

**NEVADA STATE BOARD**  
**of**  
**DENTAL EXAMINERS**

**MEETING**  
**JULY 18, 2012**  
**5:30 p.m.**

**PUBLIC COPY**

# Nevada State Board of Dental Examiners

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*President*



Donna J. Hellwinkel, D.D.S.  
*Secretary-Treasurer*

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<b>Infection Control Inspection/Survey Form:</b>			<b>Revised 8-12-2011</b>
Dental Office Name/Address:			
Licensee Name:		Owner Dentist Name:	
First Inspection	<input type="checkbox"/>	Follow Up Inspection	<input type="checkbox"/>
Inspectors:			Date:
<b>Compliance level 1-4      <i>Has a written infection control program.</i></b>			
3	Yes No	Includes a written system of sterilization process monitoring	
3	Yes No	Includes a written process for managing semicritical and critical items	
3	Yes No	Includes a written process for managing failed chemical, heat or biological monitoring	
3	Yes No	Includes written policies for use of Personal Protective Equipment (PPE)	
3	Yes No	Includes documentation of vaccinations offered to HCW with infectious exposure risk (Hepatitis B, influenza per CDC)	
3	Yes No	Includes documentation that vaccinations declined by health care workers	
3	Yes No	Includes vaccination records for all employees with exposure risks	
3	Yes No	Includes written policies and procedures for handling and management of sharps	
3	Yes No	Includes a Sharps Injury Log exist	
3	Yes No	Includes a written post exposure medical evaluation plan and 24/7 contact #	
3	Yes No	Includes documentation of post exposure follow-up for all sharps injuries involving contaminated instruments.	
3	Yes No	Includes written policies and procedures for medical waste management	
3	Yes No	Licensed waste hauler used for regulated waste---Name and/or Telephone Number:	



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3	Yes	No	Includes written policies and procedures for aseptic management during patient care
3	Yes	No	Includes written policies and procedures for surface disinfection and environmental barrier protection
3	Yes	No	Includes written policies and procedures for laboratory procedures
3	Yes	No	Includes written policy and procedure for patients known to have communicable disease on arrival (TB, influenza)
3	Yes	No	Comprehensive medical history form in use to evaluate patients
2	Yes	No	Ensures patient information routinely reviewed and updated.

<i>Record Keeping</i>			<i>Each Practice Must....</i>
3	Yes	No	Reviews the written infection control plan at least annually to ensure compliance with best practices
3	Yes	No	Documentation of Bloodborne Pathogen training at date of hire and annually thereafter
3	Yes	No	Documentation of training of health-care employees in selection and use of PPE
3	Yes	No	Documents corrective actions for all deviations from written policy
3	Yes	No	Up-to-date confidential employee health records
3	Yes	No	Employee health records kept for 30+ years <input type="checkbox"/> since opening <input type="checkbox"/> Date:
3	Yes	No	Injury/incident records
3	Yes	No	Qualified designated health care provider identified. (Use CDC: needle stick/sharps injury /exposure protocol)
3	Yes	No	Emergency telephone numbers posted
3	Yes	No	Training records kept for 3+ years
3	Yes	No	Informed refusal declination records of indicated immunizations/vaccination
4	Yes	No	Equipment repair and maintenance records
1	Yes	No	Biological weekly monitoring logs
3	Yes	No	Post exposure evaluation and follow-up records



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4	Yes	No	Maintenance log for sterilization equipment is up-to-date
3	Yes	No	Weekly biological testing logs maintained for 2+ years <input type="checkbox"/> since opening <input type="checkbox"/> Date: _____

***Has an employee training and monitoring program***

2	Yes	No	Provides and documents appropriate training for all staff assigned to process semi-critical and critical instruments
3	Yes	No	a) provides hand-on training
2	Yes	No	Monitors and documents compliance with use of PPE
2	Yes	No	Provides and documents training in hand hygiene
2	Yes	No	Provides annual Infection Control training

***Communicable Disease Control Procedures***

1	Yes	No	Single use or sterilization for critical items
	Yes	No	<b>Multi-dose vials used</b>
1	Yes	No	a) If yes, vials are only entered with new, sterile syringe with a new, sterile needle
2	Yes	No	b) Cap of multi-dose vial cleaned with alcohol based wipe before being accessed
2	Yes	No	c) Are multi-use vials discarded when expired or 28 days after initial access (as applicable)- Must have date when 1 <sup>st</sup> accessed
2	Yes	No	d) Is initial access dated on the multi-use vials?
	Yes	No	<b>Fluid infusion and administration sets (IV bags, tubing and connectors) used?</b>
1	Yes	No	a) If yes, used only on one patient
1	Yes	No	b) Disposed of after single use ?
1	Yes	No	c) Single IV bag is <u>not</u> used to mix medications for more than one patient

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1	Yes	No	d) Single dose medication/infusions are used for only one patient and discarded after use
2	Yes	No	Personnel wear utility gloves when processing contaminated instruments- Not latex type for patient care
2	Yes	No	Supplies for hand hygiene are accessible to employees at point of need
2	Yes	No	Soap and water easily accessible
2	Yes	No	Alcohol based rubs easily accessible-if used
1	Yes	No	Team members display appropriate hand hygiene techniques
<b><i>Appropriate PPE supplies accessible for employees with exposure risks</i></b>			
1	Yes	No	Gloves (Latex and latex free or just latex free)
1	Yes	No	Masks
1	Yes	No	NA Sterile Surgical Gloves--for surgical procedures (Examples: )
1	Yes	No	Safety glasses with side shield or full face shields
1	Yes	No	Disposable gowns/laundered gowns offered
2	Yes	No	Health care workers display appropriate use of PPE barriers
3	Yes	No	Running water eye wash station accessible
2	Yes	No	Appropriate barrier products available (dental dams, protective eyewear, other)
4	Yes	No	Basic first aid products and equipment available
2	Yes	No	Dental unit water lines flushed between patients for a minimum of 20 seconds
4	Yes	No	Dental unit water lines are treated to remove biofilm.
4	Yes	No	Dental unit water lines are tested to meet the potable water standard of EPA ( $\leq 500$ CFU/mL)
4	Yes	No	Dental unit water lines not meeting the potable water standard of EPA are treated and retested.



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<b><i>Cleaning, Disinfection and Sterilization of patient care devices, instruments</i></b>			
2	Yes	No	Biofilm and organic matter are removed from critical and semi-critical instruments using detergents or enzymatic cleaners prior to sterilization.
1	Yes	No	Sterilization equipment available and fully functional
	Yes	No	Number of working autoclaves: _____
	Yes	No	Number of working chemiclaves: _____
	Yes	No	Number of working dry heat sterilizers: _____
	Yes	No	Number of working Flash steam sterilizers (Statim): _____
	Yes	No	Number of working ultrasonic cleaners: _____
1	Yes	No	Endodontic files/instrumentation sterilized or disposed
1	Yes	No	Is Biological testing of sterilizer completed weekly
	Yes	No	If independent biological testing service, name: _____
2	Yes	No	If in-office biological testing, is control processed?
2	Yes	No	Sterilization cycles are verified with chemical/heat indicator. Both interior and external indicators
1	Yes	No	Critical items (any instrument that penetrates soft tissue or bone) instruments are sterilized after each use.
2	Yes	No	Proper sterilization loading technique, not overloading
1	Yes	No	Heat Tolerant Handpieces are sterilized after each use.
2	Yes	No	Sterile packs are inspected for integrity, compromised packs are reprocessed
2	Yes	No	Event-related monitoring is used to monitor package integrity and packages are appropriately stored. (Must not be used for surgical items)
2	Yes	No	Time related monitoring is used to monitor package integrity and all packages have unexpired dates. (Dates not to exceed 3 months interval) (Not required process unless surgical items)



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1	Yes	No	Single use instruments or devices are not processed and reused.
1	Yes	No	Semi-critical items are sterilized after each use if not heat sensitive.
1	Yes	No	Heat sensitive semi-critical items are high level disinfected after each use.
2	Yes	No	Practice is using an FDA approved chemical <i>sterilant</i> .
2	Yes	No	All applicable label instruction are followed on EPA-registered chemical sterilant (dilution, shelf life, storage, safe use, disposal and material compatibility)
2	Yes	No	Practice is using an FDA approved high level <i>disinfectant</i> .
2	Yes	No	Chemicals used for high level disinfection are prepared according to manufacturer's instructions (dilution, shelf life, storage, safe use, disposal and material compatibility)
2	Yes	No	Chemical used for high level disinfection are dated with expiration dates and discarded before expiration dates
<b>Aseptic Techniques:</b>			
4	Yes	No	NA Splash shields and equipment guards used on dental laboratory lathes
2	Yes	No	NA Fresh pumice and a sterilized, or new rag wheel used for each patient.
2	Yes	No	NA Are devices used to polish, trim or adjust contaminated intraoral devices being disinfected or sterilized
2	Yes	No	NA Intraoral items such as impressions, bite registrations, prostheses and orthodontic appliances are cleaned and disinfected with an intermediate-level disinfectant before manipulation in the laboratory and before placement in the patient's mouth
2	Yes	No	Dental radiology aseptic techniques is followed -single use film or barriers on electronic sensors

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<b>Environmental Infection Control</b>			
2	Yes	No	Semi-critical environmental surfaces (frequently touched surfaces that could potentially allow secondary transmission to HCW or patients) are decontaminated between patients using a high level surface disinfectant.
2	Yes	No	Noncritical environmental surfaces are decontaminated between patients
2	Yes	No	Objects and environmental surfaces are disinfected with an EPA registered tuberculocidal disinfectant at beginning of day,
2	Yes	No	Objects and environmental surfaces are disinfected with an EPA registered tuberculocidal disinfectant between patients.
2	Yes	No	Objects and environmental surfaces are disinfected with an EPA registered tuberculocidal disinfectant at the end of the day
2	Yes	No	EPA registered tuberculocidal disinfectants are used at the dilution specified by the manufacturer.
2	Yes	No	All clinical contact surfaces are protected with barriers (optional)
2	Yes	No	Clinical contact barriers are changed between patients.
2	Yes	No	Decontamination and clean areas separated in the instrument processing area
3	Yes	No	Biohazardous waste is disposed of properly

<b>Sharps</b>			
2	Yes	No	Approved sharps containers utilized and accessible
2	Yes	No	Sharps containers taken out of service and processed appropriately
2	Yes	No	Safe recapping techniques/ devices used
1	Yes	No	Sharps (needles, blades ...) are single use



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2	Yes	No	Employee use engineering controls (e.g., forceps) to retrieve contaminated
sharps from trays or containers.			

COMPLIANCE LEVEL CRITERIA LEVEL # 1-4

#1-CRITICAL –MUST BE MET. COULD RESULT IN IMMEDIATE TERMINATION OF PATIENT CARE AND EXTENDED OFFICE INABILITY TO TREAT PATIENTS

#2 –IMMEDIATE ACTION REQUIRED- REQUIRES CORRECTIVE COMPLIANCE WITHIN 7 DAYS

#3-ACTION REQUIRED-REQUIRES CORRECTIVE COMPLIANCE WITHIN 30 DAYS

#4-ACTION RECOMMENDED- NOT REQUIRED FOR COMPLIANCE AT THIS TIME –COMPLIANCE REQUIREMENTS SUBJECT TO CHANGE AS CENTER FOR DISEASE CONTROL (CDC) REQUIREMENTS MAY CHANGE.





# MMWR

## Morbidity and Mortality Weekly Report

Recommendations and Reports

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### Guidelines for Infection Control in Dental Health-Care Settings — 2003



**INSIDE: Continuing Education Examination**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION

MMWR

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\*For Continuing Dental Education (CDE), see <http://www.cde.org>.

To request additional copies of this report, contact CDC's Division of Oral Health by e-mail: [oralhealth@cdc.gov](mailto:oralhealth@cdc.gov); telephone: 770-488-6054; or fax: 770-488-6080.

#### Disclosure of Relationship

Our subject matter experts wish to disclose they have no financial interests or other relationships with the manufacture of commercial products, providers of commercial services, or commercial supporters. This report does not include any discussion of the unlabeled use of commercial products or products for investigational use.

## Guidelines for Infection Control in Dental Health-Care Settings — 2003

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### Summary

This report consolidates previous recommendations and adds new ones for infection control in dental settings. Recommendations are provided regarding 1) educating and protecting dental health-care personnel; 2) preventing transmission of bloodborne pathogens; 3) hand hygiene; 4) personal protective equipment; 5) contact dermatitis and latex hypersensitivity; 6) sterilization and disinfection of patient-care items; 7) environmental infection control; 8) dental water/waterlines, biofilms, and water quality; and 9) special considerations (e.g., dental handpieces and other devices, radiology, parenteral medications, oral surgical procedures, and dental laboratories). These recommendations were developed in collaboration with and after review by authorities on infection control from CDC and other public agencies, academia, and private and professional organizations.

### Introduction

This report consolidates recommendations for preventing and controlling infectious diseases and managing personnel health and safety concerns related to infection control in dental settings. This report 1) updates and revises previous CDC recommendations regarding infection control in dental settings (1,2); 2) incorporates relevant infection-control measures from other CDC guidelines; and 3) discusses concerns not addressed in previous recommendations for dentistry. These updates and additional topics include the following:

- application of standard precautions rather than universal precautions;
- work restrictions for health-care personnel (HCP) infected with or occupationally exposed to infectious diseases;
- management of occupational exposures to bloodborne pathogens, including postexposure prophylaxis (PEP) for work exposures to hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV);
- selection and use of devices with features designed to prevent sharps injury;

- hand-hygiene products and surgical hand antisepsis;
- contact dermatitis and latex hypersensitivity;
- sterilization of unwrapped instruments;
- dental water-quality concerns (e.g., dental unit waterline biofilms); delivery of water of acceptable biological quality for patient care; usefulness of flushing waterlines; use of sterile irrigating solutions for oral surgical procedures; handling of community boil-water advisories;
- dental radiology;
- aseptic technique for parenteral medications;
- preprocedural mouth rinsing for patients;
- oral surgical procedures;
- laser/electrosurgery plumes;
- tuberculosis (TB);
- Creutzfeldt-Jakob disease (CJD) and other prion-related diseases;
- infection-control program evaluation; and
- research considerations.

These guidelines were developed by CDC staff members in collaboration with other authorities on infection control. Draft documents were reviewed by other federal agencies and professional organizations from the fields of dental health care, public health, and hospital epidemiology and infection control. A *Federal Register* notice elicited public comments that were considered in the decision-making process. Existing guidelines and published research pertinent to dental infection-control prin-

The material in this report originated in the National Center for Chronic Disease Prevention and Health Promotion, James S. Marks, M.D., M.P.H., Director; and the Division of Oral Health, William R. Maas, D.D.S., M.P.H., Director.

ciples and practices were reviewed. Wherever possible, recommendations are based on data from well-designed scientific studies. However, only a limited number of studies have characterized risk factors and the effectiveness of prevention measures for infections associated with dental health-care practices.

Some infection-control practices routinely used by health-care practitioners cannot be rigorously examined for ethical or logistical reasons. In the absence of scientific evidence for such practices, certain recommendations are based on strong theoretical rationale, suggestive evidence, or opinions of respected authorities based on clinical experience, descriptive studies, or committee reports. In addition, some recommendations are derived from federal regulations. No recommendations are offered for practices for which insufficient scientific evidence or lack of consensus supporting their effectiveness exists.

### Background

In the United States, an estimated 9 million persons work in health-care professions, including approximately 168,000 dentists, 112,000 registered dental hygienists, 218,000 dental assistants (3), and 53,000 dental laboratory technicians (4). In this report, dental health-care personnel (DHCP) refers to all paid and unpaid personnel in the dental health-care setting who might be occupationally exposed to infectious materials, including body substances and contaminated supplies, equipment, environmental surfaces, water, or air. DHCP include dentists, dental hygienists, dental assistants, dental laboratory technicians (in-office and commercial), students and trainees, contractual personnel, and other persons not directly involved in patient care but potentially exposed to infectious agents (e.g., administrative, clerical, housekeeping, maintenance, or volunteer personnel). Recommendations in this report are designed to prevent or reduce potential for disease transmission from patient to DHCP from DHCP to patient, and from patient to patient. Although these guidelines focus mainly on outpatient, ambulatory dental health-care settings, the recommended infection-control practices are applicable to all settings in which dental treatment is provided.

Dental patients and DHCP can be exposed to pathogenic microorganisms including cytomegalovirus (CMV), HBV, HCV, herpes simplex virus types 1 and 2, HIV, *Mycobacterium tuberculosis*, staphylococci, streptococci, and other viruses and bacteria that colonize or infect the oral cavity and respiratory tract. These organisms can be transmitted in dental settings through 1) direct contact with blood, oral fluids, or other patient materials; 2) indirect contact with contaminated objects (e.g., instruments, equipment, or environmental surfaces); 3) contact of conjunctival, nasal, or oral mucosa with

droplets (e.g., spatter) containing microorganisms generated from an infected person and propelled a short distance (e.g., by coughing, sneezing, or talking); and 4) inhalation of airborne microorganisms that can remain suspended in the air for long periods (5).

Infection through any of these routes requires that all of the following conditions be present:

- a pathogenic organism of sufficient virulence and in adequate numbers to cause disease;
- a reservoir or source that allows the pathogen to survive and multiply (e.g., blood);
- a mode of transmission from the source to the host;
- a portal of entry through which the pathogen can enter the host; and
- a susceptible host (i.e., one who is not immune).

Occurrence of these events provides the chain of infection (6). Effective infection-control strategies prevent disease transmission by interrupting one or more links in the chain.

Previous CDC recommendations regarding infection control for dentistry focused primarily on the risk of transmission of bloodborne pathogens among DHCP and patients and use of universal precautions to reduce that risk (1,2,7,8). Universal precautions were based on the concept that all blood and body fluids that might be contaminated with blood should be treated as infectious because patients with bloodborne infections can be asymptomatic or unaware they are infected (9,10). Preventive practices used to reduce blood exposures, particularly percutaneous exposures, include 1) careful handling of sharp instruments; 2) use of rubber dams to minimize blood spattering; 3) handwashing; and 4) use of protective barriers (e.g., gloves, masks, protective eyewear, and gowns).

The relevance of universal precautions to other aspects of disease transmission was recognized, and in 1996, CDC expanded the concept and changed the term to *standard precautions*. Standard precautions integrate and expand the elements of universal precautions into a standard of care designed to protect HCP and patients from pathogens that can be spread by blood or any other body fluid, excretion, or secretion (11). Standard precautions apply to contact with 1) blood; 2) all body fluids, secretions, and excretions (except sweat), regardless of whether they contain blood; 3) nonintact skin; and 4) mucous membranes. Saliva has always been considered a potentially infectious material in dental infection control; thus, no operational difference exists in clinical dental practice between universal precautions and standard precautions.

In addition to standard precautions, other measures (e.g., expanded or transmission-based precautions) might be necessary to prevent potential spread of certain diseases (e.g., TB, influenza, and varicella) that are transmitted through airborne,

droplet, or contact transmission (e.g., sneezing, coughing, and contact with skin) (11). When acutely ill with these diseases, patients do not usually seek routine dental outpatient care. Nonetheless, a general understanding of precautions for diseases transmitted by all routes is critical because 1) some DHCP are hospital-based or work part-time in hospital settings; 2) patients infected with these diseases might seek urgent treatment at outpatient dental offices; and 3) DHCP might become infected with these diseases. Necessary transmission-based precautions might include patient placement (e.g., isolation), adequate room ventilation, respiratory protection (e.g., N-95 masks) for DHCP, or postponement of nonemergency dental procedures.

DHCP should be familiar also with the hierarchy of controls that categorizes and prioritizes prevention strategies (12). For bloodborne pathogens, engineering controls that eliminate or isolate the hazard (e.g., puncture-resistant sharps containers or needle-retraction devices) are the primary strategies for protecting DHCP and patients. Where engineering controls are not available or appropriate, work-practice controls that result in safer behaviors (e.g., one-hand needle recapping or not using fingers for cheek retraction while using sharp instruments or suturing), and use of personal protective equipment (PPE) (e.g., protective eyewear, gloves, and mask) can prevent exposure (13). In addition, administrative controls (e.g., policies, procedures, and enforcement measures targeted at reducing the risk of exposure to infectious persons) are a priority for certain pathogens (e.g., *M. tuberculosis*), particularly those spread by airborne or droplet routes.

Dental practices should develop a written infection-control program to prevent or reduce the risk of disease transmission. Such a program should include establishment and implementation of policies, procedures, and practices (in conjunction with selection and use of technologies and products) to prevent work-related injuries and illnesses among DHCP as well as health-care-associated infections among patients. The program should embody principles of infection control and occupational health, reflect current science, and adhere to relevant federal, state, and local regulations and statutes. An infection-control coordinator (e.g., dentist or other DHCP) knowledgeable or willing to be trained should be assigned responsibility for coordinating the program. The effectiveness of the infection-control program should be evaluated on a day-to-day basis and over time to help ensure that policies, procedures, and practices are useful, efficient, and successful (see Program Evaluation).

Although the infection-control coordinator remains responsible for overall management of the program, creating and maintaining a safe work environment ultimately requires the

commitment and accountability of all DHCP. This report is designed to provide guidance to DHCP for preventing disease transmission in dental health-care settings, for promoting a safe working environment, and for assisting dental practices in developing and implementing infection-control programs. These programs should be followed in addition to practices and procedures for worker protection required by the Occupational Safety and Health Administration's (OSHA) standards for occupational exposure to bloodborne pathogens (13), including instituting controls to protect employees from exposure to blood or other potentially infectious materials (OPIM), and requiring implementation of a written exposure-control plan, annual employee training, HBV vaccinations, and postexposure follow-up (13). Interpretations and enforcement procedures are available to help DHCP apply this OSHA standard in practice (14). Also, manufacturer's Material Safety Data Sheets (MSDS) should be consulted regarding correct procedures for handling or working with hazardous chemicals (15).

### Previous Recommendations

This report includes relevant infection-control measures from the following previously published CDC guidelines and recommendations:

- CDC. Guideline for disinfection and sterilization in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR (in press).
- 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).
- CDC. Guidelines for the prevention of intravascular catheter-related infections. MMWR 2002;51(No. RR-10).
- CDC. Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51(No. RR-16).
- CDC. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. MMWR 2001;50(No. RR-11).
- Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Hospital Infection Control Practices Advisory Committee. Guideline for prevention of surgical site infection, 1999. Infect Control Hosp Epidemiol 1999;20:250-78.
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### Selected Definitions

**Alcohol-based hand rub:** An alcohol-containing preparation designed for reducing the number of viable microorganisms on the hands.

**Antimicrobial soap:** A detergent containing an antiseptic agent.

**Antiseptic:** A germicide used on skin or living tissue for the purpose of inhibiting or destroying microorganisms (e.g., alcohols, chlorhexidine, chlorine, hexachlorophene, iodine, chloroxylenol [PCMX], quaternary ammonium compounds, and triclosan).

**Bead sterilizer:** A device using glass beads 1.2-1.5 mm diameter and temperatures 217°C-232°C for brief exposures (e.g., 45 seconds) to inactivate microorganisms. (This term is actually a misnomer because it has not been cleared by the Food and Drug Administration [FDA] as a sterilizer).

**Bioburden:** Microbiological load (i.e., number of viable organisms in or on an object or surface) or organic material on a surface or object before decontamination, or sterilization. Also known as *bioload* or *microbial load*.

**Colony-forming unit (CFU):** The minimum number (i.e., tens of millions) of separable cells on the surface of or in semi-solid agar medium that give rise to a visible colony of progeny. CFUs can consist of pairs, chains, clusters, or as single cells and are often expressed as colony-forming units per milliliter (CFUs/mL).

**Decontamination:** Use of physical or chemical means to remove, inactivate, or destroy pathogens on a surface or item so that they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

**Dental treatment water:** Nonsterile water used during dental treatment, including irrigation of nonsurgical operative sites and cooling of high-speed rotary and ultrasonic instruments.

**Disinfectant:** A chemical agent used on inanimate objects (e.g., floors, walls, or sinks) to destroy virtually all recognized pathogenic microorganisms, but not necessarily all microbial forms (e.g., bacterial endospores). The U.S. Environmental Protection Agency (EPA) groups disinfectants on the basis of whether the product label claims limited, general, or hospital disinfectant capabilities.

**Disinfection:** Destruction of pathogenic and other kinds of microorganisms by physical or chemical means. Disinfection is less lethal than sterilization, because it destroys the majority of recognized pathogenic microorganisms, but not necessarily all microbial forms (e.g., bacterial spores). Disinfection does not ensure the degree of safety associated with sterilization processes.

**Droplet nuclei:** Particles  $\leq 5 \mu\text{m}$  in diameter formed by dehydration of airborne droplets containing microorganisms that can remain suspended in the air for long periods of time.

**Droplets:** Small particles of moisture (e.g., spatter) generated when a person coughs or sneezes, or when water is converted to a fine mist by an aerator or shower head. These particles, intermediate in size between drops and droplet nuclei, can contain infectious microorganisms and tend to quickly settle from the air such that risk of disease transmission is usually limited to persons in close proximity to the droplet source.

**Endotoxin:** The lipopolysaccharide of gram-negative bacteria, the toxic character of which resides in the lipid protein. Endotoxins can produce pyrogenic reactions in persons exposed to their bacterial component.

**Germicide:** An agent that destroys microorganisms, especially pathogenic organisms. Terms with the same suffix (e.g., *virucide*, *fungicide*, *bactericide*, *tuberculocide*, and *sporicide*) indi-

cate agents that destroy the specific microorganism identified by the prefix. Germicides can be used to inactivate microorganisms in or on living tissue (i.e., antiseptics) or on environmental surfaces (i.e., disinfectants).

**Hand hygiene:** General term that applies to handwashing, antiseptic handwash, antiseptic hand rub, or surgical hand antiseptics.

**Health-care-associated infection:** Any infection associated with a medical or surgical intervention. The term *health-care-associated* replaces *nosocomial*, which is limited to adverse infectious outcomes occurring in hospitals.

**Hepatitis B immune globulin (HBIG):** Product used for prophylaxis against HBV infection. HBIG is prepared from plasma containing high titers of hepatitis B surface antibody (anti-HBs) and provides protection for 3–6 mos.

**Hepatitis B surface antigen (HBsAg):** Serologic marker on the surface of HBV detected in high levels during acute or chronic hepatitis. The body normally produces antibodies to surface antigen as a normal immune response to infection.

**Hepatitis B e antigen (HBeAg):** Secreted product of the nucleocapsid gene of HBV found in serum during acute and chronic HBV infection. Its presence indicates that the virus is replicating and serves as a marker of increased infectivity.

**Hepatitis B surface antibody (anti-HBs):** Protective antibody against HBsAg. Presence in the blood can indicate past infection with, and immunity to, HBV, or immune response from hepatitis B vaccine.

**Heterotrophic bacteria:** Those bacteria requiring an organic carbon source for growth (i.e., deriving energy and carbon from organic compounds).

**High-level disinfection:** Disinfection process that inactivates vegetative bacteria, mycobacteria, fungi, and viruses but not necessarily high numbers of bacterial spores. FDA further defines a high-level disinfectant as a sterilant used for a shorter contact time.

**Hospital disinfectant:** Germicide registered by EPA for use on inanimate objects in hospitals, clinics, dental offices, and other medical-related facilities. Efficacy is demonstrated against *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.

**Jatrogenic:** Induced inadvertently by HCP, medical (including dental) treatment, or diagnostic procedures. Used particularly in reference to an infectious disease or other complication of treatment.

**Immunization:** Process by which a person becomes immune, or protected against a disease. Vaccination is defined as the process of administering a killed or weakened infectious organism or a toxoid; however, vaccination does not always result in immunity.

**Implantable device:** Device placed into a surgically or naturally formed cavity of the human body and intended to remain there for ≥90 days.

**Independent water reservoir:** Container used to hold water or other solutions and supply it to handpieces and air and water syringes attached to a dental unit. The independent reservoir, which isolates the unit from the public water system, can be provided as original equipment or as a retrofitted device.

**Intermediate-level disinfection:** Disinfection process that inactivates vegetative bacteria, the majority of fungi, mycobacteria, and the majority of viruses (particularly enveloped viruses) but not bacterial spores.

**Intermediate-level disinfectant:** Liquid chemical germicide registered with EPA as a hospital disinfectant and with a label claim of potency as tuberculocidal (Appendix A).

**Latex:** Milky white fluid extracted from the rubber tree *Hevea brasiliensis* that contains the rubber material cis-1,4 polyisoprene.

**Low-level disinfection:** Process that inactivates the majority of vegetative bacteria, certain fungi, and certain viruses, but cannot be relied on to inactivate resistant microorganisms (e.g., mycobacteria or bacterial spores).

**Low-level disinfectant:** Liquid chemical germicide registered with EPA as a hospital disinfectant. OSHA requires low-level hospital disinfectants also to have a label claim for potency against HIV and HBV if used for disinfecting clinical contact surfaces (Appendix A).

**Microfilter:** Membrane filter used to trap microorganisms suspended in water. Filters are usually installed on dental unit waterlines as a retrofit device. Microfiltration commonly occurs at a filter pore size of 0.03–10 µm. Sediment filters commonly found in dental unit water regulators have pore sizes of 20–90 µm and do not function as microbiological filters.

**Nosocomial:** Infection acquired in a hospital as a result of medical care.

**Occupational exposure:** Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or OPIIM that can result from the performance of an employee's duties.

**OPIIM:** Other potentially infectious materials. OPIIM is an OSHA term that refers to 1) body fluids including semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures; any body fluid visibly contaminated with blood; and all body fluids in situations where differentiating between body fluids is difficult or impossible; 2) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and 3) HIV-containing cell or tissue cultures, organ

cultures; HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

**Parenteral:** Means of piercing mucous membranes or skin barrier through such events as needles, human bites, cuts, and abrasions.

**Persistent activity:** Prolonged or extended activity that prevents or inhibits proliferation or survival of microorganisms after application of a product. This activity can be demonstrated by sampling a site minutes or hours after application and demonstrating bacterial antimicrobial effectiveness when compared with a baseline level. Previously, this property was sometimes termed *residual activity*.

**Prioin:** Protein particle lacking nucleic acid that has been implicated as the cause of certain neurodegenerative diseases (e.g., scrapie, CJD, and bovine spongiform encephalopathy [BSE]).

**Retraction:** Entry of oral fluids and microorganisms into waterlines through negative water pressure.

**Seroconversion:** The change of a serological test from negative to positive indicating the development of antibodies in response to infection or immunization.

**Sterile:** Free from all living microorganisms; usually described as a probability (e.g., the probability of a surviving microorganism being 1 in 1 million).

**Sterilization:** Use of a physical or chemical procedure to destroy all microorganisms including substantial numbers of resistant bacterial spores.

**Surfactants:** Surface-active agents that reduce surface tension and help cleaning by loosening, emulsifying, and holding soil in suspension, to be more readily rinsed away.

**Ultrasonic cleaner:** Device that removes debris by a process called cavitation, in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces.

**Vaccination:** See immunization.

**Vaccine:** Product that induces immunity, therefore protecting the body from the disease. Vaccines are administered through needle injections, by mouth, and by aerosol.

**Washer-disinfector:** Automatic unit that cleans and thermally disinfects instruments, by using a high-temperature cycle rather than a chemical bath.

**Wicking:** Absorption of a liquid by capillary action along a thread or through the material (e.g., penetration of liquids through undetected holes in a glove).

## Review of Science Related to Dental Infection Control

### Personnel Health Elements of an Infection-Control Program

A protective health component for DHCP is an integral part of a dental practice infection-control program. The objectives are to educate DHCP regarding the principles of infection control, identify work-related infection risks, institute preventive measures; and ensure prompt exposure management and medical follow-up. Coordination between the dental practice's infection-control coordinator and other qualified health-care professionals is necessary to provide DHCP with appropriate services. Dental programs in institutional settings, (e.g., hospitals, health centers, and educational institutions) can coordinate with departments that provide personnel health services. However, the majority of dental practices are in ambulatory, private settings that do not have licensed medical staff and facilities to provide complete on-site health service programs. In such settings, the infection-control coordinator should establish programs that arrange for site-specific infection-control services from external health-care facilities and providers before DHCP are placed at risk for exposure. Referral arrangements can be made with qualified health-care professionals in an occupational health program of a hospital, with educational institutions, or with health-care facilities that offer personnel health services.

### Education and Training

Personnel are more likely to comply with an infection-control program and exposure-control plan if they understand its rationale (5,13,16). Clearly written policies, procedures, and guidelines can help ensure consistency, efficiency, and effective coordination of activities. Personnel subject to occupational exposure should receive infection-control training on initial assignment, when new tasks or procedures affect their occupational exposure, and at a minimum, annually (13). Education and training should be appropriate to the assigned duties of specific DHCP (e.g., techniques to prevent cross-contamination or instrument sterilization). For DHCP who perform tasks or procedures likely to result in occupational exposure to infectious agents, training should include 1) a description of their exposure risks; 2) review of prevention strategies and infection-control policies and procedures; 3) discussion regarding how to manage work-related illness and injuries, including PEP; and 4) review of work restrictions for the exposure or infection. Inclusion of DHCP with minimal exposure risks (e.g., administrative employees) in education and training programs might enhance facilitywide understand-

ing of infection-control principles and the importance of the program. Educational materials should be appropriate in content and vocabulary for each person's educational level, literacy, and language, as well as be consistent with existing federal, state, and local regulations (5,13).

#### Immunization Programs

DHCP are at risk for exposure to, and possible infection with, infectious organisms. Immunizations substantially reduce both the number of DHCP susceptible to these diseases and the potential for disease transmission to other DHCP and patients (5,17). Thus, immunizations are an essential part of prevention and infection-control programs for DHCP, and a comprehensive immunization policy should be implemented for all dental health-care facilities (17,18). The Advisory Committee on Immunization Practices (ACIP) provides national guidelines for immunization of HCP, which includes DHCP (17). Dental practice immunization policies should incorporate current state and federal regulations as well as recommendations from the U.S. Public Health Service and professional organizations (17) (Appendix B).

On the basis of documented health-care-associated transmission, HCP are considered to be at substantial risk for acquiring or transmitting hepatitis B, influenza, measles, mumps, rubella, and varicella. All of these diseases are vaccine-preventable. ACIP recommends that all HCP be vaccinated or have documented immunity to these diseases (5,17). ACIP does not recommend routine immunization of HCP against TB (i.e., inoculation with bacille Calmette-Guérin vaccine) or hepatitis A (17). No vaccine exists for HCV. ACIP guidelines also provide recommendations regarding immunization of HCP with special conditions (e.g., pregnancy, HIV infection, or diabetes) (5,17).

Immunization of DHCP before they are placed at risk for exposure remains the most efficient and effective use of vaccines in health-care settings. Some educational institutions and infection-control programs provide immunization schedules for students and DHCP. OSFIA requires that employers make hepatitis B vaccination available to all employees who have potential contact with blood or OPIM. Employers are also required to follow CDC recommendations for vaccinations, evaluation, and follow-up procedures (13). Nonpatient-care staff (e.g., administrative or housekeeping) might be included, depending on their potential risk of coming into contact with blood or OPIM. Employers are also required to ensure that employees who decline to accept hepatitis B vaccination sign an appropriate declination statement (13). DHCP unable or unwilling to be vaccinated as required or recommended should be educated regarding their exposure risks, infection-control policies and procedures for the facility, and the management

of work-related illness and work restrictions (if appropriate) for exposed or infected DHCP.

#### Exposure Prevention and Postexposure Management

Avoiding exposure to blood and OPIM, as well as protection by immunization, remain primary strategies for reducing occupationally acquired infections, but occupational exposures can still occur (19). A combination of standard precautions, engineering, work practice, and administrative controls is the best means to minimize occupational exposures. Written policies and procedures to facilitate prompt reporting, evaluation, counseling, treatment, and medical follow-up of all occupational exposures should be available to all DHCP. Written policies and procedures should be consistent with federal, state, and local requirements addressing education and training, postexposure management, and exposure reporting (see Preventing Transmission of Bloodborne Pathogens).

DHCP who have contact with patients can also be exposed to persons with infectious TB, and should have a baseline tuberculin skin test (TST), preferably by using a two-step test, at the beginning of employment (20). Thus, if an unprotected occupational exposure occurs, TST conversions can be distinguished from positive TST results caused by previous exposures (20,21). The facility's level of TB risk will determine the need for routine follow-up TSTs (see Special Considerations).

#### Medical Conditions, Work-Related Illness, and Work Restrictions

DHCP are responsible for monitoring their own health status. DHCP who have acute or chronic medical conditions that render them susceptible to opportunistic infection should discuss with their personal physicians or other qualified authority whether the condition might affect their ability to safely perform their duties. However, under certain circumstances, health-care facility managers might need to exclude DHCP from work or patient contact to prevent further transmission of infection (22). Decisions concerning work restrictions are based on the mode of transmission and the period of infectivity of the disease (5) (Table 1). Exclusion policies should 1) be written, 2) include a statement of authority that defines who can exclude DHCP (e.g., personal physicians), and 3) be clearly communicated through education and training. Policies should also encourage DHCP to report illnesses or exposures without jeopardizing wages, benefits, or job status.

With increasing concerns regarding bloodborne pathogens and introduction of universal precautions, use of latex gloves among HCP has increased markedly (7,23). Increased use of these gloves has been accompanied by increased reports of allergic reactions to natural rubber latex among HCP, DHCP, and patients

TABLE 1. Suggested work restrictions for health-care personnel infected with or exposed to major infectious diseases in health-care settings, in the absence of state and local regulations\*

Disease/problem	Work restriction	Duration
Cocci/bacteria	Restrict from patient contact and contact with patient's environment.	Until discharge ceases
Cytomegalovirus infection	No restriction	
D diarrheal disease		
Acute stage (diarrhea with other symptoms)	Restrict from patient contact, contact with patient's environment, and food-handling.	Until symptoms resolve
Convalescent stage, <i>Shigella</i> species	Restrict from care of patients at high risk.	Until symptoms resolve; consult with local and state health authorities regarding need for negative stool cultures
Enteroviral infection	Restrict from care of infants, neonates, and immunocompromised patients and their environments.	Until symptoms resolve
Hepatitis A	Restrict from patient contact, contact with patient's environment, and food-handling.	Until 7 days after onset of jaundice
Hepatitis B		
Personnel with acute or chronic hepatitis B surface antigenemia who do not perform exposure-prone procedures	No restriction; refer to state regulations. Standard precautions should always be followed.	
Personnel with acute or chronic hepatitis B e antigenemia who perform exposure-prone procedures	Do not perform exposure-prone invasive procedures until counsel from a review panel has been sought; panel should review and recommend procedures that personnel can perform, taking into account specific procedures as well as skill and technique. Standard precautions should always be observed. Refer to state and local regulations or recommendations.	Until hepatitis B e antigen is negative
Hepatitis C	No restrictions on professional activity. <sup>†</sup> HCV-positive health-care personnel should follow aseptic technique and standard precautions.	
Herpes simplex		
Genital	No restriction	
Hands (herpetic whitlow)	Restrict from patient contact and contact with patient's environment.	Until lesions heal
Orofacial	Evaluate need to restrict from care of patients at high risk.	
Human immunodeficiency virus; personnel who perform exposure-prone procedures	Do not perform exposure-prone invasive procedures until counsel from an expert review panel has been sought; panel should review and recommend procedures that personnel can perform, taking into account specific procedures as well as skill and technique. Standard precautions should always be observed. Refer to state and local regulations or recommendations.	
Measles		
Active	Exclude from duty	Until 7 days after the rash appears
Postexposure (susceptible personnel)	Exclude from duty	From fifth day after first exposure through twenty-first day after last exposure, or 4 days after rash appears
Meningococcal infection	Exclude from duty	Until 24 hours after start of effective therapy
Mumps		
Active	Exclude from duty	Until 9 days after onset of parotitis
Postexposure (susceptible personnel)	Exclude from duty	From seventh day after first exposure through twenty-sixth day after last exposure, or until 9 days after onset of parotitis

Source: Adapted from Boyard EA. Hospital Infection Control Practices Advisory Committee. Guidelines for infection control in health care personnel, 1998. Am J Infect Control 1999;25:229-34.

\* Modified from recommendations of the Advisory Committee on Immunization Practices (ACIP).

<sup>†</sup> Unless epidemiologically linked to transmission of infection.

<sup>‡</sup> Those susceptible to varicella and who are at increased risk of complications of varicella (e.g., neonates and immunocompromised persons of any age).

<sup>§</sup> Patients at high risk as defined by ACIP for complications of influenza.

TABLE 1. (Continued) Suggested work restrictions for health-care personnel infected with or exposed to major infectious diseases in health-care settings, in the absence of state and local regulations\*

Disease/problem	Work restriction	Duration
Pediculosis	Restrict from patient contact	Until treated and observed to be free of adult and immature lice
Perforate		
Active	Exclude from duty	From beginning of catarrhal stage through third week after onset of paronychia, or until 5 days after start of effective antibiotic therapy
Postexposure (asymptomatic personnel)	No restriction, prophylaxis recommended	
Postexposure (symptomatic personnel)	Exclude from duty	Until 5 days after start of effective antibiotic therapy
Rubella		
Active	Exclude from duty	Until 5 days after rash appears
Postexposure (susceptible personnel)	Exclude from duty	From seventh day after first exposure through twenty-first day after last exposure
Staphylococcus aureus infection		
Active, draining skin lesions	Restrict from contact with patients and patient's environment or food handling.	Until lesions have resolved
Carrier state	No restriction unless personnel are epidemiologically linked to transmission of the organism	
Streptococcal infection, group A	Restrict from patient care, contact with patient's environment, and food handling.	Until 24 hours after adequate treatment started
Tuberculosis		
Active disease	Exclude from duty	Until proved noninfectious
PPD converter	No restriction	
Varicella (chicken pox)		
Active	Exclude from duty	Until all lesions dry and crust
Postexposure (susceptible personnel)	Exclude from duty	From tenth day after first exposure through twenty-first day (twenty-eighth day if varicella-zoster immune globulin [VZIG] administered) after last exposure.
Zoster (shingles)		
Localized, in healthy person	Cover lesions, restrict from care of patients <sup>§</sup> at high risk	Until all lesions dry and crust
Generalized or localized in immunosuppressed person	Restrict from patient contact	Until all lesions dry and crust
Postexposure (susceptible personnel)	Restrict from patient contact	From tenth day after first exposure through twenty-first day (twenty-eighth day if VZIG administered) after last exposure; or, if vesicles occur, when lesions crust and dry
Viral respiratory infection, acute (ebola)	Consider excluding from the care of patients at high risk <sup>§</sup> or contact with such patients' environments during community outbreak of respiratory syncytial virus and influenza	Until acute symptoms resolve

Source: Adapted from Bolyard EA, Hospital Infection Control Practices Advisory Committee. Guidelines for infection control in health care personnel, 1998. Am J Infect Control 1998;26:289-354.

\* Modified from recommendations of the Advisory Committee on Immunization Practices (ACIP).

† Unless epidemiologically linked to transmission of infection.

‡ Those susceptible to varicella and who are at increased risk of complications of varicella (e.g., neonates and immunocompromised persons of any age).

§ Patients at high risk as defined by ACIP for complications of influenza.

(24-30), as well as increased reports of irritant and allergic contact dermatitis from frequent and repeated use of hand-hygiene products, exposure to chemicals, and glove use.

DHCP should be familiar with the signs and symptoms of latex sensitivity (5,31-33). A physician should evaluate DHCP exhibiting symptoms of latex allergy, because further exposure could result in a serious allergic reaction. A diagnosis is made through medical history, physical examination, and diagnostic tests. Procedures should be in place for minimizing latex-related health problems among DHCP and patients while protecting them from infectious materials. These procedures should include 1) reducing exposures to latex-containing materials by using appropriate work practices, 2) training and educating DHCP, 3) monitoring symptoms, and 4) substituting nonlatex products where appropriate (32) (see Contact Dermatitis and Latex Hypersensitivity).

#### Maintenance of Records, Data Management, and Confidentiality

The health status of DHCP can be monitored by maintaining records of work-related medical evaluations, screening tests, immunizations, exposures, and postexposure management. Such records must be kept in accordance with all applicable state and federal laws. Examples of laws that might apply include the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, 45 CFR 160 and 164, and the OSHA Occupational Exposure to Bloodborne Pathogens; Final Rule 29 CFR 1910.1030(h)(1)(i-iv) (34,13). The HIPAA Privacy Rule applies to covered entities, including certain defined health providers, health-care clearinghouses, and health plans. OSHA requires employers to ensure that certain information contained in employee medical records is 1) kept confidential; 2) not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by the OSHA standard; and 3) maintained by the employer for at least the duration of employment plus 30 years. Dental practices that coordinate their infection-control program with off-site providers might consult OSHA's Bloodborne Pathogen standard and employee Access to Medical and Exposure Records standard, as well as other applicable local, state, and federal laws, to determine a location for storing health records (13,35).

#### Preventing Transmission of Bloodborne Pathogens

Although transmission of bloodborne pathogens (e.g., HBV, HCV, and HIV) in dental health-care settings can have serious consequences, such transmission is rare. Exposure to

infected blood can result in transmission from patient to DHCP, from DHCP to patient, and from one patient to another. The opportunity for transmission is greatest from patient to DHCP, who frequently encounter patient blood and blood-contaminated saliva during dental procedures.

Since 1992, no HIV transmission from DHCP to patients has been reported, and the last HBV transmission from DHCP to patients was reported in 1987. HCV transmission from DHCP to patients has not been reported. The majority of DHCP infected with a bloodborne virus do not pose a risk to patients because they do not perform activities meeting the necessary conditions for transmission. For DHCP to pose a risk for bloodborne virus transmission to patients, DHCP must 1) be viremic (i.e., have infectious virus circulating in the bloodstream); 2) be injured or have a condition (e.g., weeping dermatitis) that allows direct exposure to their blood or other infectious body fluids; and 3) enable their blood or infectious body fluid to gain direct access to a patient's wound, traumatized tissue, mucous membranes, or similar portal of entry. Although an infected DHCP might be viremic, unless the second and third conditions are also met, transmission cannot occur.

The risk of occupational exposure to bloodborne viruses is largely determined by their prevalence in the patient population and the nature and frequency of contact with blood and body fluids through percutaneous or mucosal routes of exposure. The risk of infection after exposure to a bloodborne virus is influenced by inoculum size, route of exposure, and susceptibility of the exposed HCP (12). The majority of attention has been placed on the bloodborne pathogens HBV, HCV, and HIV, and these pathogens present different levels of risk to DHCP.

#### Hepatitis B Virus

HBV is a well-recognized occupational risk for HCP (36,37). HBV is transmitted by percutaneous or mucosal exposure to blood or body fluids of a person with either acute or chronic HBV infection. Persons infected with HBV can transmit the virus for as long as they are HBsAg-positive. The risk of HBV transmission is highly related to the HBsAg status of the source person. In studies of HCP who sustained injuries from needles contaminated with blood containing HBV, the risk of developing clinical hepatitis if the blood was positive for both HBsAg and HBeAg was 22%-31%; the risk of developing serologic evidence of HBV infection was 37%-62% (19). By comparison, the risk of developing clinical hepatitis from a needle contaminated with HBsAg-positive, HBeAg-negative blood was 1%-6%, and the risk of developing serologic evidence of HBV infection, 23%-37% (38).

Blood contains the greatest proportion of HBV infectious particle titers of all body fluids and is the most critical vehicle of transmission in the health-care setting. HBsAg is also found in multiple other body fluids, including breast milk, bile, cerebrospinal fluid, feces, nasopharyngeal washings, saliva, semen, sweat, and synovial fluid. However, the majority of body fluids are not efficient vehicles for transmission because they contain low quantities of infectious HBV, despite the presence of HBsAg (19). The concentration of HBsAg in body fluids can be 100–1,000-fold greater than the concentration of infectious HBV particles (39).

Although percutaneous injuries are among the most efficient modes of HBV transmission, these exposures probably account for only a minority of HBV infections among HCP. In multiple investigations of nosocomial hepatitis B outbreaks, the majority of infected HCP could not recall an overt percutaneous injury (40,41), although in certain studies, approximately one third of infected HCP recalled caring for a patient who was HBsAg-positive (42,43). In addition, HBV has been demonstrated to survive in dried blood at room temperature on environmental surfaces for  $\leq 1$  week (44). Thus, HBV infections that occur in HCP with no history of nonoccupational exposure or occupational percutaneous injury might have resulted from direct or indirect blood or body fluid exposures that inoculated HBV into cutaneous scratches, abrasions, burns, other lesions, or on mucosal surfaces (45–47). The potential for HBV transmission through contact with environmental surfaces has been demonstrated in investigations of HBV outbreaks among patients and HCP in hemodialysis units (48–50).

Since the early 1980s, occupational infections among HCP have declined because of vaccine use and adherence to universal precautions (51). Among U.S. dentists, >90% have been vaccinated, and serologic evidence of past HBV infection decreased from prevaccine levels of 14% in 1972 to approximately 9% in 1992 (52). During 1993–2001, levels remained relatively unchanged (Chakwan Siew, Ph.D., American Dental Association, Chicago, Illinois, personal communication, June 2003). Infection rates can be expected to decline further as vaccination rates remain high among young dentists and as older dentists with lower vaccination rates and higher rates of infection retire.

Although the potential for transmission of bloodborne infections from DHCP to patients is considered limited (53–55), precise risks have not been quantified by carefully designed epidemiologic studies (53,56,57). Reports published during 1970–1987 describe nine clusters in which patients were thought to be infected with HBV through treatment by an infected DHCP (58–67). However, transmission of HBV

from dentist to patient has not been reported since 1987, possibly reflecting such factors as 1) adoption of universal precautions, 2) routine glove use, 3) increased levels of immunity as a result of hepatitis B vaccination of DHCP, 4) implementation of the 1991 OSHA bloodborne pathogen standard (68), and 5) incomplete ascertainment and reporting. Only one case of patient-to-patient transmission of HBV in the dental setting has been documented (CDC, unpublished data, 2003). In this case, appropriate office infection-control procedures were being followed, and the exact mechanism of transmission was undetermined.

Because of the high risk of HBV infection among HCP, DHCP who perform tasks that might involve contact with blood, blood-contaminated body substances, other body fluids, or sharps should be vaccinated (2,13,17,19,69). Vaccination can protect both DHCP and patients from HBV infection and, whenever possible, should be completed when dentists or other DHCP are in training and before they have contact with blood.

Prevaccination serological testing for previous infection is not indicated, although it can be cost-effective where prevalence of infection is expected to be high in a group of potential vaccinees (e.g., persons who have emigrated from areas with high rates of HBV infection). DHCP should be tested for anti-HBs 1–2 months after completion of the 3-dose vaccination series (17). DHCP who do not develop an adequate antibody response (i.e., anti-HBs <10 mIU/mL) to the primary vaccine series should complete a second 3-dose vaccine series or be evaluated to determine if they are HBsAg-positive (17). Revaccinated persons should be retested for anti-HBs at the completion of the second vaccine series. Approximately half of nonresponders to the primary series will respond to a second 3-dose series. If no antibody response occurs after the second series, testing for HBsAg should be performed (17). Persons who prove to be HBsAg-positive should be counseled regarding how to prevent HBV transmission to others and regarding the need for medical evaluation. Nonresponders to vaccination who are HBsAg-negative should be considered susceptible to HBV infection and should be counseled regarding precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known or probable potential exposure to HBsAg-positive blood.

Vaccine-induced antibodies decline gradually over time, and 60% of persons who initially respond to vaccination will lose detectable antibodies over 12 years. Even so, immunity continues to prevent clinical disease or detectable viral infection (17). Booster doses of vaccine and periodic serologic testing to monitor antibody concentrations after completion of the vaccine series are not necessary for vaccine responders (17).

### Hepatitis D Virus

An estimated 4% of persons with acute HBV infection are also infected with hepatitis Delta virus (HDV). Discovered in 1977, HDV is a defective bloodborne virus requiring the presence of HBV to replicate. Patients coinfecting with HBV and HDV have substantially higher mortality rates than those infected with HBV alone. Because HDV infection is dependent on HBV for replication, immunization to prevent HBV infection, through either pre- or postexposure prophylaxis, can also prevent HDV infection (70).

### Hepatitis C Virus

Hepatitis C virus appears not to be transmitted efficiently through occupational exposures to blood. Follow-up studies of HCP exposed to HCV-infected blood through percutaneous or other sharps injuries have determined a low incidence of seroconversion (mean: 1.8%; range, 0%–7%) (71–74). One study determined transmission occurred from hollow-bore needles but not other sharps (72). Although these studies have not documented seroconversion associated with mucous membrane or noninfect skin exposure, at least two cases of HCV transmission from a blood splash to the conjunctiva (75,76) and one case of simultaneous transmission of HCV and HIV after noninfect skin exposure have been reported (77).

Data are insufficient to estimate the occupational risk of HCV infection among HCP but the majority of studies indicate the prevalence of HCV infection among dentists, surgeons, and hospital-based HCP is similar to that among the general population, approximately 1%–2% (78–86). In a study that evaluated risk factors for infection, a history of unintentional needlessticks was the only occupational risk factor independently associated with HCV infection (80).

No studies of transmission from HCV-infected DHCP to patients have been reported, and the risk for such transmission appears limited. Multiple reports have been published describing transmission from HCV-infected surgeons, which apparently occurred during performance of invasive procedures; the overall risk for infection averaged 0.17% (87–90).

### Human Immunodeficiency Virus

In the United States, the risk of HIV transmission in dental settings is extremely low. As of December 2001, a total of 57 cases of HIV seroconversion had been documented among HCP, but none among DHCP after occupational exposure to a known HIV-infected source (91). Transmission of HIV to six patients of a single dentist with AIDS has been reported, but the mode of transmission could not be determined (2,92,93). As of September 30, 1993, CDC had information regarding test results of >22,000 patients of 63 HIV-infected

HCP, including 33 dentists or dental students (55,93). No additional cases of transmission were documented.

Prospective studies worldwide indicate the average risk of HIV infection after a single percutaneous exposure to HIV-infected blood is 0.3% (range: 0.2%–0.5%) (94). After an exposure of mucous membranes in the eye, nose, or mouth, the risk is approximately 0.1% (76). The precise risk of transmission after skin exposure remains unknown but is believed to be even smaller than that for mucous membrane exposure.

Certain factors affect the risk of HIV transmission after an occupational exposure. Laboratory studies have determined if needles that pass through latex gloves are solid rather than hollow-bore, or are of small gauge (e.g., anesthetic needles commonly used in dentistry), they transfer less blood (36). In a retrospective case-control study of HCP, an increased risk for HIV infection was associated with exposure to a relatively large volume of blood, as indicated by a deep injury with a device that was visibly contaminated with the patient's blood, or a procedure that involved a needle placed in a vein or artery (95). The risk was also increased if the exposure was to blood from patients with terminal illnesses, possibly reflecting the higher titer of HIV in late-stage AIDS.

### Exposure Prevention Methods

Avoiding occupational exposures to blood is the primary way to prevent transmission of HBV, HCV, and HIV, to HCP in health-care settings (19,96,97). Exposures occur through percutaneous injury (e.g., a needlesstick or cut with a sharp object), as well as through contact between potentially infectious blood, tissues, or other body fluids and mucous membranes of the eye, nose, mouth, or noninfect skin (e.g., exposed skin that is chapped, abraded, or shows signs of dermatitis).

Observational studies and surveys indicate that percutaneous injuries among general dentists and oral surgeons occur less frequently than among general and orthopedic surgeons and have decreased in frequency since the mid-1980s (98–102). This decline has been attributed to safer work practices, safer instrumentation or design, and continued DHCP education (103,104). Percutaneous injuries among DHCP usually 1) occur outside the patient's mouth, thereby posing less risk for recontact with patient tissues; 2) involve limited amounts of blood; and 3) are caused by burs, syringe needles, laboratory knives, and other sharp instruments (99–102,105,106). Injuries among oral surgeons might occur more frequently during fracture reductions using wires (104,107). Experience, as measured by years in practice, does not appear to affect the risk of injury among general dentists or oral surgeons (100,104,107).

The majority of exposures in dentistry are preventable, and methods to reduce the risk of blood contacts have included use of standard precautions, use of devices with features engineered to prevent sharp injuries, and modifications of work practices. These approaches might have contributed to the decrease in percutaneous injuries among dentists during recent years (98-100,103). However, needles and other blood contacts continue to occur, which is a concern because percutaneous injuries pose the greatest risk of transmission.

Standard precautions include use of PPE (e.g., gloves, masks, protective eyewear or face shield, and gowns) intended to prevent skin and mucous membrane exposures. Other protective equipment (e.g., finger guards while suturing) might also reduce injuries during dental procedures (104).

Engineering controls are the primary method to reduce exposures to blood and OPIM from sharp instruments and needles. These controls are frequently technology-based and often incorporate safer designs of instruments and devices (e.g., self-sheathing anesthetic needles and dental units designed to shield burs in handpieces) to reduce percutaneous injuries (101,103,108).

Work-practice controls establish practices to protect DHCP whose responsibilities include handling, using, assembling, or processing sharp devices (e.g., needles, scalars, laboratory utility knives, burs, explorers, and endodontic files) or sharps disposal containers. Work-practice controls can include removing burs before disassembling the handpiece from the dental unit, restricting use of fingers in tissue retraction or palpation during suturing and administration of anesthesia, and minimizing potentially uncontrolled movements of such instruments as scalars or laboratory knives (101,105).

As indicated, needles are a substantial source of percutaneous injury in dental practice, and engineering and work-practice controls for needle handling are of particular importance. In 2001, revisions to OSHA's bloodborne pathogens standard as mandated by the Needlestick Safety and Prevention Act of 2000 became effective. These revisions clarify the need for employers to consider safer needle devices as they become available and to involve employees directly responsible for patient care (e.g., dentists, hygienists, and dental assistants) in identifying and choosing such devices (109). Safer versions of sharp devices used in hospital settings have become available (e.g., blunt suture needles, phlebotomy devices, and butterfly needles), and their impact on reducing injuries has been documented (110-112). Aspirating anesthetic syringes that incorporate safety features have been developed for dental procedures, but the low injury rates in dentistry limit assessment of their effect on reducing injuries among DHCP.

Work-practice controls for needles and other sharps include placing used disposable syringes and needles, scalpel blades, and other sharp items in appropriate puncture-resistant containers located as close as feasible to where the items were used (2,7,13,113-115). In addition, used needles should never be recapped or otherwise manipulated by using both hands, or any other technique that involves directing the point of a needle toward any part of the body (2,7,13,97,113,114). A one-handed scoop technique, a mechanical device designed for holding the needle cap to facilitate one-handed recapping, or an engineered sharps injury protection device (e.g., needles with resheathing mechanisms) should be employed for recapping needles between uses and before disposal (2,7,13,113,114). DHCP should never bend or break needles before disposal because this practice requires unnecessary manipulation. Before attempting to remove needles from nondisposable aspirating syringes, DHCP should recap them to prevent injuries. For procedures involving multiple injections with a single needle, the practitioner should recap the needle between injections by using a one-handed technique or use a device with a needle-resheathing mechanism. Passing a syringe with an unsheathed needle should be avoided because of the potential for injury.

Additional information for developing a safety program and for identifying and evaluating safer dental devices is available at

- <http://www.cdc.gov/OralHealth/infectioncontrol/forms.htm> (forms for screening and evaluating safer dental devices), and
- <http://www.cdc.gov/niosh/topics/bbp> (state legislation on needlestick safety).

#### Postexposure Management and Prophylaxis

Postexposure management is an integral component of a complete program to prevent infection after an occupational exposure to blood. During dental procedures, saliva is predictably contaminated with blood (7,114). Even when blood is not visible, it can still be present in limited quantities and therefore is considered a potentially infectious material by OSHA (13,19). A qualified health-care professional should evaluate any occupational exposure incident to blood or OPIM, including saliva, regardless of whether blood is visible, in dental settings (13).

Dental practices and laboratories should establish written, comprehensive programs that include hepatitis B vaccination and postexposure management protocols that 1) describe the types of contact with blood or OPIM that can place DHCP at risk for infection; 2) describe procedures for promptly reporting and evaluating such exposures; and 3) identify a health-

care professional who is qualified to provide counseling and perform all medical evaluations and procedures in accordance with current recommendations of the U.S. Public Health Service (PHS), including PEP with chemotherapeutic drugs when indicated. DHCP, including students, who might reasonably be considered at risk for occupational exposure to blood or OPIM should be taught strategies to prevent contact with blood or OPIM and the principles of postexposure management, including PEP options, as part of their job orientation and training. Educational programs for DHCP and students should emphasize reporting all exposures to blood or OPIM as soon as possible, because certain interventions have to be initiated promptly to be effective. Policies should be consistent with the practices and procedures for worker protection required by OSHA and with current PHS recommendations for managing occupational exposures to blood (13,19).

After an occupational blood exposure, first aid should be administered as necessary. Puncture wounds and other injuries to the skin should be washed with soap and water; mucous membranes should be flushed with water. No evidence exists that using antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk of bloodborne pathogen transmission; however, use of antiseptics is not contraindicated. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended (19). Exposed DHCP should immediately report the exposure to the infection-control coordinator or other designated person, who should initiate referral to the qualified health-care professional and complete necessary reports. Because multiple factors contribute to the risk of infection after an occupational exposure to blood, the following information should be included in the exposure report, recorded in the exposed person's confidential medical record, and provided to the qualified health-care professional:

- Date and time of exposure.
- Details of the procedure being performed, including where and how the exposure occurred and whether the exposure involved a sharp device, the type and brand of device, and how and when during its handling the exposure occurred.
- Details of the exposure, including its severity and the type and amount of fluid or material. For a percutaneous injury, severity might be measured by the depth of the wound, gauge of the needle, and whether fluid was injected; for a skin or mucous membrane exposure, the estimated volume of material, duration of contact, and the condition of the skin (e.g., chapped, abraded, or intact) should be noted.
- Details regarding whether the source material was known to contain HIV or other bloodborne pathogens, and, if

the source was infected with HIV, the stage of disease, history of antiretroviral therapy, and viral load, if known.

- Details regarding the exposed person (e.g., hepatitis B vaccination and vaccine-response status).
- Details regarding counseling, postexposure management, and follow-up.

Each occupational exposure should be evaluated individually for its potential to transmit HBV, HCV, and HIV, based on the following:

- The type and amount of body substance involved.
- The type of exposure (e.g., percutaneous injury; mucous membrane or nonintact skin exposure, or bites resulting in blood exposure to either person involved).
- The infection status of the source.
- The susceptibility of the exposed person (19).

All of these factors should be considered in assessing the risk for infection and the need for further follow-up (e.g., PEP).

During 1990-1998, PHS published guidelines for PEP and other management of health-care worker exposures to HBV, HCV, or HIV (69,116-119). In 2001, these recommendations were updated and consolidated into one set of PHS guidelines (19). The new guidelines reflect the availability of new antiretroviral agents, new information regarding the use and safety of HIV PEP, and considerations regarding employing HIV PEP when resistance of the source patient's virus to antiretroviral agents is known or suspected. In addition, the 2001 guidelines provide guidance to clinicians and exposed HCP regarding when to consider HIV PEP and recommendations for PEP regimens (19).

#### Hand Hygiene

Hand hygiene (e.g., handwashing, hand antiseptics, or surgical hand antiseptics) substantially reduces potential pathogens on the hands and is considered the single most critical measure for reducing the risk of transmitting organisms to patients and HCP (120-123). Hospital-based studies have demonstrated that noncompliance with hand hygiene practices is associated with health-care-associated infections and the spread of multiresistant organisms. Noncompliance also has been a major contributor to outbreaks (123). The prevalence of health-care-associated infections decreases as adherence of HCP to recommended hand hygiene measures improves (124-126).

The microbial flora of the skin, first described in 1938, consist of transient and resident microorganisms (127). Transient flora, which colonize the superficial layers of the skin, are easier to remove by routine handwashing. They are often acquired by HCP during direct contact with patients or contaminated environmental surfaces; these organisms are most frequently

associated with health-care-associated infections. Resident flora attached to deeper layers of the skin are more resistant to removal and less likely to be associated with such infections.

The preferred method for hand hygiene depends on the type of procedure, the degree of contamination, and the desired persistence of antimicrobial action on the skin (Table 2). For routine dental examinations and nonsurgical procedures, handwashing and hand antisepsis is achieved by using either a plain or antimicrobial soap and water. If the hands are not visibly soiled, an alcohol-based hand rub is adequate.

The purpose of surgical hand antisepsis is to eliminate transient flora and reduce resident flora for the duration of a procedure to prevent introduction of organisms in the operative wound, if gloves become punctured or torn. Skin bacteria can rapidly multiply under surgical gloves if hands are washed with soap that is not antimicrobial (127,128). Thus, an antimicrobial soap or alcohol hand rub with persistent activity should be used before surgical procedures (129-133).

Agents used for surgical hand antisepsis should substantially reduce microorganisms on intact skin, contain a nonirritating antimicrobial preparation, have a broad spectrum of activity, be fast-acting, and have a persistent effect (121,132-135). Persistence (i.e., extended antimicrobial activity that prevents or inhibits survival of microorganisms after the product is

applied) is critical because microorganisms can colonize on hands in the moist environment underneath gloves (122).

Alcohol hand rubs are rapidly germicidal when applied to the skin but should include such antiseptics as chlorhexidine, quaternary ammonium compounds, octenidine, or triclosan to achieve persistent activity (130). Factors that can influence the effectiveness of the surgical hand antisepsis in addition to the choice of antiseptic agent include duration and technique of scrubbing, as well as condition of the hands, and techniques used for drying and gloving. CDC's 2002 guideline on hand hygiene in health-care settings provides more complete information (123).

#### Selection of Antiseptic Agents

Selecting the most appropriate antiseptic agent for hand hygiene requires consideration of multiple factors. Essential performance characteristics of a product (e.g., the spectrum and persistence of activity and whether or not the agent is fast-acting) should be determined before selecting a product. Delivery system, cost per use, reliable vendor support and supply are also considerations. Because HCP acceptance is a major factor regarding compliance with recommended hand hygiene protocols (122,123,147,148), considering DHCP needs is critical and should include possible chemical allergies,

TABLE 2. Hand-hygiene methods and indications

Method	Agent	Purpose	Duration (minimum)	Indication*
Routine handwash	Water and (nonantimicrobial) soap (e.g., plain soap) <sup>1</sup>	Remove soil and transient microorganisms	15 seconds <sup>2</sup>	Before and after treating each patient (e.g., before glove placement and after glove removal). After barehanded touching of inanimate objects likely to be contaminated by blood or saliva. Before leaving the dental operatory or the dental laboratory. When visibly soiled.† Before gloving after removing gloves that are torn, cut, or punctured.
Antiseptic handwash	Water and antimicrobial soap (e.g., chlorhexidine, iodine and iodophors, chloroxylenol [PCMX], triclosan)	Remove or destroy transient microorganisms and reduce resident flora	15 seconds <sup>2</sup>	
Antiseptic hand rub	Alcohol-based hand rub <sup>3</sup>	Remove or destroy transient microorganisms and reduce resident flora	Rub hands until the agent is dry <sup>4</sup>	
Surgical antisepsis	Water and antimicrobial soap (e.g., chlorhexidine, iodine and iodophors, chloroxylenol [PCMX], triclosan) Water and non-antimicrobial soap (e.g., plain soap) <sup>5</sup> followed by an alcohol-based surgical hand-scrub product with persistent activity	Remove or destroy transient microorganisms and reduce resident flora (persistent effect)	2-5 minutes Follow manufacturer instructions for surgical hand-scrub product with persistent activity <sup>6</sup>	Before donning sterile gloves or gloves for surgical procedures <sup>7</sup>

\* (73,74,13,113,120-123,125,126,136-138).

<sup>1</sup> Feculent organisms have been found on or around bar soap during and after use (133). Use of liquid soap with hands-free dispensing controls is preferable.

<sup>2</sup> Time reported as effective in removing most transient flora from the skin. For most procedures, a vigorous rubbing together of all surfaces of premoistened lathered hands and fingers for ≥15 seconds, followed by rinsing under a stream of cool or tepid water is recommended (8,120,123,140,147). Hands should always be dried thoroughly before donning gloves.

<sup>3</sup> Alcohol-based hand rubs should contain 60%-80% ethanol or isopropanol and should not be used in the presence of visible soil or organic material. If using an alcohol-based hand rub, apply adequate amount to palm of one hand and rub hands together, covering all surfaces of the hands and fingers, until hands are dry. Follow manufacturer's recommendations regarding the volume of product to use. If hands feel dry after rubbing them together for 15-30 seconds, an insubstantial volume of product likely was applied. The drying effect of alcohol can be reduced or eliminated by adding 1%-3% glycerol or other skin-conditioning agents (123).

<sup>4</sup> After application of alcohol-based surgical hand-scrub product with persistent activity as recommended, allow hands and forearms to dry thoroughly and immediately don sterile surgical gloves (144,145). Follow manufacturer instructions (122,123,132,146).

<sup>5</sup> Before beginning surgical hand scrub, remove all arm jewelry and any hand jewelry that may make donning gloves more difficult, cause gloves to tear more readily (142,143), or interfere with glove usage (e.g., ability to wear the correct-sized glove or altered glove integrity).

skin integrity after repeated use, compatibility with lotions used, and offensive agent ingredients (e.g., scent). Discussing specific preparations or ingredients used for hand antisepsis is beyond the scope of this report. DHCP should choose from commercially available HCP handwashes when selecting agents for hand antisepsis or surgical hand antisepsis.

#### Storage and Dispensing of Hand Care Products

Handwashing products, including plain (i.e., non-antimicrobial) soap and antiseptic products, can become contaminated or support the growth of microorganisms (122). Liquid products should be stored in closed containers and dispensed from either disposable containers or containers that are washed and dried thoroughly before refilling. Soap should not be added to a partially empty dispenser, because this practice of topping off might lead to bacterial contamination (149,150). Store and dispense products according to manufacturers' directions.

#### Lotions

The primary defense against infection and transmission of pathogens is healthy, unbroken skin. Frequent handwashing with soaps and antiseptic agents can cause chronic irritant contact dermatitis among DHCP. Damage to the skin changes skin flora, resulting in more frequent colonization by staphylococci and gram-negative bacteria (151,152). The potential of detergents to cause skin irritation varies considerably, but can be reduced by adding emollients. Lotions are often recommended to ease the dryness resulting from frequent handwashing and to prevent dermatitis from glove use (153,154). However, petroleum-based lotion formulations can weaken latex gloves and increase permeability. For that reason, lotions that contain petroleum or other oil emollients should only be used at the end of the work day (122,155). Dental practitioners should obtain information from lotion manufacturers regarding interaction between lotions, gloves, dental materials, and antimicrobial products.

#### Fingernails and Artificial Nails

Although the relationship between fingernail length and wound infection is unknown, keeping nails short is considered key because the majority of flora on the hands are found under and around the fingernails (156). Fingernails should be short enough to allow DHCP to thoroughly clean underneath them and prevent glove tears (122). Sharp nail edges or broken nails are also likely to increase glove failure. Long artificial or natural nails can make donning gloves more difficult and can cause gloves to tear more readily. Hand carriage of gram-negative organisms has been determined to be greater among

wearers of artificial nails than among nonwearers, both before and after handwashing (157-160). In addition, artificial fingernails or extenders have been epidemiologically implicated in multiple outbreaks involving fungal and bacterial infections in hospital intensive-care units and operating rooms (161-164). Freshly applied nail polish on natural nails does not increase the microbial load from periungual skin if fingernails are short; however, chipped nail polish can harbor added bacteria (165,166).

#### Jewelry

Studies have demonstrated that skin underneath rings is more heavily colonized than comparable areas of skin on fingers without rings (167-170). In a study of intensive-care nurses, multivariable analysis determined rings were the only substantial risk factor for carriage of gram-negative bacilli and *Staphylococcus aureus*, and the concentration of organisms correlated with the number of rings worn (170). However, two other studies demonstrated that mean bacterial colony counts on hands after handwashing were similar among persons wearing rings and those not wearing rings (169,171). Whether wearing rings increases the likelihood of transmitting a pathogen is unknown; further studies are needed to establish whether rings result in higher transmission of pathogens in health-care settings. However, rings and decorative nail jewelry can make donning gloves more difficult and cause gloves to tear more readily (142,143). Thus, jewelry should not interfere with glove use (e.g., impair ability to wear the correct-sized glove or alter glove integrity).

#### Personal Protective Equipment

PPE is designed to protect the skin and the mucous membranes of the eyes, nose, and mouth of DHCP from exposure to blood or OPIM. Use of rotary dental and surgical instruments (e.g., handpieces or ultrasonic scalers) and air-water syringes creates a visible spray that contains primarily large-particle droplets of water, saliva, blood, microorganisms, and other debris. This spatter travels only a short distance and settles out quickly, landing on the floor, nearby operatory surfaces, DHCP, or the patient. The spray also might contain certain aerosols (i.e., particles of respirable size, <10 µm). Aerosols can remain airborne for extended periods and can be inhaled. However, they should not be confused with the large-particle spatter that makes up the bulk of the spray from handpieces and ultrasonic scalers. Appropriate work practices, including use of dental dams (172) and high-velocity air evacuation, should minimize dissemination of droplets, spatter, and aerosols (2).

Primary PPE used in oral health-care settings includes gloves, surgical masks, protective eyewear, face shields, and protective

clothing (e.g., gowns and jackets). All PPE should be removed before DHCP leave patient-care areas (13). Reusable PPE (e.g., clinician or patient protective eyewear and face shields) should be cleaned with soap and water, and when visibly soiled, disinfected between patients, according to the manufacturer's directions (2,13). Wearing gloves, surgical masks, protective eyewear, and protective clothing in specified circumstances to reduce the risk of exposures to bloodborne pathogens is mandated by OSHA (13). General work clothes (e.g., uniforms, scrubs, pants, and shirts) are neither intended to protect against a hazard nor considered PPE.

### Masks, Protective Eyewear, Face Shields

A surgical mask that covers both the nose and mouth and protective eyewear with solid side shields or a face shield should be worn by DHCP during procedures and patient-care activities likely to generate splashes or sprays of blood or body fluids. Protective eyewear for patients shields their eyes from spatter or debris generated during dental procedures. A surgical mask protects against microorganisms generated by the wearer, with >95% bacterial filtration efficiency, and also protects DHCP from large-particle droplet spatter that might contain bloodborne pathogens or other infectious microorganisms (13). The mask's outer surface can become contaminated with infectious droplets from spray of oral fluids or from touching the mask with contaminated fingers. Also, when a mask becomes wet from exhaled moist air, the resistance to airflow through the mask increases, causing more airflow to pass around edges of the mask. If the mask becomes wet, it should be changed between patients or even during patient treatment, when possible (2,174).

When airborne infection isolation precautions (expanded or transmission-based) are necessary (e.g., for TB patients), a National Institute for Occupational Safety and Health (NIOSH)-certified particulate-filter respirator (e.g., N95, N99, or N100) should be used (20). N95 refers to the ability to filter 1- $\mu$ m particles in the unloaded state with a filter efficiency of >95% (i.e., filter leakage <5%), given flow rates of  $\leq 50$  L/min (i.e., approximate maximum airflow rate of HCP during breathing). Available data indicate infectious droplet nuclei measure 1–5  $\mu$ m; therefore, respirators used in health-care settings should be able to efficiently filter the smallest particles in this range.

The majority of surgical masks are not NIOSH-certified as respirators, do not protect the user adequately from exposure to TB, and do not satisfy OSHA requirements for respiratory protection (174,175). However, certain surgical masks (i.e., surgical N95 respirator) do meet the requirements and are certified by NIOSH as respirators. The level of protection a respirator provides is determined by the efficiency of the filter

material for incoming air and how well the face piece fits or seals to the face (e.g., qualitatively or quantitatively tested in a reliable way to obtain a face-seal leakage of <10% and to fit the different facial sizes and characteristics of HCP).

When respirators are used while treating patients with diseases requiring airborne-transmission precautions (e.g., TB), they should be used in the context of a complete respiratory protection program (175). This program should include training and fit testing to ensure an adequate seal between the edges of the respirator and the wearer's face. Detailed information regarding respirator programs, including fit-test procedures are available at <http://www.cdc.gov/niosh/99-143.html> (174,176).

### Protective Clothing

Protective clothing and equipment (e.g., gowns; lab coats, gloves, masks, and protective eyewear or face shield) should be worn to prevent contamination of street clothing and to protect the skin of DHCP from exposures to blood and body substances (2,7,10,11,13,137). OSHA bloodborne pathogens standard requires sleeves to be long enough to protect the forearms when the gown is worn as PPE (i.e., when spatter and spray of blood, saliva, or OPIM to the forearms is anticipated) (13,14). DHCP should change protective clothing when it becomes visibly soiled and as soon as feasible if penetrated by blood or other potentially infectious fluids (2,13,14,137). All protective clothing should be removed before leaving the work area (13).

### Gloves and Gloving

DHCP wear gloves to prevent contamination of their hands when touching mucous membranes, blood, saliva, or OPIM, and also to reduce the likelihood that microorganisms present on the hands of DHCP will be transmitted to patients during surgical or other patient-care procedures (1,2,7,10). Medical gloves, both patient examination and surgeon's gloves, are manufactured as single-use disposable items that should be used for only one patient, then discarded. Gloves should be changed between patients and when torn or punctured.

Wearing gloves does not eliminate the need for handwashing. Hand hygiene should be performed immediately before donning gloves. Gloves can have small, unapparent defects or can be torn during use, and hands can become contaminated during glove removal (122,177–187). These circumstances increase the risk of operative wound contamination and exposure of the DHCP's hands to microorganisms from patients. In addition, bacteria can multiply rapidly in the moist environments underneath gloves, and thus, the hands should be dried thoroughly before donning gloves and washed again immediately after glove removal.

### Types of Gloves

Because gloves are task-specific, their selection should be based on the type of procedure to be performed (e.g., surgery or patient examination) (Table 3). Sterile surgeon's gloves must meet standards for sterility assurance established by FDA and are less likely than patient examination gloves to harbor pathogens that could contaminate an operative wound (188). Appropriate gloves in the correct size should be readily accessible (13).

### Glove Integrity

Limited studies of the penetrability of different glove materials under conditions of use have been conducted in the dental environment. Consistent with observations in clinical medicine, leakage rates vary by glove material (e.g., latex, vinyl, and nitrile), duration of use, and type of procedure performed (182,184,186,189–191), as well as by manufacturer (192–194). The frequency of perforations in surgeon's gloves used during outpatient oral surgical procedures has been determined to range from 6% to 16% (181,185,195,196).

Studies have demonstrated that HCP and DHCP are frequently unaware of minute tears in gloves that occur during use (186,190,191,197). These studies determined that gloves

developed defects in 30 minutes–3 hours, depending on type of glove and procedure. Investigators did not determine an optimal time for changing gloves during procedures.

During dental procedures, patient examination and surgeon's gloves commonly contact multiple types of chemicals and materials (e.g., disinfectants and antiseptics, composite resins, and bonding agents) that can compromise the integrity of latex as well as vinyl, nitrile, and other synthetic glove materials (198–206). In addition, latex gloves can interfere with the setting of vinyl polysiloxane impression materials (207–209), although the setting is apparently not adversely affected by synthetic vinyl gloves (207,208). Given the diverse selection of dental materials on the market, dental practitioners should consult glove manufacturers regarding the chemical compatibility of glove materials.

If the integrity of a glove is compromised (e.g., punctured), it should be changed as soon as possible (13,210,211). Washing latex gloves with plain soap, chlorhexidine, or alcohol can lead to the formation of glove microperforations (177,212,213) and subsequent hand contamination (138). Because this condition, known as wicking, can allow penetration of liquids through undetected holes, washing gloves is not recommended. After a hand rub with alcohol, the hands should be thoroughly

TABLE 3. Glove types and indications

Glove	Indication	Comment	Commercially available glove materials*	
			Material	Attributes†
Patient examination gloves‡	Patient care, examinations, other non-surgical procedures involving contact with mucous membranes, and laboratory procedures	Medical device regulated by the Food and Drug Administration (FDA).  Nonsterile and sterile single-use disposable. Use for one patient and discard appropriately.	Natural-rubber latex (NRL)	1, 2
			Nitrile	2, 3
			Nitrile and chloroprene (neoprene) blends	2, 3
			Nitrile & NRL blends	1, 2, 3
			Butadiene methyl methacrylate	2, 3
			Polyvinyl chloride (PVC, vinyl)	4
Surgeon's gloves‡	Surgical procedures	Medical device regulated by the FDA.  Sterile and single-use disposable. Use for one patient and discard appropriately.	Polysiloxane	4
			Styrene-based copolymer	4, 5
			NRL	1, 2
			Nitrile	2, 3
			Chloroprene (neoprene)	2, 3
			NRL and nitrile or chloroprene blends	2, 3
Nonmedical gloves	Housekeeping procedures (e.g., cleaning and disinfection)	Not a medical device regulated by the FDA.  Commonly referred to as utility, industrial, or general purpose gloves. Should be puncture- or chemical-resistant, depending on the task. Latex gloves do not provide adequate chemical protection.	Synthetic polyisoprene	2
			Styrene-based copolymer	4, 5
	Handling contaminated sharps or chemicals		Polyurethane	4
			NRL and nitrile or chloroprene blends	2, 3
			Chloroprene (neoprene)	2, 3
			Nitrile	2, 3
Not for use during patient care	Sanitize after use.	Butyl rubber	2, 3	
		Fluoroelastomer	3, 4, 6	
			Polyethylene and ethylene vinyl alcohol copolymer	3, 4, 6

\* Physical properties can vary by material, manufacturer, and protein and chemical composition.

† 1 Contains allergenic NRL proteins.

† 2 Vulcanized rubber; contains allergenic rubber processing chemicals.

† 3 Likely to have enhanced chemical or puncture resistance.

† 4 Nonvulcanized and does not contain rubber processing chemicals.

† 5 Inappropriate for use with methacrylates.

† 6 Resistant to most methacrylates.

† Medical or dental gloves include patient-examination gloves and surgeon's (i.e., surgical) gloves and are medical devices regulated by the FDA. Only FDA-cleared medical or dental patient-examination gloves and surgical gloves can be used for patient care.

dried before gloving, because hands still wet with an alcohol-based hand hygiene product can increase the risk of glove perforation (192).

FDA regulates the medical glove industry, which includes gloves marketed as sterile surgeon's and sterile or nonsterile patient examination gloves. General-purpose utility gloves are also used in dental health-care settings but are not regulated by FDA because they are not promoted for medical use. More rigorous standards are applied to surgeon's than to examination gloves. FDA has identified acceptable quality levels (e.g., maximum defects allowed) for glove manufacturers (214), but even intact gloves eventually fail with exposure to mechanical (e.g., sharps, fingernails, or jewelry) and chemical (e.g., dimethylacrylates) hazards and over time. These variables can be controlled, ultimately optimizing glove performance, by 1) maintaining short fingernails, 2) minimizing or eliminating hand jewelry, and 3) using engineering and work-practice controls to avoid injuries with sharps.

#### Sterile Surgeon's Gloves and Double-Gloving During Oral Surgical Procedures

Certain limited studies have determined no difference in postoperative infection rates after routine tooth extractions when surgeons wore either sterile or nonsterile gloves (215,216). However, wearing sterile surgeon's gloves during surgical procedures is supported by a strong theoretical rationale (2,7,137). Sterile gloves minimize transmission of microorganisms from the hands of surgical DHCP to patients and prevent contamination of the hands of surgical DHCP with the patient's blood and body fluids (137). In addition, sterile surgeon's gloves are more rigorously regulated by FDA and therefore might provide an increased level of protection for the provider if exposure to blood is likely.

Although the effectiveness of wearing two pairs of gloves in preventing disease transmission has not been demonstrated, the majority of studies among HCP and DHCP have demonstrated a lower frequency of inner glove perforation and visible blood on the surgeon's hands when double gloves are worn (181,185,195,196,198,217-219). In one study evaluating double gloves during oral surgical and dental hygiene procedures, the perforation of outer latex gloves was greater during longer procedures (i.e., >45 minutes), with the highest rate (10%) of perforation occurring during oral surgery procedures (196). Based on these studies, double gloving might provide additional protection from occupational blood contact (220). Double gloving does not appear to substantially reduce either manual dexterity or tactile sensitivity (221-223). Additional protection might also be provided by specialty products (e.g., orthopedic surgical gloves and glove liners) (224).

#### Contact Dermatitis and Latex Hypersensitivity

Occupationally related contact dermatitis can develop from frequent and repeated use of hand hygiene products, exposure to chemicals, and glove use. Contact dermatitis is classified as either irritant or allergic. Irritant contact dermatitis is common, nonallergic, and develops as dry, itchy, irritated areas on the skin around the area of contact. By comparison, allergic contact dermatitis (type IV hypersensitivity) can result from exposure to accelerators and other chemicals used in the manufacture of rubber gloves (e.g., natural rubber latex, nitrile, and neoprene), as well as from other chemicals found in the dental practice setting (e.g., methacrylates and glutaraldehyde). Allergic contact dermatitis often manifests as a rash beginning hours after contact and, similar to irritant dermatitis, is usually confined to the area of contact.

Latex allergy (type I hypersensitivity to latex proteins) can be a more serious systemic allergic reaction, usually beginning within minutes of exposure but sometimes occurring hours later and producing varied symptoms. More common reactions include runny nose, sneezing, itchy eyes, scratchy throat, hives, and itchy burning skin sensations. More severe symptoms include asthma marked by difficult breathing, coughing spells, and wheezing; cardiovascular and gastrointestinal ailments; and in rare cases, anaphylaxis and death (32,225). The American Dental Association (ADA) began investigating the prevalence of type I latex hypersensitivity among DHCP at the ADA annual meeting in 1994. In 1994 and 1995, approximately 2,000 dentists, hygienists, and assistants volunteered for skin-prick testing. Data demonstrated that 6.2% of those tested were positive for type I latex hypersensitivity (226). Data from the subsequent 5 years of this ongoing cross-sectional study indicated a decline in prevalence from 8.5% to 4.3% (227). This downward trend is similar to that reported by other studies and might be related to use of latex gloves with lower allergen content (228-230).

Natural rubber latex proteins responsible for latex allergy are attached to glove powder. When powdered latex gloves are worn, more latex protein reaches the skin. In addition, when powdered latex gloves are donned or removed, latex protein/powder particles become aerosolized and can be inhaled, contacting mucous membranes (231). As a result, allergic patients and DHCP can experience cutaneous, respiratory, and conjunctival symptoms related to latex protein exposure. DHCP can become sensitized to latex protein with repeated exposure (232-236). Work areas where only powder-free, low-allergen latex gloves are used demonstrate low or undetectable amounts of latex allergy-causing proteins (237-239) and fewer symptoms among HCP related to natural rubber latex allergy.

Because of the role of glove powder in exposure to latex protein, NIOSH recommends that if latex gloves are chosen, HCP should be provided with reduced protein, powder-free gloves (32). Nonlatex (e.g., nitrile or vinyl) powder-free and low-protein gloves are also available (31,240). Although rare, potentially life-threatening anaphylactic reactions to latex can occur; dental practices should be appropriately equipped and have procedures in place to respond to such emergencies.

DHCP and dental patients with latex allergy should not have direct contact with latex-containing materials and should be in a latex-safe environment with all latex-containing products removed from their vicinity (31). Dental patients with histories of latex allergy can be at risk from dental products (e.g., prophylaxis cups, rubber dams, orthodontic elastics, and medication vials) (241). Any latex-containing devices that cannot be removed from the treatment environment should be adequately covered or isolated. Persons might also be allergic to chemicals used in the manufacture of natural rubber latex and synthetic rubber gloves as well as metals, plastics, or other materials used in dental care. Taking thorough health histories for both patients and DHCP, followed by avoidance of contact with potential allergens can minimize the possibility of adverse reactions. Certain common predisposing conditions for latex allergy include previous history of allergies, a history of spina bifida, urogenital anomalies, or allergies to avocados, kiwis, nuts, or bananas. The following precautions should be considered to ensure safe treatment for patients who have possible or documented latex allergy:

- Be aware that latent allergens in the ambient air can cause respiratory or anaphylactic symptoms among persons with latex hypersensitivity. Patients with latex allergy can be scheduled for the first appointment of the day to minimize their inadvertent exposure to airborne latex particles.
- Communicate with other DHCP regarding patients with latex allergy (e.g., by oral instructions, written protocols, and posted signage) to prevent them from bringing latex-containing materials into the treatment area.
- Frequently clean all working areas contaminated with latex powder or dust.

- Have emergency treatment kits with latex-free products available at all times.
- If latex-related complications occur during or after a procedure, manage the reaction and seek emergency assistance as indicated. Follow current medical emergency response recommendations for management of anaphylaxis (32).

#### Sterilization and Disinfection of Patient-Care Items

Patient-care items (dental instruments, devices, and equipment) are categorized as critical, semicritical, or noncritical, depending on the potential risk for infection associated with their intended use (Table 4) (242). Critical items used to penetrate soft tissue or bone have the greatest risk of transmitting infection and should be sterilized by heat. Semicritical items touch mucous membranes or nonintact skin and have a lower risk of transmission; because the majority of semicritical items in dentistry are heat-tolerant, they also should be sterilized by using heat. If a semicritical item is heat-sensitive, it should, as a minimum, be processed with high-level disinfection (2).

Noncritical patient-care items pose the least risk of transmission of infection, contacting only intact skin, which can serve as an effective barrier to microorganisms. In the majority of cases, cleaning, or if visibly soiled, cleaning followed by disinfection with an EPA-registered hospital disinfectant is adequate. When the item is visibly contaminated with blood or OPIM, an EPA-registered hospital disinfectant with a tuberculocidal claim (i.e., intermediate-level disinfectant) should be used (2,243,244). Cleaning or disinfection of certain noncritical patient-care items can be difficult or damage the surfaces; therefore, use of disposable barrier protection of these surfaces might be a preferred alternative.

FDA-cleared sterilant/high-level disinfectants and EPA-registered disinfectants must have clear label claims for intended use, and manufacturer instructions for use must be followed (245). A more complete description of the regulatory framework in the United States by which liquid chemical germicides are evaluated and regulated is included (Appendix A).

TABLE 4. Infection-control categories of patient-care instruments

Category	Definition	Dental instrument or item
Critical	Penetrates soft tissue, contacts bone, enters into or contacts the bloodstream or other normally sterile tissues.	Surgical instruments, periodontal scalers, scalpel blades, surgical dental burs
Semicritical	Contacts mucous membranes or nonintact skin; will not penetrate soft tissue, contact bone, enter into or contact the bloodstream or other normally sterile tissue.	Dental mouth mirror, amalgam condenser, reusable dental impression trays, dental handpieces*
Noncritical	Contacts intact skin.	Radiograph head/cons, blood pressure cuff, fessobow, pulse oximeter

\* Although dental handpieces are considered a semicritical item, they should always be heat-sterilized between uses and not high-level disinfected (246). See Dental Handpieces and Other Devices Attached to Air or Waterlines for detailed information.

Three levels of disinfection, high, intermediate, and low, are used for patient-care devices that do not require sterility and two levels, intermediate and low, for environmental surfaces (242). The intended use of the patient-care item should determine the recommended level of disinfection. Dental practices should follow the product manufacturer's directions regarding concentrations and exposure time for disinfectant activity relative to the surface to be disinfected (245). A summary of sterilization and disinfection methods is included (Appendix C).

#### Transporting and Processing Contaminated Critical and Semicritical Patient-Care Items

DHCP can be exposed to microorganisms on contaminated instruments and devices through percutaneous injury, contact with nonintact skin on the hands, or contact with mucous membranes of the eyes, nose, or mouth. Contaminated instruments should be handled carefully to prevent exposure to sharp instruments that can cause a percutaneous injury. Instruments should be placed in an appropriate container at the point of use to prevent percutaneous injuries during transport to the instrument processing area (13).

Instrument processing requires multiple steps to achieve sterilization or high-level disinfection. Sterilization is a complex process requiring specialized equipment, adequate space, qualified DHCP who are provided with ongoing training, and regular monitoring for quality assurance (247). Correct cleaning, packaging, sterilizer loading procedures, sterilization methods, or high-level disinfection methods should be followed to ensure that an instrument is adequately processed and safe for reuse on patients.

#### Instrument Processing Area

DHCP should process all instruments in a designated central processing area to more easily control quality and ensure safety (248). The central processing area should be divided into sections for 1) receiving, cleaning, and decontamination; 2) preparation and packaging; 3) sterilization; and 4) storage. Ideally, walls or partitions should separate the sections to control traffic flow and contain contaminants generated during processing. When physical separation of these sections cannot be achieved, adequate spatial separation might be satisfactory if the DHCP who process instruments are trained in work practices to prevent contamination of clean areas (248). Space should be adequate for the volume of work anticipated and the items to be stored (248).

#### Receiving, Cleaning, and Decontamination

Reusable instruments, supplies, and equipment should be received, sorted, cleaned, and decontaminated in one section of the processing area. Cleaning should precede all disinfection

and sterilization processes; it should involve removal of debris as well as organic and inorganic contamination. Removal of debris and contamination is achieved either by scrubbing with a surfactant, detergent, and water, or by an automated process (e.g., ultrasonic cleaner or washer-disinfector) using chemical agents. If visible debris, whether inorganic or organic matter, is not removed, it will interfere with microbial inactivation and can compromise the disinfection or sterilization process (244,249-252). After cleaning, instruments should be rinsed with water to remove chemical or detergent residue. Splashing should be minimized during cleaning and rinsing (13). Before final disinfection or sterilization, instruments should be handled as though contaminated.

Considerations in selecting cleaning methods and equipment include 1) efficacy of the method, process, and equipment; 2) compatibility with items to be cleaned; and 3) occupational health and exposure risks. Use of automated cleaning equipment (e.g., ultrasonic cleaner or washer-disinfector) does not require presoaking or scrubbing of instruments and can increase productivity, improve cleaning effectiveness, and decrease worker exposure to blood and body fluids. Thus, using automated equipment can be safer and more efficient than manually cleaning contaminated instruments (253).

If manual cleaning is not performed immediately, placing instruments in a puncture-resistant container and soaking them with detergent, a disinfectant/detergent, or an enzymatic cleaner will prevent drying of patient material and make cleaning easier and less time-consuming. Use of a liquid chemical sterilant/high-level disinfectant (e.g., glutaraldehyde) as a holding solution is not recommended (244). Using work-practice controls (e.g., long-handled brush) to keep the scrubbing hand away from sharp instruments is recommended (14). To avoid injury from sharp instruments, DHCP should wear puncture-resistant, heavy-duty utility gloves when handling or manually cleaning contaminated instruments and devices (6). Employees should not reach into trays or containers holding sharp instruments that cannot be seen (e.g., sinks filled with soapy water in which sharp instruments have been placed). Work-practice controls should include use of a strainer-type basket to hold instruments and forceps to remove the items. Because splashing is likely to occur, a mask, protective eyewear, or face shield, and gown or jacket should be worn (13).

#### Preparation and Packaging

In another section of the processing area, cleaned instruments and other dental supplies should be inspected, assembled into sets or trays, and wrapped, packaged, or placed into container systems for sterilization. Hinged instruments should be processed open and unlocked. An internal chemical indicator should be placed in every package. In addition, an external

chemical indicator (e.g., chemical indicator tape) should be used when the internal indicator cannot be seen from outside the package. For unwrapped loads, at a minimum, an internal chemical indicator should be placed in the tray or cassette with items to be sterilized (254) (see Sterilization of Unwrapped Instruments). Dental practices should refer to the manufacturer's instructions regarding use and correct placement of chemical indicators (see Sterilization Monitoring). Critical and semicritical instruments that will be stored should be wrapped or placed in containers (e.g., cassettes or organizing trays) designed to maintain sterility during storage (2,247,255-257).

Packaging materials (e.g., wraps or container systems) allow penetration of the sterilization agent and maintain sterility of the processed item after sterilization. Materials for maintaining sterility of instruments during transport and storage include wrapped perforated instrument cassettes, peel pouches of plastic or paper, and sterilization wraps (i.e., woven and nonwoven). Packaging materials should be designed for the type of sterilization process being used (256-259).

#### Sterilization

The sterilization section of the processing area should include the sterilizers and related supplies, with adequate space for loading, unloading, and cool down. The area can also include incubators for analyzing spore tests and enclosed storage for sterile items and disposable (single-use) items (260). Manufacturer and local building code specifications will determine placement and room ventilation requirements.

**Sterilization Procedures.** Heat-tolerant dental instruments usually are sterilized by 1) steam under pressure (autoclaving), 2) dry heat, or 3) unsaturated chemical vapor. All sterilization should be performed by using medical sterilization equipment cleared by FDA. The sterilization times, temperatures, and other operating parameters recommended by the manufacturer of the equipment used, as well as instructions for correct use of containers, wraps, and chemical or biological indicators, should always be followed (243,247).

Items to be sterilized should be arranged to permit free circulation of the sterilizing agent (e.g., steam, chemical vapor, or dry heat); manufacturer's instructions for loading the sterilizer should be followed (248,260). Instrument packs should be allowed to dry inside the sterilizer chamber before removing and handling. Packs should not be touched until they are cool and dry because hot packs act as wicks, absorbing moisture, and hence, bacteria from hands (247). The ability of equipment to attain physical parameters required to achieve sterilization should be monitored by mechanical, chemical, and biological indicators. Sterilizers vary in their types of indicators and their ability to provide readings on the mechani-

cal or physical parameters of the sterilization process (e.g., time, temperature, and pressure). Consult with the sterilizer manufacturer regarding selection and use of indicators.

**Steam Sterilization.** Among sterilization methods, steam sterilization, which is dependable and economical, is the most widely used for wrapped and unwrapped critical and semicritical items that are not sensitive to heat and moisture (260). Steam sterilization requires exposure of each item to direct steam contact at a required temperature and pressure for a specified time needed to kill microorganisms. Two basic types of steam sterilizers are the gravity displacement and the high-speed prevacuum sterilizer.

The majority of tabletop sterilizers used in a dental practice are gravity displacement sterilizers, although prevacuum sterilizers are becoming more widely available. In gravity displacement sterilizers, steam is admitted through steam lines, a steam generator, or self-generation of steam within the chamber. Unsaturated air is forced out of the chamber through a vent in the chamber wall. Trapping of air is a concern when using saturated steam under gravity displacement; errors in packaging items or overloading the sterilizer chamber can result in cool air pockets and items not being sterilized.

Prevacuum sterilizers are fitted with a pump to create a vacuum in the chamber and ensure air removal from the sterilizing chamber before the chamber is pressurized with steam. Relative to gravity displacement, this procedure allows faster and more positive steam penetration throughout the entire load. Prevacuum sterilizers should be tested periodically for adequate air removal, as recommended by the manufacturer. Air not removed from the chamber will interfere with steam contact. If a sterilizer fails the air removal test, it should not be used until inspected by sterilizer maintenance personnel and it passes the test (243,247). Manufacturer's instructions, with specific details regarding operation and user maintenance information, should be followed.

**Unsaturated Chemical-Vapor Sterilization.** Unsaturated chemical-vapor sterilization involves heating a chemical solution of primarily alcohol with 0.23% formaldehyde in a closed pressurized chamber. Unsaturated chemical vapor sterilization of carbon steel instruments (e.g., dental burs) causes less corrosion than steam sterilization because of the low level of water present during the cycle. Instruments should be dry before sterilizing. State and local authorities should be consulted for hazardous waste disposal requirements for the sterilizing solution.

**Dry-Heat Sterilization.** Dry heat is used to sterilize materials that might be damaged by moist heat (e.g., bus and certain orthodontic instruments). Although dry heat has the advantages of low operating cost and being noncorrosive, it is

a prolonged process and the high temperatures required are not suitable for certain patient-care items and devices (267).

Dry-heat sterilizers used in dentistry include static-air and forced-air types.

- The static-air type is commonly called an oven-type sterilizer. Heating coils in the bottom or sides of the unit cause hot air to rise inside the chamber through natural convection.
- The forced-air type is also known as a rapid heat-transfer sterilizer. Heated air is circulated throughout the chamber at a high velocity, permitting more rapid transfer of energy from the air to the instruments, thereby reducing the time needed for sterilization.

**Sterilization of Unwrapped Instruments.** An unwrapped cycle (sometimes called *flash sterilization*) is a method for sterilizing unwrapped patient-care items for immediate use. The time required for unwrapped sterilization cycles depends on the type of sterilizer and the type of item (i.e., porous or non-porous) to be sterilized (243). The unwrapped cycle in tabletop sterilizers is preprogrammed by the manufacturer to a specific time and temperature setting and can include a drying phase at the end to produce a dry instrument with much of the heat dissipated. If the drying phase requirements are unclear, the operation manual or manufacturer of the sterilizer should be consulted. If the unwrapped sterilization cycle in a steam sterilizer does not include a drying phase, or has only a minimal drying phase, items retrieved from the sterilizer will be hot and wet, making aseptic transport to the point of use more difficult. For dry-heat and chemical-vapor sterilizers, a drying phase is not required.

Unwrapped sterilization should be used only under certain conditions: 1) thorough cleaning and drying of instruments precedes the unwrapped sterilization cycle; 2) mechanical monitors are checked and chemical indicators used for each cycle; 3) care is taken to avoid thermal injury to DHCP or patients; and 4) items are transported aseptically to the point of use to maintain sterility (134,258,262). Because all implantable devices should be quarantined after sterilization until the results of biological monitoring are known, unwrapped or flash sterilization of implantable items is not recommended (134).

Critical instruments sterilized unwrapped should be transferred immediately by using aseptic technique, from the sterilizer to the actual point of use. Critical instruments should not be stored unwrapped (269). Semicritical instruments that are sterilized unwrapped on a tray or in a container system should be used immediately or within a short time. When sterile items are open to the air, they will eventually become contaminated. Storage, even temporary, of unwrapped semicritical instruments is discouraged because it permits exposure to dust, airborne organisms, and other unnecessary contamination before use on a patient (260). A carefully written protocol for minimiz-

ing the risk of contaminating unwrapped instruments should be prepared and followed (260).

**Other Sterilization Methods.** Heat-sensitive critical and semicritical instruments and devices can be sterilized by immersing them in liquid chemical germicides registered by FDA as sterilants. When using a liquid chemical germicide for sterilization, certain poststerilization procedures are essential. Items need to be 1) rinsed with sterile water after removal to remove toxic or irritating residues; 2) handled using sterile gloves and dried with sterile towels; and 3) delivered to the point of use in an aseptic manner. If stored before use, the instrument should not be considered sterile and should be sterilized again just before use. In addition, the sterilization process with liquid chemical sterilants cannot be verified with biological indicators (263).

Because of these limitations and because liquid chemical sterilants can require approximately 12 hours of complete immersion, they are almost never used to sterilize instruments. Rather, these chemicals are more often used for high-level disinfection (249). Shorter immersion times (12–90 minutes) are used to achieve high-level disinfection of semicritical instruments or items. These powerful, sporicidal chemicals (e.g., glutaraldehyde, peracetic acid, and hydrogen peroxide) are highly toxic (244,264,265). Manufacturer instructions (e.g., regarding dilution, immersion time, and temperature) and safety precautions for using chemical sterilants/high-level disinfectants must be followed precisely (15,245). These chemicals should not be used for applications other than those indicated in their label instructions. Misapplications include use as an environmental surface disinfectant or instrument-holding solution.

When using appropriate precautions (e.g., closed containers to limit vapor release, chemically resistant gloves and aprons, goggles, and face shields), glutaraldehyde-based products can be used without tissue irritation or adverse health effects. However, dermatologic, eye irritation, respiratory effects, and skin sensitization have been reported (266–268). Because of their lack of chemical resistance to glutaraldehydes, medical gloves are not an effective barrier (200,269,270). Other factors might apply (e.g., room exhaust ventilation or 10 air exchanges/hour) to ensure DHCP safety (266,271). For all of these reasons, using heat-sensitive semicritical items that must be processed with liquid chemical germicides is discouraged; heat-tolerant or disposable alternatives are available for the majority of such items.

Low-temperature sterilization with ethylene oxide gas (ETO) has been used extensively in larger health-care facilities. Its primary advantage is the ability to sterilize heat- and moisture-sensitive patient-care items with reduced deleterious effects. However, extended sterilization times of 10–48 hours

and potential hazards to patients and DHCP requiring stringent health and safety requirements (272–274) make this method impractical for private-practice settings. Handpieces cannot be effectively sterilized with this method because of decreased penetration of ETO gas flow through a small lumen (250,275). Other types of low-temperature sterilization (e.g., hydrogen peroxide gas plasma) exist but are not yet practical for dental offices.

Bead sterilizers have been used in dentistry to sterilize small metallic instruments (e.g., endodontic files). FDA has determined that a risk of infection exists with these devices because of their potential failure to sterilize dental instruments and has required their commercial distribution cease unless the manufacturer files a premarket approval application. If a bead sterilizer is employed, DHCP assume the risk of employing a dental device FDA has deemed neither safe nor effective (276).

**Sterilization Monitoring.** Monitoring of sterilization procedures should include a combination of process parameters, including mechanical, chemical, and biological (247,248,277). These parameters evaluate both the sterilizing conditions and the procedure's effectiveness.

Mechanical techniques for monitoring sterilization include assessing cycle time, temperature, and pressure by observing the gauges or displays on the sterilizer and noting these parameters for each load (243,248). Some tabletop sterilizers have recording devices that print out these parameters. Correct readings do not ensure sterilization, but incorrect readings can be the first indication of a problem with the sterilization cycle.

Chemical indicators, internal and external, use sensitive chemicals to assess physical conditions (e.g., time and temperature) during the sterilization process. Although chemical indicators do not prove sterilization has been achieved, they allow detection of certain equipment malfunctions, and they can help identify procedural errors. External indicators applied to the outside of a package (e.g., chemical indicator tape or special markings) change color rapidly when a specific parameter is reached, and they verify that the package has been exposed to the sterilization process. Internal chemical indicators should be used inside each package to ensure the sterilizing agent has penetrated the packaging material and actually reached the instruments inside. A single-parameter internal chemical indicator provides information regarding only one sterilization parameter (e.g., time or temperature). Multiparameter internal chemical indicators are designed to react to  $\geq 2$  parameters (e.g., time and temperature; or time, temperature, and the presence of steam) and can provide a more reliable indication that sterilization conditions have been met (254). Multiparameter internal indicators are available only for steam sterilizers (i.e., autoclaves).

Because chemical indicator test results are received when the sterilization cycle is complete, they can provide an early indication of a problem and where in the process the problem might exist. If either mechanical indicators or internal or external chemical indicators indicate inadequate processing, items in the load should not be used until reprocessed (134).

Biological indicators (BIs) (i.e., spore tests) are the most accepted method for monitoring the sterilization process (278,279) because they assess it directly by killing known highly resistant microorganisms (e.g., *Geobacillus* or *Bacillus* species), rather than merely testing the physical and chemical conditions necessary for sterilization (243). Because spores used in BIs are more resistant and present in greater numbers than the common microbial contaminants found on patient-care equipment, an inactivated BI indicates other potential pathogens in the load have been killed (280).

Correct functioning of sterilization cycles should be verified for each sterilizer by the periodic use (at least weekly) of BIs (2,9,134,243,278,279). Every load containing implantable devices should be monitored with such indicators (248), and the items quarantined until BI results are known. However, in an emergency, placing implantable items in quarantine until spore tests are known to be negative might be impossible.

Manufacturer's directions should determine the placement and location of BI in the sterilizer. A control BI, from the same lot as the test indicator and not processed through the sterilizer, should be incubated with the test BI; the control BI should yield positive results for bacterial growth.

In-office biological monitoring is available; mail-in sterilization monitoring services (e.g., from private companies or dental schools) can also be used to test both the BI and the control. Although some DHCP have expressed concern that delays caused by mailing specimens might cause false-negatives, studies have determined that mail delays have no substantial effect on final test results (281,282).

Procedures to follow in the event of a positive spore test have been developed (243,247). If the mechanical (e.g., time, temperature, and pressure) and chemical (i.e., internal or external) indicators demonstrate that the sterilizer is functioning correctly, a single positive spore test probably does not indicate sterilizer malfunction. Items other than implantable devices do not necessarily need to be recalled; however the spore test should be repeated immediately after correctly loading the sterilizer and using the same cycle that produced the failure. The sterilizer should be removed from service, and all records reviewed of chemical and mechanical monitoring since the last negative BI test. Also, sterilizer operating procedures should be reviewed, including packaging, loading, and spore testing, with all persons who work with the sterilizer to determine whether operator error could be responsible (9,243,247).

Overloading, failure to provide adequate package separation, and incorrect or excessive packaging material are all common reasons for a positive BI in the absence of mechanical failure of the sterilizer unit (260). A second monitored sterilizer in the office can be used, or a loaner from a sales or repair company obtained, to minimize office disruption while waiting for the repeat BI.

If the repeat test is negative and chemical and mechanical monitoring indicate adequate processing, the sterilizer can be put back into service. If the repeat BI test is positive, and packaging, loading, and operating procedures have been confirmed as performing correctly, the sterilizer should remain out of service until it has been inspected, repaired, and rechallenged with BI tests in three consecutive empty chamber sterilization cycles (9,243). When possible, items from suspect loads dating back to the last negative BI should be recalled, rewrapped, and resterilized (9,283).

A more conservative approach has been recommended (247) in which any positive spore test is assumed to represent sterilizer malfunction and requires that all materials processed in that sterilizer, dating from the sterilization cycle having the last negative biologic indicator to the next cycle indicating satisfactory biologic indicator results, should be considered nonsterile and retrieved, if possible, and reprocessed or held in quarantine until the results of the repeat BI are known. This approach is considered conservative because the margin of safety in steam sterilization is sufficient enough that infection risk, associated with items in a load indicating spore growth, is minimal, particularly if the item was properly cleaned and the temperature was achieved (e.g., as demonstrated by acceptable chemical indicator or temperature chart) (243). Published studies are not available that document disease transmission through a nonretrieved surgical instrument after a steam sterilization cycle with a positive biological indicator (243). This more conservative approach should always be used for sterilization methods other than steam (e.g., dry heat, unsaturated chemical vapor, ETO, or hydrogen peroxide gas plasma) (243).

Results of biological monitoring should be recorded and sterilization monitoring records (i.e., mechanical, chemical, and biological) retained long enough to comply with state and local regulations. Such records are a component of an overall dental infection-control program (see Program Evaluation).

#### Storage of Sterilized Items and Clean Dental Supplies

The storage area should contain enclosed storage for sterile items and disposable (single-use) items (173). Storage practices for wrapped sterilized instruments can be either date- or event-related. Packages containing sterile supplies should be inspected before use to verify barrier integrity and dryness.

Although some health-care facilities continue to date every sterilized package and use shelf-life practices, other facilities have switched to event-related practices (243). This approach recognizes that the product should remain sterile indefinitely, unless an event causes it to become contaminated (e.g., torn or wet packaging) (284). Even for event-related packaging, minimally, the date of sterilization should be placed on the package, and if multiple sterilizers are used in the facility, the sterilizer used should be indicated on the outside of the packaging material to facilitate the retrieval of processed items in the event of a sterilization failure (247). If packaging is compromised, the instruments should be recleaned, packaged in new wrap, and sterilized again.

Clean supplies and instruments should be stored in closed or covered cabinets, if possible (285). Dental supplies and instruments should not be stored under sinks or in other locations where they might become wet.

#### Environmental Infection Control

In the dental operatory, environmental surfaces (i.e., a surface or equipment that does not contact patients directly) can become contaminated during patient care. Certain surfaces, especially ones touched frequently (e.g., light handles, unit switches, and drawer knobs) can serve as reservoirs of microbial contamination, although they have not been associated directly with transmission of infection to either DHCP or patients. Transfer of microorganisms from contaminated environmental surfaces to patients occurs primarily through DHCP hand contact (286,287). When these surfaces are touched, microbial agents can be transferred to instruments, other environmental surfaces, or to the nose, mouth, or eyes of workers or patients. Although hand hygiene is key to minimizing this transfer, barrier protection or cleaning and disinfecting of environmental surfaces also protects against health-care-associated infections.

Environmental surfaces can be divided into clinical contact surfaces and housekeeping surfaces (249). Because housekeeping surfaces (e.g., floors, walls, and sinks) have limited risk of disease transmission, they can be decontaminated with less rigorous methods than those used on dental patient-care items and clinical contact surfaces (244). Strategies for cleaning and disinfecting surfaces in patient-care areas should consider the 1) potential for direct patient contact; 2) degree and frequency of hand contact; and 3) potential contamination of the surface with body substances or environmental sources of microorganisms (e.g., soil, dust, or water).

Cleaning is the necessary first step of any disinfection process. Cleaning is a form of decontamination that renders the environmental surface safe by removing organic matter, salts,

and visible soils, all of which interfere with microbial inactivation. The physical action of scrubbing with detergents and surfactants and rinsing with water removes substantial numbers of microorganisms. If a surface is not cleaned first, the success of the disinfection process can be compromised. Removal of all visible blood and inorganic and organic matter can be as critical as the germicidal activity of the disinfecting agent (249). When a surface cannot be cleaned adequately, it should be protected with barriers (2).

#### Clinical Contact Surfaces

Clinical contact surfaces can be directly contaminated from patient materials either by direct spray or spatter generated during dental procedures or by contact with DHCP's gloved hands. These surfaces can subsequently contaminate other instruments, devices, hands, or gloves. Examples of such surfaces include

- light handles,
- switches,
- dental radiograph equipment,
- dental chairside computers,
- reusable containers of dental materials,
- drawer handles,
- faucet handles,
- countertops,
- pens,
- telephones, and
- doorknobs.

Barrier protection of surfaces and equipment can prevent contamination of clinical contact surfaces, but is particularly effective for those that are difficult to clean. Barriers include clear plastic wrap, bags, sheets, tubing, and plastic-backed paper or other materials impervious to moisture (260,288). Because such coverings can become contaminated, they should be removed and discarded between patients, while DHCP are still gloved. After removing the barrier, examine the surface to make sure it did not become soiled inadvertently. The surface needs to be cleaned and disinfected only if contamination is evident. Otherwise, after removing gloves and performing hand hygiene, DHCP should place clean barriers on these surfaces before the next patient (1,2,288).

If barriers are not used, surfaces should be cleaned and disinfected between patients by using an EPA-registered hospital disinfectant with an HIV, HBV claim (i.e., low-level disinfectant) or a tuberculocidal claim (i.e., intermediate-level disinfectant). Intermediate-level disinfectant should be used when the surface is visibly contaminated with blood or OPIM (2,244). Also, general cleaning and disinfection are recommended for clinical contact surfaces, dental unit surfaces, and countertops at the end of daily work activities and are required

if surfaces have become contaminated since their last cleaning (13). To facilitate daily cleaning, treatment areas should be kept free of unnecessary equipment and supplies.

Manufacturers of dental devices and equipment should provide information regarding material compatibility with liquid chemical germicides, whether equipment can be safely immersed for cleaning, and how it should be decontaminated if servicing is required (289). Because of the risks associated with exposure to chemical disinfectants and contaminated surfaces, DHCP who perform environmental cleaning and disinfection should wear gloves and other PPE to prevent occupational exposure to infectious agents and hazardous chemicals. Chemical- and puncture-resistant utility gloves offer more protection than patient examination gloves when using hazardous chemicals.

#### Housekeeping Surfaces

Evidence does not support that housekeeping surfaces (e.g., floors, walls, and sinks) pose a risk for disease transmission in dental health-care settings. Actual, physical removal of microorganisms and soil by wiping or scrubbing is probably as critical, if not more so, than any antimicrobial effect provided by the agent used (244,290). The majority of housekeeping surfaces need to be cleaned only with a detergent and water or an EPA-registered hospital disinfectant/detergent, depending on the nature of the surface and the type and degree of contamination. Schedules and methods vary according to the area (e.g., dental operatory, laboratory, bathrooms, or reception rooms), surface, and amount and type of contamination.

Floors should be cleaned regularly, and spills should be cleaned up promptly. An EPA-registered hospital disinfectant/detergent designed for general housekeeping purposes should be used in patient-care areas if uncertainty exists regarding the nature of the soil on the surface (e.g., blood or body fluid contamination versus routine dust or dirt). Unless contamination is reasonably anticipated or apparent, cleaning or disinfecting walls, window drapes, and other vertical surfaces is unnecessary. However, when housekeeping surfaces are visibly contaminated by blood or OPIM, prompt removal and surface disinfection is appropriate infection-control practice and required by OSHA (13).

Part of the cleaning strategy is to minimize contamination of cleaning solutions and cleaning tools (e.g., mop heads or cleaning cloths). Mops and cloths should be cleaned after use and allowed to dry before reuse, or single-use, disposable mop heads and cloths should be used to avoid spreading contamination. Cost, safety, product-surface compatibility, and acceptability by housekeepers can be key criteria for selecting a cleaning agent or an EPA-registered hospital disinfectant/

detergent. PPE used during cleaning and housekeeping procedures followed should be appropriate to the task.

In the cleaning process, another reservoir for microorganisms can be dilute solutions of detergents or disinfectants, especially if prepared in dirty containers, stored for long periods of time, or prepared incorrectly (244). Manufacturers' instructions for preparation and use should be followed. Making fresh cleaning solution each day, discarding any remaining solution, and allowing the container to dry will minimize bacterial contamination. Preferred cleaning methods produce minimal mists and aerosols or dispersion of dust in patient-care areas.

#### Cleaning and Disinfection Strategies for Blood Spills

The majority of blood contamination events in dentistry result from spatter during dental procedures using rotary or ultrasonic instrumentation. Although no evidence supports that HBV, HCV, or HIV have been transmitted from a housekeeping surface, prompt removal and surface disinfection of an area contaminated by either blood or OPIM are appropriate infection-control practices and required by OSHA (13,291).

Strategies for decontaminating spills of blood and other body fluids differ by setting and volume of the spill (113,244). Blood spills on either clinical contact or housekeeping surfaces should be contained and managed as quickly as possible to reduce the risk of contact by patients and DHCP (244,292). The person assigned to clean the spill should wear gloves and other PPE as needed. Visible organic material should be removed with absorbent material (e.g., disposable paper towels discarded in a leak-proof, appropriately labeled container). Nonporous surfaces should be cleaned and then decontaminated with either an EPA-registered hospital disinfectant effective against HBV and HIV or an EPA-registered hospital disinfectant with a tuberculocidal claim (i.e., intermediate-level disinfectant). If sodium hypochlorite is chosen, an EPA-registered sodium hypochlorite product is preferred. However, if such products are unavailable, a 1:100 dilution of sodium hypochlorite (e.g., approximately ¼ cup of 5.25% household chlorine bleach to 1 gallon of water) is an inexpensive and effective disinfecting agent (113).

#### Carpeting and Cloth Furnishings

Carpeting is more difficult to clean than nonporous hard-surface flooring, and it cannot be reliably disinfected, especially after spills of blood and body substances. Studies have documented the presence of diverse microbial populations, primarily bacteria and fungi, in carpeting (293-295). Cloth furnishings pose similar contamination risks in areas of direct patient care and places where contaminated materials are man-

aged (e.g., dental operatory, laboratory, or instrument processing areas). For these reasons, use of carpeted flooring and fabric-upholstered furnishings in these areas should be avoided.

#### Nonregulated and Regulated Medical Waste

Studies have compared microbial load and diversity of microorganisms in residential waste with waste from multiple health-care settings. General waste from hospitals or other health-care facilities (e.g., dental practices or clinical/research laboratories) is no more infective than residential waste (296,297). The majority of soiled items in dental offices are general medical waste and thus can be disposed of with ordinary waste. Examples include used gloves, masks, gowns, lightly soiled gauze or cotton rolls, and environmental barriers (e.g., plastic sheets or bags) used to cover equipment during treatment (298).

Although any item that has had contact with blood, exudates, or secretions might be infective, treating all such waste as infective is neither necessary nor practical (244). Infectious waste that carries a substantial risk of causing infection during handling and disposal is regulated medical waste. A complete definition of regulated waste is included in OSHA's bloodborne pathogens standard (13).

Regulated medical waste is only a limited subset of waste: 9%–15% of total waste in hospitals and 1%–2% of total waste in dental offices (298,299). Regulated medical waste requires special storage, handling, neutralization, and disposal and is covered by federal, state, and local rules and regulations (6,297,300,301). Examples of regulated waste found in dental-practice settings are solid waste soaked or saturated with blood or saliva (e.g., gauze saturated with blood after surgery), extracted teeth, surgically removed hard and soft tissues, and contaminated sharp items (e.g., needles, scalpel blades, and wires) (13).

Regulated medical waste requires careful containment for treatment or disposal. A single leak-resistant biohazard bag is usually adequate for containment of nonsharp regulated medical waste, provided the bag is sturdy and the waste can be discarded without contaminating the bag's exterior. Exterior contamination or puncturing of the bag requires placement in a second biohazard bag. All bags should be securely closed for disposal. Puncture-resistant containers with a biohazard label, located at the point of use (i.e., sharps containers), are used as containment for scalpel blades, needles, syringes, and unused sterile sharps (13).

Dental health-care facilities should dispose of medical waste regularly to avoid accumulation. Any facility generating regulated medical waste should have a plan for its management that complies with federal, state, and local regulations to ensure health and environmental safety.

#### Discharging Blood or Other Body Fluids to Sanitary Sewers or Septic Tanks

All containers with blood or saliva (e.g., suctioned fluids) can be inactivated in accordance with state-approved treatment technologies, or the contents can be carefully poured down a utility sink, drain, or toilet (6). Appropriate PPE (e.g., gloves, gown, mask, and protective eyewear) should be worn when performing this task (13). No evidence exists that bloodborne diseases have been transmitted from contact with raw or treated sewage. Multiple bloodborne pathogens, particularly viruses, are not stable in the environment for long periods (302), and the discharge of limited quantities of blood and other body fluids into the sanitary sewer is considered a safe method for disposing of these waste materials (6). State and local regulations vary and dictate whether blood or other body fluids require pretreatment or if they can be discharged into the sanitary sewer and in what volume.

#### Dental Unit Waterlines, Biofilm, and Water Quality

Studies have demonstrated that dental unit waterlines (i.e., narrow-bore plastic tubing that carries water to the high-speed handpiece, air/water syringe, and ultrasonic scaler) can become colonized with microorganisms, including bacteria, fungi, and protozoa (303-309). Protected by a polysaccharide slime layer known as a glycocalyx, these microorganisms colonize and replicate on the interior surfaces of the waterline tubing and form a biofilm, which serves as a reservoir that can amplify the number of free-floating (i.e., planktonic) microorganisms in water used for dental treatment. Although oral flora (303,310,311) and human pathogens (e.g., *Pseudomonas aeruginosa* [303,305,312,313], *Legionella* species [303,306,313], and nontuberculous *Mycobacterium* species [303,304]), have been isolated from dental water systems, the majority of organisms recovered from dental waterlines are common heterotrophic water bacteria (305,314,315). These exhibit limited pathogenic potential for immunocompetent persons.

#### Clinical Implications

Certain reports associate waterborne infections with dental water systems, and scientific evidence verifies the potential for transmission of waterborne infections and disease in hospital settings and in the community (306,312,316). Infection or colonization caused by *Pseudomonas* species or nontuberculous mycobacteria can occur among susceptible patients through direct contact with water (317-320) or after exposure to residual waterborne contamination of inadequately reprocessed medical instruments (321-323). Nontuberculous mycobacteria can also be transmitted to patients from tap water aero-

sols (324). Health-care-associated transmission of pathogenic agents (e.g., *Legionella* species) occurs primarily through inhalation of infectious aerosols generated from potable water sources or through use of tap water in respiratory therapy equipment (325-327). Disease outbreaks in the community have also been reported from diverse environmental aerosol-producing sources, including whirlpool spas (328), swimming pools (329), and a grocery store mist machine (330). Although the majority of these outbreaks are associated with species of *Legionella* and *Pseudomonas* (329), the fungus *Cladospirium* (331) has also been implicated.

Researchers have not demonstrated a measurable risk of adverse health effects among DHCP or patients from exposure to dental water. Certain studies determined DHCP had altered nasal flora (332) or substantially greater titers of *Legionella* antibodies in comparisons with control populations; however, no cases of legionellosis were identified among exposed DHCP (333,334). Contaminated dental water might have been the source for localized *Pseudomonas aeruginosa* infections in two immunocompromised patients (312). Although transient carriage of *P. aeruginosa* was observed in 78 healthy patients treated with contaminated dental treatment water, no illness was reported among the group. In this same study, a retrospective review of dental records also failed to identify infections (312).

Concentrations of bacterial endotoxin  $\leq 1,000$  endotoxin units/mL from gram-negative water bacteria have been detected in water from colonized dental units (335). No standards exist for an acceptable level of endotoxin in drinking water, but the maximum level permissible in United States Pharmacopoeia (USP) sterile water for irrigation is only 0.25 endotoxin units/mL (336). Although the consequences of acute and chronic exposure to aerosolized endotoxin in dental health-care settings have not been investigated, endotoxin has been associated with exacerbation of asthma and onset of hypersensitivity pneumonitis in other occupational settings (329,337).

#### Dental Unit Water Quality

Research has demonstrated that microbial counts can reach  $\leq 200,000$  colony-forming units (CFU)/mL within 5 days after installation of new dental unit waterlines (305), and levels of microbial contamination  $\leq 10^6$  CFU/mL of dental unit water have been documented (309,338). These counts can occur because dental unit waterline factors (e.g., system design, flow rates, and materials) promote both bacterial growth and development of biofilm.

Although no epidemiologic evidence indicates a public health problem, the presence of substantial numbers of pathogens in dental unit waterlines generates concern. Exposing patients or DHCP to water of uncertain microbiological quality, despite

the lack of documented adverse health effects, is inconsistent with accepted infection-control principles. Thus in 1995, ADA addressed the dental water concern by asking manufacturers to provide equipment with the ability to deliver treatment water with  $\leq 200$  CFU/mL of unfiltered output from waterlines (332). This threshold was based on the quality assurance standard established for dialysate fluid, to ensure that fluid delivery systems in hemodialysis units have not been colonized by indigenous waterborne organisms (340).

Standards also exist for safe drinking water quality as established by EPA, the American Public Health Association (APHA), and the American Water Works Association (AWWA); they have set limits for heterotrophic bacteria of  $\leq 500$  CFU/mL of drinking water (341,342). Thus, the number of bacteria in water used as a coolant/irrigant for nonsurgical dental procedures should be as low as reasonably achievable and, at a minimum,  $\leq 500$  CFU/mL, the regulatory standard for safe drinking water established by EPA and APHA/AWWA.

#### Strategies To Improve Dental Unit Water Quality

In 1993, CDC recommended that dental waterlines be flushed at the beginning of the clinic day to reduce the microbial load (2). However, studies have demonstrated this practice does not affect biofilm in the waterlines or reliably improve the quality of water used during dental treatment (315,338,343). Because the recommended value of  $\leq 500$  CFU/mL cannot be achieved by using this method, other strategies should be employed. Dental unit water that remains untreated or unfiltered is unlikely to meet drinking water standards (303-309). Commercial devices and procedures designed to improve the quality of water used in dental treatment are available (316); methods demonstrated to be effective include self-contained water systems combined with chemical treatment, in-line microfilters, and combinations of these treatments. Simply using source water containing  $\leq 500$  CFU/mL of bacteria (e.g., tap, distilled, or sterile water) in a self-contained water system will not eliminate bacterial contamination in treatment water if biofilms in the water system are not controlled. Removal or inactivation of dental waterline biofilms requires use of chemical germicides.

Patient material (e.g., oral microorganisms, blood, and saliva) can enter the dental water system during patient treatment (311,344). Dental devices that are connected to the dental water system and that enter the patient's mouth (e.g., handpieces, ultrasonic scalers, or air/water syringes) should be operated to discharge water and air for a minimum of 20-30 seconds after each patient (2). This procedure is intended to physically flush out patient material that might have entered

the turbine, air, or waterlines. The majority of recently manufactured dental units are engineered to prevent retraction of oral fluids, but some older dental units are equipped with antiretraction valves that require periodic maintenance. Users should consult the owner's manual or contact the manufacturer to determine whether testing or maintenance of antiretraction valves or other devices is required. Even with antiretraction valves, flushing devices for a minimum of 20-30 seconds after each patient is recommended.

#### Maintenance and Monitoring of Dental Unit Water

DHCP should be trained regarding water quality, biofilm formation, water treatment methods, and appropriate maintenance protocols for water delivery systems. Water treatment and monitoring products require strict adherence to maintenance protocols, and noncompliance with treatment regimens has been associated with persistence of microbial contamination in treated systems (345). Clinical monitoring of water quality can ensure that procedures are correctly performed and that devices are working in accordance with the manufacturer's previously validated protocol.

Dentists should consult with the manufacturer of their dental unit or water delivery system to determine the best method for maintaining acceptable water quality (i.e.,  $\leq 500$  CFU/mL) and the recommended frequency of monitoring. Monitoring of dental water quality can be performed by using commercial self-contained test kits or commercial water-testing laboratories. Because methods used to treat dental water systems target the entire biofilm, no rationale exists for routine testing for such specific organisms as *Legionella* or *Pseudomonas*, except when investigating a suspected waterborne disease outbreak (244).

#### Delivery of Sterile Surgical Irrigation

Sterile solutions (e.g., sterile saline or sterile water) should be used as a coolant/irrigant in the performance of oral surgical procedures where a greater opportunity exists for entry of microorganisms, exogenous and endogenous, into the vascular system and other normally sterile areas that support the oral cavity (e.g., bone or subcutaneous tissue) and increased potential exists for localized or systemic infection (see Oral Surgical Procedures). Conventional dental units cannot reliably deliver sterile water even when equipped with independent water reservoirs because the water-bearing pathway cannot be reliably sterilized. Delivery devices (e.g., bulb syringe or sterile, single-use disposable products) should be used to deliver sterile water (2,121). Oral surgery and implant handpieces, as well as ultrasonic scalers, are commercially available that bypass the dental unit to deliver sterile water or other solutions by using single-use disposable or sterilizable tubing (316).

#### Boil-Water Advisories

A boil-water advisory is a public health announcement that the public should boil tap water before drinking it. When issued, the public should assume the water is unsafe to drink. Advisories can be issued after 1) failure of or substantial interruption in water treatment processes that result in increased turbidity levels or particle counts and mechanical or equipment failure; 2) positive test results for pathogens (e.g., *Cryptosporidium*, *Giardia*, or *Shigella*) in water; 3) violations of the total coliform rule or the turbidity standard of the surface water treatment rule; 4) circumstances that compromise the distribution system (e.g., watermain break) coupled with an indication of a health hazard; or 5) a natural disaster (e.g., flood, hurricane, or earthquake) (346). In recent years, increased numbers of boil-water advisories have resulted from contamination of public drinking water systems with waterborne pathogens. Most notable was the outbreak of cryptosporidiosis in Milwaukee, Wisconsin, where the municipal water system was contaminated with the protozoan parasite *Cryptosporidium parvum*. An estimated 403,000 persons became ill (347,348).

During a boil-water advisory, water should not be delivered to patients through the dental unit, ultrasonic scaler, or other dental equipment that uses the public water system. This restriction does not apply if the water source is isolated from the municipal water system (e.g., a separate water reservoir or other water treatment device cleared for marketing by FDA). Patients should rinse with bottled or distilled water until the boil-water advisory has been cancelled. During these advisory periods, tap water should not be used to dilute germicides or for hand hygiene unless the water has been brought to a rolling boil for  $\geq 1$  minute and cooled before use (346,349-351). For hand hygiene, antimicrobial products that do not require water (e.g., alcohol-based hand rubs) can be used until the boil-water notice is cancelled. If hands are visibly contaminated, bottled water and soap should be used for handwashing; if bottled water is not immediately available, an antiseptic towelette should be used (13,122).

When the advisory is cancelled, the local water utility should provide guidance for flushing of waterlines to reduce residual microbial contamination. All incoming waterlines from the public water system inside the dental office (e.g., faucets, waterlines, and dental equipment) should be flushed. No consensus exists regarding the optimal duration for flushing procedures after cancellation of the advisory; recommendations range from 1 to 5 minutes (244,346,351,352). The length of time needed can vary with the type and length of the plumbing system leading to the office. After the incoming public water system lines are flushed, dental unit waterlines should be disinfected according to the manufacturer's instructions (346).

#### Special Considerations

##### Dental Handpieces and Other Devices Attached to Air and Waterlines

Multiple semicritical dental devices that touch mucous membranes are attached to the air or waterlines of the dental unit. Among these devices are high- and low-speed handpieces, prophylaxis angles, ultrasonic and sonic scaling tips, air abrasion devices, and air and water syringe tips. Although no epidemiologic evidence implicates these instruments in disease transmission (353), studies of high-speed handpieces using dye expulsion have confirmed the potential for retracting oral fluids into internal compartments of the device (354-358). This determination indicates that retained patient material can be expelled intraorally during subsequent uses. Studies using laboratory models also indicate the possibility for retention of vital DNA and viable virus inside both high-speed handpieces and prophylaxis angles (356,357,359). The potential for contamination of the internal surfaces of other devices (e.g., low-speed handpieces and ultrasonic scalers), has not been studied, but restricted physical access limits their cleaning. Accordingly, any dental device connected to the dental air/water system that enters the patient's mouth should be run to discharge water, air, or a combination for a minimum of 20-30 seconds after each patient (2). This procedure is intended to help physically flush out patient material that might have entered the turbine and air and waterlines (2,356,357).

Heat methods can sterilize dental handpieces and other intraoral devices attached to air or waterlines (246,275,356,357,360). For processing any dental device that can be removed from the dental unit air or waterlines, neither surface disinfection nor immersion in chemical germicides is an acceptable method. Ethylene oxide gas cannot adequately sterilize internal components of handpieces (250,275). In clinical evaluations of high-speed handpieces, cleaning and lubrication were the most critical factors in determining performance and durability (361-363). Manufacturer's instructions for cleaning, lubrication, and sterilization should be followed closely to ensure both the effectiveness of the process and the longevity of handpieces.

Some components of dental instruments are permanently attached to dental unit waterlines and although they do not enter the patient's oral cavity, they are likely to become contaminated with oral fluids during treatment procedures. Such components (e.g., handles or dental unit attachments of saliva ejectors, high-speed air evacuators, and air/water syringes) should be covered with impervious barriers that are changed after each use. If the item becomes visibly contaminated during use, DHCP should clean and disinfect with an EPA-

registered hospital disinfectant (intermediate-level) before use on the next patient.

### Saliva Ejectors

Backflow from low-volume saliva ejectors occurs when the pressure in the patient's mouth is less than that in the evacuator. Studies have reported that backflow in low-volume suction lines can occur and microorganisms be present in the lines retracted into the patient's mouth when a seal around the saliva ejector is created (e.g., by a patient closing lips around the tip of the ejector, creating a partial vacuum) (364-366). This backflow can be a potential source of cross-contamination; occurrence is variable because the quality of the seal formed varies between patients. Furthermore, studies have demonstrated that gravity pulls fluid back toward the patient's mouth whenever a length of the suction tubing holding the tip is positioned above the patient's mouth, or during simultaneous use of other evacuation (high-volume) equipment (364-366). Although no adverse health effects associated with the saliva ejector have been reported, practitioners should be aware that in certain situations, backflow could occur when using a saliva ejector.

### Dental Radiology

When taking radiographs, the potential to cross-contaminate equipment and environmental surfaces with blood or saliva is high if aseptic technique is not practiced. Gloves should be worn when taking radiographs and handling contaminated film packets. Other PPE (e.g., mask, protective eyewear, and gowns) should be used if spattering of blood or other body fluids is likely (11,13,367). Heat-tolerant versions of intraoral radiograph accessories are available and these semicritical items (e.g., film-holding and positioning devices) should be heat-sterilized before patient use.

After exposure of the radiograph and before glove removal, the film should be dried with disposable gauze or a paper towel to remove blood or excess saliva and placed in a container (e.g., disposable cup) for transport to the developing area. Alternatively, if FDA-cleared film barrier pouches are used, the film packets should be carefully removed from the pouch to avoid contamination of the outside film packet and placed in the clean container for transport to the developing area.

Various methods have been recommended for aseptic transport of exposed films to the developing area, and for removing the outer film packet before exposing and developing the film. Other information regarding dental radiography infection control is available (260,367,368). However, care should be taken to avoid contamination of the developing equipment. Protective barriers should be used, or any surfaces that

become contaminated should be cleaned and disinfected with an EPA-registered hospital disinfectant of low- (i.e., HIV and HBV claim) to intermediate-level (i.e., tuberculocidal claim) activity. Radiography equipment (e.g., radiograph tubehead and control panel) should be protected with surface barriers that are changed after each patient. If barriers are not used, equipment that has come into contact with DHCP's gloved hands or contaminated film packets should be cleaned and then disinfected after each patient use.

Digital radiography sensors and other high-technology instruments (e.g., intraoral camera, electronic periodontal probe, occlusal analyzers, and lasers) come into contact with mucous membranes and are considered semicritical devices. They should be cleaned and ideally heat-sterilized or high-level disinfected between patients. However, these items vary by manufacturer or type of device in their ability to be sterilized or high-level disinfected. Semicritical items that cannot be reprocessed by heat sterilization or high-level disinfection should, at a minimum, be barrier protected by using an FDA-cleared barrier to reduce gross contamination during use. Use of a barrier does not always protect from contamination (369-374). One study determined that a brand of commercially available plastic barriers used to protect dental digital radiography sensors failed at a substantial rate (44%). This rate dropped to 6% when latex finger cots were used in conjunction with the plastic barrier (375). To minimize the potential for device-associated infections, after removing the barrier, the device should be cleaned and disinfected with an EPA-registered hospital disinfectant (intermediate-level) after each patient. Manufacturers should be consulted regarding appropriate barrier and disinfection/sterilization procedures for digital radiography sensors, other high-technology intraoral devices, and computer components.

### Aseptic Technique for Parenteral Medications

Safe handling of parenteral medications and fluid infusion systems is required to prevent health-care-associated infections among patients undergoing conscious sedation. Parenteral medications can be packaged in single-dose ampules, vials or prefilled syringes, usually without bacteriostatic/preservative agents, and intended for use on a single patient. Multidose vials, used for more than one patient, can have a preservative, but both types of containers of medication should be handled with aseptic techniques to prevent contamination.

Single-dose vials should be used for parenteral medications whenever possible (376,377). Single-dose vials might pose a risk for contamination if they are punctured repeatedly. The leftover contents of a single-dose vial should be discarded and

never combined with medications for use on another patient (376,377). Medication from a single-dose syringe should not be administered to multiple patients, even if the needle on the syringe is changed (378).

The overall risk for extrinsic contamination of multidose vials is probably minimal, although the consequences of contamination might result in life-threatening infection (379). If necessary to use a multidose vial, its access diaphragm should be cleaned with 70% alcohol before inserting a sterile device into the vial (380,381). A multidose vial should be discarded if sterility is compromised (380,381).

Medication vials, syringes, or supplies should not be carried in uniform or clothing pockets. If trays are used to deliver medications to individual patients, they should be cleaned between patients. To further reduce the chance of contamination, all medication vials should be restricted to a centralized medication preparation area separate from the treatment area (382).

All fluid infusion and administration sets (e.g., IV bags, tubing, and connections) are single-patient use because sterility cannot be guaranteed when an infusion or administration set is used on multiple patients. Aseptic technique should be used when preparing IV infusion and administration sets, and entry into or breaks in the tubing should be minimized (378).

### Single-Use or Disposable Devices

A single-use device, also called a disposable device, is designed to be used on one patient and then discarded, not reprocessed for use on another patient (e.g., cleaned, disinfected, or sterilized) (383). Single-use devices in dentistry are usually not heat-tolerant and cannot be reliably cleaned. Examples include syringe needles, prophylaxis cups and brushes, and plastic orthodontic brackets. Certain items (e.g., prophylaxis angles, saliva ejectors, high-volume evacuator tips, and air/water syringe tips) are commonly available in a disposable form and should be disposed of appropriately after each use. Single-use devices and items (e.g., cotton rolls, gauze, and irrigating syringes) for use during oral surgical procedures should be sterile at the time of use.

Because of the physical construction of certain devices (e.g., burs, endodontic files, and broaches) cleaning can be difficult. In addition, deterioration can occur on the cutting surfaces of some carbide/diamond burs and endodontic files during processing (384) and after repeated processing cycles, leading to potential breakage during patient treatment (385-388). These factors, coupled with the knowledge that burs and endodontic instruments exhibit signs of wear during normal use, might make it practical to consider them as single-use devices.

### Preprocedural Mouth Rinses

Antimicrobial mouth rinses used by patients before a dental procedure are intended to reduce the number of microorganisms the patient might release in the form of aerosols or spatter that subsequently can contaminate DHCP and equipment operatory surfaces. In addition, preprocedural rinsing can decrease the number of microorganisms introduced in the patient's bloodstream during invasive dental procedures (389,390).

No scientific evidence indicates that preprocedural mouth rinsing prevents clinical infections among DHCP or patients, but studies have demonstrated that a preprocedural rinse with an antimicrobial product (e.g., chlorhexidine gluconate, essential oils, or povidone-iodine) can reduce the level of oral microorganisms in aerosols and spatter generated during routine dental procedures with rotary instruments (e.g., dental handpieces or ultrasonic scalers) (391-399). Preprocedural mouth rinses can be most beneficial before a procedure that requires using a prophylaxis cup or ultrasonic scaler because rubber dams cannot be used to minimize aerosol and spatter generation and, unless the provider has an assistant, high-volume evacuation is not commonly used (173).

The science is unclear concerning the incidence and nature of bacteremias from oral procedures, the relationship of these bacteremias to disease, and the preventive benefit of antimicrobial rinses. In limited studies, no substantial benefit has been demonstrated for mouth rinsing in terms of reducing oral microorganisms in dental-induced bacteremias (400,401). However, the American Heart Association's recommendations regarding preventing bacterial endocarditis during dental procedures (402) provide limited support concerning preprocedural mouth rinsing with an antimicrobial as an adjunct for patients at risk for bacterial endocarditis. Insufficient data exist to recommend preprocedural mouth rinses to prevent clinical infections among patients or DHCP.

### Oral Surgical Procedures

The oral cavity is colonized with numerous microorganisms. Oral surgical procedures present an opportunity for entry of microorganisms (i.e., exogenous and endogenous) into the vascular system and other normally sterile areas of the oral cavity (e.g., bone or subcutaneous tissue); therefore, an increased potential exists for localized or systemic infection. Oral surgical procedures involve the incision, excision, or reflection of tissue that exposes the normally sterile areas of the oral cavity. Examples include biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth (e.g., removal of erupted or unerupted tooth requiring elevation of mucoperiosteal flap, removal of bone or section of tooth,

and suturing if needed) (see Hand Hygiene, PPE, Single Use or Disposable Devices, and Dental Unit Water Quality).

### Handling of Biopsy Specimens

To protect persons handling and transporting biopsy specimens, each specimen must be placed in a sturdy, leakproof container with a secure lid for transportation (13). Care should be taken when collecting the specimen to avoid contaminating the outside of the container. If the outside of the container becomes visibly contaminated, it should be cleaned and disinfected or placed in an impervious bag (2,13). The container must be labeled with the biohazard symbol during storage, transport, shipment, and disposal (13,14).

### Handling of Extracted Teeth

#### Disposal

Extracted teeth that are being discarded are subject to the containerization and labeling provisions outlined by OSHA's bloodborne pathogens standard (13). OSHA considers extracted teeth to be potentially infectious material that should be disposed in medical waste containers. Extracted teeth sent to a dental laboratory for shade or size comparisons should be cleaned, surface-disinfected with an EPA-registered hospital disinfectant with intermediate-level activity (i.e., tuberculocidal claim), and transported in a manner consistent with OSHA regulations. However, extracted teeth can be returned to patients on request, at which time provisions of the standard no longer apply (14). Extracted teeth containing dental amalgam should not be placed in a medical waste container that uses incineration for final disposal. Commercial metal-recycling companies also might accept extracted teeth with metal restorations, including amalgam. State and local regulations should be consulted regarding disposal of the amalgam.

#### Educational Settings

Extracted teeth are occasionally collected for use in preclinical educational training. These teeth should be cleaned of visible blood and gross debris and maintained in a hydrated state in a well-constructed closed container during transport. The container should be labeled with the biohazard symbol (13,14). Because these teeth will be autoclaved before clinical exercises or study, use of the most economical storage solution (e.g., water or saline) might be practical. Liquid chemical germicides can also be used but do not reliably disinfect both external surface and interior pulp tissue (403,404).

Before being used in an educational setting, the teeth should be heat-sterilized to allow safe handling. Microbial growth can be eliminated by using an autoclave cycle for 40 minutes (405),

but because preclinical educational exercises simulate clinical experiences, students enrolled in dental programs should still follow standard precautions. Autoclaving teeth for preclinical laboratory exercises does not appear to alter their physical properties sufficiently to compromise the learning experience (405,406). However, whether autoclave sterilization of extracted teeth affects dental structure to the point that the chemical and microchemical relationship between dental materials and the dentin would be affected for research purposes on dental materials is unknown (406).

Use of teeth that do not contain amalgam is preferred in educational settings because they can be safely autoclaved (403,405). Extracted teeth containing amalgam restorations should not be heat-sterilized because of the potential health hazard from mercury vaporization and exposure. If extracted teeth containing amalgam restorations are to be used, immersion in 10% formalin solution for 2 weeks should be effective in disinfecting both the internal and external structures of the teeth (403). If using formalin, manufacturer MSDS should be reviewed for occupational safety and health concerns and to ensure compliance with OSHA regulations (15).

### Dental Laboratory

Dental prostheses, appliances, and items used in their fabrication (e.g., impressions, occlusal rims, and bite registrations) are potential sources for cross-contamination and should be handled in a manner that prevents exposure of DHCP patients, or the office environment to infectious agents. Effective communication and coordination between the laboratory and dental practice will ensure that appropriate cleaning and disinfection procedures are performed in the dental office or laboratory, materials are not damaged or distorted because of disinfectant overexposure, and effective disinfection procedures are not unnecessarily duplicated (407,408).

When a laboratory case is sent off-site, DHCP should provide written information regarding the methods (e.g., type of disinfectant and exposure time) used to clean and disinfect the material (e.g., impression, stone model, or appliance) (2,407,409). Clinical materials that are not decontaminated are subject to OSHA and U.S. Department of Transportation regulations regarding transportation and shipping of infectious materials (13,410).

Appliances and prostheses delivered to the patient should be free of contamination. Communication between the laboratory and the dental practice is also key at this stage to determine which one is responsible for the final disinfection process. If the dental laboratory staff provides the disinfection, an EPA-registered hospital disinfectant (low to intermediate) should be used, written documentation of the disinfection method

provided, and the item placed in a tamper-evident container before returning it to the dental office. If such documentation is not provided, the dental office is responsible for final disinfection procedures.

Dental prostheses or impressions brought into the laboratory can be contaminated with bacteria, viruses, and fungi (411,412). Dental prostheses, impressions, orthodontic appliances, and other prosthodontic materials (e.g., occlusal rims, temporary prostheses, bite registrations, or extracted teeth) should be thoroughly cleaned (i.e., blood and bioburden removed), disinfected with an EPA-registered hospital disinfectant with a tuberculocidal claim, and thoroughly rinsed before being handled in the in-office laboratory or sent to an off-site laboratory (2,244,249,407). The best time to clean and disinfect impressions, prostheses, or appliances is as soon as possible after removal from the patient's mouth before drying of blood or other bioburden can occur. Specific guidance regarding cleaning and disinfecting techniques for various materials is available (260,413-416). DHCP are advised to consult with manufacturers regarding the stability of specific materials during disinfection.

In the laboratory, a separate receiving and disinfecting area should be established to reduce contamination in the production area. Bringing untreated items into the laboratory increases chances for cross infection (260). If no communication has been received regarding prior cleaning and disinfection of a material, the dental laboratory staff should perform cleaning and disinfection procedures before handling. If during manipulation of a material or appliance a previously undetected area of blood or bioburden becomes apparent, cleaning and disinfection procedures should be repeated. Transfer of oral microorganisms into and onto impressions has been documented (417-419). Movement of these organisms onto dental casts has also been demonstrated (420). Certain microbes have been demonstrated to remain viable within gypsum cast materials for  $\leq 7$  days (421). Incorrect handling of contaminated impressions, prostheses, or appliances, therefore, offers an opportunity for transmission of microorganisms (260). Whether in the office or laboratory, PPE should be worn until disinfection is completed (1,2,7,10,13).

If laboratory items (e.g., burs, polishing points, rag wheels, or laboratory knives) are used on contaminated or potentially contaminated appliances, prostheses, or other material, they should be heat-sterilized, disinfected between patients, or discarded (i.e., disposable items should be used) (260,407). Heat-tolerant items used in the mouth (e.g., metal impression tray or face bow fork) should be heat-sterilized before being used on another patient (2,407). Items that do not normally contact the patient, prosthetic device, or appliance but frequently become contaminated and cannot withstand heat-sterilization (e.g., articulators, case

pans, or lathes) should be cleaned and disinfected between patients and according to the manufacturer's instructions. Pressure pots and water baths are particularly susceptible to contamination with microorganisms and should be cleaned and disinfected between patients (422). In the majority of instances, these items can be cleaned and disinfected with an EPA-registered hospital disinfectant. Environmental surfaces should be barrier-protected or cleaned and disinfected in the same manner as in the dental treatment area.

Unless waste generated in the dental laboratory (e.g., disposable trays or impression materials) falls under the category of regulated medical waste, it can be discarded with general waste. Personnel should dispose of sharp items (e.g., burs, disposable blades, and orthodontic wires) in puncture-resistant containers.

### Laser/Electrosurgery Plumes or Surgical Smoke

During surgical procedures that use a laser or electrosurgical unit, the thermal destruction of tissue creates a smoke byproduct. Laser plumes or surgical smoke represent another potential risk for DHCP (423-425). Lasers transfer electromagnetic energy into tissues, resulting in the release of a heated plume that includes particles, gases (e.g., hydrogen cyanide, benzene, and formaldehyde), tissue debris, viruses, and offensive odors. One concern is that aerosolized infectious material in the laser plume might reach the nasal mucosa of the laser operator and adjacent DHCP. Although certain viruses (e.g., varicella-zoster virus and herpes simplex virus) appear not to aerosolize efficiently (426,427), other viruses and various bacteria (e.g., human papilloma virus, HIV, coagulase-negative *Staphylococcus*, *Corynebacterium* species, and *Neisseria* species) have been detected in laser plumes (428-434). However, the presence of an infectious agent in a laser plume might not be sufficient to cause disease from airborne exposure, especially if the agent's normal mode of transmission is not airborne. No evidence indicates that HIV or HBV have been transmitted through aerosolization and inhalation (435). Although continuing studies are needed to evaluate the risk for DHCP of laser plumes and electrosurgery smoke, following NIOSH recommendations (425) and practices developed by the Association of periOperative Registered Nurses (AORN) might be practical (436). These practices include using 1) standard precautions (e.g., high-filtration surgical masks and possibly full face shields) (437); 2) central room suction units with in-line filters to collect particulate matter from minimal plumes; and 3) dedicated mechanical smoke exhaust systems with a high-efficiency filter to remove substantial amounts of laser plume particles. Local smoke evacuation systems have been recom-

mended by consensus organizations, and these systems can improve the quality of the operating field. Employers should be aware of this emerging problem and advise employees of the potential hazards of laser smoke (438). However, this concern remains unresolved in dental practice and no recommendation is provided here.

### *M. tuberculosis*

Patients infected with *M. tuberculosis* occasionally seek urgent dental treatment at outpatient dental settings. Understanding the pathogenesis of the development of TB will help DHCP determine how to manage such patients.

*M. tuberculosis* is a bacterium carried in airborne infective droplet nuclei that can be generated when persons with pulmonary or laryngeal TB sneeze, cough, speak, or sing (439). These small particles (1–5 µm) can stay suspended in the air for hours (440). Infection occurs when a susceptible person inhales droplet nuclei containing *M. tuberculosis*, which then travel to the alveoli of the lungs. Usually within 2–12 weeks after initial infection with *M. tuberculosis*, immune response prevents further spread of the TB bacteria, although they can remain alive in the lungs for years, a condition termed latent TB infection. Persons with latent TB infection usually exhibit a reactive tuberculin skin test (TST), have no symptoms of active disease, and are not infectious. However, they can develop active disease later in life if they do not receive treatment for their latent infection.

Approximately 5% of persons who have been recently infected and not treated for latent TB infection will progress from infection to active disease during the first 1–2 years after infection; another 5% will develop active disease later in life. Thus, approximately 90% of U.S. persons with latent TB infection do not progress to active TB disease. Although both latent TB infection and active TB disease are described as TB, only the person with active disease is contagious and presents a risk of transmission. Symptoms of active TB disease include a productive cough, night sweats, fatigue, malaise, fever, and unexplained weight loss. Certain immunocompromising medical conditions (e.g., HIV) increase the risk that TB infection will progress to active disease at a faster rate (441).

Overall, the risk borne by DHCP for exposure to a patient with active TB disease is probably low (20,21). Only one report exists of TB transmission in a dental office (442), and TST conversions among DHCP are also low (443,444). However, in certain cases, DHCP or the community served by the dental facility might be at relatively high risk for exposure to TB.

Surgical masks do not prevent inhalation of *M. tuberculosis* droplet nuclei, and therefore, standard precautions are not sufficient to prevent transmission of this organism. Recommen-

dations for expanded precautions to prevent transmission of *M. tuberculosis* and other organisms that can be spread by airborne, droplet, or contact routes have been detailed in other guidelines (5,11,20).

TB transmission is controlled through a hierarchy of measures, including administrative controls, environmental controls, and personal respiratory protection. The main administrative goals of a TB infection-control program are early detection of a person with active TB disease and prompt isolation from susceptible persons to reduce the risk of transmission. Although DHCP are not responsible for diagnosis and treatment of TB, they should be trained to recognize signs and symptoms to help with prompt detection. Because potential for transmission of *M. tuberculosis* exists in outpatient settings, dental practices should develop a TB control program appropriate for their level of risk (20,21).

- A community risk assessment should be conducted periodically, and TB infection-control policies for each dental setting should be based on the risk assessment. The policies should include provisions for detection and referral of patients who might have undiagnosed active TB; management of patients with active TB who require urgent dental care; and DHCP education, counseling, and TST screening.
- DHCP who have contact with patients should have a baseline TST, preferably by using a two-step test at the beginning of employment. The facility's level of TB risk will determine the need for routine follow-up TST.
- While taking patients' initial medical histories and at periodic updates, dental DHCP should routinely ask all patients whether they have a history of TB disease or symptoms indicative of TB.
- Patients with a medical history or symptoms indicative of undiagnosed active TB should be referred promptly for medical evaluation to determine possible infectiousness. Such patients should not remain in the dental-care facility any longer than required to evaluate their dental condition and arrange a referral. While in the dental health-care facility, the patient should be isolated from other patients and DHCP, wear a surgical mask when not being evaluated, or be instructed to cover their mouth and nose when coughing or sneezing.
- Elective dental treatment should be deferred until a physician confirms that a patient does not have infectious TB, or if the patient is diagnosed with active TB disease, until confirmed the patient is no longer infectious.
- If urgent dental care is provided for a patient who has, or is suspected of having active TB disease, the care should be provided in a facility (e.g., hospital) that provides airborne infection isolation (i.e., using such engineering con-

trols as TB isolation rooms, negatively pressured relative to the corridors, with air either exhausted to the outside or HEPA-filtered if recirculation is necessary). Standard surgical face masks do not protect against TB transmission; DHCP should use respiratory protection (e.g., fitted, disposable N-95 respirators).

- Settings that do not require use of respiratory protection because they do not treat active TB patients and do not perform cough-inducing procedures on potential active TB patients do not need to develop a written respiratory protection program.
- Any DHCP with a persistent cough (i.e., lasting >3 weeks), especially in the presence of other signs or symptoms compatible with active TB (e.g., weight loss, night sweats, fatigue, bloody sputum, anorexia, or fever), should be evaluated promptly. The DHCP should not return to the workplace until a diagnosis of TB has been excluded or the DHCP is on therapy and a physician has determined that the DHCP is noninfectious.

### Creutzfeldt-Jakob Disease and Other Prion Diseases

Creutzfeldt-Jakob disease (CJD) belongs to a group of rapidly progressive, invariably fatal, degenerative neurological disorders, transmissible spongiform encephalopathies (TSEs) that affect both humans and animals and are thought to be caused by infection with an unusual pathogen called a prion. Prions are isoforms of a normal protein, capable of self-propagation although they lack nucleic acid. Prion diseases have an incubation period of years and are usually fatal within 1 year of diagnosis.

Among humans, TSEs include CJD, Gerstmann-Strausler-Scheinker syndrome, fatal familial insomnia, kuru, and variant CJD (vCJD). Occurring in sporadic, familial, and acquired (i.e., iatrogenic) forms, CJD has an annual incidence in the United States and other countries of approximately 1 case/million population (445–448). In approximately 85% of affected patients, CJD occurs as a sporadic disease with no recognizable pattern of transmission. A smaller proportion of patients (5%–15%) experience familial CJD because of inherited mutations of the prion protein gene (448).

vCJD is distinguishable clinically and neuropathologically from classic CJD, and strong epidemiologic and laboratory evidence indicates a causal relationship with bovine spongiform encephalopathy (BSE), a progressive neurological disorder of cattle commonly known as mad cow disease (449–451). vCJD, was reported first in the United Kingdom in 1996 (449) and subsequently in other European countries (452). Only one case of vCJD has been reported in the United States, in an

immigrant from the United Kingdom (453). Compared with CJD patients, those with vCJD are younger (28 years versus 68 years median age at death), and have a longer duration of illness (13 months versus 4.5 months). Also, vCJD patients characteristically exhibit sensory and psychiatric symptoms that are uncommon with CJD. Another difference includes the ease with which the presence of prions is consistently demonstrated in lymphoreticular tissues (e.g., tonsil) in vCJD patients by immunohistochemistry (454).

CJD and vCJD are transmissible diseases, but not through the air or casual contact. All known cases of iatrogenic CJD have resulted from exposure to infected central nervous tissue (e.g., brain and dura mater), pituitary, or eye tissue. Studies in experimental animals have determined that other tissues have low or no detectable infectivity (243,455,456). Limited experimental studies have demonstrated that scrapie (a TSE in sheep) can be transmitted to healthy hamsters and mice by exposing oral tissues to infectious homogenate (457,458). These animal models and experimental designs might not be directly applicable to human transmission and clinical dentistry, but they indicate a theoretical risk of transmitting prion diseases through peroral exposures.

According to published reports, iatrogenic transmission of CJD has occurred in humans under three circumstances: after use of contaminated electroencephalography depth electrodes and neurosurgical equipment (459); after use of extracted pituitary hormones (460,461); and after implant of contaminated corneal (462) and dura mater grafts (463,464) from humans. The equipment-related cases occurred before the routine implementation of sterilization procedures used in health-care facilities.

Case-control studies have found no evidence that dental procedures increase the risk of iatrogenic transmission of TSEs among humans. In these studies, CJD transmission was not associated with dental procedures (e.g., root canals or extractions), with convincing evidence of prion detection in human blood, saliva, or oral tissues, or with DHCP becoming occupationally infected with CJD (465–467). In 2000, prions were not found in the dental pulps of eight patients with neuropathologically confirmed sporadic CJD by using electrophoresis and a Western blot technique (468).

Prions exhibit unusual resistance to conventional chemical and physical decontamination procedures. Considering this resistance and the invariably fatal outcome of CJD, procedures for disinfecting and sterilizing instruments potentially contaminated with the CJD prion have been controversial for years. Scientific data indicate the risk, if any, of sporadic CJD transmission during dental and oral surgical procedures is low to nil. Until additional information exists regarding the transmissibility of CJD or vCJD, special precautions in addition to

standard precautions might be indicated when treating known CJD or vCJD patients; the following list of precautions is provided for consideration without recommendation (243,249,277,469):

- Use single-use disposable items and equipment whenever possible.
- Consider items difficult to clean (e.g., endodontic files, broaches, and carbide and diamond burs) as single-use disposables and discard after one use.
- To minimize drying of tissues and body fluids on a device, keep the instrument moist until cleaned and decontaminated.
- Clean instruments thoroughly and steam-autoclave at 134°C for 18 minutes. This is the least stringent of sterilization methods offered by the World Health Organization. The complete list (469) is available at <http://www.who.int/emc-documents/tsc/whocdscnaph2003c.html>.
- Do not use flash sterilization for processing instruments or devices.

Potential infectivity of oral tissues in CJD or vCJD patients is an unresolved concern. CDC maintains an active surveillance program on CJD. Additional information and resources are available at <http://www.cdc.gov/nccdod/diseases/cjd/vcjd.htm>.

### Program Evaluation

The goal of a dental infection-control program is to provide a safe working environment that will reduce the risk of health-

care-associated infections among patients and occupational exposures among DHCP. Medical errors are caused by faulty systems, processes, and conditions that lead persons to make mistakes or fail to prevent errors being made by others (470). Effective program evaluation is a systematic way to ensure procedures are useful, feasible, ethical, and accurate. Program evaluation is an essential organizational practice; however, such evaluation is not practiced consistently across program areas, nor is it sufficiently well-integrated into the day-to-day management of the majority of programs (471).

A successful infection-control program depends on developing standard operating procedures, evaluating practices, routinely documenting adverse outcomes (e.g., occupational exposures to blood) and work-related illnesses in DHCP, and monitoring health-care-associated infections in patients. Strategies and tools to evaluate the infection-control program can include periodic observational assessments, checklists to document procedures, and routine review of occupational exposures to bloodborne pathogens. Evaluation offers an opportunity to improve the effectiveness of both the infection-control program and dental-practice protocols. If deficiencies or problems in the implementation of infection-control procedures are identified, further evaluation is needed to eliminate the problems. Examples of infection-control program evaluation activities are provided (Table 5).

TABLE 5. Examples of methods for evaluating infection-control programs

Program element	Evaluation activity
Appropriate immunization of dental health-care personnel (DHCP).	Conduct annual review of personnel records to ensure up-to-date immunizations.
Assessment of occupational exposures to infectious agents.	Report occupational exposures to infectious agents. Document the steps that occurred around the exposure and plan how such exposure can be prevented in the future.
Comprehensive postexposure management plan and medical follow-up program after occupational exposures to infectious agents.	Ensure the postexposure management plan is clear, complete, and available at all times to all DHCP. All staff should understand the plan, which should include toll-free phone numbers for access to additional information.
Adherence to hand hygiene before and after patient care.	Observe and document circumstances of appropriate or inappropriate handwashing. Review findings in a staff meeting.
Proper use of personal protective equipment to prevent occupational exposures to infectious agents.	Observe and document the use of barrier precautions and careful handling of sharps. Review findings in a staff meeting.
Routine and appropriate sterilization of instruments using a biologic monitoring system.	Monitor paper log of steam cycle and temperature strip with each sterilization load, and examine results of weekly biologic monitoring. Take appropriate action when failure of sterilization process is noted.
Evaluation and implementation of safer medical devices.	Conduct an annual review of the exposure control plan and consider new developments in safer medical devices.
Compliance of water in routine dental procedures with current drinking U.S. Environmental Protection Agency water standards (fewer than 600 CFU of heterotrophic water bacteria).	Monitor dental water quality as recommended by the equipment manufacturer, using commercial self-contained test kits, or commercial water-testing laboratories.
Proper handling and disposal of medical waste.	Observe the safe disposal of regulated and nonregulated medical waste and take preventive measures if hazardous situations occur.
Health-care-associated infections.	Assess the unscheduled return of patients after procedures and evaluate them for an infectious process. A trend might require formal evaluation.

### Infection-Control Research Considerations

Although the number of published studies concerning dental infection control has increased in recent years, questions regarding infection-control practices and their effectiveness remain unanswered. Multiple concerns were identified by the working group for this report, as well as by others during the

public comment period (Box). This list is not exhaustive and does not represent a CDC research agenda, but rather is an effort to identify certain concerns, stimulate discussion, and provide direction for determining future action by clinical, basic science, and epidemiologic investigators, as well as health and professional organizations, clinicians, and policy makers.

#### BOX. Dental infection-control research considerations

##### Education and promotion

- Design strategies to communicate, to the public and providers, the risk of disease transmission in dentistry.
- Promote use of protocols for recommended postexposure management and follow-up.
- Educate and train dental health-care personnel (DHCP) to screen and evaluate safer dental devices by using tested design and performance criteria.

##### Laboratory-based research

- Develop animal models to determine the risk of transmitting organisms through inhalation of contaminated aerosols (e.g., influenza) produced from rotary dental instruments.
- Conduct studies to determine the effectiveness of gloves (i.e., material compatibility and duration of use).
- Develop devices with passive safety features to prevent percutaneous injuries.
- Study the effect of alcohol-based hand-hygiene products on retention of latex proteins and other dental allergens (e.g., methylmethacrylate, glutaraldehyde, thimerams) on the hands of DHCP after latex glove use.
- Investigate the applicability of other types of sterilization procedures (e.g., hydrogen peroxide gas plasma) in dentistry.
- Encourage manufacturers to determine optimal methods and frequency for testing dental-unit waterlines and maintaining dental-unit water-quality standards.
- Determine the potential for internal contamination of low-speed handpieces, including the motor, and other devices connected to dental air and water supplies, as well as more efficient ways to clean, lubricate, and sterilize handpieces and other devices attached to air or waterlines.
- Investigate the infectivity of oral tissues in Creutzfeldt-Jakob disease (CJD) or variant CJD patients.
- Determine the most effective methods to disinfect dental impression materials.
- Investigate the viability of pathogenic organisms on dental materials (e.g., impression materials, acrylic resin, or gypsum materials) and dental laboratory equipment.
- Determine the most effective methods for sterilization or disinfection of digital radiology equipment.
- Evaluate the effects of repetitive reprocessing cycles on burs and endodontic files.
- Investigate the potential infectivity of vapors generated from the various lasers used for oral procedures.

##### Clinical and population-based epidemiologic research and development

- Continue to characterize the epidemiology of blood contacts, particularly percutaneous injuries, and the effectiveness of prevention measures.
- Further assess the effectiveness of double gloving in preventing blood contact during routine and surgical dental procedures.
- Continue to assess the stress placed on gloves during dental procedures and the potential for developing defects during different procedures.
- Develop methods for evaluating the effectiveness and cost-effectiveness of infection-control interventions.
- Determine how infection-control guidelines affect the knowledge, attitudes, and practices of DHCP.

## Recommendations

Each recommendation is categorized on the basis of existing scientific data, theoretical rationale, and applicability. Rankings are based on the system used by CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) to categorize recommendations:

**Category IA.** Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

**Category IB.** Strongly recommended for implementation and supported by experimental, clinical, or epidemiologic studies and a strong theoretical rationale.

**Category IC.** Required for implementation as mandated by federal or state regulation or standard. When IC is used, a second rating can be included to provide the basis of existing scientific data, theoretical rationale, and applicability. Because of state differences, the reader should not assume that the absence of a IC implies the absence of state regulations.

**Category II.** Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.

**Unresolved issue.** No recommendation. Insufficient evidence or no consensus regarding efficacy exists.

### I. Personnel Health Elements of an Infection-Control Program

#### A. General Recommendations

1. Develop a written health program for DHCP that includes policies, procedures, and guidelines for education and training; immunizations; exposure prevention and postexposure management; medical conditions, work-related illness, and associated work restrictions; contact dermatitis and latex hypersensitivity; and maintenance of records, data management, and confidentiality (IB) (5,16-18,22).
2. Establish referral arrangements with qualified health-care professionals to ensure prompt and appropriate provision of preventive services, occupationally related medical services, and postexposure management with medical follow-up (IB, IC) (5,13,19,22).

#### B. Education and Training

1. Provide DHCP 1) on initial employment, 2) when new tasks or procedures affect the employee's occupational exposure, and 3) at a minimum, annually; with education and training regarding occupational exposure to potentially infectious agents and infection-control procedures/protocols appropriate for and spe-

cific to their assigned duties (IB, IC) (5,11,13,14,16,19,22).

2. Provide educational information appropriate in content and vocabulary to the educational level, literacy, and language of DHCP (IB, IC) (5,13).

#### C. Immunization Programs

1. Develop a written comprehensive policy regarding immunizing DHCP, including a list of all required and recommended immunizations (IB) (5,17,18).
2. Refer DHCP to a prearranged qualified health-care professional or to their own health-care professional to receive all appropriate immunizations based on the latest recommendations as well as their medical history and risk for occupational exposure (IB) (5,17).

#### D. Exposure Prevention and Postexposure Management

1. Develop a comprehensive postexposure management and medical follow-up program (IB, IC) (5,13,14,19).

- a. Include policies and procedures for prompt reporting, evaluation, counseling, treatment, and medical follow-up of occupational exposures.

- b. Establish mechanisms for referral to a qualified health-care professional for medical evaluation and follow-up.

- c. Conduct a baseline TST, preferably by using a two-step test, for all DHCP who might have contact with persons with suspected or confirmed infectious TB, regardless of the risk classification of the setting (IB) (20).

#### E. Medical Conditions, Work-Related Illness, and Work Restrictions

1. Develop and have readily available to all DHCP comprehensive written policies regarding work restriction and exclusion that include a statement of authority defining who can implement such policies (IB) (5,22).

2. Develop policies for work restriction and exclusion that encourage DHCP to seek appropriate preventive and curative care and report their illnesses, medical conditions, or treatments that can render them more susceptible to opportunistic infection or exposures; do not penalize DHCP with loss of wages, benefits, or job status (IB) (5,22).

3. Develop policies and procedures for evaluation, diagnosis, and management of DHCP with suspected or known occupational contact dermatitis (IB) (32).

4. Seek definitive diagnosis by a qualified health-care professional for any DHCP with suspected latex allergy to carefully determine its specific etiology and appropriate treatment as well as work restrictions and accommodations (IB) (32).

#### E. Records Maintenance, Data Management, and Confidentiality

1. Establish and maintain confidential medical records (e.g., immunization records and documentation of tests received as a result of occupational exposure) for all DHCP (IB, IC) (5,13).
2. Ensure that the practice complies with all applicable federal, state, and local laws regarding medical recordkeeping and confidentiality (IC) (13,34).

## II. Preventing Transmission of Bloodborne Pathogens

### A. HBV Vaccination

1. Offer the HBV vaccination series to all DHCP with potential occupational exposure to blood or other potentially infectious material (IA, IC) (2,13,14,19).
2. Always follow U.S. Public Health Service/CDC recommendations for hepatitis B vaccination, serologic testing, follow-up, and booster dosing (IA, IC) (13,14,19).
3. Test DHCP for anti-HBs 1-2 months after completion of the 3-dose vaccination series (IA, IC) (14,19).
4. DHCP should complete a second 3-dose vaccine series or be evaluated to determine if they are HBsAg-positive if no antibody response occurs to the primary vaccine series (IA, IC) (14,19).
5. Retest for anti-HBs at the completion of the second vaccine series. If no response to the second 3-dose series occurs, nonresponders should be tested for HBsAg (IC) (14,19).
6. Counsel nonresponders to vaccination who are HBsAg-negative regarding their susceptibility to HBV infection and precautions to take (IA, IC) (14,19).
7. Provide employees appropriate education regarding the risks of HBV transmission and the availability of the vaccine. Employees who decline

the vaccination should sign a declination form to be kept on file with the employer (IC) (13).

### B. Preventing Exposures to Blood and OPIM

#### 1. General recommendations

- a. Use standard precautions (OSHA's blood-borne pathogen standard retains the term universal precautions) for all patient encounters (IA, IC) (11,13,19,53).

- b. Consider sharp items (e.g., needles, scalers, burs, lab knives, and wires) that are contaminated with patient blood and saliva as potentially infective and establish engineering controls and work practices to prevent injuries (IB, IC) (6,13,113).

- c. Implement a written, comprehensive program designed to minimize and manage DHCP exposures to blood and body fluids (IB, IC) (13,14,19,97).

#### 2. Engineering and work-practice controls

- a. Identify, evaluate, and select devices with engineered safety features at least annually and as they become available on the market (e.g., safer anesthetic syringes, blunt suture needle, retractable scalpel, or needleless TV systems) (IC) (13,97,110-112).

- b. Place used disposable syringes and needles, scalpel blades, and other sharp items in appropriate puncture-resistant containers located as close as feasible to the area in which the items are used (IA, IC) (2,7,13,19,113,115).

- c. Do not recap used needles by using both hands or any other technique that involves directing the point of a needle toward any part of the body. Do not bend, break, or remove needles before disposal (IA, IC) (2,7,8,13,97,113).

- d. Use either a one-handed scoop technique or a mechanical device designed for holding the needle cap when recapping needles (e.g., between multiple injections and before removing from a nondisposable aspirating syringe) (IA, IC) (2,7,8,13,14,113).

#### 3. Postexposure management and prophylaxis

- a. Follow CDC recommendations after percutaneous, mucous membrane, or nonintact skin exposure to blood or other potentially infectious material (IA, IC) (13,14,19).

### III. Hand Hygiene

#### A. General Considerations

1. Perform hand hygiene with either a nonantimicrobial or antimicrobial soap and water when hands are visibly dirty or contaminated with blood or other potentially infectious material. If hands are not visibly soiled, an alcohol-based hand rub can also be used. Follow the manufacturer's instructions (IA) (123).
  2. Indications for hand hygiene include
    - a. when hands are visibly soiled (IA, IC);
    - b. after barehanded touching of inanimate objects likely to be contaminated by blood, saliva, or respiratory secretions (IA, IC);
    - c. before and after treating each patient (IB);
    - d. before donning gloves (IB); and
    - e. immediately after removing gloves (IB, IC) (7-9, 11, 13, 113, 120-123, 125, 126, 138).
  3. For oral surgical procedures, perform surgical hand antisepsis before donning sterile surgeon's gloves. Follow the manufacturer's instructions by using either an antimicrobial soap and water, or soap and water followed by drying hands and application of an alcohol-based surgical hand-scrub product with persistent activity (IB) (121-123, 127-133, 144, 145).
  4. Store liquid hand-care products in either disposable closed containers or closed containers that can be washed and dried before refilling. Do not add soap or lotion to (i.e., top off) a partially empty dispenser (IA) (9, 120, 122, 149, 150).
- #### B. Special Considerations for Hand Hygiene and Glove Use
1. Use hand lotions to prevent skin dryness associated with handwashing (IA) (153, 154).
  2. Consider the compatibility of lotion and antiseptic products and the effect of petroleum or other oil emollients on the integrity of gloves during product selection and glove use (IB) (2, 14, 122, 155).
  3. Keep fingernails short with smooth, filed edges to allow thorough cleaning and prevent glove tears (II) (122, 123, 156).
  4. Do not wear artificial fingernails or extenders when having direct contact with patients at high risk (e.g., those in intensive care units or operating rooms) (IA) (123, 157-160).
  5. Use of artificial fingernails is usually not recommended (II) (157-160).

6. Do not wear hand or nail jewelry if it makes donning gloves more difficult or compromises the fit and integrity of the glove (II) (123, 142, 143).

### IV. PPE

#### A. Masks, Protective Eyewear, and Face Shields

1. Wear a surgical mask and eye protection with solid side shields or a face shield to protect mucous membranes of the eyes, nose, and mouth during procedures likely to generate splashing or spattering of blood or other body fluids (IB, IC) (1, 2, 7, 8, 11, 13, 137).
2. Change masks between patients or during patient treatment if the mask becomes wet (IB) (2).
3. Clean with soap and water, or if visibly soiled, clean and disinfect reusable facial protective equipment (e.g., clinician and patient protective eyewear or face shields) between patients (II) (2).

#### B. Protective Clothing

1. Wear protective clothing (e.g., reusable or disposable gown, laboratory coat, or uniform) that covers personal clothing and skin (e.g., forearms) likely to be soiled with blood, saliva, or OPIM (IB, IC) (7, 8, 11, 13, 137).
2. Change protective clothing if visibly soiled (134); change immediately or as soon as feasible if penetrated by blood or other potentially infectious fluids (IB, IC) (13).
3. Remove barrier protection, including gloves, mask, eyewear, and gown before departing work area (e.g., dental patient care, instrument processing, or laboratory areas) (IC) (13).

#### C. Gloves

1. Wear medical gloves when a potential exists for contacting blood, saliva, OPIM, or mucous membranes (IB, IC) (1, 2, 7, 8, 13).
2. Wear a new pair of medical gloves for each patient, remove them promptly after use, and wash hands immediately to avoid transfer of microorganisms to other patients or environments (IB) (1, 7, 8, 123).
3. Remove gloves that are torn, cut, or punctured as soon as feasible and wash hands before regloving (IB, IC) (13, 210, 211).
4. Do not wash surgeon's or patient examination gloves before use or wash, disinfect, or sterilize gloves for reuse (IB, IC) (13, 138, 177, 212, 213).

5. Ensure that appropriate gloves in the correct size are readily accessible (IC) (13).

6. Use appropriate gloves (e.g., puncture- and chemical-resistant utility gloves) when cleaning instruments and performing housekeeping tasks involving contact with blood or OPIM (IB, IC) (7, 13, 15).

7. Consult with glove manufacturers regarding the chemical compatibility of glove material and dental materials used (II).

#### D. Sterile Surgeon's Gloves and Double Gloving During Oral Surgical Procedures

1. Wear sterile surgeon's gloves when performing oral surgical procedures (IB) (2, 8, 137).
2. No recommendation is offered regarding the effectiveness of wearing two pairs of gloves to prevent disease transmission during oral surgical procedures. The majority of studies among HCP and DHCP have demonstrated a lower frequency of inner glove perforation and visible blood on the surgeon's hands when double gloves are worn; however, the effectiveness of wearing two pairs of gloves in preventing disease transmission has not been demonstrated (Unresolved issue).

### V. Contact Dermatitis and Latex Hypersensitivity

#### A. General Recommendations

1. Educate DHCP regarding the signs, symptoms, and diagnosis of skin reactions associated with frequent hand hygiene and glove use (IB) (5, 31, 32).
2. Screen all patients for latex allergy (e.g., take health history and refer for medical consultation when latex allergy is suspected) (IB) (32).
3. Ensure a latex-safe environment for patients and DHCP with latex allergy (IB) (32).
4. Have emergency treatment kits with latex-free products available at all times (II) (32).

### VI. Sterilization and Disinfection of Patient-Care Items

#### A. General Recommendations

1. Use only FDA-cleared medical devices for sterilization and follow the manufacturer's instructions for correct use (IB) (248).
2. Clean and heat-sterilize critical dental instruments before each use (IA) (2, 137, 243, 244, 246, 249, 407).
3. Clean and heat-sterilize semicritical items before each use (IB) (2, 249, 260, 407).
4. Allow packages to dry in the sterilizer before they are handled to avoid contamination (IB) (247).

5. Use of heat-stable semicritical alternatives is encouraged (IB) (2).

6. Reprocess heat-sensitive critical and semi-critical instruments by using FDA-cleared sterilant/high-level disinfectants or an FDA-cleared low-temperature sterilization method (e.g., ethylene oxide). Follow manufacturer's instructions for use of chemical sterilants/high-level disinfectants (IB) (243).

7. Single-use disposable instruments are acceptable alternatives if they are used only once and disposed of correctly (IB, IC) (243, 383).

8. Do not use liquid chemical sterilants/high-level disinfectants for environmental surface disinfection or as holding solutions (IB, IC) (243, 245).

9. Ensure that noncritical patient-care items are barrier-protected or cleaned, or if visibly soiled, cleaned and disinfected after each use with an EPA-registered hospital disinfectant. If visibly contaminated with blood, use an EPA-registered hospital disinfectant with a tuberculocidal claim (i.e., intermediate level) (IB) (2, 243, 244).

10. Inform DHCP of all OSHA guidelines for exposure to chemical agents used for disinfection and sterilization. Using this report, identify areas and tasks that have potential for exposure (IC) (15).

#### B. Instrument Processing Area

1. Designate a central processing area. Divide the instrument processing area, physically or, at a minimum, spatially, into distinct areas for 1) receiving, cleaning, and decontamination; 2) preparation and packaging; 3) sterilization; and 4) storage. Do not store instruments in an area where contaminated instruments are held or cleaned (II) (173, 247, 248).
2. Train DHCP to employ work practices that prevent contamination of clean areas (II).

#### C. Receiving, Cleaning, and Decontamination Work Area

1. Minimize handling of loose contaminated instruments during transport to the instrument processing area. Use work-practice controls (e.g., carry instruments in a covered container) to minimize exposure potential (II). Clean all visible blood and other contamination from dental instruments and devices before sterilization or disinfection procedures (IA) (243, 249-252).
2. Use automated cleaning equipment (e.g., ultrasonic cleaner or washer-disinfector) to remove

- debris to improve cleaning effectiveness and decrease worker exposure to blood (IB) (2,253).
3. Use work-practice controls that minimize contact with sharp instruments if manual cleaning is necessary (e.g., long-handled brush) (IC) (14).
  4. Wear puncture- and chemical-resistant/heavy-duty utility gloves for instrument cleaning and decontamination procedures (IB) (7).
  5. Wear appropriate PPE (e.g., mask, protective eyewear, and gown) when splashing or spraying is anticipated during cleaning (IC) (13).
- D. Preparation and Packaging**
1. Use an internal chemical indicator in each package. If the internal indicator cannot be seen from outside the package, also use an external indicator (II) (243,254,257).
  2. Use a container system or wrapping compatible with the type of sterilization process used and that has received FDA clearance (IB) (243,247,256).
  3. Before sterilization of critical and semicritical instruments, inspect instruments for cleanliness, then wrap or place them in containers designed to maintain sterility during storage (e.g., cassettes and organizing trays) (IA) (2,247,255,256).
- E. Sterilization of Unwrapped Instruments**
1. Clean and dry instruments before the unwrapped sterilization cycle (IB) (248).
  2. Use mechanical and chemical indicators for each unwrapped sterilization cycle (i.e., place an internal chemical indicator among the instruments or items to be sterilized) (IB) (243,258).
  3. Allow unwrapped instruments to dry and cool in the sterilizer before they are handled to avoid contamination and thermal injury (II) (260).
  4. Semicritical instruments that will be used immediately or within a short time can be sterilized unwrapped on a tray or in a container system, provided that the instruments are handled aseptically during removal from the sterilizer and transport to the point of use (II).
  5. Critical instruments intended for immediate reuse can be sterilized unwrapped if the instruments are maintained sterile during removal from the sterilizer and transport to the point of use (e.g., transported in a sterile covered container) (IB) (259).
  6. Do not sterilize implantable devices unwrapped (IB) (243,247).
  7. Do not store critical instruments unwrapped (IB) (248).
- B. Sterilization Monitoring**
1. Use mechanical, chemical, and biological monitors according to the manufacturer's instructions to ensure the effectiveness of the sterilization process (IB) (248,278,279).
  2. Monitor each load with mechanical (e.g., time, temperature, and pressure) and chemical indicators (II) (243,248).
  3. Place a chemical indicator on the inside of each package. If the internal indicator is not visible from the outside, also place an exterior chemical indicator on the package (II) (243,254,257).
  4. Place items/packages correctly and loosely into the sterilizer so as not to impede penetration of the sterilant (IB) (243).
  5. Do not use instrument packs if mechanical or chemical indicators indicate inadequate processing (IB) (243,247,248).
  6. Monitor sterilizers at least weekly by using a biological indicator with a matching control (i.e., biological indicator and control from same lot number) (IB) (2,3,243,247,278,279).
  7. Use a biological indicator for every sterilizer load that contains an implantable device. Verify results before using the implantable device, whenever possible (IB) (243,248).
  8. The following are recommended in the case of a positive spore test:
    - a. Remove the sterilizer from service and review sterilization procedures (e.g., work practices and use of mechanical and chemical indicators) to determine whether operator error could be responsible (II) (8).
    - b. Retest the sterilizer by using biological, mechanical, and chemical indicators after correcting any identified procedural problems (II).
    - c. If the repeat spore test is negative, and mechanical and chemical indicators are within normal limits, put the sterilizer back in service (II) (9,243).
  9. The following are recommended if the repeat spore test is positive:
    - a. Do not use the sterilizer until it has been inspected or repaired or the exact reason for the positive test has been determined (II) (9,243).

- b. Recall, to the extent possible, and reprocess all items processed since the last negative spore test (II) (9,243,283).
  - c. Before placing the sterilizer back in service, rechallenge the sterilizer with biological indicator tests in three consecutive empty chamber sterilization cycles after the cause of the sterilizer failure has been determined and corrected (II) (9,243,283).
10. Maintain sterilization records (i.e., mechanical, chemical, and biological) in compliance with state and local regulations (IB) (243).
- G. Storage Area for Sterilized Items and Clean Dental Supplies**
1. Implement practices on the basis of date- or event-related shelf-life for storage of wrapped, sterilized instruments and devices (IB) (243,284).
  2. Even for event-related packaging, at a minimum, place the date of sterilization, and if multiple sterilizers are used in the facility, the sterilizer used, on the outside of the packaging material to facilitate the retrieval of processed items in the event of a sterilization failure (IB) (243,247).
  3. Examine wrapped packages of sterilized instruments before opening them to ensure the barrier wrap has not been compromised during storage (II) (243,284).
  4. Reclean, repack, and resterilize any instrument package that has been compromised (II).
  5. Store sterile items and dental supplies in covered or closed cabinets, if possible (II) (285).
- VII. Environmental Infection Control**
- A. General Recommendations**
1. Follow the manufacturers' instructions for correct use of cleaning and EPA-registered hospital disinfecting products (IB, IC) (243-245).
  2. Do not use liquid chemical sterilants/high-level disinfectants for disinfection of environmental surfaces (clinical contact or housekeeping) (IB, IC) (243-245).
  3. Use PPE, as appropriate, when cleaning and disinfecting environmental surfaces. Such equipment might include gloves (e.g., puncture- and chemical-resistant utility), protective clothing (e.g., gown, jacket, or lab coat), and protective eyewear/face shield, and mask (IC) (13,15).
- B. Clinical Contact Surfaces**
1. Use surface barriers to protect clinical contact surfaces, particularly those that are difficult to clean (e.g., switches on dental chairs) and change surface barriers between patients (II) (1,2,260,288).
  2. Clean and disinfect clinical contact surfaces that are not barrier-protected, by using an EPA-registered hospital disinfectant with a low- (i.e., HIV and HBV label claims) to intermediate-level (i.e., tuberculocidal claim) activity after each patient. Use an intermediate-level disinfectant if visibly contaminated with blood (IB) (2,243,244).
- C. Housekeeping Surfaces**
1. Clean housekeeping surfaces (e.g., floors, walls, and sinks) with a detergent and water or an EPA-registered hospital disinfectant/detergent on a routine basis, depending on the nature of the surface and type and degree of contamination, and as appropriate, based on the location in the facility, and when visibly soiled (IB) (243,244).
  2. Clean mops and cloths after use and allow to dry before reuse; or use single-use, disposable mop heads or cloths (II) (243,244).
  3. Prepare fresh cleaning or EPA-registered disinfecting solutions daily and as instructed by the manufacturer (II) (243,244).
  4. Clean walls, blinds, and window curtains in patient-care areas when they are visibly dusty or soiled (II) (9,244).
- D. Spills of Blood and Body Substances**
1. Clean spills of blood or OPIM and decontaminate surface with an EPA-registered hospital disinfectant with low- (i.e., HBV and HIV label claims) to intermediate-level (i.e., tuberculocidal claim) activity, depending on size of spill and surface porosity (IB, IC) (13,113).
- E. Carpet and Cloth Furnishings**
1. Avoid using carpeting and cloth-upholstered furnishings in dental operatories, laboratories, and instrument processing areas (II) (9,293-295).
- F. Regulated Medical Waste**
1. General Recommendations
    - a. Develop a medical waste management program. Disposal of regulated medical waste must follow federal, state, and local regulations (IC) (13,301).
    - b. Ensure that DHCP who handle and dispose of regulated medical waste are trained in appropriate handling and disposal methods

and informed of the possible health and safety hazards (IC) (13).

## 2. Management of Regulated Medical Waste in Dental Health-Care Facilities

- a. Use a color-coded or labeled container that prevents leakage (e.g., biohazard bag) to contain nonsharp regulated medical waste (IC) (13).
- b. Place sharp items (e.g., needles, scalpel blades, orthodontic bands, broken metal instruments, and burs) in an appropriate sharps container (e.g., puncture resistant, color-coded, and leakproof). Close container immediately before removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping (IC) (2,8,13,113,115).
- c. Pour blood, suctioned fluids or other liquid waste carefully into a drain connected to a sanitary sewer system, if local sewage discharge requirements are met and the state has declared this an acceptable method of disposal. Wear appropriate PPE while performing this task (IC) (7,9,13).

## VIII. Dental Unit Waterlines, Biofilm, and Water Quality

### A. General Recommendations

1. Use water that meets EPA regulatory standards for drinking water (i.e.,  $\leq 500$  CFU/mL of heterotrophic water bacteria) for routine dental treatment output water (IB, IC) (341,342).
2. Consult with the dental unit manufacturer for appropriate methods and equipment to maintain the recommended quality of dental water (II) (339).
3. Follow recommendations for monitoring water quality provided by the manufacturer of the unit or waterline treatment product (II).
4. Discharge water and air for a minimum of 20–30 seconds after each patient, from any device connected to the dental water system that enters the patient's mouth (e.g., handpieces, ultrasonic scalers, and air/water syringes) (II) (2,311,344).
5. Consult with the dental unit manufacturer on the need for periodic maintenance of anticontamination mechanisms (IB) (2,311).

### B. Boil-Water Advisories

1. The following apply while a boil-water advisory is in effect:
  - a. Do not deliver water from the public water system to the patient through the dental

operative unit, ultrasonic scaler, or other dental equipment that uses the public water system (IB, IC) (341,342,346,349,350).

- b. Do not use water from the public water system for dental treatment, patient rinsing, or handwashing (IB, IC) (341,342,346,349,350).
  - c. For handwashing, use antimicrobial-containing products that do not require water for use (e.g., alcohol-based hand rubs). If hands are visibly contaminated, use bottled water, if available, and soap for handwashing or an antiseptic towelette (IB, IC) (13,122).
2. The following apply when the boil-water advisory is cancelled:
- a. Follow guidance given by the local water utility regarding adequate flushing of waterlines. If no guidance is provided, flush dental waterlines and faucets for 1–5 minutes before using for patient care (IC) (244,346,351,352).
  - b. Disinfect dental waterlines as recommended by the dental unit manufacturer (II).

## IX. Special Considerations

### A. Dental Handpieces and Other Devices Attached to Air and Waterlines

1. Clean and heat-sterilize handpieces and other intraoral instruments that can be removed from the air and waterlines of dental units between patients (IB, IC) (2,246,275,356,357,360,407).
2. Follow the manufacturer's instructions for cleaning, lubrication, and sterilization of handpieces and other intraoral instruments that can be removed from the air and waterlines of dental units (IB) (361–363).
3. Do not surface-disinfect, use liquid chemical sterilants, or ethylene oxide on handpieces and other intraoral instruments that can be removed from the air and waterlines of dental units (IC) (2,246,250,275).
4. Do not advise patients to close their lips tightly around the tip of the saliva ejector to evacuate oral fluids (II) (364–366).

### B. Dental Radiology

1. Wear gloves when exposing radiographs and handling contaminated film packages. Use other PPE (e.g., protective eyewear, mask, and gown) as appropriate if spattering of blood or other body fluids is likely (IA, IC) (11,13).

2. Use heat-tolerant or disposable intraoral devices whenever possible (e.g., film-holding and positioning devices). Clean and heat-sterilize heat-tolerant devices between patients. At a minimum, high-level disinfect semicritical heat-sensitive devices, according to manufacturer's instructions (IB) (243).
  3. Transport and handle exposed radiographs in an aseptic manner to prevent contamination of developing equipment (II).
  4. The following apply for digital radiography sensors:
    - a. Use FDA-cleared barriers (IB) (243).
    - b. Clean and heat-sterilize, or high-level disinfect, between patients, barrier-protected semicritical items. If the item cannot tolerate these procedures then, at a minimum, protect with an FDA-cleared barrier and clean and disinfect with an EPA-registered hospital disinfectant with intermediate-level (i.e., tuberculocidal claim) activity, between patients. Consult with the manufacturer for methods of disinfection and sterilization of digital radiology sensors and for protection of associated computer hardware (IB) (243).
- ### C. Aseptic Technique for Parenteral Medications
1. Do not administer medication from a syringe to multiple patients, even if the needle on the syringe is changed (IA) (378).
  2. Use single-dose vials for parenteral medications when possible (II) (376,377).
  3. Do not combine the leftover contents of single-use vials for later use (IA) (376,377).
  4. The following apply if multidose vials are used:
    - a. Cleanse the access diaphragm with 70% alcohol before inserting a device into the vial (IA) (380,381).
    - b. Use a sterile device to access a multiple-dose vial and avoid touching the access diaphragm. Both the needle and syringe used to access the multidose vial should be sterile. Do not reuse a syringe even if the needle is changed (IA) (380,381).
    - c. Keep multidose vials away from the immediate patient treatment area to prevent inadvertent contamination by spray or spatter (II).
    - d. Discard the multidose vial if sterility is compromised (IA) (380,381).

5. Use fluid infusion and administration sets (i.e., IV bags, tubings and connections) for one patient only and dispose of appropriately (IB) (378).

### D. Single-Use (Disposable) Devices

1. Use single-use devices for one patient only and dispose of them appropriately (IC) (383).

### E. Preprocedural Mouth Rinses

1. No recommendation is offered regarding use of preprocedural antimicrobial mouth rinses to prevent clinical infections among DHCP or patients. Although studies have demonstrated that a preprocedural antimicrobial rinse (e.g., chlorhexidine gluconate, essential oils, or povidone-iodine) can reduce the level of oral microorganisms in aerosols and spatter generated during routine dental procedures and can decrease the number of microorganisms introduced in the patient's bloodstream during invasive dental procedures (391–399), the scientific evidence is inconclusive that using these rinses prevents clinical infections among DHCP or patients (see discussion, Preprocedural Mouth Rinses) (Unresolved issue).

### F. Oral Surgical Procedures

1. The following apply when performing oral surgical procedures:
  - a. Perform surgical hand antisepsis by using an antimicrobial product (e.g., antimicrobial soap and water, or soap and water followed by alcohol-based hand scrub with persistent activity) before donning sterile surgeon's gloves (IB) (127–132,137).
  - b. Use sterile surgeon's gloves (IB) (2,7,121,123,137).
  - c. Use sterile saline or sterile water as a coolant/irrigant when performing oral surgical procedures. Use devices specifically designed for delivering sterile irrigating fluids (e.g., bulb syringe, single-use disposable products, and sterilizable tubing) (IB) (2,121).

### G. Handling of Biopsy Specimens

1. During transport, place biopsy specimens in a sturdy, leakproof container labeled with the biohazard symbol (IC) (2,13,14).
2. If a biopsy specimen container is visibly contaminated, clean and disinfect the outside of a

container or place it in an impervious bag labeled with the biohazard symbol, (IC) (2,13).

#### H. Handling of Extracted Teeth

1. Dispose of extracted teeth as regulated medical waste unless returned to the patient (IC) (13,14).
2. Do not dispose of extracted teeth containing amalgam in regulated medical waste intended for incineration (II).
3. Clean and place extracted teeth in a leakproof container, labeled with a biohazard symbol, and maintain hydration for transport to educational institutions or a dental laboratory (IC) (13,14).
4. Heat-sterilize teeth that do not contain amalgam before they are used for educational purposes (IB) (403,405,406).

#### I. Dental Laboratory

1. Use PPE when handling items received in the laboratory until they have been decontaminated (IA, IC) (2,7,11,13,113).
2. Before they are handled in the laboratory, clean, disinfect, and rinse all dental prostheses and prosthodontic materials (e.g., impressions, bite registrations, occlusal rims, and extracted teeth) by using an EPA-registered hospital disinfectant having at least an intermediate-level (i.e., tuberculocidal claim) activity (IB) (2,249,252,407).
3. Consult with manufacturers regarding the stability of specific materials (e.g., impression materials) relative to disinfection procedures (II).
4. Include specific information regarding disinfection techniques used (e.g., solution used and duration), when laboratory cases are sent off-site and on their return (II) (2,407,409).
5. Clean and heat-sterilize heat-tolerant items used in the mouth (e.g., metal impression trays and face-bow forks) (IB) (2,407).
6. Follow manufacturers' instructions for cleaning and sterilizing or disinfecting items that become contaminated but do not normally contact the patient (e.g., burs, polishing points, rag wheels, articulators, case pans, and lathes). If manufacturer instructions are unavailable, clean and heat-sterilize heat-tolerant items or clean and disinfect with an EPA-registered hospital disinfectant with low- (HIV, HBV effectiveness claim) to intermediate-level (tuberculocidal claim) activity, depending on the degree of contamination (II).

#### J. Laser/Electrosurgery Plumes/Surgical Smoke

1. No recommendation is offered regarding practices to reduce DHCP exposure to laser plumes/surgical smoke when using lasers in dental practice. Practices to reduce HCP exposure to laser plumes/surgical smoke have been suggested, including use of a) standard precautions (e.g., high-filtration surgical masks and possibly full face shields) (437); b) central room suction units with in-line filters to collect particulate matter from minimal plumes; and c) dedicated mechanical smoke exhaust systems with a high-efficiency filter to remove substantial amounts of laser-plume particles. The effect of the exposure (e.g., disease transmission or adverse respiratory effects) on DHCP from dental applications of lasers has not been adequately evaluated (see previous discussion, *Laser/Electrosurgery Plumes or Surgical Smoke*) (Unresolved issue).

#### K. *Mycobacterium tuberculosis*

##### 1. General Recommendations

- a. Educate all DHCP regarding the recognition of signs, symptoms, and transmission of TB (IB) (20,21).
  - b. Conduct a baseline TST, preferably by using a two-step test, for all DHCP who might have contact with persons with suspected or confirmed active TB, regardless of the risk classification of the setting (IB) (20).
  - c. Assess each patient for a history of TB as well as symptoms indicative of TB and document on the medical history form (IB) (20,21).
  - d. Follow CDC recommendations for 1) developing, maintaining, and implementing a written TB infection-control plan; 2) managing a patient with suspected or active TB; 3) completing a community risk-assessment to guide employee TSTs and follow-up; and 4) managing DHCP with TB disease (IB) (2,21).
2. The following apply for patients known or suspected to have active TB:
    - a. Evaluate the patient away from other patients and DHCP. When not being evaluated, the patient should wear a surgical mask or be instructed to cover mouth and nose when coughing or sneezing (IB) (20,21).
    - b. Defer elective dental treatment until the patient is noninfectious (IB) (20,21).

- c. Refer patients requiring urgent dental treatment to a previously identified facility with TB engineering controls and a respiratory protection program (IB) (20,21).

#### L. Creutzfeldt-Jakob Disease (CJD) and Other Prion Diseases

1. No recommendation is offered regarding use of special precautions in addition to standard precautions when treating known CJD or vCJD patients. Potential infectivity of oral tissues in CJD or vCJD patients is an unresolved issue. Scientific data indicate the risk, if any, of sporadic CJD transmission during dental and oral surgical procedures is low to nil. Until additional information exists regarding the transmissibility of CJD or vCJD during dental procedures, special precautions in addition to standard precautions might be indicated when treating known CJD or vCJD patients; a list of such precautions is provided for consideration without recommendation (see *Creutzfeldt-Jakob Disease and Other Prion Diseases*) (Unresolved issue).

#### M. Program Evaluation

1. Establish routine evaluation of the infection-control program, including evaluation of performance indicators, at an established frequency (II) (470-471).

### Infection-Control Internet Resources

Advisory Committee on Immunization Practices  
<http://www.cdc.gov/nip/ACIP/default.htm>  
 American Dental Association  
<http://www.ada.org>  
 American Institute of Architects Academy of Architecture for Health  
<http://www.aahaia.org>  
 American Society of Heating, Refrigeration, Air-conditioning Engineers  
<http://www.ashrae.org>  
 Association for Professionals in Infection Control and Epidemiology, Inc.  
<http://www.apic.org/res/guidlist.cfm>  
 CDC, Division of Healthcare Quality Promotion  
<http://www.cdc.gov/ncidod/dhqp>  
 CDC, Division of Oral Health, Infection Control  
<http://www.cdc.gov/OralHealth/infectioncontrol/index.htm>  
 CDC, *Morbidity and Mortality Weekly Report*  
<http://www.cdc.gov/mmwr>

#### CDC, NIOSH

<http://www.cdc.gov/niosh/homepage.html>  
 CDC Recommends, Prevention Guidelines System  
<http://www.phppo.cdc.gov/cdcRecommends/AdvSearchV.asp>  
 EPA, Antimicrobial Chemicals  
<http://www.epa.gov/oppad001/chemregindex.htm>  
 FDA  
<http://www.fda.gov>  
 Immunization Action Coalition  
<http://www.immunize.org/acip>  
 Infectious Diseases Society of America  
<http://www.idsociety.org/PG/loc.htm>  
 OSHA, Dentistry, Bloodborne Pathogens  
<http://www.osha.gov/SLTC/dentistry/index.html>  
<http://www.osha.gov/SLTC/bloodbornepathogens/index.html>  
 Organization for Safety and Asepsis Procedures  
<http://www.osap.org>  
 Society for Healthcare Epidemiology of America, Inc., Position Papers  
<http://www.shea-online.org/PositionPapers.html>

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## Appendix A

### Regulatory Framework for Disinfectants and Sterilants

When using the guidance provided in this report regarding use of liquid chemical disinfectants and sterilants, dental health-care personnel (DHCP) should be aware of federal laws and regulations that govern the sale, distribution, and use of these products. In particular, DHCPs should know what requirements pertain to them when such products are used. Finally, DHCP should understand the relative roles of the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and CDC.

The choice of specific cleaning or disinfecting agents is largely a matter of judgment, guided by product label claims and instructions and government regulations. A single liquid chemical germicide might not satisfy all disinfection requirements in a given dental practice or facility. Realistic use of liquid chemical germicides depends on consideration of multiple factors, including the degree of microbial killing required; the nature and composition of the surface, item, or device to be treated; and the cost, safety, and ease of use of the available agents. Selecting one appropriate product with a higher degree of potency to cover all situations might be more convenient.

In the United States, liquid chemical germicides (disinfectants) are regulated by EPA and FDA (A-1-A-3). In health-care settings, EPA regulates disinfectants that are used on environmental surfaces (housekeeping and clinical contact surfaces), and FDA regulates liquid chemical sterilants/high-level disinfectants (e.g., glutaraldehyde, hydrogen peroxide, and peracetic acid) used on critical and semicritical patient-care devices. 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, or sinks) are regulated in interstate commerce by the Antimicrobials Division, Office of Pesticide Programs, EPA, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947, as amended in 1996 (A-4). Under FIFRA, any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, including microorganisms but excluding those in or on living man or animals, must be registered before sale or distribution. To obtain a registration, a manufacturer must submit specific data regarding the safety and the effectiveness of each product.

EPA requires manufacturers to test formulations by using accepted methods for microbicidal activity, stability, and toxicity to animals and humans. Manufacturers submit these data to EPA with proposed labeling. If EPA concludes a product

may be used without causing unreasonable adverse effects, the product and its labeling are given an EPA registration number, and the manufacturer may then sell and distribute the product in the United States. FIFRA requires users of products to follow the labeling directions on each product explicitly. The following statement appears on all EPA-registered product labels under the Directions for Use heading: "It is a violation of federal law to use this product inconsistent with its labeling." This means that DHCP must follow the safety precautions and use directions on the labeling of each registered product. Not following the specified dilution, contact time, method of application, or any other condition of use is considered misuse of the product.

FDA, under the authority of the 1976 Medical Devices Amendment to the Food, Drug, and Cosmetic Act, regulates chemical germicides if they are advertised and marketed for use on specific medical devices (e.g., dental unit waterline or flexible endoscope). A liquid chemical germicide marketed for use on a specific device is considered, for regulatory purposes, a medical device itself when used to disinfect that specific medical device. Also, this FDA regulatory authority over a particular instrument or device dictates that the manufacturer is obligated to provide the user with adequate 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.

OSHA develops workplace standards to help ensure safe and healthful working conditions in places of employment. OSHA is authorized under Pub. L. 95-251, and as amended, to enforce these workplace standards. In 1991, OSHA published Occupational Exposure to Bloodborne Pathogens; final rule [29 CFR Part 1910.1030] (A-5). This standard is designed to help prevent occupational exposures to blood or other potentially infectious substances. Under this standard, OSHA has interpreted that, to decontaminate contaminated work surfaces, either an EPA-registered hospital tuberculocidal disinfectant or an EPA-registered hospital disinfectant labeled as effective against human immunodeficiency virus (HIV) and hepatitis B virus (HBV) is appropriate. Hospital disinfectants with such HIV and HBV claims can be used, provided surfaces are not contaminated with agents or concentration of agents for which higher level (i.e., intermediate-level) disinfection is recommended. In addition, as with all disinfectants, effectiveness is governed by strict adherence to the label instructions for intended use of the product.

CDC is not a regulatory agency and does not test, evaluate, or otherwise recommend specific brand-name products of chemical germicides. This report is intended to provide overall guidance for providers to select general classifications of products based on certain infection-control principles. In this report, CDC provides guidance to practitioners regarding appropriate application of EPA- and FDA-registered liquid chemical disinfectants and sterilants in dental health-care settings.

CDC recommends disinfecting environmental surfaces or sterilizing or disinfecting medical equipment, and DHCP should use products approved by EPA and FDA unless no such products are available for use against certain microorganisms or sites. However, if no registered or approved products are available for a specific pathogen or use situation, DHCP are advised to follow the specific guidance regarding unregistered or unapproved (e.g., off-label) uses for various chemical germicides. For example, no antimicrobial products are registered for use specifically against certain emerging pathogens (e.g., Norwalk virus), potential terrorism agents (e.g., variola major or *Yersinia pestis*), or Creutzfeldt-Jakob disease agents.

One point of clarification is the difference in how EPA and FDA classify disinfectants. FDA adopted the same basic terminology and classification scheme as CDC to categorize medical devices (i.e., critical, semicritical, and noncritical) and to define antimicrobial potency for processing surfaces (i.e., sterilization, and high-, intermediate- and low-level disinfection) (A-G). EPA registers environmental surface disinfectants based on the manufacturer's microbiological activity claims when registering its disinfectant. This difference has led to confusion on the part of users because the EPA does not use the terms intermediate- and low-level disinfectants as used in CDC guidelines.

CDC designates any EPA-registered hospital disinfectant without a tuberculocidal claim as a low-level disinfectant and any EPA-registered hospital disinfectant with a tuberculocidal claim as an intermediate-level disinfectant. To understand this comparison, one needs to know how EPA registers disinfectants. First, to be labeled as an EPA hospital disinfectant, the product must pass Association of Official Analytical Chemists (AOAC) effectiveness tests against three target organisms: *Salmonella choleraesuis* for effectiveness against gram-negative bacteria; *Staphylococcus aureus* for effectiveness against gram-positive bacteria; and *Pseudomonas aeruginosa* for effectiveness

against a primarily nosocomial pathogen. Substantiated label claims of effectiveness of a disinfectant against specific microorganisms other than the test microorganisms are permitted, but not required, provided that the test microorganisms are likely to be present in or on the recommended use areas and surfaces. Therefore, manufacturers might also test specifically against organisms of known concern in health-care practices (e.g., HIV, HBV, hepatitis C virus [HCV], and herpes) although it is considered likely that any products satisfying AOAC tests for hospital disinfectant designation will also be effective against these relatively fragile organisms when the product is used as directed by the manufacturer.

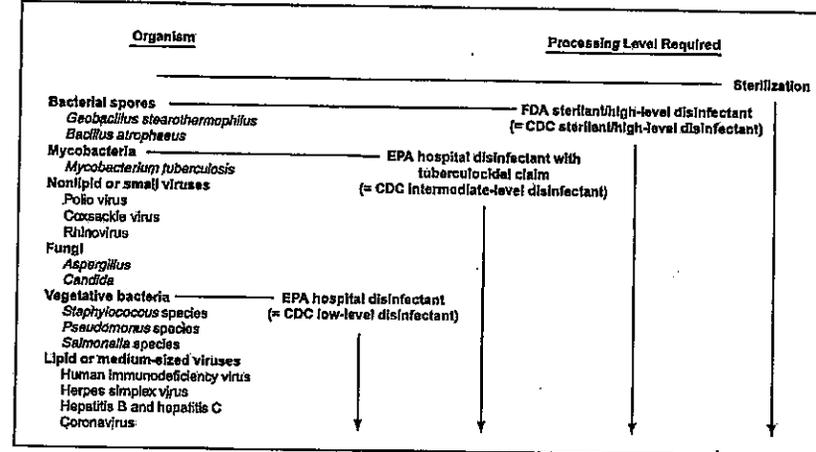
Potency against *Mycobacterium tuberculosis* has been recognized as a substantial benchmark. However, the tuberculocidal claim is used only as a benchmark to measure germicidal potency. Tuberculosis is not transmitted via environmental surfaces but rather by the airborne route. Accordingly, use of such products on environmental surfaces plays no role in preventing the spread of tuberculosis. However, because mycobacteria have among the highest intrinsic levels of resistance among the vegetative bacteria, viruses, and fungi, any germicide with a tuberculocidal claim on the label is considered capable of inactivating a broad spectrum of pathogens, including such less-resistant organisms as bloodborne pathogens (e.g., HBV, 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.

EPA also lists disinfectant products according to their labeled use against these organisms of interest as follows:

- List B. Tuberculocide products effective against *Mycobacterium* species.
- List C. Products effective against human HIV-1 virus.
- List D. Products effective against human HIV-1 virus and HBV.
- List E. Products effective against *Mycobacterium* species, human HIV-1 virus, and HBV.
- List F. Products effective against HCV.

Microorganisms vary in their resistance to disinfection and sterilization, enabling CDC's designation of disinfectants as high-, intermediate-, and low-level, when compared with EPA's designated organism spectrum (Figure). However, exceptions to this general guide exist, and manufacturer's label claims and instructions should always be followed.

FIGURE. Decreasing order of resistance of microorganisms to germicidal chemicals



Sources: Adapted from Bond WW, Ott BJ, Franke K, McCracken JE. Effective use of liquid chemical germicides on medical devices; instrument design problems. In: Block SS, ed. Disinfection, sterilization and preservation. 4<sup>th</sup> ed. Philadelphia, PA: Lea & Gebiger, 1991:1100.

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- A-1. Food and Drug Administration (FDA) and US Environmental Protection Agency (EPA). Memorandum of understanding between the FDA and EPA: notice regarding matters of mutual responsibility—regulation of liquid chemical germicides intended for use on medical devices. Rockville, MD: US Department of Health and Human Services, Public Health Service, Food and Drug Administration, US Environmental Protection Agency, 1993.
- A-2. Food and Drug Administration (FDA). Interim measures for registration of antimicrobial products/liquid chemical germicides with medical device use claims under the memorandum of understanding between EPA and FDA. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, 1994.
- A-3. 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/ocdf/397.pdf>.
- A-4. US Environmental Protection Agency. 40 CFR Parts 152, 156, and 158. Exemption of certain pesticide substances from federal insecticide, fungicide, and rodenticide act requirements. Amended 1996. Federal Register 1996;61:8876-9.
- A-5. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. Occupational exposure to bloodborne pathogens; needles 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 1993;58:64174-82. Available at <http://www.osha.gov/SLTC/demistry/index.html>.
- A-6. Spaulding EH. Role of chemical disinfection in preventing nosocomial infections. In: Proceedings of the International Conference on Nosocomial Infections, 1970. Brachman PS, Eickhoff TC, eds. Chicago, IL: American Hospital Association, 1971:247-54.

## Appendix B

## Immunizations Strongly Recommended for Health-Care Personnel (HCP)

Vaccine	Dose schedule	Indications	Major precautions and contraindications	Special considerations
Hepatitis B recombinant vaccine*	Three-dose schedule administered intramuscularly (IM) in the deltoid; 0, 1, 6—second dose administered 1 month after first dose; third dose administered 4 months after second. Booster doses are not necessary for persons who have developed adequate antibodies to hepatitis B surface antigen (anti-HBs).	Health-care personnel (HCP) at risk for exposure to blood and body fluids.	History of anaphylactic reaction to common baker's yeast. Pregnancy is not a contraindication.	No therapeutic or adverse effects on hepatitis B virus (HBV)-infected persons; cost-effectiveness of pre-exposure screening for susceptibility to HBV depends on costs of vaccination and antibody testing and prevalence of immunity in the group of potential vaccinees; health-care personnel who have ongoing contact with patients or blood should be tested 1–2 months after completing the vaccination series to determine serologic response. If vaccination does not induce adequate anti-HBs (≥10 mIU/mL), a second vaccine series should be administered.
Influenza vaccine (inactivated) <sup>†</sup>	Annual single-dose vaccination IM with current vaccine.	HCP who have contact with patients at high risk or who work in chronic-care facilities; HCP aged ≥50 years or who have high-risk medical conditions.	History of anaphylactic hypersensitivity to eggs or to other components of the vaccine.	Recommended for women who will be in the second or third trimesters of pregnancy during the influenza season and women in any stage of pregnancy who have chronic medical conditions (not associated with an increased risk of influenza). <sup>‡</sup>
Measles-mumps-rubella (MMR) vaccine	One dose administered subcutaneously (SC); second dose 24 weeks later.	HCP who were born during or after 1957 without documentation of 1) receipt of 2 doses of live vaccine on or after their first birthday, 2) physician-diagnosed measles, or 3) laboratory evidence of immunity. Vaccine should also be considered for all HCP who have no proof of immunity, including those born before 1957.	Pregnancy; immunocompromised state (including human immunodeficiency virus [HIV]-infected persons with severe immunosuppression); history of anaphylactic reactions after gelatin ingestion or receipt of neomycin; or receipt of antibody-containing blood products.	Measles, mumps, rubella (MMR) is the recommended vaccine. If recipients are also likely to be susceptible to rubella, mumps, or varicella, persons vaccinated during 1983–1987 with 1) measles-killed-virus vaccine alone, 2) killed-virus vaccine followed by live-virus vaccine, or 3) a vaccine of unknown type, should be revaccinated with two doses of live-virus measles vaccine.
Mumps live-virus vaccine	One dose SC; no booster.	HCP believed susceptible can be vaccinated; adults born before 1957 can be considered immune.	Pregnancy; immunocompromised state; history of anaphylactic reaction after gelatin ingestion or receipt of neomycin.	MMR is the recommended vaccine.
Rubella live-virus vaccine	One dose SC; no booster.	HCP, both male and female, who lack documentation of receipt of live vaccine on or after their first birthday, or lack of laboratory evidence of immunity can be vaccinated. Adults born before 1957 can be considered immune, except women of childbearing age.	Pregnancy; immunocompromised state; history of anaphylactic reaction after receipt of neomycin.	Women pregnant when vaccinated or who become pregnant within 4 weeks of vaccination should be counseled regarding theoretical risks to the fetus; however, the risk of rubella vaccine-associated malformations among these women is negligible. MMR is the recommended vaccine.
Varicella-zoster live-virus vaccine	Two 0.5 mL doses SC 4–8 weeks apart if aged ≥13 years.	HCP without reliable history of varicella or laboratory evidence of varicella immunity.	Pregnancy; immunocompromised state; history of anaphylactic reaction after receipt of neomycin or gelatin; recent receipt of antibody-containing blood products; salicylate use should be avoided for 6 weeks after vaccination.	Because 71%–83% of U.S.-born persons without a history of varicella are immune, serologic testing before vaccination might be cost-effective.

Sources: Adapted from Bolyard EA. Hospital Infection Control Practices Advisory Committee. Guidelines for infection control in health care personnel, 1998. Am J Infect Control 1999;28:529–554.

CDC. Immunization of health-care workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). MMWR 1997;46(No. RR-18).

CDC. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2003;52:1–34.

CDC. Using the attenuated influenza vaccine for prevention and control of influenza: supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2003;52(No. RR-12).

\* A federal standard based on December 1991 under the Occupational Safety and Health Act mandates that hepatitis B vaccine be made available at the employer's expense to all HCP occupationally exposed to blood or other potentially infectious materials. The Occupational Safety and Health Administration requires that employers make available to persons immunocompromised because of immune deficiencies, HIV infection, leukemia, lymphoma, generalized malignancy, or persons receiving immunosuppressive therapy with corticosteroids, antilymphing drugs, antimetabolites, or persons receiving radiation.

<sup>†</sup> Persons immunocompromised because of immune deficiencies, HIV infection, leukemia, lymphoma, generalized malignancy, or persons receiving immunosuppressive therapy with corticosteroids, antilymphing drugs, antimetabolites, or persons receiving radiation.

<sup>‡</sup> Vaccination of pregnant women after the first trimester might be preferred to avoid coincidental association with spontaneous abortions, which are most common during the first trimester. However, no adverse fetal effects have been associated with influenza vaccination.

<sup>§</sup> A live attenuated influenza vaccine (LAIV) is FDA-approved for healthy persons aged 5–49 years. Because of the possibility of transmission of vaccine virus as from recipients of LAIV to other persons and in the absence of data on the risk of illness and among immunocompromised persons infected with LAIV viruses, the inactivated influenza vaccine is preferred for HCP who have close contact with immunocompromised persons.

## 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† High temperature	Steam, dry heat, unsaturated chemical vapor	Heat-tolerant critical and semicritical	Not applicable
		Low temperature	Ethylene oxide gas, plasma sterilization	Heat-sensitive critical and semicritical	
		Liquid immersion‡	Chemical sterilants: glutaraldehyde, glutaraldehyde with phenol, hydrogen peroxide, hydrogen peroxide with peracetic acid, peracetic acid	Heat-sensitive critical and semicritical	
High-level disinfection	Destroys all microorganisms, but not necessarily high numbers of bacterial spores.	Heat-automated†	Washer-disinfector	Heat-sensitive semicritical	Not applicable
		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, including <i>Mycobacterium bovis</i> . <sup>§</sup> 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	Critical contact surfaces; blood spill on housekeeping surfaces
Low-level disinfection	Destroys the majority of vegetative bacteria, certain fungi, and viruses. Does not include <i>Mycobacterium bovis</i> . <sup>§</sup>	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 critical contact surfaces (e.g., quaternary ammonium compounds, some phenolics, some iodophors)	Noncritical without visible blood	Critical 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/oppoed01/chemreg/ndr.html>, 2) <http://www.fda.gov/cdrh/ndr.html>, and 3) <http://www.fda.gov/cdrh/ndr.html>.

<sup>†</sup> 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 disinfection as a sterilant used under the same contact conditions as sterilization except for a shorter immersion time (C-1).

<sup>‡</sup> 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 such less resistant organisms, including bloodborne pathogens (e.g., HIV, hepatitis C virus [HCV], and HTLV). 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.

<sup>§</sup> 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 600 ppm to 800 ppm of chlorine (1:100 dilution of 5.25% bleach and tap water, or approximately 1/2 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 *Salmoneilla 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/ocd/397.pdf>
- C-2. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. Occupational exposure to bloodborne

pathogens; needles/sharps 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.osta.gov/SITC/density/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).



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1. Read this *MMWR* (Vol. 52, RR-17), which contains the correct answers to the questions beginning on the next page.
2. Go to the *MMWR* Continuing Education Internet site at <http://www.cdc.gov/mmwr/cme/conted.html>.
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4. Fill out and submit the registration form.
5. Select exam questions. To receive continuing education credit, you must answer all of the questions. Questions with more than one correct answer will instruct you to "indicate all that apply."
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7. Immediately print your Certificate of Completion for your records.

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1. Read this *MMWR* (Vol. 52, RR-17), which contains the correct answers to the questions beginning on the next page.
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**Goal and Objectives**

This *MMWR* provides recommendations regarding infection control practices for dentistry settings. These recommendations were prepared by CDC staff after consultation with staff from other federal agencies and specialists in dental infection control. The goal of this report is to minimize the risk of disease transmission in dental health-care settings through improved understanding and practice of evidence-based infection control strategies. Upon completion of this continuing education activity, the reader should be able to 1) list the major components of a personnel health infection-control program in the dental setting; 2) list key measures for preventing transmission of bloodborne pathogens; 3) describe key elements of instrument processing and sterilization; 4) describe dental water quality concepts; and 5) demonstrate the importance of developing an infection-control program evaluation.

To receive continuing education credit, please answer all of the following questions.

1. The components of a personnel health infection control program in a dental setting should include which of the following?
  - A. Infection control education and training for dental staff.
  - B. Appropriate immunizations against vaccine-preventable diseases.
  - C. Exposure prevention and postexposure management strategies.
  - D. Policies regarding work-related illness and work restrictions.
  - E. Confidentiality of work-related medical evaluations for dental staff.
  - F. All of the above.
2. Which of the following is true regarding standard infection-control precautions?
  - A. Standard precautions are strategies used to reduce the risk of transmission of pathogens in the health-care setting.
  - B. Standard precautions should be used in caring for all patients, regardless of their infectious status.
  - C. Expanded or transmission-based precautions are used beyond standard precautions to interrupt the spread of certain pathogens.
  - D. Standard precautions apply to exposure to blood, all body fluids and secretions (except sweat), nonintact skin, and mucous membranes.
  - E. All of the above.
  - F. None of the above.
3. Factors to consider in assessing need for follow-up after an occupational blood or body fluid exposure include...
  - A. the type of exposure.
  - B. the type of body fluid.
  - C. the bloodborne pathogen infection status of the source.
  - D. the susceptibility of the exposed person.
  - E. all of the above.
  - F. none of the above.
4. Which of the following is not usually worn as personal protective equipment when anticipating splatter of blood or body fluids?
  - A. Jacket with long sleeves.
  - B. Gloves.
  - C. Head covering.
  - D. Protective eyewear or face shield.
  - E. Face mask.
5. Which of the following is not true regarding gloves?
  - A. Certain hand lotions can affect the integrity of gloves.
  - B. Wearing gloves replaces the need for handwashing.
  - C. Sterile surgical gloves are recommended for oral surgical procedures.
  - D. The Food and Drug Administration (FDA) has identified glove failure rates for manufacturers.
  - E. Certain glove materials can interfere with the setting of impression materials.
6. Which of the following statements regarding processing of contaminated instruments is true?
  - A. Instruments should be processed in an area separate from where clean instruments are stored.
  - B. Personnel should wear heavy-duty utility gloves.
  - C. Instruments only need cleaning if they have visible contamination.
  - D. Instruments should be heat-sterilized unless they are heat-sensitive.
  - E. Cleaning an instrument precedes all sterilization and disinfection processes.
  - F. A, B, D, and E are correct.
7. Which of the following statements is true regarding monitoring the correct functioning of a sterilizer?
  - A. A chemical indicator should be placed in a visible area of the package before sterilization processing.
  - B. A biological indicator spore test should be processed through a sterilizer cycle at least once a week.
  - C. A biological indicator control test matching the same lot of the spore test should be submitted with the sterilizer spore test.
  - D. Mechanical assessment of sterilizer cycle time and temperature should be monitored.
  - E. All of the above.
8. Low- to intermediate-level disinfectants used to clean environmental surfaces... (indicate all that apply)
  - A. rapidly inactivate human immunodeficiency virus and hepatitis B virus on clinical contact and housekeeping surfaces.
  - B. must be FDA-registered.
  - C. are used after prompt removal of blood or body substance contamination on a surface.
  - D. are appropriate to disinfect floors, depending on type of contamination.
  - E. all of the above.
  - F. A, C, and D are correct.
9. Which of the following statements is true regarding dental unit waterlines?
  - A. If municipal water is the source that enters the dental unit waterline, output will always meet drinking water quality.
  - B. Flushing the waterlines for 20 minutes at the beginning of the day reduces the biofilm in the waterlines.
  - C. Dentists should consult with the manufacturer of the dental unit or water delivery system to determine the best method for maintaining optimal water quality.
  - D. Dental unit waterlines can reliably deliver optimal water quality when used for irrigation during a surgical procedure.
  - E. All of the above.
  - F. A, B, and D are correct.
10. Which of the following is true regarding a dental clinic infection control program evaluation?
  - A. A method to ensure a safe working environment should be in place to reduce the risk of health-care-associated infections among patients and occupational exposures among dental health-care personnel.
  - B. Evaluation of a program should include documenting periodic observational assessments, reviewing completed checklists, and reviewing occupational exposures.
  - C. An evaluation program does not improve an infection control program.
  - D. A and B are correct.
  - E. A and C are correct.
  - F. All of the above.
11. Indicate your work setting.
  - A. Private dental practice.
  - B. Hospital dental setting.
  - C. Academic institution.
  - D. Laboratory.
  - E. Other public health setting.
  - F. Other.

12. Which best describes your professional activities?
- A. Dentist
  - B. Dental hygienist
  - C. Dental laboratory staff
  - D. Dental office staff
  - E. Other medical profession.
13. I plan to use these recommendations as the basis for... (Indicate all that apply)
- A. health education material
  - B. insurance reimbursement policies
  - C. local practice guidelines
  - D. public policy
  - E. other
14. Each month, approximately how many dental patients do you treat?
- A. None
  - B. 1-10
  - C. 11-50
  - D. 51-100
  - E. 101-200
  - F. >200
15. How much time did you spend reading this report and completing the exam?
- A. <2.0 hours
  - B. >2.0 hours but <3.0 hours
  - C. >3.0 hours but <4.0
  - D. >4.0 hours
16. After reading this report, I am confident I can list the major components of a personnel health infection control program in the dental setting.
- A. Strongly agree
  - B. Agree
  - C. Neither agree nor disagree
  - D. Disagree
  - E. Strongly disagree

17. After reading this report, I am confident I can list key measures for preventing transmission of bloodborne pathogens.
- A. Strongly agree
  - B. Agree
  - C. Neither agree nor disagree
  - D. Disagree
  - E. Strongly disagree
18. After reading this report, I am confident I can describe key elements of instrument processing and sterilization.
- A. Strongly agree
  - B. Agree
  - C. Neither agree nor disagree
  - D. Disagree
  - E. Strongly disagree
19. After reading this report, I am confident I can describe dental water quality concepts.
- A. Strongly agree
  - B. Agree
  - C. Neither agree nor disagree
  - D. Disagree
  - E. Strongly disagree
20. After reading this report, I am confident I can demonstrate the importance of developing an infection-control program evaluation.
- A. Strongly agree
  - B. Agree
  - C. Neither agree nor disagree
  - D. Disagree
  - E. Strongly disagree
21. The objectives are relevant to the goal of this report.
- A. Strongly agree
  - B. Agree
  - C. Neither agree nor disagree
  - D. Disagree
  - E. Strongly disagree

22. The teaching strategies used in this report (text, figures, boxes, and tables) were useful.
- A. Strongly agree
  - B. Agree
  - C. Neither agree nor disagree
  - D. Disagree
  - E. Strongly disagree
23. Overall, the presentation of the report enhanced my ability to understand the material.
- A. Strongly agree
  - B. Agree
  - C. Neither agree nor disagree
  - D. Disagree
  - E. Strongly disagree
24. These recommendations will affect my practice.
- A. Strongly agree
  - B. Agree
  - C. Neither agree nor disagree
  - D. Disagree
  - E. Strongly disagree
25. The content of this activity was appropriate for my educational needs.
- A. Strongly agree
  - B. Agree
  - C. Neither agree nor disagree
  - D. Disagree
  - E. Strongly disagree
26. The availability of continuing education credit influenced my decision to read this report.
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  - B. Agree
  - C. Neither agree nor disagree
  - D. Disagree
  - E. Strongly disagree
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  - F. Other

(Continued on pg CE-4)

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# Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

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This guideline discusses use of products by healthcare personnel in healthcare settings such as hospitals, ambulatory care and home care; the recommendations are not intended for consumer use of the products discussed.

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**EXECUTIVE SUMMARY**

The Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, presents evidence-based recommendations on the preferred methods for cleaning, disinfection and sterilization of patient-care medical devices and for cleaning and disinfecting the healthcare environment. This document supersedes the relevant sections contained in the 1985 Centers for Disease Control (CDC) Guideline for Handwashing and Environmental Control.<sup>1</sup> Because maximum effectiveness from disinfection and sterilization results from first cleaning and removing organic and inorganic materials, this document also reviews cleaning methods. The chemical disinfectants discussed for patient-care equipment include alcohols, glutaraldehyde, formaldehyde, hydrogen peroxide, iodophors, ortho-phthalaldehyde, peracetic acid, phenolics, quaternary ammonium compounds, and chloroxes. The choice of disinfectant, concentration, and exposure time is based on the risk for infection associated with use of the equipment and other factors discussed in this guideline. The sterilization methods discussed include steam sterilization, ethylene oxide (ETO), hydrogen peroxide gas plasma, and liquid peracetic acid. When properly used, these cleaning, disinfection, and sterilization processes can reduce the risk for infection associated with use of invasive and noninvasive medical and surgical devices. However, for these processes to be effective, health-care workers should adhere strictly to the cleaning, disinfection, and sterilization recommendations in this document and to instructions on product labels.

In addition to updated recommendations, new topics addressed in this guideline include 1) inactivation of antibiotic-resistant bacteria, bioterrorist agents, emerging pathogens, and bloodborne pathogens; 2) toxicologic, environmental, and occupational concerns associated with disinfection and sterilization practices; 3) disinfection of patient-care equipment used in ambulatory settings and home care; 4) new sterilization processes, such as hydrogen peroxide gas plasma and liquid peracetic acid; and 5) disinfection of complex medical instruments (e.g., endoscopes).

**INTRODUCTION**

In the United States, approximately 48.5 million surgical procedures and even more invasive medical procedures—including approximately 5 million gastrointestinal endoscopies—are performed each year.<sup>2</sup> Each procedure involves contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogens that can lead to infection. Failure to properly disinfect or sterilize equipment carries not only risk associated with breach of host barriers but also risk for person-to-person transmission (e.g., hepatitis B virus) and transmission of environmental pathogens (e.g., *Pseudomonas aeruginosa*).

Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Because sterilization of all patient-care items is not necessary, health-care policies must identify, primarily on the basis of the items' intended use, whether cleaning, disinfection, or sterilization is indicated.

Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization.<sup>3-12</sup> Failure to comply with scientifically-based guidelines has led to numerous outbreaks.<sup>4-12</sup> This guideline presents a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes; the approach is based on well-designed studies assessing the efficacy (through laboratory investigations) and effectiveness (through clinical studies) of disinfection and sterilization procedures.

**METHODS**

This guideline resulted from a review of all MEDLINE articles in English listed under the MeSH headings of *disinfection* or *sterilization* (focusing on health-care equipment and supplies) from January 1990 through August 2006. References listed in these articles also were reviewed. Selected articles published before 1990 were reviewed and, if still relevant, included in the guideline. The three major peer-reviewed journals in infection control—*American Journal of Infection Control*, *Infection Control and Hospital Epidemiology*, and *Journal of Hospital Infection*—were searched for relevant articles published from January 1990 through August 2006. Abstracts presented at the annual meetings of the Society for Healthcare Epidemiology of America and Association for professionals in Infection Control and Epidemiology, Inc. during 1997–2006 also were reviewed; however, abstracts were not used to support the recommendations.

**DEFINITION OF TERMS**

*Sterilization* describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, ETO gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health-care facilities. Sterilization is intended to convey an absolute meaning; unfortunately, however, some health professionals and the technical and commercial literature refer to "disinfection" as "sterilization" and items as "partially sterile." When chemicals are used to destroy all forms of microbiologic life, they can be called chemical sterilants. These same germicides used for shorter exposure periods also can be part of the disinfection process (i.e., high-level disinfection).

*Disinfection* describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects (Tables 1 and 2). In health-care settings, objects usually are disinfected by liquid chemicals or wet pasteurization. Each of the various factors that affect the efficacy of

disinfection can nullify or limit the efficacy of the process.

Factors that affect the efficacy of both disinfection and sterilization include prior clearing of the object; organic and inorganic load present; type and level of microbial contamination; concentration of and exposure time to the germicide; physical nature of the object (e.g., cravices, hinges, and lumens); presence of biofilms; temperature and pH of the disinfection process; and in some cases, relative humidity of the sterilization process (e.g., ethylene oxide).

Unlike sterilization, disinfection is not sporidial. A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called *chemical sterilants*. At similar concentrations but with shorter exposure periods (e.g., 20 minutes for 2% glutaraldehyde), these same disinfectants will kill all microorganisms except large numbers of bacterial spores; they are called *high-level disinfectants*. *Low-level disinfectants* can kill most vegetative bacteria, some fungi, and some viruses in a practical period of time (≤10 minutes). *Intermediate-level disinfectants* might be ideal for mycobacteria, vegetative bacteria, most viruses, and most fungi but do not necessarily kill bacterial spores. Germicides differ markedly, primarily in their antimicrobial spectrum and rapidity of action.

Cleaning is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. Decontamination removes pathogenic microorganisms from objects so they are safe to handle, use, or discard.

Terms with the suffix *cide* or *cidal* for killing action also are commonly used. For example, a *germicide* is an agent that can kill microorganisms, particularly pathogenic organisms ("germs"). The term *germicide* includes both antiseptics and disinfectants. *Antiseptics* are germicides applied to living tissue and skin; *disinfectants* are antimicrobials applied only to inanimate objects. In general, antiseptics are used only on the skin and not for surface disinfection, and disinfectants are not used for skin antiseptics because they can injure skin and other tissues. *Virucide*, *fungicide*, *bactericide*, *sporicide*, and *tuberculocide* can kill the type of microorganism identified by the prefix. For example, a *bactericide* is an agent that kills bacteria.

A RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

More than 30 years ago, Earle H. Spaulding devised a rational approach to disinfection and sterilization of patient-care items and equipment.<sup>14</sup> This classification scheme is so clear and logical that it has been refined, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization.<sup>15,16,17,18,19</sup> Spaulding believed the nature of disinfection could be understood readily if instruments and items for patient care were categorized as critical, semicritical, and noncritical according to the degree of risk for infection involved in use of the items. The CDC *Guideline for Handwashing and Hospital Environmental Control*,<sup>21</sup> *Guidelines for the Prevention of Transmission of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) to Health-Care and Public-Safety Workers*,<sup>22</sup> and *Guidelines for Environmental Infection Control in Health-Care Facilities*<sup>23</sup> employ this terminology.

Critical Items

Critical items confer a high risk for infection if they are contaminated with any microorganism. Thus, objects that enter sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. Most of the items in this category should be purchased as sterile or be sterilized with steam if possible. Heat-sensitive objects can be treated with EO, hydrogen peroxide gas plasma; or if other methods are unusable, by liquid chemical sterilants. Germicides categorized as chemical sterilants include 2.4% glutaraldehyde-based formulations, 0.86% glutaraldehyde with 1.64% phenolphthalein, 7.5% stabilized hydrogen peroxide, 7.5% hydrogen peroxide with 0.23% peracetic acid, 0.2% peracetic acid, and 0.08% peracetic acid with 1.0% hydrogen peroxide. Liquid chemical sterilants reliably produce sterility only if cleaning precedes treatment and if proper guidelines are followed regarding concentration, contact time, temperature, and pH.

Semicritical Items

Semicritical items contact mucous membranes or nonintact skin. This category includes respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades,<sup>24</sup> esophageal manometry probes, cystoscopes,<sup>25</sup> anorectal manometry catheters, and diaphragm fitting rings. These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are permissible. Intact mucosa membranes, such as those of the lungs and the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria, and viruses. Semicritical items minimally require high-level disinfection using chemical disinfectants. Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, and peracetic acid with hydrogen peroxide are cleared by the Food and Drug Administration (FDA) and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met (Table 1). When a disinfectant is selected for use with certain patient-care items, the chemical compatibility after extended use with the items to be disinfected also must be considered.

High-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The FDA definition of high-level disinfection is a sterilant used for a shorter contact time to achieve a 6-log<sub>10</sub> kill of an appropriate *Mycobacterium* species. Cleaning followed by high-level disinfection should eliminate enough pathogens to prevent transmission of infection.<sup>26,27</sup>

Laparoscopes and arthroscopes entering sterile tissue ideally should be sterilized between patients. However, in the United States, this equipment sometimes undergoes only high-level disinfection between patients.<sup>28,29</sup> As with flexible endoscopes, these devices can be difficult to clean and high-level disinfect or sterilize because of intricate device design (e.g., long narrow lumens, hinges), meticulous

cleaning must precede any high-level disinfection or sterilization process. Although sterilization is preferred, no reports have been published of outbreaks resulting from high-level disinfection of these scopes when they are properly cleaned and high-level disinfected. Newer models of these instruments can withstand steam sterilization that for critical items would be preferable to high-level disinfection.

Rinsing endoscopes and flushing channels with sterile water, filtered water, or tap water will prevent adverse effects associated with disinfectant retained in the endoscope (e.g., disinfectant-induced colitis). Items can be rinsed and flushed using sterile water after high-level disinfection to prevent contamination with organisms in tap water, such as nontuberculous mycobacteria,<sup>30,31,32</sup> Legionella,<sup>33,34</sup> or gram-negative bacilli such as *Pseudomonas*.<sup>35,37,38,39</sup> Alternatively, a tapwater or filtered water (0.2µ filter) rinse should be followed by an alcohol rinse and forced air drying.<sup>28,34,40</sup> Forced-air drying markedly reduces bacterial contamination of stored endoscopes, most likely by removing the wet environment favorable for bacterial growth.<sup>29</sup> After rinsing, items should be dried and stored (e.g., packaged) in a manner that protects them from recontamination.

Some items that may come in contact with nonintact skin for a brief period of time (e.g., hydrotherapy tanks, bed side rails) are usually considered noncritical surfaces and are disinfected with intermediate-level disinfectants (i.e., phenolic, iodophor, alcohol, chlorine).<sup>23</sup> Since hydrotherapy tanks have been associated with spread of infection, some facilities have chosen to disinfect them with recommended levels of chlorine.<sup>22,41</sup>

In the past, high-level disinfection was recommended for mouthpieces and splanometry tubing (e.g., glutaraldehyde) but cleaning the interior surfaces of the splanometer was considered unnecessary.<sup>42</sup> This was based on a study that showed that mouthpieces and splanometry tubing become contaminated with microorganisms but there was no bacterial contamination of the surfaces inside the splanometer. Filters have been used to prevent contamination of this equipment distal to the filter; such filters and the proximal mouthpiece are changed between patients.

Noncritical Items

Noncritical items are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is "not critical." In this guideline, noncritical items are divided into noncritical patient care items and noncritical environmental surfaces.<sup>43,44</sup> Examples of noncritical patient care items are bedpans, blood pressure cuffs, crutches and computers.<sup>45</sup> In contrast to critical and some semicritical items, most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. Virtually no risk has been documented for transmission of infectious agents to patients through noncritical items.<sup>46</sup> When they are used as noncritical items and do not contact non-intact skin and/or mucous membranes, Table 1 lists several low-level disinfectants that may be used for noncritical items. Most Environmental Protection Agency (EPA)-registered disinfectants have a 10-minute label claim. However, multiple investigators have demonstrated the effectiveness of these disinfectants against vegetative bacteria (e.g., *Listeria*, *Escherichia coli*, *Salmonella*, vancomycin-resistant Enterococci, methicillin-resistant *Staphylococcus aureus*), yeasts (e.g., *Candida*), mycobacteria (e.g., *Mycobacterium tuberculosis*), and viruses (e.g., poliovirus) at exposure times of 30–60 seconds.<sup>44</sup> Federal law requires all applicable label instructions on EPA-registered products to be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use, and disposal). If the user selects exposure conditions (e.g., exposure time) that differ from those on the EPA-registered product label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).<sup>46</sup>

Noncritical environmental surfaces include bed rails, some food utensils, bedside tables, patient furniture and floors. Noncritical environmental surfaces frequently touched by hand (e.g., bedside tables,

bed rails) potentially could contribute to secondary transmission by contaminating hands of health-care workers or by contacting medical equipment that subsequently contacts patients.<sup>47,48,49,50,51,52</sup> Mops and reusable cleaning cloths are regularly used to achieve low-level disinfection on environmental surfaces. However, they often are not adequately cleaned and disinfected, and if the water-disinfectant mixture is not changed regularly (e.g., after every three to four rooms, at no longer than 60-minute intervals), the mopping procedure actually can spread heavy microbial contamination throughout the health-care facility.<sup>53</sup> In one study, standard laundering provided acceptable decontamination of heavily contaminated mopheads but chemical disinfection with a phenolic was less effective.<sup>54</sup> Frequent laundering of mops (e.g., daily), therefore, is recommended. Single-use disposable towels impregnated with a disinfectant also can be used for low-level disinfection when spot-cleaning of noncritical surfaces is needed.<sup>55</sup>

Changes in Disinfection and Sterilization Since 1981

The Table in the CDC *Guideline for Environmental Control* prepared in 1981 as a guide to the appropriate selection and use of disinfectants has undergone several important changes (Table 1).<sup>23</sup> First, formaldehyde-alcohol has been deleted as a recommended chemical sterilant or high-level disinfectant because it is irritating and toxic and not commonly used. Second, several new chemical sterilants have been added, including hydrogen peroxide, peracetic acid,<sup>56,56,57</sup> and peracetic acid and hydrogen peroxide in combination. Third, 3% phenolics and iodophors have been deleted as high-level disinfectants because of their unproven efficacy against bacterial spores, *M. tuberculosis*, and/or some fungi.<sup>58,59</sup> Fourth, isopropyl alcohol and ethyl alcohol have been excluded as high-level disinfectants because of their inability to inactivate bacterial spores and because of the inability of isopropyl alcohol to inactivate hydrophilic viruses (i.e., poliovirus, coxsackievirus).<sup>60</sup> Fifth, a 1:18 dilution of 2.0% glutaraldehyde-7.05% phenol-1.20% sodium phenate (which contained 0.125% glutaraldehyde, 0.440% phenol, and 0.076% sodium phenate when diluted) has been deleted as a high-level disinfectant because this product was removed from the marketplace in December 1991 because of a lack of bactericidal activity in the presence of organic matter; a lack of fungicidal, tuberculocidal and sporidial activity; and reduced virucidal activity.<sup>61,62,63,63,64</sup> Sixth, the exposure time required to achieve high-level disinfection has been changed from 10–30 minutes to 12 minutes or more depending on the FDA-cleared label claim and the scientific literature.<sup>27,56,57,76,76,76</sup> A glutaraldehyde and an ortho-phthalaldehyde have an FDA-cleared label claim of 5 minutes when used at 35°C and 25°C, respectively, in an automated endoscope reprocessor with FDA-cleared capability to maintain the solution at the appropriate temperatures.<sup>65</sup>

In addition, many new subjects have been added to the guideline. These include inactivation of emerging pathogens, bioterrorist agents, and bloodborne pathogens; biologic, environmental, and occupational concerns associated with disinfection and sterilization practices; disinfection of patient-care equipment used in ambulatory and home care; inactivation of antibiotic-resistant bacteria; new sterilization processes, such as hydrogen peroxide gas plasma and liquid peracetic acid; and disinfection of complex medical instruments (e.g., endoscopes).

## DISINFECTING OF HEALTHCARE EQUIPMENT

## Concerns about Implementing the Spaulding Scheme

One problem with implementing the aforementioned scheme is oversimplification. For example, the scheme does not consider problems with reprocessing of complicated medical equipment that often is heat-sensitive or prone to inactivating certain types of infectious agents (e.g., prions, such as Creutzfeldt-Jakob disease [CJD] agent). Thus, in these situations, choosing a method of disinfection remains difficult, even after consideration of the categories of risk to patients. This is true particularly for medical devices (e.g., endoscopes, laparoscopes) in the critical category because of controversy about whether they should be sterilized or high-level disinfected.<sup>28,29</sup> Heat-stable scopes (e.g., many rigid scopes) should be steam sterilized. Some of these items cannot be steam sterilized because they are heat-sensitive; additionally, sterilization using ethylene oxide (EtO) can be too time-consuming for routine use between patients (new technologies, such as hydrogen peroxide gas plasma and peracetic acid reprocessor, provide faster cycle times). However, evidence that sterilization of these items improves patient care by reducing the infection risk is lacking.<sup>28,29,31</sup> Many newer models of these instruments can withstand steam sterilization, which for critical items is the preferred method.

Another problem with implementing the Spaulding scheme is processing of an instrument in the semicritical category (e.g., endoscope) that would be used in conjunction with a critical instrument that contacts sterile body tissues. For example, is an endoscope used for upper gastrointestinal tract investigation still a semicritical item when used with sterile biopsy forceps or in a patient who is bleeding heavily from esophageal varices? Provided that high-level disinfection is achieved, and all microorganisms except bacterial spores have been removed from the endoscope, the device should not represent an infection risk and should remain in the semicritical category.<sup>28,29</sup> Infection with spore-forming bacteria has not been reported from appropriately high-level disinfected endoscopes.

An additional problem with implementation of the Spaulding system is that the optimal contact time for high-level disinfection has not been defined or varies among professional organizations, resulting in different strategies for disinfecting different types of semicritical items (e.g., endoscopes, application bronchoscopes, endovascular transducers, cryosurgical instruments, and diagnostic filing rings). Until simpler and effective alternatives are identified for device disinfection in clinical settings, following this guideline, other CDC guidelines,<sup>1,22,29,30</sup> and FDA-cleared instructions for use liquid chemical sterilants/high-level disinfectants would be prudent.

## Reprocessing of Endoscopes

Physicians use endoscopes to diagnose and treat numerous medical disorders. Even though endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine, the incidence of infection associated with their use reportedly is very low (about 1 in 1.8 million procedures),<sup>32</sup> more healthcare-associated outbreaks have been linked to contaminated endoscopes than to any other medical device.<sup>6,4,12,33</sup> To prevent the spread of health-care-associated infections, all heat-sensitive endoscopes (e.g., gastrointestinal endoscopes, bronchoscopes, nasopharyngoscopes) must be properly cleaned and, at a minimum, subjected to high-level disinfection after each use. High-level disinfection can be expected to destroy all microorganisms, although when high numbers of bacterial spores are present, a few spores might survive.

Because of the types of body cavities they enter, flexible endoscopes acquire high levels of microbial contamination (bioburden) during each use.<sup>34</sup> For example, the bioburden found on flexible gastrointestinal endoscopes after use has ranged from 10<sup>7</sup> colony forming units (CFU)/mL to 10<sup>10</sup> CFU/mL, with the highest levels found in the suction channels.<sup>35,36</sup> The average load on bronchoscopes before cleaning was 0.4x10<sup>7</sup> CFU/mL. Cleaning reduces the level of microbial contamination by 4–6 log<sub>10</sub>.<sup>37,38</sup> Using human immunodeficiency virus-contaminated endoscopes, several investigators have shown that cleaning completely eliminates the microbial contamination on the scopes.<sup>39,40</sup> Similarly, other investigators found that EtO sterilization or soaking in 2% glutaraldehyde for 20 minutes was effective only when the device first was properly cleaned.<sup>41</sup>

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FDA maintains a list of cleared liquid chemical sterilants and high-level disinfectants that can be used to reprocess sensitive medical devices, such as flexible endoscopes (<http://www.fda.gov/cdrh/ode/chem/chem.htm>). At this time, the FDA-cleared and marketed formulations include: 2.4% glutaraldehyde, 0.55% ortho-phthalaldehyde (OPA), 0.95% glutaraldehyde with 1.04% phenol/phenate, 7.35% hydrogen peroxide with 0.23% peracetic acid, 1.0% hydrogen peroxide with 0.08% peracetic acid, and 7.5% hydrogen peroxide.<sup>42</sup> These products have excellent antimicrobial activity; however, some oxidizing chemicals (e.g., 7.5% hydrogen peroxide, and 1.0% hydrogen peroxide with 0.08% peracetic acid [after product is no longer marketed]) reportedly have caused cosmetic and functional damage to endoscopes.<sup>43</sup> Users should check with device manufacturers for information about peroxide compatibility with their device. If the germicide is FDA-cleared, then it is safe when used according to label directions; however, professionals should review the scientific literature for newly available data regarding human safety or materials compatibility. EtO sterilization of flexible endoscopes is infrequent because it requires a lengthy processing and aeration time (e.g., 12 hours) and is a potential hazard to staff and patients. The two products most commonly used for reprocessing endoscopes in the United States are glutaraldehyde and an automated, liquid chemical sterilization process that uses peracetic acid.<sup>42</sup> The American Society for Gastrointestinal Endoscopy (ASGE) recommends glutaraldehyde solutions that do not contain surfactants because the soapy residues of surfactants are difficult to remove during rinsing.<sup>44</sup> Ortho-phthalaldehyde has begun to replace glutaraldehyde in many health-care facilities because it has several potential advantages over glutaraldehyde: it is not known to irritate the eyes and nasal passages, does not require activation or exposure monitoring, and has a 12-minute high-level disinfection claim in the United States.<sup>45</sup> Disinfectants that are not FDA-cleared and should not be used for reprocessing endoscopes include iodophors, chlorine solutions, alcohols, quaternary ammonium compounds, and phenolics. These solutions might still be in use outside the United States, but their use should be strongly discouraged because of lack of proven efficacy against all microorganisms or materials incompatibility.

FDA clearance of the contact conditions listed on germicide labeling is based on the manufacturer's test results (<http://www.fda.gov/cdrh/ode/chem/chem.htm>). Manufacturers test the product under worst-case conditions for germicide formulation (i.e., minimum recommended concentration of the active ingredient), and include organic soil. Typically manufacturers use 5% serum as the organic soil and which the device is exposed during actual use and that would remain on the device in the absence of cleaning. This method ensures that the contact conditions completely eliminate the test microorganism (e.g., 10<sup>7</sup> to 10<sup>8</sup> *Mycobacterium tuberculosis* in organic soil and died on a scope) if inoculated in the most difficult areas for the disinfectant to penetrate and contact in the absence of cleaning and thus provides a margin of safety.<sup>46</sup> For 2.4% glutaraldehyde that requires a 45-minute immersion at 25°C to achieve high-level disinfection (i.e., 100% kill of *M. tuberculosis*), FDA itself does not conduct testing but relies solely on the disinfectant manufacturer's data. Data suggest that *M. tuberculosis* levels can be reduced by at least 8 log<sub>10</sub> units (4 to 10 log<sub>10</sub>)<sup>47,48,49,50,51,52</sup> followed by chemical disinfection for 20 minutes at 20°C (4 to 6 log<sub>10</sub>).<sup>53,54,55,56,57</sup> On the basis of these data, APIC,<sup>58</sup> the Society of Gastroenterology Nurses and Associates (SGNA),<sup>59,60,61</sup> the ASGE,<sup>62</sup> American College of Chest Physicians,<sup>63</sup> and a multi-society guideline<sup>64</sup> recommend alternative contact conditions with 2% glutaraldehyde to achieve high-level disinfection (e.g., that equipment be immersed in 2% glutaraldehyde at 20°C for at least 20 minutes for high-level disinfection). Federal regulations are to follow the FDA-cleared label claim for high-level disinfectants. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 25°C range from 20–30 minutes, depending upon the product based on three tier testing which includes AQC sporicidal tests, simulated use testing with microbials, and in-use testing. The studies supporting the efficacy of >2% glutaraldehyde for 20 minutes at 20°C assume adequate cleaning prior to disinfection, whereas the FDA-cleared label claim incorporates an added margin of safety to accommodate possible lapses in cleaning practices. Facilities that have chosen to apply the 20 minute duration at 20°C have done so based on the IA recommendation in the July 2003 SHEA position paper, "Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes."<sup>19,32,33,34,36,38,41,64,65</sup>

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Flexible endoscopes are particularly difficult to disinfect<sup>122</sup> and easy to damage because of their intricate design and delicate materials.<sup>123</sup> Meticulous cleaning must precede any sterilization or high-level disinfection of these instruments. Failure to perform good cleaning can result in sterilization or disinfection failure, and outbreaks of infection can occur. Several studies have demonstrated the importance of cleaning in experimental studies with the duck hepatitis B virus (HBV)<sup>124,125</sup>, HIV<sup>126</sup> and *Helicobacter pylori*.

An examination of health-care-associated infections related only to endoscopes through July 1992 found 281 infections transmitted by gastrointestinal endoscopy and 95 transmitted by bronchoscopy. The clinical spectrum ranged from asymptomatic colonization to death. *Salmonella* species and *Pseudomonas aeruginosa* repeatedly were identified as causative agents of infections transmitted by gastrointestinal endoscopy, and *M. tuberculosis*, atypical mycobacteria, and *P. aeruginosa* were the most common causes of infections transmitted by bronchoscopy.<sup>74</sup> Major reasons for transmission were inadequate cleaning, improper selection of a disinfecting agent, and failure to follow recommended cleaning and disinfection procedures.<sup>74,75,76</sup> and flaws in endoscope design.<sup>74,75,76</sup> or automated endoscope reprocessors.<sup>7,18</sup> Failure to follow established guidelines has continued to result in infections associated with gastrointestinal endoscopes<sup>7</sup> and bronchoscopes.<sup>7,12</sup> Potential device-associated problems should be reported to the FDA Center for Devices and Radiologic Health. One multi-site investigation found that 23.9% of the bacterial cultures from the internal channels of 71 gastrointestinal endoscopes grew >100,000 colonies of bacteria after completion of all disinfection and sterilization procedures (nine of 23 facilities were using a product that has been removed from the marketplace [six facilities using 1:10 glutaraldehyde solution], is not FDA-cleared as a high-level disinfectant [an iodophor] or no disinfecting agent) and before use in next patient.<sup>77</sup> The incidence of postendoscopic procedure infections from an improperly processed endoscope has not been rigorously assessed.

Automated endoscope reprocessors (AER) offer several advantages over manual reprocessing: they automate and standardize several important reprocessing steps<sup>128,129</sup>, reduce the likelihood that an essential reprocessing step will be skipped, and reduce personnel exposure to high-level disinfectants or chemical sterilants. Failure of AERs has been linked to outbreaks of infections<sup>130</sup> or colonization.<sup>131,132</sup> and the AER water filtration system might not be able to reliably provide "sterile" or bacteria-free rinse water.<sup>133,134</sup> Establishment of correct connectors between the AER and the device is critical to ensure complete flow of disinfectants and rinse water.<sup>7,127</sup> In addition, some endoscopes such as the duodenoscopes (e.g., endoscopic retrograde cholangiopancreatography [ERCP]) contain features (e.g., elevator-wire channel) that require a flushing pressure that is not achieved by most AERs and must be reprocessed manually using a 2- to 5-mL syringe, until new duodenoscopes equipped with a wider elevator-channel that allows for reliable reprocessing become available.<sup>135</sup> Outbreaks involving removable endoscope parts<sup>136,137</sup> such as suction valves and endoscope accessories designed to be inserted through flexible endoscopes such as biopsy forceps emphasize the importance of cleaning to remove all foreign matter before high-level disinfection or sterilization.<sup>140</sup> Some types of valves are now available as single-use, disposable products (e.g., bronchoscopy valves) or steam sterilizable products (e.g., gastrointestinal endoscope valves).

AERs need further development and redesign.<sup>7,141</sup> as do endoscopes<sup>123,142</sup>, so that they do not represent a potential source of infectious agents. Endoscopes employing disposable components (e.g., protective barrier devices or sheaths) might provide an alternative to conventional liquid chemical high-level disinfection/sterilization.<sup>143,144</sup> Another new technology is a swallowable camera-in-a-capsule that travels through the digestive tract and transmits color pictures of the small intestine to a receiver worn outside the body. This capsule currently does not replace colonoscopies.

Published recommendations for cleaning and disinfecting endoscopic equipment should be strictly followed.<sup>19,32,33,119,144,145</sup> Unfortunately, audits have shown that personnel do not consistently adhere to guidelines on reprocessing<sup>146–149</sup> and outbreaks of infection continue to occur.<sup>148,149</sup> To ensure

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reprocessing personnel are properly trained, each person who reprocesses endoscopic instruments should receive initial and annual competency testing.<sup>14,140</sup>

In general, endoscope disinfection or sterilization with a liquid chemical sterilant involves five steps after leak testing:

1. Clean: mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion).
2. Disinfect: immerse endoscope in high-level disinfectant (or chemical sterilant) and perfuse (eliminates use testing with microbials and in-use testing). The disinfectant should be introduced into all accessible channels, such as the suction/irrigation channel and air/water channel and expose for a time recommended for specific products.
3. Rinse: rinse the endoscope and all channels with sterile water, filtered water (commonly used with AERs) or tap water (i.e., high-quality potable water that meets federal clean water standards at the point of use).
4. Dry: rinse the insertion tube and inner channels with alcohol, and dry with forced air after disinfection and before storage.

Store: store the endoscope in a way that prevents recontamination and promotes drying (e.g., hang vertically). Drying the endoscope (steps 3 and 4) is essential to greatly reduce the chance of recontamination of the endoscope by microorganisms that can be present in the rinse water.<sup>119,120</sup> One study demonstrated that reprocessed endoscopes (i.e., air/water channel, suction/blowby channel) generally were negative (100% after 24 hours; 90% after 7 days [1 CFU of coagulase-negative *Staphylococcus* in one channel]) for bacterial growth when stored by hanging vertically in a ventilated cabinet.<sup>150</sup> Other investigators found all endoscopes were positive during the subsequent 5-day assessment (skin bacteria cultured from endoscope surfaces). All flush-through samples remained sterile.<sup>151</sup> Because tapwater can contain low levels of microorganisms,<sup>152</sup> some researchers have suggested that only sterile water (which can be prohibitively expensive)<sup>153</sup> or AER filtered water be used. The suggestion to use only sterile water or filtered water is not consistent with published guidelines that allow tapwater with an alcohol rinse and forced air-drying<sup>19,32,33,119,120</sup> or the scientific literature.<sup>154,155</sup> In addition, no evidence of disease transmission has been found when tap water rinse is followed by an alcohol rinse and forced-air drying. AERs produce filtered water by passage through a bacterial filter (e.g., 0.2 µm). Filtered rinse water was identified as a source of bacterial contamination in a study that cultured the accessory and suction channels of endoscopes and the internal channels of AERs during 1998–2001 and reported 8.7% of samples collected during 1998–1998 had bacterial growth, with 54% being *Pseudomonas* species. After a system of hot water flushing of the piping (60°C for 80 minutes) was introduced, the frequency of positive cultures fell to approximately 2% with only rare isolation of >10 CFU/mL.<sup>161</sup> In know whether an endoscope has been appropriately cleaned and disinfected (e.g., using a room or healthcare facility personnel can consider random bacterial surveillance cultures of processed endoscopes to ensure high-level disinfection or sterilization.<sup>162,163</sup> Reprocessed endoscopes that represent exogenous environmental contamination (e.g., coagulase-negative *Staphylococcus*, *Bacillus* species, diphtheroids). Although recommendations exist for the final rinse water used during endoscope reprocessing to be microbiologically cultured at least monthly<sup>145</sup>, a microbiologic standard has not been

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set, and the value of routine endoscope cultures has not been shown.<sup>196</sup> In addition, neither the routine culture of reprocessed endoscopes nor the final rinse water has been validated by comparing viable counts on an endoscope to infection after an endoscopic procedure. If reprocessed endoscopes were cultured, sampling the endoscope would assess water quality and other important steps (e.g., disinfectant effectiveness, exposure time, cleaning) in the reprocessing procedure. A number of methods for sampling endoscopes and water have been described.<sup>197,198,199,200,201</sup> Novel approaches (e.g., detection of adenine triphosphate [ATP]) to evaluate the effectiveness of endoscope cleaning<sup>196,202</sup> or endoscope reprocessing<sup>203</sup> also have been evaluated, but no method has been established as a standard for assessing the outcome of endoscope reprocessing.

The carrying case used to transport clean and reprocessed endoscopes outside the health-care environment should not be used to store an endoscope or to transport the instrument within the health-care facility. A contaminated endoscope should never be placed in the carrying case because the case can also become contaminated. When the endoscope is removed from the case, properly reprocessed, and put back in the case, the case could recontaminate the endoscope. A contaminated carrying case should be discarded (Olympus America, June 2002, written communication).

Infection-control professionals should ensure that institutional policies are consistent with national guidelines and conduct infection-control audits periodically (e.g., at least annually) in areas where endoscopes are reprocessed to ensure policy compliance. Breaches in policy should be documented and corrective action instituted. In incidents in which endoscopes were not exposed to a high-level disinfection process, patients exposed to potentially contaminated endoscopes have been assessed for possible acquisition of HIV, HBV, and hepatitis C virus (HCV). A 14-day method for managing a failure incident associated with high-level disinfection or sterilization has been described (Rutala WA, 2006 #12512). The possible transmission of bloodborne and other infectious agents highlights the importance of rigorous infection control.<sup>172,173</sup>

**Laparoscopes and Arthroscopes**

Although high-level disinfection appears to be the minimum standard for processing laparoscopes and arthroscopes between patients<sup>204,205,206,207</sup>, this practice continues to be debated.<sup>196,198</sup> However, neither side in the high-level disinfection versus sterilization debate has sufficient data on which to base its conclusions. Proponents of high-level disinfection refer to membership surveys<sup>208</sup> or institutional experiences<sup>209</sup> involving more than 117,000 and 10,000 laparoscopic procedures, respectively, that cite a low risk for infection (<0.3%) when high-level disinfection is used for gynecologic laparoscopic equipment. Only one infection in the membership survey was linked to spores. In addition, growth of common skin microorganisms (e.g., *Staphylococcus epidermidis*, *diphtheroides*) has been documented from the umbilical area even after skin preparation with povidone-iodine and ethyl alcohol. Similar organisms were recovered in some instances from the pelvic serosal surfaces or from the laparoscopic telescopes, suggesting that the microorganisms probably were carried from the skin into the peritoneal cavity.<sup>172,173</sup> Proponents of sterilization focus on the possibility of transmitting infection by spore-forming organisms. Researchers have proposed several reasons why sterility was not necessary for all laparoscopic equipment: only a limited number of organisms (usually  $\leq 10$ ) are introduced into the peritoneal cavity during laparoscopy; minimal damage is done to inner abdominal structures with little devitalized tissue; the peritoneal cavity tolerates small numbers of spore-forming bacteria; equipment is simple to clean and disinfect; surgical sterility is relative; the natural bioflora on rigid lumined devices is low;<sup>210</sup> and no evidence exists that high-level disinfection instead of sterilization increases the risk for infection.<sup>211,212</sup> With the advent of laparoscopic cholecystectomy, concern about high-level disinfection is justifiable because the degree of tissue damage and bacterial contamination is greater than with laparoscopic procedures in gynecology. Failure to completely disassemble, clean, and high-level disinfect laparoscope parts has led to infections in patients.<sup>213</sup> Data from one study suggested that disassembly, cleaning, and proper reassembly of laparoscopic equipment used in gynecologic procedures before steam sterilization presents no risk for infection.<sup>214</sup>

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As with laparoscopes and other equipment that enter sterile body sites, arthroscopes ideally should be sterilized before used. Older studies demonstrated that these instruments were commonly (67%) only high-level disinfected in the United States.<sup>208</sup> A later survey (with a response rate of only 6%) reported that high-level disinfection was used by 31% and a sterilization process in the remainder of the health-care facilities.<sup>209</sup> High-level disinfection rather than sterilization presumably has been used because the incidence of infection is low and the few infections identified probably are unrelated to the use of high-level disinfection rather than sterilization. A retrospective study of 12,505 arthroscopic procedures found an infection rate of 0.04% (five infections) when arthroscopes were soaked in 2% glutaraldehyde for 15–20 minutes. Four infections were caused by *S. aureus*; the fifth was an anaerobic streptococcal infection.<sup>215</sup> Because these organisms are very susceptible to high-level disinfectants, such as 2% glutaraldehyde, the infections most likely originated from the patient's skin. Two cases of *Clostridium perfringens* arthritis have been reported when the arthroscope was disinfected with glutaraldehyde for an exposure time that is not effective against spores.<sup>216,217</sup>

Although only limited data are available, the evidence does not demonstrate that high-level disinfection of arthroscopes and laparoscopes poses an infection risk to the patient. For example, a prospective study that compared the reprocessing of arthroscopes and laparoscopes (per 1,000 procedures) with EIO sterilization to high-level disinfection with glutaraldehyde found no statistically significant difference in infection risk between the two methods (i.e., EIO, 7,511,000 procedures; glutaraldehyde, 2,541,000 procedures).<sup>218</sup> Although the debate for high-level disinfection versus sterilization of laparoscopes and arthroscopes will go unsettled until well-designed, randomized clinical trials are published, this guideline should be followed.<sup>172</sup> That is, laparoscopes, arthroscopes, and other scopes that enter normally sterile tissue should be sterilized before each use; if this is not feasible, they should receive at least high-level disinfection.

**Tonometers, Cervical Diaphragm Fitting Rings, Cryosurgical Instruments, and Endocavitary Probes**

Disinfection strategies vary widely for other semicritical items (e.g., application tonometers, rectal/vaginal probes, cryosurgical instruments, and diaphragm fitting rings). FDA requests that device manufacturers include at least one validated cleaning and disinfection/sterilization protocol in the labeling for their devices. As with all medications and devices, users should be familiar with the label instructions. One study revealed that no uniform technique was in use for disinfection of application tonometers, with disinfectant contact times varying from <15 sec to 20 minutes.<sup>219</sup> In view of the potential for transmission of viruses (e.g., herpes simplex virus [HSV], adenovirus 8, or HIV)<sup>220</sup> by tonometer tips, CDC recommended that the tonometer tip be wiped clean and disinfected for 5–10 minutes with either 3% hydrogen peroxide, 5000 ppm chlorine, 70% ethyl alcohol, or 70% isopropyl alcohol.<sup>221</sup> However, more recent data suggest that 3% hydrogen peroxide and 70% isopropyl alcohol are not effective against adenovirus capable of causing epidemic keratoconjunctivitis and similar viruses and should not be used for disinfecting application tonometers.<sup>222,223</sup> Structural damage to Schlotz tonometers has been observed with a 10 sodium hypochlorite (5,000 ppm chlorine) and 3% hydrogen peroxide.<sup>224</sup> After disinfection, the tonometer should be thoroughly rinsed in tapwater and air dried before use. Although these disinfectants and exposure times should kill pathogens that can infect the eyes, no study directly support this.<sup>225,226</sup> The guidelines of the American Academy of Ophthalmology for preventing infections in ophthalmology focus on only one potential pathogen: HIV.<sup>227</sup> Because a short and simple decontamination procedure is desirable in the clinical setting, swabbing the tonometer tip with a 70% isopropyl alcohol wipe sometimes is practiced.<sup>228</sup> Preliminary reports suggest that wiping the tonometer tip with an alcohol swab and then allowing the alcohol to evaporate might be effective in eliminating HSV, HIV, and adenovirus.<sup>229,230,231</sup> However, because these studies involved only a few replicates and were conducted in a controlled laboratory setting, further studies are needed before this technique can be recommended. In addition, two reports have found that disinfection of pneumoconifer tips between uses with a 70% isopropyl alcohol wipe contributed to outbreaks of epidemic keratoconjunctivitis caused

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by adenovirus type 8.<sup>232,234</sup>

Limited studies have evaluated disinfection techniques for other items that contact mucous membranes, such as diaphragm fitting rings, cryosurgical probes, transesophageal echocardiography probes,<sup>235</sup> flexible cystoscopes<sup>236</sup> or vaginal/rectal probes used in sonographic scanning. Lettau, Bond, and McDonnell of CDC supported the recommendation of a diaphragm fitting ring manufacturer that involved using a soap-and-water wash followed by a 15-minute immersion in 70% alcohol.<sup>237</sup> This disinfection method should be adequate to inactivate HIV, HBV, and HSV even though alcohol are not classified as high-level disinfectants because their activity against pleomorphic viruses is somewhat limited.<sup>238</sup> No data are available regarding inactivation of human papillomavirus (HPV) by alcohol or other disinfectants because in vitro replication of complete viruses has not been achieved. Thus, even though alcohol for 15 minutes should kill pathogens of relevance in gynecology, no clinical studies directly support this practice.

Vaginal probes are used in sonographic scanning. A vaginal probe and all endocavitary probes without a probe cover are semicritical devices because they have direct contact with mucous membranes (e.g., vagina, rectum, pharynx). While use of the probe cover could be considered as changing the category, this guideline proposes use of a new condom/probe cover for the probe for each patient, and because condom/probe covers can fail.<sup>239,240</sup> The probe also should be high-level disinfected. The relevance of this recommendation is reinforced with the findings that sterile transvaginal ultrasound probe covers have a very high rate of perforations even before use (0%, 25%, and 65% perforations from three suppliers).<sup>241</sup> One study found, after occlude retrieval use, a very high rate of perforations in used endocavitary probe covers from two suppliers (75% and 81%).<sup>242</sup> Other studies demonstrated a lower rate of perforations after use of condoms (2.0% and 0.9%)<sup>243,244</sup>. Condoms have been found superior to commercially available probe covers for covering the ultrasound probe (1.7% for condoms versus 8.3% leakage for probe covers).<sup>245</sup> These studies underscore the need for routine probe disinfection between examinations. Although most ultrasound manufacturers recommend use of 2% glutaraldehyde for high-level disinfection of contaminated transvaginal transducers, the use of this agent has been questioned because it might shorten the life of the transducer and might have toxic effects on the gametes and embryo.<sup>246</sup> An alternative procedure for disinfecting the vaginal transducer involves the mechanical removal of the gel from the transducer, cleaning the transducer in soap and water, wiping the transducer with 70% alcohol or soaking it for 2 minutes in 500 ppm chlorine, and rinsing with tap water and air drying.<sup>247</sup> The effectiveness of this and other methods<sup>248</sup> has not been validated in either rigorous laboratory experiments or in clinical use. High-level disinfection with a product (e.g., hydrogen peroxide) that is not toxic to staff, patients, probes, and retrieved cells should be used until the effectiveness of alternative procedures against microbes of importance at the cavity site is demonstrated by well-designed experimental scientific studies. Other probes such as rectal, cryosurgical, and transesophageal probes or devices also should be high-level disinfected between patients.

Ultrasound probes used during surgical procedures also can contact sterile body sites. These probes can be covered with a sterile sheath to reduce the level of contamination on the probe and reduce the risk for infection. However, because the sheath does not completely protect the probe, the probe should be sterilized between each patient use as with other critical items. If this is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.

Some cryosurgical probes are not fully immersible. During reprocessing, the tip of the probe should be immersed in a high-level disinfectant for the appropriate time; any other portion of the probe that could have mucous membrane contact can be disinfected by immersion or by wrapping with a cloth soaked in a high-level disinfectant to allow the recommended contact time. After disinfection, the probe should be rinsed with tap water and dried before use. Health-care facilities that use nonimmersible probes should replace them as soon as possible with fully immersible probes.

As with other high-level disinfection procedures, proper cleaning of probes is necessary to ensure the success of the subsequent disinfection.<sup>249</sup> One study demonstrated that vegetative bacteria

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inoculated on vaginal ultrasound probe decreased when the probe was cleaned with a towel.<sup>250</sup> No information is available about either the level of contamination of such probes by potential viral pathogens such as HBV and HPV or their removal by cleaning (such as with a towel). Because these pathogens might be present in vaginal end rectal secretions and contaminate probes during use, high-level disinfection of the probes after such use is recommended.

**Dental Instruments**

Scientific articles and increased publicity about the potential for transmitting infectious agents in dentistry have focused attention on dental instruments as possible agents for pathogen transmission.<sup>251</sup> The American Dental Association recommends that surgical and other instruments that normally penetrate soft tissue or bone (e.g., extraction forceps, scalpel blades, bone chisels, periodontal scalers, and surgical burs) be classified as critical devices that should be sterilized after each use or discarded. Instruments not intended to penetrate oral soft tissue or bone (e.g., amalgam condensers, and air/water syringes) but that could contact oral tissue are classified as semicritical, but sterilization after each use is recommended if the instruments are heat-tolerant.<sup>252</sup> If a semicritical item is heat-sensitive, it should, at a minimum, be processed with high-level disinfection.<sup>253,254</sup> Handpieces can be contaminated internally with patient material and should be heat sterilized after each patient. Handpieces that cannot be heat sterilized should not be used.<sup>255</sup> Methods of sterilization that can be used for critical or semicritical dental instruments and materials that are heat-stable include steam under pressure (autoclave), chemical (formaldehyde) vapor, and dry heat (e.g., 320°F for 2 hours). Dental professionals most commonly use the steam sterilizer.<sup>256</sup> All three sterilization procedures can damage some dental instruments, including steam-sterilized hand pieces.<sup>257</sup> Heat-tolerant alternatives are available for most clinical dental applications and are preferred.<sup>258</sup>

CDC has divided noncritical surfaces in dental offices into clinical contact and housekeeping surfaces.<sup>259</sup> Clinical contact surfaces are surfaces that might be touched frequently with gloved hands during patient care or that might become contaminated with blood or other potentially infectious material and subsequently contact instruments, hands, gloves, or devices (e.g., light handles, switches, dental X-ray equipment, chair-side computers). Barrier protective coverings (e.g., clear plastic wrap) can be used for these surfaces, particularly those that are difficult to clean (e.g., light handles, chair switches). The coverings should be changed when visibly soiled or damaged and routinely (e.g., between patients). Protected surfaces should be disinfected at the end of each day or if contamination is evident. If not barrier-protected, these surfaces should be disinfected between patients with an intermediate-disinfectant (i.e., EPA-registered hospital disinfectant with tuberculocidal claim) or low-level disinfectant (i.e., EPA-registered hospital disinfectant with an HBV and HIV label claim).<sup>18,259,260</sup>

Most housekeeping surfaces need to be cleaned only with a detergent and water or an EPA-registered hospital disinfectant, depending of the nature of the surface and the type and degree of contamination. When housekeeping surfaces are visibly contaminated by blood or body substances, however, prompt removal and surface disinfection is a sound infection control practice and required by the Occupational Safety and Health Administration (OSHA).<sup>261,262</sup>

Several studies have demonstrated variability among dental practices while trying to meet these recommendations.<sup>263,264</sup> For example, 68% of respondents believed they were sterilizing their instruments but did not use appropriate chemical sterilants or exposure times and 48% of respondents did not challenge autoclaves with biological indicators.<sup>265</sup> Other investigators using biologic indicators have found a high proportion (45%–65%) of positive spore tests after assessing the efficacy of sterilizers used in dental offices. In one study of Minnesota dental offices, operator error, rather than mechanical malfunction,<sup>266</sup> caused 87% of sterilization failures. Common factors in the improper use of sterilizers include chamber overload, low temperature setting, inadequate exposure time, failure to preheat the sterilizer, and interruption of the cycle.

Mail-return sterilization monitoring services use spore strips to test sterilizers in dental clinics, but

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delay caused by mailing to the test laboratory could potentially cause false-negative results. Studies revealed, however, that the post-sterilization time and temperature after a 7-day delay had no influence on the test results.<sup>213</sup> Delays (7 days at 27°C and 37°C, 3-day mail delay) did not cause any predictable pattern of inaccurate spore tests.<sup>213</sup>

**Disinfection of HBV, HCV, HIV- or TB-Contaminated Devices**

The CDC recommendation for high-level disinfection of HBV, HCV, HIV- or TB-contaminated devices is appropriate because experiments have demonstrated the effectiveness of high-level disinfectants to inactivate these and other pathogens that might contaminate semicritical devices.<sup>214, 215, 216, 217, 218</sup> Nonetheless, some healthcare facilities have modified their disinfection procedures when endoscopes are used with a patient known or suspected to be infected with HBV, HIV, or *M. tuberculosis*.<sup>219, 220</sup> This is inconsistent with the concept of Standard Precautions that presumes all patients are potentially infected with bloodborne pathogens.<sup>221</sup> Several studies have highlighted the inability to distinguish HBV- or HIV-infected patients from noninfected patients on clinical grounds.<sup>222, 223</sup> In addition, mycobacterial infection is unlikely to be clinically apparent in many patients. In most instances, hospitals that altered their disinfection procedure used EIO sterilization on the endoscopic instruments because they believed this practice reduced the risk for infection.<sup>224, 225</sup> EIO is not routinely used for endoscope sterilization because of the lengthy processing time. Endoscopes and other semicritical devices should be managed the same way regardless of whether the patient is known to be infected with HBV, HCV, HIV or *M. tuberculosis*.

An evaluation of a manual disinfection procedure to eliminate HCV from experimentally contaminated endoscopes provided some evidence that cleaning and 2% glutaraldehyde for 20 minutes should prevent transmission.<sup>226</sup> A study that used experimentally contaminated hysteroscopes detected HCV by polymerase chain reaction (PCR) in one (3%) of 34 samples after cleaning with a detergent, but no samples were positive after treatment with a 2% glutaraldehyde solution for 20 minutes.<sup>227</sup> Another study demonstrated complete elimination of HCV (as detected by PCR) from endoscopes used on chronically infected patients after cleaning and disinfection for 3–5 minutes in glutaraldehyde.<sup>228</sup> Similarly, PCR was used to demonstrate complete elimination of HCV after standard disinfection of experimentally contaminated endoscopes,<sup>229</sup> and endoscopes used on HCV-antibody-positive patients had no detectable HCV RNA after high-level disinfection.<sup>230</sup> The inhibitory activity of a phenolic and a chlorine compound on HCV showed that the phenolic inhibited the binding and replication of HCV, but the chlorine was ineffective, probably because of its low concentration and its neutralization in the presence of organic matter.<sup>231</sup>

**Disinfection in the Hemodialysis Unit**

Hemodialysis systems include hemodialysis machines, water supply, water-treatment systems, and distribution systems. During hemodialysis, patients have acquired bloodborne viruses and pathogenic bacteria.<sup>232, 233</sup> Cleaning and disinfection are important components of infection control in a hemodialysis center. EPA and FDA regulate disinfectants used to reprocess hemodialyzers, hemodialysis machines, and water-treatment systems.

Noncritical surfaces (e.g., dialysis bed or chair, countertops, external surfaces of dialysis machines, and equipment [scissors, hemostats, clamps, blood pressure cuffs, stethoscopes]) should be disinfected with an EPA-registered disinfectant unless the item is visibly contaminated with blood; in that case a tuberculocidal agent (or a disinfectant with specific label claims for HBV and HIV) or a 1:100 dilution of a hypochlorite solution (500–800 ppm free chlorine) should be used.<sup>234, 235</sup> This procedure accomplishes two goals: it removes soil on a regular basis and maintains an environment that is consistent with good patient care. Hemodialyzers are disinfected with peracetic acid, formaldehyde, glutaraldehyde, heat pasteurization with citric acid, and chlorine-containing compounds.<sup>236</sup> Hemodialysis systems usually are disinfected by chlorine-based disinfectants (e.g., sodium hypochlorite), aqueous

formaldehyde, heat pasteurization, ozone, or peracetic acid.<sup>236, 237</sup> All products must be used according to the manufacturers' recommendations. Some dialysis systems use hot-water disinfection to control microbial contamination.

At its high point, 62% of U.S. chronic hemodialysis centers were reprocessing (i.e., reusing) dialyzers for the same patient using high-level disinfection.<sup>238</sup> However, one of the large dialysis organizations has decided to phase out reuse and, by 2002 the percentage of dialysis facilities reprocessing hemodialyzers had decreased to 63%.<sup>239</sup> The two commonly used disinfectants to reprocess dialyzers were peracetic acid and formaldehyde; 72% used peracetic acid and 20% used formaldehyde to disinfect hemodialyzers. Another 4% of the facilities used either glutaraldehyde or heat pasteurization in combination with citric acid. Infection-control practices, methodologies, including disinfection and sterilization and the use of dedicated machines for hepatitis B surface antigen (HBsAg)-positive patients, in the hemodialysis setting were detailed in two reviews.<sup>240, 241</sup> The Association for the Advancement of Medical Instrumentation (AAMI) has published recommendations for the reuse of hemodialyzers.<sup>242</sup>

**Inactivation of *Clostridium difficile***

The source of health-care-associated acquisition of *Clostridium difficile* in nonendemic settings has not been determined. The environment and carriage on the hands of health-care personnel have been considered possible sources of infection.<sup>243, 244</sup> Carpeted rooms occupied by a patient with *C. difficile* were more heavily contaminated with *C. difficile* than were noncarpeted rooms.<sup>245</sup> Because *C. difficile* spore-production can increase when exposed to nonchlorine-based cleaning agents and the spores are more resistant than vegetative cells to commonly used surface disinfectants,<sup>246</sup> some investigators have recommended use of dilute solutions of hypochlorite (1,000 ppm available chlorine) for routine environmental disinfection of rooms of patients with *C. difficile*-associated diarrhea or colitis,<sup>247</sup> to reduce the incidence of *C. difficile* diarrhea,<sup>248</sup> or in units with high *C. difficile* rates.<sup>249</sup> Stool samples of patients with symptomatic *C. difficile* colitis contain spores of the organism, as demonstrated by ethanol treatment of the stool to reduce the overgrowth of fecal flora when isolating *C. difficile* in the laboratory.<sup>250, 251</sup> *C. difficile*-associated diarrhea rates were shown to have decreased markedly in a bone-marrow transplant unit (from 8.6 to 3.3 cases per 1,000 patient-days) during a period of bleach disinfection (1:10 dilution) of environmental surfaces compared with cleaning with a quaternary ammonium compound. Because no EPA-registered products exist that are specific for inactivating *C. difficile* spores, use of diluted hypochlorite should be considered in units with high *C. difficile* rates. Acidified bleach and regular bleach (5000 ppm chlorine) can inactivate 10<sup>6</sup> *C. difficile* spores in <10 minutes.<sup>252</sup> However, studies have shown that asymptomatic patients constitute an important reservoir within the health-care facility and that person-to-person transmission is the principal means of transmission between patients. Thus, combined use of hand washing, barrier precautions, and meticulous environmental cleaning with an EPA-registered disinfectant (e.g., germicidal detergent) should effectively prevent spread of the organism.<sup>253</sup>

Contaminated medical devices, such as colonoscopes and thermometers, can be vehicles for transmission of *C. difficile* spores.<sup>254</sup> For this reason, investigators have studied commonly used disinfectants and exposure times to assess whether current practices can place patients at risk. Data demonstrate that 2% glutaraldehyde,<sup>255, 256, 257</sup> and peracetic acid<sup>257, 258</sup> reliably kill *C. difficile* spores using exposure times of 5–20 minutes. ortho-Phthalaldehyde and 20.2% peracetic acid (WA Rulata, personal communication, April 2006) also can inactivate ≥10<sup>6</sup> *C. difficile* spores in 10–12 minutes at 20°C.<sup>254</sup> Sodium dichloroacrylate at a concentration of 1000 ppm available chlorine exhibited lower log<sub>10</sub> reduction factors against *C. difficile* spores at 10 min, ranging from 0.7 to 1.5, than 0.26% peracetic acid with log<sub>10</sub> reduction factors ranging from 2.7 to 6.0.<sup>259</sup>

**OSHA Bloodborne Pathogen Standard**  
In December 1991, OSHA promulgated a standard entitled "Occupational Exposure to

Bloodborne Pathogens" to eliminate or minimize occupational exposure to bloodborne pathogens.<sup>264</sup> One component of this requirement is that all equipment and environmental and working surfaces be cleaned and decontaminated with an appropriate disinfectant after contact with blood or other potentially infectious materials. Even though the OSHA standard does not specify the type of disinfectant or procedure, the OSHA official compliance document<sup>265</sup> suggested that a germicide must be tuberculocidal to kill the HBV. To follow the OSHA compliance document a tuberculocidal disinfectant (e.g., phenolic, and chlorine) would be needed to clean a blood spill. However, in February 1997, OSHA amended its policy and stated that EPA-registered disinfectants labeled as effective against HIV and HBV would be considered as appropriate disinfectants.<sup>266</sup> . . . provided such surfaces have not become contaminated with agent(s) or volumes or concentrations of agent(s) for which higher level disinfection is recommended.<sup>267</sup> When bloodborne pathogens other than HBV or HIV are of concern, OSHA continues to require use of EPA-registered tuberculocidal disinfectants or hypochlorite solution (diluted 1:10 or 1:100 with water).<sup>268, 269</sup> Studies demonstrate that, in the presence of large blood spills, a 1:10 final dilution of EPA-registered hypochlorite solution initially should be used to inactivate bloodborne viruses<sup>270</sup> to minimize risk for infection to health-care personnel from percutaneous injury during cleanup.

**Emerging Pathogens (*Cryptosporidium*, *Helicobacter pylori*, *Escherichia coli* O157:H7, Rotavirus, Human Papilloma Virus, Norovirus, Severe Acute Respiratory Syndrome [SARS] Coronavirus)**  
Emerging pathogens are of growing concern to the general public and infection-control professionals. Relevant pathogens include *Cryptosporidium parvum*, *Helicobacter pylori*, *E. coli* O157:H7, HIV, HCV, rotavirus, norovirus, severe acute respiratory syndrome (SARS) coronavirus, multidrug-resistant *M. tuberculosis*, and nontuberculous mycobacteria (e.g., *M. chelonae*). The susceptibility of each of these pathogens to chemical disinfectants and sterilants has been studied. With the exceptions discussed below, all of these emerging pathogens are susceptible to currently available chemical disinfectants and sterilants.<sup>271</sup>

*Cryptosporidium* is resistant to chlorine at concentrations used in potable water. *C. parvum* is not completely inactivated by most disinfectants used in healthcare including ethyl alcohol,<sup>272</sup> glutaraldehyde,<sup>273, 274</sup> 5.25% hypochlorite,<sup>271</sup> peracetic acid,<sup>271</sup> ortho-phthalaldehyde,<sup>275</sup> phenol,<sup>271, 272</sup> povidone-iodine,<sup>271, 274</sup> and quaternary ammonium compounds.<sup>271</sup> The only chemical disinfectants and sterilants able to inactivate greater than 3 log<sub>10</sub> of *C. parvum* were 6% and 7.6% hydrogen peroxide.<sup>271</sup> Sterilization methods will fully inactivate *C. parvum*, including steam,<sup>271</sup> EIO,<sup>271, 272</sup> and hydrogen peroxide gas plasma.<sup>271</sup> Although most disinfectants are ineffective against *C. parvum*, current cleaning and disinfection practices appear effective to prevent healthcare-associated transmission. For example, endoscopes are unlikely to be an important vehicle for transmitting *C. parvum* because the results of bacterial studies indicate mechanical cleaning will remove approximately 10<sup>6</sup> organisms, and drying results in rapid loss of *C. parvum* viability (e.g., 30 minutes, 2.9 log<sub>10</sub> decrease; and 60 minutes, 3.8 log<sub>10</sub> decrease).<sup>271</sup>

Chlorine at ~1 ppm has been found capable of eliminating approximately 4 log<sub>10</sub> of *E. coli* O157:H7 within 1 minute in a suspension test.<sup>276</sup> Electrolyzed oxidizing water at 23°C was effective in 10 minutes in producing a 5-log<sub>10</sub> reduction in *E. coli* O157:H7 inoculated onto kitchen cutting boards.<sup>277</sup> The following disinfectants inactivated >5 log<sub>10</sub> of *E. coli* O157:H7 within 30 seconds: a quaternary ammonium compound, a phenolic, a hypochlorite (1:10 dilution of 5.25% bleach), and ethanol.<sup>278</sup> Disinfectants including chlorine compounds can reduce *E. coli* O157:H7 experimentally inoculated onto alfalfa seeds or sprouts<sup>279, 280</sup> or beef carcass surfaces.<sup>277</sup>

Data are limited on the susceptibility of *H. pylori* to disinfectants. Using a suspension test, one study assessed the effectiveness of a variety of disinfectants against nine strains of *H. pylori*.<sup>281</sup> Ethanol (80%) and glutaraldehyde (0.5%) killed all strains within 15 seconds; chlorhexidine gluconate (0.05%), 1.0%, benzalkonium chloride (0.025%, 0.1%), alkyldimethylammonium hydrochloride (0.1%), povidone-iodine (0.1%), and sodium hypochlorite (150 ppm) killed all strains within 30 seconds. Both ethanol

(60%) and glutaraldehyde (0.5%) retained similar bactericidal activity in the presence of organic matter; the other disinfectants showed reduced bactericidal activity. In particular, the bactericidal activity of povidone-iodine (0.1%) and sodium hypochlorite (150 ppm) markedly decreased in the presence of dried yeast solution with killing times increased to 5–10 minutes and 6–30 minutes, respectively.

Immersion of biopsy forceps in formalin before obtaining a specimen does not affect the ability to culture *H. pylori* from the biopsy specimen.<sup>282</sup> The following methods are ineffective for eliminating *H. pylori* from endoscopes: cleaning with soap and water,<sup>196, 278</sup> immersion in 70% ethanol for 3 minutes,<sup>283</sup> installation of 70% ethanol,<sup>196</sup> installation of 30 ml of 83% methanol,<sup>284</sup> and installation of 0.2% Hyamine solution.<sup>285</sup> The differing results with regard to the efficacy of ethyl alcohol against *Helicobacter* are unexplained. Cleaning followed by use of 2% alkaline glutaraldehyde (or automated peracetic acid) has been demonstrated by culture to be effective in eliminating *H. pylori*.<sup>196, 278, 281</sup> Epidemiologic investigations of patients who had undergone endoscopy with endoscopes mechanically washed and disinfected with 2.0%–2.3% glutaraldehyde have revealed no evidence of person-to-person transmission of *H. pylori*.<sup>286, 287</sup> Disinfection of experimentally contaminated endoscopes using 2% glutaraldehyde (10-minute, 20-minute, 45-minute exposure times) or the peracetic acid system (with and without active peracetic acid) has been demonstrated to be effective in eliminating *H. pylori*.<sup>288</sup> *H. pylori* DNA has been detected by PCR in fluid flushed from endoscope channels after cleaning and disinfection with 2% glutaraldehyde.<sup>284</sup> The clinical significance of this finding is unclear. *In vivo* experiments have demonstrated a >3.5-log<sub>10</sub> reduction in *H. pylori* after exposure to 0.5 mg/L of free chlorine for 80 seconds.<sup>289</sup>

An outbreak of healthcare-associated rotavirus gastroenteritis on a pediatric unit has been reported.<sup>290</sup> Person to person through the hands of health-care workers was proposed as the mechanism of transmission. Prolonged survival of rotavirus on environmental surfaces (30 minutes to >10 days at room temperature) and hands (>4 hours) has been demonstrated. Rotavirus survived in feces can survive longer.<sup>291, 292</sup> Vectors have included hands, fomites, air, water, and food.<sup>293, 294</sup> Products with demonstrated efficacy (>3 log<sub>10</sub> reduction in virus) against rotavirus within 1 minute include: 95% ethanol, 70% isopropanol, some phenolics, 2% glutaraldehyde, 0.35% peracetic acid, and some quaternary ammonium compounds.<sup>295, 296, 297</sup> In a human challenge study, a disinfectant spray (0.1% ortho-phthalaldehyde and 79% ethanol), sodium hypochlorite (800 ppm free chlorine), and a phenol-based product (1.7% phenol diluted 1:250 in tapwater) when sprayed onto contaminated stainless steel disks, were effective in interrupting transfer of a human rotavirus from stainless steel to fingertips of volunteers after an exposure time of 3–10 minutes. A quaternary ammonium product (7.5% quaternary ammonium compound diluted 1:128 in tapwater) and tapwater allowed transfer of virus.<sup>298</sup>

No data exist on the inactivation of HPV by alcohol or other disinfectants because *in vitro* replication of complete viruses has not been achieved. Similarly, little is known about inactivation of noroviruses (members of the family *Caliciviridae* and important causes of gastroenteritis in humans) because they cannot be grown in culture. Improper distribution of environmental surfaces contaminated by feces or vomitus of infected patients is believed to play a role in the spread of noroviruses in some settings.<sup>299, 300</sup> Prolonged survival of a norovirus surrogate (i.e., feline calicivirus virus [FCV], a closely related cultivable virus) has been demonstrated (e.g., at room temperature, FCV in a dried saline survived for 21–18 days).<sup>277</sup> Inactivation studies with FCV have shown the effectiveness of chlorine, glutaraldehyde, and iodine-based products whereas the quaternary ammonium compound, detergent, and ethanol failed to inactivate the virus completely.<sup>277</sup> An evaluation of the effectiveness of several disinfectants against the feline calicivirus found that bleach diluted to 1000 ppm of available chlorine reduced efficacy of FCV by 4.5 logs in 1 minute. Other effective (log<sub>10</sub> reduction factor of >4 in virus) disinfectants included accelerated hydrogen peroxide, 5,000 ppm (3 min); chlorine dioxide, 1,000 ppm chlorine (1 min); a mixture of four quaternary ammonium compounds, 2,470 ppm (10 min); 75% ethanol with 0.1% quaternary ammonium compound (3 min); and 75% ethanol (10 min).<sup>299</sup> A quaternary ammonium compound exhibited activity against feline calicivirus supernatants dried on hard surface carriers in 10 minutes.<sup>301</sup> Seventy percent ethanol and 70% 1-propanol reduced FCV by a 3–4-log<sub>10</sub>

reduction in 30 seconds<sup>360</sup>.

CDC announced that a previously unrecognized human virus from the coronavirus family is the leading hypothesis for the cause of a described syndrome of SARS<sup>361</sup>. Two coronaviruses that are known to infect humans cause one third of common colds and can cause gastroenteritis. The virucidal efficacy of chemical germicides against coronavirus has been investigated. A study of disinfectants against coronavirus 229E found several that were effective after a 1-minute contact time; these included sodium hypochlorite (at a free chlorine concentration of 1,000 ppm and 5,000 ppm), 70% ethyl alcohol, and povidone-iodine (1% iodine)<sup>362</sup>. In another study, 70% ethanol, 50% isopropanol, 0.05% benzalkonium chloride, 50 ppm iodine in Iodophor, 0.23% sodium chlorine, 1% cresol soap and 0.7% formaldehyde inactivated >3 logs of two animal coronaviruses (mouse hepatitis virus, canine coronavirus) after a 10-minute exposure time<sup>363</sup>. The activity of povidone-iodine has been demonstrated against human coronavirus 229E and OC43<sup>364</sup>. A study also showed complete inactivation of the SARS coronavirus by 70% ethanol and povidone-iodine with an exposure times of 1 minute and 2.5% glutaraldehyde with an exposure time of 5 minutes<sup>365</sup>. Because the SARS coronavirus is stable in feces and urine at room temperature for at least 1–2 days (WHO, 2003): [http://www.who.int/csr/resources/publications/2003\\_04/infodoc.html](http://www.who.int/csr/resources/publications/2003_04/infodoc.html), surfaces might be a possible source of contamination and lead to infection with the SARS coronavirus and should be disinfected. Until more precise information is available, environments in which SARS patients are housed should be considered heavily contaminated, and rooms and equipment should be thoroughly disinfected daily and after the patient is discharged. EPA-registered disinfectants or 1:100 dilution of household bleach and water should be used for surface disinfection and disinfection on noncritical patient-care equipment. High-level disinfection and sterilization of a noncritical and critical medical devices, respectively, does not need to be altered for patients with known or suspected SARS.

Free-living amoeba can be pathogenic and can harbor agents of pneumonia such as *Legionella pneumophila*. Limited studies have shown that 2% glutaraldehyde and peracetic acid do not completely inactivate *Acanthamoeba polyphaga* in a 20-minute exposure time for high-level disinfection. *A* amoebae are found to contaminate instruments and facilitate infection, longer immersion times or other disinfectants may need to be considered<sup>366</sup>.

**Inactivation of Bioterrorist Agents**

Publications have highlighted concerns about the potential for biological terrorism<sup>367,368</sup>. CDC has categorized several agents as "high priority" because they can be easily disseminated or transmitted from person to person, cause high mortality, and are likely to cause public panic and social disruption<sup>369</sup>. These agents include *Bacillus anthracis* (the cause of anthrax), *Yersinia pestis* (plague), variola major (smallpox), *Clostridium botulinum* toxin (botulinum), *Francisella tularensis* (tularemia), *Rift Valley fever virus* (Ebola hemorrhagic fever, Marburg hemorrhagic fever) and *arenaviruses* (Lassa [Lassa fever], Junin [Argentine hemorrhagic fever]), and related viruses<sup>370</sup>.

A few comments can be made regarding the role of sterilization and disinfection of potential agents of bioterrorism<sup>371</sup>. First, the susceptibility of these agents to germicides *in vitro* is similar to that of other related pathogens. For example, variola is similar to vaccinia<sup>372,373</sup> and *B. anthracis* is similar to *B. atrophaeus* (former *B. subtilis*)<sup>374</sup>. *B. subtilis* spores, for instance, proved as resistant as, if not more resistant than, *B. anthracis* spores (>6 logs reduction of *B. anthracis* spores in 5 minutes with acidified bleach [5,250 ppm chlorine])<sup>375</sup>. Thus, one can extrapolate from the larger database available on the susceptibility of genetically similar organisms<sup>376</sup>. Second, many of the potential bioterrorist agents are stable enough in the environment that contaminated environmental surfaces or fomites could lead to transmission of agents such as *B. anthracis*, *F. tularensis*, variola major, *C. botulinum* toxin, and *C. botulinum*<sup>377</sup>. Third, data suggest that current disinfection and sterilization practices are appropriate for managing patient-care equipment and environmental surfaces when potentially contaminated patients are evaluated and/or admitted in a health-care facility after exposure to a bioterrorist agent. For example,

facility can use a commercially available small-scale treatment method (e.g., neutralize glutaraldehyde with glycine).

Safe disposal of regulated chemicals is important throughout the medical community. For disposal of large volumes of spent solutions, users might decide to neutralize the microbicidal activity before disposal (e.g., glutaraldehyde). Solutions can be neutralized by reaction with chemicals such as sodium bisulfite<sup>378,379</sup> or glycine<sup>380</sup>.

European authors have suggested that instruments and ventilation therapy equipment should be disinfected by heat rather than by chemicals. The concerns for chemical disinfection include toxic side effects for the patient caused by chemical residues on the instrument or object, occupational exposure to toxic chemicals, and recontamination by rinsing the disinfectant with microbially contaminated tap water<sup>381</sup>.

**Disinfection in Ambulatory Care, Home Care, and the Home**

With the advent of managed healthcare, increasing numbers of patients are now being cared for in ambulatory-care and home settings. Many patients in these settings might have communicable diseases, immunocompromising conditions, or invasive devices. Therefore, adequate disinfection in these settings is necessary to provide a safe patient environment. Because the ambulatory-care setting (i.e., outpatient facility) provides the same risk for infection as the hospital, the Spaulding classification scheme described in this guideline should be followed (Table 1)<sup>37</sup>.

The home environment should be much safer than hospitals or ambulatory care. Epidemics should not be a problem, and cross-infection should be rare. The health-care provider is responsible for providing the responsible family member information about infection-control procedures to follow in the home, including hand hygiene, proper cleaning and disinfection of equipment, and safe storage of cleaned and disinfected devices. Among the products recommended for home disinfection of reusable objects are bleach, alcohol, and hydrogen peroxide. APIC recommends that reusable objects (e.g., tracheostomy tubes) that touch mucous membranes be disinfected by immersion in 70% isopropyl alcohol for 5 minutes<sup>382</sup>. In 3% hydrogen peroxide for 30 minutes. Additionally, a 1:50 dilution of 5.25%–8.15% sodium hypochlorite (household bleach) for 5 minutes should be effective<sup>383,384</sup>. Noncritical items (e.g., blood pressure cuffs, crutches) can be cleaned with a detergent. Blood spills should be handled according to OSHA regulations as previously described (see section on OSHA Bloodborne Pathogen Standard). In general, sterilization of critical items is not practical in homes but theoretically could be accomplished by chemical sterilants or boiling. Single-use disposable items can be used or reusable items sterilized in a hospital<sup>385,386</sup>.

Some environmental groups advocate "environmentally safe" products as alternatives to commercial germicides in the home-care setting. These include, for example, ammonia, baking soda, vinegar, Borax, liquid detergent) are not registered with EPA and should not be used for disinfection because they are ineffective against *S. aureus*. Borax, baking soda, and detergents also are ineffective against *Salmonella* Typhi and *E. coli*; however, undiluted vinegar and ammonia are effective against *S. Typhi* and *E. coli*<sup>387,388,389</sup>. Common commercial disinfectants designed for home use also are effective against selected antibiotic-resistant bacteria<sup>39</sup>.

Public concerns have been raised that the use of antimicrobials in the home can promote development of antibiotic-resistant bacteria<sup>390,391</sup>. This issue is unresolved and needs to be considered further through scientific and clinical investigations. The public health benefits of using disinfectants in the home are unknown. However, some facts are known: many sites in the home kitchen and bathroom are microbially contaminated<sup>392</sup>, use of hypochlorites markedly reduces bacteria<sup>393</sup>, and good standards of hygiene (e.g., food hygiene, hand hygiene) can help reduce infections in the home<sup>394,395</sup>. In addition, laboratory studies indicate that many commercially prepared household disinfectants are effective against common pathogens<sup>396</sup> and can interrupt surface-to-human transmission of pathogens<sup>39</sup>. The "targeted

sodium hypochlorite can be used for surface disinfection (see <http://www.epa.gov/pesticides/factsheets/chemicals/biochemicals/bleach.html>). In instances where the health-care facility is the site of a bioterrorist attack, environmental decontamination might require special decontamination procedures (e.g., chlorine dioxide gas for *B. anthracis* spores). Because no antimicrobial products are registered for decontamination of biologic agents after a bioterrorist attack, EPA has granted a crisis exemption for each product (see <http://www.epa.gov/pesticides/factsheets/chemicals/biochemicals/bleach.html>). Of only theoretical concern is the possibility that a bioterrorist agent could be engineered to be less susceptible to disinfection and sterilization processes<sup>397</sup>.

**Toxicological, Environmental and Occupational Concerns**

Health hazards associated with the use of germicides in health-care facilities vary from mucous membrane irritation to death, with the latter involving accidental injection by mentally disabled patients<sup>398</sup>. Although their degrees of toxicity vary<sup>399,400</sup>, all disinfectants should be used with the proper safety precautions<sup>39</sup> and only for the intended purpose.

Key factors associated with assessing the health risk of a chemical exposure include the duration, intensity (i.e., how much chemical is involved), and route (e.g., skin, mucous membranes, and inhalation) of exposure. Toxicity may be acute or chronic. Acute toxicity usually results from an accidental spill of a chemical substance. Exposure to sulfonamides and other products an emergency situation. Chronic toxicity results from repeated exposure to low levels of the chemical over a prolonged period. Employers are responsible for informing workers about the chemical hazards in the workplace and implementing control measures. The OSHA Hazard Communication Standard (29 CFR 1010.1200, 1015.09, 1017.28, 1018.50, 1926.59, and 1926.21) requires manufacturers and importers of hazardous chemicals to develop Material Safety Data Sheets (MSDS) for each chemical or mixture of chemicals. Employers must have these data sheets readily available to employees who work with the products to which they could be exposed.

Exposure limits have been published for many chemicals used in health care to help provide a safe environment and, as relevant, are discussed in each section of this guideline. Only the exposure limits published by OSHA carry the legal force of regulations. OSHA publishes a limit as a time-weighted average (TWA), that is, the average concentration for a normal 8-hour work day and a 40-hour work week to which nearly all workers can be repeatedly exposed to a chemical without adverse health effects. For example, the permissible exposure limit (PEL) for EOC is 1.0 ppm, 8 hour TWA. The CDC National Institute for Occupational Safety and Health (NIOSH) develops recommended exposure limits (RELs). RELs are occupational exposure limits recommended by NIOSH as being protective of worker health and safety over a working lifetime. This limit is frequently expressed as a 40-hour TWA exposure for up to 10 hours per day during a 40-hour work week. These exposure limits are designed for inhalation exposures. Irritant and allergic effects can occur below the exposure limits, and skin contact can result in dermal effects or systemic absorption without inhalation. The American Conference on Governmental Industrial Hygienists (ACGIH) also has published exposure limits<sup>377</sup>. Information about workplace exposures and methods to reduce them (e.g., work practices, engineering controls, PPE) is available on the OSHA (<http://www.osha.gov>) and NIOSH (<http://www.cdc.gov/niosh>) websites.

Some states have excluded or limited concentrations of certain chemical germicides (e.g., glutaraldehyde, formaldehyde, and some phenols) from disposal through the sewer system. These rules are intended to minimize environmental harm. If health-care facilities exceed the maximum allowable concentration of a chemical (e.g., >5.0 mg/L), they have three options. First, they can switch to alternative products; for example, they can change from glutaraldehyde to another disinfectant for high-level disinfection or from phenolics to quaternary ammonium compounds for low-level disinfection. Second, the health-care facility can collect the disinfectant and dispose of it as a hazardous chemical. Third, the

hygiene concept—which means identifying situations and areas (e.g., food-preparation surfaces and bathroom) where risk exists for transmission of pathogens—may be a reasonable way to identify when disinfection might be appropriate<sup>390</sup>.

**Susceptibility of Antibiotic-Resistant Bacteria to Disinfectants**

As with antibiotics (or acquired "resistance") of bacteria to disinfectants can arise by either chromosomal gene mutation or acquisition of plasmids or transposons<sup>391,392,393,394,395,396</sup>. When changes occur in bacterial susceptibility to disinfectants, antibiotic ineffective against an infection previously treatable by that antibiotic, the bacteria are referred to as "resistant." In contrast, reduced susceptibility to disinfectants does not correlate with failure of the disinfectant because concentrations used in disinfection still greatly exceed the MIC level. Thus, the word "resistance" when applied to these changes is incorrect, and the preferred term is "reduced susceptibility" or "increased tolerance"<sup>396,397</sup>. No data are available that show that antibiotic-resistant bacteria are less sensitive to the liquid chemical germicides than antibiotic-sensitive bacteria at currently used germicide contact conditions and concentrations.

MRSA and vancomycin-resistant *Enterococcus* (VRE) are important health-care-associated agents. Some antiseptics and disinfectants have been known for years to be, because of MICs, somewhat less inhibitory to *S. aureus* strains that contain a plasmid-carrying gene encoding resistance to the antibiotic gentamicin<sup>398</sup>. For example, gentamicin resistance has been shown to also encode reduced susceptibility to propamidine, quaternary ammonium compounds, and ethidium bromide<sup>399</sup>, and MRSA strains have been found to be less susceptible than methicillin-sensitive *S. aureus* (MSSA) strains to chlorhexidine, propamidine, and the quaternary ammonium compound cetrimide<sup>400</sup>. In other studies, MRSA and MSSA strains have been equally sensitive to phenolics and chlorhexidine, but MRSA strains were slightly more tolerant to quaternary ammonium compounds<sup>399</sup>. Two gene families (qacA and qacB) now referred to as *smr* and *qacAB*) are involved in providing protection against agents that are components of disinfectant formulations such as quaternary ammonium compounds. Staphylococci have been proposed to evade destruction because the protein specified by the *qacA* determinant is a cytoplasmic-membrane-associated protein involved in an efflux system that actively reduces intracellular accumulation of toxicants, such as quaternary ammonium compounds, to intracellular targets<sup>401</sup>.

Other studies demonstrated that plasmid-mediated formaldehyde tolerance is transferable from *Serratia marcescens* to *E. coli*<sup>402</sup> and plasmid-mediated quaternary ammonium tolerance is transferable from *S. aureus* to *E. coli*<sup>403</sup>. Tolerance to mercury and silver also is plasmid borne<sup>391,399,404</sup>.

Because the concentrations of disinfectants used in practice are much higher than the MICs observed, even for the more tolerant strains, the clinical relevance of these observations is questionable. Several studies have found antibiotic-resistant hospital strains of common health-care-associated pathogens (i.e., *Enterococcus*, *P. aeruginosa*, *Klebsiella pneumoniae*, *E. coli*, *S. aureus*, and *S. epidermidis*) to be equally susceptible to disinfectants as antibiotic-sensitive strains<sup>53,324,334</sup>. The susceptibility of glycopeptide-intermediate *S. aureus* was similar to vancomycin-susceptible, MRSA<sup>405</sup>. On the basis of these data, routine disinfection and housekeeping protocols do not need to be altered because of antibiotic resistance. A study that evaluated the efficacy of selected cleaning methods (e.g., QUAT-sprayed cloth, and QUAT-immersed cloth) for eliminating VRE found that currently used disinfection processes most likely are highly effective in eliminating VRE. However, surface disinfection must involve contact with all contaminated surfaces<sup>406</sup>. A new method using an invisible fluorescent marker to objectively evaluate the thoroughness of cleaning activities in patient rooms might lead to improvement in cleaning of all objects and surfaces but needs further evaluation<sup>390</sup>.

Lastly, does the use of antiseptics or disinfectants facilitate the development of disinfectant-tolerant organisms? Evidence and reviews indicate enhanced tolerance to disinfectants can be

developed in response to disinfectant exposure.<sup>324,325,346,347,351</sup> However, the level of tolerance is not important in clinical terms because it is low and unlikely to compromise the effectiveness of disinfectants of which much higher concentrations are used.<sup>347,348</sup>

The issue of whether low-level tolerance to germicides selected for antibiotic-resistant strains is unsettled but might depend on the mechanism by which tolerance is obtained. For example, changes in the permeability barrier or efflux mechanisms might affect susceptibility to both antibiotics and germicides, but specific changes to a target site might not. Some researchers have suggested that use of disinfectants or antiseptics (e.g., triclosan) could facilitate development of antibiotic-resistant microorganisms.<sup>334,335,367</sup> Although evidence in laboratory studies indicates low-level resistance to triclosan, the concentrations of triclosan in these studies were low (generally <1 µg/mL) and dissimilar from the higher levels used in antimicrobial products (2,000–20,000 µg/mL).<sup>344,345</sup> Thus, researchers can create laboratory-derived mutants that demonstrate reduced susceptibility to antiseptics or disinfectants. In some experiments, such bacteria have demonstrated reduced susceptibility to certain antibiotics.<sup>368</sup> There is no evidence that using antiseptic or disinfectant selects for antibiotic-resistant organisms in nature or that such mutants survive in nature.<sup>369</sup> In addition, the action of antibiotics and the action of disinfectants differ fundamentally. Antibiotics are selectively toxic and generally have a single target site in bacteria, thereby inhibiting a specific biosynthetic process. Germicides generally are considered nonspecific antimicrobials because of a multiplicity of toxic-effect mechanisms or target sites and are broader spectrum in the types of microorganisms against which they are effective.<sup>344,347</sup>

The rational use of disinfectants in some environments (e.g., pharmacy production units) has been recommended and practiced in an attempt to prevent development of resistant microbes.<sup>367,368</sup> There have been only rare case reports that appropriately used disinfectants have resulted in a clinical problem arising from the selection or development of nonsusceptible microorganisms.<sup>368</sup>

#### Surface Disinfection

##### Is Surface Disinfection Necessary?

The effective use of disinfectants is part of a multibarrier strategy to prevent health-care-associated infections. Surfaces are considered noncritical items because they contact intact skin. Use of noncritical items or contact with noncritical surfaces carries little risk of causing an infection in patients or staff. Thus, the routine use of germicidal chemicals to disinfect hospital floors and other noncritical items is controversial.<sup>370</sup> A 1991 study expanded the Spaulding scheme by dividing the noncritical environmental surfaces into housekeeping surfaces and medical equipment surfaces.<sup>371</sup> The classes of disinfectants used on housekeeping and medical equipment surfaces can be similar. However, the frequency of decontaminating can vary (see Recommendations). Medical equipment surfaces (e.g., blood pressure cuffs, stethoscopes, hemodialysis machines, and X-ray machines) can become contaminated with infectious agents and contribute to the spread of health-care-associated infections.<sup>344,372</sup> For this reason, noncritical medical equipment surfaces should be disinfected with an EPA-registered low- or intermediate-level disinfectant. Use of a disinfectant will provide antimicrobial activity that is likely to be achieved with minimal additional cost or work.

Environmental surfaces (e.g., bedside table) also could potentially contribute to cross-transmission by contamination of health-care personnel from hand contact with contaminated surfaces, medical equipment, or patients.<sup>36,373,377</sup> A paper reviews the epidemiologic and microbiologic data (Table 3) regarding the use of disinfectants on noncritical surfaces.<sup>378</sup>

Of the seven reasons to use a disinfectant on noncritical surfaces, five are particularly noteworthy and support the use of a germicidal detergent. First, hospital floors become contaminated with microorganisms from soiling (e.g., contact with shoes, wheels, and other objects) and occasionally by spills. The removal of microbes is a component in controlling health-care-associated infections. In an investigation of the cleaning of hospital floors, the use of soap and water (80% reduction) was less effective in reducing the numbers of bacteria than was a phenolic disinfectant (94%–99.9%

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reduction).<sup>379</sup> However, a few hours after floor disinfection, the bacterial count was nearly back to the pretreatment level. Second, detergents become contaminated and result in seeding the patient's environment with bacteria. Investigators have shown that mop water becomes increasingly dirty during cleaning and becomes contaminated if soap and water is used rather than a disinfectant. For example, in one study, bacterial contamination in soap and water without a disinfectant increased from 10 CFU/mL to 34,000 CFU/mL after cleaning a ward, whereas contamination in a disinfectant solution did not change (20 CFU/mL).<sup>380</sup> Contamination of surfaces close to the patient that are frequently touched by the patient or staff (e.g., bed rails) could result in patient exposures.<sup>381</sup> In a study, using of detergents on floors and patient room furniture, increased bacterial contamination of the patients' environmental surfaces was found after cleaning (average increase = 103.6 CFU/24cm<sup>2</sup>).<sup>382</sup> In addition, a *P. aeruginosa* outbreak was reported in a hematology-oncology unit associated with contamination of the surface cleaning equipment when nongermicidal cleaning solutions instead of disinfectants were used to decontaminate the patients' environment.<sup>383</sup> and another study demonstrated the role of environmental cleaning in controlling an outbreak of *Aerobacter baumannii*.<sup>384</sup> Studies also have shown that, in situations where the cleaning procedure failed to eliminate contamination from the surface and the cloth is used to wipe another surface, the contamination is transferred to that surface and the hands of the person holding the cloth.<sup>385</sup> Third, the CDC Infection Guidelines recommends that noncritical equipment contaminated with blood, body fluids, secretions, or excretions be cleaned and disinfected after use. The same guidelines recommends that, in addition to cleaning, disinfection of the bedside equipment and environmental surfaces (e.g., bedrails, bedside tables, carts, commodes, door-knobs, and faucet handles) is indicated for certain pathogens, e.g., enterococci, which can survive in the inanimate environment for prolonged periods.<sup>386</sup> Fourth, OSHA requires that surfaces contaminated with blood and other potentially infectious materials (e.g., amniotic, pleural fluid) be disinfected. Fifth, using a single product throughout the facility can simplify both training and appropriate practices.

Reasons also exist for using a detergent alone on floors because noncritical surfaces contribute minimally to endemic health-care-associated infections,<sup>370</sup> and no differences have been found in health-care-associated infections rates when floors are cleaned with detergent rather than disinfectant.<sup>387,388</sup> However, these studies have been small and of short duration and suffer from low statistical power because the outcome—health-care-associated infections—is of low frequency. The low rate of infections makes the efficacy of an intervention statistically difficult to demonstrate. Because housekeeping surfaces are associated with the lowest risk for disease transmission, some researchers have suggested that either detergents or a disinfectant/detergent can be used.<sup>370</sup> No data exist that show reduced health-care-associated infection rates with use of surface disinfection of floors, but some data demonstrate reduced microbial load associated with the use of disinfectants. Given this information, other information showing that environmental surfaces (e.g., bedside table, bed rails) close to the patient and in outpatient settings<sup>389</sup> can be contaminated with epidemiologically important microbes (such as VRE and MRSA)<sup>390</sup> and data showing these organisms survive on various hospital surfaces<sup>391,392</sup>; and data showing some researchers have suggested that such surfaces should be disinfected on a regular schedule.<sup>393</sup> Spot decontamination of fabrics that remain in the hospital while patients move in and out (e.g., privacy curtains) also should be considered. One study demonstrated the effectiveness of spraying the fabric with 3% hydrogen peroxide.<sup>394</sup> Future studies should evaluate the level of contamination on noncritical environmental surfaces as a function of high and low hand contact and whether some surfaces (e.g., bed rails) near the patient with high contact frequencies require more frequent disinfection. Regardless of whether a detergent or disinfectant is used on surfaces in a health-care facility, surfaces should be cleaned routinely and when dirty or soiled to provide an aesthetically pleasing environment and to prevent potentially contaminating objects from serving as a source for health-care-associated infections.<sup>395</sup> The value of designing surfaces (e.g., heat-stable polystyrene) that kill bacteria on contact<sup>396</sup> or have sustained antimicrobial activity<sup>397</sup> should be further evaluated.

Several investigators have recognized heavy microbial contamination of wet mops and cleaning cloths and the potential for spread of such contamination.<sup>380,401</sup> They have shown that wiping hard surfaces with contaminated cloths can contaminate hands, equipment, and other surfaces.<sup>38,402</sup> Data

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have been published that can be used to formulate effective policies for decontamination and maintenance of reusable cleaning cloths. For example, heat was the most reliable treatment of cleaning cloths as a detergent washing followed by drying at 80°C for 2 hours produced elimination of contamination. However, the dry heating process might be a fire hazard if the mop head contains petroleum-based products or lint builds up within the equipment or vent hose (American Health Care Association, personal communication, March 2003). Alternatively, immersing the cloth in hypochlorite (4,000 ppm) for 2 minutes produced no detectable surviving organisms in 10 of 13 cloths.<sup>403</sup> If reusable cleaning cloths or mops are used, they should be decontaminated regularly to prevent surface contamination during cleaning with subsequent transfer of organisms from these surfaces to patients or equipment by the hands of health-care workers. Some hospitals have begun using a new mopping technique involving microfiber materials to clean floors. Microfibers are densely constructed, polyester and polyamide (nylon) fibers, that are approximately 1/16 the thickness of a human hair. The positively charged microfibers attract dust (which has a negative charge) and are more absorbent than a conventional, cotton-loop mop. Microfiber materials also can be wet with disinfectants, such as quaternary ammonium compounds. In one study, the microfiber system tested demonstrated superior microbial removal compared with conventional string mops when used with a detergent cleaner (94% vs 68%). The use of a disinfectant did not improve the microbial elimination demonstrated by the microfiber system (95% vs 94%). However, use of disinfectant significantly improved microbial removal when a conventional string mop was used (95% vs 68%) (WA Rutala, unpublished data, August 2006). The microfiber system also prevents the possibility of transferring microbes from room to room because a new microfiber pad is used in each room.

#### Contact Times for Surface Disinfectants

An important issue concerning use of disinfectants for noncritical surfaces in health-care settings is that the contact time specified on the label of the product is often too long to be practically followed. The labels of most products registered by EPA for use against HIV, HBV, or *M. tuberculosis* specify a contact time of 10 minutes. Such a long contact time is not practical for disinfection of environmental surfaces in a health-care setting because most health-care facilities apply a disinfectant and allow it to dry (<1 minute). Multiple scientific papers have demonstrated significant microbial reduction with contact times of 30 to 60 seconds.<sup>164,404,405</sup> In addition, EPA will approve a shortened contact time for any product for which the manufacturers will submit confirmatory efficacy data.

Currently, some EPA-registered disinfectants have contact times of one to three minutes. By law, users must follow all applicable label instructions for EPA-registered products. Ideally, product users should consider and use products that have the shortest contact time. However, disinfectant manufacturers also need to obtain EPA approval for shortened contact times so these products will be used correctly and effectively in the health-care environment.

#### Air Disinfection

Disinfectant spray-fog techniques for antimicrobial control in hospital rooms has been used. This technique of spraying disinfectants is an unsatisfactory method of decontaminating air and surfaces and is not recommended for general infection control in routine patient-care areas.<sup>38</sup> Disinfectant fogging is rarely, if ever, used in U.S. healthcare facilities for air- and surface disinfection in patient-care areas. Methods (e.g., filtration, ultraviolet germicidal irradiation, chlorine dioxide) to reduce air contamination in the healthcare setting are discussed in another guideline.<sup>32</sup>

#### Microbial Contamination of Disinfectants

Contaminated disinfectants and antiseptics have been occasional vehicles of health-care infections and pseudoutbreaks for more than 50 years. Published reports describing contaminated disinfectants and antiseptic solutions leading to health-care-associated infections have been summarized

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<sup>404</sup> Since this summary additional reports have been published.<sup>405-408</sup> An examination of reports of disinfectants contaminated with microorganisms revealed noteworthy observations. Perhaps most importantly, high-level disinfectants/liquid chemical sterilants have not been associated with outbreaks due to intrinsic or extrinsic contamination. Members of the genus *Pseudomonas* (e.g., *P. aeruginosa*) are the most frequent isolates from contaminated disinfectants—recovered from 80% of contaminated products. Their ability to remain viable or grow in use-dilutions of disinfectants is unparalleled. This survival advantage for *Pseudomonas* results presumably from their nutritional versatility, their unique outer membrane that constitutes an effective barrier to the passage of germicides, and/or efflux systems.<sup>409</sup> Although the concentrated solutions of the disinfectants have not been demonstrated to be contaminated at the point of manufacture, an undiluted phenolic was contaminated by a *Pseudomonas* sp. during use.<sup>410</sup> In most of the reports that describe lines associated with contaminated disinfectants, the product was used to disinfect patient-care equipment, such as cytoscopes, cardiac catheters, and thermometers. Germicides used as disinfectants that were reported to have been contaminated include chlorhexidine, quaternary ammonium compounds, phenolics, and pine oil.

The following control measures should be instituted to reduce the frequency of bacterial growth in disinfectants and the threat of serious health-care-associated infections from the use of such contaminated products.<sup>411</sup> First, some disinfectants should not be diluted; those that are diluted must be prepared correctly to achieve the manufacturers' recommended use-dilutions. Second, infection-control professionals must learn from the literature what inappropriate activities result in intrinsic contamination (i.e., at the point of use) of germicides and train users to prevent recurrence. Common sources of extrinsic contamination of germicides in the reviewed literature are the water to make working dilutions, contaminated containers, and general contamination of the hospital area where the germicides are prepared and/or used. Third, stock solutions of germicides must be stored as indicated on the product label. EPA verifies manufacturers' efficacy claims against microorganisms. These measures should provide assurance that products meeting the EPA registration requirements can achieve a certain level of antimicrobial activity when used as directed.

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## FACTORS AFFECTING THE EFFICACY OF DISINFECTION AND STERILIZATION

The activity of germicides against microorganisms depends on a number of factors, some of which are intrinsic qualities of the organism, others of which are the chemical and external physical environment. Awareness of these factors should lead to better use of disinfection and sterilization processes and will be briefly reviewed. More extensive consideration of these and other factors is available elsewhere.<sup>13, 14, 15, 411-413</sup>

## Number and Location of Microorganisms

All other conditions remaining constant, the larger the number of microbes, the more time a germicide needs to destroy all of them. Spaulding illustrated this relation when he employed identical test conditions and demonstrated that it took 30 minutes to kill 10 *B. anthracis* (formerly *Bacillus subtilis*) spores but 3 hours to kill 100,000 *Bacillus anthracis* spores. This reinforces the need for scrupulous cleaning of medical instruments before disinfection and sterilization. Reducing the number of microorganisms that must be inactivated through meticulous cleaning, increases the margin of safety when the germicide is used according to the labeling and shortens the exposure time required to kill the entire microbial load. Researchers also have shown that aggregated or clumped cells are more difficult to inactivate than monodispersed cells.<sup>14</sup>

The location of microorganisms also must be considered when factors affecting the efficacy of germicides are assessed. Medical instruments with multiple pieces must be disassembled and equipment such as endoscopes that have crevices, joints, and channels are more difficult to disinfect than are flat-surface equipment because penetration of the disinfectant of all parts of the equipment is more difficult. Only surfaces that directly contact the germicide will be disinfected, so there must be no air pockets and the equipment must be completely immersed for the entire exposure period. Manufacturers should be encouraged to produce equipment engineered for ease of cleaning and disinfection.

## Innate Resistance of Microorganisms

Microorganisms vary greatly in their resistance to chemical germicides and sterilization processes (Figure 1).<sup>14, 414</sup> Innate resistance mechanisms in microorganisms to disinfectants vary. For example, spores are resistant to disinfectants because the spore coat and cortex act as a barrier. Mycobacteria have a waxy cell wall that prevents disinfectant entry, and gram-negative bacteria possess an outer membrane that acts as a barrier to the uptake of disinfectants.<sup>14, 415, 416</sup> Implicit in all disinfection strategies is the consideration that the most resistant microbial subpopulation controls the sterilization or disinfection time. That is, to destroy the most resistant type of microorganisms (i.e., bacterial spores), the user needs to employ exposure times and a concentration of germicide needed to achieve complete destruction. Except for prions, bacterial spores possess the highest innate resistance to chemical germicides, followed by cocci (e.g., *Cryptosporidium*), mycobacteria (e.g., *M. tuberculosis*), nonlipid or small viruses (e.g., poliovirus, and coxsackievirus), fungi (e.g., *Aspergillus*, and *Candida*), vegetative bacteria (e.g., *Staphylococcus*, and *Pseudomonas*) and lipid or medium-size viruses (e.g., herpes, and HIV). The germicidal resistance exhibited by the gram-positive and gram-negative bacteria is similar with some exceptions (e.g., *P. aeruginosa* which shows greater resistance to some disinfectants).<sup>14, 415, 416</sup> *P. aeruginosa* also is significantly more resistant to a variety of disinfectants in its "naturally occurring" state than are cells subcultured on laboratory media.<sup>415, 417</sup> *Rickettsiae*, *Chlamydiae*, and mycoplasma cannot be placed in this scale of relative resistance because information about the efficacy of germicides against these agents is limited.<sup>14</sup> Because these microorganisms contain lipid and are similar in structure and composition to other bacteria, they can be predicted to be inactivated by the same germicides that destroy lipid viruses and vegetative bacteria. A known exception to this supposition is *Coxsackie burnetii*, which has demonstrated resistance to disinfectants.<sup>14</sup>

## Concentration and Potency of Disinfectants

With other variables constant, and with one exception (iodophors), the more concentrated the

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disinfectant, the greater its efficacy and the shorter the time necessary to achieve microbial kill. Generally not recognized, however, is that all disinfectants are not similarly affected by concentration adjustments. For example, quaternary ammonium compounds and phenol have a concentration exponent of 1 and 5, respectively; thus, halving the concentration of a quaternary ammonium compound requires doubling its disinfecting time, but halving the concentration of a phenol solution requires a 64-fold (i.e., 2<sup>6</sup>) increase in its disinfecting time.<sup>14, 418, 419</sup>

Considering the length of the disinfecting time, which depends on the potency of the germicide, also is important. This was illustrated by Spaulding who demonstrated using the much-loop test that 70% isopropyl alcohol destroyed 10<sup>6</sup> *M. tuberculosis* in 5 minutes, whereas a simultaneous test with 3% phenolic required 2-3 hours to achieve the same level of microbial kill.<sup>14</sup>

## Physical and Chemical Factors

Several physical and chemical factors also influence disinfectant procedures: temperature, pH, relative humidity, and water hardness. For example, the activity of most disinfectants increases as the temperature increases, but some exceptions exist. Furthermore, too great an increase in temperature causes the disinfectant to degrade and weakens its germicidal activity and thus might produce a potential health hazard.

An increase in pH improves the antimicrobial activity of some disinfectants (e.g., glutaraldehyde, quaternary ammonium compounds) but decreases the antimicrobial activity of others (e.g., phenols, hypochlorites, and iodine). The pH influences the antimicrobial activity by altering the disinfectant molecule or the cell surface.<sup>14</sup>

Relative humidity is the single most important factor influencing the activity of gaseous disinfectants/sterilants, such as EtO, chlorine dioxide, and formaldehyde.

Water hardness (i.e., high concentration of divalent cations) reduces the rate of kill of certain disinfectants because divalent cations (e.g., magnesium, calcium) in the hard water interact with the disinfectant to form insoluble precipitates.<sup>14, 420</sup>

## Organic and Inorganic Matter

Organic matter in the form of serum, blood, pus, or fecal or lubricant material can interfere with the antimicrobial activity of disinfectants in at least two ways. Most commonly, interference occurs by a chemical reaction between the germicide and the organic matter resulting in a complex that is less germicidal or nongermicidal, leaving less of the active germicide available for attacking microorganisms. Chlorine and iodine disinfectants, in particular, are prone to such interaction. Alternatively, organic material can protect microorganisms from attack by acting as a physical barrier.<sup>14, 421</sup>

The effects of inorganic contaminants on the sterilization process were studied during the 1950s and 1960s.<sup>422, 423</sup> These and other studies show the protection by inorganic contaminants of microorganisms to all sterilization processes results from occlusion in salt crystals.<sup>422, 423</sup> This further emphasizes the importance of meticulous cleaning of medical devices before any sterilization or disinfection procedure because both organic and inorganic soils are easily removed by washing.<sup>424</sup>

## Duration of Exposure

Items must be exposed to the germicide for the appropriate minimum contact time. Multiple investigators have demonstrated the effectiveness of low-level disinfectants against vegetative bacteria (e.g., *Listeria*, *E. coli*, *Salmonella*, VRE, MRSA), yeasts (e.g., *Candida*), mycobacteria (e.g., *M. tuberculosis*), and viruses (e.g., poliovirus) at exposure times of 30-60 seconds.<sup>444</sup> By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability for any injuries resulting from occlusion and is potentially subject to enforcement action under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

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All lumens and channels of endoscopic instruments must contact the disinfectant. Air pockets interfere with the disinfection process, and items that float on the disinfectant will not be disinfected. The disinfectant must be introduced reliably into the internal channels of the device. The exact times for disinfecting medical items are somewhat elusive because of the effect of the aforementioned factors on disinfection efficacy. Certain contact times have proved reliable (Table 1), but, in general, longer contact times are more effective than shorter contact times.

## Biofilms

Microorganisms may be protected from disinfectants by production of thick masses of cells<sup>425</sup> and extracellular materials, or biofilms.<sup>426, 427</sup> Biofilms are microbial communities that are tightly attached to surfaces and cannot be easily removed. Once these masses form, microbes within them can be resistant to disinfectants by multiple mechanisms, including physical characteristics of older biofilms, genotypic variation of the bacteria, microbial production of neutralizing enzymes, and physiologic gradients within the biofilm (e.g., pH). Bacteria within biofilms are up to 1,000 times more resistant to antimicrobials than are the same bacteria in suspension.<sup>428</sup> Although new decontamination methods<sup>429</sup> are being investigated for removing biofilms, chlorine and monochloramines can effectively inactivate biofilm bacteria.<sup>430</sup> Investigators have hypothesized that the glycocalyx-like cellular masses on the interior walls of polyvinyl chloride pipe would protect embedded organisms from some disinfectants and be a reservoir for continuous contamination.<sup>429, 431, 432</sup> Biofilms have been found in whirlpools,<sup>433</sup> dental unit waterlines,<sup>434</sup> and numerous medical devices (e.g., contact lenses, pacemakers, hemodialysis systems, urinary catheters, central venous catheters, endoscopes)<sup>434, 435, 436, 437</sup>. Their presence can have serious implications for immunocompromised patients and patients who have indwelling medical devices. Some enzymes<sup>438, 439, 440</sup> and detergents<sup>438</sup> can degrade biofilms or reduce numbers of viable bacteria within a biofilm, but no products are EPA-registered or FDA-cleared for this purpose.

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## CLEANING

Cleaning is the removal of foreign material (e.g., soil, and organic material) from objects and is normally accomplished using water with detergents or enzymatic products. Thorough cleaning is required before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. Also, if soiled materials dry or bake onto the instruments, the removal process becomes more difficult and the disinfection or sterilization process less effective or ineffective. Surgical instruments should be preassembled or rinsed to prevent drying of blood and to soften or remove blood from the instruments.

Cleaning is done manually in use areas without mechanical units (e.g., ultrasonic cleaners or washer-disinfectors) or for fragile or difficult-to-clean instruments. With manual cleaning, the two essential components are friction and fluidics. Friction (e.g., rubbing/scrubbing the soiled area with a brush) is an old and dependable method. Fluidics (i.e., fluids under pressure) is used to remove soil and debris from internal channels after brushing and when the design does not allow passage of a brush through a channel.<sup>441</sup> When a washer-disinfecter is used, care should be taken in loading instruments: hinged instruments should be opened fully to allow adequate contact with the detergent solution; stacking of instruments in washers should be avoided; and instruments should be disassembled as much as possible.

The most common types of mechanical or automatic cleaners are ultrasonic cleaners, washer-decontaminators, washer-disinfectors, and washer-sterilizers. Ultrasonic cleaning removes soil by cavitation and implosion in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces. Bacterial contamination can be present in used ultrasonic cleaning solutions (and other used detergent solutions) because these solutions generally do not make antibacterial label claims.<sup>442</sup> Even though ultrasonic alone does not significantly inactivate bacteria, sonication can act synergistically to increase the cidal efficacy of a disinfectant.<sup>443</sup> Users of ultrasonic cleaners should be aware that the cleaning fluid could result in endotoxin contamination of surgical instruments, which could cause severe inflammatory reactions.<sup>444</sup> Washer-sterilizers are modified steam sterilizers that clean by filling the chamber with water and detergent through which steam passes to provide agitation. Instruments are subsequently rinsed and subjected to a short steam-sterilization cycle. Another washer-sterilizer employs rotating spray arms for a wash cycle followed by a steam sterilization cycle at 285°F.<sup>444, 445</sup> Washer-decontaminators/disinfectors act like a dishwasher that uses a combination of water circulation and detergents to remove soil. These units sometimes have a cycle that subjects the instruments to a heat process (e.g., 93°C for 10 minutes).<sup>441</sup> Washer-disinfectors are generally computer-controlled units for cleaning, disinfecting, and drying solid and hollow surgical and medical equipment. In one study, cleaning (measured as 5-6 log<sub>10</sub> reduction) was achieved on surfaces that had adequate contact with the water flow in the machine.<sup>446</sup> Detailed information about cleaning and preparing supplies for terminal sterilization is provided by professional organizations,<sup>13, 447</sup> and books.<sup>448</sup> Studies have shown that manual and mechanical cleaning of endoscopes achieves approximately a 4-log<sub>10</sub> reduction of contaminating organisms.<sup>449, 450, 451, 452</sup> Thus, cleaning alone effectively reduces the number of microorganisms on contaminated equipment. In a quantitative analysis of residual protein contamination of reprocessed surgical instruments, median levels of residual protein contamination per instrument for five trays were 267, 260, 163, 456, and 766 µg.<sup>453</sup> In another study, the median amount of protein from reprocessed surgical instruments from different hospitals ranged from 8 µg to 91 µg.<sup>454</sup> When manual methods were compared with automated methods for cleaning reusable accessory devices used for minimally invasive surgical procedures, the automated method was more efficient for cleaning biopsy forceps and parted and nonparted laparoscopic devices and achieved a >99% reduction in soil parameters (i.e., protein, carbohydrate, hemoglobin) in the parted and nonparted laparoscopic devices.<sup>455, 456</sup>

For instrument cleaning, a neutral or near-neutral pH detergent solution commonly is used because such solutions generally provide the best material compatibility profile and good soil removal.

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Enzymes, usually proteases, sometimes are added to neutral pH solutions to assist in removing organic material. Enzymes in these formulations attack proteins that make up a large portion of common soil (e.g., blood, pus). Cleaning solutions also can contain lipases (enzymes active on fats) and amylases (enzymes active on starches). Enzymatic cleaners are not disinfectants, and proteinaceous enzymes can be inactivated by germicides. As with all chemicals, enzymes must be rinsed from the equipment or adverse reactions (e.g., fever, residual amounts of high-level disinfectants, proteinaceous residue) could result.<sup>462,463</sup> Enzyme solutions should be used in accordance with manufacturer's instructions, which include proper dilution of the enzymatic detergent and contact with equipment for the amount of time specified on the label.<sup>462</sup> Detergent enzymes can result in asthma or other allergic effects in users. Neutral pH detergent solutions that contain enzymes are compatible with metals and other materials used in medical instruments and are the best choice for cleaning delicate medical instruments, especially flexible endoscopes.<sup>467</sup> Alkaline-based cleaning agents are used for processing medical devices because they efficiently dissolve protein and fat residues<sup>464</sup>; however, they can be corrosive.<sup>467</sup> Some data demonstrate that enzymatic cleaners are more effective than neutral detergents.<sup>465,466</sup> In removing microorganisms from surfaces but two more recent studies found no difference in cleaning efficiency between enzymatic and alkaline-based cleaners.<sup>465,466</sup> Another study found no significant difference between enzymatic and non-enzymatic cleaners in terms of microbial cleaning efficacy.<sup>467</sup> A new non-enzyme, hydrogen peroxide-based formulation (not FDA-cleared) was as effective as enzymatic cleaners in removing protein, blood, carbohydrate, and endotoxin from surface test carriers.<sup>468</sup> In addition, this product effected a 5-log<sub>10</sub> reduction in microbial loads with a 3-minute exposure at room temperature.<sup>468</sup>

Although the effectiveness of high-level disinfection and sterilization mandates effective cleaning, no "real-time" tests exist that can be employed in a clinical setting to verify cleaning. If such tests were commercially available they could be used to ensure an adequate level of cleaning.<sup>469,470</sup> The only way to ensure adequate cleaning is to conduct a reprocessing verification test (e.g., microbiologic sampling), but this is not routinely recommended.<sup>475</sup> Verification of the cleaning processes in a laboratory-testing program is possible by microorganism detection, chemical detection for organic contaminants, radiolabeled tagging, and chemical detection for specific ions.<sup>426,471</sup> During the past few years, data have been published describing use of an artificial soil, protein, endotoxin, X-ray contrast medium, or blood to verify the manual or automated cleaning process.<sup>469,472-477</sup> and adenosine triphosphate bioluminescence and microbiologic sampling to evaluate the effectiveness of environmental surface cleaning.<sup>176,478</sup> At a minimum, all instruments should be individually inspected and be visibly clean.

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## DISINFECTION

Many disinfectants are used alone or in combinations (e.g., hydrogen peroxide and peracetic acid) in the health-care setting. These include alcohols, chlorines and chlorine compounds, formaldehyde, glutaraldehyde, ortho-phthalaldehyde, hydrogen peroxide, iodophors, peracetic acid, phenolics, and quaternary ammonium compounds. Commercial formulations based on these chemicals are considered unique products and must be registered with EPA or cleared by FDA. In most instances, a given product is designed for a specific purpose and is to be used in a certain manner. Therefore, users should read labels carefully to ensure the correct product is selected for the intended use and applied efficiently.

Disinfectants are not interchangeable, and incorrect concentrations and inappropriate disinfectants can result in excessive costs. Because occupational diseases among cleaning personnel have been associated with use of several disinfectants (e.g., formaldehyde, glutaraldehyde, and chlorine), precautions (e.g., gloves and proper ventilation) should be used to minimize exposure.<sup>76,44,44</sup> Asthma and reactive airway diseases can occur in sensitized persons exposed to any airborne chemical, including germicides. Clinically important asthma can occur at levels below ceiling levels regulated by OSHA or recommended by NIOSH. The preferred method of control is elimination of the chemical (through engineering controls or substitution) or relocation of the worker.

The following overview of the performance characteristics of each provides users with sufficient information to select an appropriate disinfectant for any item and use it in the most efficient way.

Chemical Disinfectants  
Alcohol

**Overview.** In the health-care setting, "alcohol" refers to two water-soluble chemical compounds—ethyl alcohol and isopropyl alcohol—that have generally undemanded germicidal characteristics.<sup>480</sup> FDA has not cleared any liquid chemical sterilant or high-level disinfectant with alcohol as the main active ingredient. These alcohols are rapidly bactericidal rather than bacteriostatic against vegetative forms of bacteria; they also are tuberculocidal, fungicidal, and virucidal but do not destroy bacterial spores. Their activity drops sharply when diluted below 60% concentration, and the optimum bactericidal concentration is 60%–90% solutions in water (volume/volume)<sup>480,481</sup>.

**Mode of Action.** The most feasible explanation for the antimicrobial action of alcohol is denaturation of proteins. This mechanism is supported by the observation that absolute ethyl alcohol, a dehydrating agent, is less bactericidal than mixtures of alcohol and water because proteins are denatured more quickly in the presence of water.<sup>482,483</sup> Protein denaturation also is consistent with observations that alcohol destroys the dehydrogenase of *Escherichia coli*<sup>484</sup>, and that ethyl alcohol increases the lag phase of *Enterobacter aerogenes*<sup>485</sup> and that the lag phase could be reversed by adding certain amino acids. The bacteriostatic action was believed caused by inhibition of the production of metabolites essential for rapid cell division.

**Microbicidal Activity.** Methyl alcohol (methanol) has the weakest bactericidal action of the alcohols and thus seldom is used in health care.<sup>486</sup> The bactericidal activity of various concentrations of ethyl alcohol (ethanol) was examined against a variety of microorganisms in exposure periods ranging from 10 seconds to 1 hour.<sup>487</sup> *Pseudomonas aeruginosa* was killed in 10 seconds by all concentrations of ethanol from 30% to 100% (v/v), and *Serratia marcescens*, *E. coli* and *Salmonella typhosa* were killed in 10 seconds by all concentrations of ethanol from 40% to 100%. The gram-positive organisms *Staphylococcus aureus* and *Streptococcus pyogenes* were slightly more resistant, being killed in 10 seconds by ethyl alcohol concentrations of 60%–85%. Isopropyl alcohol (isopropanol) was slightly more bactericidal than ethyl alcohol for *E. coli* and *S. aureus*.<sup>488</sup>

Ethyl alcohol, at concentrations of 60%–90%, is a potent virucidal agent inactivating all of the lipophilic viruses (e.g., herpes, varicella, and influenza virus) and many hydrophilic viruses (e.g.,

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adenovirus, enterovirus, rhinovirus, and rotavirus but not hepatitis A virus (HAV)<sup>489</sup> or poliovirus<sup>490</sup>. Isopropyl alcohol is not active against the nonlipid enteroviruses but is fully active against the lipid viruses.<sup>72</sup> Studies also have demonstrated the ability of ethyl and isopropyl alcohol to inactivate the hepatitis B virus (HBV)<sup>294,295</sup> and the hepatitis virus,<sup>491</sup> and ethyl alcohol to inactivate human immunodeficiency virus (HIV)<sup>297</sup>, rotavirus, echovirus, and astrovirus.<sup>492</sup>

In tests of the effect of ethyl alcohol against *M. tuberculosis*, 95% ethanol killed the tubercle bacilli in sputum or water suspension within 15 seconds.<sup>493</sup> In 1954, Spaulding stated that alcohols were the germicide of choice for tuberculocidal activity, and they should be the standard by which all other tuberculocides are compared. For example, he compared the tuberculocidal activity of iodophor (450 ppm), a substituted phenol (3%), and isopropanol (70% volume) using the mucin-loop test (10<sup>7</sup> *M. tuberculosis* per loop) and determined the contact times needed for complete destruction were 120–180 minutes, 45–60 minutes, and 5 minutes, respectively. The mucin-loop test is a severe test developed to produce long survival times. Thus, these figures should not be extrapolated to the exposure times needed when these germicides are used on medical or surgical material.<sup>494</sup>

Ethyl alcohol (70%) was the most effective concentration for killing the tissue phase of *Cryptosporidium parvum*, *Blaschkea dermatitidis*, *Coccidiodies immitis*, and *Histoplasma capsulatum* and the culture phases of the latter three organisms aerosolized on various surfaces. The culture phase was more resistant to the action of ethyl alcohol and required about 20 minutes to disinfect the contaminated surface, compared with <1 minute for the tissue phase.<sup>495,496</sup>

Isopropyl alcohol (20%) is effective in killing the cysts of *Acanthamoeba cubanensis* (500) as are chlorhexidine, hydrogen peroxide, and thimerosal.<sup>497</sup>

**Uses.** Alcohols are not recommended for sterilizing medical and surgical materials principally because they lack sporicidal action and they cannot penetrate protein-rich materials. Fatal postoperative wound infections with *Clostridium* have occurred when alcohols were used to sterilize surgical instruments contaminated with bacterial spores.<sup>498</sup> Alcohols have been used effectively to disinfect oral and rectal thermometers<sup>499,500</sup>, hospital gowns,<sup>501</sup> and stethoscopes.<sup>502</sup> Alcohols have been used to disinfect fiberoptic endoscopes.<sup>393,503</sup> but failure of this disinfectant have led to infection.<sup>296,504</sup> Alcohol towels have been used for years to disinfect small surfaces such as rubber stoppers of multiple-dose medication vials or vaccine bottles. Furthermore, alcohol occasionally is used to disinfect external surfaces of equipment (e.g., stethoscopes, ventilators, manual ventilation bags)<sup>505</sup>, CPR manikins<sup>506</sup>, ultrasound instruments<sup>507</sup> or medication preparation areas. Two studies demonstrated the effectiveness of 70% isopropyl alcohol to disinfect reusable transducer heads in a controlled environment.<sup>508,509</sup> In contrast, three bloodstream infection outbreaks have been described when alcohol was used to disinfect transducer heads in an intensive-care setting.<sup>510</sup>

The documented shortcomings of alcohols on equipment are that they damage the shellac mountings of lensed instruments, tend to swell and harden rubber and certain plastic tubing after prolonged and repeated use, bleach rubber and plastic ties<sup>511</sup> and damage tonometer tips (by delamination of the glue) after the equivalent of 1 working year of routine use.<sup>512</sup> Tonometer biphisms soaked in alcohol for 4 days developed rough front surfaces that potentially could cause corneal damage; this appeared to be caused by weakening of the cementing substances used to fabricate the biphisms.<sup>513</sup> Corneal opacification has been reported when tonometer tips were swabbed with alcohol immediately before measurement of intraocular pressure.<sup>514</sup> Alcohols are flammable and consequently must be stored in a cool, well-ventilated area. They also evaporate rapidly, making extended exposure time difficult to achieve unless the items are immersed.

## Chlorine and Chlorine Compounds

**Overview.** Hypochlorites, the most widely used of the chlorine disinfectants, are available as liquid (e.g., sodium hypochlorite) or solid (e.g., calcium hypochlorite). The most prevalent chlorine

products in the United States are aqueous solutions of 6.25%–6.15% sodium hypochlorite (see glossary), usually called household bleach. They have a broad spectrum of antimicrobial activity, do not leave toxic residues, are unaffected by water hardness, are inexpensive and fast acting<sup>515</sup>, remove dried or fixed organisms and biofilms from surfaces<sup>516</sup>, and have a low incidence of serious toxicity.<sup>515,517</sup> Sodium hypochlorite is a powerful oxidizing agent (5.25–6.15%) can produce ocular irritation or corneal burns<sup>518,519</sup>, and gastric burns.<sup>518,520</sup> Other disadvantages of hypochlorites include corrosiveness to metals in high concentrations (>500 ppm), inactivation by organic matter, discoloring or "bleaching" of fabrics, release of toxic chlorine gas when mixed with ammonia or acid (e.g., household cleaning agents)<sup>521,522</sup>, and relative stability.<sup>523</sup> The microbicidal activity of chlorine is attributed largely to undissociated hypochlorous acid (HOCl). The dissociation of HOCl to the less microbicidal form (hypochlorite ion OCl<sup>-</sup>) depends on pH. The disinfecting efficacy of chlorine decreases with an increase in pH that parallels the conversion of undissociated HOCl to OCl<sup>-</sup>.<sup>524</sup> A potential hazard is production of the carcinogen bis(chloromethyl) ether when hypochlorite solutions contact formaldehyde<sup>525</sup> and the production of the animal carcinogen trihalomethane when hot water is hypochloritized.<sup>526</sup> After reviewing environmental fate and ecologic data, EPA has determined the currently registered uses of hypochlorites will not result in unreasonable adverse effects to the environment.<sup>527</sup>

Alternative compounds that release chlorine and are used in the health-care setting include demand-release chlorine dioxide, sodium dichloroacrylate, and chloramine-T. The advantage of these compounds over the hypochlorites is that they retain chlorine longer and exert a more prolonged bactericidal effect. Sodium dichloroacrylate tablets are stable, and for two reasons, the microbicidal activity of solutions prepared from sodium dichloroacrylate tablets might be greater than that of sodium hypochlorite solutions containing the same total available chlorine. First, with sodium dichloroacrylate, only 50% of the total available chlorine is free (HOCl and OCl<sup>-</sup>), whereas the remainder is combined (monochloroacrylate or dichloroacrylate), and as free available chlorine is used up, the latter is released to restore the equilibrium. Second, solutions of sodium dichloroacrylate are acidic, whereas sodium hypochlorite solutions are alkaline, and the more microbicidal type of chlorine (HOCl) is believed to predominate.<sup>528,529</sup> Chlorine dioxide-based disinfectants are prepared fresh as required by mixing the two components (base solution [citric acid preservatives and corrosion inhibitors] and the activator solution [sodium chlorite]). In vitro suspension tests showed that solutions containing about 140 ppm chlorine dioxide achieved a reduction factor exceeding 10<sup>6</sup> of *S. aureus* in 1 minute and of *Bacillus atrophaeus* spores in 2.5 minutes in the presence of 5 g/L bovine albumin. The potential for damaging equipment requires consideration because long-term use can damage the outer plastic coat of the insertion tube.<sup>530</sup> In another study, chlorine dioxide solutions at either 600 ppm or 30 ppm killed *Mycobacterium avium-intracellulare* within 60 seconds after contact but contamination by organic material significantly affected the microbicidal properties.<sup>531</sup>

The microbicidal activity of a new disinfectant, "superoxidized water," has been examined. The concept of electrolyzing saline to create a disinfectant or antiseptic is appealing because the basic materials of saline and electricity are inexpensive and the end product (i.e., water) does not damage the environment. The main products of this water are hypochlorous acid (e.g., at a concentration of about 144 mg/L) and chlorine. As with any germicide, the antimicrobial activity of superoxidized water is strongly affected by the concentration of the active ingredient (available free chlorine).<sup>532</sup> One manufacturer generates the disinfectant at the point of use by passing a saline solution over coated titanium electrodes at 9 amps. The product generated has a pH of 5.0–6.5 and an oxidation-reduction potential (redox) of >950 mV. Although superoxidized water is intended to be generated fresh at the point of use, when tested under clean conditions the disinfectant was effective within 5 minutes when 48 hours old.<sup>533</sup> Unfortunately, the equipment required to produce the product can be expensive because parameters such as pH, current, and redox potential must be closely monitored. The solution is nontoxic to biologic tissues. Although the United Kingdom manufacturer claims the solution is noncorrosive and nondamaging to endoscopes and processing equipment, one flexible endoscope manufacturer (Glympus Key-Med, United Kingdom) has voided the warranty on the endoscopes if superoxidized water is used to disinfect them.<sup>534</sup> As with any germicide formulation, the user should check with the device manufacturer for

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compatibility with the peroxide. Additional studies are needed to determine whether this solution could be used as an alternative to other disinfectants or antiseptics for hand washing, skin antiseptics, room cleaning, or equipment disinfection (e.g., endoscopes, dialyzers).<sup>338,339</sup> In October 2002, the FDA cleared superoxidized water as a high-level disinfectant (FDA personal communication, September 10, 2002).

**Mode of Action.** The exact mechanism by which free chlorine destroys microorganisms has not been elucidated. Inactivation by chlorine can result from a number of factors: oxidation of sulfhydryl enzymes and amino acids; ring chlorination of amino acids; loss of intracellular contents; decreased uptake of nutrients; inhibition of protein synthesis; decreased oxygen uptake; oxidation of respiratory components; decreased acetone phosphate production; breaks in DNA; and depressed DNA synthesis.<sup>340,341</sup> The actual microbicidal mechanism of chlorine might involve a combination of these factors or the effect of chlorine on critical sites.<sup>342</sup>

**Microbicidal Activity.** Low concentrations of free available chlorine (e.g., HOCl, OCl<sup>-</sup>, and elemental chlorine-C<sub>2</sub>) have a biocidal effect on mycoplasmas (25 ppm) and vegetative bacteria (<5 ppm) in seconds in the absence of an organic load.<sup>343,344</sup> Higher concentrations (1,000 ppm) of chlorine are required to kill *M. tuberculosis* using the Association of Official Analytical Chemists (AOAC) tuberculocidal test.<sup>345</sup> A concentration of 100 ppm will kill ≥99.9% of *B. anthracis* spores within 5 minutes<sup>346,347</sup> and destroy mycotic agents in <1 hour.<sup>348</sup> Activated bleach and regular bleach (5,000 ppm chlorine) can inactivate 10<sup>8</sup> *Clostridium difficile* spores in ≤10 minutes.<sup>349</sup> One study reported that 25 different viruses were inactivated in 10 minutes with 200 ppm available chlorine.<sup>350</sup> Several studies have demonstrated the effectiveness of diluted sodium hypochlorite and other disinfectants to inactivate HIV.<sup>351</sup> Chlorine (500 ppm) showed inhibition of *Legionella* after 30 seconds of exposure.<sup>352</sup> In experiments using the AOAC Use-Dilution Method, 100 ppm of free chlorine killed 10<sup>6</sup>-10<sup>7</sup> *S. aureus*, *Salmonella choleraesuis*, and *P. aeruginosa* in <10 minutes.<sup>353</sup> Because household bleach contains 5.25%-8.15% sodium hypochlorite, or 52,500-81,500 ppm available chlorine, a 1:1,000 dilution provides about 53-62 ppm available chlorine, and a 1:10 dilution of household bleach provides about 6250-8150 ppm.

Data are available for chlorine dioxide that support manufacturers' bactericidal, fungicidal, sporocidal, tuberculocidal, and virucidal label claims.<sup>354-356</sup> A chlorine dioxide generator has been shown effective for decontaminating flexible endoscopes,<sup>357</sup> but it is not currently FDA-cleared for use as a high-level disinfectant.<sup>358</sup> Chlorine dioxide can be produced by mixing solutions, such as a solution of chlorine with a solution of sodium chlorite.<sup>359</sup> In 1989, a chlorine dioxide product was voluntarily removed from the market when its use caused leakage of cellulose-based dialyzer membranes, which allowed bacteria to migrate from the dialysis fluid side of the dialyzer to the blood side.<sup>360</sup>

Sodium dichloroacrylate at 2,500 ppm available chlorine is effective against bacteria in the presence of up to 20% plasma, compared with 10% plasma for sodium hypochlorite at 2,500 ppm.<sup>361</sup>

"Superoxidized water" has been tested against bacteria, mycobacteria, viruses, fungi, and spores *in vitro*.<sup>362</sup> Freshly generated superoxidized water is rapidly effective (<2 minutes) in achieving a 5-log<sub>10</sub> reduction of pathogenic microorganisms (i.e., *M. tuberculosis*, *M. chelonae*, poliovirus, HIV, multidrug-resistant *S. aureus*, *E. coli*, *Candida albicans*, *Enterococcus faecalis*, *P. aeruginosa*) in the absence of organic loading. However, the biocidal activity of this disinfectant decreased substantially in the presence of organic material (e.g., 5% horse serum).<sup>363,364</sup> No bacteria or viruses were detected on artificially contaminated endoscopes after 5-minute exposure to superoxidized water,<sup>365</sup> and HBV-DNA was not detected from any endoscope experimentally contaminated with HBV-positive blood sera after a disinfectant exposure time of 7 minutes.<sup>366</sup>

**Uses.** Hypochlorites are widely used in healthcare facilities in a variety of settings.<sup>368</sup> Inorganic chlorine solution is used for disinfecting tonometer heads<sup>369</sup> and for spot-disinfection of countertops and floors. A 1:10-1:100 dilution of 5.25%-8.15% sodium hypochlorite (i.e., household bleach)<sup>22,23,26,368,369</sup> or

an EPA-registered tuberculocidal disinfectant<sup>11</sup> has been recommended for decontaminating blood spills. For small spills of blood (i.e., drops of blood) on nonporous surfaces, the area can be disinfected with a 1:100 dilution of 5.25%-8.15% sodium hypochlorite or an EPA-registered tuberculocidal disinfectant. Because hypochlorites and other germicides are substantially inactivated in the presence of blood,<sup>364,365,368,369</sup> large spills of blood require that the surface be cleaned before an EPA-registered disinfectant or a 1:10 (final concentration) solution of household bleach is applied.<sup>367</sup> If a sharp injury is possible, the surface initially should be decontaminated<sup>370,371</sup>, then cleaned and disinfected (1:10 final concentration).<sup>372</sup> Extreme care always should be taken to prevent percutaneous injury. At least 500 ppm available chlorine for 10 minutes is recommended for decontaminating CPR training manikins. Full-strength bleach has been recommended for self-disinfection of needles and syringes used for fixed-dose injection when needle-exchange programs are not available. The difference in the recommended concentrations of bleach reflects the difficulty of cleaning the interior of needles and syringes and the use of needles and syringes for parenteral injection.<sup>368</sup> Clinicians should not alter their use of chlorine on environmental surfaces on the basis of testing methodologies that do not simulate actual disinfection practices.<sup>368,369</sup> Other uses in healthcare include use as an irrigating agent in endodontic treatment<sup>373</sup> and as a disinfectant for manikins, laundry, dental appliances, hydrotherapy tanks,<sup>374,375</sup> regulated medical waste before disposal,<sup>376</sup> and the water distribution system in hemodialysis centers and hemodialysis machines.<sup>377</sup>

Chlorine long has been used as the disinfectant in water treatment. Hyperchlorination of a Legionella-contaminated hospital water system<sup>378</sup> resulted in a dramatic decrease (from 30% to 1.5%) in the isolation of *L. pneumophila* from water outlets and a cessation of healthcare-associated Legionnaires' disease in an enclosed unit.<sup>379</sup> Water disinfection with monochloramine by municipal water-treatment plants substantially reduced the risk for healthcare-associated Legionnaires' disease.<sup>380</sup> Chlorine dioxide also has been used to control Legionella in a hospital water supply.<sup>381</sup> Chloramine T<sup>382</sup> and hypochlorites<sup>31</sup> have been used to disinfect hydrotherapy equipment.

Hypochlorite solutions in tap water at a pH >8 stored at room temperature (23°C) in closed, opaque plastic containers can lose up to 40%-50% of their free available chlorine level over 1 month. Thus, if a user wished to have a solution containing 500 ppm of available chlorine at day 30, he or she should prepare a solution containing 1,000 ppm of chlorine at time 0. Sodium hypochlorite solution does not decompose after 30 days when stored in a closed brown bottle.<sup>383</sup>

The use of powders, composed of a mixture of a chlorine-releasing agent with highly absorbent resin, for disinfecting spills of body fluids has been evaluated by laboratory tests and hospital ward trials. The inclusion of acrylic resin particles in formulations markedly increases the volume of fluid that can be soaked up because the resin can absorb 200-300 times its own weight of fluid, depending on the fluid consistency. When experimental formulations containing 1%, 5%, and 10% available chlorine were evaluated by a standardized surface test, those containing 10% demonstrated bactericidal activity. One problem with chlorine-releasing granules is that they can generate chlorine fumes when applied to urine.<sup>384</sup>

**Formaldehyde**

**Overview.** Formaldehyde is used as a disinfectant and sterilant in both its liquid and gaseous states. Liquid formaldehyde will be considered briefly in this section, and the gaseous form is reviewed elsewhere.<sup>385</sup> Formaldehyde is sold and used principally as a water-based solution called formalin, which is 37% formaldehyde by weight. The aqueous solution is a bactericidal, tuberculocidal, fungicidal, virucidal and sporicidal.<sup>72,385,386</sup> OSHA indicated that formaldehyde should be handled in the workplace as a potential carcinogen and set an employee exposure standard for formaldehyde that limits an 8-hour time-weighted average exposure concentration of 0.75 ppm.<sup>387,388</sup> The standard includes a second permissible exposure limit in the form of a short-term exposure limit (STEL) of 2 ppm that is the maximum exposure allowed during a 15-minute period.<sup>389</sup> Ingestion of formaldehyde can be fatal, and long-term exposure to formaldehyde in the air or on the skin can cause asthma-like respiratory problems and skin irritation, such as dermatitis and itching. For these reasons, employees should have limited direct contact

with formaldehyde, and these considerations limit its role in sterilization and disinfection processes. Key provisions of the OSHA standard that protects workers from exposure to formaldehyde appear in Title 29 of the Code of Federal Regulations (CFR) Part 1910.1045 (and equivalent regulations in states with OSHA-approved state plans).<sup>417</sup>

**Mode of Action.** Formaldehyde inactivates microorganisms by alkylating the amino and sulfhydryl groups of proteins and ring nitrogen atoms of purine bases.<sup>390</sup>

**Microbicidal Activity.** Varying concentrations of aqueous formaldehyde solutions destroy a wide range of microorganisms. Inactivation of poliovirus in 10 minutes required an 8% concentration of formalin, but all other viruses are inactivated in 10 minutes by 2% formalin.<sup>391</sup> Four percent formaldehyde is a tuberculocidal agent, inactivating 10<sup>8</sup> *M. tuberculosis* in 2 minutes.<sup>392</sup> and 2.5% formaldehyde inactivated about 10<sup>7</sup> *Salmonella* Typhi in 10 minutes in the presence of organic matter.<sup>393</sup> The sporicidal action of formaldehyde was slower than that of glutaraldehyde in comparative tests with 4% aqueous formaldehyde and 2% glutaraldehyde against the spores of *D. anthracis*.<sup>394</sup> The formaldehyde solution required 2 hours of contact to achieve an inactivation factor of 10<sup>6</sup>, whereas glutaraldehyde required only 15 minutes.

**Uses.** Although formaldehyde-alcohol is a chemical sterilant and formaldehyde is a high-level disinfectant, the health-care uses of formaldehyde are limited by its irritating fumes and its pungent odor even at very low levels (<1 ppm). For these reasons and others—such as its role as a suspected human carcinogen linked to nasal cancer and lung cancer<sup>395</sup>, this germicide is excluded from Table 1. When it is used, direct exposure to employees generally is limited; however, excessive exposures to formaldehyde have been documented for employees of renal transplant units<sup>396,397</sup> and students in a gross anatomy laboratory.<sup>398</sup> Formaldehyde is used in the health-care setting to prepare viral vaccines (e.g., poliovirus and influenza); as an embalming agent; and to preserve anatomic specimens; and historically has been used to sterilize surgical instruments, especially when mixed with ethanol. A 1997 survey found that formaldehyde was used for reprocessing hemodialyzers by 34% of U.S. hemodialysis centers—a 60% decrease from 1983.<sup>399,400</sup> If used at room temperature, a concentration of 4% with a minimum exposure of 24 hours is required to disinfect disposable hemodialyzers reused on the same patient.<sup>401,402</sup> Aqueous formaldehyde solutions (1%-2%) also have been used to disinfect the internal fluid pathways of dialysis machines.<sup>403</sup> To minimize a potential health hazard to dialysis patients, the dialysis equipment must be thoroughly rinsed and tested for residual formaldehyde before use.

Panformaldehyde, a solid polymer of formaldehyde, can be vaporized by heat for the gaseous decontamination of laminar flow biologic safety cabinets when maintenance work or filter changes require access to the sealed portion of the cabinet.

**Glutaraldehyde**

**Overview.** Glutaraldehyde is a saturated dialdehyde that has gained wide acceptance as a high-level disinfectant and chemical sterilant.<sup>404</sup> Aqueous solutions of glutaraldehyde are acidic and generally in this state are not sporicidal. Only when the solution is "activated" (made alkaline) by use of alkalinizing agents to pH 7.5-8.5 does the solution become sporicidal. Once activated, these solutions have a shelf-life of minimally 14 days because of the polymerization of the glutaraldehyde molecules at alkaline pH levels. This polymerization blocks the active sites (aldehyde groups) of the glutaraldehyde molecules that are responsible for its biocidal activity.

Novel glutaraldehyde formulations (e.g., glutaraldehyde-phenol-sodium phenolate, potentialized acid glutaraldehyde, stabilized alkaline glutaraldehyde) produced in the past 30 years have overcome the problem of rapid loss of activity (e.g., use-life 28-30 days) while generally maintaining excellent microbicidal activity.<sup>405-408</sup> However, antimicrobial activity depends not only on age but also on use conditions, such as dilution and organic stress. Manufacturers' literature for these preparations suggests the neutral or alkaline glutaraldehydes possess microbicidal and anticoncoron properties superior to

those of acid glutaraldehyde, and a few published reports substantiate these claims.<sup>409,410</sup> However, two studies found no difference in the microbicidal activity of alkaline and acid glutaraldehydes.<sup>411,412</sup> The use of glutaraldehyde-based solutions in health-care facilities is widespread because of their advantages, including excellent biocidal properties; activity in the presence of organic matter (20% bovine serum); and noncorrosive action to endoscopic equipment, thermometers, rubber, or plastic equipment (Tables 4 and 5).

**Mode of Action.** The biocidal activity of glutaraldehyde results from its alkylation of sulfhydryl, hydroxyl, carbonyl, and amino groups of microorganisms, which alters RNA, DNA, and protein synthesis. The mechanism of action of glutaraldehydes are reviewed extensively elsewhere.<sup>382,404</sup>

**Microbicidal Activity.** The *in vitro* inactivation of microorganisms by glutaraldehydes has been extensively investigated and reviewed.<sup>382,413</sup> Several investigators showed that ≥2% aqueous solutions of glutaraldehyde, buffered to pH 7.5-8.5 with sodium bicarbonate effectively killed vegetative bacteria in <2 minutes; *M. tuberculosis*, fungi, and viruses in <10 minutes; and spores of *Bacillus* and *Clostridium* in 3 hours.<sup>342,392,407</sup> Spores of *C. difficile* are more readily killed by 2% glutaraldehyde than are spores of other species of *Clostridium* and *Bacillus*.<sup>382,414</sup> Microorganisms with substantial resistance to glutaraldehyde have been reported, including some mycobacteria (*M. chelonae*, *Mycobacterium avium-intracellulare*, *M. xenopii*),<sup>415,416</sup> *Methylobacterium mesophilum*,<sup>417</sup> *Trichosporon*, fungal ascomycetes (e.g., *Microascus cinereus*, *Chesterium globosum*), and *Cryptosporidium*.<sup>418,419</sup> *M. chelonae* persisted in a 0.2% glutaraldehyde solution used to store porcine prosthetic heart valves.<sup>404</sup>

Two percent alkaline glutaraldehyde solution inactivated 10<sup>8</sup> *M. tuberculosis* cells on the surface of penicillin vials within 5 minutes at 18°C.<sup>420</sup> However, subsequent studies<sup>421</sup> questioned the microbicidal power of glutaraldehydes. Two percent alkaline glutaraldehyde has slow action (20 to >30 minutes) against *M. tuberculosis* and compares unfavorably with alcohol, formaldehydes, iodine, and phenol.<sup>422</sup> Suspensions of *M. avium*, *M. intracellulare*, and *M. goodii* were more resistant to inactivation by a 2% alkaline glutaraldehyde (estimated time to complete inactivation—60 minutes) than were virulent *M. tuberculosis* (estimated time to complete inactivation—25 minutes).<sup>423</sup> The rate of kill was directly proportional to the temperature, and a standardized suspension of *M. tuberculosis* could not be sterilized within 10 minutes.<sup>424</sup> An FDA-approved chemical sterilant containing 2.5% glutaraldehyde uses increased temperature (55°C) to reduce the time required to achieve high-level disinfection (5 minutes),<sup>425,426</sup> but its use is limited to automatic endoscope reprocessors equipped with a heater. In another study employing membrane filters for measurement of microbicidal activity of 2% alkaline glutaraldehyde, complete inactivation was achieved within 20 minutes at 20°C when the test inoculum was 10<sup>7</sup> *M. tuberculosis* per membrane.<sup>427</sup> Several investigators<sup>428,429,430,431,432,433,434,435</sup> have demonstrated that glutaraldehyde solutions inactivate 2.4 to >10 log<sub>10</sub> of *M. tuberculosis* in 10 minutes (including multidrug-resistant *M. tuberculosis*) and 0.5 to 1.0 log<sub>10</sub> of *M. tuberculosis* in 20 minutes. On the basis of these data and other studies, 20 minutes at room temperature is considered the minimum exposure time needed to reliably kill *Mycobacteria* and other vegetative bacteria with ≥2% glutaraldehyde.<sup>72,73,75,82,83,84,85,86,87,88,89,90,91,92,93,94,95,96,97,98,99,100,101,102,103,104,105,106,107,108,109,110,111,112,113,114,115,116,117,118,119,120,121,122,123,124,125,126,127,128,129,130,131,132,133,134,135,136,137,138,139,140,141,142,143,144,145,146,147,148,149,150,151,152,153,154,155,156,157,158,159,160,161,162,163,164,165,166,167,168,169,170,171,172,173,174,175,176,177,178,179,180,181,182,183,184,185,186,187,188,189,190,191,192,193,194,195,196,197,198,199,200,201,202,203,204,205,206,207,208,209,210,211,212,213,214,215,216,217,218,219,220,221,222,223,224,225,226,227,228,229,230,231,232,233,234,235,236,237,238,239,240,241,242,243,244,245,246,247,248,249,250,251,252,253,254,255,256,257,258,259,260,261,262,263,264,265,266,267,268,269,270,271,272,273,274,275,276,277,278,279,280,281,282,283,284,285,286,287,288,289,290,291,292,293,294,295,296,297,298,299,300,301,302,303,304,305,306,307,308,309,310,311,312,313,314,315,316,317,318,319,320,321,322,323,324,325,326,327,328,329,330,331,332,333,334,335,336,337,338,339,340,341,342,343,344,345,346,347,348,349,350,351,352,353,354,355,356,357,358,359,360,361,362,363,364,365,366,367,368,369,370,371,372,373,374,375,376,377,378,379,380,381,382,383,384,385,386,387,388,389,390,391,392,393,394,395,396,397,398,399,400,401,402,403,404,405,406,407,408,409,410,411,412,413,414,415,416,417,418,419,420,421,422,423,424,425,426,427,428,429,430,431,432,433,434,435,436,437,438,439,440,441,442,443,444,445,446,447,448,449,450,451,452,453,454,455,456,457,458,459,460,461,462,463,464,465,466,467,468,469,470,471,472,473,474,475,476,477,478,479,480,481,482,483,484,485,486,487,488,489,490,491,492,493,494,495,496,497,498,499,500,501,502,503,504,505,506,507,508,509,510,511,512,513,514,515,516,517,518,519,520,521,522,523,524,525,526,527,528,529,530,531,532,533,534,535,536,537,538,539,540,541,542,543,544,545,546,547,548,549,550,551,552,553,554,555,556,557,558,559,560,561,562,563,564,565,566,567,568,569,570,571,572,573,574,575,576,577,578,579,580,581,582,583,584,585,586,587,588,589,590,591,592,593,594,595,596,597,598,599,600,601,602,603,604,605,606,607,608,609,610,611,612,613,614,615,616,617,618,619,620,621,622,623,624,625,626,627,628,629,630,631,632,633,634,635,636,637,638,639,640,641,642,643,644,645,646,647,648,649,650,651,652,653,654,655,656,657,658,659,660,661,662,663,664,665,666,667,668,669,670,671,672,673,674,675,676,677,678,679,680,681,682,683,684,685,686,687,688,689,690,691,692,693,694,695,696,697,698,699,700,701,702,703,704,705,706,707,708,709,710,711,712,713,714,715,716,717,718,719,720,721,722,723,724,725,726,727,728,729,730,731,732,733,734,735,736,737,738,739,740,741,742,743,744,745,746,747,748,749,750,751,752,753,754,755,756,757,758,759,760,761,762,763,764,765,766,767,768,769,770,771,772,773,774,775,776,777,778,779,780,781,782,783,784,785,786,787,788,789,790,791,792,793,794,795,796,797,798,799,800,801,802,803,804,805,806,807,808,809,810,811,812,813,814,815,816,817,818,819,820,821,822,823,824,825,826,827,828,829,830,831,832,833,834,835,836,837,838,839,840,841,842,843,844,845,846,847,848,849,850,851,852,853,854,855,856,857,858,859,860,861,862,863,864,865,866,867,868,869,870,871,872,873,874,875,876,877,878,879,880,881,882,883,884,885,886,887,888,889,890,891,892,893,894,895,896,897,898,899,900,901,902,903,904,905,906,907,908,909,910,911,912,913,914,915,916,917,918,919,920,921,922,923,924,925,926,927,928,929,930,931,932,933,934,935,936,937,938,939,940,941,942,943,944,945,946,947,948,949,950,951,952,953,954,955,956,957,958,959,960,961,962,963,964,965,966,967,968,969,970,971,972,973,974,975,976,977,978,979,980,981,982,983,984,985,986,987,988,989,990,991,992,993,994,995,996,997,998,999,1000</sup>

Glutaraldehyde is commonly diluted during use, and studies showed a glutaraldehyde concentration decline after a few days of use in an automatic endoscope washer.<sup>406,409</sup> The decline occurs because instruments are not thoroughly dried and water is carried in with the instrument, which increases the solution volume and dilutes its effective concentration.<sup>411</sup> This emphasizes the need to ensure that semicritical equipment is disinfected with an acceptable concentration of glutaraldehyde. Data suggest that 1.0%-1.5% glutaraldehyde is the minimum effective concentration of glutaraldehyde. Glutaraldehyde solutions when used as a high-level disinfectant.<sup>72,84,280,282</sup> Chemical test strips or liquid chemical monitors<sup>414,411</sup> are available for determining whether an effective concentration of glutaraldehyde is present despite repeated use and dilution. The frequency of testing should be based on how frequently the solutions are used (e.g., used daily, test daily; used weekly, test before use; used 30 times per day, test each 10th use), but the strips should not be used to extend the use life beyond the expiration date. Data suggest the chemicals in the test strip deteriorate with time<sup>412</sup> and a

manufacturer's expiration date should be placed on the bottles. The bottle of test strips should be dated when opened and used for the period of time indicated on the bottle (e.g., 120 days). The results of test strip monitoring should be documented. The glutaraldehyde test kits have been preliminarily evaluated for accuracy and range<sup>612</sup> but the reliability has been questioned<sup>613</sup>. To ensure the presence of minimum effective concentration of the high-level disinfectant, manufacturers of some chemical test strips recommend the use of quality-control procedures to ensure the strips perform properly. If the manufacturer of the chemical test strip recommends a quality-control procedure, users should comply with the manufacturer's recommendations. The concentration should be considered unacceptable or unsafe when the test indicates a dilution below the product's minimum effective concentration (MEC) (generally to  $\leq 1.0\%$ – $1.5\%$  glutaraldehyde) by the indicator not changing color.

A 2.0% glutaraldehyde–7.05% phenol–1.20% sodium phenate product that contained 0.125% glutaraldehyde–0.44% phenol–0.075% sodium phenate when diluted 1:16 is not recommended as a high-level disinfectant because it lacks bactericidal activity in the presence of organic matter and lacks tuberculocidal, fungicidal, virucidal, and sporicidal activity<sup>614,615,616,617,618,619</sup>. In December 1991, EPA issued an order to stop the sale of all batches of this product because of efficacy data showing the product is not effective against spores and possibly other microorganisms or inanimate objects as claimed on the label<sup>620</sup>. FDA has cleared a glutaraldehyde–phenol/phenate concentrate as a high-level disinfectant that contains 1.12% glutaraldehyde with 1.53% phenol/phenate at its use concentration. Other FDA cleared glutaraldehyde sterilants that contain 2.4%–3.4% glutaraldehyde are used uncultured<sup>621</sup>.

**Uses.** Glutaraldehyde is used most commonly as a high-level disinfectant for medical equipment such as endoscopes<sup>614,622,623</sup>, spirometry tubing, dialyzers<sup>614</sup>, transducers, anesthesia and respiratory therapy equipment<sup>624</sup>, hemodialysis proportioning and dialysate delivery systems<sup>624,625</sup>, and reuse of laparoscopic disposable plastic trocars<sup>614</sup>. Glutaraldehyde is noncorrosive to metal and does not damage lensed instruments, rubber, or plastics. Glutaraldehyde should not be used for cleaning nonmetal surfaces because it is too toxic and expensive.

Collitis believed caused by glutaraldehyde exposure from residual disinfecting solution in endoscope solution channels has been reported and is preventable by careful endoscope rinsing<sup>626,627,628</sup>. One study found that residual glutaraldehyde levels were higher and more variable after manual disinfection (<0.2 mg/L to 159.5 mg/L) than after automatic disinfection (0.2–6.3 mg/L)<sup>629</sup>. Similarly, keratopathy and corneal decompensation were caused by ophthalmic instruments that were inadequately rinsed after soaking in 2% glutaraldehyde<sup>630,631</sup>.

Healthcare personnel can be exposed to elevated levels of glutaraldehyde vapor when equipment is processed in poorly ventilated rooms, when spills occur, when glutaraldehyde solutions are activated or changed<sup>632</sup>, or when open immersion baths are used. Acute or chronic exposure can result in skin irritation or dermatitis, mucous membrane irritation (eye, nose, mouth), or pulmonary symptoms<sup>614,633,634</sup>. Epistaxis, allergic contact dermatitis, asthma, and rhinitis also have been reported in healthcare workers exposed to glutaraldehyde<sup>635,636,637</sup>.

Glutaraldehyde exposure should be monitored to ensure a safe work environment. Testing can be done by four techniques: a silica gel tubeless chromatography with a flame ionization detector, dimethylphenylhydrazine (DNPH)-impregnated filter cassette/high-performance liquid chromatography (HPLC) with an ultraviolet (UV) detector, a passive badge/HPLC, or a handheld glutaraldehyde air monitor<sup>638</sup>. The silica gel tube and the DNPH-impregnated cassette are suitable for monitoring the 0.05 ppm ceiling limit. The passive badge, with a 0.02 ppm limit of detection, is considered marginal at the American Council of Governmental Industrial Hygienists (ACGIH) ceiling level. The ceiling level is considered too close to the glutaraldehyde meter's 0.03 ppm limit of detection to provide confidence in the readings<sup>639</sup>. ACGIH does not require a specific monitoring schedule for glutaraldehyde; however, a monitoring schedule is needed to ensure the level is less than the ceiling limit. For example, monitoring

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should be done initially to determine glutaraldehyde levels, after procedural or equipment changes, and in response to worker complaints<sup>640</sup>. In the absence of an OSHA permissible exposure limit, if the glutaraldehyde level is higher than the ACGIH ceiling limit of 0.05 ppm, corrective action and repeat monitoring would be prudent<sup>641</sup>.

Engineering and work-practice controls that can be used to resolve these problems include ducted exhaust hoods, air systems that provide 7–15 air exchanges per hour, ductless fume hoods with absorbents for the glutaraldehyde vapor, light-fitting lids on immersion baths, personal protection (e.g., nitrile or butyl rubber gloves but not natural latex gloves, goggles) to minimize skin or mucous membrane contact, and automated endoscope processors<sup>642</sup>. If engineering controls fail to maintain levels below the ceiling limit, institutions can consider the use of respirators (e.g., a half-face respirator with organic vapor cartridge<sup>643</sup> or a type "C" supplied air respirator with a full facepiece operated in a positive pressure mode)<sup>641</sup>. In general, engineering controls are preferred over work-practice and administrative controls because they do not require active participation by the health-care worker. Even though enforcement of the OSHA ceiling limit was suspended in 1993 by the U.S. Court of Appeals<sup>644</sup>, limiting employee exposure to 0.05 ppm (according to ACGIH) is prudent because, at this level, glutaraldehyde can irritate the eyes, throat, and nose<sup>614,645,646,647</sup>. If glutaraldehyde is disposed through the sanitary sewer system is restricted, sodium bisulfite can be used to neutralize the glutaraldehyde and make it safe for disposal.

#### Hydrogen Peroxide

**Overview.** The literature contains several accounts of the properties, germicidal effectiveness, and potential uses for stabilized hydrogen peroxide in the health-care setting. Published reports ascribe good germicidal activity to hydrogen peroxide and attest to its bactericidal, virucidal, sporicidal, and fungicidal properties<sup>648,649</sup>. (Tables 4 and 5) The FDA website lists cleared liquid chemical sterilants and high-level disinfectants containing hydrogen peroxide and their cleared contact conditions.

**Mode of Action.** Hydrogen peroxide works by producing destructive hydroxyl free radicals that can attack membrane lipids, DNA, and other essential cell components. Catalase, produced by aerobic organisms and facultative anaerobes that possess cytochrome systems, can protect cells from metabolically produced hydrogen peroxide by degrading hydrogen peroxide to water and oxygen. This defense is overwhelmed by the concentrations used for disinfection<sup>650,651</sup>.

**Microbicidal Activity.** Hydrogen peroxide is active against a wide range of microorganisms, including bacteria, yeasts, fungi, viruses, and spores<sup>648,652</sup>. A 0.5% accelerated hydrogen peroxide demonstrated bactericidal and virucidal activity in 1 minute and mycobactericidal and fungicidal activity in 5 minutes<sup>653</sup>. Bactericidal effectiveness and stability of hydrogen peroxide in urine has been demonstrated against a variety of health-care-associated pathogens; organisms with high cellular catalase activity (e.g., *S. aureus*, *S. marcescens*, and *Proteus mirabilis*) required 30–60 minutes of exposure to 0.6% hydrogen peroxide for a 10<sup>7</sup> reduction in cell counts, whereas organisms with lower catalase activity (e.g., *E. coli*, *Staphylococcus* species, and *Pseudomonas* species) required only 15 minutes' exposure<sup>654</sup>. In an investigation of 3%, 10%, and 16% hydrogen peroxide for reducing spore-forming bacterial populations, a complete kill of 10<sup>7</sup> spores (i.e., *Bacillus* species) occurred with a 10% concentration and a 60-minute exposure time. A 3% concentration for 150 minutes killed 10<sup>6</sup> spores in six of seven exposure trials<sup>655</sup>. A 10% hydrogen peroxide solution resulted in a 10<sup>4</sup> decrease in *A. baumannii* spores, and a  $\geq 10^5$  decrease when tested against 13 other pathogens in 30 minutes at 20°C<sup>656,657</sup>. A 3.0% hydrogen peroxide solution was ineffective against VRE after 3 and 10 minutes exposure time<sup>658</sup> and caused only a 2-log<sub>10</sub> reduction in the number of *Acanthamoeba* cysts in approximately 2 hours<sup>659</sup>. A 7% stabilized hydrogen peroxide proved to be sporicidal (5 hours of exposure), mycobactericidal (20 minutes), fungicidal (5 minutes) at full strength, virucidal (5 minutes), and bactericidal (3 minutes) at a 1:16 dilution when a quantitative carrier test was used<sup>660</sup>. The 7% solution of hydrogen peroxide, tested after 14 days of stress (in the form of germ-loaded carriers and respiratory therapy equipment), was sporicidal (>7 log<sub>10</sub> reduction in 6 hours), mycobactericidal (>8.5 log<sub>10</sub> reduction in 25

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minutes), fungicidal (>5 log<sub>10</sub> reduction in 20 minutes), bactericidal (>6 log<sub>10</sub> reduction in 5 minutes) and virucidal (5 log<sub>10</sub> reduction in 5 minutes)<sup>661</sup>. Synergistic sporicidal effects were observed when spores were exposed to a combination of hydrogen peroxide (5.9%–22.6%) and peracetic acid<sup>662</sup>. Other studies demonstrated the antiviral activity of hydrogen peroxide against rhinovirus<sup>663</sup>. The time required for inactivating three serotypes of rhinovirus using a 3% hydrogen peroxide solution was 6–8 minutes; this time increased with decreasing concentrations (16–20 minutes at 1.5%, 50–60 minutes at 0.75%)<sup>664</sup>.

Concentrations of hydrogen peroxide from 16% to 25% show promise as chemical sterilants. The product marketed as a premixed, ready-to-use chemical that contains 7.5% hydrogen peroxide and 0.85% phosphoric acid (to maintain a low pH)<sup>665</sup>. The mycobactericidal activity of 7.5% hydrogen peroxide has been corroborated in a study showing the inactivation of >10<sup>7</sup> multidrug-resistant *M. tuberculosis* after a 10-minute exposure<sup>666</sup>. Thirty minutes were required for >99.9% inactivation of poliovirus and HAV<sup>667</sup>. Three percent and 6% hydrogen peroxide were unable to inactivate HAV in 1 minute in a carrier test<sup>668</sup>. When the effectiveness of 7.5% hydrogen peroxide at 10 minutes was compared with 2% alkaline glutaraldehyde at 20 minutes in manual disinfection of endoscopes, no significant difference in germicidal activity was observed<sup>669</sup>. No complaints were received from the nursing or medical staff regarding odor or toxicity. In one study, 6% hydrogen peroxide (unused product was 7.5%) was more effective in the high-level disinfection of flexible endoscopes than was the 2% glutaraldehyde solution<sup>670</sup>. A new, rapid-acting 13.4% hydrogen peroxide formulation (that is not yet FDA-cleared) has demonstrated sporicidal, mycobactericidal, fungicidal, and virucidal efficacy. Manufacturer data demonstrate that this solution sterilizes in 30 minutes and provides high-level disinfection in 5 minutes<sup>671</sup>. This product has not been used long enough to evaluate material compatibility to endoscopes and other semirigid devices, and further assessment by instrument manufacturers is needed.

Under normal conditions, hydrogen peroxide is extremely stable when properly stored (e.g., in dark containers). The decomposition or loss of potency in small containers is less than 2% per year at ambient temperatures<sup>672</sup>.

**Uses.** Commercially available 3% hydrogen peroxide is a stable and effective disinfectant when used on inanimate surfaces. It has been used in concentrations from 2% to 6% for disinfecting soft contact lenses (e.g., 3% for 2–3 hrs)<sup>673,674,675</sup>, tonometer biprisms<sup>676</sup>, ventilators<sup>677</sup>, fabrics<sup>678</sup>, and endoscopes<sup>679</sup>. Hydrogen peroxide was effective in spot-disinfecting fabrics in patients' rooms<sup>680</sup>. Corneal damage from a hydrogen peroxide-soaked tonometer tip that was not properly rinsed has been reported<sup>681</sup>. Hydrogen peroxide also has been instilled into urinary drainage bags in an attempt to eliminate the bag as a source of bladder bacteriuria and environmental contamination<sup>682</sup>. Although the institution of hydrogen peroxide into the bag reduced microbial contamination of the bag, this procedure did not reduce the incidence of catheter-associated bacteriuria<sup>683</sup>.

A chemical irritation resembling pseudomembranous colitis caused by either 3% hydrogen peroxide or a 2% glutaraldehyde has been reported<sup>684</sup>. An epidemic of pseudomembrane-like enteritis and colitis in seven patients in a gastrointestinal endoscopy unit also has been associated with inadequate rinsing of 3% hydrogen peroxide from the endoscope<sup>685</sup>.

As with other chemical sterilants, dilution of the hydrogen peroxide must be monitored by regularly testing the minimum effective concentration (i.e., 7.5%–6.0%). Compatibility testing by Olympus America of the 7.5% hydrogen peroxide found both cosmetic changes (e.g., discoloration of black anodized metal finishes)<sup>686</sup> and functional changes with the tested endoscopes (Olympus, written communication, October 15, 1993).

#### Iodophors

**Overview.** Iodine solutions or tinctures long have been used by health professionals primarily as antiseptics on skin or tissue. Iodophors, on the other hand, have been used both as antiseptics and

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disinfectants. FDA has not cleared any liquid chemical sterilant or high-level disinfectants with iodophors as the main active ingredient. An iodophor is a combination of iodine and a solubilizing agent or carrier; the resulting complex provides a sustained-release reservoir of iodine and releases small amounts of free iodine in aqueous solution. The best-known and most widely used iodophor is povidone-iodine, a compound of polyvinylpyrrolidone with iodine. This product and other iodophors retain the germicidal efficacy of iodine but unlike iodine generally are nonstaining and relatively free of toxicity and irritancy<sup>674,675</sup>.

Several reports that documented intrinsic microbial contamination of antiseptic formulations of povidone-iodine and poloxamer-iodine<sup>676,677</sup> caused a reappraisal of the chemistry and use of iodophors<sup>678</sup>. Free iodine (I<sub>2</sub>) contributes to the bactericidal activity of iodophors and dilutions of iodophors demonstrate more rapid bactericidal action than does a full-strength povidone-iodine solution. The reason for the observation that dilution increases bactericidal activity is unclear, but dilution of povidone-iodine might weaken the iodine linkage to the carrier polymer with an accompanying increase of free iodine in solution<sup>679</sup>. Therefore, iodophors must be diluted according to the manufacturers' directions to achieve antimicrobial activity.

**Mode of Action.** Iodine can penetrate the cell wall of microorganisms quickly, and the lethal effects are believed to result from disruption of protein and nucleic acid structure and synthesis.

**Microbicidal Activity.** Published reports on the *In vitro* antimicrobial efficacy of iodophors demonstrate that iodophors are bactericidal, mycobactericidal, and virucidal but can require prolonged contact times to kill certain fungi and bacterial spores<sup>14,675,680,681,682</sup>. Three brands of povidone-iodine solution have demonstrated more rapid kill (seconds to minutes) of *S. aureus* and *M. chelonae* at a 1:100 dilution than did the stock solution<sup>683</sup>. The virucidal activity of 75–150 ppm available iodine was demonstrated against seven viruses<sup>674</sup>. Other investigators have questioned the efficacy of iodophors against poliovirus in the presence of organic matter<sup>684</sup> and rotavirus SA-11 in distilled or tapwater<sup>685</sup>. Manufacturer data demonstrate that commercial iodophors are not sporicidal, but they are tuberculocidal, fungicidal, virucidal, and bactericidal at their recommended use-dilution.

**Uses.** Besides their use as an antiseptic, iodophors have been used for disinfecting blood culture bottles and medical equipment, such as hydrotherapy tanks, thermometers, and endoscopes. Antiseptic iodophors are not suitable for use as hard-surface disinfectants because of concentration differences. Iodophors formulated as antiseptics contain less free iodine than do those formulated as disinfectants<sup>674</sup>. Iodine or iodine-based antiseptics should not be used on silicone catheters because they can adversely affect the silicone tubing<sup>686</sup>.

#### Ortho-phthalaldehyde (OPA)

**Overview.** Ortho-phthalaldehyde is a high-level disinfectant that received FDA clearance in October 1999. It contains 0.65% 1,2-benzeneisothiocarbonyl aldehyde (OPA). OPA solution is a clear, colorless liquid with a pH of 7.5. (Tables 4 and 5)

**Mode of Action.** Preliminary studies on the mode of action of OPA suggest that both OPA and glutaraldehyde interact with amino acids, proteins, and microorganisms. However, OPA is a less potent cross-linking agent. This is compensated for by the lipophilic aromatic nature of OPA that is likely to assist its uptake through the outer layers of mycobacteria and gram-negative bacteria<sup>687,688</sup>. OPA appears to kill spores by blocking the spore germination process<sup>689</sup>.

**Microbicidal Activity.** Studies have demonstrated excellent microbicidal activity *in vitro*<sup>688,690,691,692</sup>. For example, OPA has superior mycobactericidal activity (5-log<sub>10</sub> reduction in 5 minutes) to glutaraldehyde. The mean times required to produce a 6-log<sub>10</sub> reduction for *M. bovis* using 0.21% OPA was 8 minutes, compared with 32 minutes using 1.6% glutaraldehyde<sup>693</sup>. OPA showed good activity against the mycobacteria tested, including the glutaraldehyde-resistant strains, but 0.5% OPA was not sporicidal with 220 minutes of exposure. Increasing the pH from its unadjusted level (about 6.5) to pH 8 improved the sporicidal activity of OPA<sup>694</sup>. The level of biocidal activity was directly related to the

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temperature. A greater than 6-log<sub>10</sub> reduction of *B. anthracis* spores was observed in 3 hours at 35°C, than in 24 hours at 20°C. Also, with an exposure time <5 minutes, biocidal activity decreased with increasing serum concentration. However, efficacy did not differ when the exposure time was ≥10 minutes.<sup>70</sup> In addition, OPA is effective (>5-log<sub>10</sub> reduction) against a wide range of microorganisms, including glutaraldehyde-resistant mycobacteria and *B. anthracis* spores.<sup>70</sup>

The influence of laboratory adaptation of test strains, such as *P. aeruginosa*, to 0.55% OPA has been evaluated. Resistant and multiresistant strains increased substantially in susceptibility to OPA after laboratory adaptation (log<sub>10</sub> reduction factors increased by 0.54 and 0.91 for resistant and multiresistant strains, respectively).<sup>70</sup> Other studies have found naturally occurring cells of *P. aeruginosa* were more resistant to a variety of disinfectants than were subcultured cells.<sup>70</sup>

**Uses.** OPA has several potential advantages over glutaraldehyde. It has excellent stability over a wide pH range (pH 3–9), is not a known irritant to the eyes and nasal passages,<sup>70</sup> does not require exposure monitoring, has a barely perceptible odor, and requires no activation. OPA, like glutaraldehyde, has excellent material compatibility. A potential disadvantage of OPA is that it stains proteins gray (including unprotected skin) and thus must be handled with caution.<sup>70</sup> However, skin staining would indicate improper handling that requires additional training and/or personal protective equipment (e.g., gloves, eye and mouth protection, and fluid-resistant gowns). OPA residues remaining on inadequately water-rinsed transesophageal echo probes can stain the patient's mouth.<sup>70</sup> Meticulous cleaning, using the correct OPA exposure time (e.g., 12 minutes) and copious rinsing of the probe with water should eliminate this problem. The results of one study provided a basis for a recommendation that rinsing of instruments disinfected with OPA will require at least 250 mL of water per channel to reduce the chemical residue to a level that will not compromise patient or staff safety (<1 ppm).<sup>70</sup> Personal protective equipment should be worn when contaminated instruments, equipment, and chemicals are handled.<sup>70</sup> In addition, equipment must be thoroughly rinsed to prevent discoloration of a patient's skin or mucous membrane.

In April 2004, the manufacturer of OPA disseminated information to users about patients who reportedly experienced an anaphylaxis-like reaction after cystoscopy where the scope had been reprocessed using OPA. Of approximately 1 million urologic procedures performed using instruments reprocessed using OPA, 24 cases (17 cases in the United States, six in Japan, one in the United Kingdom) of anaphylaxis-like reactions have been reported after repeated cystoscopy (typically after four to nine treatments). Preventive measures include removal of OPA residues by thorough rinsing and not using OPA for reprocessing urologic instrumentation used to treat patients with a history of bladder cancer (Nevine Erian, personal communication, June 4, 2004; Product Notification, Advanced Sterilization Products, April 22, 2004).<sup>70</sup>

A few OPA clinical studies are available. In a clinical-use study, OPA exposure of 100 endoscopes for 5 minutes resulted in a >5-log<sub>10</sub> reduction in bacterial load. Furthermore, OPA was effective over a 14-day use cycle.<sup>70</sup> Manufacturer data show that OPA will last longer in an automatic endoscope reprocessor before reaching its MEC limit (MEC after 82 cycles) than will glutaraldehyde (MEC after 40 cycles).<sup>70</sup> High-resolution liquid chromatography confirmed that OPA levels are maintained above 0.3% for at least 50 cycles.<sup>70,71</sup> OPA must be disposed in accordance with local and state regulations. If OPA disposal through the sanitary sewer system is restricted, glycine (25 grams/gallon) can be used to neutralize the OPA and make it safe for disposal.

The high-level disinfectant label claims for OPA solution at 20°C vary worldwide (e.g., 5 minutes in Europe, Asia, and Latin America; 10 minutes in Canada and Australia; and 12 minutes in the United States). These label claims differ worldwide because of differences in the test methodology and requirements for licensure. In an automated endoscope reprocessor with an FDA-cleared capability to maintain solution temperatures at 25°C, the contact time for OPA is 5 minutes.

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#### Paracetic Acid

**Overview.** Paracetic, or peroxyacetic, acid is characterized by rapid action against all microorganisms. Special advantages of paracetic acid are that it lacks harmful decomposition products (i.e., acetic acid, water, oxygen, hydrogen peroxide), enhances removal of organic material,<sup>72</sup> and leaves no residue. It remains effective in the presence of organic matter and is sporidicidal even at low temperatures (Tables 4 and 5). Paracetic acid can corrode copper, brass, bronze, plain steel, and galvanized iron but these effects can be reduced by additives and pH modifications. It is considered unstable, particularly when diluted; for example, a 1% solution loses half its strength through hydrolysis in 6 days, whereas 40% paracetic acid loses 1%–2% of its active ingredients per month.<sup>72</sup>

**Mode of Action.** Little is known about the mechanism of action of paracetic acid, but it is believed to function similarly to other oxidizing agents—that is, it denatures proteins, disrupts the cell wall permeability, and oxidizes sulfhydryl and sulfur bonds in proteins, enzymes, and other metabolites.<sup>72</sup>

**Microbicidal Activity.** Paracetic acid will inactivate gram-positive and gram-negative bacteria, fungi, and yeasts in ≤5 minutes at <100 ppm. In the presence of organic matter, 200–500 ppm is required. For viruses, the dosage range is wide (12–2250 ppm), with poliovirus inactivated in yeast extract in 15 minutes with 1,500–2,250 ppm. In one study, 3.5% paracetic acid was ineffective against HAV after 1-minute exposure using a carrier load.<sup>72</sup> Paracetic acid (0.25%) was effective (log<sub>10</sub> reduction factor >5) against all test strains of mycobacteria (*M. tuberculosis*, *M. avium-intracellulare*, *M. chelonae*, and *M. fortuitum*) within 20–30 minutes in the presence or absence of an organic load.<sup>72,73</sup> With bacterial spores, 500–10,000 ppm (0.05%–1%) inactivates spores in 15 seconds to 30 minutes using a spore suspension test.<sup>72,74,75</sup>

**Uses.** An automated machine using paracetic acid to chemically sterilize medical (e.g., endoscopes, arthroscopy, surgical, and dental instruments) is used in the United States.<sup>72,76</sup> As previously noted, dental handpieces should be steam sterilized. The solution, 0.5% paracetic acid, is diluted to 0.2% with filtered water at 50°C. Simulated-use trials have demonstrated excellent microbiological activity,<sup>71,72,73,74</sup> and three clinical trials have demonstrated both excellent microbial killing and no clinical failures leading to infection.<sup>72,73,74</sup> The high efficacy of the system was demonstrated in a comparison of the efficacies of the system with that of ethylene oxide. Only the paracetic acid system completely killed 6 log<sub>10</sub> of *M. chelonae*, *E. faecalis*, and *B. anthracis* spores with both an organic and inorganic challenge. An evaluation that compared the costs, performance, and maintenance of urologic endoscopic equipment processed by high-level disinfection (with glutaraldehyde) with those of the paracetic acid system reported no clinical differences between the two systems. However, the use of this system led to higher costs than the high-level disinfection, including costs for processing (\$8.11 vs. \$0.45 per cycle), purchasing and training (\$24,845 vs. \$16), installation (\$5,800 vs. \$0), and endoscope repairs (\$6,037 vs. \$445).<sup>72</sup> Furthermore, three clusters of infection using the paracetic acid automated endoscope reprocessor were linked to inadequately processed bronchoscopes when inappropriate channel connectors were used with the system.<sup>72</sup> These clusters highlight the importance of training, proper model-specific endoscope reprocessor systems, and quality-control procedures to ensure compliance with endoscope manufacturer recommendations and professional organization guidelines. An alternative high-level disinfectant available in the United Kingdom contains 0.35% paracetic acid. Although this product is rapidly effective against a broad range of microorganisms,<sup>44,72,73,77</sup> it tarnishes the metal of endoscope and is unstable, resulting in only a 24-hour use life.<sup>72</sup>

#### Paracetic Acid and Hydrogen Peroxide

**Overview.** Two chemical solutions are available that contain paracetic acid plus hydrogen peroxide (i.e., 0.08% paracetic acid plus 1.0% hydrogen peroxide [no longer marketed]; and 0.23% paracetic acid plus 7.35% hydrogen peroxide (Tables 4 and 5)).

**Microbicidal Activity.** The bactericidal properties of paracetic acid and hydrogen peroxide have been demonstrated.<sup>72</sup> Manufacturer data demonstrated the combination of paracetic acid and

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hydrogen peroxide inactivated all microorganisms except bacterial spores within 20 minutes. The 0.08% paracetic acid plus 1.0% hydrogen peroxide product effectively inactivated glutaraldehyde-resistant mycobacteria.<sup>72</sup>

**Uses.** The combination of paracetic acid and hydrogen peroxide has been used for disinfecting hemodialyzers.<sup>72</sup> The percentage of dialysis centers using a paracetic acid-hydrogen peroxide-based disinfectant for reprocessing dialyzers increased from 5% in 1983 to 55% in 1997.<sup>72</sup> Olympus America does not endorse use of 0.08% paracetic acid plus 1.0% hydrogen peroxide (Olympus America, personal communication, April 15, 1998) on any Olympus endoscope because of cosmetic and functional damage and will not assume liability for chemical damage resulting from use of this product. This product is not currently available. FDA has cleared a newer chemical alternative with 0.23% paracetic acid and 7.35% hydrogen peroxide (Tables 4 and 5). After testing the 7.35% hydrogen peroxide and 0.23% paracetic acid product, Olympus America concluded it was not compatible with the company's flexible gastrointestinal endoscopes; this conclusion was based on immersion studies where the test insertion tubes had failed because of swelling and loosening of the black polymer layer of the tube (Olympus America, personal communication, September 13, 2000).

#### Phenolics

**Overview.** Phenol has occupied a prominent place in the field of hospital disinfection since its initial use as a germicide by Lister in his pioneering work on antiseptic surgery. In the past 30 years, however, work has concentrated on the numerous phenol derivatives or phenolics and their antimicrobial properties. Phenol derivatives originate when a functional group (e.g., alkyl, phenyl, benzyl, halogen) replaces one of the hydrogen atoms on the aromatic ring. Two phenol derivatives commonly found as constituents of hospital disinfectants are *ortho*-phenylphenol and *ortho*-benzyl-para-chlorophenol. The antimicrobial properties of these compounds and many other phenol derivatives are much improved over those of the parent chemical. Phenolics are absorbed by porous materials, and the residual disinfectant can irritate tissue. In 1970, deplimentation of the skin was reported to be caused by phenolic germicidal detergents containing *para*-tertiary butylphenol and *para*-tertiary amylphenol.<sup>77</sup>

**Mode of Action.** In high concentrations, phenol acts as a gross proteolytic poison, penetrating and disrupting the cell wall and precipitating the cell proteins. Low concentrations of phenol and higher molecular-weight phenol derivatives cause bacterial death by inactivation of essential enzyme systems and leakage of essential metabolites from the cell wall.<sup>72</sup>

**Microbicidal Activity.** Published reports on the antimicrobial efficacy of commonly used phenolics showed they were bactericidal, fungicidal, virucidal, and tuberculocidal.<sup>78,79,80,81,82,83,84,85,86,87,88,89,90,91,92,93,94,95,96,97,98,99,100,101,102,103,104,105,106,107,108,109,110,111,112,113,114,115,116,117,118,119,120,121,122,123,124,125,126,127,128,129,130,131,132,133,134,135,136,137,138,139,140,141,142,143,144,145,146,147,148,149,150,151,152,153,154,155,156,157,158,159,160,161,162,163,164,165,166,167,168,169,170,171,172,173,174,175,176,177,178,179,180,181,182,183,184,185,186,187,188,189,190,191,192,193,194,195,196,197,198,199,200,201,202,203,204,205,206,207,208,209,210,211,212,213,214,215,216,217,218,219,220,221,222,223,224,225,226,227,228,229,230,231,232,233,234,235,236,237,238,239,240,241,242,243,244,245,246,247,248,249,250,251,252,253,254,255,256,257,258,259,260,261,262,263,264,265,266,267,268,269,270,271,272,273,274,275,276,277,278,279,280,281,282,283,284,285,286,287,288,289,290,291,292,293,294,295,296,297,298,299,300,301,302,303,304,305,306,307,308,309,310,311,312,313,314,315,316,317,318,319,320,321,322,323,324,325,326,327,328,329,330,331,332,333,334,335,336,337,338,339,340,341,342,343,344,345,346,347,348,349,350,351,352,353,354,355,356,357,358,359,360,361,362,363,364,365,366,367,368,369,370,371,372,373,374,375,376,377,378,379,380,381,382,383,384,385,386,387,388,389,390,391,392,393,394,395,396,397,398,399,400,401,402,403,404,405,406,407,408,409,410,411,412,413,414,415,416,417,418,419,420,421,422,423,424,425,426,427,428,429,430,431,432,433,434,435,436,437,438,439,440,441,442,443,444,445,446,447,448,449,450,451,452,453,454,455,456,457,458,459,460,461,462,463,464,465,466,467,468,469,470,471,472,473,474,475,476,477,478,479,480,481,482,483,484,485,486,487,488,489,490,491,492,493,494,495,496,497,498,499,500,501,502,503,504,505,506,507,508,509,510,511,512,513,514,515,516,517,518,519,520,521,522,523,524,525,526,527,528,529,530,531,532,533,534,535,536,537,538,539,540,541,542,543,544,545,546,547,548,549,550,551,552,553,554,555,556,557,558,559,560,561,562,563,564,565,566,567,568,569,570,571,572,573,574,575,576,577,578,579,580,581,582,583,584,585,586,587,588,589,590,591,592,593,594,595,596,597,598,599,600,601,602,603,604,605,606,607,608,609,610,611,612,613,614,615,616,617,618,619,620,621,622,623,624,625,626,627,628,629,630,631,632,633,634,635,636,637,638,639,640,641,642,643,644,645,646,647,648,649,650,651,652,653,654,655,656,657,658,659,660,661,662,663,664,665,666,667,668,669,670,671,672,673,674,675,676,677,678,679,680,681,682,683,684,685,686,687,688,689,690,691,692,693,694,695,696,697,698,699,700,701,702,703,704,705,706,707,708,709,710,711,712,713,714,715,716,717,718,719,720,721,722,723,724,725,726,727,728,729,730,731,732,733,734,735,736,737,738,739,740,741,742,743,744,745,746,747,748,749,750,751,752,753,754,755,756,757,758,759,760,761,762,763,764,765,766,767,768,769,770,771,772,773,774,775,776,777,778,779,780,781,782,783,784,785,786,787,788,789,790,791,792,793,794,795,796,797,798,799,800,801,802,803,804,805,806,807,808,809,810,811,812,813,814,815,816,817,818,819,820,821,822,823,824,825,826,827,828,829,830,831,832,833,834,835,836,837,838,839,840,841,842,843,844,845,846,847,848,849,850,851,852,853,854,855,856,857,858,859,860,861,862,863,864,865,866,867,868,869,870,871,872,873,874,875,876,877,878,879,880,881,882,883,884,885,886,887,888,889,890,891,892,893,894,895,896,897,898,899,900,901,902,903,904,905,906,907,908,909,910,911,912,913,914,915,916,917,918,919,920,921,922,923,924,925,926,927,928,929,930,931,932,933,934,935,936,937,938,939,940,941,942,943,944,945,946,947,948,949,950,951,952,953,954,955,956,957,958,959,960,961,962,963,964,965,966,967,968,969,970,971,972,973,974,975,976,977,978,979,980,981,982,983,984,985,986,987,988,989,990,991,992,993,994,995,996,997,998,999,1000.</sup>

Manufacturers' data using the standardized AOAC methods demonstrate that commercial phenolics are not sporidicidal but are tuberculocidal, fungicidal, virucidal, and bactericidal at their recommended use-dilution. Attempts to substantiate the bactericidal label claims of phenolics using the AOAC Use-Dilution Method occasionally have failed.<sup>418,772</sup> However, results from these same studies have varied dramatically among laboratories testing identical products.

**Uses.** Many phenolic germicides are EPA-registered as disinfectants for use on environmental surfaces (e.g., bedside tables, beds, and laboratory surfaces) and noncritical medical devices. Phenolics are not FDA-cleared as high-level disinfectants for use with semicritical items but could be used to pre-clean or decontaminate critical and semicritical devices before terminal sterilization or high-

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#### level disinfection.

The use of phenolics in nurseries has been questioned because of hyperbilirubinemia in infants placed in bassinets. In nurseries, phenolic disinfectants were used.<sup>72</sup> In addition, bilirubin levels were reported to increase in phenolic-exposed infants, compared with nonphenolic-exposed infants. When the phenolic was prepared according to the manufacturer's recommendation and used to clean nursery floors, they must be diluted as recommended on the product label. Phenolics (and other disinfectants) should not be used to clean infant bassinets and incubators while occupied. If phenolics are used to terminally clean infant bassinets and incubators, the surfaces should be rinsed thoroughly with water and dried before reuse of infant bassinets and incubators.<sup>72</sup>

#### Quaternary Ammonium Compounds

**Overview.** The quaternary ammonium compounds are widely used as disinfectants. Healthcare-associated infections have been reported from contaminated quaternary ammonium compounds used to disinfect patient-care supplies or equipment, such as cystoscopes or cardiac catheters.<sup>141,742</sup> The quaternaries are good cleaning agents, but high water hardness<sup>743</sup> and materials such as cotton and gauze pads can make them less microbicidal because of insoluble precipitates or cotton and gauze pads absorb the active ingredients, respectively. One study showed a significant decline (~40%–50% lower at 1 hour) in the concentration of quaternaries released when cotton rags or cellulose-based wipes were used in the open-bucket system, compared with the stainless steel buckets in the closed-bucket system.<sup>744</sup> As with several other disinfectants (e.g., phenolics, iodophors) gram-negative bacteria can survive or grow in them.<sup>49</sup>

Chemically, the quaternaries are organically substituted ammonium compounds in which the nitrogen atom has a valence of 5, four of the substituent radicals (R1–R4) are alkyl or heterocyclic radicals of a given size or chain length, and the fifth (R5) is a halide, sulfate, or similar radical.<sup>745</sup> Each compound exhibits its own antimicrobial characteristics, hence the search for one compound with outstanding antimicrobial properties. Some of the chemical names of quaternary ammonium compounds used in healthcare are alkyl dimethyl benzyl ammonium chloride, alkyl didecyl dimethyl ammonium chloride, and dialkyl dimethyl ammonium chloride. The newer quaternary ammonium compounds (i.e., fourth generation), referred to as twin-chain or dialkyl quaternaries (e.g., didecyl dimethyl ammonium bromide and dodecyl dimethyl ammonium bromide), purportedly remain active in hard water and are tolerant of anionic residues.<sup>746</sup>

A few case reports have documented occupational asthma as a result of exposure to benzalkonium chloride.<sup>747</sup>

**Mode of Action.** The bactericidal action of the quaternaries has been attributed to the inactivation of energy-producing enzymes, denaturation of essential cell proteins, and disruption of the cell membrane.<sup>49</sup> Evidence exists that supports these and other possibilities.<sup>745,746</sup>

**Microbicidal Activity.** Results from manufacturers' data sheets and from published scientific literature indicate that the quaternaries sold as hospital disinfectants are generally fungicidal, bactericidal, and virucidal against lipophilic (enveloped) viruses; they are not sporidicidal and generally not tuberculocidal or virucidal against hydrophilic (nonenveloped) viruses.<sup>4,448,452,454,455,456,457,458,459,460,461,462,463,464,465,466,467,468,469,470,471,472,473,474,475,476,477,478,479,480,481,482,483,484,485,486,487,488,489,490,491,492,493,494,495,496,497,498,499,500,501,502,503,504,505,506,507,508,509,510,511,512,513,514,515,516,517,518,519,520,521,522,523,524,525,526,527,528,529,530,531,532,533,534,535,536,537,538,539,540,541,542,543,544,545,546,547,548,549,550,551,552,553,554,555,556,557,558,559,560,561,562,563,564,565,566,567,568,569,570,571,572,573,574,575,576,577,578,579,580,581,582,583,584,585,586,587,588,589,590,591,592,593,594,595,596,597,598,599,600,601,602,603,604,605,606,607,608,609,610,611,612,613,614,615,616,617,618,619,620,621,622,623,624,625,626,627,628,629,630,631,632,633,634,635,636,637,638,639,640,641,642,643,644,645,646,647,648,649,650,651,652,653,654,655,656,657,658,659,660,661,662,663,664,665,666,667,668,669,670,671,672,673,674,675,676,677,678,679,680,681,682,683,684,685,686,687,688,689,690,691,692,693,694,695,696,697,698,699,700,701,702,703,704,705,706,707,708,709,710,711,712,713,714,715,716,717,718,719,720,721,722,723,724,725,726,727,728,729,730,731,732,733,734,735,736,737,738,739,740,741,742,743,744,745,746,747,748,749,750,751,752,753,754,755,756,757,758,759,760,761,762,763,764,765,766,767,768,769,770,771,772,773,774,775,776,777,778,779,780,781,782,783,784,785,786,787,788,789,790,791,792,793,794,795,796,797,798,799,800,801,802,803,804,805,806,807,808,809,810,811,812,813,814,815,816,817,818,819,820,821,822,823,824,825,826,827,828,829,830,831,832,833,834,835,836,837,838,839,840,841,842,843,844,845,846,847,848,849,850,851,852,853,854,855,856,857,858,859,860,861,862,863,864,865,866,867,868,869,870,871,872,873,874,875,876,877,878,879,880,881,882,883,884,885,886,887,888,889,890,891,892,893,894,895,896,897,898,899,900,901,902,903,904,905,906,907,908,909,910,911,912,913,914,915,916,917,918,919,920,921,922,923,924,925,926,927,928,929,930,931,932,933,934,935,936,937,938,939,940,941,942,943,944,945,946,947,948,949,950,951,952,953,954,955,956,957,958,959,960,961,962,963,964,965,966,967,968,969,970,971,972,973,974,975,976,977,978,979,980,981,982,983,984,985,986,987,988,989,990,991,992,993,994,995,996,997,998,999,1000.</sup>

Attempts to reproduce the manufacturers' bactericidal and tuberculocidal claims using the AOAC

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tests with a limited number of quaternary ammonium compounds occasionally have failed<sup>73,416,727</sup>. However, test results have varied extensively among laboratories testing identical products<sup>416,727</sup>.

**Uses.** The quaternaries commonly are used in ordinary environmental sanitation of noncritical surfaces, such as floors, furniture, and walls. EPA-registered quaternary ammonium compounds are appropriate to use for disinfecting medical equipment that contacts intact skin (e.g., blood pressure cuffs).

## MISCELLANEOUS INACTIVATING AGENTS

## Other Germicides

Several compounds have antimicrobial activity but for various reasons have not been incorporated into the armamentarium of health-care disinfectants. These include mercurials, sodium hydroxide,  $\beta$ -propiolactone, chlorhexidine gluconate, catrimide-chlorhexidine, glycols (triethylene and propylene), and the Tego disinfectants. Two authoritative references examine these agents in detail<sup>34,412</sup>.

A peroxygen-containing formulation had marked bactericidal action when used as a 1% weight/volume solution and virucidal activity at 3%<sup>46</sup>, but did not have mycobactericidal activity at concentrations of 2.3% and 4% and exposure times ranging from 30 to 120 minutes<sup>728</sup>. It also required 20 hours to kill *E. strophaceus* spores<sup>721</sup>. A powder-based peroxygen compound for disinfecting contaminated spill was strongly and rapidly bactericidal<sup>729</sup>.

In preliminary studies, nanocemulsions (composed of detergents and lipids in water) showed activity against vegetative bacteria, enveloped viruses and *Candida*. This product represents a potential agent for use as a topical biocidal agent.<sup>735-736</sup>

New disinfectants that require further evaluation include glucoprotamin<sup>724</sup>, tertiary amines<sup>724</sup>, and a light-activated antimicrobial coating<sup>727</sup>. Several other disinfection technologies might have potential applications in the health-care setting<sup>724</sup>.

## Metals as Microbicides

Comprehensive reviews of antiseptics<sup>728</sup>, disinfection<sup>471</sup>, and anti-infective chemotherapy<sup>726</sup> barely mention the antimicrobial activity of heavy metals<sup>731,732</sup>. Nevertheless, the anti-infective activity of some heavy metals has been known since antiquity. Heavy metals such as silver have been used for prophylaxis of conjunctivitis of the newborn, topical therapy for burn wounds, and bonding to indwelling catheters, and the use of heavy metals as antiseptics or disinfectants is again being explored<sup>182</sup>. Inactivation of bacteria on stainless steel surfaces by zirconium ceramic coatings containing silver and zinc ions has also been demonstrated<sup>734,733</sup>.

Metals such as silver, iron, and copper could be used for environmental control, disinfection of water, or reusable medical devices or incorporated into medical devices (e.g., intravascular catheters)<sup>466,734,735,736</sup>. A comparative evaluation of six disinfectant formulations for residual antimicrobial activity demonstrated that only the silver disinfectant demonstrated significant residual activity against *S. aureus* and *P. aeruginosa*<sup>737</sup>. Preliminary data suggest metals are effective against a wide variety of microorganisms.

Clinical uses of other heavy metals include copper- $\beta$ -quinoxaline as a fungicide against *Aspergillus*, copper-silver ionization for *Legionella* disinfection<sup>477,478</sup>, organic mercurials as an antiseptic (e.g., mercurochrome) and preservative/disinfectant (e.g., thimerosal [currently being removed from vaccines]) in pharmaceuticals and cosmetics<sup>732</sup>.

## Ultraviolet Radiation (UV)

The wavelength of UV radiation ranges from 328 nm to 210 nm (3280 Å to 2100 Å). Its maximum bactericidal effect occurs at 240–280 nm. Mercury vapor lamps emit more than 90% of their radiation at 253.7 nm, which is near the maximum microbicidal activity<sup>775</sup>. Inactivation of microorganisms results from destruction of nucleic acid through induction of thymine dimers. UV radiation has been employed in the disinfection of drinking water<sup>774</sup>, air<sup>772</sup>, titanium implants<sup>774</sup>, and contact lenses<sup>774</sup>. Bacteria and viruses are more easily killed by UV light than are bacterial spores<sup>775</sup>. UV radiation has several potential applications, but unfortunately its germicidal effectiveness and use is influenced by organic matter; wavelength; type of suspension; temperature; type of microorganism; and UV intensity, which is affected by distance and dirty tubes<sup>774</sup>. The application of UV radiation in the health-care environment (i.e.,

operating rooms, isolation rooms, and biologic safety cabinets) is limited to destruction of airborne organisms or inactivation of microorganisms on surfaces. The effect of UV radiation on postoperative wound infections was investigated in a double-blind, randomized study in five university medical centers. After following 14,654 patients over a 2-year period, the investigators reported the overall wound infection rate was unaffected by UV radiation, although postoperative infection in the "refined clean" surgical procedures decreased significantly (3.8%–2.9%)<sup>783</sup>. No data support the use of UV lamps in isolation rooms, and this practice has caused at least one epidemic of UV-induced skin erythema and keratocconjunctivitis in hospital patients and visitors<sup>784</sup>.

## Pasteurization

Pasteurization is not a sterilization process; its purpose is to destroy all pathogenic microorganisms. However, pasteurization does not destroy bacterial spores. The time-temperature relation for hot-water pasteurization is generally ~70°C (158°F) for 30 minutes. The water temperature and time should be monitored as part of a quality-assurance program<sup>722</sup>. Pasteurization of respiratory therapy<sup>785,786</sup> and anesthesia equipment<sup>785</sup> is a recognized alternative to chemical disinfection. The efficacy of this process has been tested using an inoculum that the authors believed might simulate contamination by an infected patient. Use of a large inoculum ( $10^7$ ) of *P. aeruginosa* or *Acinetobacter calcoaceticus* in sets of respiratory tubing before processing demonstrated that machine-assisted chemical processing was more efficient than machine-assisted pasteurization with a disinfection failure rate of 8% and 83%, respectively<sup>785</sup>. Other investigators found hot water disinfection to be effective (inactivation factor >5 log<sub>10</sub>) against multiple bacteria, including multidrug-resistant bacteria, for disinfecting reusable anesthesia or respiratory therapy equipment<sup>784,786</sup>.

## Flushing and Washer-Disinfectors

Flushing and washer-disinfectors are automated and closed equipment that clean and disinfect objects from bedpans and washbasins to surgical instruments and anesthesia tubes. Items such as bedpans and urinals can be cleaned and disinfected in flushing-disinfectors. They have a short cycle of a few minutes. They clean by flushing with warm water, possibly with a detergent, and then disinfect by flushing the items with hot water or with steam. Because this machine empties, cleans, and disinfects, manual cleaning is eliminated, fewer disposable items are needed, and fewer chemical germicides are used. A microbiologic evaluation of one washer/disinfecter demonstrated complete inactivation of suspensions of *E. faecalis* or poliovirus<sup>787</sup>. Other studies have shown that strains of *Enterococcus faecalis* can survive the British Standard for heat disinfection of bedpans (80°C for 1 minute). The significance of this finding with reference to the potential for enterococci to survive and disseminate in the health-care environment is debatable<sup>784,788</sup>. These machines are available and used in many European countries.

Surgical instruments and anesthesia equipment are more difficult to clean. They are run in washer-disinfectors on a longer cycle of approximately 20–30 minutes with a detergent. These machines also disinfect by hot water at approximately 80°C<sup>774</sup>.

## THE REGULATORY FRAMEWORK FOR DISINFECTANTS AND STERILANTS

Before using the guidance provided in this document, health-care workers should be aware of the federal laws and regulations that govern the sale, distribution, and use of disinfectants and sterilants. In particular, health-care workers need to know what requirements pertain to them when they apply these products. Finally, they should understand the relative roles of EPA, FDA, and CDC so the context for the guidance provided in this document is clear.

## EPA and FDA

In the United States, chemical germicides formulated as sanitizers, disinfectants, or sterilants are regulated in interstate commerce by the Antimicrobials Division, Office of Pesticides Program, EPA, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947, as amended<sup>789</sup>. Under FIFRA, any substance or mixture of substances toxic when in or on living humans or animals or mitigate any pest (including microorganisms) but excluding those in or on living humans or animals must be registered before sale or distribution. To obtain a registration, a manufacturer must submit specific data about the safety and effectiveness of each product. For example, EPA requires manufacturers of sanitizers, disinfectants, or chemical sterilants to test formulations by using accepted methods for microbicidal activity, stability, and toxicity to animals and humans. The manufacturers submit this data to EPA along with proposed labeling. If EPA concludes the product can be used without causing "unreasonable adverse effects," then the product and its labeling are registered, and the manufacturer can sell and distribute the product in the United States.

FIFRA also requires users of products to follow explicitly the labeling directions on each product. The following standard statement appears on all labels under the "Directions for Use" heading: "It is a violation of federal law to use this product in a manner inconsistent with its labeling." This statement means a health-care worker must follow the safety precautions and use directions on the labeling of each registered product. Failure to follow the specified use-dilution, contact time, method of application, or any other condition of use is considered a misuse of the product and potentially subject to enforcement action under FIFRA.

In general, EPA regulates disinfectants and sterilants used on environmental surfaces, and not those used on critical or semicritical medical devices; the latter are regulated by FDA. In June 1983, FDA and EPA issued a "Memorandum of Understanding" that divided responsibility for review and surveillance of chemical germicides between the two agencies. Under this agreement, FDA regulates liquid chemical sterilants used on critical and semicritical devices, and EPA regulates disinfectants used on noncritical surfaces and gaseous sterilants<sup>789</sup>. In 1995, Congress passed the Food Quality Protection Act (FQPA). This act amended FIFRA in regard to several types of products regulated by both EPA and FDA. One provision of FQPA removed regulation of liquid chemical sterilants used on critical and semicritical medical devices from EPA's jurisdiction, and it now rests solely with FDA<sup>790,791</sup>. EPA continues to register nonmedical chemical sterilants. FDA and EPA have considered the impact of FQPA, and in January 2000, FDA published its final guidance document on product submissions and labeling. Antiseptics are considered antimicrobial drugs used on living tissue and thus are regulated by FDA under the Food, Drug and Cosmetic Act. FDA regulates liquid chemical sterilants and high-level disinfectants intended to process critical and semicritical devices. FDA has published recommendations on the types of test methods that manufacturers should submit to FDA for 510(k) clearance for such agents.

## CDC

At CDC, the mission of the Coordinating Center for Infectious Diseases is to guide the public on how to prevent and respond to infectious diseases in both health-care settings and at home. With respect to disinfectants and sterilants, part of CDC's role is to inform the public (in this case health-care personnel) of current scientific evidence pertaining to these products, to comment about their safety and efficacy, and to recommend which chemicals might be most appropriate or effective for specific microorganisms and settings.

**Test Methods**

The methods EPA has used for registration are standardized by the AOAC International; however, a survey of scientific literature reveals a number of problems with these tests that were reported during 1987–1990.<sup>16, 76, 77, 83, 79, 75, 84, 85</sup> that cause them to be neither accurate nor reproducible.<sup>16, 72</sup> As part of their regulatory authority, EPA and FDA support development and validation of methods for assessing disinfection claims.<sup>86, 87</sup> For example, EPA has supported the work of Dr. Syed Sattar and co-workers who have developed a two-tier quantitative carrier test to assess sporidial, mycobactericidal, bactericidal, fungicidal, virucidal, and protozoocidal activity of chemical germicides.<sup>81, 82</sup> EPA is accepting label claims against hepatitis B virus (HBV) using a surrogate organism, the duck HBV, to quantify disinfectant activity.<sup>82, 83</sup> EPA also is accepting labeling claims against hepatitis C virus using the bovine viral diarrhea virus as a surrogate.

For nearly 30 years, EPA also performed intramural preregistration and postregistration efficacy testing of some chemical disinfectants in its own laboratories. In 1982, this was stopped, reportedly for budgetary reasons. At that time, manufacturers did not need to have microbiologic activity claims verified by EPA or an independent testing laboratory when registering a disinfectant or chemical sterilant.<sup>82</sup> This occurred when the frequency of contaminated germicides and infections secondary to their use had increased.<sup>88</sup> Investigations demonstrating that interlaboratory reproducibility of test results was poor and manufacturers' label claims were not verifiable.<sup>91, 92</sup> and a symposium sponsored by the American Society for Microbiology<sup>89</sup> heightened awareness of these problems and reconfirmed the need to improve the AOAC methods and reinstate a microbiologic activity verification program. A General Accounting Office report entitled *Disinfectants: EPA Lacks Assurance They Work*<sup>90</sup> seemed to provide the necessary impetus for EPA to initiate cooperative measures, including cooperative agreements to improve the AOAC methods and independent verification testing for all products labeled as sporidial and disinfectants labeled as tuberculocidal. For example, of 26 sterilant products tested by EPA, 15 were cancelled because of product failure. A list of products registered with EPA and labeled for use as sterilants or tuberculocides or against HIV and/or HBV is available through EPA's website at <http://www.epa.gov/opaq/001/chemindex.htm>. Organizations (e.g., Organization for Economic Cooperation and Development) are working to standardize requirements for germicide testing and registration.

**Neutralization of Germicides**

One of the difficulties associated with evaluating the bactericidal activity of disinfectants is prevention of bacteriostasis from disinfectant residues carried over into the subculture media. Likewise, small amounts of disinfectants on environmental surfaces can make an accurate bacterial count difficult to get when sampling of the health-care environment as part of an epidemiologic or research investigation. One way these problems may be overcome is by employing neutralizers that inactivate residual disinfectants.<sup>93, 94</sup> Two commonly used neutralizers for chemical disinfectants are Lefebvre Media and D/E Neutralizing Media. The former contains lecithin to neutralize quaternaries and polysorbate 80 (Tween 80) to neutralize phenolics, hexachlorophene, formalin, and with lactin, ethanol. The D/E Neutralizing media will neutralize a broad spectrum of antiseptic and disinfectant chemicals, including quaternary ammonium compounds, phenols, iodine and chlorine compounds, mercaptals, formaldehyde, and glutaraldehyde.<sup>95</sup> A review of neutralizers used in germicide testing has been published.<sup>96</sup>

**STERILIZATION**

Most medical and surgical devices used in healthcare facilities are made of materials that are heat stable and therefore undergo heat, primarily steam, sterilization. However, since 1950, there has been an increase in medical devices and instruments made of materials (e.g., plastics) that require low-temperature sterilization. Ethylene oxide gas has been used since the 1950s for heat- and moisture-sensitive medical devices. Within the past 16 years, a number of new, low-temperature sterilization systems (e.g., hydrogen peroxide gas plasma, peracetic acid immersion, ozone) have been developed and are being used to sterilize medical devices. This section reviews sterilization technologies used in healthcare and makes recommendations for their optimum performance in the processing of medical devices.<sup>1-11, 111-120</sup>

Sterilization destroys all microorganisms on the surface of an article or in a fluid to prevent disease transmission associated with the use of that item. While the use of inadequately sterilized critical items represents a high risk of transmitting pathogens, documented transmission of pathogens associated with an inadequately sterilized critical item is exceedingly rare.<sup>121, 122</sup> This is likely due to the wide margin of safety associated with the sterilization processes used in healthcare facilities. The concept of what constitutes "sterile" is measured as a probability of sterility for each item to be sterilized. This probability is commonly referred to as the sterility assurance level (SAL) of the product and is defined as the probability of a single viable microorganism occurring on a product after sterilization. SAL is normally expressed as 10<sup>-6</sup>. For example, if the probability of a spore surviving were one in one million, the SAL would be 10<sup>-6</sup>.<sup>123, 124</sup> In short, a SAL is an estimate of lethality of the entire sterilization process and is a conservative calculation. Dual SALs (e.g., 10<sup>-3</sup> SAL for blood culture tubes, drainage bags; 10<sup>-4</sup> SAL for catheters, implants) have been used in the United States for many years and the choice of a 10<sup>-6</sup> SAL was strictly arbitrary and not associated with any adverse outcomes (e.g., patient infections).<sup>122</sup>

Medical devices that have contact with sterile body tissues or fluids are considered critical items. These items should be sterile when used because any microbial contamination could result in disease transmission. Such items include surgical instruments, biopsy forceps, and implanted medical devices. If these items are heat resistant, the recommended sterilization process is steam sterilization, because it has the largest margin of safety due to its reliability, consistency, and lethality. However, reprocessing heat- and moisture-sensitive items requires use of a low-temperature sterilization technology (e.g., ethylene oxide, hydrogen peroxide gas plasma, peracetic acid).<sup>125</sup> A summary of the advantages and disadvantages for commonly used sterilization technologies is presented in Table 6.

**Steam Sterilization**

**Overview.** Of all the methods available for sterilization, moist heat in the form of saturated steam under pressure is the most widely used and the most dependable. Steam sterilization is nonporous, inexpensive,<sup>126</sup> rapidly microbicidal, sporidial, and rapidly heats and penetrates fabrics (Table 6).<sup>127</sup> Like all sterilization processes, steam sterilization has some deleterious effects on some materials, including corrosion and combustion of lubricants associated with dental handpieces<sup>128</sup>; reduction in ability to transmit light associated with laryngoscopes<sup>129</sup>; and increased hardening time (2.5 fold) with plaster-cast.<sup>130</sup>

The basic principle of steam sterilization, as accomplished in an autoclave, is to expose each item to direct steam contact at the required temperature and pressure for the specified time. Thus, there are four parameters of steam sterilization: steam, pressure, temperature, and time. The ideal steam for sterilization is dry saturated steam and entrained water (dynamics fraction >87%)<sup>131, 132</sup>. Pressure serves as a means to obtain the high temperatures necessary to quickly kill microorganisms. Specific temperatures must be obtained to ensure the microbicidal activity. The two common steam-sterilizing temperatures are 121°C (250°F) and 132°C (270°F). These temperatures (and other high temperatures)<sup>133</sup> must be maintained for a minimal time to kill microorganisms. Recognized minimum exposure periods for sterilization of wrapped healthcare supplies are 30 minutes at 121°C (250°F) in a gravity displacement

sterilizer or 4 minutes at 132°C (270°F) in a prevacuum sterilizer (Table 7). At constant temperatures, sterilization times vary depending on the type of item (e.g., metal versus rubber, plastic, items with lumens), whether the item is wrapped or unwrapped, and the sterilizer type.

The two basic types of steam sterilizers (autoclaves) are the gravity displacement autoclave and the high-speed prevacuum sterilizer. In the former, steam is admitted at the top or the side of the sterilizing chamber and, because the steam is lighter than air, forces air out the bottom of the chamber through the drain vent. The gravity displacement autoclaves are primarily used to process laboratory media, water, pharmaceutical products, regulated medical waste, and nonporous articles whose surfaces have direct steam contact. For gravity displacement sterilizers the penetration time into porous items is prolonged because of incomplete air elimination. This point is illustrated with the decontamination of 10 lbs of microbiological waste, which requires at least 45 minutes at 121°C because the entrapped air remaining in a load of waste greatly retards steam permeation and heating efficiency.<sup>131, 132</sup> The high-speed prevacuum sterilizers are similar to the gravity displacement sterilizers except they are fitted with a vacuum pump (or ejector) to ensure air removal from the sterilizing chamber and load before the steam is admitted. The advantage of using a vacuum pump is that there is nearly instantaneous steam penetration even into porous loads. The Bowie-Dick test is used to detect air leaks and inadequate air removal and consists of folded 100% cotton surgical towels that are clean and preconditioned. A commercially available Bowie-Dick type test sheet should be placed in the center of the pack. The test pack should be placed horizontally in the front, bottom section of the sterilizer rack, near the door and over the drain, in an otherwise empty chamber and run at 134°C for 3.5 minutes.<sup>134, 135</sup> The test is used each day the vacuum-type steam sterilizer is used, before the first processed load. Air that is not removed from the chamber will interfere with steam contact. Smaller disposable test packs (or process challenge devices) have been devised to replace the stack of folded towels for testing the efficacy of the vacuum system in a prevacuum sterilizer.<sup>133</sup> These devices are "designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process."<sup>134, 135</sup> They should be representative of the load and simulate the greatest challenge to the load.<sup>133</sup> Sterilizer vacuum performance is acceptable if the sheet inside the test pack shows a uniform color change. Entrapped air will cause a spot to appear on the test sheet, due to the inability of the steam to reach the chemical indicator. If the sterilizer fails the Bowie-Dick test, do not use the sterilizer until it is inspected by the sterilizer maintenance personnel and passes the Bowie-Dick test.<sup>134, 135</sup>

Another design in steam sterilization is a steam flush-pressure pulsing process, which removes air rapidly by repeatedly alternating a steam flush and a pressure pulse above atmospheric pressure. Air is rapidly removed from the load as with the prevacuum sterilizer, but air leaks do not affect this process because the steam in the sterilizing chamber is always above atmospheric pressure. Typical sterilization temperatures and times are 132°C to 135°C with 3 to 4 minutes exposure time for porous loads and instruments.<sup>136, 137</sup>

Like other sterilization systems, the steam cycle is monitored by mechanical, chemical, and biological monitors. Steam sterilizers usually are monitored using a printout (or graphically) by measuring temperature, the time at the temperature, and pressure. Typically, chemical indicators are affixed to the outside and incorporated into the pack to monitor the temperature or time and temperature. The effectiveness of steam sterilization is monitored with a biological indicator containing spores of *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*). Positive spore test results are a relatively rare event<sup>138</sup> and can be attributed to operator error, inadequate steam delivery,<sup>139</sup> or equipment malfunction.

Portable (table-top) steam sterilizers are used in outpatient, dental, and rural clinics.<sup>140</sup> These sterilizers are designed for small instruments, such as hypodermic syringes and needles and dental instruments. The ability of the sterilizer to reach physical parameters necessary to achieve sterilization should be monitored by mechanical, chemical, and biological indicators.

**Microbicidal Activity.** The oldest and most recognized agent for inactivation of microorganisms is heat. D-values (time to reduce the surviving population by 90% or 1 log) allow a direct comparison of the heat resistance of microorganisms. Because a D-value can be determined at various temperatures, a subscript is used to designate the exposure temperature (i.e., D<sub>121°C</sub>). D<sub>121°C</sub> values for *Geobacillus stearothermophilus* used to monitor the steam sterilization process range from 1 to 2 minutes. Heat-resistant spore-forming bacteria, yeasts, and fungi have such long D<sub>121°C</sub> values that they cannot be experimentally measured.<sup>141</sup>

**Mode of Action.** Moist heat destroys microorganisms by the irreversible coagulation and denaturation of enzymes and structural proteins. In support of this fact, it has been found that the presence of moisture significantly affects the coagulation temperature of proteins and the temperature at which microorganisms are destroyed.

**Uses.** Steam sterilization should be used whenever possible on all critical and semicritical items that are heat and moisture resistant (e.g., steam sterilizable respiratory therapy and anesthesia equipment), even when not essential to prevent pathogen transmission. Steam sterilizers also are used in healthcare facilities to decontaminate microbiological waste and sharps containers.<sup>132, 142</sup> but additional exposure time is required in the gravity displacement sterilizer for these items.

**Flash Sterilization**

**Overview.** Flash steam sterilization was originally defined by Underwood and Perkins as sterilization of an unwrapped object at 132°C for 3 minutes at 27–28 lbs. of pressure in a gravity displacement sterilizer.<sup>143</sup> Currently, the time required for flash sterilization depends on the type of sterilizer and the type of item (i.e., porous vs non-porous items) (see Table 8). Although the wrapped method of sterilization is preferred for the reasons listed below, correctly performed flash sterilization is an effective process for the sterilization of critical medical devices.<sup>144, 145</sup> Flash sterilization is a modification of conventional steam sterilization (either gravity, prevacuum, or steam-flush pressure-pulse) in which the flashed item is placed in an open tray or is placed in a specially designed, covered, rigid container to allow for rapid penetration of steam. Historically, it is not recommended as a routine sterilization method because of the lack of timely biological indicators to monitor performance, absence of protective packaging following sterilization, possibility for contamination of processed items during transportation to the operating rooms, and the sterilization cycle parameters (i.e., time, temperature, pressure) are minimal. To address some of these concerns, many healthcare facilities have done the following: placed equipment for flash sterilization in close proximity to operating rooms to facilitate aseptic delivery to the point of use (usually the sterile field in an ongoing surgical procedure); extended the exposure time to ensure lethality comparable to sterilized wrapped items (e.g., 4 minutes at 132°C)<sup>146, 147</sup>; used biological indicators that provide results in 1 hour for flash-sterilized items<sup>148, 149</sup>; and used protective packaging that permits steam penetration.<sup>152, 177-181, 183, 185</sup> Further, some rigid, reusable sterilization container systems have been designed and validated by the container manufacturer for use with flash cycles. When sterile items are open to air, they will eventually become contaminated. Thus, the longer a sterile item is exposed to air, the greater the number of microorganisms that will settle on it. Sterilization cycle parameters for flash sterilization are shown in Table 8.

A few adverse events have been associated with flash sterilization. When evaluating an increased incidence of neurosurgical infections, the investigators noted that surgical instruments were flash sterilized between cases and 2 of 3 craniofacial infections involved plate implants that were flash sterilized.<sup>150</sup> A report of two patients who received burns during surgery from instruments that had been flash sterilized reinforced the need to develop policies and educate staff to prevent the use of instruments hot enough to cause clinical burns.<sup>151</sup> Staff should use precautions to prevent burns with potentially hot instruments (e.g., transport tray using heat-protective gloves). Patient burns may be prevented by either air-cooling the instruments or immersion in sterile fluid (e.g., saline).

Uses. Flash sterilization is considered acceptable for processing cleaned patient-care items that

cannot be packaged, sterilized, and stored before use. It also is used when there is insufficient time to sterilize an item by the preferred package method. Flash sterilization should not be used for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time.<sup>117</sup> Because of the potential for serious infections, flash sterilization is not recommended for implantable devices (i.e., devices placed into a surgically or naturally formed cavity of the human body); however, flash sterilization may be unavoidable for some cases (e.g., orthopedic screw, plates). If flash sterilization of an implantable device is unavoidable, recording (i.e., lead identification, patient's name/hospital identifier, and biological indicator result) is essential for epidemiologic tracking (e.g., of surgical site infection, tracing results of biological indicators to patients who received the item to document sterility), and for an assessment of the reliability of the sterilization process (e.g., evaluation of biological monitoring records and sterilization maintenance records noting preventive maintenance and repairs with dates).

#### Low-Temperature Sterilization Technologies

Ethylene oxide (ETO) has been widely used as a low-temperature sterilant since the 1950s. It has been the most commonly used process for sterilizing temperature- and moisture-sensitive medical devices and supplies in healthcare institutions in the United States. Two types of ETO sterilizers are available, mixed gas and 100% ETO. Until 1995, ethylene oxide sterilizers combined ETO with a chlorofluorocarbon (CFC) stabilizing agent, most commonly in a ratio of 12% ETO mixed with 88% CFC (referred to as 12/88 ETO).

For several reasons, healthcare personnel have been exploring the use of new low-temperature sterilization technologies.<sup>118,119</sup> First, CFCs were phased out in December 1995 under provisions of the Clean Air Act.<sup>120</sup> CFCs were classified as a Class I substance under the Clean Air Act because of scientific evidence linking them to destruction of the earth's ozone layer. Second, some states (e.g., California, New York, Michigan) require the use of ETO abatement technology to reduce the amount of ETO being released into ambient air from 90 to 89.9% depending on the state. Third, OSHA regulates the acceptable vapor levels of ETO (i.e., 1 ppm averaged over 8 hours) due to concerns that ETO exposure represents an occupational hazard.<sup>121</sup> These concerns have led to the development of alternative technologies for low-temperature sterilization in the healthcare setting.

Alternative technologies to ETO with chlorofluorocarbon that are currently available and cleared by the FDA for medical equipment include 100% ETO; ETO with a different stabilizing gas, such as carbon dioxide or hydrochlorofluorocarbons (HCFC); immersion in peracetic acid; hydrogen peroxide gas plasma; and ozone. Technologies under development for use in healthcare facilities, but not cleared by the FDA, include vaporized hydrogen peroxide, vapor phase peracetic acid, gaseous chlorine dioxide, ionizing radiation, or pulsed light.<sup>122,123,124</sup> However, there is no guarantee that these new sterilization technologies will receive FDA clearance for use in healthcare facilities.

These new technologies should be compared against the characteristics of an ideal low-temperature (<60°C) sterilant (Table 5).<sup>125</sup> While it is apparent that all technologies will have limitations (Table 5), understanding the limitations imposed by restrictive device designs (e.g., long, narrow lumens) is critical for proper application and technology.<sup>126</sup> For example, the development of increasingly small and complex endoscopes presents a difficult challenge for current sterilization processes. This occurs because microorganisms are in direct contact with the sterilant for inactivation to occur. Several peer-reviewed scientific publications have data demonstrating concerns about the efficacy of several of the low-temperature sterilization processes (i.e., gas plasma, vaporized hydrogen peroxide, ETO, peracetic acid), particularly when the test organisms are challenged in the presence of serum and salt and a narrow lumen vehicle.<sup>126,127,128,129,130</sup> Factors shown to affect the efficacy of sterilization are shown in Table 10.

#### Ethylene Oxide "Gas" Sterilization

**Overview.** ETO is a colorless gas that is flammable and explosive. The four essential

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parameters (operational ranges) are: gas concentration (450 to 1200 mg/L); temperature (37 to 63°C); relative humidity (40 to 80% [water molecules carry ETO to reactive sites]); and exposure time (1 to 6 hours). These influence the effectiveness of ETO sterilization.<sup>131,132,133</sup> Within certain limitations, an increase in gas concentration and temperature may shorten the time necessary for achieving sterilization.

The main disadvantages associated with ETO are the lengthy cycle time, the cost, and its potential hazards to patients and staff; the main advantage is that it can sterilize heat- or moisture-sensitive medical equipment without deleterious effects on the material used in the medical device (Table 6). Acute exposure to ETO may result in irritation (e.g., to skin, eyes, gastrointestinal or respiratory tracts) and central nervous system depression.<sup>134,135</sup> Chronic inhalation has been linked to the formation of cataracts, cognitive impairment, neurologic dysfunction, and disabling polyneuropathy.<sup>136,137,138</sup> Occupational exposure in healthcare facilities has been linked to hematologic changes<sup>139</sup> and an increased risk of spontaneous abortions and various cancers.<sup>14,140,141</sup> ETO should be considered a known human carcinogen.<sup>142</sup>

The basic ETO sterilization cycle consists of five stages (i.e., preconditioning and humidification, gas introduction, exposure, evacuation, and air washes) and takes approximately 2 1/2 hrs excluding transfer time. Mechanical aeration for 8 to 12 hours at 50 to 60°C allows desorption of the toxic ETO residual contained in exposed absorbent materials. Most modern ETO sterilizers combine sterilization and aeration in the same chamber as a continuous process. These ETO models minimize potential ETO exposure during door opening and load transfer to the aerator. Ambient room aeration also will achieve desorption of the toxic ETO but requires 7 days at 20°C. There are no federal regulations for ETO sterilizer emission; however, many states have promulgated emission-control regulations.<sup>143</sup>

The use of ETO evolved when few alternatives existed for sterilizing heat- and moisture-sensitive medical devices; however, favorable properties (Table 6) account for its continued widespread use.<sup>144</sup> Two ETO gas mixtures are available to replace ETO-chlorofluorocarbon (CFC) mixtures for large capacity, tank-supplied sterilizers. The ETO-carbon dioxide (CO<sub>2</sub>) mixture consists of 8.0% ETO and 91.0% CO<sub>2</sub>. This mixture is less expensive than ETO-hydrochlorofluorocarbon (HCFC), but a disadvantage is the need for pressure vessels rated for steam sterilization, because higher pressures (28-pal gauge) are required. The other mixture, which is a drop-in CFC replacement, is ETO mixed with HCFC. HCFCs are approximately 50-fold less damaging to the earth's ozone layer than are ETO CFCs. The EPA will begin regulation of HCFC in the year 2015 and will terminate production in the year 2030. Two companies offer ETO-HCFC mixtures as drop-in replacement for CFC-12; one mixture consists of 8.6% ETO and 91.4% HCFC, and the other mixture is composed of 70% ETO and 30% HCFC.<sup>145</sup> An alternative to the pressurized mixed gas ETO systems is 100% ETO. The 100% ETO sterilizers using unit-dose cartridges eliminate the need for external tanks.

ETO is absorbed by many materials. For this reason, following sterilization the item must undergo aeration to remove residual ETO. Guidelines have been promulgated regarding allowable ETO levels for devices that remain in the device if used, how often, and how long in order to pose a minimal risk to patients in normal product use.<sup>146</sup>

ETO toxicity has been established in a variety of animals. Exposure to ETO can cause eye pain, sore throat, difficulty breathing and blurred vision. Exposure can also cause dizziness, nausea, headache, convulsions, hiccups and vomiting and coughing.<sup>147</sup> In a variety of *in vitro* and animal studies, ETO has been demonstrated to be carcinogenic. ETO has been linked to spontaneous abortion, genetic damage, nerve damage, peripheral paralysis, muscle weakness, and impaired thinking and memory.<sup>148</sup> Occupational exposure in healthcare facilities has been linked to an increased risk of spontaneous abortions and various cancers.<sup>14,149</sup> Injuries (e.g., lacerations) to patients have been associated with ETO sterilizers in implants used in surgical procedures.<sup>150</sup> Residual ETO in capillary flow dialysis membranes has been shown to be neurotoxic *in vitro*.<sup>151</sup> OSHA has established a PEL of 1 ppm airborne ETO in the workplace, expressed as a TWA for an 8-hour work shift in a 40-hour work week. The "action level" for ETO is 0.5 ppm, expressed as an 8-hour TWA, and the short-term excursion limit is 5 ppm, expressed as

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a 15-minute TWA.<sup>152</sup> For details of the requirements in OSHA's ETO standard for occupational exposures, see Title 29 of the Code of Federal Regulations (CFR) Part 1910.1047.<sup>153</sup> Several personnel monitoring methods (e.g., charcoal tubes and passive sampling devices) are in use.<sup>154</sup> OSHA has established a PEL of 5 ppm for ethylene chlorohydrin (a toxic by-product of ETO) in the workplace.<sup>155</sup> Additional information regarding use of ETO in health care facilities is available from NIOSH.

**Mode of Action.** The microbicidal activity of ETO is considered to be the result of alkylation of protein, DNA, and RNA. Alkylation, or the replacement of a hydrogen atom with an alkyl group, within cells prevents normal cellular metabolism and replication.<sup>156</sup>

**Microbicidal Activity.** The excellent microbicidal activity of ETO has been demonstrated in several studies.<sup>157,158,159,160</sup> and summarized in published reports.<sup>161</sup> ETO inactivates all microorganisms although bacterial spores (especially *B. anthracis*) are more resistant than other microorganisms. For this reason *B. anthracis* is the recommended biological indicator.

Like all sterilization processes, the effectiveness of ETO sterilization can be altered by lumen length, lumen diameter, inorganic salts, and organic materials.<sup>162,163,164,165,166</sup> For example, although ETO is not used commonly for reprocessing endoscopes,<sup>167</sup> several studies have shown failure of ETO in inactivating contaminating spores in endoscope channels<sup>168</sup> or lumen test units.<sup>169,170,171</sup> and residual ETO levels averaging 68.2 ppm even after the standard degassing time.<sup>172</sup> Failure of ETO also has been observed when dental handpieces were contaminated with *Streptococcus mutans* and exposed to ETO.<sup>173</sup> It is recommended that dental handpieces be steam sterilized.

**Uses.** ETO is used in healthcare facilities to sterilize critical items (and sometimes semicritical items) that are moisture or heat sensitive and cannot be sterilized by steam sterilization.

#### Hydrogen Peroxide Gas Plasma

**Overview.** New sterilization technology based on plasma was patented in 1987 and marketed in the United States in 1993. Gas plasmas have been referred to as the fourth state of matter (i.e., liquids, solids, gases, and gas plasmas). Gas plasmas are generated in an enclosed chamber under deep vacuum using radio frequency or microwave energy to excite the gas molecules and produce charged particles, many of which are in the form of free radicals. A free radical is an atom with an unpaired electron and is a highly reactive species. The proposed mechanism of action of this device is the production of free radicals within a plasma field that are capable of interacting with essential cell components (e.g., enzymes, nucleic acids) and thereby disrupt the metabolism of microorganisms. The type of used gas and the depth of the vacuum are two important variables that can determine the effectiveness of this process.

In the late 1980s the first hydrogen peroxide gas plasma system for sterilization of medical and surgical devices was field-tested. According to the manufacturer, the sterilization chamber is evacuated and hydrogen peroxide solution is injected from a cassette and is vaporized in the sterilization chamber to a concentration of 9 mg/L. The hydrogen peroxide vapor diffuses through the chamber (50 minutes), exposes all surfaces of the load to the sterilant, and initiates the inactivation of microorganisms. An electrical field created by a radio frequency is applied to the chamber to create a gas plasma. Microbicidal free radicals (e.g., hydroxyl and hydroperoxyl) are generated in the plasma. The excess gas is removed and in the final stage (i.e., vent) of the process the sterilization chamber is returned to atmospheric pressure by introduction of high-efficiency filtered air. The by-products of the cycle (e.g., water vapor, oxygen) are nontoxic and eliminate the need for aeration. Thus, the sterilized materials can be handled safely, either for immediate use or storage. The process operates in the range of 37-44°C and has a cycle time of 75 minutes. If any moisture is present on the objects the vacuum will not be achieved and the cycle aborts.<sup>174,175,176</sup>

A newer version of the unit improves sterilizer efficacy by using two cycles with a hydrogen

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peroxide diffusion stage and a plasma stage per sterilization cycle. This revision, which is achieved by a software modification, reduces total processing time from 73 to 52 minutes. The manufacturer believes that the enhanced activity obtained with this system is due in part to the pressure changes that occur during the injection and diffusion phases of the process and is the fact that the process consists of two equal and consecutive half cycles, each with a separate injection of hydrogen peroxide.<sup>177,178</sup> This system and a smaller version<sup>179,180</sup> have received FDA 510(k) clearances with limited application for sterilization of medical devices (Table 6). The biological indicator used with this system is *Bacillus atrophaeus* spores.<sup>181</sup> The newest version of the unit, which employs a new vaporization system that removes most of the water from the hydrogen peroxide, has a cycle time from 28-38 minutes (see manufacturer's literature for device dimension restrictions).

Penetration of hydrogen peroxide vapor into long or narrow lumens has been addressed outside the United States by the use of a diffusion enhancer. This is a small, breakable glass ampoule of concentrated hydrogen peroxide (50%) with an elastic connector that is inserted into the device lumen and crushed immediately before sterilization.<sup>182,183</sup> The diffusion enhancer has been shown to sterilize bronchoscopes contaminated with *Mycobacterium tuberculosis*.<sup>184</sup> At the present time, the diffusion enhancer is not FDA cleared.

Another gas plasma system, which differs from the above in several important ways, including the use of peracetic acid-acetic acid-hydrogen peroxide vapor, was removed from the marketplace because of reports of corneal destruction to patients when ophthalmic surgery instruments had been processed in the sterilizer.<sup>185,186</sup> In this investigation, exposure of potentially wet ophthalmologic surgical instruments with small bores and brass components to the plasma gas led to degradation of the brass to copper and zinc.<sup>187,188</sup> The experimenters showed that when rabbit eyes were exposed to the residues of the gas plasma-sterilized instruments, corneal decompensation was documented. This toxicity is highly unlikely with the hydrogen peroxide gas plasma process since a toxic, soluble form of copper would not form (LA Feldman, written communication, April 1993).

**Mode of Action.** This process inactivates microorganisms primarily by the combined use of hydrogen peroxide gas and the generation of free radicals (hydroxyl and hydroperoxyl free radicals) during the plasma phase of the cycle.

**Microbicidal Activity.** This process has the ability to inactivate a broad range of microorganisms, including resistant bacterial spores. Studies have been conducted against vegetative bacteria (including mycobacteria), yeasts, fungi, viruses, and bacterial spores.<sup>189,190,191,192,193</sup> Like all sterilization processes, the effectiveness can be altered by lumen length, lumen diameter, inorganic salts, and organic materials.<sup>194,195,196,197,198</sup>

**Uses.** Materials and devices that cannot tolerate high temperature and humidity, such as some plastics, electrical devices, and corrosion-susceptible metal alloys, can be sterilized by hydrogen peroxide gas plasma. This method has been compatible with most (>95%) medical devices and materials tested.<sup>199,200,201</sup>

#### Peracetic Acid Sterilization

**Overview.** Peracetic acid is a highly biocidal oxidizer that maintains its efficacy in the presence of organic soil. Peracetic acid removes surface contaminants (primarily protein) on endoscopic tubing.<sup>202</sup>

An automated machine using peracetic acid to sterilize medical, surgical, and dental instruments chemically (e.g., endoscopes, arthroscopes) was introduced in 1988. This microprocessor-controlled, low-temperature sterilization method is commonly used in the United States.<sup>203</sup> The sterilant, 35% peracetic acid, and an antimicrobial agent are supplied in a single-dose container. The container is punctured at the time of use, immediately prior to closing the lid and initiating the cycle. The concentrated peracetic acid is diluted to 0.2% with filtered water (0.2 um) at a temperature of approximately 60°C. The diluted peracetic acid is circulated within the chamber of the machine and

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pumped through the channels of the endoscope for 12 minutes, decontaminating exterior surfaces, lumens, and accessories. Interchangeable trays are available to permit the processing of up to three rigid endoscopes or one flexible endoscope. Connectors are available for most types of flexible endoscopes for the irrigation of all channels by directed flow. Rigid endoscopes are placed within a fidded container, and the sterilant fits the lumens either by immersion in the circulating sterilant or by use of channel connectors to direct the sterilant into the lumens (5) (see below for the importance of channel connectors). The peracetic acid is discarded via the sewer and the instrument rinsed four times with filtered water. Concern has been raised that filtered water may be inadequate to maintain sterility.<sup>141</sup> Limited data have shown that low-level bacterial contamination may follow the use of filtered water in an AER but no data has been published on AERs using the peracetic acid system.<sup>141</sup> Clean filtered air is passed through the chamber of the machine and endoscope channels to remove excess water.<sup>141</sup> As with any sterilization process, the system can only sterilize surfaces that can be contacted by the sterilant. For example, bronchoscopy-related infections occurred when bronchoscopes were processed using the wrong connector.<sup>142,143</sup> Investigation of these incidents revealed that bronchoscopes were inadequately reprocessed when inappropriate channel connectors were used and when there were inconsistencies between the reprocessing instructions provided by the manufacturer of the bronchoscopes and the manufacturer of the automatic endoscope reprocessor.<sup>142</sup> The importance of channel connectors to achieve sterilization was also shown for rigid lumen devices.<sup>143,144</sup>

The manufacturers suggest the use of biological monitors (*G. stearothermophilus* spore strips) both at the time of installation and routinely to ensure effectiveness of the process. The manufacturer's clip must be used to hold the strip in the designated spot in the machine as a broader clamp will not allow the sterilant to reach the spore trapped under it.<sup>145</sup> One investigator reported a 3% failure rate when the appropriate clips were used to hold the spore strip within the machine.<sup>145</sup> The use of biological monitors designed to monitor either steam sterilization or ETO for a liquid chemical sterilizer has been questioned for several reasons including spore wash-off from the filter paper strips which may cause false valid monitoring.<sup>146,147</sup> The processor is equipped with a conductivity probe that will automatically abort the cycle if the buffer system is not detected in a fresh container of the peracetic acid solution. A chemical monitoring strip that detects that the active ingredient is >1500 ppm is available for routine use as an additional process control.

**Made of Action.** Only limited information is available regarding the mechanism of action of peracetic acid, but it is thought to function as other oxidizing agents, i.e., it denatures proteins, disrupts cell wall permeability, and oxidizes sulfhydryl and sulfur bonds in proteins, enzymes, and other metabolites.<sup>148,149</sup>

**Microbicidal Activity.** Peracetic acid will inactivate gram-positive and gram-negative bacteria, fungi, and yeasts in <5 minutes at <100 ppm. The manufacturer's label states that 200-500 ppm is required. For viruses, the dosage range is wide (12-2250 ppm), with poliovirus inactivation in yeast extract in 15 minutes with 1500 to 2250 ppm. Bacterial spores in suspension are inactivated in 15 seconds to 30 minutes with 500 to 10,000 ppm (0.05 to 1%).<sup>150</sup>

Simulated-use trials have demonstrated microbicidal activity<sup>111, 719-722</sup> and three clinical trials have demonstrated microbial killing and no clinical failures leading to infection.<sup>69, 723, 724</sup> Alfa and co-workers, who compared the peracetic acid system with ETO, demonstrated the high efficacy of the system. Only the peracetic acid system was able to completely kill 6-log<sub>10</sub> of *Mycobacterium chelonae*, *Enterococcus faecalis*, and *B. atrophaeus* spores with both an organic and inorganic challenge.<sup>725</sup> Like other sterilization processes, the efficacy of the process can be diminished by soil challenges<sup>726</sup> and dust conditions.<sup>727</sup>

**Uses.** This automated machine is used to chemically sterilize medical (e.g., GI endoscopes) and surgical (e.g., flexible arthroscopes) instruments in the United States. Lumened endoscopes must be connected to an appropriate channel connector to ensure that the sterilant has direct contact with the contaminated lumen.<sup>145, 148, 149</sup> Olympus America has not listed this system as a compatible product for

With respect to the results by Alfa and co-workers<sup>69</sup>, Jacobs showed that the use of the tissue culture media created a technique-induced sterilization failure.<sup>728</sup> Jacobs et al. showed that microorganisms mixed with tissue culture media, used as a surrogate body fluid, formed physical crystals that protected the microorganisms used as a challenge. If the carriers were exposed for 60 sec to nonflowing water, the salts dissolved and the protective effect disappeared. Since any device would be exposed to water for a short period of time during the washing procedure, these protective effects would have little clinical relevance.<sup>729</sup>

Narrow lumens provide a challenge to some low-temperature sterilization processes. For example, Rutala and colleagues showed that, as lumen size decreased, increased failures occurred with some low-temperature sterilization technologies. However, some low-temperature processes such as ETO-H2O2 and the hydrogen peroxide gas plasma process remained effective even when challenged by a lumen as small as 1 mm in the absence of salt and serum.<sup>730</sup>

The importance of allowing the sterilant to come into contact with the inoculated carrier is demonstrated by comparing the results of two investigators who studied the peracetic acid immersion system. Alfa and co-workers demonstrated excellent activity of the peracetic acid immersion system against three test organisms using a narrow-lumen device. In these experiments, the lumen test object was connected to channel irrigators, which ensured that the sterilant had direct contact with the contaminated carrier.<sup>731</sup> This effectiveness was achieved through a combination of organism wash-off and peracetic acid sterilant killing the test organisms.<sup>732</sup> The data reported by Rutala et al. demonstrated failure of the peracetic acid immersion system to eliminate *Geobacillus stearothermophilus* spores from a carrier placed in a lumen test object. In these experiments, the lumen test unit was not connected to channel irrigators. The authors attributed the failure of the peracetic acid immersion system to eliminate the high levels of spores from the center of the test unit to the inability of the peracetic acid to diffuse into the center of 40-cm long, 3-mm diameter tubes. This may be caused by an air lock or air bubbles formed in the lumen, impeding the flow of the sterilant through the long and narrow lumen and limiting complete access to the *Geobacillus*.<sup>733,734</sup> Experiments using a channel connector specifically designed for 1-, 2-, and 3-mm lumen test units with the peracetic acid immersion system were completely effective in eliminating an inoculum of 10<sup>8</sup> *Geobacillus stearothermophilus* spores.<sup>735</sup> The restricted diffusion environment that exists in the test conditions would not exist with flexible scopes processed in the peracetic acid immersion system, because the scopes are connected to channel irrigators to ensure that the sterilant has direct contact with contaminated surfaces. Alfa and associates attributed the efficacy of the peracetic acid immersion system to the ability of the liquid chemical process to dissolve salts and remove protein and bacteria due to the flushing action of the fluid.<sup>736</sup>

**Bioburden of Surgical Devices**

In general, used medical devices are contaminated with a relatively low bioburden of organisms.<sup>174, 911, 912</sup> Nystrom evaluated medical instruments used in general surgery, gynecological, orthopedic, and ear-nose-throat operations and found that 62% of the instruments were contaminated with <10<sup>3</sup> organisms after use, 82% with <10<sup>4</sup>, and 91% with <10<sup>5</sup>. After being washed in an instrument washer, more than 98% of the instruments had <10<sup>3</sup> organisms, and none >10<sup>5</sup> organisms.<sup>911</sup> Other investigators have published similar findings.<sup>913, 914</sup> For example, after a standard cleaning procedure, 72% of 50 surgical instruments contained <10<sup>3</sup> organisms, 83% <10<sup>4</sup>, and only 6% had >3 X 10<sup>5</sup>. In another study of rigid-lumen medical devices, the bioburden on both the inner and outer surface of the lumen ranged from 10<sup>1</sup> to 10<sup>7</sup> organisms per device. After cleaning, 83% of the devices had a bioburden <10<sup>3</sup> organisms.<sup>915</sup> In all of these studies, the contaminating microflora consisted mainly of vegetative bacteria, usually of low pathogenicity (e.g., coagulase-negative *Staphylococcus*).<sup>174, 911, 912</sup>

An evaluation of the microbial load on used critical medical devices such as spinal anesthesia needles and angiographic catheters demonstrated that mesophilic microorganisms were detected at levels of 10<sup>1</sup> to 10<sup>5</sup> in only two of the needles. The bioburden on used angiographic

use in reprocessing Olympus bronchoscopes and gastrointestinal endoscopes (Olympus America, January 30, 2002, written communication).

**Microbicidal Activity of Low-Temperature Sterilization Technologies**

Sterilization processes used in the United States must be cleared by FDA, and they require that sterilizer microbial performance be tested under simulated-use conditions.<sup>151</sup> FDA requires that the test article be inoculated with 10<sup>7</sup> colony-forming units of the most resistant test organism and prepared with organic and inorganic test loads as would occur after actual use. FDA requires manufacturers to use organic soil (e.g., 5% fetal calf serum), dried onto the device with the inoculum, to represent soil remaining on the device following marginal cleaning. However, 5% fetal calf serum as a measure of marginal cleaning has not been validated by measurements of protein load on devices following use and the level of protein removal by various cleaning methods. The inocula must be placed in various locations of the test articles, including those least favorable to penetration and contact with the sterilant (e.g., lumens). Cleaning before sterilization is not allowed in the demonstration of sterilization efficacy.<sup>152</sup> Several studies have evaluated the relative microbicidal efficacy of these low-temperature sterilization technologies (Table 1). These studies have either tested the activity of a sterilization process against specific microorganisms<sup>153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000.</sup>

The effect of salts and serums on the sterilization process were studied initially in the 1950s and 1960s.<sup>24, 99</sup> These studies showed that a high concentration of crystalline-type materials and a low protein content provided greater protection to spores than did serum with a high protein content.<sup>25</sup> A study by Doyle and Ernst demonstrated resistance of spores by crystalline material applied not only to low-temperature sterilization technology but also to steam and dry heat.<sup>26</sup> These studies showed that the required inactivation of *Bacillus atrophaeus* spores in calcium carbonate crystals dramatically increased the time required for inactivation to 150 minutes for ETO (54°C), 30 seconds to 50 hours for dry heat (121°C), 30 seconds to 2 weeks for ETO (54°C). Investigators have corroborated and extended these findings.<sup>428, 429, 231, 430, 232, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000.</sup>

Alfa and colleagues demonstrated a 6-log<sub>10</sub> reduction of the microbial inoculum of porcelain bactericides using a mixture of vegetative and spore-forming organisms (Table 11).<sup>166</sup> However, if the bacterial inoculum was in tissue culture medium supplemented with 10% serum, only the ETO 12/88 and ETO-H2O2 sterilization mixtures could sterilize 95% to 97% of the porcelain carriers. The serums and 100% ETO sterilizer demonstrated significantly reduced activity (Table 11). For all sterilizers evaluated using porcelain carriers (i.e., ETO 12/88, 100% ETO, hydrogen peroxide gas plasma), there was a 3- to 6-log<sub>10</sub> reduction of inoculated bacteria even in the presence of serum and salt. For each sterilizer evaluated, the ability to inactivate microorganisms in the presence of salt and serum was reduced even further when the inoculum was placed in a narrow-lumen test object (3 mm diameter by 125 cm long). Although there was a 2- to 4-log<sub>10</sub> reduction in microbial kill, less than 50% of the lumen test objects were sterile when processed using any of the sterilization methods evaluated using the peracetic acid immersion system (Table 11).<sup>21</sup> Complete killing (or removal) of 6-log<sub>10</sub> of *Enterococcus faecalis*, *Mycobacterium chelonae*, and *Bacillus atrophaeus* spores in the presence of salt and serum and lumen test objects was observed only for the peracetic acid immersion system.

catheters and sheath introducers exceeded 10<sup>3</sup> CFUs on 14% (3 of 21) and 24% (6 of 25), respectively.<sup>737</sup>

**Effect of Cleaning on Sterilization Efficacy**

The effect of salt and serum on the efficacy of low-temperature sterilization technologies has raised concern regarding the margin of safety of these technologies. Experiments have shown that salts have the greatest impact on protecting microorganisms from killing.<sup>25, 26</sup> However, other studies have suggested that these concerns may not be clinically relevant. One study evaluated the relative rates of removal of inorganic salts, organic soil, and microorganisms from medical devices to better understand the dynamics of the cleaning process.<sup>738</sup> These tests were conducted by inoculating Alfa soil (tissue-culture media and 10% fetal bovine serum)<sup>739</sup> containing 10<sup>8</sup> *G. stearothermophilus* spores onto the surface of a stainless-steel surgical blade. After drying for 30 minutes at 55°C followed by 30 minutes at room temperature, the samples were placed in water at room temperature. The blades were removed at specified times, and the concentration of total protein and chloride ion was measured. The results showed that soaking in deionized water for 60 seconds resulted in a 95% release rate of chloride ion from NaCl solution in 20 seconds, Alfa soil in 30 seconds, and fetal bovine serum in 120 seconds. Thus, contact with water for short periods, even in the presence of protein, rapidly leads to dissolution of salt crystals and complete inactivation of spores by a low-temperature sterilization process (Table 10). Based on these experimental data, cleaning procedures would eliminate the detrimental effect of high salt content on a low-temperature sterilization process.

These articles<sup>428, 429, 721</sup> assessing low-temperature sterilization technology reinforce the importance of meticulous cleaning before sterilization. These data support the critical need for healthcare facilities to develop rigid protocols for cleaning contaminated objects before sterilization.<sup>72</sup> Sterilization of instruments and medical devices is compromised if the process is not preceded by meticulous cleaning.

The cleaning of any narrow-lumen medical device used in patient care presents a major challenge to reprocessing areas. While attention has been focused on flexible endoscopes, cleaning issues related to other narrow-lumen medical devices such as sphincterotomies have been investigated.<sup>915</sup> This study compared manual cleaning with that of automated cleaning with a narrow-lumen cleaner and found that only retro-flushing with the narrow lumen cleaner provided adequate cleaning of the three channels. If reprocessing was delayed for more than 24 hours, retro-flush cleaning was no longer effective and ETO sterilization failure was detected when devices were held for 7 days.<sup>915</sup> In another study involving simulated-use cleaning of laparoscopic devices, Alfa found that minimally the use of retro-flushing should be used during cleaning of non-ported laparoscopic devices.<sup>14</sup>

**Other Sterilization Methods**

**Ionizing Radiation.** Ster

are not suitable for most materials<sup>69</sup>. The most common time-temperature relationships for sterilization with hot air sterilizers are 170°C (340°F) for 60 minutes, 160°C (320°F) for 120 minutes, and 150°C (302°F) for 150 minutes. *B. atrophaeus* spores should be used to monitor the sterilization process for dry heat because they are more resistant to dry heat than are *G. steirthermophilus* spores. The primary lethal process is considered to be coagulation of cell constituents.

There are two types of dry-heat sterilizers: the static-air type and the forced-air type. The static-air type is referred to as the oven-type sterilizer as heating coils in the bottom of the unit cause the hot air to rise inside the chamber via gravity convection. This type of dry-heat sterilizer is much slower in heating, requires longer time to reach sterilizing temperature, and is less uniform in temperature control throughout the chamber than is the forced-air type. The forced-air or mechanical convection sterilizer is equipped with a motor-driven blower that circulates heated air throughout the chamber at a high velocity, permitting a more rapid transfer of energy from the air to the instruments<sup>70</sup>.

**Liquid Chemicals.** Several FDA-cleared liquid chemical sterilants include indications for sterilization of medical devices (Tables 4 and 5)<sup>71</sup>. The indicated contact times range from 3 hours to 12 hours. However, except for a few of the products, the contact time is based only on the conditions to pass the AOAC Sporidical Test as a sterilant and not on simulated use testing with devices. These solutions are commonly used as high-level disinfectants when a shorter processing time is required. Generally, chemical liquid sterilants cannot be monitored using a biological indicator to verify sterility<sup>72</sup>.

The survival kinetics for thermal sterilization methods, such as steam and dry heat, have been studied and characterized extensively, whereas the kinetics for sterilization with liquid sterilants are less well understood<sup>73</sup>. The information that is available in the literature suggests that sterilization processes based on liquid chemical sterilants, in general, may not convey the same sterility assurance level as sterilization achieved using thermal or physical methods<sup>74</sup>. The data indicate that the survival curves for liquid chemical sterilants may not exhibit logarithmic kinetics and the shape of the survival curve may vary depending on the formulation, chemical nature and stability of the liquid chemical sterilant. In addition, the design of the AOAC Sporidical Test does not provide quantification of the microbial challenge. Therefore, sterilization with a liquid chemical sterilant may not convey the same sterility assurance as other sterilization methods.

One of the differences between thermal and liquid chemical processes for sterilization of devices is the accessibility of microorganisms to the sterilant. Heat can penetrate barriers, such as biofilm, tissue, and blood, to attach organisms kill, whereas liquids cannot adequately penetrate these barriers. In addition, the viscosity of some liquid chemical sterilants impedes their access to organisms in the narrow lumens and mated surfaces of devices<sup>75</sup>. Another limitation to sterilization of devices with liquid chemical sterilants is the post-processing environment of the device. Devices cannot be wrapped or adequately contained during processing in a liquid chemical sterilant to maintain sterility following processing and during storage. Furthermore, devices may require rinsing following exposure to the liquid chemical sterilant which typically is not sterile. Therefore, due to the inherent limitations of using liquid chemical sterilants, their use should be restricted to reprocessing critical devices that are heat-sensitive and incompatible with other sterilization methods.

Several published studies compare the sporidical effect of liquid chemical germicides against spores of *Bacillus* and *Clostridium*<sup>76, 77</sup>.

**Performic Acid.** Performic acid is a fast-acting sporicide that was incorporated into an automated endoscope reprocessing system<sup>78</sup>. Systems using performic acid are not currently FDA cleared.

**Filtration.** Although filtration is not a lethally-effective process and is not an FDA-cleared sterilization method, this technology is used to remove bacteria from thermolabile pharmaceutical fluids

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that cannot be purified by any other means. In order to remove bacteria, the membrane pore size (e.g., 0.22 µm) must be smaller than the bacteria and uniform throughout<sup>79</sup>. Some investigators have appropriately questioned whether the removal of microorganisms by filtration really is a sterilization method because of slight bacterial passage through filters, viral passage through filters, and transference of the sterile filtrate into the final container under aseptic conditions entail a risk of contamination<sup>80</sup>.

**Microwave.** Microwaves are used in medicine for disinfection of soft contact lenses, dental instruments, dentures, milk, and urinary catheters for intermittent self-catheterization<sup>81, 82</sup>. However, microwaves must only be used with products that are compatible (e.g., do not melt)<sup>83</sup>. Microwaves are radio-frequency waves, which are usually used at a frequency of 2450 MHz. The microwaves produce friction of water molecules in an alternating electrical field. The intermolecular friction derived from the vibrations generates heat and some authors believe that the effect of microwaves depends on the heat produced while others postulate a nonthermal lethal effect<sup>84, 85</sup>. The initial reports showed microwaves to be an effective microbicide. The microwaves produced by a "home-type" microwave oven (2.45 GHz) completely inactivate bacterial cultures, mycobacteria, viruses, and *G. steirthermophilus* spores within 60 seconds to 6 minutes depending on the challenge organism<sup>86, 87</sup>. Another study confirmed these results but also found that higher power microwaves in the presence of water may be needed for sterilization<sup>88</sup>. Complete destruction of *Mycobacterium bovis* was obtained with 4 minutes of microwave exposure (600W, 2450 MHz)<sup>89</sup>. The effectiveness of microwave ovens for different sterilization and disinfection purposes should be tested and demonstrated as test conditions affect the results (e.g., presence of water, microwave power). Sterilization of metal instruments can be accomplished but requires certain precautions<sup>90</sup>. Of concern is that home-type microwave ovens may not have even distribution of microwave energy over the entire load. Dry devices (there may be hot and cold spots on solid medical devices); hence there may be areas that are not sterilized or disinfected. The use of microwave ovens to disinfect intermittent-use catheters also has been suggested. Researcher's found that test bacteria (e.g., *E. coli*, *Klebsiella pneumoniae*, *Candida albicans*) were eliminated from red rubber catheters within 5 minutes<sup>91</sup>. Microwaves used for sterilization of medical devices have not been FDA cleared.

**Glass Bead "Sterilizer".** Glass bead "sterilizer" uses small glass beads (1.2-1.5 mm diameter) and high temperature (217°C-232°C) for brief exposure times (e.g., 45 seconds) to inactivate microorganisms. These devices have been used for several years in the dental profession<sup>92, 93</sup>. FDA believes there is a risk of infection with this device because of potential failure to sterilize dental instruments and their use should be discontinued until the device has received FDA clearance.

**Vaporized Hydrogen Peroxide (VHP®).** Hydrogen peroxide solutions have been used as chemical sterilants for many years. However, the VHP® was not developed for the sterilization of medical equipment. One method for delivering VHP to the reaction site uses a deep vacuum to pull liquid hydrogen peroxide (30-35% concentration) from a disposable cartridge through a heated vaporizer and then, following vaporization, into the sterilization chamber. A second approach to VHP delivery is the flow-through approach in which the VHP is carried into the sterilization chamber by a carrier gas such as air using either a slight negative pressure (vacuum) or slight positive pressure. Applications of this technology include vacuum systems for industrial sterilization of medical devices and aseptic systems for decontaminating large and small areas<sup>94</sup>. VHP offers several appealing features that include rapid cycle time (e.g., 30-45 minutes); low temperature; environmentally safe by-products (H<sub>2</sub>O, oxygen [O<sub>2</sub>]); good material compatibility; and safe operation, installation and monitoring. VHP has limitations including that cellulose cannot be processed; nylon becomes brittle; and VHP penetration capabilities are less than those of ETO. VHP has not been cleared by FDA for sterilization of medical devices in healthcare facilities.

The feasibility of utilizing vapor-phase hydrogen peroxide as a surface decontaminant and sterilizer was evaluated in a centrifuge decontamination application. In this study, vapor-phase hydrogen peroxide was shown to possess significant sporidical activity<sup>95</sup>. In preliminary studies, hydrogen

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peroxide vapor decontamination has been found to be a highly effective method of eradicating MRSA, *Serratia marcescens*, *Clostridium botulinum* spores and *Clostridium difficile* from rooms, furniture, surfaces and/or equipment; however, further investigation of this method to demonstrate both safety and effectiveness in reducing infection rates are required<sup>96, 97</sup>.

**Ozone.** Ozone has been used for years as a drinking water disinfectant. Ozone is produced when O<sub>2</sub> is energized and split into two monatomic (O<sub>3</sub>) molecules. The monatomic oxygen molecules then collide with O<sub>2</sub> molecules to form ozone, which is O<sub>3</sub>. Thus, ozone consists of O<sub>2</sub> with a loosely bonded third oxygen atom that is readily available to attach to, and oxidize, other molecules. This additional oxygen atom makes ozone a powerful oxidant that destroys microorganisms but is highly unstable (i.e., half-life of 22 minutes at room temperature).

A new sterilization process, which uses ozone as the sterilant, was cleared by FDA in August 2003 for processing reusable medical devices. The sterilizer creates its own sterilant internally from USP grade oxygen, steam-quality water and electricity; the sterilant is converted back to oxygen and water vapor at the end of the cycle by a passing through a catalyst before being exhausted into the room. The duration of the sterilization cycle is about 4 h and 15 m, and it occurs at 30-35°C. Microbial efficacy has been demonstrated by achieving a SAL of 10<sup>-6</sup> with a variety of microorganisms to include the most resistant microorganism, *Sporobacillus steirthermophilus*.

The ozone process is compatible with a wide range of commonly used materials including stainless steel, titanium, anodized aluminum, ceramic, glass, silica, PVC, Teflon, silicone, polypropylene, polyethylene and acrylic. In addition, rigid lumen devices of the following diameter and length can be processed: internal diameter (ID): > 2 mm, length ≤ 25 cm; ID > 3 mm, length ≤ 47 cm; and ID > 4 mm, length ≤ 60 cm.

The process should be safe for use by the operator because there is no handling of the sterilant, no toxic emissions, no residue to aerate, and low operating temperature means there is no danger of an accidental burn. The cycle is monitored using a self-contained biological indicator and a chemical indicator. The sterilization chamber is small, about 4 ft<sup>3</sup> (Whitman communication, S. Dufresne, July 2004).

A gaseous ozone generator was investigated for decontamination of rooms used to house patients colonized with MRSA. The results demonstrated that the device tested would be inadequate for the decontamination of a hospital room<sup>98</sup>.

**Formaldehyde Steam.** Low-temperature steam with formaldehyde is used as a low-temperature sterilization method in many countries, particularly in Scandinavia, Germany, and the United Kingdom. The process involves the use of formalin, which is vaporized into a formaldehyde gas that is admitted into the sterilization chamber. A formaldehyde concentration of 8-16 mg/l is generated at an operating temperature of 70-75°C. The sterilization cycle consists of a series of stages that include an initial vacuum to remove air from the chamber and load, followed by steam admission to the chamber with the vacuum pump running to purge the chamber of air and to heat the load, followed by a series of pulses of formaldehyde gas, followed by steam. Formaldehyde is removed from the sterilizer and load by repeated alternate evacuations and flushing with steam and air. This system has some advantages, e.g., the cycle time for formaldehyde gas is faster than that for ETO and the cost per cycle is relatively low. However, ETO is more penetrating and operates at lower temperatures than do steam/formaldehyde sterilizers. Low-temperature steam formaldehyde sterilization has been found effective against vegetative bacteria, mycobacteria, *B. atrophaeus* and *G. steirthermophilus* spores and *Candida albicans*<sup>99, 100</sup>.

Formaldehyde vapor cabinets also may be used in healthcare facilities to sterilize heat-sensitive medical equipment<sup>101</sup>. Commonly, there is no circulation of formaldehyde and no temperature and humidity controls. The release of gas from paraformaldehyde tablets (placed on the lower tray) is slow and produces a low partial pressure of gas. The microbial quality of this procedure is unknown<sup>102</sup>.

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Reliable sterilization using formaldehyde is achieved when performed with a high concentration of gas, at a temperature between 60° and 80°C and with a relative humidity of 75 to 100%.

Studies indicate that formaldehyde is a mutagen and a potential human carcinogen, and OSHA regulates formaldehyde. The permissible exposure limit for formaldehyde in work areas is 0.75 ppm measured as a 8-hour TWA. The OSHA standard includes a 2 ppm STEL (i.e., maximum exposure allowed during a 15-minute period). As with the ETO standard, the formaldehyde standard requires that the employer conduct initial monitoring to identify employees who are exposed to formaldehyde at or above the action level or STEL. If this exposure level is maintained, employers may discontinue exposure but must still have in a change order add exposure levels or an employee reports formaldehyde-related signs and symptoms<sup>103, 104</sup>. The formaldehyde steam sterilization system has not been FDA cleared for use in healthcare facilities.

**Gaseous chlorine dioxide.** A gaseous chlorine dioxide system for sterilization of healthcare products was developed in the late 1980s<sup>105, 106, 107</sup>. Chlorine dioxide is not mutagenic or carcinogenic in humans. As the chlorine dioxide concentration increases, the time required to achieve sterilization becomes progressively shorter. For example, only 30 minutes were required at 40 mg/l to sterilize the 10<sup>6</sup> *B. atrophaeus* spores at 30° to 32°C<sup>108</sup>. Currently, no gaseous chlorine dioxide system is FDA cleared.

**Vaporized Paraformic Acid.** The sporidical activity of paraformic acid vapor at 20, 40, 60, and 80% relative humidity and 25°C was determined on *Bacillus atrophaeus* spores on paper and glass surfaces. Appreciable activity occurred within 10 minutes of exposure to 4 mg of paraformic acid per liter at 40% or higher relative humidity<sup>109</sup>. No vaporized paraformic acid system is FDA cleared.

**Infrared radiation.** An infrared radiation prototype sterilizer was investigated and found to destroy *B. atrophaeus* spores. Some of the possible advantages of infrared technology include short cycle time, low energy consumption, no cycle residuals, and no toxicologic or environmental effects. This may provide an alternative technology for sterilization of selected heat-resistant instruments but there are no FDA-cleared systems for use in healthcare facilities<sup>110</sup>.

The other sterilization technologies mentioned above may be used for sterilization of critical medical items if used by the FDA and ideally, the microbial effectiveness of the technology has been published in the scientific literature. The selection and use of disinfectants, chemical sterilants and sterilization processes in the healthcare field is dynamic, and products may become available that are not in existence when this guideline was written. As newer disinfectants and sterilization processes become available, persons or committees responsible for selecting disinfectants and sterilization processes should be guided by products cleared by FDA and EPA as well as information in the scientific literature.

#### Sterilization Practices

**Overview.** The delivery of sterile products for use in patient care depends not only on the effectiveness of the sterilization process but also on the unit design, decontamination, disassembling and packaging of the device, loading the sterilizer, monitoring, sterilant quantity and quality, and the appropriateness of the cycle for the load contents, and other aspects of device reprocessing. Healthcare personnel should perform most cleaning, disinfecting, and sterilization of patient-care supplies in a central processing department in order to more easily control quality. The aim of central processing is to orderly processing of medical and surgical instruments to protect patients from infections while minimizing risks to staff and preserving the value of the items being reprocessed<sup>111</sup>. Healthcare facilities should promote the same level of efficiency and safety in the preparation of supplies in other areas (e.g., operating room, respiratory therapy) as is practiced in central processing.

Ensuring consistency of sterilization practices requires a comprehensive program that ensures operator competence and proper methods of cleaning and wrapping instruments, loading the sterilizer,

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operating the sterilizer, and monitoring of the entire process. Furthermore, care must be consistent from an infection prevention standpoint in all patient-care settings, such as hospital and outpatient facilities.

**Sterilization Cycle Verification.** A sterilization process should be verified before it is put into use in healthcare settings. All steam, ETO, and other low-temperature sterilizers are tested with biological and chemical indicators upon installation, when the sterilizer is relocated, redesigned, after major repair and after a sterilization failure has occurred to ensure they are functioning prior to placing them into routine use. Three consecutive empty steam cycles are run with a biological and chemical indicator in an appropriate test package or tray. Each type of steam cycle used for sterilization (e.g., vacuum-assisted, gravity) is tested separately. In a reprocessor steam sterilizer three consecutive empty cycles are also run with a Bowie-Dick test. The sterilizer is not put back into use until all biological indicators are negative and chemical indicators show a correct end-point response.<sup>111-114, 115, 116</sup>

Biological and chemical indicator testing is also done for ongoing quality assurance testing of representative samples of actual products being sterilized and product testing when major changes are made in packaging, wraps, or load configuration. Biological and chemical indicators are placed in products, which are processed in a full load. When three consecutive cycles show negative biological indicators and chemical indicators with a correct end-point response, you can put the change made into routine use.<sup>111-114, 115</sup> Items processed during the three validation cycles should be quarantined until the test results are negative.

**Physical Facilities.** The central processing area(s) ideally should be divided into at least three areas: decontamination, packaging, and sterilization and storage. Physical barriers should separate the decontamination area from the other sections to contain contamination on used items. In the decontamination area reusable contaminated supplies (and possibly disposable items that are reused) are received, sorted, and decontaminated. The recommended airflow pattern should contain contaminants within the decontamination area and minimize the flow of contaminants to the clean areas. The American Institute of Architects<sup>390</sup> recommends negative pressure and no fewer than six air changes per hour in the decontamination area (AAMI recommends 10 air changes per hour) and 10 air changes per hour with positive pressure in the sterilizer equipment room. The packaging area is for inspecting, assembling, and packaging clean, but not sterile, material. The sterile storage area should be a limited access area with a controlled temperature (may be as high as 75°F) and relative humidity (30-60%) in all work areas except sterile storage, where the relative humidity should not exceed 70%.<sup>111</sup> The floors and walls should be constructed of materials capable of withstanding chemical agents used for cleaning or disinfecting. Ceilings and wall surfaces should be constructed of non-shedding materials. Physical arrangements of processing areas are presented schematically in four references.<sup>111, 119, 120, 127</sup>

**Cleaning.** As repeatedly mentioned, items must be cleaned using water with detergents or enzymatic cleaners before processing. Cleaning reduces the bioburden and removes foreign material (i.e., organic residue or debris) that interferes with the sterilization process by acting as a barrier to the sterilization agent.<sup>119, 124, 125, 115, 116</sup> Surgical instruments are generally prewashed or pre-rinsed to prevent drying of blood and tissue. Pre-cleaning in patient-care areas may be needed on items that are heavily soiled with feces, sputum, blood, or other material. Items sent to central processing without removing gross soil may be difficult to clean because of dried secretions and excretions. Cleaning and decontamination should be done as soon as possible after items have been used.

Several types of mechanical cleaning machines (e.g., utensil washer-sanitizer, ultrasonic cleaner, washer-sterilizer, dishwasher, washer) may facilitate cleaning and decontamination of most items. This equipment often is automated and may increase productivity, improve cleaning effectiveness, and decrease worker exposure to blood and body fluids. Delicate and inflexible objects and heat- or moisture-sensitive articles may require careful cleaning by hand. All used items sent to the central processing area should be considered contaminated (unless decontaminated in the area of origin) and handled with gloves (forceps or tongs are sometimes needed to avoid exposure to sharps), and decontaminated by one of the aforementioned methods to render them safer to handle. Items composed

of more than one removable part should be disassembled. Care should be taken to ensure that all parts are kept together, so that reassembly can be accomplished efficiently.<sup>111</sup>

Investigators have described the degree of cleanliness by visual and microscopic examination. One study found 91% of the instruments to be clean visually but, when examined microscopically, 84% of the instruments had residual debris. Sites that contained residual debris included junctions between knurling sleeves and collaring mechanisms of laparoscopic instruments and articulations and grooves of forceps. More research is needed to understand the clinical significance of these findings<sup>111</sup> and how to ensure proper cleaning.

Personnel working in the decontamination area should wear household-cleaning-type rubber or plastic gloves when handling or cleaning contaminated instruments and devices. Face masks, eye protection such as goggles or full-length facemasks, and appropriate gowns should be worn when exposure to blood and contaminated fluids may occur (e.g., when manually cleaning contaminated devices)<sup>111</sup>. Contaminated instruments are a source of microorganisms that could inoculate personnel through nonintact skin on the hands or through contact with the mucous membranes of eyes, nose, or mouth.<sup>111, 112</sup> Reusable sharps that have been in contact with blood present a special hazard. Employees must not reach with their gloved hands into trays or containers that hold these sharps to relieve them.<sup>111</sup> Rather, employees should use engineering controls (e.g., forceps) to relieve these devices.

**Packaging.** Once items are cleaned, dried, and inspected, those requiring sterilization must be wrapped or placed in rigid containers and should be arranged in instrument trays/baskets according to the guidelines provided by the AAMI and other professional organizations.<sup>111, 114, 115, 116, 122</sup> These guidelines state that hinged instruments should be opened; items with removable parts should be disassembled unless the device manufacturer or researchers provide specific instructions or test data to the contrary<sup>111</sup>; complex instruments should be prepared and sterilized according to device manufacturer's instructions and test data; devices with concave surfaces should be positioned to facilitate drainage of water; heavy items should be positioned not to damage delicate items; and the weight of the instrument set should be based on the design and density of the instruments and the distribution of metal mass.<sup>111, 112</sup> While there is no longer a specified sterilization weight limit for surgical sets, heavy metal mass is a cause of wet packs (i.e., moisture inside the case and tray after completion of the sterilization cycle).<sup>111</sup> Other parameters that may influence drying are the density of the wraps and the design of the set.<sup>111</sup>

There are several choices in methods to maintain sterility of surgical instruments, including rigid containers, peel-open pouches (e.g., self-seal or heat-sealed plastic and paper pouches), roll stock or reels (i.e., paper-plastic combinations of tubing designed to allow the user to cut and seal the ends to form a pouch)<sup>119</sup> and sterilization wraps (woven and nonwoven). Healthcare facilities may use all of these packaging options. The packaging material must allow penetration of the sterilant, provide protection against contact contamination during handling, provide an effective barrier to microbial penetration, and maintain the sterility of the processed item after sterilization.<sup>110</sup> An ideal sterilant would successfully address barrier effectiveness, penetrability (i.e., allows steam to penetrate), aeration (e.g., allows ETO to disperse), ease of use, drapability, flexibility, puncture resistance, tear strength, toxicity, odor, waste disposal, firing, cost, and transparency.<sup>110</sup> Unacceptable packaging for use with ETO (e.g., foil, polyvinylchloride, and polyethylene chloride [lithium-type transparent wrap])<sup>110</sup> or hydrogen peroxide gas plasma (e.g., fibers and paper) should not be used to wrap medical items.

In central processing, double wrapping can be done sequentially or nonsequentially (i.e., simultaneous wrapping). Wrapping should be done in a manner to avoid tearing and gapping. The sequential wrap uses sheets of the standard sterilization wrap, one wrapped after the other. This procedure creates a package within a package. The nonsequential process uses two sheets wrapped at the same time so that the wrapping needs to be performed only once. This latter method provides

multiple layers of protection of surgical instruments from contamination and saves time since wrapping is done only once. Multiple layers are still common practice due to the rigors of handling within the facility even though the barrier efficacy of a single sheet of wrap has improved over the years.<sup>110</sup> Written and illustrated procedures for preparation of items to be packaged should be readily available and used by personnel when packaging procedures are performed.<sup>114</sup>

**Loading.** All items to be sterilized should be arranged so all surfaces will be directly exposed to the sterilizing agent. Thus, loading procedures must allow for free circulation of steam (or another sterilant) around each item. Historically, it was recommended that muslin fabric packs should not exceed the maximal dimensions, weight, and density of 12 inches wide x 12 inches high x 20 inches long, 12 lbs, and 7.2 lbs per cubic foot, respectively. Due to the variety of textiles and metal/plastic containers on the market, the textile and metal/plastic container manufacturer and the sterilizer manufacturers should be consulted for instructions on pack preparation and density parameters.<sup>119</sup>

There are several important basic principles for loading a sterilizer: allow for proper sterilant circulation; perforated trays should be placed so the tray is parallel to the shelf; nonperforated containers should be placed on their edge (e.g., beakers); small items should be loosely placed in wire baskets; and peel packs should be placed on edge in perforated or mesh bottom racks or baskets.<sup>114, 115, 128</sup>

**Storage.** Studies in the early 1970s suggested that wrapped surgical trays remained sterile for varying periods depending on the type of material used to wrap the trays. Safe storage times for sterile packs vary with the porosity of the wrapper and storage conditions (e.g., upon versus closed cabinets). Heat-sealed, plastic peel-down pouches and wrapped packs sealed in 3-mil (3/1000 inch) polyethylene overwrap have been reported to be sterile for as long as 9 months after sterilization. The 3-mil polyethylene is applied after sterilization to extend the shelf life for infrequently used items.<sup>110</sup> Staples wrapped in double-thickness muslin comprising four layers, or equivalent, remain sterile for at least 30 days. Any item that has been sterilized should not be used after the expiration date has been exceeded or if the sterilized package is wet, torn, or punctured.

Although some hospitals continue to date every sterilized product and use the time-related shelf-life practice, many hospitals have switched to an event-related shelf-life practice. This latter practice recognizes that the product should remain sterile until some event causes the item to become contaminated (e.g., tear in packaging, packaging becomes wet, seal is broken)<sup>110</sup>. Event-related factors that contribute to the contamination of a product include bioburden (i.e., the amount of contamination in the environment), air movement, traffic, location, humidity, insects, vermin, flooding, storage area space, open/closed shelving, temperature, and the properties of the wrap materials.<sup>110, 112</sup> There are data that support the event-related shelf-life practice.<sup>110, 112</sup> One study examined the effect of time on the sterile integrity of paper pouches, peel pouches, and nylon sleeves. The most important finding was the absence of a trend toward an increased rate of contamination over time for any pack when placed in covered storage.<sup>111</sup> Another evaluated the effectiveness of event-related outdating by microbiologically testing sterilized items. During the 2-year study period, all of the items tested were sterile.<sup>112</sup> The contamination of a sterile item is event-related and the probability of contamination increases with increased handling.<sup>112</sup>

Following the sterilization process, medical and surgical devices must be handled using aseptic technique in order to prevent contamination. Sterile supplies should be stored far enough from the floor (8 to 10 inches), the ceiling (5 inches unless near a sprinkler head [18 inches from sprinkler head]), and the outside walls (2 inches) to allow for adequate air circulation, ease of cleaning, and compliance with local fire codes (e.g., supplies must be at least 18 inches from sprinkler heads). Medical and surgical supplies should not be stored under sinks or in other locations where they can become wet. Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces. Closed or covered cabinets are ideal but open shelving may be used for storage. Any package that has fallen or been dropped on the floor must be inspected for damage to the packaging and

contents (if the items are breakable). If the package is heat-sealed in impervious plastic and the seal is still intact, the package should be considered not contaminated. If undamaged, items packaged in plastic need not be reprocessed.

**Monitoring.** The sterilization procedure should be monitored routinely by using a combination of mechanical, chemical, and biological indicators to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items. The mechanical monitors for steam sterilization include the daily assessment of cycle time and temperature by examining the temperature record chart (or computer printout) and an assessment of pressure via the pressure gauge. The mechanical monitors for ETO include time, temperature, and pressure recorders that provide data via computer printouts, gauges, and/or displays.<sup>111</sup> Generally, two essential elements for ETO sterilization (i.e., the gas concentration and humidity) cannot be monitored in healthcare ETO sterilizers.

Chemical indicators are convenient, are inexpensive, and indicate that the item has been exposed to the sterilization process. In one study, chemical indicators were more likely than biological indicators to inaccurately indicate sterilization at marginal sterilization times (e.g., 2 minutes).<sup>110</sup> Chemical indicators should be used in conjunction with biological indicators, but based on current studies should not replace them because they indicate sterilization at marginal sterilization time and because only a biological indicator consisting of resistant spores can measure the microbial killing power of the sterilization process.<sup>110, 112</sup> Chemical indicators are affixed on the outside of each pack to show that the package has been processed through a sterilization cycle, but these indicators do not prove sterilization has been achieved. Preferably, a chemical indicator also should be placed on the inside of each pack to verify sterilant penetration. Chemical indicators usually are either heat- or chemical-sensitive dyes that change color when one or more sterilization parameters (e.g., steam-time, temperature, and/or saturated steam; ETO-time, temperature, relative humidity and/or ETO concentration) are present. Chemical indicators have been grouped into five classes based on their ability to monitor one or multiple sterilization parameters.<sup>111</sup> If the internal and/or external indicator suggests inadequate processing, the item should not be used.<sup>115</sup> An air-removal test (Bowie-Dick Test) must be performed daily in an empty dynamic-air-removal sterilizer (e.g., prevacuum steam sterilizer) to ensure air removal.

Biological indicators are recognized by most authorities as being closest to the ideal monitors of the sterilization process.<sup>114, 115</sup> because they measure the sterilization process directly by using the most resistant microorganisms (i.e., *Bacillus* spores), and not by merely testing the physical and chemical conditions necessary for sterilization. Since the *Bacillus* spores used in biological indicators are more resistant and present in greater numbers than are the common microbial contaminants found on patient-care equipment, the demonstration that the biological indicator has been inactivated strongly implies that other potential pathogens in the load have been killed.<sup>114</sup>

An ideal biological monitor of the sterilization process should be easy to use, be inexpensive, not be subject to exogenous contamination, provide positive results as soon as possible after the cycle so that corrective action may be accomplished, and provide positive results only when the sterilization parameters (e.g., steam-time, temperature, and/or saturated steam; ETO-time, temperature, relative humidity and/or ETO concentration) are inadequate to kill microbial contaminants.<sup>114</sup>

Biological indicators are the only process indicators that directly monitor the lethality of a given sterilization process. Spores used to monitor a sterilization process have demonstrated resistance to the sterilizing agent and are more resistant than the bioburden found on medical devices.<sup>111, 112</sup> *B. atrophaeus* spores (10<sup>7</sup>) are used to monitor ETO and dry heat, and *G. stearothermophilus* spores (10<sup>8</sup>) are used to monitor steam sterilization, hydrogen peroxide gas plasma, and liquid peracetic acid sterilizers. *G. stearothermophilus* is incubated at 55-60°C, and *B. atrophaeus* is incubated at 35-37°C. Steam and low temperature sterilizers (e.g., hydrogen peroxide gas plasma, peracetic acid) should be monitored at least weekly with the appropriate commercial preparation of spores. If a sterilizer is used frequently (e.g., several loads per day), daily use of biological indicators allows earlier discovery of

equipment malfunctions or procedural errors and thus minimizes the extent of patient surveillance and product recall needed in the event of a positive biological indicator<sup>111</sup>. Each load should be monitored if it contains implantable objects. If feasible, implantable items should not be used until the results of spore tests are known to be negative.

Originally, spore-strip biological indicators required up to 7 days of incubation to detect viable spores from marginal cycles (i.e., when few spores remained viable). The next generation of biological indicator was self-contained in plastic vials containing a spore-coated paper strip and a growth media in a crushable glass ampoule. This indicator had a maximum incubation of 48 hours but significant failures could be detected in <math>\leq 24</math> hours. A rapid-readout biological indicator that detects the presence of enzymes of *G. stearothermophilus* by reading a fluorescent product produced by the enzymatic breakdown of a nonfluorescent substrate has been marketed for the more than 10 years. Studies demonstrate that the sensitivity of rapid-readout tests for steam sterilization (1 hour for 132°C gravity sterilizers, 3 hrs for 121°C gravity and 132°C vacuum sterilizers) parallels that of the conventional sterilization-specific biological indicators<sup>114,115,116,117</sup> and the fluorescent rapid readout results reliably predict 24- and 48-hour and 7-day growth<sup>117</sup>. The rapid-readout biological indicator is a dual indicator system as it also detects acid metabolites produced during growth of the *G. stearothermophilus* spores. This system is different from the indicator system consisting of an enzyme system of bacterial origin without spores. Independent comparative data using suboptimal sterilization cycles (e.g., reduced time or temperature) with the enzyme-based indicator system have not been published<sup>117</sup>.

A new rapid-readout ETO biological indicator has been designed for rapid and reliable monitoring of ETO sterilization processes. The indicator has been cleared by the FDA for use in the United States<sup>118</sup>. The rapid-readout ETO biological indicator detects the presence of *B. strophus* by detecting a fluorescent signal indicating the activity of an enzyme present within the *B. strophus* organism, beta-glucosidase. The fluorescence indicates the presence of an active spore-associated enzyme and a sterilization process failure. This indicator also detects acid metabolites produced during growth of the *B. strophus* spores. Per manufacturer's data, the enzyme always was detected whenever viable spores were present. This was expected because the enzyme is relatively ETO resistant and is inactivated at a slightly longer exposure time than the spore. The rapid-readout ETO biological indicator can be used to monitor 100% ETO, and ETO-HCFC mixture sterilization cycles. It has not been tested in ETO- $\text{CO}_2$  mixture sterilization cycles.

The standard biological indicator used for monitoring full-cycle steam sterilizers does not provide reliable monitoring flash sterilizers<sup>119</sup>. Biological indicators specifically designed for monitoring flash sterilization are now available, and studies comparing them have been published<sup>120,121,122</sup>.

Since sterilization failure can occur (about 1% for steam)<sup>123</sup>, a procedure to follow in the event of positive spore tests with steam sterilization has been provided by CDC and the Association of periOperative Registered Nurses (AORN). The 1981 CDC recommendation is that "objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the steam sterilizer or the sterilization procedure is defective." The rationale for this recommendation is that single positive spore tests in sterilizers occur sporadically. They may occur for reasons such as slight variation in the resistance of the spores<sup>124</sup>. Improper use of the sterilizer, and laboratory contamination during culture (uncommon with self-contained spore tests). If the mechanical (e.g., time, temperature, pressure in the steam sterilizer) and chemical (internal and/or external) indicators suggest that the sterilizer was functioning properly, a single positive spore test probably does not indicate sterilizer malfunction but the spore test should be repeated immediately<sup>125</sup>. If the spore tests remain positive, use of the sterilizer should be discontinued until it is serviced<sup>126</sup>. Similarly, AORN states that a single positive spore test does not necessarily indicate a sterilizer failure. If the test is positive, the sterilizer should immediately be rechallenged for proper use and function. Items, other than implantable ones, do not necessarily need to be recalled unless a sterilizer malfunction is found. If a sterilizer malfunction is discovered, the items must be considered nonsterile, and the items from the suspect load(s) should be recalled, insofar as

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possible, and reprocessed<sup>124</sup>. A suggested protocol for management of positive biological indicators is shown in Table 12. A more conservative approach also has been recommended<sup>127</sup> in which any positive spore test is assumed to represent sterilizer malfunction and requires that all materials processed in that sterilizer, dating from the sterilization cycle having the last negative biologic indicator to the next cycle showing satisfactory biologic indicator challenge results, must be considered nonsterile and retrieved, if possible, and reprocessed. This more conservative approach should be used for sterilization methods other than steam (e.g., ETO, hydrogen peroxide gas plasma). However, no action is necessary if there is strong evidence for the biological indicator being defective<sup>128</sup> or the growth medium contained a *Bacillus* contaminant<sup>129</sup>.

If patient-care items were used before retrieval, the infection control professional should assess the risk of infection in collaboration with central processing, surgical services, and risk management staff. The factors that should be considered include the chemical indicator result (e.g., nonreactive chemical indicator may indicate temperature not achieved); the results of other biological indicators that followed the positive biological indicator (e.g., positive on Tuesday, negative on Wednesday); the parameters of the sterilizer associated with the positive biological indicator (e.g., reduced time at correct temperature); the time-temperature chart for the process; and the microbial load associated with decontaminated surgical instruments (e.g., 85% of decontaminated surgical instruments have less than 100 CFU). The margin of safety in steam sterilization is sufficiently large that there is minimal infection risk associated with items in a load that show spore growth, especially if the item was properly cleaned and the temperature was achieved (e.g., as shown by acceptable chemical indicator or temperature chart). There are no published studies that document disease transmission via a nonsterilized surgical instrument following a sterilization cycle with a positive biological indicator.

False-positive biological indicators may occur from improper testing or faulty indicators. The latter may occur from improper storage, processing, product contamination, material failure, or variation in resistance of spores. Gram stain and subculture of a positive biological indicator may determine if a contaminant has created a false-positive result<sup>130,131</sup>. However, in one incident, the broth used as growth medium contained a contaminant, *B. coagulans*, which resulted in broth turbidity at 55°C<sup>132</sup>. Testing of paired biological indicators from different manufacturers can assist in assessing a product defect<sup>130</sup>. False-positive biological indicators due to intrinsic contamination when using self-contained biological indicators should be uncommon. A biological indicator should not be considered a false-positive indicator until a thorough analysis of the entire sterilization process shows this to be likely.

The size and composition of the biological indicator test pack should be standardized to create a significant challenge to air removal and sediment penetration and to obtain interpretable results. There is a standard 16-towel pack recommended by AAMI for steam sterilization<sup>112,113,133</sup> consisting of 16 clean, pre-conditioned, reusable tucks or absorbent surgical towels each of which is approximately 18 inches by 28 inches. Each towel is folded lengthwise into thirds and then folded widthwise in the middle. One or more biological indicators are placed between the eight and ninth towels in the approximate geometric center of the pack. When the towels are folded and placed one on top of another, to form a stack (approximately 8 inch height) it should weigh approximately 3 pounds and should have a density of approximately 11.3 pounds per cubic foot<sup>134</sup>. This test pack has not gained universal use as a standard pack that simulates the actual in-use conditions of steam sterilizers. Commercially available disposable test packs that have been shown to be equivalent to the AAMI 16 towel test pack also may be used. The test pack should be placed flat in an otherwise fully loaded sterilizer chamber, in the area least favorable to sterilization (i.e., the area representing the greatest challenge to the biological indicator). This area is normally in the front, bottom section of the sterilizer, near the drain<sup>11,112</sup>. A control biological indicator from the lot used for testing should be left unexposed to the sterilant, and then incubated to verify the sterilization viability of the test spores and proper incubation. The most conservative approach would be to use a control for each run; however, less frequent use may be adequate (e.g., weekly). There also is a routine test pack for ETO where a biological indicator is placed in a plastic syringe with plunger, then placed in the folds of a clean surgical towel, and wrapped. Alternatively, commercially available disposal

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test packs that have been shown to be equivalent to the AAMI test pack may be used. The test pack is placed in the center of the sterilizer load<sup>114</sup>. Sterilization records (mechanical, chemical, and biological) should be retained for a time period in compliance with standards (e.g., Joint Commission for the Accreditation of Healthcare Facilities requests 3 years) and state and federal regulations.

In Europe, biological monitors are not used routinely to monitor the sterilization process. Instead, release of sterilizer items is based on monitoring the physical conditions of the sterilization process that is termed "parametric release." Parametric release requires that there is a defined quality system in place at the facility performing the sterilization and that the sterilization process be validated for the items being sterilized. As present in Europe, parametric release is accepted for steam, dry heat, and ionizing radiation processes, as the physical conditions are understood and can be monitored directly<sup>135</sup>. For example, with steam sterilizers the load could be monitored with probes that would yield data on temperature, time, and humidity at representative locations in the chamber and compared to the specifications developed during the validation process.

Periodic infection control rounds to areas using sterilizers to standardize the sterilizer's use may identify correctable variations in operator competence; documentation of sterilization records, including chemical and biological indicator test results; sterilizer maintenance and wrapping; and load numbering of packs. These rounds also may identify improvement activities to ensure that operators are adhering to established standards<sup>136</sup>.

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## REUSE OF SINGLE-USE MEDICAL DEVICES

The reuse of single-use medical devices began in the late 1970s. Before this time most devices were considered reusable. Reuse of single-use devices increased as a cost-saving measure. Approximately 20 to 30% of U.S. hospitals reported that they reuse at least one type of single-use device. Reuse of single-use devices involves regulatory, ethical, medical, legal and economic issues and has been extremely controversial for more than two decades<sup>137</sup>. The U.S. public has expressed increasing concern regarding the risk of infection and injury when reusing medical devices intended and labeled for single use. Although some investigators have demonstrated it is safe to reuse disposable medical devices such as cardiac electrophysiology catheters<sup>138,139</sup> additional studies are needed to define the risks<sup>140</sup> and document the benefits. In August 2000, FDA released a guidance document on single-use devices reprocessed by third parties or hospitals<sup>141</sup>. In this guidance document, FDA states that hospitals or third-party reprocessors will be considered "manufacturers" and regulated in the same manner. A reused single-use device will have to comply with the same regulatory requirements of the device when it was originally manufactured. This document presents FDA's intent to enforce premarket submission requirements within 6 months (February 2001) for class III devices (e.g., cardiovascular intra-aortic balloon pump, transluminal coronary angioplasty catheter); 12 months (August 2001) for class II devices (e.g., blood pressure cuff, borescope biopsy forceps); and 18 months (February 2002) for class I devices (e.g., disposable medical scissors, ophthalmic forceps). FDA uses two types of premarket requirements for nonexempt class I and II devices, a 510(k) submission that may have to show that the device is as safe and effective as the same device when new, and a premarket approval application. The 510(k) submission must provide scientific evidence that the device is safe and effective for its intended use. FDA allowed hospitals a year to comply with the nonpremarket requirements (registration and listing, reporting adverse events associated with medical devices, quality system regulations, and proper labeling). The options for hospitals are to stop reprocessing single-use devices, comply with the rules, or outsource to a third-party reprocessor. FDA guidance document does not apply to permanently implantable pacemakers, hemodialyzers, opened but unused single-use devices, or healthcare settings other than acute-care hospitals. The reuse of single use medical devices continues to be an evolving area of regulations. For this reason, healthcare workers should refer to FDA for the latest guidance ([www.fda.gov](http://www.fda.gov))<sup>142</sup>.

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**CONCLUSION**

When properly used, disinfection and sterilization can ensure the safe use of invasive and non-invasive medical devices. However, current disinfection and sterilization guidelines must be strictly followed.

**WEB-BASED DISINFECTION AND STERILIZATION RESOURCES**

- Additional information about disinfection and sterilization is available at the following dedicated websites:
- Food and Drug Administration, Rockville, Maryland  
<http://www.fda.gov/cdrh/odegermiab.html>
  - Environmental Protection Agency, Washington, D.C.  
<http://www.epa.gov/pest001/chemreg/index.htm>
  - Centers for Disease Control and Prevention, Atlanta, Georgia  
<http://www.cdc.gov/ncddod/dhqp/starfile.html>
  - University of North Carolina, Chapel Hill, North Carolina  
<http://www.cdisinfectionandsterilization.org>

**RECOMMENDATIONS FOR DISINFECTION AND STERILIZATION IN HEALTHCARE FACILITIES**

**A. Rationale**

The ultimate goal of the Recommendations for Disinfection and Sterilization in Health-Care Facilities, 2008, is to reduce rates of health-care-associated infections through appropriate use of both disinfection and sterilization. Each recommendation is categorized according to scientific evidence, theoretical rationale, applicability, and federal regulations. Examples are included in some recommendations to aid the reader; however, these examples are not intended to define the only method of implementing the recommendation. The CDC system for categorizing recommendations is defined in the following (Rankings) section.

**B. Rankings**

- Category IA.** Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
- Category IB.** Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and by a strong theoretical rationale.
- Category IC.** Required by state or federal regulations. Because of state differences, readers should not assume that the absence of an IC recommendation implies the absence of state regulations.
- Category II.** Suggested for implementation and supported by suggestive clinical or epidemiologic studies or by a theoretical rationale.
- No recommendation.** Unresolved issue. These include practices for which insufficient evidence or no consensus exists regarding efficacy.

**C. Recommendations**

**1. Occupational Health and Exposure**

- a. Inform each worker of the possible health effects of his or her exposure to infectious agents (e.g., hepatitis B virus [HBV], hepatitis C virus, human immunodeficiency virus [HIV]), and/or chemicals (e.g., EIO, formaldehyde). The information should be consistent with Occupational Safety and Health Administration (OSHA) requirements and identify the areas and tasks in which potential exists for exposure. *Category II, IC.*<sup>274, 275, 276, 277</sup>
- b. Educate health-care workers in the selection and proper use of personal protective equipment (PPE). *Category II, IC.*
- c. Ensure that workers wear appropriate PPE to preclude exposure to infectious agents or chemicals through the respiratory system, skin, or mucous membranes of the eyes, nose, or mouth. PPE can include gloves, gowns, masks, and eye protection. The exact type of PPE depends on the infectious or chemical agent and the anticipated duration of exposure. The employer is responsible for making such equipment and training available. *Category II, IC.*<sup>214, 267-269</sup>
- d. Establish a program for monitoring occupational exposure to regulated chemicals (e.g., formaldehyde, EIO) that adheres to state and federal regulations. *Category II, IC.*<sup>267, 268, 269</sup>
- e. Exclude healthcare workers with weeping dermatitis of hands from direct contact with patient-care equipment. *Category IB.*<sup>102, 103</sup>

**2. Cleaning of Patient-Care Devices**

- a. In hospitals, perform most cleaning, disinfection, and sterilization of patient-care devices in a central processing department in order to more easily control quality. *Category II, IC.*<sup>226, 227, 228</sup>
- b. Meticulously clean patient-care items with water and detergent, or with water and enzymatic cleaners before high-level disinfection or sterilization procedures. *Category IB.*<sup>4, 13, 15, 16, 19, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 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999, 1000</sup>
- c. Remove visible organic residue (e.g., residue of blood and tissue) and inorganic salts with cleaning. Use cleaning agents that are capable of removing visible organic and inorganic residues. *Category IB.*<sup>226-228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000</sup>

- ii. Clean medical devices as soon as practical after use (e.g., at the point of use) because soiled materials become dried onto the instruments. Dried or baked materials on the instrument make the removal process more difficult and the disinfection or sterilization process less effective or ineffective. *Category IB.*<sup>65, 66, 67, 68, 69, 70, 71, 72, 73, 74</sup>
- c. Perform either manual cleaning (i.e., using friction) or mechanical cleaning (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizer). *Category IB.*<sup>56, 58, 61, 62</sup>
- d. If using an automatic washer-disinfector, ensure that the unit is used in accordance with the manufacturer's recommendations. *Category IB.*<sup>7, 133, 134, 273</sup>
- e. Ensure that the detergents or enzymatic cleaners selected are compatible with the metals and other materials used in medical instruments. Ensure that the rinse step is adequate for removing cleaning residues to levels that will not interfere with subsequent disinfection/sterilization processes. *Category II.*<sup>238, 239</sup>
- f. Inspect equipment surfaces for breaks in integrity that would impair either cleaning or disinfection/sterilization. Discard or repair equipment that no longer functions as intended or cannot be properly cleaned, and disinfected or sterilized. *Category II.*<sup>244</sup>
- g. **Indications for Sterilization, High-Level Disinfection, and Low-Level Disinfection**
  - a. Before use on each patient, sterilize critical medical and surgical devices and instruments that enter normally sterile tissue or the vascular system or through which a sterile body fluid flows (e.g., blood). See recommendation 7g for exceptions. *Category IA.*<sup>178, 485, 493, 492, 493, 494, 495</sup>
  - b. Provide, at a minimum, high-level disinfection for semicritical patient-care equipment (e.g., gastrointestinal endoscopes, endotracheal tubes, anesthesia breathing circuits, and respiratory therapy equipment) that touches either mucous membranes or nonintact skin. *Category IA.*<sup>524, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542</sup>
  - c. Perform low-level disinfection for noncritical patient-care surfaces (e.g., bedrails, over-the-bed table) and equipment (e.g., blood pressure cuff) that touch intact skin (see Recommendation 5g). *Category II.*<sup>17, 484, 524, 527, 528, 529, 530, 532, 493</sup>
4. **Selection and Use of Low-Level Disinfectants for Noncritical Patient-Care Devices**
  - a. Process noncritical patient-care devices using a disinfectant and the concentration of germicide listed in Table 1. *Category IB.*<sup>17, 24-28, 34-37, 42, 378, 382, 421</sup>
  - b. Disinfect noncritical medical devices (e.g., blood pressure cuff) with an EPA-registered hospital disinfectant using the label's safety precautions and use directions. Most EPA-registered hospital disinfectants have a label contact time of 10 minutes. However, multiple scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens with a contact time of at least 1 minute. By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability from any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA. *Category IB.*<sup>17, 47, 48, 76, 77, 83-87, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183</sup>

- d. Clean walls, blinds, and window curtains in patient-care areas when these surfaces are visibly contaminated or soiled. *Category II.* 327, 365, 404
- e. Prepare disinfecting (or detergent) solutions as needed and replace these with fresh solution frequently (e.g., mop and mopping solution every three patient rooms, change no less often than at 60-minute intervals) according to the facility's policy. *Category IB.* 19, 379
- f. Decontaminate mop heads and cleaning cloths regularly to prevent contamination (e.g., launder and dry at least daily). *Category II.* 39, 402, 403
- g. Use a one-step process and an EPA-registered hospital disinfectant designed for housekeeping purposes in patient care areas where 1) uncertainty exists about the nature of the soil on the surfaces (e.g., blood or body fluid contamination versus routine dust or dirt); or 2) uncertainty exists about the presence of multidrug resistant organisms on such surfaces. See 5n for recommendations regarding cleaning and disinfecting blood-contaminated surfaces. *Category II.* 23, 47, 48, 51, 273, 274, 282, 415, 467
- h. Detergent and water are adequate for cleaning surfaces in nonpatient-care areas (e.g., administrative offices). *Category II.* 23
- i. Do not use high-level disinfectant/liquid chemical sterilants for disinfection of non-critical surfaces. *Category IB.* 29, 46, 219
- j. Wet-dust horizontal surfaces regularly (e.g., daily, three times per week) using clean cloths moistened with an EPA-registered hospital disinfectant (or detergent). Prepare the disinfectant (or detergent) as recommended by the manufacturer. *Category II.* 19, 273, 366, 402, 403, 408
- k. Disinfect noncritical surfaces with an EPA-registered hospital disinfectant according to the label's safety precautions and use directions. Most EPA-registered hospital disinfectants have a label contact time of 10 minutes. However, many scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens with a contact time of at least 1 minute. By law, the user must follow all applicable label instructions on EPA-registered products. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA. *Category II.* IC, 17, 47, 48, 51, 15, 27, 30, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 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989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000
- l. Do not use disinfectants to clean infant bassinets and incubators while these items are occupied. If disinfectants (e.g., phenolics) are used for the terminal cleaning of infant bassinets and incubators, thoroughly rinse the surfaces of these items with water and dry them before these items are reused. *Category IB.* 17, 778, 780
- m. Promptly clean and decontaminate spills of blood and other potentially infectious materials. Discard blood-contaminated items in compliance with federal regulations. *Category IB.* IC, 214
- n. For site decontamination of spills of blood or other potentially infectious materials (OPIM), implement the following procedures. Use protective gloves and other PPE (e.g., when sharps are involved use forceps to pick up sharps, and discard these items in a puncture-resistant container) appropriate for this task. Disinfect areas contaminated with blood spills using an EPA-registered tuberculocidal agent, a registered germicide on the EPA Lists D and E (i.e., products with 0.5%–6.15% sodium hypochlorite solutions are selected use a 1:100 dilution (e.g., 1:100 dilution of a 5.25–6.15% sodium hypochlorite solution provides 525–616 ppm available chlorine) to decontaminate nonporous surfaces after a small spill (e.g., <10 mL) of either blood or OPIM. If a spill involves large amounts (e.g., >10 mL) of blood or OPIM, or involves a culture spill in the laboratory, use a 1:10 dilution for the first application of hypochlorite solution before cleaning in order to reduce the risk of infection during the cleaning process in the event of a sharp injury. Follow this decontamination process with a terminal disinfection, using a 1:100 dilution of sodium hypochlorite. *Category IB.* IC, 215, 216
- o. If the spill contains large amounts of blood or body fluids, clean the visible matter with disposable absorbent material, and discard the contaminated materials in appropriate, labeled containment. *Category II.* IC, 44, 214
- p. Use protective gloves and other PPE appropriate for this task. *Category II.* IC, 44, 214

- ortho-phthalaldehyde, hydrogen peroxide, and both hydrogen peroxide and peracetic acid to achieve high-level disinfection followed by rinsing and drying (see Table 1 for recommended concentrations). *Category IB.* 1, 4, 4, 17, 26, 66, 106, 113, 143, 144
- n. Extend exposure times beyond the minimum effective time for disinfecting semicritical patient-care equipment cautiously and conservatively because extended exposure to a high-level disinfectant is more likely to damage delicate and intricate instruments such as flexible endoscopes. The exposure times vary among the Food and Drug Administration (FDA)-cleared high-level disinfectants (Table 2). *Category IB.* 17, 45, 75, 74, 63
- o. Federal regulations are to follow the FDA-cleared label claim for high-level disinfectants. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 25°C range from 20–90 minutes, depending upon the product based on three tier testing which includes AOAC sporicidal tests, simulated use testing with mycobacterial and in-use testing. *Category IC.*
- p. Several scientific studies and professional organizations support the efficacy of >2% glutaraldehyde for 20 minutes at 20°C that efficacy assumes adequate cleaning prior to disinfection, whereas the FDA-cleared label claim incorporates an added margin of safety to accommodate possible issues in cleaning practices. Facilities that have chosen to apply the 20 minute duration at 20°C have done so based on the IA recommendation in the July 2003 S3EA position paper, "Multi-society Guidelines for Reprocessing Flexible Gastrointestinal Endoscopes." 17, 18, 24, 27, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 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1000
- q. When using FDA-cleared high-level disinfectants, use manufacturers' recommended exposure conditions. Certain products may require a shorter exposure time (e.g., 0.55% ortho-phthalaldehyde for 12 minutes at 20°C, 7.35% hydrogen peroxide plus 0.23% peracetic acid for 15 minutes at 20°C) than glutaraldehyde at room temperature because of their rapid inactivation of mycobacteria or reduced exposure time because of increased mycobactericidal activity at elevated temperature (e.g., 2.5% glutaraldehyde at 5 minutes at 35°C). *Category IB.* 23, 114, 149, 404, 405, 406
- r. Select a disinfectant or chemical sterilant that is compatible with the device that is being reprocessed. Avoid using reprocessing chemicals on an endoscope if the endoscope manufacturer warns against using these chemicals because of functional damage (with or without cosmetic damage). *Category IB.* 19, 113, 116
- s. Completely immerse the endoscope in the high-level disinfectant, and ensure all channels are perfused. As soon as is feasible, phase out nonimmersion endoscopes. *Category IB.* 19, 113, 114, 115, 116, 117, 118, 119, 120
- t. After high-level disinfection, rinse endoscopes and flush channels with sterile water, filtered water, or tapwater to prevent adverse effects on patients associated with disinfectant retained in the endoscope (e.g., disinfectant induced colitis). Follow this water rinse with a rinse with 70%–90% ethyl or isopropyl alcohol. *Category IB.* 17, 31, 34, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141,

- sterilized after each use or discarded. In addition, after each use, sterilize dental instruments that are not intended to penetrate oral soft tissue or bone (e.g., amalgam condensers, air-water syringes) but that might contact oral tissues and are heat-labile, although classified as semicritical. Clean and, at a minimum, high-level disinfect heat-sensitive semicritical items. *Category IA.* <sup>43, 206-211</sup>
  - b. Noncritical clinical contact surfaces, such as uncovered operatory surfaces (e.g., countertops, switches, light handles), should be barrier-protected or disinfected between patients with an intermediate-disinfectant (i.e., EPA-registered hospital disinfectant with a tuberculocidal claim) or low-level disinfectant (i.e., EPA-registered hospital disinfectant with HIV and HBV claim). *Category IB.* <sup>43, 206-211</sup>
  - c. Barrier protective coverings can be used for noncritical clinical contact surfaces that are touched frequently with gloved hands during the delivery of patient care, that are likely to become contaminated with blood or body substances, or that are difficult to clean. Change these coverings when they are visibly soiled, when they become damaged, and on a routine basis (e.g., between patients). Disinfect protected surfaces at the end of the day or if visibly soiled. *Category II.* <sup>43, 211</sup>
9. **Processing Patient-Care Equipment Contaminated with Bloodborne Pathogens (HBV, Hepatitis C Virus, HIV), Antibiotic-Resistant Bacteria (e.g., Vancomycin-Resistant Enterococci, Methicillin-Resistant Staphylococcus aureus, Multidrug-Resistant Tuberculosis), or Emerging Pathogens (e.g., Cryptosporidium, Helicobacter pylori, Escherichia coli O157:H7, Clostridium difficile, Mycobacterium tuberculosis, Severe Acute Respiratory Syndrome Coronavirus), or Bioterrorist Agents**
- a. Use standard sterilization and disinfection procedures for patient-care equipment (as recommended in this guideline), because these procedures are adequate to sterilize or disinfect instruments or devices contaminated with blood or other body fluids from persons infected with bloodborne pathogens or emerging pathogens, with the exception of prions. No changes in these procedures for cleaning, disinfecting, or sterilizing are necessary for removing bloodborne and emerging pathogens other than prions. *Category IA.* <sup>21, 23, 60-62, 73, 74-81, 108, 110-121, 123, 126, 127, 224-232, 236, 244, 262, 268, 271-273, 279, 282, 293, 301, 307, 347, 464</sup>
10. **Disinfection Strategies for Other Semicritical Devices**
- a. Even if probe covers have been used, clean and high-level disinfect other semicritical devices such as rectal probes, vaginal probes, and cryosurgical probes with a product that is not toxic to staff, patients, probes, and retrieved germ cells (if applicable). Use a high-level disinfectant at the FDA-cleared exposure time. (See Recommendations 7o and 11e for exceptions.) *Category IB.* <sup>11, 29</sup>
  - b. When probe covers are available, use a probe cover or condom to reduce the level of microbial contamination. *Category II.* <sup>11, 29</sup> Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers because these sheaths and condoms can fail. *Category IB.* <sup>11, 29</sup>
  - c. After high-level disinfection, rinse all items. Use sterile water, filtered water or tapwater followed by an alcohol rinse for semicritical equipment that will have contact with mucous membranes of the upper respiratory tract (e.g., nose, pharynx, esophagus). *Category II.* <sup>11, 29, 33, 107</sup>
  - d. There is no recommendation to use sterile or filtered water rather than tapwater for rinsing semicritical equipment that contact the mucous membranes of the rectum (e.g., rectal probes, anoscope) or vagina (e.g., vaginal probes). *Unresolved Issue.* <sup>11</sup>
  - e. Wipe clean tonometer tips and then disinfect them by immersing for 5-10 minutes in either 5000 ppm chlorine or 70% ethyl alcohol. None of these listed disinfectant products are FDA-cleared high-level disinfectants. *Category II.* <sup>9, 10, 106, 109</sup>
11. **Disinfection by Healthcare Personnel in Ambulatory Care and Home Care**
- a. Follow the same classification scheme described above (i.e., that critical devices require sterilization, semicritical devices require high-level disinfection, and noncritical equipment

- requires low-level disinfection) in the ambulatory-care (outpatient medical/surgical facilities) setting because risk for infection in this setting is similar to that in the hospital setting (see Table 1). *Category IB.* <sup>43, 17, 230</sup>
  - b. When performing care in the home, clean and disinfect reusable objects that touch mucous membranes (e.g., tracheostomy tubes) by immersing these objects in a 1:50 dilution of 5.25%-6.15% sodium hypochlorite (household bleach) (3 minutes), 70% isopropyl alcohol (5 minutes), or 3% hydrogen peroxide (30 minutes) because the home environment is, in most instances, safer than either hospital or ambulatory care settings because person-to-person transmission is less likely. *Category II.* <sup>207, 208, 209, 211</sup>
  - c. Clean noncritical items that would not be shared between patients (e.g., crutches, blood pressure cuffs) in the home setting with a detergent or commercial household disinfectant. *Category II.* <sup>83, 207</sup>
12. **Microbial Contamination of Disinfectants**
- a. Institute the following control measures to reduce the occurrence of contaminated disinfectants: 1) prepare the disinfectant correctly to achieve the manufacturer's recommended use-dilution; and 2) prevent common sources of extrinsic contamination of germicides (e.g., container contamination or surface contamination of the healthcare environment where the germicide are prepared and/or used). *Category IB.* <sup>49, 63, 103</sup>
13. **Flash Sterilization**
- a. Do not flash sterilize implanted surgical devices unless doing so is unavoidable. *Category II.* <sup>24, 250</sup>
  - b. Do not use flash sterilization for convenience, as an alternative to purchasing additional instrument sets, or to save time. *Category II.* <sup>117, 202</sup>
  - c. When using flash sterilization, make sure the following parameters are met: 1) clean the item before placing it in the sterilizing container (that are FDA cleared for use with flash sterilization) or tray; 2) prevent exogenous contamination of the item during transport from the sterilizer to the patient; and 3) monitor sterilizer function with mechanical, chemical, and biologic monitors. *Category IB.* <sup>112, 113, 244, 247, 249</sup>
  - d. Do not use packaging materials and containers in flash sterilization cycles unless the sterilizer and the packaging material/container are designed for this use. *Category IB.* <sup>112, 113, 1027</sup>
  - e. When necessary, use flash sterilization for patient-care items that will be used immediately (e.g., to process an inadvertently dropped instrument). *Category IB.* <sup>112, 117, 119, 249</sup>
  - f. When necessary, use flash sterilization for processing patient-care items that cannot be packaged, sterilized, and stored before use. *Category IB.* <sup>114, 241</sup>
14. **Methods of Sterilization**
- a. Steam is the preferred method for sterilizing critical medical and surgical instruments that are not damaged by heat, steam, pressure, or moisture. *Category IA.* <sup>10, 121, 225, 418, 422, 441, 508, 1027</sup>
  - b. Cool steam- or heat-sterilized items before they are handled or used in the operative setting. *Category IB.* <sup>10</sup>
  - c. Follow the sterilization times, temperatures, and other operating parameters (e.g., gas concentration, humidity) recommended by the manufacturers of the instruments, the sterilizer, and the container or wrap used, and that are consistent with guidelines published by government agencies and professional organizations. *Category IB.* <sup>111-113, 116, 124, 227, 441, 1028-1029</sup>
  - d. Use low-temperature sterilization technologies (e.g., EtO, hydrogen peroxide gas plasma) for reprocessing critical patient-care equipment that is heat or moisture sensitive. *Category IA.* <sup>49a, 721, 102, 104, 226, 478, 511, 512, 521, 1027</sup>
  - e. Completely sterile surgical and medical items that have been sterilized in the EtO sterilizer (e.g., polyvinylchloride tubing) requires 12 hours at 50°C, 8 hours at 60°C before using these items in patient care. *Category IB.* <sup>44</sup>
  - f. Sterilization using the peracetic acid immersion system can be used to sterilize heat-sensitive

- impermeable medical and surgical items. *Category IB.* <sup>10, 717-718, 721-724</sup>
  - g. Critical items that have been sterilized by the peracetic acid immersion process must be used immediately (i.e., items are not completely protected from contamination, making long-term storage unacceptable). *Category II.* <sup>117, 225</sup>
  - h. Dry-heat sterilization (e.g., 340°F for 60 minutes) can be used to sterilize items (e.g., powders, oils) that can sustain high temperatures. *Category IB.* <sup>113, 227</sup>
  - 1. Comply with the sterilizer manufacturer's instructions regarding the sterilizer cycle parameters (e.g., time, temperature, concentration). *Category IB.* <sup>106, 728, 817, 819, 819</sup>
  - j. Because narrow-lumen devices provide a challenge to all low-temperature sterilization technologies and direct contact is necessary for the sterilant to be effective, ensure that the sterilant has direct contact with contaminated surfaces (e.g., scopes processed in peracetic acid must be connected to channel irrigators). *Category IB.* <sup>117, 728, 828, 845, 846, 871, 1029</sup>
15. **Packaging**
- a. Ensure that packaging materials are compatible with the sterilization process and have received FDA 510(k) clearance. *Category IB.* <sup>111-113, 116, 108</sup>
  - b. Ensure that packaging is sufficiently strong to resist punctures and tears to provide a barrier to microorganisms and moisture. *Category IB.* <sup>45, 411-414, 416, 502</sup>
16. **Monitoring of Sterilizers**
- a. Use mechanical, chemical, and biologic monitors to ensure the effectiveness of the sterilization process. *Category IB.* <sup>111-113, 116, 104, 107, 109, 117</sup>
  - b. Monitor each load with mechanical (e.g., time, temperature, pressure) and chemical (internal and external) indicators. If the internal chemical indicator is visible, an external indicator is not needed. *Category II.* <sup>111-113, 116, 104, 107, 109, 117, 102</sup>
  - c. Do not use processed items if the mechanical (e.g., time, temperature, pressure) or chemical (internal and/or external) indicators suggest inadequate processing. *Category IB.* <sup>111-113, 116, 102</sup>
  - d. Use biologic indicators to monitor the effectiveness of sterilizers at least weekly with an FDA-cleared commercial preparation of spores (e.g., *Geobacillus stearothermophilus* for steam) intended specifically for the type and cycle parameters of the sterilizer. *Category IB.* <sup>1, 111, 113-115, 116, 104, 107, 109, 117</sup>
  - e. After a single positive biologic indicator used with a method other than steam sterilization, treat as nonsterile all items that have been processed in that sterilizer, dating from the sterilization cycle having the last negative biologic indicator to the next cycle showing satisfactory biologic indicator results. These nonsterile items should be retrieved if possible and reprocessed. *Category II.* <sup>1</sup>
  - f. After a positive biologic indicator with steam sterilization, objects other than implantable objects do not need to be recalled because of a single positive spore test unless the sterilizer or the sterilization procedure is defective as determined by maintenance personnel or inappropriate cycle settings. If additional spore tests remain positive, consider the items nonsterile and recall and reprocess the items from the implicated load(s). *Category II.* <sup>1</sup>
  - g. Use biologic indicators for every load containing implantable items and quarantine items, whenever possible, until the biologic indicator is negative. *Category IB.* <sup>111-113, 116</sup>
17. **Load Configuration**
- a. Place items correctly and loosely into the basket, shelf, or cart of the sterilizer so as not to impede the penetration of the sterilant. *Category IB.* <sup>44, 45a, 111, 113, 114, 115, 120</sup>
18. **Storage of Sterile Items**
- a. Ensure the sterile storage area is a well-ventilated area that provides protection against dust, moisture, insects, and temperature and humidity extremes. *Category II.* <sup>44, 113, 108, 109</sup>
  - b. Store sterile items so the packaging is not compromised (e.g., punctured, bent). *Category II.* <sup>44, 113, 108, 109</sup>

- c. Label sterilized items with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and, if applicable, the expiration date. *Category IB.* <sup>111, 112, 114, 115, 117</sup>
  - d. The shelf life of a packaged sterile item depends on the quality of the wrapper, the storage conditions, the conditions during transport, the amount of handling, and other events (moisture) that compromise the integrity of the package. If event-related storage of sterile items is used, then packaged sterile items can be used indefinitely unless the packaging is compromised (see f and g below). *Category IB.* <sup>111, 112, 104, 106, 112, 108, 109</sup>
  - e. Evaluate packages before use for loss of integrity (e.g., torn, wet, punctured). The pack can be used unless the integrity of the packaging is compromised. *Category II.* <sup>114, 106</sup>
  - f. If the integrity of the packaging is compromised (e.g., torn, wet, or punctured), repack and reprocess the pack before use. *Category II.* <sup>114, 106</sup>
  - g. If time-related storage of sterile items is used, label the pack at the time of sterilization with an expiration date. Once this date expires, reprocess the pack. *Category II.* <sup>114, 106</sup>
19. **Quality Control**
- a. Provide comprehensive and intensive training for all staff assigned to reprocess semicritical and critical medical/surgical instruments to ensure they understand the importance of reprocessing these instruments. To achieve and maintain competency, train each member of the staff that reprocesses semicritical and/or critical instruments as follows: 1) provide hands-on training according to the institution's policy for reprocessing critical and semicritical devices; 2) supervise all work until competency is documented for each reprocessing task; 3) conduct competency testing at beginning of employment and regularly thereafter (e.g., annually); and 4) review the written reprocessing instructions regularly to ensure they comply with the scientific literature and the manufacturer's instructions. *Category IB.* <sup>114, 104, 114, 124, 104, 728, 819, 819</sup>
  - b. Compare the reprocessing instructions (e.g., for the appropriate use of endoscope connectors, the packaging/reprocessing of specific lumens) provided by the instrument manufacturer and the sterilizer manufacturer and resolve any conflicting recommendations by communicating with both manufacturers. *Category IB.* <sup>114, 728</sup>
  - c. Conduct infection control rounds periodically (e.g., annually) in high-risk reprocessing areas (e.g., the Gastroenterology Clinic, Central Processing); ensure reprocessing instructions are current and accurate and are correctly implemented. Document all deviations from policy. All stakeholders should identify what corrective actions will be implemented. *Category IB.* <sup>104, 102</sup>
  - d. Include the following in a quality control program for sterilized items: a) sterilizer maintenance contract with records of service; a system of process monitoring; air-removal testing for prevacuum steam sterilizers; visual inspection of packaging materials; and traceability of load contents. *Category II.* <sup>111-113, 111</sup>
  - e. For each sterilization cycle, record the type of sterilizer and cycle used; the load identification number; the load contents; the exposure parameters (e.g., time and temperature); the operator's name or initials; and the results of mechanical, chemical, and biological monitoring. *Category II.* <sup>114, 104, 102</sup>
  - f. Retain sterilization records (mechanical, chemical, and biological) for a time period that complies with standards (e.g., 3 years), statutes or regulations, and state and federal regulations. *Category II.* <sup>110, 102</sup>
  - g. Prepare and package items to be sterilized so that sterility can be achieved and maintained to the point of use. Consult the Association for the Advancement of Medical Instrumentation or the manufacturer of surgical instruments, sterilizers, and container systems for guidelines for the density of wrapped packages. *Category II.* <sup>111-113, 111</sup>
  - h. Periodically review policies and procedures for sterilization. *Category II.* <sup>102</sup>
  - i. Perform preventive maintenance on sterilizers by qualified personnel who are guided by the manufacturer's instruction. *Category II.* <sup>111-113, 111</sup>

20. **Reuse of Single-Use Medical Devices**
- a. Adherence to the FDA enforcement document for single-use devices reprocessed by hospitals. FDA considers the hospital that reprocesses a single-use device as the manufacturer of the device and regulates the hospital using the same standards by which it regulates the original equipment manufacturer. Category II, IC. <sup>93</sup>

**PERFORMANCE INDICATORS**

1. Monitor adherence to high-level disinfection and/or sterilization guidelines for endoscopes on a regular basis. This monitoring should include ensuring the proper training of persons performing reprocessing and their adherence to all endoscope reprocessing steps, as demonstrated by competency testing at commencement of employment and annually.
2. Develop a mechanism for the occupational health service to report all adverse health events potentially resulting from exposure to disinfectants and sterilants; review such exposures; and implement engineering, work practice, and PPE to prevent future exposures.
3. Monitor possible sterilization failures that resulted in instrument recall. Assess whether additional training of personnel or equipment maintenance is required.

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**GLOSSARY**

- Action level:** concentration of a regulated substance (a.g., ethylene oxide, formaldehyde) within the employee breathing zone, above which OSHA requirements apply.
- Activation of a sterilant:** process of mixing the contents of a chemical sterilant that come in two containers (small vial with the activator solution; container of the chemical) Keeping the two chemicals separate until use extends the shelf life of the chemicals.
- Aeration:** method by which ethylene oxide (EtO) is removed from EtO-sterilized items by warm air circulation in an enclosed cabinet specifically designed for this purpose.
- Antimicrobial agent:** any agent that kills or suppresses the growth of microorganisms.
- Antiseptic:** substance that prevents or arrests the growth or action of microorganisms by inhibiting their activity or by destroying them. The term is used especially for preparations applied topically to living tissues.
- Asepsis:** prevention of contact with microorganisms.
- Autoclave:** device that sterilizes instruments or other objects using steam under pressure. The length of time required for sterilization depends on temperature, vacuum, and pressure.
- Bacterial count:** method of estimating the number of bacteria per unit sample. The term also refers to the estimated number of bacteria per unit sample, usually expressed as number of colony-forming units.
- Bactericide:** agent that kills bacteria.
- Bioburden:** number and types of viable microorganisms with which an item is contaminated; also called *bioload* or *microbial load*.
- Biofilm:** accumulated mass of bacteria and extracellular material that is tightly adhered to a surface and cannot be easily removed.
- Biologic indicator:** device for monitoring the sterilization process. The device consists of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the sterilization process being monitored. Biologic indicators are intended to demonstrate whether conditions were adequate to achieve sterilization. A negative biologic indicator does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.
- Bleach:** Household bleach (5.25% or 6.00%–8.15% sodium hypochlorite depending on manufacturer) usually diluted in water at 1:10 or 1:100. Approximate dilutions are 1.5 cups of bleach in a gallon of water for a 1:10 dilution (~6,000 ppm) and 0.25 cup of bleach in a gallon of water for a 1:100 dilution (~600 ppm). Sodium hypochlorite products that make pesticidal claims, such as sanitization or disinfection, must be registered by EPA and be labeled with an EPA Registration Number.

Bleach Solution	Dilution	Chlorine (ppm)
5.25-6.15%	None	52,500-61,500
	1:10	5,250-6,150
	1:100	525-615
	1:1000	53-62

**Bowie-Dick test:** diagnostic test of a sterilizer's ability to remove air from the chamber of a prevacuum steam sterilizer. The air-removal or Bowie-Dick test is not a test for sterilization.

**Ceiling limit:** concentration of an airborne chemical contaminant that should not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling must be assessed as a 15-minute time-weighted average exposure.

**Centigrade or Celsius:** a temperature scale (0°C = freezing point of water; 100°C = boiling point of water at sea level). Equivalents mentioned in the guideline are as follows: 20°C = 68°F; 25°C = 77°F; 121°C = 250°F; 132°C = 270°F; 134°C = 273°F. For other temperatures the formula is:  $F^{\circ} = (C^{\circ} \times 9/5) + 32$  or  $C^{\circ} = (F^{\circ} - 32) \times 5/9$ .

**Central processing or Central service department:** the department within a health-care facility that processes, issues, and controls professional supplies and equipment, both sterile and nonsterile, for some or all patient-care areas of the facility.

**Challenge test pack:** pack used in installation, qualification, and ongoing quality assurance testing of health-care facility sterilizers.

**Chemical indicator:** device for monitoring a sterilization process. The device is designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators are intended to detect potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a chemical indicator does not prove the item accompanied by the indicator is necessarily sterile. The Association for the Advancement of Medical Instrumentation has defined five classes of chemical indicators: Class 1 (process indicator); Class 2 (Bowie-Dick test indicator); Class 3 (single-parameter indicator); Class 4 (multi-parameter indicator); and Class 5 (integrating indicator).

**Contact time:** time a disinfectant is in direct contact with the surface or item to be disinfected. For surface disinfection, this period is framed by the application to the surface until complete drying has occurred.

**Container system, rigid container:** sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents.

**Contaminated:** state of having actual or potential contact with microorganisms. As used in health care, the term generally refers to the presence of microorganisms that could produce disease or infection.

**Control, positive:** biologic indicator, from the same lot as a fast biologic indicator, that is left unexposed to the sterilization cycle and then incubated to verify the viability of the test biologic indicator.

**Cleaning:** removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms 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.

**Culture:** growth of microorganisms in or on a nutrient medium; to grow microorganisms in or on such a medium.

**Culture medium:** substance or preparation used to grow and cultivate microorganisms.

**Cup:** 8 fluid ounces.

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**Decontamination:** according to OSHA, "the use of physical or chemical means to remove, inactivate, or destroy biohazardous 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). In health-care facilities, the term generally refers to all pathogenic organisms.

**Decontamination area:** area of a health-care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

**Detergent:** cleaning agent that makes no antimicrobial claims on the label. They comprise a hydrophilic component and a lipophilic component and can be divided into four types: anionic, amphoteric, cationic, and non-ionic detergents.

**Disinfectant:** usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects. EPA groups disinfectants by product label claims of "limited," "general," or "hospital" disinfection.

**Disinfection:** thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

**D value:** time or radiation dose required to inactivate 90% of a population of the test microorganism under stated exposure conditions.

**Endoscope:** an instrument that allows examination and treatment of the interior of the body canals and hollow organs.

**Enzyme cleaner:** a solution used before disinfecting instruments to improve removal of organic material (e.g., proteases to assist in removing protein).

**EPA Registration Number or EPA Reg. No.:** a hyphenated, two- or three-part number assigned by EPA to identify each germicidal product registered within the United States. The first number is the company identification number, the second is the specific product number, and the third (when present) is the company identification number for a supplemental registrant.

**Exposure time:** period in a sterilization process during which items are exposed to the sterilant at the specified sterilization parameters. For example, in a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

**Flash sterilization:** process designed for the steam sterilization of unwrapped patient-care items for immediate use (or placed in a specially designed, covered, rigid container to allow for rapid penetration of steam).

**Fungicide:** agent that destroys fungi (including yeasts) and/or fungal spores pathogenic to humans or other animals in the inanimate environment.

**General disinfectant:** EPA-registered disinfectant labeled for use against both gram-negative and gram-positive bacteria. Efficacy is demonstrated against both *Salmonella choleraesuis* and *Staphylococcus aureus*. Also called *broad-spectrum disinfectant*.

**Germicide:** agent that destroys microorganisms, especially pathogenic organisms.

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**Germicidal detergent:** detergent that also is EPA-registered as a disinfectant.

**High-level disinfectant:** agent capable of killing bacterial spores when used in sufficient concentration under suitable conditions. It therefore is expected to kill all other microorganisms.

**Hospital disinfectant:** disinfectant registered for use in hospitals, clinics, dental offices, and any other medical-related facility. Efficacy is demonstrated against *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*. EPA has registered approximately 1,200 hospital disinfectants.

**Huck towel:** all-cotton surgical towel with a honey-comb weave; both warp and fill yarns are tightly twisted. Huck towels can be used to prepare biologic indicator challenge test packs.

**Implantable device:** according to FDA, "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more" [21 CFR 812.3(d)].

**Inanimate surface:** nonliving surface (e.g., floors, walls, furniture).

**Incubator:** apparatus for maintaining a constant and suitable temperature for the growth and cultivation of microorganisms.

**Infectious microorganisms:** microorganisms capable of producing disease in appropriate hosts.

**Inorganic and organic load:** naturally occurring or artificially placed inorganic (e.g., metal salts) or organic (e.g., proteins) contaminants on a medical device before exposure to a microbicidal process.

**Intermediate-level disinfectant:** agent that destroys all vegetative bacteria, including tubercle bacilli, lipid and some nonlipid viruses, and fungi, but not bacterial spores.

**Limited disinfectant:** disinfectant registered for use against a specific major group of organisms (gram-negative or gram-positive bacteria). Efficacy has been demonstrated in laboratory tests against either *Salmonella choleraesuis* or *Staphylococcus aureus* bacteria.

**Lipid virus:** virus surrounded by an envelope of lipoprotein in addition to the usual core of nucleic acid surrounded by a coat of protein. This type of virus (e.g., HIV) is generally easily inactivated by many types of disinfectants. Also called *enveloped or lipophilic virus*.

**Low-level disinfectant:** agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores.

**Mechanical Indicator:** devices that monitor the sterilization process (e.g., graphs, gauges, printouts).

**Medical device:** instrument, apparatus, material, or other article, whether used alone or in combination, including software necessary for its application, intended by the manufacturer to be used for human beings for

- diagnosis, prevention, monitoring treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, or alleviation of or compensation for an injury or handicap;
- investigation, replacement, or modification of the anatomy or of a physiologic process; or
- control of conception

and that does not achieve its primary intended action in or on the human body by pharmacologic, immunologic, or metabolic means but might be assisted in its function by such means.

**Microbicide:** any substance or mixture of substances that effectively kills microorganisms.

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**Microorganisms:** animals or plants of microscopic size. As used in health care, generally refers to bacteria, fungi, viruses, and bacterial spores.

**Minimum effective concentration (MEC):** the minimum concentration of a liquid chemical germicide needed to achieve the claimed microbicidal activity as determined by dose-response testing. Sometimes used interchangeably with *minimum recommended concentration*.

**Muslin:** loosely woven (by convention, 140 threads per square inch), 100% cotton cloth. Formerly used as a wrap for sterile packs or a surgical drape. Fabric wraps used currently consist of a cotton-polyester blend.

**Mycobacteria:** bacteria with a thick, waxy coat that makes them more resistant to chemical germicides than other types of vegetative bacteria.

**Nonlipid viruses:** generally considered more resistant to inactivation than lipid viruses. Also called *nonenveloped or hydrophilic viruses*.

**One-step disinfection process:** simultaneous cleaning and disinfection of a noncritical surface or item.

**Pasteurization:** process developed by Louis Pasteur of heating milk, wine, or other liquids to 65–77°C (or the equivalent) for approximately 30 minutes to kill or markedly reduce the number of pathogenic and spoilage organisms other than bacterial spores.

**Parametric release:** declaration that a product is sterile on the basis of physical and/or chemical process data rather than on sample testing or biologic indicator results.

**Pentacylinder:** canister inoculated with the test bacteria for in vitro tests of germicides. Can be constructed of stainless steel, porcelain, glass, or other materials and are approximately 8 x 10 mm in diameter.

**Permissible exposure limit (PEL):** time-weighted average maximum concentration of an air contaminant to which a worker can be exposed, according to OSHA standards. Usually calculated over 8 hours, with exposure considered over a 40-hour work week.

**Personal protective equipment (PPE):** specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts) not intended to function as protection against a hazard are not considered to be PPE.

**Parts per million (ppm):** common measurement for concentrations by volume of trace contaminant gases in the air (for chemicals in a liquid); 1 volume of contaminated gas per 1 million volumes of contaminated air or 1 g in 1,000,000 both equal 1 ppm. Parts per million =  $\mu\text{g/mL}$  or  $\text{mg/L}$ .

**Prions:** transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including sheep and goats, bovine spongiform encephalopathy in cattle, and Creutzfeldt-Jakob disease in humans. They are unlike any other infectious pathogens because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (PrP). Prions are extremely resistant to inactivation by sterilization processes and disinfecting agents.

**Process challenge device (PCD):** item designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process and used to assess the effective performance of the process. A PCD is a challenge test pack or test tray that contains a biologic indicator, a Class 5 integrating indicator, or an enzyme-only indicator.

**QUAT:** abbreviation for *quaternary ammonium compound*, a surface-active, water-soluble disinfecting

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substance that has four carbon atoms linked to a nitrogen atom through covalent bonds.

**Recommended exposure limit (REL):** occupational exposure limit recommended by NIOSH as being protective of worker health and safety over a working lifetime. Frequently expressed as a 40-hour time-weighted-average exposure for up to 10 hours per day during a 40-work week.

**Reprocess:** method to ensure proper disinfection or sterilization; can include cleaning, inspection, wrapping, sterilizing, and storing.

**Sanitizor:** agent that reduces the number of bacterial contaminants to safe levels as judged by public health requirements. Commonly used with substances applied to inanimate objects. According to the protocol for the official sanitizer test, a sanitizer is a chemical that kills 99.999% of the specific test bacteria in 30 seconds under the conditions of the test.

**Shelf life:** length of time an undiluted or use dilution of a product can remain active and effective. Also refers to the length of time a sterilized product (e.g., sterile instrument set) is expected to remain sterile.

**Spaulding classification:** strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semicritical, or noncritical on the basis of risk to patient safety from contamination on a device. The system also established three levels of germicidal activity (sterilization, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semicritical, and noncritical).

**Spore:** relatively water-poor round or elliptical resting cell consisting of condensed cytoplasm and nucleus surrounded by an impervious cell wall or coat. Spores are relatively resistant to disinfectant and sterilant activity and drying conditions (specifically in the genera *Bacillus* and *Clostridium*).

**Spore strip:** paper strip impregnated with a known population of spores that meets the definition of biological indicators.

**Steam quality:** steam characteristic reflecting the dryness fraction (weight of dry steam in a mixture of dry saturated steam and entrained water) and the level of noncondensable gas (air or other gas that will not condense under the conditions of temperature and pressure used during the sterilization process). The dryness fraction (i.e., the proportion of completely dry steam in the steam being considered) should not fall below 97%.

**Steam sterilization:** sterilization process that uses saturated steam under pressure for a specified exposure time and at a specified temperature, as the sterilizing agent.

**Steam sterilization, dynamic air removal type:** one of two types of sterilization cycles in which air is removed from the chamber and the load by a series of pressure and vacuum excursions (prevacuum cycle) or by a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush-pressure-pulse cycle).

**Sterile or Sterility:** state of being free from all living microorganisms. In practice, usually described as a probability function, e.g., as the probability of a microorganism surviving sterilization being one in one million.

**Sterility assurance level (SAL):** probability of a viable microorganism being present on a product unit after sterilization. Usually expressed as  $10^{-6}$ ; a SAL of  $10^{-6}$  means  $\leq 1$  million chances that a single viable microorganism is present on a sterilized item. A SAL of  $10^{-6}$  generally is accepted as appropriate for items intended to contact compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers). The sterilizer manufacturer is responsible for ensuring the sterilizer can achieve the desired SAL. The

user is responsible for monitoring the performance of the sterilizer to ensure it is operating in conformance to the manufacturer's recommendations.

**Sterilization:** validated process used to render a product free of all forms of viable microorganisms. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

**Sterilization area:** area of a health-care facility designed to house sterilization equipment, such as steam ethylene oxide, hydrogen peroxide gas plasma, or ozone sterilizers.

**Sterilizer:** apparatus used to sterilize medical devices, equipment, or supplies by direct exposure to the sterilizing agent.

**Sterilizer, gravity-displacement type:** type of steam sterilizer in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber. Typical operating temperatures are 121–123°C (250–254°F) and 132–135°C (270–275°F).

**Sterilizer, prevacuum type:** type of steam sterilizer that depends on one or more pressure and vacuum excursions at the beginning of the cycle to remove air. This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system and because of the usually higher operating temperature (132–135°C [270–276°F]; 141–144°C [285–291°F]). This type of sterilizer generally provides for shorter exposure time and accelerated drying of fabric loads by pulling a further vacuum at the end of the sterilizing cycle.

**Sterilizer, steam-flush pressure-pulse type:** type of sterilizer in which a repeated sequence consisting of a steam flush and a pressure pulse removes air from the sterilizing chamber and processed materials using steam at above atmospheric pressure (no vacuum is required). Like a prevacuum sterilizer, a steam-flush pressure-pulse sterilizer rapidly removes air from the sterilizing chamber and wrapped items; however, the system is not susceptible to air leaks because air is removed with the sterilizing chamber pressure at above atmospheric pressure. Typical operating temperatures are 121–123°C (250–254°F), 132–135°C (270–276°F), and 141–144°C (285–291°F).

**Surfactant:** agent that reduces the surface tension of water or the tension at the interface between water and another liquid; a wetting agent found in many sterilants and disinfectants.

**Tabletop steam sterilizer:** a compact gravity-displacement steam sterilizer that has a chamber volume of not more than 2 cubic feet and that generates its own steam when distilled or deionized water is added.

**Time-weighted average (TWA):** an average of all the concentrations of a chemical to which a worker has been exposed during a specific sampling time, reported as an average over the sampling time. For example, the permissible exposure limit for ethylene oxide is 1 ppm as an 8-hour TWA. Exposures above the ppm limit are permitted if they are compensated for by equal or longer exposures below the limit during the 8-hour workday as long as they do not exceed the ceiling limit; short-term exposure limit; or, in the case of ethylene oxide, excursion limit of 5 ppm averaged over a 15-minute sampling period.

**Tuberculocide:** an EPA-classified hospital disinfectant that also kills *Mycobacterium tuberculosis* (tubercle bacilli). EPA has registered approximately 200 tuberculocides. Such agents also are called *mycobactericides*.

**Use-life:** the length of time a diluted product can remain active and effective. The stability of the chemical and the storage conditions (e.g., temperature and presence of air, light, organic matter, or metals)

determine the use-life of antimicrobial products.

**Vegetative bacteria:** bacteria that are devoid of spores and usually can be readily inactivated by many types of germicides.

**Virucide:** an agent that kills viruses to make them noninfective.

Adapted from Association for the Advancement of Medical Instrumentation,<sup>21,21A,21B</sup> Association of peri-Operating Registered Nurses (AORN),<sup>21C</sup> American Hospital Association,<sup>21D</sup> and Block,<sup>16,16A</sup>

Table 1. Methods of sterilization and disinfection.

Object	Sterilization		High-level (semicritical items) [except dental] will come in contact with mucous membrane or noncritical items	Disinfection	
	Procedure	Exposure time		Intermediate-level (some semicritical items and noncritical items)	Low-level (semicritical items; will come in contact with intact skin)
Smooth, hard surface <sup>1A</sup>	A	MR	D	K <sup>1</sup>	L
	B	MR	E	L <sup>3</sup>	M
	C	MR	F	N	N
	D	10 h at 20–25°C	H	O	O
	F	6 h	I <sup>4</sup>		
	G	12 m at 50–56°C	J		
	H	3–8 h			
Rubber tubing and catheters <sup>1A</sup>	A	MR	D		
	B	MR	E		
	C	MR	F		
	D	10 h at 20–25°C	H		
	F	6 h	I <sup>4</sup>		
	G	12 m at 50–56°C	J		
	H	3–8 h			
Polyethylene tubing and catheters <sup>1A,7</sup>	A	MR	D		
	B	MR	E		
	C	MR	F		
	D	10 h at 20–25°C	H		
	F	6 h	I <sup>4</sup>		
	G	12 m at 50–56°C	J		
	H	3–8 h			
Lensed instruments <sup>8</sup>	A	MR	D		
	B	MR	E		
	C	MR	F		
	D	10 h at 20–25°C	H		
	F	6 h	I <sup>4</sup>		
	G	12 m at 50–56°C	J		
	H	3–8 h			
Thermometers (oral and rectal) <sup>9</sup>					K <sup>1</sup>
Hinged instruments <sup>8</sup>	A	MR	D		
	B	MR	E		
	C	MR	F		
	D	10 h at 20–25°C	H		
	F	6 h	I <sup>4</sup>		
	G	12 m at 50–56°C	J		
	H	3–8 h			

Modified from Rubala and Simmons,<sup>1A,7,16,16A</sup> The selection and use of disinfectants in the health-care field is dynamic, and products may become available that are not in existence when this guideline was written. As newer disinfectants become available, persons or committees responsible for selecting disinfectants and sterilization processes should be guided by products cleared by the FDA and the EPA as well as information in the scientific literature.

- A. Heat sterilization, including steam or hot air (see manufacturer's recommendations, steam sterilization processing time from 3-30 minutes)
- B. Ethylene oxide gas (see manufacturer's recommendations, generally 1-6 hours processing time plus aeration time of 8-12 hours at 60-90°C)
- C. Hydrogen peroxide gas plasma (see manufacturer's recommendations for internal diameter and length restrictions, processing time between 45-72 minutes)
- D. Glutaraldehyde-based formulations (2% glutaraldehyde, caution should be exercised with all glutaraldehyde formulations when further in-use dilution is anticipated); glutaraldehyde (1.12%) and 1.93% phenolphthalein. One glutaraldehyde-based product has a high-level disinfection claim of 5 minutes at 35°C.
- E. Ortho-phthalaldehyde (OPA) 0.35%
- F. Hydrogen peroxide 7.5% (will corrode copper, zinc, and brass)
- G. Peroxycetic acid, concentration variable but 0.2% or greater is sporicidal. Peroxycetic acid immersion system operates at 50-60°C.
- H. Hydrogen peroxide (7.35%) and 0.23% peracetic acid; hydrogen peroxide 1% and peracetic acid 0.08% (will corrode metal instrument)
- I. Wet pasteurization at 70°C for 30 minutes with detergent cleaning
- J. Hypochlorite, single use chlorine generated on-site by electrolyzing saline containing >650-875 active free chlorine; (will corrode metal instruments)
- K. Ethyl or isopropyl alcohol (70-60%)
- L. Sodium hypochlorite (5.25-6.15% household bleach diluted 1:500 provides >100 ppm available chlorine)
- M. Phenolic germicidal detergent solution (follow product label for use-dilution)
- N. Iodophor germicidal detergent solution (follow product label for use-dilution)
- O. Quaternary ammonium germicidal detergent solution (follow product label for use-dilution)
- NR. Manufacturer's recommendations
- NA. Not applicable

<sup>1</sup> See text for discussion of hydrotherapy.  
<sup>2</sup> The longer the exposure to a disinfectant, the more likely it is that all microorganisms will be eliminated. Follow the EPA-cleared high-level disinfection claim. Ten-minute exposure is not adequate to disinfect tray objects, especially those that are difficult to clean because they have narrow channels or other areas that can harbor organic material and bacteria. Twenty-minute exposure at 22°C is the minimum time needed to reliably kill *M. tuberculosis* and resistant-tubercle mycobacteria with a 2% glutaraldehyde. Some high-level disinfectants have a reduced exposure time (e.g., ortho-phthalaldehyde at 12 minutes at 20°C) because of their rapid activity against mycobacteria or reduced exposure time due to increased mycobactericidal activity at elevated temperature (e.g., 2.5% glutaraldehyde at 5 minutes at 35°C, 0.55% OPA at 5 min at 25°C in automated endoscope reprocessor).  
<sup>3</sup> Tubing must be completely rinsed for high-level disinfection and liquid chemical sterilization; care must be taken to avoid entrapment of air bubbles during immersion.  
<sup>4</sup> Material compatibility should be investigated when appropriate.  
<sup>5</sup> A concentration of 1000 ppm available chlorine should be considered when cultures or concentrated preparations of microorganisms have spilled (5.25% to 6.15% household bleach diluted 1:50 provides >1000 ppm available chlorine). This solution may corrode some surfaces.  
<sup>6</sup> Pasteurization (washer-disinfector) of respiratory therapy or anesthesia equipment is a recognized alternative to high-level disinfection. Some data challenge the efficacy of some pasteurization units.  
<sup>7</sup> Thermolability should be investigated when appropriate.  
<sup>8</sup> Do not mix acids and oxidizers at any stage of handling or processing.  
<sup>9</sup> By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered products label, the user assumes liability from any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA.

Table 2. Properties of an ideal disinfectant.

Broad spectrum; should have a wide antimicrobial spectrum
Fast acting; should produce a rapid kill
Not affected by environmental factors; should be active in the presence of organic matter (e.g., blood, sputum, feces) and compatible with soaps, detergents, and other chemicals encountered in use
Non-toxic; should not be harmful to the user or patient
Surface compatibility; should not corrode instruments and metallic surfaces and should not cause the deterioration of cloth, rubber, plastics, and other materials
Residual effect on treated surfaces; should leave an antimicrobial film on the treated surface
Easy to use with clear label directions
Odorless; should have a pleasant odor or no odor to facilitate its routine use
Economical; should not be prohibitively high in cost
Solubility; should be soluble in water
Stability; should be stable in concentrate and use-dilution
Cleaner should have good cleaning properties
Environmentally friendly; should not damage the environment on disposal
Modified from Molnar <sup>108</sup> .

Table 3. Epidemiologic evidence associated with the use of surface disinfectants or detergents on noncritical environmental surfaces.

**Justification for Use of Disinfectants for Noncritical Environmental Surfaces**  
 Surfaces may contribute to transmission of epidemiologically important microbes (e.g., vancomycin-resistant Enterococci, methicillin-resistant *S. aureus*, viruses)  
 Disinfectants are needed for surfaces contaminated by blood and other potentially infective material  
 Disinfectants are more effective than detergents in reducing microbial load on floors  
 Detergents become contaminated and result in seeding the patient's environment with bacteria  
 Disinfection of noncritical equipment and surfaces is recommended for patients on isolation precautions by the Centers for Disease Control and Prevention.  
 Advantage of using a single product for decontamination of noncritical surfaces, both floors and equipment  
 Some newer disinfectants have persistent antimicrobial activity  
**Justification for Using a Detergent on Noncritical Environmental Surfaces**  
 Noncritical surfaces contribute minimally to endemic healthcare-associated infections  
 No difference in healthcare-associated infection rates when floors are cleaned with detergent versus disinfectant  
 No environmental impact (aquatic or terrestrial) issues with disposal  
 No occupational health exposure issues  
 Lower costs  
 Use of antiseptic/disinfectants selects for antibiotic-resistant bacteria (?)  
 More aesthetically pleasing floor  
 Modified from Rutala<sup>107</sup>.

Figure 1. Decreasing order of resistance of microorganisms to disinfection and sterilization and the level of disinfection or sterilization.

Resistant	Level
Prions (Creutzfeldt-Jakob Disease)	Prion reprocessing
Bacterial spores ( <i>Bacillus anthracis</i> )	Sterilization
Cocidia ( <i>Cryptosporidium</i> )	
Mycobacteria ( <i>M. tuberculosis</i> , <i>M. terrae</i> )	High
Nonlipid or small viruses (polio, coxsackie)	Intermediate
Fungi ( <i>Aspergillus</i> , <i>Candida</i> )	
Vegetative bacteria ( <i>S. aureus</i> , <i>P. aeruginosa</i> )	Low
Lipid or medium-sized viruses (HIV, herpes, hepatitis B)	
Susceptible	

Modified from Russell and Favero<sup>109,110</sup>.

Table 4. Comparison of the characteristics of selected chemicals used as high-level disinfectants or chemical sterilants.

	HP (7.5%)	PA (0.2%)	Glut (≥2.0%)	OPA (0.55%)	HPFA (7.35%)/0.23%
HLD Claim	30 m @ 20°C	NA	20-60 m @ 20°-25°C	12 m @ 20°C, 5 m @ 25°C in AER	15m @ 20°C
Sterilization Claim	6 h @ 20°	12m @ 50-55°	10 h @ 20°-25°C	None	3 h @ 20°C
Activation	No	No	Yes (alkaline pH)	No	No
Reuse Life <sup>1</sup>	21d	Single use	14-30 d	14d	14d
Shelf Life Stability <sup>2</sup>	2 y	6 mo	2 y	2 y	2 y
Disposal Restrictions	None	None	Local <sup>3</sup>	Local <sup>3</sup>	None
Materials Compatibility	Good	Good	Excellent	Excellent	No data
Monitor MEC <sup>4</sup>	Yes (5%)	No	Yes (1.5% or higher)	Yes (0.3% OPA)	No
Safety	Serious eye damage (tealily glasses)	Serious eye and skin damage (tealily glasses)	Respiratory	Eye irritant, stains skin	Eye damage
Processing	Manual or automated	Automated	Manual or automated	Manual or automated	Manual
Organic material resistance	Yes	Yes	Yes	Yes	Yes
OSHA exposure limit	1 ppm TWA	None	None <sup>5</sup>	None	HP-1 ppm TWA
Cost profile (per cycle) <sup>6</sup>	+(manual), ++ (automated)	++++ (manual), ++ (automated)	+(manual), ++ (automated)	++ (manual)	++ (manual)

Modified from Rutala<sup>14</sup>  
 Abbreviations: HLD=high-level disinfectant; HP=hydrogen peroxide; PA=peracetic acid; glut=glutaraldehyde; PA/HP=peracetic acid and hydrogen peroxide; OPA=ortho-phthalaldehyde (FDA cleared as a high-level disinfectant, included for comparison to other chemical agents used for high-level disinfection); m=minutes; h=hours; NA=not applicable; TWA=time-weighted average for a conventional 8-hour workday.  
<sup>1</sup>number of days a product can be reused as determined by re-use protocol  
<sup>2</sup>Time a product can remain in storage (unused)  
<sup>3</sup>No U.S. EPA regulations but some states and local authorities have additional restrictions  
<sup>4</sup>MEC=minimum effective concentration is the lowest concentration of active ingredients at which the product is still effective  
<sup>5</sup>Conc soln=concentrated solution  
<sup>6</sup>The ceiling limit recommended by the American Conference of Governmental Industrial Hygienists is 0.05 ppm.  
<sup>7</sup>per cycle cost profile considers cost of the processing solution (suggested list price to healthcare facilities in August 2001) and assumes maximum use life (e.g., 21 days for hydrogen peroxide, 14 days for glutaraldehyde), 5 reprocessing cycles per day, 1-gallon basin for manual processing, and 4-gallon tank for automated processing. + = least expensive; ++++ = most expensive

Table 5. Summary of advantages and disadvantages of chemical agents used as chemical sterilants or as high-level disinfectants.

Sterilization Method	Advantages	Disadvantages
Peracetic Acid/Hydrogen Peroxide	<ul style="list-style-type: none"> <li>No activation required</li> <li>Odor or irritation not significant</li> </ul>	<ul style="list-style-type: none"> <li>Materials compatibility concerns (steel, brass, copper, zinc) both cosmetic and functional</li> <li>Limited clinical experience</li> <li>Potential for eye and skin damage</li> </ul>
Glutaraldehyde	<ul style="list-style-type: none"> <li>Numerous use studies published</li> <li>Relatively inexpensive</li> <li>Excellent sporicidal compatibility</li> </ul>	<ul style="list-style-type: none"> <li>Respiratory irritation from glutaraldehyde vapor</li> <li>Pungent and irritating odor</li> <li>Relatively slow mycobactericidal activity</li> <li>Coagulates blood and feces tissue to surfaces</li> <li>Allergic contact dermatitis</li> <li>Glutaraldehyde vapor monitoring recommended</li> </ul>
Hydrogen Peroxide	<ul style="list-style-type: none"> <li>No activation required</li> <li>May enhance removal of organic matter and organisms</li> <li>No disposal issues</li> <li>No odor or irritation issues</li> <li>Does not coagulate blood or fix tissues to surfaces</li> <li>Inactivates <i>Cryptosporidium</i></li> <li>Use studies published</li> </ul>	<ul style="list-style-type: none"> <li>Materials compatibility concerns (brass, zinc, copper, and nickel/alloy plating) both cosmetic and functional</li> <li>Serious eye damage with contact</li> </ul>
Ortho-phthalaldehyde	<ul style="list-style-type: none"> <li>Fast acting high-level disinfectant</li> <li>No activation required</li> <li>Odor not significant</li> <li>Excellent materials compatibility claimed</li> <li>Does not coagulate blood or fix tissues to surfaces stained</li> </ul>	<ul style="list-style-type: none"> <li>Stains skin, mucous membranes, clothing, and environmental surfaces</li> <li>Repeated exposure may result in hypersensitivity in some patients with bladder cancer</li> <li>More expensive than glutaraldehyde</li> <li>Eye irritation with contact</li> <li>Slow sporicidal activity</li> </ul>
Peracetic Acid	<ul style="list-style-type: none"> <li>Rapid sterilization cycle time (30-45 minutes)</li> <li>Low temperature (50-55°C) rapid immersion sterilization</li> <li>Environmental friendly byproducts (acetic acid, O<sub>2</sub>, H<sub>2</sub>O)</li> <li>Fully enolized</li> <li>Single-use system eliminates need for concentration testing</li> <li>Standardized cycle</li> <li>May enhance removal of organic material and endotoxin</li> <li>No adverse health effects to operators under normal operating conditions</li> <li>Compatible with many materials and instruments</li> <li>Does not coagulate blood or fix tissues to surfaces</li> <li>Sterilized flows through scope facilitating coil, protein, and microbe removal</li> <li>Rapidly sporicidal</li> <li>Provides procedure standardization (constant dilution, perfusion of channel, temperature, exposure)</li> </ul>	<ul style="list-style-type: none"> <li>Potential material incompatibility (e.g., aluminum anodized coating becomes dull)</li> <li>Used for immovable instruments only</li> <li>Biological indicator may not be suitable for routine monitoring</li> <li>One scope or a small number of instruments can be processed in a cycle</li> <li>More expensive (endoscope repairs, opening coils, purchase cost) than high-level disinfection</li> <li>Before eye and skin damage (concentrated solution) with contact</li> <li>Potential-use system, no sterile storage</li> </ul>

Modified from Rutala<sup>14</sup>  
<sup>14</sup>All products effective in presence of organic soil, relatively easy to use, and have a broad spectrum of antimicrobial activity (bacteria, fungi, viruses, bacterial spores, and mycobacteria). The above characteristics are documented in the literature; contact the manufacturer of the instrument and solution for additional information. All products listed above are FDA-cleared as chemical sterilants except OPA, which is an FDA-cleared high-level disinfectant.

Table 6. Summary of advantages and disadvantages of commonly used sterilization technologies.

Sterilization Method	Advantages	Disadvantages
Steam	<ul style="list-style-type: none"> <li>Nontoxic to patients, staff, environment</li> <li>Cycle easy to control and monitor</li> <li>Rapidly microbicidal</li> <li>Least affected by organic/inorganic soils among sterilization processes listed</li> <li>Rapid cycle time</li> <li>Penetrates medical packing device lumens</li> </ul>	<ul style="list-style-type: none"> <li>Deleterious for heat-sensitive instruments</li> <li>Microsurgical instruments damaged by repeated exposure</li> <li>May leave instruments wet, causing them to rust</li> <li>Potential for burns</li> </ul>
Hydrogen Peroxide Gas Plasma	<ul style="list-style-type: none"> <li>Safe for the environment</li> <li>Leaves no toxic residues</li> <li>Cycle time is 28-75 minutes (varies with model type) and no aeration necessary</li> <li>Used for heat- and moisture-sensitive items since process temperature &lt;50°C</li> <li>Simple to operate, install (208 V outlet), and monitor</li> <li>Compatible with most medical devices</li> <li>Only requires electrical outlet</li> </ul>	<ul style="list-style-type: none"> <li>Cellulose (paper), stone and liquids cannot be processed</li> <li>Sterilization chamber size from 1.8-8.4 m<sup>3</sup> total volume (varies with model type)</li> <li>Some endoscopes or medical devices with long or narrow lumens cannot be processed at this time in the United States (see manufacturer's recommendations for internal diameter and length restrictions)</li> <li>Requires synthetic packaging (polypropylene wraps, polyolefin pouches) and special container tray</li> <li>Hydrogen peroxide may be toxic at levels greater than 1 ppm/TWA</li> </ul>
100% Ethylene Oxide (ETO)	<ul style="list-style-type: none"> <li>Penetrates packaging materials, device lumens</li> <li>Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and ETO exposure</li> <li>Simple to operate and monitor</li> <li>Compatible with most medical materials</li> </ul>	<ul style="list-style-type: none"> <li>Requires aeration time to remove ETO residue</li> <li>Sterilization chamber size from 4.0-7.9 m<sup>3</sup> total volume (varies with model type)</li> <li>ETO is toxic, a carcinogen, and flammable</li> <li>ETO emission regulated by states but catalytic cell removes 99.9% of ETO and converts it to CO<sub>2</sub> and H<sub>2</sub>O</li> <li>ETO cartridges should be stored in flammable liquid storage cabinet</li> <li>Lengthy cycle/aeration time</li> </ul>
ETO Mixtures 0.5% ETO/1.4% H <sub>2</sub> CO 10% ETO/90% H <sub>2</sub> CO 0.5% ETO/0.5% CO <sub>2</sub>	<ul style="list-style-type: none"> <li>Penetrates medical packaging and many plastics</li> <li>Compatible with most medical materials</li> <li>Cycle easy to control and monitor</li> </ul>	<ul style="list-style-type: none"> <li>Some states (e.g., CA, NY, MI) require ETO emission reduction of 90-99.5%</li> <li>CO<sub>2</sub> (wet gas that eliminates sporicidal hazard) banned in 1995</li> <li>Potential hazards to staff and patients</li> <li>Lengthy cycle/aeration time</li> <li>ETO is toxic, a carcinogen, and flammable</li> </ul>
Peracetic Acid	<ul style="list-style-type: none"> <li>Rapid cycle time (30-45 minutes)</li> <li>Low temperature (50-55°C) rapid immersion sterilization</li> <li>Environmental friendly byproducts</li> <li>Sterilized flows through endoscope which facilitates coil, protein and microbe removal</li> </ul>	<ul style="list-style-type: none"> <li>Potential-use system, no sterile storage</li> <li>Biological indicator may not be suitable for routine monitoring</li> <li>Used for immovable instruments only</li> <li>Some material incompatibility (e.g., aluminum anodized coating becomes dull)</li> <li>One scope or a small number of instruments processed in a cycle</li> <li>Potential for serious eye and skin damage (concentrated solution) with contact</li> </ul>

Modified from Rutala<sup>14</sup>  
 Abbreviations: CO<sub>2</sub>=carbon dioxide, H<sub>2</sub>CO=hydrochloroform, etc.

Table 7. Minimum cycle times for steam sterilization cycles

Type of sterilizer	Item	Exposure time at 250°F (121°C)	Exposure time at 270°F (132°C)	Drying time
Gravity displacement	Wrapped Instruments	30 min	15 min	15-30 min
	Textile packs	30 min	25 min	15 min
Dynamic-air-removal (e.g., prevacuum)	Wrapped utensils	30 min	15 min	15-30 min
	Textile packs		4 min	20-30 min
	Wrapped utensils		4 min	5-20 min
	Textile packs		4 min	20 min

Modified from Association for the Advancing of Medical Instrumentation.<sup>15, 17, 18</sup>

Table 8. Examples of flash steam sterilization parameters.

Type of sterilizer	Load configuration	Temperature	Time
Gravity displacement	Nonporous items only (i.e., routine metal instruments, no lumens)	132°C (270°F)	3 minutes
	Nonporous and porous items (e.g., rubber or plastic items, items with lumens) sterilized together	132°C (270°F)	10 minutes
Prevacuum	Nonporous items only (i.e., routine metal instruments, no lumens)	132°C (270°F)	3 minutes
	Nonporous and porous items (e.g., rubber or plastic items, items with lumens) sterilized together	132°C (270°F)	4 minutes
Steam-flush pressure-pulse	Nonporous or mixed nonporous/porous items	132°C (270°F) Manufacturers' instruction	4 minutes

Modified from Association for the Advancement of Medical Instrumentation, #12, #13

Table 9. Characteristics of an ideal low-temperature sterilization process.

High efficacy; the agent should be virucidal, bactericidal, tuberculocidal, fungicidal and sporicidal
Rapid activity; ability to quickly achieve sterilization
Strong penetrability; ability to penetrate common medical-device packaging materials and penetrate into the interior of device lumens
Material compatibility; produces only negligible changes in the appearance or the function of processed items and packaging materials even after repeated cycling
Non-toxic; presents no toxic health risk to the operator or the patient and poses no hazard to the environment
Organic material resistance; withstands reasonable organic material challenge without loss of efficacy
Adaptability; suitable for large or small (point of use) installations
Monitoring capability; monitored easily and accurately with physical, chemical, and biological process monitors
Cost effectiveness; reasonable cost for installation and for routine operation

Modified from Schneider, #81

Table 10. Factors affecting the efficacy of sterilization.

Factors	Effect
Cleaning <sup>1</sup>	Failure to adequately clean instrument results in higher bioburden, protein load, and salt concentration. These will decrease sterilization efficacy.
Bioburden <sup>2</sup>	The natural bioburden of used surgical devices is 10 <sup>4</sup> to 10 <sup>5</sup> organisms (primarily vegetative bacteria), which is substantially below the 10 <sup>5</sup> -10 <sup>6</sup> spores used with biological indicators.
Pathogen type	Spore-forming organisms are most resistant to sterilization and are the test organisms required for FDA clearance. However, the contaminating microflora on used surgical instruments consists mainly of vegetative bacteria.
Protein <sup>1</sup>	Residual protein decreases efficacy of sterilization. However, cleaning appears to rapidly remove protein load.
Salt <sup>1</sup>	Residual salt decreases efficacy of sterilization more than does protein load. However, cleaning appears to rapidly remove salt load.
Biofilm accumulation <sup>3</sup>	Biofilm accumulation reduces efficacy of sterilization by impaling exposure of the sterilant to the microbial cell.
Lumen length	Increasing lumen length impairs sterilant penetration. May require forced flow through lumen to achieve sterilization.
Lumen diameter	Decreasing lumen diameter impairs sterilant penetration. May require forced flow through lumen to achieve sterilization.
Restricted flow	Sterilant must come into contact with microorganisms. Device designs that prevent or inhibit this contact (e.g., sharp bends, blind lumens) will decrease sterilization efficacy.
Device design and construction	Materials used in construction may affect compatibility with different sterilization processes and affect sterilization efficacy. Design issues (e.g., screws, hinges) will also affect sterilization efficacy.

Modified from Alta and Rutala, #16, #15 <sup>1</sup> Factor only relevant for reused surgical/medical devices

Table 11. Comparative evaluation of the microbicidal activity of low-temperature sterilization technology.

Challenge	Sterilants Sterilized by Various Low-Temperature Sterilization Technologies						Reference
	ETO-1233	100% ETO	HFCO-ETO	HPSP-104	HPGP-1002	PA	
No salt or serum <sup>1</sup>	100%	100%	98%	100%	ND	ND	Alta <sup>21</sup>
10% serum and 0.65% salt <sup>2</sup>	97%	88%	95%	37%	ND	ND	Alta <sup>21</sup>
Lumen (125 cm long x 3 mm wide) without serum or salt <sup>3</sup>	ND	94%	94%	ND	ND	ND	Alta <sup>21</sup>
Lumen (125 cm long x 3 mm wide) with 10% serum and 0.65% salt <sup>4</sup>	44%	40%	49%	35%	ND	100% <sup>5</sup>	Alta <sup>21</sup>
Lumen (40 cm long x 3 mm wide) <sup>6</sup>	ND	ND	100%	95%	100%	5%	Rutala <sup>22</sup>
Lumen (40 cm long x 2 mm wide) <sup>7</sup>	ND	ND	100%	93%	100%	ND	Rutala <sup>22</sup>
Lumen (40 cm long x 1 mm wide) <sup>8</sup>	ND	ND	100%	25%	100%	ND	Rutala <sup>22</sup>
Lumen (40 cm long x 3 mm wide) <sup>9</sup>	ND	ND	100%	100%	100%	ND	Rutala <sup>22</sup>

Modified from Rutala, #25  
Abbreviations: ETO=ethylene oxide; HFCO=hydrochlorofluorocarbon; ND=no data; HPGP=hydrogen peroxide gas plasma; PA=peracetic acid.

<sup>1</sup>Test organisms included *Enterococcus faecalis*, *Mycobacterium chelonae*, and *Bacillus atrophaeus* spores.

<sup>2</sup>Test organisms included *E. faecalis*, *P. aeruginosa*, *E. coli*, *M. chelonae*, *B. atrophaeus* spores, *G. stearothermophilus* spores, and *E. circulans* spores.

<sup>3</sup>Test organism was *G. stearothermophilus* spores. The lumen test units had a removable 5 cm center piece (1.2 cm diameter) of stainless steel sealed to the narrower steel tubing by hard rubber septums.

<sup>4</sup>Test organism was *G. stearothermophilus* spores. The lumen test unit was a straight stainless steel tube.

Table 12. Suggested protocol for management of positive biological indicator in a steam sterilizer.

1. Take the sterilizer out of service. Notify area supervisor and infection control department.
  2. Objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or the sterilization procedure is defective. As soon as possible, repeat biological indicator test in three consecutive sterilizer cycles. If additional spore tests remain positive, the items should be considered nonsterile, and supplies processed since the last acceptable (negative) biological indicator should be recalled. The items from the suspect load(s) should be recalled and reprocessed.
  3. Check to ensure the sterilizer was used correctly (e.g., verify correct time and temperature setting). If not, repeat using appropriate settings and recall and reprocess all inadequately processed items.
  4. Check with hospital maintenance for irregularities (e.g., electrical) or changes in the hospital steam supply (i.e., from standard  $\geq 97\%$  steam,  $< 3\%$  moisture). Any abnormalities should be reported to the person who performs sterilizer maintenance (e.g., medical engineering, sterilizer manufacturer).
  5. Check to ensure the correct biological indicator was used and appropriately interpreted. If not, repeat using appropriate settings.
    - If all three repeat biological indicators from three consecutive sterilizer cycles (step 2 above) are negative, put the sterilizer back in service.
    - If one or both biological indicators are positive, do one or more of the following until problem is resolved.
      - A. Request an inspection of the equipment by sterilizer maintenance personnel.
      - B. Have hospital maintenance inspect the steam supply lines.
      - C. Discuss the abnormalities with the sterilizer manufacturer.
    - Repeat the biological indicator using a different manufacturer's indicator.
- If step 7 does not resolve the problem
- Close sterilizer down until the manufacturer can assure that it is operating properly. Retest at that time with biological indicators in three consecutive sterilizer cycles.
- Modified from Bryce.<sup>68</sup>

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