

**TITLE 16. DENTAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS**

MODIFIED TEXT

Changes to the originally proposed language are shown by double underline for new text and double strikeout for deleted text.

Amend Section 1005 of Division 10 of Title 16 of the California Code of Regulations, to read as follows:

ARTICLE 1. GENERAL PROVISIONS

§ 1005. Minimum Standards for Infection Control

(a) Definitions of terms used in this section:

(1) "Standard precautions" ~~is~~ are a set of combined precautions that include the major components of universal precautions (designed to reduce the risk of transmission of blood-borne pathogens) and body substance isolation (designed to reduce the risk of transmission of pathogens from moist body substances). Include 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~~injection practices. Similar to universal precautions, Standard precautions are~~ shall be used for care of all patients regardless of their diagnoses ~~of~~ or personal infectious status.

(2) "Critical ~~instruments-items~~" confer a high risk for infection if they are contaminated with any microorganism. These include all instruments, are surgical devices, and other instruments-items used to penetrate soft tissue or bone.

(3) "Semi-critical ~~instruments-items~~" are surgical instruments, devices and other instruments-items that are not used to penetrate soft tissue or bone, but contact oral tissue-mucous membranes, non-intact skin or other potentially infectious materials (OPIM).

(4) "Non-critical ~~instruments-items and devices~~" are instruments, and 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 but 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. ~~All germicides must be used in accordance with intended use and label instructions.~~

(9) "Sterilization" ~~kills all forms of microbial life.~~ 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. ~~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.~~

~~(10)~~(11) "Personal Protective Equipment" (PPE) is specialized clothing or equipment worn or used for protection against a hazard. PPE includes items may include, but are not limited to, such as gloves, masks, respiratory devices, protective eyewear and protective attire (shoes, gowns/labcoats) which are intended to prevent exposure to blood, and 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.

~~(11)~~(12) "Other Potentially Infectious Materials" (OPIM) means any one of the following:

(A) ~~H~~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) ~~A~~any unfixed tissue or organ (other than intact skin) from a human (living or dead);

~~(C) Human Immunodeficiency Virus (HIV) containing cell or tissue cultures, organ culture and blood, or other tissues from experimental animals~~ 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 Licensees 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-~~DOSH~~Cal/OSHA).

~~(c) All licensees shall comply with and enforce the following minimum precautions to minimize the transmission of pathogens in health care settings:~~

~~(1) Standard precautions shall be practiced in the care of all patients.~~

~~(2) A written protocol shall be developed, by the licensee 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 Health care workers DHCP shall wear surgical facemasks in combination with either chin length plastic face shields or protective eyewear when treating patients 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. Puncture-resistant utility gloves and other PPE shall be worn when handling hazardous chemicals. After each patient, and during patient treatment if applicable, masks shall be changed and disposed, if moist or contaminated. After each patient, treatment, and face shields and protective eyewear shall be cleaned, and disinfected, if contaminated or disposed.~~

~~(5) Gowns Protective attire shall be worn for disinfection, sterilization, and housekeeping procedures involving the use of germicides or handling contaminated items. All Health care workers 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. their clothing or skin is likely to be soiled with blood or OPIM. Gowns Protective attire must be changed daily or between patients if it they should become moist or visibly soiled. Protective attire All PPE used during patient care must shall be removed when leaving laboratories or areas of patient care activities.~~

Reusable gowns shall be laundered in accordance with ~~Cal DOSH~~ Cal/OSHA Bloodborne Pathogens Standards (Title 8, Cal. Code Regs., section 5193).

Hand Hygiene:

(6) ~~All Health care workers~~ 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. CDC Guidelines shall be followed for work restrictions. 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 Health care workers~~ 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.

Gloves:

(8) ~~Medical exam gloves shall be worn whenever there is a potential for contact with mucous membranes, blood, or OPIM, or germicidal agents and during all pre-clinical, clinical, post-clinical, and laboratory procedures. When cleaning 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 Healthcare workers 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.

~~(9)(10)(12)~~ Heat stable eCritical and semi-critical instruments, items and devices shall be discarded or pre-cleaned, packaged or wrapped and sterilized after each use. Methods of sterilization shall include shall be cleaned and sterilized before use by using steam under pressure (autoclaving), dry heat, or chemical (formaldehyde) 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, in the form of package or being wrapped before sterilization if they are not to be used immediately after being sterilized. 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. FDA cleared chemical sterilants/disinfectants shall be used for sterilization of heat sensitive critical items and for high level disinfection of heat sensitive semi-critical items.

~~(10)(11)(13)~~ Critical and sSemi-critical instruments or containers of critical and semi-critical instruments instruments, items, and devices shall be pre-cleaned, packaged or wrapped and sterilized after each use. by a heat or vapor mMethods 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. Shall be packaged or wrapped in the form of package or being wrapped before sterilization. Before sterilization if they are not to be used immediately after being sterilized. These packages or containers shall remain sealed unless the instruments within them are placed onto a setup tray and covered with a moisture impervious barrier on the day the instruments will be used 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.

~~(12)(14)~~ Non-critical surfaces and patient care items shall be cleaned and disinfected with an United States Environmental Protection Agency (EPA) California Environmental Protection Agency (Cal/EPA)-registered hospital disinfectant (low-level disinfectant) labeled effective against HBV and HIV. When the item is visibly contaminated with blood or OPIM, an Cal/EPA-registered hospital intermediate-level disinfectant with a tuberculocidal claim (intermediate-level disinfectant) shall be used.

~~(11)(13)(15)~~ All high-speed dental hand pieces, low-speed hand pieces, rotary components used intraorally, and other dental unit attachments such as reusable air/water syringe tips and ultrasonic scaler tips, shall be packaged, labeled and heat-sterilized between patients in a manner consistent with the same sterilization practices as a semi-critical instrument or item.

~~(12)(14)~~(16) Single use disposable instruments items such as (e.g. 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.

~~(13)~~ 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 according to all applicable regulations.

~~(14)(15)~~(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 testing monitor). Test results must shall be documented and maintained for 12 months.

Irrigation:

~~(15)(16)~~(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:

~~(16)(17)~~(19) If non-critical items or surfaces likely to be contaminated are difficult manufactured in a manner preventing cleaning and disinfection, to clean and disinfect they shall be protected with disposable impervious barriers. Disposable barriers shall be changed when visibly soiled or damaged and between patients. 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.

~~(17)(18)~~(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.

~~(18)(19)~~(21) Dental unit water lines shall be anti-retractive. 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, and or other devices. The dental unit lines and devices shall be flushed between each patient for a minimum of twenty (20) seconds.

~~(19)(20)~~(22) Contaminated solid waste shall be disposed of according to applicable local, state, and federal environmental standards.

Lab Areas:

~~(20)(21)(23)~~ Splash shields and equipment guards shall be used on dental laboratory lathes. Fresh pumice and a ~~disinfected, sterilized,~~ or new rag-wheel 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 recleaned, packaged in new wrap, and sterilized again. Sterilized items will be and stored in a manner so as to prevent contamination.

~~(21)(22)(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.

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

[1] Cal/EPA contacts: WEBSITE www.cdpr.ca.gov or Main Information Center (916) 324-0419.

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