

Infection Control

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In the dental field since 1972, Leslie helps simplify complex regulations. She provides in office training, compliance audits, consulting, workshops, and mock inspections. For the 8th year in a row, she has been listed as a “Leader In Consulting” by Dentistry Today. She is authorized by the Department of Labor, The Academy of General Dentistry, and the California Dental Board to provide continuing education. Leslie is the founder of Leslie Canham and Associates, LLC.

DENTAL BOARD OF CALIFORNIA INFECTION CONTROL REGULATIONS

California Code of Regulations Title 16 §1005. Minimum Standards for Infection Control. Effective 8/20/11

(a) Definitions of terms used in this section:

- (1) "Standard precautions" are a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, in any setting in which healthcare is delivered. These include hand hygiene, use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure, and safe handling of sharps. Standard precautions shall be used for care of all patients regardless of their diagnoses or personal infectious status.
- (2) "Critical items" confer a high risk for infection if they are contaminated with any microorganism. These include all instruments, devices, and other items used to penetrate soft tissue or bone.
- (3) "Semi-critical items" are instruments, devices and other items that are not used to penetrate soft tissue or bone, but contact oral mucous membranes, non-intact skin or other potentially infectious materials (OPIM).
- (4) "Non-critical items" are instruments, devices, equipment, and surfaces that come in contact with soil, debris, saliva, blood, OPIM and intact skin, but not oral mucous membranes.
- (5) "Low-level disinfection" is the least effective disinfection process. It kills some bacteria, some viruses and fungi, but does not kill bacterial spores or mycobacterium tuberculosis var bovis, a laboratory test organism used to classify the strength of disinfectant chemicals.
- (6) "Intermediate-level disinfection" kills mycobacterium tuberculosis var bovis indicating that many human pathogens are also killed. This process does not necessarily kill spores.
- (7) "High-level disinfection" kills some, but not necessarily all, bacterial spores. This process kills mycobacterium tuberculosis var bovis, bacteria, fungi, and viruses.
- (8) "Germicide" is a chemical agent that can be used to disinfect items and surfaces based on the level of contamination.
- (9) "Sterilization" is a validated process used to render a product free of all forms of viable microorganisms.
- (10) "Cleaning" is the removal of visible soil (e.g., organic and inorganic material) debris and OPIM from objects and surfaces and shall be accomplished manually or mechanically using water with detergents or enzymatic products.
- (11) "Personal Protective Equipment" (PPE) is specialized clothing or equipment worn or used for protection against a hazard. PPE items may include, but are not limited to, gloves, masks, respiratory devices, protective eyewear and protective attire which are intended to prevent exposure to blood, body fluids and OPIM, and chemicals used for infection control. General work attire such as uniforms, scrubs, pants and shirts, are not considered to be PPE.
- (12) "Other Potentially Infectious Materials" (OPIM) means any one of the following:
 - (A) Human body fluids such as saliva in dental procedures and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
 - (B) Any unfixed tissue or organ (other than intact skin) from a human (living or dead);
 - (C) Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV:
 - (i) Cell, tissue, or organ cultures from humans or experimental animals;
 - (ii) Blood, organs, or other tissues from experimental animals; or
 - (iii) Culture medium or other solutions.
- (13) "Dental Healthcare Personnel" (DHCP) are all paid and non-paid 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 includes 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).

(b) All DHCP shall comply with infection control precautions and enforce the following minimum precautions to minimize the transmission of pathogens in health care settings mandated by the California Division of Occupational Safety and Health (Cal/OSHA).

- (1) Standard precautions shall be practiced in the care of all patients.
- (2) A written protocol shall be developed, maintained, and periodically updated for proper instrument processing, operatory cleanliness, and management of injuries. The protocol shall be made available to all DHCP at the dental office.
- (3) A copy of this regulation shall be conspicuously posted in each dental office.

Personal Protective Equipment:

- (4) All DHCP shall wear surgical facemasks in combination with either chin length plastic face shields or protective eyewear whenever there is potential for aerosol spray, splashing or spattering of the following: droplet nuclei, blood, chemical or germicidal agents or OPIM. Chemical-resistant utility gloves and appropriate, task specific PPE shall be worn when handling hazardous chemicals. After each patient treatment masks shall be changed and disposed. After each patient treatment, face shields and protective eyewear shall be cleaned, disinfected, or disposed.
- (5) Protective attire shall be worn for disinfection, sterilization, and housekeeping procedures involving the use of germicides or handling contaminated items. All DHCP shall wear reusable or disposable protective attire whenever there is a potential for aerosol spray, splashing or spattering of blood, OPIM, or chemicals and germicidal agents. Protective attire must be changed daily or between patients if they should become moist or visibly soiled. All PPE used during patient care shall be removed when leaving laboratories or areas of patient care activities. Reusable gowns shall be laundered in accordance with Cal/OSHA Bloodborne Pathogens Standards (Title 8, Cal. Code Regs., section 5193).

Hand Hygiene:

- (6) All DHCP shall thoroughly wash their hands with soap and water at the start and end of each workday. DHCP shall wash contaminated or visibly soiled hands with soap and water and put on new gloves before treating each patient. If hands are not visibly soiled or contaminated an alcohol based hand rub may be used as an alternative to soap and water. Hands shall be thoroughly dried before donning gloves in order to prevent promotion of bacterial growth and washed again immediately after glove removal. A DHCP shall refrain from direct patient care if conditions are present that may render the DHCP or patients more susceptible to opportunistic infection or exposure.
- (7) All DHCP who have exudative lesions or weeping dermatitis of the hand shall refrain from all direct patient care and from handling patient care equipment until the condition resolves.

- Live Seminars
- Live Webinars
- Home Study

Gloves:

- (8) Medical exam gloves shall be worn whenever there is contact with mucous membranes, blood, OPIM, and during all pre-clinical, clinical, post-clinical, and laboratory procedures. When processing contaminated sharp instruments, needles, and devices, DHCP shall wear heavy-duty utility gloves to prevent puncture wounds. Gloves must be discarded when torn or punctured, upon completion of treatment, and before leaving laboratories or areas of patient care activities. All DHCP shall perform hand hygiene procedures before donning gloves and after removing and discarding gloves. Gloves shall not be washed before or after use.

Needle and Sharps Safety:

- (9) Needles shall be recapped only by using the scoop technique or a protective device. Needles shall not be bent or broken for the purpose of disposal. Disposable needles, syringes, scalpel blades, or other sharp items and instruments shall be placed into sharps containers for disposal as close as possible to the point of use according to all applicable local, state, and federal regulations.

Sterilization and Disinfection:

- (10) All germicides must be used in accordance with intended use and label instructions.
- (11) Cleaning must precede any disinfection or sterilization process. Products used to clean items or surfaces prior to disinfection procedures shall be used according to all label instructions.
- (12) Critical instruments, items and devices shall be discarded or pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization shall include steam under pressure (autoclaving), chemical vapor, and dry heat. If a critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection and packaged or wrapped upon completion of the disinfection process. These instruments, items, and devices, shall remain sealed and stored in a manner so as to prevent contamination, and shall be labeled with the date of sterilization and the specific sterilizer used if more than one sterilizer is utilized in the facility.
- (13) Semi-critical instruments, items, and devices shall be pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization include steam under pressure (autoclaving), chemical vapor and dry heat. If a semi-critical item is heat sensitive, it shall, at minimum, be processed with high level disinfection and packaged or wrapped upon completion of the disinfection process. These packages or containers shall remain sealed and shall be stored in a manner so as to prevent contamination, and shall be labeled with the date of sterilization and the specific sterilizer used if more than one sterilizer is utilized in the facility.
- (14) Non-critical surfaces and patient care items shall be cleaned and disinfected with a California Environmental Protection Agency (Cal/EPA)-registered hospital-grade disinfectant (low-level disinfectant) labeled effective against HBV and HIV. When the item is visibly contaminated with blood or OPIM, a Cal/EPA-registered hospital-grade intermediate-level disinfectant with a tuberculocidal claim shall be used.
- (15) All high-speed dental hand pieces, low-speed hand pieces, rotary components and dental unit attachments such as reusable air/water syringe tips and ultrasonic scaler tips, shall be packaged, labeled and heat-sterilized in a manner consistent with the same sterilization practices as a semi-critical item.
- (16) Single use disposable items such as prophylaxis angles, prophylaxis cups and brushes, tips for high-speed evacuators, saliva ejectors, air/water syringe tips, and gloves shall be used for one patient only and discarded.
- (17) Proper functioning of the sterilization cycle of all sterilization devices shall be verified at least weekly through the use of a biological indicator (such as a spore test). Test results shall be documented and maintained for 12 months.

Irrigation:

- (18) Sterile coolants/irrigants shall be used for surgical procedures involving soft tissue or bone. Sterile coolants/irrigants must be delivered using a sterile delivery system.

Facilities:

- (19) If non-critical items or surfaces likely to be contaminated are manufactured in a manner preventing cleaning and disinfection they shall be protected with disposable impervious barriers. Disposable barriers shall be changed when visibly soiled or damaged and between patients.
- (20) Clean and disinfect all clinical contact surfaces that are not protected by impervious barriers using a California Environmental Protection Agency (Cal-EPA) registered, hospital-grade low- to intermediate-level disinfectant after each patient. The low-level disinfectants used shall be labeled effective against HBV and HIV. Use disinfectants in accordance with the manufacturer's instructions. Clean all housekeeping surfaces (e.g. floors, walls, sinks) with a detergent and water or a Cal-EPA registered, hospital-grade disinfectant. Products used to clean items or surfaces prior to disinfection procedures shall be clearly labeled and follow all material safety data sheet (MSDS) handling and storage instructions.
- (21) Dental unit water lines shall be anti-retractable. At the beginning of each workday, dental unit lines and devices shall be purged with air or flushed with water for at least two (2) minutes prior to attaching handpieces, scalers, air water syringe tips, or other devices. The dental unit lines and devices shall be flushed between each patient for a minimum of twenty (20) seconds.
- (22) Contaminated solid waste shall be disposed of according to applicable local, state, and federal environmental standards.

Lab Areas:

- (23) Splash shields and equipment guards shall be used on dental laboratory lathes. Fresh pumice and a sterilized or new ragwheel shall be used for each patient. Devices used to polish, trim, or adjust contaminated intraoral devices shall be disinfected or sterilized, properly packaged or wrapped and labeled with the date and the specific sterilizer used if more than one sterilizer is utilized in the facility. If packaging is compromised, the instruments shall be re-cleaned, packaged in new wrap, and sterilized again. Sterilized items will be stored in a manner so as to prevent contamination.
- (24) All intraoral items such as impressions, bite registrations, prosthetic and orthodontic appliances shall be cleaned and disinfected with an intermediate-level disinfectant before manipulation in the laboratory and before placement in the patient's mouth. Such items shall be thoroughly rinsed prior to placement in the patient's mouth.

- (c) The Dental Board of California and Dental Hygiene Committee of California shall review this regulation annually and establish a consensus.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Section 1680, Business and Professions Code.

- In Office Training
- 8 Hour Infection Control Course for Unlicensed Dental Assistants
- Mock OSHA Inspections

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Infection Prevention Checklist

Section II: Direct Observation of Personnel and Patient-Care Practices

II.1 Hand Hygiene is Performed Correctly

Facility name:.....
Completed by:.....
Date:.....

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. When hands are visibly soiled	<input type="checkbox"/> Yes <input type="checkbox"/> No	
B. After barehanded touching of instruments, equipment, materials and other objects likely to be contaminated by blood, saliva, or respiratory secretions	<input type="checkbox"/> Yes <input type="checkbox"/> No	
C. Before and after treating each patient	<input type="checkbox"/> Yes <input type="checkbox"/> No	
D. Before putting on gloves	<input type="checkbox"/> Yes <input type="checkbox"/> No	
E. Immediately after removing gloves	<input type="checkbox"/> Yes <input type="checkbox"/> No	
F. Surgical hand scrub is performed before putting on sterile surgeon's gloves for all surgical procedures	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Note: <i>Examples of surgical procedures include biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth.</i>		

II.2 Personal Protective Equipment (PPE) is Used Correctly

Elements To Be Assessed	Assessment	Notes/Areas For Improvement
A. PPE is removed before leaving the work area (e.g., dental patient care, instrument processing, or laboratory areas)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
B. Hand hygiene is performed immediately after removal of PPE	<input type="checkbox"/> Yes <input type="checkbox"/> No	
C. Masks, Protective Eyewear, and Face Shields		
a. DHCP wear surgical masks during procedures that are likely to generate splashes or sprays of blood or other body fluids	<input type="checkbox"/> Yes <input type="checkbox"/> No	
b. DHCP wear eye protection with solid side shields or a face shield during procedures that are likely to generate splashes or sprays of blood or other body fluids	<input type="checkbox"/> Yes <input type="checkbox"/> No	
c. DHCP change masks between patients and during patient treatment if the mask becomes wet	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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CDC Statement on Reprocessing Dental Handpieces

April 11, 2018

CDC recognizes that the dental community requires clear, consistent guidelines on the best way to reprocess dental handpiece devices between patient encounters. CDC guidelines for infection prevention and control state that, between patients, dental health care personnel (DHCP) should clean and heat-sterilize handpieces and other intraoral instruments that can be removed from the air and waterlines of dental units.¹ This recommendation is based on studies that have shown that the internal components of air-driven dental handpieces (both low-speed and high-speed devices) can become contaminated with patient material during use, and this material can then be expelled into the mouth of other patients during subsequent uses.²⁻⁵ For handpieces and other intraoral instruments that can be removed from the air and waterlines of dental units, CDC continues to recommend that DHCP follow CDC guidelines to clean and heat sterilize.

Dental handpieces are medical devices regulated by the US Food and Drug Administration (FDA). Some handpieces are independent of air and waterlines (e.g., cordless devices). For these devices, CDC recommends that DHCP follow current FDA regulations. DHCP should use FDA-cleared devices⁶ and follow the validated manufacturer's instructions for use for reprocessing (cleaning, lubricating, and/or sterilizing) these devices.⁷

In 2015, FDA released [updated guidance for reprocessing medical devices in health care settings](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf) [PDF - 805KB] (<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf>). This guidance gives manufacturers of reusable medical devices recommendations on how to write and scientifically validate reprocessing instructions. Reusable devices that received FDA clearance before 2015 might not have reprocessing instructions that meet the requirements of the 2015 guidance. According to FDA, "reprocessing instructions for some older, legally-marketed, reusable devices may not be consistent with state-of-the-art science and therefore may not ensure that device is clean, disinfected, or sterile." It is incumbent upon the device manufacturer to provide sufficient instructions on how to prepare devices for use on the next patient.

If a dental handpiece cannot be heat sterilized and does not have FDA clearance with validated instructions for reprocessing, DHCP should not use that device.⁷ If DHCP are concerned about the validity of the manufacturer's instructions for reprocessing or believe that the instructions are not consistent with basic infection prevention and control principles, they should contact the manufacturer to request documentation of FDA clearance. If the manufacturer is not able to provide sufficient information, DHCP can contact FDA's Office of Compliance at OCMedicalDeviceCo@fda.hhs.gov (OCMedicalDeviceCo@fda.hhs.gov) or (240) 402-7675 for assistance.

In Summary

1. Clean and heat sterilize handpieces and other intraoral instruments that can be removed from the air lines and waterlines of dental units.

2. For handpieces that do not attach to air lines and waterlines, use FDA-cleared devices and follow the validated manufacturer's instructions for reprocessing these devices.
3. If a dental handpiece cannot be heat sterilized and does not have FDA clearance with validated instructions for reprocessing, do not use that device.

References

1. Centers for Disease Control and Prevention. Guidelines for infection control in dental health-care settings—2003 [PDF - 1.25 MB] (<https://www.cdc.gov/mmwr/PDF/rr/rr5217.pdf>). *MMWR Recomm Rep*. 2003;52(RR-17):1–61.
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6. US Food and Drug Administration. 510(k) Premarket Notifications (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>) . Accessed March 28, 2018.
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Infection Control Guidelines
MMWR Report
[http://www.cdc.gov/oralhealth/
InfectionControl/guidelines/index.htm](http://www.cdc.gov/oralhealth/InfectionControl/guidelines/index.htm)

Guideline for Disinfection and Sterilization
in Healthcare Facilities, 2008
http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

Centers for Disease Control
U.S. Dept. Of Health & Human Services-
Voice Information Services
404-332-4565
www.cdc.gov

American Dental Association
1-800-621-8099
www.ada.org

California Dental Association
800-736-8702
OSHA "Regulatory Compliance Manual"
www.cda.org

Dental Board of California
916-263-2300
www.dbc.ca.gov

Dental Hygiene Board Of Calif
916-263-2595
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Organization for Safety, Asepsis and
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BOOK "From Policy To Practice"

California Dept. of Health Services
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Website for Hepatitis Information
www.hepatitisneighborhood.com

U.S. Air Force Dental Evaluation and
Consultation Services (formerly USAF
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decs.nhgl.med.navy.mil

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