

**DENTAL BOARD OF CALIFORNIA**  
**FINAL STATEMENT OF REASONS**

**Hearing Date:** October 11, 2010

**Subject Matter of Proposed Regulations:** Minimum Standards for Infection Control

**Section(s) Affected:** California Code of Regulations, Title 16, Division 10, Section 1005

**Updated Information:**

The Initial Statement of Reasons is included in the file. The information contained therein is updated as follows:

The Board currently regulates a total of 72,866 licensees; consisting of 37,508 dentists, 34,084 registered dental assistants, and 1,277 registered dental assistants in extended functions. The Board's highest priority is the protection of the public when exercising its licensing, regulatory, and disciplinary functions. The primary methods by which the Board achieves this goal are: issuing licenses to eligible applicants; investigating complaints against licensees and disciplining licensees for violations of the Dental Practice Act (DPA); monitoring licensees whose licenses have been placed on probation; and managing the Diversion Program for licensees, whose practice may be impaired due to abuse of dangerous drugs or alcohol.

Recommendations and comments received during the 45-day public comment period and at the October 11, 2010 regulatory hearing were considered by the Board at their November 4, 2010 meeting. A number of modifications were made to the Minimum Standards for Infection Control regulations based upon comments received from the Dental Hygiene Committee of California, the California Association of Dental Assisting Teachers, and the California Dental Association. The comments received and the Board's responses are detailed under "Summary of Comments Received During the 45-Day Comment Period".

The modified text was noticed on the Board's web site and mailed on November 15, 2010. The 15-day public comment period began on November 16, 2010 and ended on December 1, 2010. The Board received comments from the Dental Assisting Alliance, the California Association of Orthodontists, and OSHA Review, Inc. Comments were considered by the Board at its December 14, 2010 meeting. The comments received and the Board's responses are detailed under "Summary of Comments Received During the 15-Day Comment Period".

During the review of the regulation text by the Office of Administrative Law, the regulation text (Order of Adoption) was further modified with non-substantial changes and other minor editing. The modifications included minor wording additions and corrections to improve clarity, correction of punctuation, correction of subsection

numbering, and correction of the showing of the existing text of the regulation (as currently printed in the California Code of Regulations) and of the underline/strikeout showing changes to that text. None of these changes materially altered the requirements, rights, responsibilities, conditions, or prescriptions contained in the modified regulation text made available during the 15-day public comment period.

**Local Mandate:**

A mandate is not imposed on local agencies or school districts.

**Small Business Impact:**

This action will not have a significant adverse economic impact on small businesses.

**Consideration of Alternatives:**

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the board would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

**Summary of Comments Received During the 45-Day Comment Period:**

The Board received the following recommendations and objections during the 45-day public comment period:

**Comment from the Dental Hygiene Committee of California:**

The Dental Hygiene Committee suggested modifying the text in section 1005(b)(10) by deleting “in the form of package or being wrapped before sterilization if they are not to be used immediately after being sterilized” and replacing with “and packaged or wrapped upon completion of the disinfection process.” In section 1005(b)(11) they suggested deleting “in the form of package or being wrapped before sterilization” and replacing with “and packaged or wrapped upon completion of the disinfection process.” The Board accepted the proposed modifications. The Board raised concern that specifying “formaldehyde” as the only chemical vapor method of sterilization is not correct as there are various methods of chemical vapor sterilization that can be used for infection control. The Board accepted the comment with an amendment to remove the word “formaldehyde” from section 1005(b)(10) and voted to modify the text. .

**Comment from Earl Johnson, DDS, Health Sciences Clinical Professor, University of California San Francisco School of Dentistry:**

Dr. Earl Johnson commented that wrapping or packaging a heat sensitive item before submersion in a disinfectant would severely restrict the disinfectant’s ability to contact the contaminated instrument, reduce the reliability of the disinfection process and create a very wet package that cannot be dried easily before storage and its ultimate use. Dr. Johnson suggested editing the text in section 1005(b)(10) to clarify instruments are to be packaged after sterilization. The Board rejected Dr. Johnson’s comment because the Board previously approved a comment from the Dental Hygiene Committee of California that specified that the disinfection process must be complete before packaging and wrapping. The Board is statutorily mandated to work with the Dental Hygiene

Committee of California to reach a consensus on minimum standards for infection control as specified in Business and Professions Code section 1680(ad). The Board has worked well over two years over the course of several public meetings to reach such a consensus.

*Comment from the California Association of Dental Assisting Teachers:*

The California Association of Dental Assisting Teachers (CADAT) suggested modifying the text in sections 1005(b)(10) and 1005(b)(11) to clarify instruments should be wrapped upon completion of the disinfection process and in section 1005(b)(11) adding the descriptive words “autoclaving” and “formaldehyde”. The Board rejected CADAT’s comment because the Board previously approved a comment from the Dental Hygiene Committee of California that specified that the disinfection process must be complete before packaging and wrapping. The Board is statutorily mandated to work with the Dental Hygiene Committee of California to reach a consensus on minimum standards for infection control as specified in Business and Professions Code section 1680(ad). The Board has worked well over two years over the course of several public meetings to reach such a consensus. However, the Board voted to utilize some of CADAT’s suggested modifications to section 1005(b)(11) to provide consistency with section 1005(b)(10). These modifications specified that semi-critical “instruments, items, and devices” are required to be pre-cleansed, packaged or wrapped and sterilized after each use and specified that the sterilization method of “steam under pressure” is limited to “autoclaving”.

*Comment from the Dental Assisting Alliance:*

The Dental Assisting Alliance commented that sections 1005(b)(10) and 1005(b)(11) are incorrect and therefore unclear because it is not appropriate or effective to wrap a heat-sensitive item before high-level disinfection or sterilization of the item, since the method of high level disinfection or sterilization for heat-sensitive items is by immersion in a liquid chemical sterilant/disinfectant. They commented that wrapping instruments after high level disinfecting or cold sterile processing is inconsistent with the Center for Disease Control’s (CDC) guidelines. They suggested revising the language to reflect that if an item is stored after sterilization it must be re-sterilized immediately before use. The Board rejected the Dental Assisting Alliance’s comment because the Board previously approved a comment from the Dental Hygiene Committee of California that specified that the disinfection process must be complete before packaging and wrapping. The Board is statutorily mandated to work with the Dental Hygiene Committee of California to reach a consensus on minimum standards for infection control as specified in Business and Professions Code section 1680(ad). The Board has worked well over two years over the course of several public meetings to reach such a consensus.

*Comments from the California Dental Association (CDA):*

*CDA Comment 1:*

The California Dental Association recommended replacing the phrase “safe injection practices” with “safe handling of sharps” in Section 1005(a)(1) to broaden the focus from

needles to all dental sharps. The Board accepted the comment and voted to modify the text.

CDA Comment 2:

The California Dental Association recommended adding the term “instruments” in the second sentence of Section 1005(a)(2) to be consistent with the definition in Section 1005(a)(3). The Board accepted the comment and voted to modify the text.

CDA Comment 3:

The California Dental Association recommended deleting “is the least effective disinfection process” from Section 1005(a)(5). They commented that the language was unnecessary and that neither the definition for intermediate-level disinfection nor the definition for high-level disinfection included such a statement. The Board rejected the comment because the definition was necessary to clearly delineate the distinction between disinfection levels for infection control.

CDA Comment 4:

The California Dental Association recommended removing “germicides must be used in accordance with intended use and label instructions” from the second sentence of Section 1005(a)(8) and moving it to Section 1005(b) because it is a practice standard. The Board accepted the comment and voted to modify the text.

CDA Comment 5:

The California Dental Association recommended removing the second and third sentences from Section 1005(a)(10) and moving them to Section 1005(b) because it is a practice standard. The Board accepted the comment and voted to modify the text.

CDA Comment 6:

The California Dental Association made multiple recommendations for Section 1005(a)(11). They recommended removing the examples contained within the parenthesis because they were unnecessary. They recommended changing any mention of gowns and labcoats to “protective attire”. They recommended removing references to “shoes” because it could be interpreted that employers would be required to provide shoes to employees. Cal/OSHA required employers to pay for their personal protective equipment to perform their jobs safely. The Board accepted the comment and voted to modify the text.

CDA Comment 7:

The California Dental Association proposed modified language for the definition of “Other Potentially Infectious Materials” in Section 1005(a)(12). They also recommended using the language from Cal/OSHA’s definition in the Bloodborne Pathogens Standard (Section 5193 Title 8 CCR). The Board voted unanimously to reject using the language from (1) of Cal/OSHA’s definition for “Other Potentially Infectious Materials” because the Board’s current definition is derived from Cal/OSHA’s definition and is specific to the practice of dentistry. It is unnecessary to include the entire definition as specified by

Cal/OSHA because it is not specific to dental care services. The Board accepted CDA's proposed modified language for Section 1005(a)(12)(C) and voted to modify the text.

*CDA Comment 8:*

The California Dental Association proposed language modifications to Section 1005(b) to provide clarity that subdivision (b) requires compliance with Cal/OSHA requirements for infection control, specifically bloodborne pathogens and aerosol transmitted diseases and specific PPE requirements during chemical handling. The California Dental Association further suggested modifying the text to correctly reference the California Division of Occupational Safety and Health as "Cal/OSHA" rather than "Cal-DOSH". The Board rejected the comment because the suggested modified text was unnecessary, did not provide further clarity, and only restructured the sentence containing the same content. However, the Board voted to modify the language to correctly identify the California Division of Occupational Safety and Health as Cal/OSHA.

*Comment 9:*

The California Dental Association proposed language modifications to Section 1005(b)(4) to clarify the personal protective equipment requirements for chemical handling. They suggested specifying that chemical-resistant utility gloves and appropriate, task specific PPE shall be worn when handling hazardous chemicals rather than puncture-resistant gloves. The Board accepted the comment and voted to modify the text.

*Comment 10:*

The California Dental Association proposed language modifications in Section 1005(b)(5) to change the terms "gowns" to "protective attire", "Cal-DOSH" to "Cal/OSHA", and "splattering" to "spattering" to be consistent with previous sections. The Board accepted the comment and voted to modify the text.

*Comment 11:*

The California Dental Association suggested adding language to Section 1005(b)(6) to recommend that dental healthcare personnel thoroughly wash their hands with soap and water at the start of each work day and suggested further defining "work restrictions" and/or cite CDC's guidelines. The Board accepted the comment and suggested using "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" to clarify work restrictions. The Board voted to modify the text.

*Comment 12:*

The California Dental Association proposed modifying Section 1005(b)(8) to remove the reference to "germicidal agents" because medical gloves do not protect against chemicals. They suggested that chemical-resistant and chemical compatible gloves should be worn when handling chemicals. They suggested changing "cleaning" to "processing contaminated" to distinguish handling instruments during patient treatment

from processing/cleaning contaminated sharp instruments when treatment is completed. The Board accepted the comment and voted to modify the text.

Comment 13:

The California Dental Association provided a comment on Section 1005(b)(9) stating that requiring the use of “puncture-resistant” gloves when “cleaning” sharps implies that direct handling of sharps is acceptable. They suggested that language be added stating that Cal/OSHA prohibits direct handling of contaminated sharps. The Board rejected this comment because sharps containers are designed so that hands are not able to reach into the containers. It would be an unnecessary change and did not provide further clarity.

Comment 14:

The California Dental Association provided comments regarding Sections 1005(b)(10) and 1005(b)(11). They commented that the language appeared to require pre-packing of heat sensitive critical instruments processed by high-level disinfectants. They suggested that since the primary high-level disinfectants used in dentistry are chemical liquids, it was not clear how one would package and then process items using liquid high-level disinfectants. They suggested that, since it is impossible and against such disinfectants label usage to effectively achieve liquid high-level disinfection if the instruments are pre-packaged, it cannot be determined how dentists and dental healthcare professionals could comply with the requirement. Additionally, CDA suggested adding language to require event related or dated related labeling of each package. They commented that the Centers for Disease Control and Injury Prevention (CDC) recognize that packaged instruments should remain sterile indefinitely, unless an event causes it to become contaminated (e.g., torn or wet packaging). CDC advises date and event-related packaging to include the date of sterilization and the sterilizer used if multiple sterilizers are used in the facility, on the outside of the packaging material to facilitate the retrieval of processed items in the event of a sterilization failure. CDA encouraged the Board to retain language allowing sterilized items to be placed “on a setup tray and covered with a moisture impervious barrier on the day the instruments will be used.” CDA also suggested changing “pre-clean” to simply “clean” or following “pre-clean” with “clean.” If you “pre-clean” an item, it still needs to be cleaned. They also suggested removing or clarifying “in the form of package.” The Board rejected this comment because the previously accepted comment from the Dental Hygiene Committee of California specified that the disinfection process must be complete before packaging and wrapping critical and semi-critical items. The Board is statutorily mandated to work with the Dental Hygiene Committee of California to reach a consensus on minimum standards for infection control as specified in Business and Professions Code section 1680(ad). The Board has worked well over two years over the course of several public meetings to reach such a consensus.

Comment 15:

The California Dental Association proposed modifications to Section 1005(b)(12) to change the reference of the “United States Environmental Protection Agency” to “California Environmental Protection Agency (Cal/EPA)” to be legal and consistent with

Section 1005 (b) (18). Legally, only Cal/EPA registered disinfectants are legal for use in California. Many disinfectants are registered with the Federal EPA, but do not meet California standards and are therefore illegal to purchase and use. The Board accepted the comment and voted to modify the text.

Comment 16:

The California Dental Association suggested deleting “instrument” in Section 1005(b)(13) to be consistent with definition of “semi-critical item” in Section 1005(a)(3). The Board accepted the comment and voted to modify the text.

Comment 17:

The California Dental Association suggested removing the reference to “spore testing monitor” in Section 1005 (b)(15) and change it to read “spore test” because they are unaware of the existence of a “spore testing monitor” The Board accepted the comment and voted to modify the text.

Comment 18:

The California Dental Association suggested modifications to Sections 1005(b)(17) and 1005(b)(18). They suggested moving the third sentence “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” to Section 1005 (b) (18) where cleaning is referenced. This section discusses barriers, not cleaning. They suggested using the term “germicide” instead of “disinfectant” to be consistent with 1005 (a) (8). The Board accepted the comment and voted to modify the text.

Comment 19:

The California Dental Association suggested modifying Section 1005(b)(21) to add language regarding labeling. They suggested the language state: “(21) Splash shields and equipment guards shall be used on dental laboratory lathes. Fresh pumice and a 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 properly 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 stored in a manner so as to prevent contamination.” The Board voted to delete the word properly as there is no way to define “properly”. The Board accepted the comment with the deletion of the word “properly” and voted to modify the text.

Comments from OSHA Review, Incorporated:

OSHA Review, Inc. Comment 1:

OSHA Review Incorporated commented that they feel it is not correct to use the terms “low-level disinfection” or “intermediate-level disinfection” as recommended by the Centers for Disease Control (CDC). They maintain that the proposed language under review is unnecessary, confusing, and in conflict with State and Federal Law. OSHA Review Incorporated proposed replacing the definitions for “low-level disinfection” and “intermediate-level disinfection” with the following definition: ““Disinfection” describes a

process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal. Factors that affect the efficacy of disinfection include prior cleaning of the object; organic and inorganic load present; type and level of microbial contamination; concentration of and exposure time to the germicide ; presence of biofilms, and temperatures and pH of the disinfection process.” OSHA Review, Inc. stated that the terms “low-level disinfection” and “intermediate-level disinfection” are not recognized by the US EPA, Cal/EPA, or Cal/OSHA and that under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), it is illegal to make claims of disinfection efficacy not specifically supported by the product label.

The Board rejected these comments and the recommended modified text. The proposed regulatory amendments to the existing definitions for “low-level disinfection” and “intermediate-level disinfection” were grammatical and did not make substantive changes to the definitions. The definitions for “low-level disinfection” and “intermediate-level disinfection” are consistent with the Spaulding classification contained in the CDC’s *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*. The Spaulding classification is a strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semicritical, or noncritical on the basis of risk to patient safety from contamination on a device. The system also establishes levels of germicidal activity (sterilization, high-level disinfection, intermediate-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semicritical, and noncritical). These classifications are used to determine the level of processing required but do not imply efficacy of disinfectant. Table 1 in the CDC’s *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008* illustrates the Spaulding classification system and references the names of disinfectants and categorizes them as “high-level”, “intermediate-level”, or “low-level” disinfectant. The disinfectants cited are registered with Cal/EPA. These proposed regulations are intended to identify the standard precautionary practices necessary to prevent the risk of transmitting infectious diseases in dental healthcare facilities. The Board rejected the comment because it is necessary to clearly delineate disinfection levels to be used during infection control practices in dental healthcare settings. The suggested modifications diminish the specificity of the definitions of disinfection. The Dental Board is not charged with the authority to enforce another agency’s standards and the Board does not set the minimum standards for disinfecting products and disinfection labels. These regulations do not preclude licensees or dental healthcare facilities from complying with other State and Federal law, especially Cal/OSHA, Cal/EPA, Federal EPA, and FIFRA. For example, references to “low-level disinfection” and “intermediate-level disinfection” contained in Sections 1005(b)(14) and 1005(b)(20) are relative to the disinfection and sterilization of non-critical surfaces, patient care items, and clinical contact surfaces that are not protected by impervious barriers. These sections specify that the disinfectant products used shall be Cal/EPA registered and also specify the efficacy associated with those registered disinfectants (i.e. labeled effective against HBV and HIV; tuberculocidal claim). Furthermore, Board staff has reviewed the legal authority cited by the commenter

(Federal Register 19174/Vol. 51/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162) and does not find the Board's proposed regulations to be inconsistent with the cited legal authority.

OSHA Review, Inc. Comment 2:

OSHA Review Incorporated suggested changing the language in section 1005(a)(8) to ““Germicide” is a chemical sterilizing and/or disinfecting agent that can be used to sterilize and/or disinfect items and surfaces based on the level of contamination.” The Board rejected the comment because the recommended change is unnecessary and did not make any substantive change.

Additionally, OSHA Review Incorporated recommended the second sentence in section 1005(a)(8) be removed because it is not part of the definition of the term “germicide” but rather a practice standard that is addressed in section 1005(b)(18). The Board accepted a previous comment containing a recommendation made by the California Dental Association and moved the second sentence of section 1005(a)(8) to section 1005(b)(10).

OSHA Review, Inc. Comment 3:

OSHA Review Incorporated suggested changing the language in paragraph 1005(b)(12) to: “Non-critical surfaces and patient care items shall be cleaned with an appropriate cleaning product and disinfected using a Cal/EPA registered, hospital grade disinfectant legally sold in California registered as effective against tuberculosis var bovis or registered as effective against HIV and HBV. Disinfectants shall be used in accordance with the manufacturer's intended use and label instructions.” OSHA Review Incorporated stated that efficacy against HIV and HBV is necessary at a minimum for all disinfectants because these organisms were the target organisms specified in Senate Bill 1070, the 1991 legislation that provided the motive to the original Dental Board's infection control regulations. Additionally, OSHA Review Incorporated commented that it is important to define that a cleaner, not a disinfectant, must be used to clean, unless the disinfectant is labeled (with Cal/EPA approved labels) as cleaner and disinfectant. They stated that the current regulation and the proposed language under review are confusing and in conflict with State and Federal Law. OSHA Review, Incorporated stated that the terms “low-level disinfection” and “intermediate-level disinfection” are not recognized by the US EPA, Cal/EPA, or Cal/OSHA and that under the FIFRA, it is illegal to make claims of disinfection efficacy not specifically supported by the product label. OSHA Review Incorporated also commented that because cleaning is a necessary first step prior to disinfection which must be performed using a labeled cleaning product, it is difficult to anticipate a case where a non-critical surface would be visibly contaminated prior to disinfection, if cleaning is done prior to disinfection.

The Board rejected these comments and the recommended modified text. The Board's proposed language is clear in that non-critical items and patient care items shall be cleaned and then disinfected. Section 1005(b)(11) clearly states that cleaning must precede any disinfection or sterilization process and that products used to clean items or surfaces prior to disinfection shall be used according to all label instructions.

Cleaning is clearly a separate process. Using the term “appropriate cleaner” could cause clarity issues because the word “appropriate” is vague and does not specify what constitutes “appropriate”.

The Board’s proposed language clearly specifies that an Cal/EPA-registered hospital disinfectant labeled effective against HBV and HIV shall be used on non-critical surfaces and patient care items. The language also clearly specifies that an Cal/EPA-registered hospital disinfectant with a tuberculocidal claim shall be used with the item is visibly contaminated with blood or other potentially infectious material. The suggested language from OSHA Review Incorporated does not clearly delineate in what circumstances each Cal/EPA-registered disinfectant shall be used.

The terms “low-level disinfection” and “intermediate-level disinfection” are consistent with the Spaulding classification contained in the CDC’s *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*. The Spaulding classification is a strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semicritical, or noncritical on the basis of risk to patient safety from contamination on a device. The system also establishes levels of germicidal activity (sterilization, high-level disinfection, intermediate-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semicritical, and noncritical). These classifications are used to determine the level of processing required but do not imply efficacy of disinfectant. Table 1 in the CDC’s *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008* illustrates the Spaulding classification system and references the names of disinfectants and categorizes them as “high-level”, “intermediate-level”, or “low-level” disinfectant. The disinfectants cited are registered with Cal/EPA. These proposed regulations are intended to identify the standard precautionary practices necessary to prevent the risk of transmitting infectious diseases in dental healthcare facilities. The Board rejected the comment because it is necessary to clearly delineate disinfection levels to be used during infection control practices in dental healthcare settings. The suggested modifications diminish the specificity of the definitions of disinfection. The Dental Board is not charged with the authority to enforce another agency’s standards and the Board does not set the minimum standards for disinfecting products and disinfection labels. These regulations do not preclude licensees or dental healthcare facilities from complying with other State and Federal law, especially Cal/OSHA, Cal/EPA, Federal EPA, and FIFRA. For example, references to “low-level disinfection” and “intermediate-level disinfection” contained in Sections 1005(b)(14) and 1005(b)(20) are relative to the disinfection and sterilization of non-critical surfaces, patient care items, and clinical contact surfaces that are not protected by impervious barriers. These sections specify that the disinfectant products used shall be Cal/EPA registered and also specify the efficacy associated with those registered disinfectants (i.e. labeled effective against HBV and HIV; tuberculocidal claim). Furthermore, Board staff has reviewed the legal authority cited by the commenter (Federal Register 19174/Vol. 51/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162) and does not find the Board’s proposed regulations to be inconsistent with the cited legal authority.

OSHA Review Incorporated commented that because cleaning is a necessary first step prior to disinfection, which must be performed using a labeled cleaning product, it is difficult to anticipate a case where a non-critical surface would be visibly contaminated prior to disinfection, if cleaning is done prior to disinfection. The Board rejected this comment because it is necessary to specify the use of an Cal/EPA-registered disinfectant with a tuberculocidal claim when an item is visibly soiled with blood or other potentially infectious material. Dental healthcare personnel receive extensive education and training in infection control practices and maintain the knowledge and competency necessary to determine which items have been soiled and require disinfecting with a tuberculocidal claim after cleaning.

OSHA Review Incorporated commented that the reference to US EPA is not legal, as all disinfectants and germicides used in California must be registered by Cal/EPA. OSHA Review Incorporated stated that all Cal/EPA registered disinfectants must have current US EPA registration, but not vice versa and that Cal/EPA requirements are more stringent than Federal requirements. The Board accepted a previous comment containing the same recommendation made by the California Dental Association and changed “United State Environmental Protection Agency (EPA)” to “California Environmental Protection Agency (Cal/EPA)”.

*OSHA Review, Inc. Comment 4:*

OSHA Review Incorporated suggested changing the language in paragraph 1005(b)(18) to: “All clinical contact surfaces that are not protected by impervious barriers shall be cleaned with an appropriate cleaning product and disinfected using a Cal/EPA registered, hospital grade disinfectant legally sold in California registered effective against tuberculosis var bovis or registered against HIV and HBV. Disinfectants shall be used in accordance with the manufacturer's intended use and label instructions. All housekeeping surfaces (e.g. floors, walls, sinks) shall be cleaned with a detergent and water or a Cal/EPA registered hospital grade disinfectant.” OSHA Review Incorporated commented that the efficacy against HIV and HBV is necessary at a minimum for all disinfectants because these organisms were the target organisms specified in Senate Bill 1070, the 1991 legislation that provided the motive to the original Dental Board's infection control regulations. They commented that it is important to define that a cleaner, not a disinfectant, must be used to clean, unless the disinfectant is labeled, with Cal/EPA approved label, as a cleaner and disinfectant. Additionally, they commented that the terms “low-level disinfection” and “intermediate-level disinfection” are not recognized by the US EPA, Cal/EPA, or Cal/OSHA and that under FIFRA, it is illegal to make claims of disinfection efficacy not specifically supported by the product label. They stated that this prohibition includes third parties implying efficacy by a disinfectant's label claim.

The Board rejected these comments and the recommended modified text. The Board's proposed language is clear that all clinical contact surfaces that are not protected by impervious barriers shall be cleaned and disinfected using a Cal/EPA registered disinfectant after each patient. Section 1005(b)(11) clearly states that cleaning must precede any disinfection or sterilization process and that products used to clean items

or surfaces prior to disinfection shall be used according to all label instructions. Cleaning is clearly a separate process. Using the term “appropriate cleaner” could cause clarity issues because the word “appropriate” is vague and does not specify what constitutes “appropriate”.

The terms “low-level disinfection” and “intermediate-level disinfection” are consistent with the Spaulding classification contained in the CDC’s *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*. The Spaulding classification is a strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semicritical, or noncritical on the basis of risk to patient safety from contamination on a device. The system also establishes levels of germicidal activity (sterilization, high-level disinfection, intermediate-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semicritical, and noncritical). These classifications are used to determine the level of processing required but do not imply efficacy of disinfectant. Table 1 in the CDC’s *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008* illustrates the Spaulding classification system and references the names of disinfectants and categorizes them as “high-level”, “intermediate-level”, or “low-level” disinfectant. The disinfectants cited are registered with Cal/EPA. These proposed regulations are intended to identify the standard precautionary practices necessary to prevent the risk of transmitting infectious diseases in dental healthcare facilities. The Board rejected the comment because it is necessary to clearly delineate disinfection levels to be used during infection control practices in dental healthcare settings. The suggested modifications diminish the specificity of the definitions of disinfection. The Dental Board is not charged with the authority to enforce another agency’s standards and the Board does not set the minimum standards for disinfecting products and disinfection labels. These regulations do not preclude licensees or dental healthcare facilities from complying with other State and Federal law, especially Cal/OSHA, Cal/EPA, Federal EPA, and FIFRA. References to “low-level disinfection” and “intermediate-level disinfection” in Sections 1005(b)(14) and 1005(b)(20) are relative to the disinfection and sterilization of non-critical surfaces, patient care items, and clinical contact surfaces that are not protected by impervious barriers. These sections specify that the disinfectant products used shall be Cal/EPA registered and also specify the efficacy associated with those registered disinfectants (i.e. labeled effective against HBV and HIV; tuberculocidal claim). Furthermore, Board staff has reviewed the legal authority cited by the commenter (Federal Register 19174/Vol. 51/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162) and does not find the Board’s proposed regulations to be inconsistent with the cited legal authority. The remaining suggested modifications were unnecessary and did not make substantive changes to the text.

OSHA Review, Inc. Comment 5:

OSHA Review Incorporated suggested changing the language in paragraph 1005(b)(22) to: “All intraoral items such as impressions, bite registrations, prosthetic and orthodontic appliances shall be cleaned with an appropriate cleaning product and disinfected using a Cal/EPA registered, hospital grade disinfectant legally sold in California registered effective against tuberculosis var bovis or registered against HIV and HBV 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. Disinfectants shall be used in accordance with the manufacturer's intended use and label instructions.” OSHA Review Incorporated commented that the efficacy against HIV and HBV is necessary at a minimum for all disinfectants because these organisms were the target organisms specified in Senate Bill 1070, the 1991 legislation that provided the motive to the original Dental Board's infection control regulations. They commented that it is important to define that a cleaner, not a disinfectant, must be used to clean, unless the disinfectant is labeled, with Cal/EPA approved label, as a cleaner and disinfectant. Additionally, they commented that the terms “low-level disinfection” and “intermediate-level disinfection” are not recognized by the US EPA, Cal/EPA, or Cal/OSHA and that under FIFRA, it is illegal to make claims of disinfection efficacy not specifically supported by the product label. They stated that this prohibition includes third parties implying efficacy by a disinfectant's label claim. OSHA Review Incorporated commented that all disinfectants used in California must be registered by Cal/EPA, to be consistent with existing laws and previous sections of California Code of Regulations, Title 16, Section 1005 relative to the minimum standards for infection control.

The Board rejected these comments and the recommended modified text. The proposed regulatory amendments to section 1005(b)(22) were grammatical and did not make substantive changes. Section 1005(b)(22) is consistent with the other provisions contained within California Code of Regulations, Title 16, Section 1005. Section 1005(b)(11) clearly states that cleaning must precede any disinfection or sterilization process and that products used to clean items or surfaces prior to disinfection shall be used according to all label instructions. Cleaning is clearly a separate process. Using the term “appropriate cleaner” could cause clarity issues because the work “appropriate” can be vague and does not specify what constitutes “appropriate”.

The terms “low-level disinfection” and “intermediate-level disinfection” are consistent with the Spaulding classification contained in the CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*. The Spaulding classification is a strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semicritical, or noncritical on the basis of risk to patient safety from contamination on a device. The system also establishes levels of germicidal activity (sterilization, high-level disinfection, intermediate-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semicritical, and noncritical). These classifications are used to determine the level of processing required but do not imply efficacy of disinfectant. Table 1 in the CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008* illustrates the Spaulding classification system and references the names of disinfectants and categorizes them as “high-level”, “intermediate-level”, or “low-level” disinfectant. The disinfectants cited are registered with Cal/EPA. These proposed regulations are intended to identify the standard precautionary practices necessary to prevent the risk of transmitting infectious diseases in dental healthcare facilities. The Board rejected the comment because it is necessary to clearly delineate disinfection levels to be used during infection control practices in dental healthcare settings. The suggested

modifications diminish the specificity of the definitions of disinfection. The Dental Board is not charged with the authority to enforce another agency's standards and the Board does not set the minimum standards for disinfecting products and disinfection labels. These regulations do not preclude licensees or dental healthcare facilities from complying with other State and Federal law, especially Cal/OSHA, Cal/EPA, Federal EPA, and FIFRA. For example, references to "low-level disinfection" and "intermediate-level disinfection" contained in Sections 1005(b)(14) and 1005(b)(20) are relative to the disinfection and sterilization of non-critical surfaces, patient care items, and clinical contact surfaces that are not protected by impervious barriers. These sections specify that the disinfectant products used shall be Cal/EPA registered and also specify the efficacy associated with those registered disinfectants (i.e. labeled effective against HBV and HIV; tuberculocidal claim). Furthermore, Board staff has reviewed the legal authority cited by the commenter (Federal Register 19174/Vol. 51/ Wednesday, May 28, 1986/ Rules and Regulations EPA 40 CFR Part 162) and does not find the Board's proposed regulations to be inconsistent with the cited legal authority.

#### Board Sub-Committee Recommendation

The subcommittee recommended modifications to "Sterilization and Disinfection" to maintain maximum public protection. The subcommittee stated that the labeling of critical and semi-critical items with the date of sterilization and the sterilizer used will allow for the retrieval of processed items in the event of a sterilization failure. The subcommittee recommended adding "and shall be properly labeled with the date of sterilization and the specific sterilizer used if more than one sterilizer is utilized in the facility." The Board accepted the subcommittee's recommendation with an amendment to delete the term "properly" because the term is too vague and voted to modify the text.

#### **Summary of Comments Received During the 15-Day Comment Period:**

The Board received the following recommendations and objections during the 15-day public comment period:

#### Comment from the Dental Assisting Alliance:

The Dental Assisting Alliance suggested editorial modifications to Sections 1005(b)(12) and 1005 (b)(13) to the clarify the Board's intent regarding the sterilization process for critical and semi-critical items. The Board rejected the comment because it was not specific to the noticed modified text and the editorial changes were unnecessary. The existing accepted language is sufficient to promote safe sterilization and disinfection practices and is clear that the pre-cleaning, packaging or wrapping, and sterilization of critical items and semi-critical items is the process that should be followed after each use.

#### Comment from Earl Johnson, DDS, California Association of Orthodontists:

Dr. Earl Johnson's comment addressed concerns with packaging instruments prior to dry-heat sterilization. Staff recommended rejection of the comment because research found that according to the Centers for Disease Control (CDC), the acceptable materials to be used for packaging during dry heat sterilization include paper bags,

aluminum foil, polyfilm plastic tubing, and wrapped perforated cassettes. The text supports the CDC's recommendations and promotes safe infection control practices for patient protection. Dr. Johnson provided public comment that the CDC regulations for sterilization were written 20 years ago and they don't work. He maintained that you cannot wrap the instruments before dry heat sterilization because the wrapper itself impedes the sterilization process. The Board rejected the comment because, according to the Centers for Disease Control (CDC), the acceptable materials to be used for packaging during dry heat sterilization include paper bags, aluminum foil, polyfilm plastic tubing, and wrapped perforated cassettes. For dry heat, the CDC states that the packaging material should not insulate items from heat and should not be destroyed by the temperature used. The currently written text supports the CDC's recommendations and promotes safe infection control practices for patient protection.

*Comments from OSHA Review Incorporated:*

OSHA Review, Inc. provided comments during the modified text public comment period in response to the Board's rejection of OSHA Review, Inc.'s comments submitted during the initial 45-day public comment period. The Board rejected the comment because the comments were not specific to the modified text and the suggested modifications do not further promote better infection control practices than what is currently written in the regulatory language. The current language is consistent with the CDC's recommendations for non-critical clinical surfaces.