

Technical Information Report

AAMI TIR67: 2018

Promoting safe practices
pertaining to the use of
sterilant and disinfectant
chemicals in health care
facilities

Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in health care facilities

Approved 23 February 2018 by
Association for the Advancement of Medical Instrumentation

Abstract: This technical information report (TIR) provides additional guidance to sterile processing managers and others regarding compliance with occupational safety and environmental regulations.

Keywords: disinfectant, EPA, OSHA, preventing exposure, regulation, risk, safety, standard, statute, sterilant

AAMI Technical Information Report

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

CAUTION NOTICE: This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Published by

AAMI
4301 N. Fairfax Dr., Ste. 301
Arlington, VA 22203-1633

© 2018 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI at 4301 N. Fairfax Dr., Ste. 301, Arlington, VA 22203-1633. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 978-1-57020-697-9

Contents

Page

Committee representation	iv
Foreword	vii
Introduction	1
1 Scope	2
2 Definitions	2
3 U.S. legal and regulatory structure	9
4 Consensus and other standards	12
5 Occupational safety laws applicable to safe use of sterilant and disinfectant chemicals and other chemicals in health care	16
6 Environmental laws pertaining to chemical use in health care	33
7 Hazard and risk analysis	35
8 Promoting safe practices	39
9 Response to exposure	49
Annex A (informative) Contact information for occupational safety offices in states and territories	54
Bibliography	59

Committee representation

Association for the Advancement of Medical Instrumentation

Chemical Sterilants Hospital Practices Working Group

This technical information report was developed by the AAMI Chemical Sterilants Hospital Practices Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the TIR does not necessarily mean that all working group members voted for its approval. At the time this TIR was published, the **AAMI Chemical Sterilants Hospital Practices Working Group** had the following members:

Chair: Janet Prust

Members: Anas Aljabo, SteriPro Canada Inc
Nola Bayes, Sanford Health
Marcia Benedict, STERIS Corporation
Jon Burdach, PhD, Nanosonics Limited
Jennifer Burrell, St. Luke's Hospital and Health Network
Xiaolan Chen, Johnson & Johnson
Nancy Chobin, RN, CSPDM, Sterile Processing University LLC
Ramona Conner, RN, MSN, CNOR, FAAN, Association of periOperative Registered Nurses
Jacqueline Daley
Mary Ann Drosnock, Healthmark Industries Company Inc
Gordon Ely, MiMedx Group
Gloria Frost, Cardinal Health
Zory Glaser, PhD, Johns Hopkins University School of Public Health
Rachel Hill, Becton Dickinson & Company
Nupur Jain, Intuitive Surgical Inc
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service
Materiel Management
Doug Kruger
Jean-Luc Lemyre, TSO₃ Inc
Stacey MacArthur
Jo Ann Maltais, Maltais Consulting
Jason Marosi
Elaine Mayhall, PhD, FDA/CDRH
Candace McManus, PhD
Astrid Merrifield, Boston Scientific Corporation
Rusty Mills, GE Healthcare
Frank Myers, UC San Diego Healthcare System
Richard Ormsbee, Cantel Inc
Alpa Patel, Nelson Laboratories LLC
Janet Prust, 3M Healthcare
Cheron Rojo, Valley Children's Hospital
Mandy Ryan, Stryker Instruments Division
Mike Schoene, Bausch & Lomb Inc
Rose Seavey, Seavey Healthcare Consulting, LLC
Frank Sizemore, Wake Forest University Baptist Medical Center
Joan Spear, B Braun of America Inc
Karen Swanson, Connecticut Children's Medical Center
Radhakrishna Tirumalai, US Pharmacopeia Convention Inc
Dawn Tomac, Association for Professionals in Infection Control and Epidemiology
Donald Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc
Richard Warburton, ChemDAQ Inc
Jill Warren, WuXi AppTec Inc
Roberto Zumbado, Philips

Alternates: Dave Dion, Cardinal Health
Christopher Dugard, FDA/CDRH
Susan Flynn, 3M Healthcare

Elyse Gaudreau, TSO₃ Inc
Brent Geiger, Cantel Inc
Sharon Hadley, STERIS IMS
David Hilliker, ChemDAQ Inc
Nancy Kaiser, STERIS Corporation
Kaumudi Kulkarni, Healthmark Industries Company Inc
Elan Lopezcuba, Becton Dickinson & Company
Patrick McCormick, Bausch & Lomb Inc
Kathleen McMullen, Association for Professionals in Infection Control and Epidemiology
Emily Mitzel, Nelson Laboratories LLC
Navid Omidbakhsh, Johnson & Johnson
Leslie Tavares, WuXi AppTec Inc
Brian Wallace, Intuitive Surgical Inc
Jon Wood, International Association of Healthcare Central Service
Materiel Management
Bryan Worwa, Boston Scientific Corporation

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

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

Cochairs: Michael Scholla, PhD
Patrick Weixel

Members: Anas Aljabo, SteriPro Canada Inc.
Brett Anderson, Cochlear Ltd
Hank Balch, University Health System
Richard Bancroft, Steris Corporation
Marie Brewer
Trabue Bryans, BryKor LLC
Jon Burdach, Nanosonics Limited
Tim Carlson, Becton Dickinson & Company
Phil Cogdill, Medtronic Inc Campus
Sean Colwell, WuXi AppTec Inc
Ramona Conner, Association of Perioperative Registered Nurses
Lena Cordie, Qualitas Professional Services LLC
Jackie Daley
Gordon Ely, MiMedx Group
Lisa Foster, Adiuvo QS & SA Consulting
Joel Gorski, NAMSA
Joyce Hansen, Johnson & Johnson
Stephanie Homuth, Homuth, Stephanie
Clark Houghtling, Cosmed Group Inc
Sue Klacik, International Association of Healthcare Central Service
Materiel Management
Byron Lambert, Abbott Laboratories
Michelle Luebke, Baxter Healthcare Corporation
Patrick McCormick, Bausch & Lomb Inc
Gerry O'Dell, Gerry O'Dell Consulting
Adrian Ponce, Verrix LLC
Janet Prust, 3M Healthcare
Nancy Rakiewicz, IUVO BioScience
Michael Scholla, PhD, DuPont Tyvek Medical and Pharmaceutical Protection
Linda Schultz, Northside Hospital Surgical Services Atlanta
Joan Spear, B Braun of America Inc
Patrick Weixel, FDA/CDRH
Sid Wiggs
Martell Winters, Nelson Laboratories LLC
Stephen Yeadon, Boston Scientific Corporation
Bill Young, Sterigenics International
Roberto Zumbado, Philips

Alternates: Stacy Bohl, Boston Scientific Corporation
Greg Crego, IUVO BioScience
Niki Fidopiastis, Sterigenics International
Dan Floyd, DuPont Tyvek Medical and Pharmaceutical Protection
Gerry McDonnell, Johnson & Johnson
Kim Patton, Becton Dickinson & Company
Christine Render, Cosmed Group Inc
Mike Sadowski, Baxter Healthcare Corporation
Craig Wallace, 3M Healthcare
Lisa Ward, Steris Corporation
Jon Wood, International Association of Healthcare Central Service
Materiel Management

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

Foreword

This technical information report (TIR) was developed by the AAMI Chemical Sterilants Hospital Practices Working group under the auspices of the AAMI Sterilization Standards Committee. The objective of this TIR is to provide comprehensive background information on the U.S. federal regulations and industrial hygiene recommendations related to occupational exposure to chemical sterilants used in the health care setting for reprocessing medical devices.

Federal occupational safety laws are broadly written for all industries. This TIR focuses specifically on chemical sterilants used in the health care setting and the aspects of the regulations that apply. This document is not intended to interpret federal law and health care facilities should use this information only as background education to become familiar with the requirements. Health care facilities should not make legal decisions based the information in this TIR but refer to facility employee health and legal counsel. The content and recommendations in this TIR will be reviewed and updated periodically as requirements for occupational safety related to the use of chemical sterilants change.

The objective of this TIR is to assist health care management and personnel who use sterilant and disinfectant chemicals to improve occupational safety by providing relevant regulatory and general advice about safe use of these chemicals.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington VA 22203-1633.

NOTE—This foreword does not contain provisions of AAMI TIR67, *Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in health care facilities*, but it does provide important information about the development and intended use of the document.

Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in health care facilities

NOTE—This technical information report (TIR) is not a standard, and the material contained herein is informative in nature. In some instances, the committee has used the terms “shall” and “must” based on its knowledge of requirements contained in relevant standards, regulatory requirements, or both.

Introduction

Sterilant and disinfectant chemicals are usually broad-based biocidal chemicals that effectively destroy a broad range of pathogens including bacteria, fungi, protozoa, and viruses; some chemical sterilants also destroy the more resistant sporicidal forms of bacteria. These chemicals play an essential role in modern health care, and their use has a direct and vital impact on patient care. They are essential to the sterilization or disinfection of heat-sensitive devices such as flexible endoscopes. At the same time, these chemicals can pose various levels of risk for health care personnel that handle them.

Often, sterilant and high-level disinfectant (HLD) chemicals are used within equipment such as sterilizers, automatic endoscope reprocessors, and similar equipment that has been designed by the manufacturers to be as safe as possible for the operators. Proper use of such equipment by well-trained operators who have a good knowledge of safe use of the sterilant and disinfectant chemicals and how to mitigate those risks is an important aspect for the safe use of these chemicals.

However, the injury rate in health care is higher than in almost all other industries. In 2009, the Healthcare and Social Assistance (HCSA) Sector Council of the National Occupational Research Agenda (NORA) (in partnership with the Centers for Disease Control and Prevention [CDC]) examined the health care sector for the causes of the high accident rate, and the following conclusion was drawn:

“The HCSA sector is burdened by the historical and entrenched belief that patient care issues supersede the personal safety and health of workers and that it is acceptable for HCSA workers to have less than optimal protections against the risks of hazardous exposures or injuries.” [NORA, 2009]

As far as chemical safety was concerned, the NORA report went on to say:

“HCSA workers are also at increased risk for many of the types of adverse health effects potentially caused by hazardous chemical exposures, including cancer, adverse reproductive outcomes, and work-related asthma and dermatitis. Although a wide range of hazards exists, a key barrier to addressing them is the misconception that HCSA work is safer than other work involving exposure to chemical and physical hazards. Improved health and hazard surveillance could help to address this issue, as would epidemiological studies to better evaluate relationships between hazardous exposures in the HCSA sector and development of work-related health outcomes such as cancer, adverse reproductive outcomes, asthma, and skin disorders.”

The purpose of this TIR is to assist health care facilities that use sterilant and disinfectant chemicals in improving their occupational safety by providing relevant regulatory and general advice about the safe use of these chemicals.

In the United States, there is an extensive network of overlapping regulations that control the use of chemical sterilants and disinfectants and that are intended to protect workers from exposure in the workplace and in the environment. Although these various regulations are available on the websites of the respective local and federal government agencies, they can be difficult to find, especially if the reader is unaware of which regulations apply.

Another problem for readers is that chemical safety regulations are often written to apply across all or at least many very diverse industries and so are broadly written and often contain considerable matter that is not relevant to chemical sterilization in a health care facility. Thus, the same Occupational Safety and Health Administration (OSHA) regulations apply to the use of hydrogen peroxide in a hospital sterile processing department as to a titanium foundry pickling titanium ingots in an acidified hydrogen peroxide bath to remove mill scale. Therefore, this TIR is written to clarify the

chemical safety regulations for applications specific to the use of sterilant and disinfectant chemicals in sterile processing in health care facilities.

This TIR does not address infection control for patient safety or prevention of infection of workers under OSHA's bloodborne pathogen standard. These topics are too large to be treated adequately within the limitations of this TIR. Nor will this TIR specifically address chemical hazards found in other parts of the hospital such as formaldehyde in pathology, antineoplastic drugs in the pharmacy, or assorted chemicals in the laboratories. Each of these areas has unique requirements that are not addressed in this document, although it is hoped that the overview of the regulatory structure described here will be helpful to other departments as well.

This TIR is intended to provide practical information to managers of departments using sterilant and disinfectant chemicals to assist them in finding regulatory information about the safe use of the chemicals and general information on risk analysis and chemical safety. The key to chemical safety is understanding the regulations, assessing the hazards and risks of the chemicals being used, minimizing the risk where possible, and being prepared for problems before they arise. The goal is to provide an overview of the information and sufficient references so that users can find the original text in the regulations. Regulations often change over time, and users should refer to the original regulations for more information.

This TIR provides an overview of the legal framework and the regulations pertaining to occupational safety in health care. This report should not be taken as legal advice and any legal questions should be referred to the facility legal counsel.

1 Scope

This TIR provides guidance on compliance with occupational safety and environmental statutes and regulations pertaining to the use of liquid chemical sterilants (LCSs) and HLDs and other disinfectant chemicals in health care. This TIR does not address cytotoxic compounds such as antineoplastic agents or other pharmaceuticals, nor does it address other health care safety issues such as ergonomics, bloodborne pathogens, or needle sticks. This document does not specifically discuss dialysis, although many of the occupational safety regulatory compliance requirements for the chemical disinfectants used in dialysis are similar to those discussed in this document.

2 Definitions

For the purposes of this TIR, the following definitions apply:

- 2.1 absorb:** To take up or receive a vapor or liquid into a solid material.
- 2.2 ACGIH®:** American Conference of Governmental Industrial Hygienists, a nonprofit professional society dedicated to the advancement of occupational and environmental health.
- 2.3 action level:** 1) For certain chemicals, such as ethylene oxide and formaldehyde, 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. The action level for both ethylene oxide and formaldehyde is 0.5 ppm calculated as an 8 hour TWA.
- 2.4 adsorb:** To 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 American National Standards Institute (ANSI):** Organization that facilitates the development of American National Standards (ANS) by accrediting the procedures of standards-developing organizations such as AAMI.
- 2.9 asepsis:** Prevention of contact with microorganisms.
- 2.10 assigned protection factor (APF):** Workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program.
- 2.11 bacterial count:** Method of estimating the number of bacteria per unit sample.

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

2.12 bioburden: Population of viable microorganisms on or in a product and/or a sterile barrier system.

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

2.13 biofilm: Accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily. [Donlan, 2002].

NOTE—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.

2.14 ceiling limit: According to OSHA, “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] See also **threshold limit value (TLV®)**.

2.15 Centers for Disease Control and Prevention (CDC): Federal public health agency, in the U.S. Department of Health and Human Services, whose mission is to protect public health and safety through the control and prevention of disease, injury, and disability. [<https://www.cdc.gov>]

2.16 chemical sterilization: Process, using a chemical agent, designed to render a product free of viable microorganisms.

2.17 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—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.

2.18 Clean Air Act (CAA): Federal law that regulates air emissions of pollutants from stationary and mobile sources. [42 U.S.C. §7401 et seq. (1970)]

2.19 Clean Water Act (CWA): Federal law that establishes the basic structure for regulating discharges of pollutants into the waters of the United States and regulating quality standards for surface waters. The basis of the CWA was enacted in 1948 and was called the Federal Water Pollution Control Act, but the Act was significantly reorganized and expanded in 1972. “Clean Water Act” became the Act’s common name with amendments in 1972. [33 U.S.C. §1251 et seq. (1972)]

2.20 Code of Federal Regulations (CFR): Collation of all federal regulations organized by subject. The CFR is divided into 50 titles that represent broad areas subject to federal regulation and is published every year at four staggered times. Title 29 pertains to the Department of Labor, which is in turn subdivided by subject into chapters and parts. For example, Chapter XVII is for the Occupational Safety and Health Administration, Department of Labor (parts 1900–1926), and part 1910 corresponds to Occupational Safety and Health standards.

2.21 combustible liquid: According to OSHA, a combustible liquid is defined as follows:

“Combustible liquid: any liquid having a flash point at or above 100°F (37.8°C). Combustible liquids shall be divided into two classes as follows:

- Class II liquids shall include those with flash points at or above 100°F (37.8°C) and below 140°F (60°C), except any mixture having components with flash points of 200°F (93.3°C) or higher, the volume of which make up 99 percent or more of the total volume of the mixture.
- Class III liquids shall include those with flash points at or above 140°F (60°C). Class III liquids are subdivided into two subclasses:
 - o Class IIIA liquids shall include those with flash points at or above 140°F (60°C) and below 200°F (93.3°C), except any mixture having components with flash points of 200°F (93.3°C), or higher, the total volume of which make up 99 percent or more of the total volume of the mixture.
 - o Class IIIB liquids shall include those with flash points at or above 200°F (93.3°C). This section does not regulate Class IIIB liquids. Where the term “Class III liquids” is used in this section, it shall mean only Class IIIA liquids.

"When a combustible liquid is heated to within 30°F (16.7°C) of its flash point, it shall be handled in accordance with the requirements for the next lower class of liquids." [29 CFR 1910.106]

2.22 Compressed Gas Association (CGS): Professional organization focused on the development of industry standards, on the pursuit of uniform government regulations, and on technical and safety matters related to the use of compressed gases. [www.cganet.com]

2.23 consensus standard: Standard developed by a private-sector standards body using a consensus process.

2.24 continuous monitoring: Collecting air samples to determine acceptable air quality by detecting known air contaminants. Continuous monitoring devices periodically collect samples of air on a constant basis to determine acceptability against a defined standard.

2.25 critical device: Any device introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body.

2.26 decontamination: According to the OSHA's bloodborne pathogens standard, "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal." [29 CFR 1910.1030]

NOTE 1—The term is generally used in health care facilities with reference to all pathogenic organisms, not just those transmitted by blood.

NOTE 2—In the context of this TIR, "use" refers to use by health care personnel, not necessarily use in patient care.

2.27 disinfection: Process that kills pathogenic and other microorganisms by physical or chemical means.

NOTE—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.

2.28 emergency response planning guidelines (ERPGs): Air concentration guidelines that apply to single exposures to agents and that are intended for use as tools to assess the adequacy of accident prevention and emergency response plans, including transportation emergency planning, community emergency response plans and incident prevention and mitigation. The ERPGs are developed by the American Industrial Hygiene Association (AIHA). The AIHA also develops ERPGs for responding to potential releases of airborne substances for use in community emergency planning.

NOTE—ERPG® is a registered trademark of the AIHA.

2.29 employee breathing zone: Sphere approximately 2 feet in diameter surrounding the head. [OSHA, 1984]

NOTE—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.

2.30 engineering controls: Controls that help 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).

2.31 EPA: U.S. Environmental Protection Agency.

2.32 ethylene oxide (EO): Gas, with the molecular formula C₂H₄O, that is widely used for gaseous sterilization of medical devices. Ethylene oxide is often also abbreviated as EtO.

2.33 excursion limit: Short-term exposure limit defined by OSHA for ethylene oxide: "The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes." [1910.1047(c)(2)]

2.34 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—The exhaust source creates negative pressure, thereby drawing contaminated air into ducts or hoods and propelling it outdoors.

2.35 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.

2.36 FDA: U.S. Food and Drug Administration.

2.37 Federal Food, Drug, and Cosmetic Act (FDCA): Law giving authority to FDA to oversee the safety of food, drugs, and cosmetics.

2.38 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): Law that provides for federal regulation of pesticide distribution, sale, and use. All pesticides distributed or sold in the United States must be registered (licensed) by EPA.

2.38 flammable liquid: As defined by OSHA (1910.106(a) (19) (i-v) any liquid having a flashpoint at or below 199.4 °F (93 °C). Flammable liquids are divided into four categories as follows:

- Category 1 shall include liquids having flashpoints below 73.4 °F (23 °C) and having a boiling point at or below 95 °F (35 °C).
- Category 2 shall include liquids having flashpoints below 73.4 °F (23 °C) and having a boiling point above 95 °F (35 °C).
- Category 3 shall include liquids having flashpoints at or above 73.4 °F (23 °C) and at or below 140 °F (60 °C). When a Category 3 liquid with a flashpoint at or above 100 °F (37.8 °C) is heated for use to within 30 °F (16.7 °C) of its flashpoint, it shall be handled in accordance with the requirements for a Category 3 liquid with a flashpoint below 100 °F (37.8 °C).
- Category 4 shall include liquids having flashpoints above 140 °F (60 °C) and at or below 199.4 °F (93 °C). When a Category 4 flammable liquid is heated for use to within 30 °F (16.7 °C) of its flashpoint, it shall be handled in accordance with the requirements for a Category 3 liquid with a flashpoint at or above 100 °F (37.8 °C).

When liquid with a flashpoint greater than 199.4 °F (93 °C) is heated for use to within 30 °F (16.7 °C) of its flashpoint, it shall be handled in accordance with the requirements for a Category 4 flammable liquid.

Note—Flash point is the basis for classification of flammable and combustible liquids because it is directly related to a liquid's ability to generate vapor, i.e., its volatility. Since it is the vapor of the liquid, not the liquid itself that burns, vapor generation becomes the primary factor in determining the fire hazard. Liquids having flash points below ambient storage temperatures generally display a rapid rate of flame spread over the surface of the liquid, since it is not necessary for the heat of the fire to expend its energy in heating the liquid to generate more vapor.

2.39 gaseous chemical sterilization (GCS): Validated process employing gaseous chemical sterilants (e.g., ethylene oxide [EO], hydrogen peroxide, ozone).

2.40 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."

2.41 health care facility: Hospital, nursing home, extended-care facility, freestanding surgical center, clinic, medical office, or dental office.

2.42 high-level disinfectant (HLD): Agent capable of killing bacterial spores when used in sufficient concentration under suitable conditions.

NOTE—According to the FDA, a HLD is a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass the AOAC sporidical activity test as a sterilant. (AOAC International is a nonprofit organization that develops analytical test methods [www.aoc.org].)

2.43 high-level disinfection: Process that kills all microbial organisms but not necessarily large numbers of bacterial spores.

NOTE—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.

2.44 Immediately Dangerous to Life or Health (IDLH): Conditions that pose a threat of exposure to airborne contaminants when that exposure is likely to cause death or immediate or delayed permanent adverse health effects, or to prevent escape from such an environment. [NIOSH, 2004] IDLH values for chemicals can be found at www.cdc.gov/niosh/idlh/intridl4.html.

2.45 industrial hygienist: Professional trained to anticipate, recognize, measure, evaluate, and control health hazards in the workplace.

2.46 intermediate-level disinfection: Process that kills viruses, mycobacteria, fungi, and vegetative bacteria, but not necessarily bacterial spores.

2.47 lethal concentration 50 (LC₅₀): Concentration of a compound that is sufficient to kill 50% of the test population within a specified time period. For example, the LC₅₀ of EO is at least 800 ppm when tested on albino rats for four hours. [NIOSH, 1994]

2.48 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.

2.49 local exhaust hood: System designed to capture contaminated air and conduct it into an exhaust duct. Also termed *venting hood*.

2.50 low-level disinfection: Process that kills most vegetative bacteria, some viruses, and some fungi, but not mycobacteria or bacterial spores.

2.51 manufacturer's written instruction for use (IFU): Written recommendations provided by the manufacturer of a device that provide instructions for operation and safe and effective processing.

2.52 microbicidal process: Process designed to provide a particular level of microbial lethality (kill).

NOTE—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.

2.53 microorganism: Entity, encompassing bacteria, fungi, protozoa, and viruses, of microscopic size.

2.54 NIOSH: U.S. National Institute of Occupational Safety and Health. NIOSH was created under the 1970 Occupational Safety and Health Act and is charged with occupational safety research and development of best practices.

2.55 noncritical devices: Medical devices that only contact intact patient skin.

NOTE—Examples include, but are not limited to, bedpans, reusable anesthesia masks, and blood pressure cuffs.

2.56 OEL: Occupational exposure limit.

2.57 OPA: o-phthalaldehyde, a commonly used high-level disinfectant.

2.58 OSHA: U.S. Occupational Safety and Health Administration. OSHA was created under the 1970 Occupational Safety and Health Act and is charged with promulgating occupational safety standards and enforcing them.

2.59 parts per million (ppm): Parts per million, a measure of the relative concentration of one component of a mixture. Typically, liquid concentrations are measured as ppm weight/weight, so a 10 ppm solution of component X has 10 micrograms of component X in 1 gram of solution. 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. In both cases, common usage is to refer to the concentration as ppm.

NOTE—Concentrations in solution are treated similarly, so a 1% solution is 1% by weight and a 1% gas mixture is 1% by volume.

2.60 permissible exposure limits (PELs): According to OSHA, "occupational exposure 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] See also **threshold limit value (TLV®)**.

2.61 personal protective equipment (PPE): According to OSHA, "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]

2.62 prions: Transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including scrapie in sheep and goats, bovine spongiform encephalopathy (BSE) in cattle, and Creutzfeldt-Jakob disease in humans. They are unlike any other infectious pathogens, including viruses, because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (PrP). Prion diseases are disorders of protein configuration involving template-assisted replication and resulting in abnormal protein

accumulation in the brain, which causes neuronal dysfunction, degeneration, and death. Prions are extremely resistant to inactivation by heat and disinfecting agents. [Baron, et al., 2001]

2.63 process challenge device (PCD): Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.

NOTE—For purposes of this TIR, a PCD is a challenge test pack containing a BI or a BI and a CI. See AAMI TIR31.

2.64 processing area: Area of a health care facility in which decontaminated, clean instruments 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.

2.65 qualified: As the term is used with respect to personnel, prepared by training and experience to perform a specified task.

2.66 recognized consensus standard: Consensus standard that the FDA has evaluated and recognized for use in satisfying a regulatory requirement and for which FDA has published a notice in the *Federal Register*.

2.67 recommended exposure limit: Occupational exposure level that NIOSH believes would be protective of worker safety and health over a working lifetime.

2.68 Registry of Toxic Effects of Chemical Substances (RTECS): NIOSH-generated compendium of data “extracted from the open scientific literature. Six types of toxicity data are included in the file: (1) primary irritation; (2) mutagenic effects; (3) reproductive effects; (4) tumorigenic effects; (5) acute toxicity; and (6) other multiple dose toxicity. Specific numeric toxicity values such as LD₅₀, LC₅₀, TDLo, and TCLo are noted as well as species studied and route of administration used. For each citation, the bibliographic source is listed thereby enabling the user to access the actual studies cited. No attempt has been made to evaluate the studies cited in RTECS.” [www.cdc.gov/niosh/rtecs/]

2.69 regulation: Law created by a governmental administrative agency. The administrative agency can create regulations if authorized by a statute passed by the national or state legislature.

2.70 reusable medical device: Device intended for repeated use on different patients, with appropriate decontamination and other processing between uses.

2.71 safety data sheet (SDS): Document mandated under the OSHA hazard communication standard [29 CFR 1910.1200] that is to be provided with all commercial sales of chemicals and that summarizes the hazards associated with the chemicals.

2.72 SCBA: Self-contained breathing apparatus.

2.73 semicritical devices: Medical devices that contact intact mucous membranes or non-intact skin, but that do not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

NOTE 1—Examples include, but are not limited to, gastrointestinal endoscopes and respiratory therapy equipment.

NOTE 2—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.

2.74 short-term exposure limit (STEL): According to OSHA's air contaminants standard, “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. 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] See also **threshold limit value (TLV-STEL)**.

NOTE—For ethylene oxide, OSHA defines the STEL as an excursion limit (EL); see **excursion limit**.

2.75 standards-developing organizations (SDOs): Organizations that develop consensus standards following ANSI protocols for standards development.

2.76 statute: Law passed by a national or state legislative body. Federal statutes are passed by the U.S. Congress, and state statutes are passed by state legislatures.

2.77 sterilant/sterilization agent: Physical or chemical entity or combination of entities having sufficient microbiocidal activity to achieve sterility under defined conditions.

2.78 sterile: Free from viable microorganisms.

NOTE—In practice, no such absolute statement regarding the absence of microorganisms can be proven. See **sterilization**.

2.79 sterility assurance level (SAL): Probability of a single viable microorganism occurring on an item after sterilization.

NOTE 1—SAL is usually expressed as 10^{-n} .

NOTE 2—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—SAL cannot be directly measured by a sterilization indicator.

2.80 sterilization: Validated process used to render a product free from viable microorganisms.

NOTE—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**.

2.81 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, 2017]. 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.”

NOTE—TLV is a registered trademark of the ACGIH.

2.82 time-weighted average (TWA): According to OSHA's air contaminants standard, “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®)**.

The time-weighted average is calculated as the average exposure to a gas or vapor over time, typically 8 hours, although 15 minutes is also commonly used (for purposes of short-term exposure limits [STELs]). For example, constant exposure to a gas at 1 ppm for 8 hours is the same TWA as exposure to a gas at 2 ppm for 4 hours or 4 ppm for 2 hours.. OSHA defines TWA as the cumulative exposure for an 8-hour work shift, which “shall be computed as follows [29 CFR 1910.1000(d)(1)]:

$$E = (C_a T_a + C_b T_b + \dots + C_n T_n) \div 8$$

Where:

- E is the equivalent exposure for the working shift.
- C is the concentration during any period of time T where the concentration remains constant.
- T is the duration in hours of the exposure at the concentration C, where $\sum(T_a \rightarrow T_n) = 8$ hours.”

2.83 torr: Unit of pressure. 1 Torr ~ 1 mm of mercury, ~ 133.3 Pa; 760 Torr = 1 atmosphere pressure.

2.84 Toxic Substances Control Act of 1976 (TSCA): Law that provides the EPA with authority to require reporting, record-keeping, and testing requirements, and to impose restrictions relating to chemical substances and/or mixtures. Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides, which are regulated by other statutes and/or agencies.

2.85 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.

2.86 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.

2.87 validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

NOTE 1—Validation covers three activities: installation qualification, operational qualification, and performance qualification.

NOTE 2—Validation is performed by the device manufacturer.

2.88 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.

2.89 workplace environmental exposure levels (WEELs): Occupational exposure levels developed by the American Industrial Hygiene Association. WEELs are now managed by the Occupational Alliance for Risk Science (OARS) which is managed by Toxicology for Risk Assessment (TERA). [<https://www.aiha.org/get-involved/AIHAGuidelineFoundation/WEELs/Pages/default.aspx>]

3 U.S. legal and regulatory structure

3.1 General considerations

This chapter provides an overview of the legal framework for regulation of chemical safety in the United States, which has 51 separate sovereign jurisdictions: the federal government and the 50 states.

3.2 Statutes

A statute can be defined as a formal written enactment of a legislative body. The Occupational Safety and Health Act of 1970 is a federal statute and is the primary workplace safety law in the United States. Statutes are written very broadly and apply to almost all work environments (excluding, for example, the military) and to all kinds of hazards (e.g., chemical, electrical, commercial diving). An important achievement was to create OSHA and provide a mandate to regulate workplace safety.

3.3 Regulations

Health care facilities should be aware of all federal, state, and local regulations pertaining to chemical sterilants and disinfectants. Federal regulations are created by publishing them in the *Federal Register* and allowing a period for interested parties to comment, as required by the Administrative Procedures Act of 1946. Administrative agencies, such as OSHA or the FDA, are government agencies that are created and empowered by a statute to perform specific tasks. The EPA, for example, has been given the responsibility to regulate pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and it is up to the EPA to develop specific regulations for how to implement this mandate. Many of the administrative agencies are also responsible for enforcement of the regulations.

Although a statute is usually written in broad terms, the associated regulations are much more specific. For example, a regulation can define a specific OSHA permissible exposure limit (PEL) for a chemical sterilant.

Similarly to statutes, regulations are often amended and they are codified in the *Code of Federal Regulations* (CFR). Most of the OSHA regulations relevant to health care fall under part 1910 of the CFR. OSHA's hazard communication standard, for example, can be found at 29 CFR 1910.1200. The entire CFR can be found at www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

NOTE—The law often changes. Therefore, it is important to ensure that the latest version of the CFR is used.

Most states have a similar codification scheme for their regulations, as well as analogous procedures.

3.4 General duties

Agencies are responsible for enforcing their regulations and the parent statutes. If there are no specific regulations for a particular situation, agencies can often still act if there is a general duty created by the statute. One of the best known examples of this is the General Duty Clause in the Occupational Safety and Health Act (1970):

“(a) Each employer —

“(1) 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.”
[OSH Act §5]

For example, if an employer is using a chemical for which there is no explicit OSHA PEL, but employees are experiencing occupational exposure to that chemical and being sickened, then OSHA can prosecute the employer under the General Duty Clause.

For OSHA to take action, it must be shown that employees were exposed to the chemical at concentrations above safe levels. For a completely unknown chemical, this can be difficult, but OSHA's task becomes much easier if there is a recognized occupational exposure limit, such as an American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value (TLV) or National Institute for Occupational Safety and Health (NIOSH) recommended exposure limit (REL). If an employer was allowing its employees to be overexposed, OSHA could use the General Duty Clause to enforce a safe workplace requirement.

3.5 Regulations vs. consensus standards

Regulations are legal requirements promulgated by governments. Consensus standards are developed and issued by private organizations and so generally do not have the force of law. Standards can be adopted by legislators and become legal requirements, but the legal authority of the standard comes from the legislature, not the standards organization.

OSHA has incorporated many standards into its regulations; a list of them is available at 29 CFR 1910.6. Examples include the adoption of some of the Compressed Gas Association standards, such as the C-6-1968 and C-8-1962 standards cited in 29 CFR 1910.101(a).

Some nations, states, and provinces, as well as OSHA, have adopted specific ACGIH TLVs into law; but some, like Canada's federal government, directly reference the current ACGIH TLVs. [Canada Occupational Health and Safety Regulations (SOR/86-304), 10.19(1)(a), available at <http://laws-lois.justice.gc.ca/eng/regulations/SOR-86-304/page-24.html#h-122>]. As AAMI updates applicable standards (relative to a state that has adopted AAMI standards as law, such as New Jersey) or the ACGIH updates TLVs, these changes immediately become legally binding in the jurisdictions that reference the current edition.

A TIR is not a standard; it is informative in nature.

3.6 State and federal law

Each state can promulgate its own occupational safety legislation and regulations, but under the U.S. Constitution (Article VI) federal law preempts state law, unless the state law is more restrictive than the OSHA standard. In that case, the state law would prevail. Thus, all private employers need to follow the OSHA PELs.

Most states have a government body responsible for occupational safety. Section 18 of the OSH Act of 1970 allows states to take responsibility for Section 6, "Occupational Safety and Health Standards," subject to the approval of OSHA. Twenty-five states, the U.S. Virgin Islands, and Puerto Rico have approved state plans [<https://www.osha.gov/dcsp/osp/>], although five only cover the public sector (Connecticut, Illinois, New York, New Jersey, and the U.S. Virgin Islands). Most states have adopted the federal standards with little or no modification, but some have more stringent standards. Some states, such as California, are not partners with OSHA under §18 of the OSH Act but still have their own occupational safety laws and permissible exposure limits. Most of their PELs track the OSHA air contaminants standard [29 CFR 1910.1000, Table Z-1], but some STELs are more restrictive [http://www.dir.ca.gov/title8/5155table_ac1.html]. Users should determine which state laws apply to their situation. A list of state occupational safety agencies and their contact information is provided in Annex A.

3.7 Summary of regulations for chemical sterilants and disinfectants

Table 1 provides a summary of various regulations, standards, and recommendations that apply to chemical sterilants and disinfectants.

Table 1—Summary of regulations, standards, and recommendations for chemical sterilants and disinfectants

Description	Regulatory body	Statutes and regulations	Standards and recommendations
Liquid chemical sterilants/high-level disinfectants (intended to prepare critical and semicritical medical devices for clinical use)	FDA	FDCA 21 CFR 880.6885 Final Rule [Federal Register DOC # 00-14462] FIFRA; PR 94-4 MOU	ANSI/AAMI ST58: <i>Chemical sterilization and high-level disinfection in health care facilities</i> ANSI/AAMI ST41: <i>Ethylene oxide sterilization in health care facilities: Safety and effectiveness</i>
Antimicrobial pesticides	EPA	FIFRA EPA registration	CDC/HICPAC: <i>Guideline for sterilization and disinfection in healthcare facilities</i>
General-purpose disinfectants (including intermediate-level hospital disinfectants with or without a tuberculocidal claim)	FDA	FDCA 21 CFR 880.6890	

Table 2 provides applicable information for the use of disinfectants and chemical sterilants in the health care setting.

Table 2—Summary of regulations, standards, and recommendations for the use of chemical disinfectants and sterilants in the health care setting

Description	Regulatory body	Statutes and regulations	Standards, recommendations, and other sources of information
Environmental operating conditions			ANSI/ASHE/ASHRAE 170 Manufacturer's SDS and IFU
Ethylene oxide	OSHA Local and state regulations EPA	29 CFR 1910.104 EPA Reregistration Decision: EPA 738-R-008-003 (EPA, 2008)	ANSI/AAMI ST41: <i>Ethylene oxide sterilization in health care facilities: Safety and effectiveness</i> NFPA 560: <i>Standard for the storage, handling, and use of ethylene oxide for sterilization and fumigation</i> Manufacturer's SDS and IFU
Occupational exposure limits	OSHA	29 CFR 1910.1000 (air contaminants standard)	Manufacturer's SDS
PPE	OSHA	OSHA 3151-12R (OSHA, 2004)	ANSI/AAMI ST58: <i>Chemical sterilization and high-level disinfection in health care facilities</i>

Description	Regulatory body	Statutes and regulations	Standards, recommendations, and other sources of information
			ANSI/AAMI ST41: <i>Ethylene oxide sterilization in health care facilities: Safety and effectiveness</i> Manufacturer's SDS and IFU
Occupational safety training, labeling, etc.	OSHA	29 CFR 1910.1200	ANSI/AAMI ST41: <i>Ethylene oxide sterilization in health care facilities: Safety and effectiveness</i> Manufacturer's SDS and IFU
Disposal	EPA State and local regulations	33 U.S.C. 1251 et seq. (Clean Water Act)	Manufacturer's SDS and IFU

4 Consensus and other standards

4.1 Consensus standards

Consensus standards in the United States are created by standards-developing organizations (SDOs) that follow the procedures required by the American National Standards Institute (ANSI). There are currently several hundred SDOs accredited by ANSI, and there are more than 10,000 American National Standards.

ANSI is the sole U.S. representative to the two major non-treaty international standards organizations, the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC). Many U.S. developed standards go on to become international standards and many U.S. standards are harmonized to international standards.

Further details of ANSI's role in standards development can be found at www.ansi.org.

4.1.1 AAMI standards

AAMI has developed a number of standards that are relevant to the safe use of sterilant and disinfectant chemicals and other chemicals in health care sterile processing. The primary standard for operations in sterile processing is ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, which provides general information about ventilation, humidity, employee training, etc., including some general guidance on the use of chemicals.

ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities*, provides guidance on the use of chemical sterilants. It includes annexes for FDA-cleared chemical sterilants and high-level disinfectants, each of which includes information on the following:

- a) The properties and applications of the sterilization/HLD system
- b) The safe use of the chemical, including
 - occupational exposure limits,
 - health effects (short-term and long-term),
 - personal protective equipment (eyes, skin, respiratory),
 - ventilation, and
 - safety guidelines.