STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

STATE AND CONSUMER SERVICES AGENCY • ARNOLD SCHWARZENEGGER, GOVERNOR

Dental Hygiene Committee of California
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MEMORANDUM	
DATE	June 8, 2010
TO	DHCC Committee Members
FROM	Lori Hubble, Executive Officer Dental Hygiene Committee of California
SUBJECT	**AGENDA ITEM 6 –** Proposed Dental Board of California Regulations – California Code of Regulations §1005 – Infection Control

Background

Title 16, CCR Section 1005 (d). Infection Control Regulations requires an annual review by the Dental Board of California. Due to numerous administrative staff changes, including several executive officers and the Board's sunset to a bureau in July 2008, the regulations had not been updated since 2005. The following is a chronological review as related to DHCC:

DATE	EVENT	ACTION
February 26, 2010	DBC Meeting in San Diego	• DBC votes to accept proposed infection control regulatory language recommended by the ad hoc committee chaired by Dr. Huong Le, DBC member. • DB staff directed to notice regulations for hearing in order to expedite the hearing process
March 22, 2010	DHCC Meeting in Ontario	• DHCC considers accepting DBC's proposed regulatory language for Infection Control. • DHCC considers possibility that DBC inadvertently accepted and recommended incomplete language for hearing due to the original time frame and staff turnover since 2005. • DHCC considers offering its own recommendations before the regulatory language is noticed for hearing • DHCC determines that DHCC's and DB's Legal Counsel would meet to review the current regulations and, if necessary, inform DHCC of any language discrepancies in order that a letter could be sent to DBC requesting proper notice. • DHCC President, Lee appoints a two member ad hoc committee, Cathy DiFrancesco and Miriam DeLaRoi to review DB's proposed infection control regulations, Caldosh regulations and CDC guideline regarding minimum infection control standards.
April 11, 2010	DCA Headquarters	• Discovery of Dental Practice Act Section 1680 (ad) requiring DHCC and DB to review the infection control regulations and establish consensus. "The board shall review infection control guidelines, if necessary, on an annual basis and proposed changes shall be reviewed by the Dental Hygiene Committee of California to establish a

		consensus. The committee shall submit any recommended changes to the infection control guidelines for review to establish a consensus."
April 12, 2010	DCA Headquarters	• Executive Officers, Lori Hubble, DHCC and Richard DeCuir, DB , Legal Counsel for DHCC and Legal Counsel for DB discussed concerns regarding initiation of the rulemaking process prior to providing the opportunity for DHCC input. • It is decided that if DHCC agrees to a special meeting prior to DB's next scheduled meeting on July 26th, then Mr. DeCuir is to speak with DB President, John Bettinger, DDS to notice the proposed regulations after the July Board meeting to allow a review of the Committee's input at the Board's July meeting. • DHCC President, Lee agrees to hold a special meeting on June 8, 2010 to discuss the Committee's input.
May 6, 2010	DB Meeting in South San Francisco	• During its Activities Updates, Agenda Item #6, DHCC provides highlighted copies of B & P Section 1680 (ad) for DB members, as no references were provided for Agenda Item #10 regarding the requirement for the DB & DHCC to reach consensus on infection control regulations. • The Board approves the corrected text for notice of the proposed infection control regulations. • DB members question the reconsideration for input and EO Lori Hubble relates the discussion occurring on April 12th. • The Board votes to reconsider its action to initiate the rulemaking process so that the Board can receive input from DHCC prior to noticing the proposed amendments, as mandated by statute 1680 (ad). The Board will review DHCC's recommendations at its July 26, 2010 meeting. • DB President, Bettinger thanks DHCC for holding a special meeting.
June 8, 2010	DHCC Teleconference	• DHCC to discuss and accept proposed regulatory language for infection control standards prepared by members DiFrancesco and DeLaRoi. • DHCC input to be sent to DB for July 26th 2010 meeting in Sacramento. • DHCC to discuss and consider Executive Officer and President to act on its behalf, if consensus is not reached between DHCC and DB.

Attached are the proposed regulations with the accompanying rationale. Please review and be prepared to provide your comments.

MEMORANDUM	
DATE	June 8, 2010
TO	DHCC Committee Members
FROM	Members Miriam DeLaRoi, RDHAP and Cathy DiFrancesco, RDH Dental Hygiene Committee of California
SUBJECT	**AGENDA ITEM 6 –** Proposed Dental Board of California Regulations California Code of Regulations **§**1005 – Infection Control

Our combined proposed amendments and the stated rationale for the proposed changes are as follows. As requested by the DHCC Ad-Hoc Committee, we have highlighted and double underlined our proposed language.

For your reference:

DHCC proposed language-teal highlighted areas and red stated rationale

CDHA proposed language-yellow highlighted language with blue stated rationale

CADAT proposals-gray highlighted areas and olive stated rationale

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TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS
DIVISION 10. DENTAL BOARD OF CALIFORNIA
CHAPTER 1. GENERAL PROVISIONS APPLICABLE TO ALL LICENSEES
ARTICLE 1. GENERAL PROVISIONS

Section 1005. Minimum Standards for Infection Control

(a) Definitions of terms used in this section:

(1) "Standard precautions" ~~is 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 injection practices. ~~Similar to universal precautions,~~ S~~s~~tandard precautions ~~are~~ shall be used for care of all patients regardless of their diagnoses ~~of~~ or personal infectious status.

(2) CDC Rationale: 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.

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

CADAT Rationale: Consistency with use of terms throughout document.

(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, ~~or~~ nonintact skin or other potentially infectious materials (OPIM).

DHCC Rationale: Reference to OPIM may be a more contemporary term to describe potential contaminates in this area.

CADAT Rationale: The term "nonintact skin" has become an antiquated term that is not generally used as a standard within the educational setting. We believe the reference to OPIM may be a more contemporary term to describe potential contaminates in this area.

(4) "Non-critical ~~instruments~~ items ~~and devices~~" are instruments, ~~and~~ devices ,equipment, and ~~other items~~surfaces that come in contact with soil, debris, saliva, blood, other infectious potentially materials OPIM and intact skin, but not oral mucous membranes.

DHCC Rationale: (a) Adding these suggested words keeps the text consistent and in agreement with CDC guidelines; (b) The addition of "equipment" addresses those extraoral items contaminated indirectly during clinical procedures; (c) The inclusion of the term "oral" to describe mucous membranes is consistent with the definition stated in the above section (3).

CDC Rationale: 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.

(5) "Low-level disinfection" is the least effective disinfection process, kills some bacteria, 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, 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), ~~and~~ debris and other potentially infectious material (OPIM) from objects and surfaces and ~~normally is~~ shall be accomplished manually or mechanically using water with detergents or enzymatic products. ~~Meticulous~~ Cleaning must precede any ~~high-level~~ disinfection or sterilization process. Products used to clean items or surfaces prior to disinfection procedures shall be used according to all label instructions.

CDC Rationale: 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 in Appendix A of CDC guidelines).

CDC Rationale: Cleaning: 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*).

CADAT Rationale: a) The term "visible soil" and the stated example suggests that cleaning is only necessary when contamination is visible which is not the case when contamination by saliva is present. Our proposed language allows for contamination that is seen as well as unseen (OPIM) as defined in this section (12); b) The term "normally" suggests personnel may choose a less than normal alternative to the process of cleaning; c) The term "meticulous" is subject to interpretation and may be difficult to define and defend during an inspection process; and d) In accordance with the Cal-EPA standards for use of disinfection products as defined in this section (8), the pre-cleaning of surfaces prior to the use of a germicidal disinfectant may not be isolated to high-level products only.

~~(10)~~(11) "Personal Protective Equipment" (PPE) is specialized clothing or equipment for protection against a hazard. PPE i~~I~~ncludes items 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 other potentially infectious materials (OPIM). General work attire, such as uniforms, scrubs, pants and shirts, are not considered to be PPE.

DHCC Rationale: PPE is used throughout this text and should be defined. OSHA 1910.132(a) specifies that PPE includes protective equipment for extremities (feet, hands). With the rise in respiratory diseases and infections (e.g., Tuberculosis, H1N1 (swine flu) and Avian influenza

(bird flu)), it is imperative to consider these and other potentially contagious microbes now and for the unknown future.

OSHA **1910.132(a)**

Application. Protective equipment, including personal protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers, shall be provided, used, and maintained in a sanitary and reliable condition wherever it is necessary by reason of hazards of processes or environment, chemical hazards, radiological hazards, or mechanical irritants encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation or physical contact.

OSHA 1910.132(b)

Employee-owned equipment. Where employees provide their own protective equipment, the employer shall be responsible to assure its adequacy, including proper maintenance, and sanitation of such equipment.

Rationale from CDC: 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.

CADAT Rationale: The acronym “PPE” is a standardized term used educationally and within the profession; allows for ease of reference in other areas of this regulation.

~~(11)~~(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) HIV-containing cell or tissue cultures, organ culture and blood, or other tissues from experimental animals.

(13) “Dental Healthcare Professionals,” as defined by the Centers for Disease Control (CDC), are “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 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).”

DHCC Rationale: Adding this definition and acronym keeps the text current and in agreement with CDC guidelines.

(b) All ~~ll icensees~~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-DOSH).

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

DHCC Rational: it is recommended to add the information from (c) to (b).

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

(2) A written protocol shall be developed, ~~by the licensee~~maintained, and changes periodically updated for proper instrument processing, operatory cleanliness, and management of injuries.

DHCC Rationale: A dental facility may choose to utilize professional organizations or contractors to assist in meeting the written protocol requirement; therefore, removing "licensee" allows for other options, if or when needed.

(3) A copy of this regulation shall be conspicuously posted in each dental office.

CADAT Rationale: a) We suggest moving subsections (1) – (3) above to attend section (b) rather than section (c) for clarity and more consistent reference to policies defined by Cal-DOSH for protocols and procedures; b) Given that written protocols may change within a dental facility based on changes in equipment, products, and procedures, we recommend adding a maintenance provision to address currency of all written protocols; and c) the dental facility may choose to utilize professional organizations or contractors to help meet the written protocol requirement; therefore, we recommend removing the "licensee" as referenced.

Personal Protective Equipment:

(4) All h~~H~~ealth care personnel~~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 droplet nuclei, blood, chemical and germicidal agents and/or OPIM. Puncture-resistant utility gloves and other PPE shall be worn when handling hazardous chemicals. ~~-~~and ~~A~~after each patient and during patient treatment if applicable, masks shall be changed if moist or contaminated. After each patient, face shields and protective eyewear shall be cleaned and disinfected~~, if contaminated~~.

DHCC Rationale: Adding the words "aerosol spray and droplet nuclei" keeps the text current with guidelines defined by the CDC and the use of standard precautions. It is recommended to remove the words "if contaminated" in order to remove leeway for assumption.

CDC Rationale: 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.

CADAT Rationale: Existing language does not address the use of PPE such as facemasks for use during procedures involving hazards other than blood or OPIM. Masks and protective eyewear should be worn for disinfection, sterilization and housekeeping procedures involving the use of germicides or handling contaminated items.

(5) Gowns shall be worn for disinfection, sterilization, and housekeeping procedures involving the use of germicides or handling contaminated items. All ~~hHealth care personnelworkers~~DHCP shall wear reusable or disposable protective attire whenever there is a potential for aerosol spray, splashing or splattering of blood, ~~or~~ OPIM, chemicals and germicidal agents. ~~their clothing or skin is likely to be soiled with blood or OPIM~~. Gowns must be changed daily or between patients if ~~it~~ they should become moist or visibly soiled. Protective attire must be removed when leaving laboratories or areas of patient care activities. Reusable gowns shall be laundered in accordance with Cal-DOSH Bloodborne Pathogens Standards~~.~~ (Title 8, Cal. Code Regs., section 5193). All PPE used during patient-care shall be removed before DHCP leave patient-care areas.

DHCC Rationale: Adding the purpose of wearing gowns to the beginning of (2) lends itself to complete understanding and importance.

DHCC Rationale: Adding the Sentence, "All PPE used during patient-care shall be removed before DHCP leave patient-care areas," makes the text current and in agreement with CDC guidelines.

CDC Rationale: 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.

CADAT Rationale: Existing language does not address the use of PPE such as gowns for use during procedures involving hazards other than blood or OPIM. Gowns should be worn for disinfection, sterilization and housekeeping procedures involving the use of germicides or handling contaminated items.

Hand Hygiene:

(6) All ~~hHealth care personnelworkers~~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.

CDC Rationale: Gloves and Gloving
Wearing gloves does not eliminate the need for hand washing. 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.

CDHA Rationale: Many exudative lesions require DHCP to stay out of the work environment completely. The CDC also gives the guidelines of what other diseases require you to stay out of work. (MMWR 2003 report page 8&9 CDC)

(7) All ~~hHealth care personnelworkers~~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 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 ~~hHealth care personnelworkers~~DHCP shall perform hand hygiene procedures before donning gloves and after removing and discarding gloves. Gloves shall not be washed before or after use.

CDC Rationale: To avoid injury from sharp instruments, DHCP should wear puncture-resistant, heavy-duty **u**tility gloves when handling or manually cleaning contaminated instruments and devices

CDC Rationale: Wearing gloves does not eliminate the need for hand washing. 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.

CDC Rationale: 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.

CADAT Rationale: a) The term "potential for" has allowed healthcare personnel to believe they can choose to wear or not wear gloves based on their interpretation of "potential harm"; b) We believe the proposed amendments call for more clearly defined parameters as to the circumstances under which gloves must be worn; included are those procedures such as pre-clinical set-up of sterilized instruments, all clinical contact procedures, post clinical operatory disinfection procedures, and manipulation of contaminated items in a laboratory; c) Unless more clearly defined language exists, as proposed, operators will continue to remove and re-use gloves for the same patient.

(9) Sterile surgeon's gloves shall be worn when performing oral surgical procedures.

CDC Rationale: 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.

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).

Needle and Sharps Safety:

(10) 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 and according to all applicable local, state, and federal regulations.

CDC Rationale: 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.

Sterilization and Disinfection:

~~(9)~~(11) ~~Heat stable c~~Critical ~~and semi critical~~ instruments, items and devices shall be pre-cleaned, packaged or wrapped and sterilized after each use or discarded. 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 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, ~~unless used immediately~~, shall remain~~ed~~ sealed and stored in a manner so as to prevent contamination. ~~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.~~

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

CADAT Rationale: a) We suggest reiterating the pre-cleaning process for instruments prior to sterilization procedures for consistency and clarity; b) The proposed language regarding packaging and wrapping of instruments is not clear and appears to have been erroneously merged with language pertaining to high-level disinfection. We propose including the term "shall" and itemize the three qualified devices for sterilization processes; c) The term "should, at minimum" suggests the operator may choose not to perform the process of high-level disinfection; and d) We do not believe patient safety is preserved to allow a critical item, likely surgical in nature, to be processed or used without pre-packaging or wrapping regardless of the timeliness in which it will be used; therefore, we recommend removal of language regarding "immediate use" for critical items.

~~(10)~~(12) ~~Critical and s~~Semi-critical ~~instruments or containers of critical and semi critical instruments~~ items ~~should be~~shall be pre-cleaned, packaged or wrapped and sterilized after each use. ~~by a heat or vapor m~~Methods of sterilization include steam under pressure, chemical vapor and dry heat. If a semi-critical item is heat sensitive, it ~~should be~~shall, at minimum, be processed with high level disinfection ~~shall be packaged or wrapped~~ in the form of package or being wrapped before sterilization, ~~if they are not to be used immediately.~~ ~~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.

CADAT Rationale: a) We suggest reiterating the pre-cleaning process for instruments prior to sterilization procedures for consistency and clarity; b) The proposed language regarding packaging and wrapping of instruments is not clear and appears to have been erroneously merged with language pertaining to high-level disinfection. We propose including the term "shall" and itemize the three qualified devices for sterilization processes; c) The term "should, at minimum" suggests the proposed operator may choose not to perform the process of high-level disinfection; and d) For the purposes of clarity, enforceability and educational understanding, we ask that the Board define the term "immediate" or remove it from the regulatory language.

(13) Non-critical surfaces and patient-care items shall be cleaned and disinfected with an EPA-registered hospital disinfectant (low-level disinfectant) labeled effective against HBV and HIV. When the item is visibly contaminated with blood or OPIM, an EPA-registered hospital disinfectant with a tuberculocidal claim (intermediate-level disinfectant) shall be used.

Rationale from CDC: 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.

CADAT Rationale: Dental healthcare workers have not received regulatory direction as to the proper handling of non-critical items. The proposed addition addresses the category of devices used in dentistry as defined in section (a)(4) of this regulation and is consistent with language in the "facilities" section of the regulation.

~~(11)~~(14) All high-speed dental hand pieces, low-speed hand piece, rotary components ~~used intraorally,~~ and ~~other~~ dental unit attachments such as reusable air/water syringe tips and ultrasonic scaler tips, shall be packaged and heat-sterilized ~~between patients.~~ in a manner consistent with the same sterilization practices as a semi-critical instrument or item.

~~(12)~~(15) 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.

CADAT Rationale: a) We suggest the broader language of "items" rather than instruments to allow for a variety of disposable references; and b) certain PPE have not been adequately defined as "single-use" and the proposed language provides the necessary clarity.

~~(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 as close as possible to the point of use and according to all applicable regulations.~~

DHCC Rationale: Moved prior to sterilization and disinfection for ease of use and reference.

~~(14)~~(16) 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 be documented and maintained for 12 months.
Irrigation:

~~(15)~~(17) 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)~~(18) If non-critical items or surfaces likely to be contaminated are ~~difficult~~ engineered 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 ~~routinely~~ 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***.

DHCC Rationale: Using the word "routinely" allows the regulation to be open to interpretation.

CDC Rationale: 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.

CDC Rationale: 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 in Appendix A of CDC guidelines).

OSHA 1910.1200(b)(3)(i)

Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;

OSHA 1910.1200(b)(3)(ii)

Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible during each workshift to laboratory employees when they are in their work areas;

CADAT Rationale: a) As defined in section (a)(4) and proposed section (c)(8) of this regulation, only items or surfaces defined as non-critical may be considered for cleaning and disinfection using a germicidal product; b) The term "difficult" has been a clarity issue for those teaching and using the regulations. We suggest addressing the intent of the language using general terms as proposed above; c) the term "routine" is open for interpretation by the user and may be defined differently by each office making it potentially difficult to defend; and *d) Barrier Protection is changed between every patient, not just routinely. Barrier protection is defined as: "An item that blocks the penetration of microorganisms, particulates, and fluids, thereby reducing the potential contamination of the underlying surface. The surface is cleaned and disinfected if it becomes contaminated" (MMWR 2003, 2008).*

~~(17)~~(19) Clean and disinfect all clinical contact surfaces that are not protected by impervious barriers using a 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.

~~(18)~~(20) 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 other devices. The dental unit lines and devices shall be flushed between each patient for a minimum of twenty (20) seconds.

CDC Rationale: 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.

~~(19)~~(21) Contaminated solid waste shall be disposed of according to applicable local, state, and federal environmental standards.
Lab Areas:

~~(20)~~(22) 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 and stored in a manner so as to ~~avoid~~ prevent contamination.

CADAT Rationale: The proposed edit provides consistency with language used in this regulation, section "sterilization and disinfection."

~~(21)~~(23) All i~~I~~ntraoral 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) The Dental Board of California and Dental Hygiene Committee of California shall review this regulation biennially ~~annually~~ , and establish a consensus.

DHCC Rationale: Section 1680 (ad) of the Business and Professions Code requires both the DHCC and DB to review infection control regulations 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.