Recommendations for Disinfection and Sterilization in Healthcare Facilities

Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

WHAT TO KNOW

Below are tables summarizing recommendations for this guideline.

Rationale and Rankings

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

Rank	Description
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

#	Recommendation	Category
1.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., EtO, 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.	II, IC
1.b.	Educate health-care workers in the selection and proper use of personal protective equipment (PPE).	II, IC
1.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.	II, IC
1.d.	Establish a program for monitoring occupational exposure to regulated chemicals (e.g., formaldehyde, EtO) that adheres to state and federal regulations.	II, IC
1.e.	Exclude healthcare workers with weeping dermatitis of hands from direct contact with patient-care equipment.	IB

Recommendations for Occupational health and exposure: by ID number and category.

2. Cleaning of Patient-Care Devices

#	Recommendation	Category
2.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.	II
2.b.	Meticulously clean patient-care items with water and detergent, or with water and enzymatic cleaners before high-level disinfection or sterilization procedures.	IB
2.b.i.	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.	IB
2.b.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.	IB
2.c.	Perform either manual cleaning (i.e., using friction) or mechanical cleaning (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizers).	IB
2.d.	If using an automatic washer/disinfector, ensure that the unit is used in accordance with the manufacturer’s recommendations.	IB
2.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.	II
2.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.	II

Recommendations for Cleaning of patient-care devices: by ID number and category.

3. Indications for Sterilization, High-Level Disinfection, and Low-Level Disinfection

#	Recommendation	Category
3.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.	IA
3.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.	IA

#	Recommendation	Category
3.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).	II

Indications for sterilization and disinfection: by ID number and category.

4. Selection and Use of Low-Level Disinfectants for Noncritical Patient-Care Devices

#	Recommendation	Category
4.a.	Process noncritical patient-care devices using a disinfectant and the concentration of germicide listed in Table 1.	IB
4.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.	IB
4.c.	Ensure that, at a minimum, noncritical patient-care devices are disinfected when visibly soiled and on a regular basis (such as after use on each patient or once daily or once weekly).	II
4.d.	If dedicated, disposable devices are not available, disinfect noncritical patient-care equipment after using it on a patient who is on contact precautions before using this equipment on another patient.	IB

4. Selection and Use of Low-Level Disinfectants for Noncritical Patient-Care Devices

5. Cleaning and Disinfecting Environmental Surfaces in Healthcare Facilities

Edit [February 2017]

Edit: An * indicates recommendations that were renumbered for clarity. The renumbering does not constitute change to the intent of the recommendations.

#	Recommendation	Category
5.a.	Clean housekeeping surfaces (e.g., floors, tabletops) on a regular basis, when spills occur, and when these surfaces are visibly soiled.	II
5.b.	Disinfect (or clean) environmental surfaces on a regular basis (e.g., daily, three times per week) and when surfaces are visibly soiled.	II
5.c.	Follow manufacturers' instructions for proper use of disinfecting (or detergent) products — such as recommended use-dilution, material compatibility, storage, shelf-life, and safe use and disposal.	II
5.d.	Clean walls, blinds, and window curtains in patient-care areas when these surfaces are visibly contaminated or soiled.	II
5.e.	Prepare disinfecting (or detergent) solutions as needed and replace these with fresh solution frequently (e.g., replace floor mopping solution every three patient rooms, change no less often than at 60-minute intervals), according to the facility's policy.	IB
5.f.	Decontaminate mop heads and cleaning cloths regularly to prevent contamination (e.g., launder and dry at least daily).	II
5.g.	Use a one-step process and an EPA-registered hospital disinfectant designed for housekeeping purposes in patient care areas where	II

#	Recommendation	Category
	• uncertainty exists about the nature of the soil on the surfaces (e.g., blood or body fluid contamination versus routine dust or dirt); or • uncertainty exists about the presence of multidrug resistant organisms on such surfaces. See recommendation 5n for recommendations requiring cleaning and disinfecting blood-contaminated surfaces.	
5.h.	Detergent and water are adequate for cleaning surfaces in nonpatient-care areas (e.g., administrative offices).	II
5.i.	Do not use high-level disinfectants/liquid chemical sterilants for disinfection of non-critical surfaces.	IB
5.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.	II
5.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.	II, IC
5.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.	IB
5.m.	Promptly clean and decontaminate spills of blood and other potentially infectious materials. Discard blood-contaminated items in compliance with federal regulations.	IB, IC
5.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 specific label claims for HIV or HBV or freshly diluted hypochlorite solution).	II, IC
5.n.1. *	If sodium hypochlorite solutions are selected use a 1:100 dilution (e.g., 1:100 dilution of a 5.25-6.15% sodium hypochlorite provides 525-615 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.	IB, IC
5.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.	II, IC
5.p.	Use protective gloves and other PPE appropriate for this task.	II, IC
5.q.	***C. difficile* Update [April 2019]** ⚠ This recommendation was updated to reflect changes in Federal regulatory approvals: LIST K: EPA's Registered Antimicrobial Products Effective against Clostridium difficile Spores external icon **Update:** Use an EPA-registered sporicidal disinfectant in units with high rates of endemic *Clostridium difficile* infection or in an outbreak setting.	New Categorization Scheme: **Recommendation**
5.r.	If chlorine solution is not prepared fresh daily, it can be stored at room temperature for up to 30 days in a capped, opaque plastic bottle with a 50% reduction in chlorine concentration after 30 days of storage	IB

#	Recommendation	Category
	(e.g., 1000 ppm chlorine [approximately a 1:50 dilution] at day 0 decreases to 500 ppm chlorine by day 30).	
5.s.	An EPA-registered sodium hypochlorite product is preferred, but if such products are not available, generic versions of sodium hypochlorite solutions (e.g., household chlorine bleach) can be used.	II

Recommendations for Cleaning and disinfecting environmental surfaces: by ID number and category.

6. Disinfectant Fogging

#	Recommendation	Category
6.a.	Do not perform disinfectant fogging for routine purposes in patient-care areas. ### Environmental Fogging [December 2009] **Clarification Statement:** CDC and HICPAC have recommendations in both *2003 Guidelines for Environmental Infection Control in Health-Care Facilities* and the *2008 Guideline for Disinfection and Sterilization in Healthcare Facilities* that state that the CDC does not support disinfectant fogging. Specifically, the 2003 and 2008 Guidelines state: • 2003: “Do not perform disinfectant fogging for routine purposes in patient-care areas. Category IB” • 2008: “Do not perform disinfectant fogging in patient-care areas. Category II” These recommendations refer to the spraying or fogging of chemicals (e.g., formaldehyde, phenol-based agents, or quaternary ammonium compounds) as a way to decontaminate environmental surfaces or disinfect the air in patient rooms. The recommendation against fogging was based on studies in the 1970’s that reported a lack of microbicidal efficacy (e.g., use of quaternary ammonium compounds in mist applications) but also adverse effects on healthcare workers and others in facilities where these methods were utilized. Furthermore, some of these chemicals are not EPA-registered for use in fogging-type applications. These recommendations do not apply to newer technologies involving fogging for room decontamination (e.g., ozone mists, vaporized hydrogen peroxide) that have become available since the 2003 and 2008 recommendations were made. These newer technologies were assessed by CDC and HICPAC in the 2011 Guideline for the Prevention and Control of Norovirus Gastroenteritis Outbreaks in Healthcare Settings, which makes the recommendation: **“More research is required to clarify the effectiveness and reliability of fogging, UV irradiation, and ozone mists to reduce norovirus environmental contamination. (No recommendation/unresolved issue)”** The 2003 and 2008 recommendations still apply; however, CDC does not yet make a recommendation regarding these newer technologies. This issue will be revisited as additional evidence becomes available.	II

Recommendations for Disinfectant fogging: by ID number and category.

7. High-Level Disinfection of Endoscopes

Edit [February 2017]

Edit: An * indicates recommendations that were renumbered for clarity. The renumbering does not constitute change to the intent of the recommendations.

#	Recommendation	Category
7.a.	To detect damaged endoscopes, test each flexible endoscope for leaks as part of each reprocessing cycle. Remove from clinical use any instrument that fails the leak test, and repair this instrument.	II
7.b.	Immediately after use, meticulously clean the endoscope with an enzymatic cleaner that is compatible with the endoscope. Cleaning is necessary before both automated and manual disinfection.	IA
7.c.	Disconnect and disassemble endoscopic components (e.g., suction valves) as completely as possible and completely immerse all components in the enzymatic cleaner. Steam sterilize these components if they are heat stable.	IB
7.d.	Flush and brush all accessible channels to remove all organic (e.g., blood, tissue) and other residue. Clean the external surfaces and accessories of the devices by using a soft cloth or sponge or brushes. Continue brushing until no debris appears on the brush.	IA
7.e.	Use cleaning brushes appropriate for the size of the endoscope channel or port (e.g., bristles should contact surfaces). Cleaning items (e.g., brushes, cloth) should be disposable or, if they are not disposable, they should be thoroughly cleaned and either high-level disinfected or sterilized after each use.	II
7.f.	Discard enzymatic cleaners (or detergents) after each use because they are not microbicidal and, therefore, will not retard microbial growth.	IB
7.g.	Process endoscopes (e.g., arthroscopes, cystoscope, laparoscopes) that pass through normally sterile tissues using a sterilization procedure before each use; if this is not feasible, provide at least high-level disinfection. High-level disinfection of arthroscopes, laparoscopes, and cystoscope should be followed by a sterile water rinse.	IB
7.h.	Phase out endoscopes that are critical items (e.g., arthroscopes, laparoscopes) but cannot be steam sterilized. Replace these endoscopes with steam sterilizable instruments when feasible.	II
7.i.	Mechanically clean reusable accessories inserted into endoscopes (e.g., biopsy forceps or other cutting instruments) that break the mucosal barrier (e.g., ultrasonically clean biopsy forceps) and then sterilize these items between each patient.	IA
7.j.	Use ultrasonic cleaning of reusable endoscopic accessories to remove soil and organic material from hard-to-clean areas.	II
7.k.	Process endoscopes and accessories that contact mucous membranes as semicritical items, and use at least high-level disinfection after use on each patient.	IA
7.l.	Use an FDA-cleared sterilant or high-level disinfectant for sterilization or high-level disinfection (Table 1).	IA
7.m.	After cleaning, use formulations containing glutaraldehyde, glutaraldehyde with phenol/phenate, 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).	IB
7.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).	IB
7.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.	IC
7.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 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" Flexible GI Endoscope Reprocessing [June 2011] **Update:** Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011 Cdc-pdfpdf icon[PDF – 547KB]Externalexternal icon PDF	

#	Recommendation	Category
7.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).	IB
7.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).	IB
7.s.	Completely immerse the endoscope in the high-level disinfectant, and ensure all channels are perfused. As soon as is feasible, phase out nonimmersible endoscopes.	IB
7.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.	IB
7.u.	After flushing all channels with alcohol, purge the channels using forced air to reduce the likelihood of contamination of the endoscope by waterborne pathogens and to facilitate drying.	IB
7.v.	Hang endoscopes in a vertical position to facilitate drying.	II
7.w.	Store endoscopes in a manner that will protect them from damage or contamination.	II
7.x.	Sterilize or high-level disinfect both the water bottle used to provide intraprocedural flush solution and its connecting tube at least once daily. After sterilizing or high-level disinfecting the water bottle, fill it with sterile water.	IB
7.y.	Maintain a log for each procedure and record the following: patient's name and medical record number (if available), procedure, date, endoscopist, system used to reprocess the endoscope (if more than one system could be used in the reprocessing area), and serial number or other identifier of the endoscope used.	II
7.z.	Design facilities where endoscopes are used and disinfected to provide a safe environment for healthcare workers and patients. Use air-exchange equipment (e.g., the ventilation system, out-exhaust ducts) to minimize exposure of all persons to potentially toxic vapors (e.g., glutaraldehyde vapor). Do not exceed the allowable limits of the vapor concentration of the chemical sterilant or high-level disinfectant (e.g., those of ACGIH and OSHA).	IB, IC
7.aa.	Routinely test the liquid sterilant/high-level disinfectant to ensure minimal effective concentration of the active ingredient. Check the solution each day of use (or more frequently) using the appropriate chemical indicator (e.g., glutaraldehyde chemical indicator to test minimal effective concentration of glutaraldehyde) and document the results of this testing. Discard the solution if the chemical indicator shows the concentration is less than the minimum effective concentration. Do not use the liquid sterilant/high-level disinfectant beyond the reuse-life recommended by the manufacturer (e.g., 14 days for ortho-phthalaldehyde).	IA
7.ab. *	Provide personnel assigned to reprocess endoscopes with device-specific reprocessing instructions to ensure proper cleaning and high-level disinfection or sterilization. Require competency testing on a regular basis (e.g., beginning of employment, annually) of all personnel who reprocess endoscopes.	IA
7.ac. *	Educate all personnel who use chemicals about the possible biologic, chemical, and environmental hazards of performing procedures that require disinfectants.	IB, IC
7.ad. *	Make PPE(e.g., gloves, gowns, eyewear, face mask or shields, respiratory protection devices) available and use these items appropriately to protect workers from exposure to both chemicals and microorganisms (e.g., HBV).	IB, IC
7.ae. *	If using an automated endoscope reprocessor (AER), place the endoscope in the reprocessor and attach all channel connectors according to the AER manufacturer's instructions to ensure exposure of all internal surfaces to the high-level disinfectant/chemical sterilant.	IB
7.af. *	If using an AER, ensure the endoscope can be effectively reprocessed in the AER. Also, ensure any required manual cleaning/disinfecting steps are performed (e.g., elevator wire channel of duodenoscopes might not be effectively disinfected by most AERs).	IB
7.ag. *	Review the FDA advisories and the scientific literature for reports of deficiencies that can lead to infection because design flaws and improper operation and practices have compromised the effectiveness of AERs.	II

#	Recommendation	Category
7.ah. *	Develop protocols to ensure that users can readily identify an endoscope that has been properly processed and is ready for patient use.	II
7.ai. *	Do not use the carrying case designed to transport clean and reprocessed endoscopes outside of the healthcare environment to store an endoscope or to transport the instrument within the healthcare environment.	II
7.aj. *	No recommendation is made about routinely performing microbiologic testing of either endoscopes or rinse water for quality assurance purposes.	Unresolved Issue
7.ak. *	If environmental microbiologic testing is conducted, use standard microbiologic techniques.	II
7.al. *	If a cluster of endoscopy-related infections occurs, investigate potential routes of transmission (e.g., person-to-person, common source) and reservoirs.	IA
7.am. *	Report outbreaks of endoscope-related infections to persons responsible for institutional infection control and risk management and to FDA.	IB
7.am.1. *	Notify the local and the state health departments, CDC, and the manufacturer(s)	II
7.an. *	No recommendation is made regarding the reprocessing of an endoscope again immediately before use if that endoscope has been processed after use according to the recommendations in this guideline.	Unresolved issue
7.ao. *	Compare the reprocessing instructions provided by both the endoscope's and the AER's manufacturer's instructions and resolve any conflicting recommendations.	IB

Recommendations for High-level disinfection of endoscopes: by ID number and category.

8. Management of Equipment and Surfaces in Dentistry

#	Recommendation	Category
8.a.	Dental instruments that penetrate soft tissue or bone (e.g., extraction forceps, scalpel blades, bone chisels, periodontal scalers, and surgical burs) are classified as critical and should be 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-tolerant, although classified as semicritical. Clean and, at a minimum, high-level disinfect heat-sensitive semicritical items.	IA
8.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).	IB
8.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.	II

Recommendations for Management of equipment and surfaces in dentistry: by ID number and category.

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

#	Recommendation	Category
9.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	IA

#	Recommendation	Category
	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.	

Recommendations for Processing contaminated patient-care equipment: by ID number and category.

10. Disinfection Strategies for Other Semicritical Devices

#	Recommendation	Category
10.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 Recommendation 7p for exceptions.)	IB
10.b.	When probe covers are available, use a probe cover or condom to reduce the level of microbial contamination.	II
	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.	IB
10.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).	II
10.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
10.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.	II

Recommendations for Disinfection strategies for other semicritical devices: by ID number and category.

11. Disinfection by Healthcare Personnel in Ambulatory Care and Home Care

#	Recommendation	Category
11.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).	IB
11.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.	II
11.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.	II

Recommendations for Disinfection by healthcare personnel in ambulatory care and home care: by ID number and category.

12. Microbial Contamination of Disinfectants

#	Recommendation	Category
12.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).	IB

Recommendations for Microbial contamination of disinfectants: by ID number and category.

13. Flash Sterilization

#	Recommendation	Category
13.a.	Do not flash sterilize implanted surgical devices unless doing so is unavoidable.	IB
13.b.	Do not use flash sterilization for convenience, as an alternative to purchasing additional instrument sets, or to save time.	II
13.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.	IB
13.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.	IB
13.e.	When necessary, use flash sterilization for patient-care items that will be used immediately (e.g., to reprocess an inadvertently dropped instrument).	IB
13.f.	When necessary, use flash sterilization for processing patient-care items that cannot be packaged, sterilized, and stored before use.	IB

Recommendations for Flash sterilization: by ID number and category.

14. Methods of Sterilization

#	Recommendation	Category
14.a.	Steam is the preferred method for sterilizing critical medical and surgical instruments that are not damaged by heat, steam, pressure, or moisture.	IA
14.b.	Cool steam- or heat-sterilized items before they are handled or used in the operative setting.	IB
14.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.	IB
14.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.	IA
14.e.	Completely aerate 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.	IB
14.f.	Sterilization using the peracetic acid immersion system can be used to sterilize heat-sensitive immersible medical and surgical items.	IB
14.g.	Critical items that have been sterilized by the peracetic acid immersion process must be used immediately (i.e., items are not	II

#	Recommendation	Category
	completely protected from contamination, making long-term storage unacceptable).	
14.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.	IB
14.i.	Comply with the sterilizer manufacturer's instructions regarding the sterilizer cycle parameters (e.g., time, temperature, concentration).	IB
14.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).	IB

Recommendations for Methods of sterilization: by ID number and category.

15. Packaging

#	Recommendation	Category
15.a.	Ensure that packaging materials are compatible with the sterilization process and have received FDA 510[k] clearance.	IB
15.b.	Ensure that packaging is sufficiently strong to resist punctures and tears to provide a barrier to microorganisms and moisture.	IB

Recommendations for Packaging: by ID number and category.

16. Monitoring of Sterilizers

#	Recommendation	Category
16.a.	Use mechanical, chemical, and biologic monitors to ensure the effectiveness of the sterilization process.	IB
16.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.	II
16.c.	Do not use processed items if the mechanical (e.g., time, temperature, pressure) or chemical (internal and/or external) indicators suggest inadequate processing.	IB
16.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.	IB
16.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.	II
16.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).	II
16.g.	Use biologic indicators for every load containing implantable items and quarantine items, whenever possible, until the biologic indicator is negative.	IB

Recommendations for Monitoring of sterilizers: by ID number and category.

17. Load Configuration

#	Recommendation	Category
17.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.	IB

Recommendations for Load configuration: by ID number and category.

18. Storage of Sterile Items

#	Recommendation	Category
18.a.	Ensure the sterile storage area is a well-ventilated area that provides protection against dust, moisture, insects, and temperature and humidity extremes.	II
18.b.	Store sterile items so the packaging is not compromised (e.g., punctured, bent).	II
18.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.	IB
18.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 recommendations f and g below).	IB
18.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.	II
18.f.	If the integrity of the packaging is compromised (e.g., torn, wet, or punctured), repack and reprocess the pack before use.	II
18.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.	II

Recommendations for Storage of sterile items: by ID number and category.

19. Quality Control

#	Recommendation	Category
19.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 institutional 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 manufacturers' instructions.	IB
19.b.	Compare the reprocessing instructions (e.g., for the appropriate use of endoscope connectors, the capping/noncapping of specific lumens) provided by the instrument manufacturer and the sterilizer manufacturer and resolve any conflicting recommendations by communicating with both manufacturers.	IB
19.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.	IB
19.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.	II
19.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.	II

#	Recommendation	Category
19.f.	Retain sterilization records (mechanical, chemical, and biological) for a time period that complies with standards (e.g., 3 years), statutes of limitations, and state and federal regulations.	II, IC
19.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 manufacturers of surgical instruments, sterilizers, and container systems for guidelines for the density of wrapped packages.	II
19.h.	Periodically review policies and procedures for sterilization.	II
19.i.	Perform preventive maintenance on sterilizers by qualified personnel who are guided by the manufacturer's instruction.	II

Recommendations for Quality control: by ID number and category.

20. Reuse of Single-Use Medical Devices

#	Recommendation	Category
20.a.	Adhere 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.	II, IC

Recommendations for Reuse of single-use medical devices: by ID number and category.

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