# Technical Information Report

# AAMI TIR68: 2018

## Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces

AAMI
Advancing Safety in Health Technology

# Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces

Developed by
**AAMI**

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**AAMI**

**Abstract:** Provides guidance on the selection and use of low and intermediate-level disinfectants and disinfection processes for safe and effective use.

**Keywords:** low-level disinfection, intermediate-level disinfection, environmental surfaces

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### 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
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Melinda Elammari (Independent Expert)
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Gloria Frost, Cardinal Health
Zory Glaser, PhD, Johns Hopkins University School of Public Health
Nupur Jain, Intuitive Surgical Inc
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service Materiel Management
Doug Kruger (Independent Expert)
Erin Kyle, Association of periOperative Registered Nurses
Jean-Luc Lemyre, $TSO_3$ Inc
Stacey MacArthur (Independent Expert)
Jo Ann Maltais, Maltais Consulting
Jason Marosi (Independent Expert)
Elaine Mayhall, PhD, FDA/CDRH
Candace McManus, PhD
Astrid Merrifield, Boston Scientific Corporation
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Alpa Patel, Nelson Laboratories LLC
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Mike Schoene, Bausch & Lomb Inc
Rose Seavey, Seavey Healthcare Consulting, LLC
Frank Sizemore, Wake Forest University Baptist Medical Center
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Radhakrishna Tirumalai, US Pharmacopeia Convention Inc
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Donald Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc
Sunny Vestal, Baylor Scott & White Medical Center
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, $TSO_3$ Inc
Brent Geiger, Cantel Inc
Rachel Hill, Becton Dickinson & Company
David Hilliker, ChemDAQ Inc
Nancy Kaiser, STERIS Corporation
Kaumudi Kulkarni, Healthmark Industries Company Inc
Patrick McCormick, Bausch & Lomb Inc
Kathleen McMullen, Association for Professionals in Infection Control and Epidemiology
Emily Mitzel, Nelson Laboratories LLC
Navid Omidbakhsh, Johnson & Johnson
Sasi Songthong, WuXi AppTec Inc
Brian Wallace, Intuitive Surgical Inc
Jon Wood, International Association of Healthcare Central Service Materiel Management
Bryan Worwa, Boston Scientific Corporation

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

*Chair:*
Michael H. Scholla, MS, PhD
Patrick Weixel

*Members:*
Anas Aljabo, PhD, SteriPro Canada Inc
Brett Anderson, Cochlear Ltd
Hank Balch, University Health System
Richard Bancroft, STERIS Corporation
Marie Brewer (Independent Expert)
Trabue D. Bryans, BryKor LLC
Jon Burdack, PhD, Nanosonics Limited
Tim Carlson, Becton Dickinson & Company
Phil Cogdill, Medtronic Inc
Sean Colwell, WuXi AppTec Inc
Lena Cordie, Qualitas Professional Services LLC
Jacqueline Daley (Independent Expert)
Gordon Ely, MiMedx Group
Lisa Foster, Adiuvo QS & SA Consulting
Joel R. Gorski, PhD, NAMSA
Joyce Hansen, Johnson & Johnson
Stephanie Homuth (Independent Expert)
Clark Houghtling, Cosmed Group Inc
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service Materiel Management
Erin Kyle, Association of periOperative Registered Nurses
Byron J. Lambert, PhD, Abbott Laboratories
Michelle Luebke, Baxter Healthcare Corporation
Patrick J. McCormick, Bausch & Lomb Inc
Gerry O'Dell, Gerry O'Dell Consulting
Adrian Ponce, Verrix LLC
Janet Prust, 3M Healthcare
Nancy Rakiewicz, IUVO BioScience
Michael H. Scholla, MS, PhD, Dupont Protection Technologies
Linda Schultz, Northside Hospital Surgical Services Atlanta
Kristen Singleton, Getinge USA
Joan Spear, B Braun of America Inc
Sid Wiggs (Independent Expert)
Patrick Weixel, FDA/CDRH
Stephen Yeadon, Boston Scientific Corporation

William E. Young, Sterigenics International
Roberto Zumbado, Philips

*Alternates:*
Stacy Bohl, Boston Scientific Corporation
Greg Crego, IUVO BioScience
Dan Floyd, DuPont Protection Technolopgies
Bob Marrs, B Braun of America Inc
Gerry McDonnell, PhD, Johnson & Johnson
David McGoldrick, Abbott Laboratories
Kimberly Patton, Becton Dickinson & Company
Christine Render, Cosmed Group Inc
Michael Sadowski, Baxter Healthcare Corporation
Mark Smith, Getinge USA
Craig Wallace, 3M Healthcare
Lisa Ward, STERIS Corporation
Jill Warren, WuXi AppTec Inc
Martell Kress Winters, SM, Sotera Health
Jon Wood, International Association of Healthcare Central Service Materiel Management

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## Foreword

This technical information report was developed by the AAMI Hospital Chemical Sterilants Practices Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this technical information report is to provide guidance on the selection and use of low and intermediate-level disinfectants and disinfection processes for safe and effective use by all healthcare personnel who perform low and intermediate-level disinfection processes on patient care medical devices, medical equipment, and their accessories, and who have responsibility for cleaning and disinfecting environmental surfaces in medical device processing areas.

As used within the context of this document, "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; "may" is used to indicate that a course of action is permissible within the limits of the technical information report; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

This technical information report should be considered flexible and dynamic. As technology advances and as new data are brought forward, the technical information report will be reviewed and, if necessary, revised.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards Dept, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the AAMI TIR68, *Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces* (AAMI TIR68:2018), but it does provide important information about the development and intended use of the document.

# Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces

## Introduction

Appropriate, efficacious cleaning and disinfection of noncritical medical devices and equipment surfaces and of critical and semi-critical medical devices prior to high-level disinfection or sterilization by means of intermediate-level disinfection or low-level disinfection are important aspects of infection prevention and control for both patients and healthcare user safety. Cleaning and the various levels of disinfection are intended to help prevent transmission of infectious organisms that can cause disease. Transmissions can include person-to-person transmission (e.g., methicillin resistant *Staphylococcus aureus* (MRSA)*)* and also transmission of environmental pathogens (e.g., *Pseudomonas aeruginosa*). Unfortunately, outbreaks in healthcare facilities are not an uncommon occurrence and numerous published outbreaks have been traced to contaminated medical devices, equipment and even the disinfectants used. The increase in emerging and re-emerging pathogens and drug resistant pathogens presents a higher risk to patients and as a result there is a heightened need for thorough understanding of appropriate disinfection procedures and protocols to help prevent transmission of these microorganisms.

Use of chemical disinfectants was one of the first processes implemented to reduce patient infection risk, beginning in the mid-19$^{th}$ century. Even though disinfectants have been used for a very long period of time and much is known regarding the use and limitations, it is the multitude of available types of products from manufacturers that makes proper use more challenging today than in the past. The same chemical disinfectant from two different manufacturers can have different formulations and use instructions. Some general use disinfectants such as alcohol and chlorine are also used as household antiseptics or disinfectants but with different concentrations and use applications and might not all have hospital appropriate claims or proper registrations. Hospital grade disinfectants require specific knowledge of the appropriate products, claims and use procedures for healthcare applications.

Current AAMI standards appropriately address critical and some semi-critical patient care items that are terminally sterilized or high level disinfected with the information available in ANSI/AAMI ST79, ANSI/AAMI ST41, ANSI/AAMI ST58 and ANSI/AAMI ST91. Existing information and guidelines for processing of non-critical devices from other organizations outside of AAMI are typically very broad and not focused on sterile processing area applications. This document is written to provide relevant information for safely cleaning and appropriately disinfecting medical devices and environmental surfaces. It is intended to provide an easy-to-use format for primary use by healthcare personnel responsible for processing medical devices, as well as by personnel responsible for cleaning and disinfecting the processing area. Historically, disinfection of many of these types of items was not completed by sterile processing staff. However, with the increased awareness of healthcare associated infections (HAIs) and documented outbreaks tied to improper cleaning and disinfection procedures, the role of sterile processing personnel and the need for their recognized expertise has expanded beyond sterilization related procedures and often includes responsibility for medical device disinfection practices throughout the health care facility.

Items requiring low or intermediate-level disinfection may include non-critical patient-contacting medical devices, non-critical patient care equipment, and environmental surfaces. Guidance for cleaning and disinfection of environmental surfaces outside of the sterile processing area, provided in documents from CDC, APIC, ASHE and other professional organizations, is not discussed here. However, information on the appropriate processes for environmental cleaning and disinfection of the sterile processing area is provided in this document and is included to address the specific requirements necessitated by the nature of the work performed (e.g. cleaning and decontamination of used and potentially infectious medical devices) in the area which can require additional considerations compared to other areas within the environment of care in the healthcare facility.

Low and intermediate-level chemical disinfectants are biocidal solutions applied to inanimate objects such as medical devices used for patient care (e.g., tonometers, stethoscopes) and environmental surfaces. There are several different categories of chemical disinfectants with various performance characteristics and considerations for use as described in this document. Chemical disinfectants are available in a range of formats including liquids, impregnated wipes, sprays, concentrated powders and gases or vapors. Considerations in choosing the correct disinfectant for the task includes: degree of microbicidal activity required, the characteristics of the item to be disinfected, the device manufacturer's IFU, the disinfectant manufacturer's IFU, and the cost and ease of use of the available products.

Chemical disinfectants are classified as biocides and are intended to destroy and inhibit growth of microorganisms and can be ineffective or harmful to the user if not handled according to regulations and the manufacturer's IFU. Efficacy of chemical disinfectants, also referred to as germicides, can be impacted by multiple factors related to the process. Factors such as presence of organic soil on the item, design of the device, disinfectant dilution, contact time and temperature, mode of action, and microbial load in reusable solutions can all have a significant impact on efficacy. User knowledge of the proper use of a disinfectant is critical for rendering the item safe for use in patient care. All chemical disinfectants must be properly disposed of after use (Block).

Cleaning and disinfection terms are often used in conjunction with each other to describe the process of rendering a medical device or environmental surface safe for use and handling. In some cases, the same chemical solution can be used to complete both cleaning and disinfection (e.g. environmental surfaces) but for other applications, e.g. medical devices, it is typically two separate steps (or three, if the surface requires rinsing prior to subsequent processing). The appropriate process is dependent on the specific product being used and the surface being disinfected. It is often required for a surface or item to be free of visible organic matter, dirt or dust prior to use of a chemical disinfectant to achieve efficacy.

Low-level and intermediate-level disinfectants are regulated in the U.S. by the United States Food and Drug Administration (FDA). However, they are under dual regulation also by the Environmental Protection Agency (EPA) as antimicrobial pesticides. Regulation sets requirements for both manufacturers and users for intermediate and low-level chemical disinfectants. The product manufacturer's IFU must be followed to safely and effectively use these categories of products. When chemical disinfectants are used for liquid chemical sterilization or high level disinfection or sterilization of reusable medical devices, the sterilant or disinfectant chemistry and any related systems are regulated solely by the FDA.

# 1 Scope

This Technical Information Report (TIR) is intended for reference and use by all healthcare personnel who perform low and intermediate-level disinfection processes on patient care medical devices, medical equipment, and their accessories, and who have responsibility for cleaning and disinfecting environmental surfaces in medical device processing areas. This TIR provides guidance on the selection and use of low and intermediate-level disinfectants and disinfection processes for safe and effective use.

### 1.1 Inclusions

This TIR includes:

a) cleaning and disinfection of non-critical patient care items, devices and patient care equipment and accessories, cleaning and disinfection of electronic accessories for devices, and other non-critical devices (e.g., MR coils, MR/CT tables, X-ray detector plates, NICU incubators, cables, smaller console equipment, IV pumps and poles);

b) processes for categories of items that are terminally processed with low or intermediate disinfection;

c) chemical disinfection of items that are made safe to handle through low or intermediate disinfection to proceed to further processing, e.g. critical medical devices that will be terminally sterilized or semi-critical items that will be high-level disinfected;

d) recommendations for cleaning and disinfection of environmental surfaces in the sterile processing area; and

e) guidance on use of disinfectants and disinfection processes intended for items that:

   1) undergo final processing prior to reuse

   2) items that undergo processing to be made safe to handle prior to further processing (high-level disinfection or sterilization)

   3) environmental surfaces in medical device processing areas.

### 1.2 Exclusions

Non-critical environmental surfaces, (e.g., table tops, bed rails, privacy curtains) outside the sterilization or high level disinfection processing areas. This document also excludes high level disinfection and thermal disinfection processes for semi-critical devices, and disinfection achieved by physical means. Disinfection by a physical means would include methods such as pasteurization.

High level disinfection of endoscopes is covered by ANSI/AAMI ST91 and is outside the scope of this document. Similarly, sterilization processes, including steam sterilization, high level disinfection/chemical sterilization, and ethylene oxide sterilization, which are covered in ANSI/AAMI ST79, ANSI/AAMI ST58 and ANSI/AAMI ST41, respectively, are excluded from this document.

## 2 Definitions

**2.1 acid:** Substance having a pH of less than 7.

**2.2 aerosolization**: Production of mist or spray.

**2.3 antibacterial:** Chemical agent or compound that counteracts, inhibits, and/or destroys bacteria.

**2.4 antimicrobial:** Chemical or material capable of destroying or inhibiting the growth of microorganisms.

**2.5 aqueous**: Water; prepared with water.

**2.6 bactericide:** Chemical agent that kills bacteria.

**2.7 bacteriostatic:** Chemical agent that retards, inhibits, and/or prevents the growth of bacteria.

**2.8 contamination:** Presence of soil, pollution, or undesirable microorganisms.

**2.9 cross-contamination:** transfer of contaminants from one person, object, or work location to another.

**2.10 cleaning**: Removal of contamination from an item to the extent necessary for further processing or for the intended use. Cleaning of environmental surfaces also typically requires removal of organic and inorganic soil to allow for efficacy of intermediate and low-level disinfectants.

**2.11 decontamination**: Cleaning, disinfection or sterilization of potentially contaminated articles to make them suitable for use. (From ANSI/AAMI ST79:2017: “The use of physical or chemical means to remove, inactivate, or destroy blood-borne 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—The term is generally used in health care facilities to refer to all pathogenic organisms, not just those transmitted by blood.

**2.12 disinfectant**: An agent that destroys pathogenic and other kinds of microorganisms by chemical or physical means. A disinfectant destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores.

**2.13 disinfection**: A process that destroys pathogens and other microorganisms by physical or chemical means. Disinfection processes do not ensure the same margin of safety associated with sterilization processes. The lethality of the disinfection process may vary, depending on the nature of the disinfectant, which leads to the following subcategories:

a. High-Level Disinfection: A lethal process utilizing a high level disinfectant or liquid chemical sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.

b. Intermediate-Level Disinfection: A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but not all bacterial spores.

c. Low-Level Disinfection: A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi, and lipid viruses.

**2.14 biocide/germicide/microbicide**: An agent that destroys microorganisms, including pathogenic organisms. Other terms with the suffix -cide (e.g., virucide, fungicide, bactericide, sporicide, and tuberculocide) indicate an agent that destroys the microorganism identified by the prefix; these terms are traditionally used with EPA-regulated products.

**2.15 inanimate:** Not alive.

**2.16 instructions for use (IFU):** Written recommendations provided by the manufacturer that provide instructions for operation and safe and effective use of its device.

**2.17 intermediate-level disinfection:** See disinfection.

**2.18 material safety data sheet (MSDS):** Older term for document specifying the properties of a material, its potential hazardous effects on humans and the environment, and the precautions necessary to handle and dispose of the material safely. Currently known as SDS – Safety Data Sheet.

NOTE—See 2.23.

**2.19 pH:** Measure of alkalinity or acidity using a scale of 0 to 14, with 7 being neutral.

**2.20 PPE:** Personal protective equipment, specialized clothing or equipment worn to protect against a hazard.

**2.21 residual:** What remains or is left over.

**2.22 reusable medical device:** Device intended for repeated use on different patients, or the same patient, with appropriate cleaning and disinfection between uses.

**2.23 SDS:** Safety data sheet. Previously referred to at MSDS – material safety data sheet. This document is required to be provided by the manufacturer of chemicals used in the workplace, such as disinfectants.

**2.24 soluble:** A material capable of being dissolved.

**2.25 solution:** A homogenous mixture comprising a soluble compound which has been dissolved in a solvent.

**2.26 Spaulding Classifications:** A scheme that is used to describe the potential risk of patient infection caused by the intended use of the device and the appropriate microbicidal processes to assure its safe reuse. This scheme classifies devices into three categories based on whether they may contact intact skin (non-critical medical device), mucosal membranes (semi-critical medical device), or enter normally sterile body areas (critical medical device).

NOTE—This can include devices or medical equipment that do not directly contact intact skin but can become contaminated during patient care.

**2.27 wet contact time:** The entire contact time the item must remain wet with the disinfectant to achieve stated efficacy. If the disinfectant evaporates or the item is allowed to dry before the total contact exposure time is met, the disinfectant must be reapplied and continue with the exposure time until the wet contact time has been achieved.

# 3 Disinfectant classifications and general applications

### 3.1 General descriptions

The United States Food and Drug Administration (FDA) places disinfectants indicated for use on medical devices into two classifications[1]:

1.) Liquid chemical sterilants (LCS), including those used as high level disinfectants (HLD), intended for use as the terminal step in processing critical and semi-critical medical devices prior to patient use; high-level disinfectants are intended for use as the terminal step in processing semi-critical medical devices prior to patient use. High-level disinfectants are used primarily for high level disinfection of certain semi-critical medical devices that cannot withstand a sterilization process.

2.) General purpose disinfectants (GPD) intended to process non-critical medical devices and equipment surfaces or to preclean or decontaminate critical or semi-critical medical devices prior to terminal sterilization or high level disinfection.

### 3.2 Regulatory jurisdiction

FDA has sole regulatory jurisdiction over liquid chemical sterilants/ high-level disinfectants intended for use to process reusable heat sensitive critical and semi-critical medical devices and requires premarket review and clearance as Class II medical devices.

GPDs intended for use on medical devices are under dual regulation by the FDA and the Environmental Protection Agency (EPA). GPDs are Class I medical devices that are exempt from premarket review and clearance by FDA; however, they are required to be registered and listed with FDA. GPDs regulated by FDA include low-level disinfectants and intermediate-level disinfectants.

GPDs also require EPA registration as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prior to marketing. EPA reviews efficacy and safety data as part of the pesticide registration process. Fulfillment of EPA's registration requirements meets FDA's section 510(k) requirement for those products. GPDs are classified by EPA as hospital disinfectants with or without a tuberculocidal claim. Table 1 shows the difference in terminology used for GPDs.

**Table 1—Classification of general purpose disinfectants**

| FDA Product Classification | EPA Product Classification |
|---|---|
| Intermediate-level disinfectant | Hospital disinfectant with a tuberculocidal claim |
| Low-level disinfectant | Hospital disinfectant without a tuberculocidal claim |

As part of the EPA registration process, EPA requires that registrants of disinfectants intended for use on medical devices include the following statement on their product labels:

> "This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection"

Disinfectants intended for use on clinical contact surfaces (e.g., light handles, radiographic-ray heads, or drawer knobs) or housekeeping surfaces (e.g., floors, walls, furnishings, or sinks) are regulated solely by EPA.

The interim terms of the 1993 Memorandum of Understanding (MOU) between FDA and EPA regarding Regulation of liquid chemical germicides intended for use on medical devices and its 1994 amendment[2, 3] were partially satisfied when rulemaking by EPA and FDA regarding these germicides was completed. In 1996, passage of the Food Quality Protection Act (FQPA) exempted liquid chemical sterilants from the definition of a pesticide under FIFRA and gave FDA sole regulatory authority over liquid chemical sterilants and subordinate claims as a high level disinfectant. On June 8, 2000 FDA published the Final Rule [FR DOC # 00-14462] classifying liquid chemical sterilants/high level disinfectants as Class II medical devices with special controls under 21 CFR 880.6885.

General purpose disinfectants were unaffected by passage of FQPA and remained under the jurisdiction of both EPA and FDA. On June 8, 2000 FDA published the Final Rule classifying general purpose disinfectants as Class I medical devices with general controls under 880.6890 and exempting them from premarket notification requirements. Fulfillment of EPA's registration requirements fulfills FDA's section 510(k) requirement for those products. Although GPDs used on medical devices remain under dual regulation, exempting GPDs from premarket 510(k) requirements minimizes redundant regulation of these products by FDA and EPA. Table 2 shows FDA and EPA registered product categories.

**Table 2—FDA and EPA registered product categories**

| Product | FDA Category | EPA Category |
|---|---|---|
| Cleaning only | Not regulated | Not regulated |
| Cleaning + Disinfectant combo product | Class 1 device 510(k) exempt | Registered |
| Disinfectant only wipe – low or intermediate-level disinfectant | Class 1 device 510(k) exempt | Registered |
| Disinfectant only – high level | Class 2 device | Not regulated |

### 3.3 Choosing the appropriate disinfectant

The choice of chemical germicide(s) to effectively disinfect medical devices and patient care equipment can depend on various factors, including the type of contact the device has with the patient or user, the degree of microbial killing required, the type and composition of the surface or device to be disinfected, and the cost, safety, and ease of use of available disinfecting products.

- Generally, high-level disinfectants are formulated for use on heat sensitive semi-critical medical devices, but not on environmental surfaces such as laboratory benches or floors. Some are used to disinfect non-critical medical devices and equipment surfaces, and may also be used in laboratories for disinfection of laboratory benches and in healthcare facilities to clean and disinfect environmental surfaces and for housekeeping purposes.
- High-level disinfectant solutions are toxic and require extensive rinsing to remove the toxic residues from devices and surfaces. Therefore, devices, equipment, or environmental surfaces should not be disinfected by wiping with high-level disinfectant solutions.

FDA recommends that the device manufacturer provide the user with adequate written instructions for the safe and effective use of that device. These instructions must include methods to clean and disinfect or sterilize the item if it is to be marketed as a reusable medical device.

These links provide some of the relevant references:

- Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants (2000): http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077575.pdf
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (2015): http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf
- https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html
- http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5217a2.htm
- http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf

### 3.4 Spaulding classifications

The level of disinfection applicable to a medical device depends on the nature of their clinical use. Selecting the appropriate disinfection level for healthcare purposes is generally based on the Spaulding classification scheme. This scheme is used to describe the potential risk of infection caused by the device and the appropriate microbicidal processes to control that risk. Based on these considerations, for disinfection purposes medical devices can be grouped under three categories:

A. Critical Devices

Critical devices are devices that are introduced directly into the bloodstream or which contact a normally sterile tissue or body-space during use. There is a likelihood of microbial transmission and risk of infection (subclinical or clinical) if the device is not sterile. Users should be instructed to disassemble (if applicable), thoroughly clean, and sterilize critical devices after each use.

Examples of critical devices include surgical instruments, irrigation systems for sterile instruments in sterile tissues, endoscopes used in sterile body cavities (such as laparoscopes, arthroscopes, intravascular endoscopes) and all endoscope biopsy accessories.

B. Semi-Critical Devices

Semi-critical devices are devices that contact intact mucous membranes or non-intact skin. They do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body. Intact mucosal surfaces are relatively resistant to small numbers of spores. However, these devices should be reprocessed to be free from all microorganisms. Users should be instructed to thoroughly clean these devices and then reprocess them by sterilization. If the device design does not permit sterilization (e.g., device materials cannot withstand sterilization), then high level disinfection should be used.

Examples of semi-critical devices include endotracheal tubes, laryngoscope blades and other respiratory equipment, esophageal manometry probes, and diaphragm fitting rings.

C. Non-Critical Devices

Non-critical devices are instruments and other devices whose surfaces contact only intact skin and do not penetrate it. Non-critical devices also include devices that do not directly contact the patient but may become contaminated with microorganisms and organic soil (e.g., blood, body fluids) during patient care, even when such devices may not be visibly contaminated. CDC recommends thorough cleaning, then intermediate or low-level disinfection for non-critical devices depending on the nature and extent of contamination.

Examples of devices that contact only intact skin include blood pressure cuffs, stethoscopes, and skin electrodes. Examples of devices that have no direct patient contact, yet may become contaminated during patient care, include infusion pumps and ventilators.

## 4 Categories of devices

The complexity and variety among medical devices can make identifying the correct category for any particular device challenging. Understanding the category is important for selection of the appropriate disinfection process. Table 3 provides listings of devices and equipment by general category according to Spaulding's classification and other references. This table is not all inclusive but intended to provide general information. Classification can vary based on product labeling.

**Table 3—General listing of devices by category**

| Non-critical items | Semi-critical items | Critical items |
|---|---|---|
| • Patient care equipment<br>• Hospital beds, traction equipment<br>• Keyboards, touch screens, mouse<br>• Blood glucose meters<br>• Stethoscopes<br>• Blood pressure measuring equipment and holders<br>• Infusion pumps and poles<br>• Light cords connected to video monitors and processes<br>• Signaling equipment<br>• Oximeters | • Tonometers<br>• Cervical diaphragm rings<br>• Cryosurgical instruments<br>• Endo-cavity probes<br>• Gastrointestinal endoscopes (non therapeutic)<br>• Speculums<br>• Respiratory therapy equipment<br>• Respiratory equipment<br>• Anesthesia equipment<br>• Endotracheal tubes<br>• Non-invasive flexible and rigid fiber optic endoscopes<br>• Laryngoscope blades<br>• Bronchoscopes | • Surgical instruments<br>• Laparoscopes<br>• Implantable devices<br>• Power equipment<br>• Laparoscopic equipment<br>• Arthroscopes<br>• Intravascular endoscopes<br>• Scalpels<br>• Therapeutic endoscopes |

# 5 Personnel considerations

### 5.1 Training and education

As with all healthcare facility processing activities it is essential that the individuals performing and managing the disinfection processes meet qualifications including completion of education and training before being assigned to disinfection duties in order to perform these complex tasks safely and effectively. Thereafter, annual competencies should be verified including the safe use and handling of the specific chemical disinfectants. Written training materials/manual should document all aspects of training and competencies. All training and other informational materials should be available to the trained user.

For new users, the education and training should include:

a) initial orientation and on-the-job training;

b) required general attire and definitions of restricted areas;

c) basic information and understanding of the principles of low and intermediate-level disinfection practices;

d) description of how effective disinfection relates to infection prevention;

e) compliance requirements of or with applicable state and federal regulations and facility policy as well as information on various practice guidelines:

   1) OSHA blood borne pathogens standard (29 CFR 1910.1030);

   2) OSHA Hazard Communications standard (29 CFR 1910.1200); and

   3) Universal precautions (Standard Precautions).

f) the importance and method to understand and follow IFU;

g) the importance of using the correct contact time;

h) using the correct dilution;

i) the importance of using the correct temperature if required;

j) the selection and correct use of personal protection equipment (PPE);

k) safe handling of chemical disinfectants including recommended ventilation;

l) procedures for spills and exposures per SDS; and

m) an assessment of demonstrated competencies.

### 5.2 Personal protective equipment

Personnel should take precautions to avoid direct contact with chemical disinfectants. Personal protective equipment (PPE) should be worn to protect the user from potential or accidental exposure to disinfectants, in addition to or in combination with the PPE requirements for blood borne pathogens. The PPE is designed to protect skin, eyes, mucous membranes and clothing from splashes. ANSI/AAMI ST58: 2013 provides detailed information on appropriate considerations for PPE selection and use. The disinfectant manufacturer's instruction for use and the Safety Data Sheets (SDS) also provide information on the appropriate PPE to use when handling the disinfectants.

Service and other personnel should be provided information related to the potential hazards in the environment, regulations and importance of various measures of protective work practices, use of PPE and emergency procedures.

### 5.3 Health and user hygiene considerations

Health and user personal hygiene are also important considerations and include facility policy on vaccinations and appropriate steps to take in case of an exposure. Attire should be consistent with facility policy; in the health care environment this includes a clean uniform. Any soiled or wet attire should be replaced. Necklaces, rings and other jewelry should not be worn as they can harbor contamination.

### 5.4 Roles and responsibilities

Each member of the processing team has a role to play in ensuring safe and effective use of intermediate-level and low-level disinfectants, especially the operator or technician performing the task, department management, facility educator and the manufacturers of the disinfectants and equipment that are used. Policy and procedures should be established related to use of disinfectants and those policies should be written and readily available to staff. The staff must be trained, and their competency assessed and documented after training and periodically thereafter. See Table 4 (RACI Matrix) for a recommendation of the roles and responsibilities for the members of the processing team.

**Table 4—RACI Matrix**

| Role | Establish policy and procedure | Training and competency assessment | Safe and Effective Use |
|---|---|---|---|
| Operator/ technician or assistant | C | A | R |
| Department Manager | R, A | R | R |
| Educator | A | R | A |
| Manufacturer | C | C | A |

Relationship Code: R=Responsible, A=Accountable, C=Consultation, I=Informed

## 6 Processing items to allow safe handling

For items that do not go through an automated cleaning and disinfection process, disinfection procedures for the item should be described by the device or equipment manufacturer's IFU. This may include the use of a liquid chemical disinfectant or disinfectant wipes. Only the type of cleaning or disinfectant chemical(s) recommended by the device or equipment manufacturer's IFU should be used. If adequate information is not provided by the manufacturer, the item should not be used or reprocessed until adequate information is available.

# 7 Considerations prior to low-level or intermediate-level disinfection

### 7.1 Cleaning

Cleaning is defined as the physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use. Residual soil can inactivate disinfectants and decrease their effectiveness. Therefore, a device must first be thoroughly cleaned to remove soil and contaminants before it can be successfully disinfected. (See also Section 8.)

### 7.2 Environments

Cleaning and disinfection procedures occur in multiple environments each with important considerations for both the effectiveness of the process as well as safety and consideration for the staff, patients and families present in the area. Low and intermediate-level disinfection processes are commonly performed in:

a) acute health care setting such as hospital sterile processing departments, operating rooms, patient care units and other areas such as labor & delivery, etc.;

b) ambulatory settings including outpatient surgery centers, endoscopy centers, dialysis centers and other areas;

c) clinics including physician offices, dental offices, free standing clinics in commercial spaces;

d) long term care, assisted care living and transitional care units;

e) patient's home environment; and

f) other processing areas.

While the various environments present different challenges related to the selection and use of disinfectants, users in all environments require training and education to provide low-level disinfection or intermediate-level disinfection safely and effectively. Manufacturers' IFU should always be followed and users are legally required to do so by EPA labeling.

### 7.3 Equipment

Many different types of equipment and supplies are used to perform low-level disinfection and intermediate-level disinfection processes. The equipment should be in good condition and working order. Equipment should be assessed before each use and replaced if damaged or compromised. Equipment maintenance should be performed according to the manufacturers' recommendations. Damaged equipment should not be used; it should be replaced or repaired. Equipment can include:

a) containers such as basins, bins, buckets, tubs or sinks;

b) cleaning tools or implements such as brushes, mops, microfiber mops, etc.;

c) dispensing systems designed to assist with proper dilution, i.e. manual pumps, proportioners, dosing systems;

d) equipment to transport medical devices to the disinfection area; and

e) cleaning verification monitoring systems.

### 7.4 Occupational safety

Use of chemical disinfectants may pose a potential risk to the users who handle these materials and present a risk of exposure through splashing or contact on the eyes, face or skin. Chemical disinfectants should be used in well ventilated areas to avoid exposures to aerosols and/or vapor concentrations exceeding occupational exposure levels. Some types can also present a respiratory exposure when fumes are inhaled or through other routes of exposure. Healthcare facilities must follow the requirements of the OSHA Hazard Communication Standard (29 CFR 1910.1200) which requires that employers provide information about chemicals used in the work area and potential hazards (SDS, labels), how to recognize potential over exposure and how to work so as to prevent chemical

exposure to themselves and others. Employers need to take measures to ensure that employees are not exposed to chemicals and Healthcare facilities are required to conduct and document a hazard assessment, including assessing potential chemical exposures, to determine which specific hazards require the use of PPE (29 CFR 1910.132(d) & 1200 (h)). In addition, if employees are handling items with potential biological contamination, they must be trained in OSHA's bloodborne Pathogen Standard (29 CFR 1910.1030), the risks associated with biological hazards should be included in the employer's hazard assessment, and employees provided with the PPE and other means necessary to work safely.

NOTE—NIOSH recommends that employers use a hierarchy of controls to mitigate the risk of chemical exposure or exposure to other risks, the hierarchy being Elimination, substitution, engineering controls, administrative controls, PPE. PPE should only be used when none of the higher control methods are practical (https://www.cdc.gov/niosh/topics/hierarchy/default.html).

Key factors for safe use of PPE may include:

a) hazard assessment;

b) recommended type of PPE identified and available;

c) employee training in the donning (putting on) and doffing (removal) of PPE;

d) fit of PPE to the specific user; and

e) availability of an up-to-date SDS and manufacturer's instruction for use for both the PPE and the disinfectant.

When the chemical is not corrosive, one intervening door can be present, provided that it opens in the same direction of travel as the person attempting to reach the emergency eyewash/shower equipment and the door is equipped with a closing mechanism that cannot be locked to impede access to the equipment.

Types of typically required PPE and emergency equipment:

a) Eye protection may include goggles or full length face shield and is used to avoid contact of the eyes with the chemical disinfectant. An eyewash station that complies with ANSI Z358.1 is required within 10 feet of where the chemical is mixed or used. The emergency eyewash should be maintained per the manufacturer's written instructions, tested weekly for flushing action and water temperature (the recommended water temperature is 60-100ºF).

b) Skin protection, to protect against exposure to the disinfectant, includes the recommended gloves which should be impervious to the chemical. Forearms should be covered with elbow length gloves or long impervious sleeves. Isolation gowns or aprons or a higher level of AAMI PB70 gown might also be needed.

c) Face masks that protect the mouth, chin and nose.

d) Respiratory protection as indicated by the hazard review.

e) Head covering as indicated.

ANSI/AAMI ST58:2013 provides additional detailed information on appropriate considerations for PPE selection and use.

### 7.5 Environmental safety

Chemical disinfectants must be disposed of according to the manufacturer's IFU and local and state regulations, as some types can be hazardous to the environment if disposed in the sanitary sewer systems. Consult the SDS and manufacturer's IFU for disposal and spill containment instructions.

## 8 Cleaning considerations

### 8.1 Importance of cleaning

For all reusable medical devices, the first and most important step is thorough cleaning to remove organic soil and contaminants from the device. If a device has not been thoroughly cleaned, it is not safe for patient use and the

functionality of the device could be compromised. In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent organic and inorganic soil (e.g. blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination. It is then rinsed, and in some cases dried before proceeding to the disinfection step. Although cleaning also removes a large number of microorganisms, its primary function is to remove organic soil and contaminants and allow successful disinfection of the device. Cleaning of environmental surfaces also requires removal of organic and inorganic soil to allow for efficacy of intermediate and low-level disinfectant. Residual organic matter or large numbers of microorganisms can significantly reduce the effectiveness of the subsequent intermediate or low-level disinfection process.

Some products are available that can be used for both cleaning and disinfecting and it is important to fully understand the product use instructions.

Rinsing is intended to remove cleaning agent and soil residues from the device that may impact the effectiveness of subsequent disinfection step. The appropriate water quality and method of rinsing or other methods of removing residual cleaning agents or debris should be performed according to manufacturer's IFU.

The amount of cleaning agent residue that remains on a device or surface will vary depending on the conditions of use for the cleaning agent, the specific component materials of the reprocessed devices, and the methods used to reduce residuals during rinsing. Therefore, it is essential to closely follow the cleaning agent IFU.

Drying the device before proceeding to the disinfection step may be required because excess liquid may dilute the disinfectant. After devices are rinsed, they should be visually inspected for cleanliness and working condition and then dried (e.g., with a clean lint-free cloth), in accordance with the device manufacturer’s IFU, before disinfection.

Residual soils can prevent contact of all surfaces with the disinfectant. Personnel should visually inspect each device carefully to detect any visible soil. Visual inspection alone may not be sufficient for assessing the effectiveness of the cleaning process. The use of objective methods that are able to verify cleaning effectiveness by measuring soil that is not detectable by visual inspection alone may be considered in the facility’s cleaning policies and procedures.

### 8.2 Device and surface preparation for cleaning

Contaminated devices and surfaces should be prepared for cleaning. Preparation includes removing any covering, debris, waste or disposable components of the item. Procedures should be developed to ensure that personnel comply with OSHA regulations (29 CFR 1910.1030) for handling contaminated items.

Some medical devices might require disassembly prior to cleaning. A copy of the device manufacturer’s IFU should be available in the cleaning area for staff reference. Hidden surfaces and crevices can interfere with cleaning and subsequent disinfection. The device manufacturer’s IFU must be followed for disassembly of all items. The items needed to perform the process should be provided. Care should be taken to ensure that all small parts (e.g., screws, nuts, and washers) are contained to prevent loss and separation from the device.

Devices with lumens are more difficult to clean effectively than devices without lumens, and care should be taken to ensure that thorough cleaning is performed. All surfaces of the lumen must be thoroughly cleaned first, usually with a brush, of the size and type specified by the device manufacturer, to create friction inside the lumen to remove soils.

Unless contraindicated by the device manufacturer’s IFU, the lumen of a device should be flushed with a cleaning agent (preferably an enzymatic cleaning solution), vigorously brushed with a brush having bristles of the appropriate material, size and length, as specified by the device manufacturer (which will create friction against the lumen walls), and then rinsed with the quality of water specified by the device manufacturer. Any stylets or plugs should be removed before cleaning.

### 8.3 Cleaning agents

Cleaning agents are materials used to remove soil (organic, inorganic, and biological matter) from medical devices so that they can be further processed for their final intended use (Spaulding, 1968). Such materials include items used for physical or chemical removal of soils by wiping, brushing, or flushing with liquids that facilitate the cleaning process.

Cleaning agents are generally categorized as either enzyme-based or non-enzyme-based. Each cleaning agent consists of a combination of active and inert chemical ingredients and has a specific intended use. Consequently, cleaning agents vary in efficacy, safety, and materials compatibility. Enzyme detergents are commonly used in the processing of difficult-to-clean devices such as vascular instruments, instruments with hinges, micro-instruments, orthopedic instruments, and instruments with lumens (e.g., flexible endoscopes) (Fushimi et al., 2002a). Most medical device detergent manufacturers offer several types of formulations. Various forms of detergents are available, including solutions, sprays and foams. Most, but not all detergents, are provided at neutral pH; the exact pH can be product-specific.

Non-enzyme detergents use a variety of chemical agents to aid cleaning. An important component of these products is detergent, which is widely used for cleaning medical devices. Detergents are any of a group of synthetic, organic, liquid, or water-soluble powders containing wetting and emulsifying agents that suspend soil and prevent the re-deposition of insoluble compounds or scum on the device or the surface of the cleaning solution.

Detergents of neutral pH (6-8) are usually recommended for cleaning because metal surfaces can be damaged by harsher pH conditions (either acid or alkaline).

Cleaning agents to be used in a validated cleaning process should be compatible with the materials used in the medical device to be cleaned and with the materials used in cleaning equipment that may be used. Personnel should consult the device manufacturer's IFU to determine the appropriate type of cleaning agent. The cleaning agent manufacturer's IFU should be followed. For example, cleaning chemicals should be easy to remove from the medical device by rinsing with readily available water of defined properties, so that the device does not retain residual chemicals in amounts that can harm humans, damage the device, interact with disinfectants, or create other hazardous situations. An ideal cleaning agent

a) is nonabrasive;

b) is low-foaming;

c) is free-rinsing;

d) is biodegradable and environmentally friendly;

e) provides for rapid soil dispersion or suspension;

f) is nontoxic in the specified use dilution;

g) is effective on clinically relevant soils under specified use conditions;

h) has a long shelf life; and

i) is cost-effective.

Personnel should consult the device manufacturer's IFU for directions on cleaning and disinfection, as the instructions often vary depending on the phase of processing. The processing instructions should include recommendations for the particular type of cleaning equipment and/or cleaning agent that should be used.

### 8.4 Cleaning patient care equipment

Patient care equipment should be maintained as free of gross soil as possible during use. Cleaning should begin as soon as possible after device/ equipment have been used or on a regular interval during use when possible. A copy of the equipment manufacturer’s User Manual should be available for reference regarding the recommended cleaning

process and chemicals. Personnel should disassemble equipment as recommended by the manufacturer to ensure that all surfaces are effectively cleaned.

Devices should be manually cleaned in accordance with the IFU using the recommended disinfectant chemical(s) and equipment (unless mechanical cleaning units are not available or instruments are too fragile or difficult to clean with a mechanical cleaning unit) recommended. To be effective, cleaning agents and methods must remove residual organic soil without damaging the device.

The cleaning solution should be changed as recommended by the detergent manufacturer or on a frequent basis to ensure the effectiveness of cleaning agent. Utility water (tap water) can be used for rinsing, unless IFU requires the use of critical water. All surfaces should then be thoroughly rinsed to remove any traces of enzymes, detergents, and residual soil. The cleaning agent manufacturer and the device manufacturer should provide comprehensive instructions for rinsing that describe the type and quality of the rinse water and the volume and duration of the rinse. See AAMI TIR34 for recommendations regarding the quality of water for the final rinse.

Cloths or wipes used for cleaning should be clean, lint-free and changed frequently. Towels should also be clean and lint-free. Single-use cleaning implements should be discarded after each use. Cleaning of brushes and other cleaning implements reduces biofilm-forming microorganisms and thus minimizes the formation of biofilm. Reusable brushes should be cleaned and disinfected at least each shift.

# 9 Disinfectants, applications and effectiveness

### 9.1 General information

Low-level and intermediate-level chemical disinfectants are typically made as formulations with a variety of ingredients, in addition to the active component(s), that are included to maintain both the efficacy and stability of the disinfectant product. These ingredients can be used to solubilize the active ingredient(s) both in concentrate and use dilution, handle the variability of water quality utilized for dilution, and promote wetting of a surface to allow for adequate contact time.

### 9.2 Classifications, mode of action and considerations for use

These formulations are submitted, reviewed, and approved by the EPA for efficacy, safety and stability, even when they are additionally regulated as 510(k) exempt medical devices by the FDA. It is important to utilize an EPA registered (approved) disinfectant to assure that efficacy claims, including spectrum of activity, use dilution and IFU, are appropriate and backed by scientific evidence. In addition, safety and stability of these products are also verified as part of the EPA review process. Even alcohol and bleach products should have the appropriate registration and claims prior to utilization within a healthcare facility for low-level or intermediate-level disinfection purposes. Chemical disinfectants are typically made as formulations. Table 5 provides the various classes of chemical disinfectants and their active ingredients, provides some examples, and describes the typical activity level and mode of action. The mode of action is the mechanism by which the chemical inactivates or destroys microorganisms. Table 6 describes the typical processing steps by device type or category. Table 7 provides considerations for use by class of disinfectant.

**Table 5—Classes and example of chemical disinfectants**

| Classes of chemical disinfectant active ingredients | Non-limiting Examples | Typical activity level (may vary – see label) | Mode of Action * |
|---|---|---|---|
| Alcohols | Isopropyl alcohol (IPA) or Ethanol | Intermediate | Denaturation of proteins |
| Quaternary Ammonium | Benzyl-C12-18 alkyldimethyl, chlorides (ADBAC), di-C8-10 alkyldimethyl, chlorides (DDAC) | Low or intermediate | Generalized membrane damage including: enzyme inactivation, denaturation of proteins, disruption of cell membranes |
| Quaternary Ammonium + Alcohol | Benzyl-C12-18 alkyldimethyl, chlorides (ADBAC), di-C8-10 alkyldimethyl, chlorides (DDAC), isopropyl alcohol (IPA) | Intermediate | Generalized membrane damage including: enzyme inactivation, denaturation of proteins, disruption of cell membranes, denaturation of proteins |
| Iodophors | Povidone iodine | Low | Oxidation, Iodination |
| Phenols | Para-tertiary amyl phenol (PTAP), ortho-Benzyl para-chloro-phenol (OBPCP) | Low or Intermediate | Generalized membrane damage including:<br><br>Penetration and disruption of cell wall, precipitation of proteins |
| Chlorinated compounds | Hypochlorite, Sodium dichloroisocyanurate, Chloramine T | Low or intermediate | Oxidation, chlorination |
| Oxidizers | Peracetic acid, Hydrogen peroxide | Low or intermediate | Oxidation, disruption of cell wall permeability, denaturation of proteins |

***CDC 2008, Block (5th edition), Disinfection and Decontamination (2008), Disinfection, Sterilization and Antisepsis (2010) Handbook of Disinfectants and Antiseptics (1996)**

**Table 6—Typical processing steps by device types/categories**

| | Medical Device | |
|---|---|---|
| | Non-critical patient care items | Non-immersibles, heat sensitive* |
| Non-limiting examples | Wheel chair, walker, portable toilet, IV pump, IV poles | Electronic equipment, Electrical/ mechanical equipment, non-critical tools, cameras, or surgical trays prior to subsequent high level disinfection or sterilization ** |
| Process | | |
| **Cleaning** | x | x |
| **Rinsing** | x | x |
| **Low-level disinfection** | x | X or next one |
| **Intermediate-level disinfection** | | x |
| **Rinsing** | possibly | X** |
| **Drying** | possibly | x |
| * Undergo subsequent sterilization process | | |
| * Must be made safe to handle on the clean side if not compatible with washer/disinfector<br>** Lack of thorough rinsing can result in interaction with subsequent chemical high level disinfection or sterilization process | | |

**Table 7—Considerations for use by class of disinfectant**

| Classes of chemical disinfectants* | Applications and safe use considerations for user and patient | Conditions for effectiveness | Advantages | Disadvantages |
|---|---|---|---|---|
| Alcohols (Isopropyl alcohol or Ethanol) | PPE | Clean and dry surface, assurance of wet time | Rapid bactericidal activity<br>Low residue<br>Does not stain surfaces<br>Can also serve as drying agent | Activity is dramatically affected by residual moisture and organic load.<br>Some plastics and elastomers are not compatible.<br>Flammable<br>Wet contact times may be hard to achieve due to volatility.<br>No residual activity. |
| Quaternary Ammonium Compounds | PPE, rinsing | Cotton and charcoal should not be used with this disinfectant | Detergent properties<br>Residual activity | Can be inactivated by organic material<br>Not compatible with soap |

| Classes of chemical disinfectants* | Applications and safe use considerations for user and patient | Conditions for effectiveness | Advantages | Disadvantages |
|---|---|---|---|---|
| | | since these products may absorb or neutralize it | | Generally only tuberculocidal in ready-to-use formulations<br>Difficult to rinse, residue is often cytotoxic<br>Higher potential to leave a film that can result in patient irritation |
| Iodophors | PPE, rinsing | Clean Surface | Rapid activity | May stain surfaces<br>Corrosive to metals and detrimental to some plastics<br>Activity affected by organic material<br>No residual activity |
| Phenolics | PPE, rinsing | Clean surface | Broad spectrum effectiveness<br>Residual activity | Detrimental to some plastics<br>May be inactivated by organic material (less than some other disinfectants)<br>May be difficult to rinse<br>Higher potential to leave a film that can result in patient irritation |
| Chlorinated compounds | PPE, rinsing | Clean surface | Broad spectrum effectiveness,<br>Fast acting | Corrosive to metals<br>Stains many surfaces<br>Inactivated by organic material<br>Unstable<br>Can have strong odor |
| Peracetic Acid | PPE, rinsing | Clean surface | Broad spectrum effectiveness,<br>Fast acting,<br>Breaks down to non-hazardous components | Corrosive to some materials<br>Can have strong odor |
| Hydrogen Peroxide | PPE, rinsing | Clean surface | Broad spectrum effectiveness,<br>Fast acting<br>Breaks down to non-hazardous components | Corrosive to some materials |

* All of the claim structures of disinfectants are formulation dependent. EPA registration is important in order to understand claims (spectrum of activity) and use instructions necessary for effective use.

NOTE—Some disinfectants can act as a fixative for residual protein, making it more difficult

**9.3 Product selection considerations/purchase decisions**

Due to the wide variety and multiple manufacturers of disinfectants, product selection and purchase decisions require careful consideration. The following information should be obtained to assist with making well-informed selection and purchase determinations.

1) How and where will the product be used?
2) What is the dosage form (Concentrate, Ready-to Use, Foam, Liquid, Wipe, Spray, etc.?)
    (a) For example, when using a product to wipe down large surfaces where a large quantity of product is used routinely, a concentrate might make sense, but if use is on a small item in a

remote area of a facility with limited access to water for dilution the preference might be a Ready-To -Use product.

3) Is the product EPA registered?
    (a) A disinfectant product with an EPA registration will have been reviewed and approved for safety and the effectiveness of labeled claims. Since any claims require submission of data, they are both evidence based and tied to the specific product formulation and IFU.
4) What is the spectrum of activity/product claims (e.g. Gram positive and Gram negative bacteria, fungi, viruses and mycobacterium)?
    (a) A medical device exposed to potentially infectious tissue that needs to be made safe to handle by healthcare personnel prior to undergoing subsequent processing may need a different spectrum of activity/claim structure than a product used to disinfect a wheelchair.
5) What contact time/wet time is required for activity?
    (a) If a product has a specified contact time and it is difficult to keep the device or surface wet for the stated time frame it may require re-application as specified by the manufacturer.
6) What is the compatibility with materials of construction of the device or equipment?
    (a) Certain products have incompatibilities with various materials (metals, plastics, etc.) such that their use to disinfect devices made of those materials may be detrimental to the devices.
7) What is the organic load tolerance?
    (a) The ability of a product to work in the presence of some soil may provide a more consistent result. If organic load of the item to be disinfected is inherently low, then this tolerance may not matter.
8) Are there any flammability concerns with the disinfectant?
    (a) Understanding the flammability/combustibility profile of a given product and how and where it may be used are important in determining a product's fit. Products that are flammable may be perfectly acceptable in the right environment or process, but not in others.
9) Are there any safety concerns using this product?
    (a) Consult the SDS and manufacturer's IFU for safety concerns such as irritation/corrosivity to skin or eyes, sensitization, respiratory exposure risks, and the appropriate safety measures that should be employed.
10) Is there a potential residue? How easy is it to rinse?
    (a) The amount of residue in a no rinse application and/or difficulty in rinsing in an application requiring rinsing, can both negatively impact usability of a disinfectant product.
11) What is the cost per use?
    (a) Total cost should be considered, but should not be the only factor. An inexpensive but ineffective, hard to use, or damaging product could actually cost more in the long run.

### 9.4 How to read and interpret labels

For germicides regulated by the EPA under FIFRA the labeling includes a statement: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." A hospital disinfectant with a claim that it is effective against mycobacteria can be used, per the label instructions, as an intermediate level disinfectant. As a result, the ability to read and understand labels takes on a higher level of importance and compliance requirement for the facility. When the germicide is intended to 1) Process noncritical medical devices and medical equipment surfaces, or 2) Preclean or decontaminate critical or semi-critical medical devices prior to terminal sterilization or high level disinfection, these disinfectants are also labeled as medical devices.

The FDA requirements for labeling of medical devices, including low-level or intermediate-level disinfectants, are outlined in 21 CFR Part 801. A specific statement required for low-level and intermediate-level disinfectants used on medical devices is discussed in section 4.2.

The EPA requirements for labeling of a low-level or intermediate-level disinfectant are outlined in the Federal Code of Regulations under 40 CFR part 156 for pesticides and devices.

The general contents of every low-level and intermediate-level disinfectant label will include:

a) product name and reorder or catalog number;

b) brand or trademark under which the product is sold;

c) name and address of the producer (or registrant) and producing establishment number;

d) an ingredient statement;

e) directions for use;

f) the net contents;

g) the product EPA registration number;

h) hazard and precautionary statements; and

i) storage and disposal instructions.

**Ingredient statement.** All labels will display on the front panel an ingredient statement listing the active ingredient(s) by the accepted common name, followed by the chemical name, and the percentage by weight of each active ingredient. The ingredient statement will also include a total percentage of all "inactive ingredients". This information is required as part of the manufacturer's submission and regulatory review process for the disinfectant products. All ingredients are reviewed for safety. The inactive components are not required to be listed individually on the label unless considered to be a safety concern to humans or the environment.

**Hazard and precautionary statements**. The signal word(s), child hazard warnings, and in some cases, the first aid statement are located on the front panels. Other human hazard and precautionary statements may appear on other panels of the label and in supplemental labeling.

Typical precautionary statements for human hazards are required based on the toxicity category and the type of hazard and describe the particular hazard, the route(s) of exposure, and the precautions to be taken to avoid accident, injury or toxic effect, or to mitigate the effect.

Warning statements for physical or chemical hazards are required if there are flammability or explosive characteristics. The types of warnings are determined by the disinfectant's flash point or use of pressurized containers. In addition, there may be other hazards (such as oxidizing potential, chemical reactions, etc.) that may be required.

There are also hazard and precautionary statements required for environmental hazards to "non-target" organisms, such as toxicity to fish or birds.

Worker protection statements are meant to reduce the risk of illness or injury resulting from exposure and include information such as the PPE required and recommended.

**Directions for Use**. This section of a label describes how the product can legally be used and how it must not be used. It includes the sites of application, the organisms it has been tested on and found to be effective against, application methods, amount to be applied and rate of application and any restrictions for use. Where certain directions or precautions are necessary to achieve effective use, they are stated in mandatory terms such as "must", "will", "do not". Any items listed as recommendations that are not necessary for effectiveness use terms such as "recommended", "can", "should", and "may".

The general statements on where to use the product and its intended uses are the first section in the directions for use. Although considered part of the directions for use, some labels may not be titled in that manner. Complete information on how to prepare, handle and apply the product are included with approved labeling. If it is a "Ready-to Use" product, this should be stated or if it is a concentrated product, the dilution instructions will state, for example, "mix "X" amount of the product, with "Y" amount of water.

The types of testing conducted and the conditions (dilution, time, temperature, water quality, organic load) of that testing are included with a listing of organisms the product is deemed to be effective against. Although the product may be effective against other organisms, only those against which it has been tested may be displayed on the label. There may be various contact times and dilution rates given for various organisms. The product should be used at the highest concentration and longest time for the organisms of concern.

The above information is considered important as part of the product IFU. There is typically a sub-section of the label with a specific title that includes preparation and application information. This section will define surface preparation prior to product application/disinfection (e.g., pre-cleaning, drying), how the product should be diluted, how it should be applied (e.g., mop, cloth, brush), the required wet contact time, how often the solution should be refreshed and how long a diluted solution should be stable.

**Storage and disposal.** This section of the labeling describes how to store a product, dispose of leftover product, clean an empty container, and dispose of an empty container if recycling or reconditioning is not an option. In addition, there may be instructions on how to dispose of the product rinsate and how to return the container for refilling (for sale or distribution), if it can be reused.

See 21CFR part 801, 40CFR Part 156, or EPA pesticide Registration Label Review manual for more information.

### 9.5 General safe handling and disposal considerations

Intermediate or low-level disinfectant solutions should be disposed of in accordance with the manufacturer's label instructions, the SDS of the materials, and with federal, state, and local ordinances. The environmental impact of each product, regarding formulation and concentration, needs to be considered separately.

If there are no disposal restrictions or special requirements, solutions may be discarded, along with copious amounts of cold utility water, into a drain connected to a sanitary sewer. Care should be taken to ensure that adequate ventilation is provided to prevent inhalation of disinfectant vapors during disposal. Empty containers should be disposed of in accordance with the disposal instructions given on person for whom the product is produced. See Table 8.

**Table 8—Disposal considerations by categories of chemical disinfectants**

| Classes of chemical disinfectants | Disposal Considerations |
|---|---|
| Alcohols | The liquid product is a RCRA hazardous waste for the characteristic of ignitability with a waste code of D001. (See 40 CFR Part 261.20 – 261.33)<br><br>Aerosol containers should be emptied and depressurized before disposal. Handle empty containers with care because of flammability of residual vapors. Empty containers should be decontaminated by rinsing with water prior to disposal or recycling. Empty containers may be recycled. Any liquid product should be managed as a hazardous waste.<br><br>All disposal activities must comply with federal, state and local regulations. Local regulations may be more stringent than state or national requirements.<br><br>Environmental precautions: Take precautions to prevent contamination of ground and surface waters. Do not flush into sewer or storm drains. |
| Quaternary Ammonium | This product (either "as sold" or "diluted at use") should not be allowed to enter drains, water courses or the soil. RCRA hazardous waste D002 (corrosive). Where possible recycling is preferred to disposal or incineration. If recycling is |

| Classes of chemical disinfectants | Disposal Considerations |
|---|---|
| | not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.<br><br>Dispose of any unused product. Thorough rinsing of traces is required. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not reuse containers. |
| Iodophors | Prevent entry into waterway, sewers, basements or confined areas. Rinse containers in water prior to disposing. Containers may be recycled where permitted. Refer to local Waste Management Regulations for other approved methods. |
| Phenols | Product may be flushed to a sanitary sewer with copious amounts of water, in accordance with state, local and federal regulations. Disposal restrictions in some states. For additional guidance, contact the State Water Board or the Regional Office of the EPA. |
| Amines | In general, all containers should be fully emptied and/or decontaminated with water before disposal. Depending on the SDS Disposal Considerations from a manufacturer SDS, these containers may be either recycled or disposed of in a sanitary land-fill. Do not reuse containers. |
| Chlorinated compounds | Avoid release to the environment. Dispose of material through a licensed waste contractor. Decontamination and destruction of containers should be considered.<br><br>If empty container retains product residues, all label precautions must be observed. |
| Oxidizers | This product is a hazardous waste according to Federal regulations (40 CFR 261.4(b)(4)): D002 Corrosive waste. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the waste solution meets RCRA criteria for hazardous waste. Dispose in compliance with all Federal, state, and local laws and regulations.<br><br>When diluted as stated on the product label, is not classified as hazardous according to OSHA 29CFR 1910.1200 (HazCom 2012-GHS). Undiluted material should not be allowed to enter storm or sanitary sewer system.<br><br>Do not re-use containers. |

*Table a compilation from 40 CFR parts 156.62 and 156.64

## 10 Risk assessment for low-level disinfection and Intermediate-level disinfection processes

Risk assessment is an important part of the facility quality management system. Improper use of low and intermediate-level disinfectants can represent a potential risk to both patients and staff. A risk assessment process is a means to involve a cross-functional team to develop policy and procedures and identify the risk of inadequate or improper use of intermediate level or low level disinfectants that could cause a disinfection failure or other defect in the processing practice. Risk assessment helps to identify potential issues and allow risk mitigations actions to reduce the overall likelihood of a problem to be incorporated in the facility policy and procedures. Table 9 provides Risk Assessment

questions and describes potential risk and benefit and is intended for use as a starting point for facilities to assess the considerations and potential risk.

**Table 9—Risk assessment considerations**

| Risk Question | Benefit | Risk |
|---|---|---|
| If the patient care item is being used directly on patients, does it leave a residue? | None. | A residue can result in harm to a patient. |
| Is the use consistent with the written IFU from the disinfectant manufacturer? | Following the written IFU from the disinfectant manufacturer ensures the efficacy of the disinfectant. | Not following the written IFU may compromise the disinfection process. Not following the written IFU can damage the equipment. |
| Is the disinfectant consistent with the written IFU from the equipment/device manufacturer? | Using the disinfectant recommended for the equipment reduces damage to the equipment. | Using a disinfectant not recommended for the equipment can damage the equipment which can increase costs or the damaged equipment may have a negative impact on patient care. |
| Does the disinfectant release noxious fumes that could be hazardous to personnel or patients? | None. | Irritating fumes can be harmful. |
| Does the healthcare facility have the ability to store and use the disinfectant at specific storage conditions? | Storing the disinfectants according to the IFU will assure the disinfectant will be effective. | Failing to appropriately store the disinfectants can render the disinfectant ineffective or may cause an unsafe condition. |
| Is it possible to follow the wet contact time as required in the labeling? | None. | The disinfectant may evaporate quickly thus not having adequate contact time, or require re-application. Parts of the equipment may be difficult to reach or non-wetting. |
| Is a spill kit available to safely clean up the spilled disinfectant? | Having the correct type of spill kit available will provide the correct type of chemicals to remove the spilled chemical. | Not cleaning up or removing spilled chemicals can result in personnel or patient injury. |

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