

Appendix C

Methods for Sterilizing and Disinfecting Patient-Care Items and Environmental Surfaces*

Process	Result	Method	Examples	Health-care application	
				Type of patient-care item	Environmental surfaces
Sterilization	Destroys all microorganisms, including bacterial spores.	Heat-automated	Steam, dry heat, unsaturated chemical vapor	Heat-tolerant critical and semicritical	Not applicable
		High temperature			
		Low temperature	Ethylene oxide gas, plasma sterilization		
High-level disinfection	Destroys all microorganisms, but not necessarily high numbers of bacterial spores.	Liquid immersion [†]	Chemical sterilants. Glutaraldehyde, glutaraldehydes with phenol, hydrogen peroxide, hydrogen peroxide with peracetic acid, peracetic acid	Heat-sensitive critical and semicritical	Not applicable
		Heat-automated	Washer-disinfector		
		Liquid immersion [†]	Chemical sterilants/high-level disinfectants. Glutaraldehyde, glutaraldehyde with phenol, hydrogen peroxide, hydrogen peroxide with peracetic acid, ortho-phthalaldehyde		
Intermediate-level disinfection	Destroys vegetative bacteria and the majority of fungi and viruses. Inactivates <i>Mycobacterium bovis</i> . [§] Not necessarily capable of killing bacterial spores.	Liquid contact	U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant with label claim of tuberculocidal activity (e.g., chlorine-containing products, quaternary ammonium compounds with alcohol, phenolics, iodophors, EPA-registered chlorine-based product [¶])	Noncritical with visible blood	Clinical contact surfaces; blood spills on housekeeping surfaces
Low-level disinfection	Destroys the majority of vegetative bacteria, certain fungi, and viruses. Does not inactivate <i>Mycobacterium bovis</i> . [§]	Liquid contact	EPA-registered hospital disinfectant with no label claim regarding tuberculocidal activity. ^{**} The Occupational Safety and Health Administration also requires label claims of human immunodeficiency virus (HIV) and hepatitis B virus (HBV) potency for clinical contact surfaces (e.g., quaternary ammonium compounds, some phenolics, some iodophors)	Noncritical without visible blood	Clinical contact surfaces; housekeeping surfaces

* EPA and the Food and Drug Administration (FDA) regulate chemical germicides used in health-care settings. FDA regulates chemical sterilants used on critical and semicritical medical devices, and the EPA regulates gaseous sterilants and liquid chemical disinfectants used on noncritical surfaces. FDA also regulates medical devices, including sterilizers. More information is available at 1) <http://www.epa.gov/oppad001/chemregindex.htm>, 2) <http://www.fda.gov/cdrh/index.html>, and 3) <http://www.fda.gov/cdrh/ode/germlab.html>.

† Contact time is the single critical variable distinguishing the sterilization process from high-level disinfection with FDA-cleared liquid chemical sterilants. FDA defines a high-level disinfectant as a sterilant used under the same contact conditions as sterilization except for a shorter immersion time (C-1).

§ The tuberculocidal claim is used as a benchmark to measure germicidal potency. Tuberculosis (TB) is transmitted via the airborne route rather than by environmental surfaces and, accordingly, use of such products on environmental surfaces plays no role in preventing the spread of TB. Because mycobacteria have among the highest intrinsic levels of resistance among vegetative bacteria, viruses, and fungi, any germicide with a tuberculocidal claim on the label (i.e., an intermediate-level disinfectant) is considered capable of inactivating a broad spectrum of pathogens, including much less resistant organisms, including bloodborne pathogens (e.g., HBV, hepatitis C virus [HCV], and HIV). It is this broad-spectrum capability, rather than the product's specific potency against mycobacteria, that is the basis for protocols and regulations dictating use of tuberculocidal chemicals for surface disinfection.

¶ Chlorine-based products that are EPA-registered as intermediate-level disinfectants are available commercially. In the absence of an EPA-registered chlorine-based product, a fresh solution of sodium hypochlorite (e.g., household bleach) is an inexpensive and effective intermediate-level germicide. Concentrations ranging from 500 ppm to 800 ppm of chlorine (1:100 dilution of 5.25% bleach and tap water, or approximately 1/4 cup of 5.25% bleach to 1 gallon of water) are effective on environmental surfaces that have been cleaned of visible contamination. Appropriate personal protective equipment (e.g., gloves and goggles) should be worn when preparing hypochlorite solutions (C-2, C-3). Caution should be exercised, because chlorine solutions are corrosive to metals, especially aluminum.

** Germicides labeled as "hospital disinfectant" without a tuberculocidal claim pass potency tests for activity against three representative microorganisms: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis*.

References

C-1. Food and Drug Administration. Guidance for industry and FDA reviewers: content and format of premarket notification [510(k)] submissions for liquid chemical sterilants/high level disinfectants. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, 2000. Available at <http://www.fda.gov/cdrh/ode/397.pdf>.

C-2. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. Occupational exposure to bloodborne pathogens; needlesticks and other sharps injuries; final rule. Federal Register 2001;66:5317-25. As amended from and includes 29 CFR Part 1910.1030. Occupational exposure to bloodborne pathogens; final rule. Federal Register 1991;56:64174-82. Available at <http://www.osha.gov/SLTC/dentistry/index.html>.

C-3. CDC. Guidelines for environmental infection control in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR 2003;52(No. RR-10).