variable.

EO specificity: Usually poor. Depending on the design of the solid-state element, many air contaminants other than EO could be sensed; thus, a false positive reading for EO could be obtained.

Lower detectable limit for EO: Not less than 10 ppm, but usually set at higher levels because of sensitivity to other airborne contaminants that might be present.

Other comments: Metal oxide semiconductor sensors operate at high temperatures and so need a lot of power. Therefore they are most commonly found as area monitors. These systems are sensitive to most hydrocarbons and common organic vapors such as alcohols, therefore, these devices are generally used as gross leak detectors with factory-set alarm levels at 20 ppm and 50 ppm because of the low EO sensitivity. These detectors can be used to detect large EO leaks, but lack the sensitivity needed for TWA measurements at the OSHA PELs.

S.12.3.2.1.8 Electrochemical sensors

Principle of operation: Ambient room air is delivered either by a pump or diffusion to a cell within the device. When the target gas diffuses through the cell membrane face, an electrochemical reaction takes place, producing an electrical current signal proportional to the concentration of the contaminant. This signal is then amplified, temperature compensated, and fed to a microprocessor, to convert the signal to show the concentration of the target gas.

Portability: Both portable and area models are available.

Ease of operation:

Preparation and use: simple to moderate.

Data collection: simple.

Accuracy: The accuracy depends on the accuracy of the instrument and the calibration gas used to calibrate it. Typical values for accuracy are the larger of +/- 15% of reading or 0.2 ppm. Contact the instrument manufacturer for details.

Application: Suitable for instantaneous reading, TWA values and emergency alarms.

EO specificity: Contaminants other than EO can produce interferences, although some manufacturers reduce some interferences by means of chemical filters.

Lower detectable limit for EO: Less than 0.2 ppm (depends on manufacturer).

Other comments: Data acquisition (personal computer–based) modules are available that can be connected to area monitors to track EO levels continuously and simultaneously from each point. Systems are also available that are capable of monitoring both EO and hydrogen peroxide.

S.12.3.2.1.9 Gas chromatographs

Principle of operation: Gas chromatographs (GCs) draw in a sample of air and pass a sample into a packed column that separates the components so that different components exit the column at different times to a detector. The detectors are usually flame ionization detectors or photoionization detectors. In the presence of the contaminant, the detector measures the generated ions. The measured response is proportional to the contaminant concentration.

Portability: Most are stationary. Sophisticated units can be equipped with multipoint samplers that incorporate microprocessors for control, data generation, and analysis.

Ease of operation:

Preparation and use: moderate to difficult, depending on the degree of automation.

Data collection: moderate to difficult, depending on the degree of automation.

Accuracy: Adequate if used properly.

EO specificity: Usually excellent.

Lower detectable limit for EO: As low as 20 parts per billion for some photoionization detectors (as demonstrated under laboratory—but not sterilizer workplace—conditions), 1 to 5 ppm for most flame ionization detectors.

Other comments: Calibration of the instrument is critical and is required. The user should require the instrument supplier to provide specific calibration instructions. Calibration can be difficult in some instances. GCs need a supply of clean carrier gas, and hydrogen gas is needed for a flame ionization detector;' and for some models gas generators are available.

S.12.3.2.1.10 Infrared spectrophotometers

Principle of operation: A sample of air is drawn into a cell, where it is exposed to infrared light. Certain contaminants absorb certain wavelengths of infrared light. Through measurement of the amount of absorption, the concentration of the contaminant can be determined.

Portability: Multipoint sampling units are stationary. Some other types are portable.

Ease of operation:

Preparation and use: moderate to difficult.

Data collection: difficult.

Accuracy: Variable.

EO specificity: Variable.

Lower detectable limit for EO: Less expensive units usually do not detect EO concentrations lower than 5 ppm. More expensive units are capable of detecting concentrations of approximately 0.3 ppm.

Other comments: Steam or water vapor can interfere with the analysis or damage certain parts of some infrared analyzers. Temperature changes will also affect the analysis. Some units are capable of downloading data to a personal computer and printer.

Infrared sensors are used as combustible gas sensors for EO, which provides an output in terms of percent of the lower explosive limit. The sensitivity of an infrared sensor depends on the types of detector and especially on the path length. The complex optics needed to get a path length sufficient to detect, 1 ppm makes infrared an expensive option for routine monitoring of EO in a health care environment. Shorter path lengths can be used if the sample is collected over time and then measured. Infrared sensors are commonly used for emission monitoring for medical device manufacturers.

S.12.3.2.1.11 Photoionization detectors (PID) (without gas chromatographs)

Principle of operation: Air is supplied to a detector, where certain contaminants interact with ultraviolet light, producing ions. These ions produce an electric current, the strength of which is related to the contaminant concentration.

Portability: Most are portable.

Ease of operation:

Preparation and use: moderate.

Data collection: simple.

Accuracy: Variable.

EO specificity: Numerous contaminants other than EO can produce positive interferences.

Lower detectable limit for EO: Some are capable of detecting concentrations much lower than 0.1 ppm.

Other comments:

PID detectors have very good sensitivity (ppb is typical), but they are not selective against other VOCs in the air and the detectors have limited life before they need maintenance (e.g. cleaning the lamp).

S.12.3.2.2 Instrumental EO detection technologies

For information on portability, ease of operation, EO specificity, the lower detectable limit for EO, and other characteristics of these devices, the manufacturer's specifications should be consulted. The properties of the most commonly used methods are summarized in Table S.6.

Table S.6—Summary of instrumental EO detection technologies

Detection Technology	MOS sensors	Electrochemical sensors	Gas Chromatographs	Infrared	Photoionization
Portable	Yes	Yes	No	Yes/No	Yes
Use	Continuous	Continuous	Continuous	Continuous	Continuous
Instantaneous reading	Yes	Yes	Yes (periodic sampling)	Yes	Yes
TWA measurement	No	Yes	Yes	Yes	No
Selective to EO	No	Varies with model	Yes	Yes	No
Ease of Use	Easy	Easy	Easy	Easy	Easy
Ease of Data Collection	Easy	Easy	Easy	Easy	Easy
Lower detection limit	~ 10 ppm	0.1 ppm	0.05 ppm	0.25 ppb	20 ppb

S.12.3.2.3 Continuous monitoring

Although the OSHA standard on occupational exposure to EO (29 CFR 1910.1047) does not specifically require a health care facility to have a continuous monitoring system, it does specify that means must be developed to promptly alert employees of a leak or spill. Therefore, for the health and safety of employees, AAMI recommends continuous monitoring of the workplace environment. Monitors should be capable of monitoring the various locations in which leaks or spills could occur. Therefore, the appropriate monitor depends on the number of points requiring this type of monitoring. The equipment should be capable of being set at a level that will avoid a high frequency of interferences from other chemicals used in the workplace. The equipment should also be capable of providing both visible and audible alarms.

Some automated can also be interfaced with controls to increase ventilation when the OSHA action level, PEL, or EL is exceeded.

S.12.3.3 Summary

As indicated previously, each type of EO monitor has advantages and disadvantages. In selection of such equipment, careful review of the unit's intended use and capabilities is required. In general, the following questions should be answered to the prospective user's satisfaction before an area monitor is purchased:

a) Is the monitor needed for personal monitoring or area monitoring?

b) Do you want a device which will give an alarm in the event of an EO leak?

c) Do you want a device which can detect EO at low enough levels to measure TWAs at OSHA PEL levels?

d) Does the workplace contain air contaminants other than EO that could interfere with the monitor's detection system? (The user should obtain a written statement from the manufacturer.)

e) Does the analyzer require calibration? If so, how is the calibration performed, who performs the calibration (user or manufacturer) and how often is calibration needed? If a gaseous reference sample is required, the user should obtain a written statement from the gas supplier regarding the stability and availability of the gas mixture, as well as any other special handling instructions. Some manufacturers provide a calibration service.

f) What maintenance work might be necessary for the instrument? Who will perform the maintenance? (In other words, will it be necessary to return the instrument to the factory, or is field service available?)

g) What other health care facilities or organizations have purchased this instrument? (The user might wish to contact the health care facilities or organizations and ask them if they are satisfied with the instrument.)

h) What is the lowest concentration of EO that can be measured accurately by the instrument? At that level, what is its accuracy and repeatability? Written documentation should be requested.

i) Is any special training required to operate the instrument? If so, does the instrument manufacturer provide such training?

j) What accessory equipment is available for use with the instrument?

k) Can the instrument log data and/or interface with a computer interface. What reports are available for analysis of the data and what is the data format if the data can be exported.

l) Is the location being monitored classified as hazardous?. For classified areas only intrinsically safe or explosion proof equipment is permitted, The manufacturer must verify that the equipment has the necessary approvals for this application. The approvals will indicate the name of the test lab and the standards against which the equipment was satisfactorily tested.

m) What is the overall cost of the instrument, including initial purchase, cost of accessories and on-going costs such as maintenance and calibration costs? Include also the time needed to perform these functions if these functions are performed by facility personnel.

S.12.4 Contract services

S.12.4.1 Advantages and disadvantages of contract services

Many companies and organizations offer services that include EO monitoring. The breadth of additional services available varies significantly from contractor to contractor. Some will perform only personnel monitoring; others will conduct a complete survey of the health care facility to identify sources of EO leakage and will provide recommendations for possible solutions to identified problems.

Using a contract service has the following advantages:

a) Reputable contractors are familiar with the causes of potential EO exposure, enabling them to save time at the outset in identifying where problems could exist. Engineering or work-practice solutions can then be designed and implemented.

b) Contract services can be performed on a shared-service basis; that is, several health care facilities can jointly contract with the contractor. Discounts for services might be available under such circumstances.

c) The same contractor might be able to provide services meeting similar needs in other departments (e.g., monitoring waste anesthetic gases in the operating room).

The major disadvantage of relying solely on contract services is that once the contractor completes the work, there is no ongoing means of identifying the airborne EO in the facility since leaks can develop at any time. Depending on the amount of EO sterilization performed, the location of the EO sterilization facility, the number of people normally present in and around the EO sterilization facility, and other factors, this situation could be unacceptable. In that case, some form of ongoing monitoring program using the methods previously described should be implemented. Facilities should also compare the cost of contract services compared to purchasing their EO gas monitoring equipment that will provide continuous monitoring in real time.

S.12.4.2 Finding contract service organizations

There are a variety of ways to find contract service organizations:

a) Most industrial hygiene companies have websites describing the services they offer and their contact information for further details.

b) The local or state health department, occupational health consulting services, workers' compensation or other insurance carriers, or universities can be approached to determine whether they provide consultant services and, if not, to secure their recommendations.

c) Nearby health care facilities can be contacted to learn their experiences with consultants and to obtain their recommendations.

d) Sterilizer manufacturers and EO suppliers can usually provide suggestions.

e) Technical journals, such as the *American Industrial Hygiene Association Journal*, often contain consultant advertisements.

f) Professional societies such as the American Industrial Hygiene Association can often provide a list of consultants and accredited laboratories in the region.

g) If a local consultant is not available, a cooperative effort (shared service) to bring in a reputable consultant can be considered.

S.12.4.3 Selection criteria

After a list of possible service organizations is prepared, the following steps should be taken in the selection process:

a) The consultant should be asked for references—preferably nearby clients with similar operations.

b) The consultant should describe the specific qualifications and years of technical experience of the individuals who perform the work. (e.g., certified industrial hygienist). Certified safety professional or biomedical equipment technician could also be valid, with appropriate experience.)

c) The individuals who perform the work should be interviewed. During the interview, the following questions should be asked:

   1) How many EO facilities has the individual tested?

   2) Is the individual familiar with the EO sterilization process? (Ask follow-up questions.)

   3) What kind of equipment will be used to perform the work? What interferences might affect the EO monitoring?

   4) What areas of the facility will be examined?

d) If activated carbon tubes, PSDs, or other personnel samples are to be collected, the contractor should be asked to verify that blank or control samples are submitted.

e) The contractor should specify who performs the analysis of the adsorbent and describe the level of experience of this individual.

f) The general operation, the number and types of sterilizers, the work practices, the number of employees per shift, and the facility layout should be discussed before monitoring begins. Agreement should be reached in advance about which activities will be monitored and which ancillary tests (e.g., ventilation tests) will be performed. Both personnel monitoring and area monitoring are desirable. It should be specified that all work shifts when EO is used will be surveyed.

g) The contractor should be asked whether ventilation checks will be performed (e.g., local exhaust hoods, air exchange rate, location of building intake in relation to the sterilizer exhaust points, positive- and negative-pressure areas).

h) The contractor should describe the report that it will issue on completing the work and provide an example of the report format. The user and contractor should agree on the date on which the report will be issued and who will receive a copy. The report should contain at least the following information:

    1) the date monitoring was performed;

    2) a detailed description of the operations performed;

    3) the names or identity numbers of the personnel monitored;

    4) if applicable, the most recent calibration date of the monitoring devices and the calibration technique used;

    5) the exact locations of the sampling devices (photographs or maps are very helpful);

    6) the specific times that samples were collected, with notations concerning other pertinent activities (e.g., the sterilizer door being opened, the sterilized items being transferred to the aerator, the EO cylinder being changed);

    7) the EO concentrations, in ppm, at each sample location (as an 8-hour TWA, 6-hour TWA, 15-minute excursion level, or other specified time period);

    8) a description of the sampling and analytical techniques used;

    9) the name of the contractor's organization;

    10) the names and qualifications of the survey personnel who did the work at the facility;

    11) the temperature and relative humidity of the area that was surveyed; and

    12) an authorized signature with a title.

i) The contractor's fee should be discussed.

j) The possibility of follow-up visits should be discussed. How many visits and when they will be scheduled should be determined.

k) After the contractor has been selected, it is important to ensure that the contractor will provide ample advance notice before coming to the facility so that the appropriate supervisor can schedule time for the survey and so that actual normal operations (including EO sterilization processes) will occur during the survey. A simulated load outside of the normal routine should not be surveyed.

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