

2005 Evergreen St., Suite 1550, Sacramento, CA 95815
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# DENTAL BOARD OF CALIFORNIA DENTAL ASSISTING COUNCIL

### NOTICE OF MEETING May 14, 2025

#### **Council Members**

De'Andra Epps-Robbins, RDA, Chair Jeri Fowler, RDAEF, OA, Vice Chair Jessica Gerlach, RDA, OA Lilia Larin, DDS Cara Miyasaki, RDA, RDHEF, MS Rosalinda Olague, RDA, PhD(c) Carie Smith, RDAEF, OA Action may be taken on any item listed on the agenda.

The Dental Assisting Council (Council) of the Dental Board of California (Board) will meet in-person in accordance with Government Code section 11123, subdivision (a), at 8:30 a.m., on Wednesday, May 14, 2025, at the following location:

Hilton Anaheim
777 W. Convention Way (Fourth Floor, Huntington Room)
Anaheim, CA 92802
(714) 750-4321 (Hotel)
(916) 263-2300 or (877) 729-7789 (Board Office)

#### **AGENDA**

- 1. Call to Order/Roll Call/Establishment of a Quorum
- 2. Public Comment on Items Not on the Agenda [4]
  Note: The Council may not discuss or take action on any matter raised during this
  Public Comment section, except to decide whether to place the matter on the
  agenda of a future meeting. (Government Code Sections 11125 and 11125.7(a).)
- 3. Discussion and Possible Action on February 6, 2025 Meeting Minutes [5-19]
- 4. Assistant Executive Officer Report [20]
- 5. Update on Dental Assisting Examination Statistics [21-22]
  - a. Registered Dental Assistant General Written and Law and Ethics Examinations
  - b. Registered Dental Assistant in Extended Functions General Written Examination
  - c. Orthodontic Assistant Written Examination
  - d. Dental Sedation Assistant Written Examination

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- 6. Update on Dental Assisting Licensing Statistics [23-33]
  - a. Registered Dental Assistant License
  - b. Registered Dental Assistant in Extended Functions License
  - c. Orthodontic Assistant Permit
  - d. Dental Sedation Assistant Permit
  - e. Abandoned Dental Assisting Applications
- 7. Update and Discussion on Registered Dental Assistant and Registered Dental Assistant in Extended Functions Educational Programs and Courses Application Approvals and Re-Evaluations [34-39]
- Update, Discussion, and Possible Recommendation to the Board on Legislative Proposal to Add Business and Professions Code (BPC) Section 1778 Relating to Board Approval of Dental Assistant Educational Programs and Courses [40-52]
- 9. Update, Discussion, and Possible Recommendation to the Board on Legislation [53-55]
  - a. AB 873 (Alanis, 2025) Dentistry: dental assistants: infection control course
- 10. Discussion and Possible Recommendation to the Board on Legislative Proposal to Amend BPC, Division 2, Chapter 4, Article 7 Title Regarding Dental Auxiliaries [56]
- 11. Discussion and Possible Recommendation to the Board on Legislative Proposal to Amend BPC Sections 1753 and 1753.5 Regarding Authorized Duties and Procedures of Registered Dental Assistants in Extended Functions [57-63]
- 12. Update, Discussion, and Possible Recommendations to the Board on Proposed Regulations
  - a. Status Update on Pending Regulations [64]
  - b. Discussion and Possible Action to Recommend Initiation of a Rulemaking to Amend California Code of Regulations (CCR), Title 16, Section 1005 Regarding Minimum Standards for Infection Control [65-147]

#### 13. Adjournment

Information regarding the meeting is available by contacting the Board at (916) 2632300 or (877) 729-7789, email: DentalBoard@dca.ca.gov, or send a written request to the Dental Board of California, 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815. This agenda can be found on the Dental Board of California website at <a href="document-dbc.ca.gov">dbc.ca.gov</a>. The time and order of agenda items are subject to change at the discretion of the Council Chair and may be taken out of order. In accordance with the BagleyKeene Open Meeting Act, all meetings of the Council are open to the public.

The meeting will be webcast, provided there are no unforeseen technical difficulties or limitations. To view the webcast, please visit <u>thedcapage.wordpress.com/webcasts/</u>. The meeting will not be cancelled if webcast is not available. Meeting adjournment may

Dental Assisting Council Meeting Agenda May 14, 2025 not be webcast if it is the only item that occurs after a closed session. Members of the public may, but are not obligated to, provide their names or personal information as a condition of observing or participating in the meeting. (Government Code section 11124.)

Government Code section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by the Council prior to the Council taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issue before the Council, but the Council Chair may, at their discretion, apportion available time among those who wish to speak. Individuals may appear before the Council to discuss items not on the agenda; however, the Council can neither discuss nor take official action on these items at the time of the same meeting (Government Code sections 11125, 11125.7(a)).

This meeting location is accessible to the physically disabled. A person who needs disability-related accommodations or modifications to participate in the meeting may make a request by contacting Christy Bell, Assistant Executive Officer, at Dental Board of California, 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815, or by phone at (916) 263-2300. Providing your request at least five (5) business days prior to the meeting will help ensure availability of the requested accommodations. TDD Line: (877) 729-7789



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### MEMORANDUM

DATE	April 21, 2025
то	Members of the Dental Assisting Council
FROM	Mirela Taran, Administrative Analyst Dental Board of California
SUBJECT	Agenda Item 2.: Public Comment on Items Not on the Agenda

### **Notes**



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### DENTAL BOARD OF CALIFORNIA DENTAL ASSISTING COUNCIL MEETING MINUTES February 6, 2025

Pursuant to Government Code section 11122.5, subdivision (a), the Dental Assisting Council (Council) of the Dental Board of California (Board) met in-person with additional public participation available by teleconference/WebEx Events on Thursday, February 6, 2025, with the following location available for Council and public member participation:

Department of Consumer Affairs 1625 N. Market Blvd., Hearing Room #102 Sacramento, CA 95834

#### **Members Present:**

De'Andra Epps-Robbins, RDA, Chair Jeri Fowler, RDAEF, OA, Vice Chair Jessica Gerlach, RDA, OA Lilia Larin, DDS Cara Miyasaki, RDA, RDHEF, MS Rosalinda Olague, RDA, PhD(c) Carie Smith, RDAEF, OA

#### **Staff Present:**

Tracy A. Montez, Ph.D., Executive Officer Christy Bell, Assistant Executive Officer Ryan Blonien, Enforcement Chief (North)

Jodi Ortiz, Chief of Licensing and Examination Division

Paige Ragali, Chief of Administration and Compliance

Tina Vallery, Chief of License and Program Compliance and Dental Assisting

Victor Libet, License and Program Compliance Unit Manager

Jessica Olney, Anesthesia Unit Manager

Wilbert Rumbaoa, Administrative Services Unit Manager

Jerry Fuhrman, Investigator

Brant Nelson, Legislative and Regulatory Specialist

Mirela Taran, Administrative Analyst

Joseph Tippins, Investigator

Sarah Irani, Facilitator and Strategic Planner, SOLID, Department of Consumer Affairs (DCA)

Bryce Penney, Television Specialist, Office of Public Affairs, DCA Kristy Schieldge, Regulations Counsel, Attorney IV, Legal Affairs Division, DCA Tara Welch, Board Counsel, Attorney IV, Legal Affairs Division, DCA

#### Agenda Item 1: Call to Order/Roll Call/Establishment of a Quorum

Council Chair, Ms. De'Andra Epps-Robbins, called the meeting to order at 8:39 a.m.; seven members of the Council were present, and a quorum was established.

### Agenda Item 2: Public Comment on Items Not on the Agenda

There were no public comments made on this item.

Agenda Item 3: Discussion and Possible Action on November 7, 2024 Meeting Minutes Motion/Second/Call the Question (M/S/C) (Fowler/Smith) to approve the November 7, 2024 Meeting Minutes.

Chair Epps-Robbins requested public comment before the Council acted on the motion. There were no public comments made on the motion.

Chair Epps-Robbins called for the vote on the motion. Ms. Mirela Taran took a roll call vote on the motion.

Ayes: Epps-Robbins, Fowler, Gerlach, Miyasaki, Olague, Smith.

Nays: None.

Abstentions: Larin. Absent: None. Recusals: None.

The motion passed and the Minutes were approved.

#### Agenda Item 4: Assistant Executive Officer Report

Christy Bell reported that she joined the Board in December of 2022 and has been with DCA for over 10 years working in various positions. She noted the Board's 2022-2025 Strategic Plan is concluding, and strategic planning will be discussed furthermore at the May Board meeting. Additionally, the 2025 Dental Practice Act (DPA) will be available soon, and there will be information on the Board's webpage on how to order it.

Chair Epps-Robbins requested public comment on this item. There were no public comments made on this item.

#### Agenda Item 5: Update on Dental Assisting Examination Statistics

Ms. Bell provided the report, which is available in the meeting materials.

Chair Epps-Robbins requested public comment on this item. There were no public comments made on this item.

#### Agenda Item 6: Update on Dental Assisting Licensing Statistics

Ms. Bell provided the report, which is available in the meeting materials.

Regarding page 17 of the meeting materials on the Dental Assistant Applications (1020) Abandoned by Month chart, Council Member Lilia Larin voiced that there were 1,104 total abandoned applications for registered dental assistant (RDA) licensure in 23-24. She asked what is the reason that applicants abandon their application. Ms. Bell responded that an application is abandoned if an applicant applies, there are deficiencies, and they fail to remediate those deficiencies within the year that they have. She noted that examples of deficiencies could include that they did not pay the fee and did not provide the necessary documentation to prove that they meet the qualifications.

Council Member Larin inquired whether Board staff follow up with applicants regarding their deficiencies. Ms. Bell responded that when the Board receives an application and it is incomplete, staff notify the applicant by letter, usually more than once, that there are items outstanding. She added the Board has changed its process to reach out and call applicants to help facilitate the process.

Council Member Cara Miyasaki noted that on page 22 of the meeting materials, the registered dental assistant in extended functions (RDAEF), orthodontic assistant, and dental sedation assistant retention rates seem fairly high, but the dental assistant retention rate is 33%. She expressed that if the delinquent ones are considered, it drops down to 29%. Council Member Miyasaki conveyed that she believes this is not a great thing for the workforce. Looking at the documents for the new programs and new courses on pages 26 and 28 of the meeting materials, she conveyed that is discloses the new programs and courses that are being approved, and voiced that this creates a burden for Board staff. She noted the RDA retention rate and that if RDAs, who pay for these 10 and 12 week programs, which are \$2,500 to \$5,000, fall out of the workforce, then they have paid all this money to get into the workforce. She voiced that she is trying to appeal to the stakeholders to see if there is anything that can be done about this retention rate. Council Member Miyasaki added that there are new programs popping up to create more dental assistants, but if RDAs are just retained, then maybe it is not necessary to have more dental assistants, who have to take the infection control class, which creates a lot of burden to Board staff.

Chair Epps-Robbins requested public comment on this item. The Council received public comment.

Shari Becker, representing herself, voiced that she is curious whether there is any type of questionnaire on those who are coming out of the profession which shows where they are going and why are they going away. She expressed that this statistic is eye opening.

Tracy Montez verbalized that the ratio reflects the licensee address of record and noted that an individual may have an address in one area but actually work in multiple areas. She added this is an excellent comment for the Board's stakeholders to explore because as a regulatory Board, the Board's responsibility is not necessarily retention per se, but the Board has done its job in terms of creating ways to get licensed and

trying to reduce any artificial barriers to licensure. Dr. Montez stated it is an excellent idea for the Board's stakeholders to do surveys or something like that, and then that information may feed back into the Board as perhaps there is something the Board can do with regard to access.

Regarding the topic of surveys and questionnaires, Council Member Rosalinda Olague voiced that DentalPost posted their 2025 dental salary survey report; there is great insight there from hiring wages to turnovers. She highly encouraged anyone looking at the Allied Health profession to review that document.

Agenda Item 7: Update on Registered Dental Assistant and Registered Dental Assistant in Extended Functions Educational Programs and Courses Application Approvals Ms. Bell provided the report, which is available in the meeting materials.

Regarding the infection control course, Council Member Larin asked whether this includes the eight-hour course or the two-hour course, and how accessible the eight-hour course is. Ms. Bell responded this is the previously implemented 2024 infection control course. She stated Board staff would have to get more information on where the courses are located. Ms. Bell added there is a table on the Board's website under the dental assisting tab that lists all of the courses that are available and the contact information, which might be a good starting point.

Regarding page 28 of the meeting materials, Council Member Miyasaki reiterated some of these courses these dental assistants are taking are costly. The 10 and 12 week programs that are popping up are between \$2,500 to \$5,000. If they go through a more extensive program, such as a for profit, the tuition could be up to \$20,000. She added that if the retention rate could be higher, then the students would not be out of pocket if they decide to leave the profession.

Chair Epps-Robbins requested public comment on this item. There were no public comments made on this item.

<u>Agenda Item 8: Update, Discussion, and Possible Recommendations to the Board on Proposed Regulations</u>

Agenda Item 8.a.: Status Update on Pending Regulations

Brant Nelson provided the report, which is available in the meeting materials.

Regarding the dental assisting regulations working group, Mr. Nelson noted he has been working with the working group subject matter expert, Council Member Miyasaki, and Kristy Schieldge, and the Board's subject matter expert colleagues at the Dental Hygiene Board of California (DHBC) to develop the Board's proposed language for minimum standards for infection control. Mr. Nelson noted Board staff are currently working on dental assisting applications for the May 2025 Board meeting, and they will be applying feedback from the Board's application for dentist licensure and fees

rulemaking. Going forward, Board staff will be continuing regulatory work on dental assisting programs and courses.

Council Member Miyasaki thanked the members of the working group and noted that it was a huge learning curve and a really great process.

Dr. Montez clarified there were two separate working groups. The infection control working group consisted of Joanne Pacheco, former Board and Council member, and Council Member Miyasaki. On the other hand, the dental assisting regulation workgroup, consists of Council Member Jeri Fowler and Council Member Miyasaki. Dr. Montez conveyed the working group is wrapping up the infection control, and then Board staff will go back to dental assisting to continue on with proposed revisions to the other articles in the Board's current regulations.

Chair Epps-Robbins requested public comment on this item. There were no public comments made on this item.

Agenda Item 8.b.: Discussion and Possible Recommendation to Initiate a Rulemaking to Amend California Code of Regulations, Title 16, Section 1005 Regarding Minimum Standards for Infection Control

Mr. Nelson provided the report, which is available in the meeting materials.

Ms. Schieldge clarified the working group concluded its work in November, but the proposal was not ready for the Council's review at that time. Board staff presented the proposal to DHBC, which approved the draft in Attachment 1 to the meeting materials. At the DHBC meeting, the California Dental Association (CDA) raised concerns about requiring a top shield, in addition to a side shield, which was the original recommendation from the working group. Upon re-review by the working group following the DHBC meeting, the working group agreed to remove the top shield requirement, which is reflected in Attachment 2 to the meeting materials. Board staff is recommending the Council recommend Attachment 2 to the Board.

(M/S/C) (Miyasaki/Gerlach) to recommend the Board approve the proposed regulatory text in Attachment 2, and request that staff provide Attachment 2 to the Dental Hygiene Board of California for their review and reconsideration of their prior action on this item, and to obtain a consensus with this Board on the Guidelines. Upon receiving notice that the Dental Hygiene Board of California has approved Attachment 2 and thereby reached consensus with this Board, the Council recommends the Board further direct staff to submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency for review. If no adverse comments are received, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any non-substantive changes to the text and the package, and set the matter for a hearing if requested. If after the 45-day public comment period, no adverse comments are received, and no public hearing is requested, authorize the Executive Officer to take all steps necessary to complete the rulemaking, and adopt the

proposed regulations as noticed for California Code of Regulations (CCR), title 16, section 1005.

Chair Miyasaki requested public comment before the Council acted on the motion. The Council received public comment.

Ms. Becker, representing herself, asked if this will be going back for a 45-day public comment period. Ms. Schieldge responded that it will. Ms. Schieldge requested that if there are issues with the text, the issues are worked out now before it is filed. She stated it would be more beneficial to address the issues now, rather than hold it up later to bring it back to the Board for further modifications. She noted there is the extra step of going to the DHBC for their approval. Ms. Schieldge added that would extend the amount of time involved if the issues are not discussed and addressed prior to filing the rulemaking package.

Melodi Randolph, representing the Dental Assisting Alliance, noted that hand scrubbing on page three being mentioned first seems like that is an acceptable alternative to using the ultrasonic. Therefore, they would recommend that be listed last. On top of page six where it says "protective attire shall be changed daily or immediately if they should become moist or visibly soiled", she believes there might be a question on the addition of the word "immediately" where you would have to stop the procedure to change your gown if visibly soiled seems to be problematic. On the bottom of page six, subparagraph (B), Ms. Randolph noted that "chemical and puncture-resistant utility gloves shall be available at the point of use and worn by DHCP for clinical care break-down (setting up or breaking down a treatment room)" seems to indicate the use of utility gloves to set up a treatment room, which is not how infection control is done. When a treatment room is set up, the hands are clean; therefore, that would be hugely problematic. Furthermore, the top of page seven indicates sterilizing the utility gloves, which she understands that they can be sterilized, but to require them to be sterilized after each use is overkill and would not be something offices would do regularly. She suggested to possibly change that word from "sterilized" to "disinfected" which would make sense. On page eight, Ms. Randolph noted the addition of the word immediately in "critical instruments, items, and devices shall be discarded or pre-cleaned, packaged or wrapped, and sterilized immediately after each use". She conveyed that offices, when they are very busy, cannot sterilize their instruments immediately after use. A lot of times they will sit in a preclean or presoak or they will need to sit for an hour or so before they are sterilized. She believes that to sterilize them immediately is unrealistic. Ms. Randolph asked to add a clarification on the top of page nine regarding sterilizing low-speed handpieces. She noted that in her interpretation, that includes the quick connect or the motor of the slow speed, and many offices do not sterilize the motor of the slow speed, just the nose cone. She verbalized that it would be great to have some clarification in there if the motor also has to be sterilized or if just the nose cone is acceptable.

Tooka Zokaie, representing CDA, commented that in the past 60 days, CDA has received numerous complaints from dental members about challenges regarding the

timing of the eight-hour infection control course to be before exposure to blood and saliva. She indicated that this has been 10% of their member interactions surpassing other topics by 23%.

Dr. Bruce Whitcher, CDA representative, thanked those who worked on this for incorporating one of their recommended changes, which was the removal of top shields from the safety eyewear requirements. He stated that he could not find any source for the proposed top shields standard as to why that type of eyewear would be suitable for use in dentistry and noted that the top shields standards is an industrial standard and different from what we do.

Ms. Zokaie noted that CDA thanks the Board for aligning standards with Occupational Safety and Health Administration (OSHA) and Centers for Disease Control and Prevention (CDC) for the personal protective equipment (PPE) requirements.

Eloise Reed, representing herself, indicated that she teaches infection control courses, both eight-hour infection control and review classes for the licentiates in California, and stated that she concurs with Ms. Randolph and Ms. Becker with their identified needs for change on the minimum standards for infection control.

Leslie Canham, RDA, disclosed that she is a certified in dental infection prevention control and a registered provider for the infection control two-hour course and the eighthour course. She noted that in the minimum standards for infection control and the draft regulation in the attachment, she sees a number of flaws in various areas as already pointed out but is particularly concerned with the dental unit waterline information, that there is no recommendation or no requirement for dental unit water line testing. Per CDC guidelines, purging and fleshing is appropriate; however, as stated in the CDC guidelines from 2002, studies demonstrate that this practice does not affect biofilm in the dental unit waterlines or reliably improve dental unit water quality during dental treatment. Without monitoring, there is no way of knowing if there is colonization of bacteria that could be particularly harmful to patients. Citing the Children's Dental Group event in 2016 with the non-tubercular mycobacterium outbreak with over 73 children affected and 72 hospitalized, Ms. Canham voiced concern that there is not any mention in the dental unit water line section about monitoring water quality and not performing any kind of strategy to improve water quality upon a fail of dental unit water quality monitoring levels. She would be interested in providing assistance in reviewing these infection control draft regulations.

Ms. Schieldge asked for clarification on whether Ms. Canham was referring to the text on page 10, "[(D) Dental] unit water lines shall be anti-retractive..." and "[t]he dental unit lines and devices shall be flushed between each patient and after the final patient of the day for a minimum of twenty (20) seconds." Ms. Canham confirmed that she was referring to the referenced text.

(M/S/C) (Miyasaki/Olague) to rescind the prior motion.

(M/S/C) (Olague/Fowler) to take back public comment and any discussion that the Council has to the working group and have this come back to a future Council meeting.

Council Member Miyasaki, as part of the working group, stated she thought it was important for the proposal to go back to the working group rather than create language on the fly.

Ms. Schieldge clarified if the Council approves the motion, the proposal would go back to the working group with potentially new revisions to the text in response to the public comments received during this meeting. In response to a question by Ms. Fowler on the next steps should the motion pass and revisions made, Ms. Schieldge stated it was hard to say whether there will be any revisions at this time because there has not been time to think through, analyze, and have the working group's experts opine on the public comments

Chair Epps-Robbins requested public comment before the Council acted on the motion. The Council received public comment.

Ms. Becker, on behalf on the Alliance, agreed the language should be sent back to the working group for reconsideration.

William Kushner, (Doctor of Dental Surgery (DDS)), California Academy of General Dentistry, voiced support for the motion to refer back to the working group for review, discussion, and reimplementation of a revised [proposal].

Dr. Montez explained it is critically important that the Board's stakeholders review meeting materials, as these materials have been presented at prior meetings, and added that the process is now delayed and will need to come to the May Board meeting and will have to go to the Council and the DHBC. She supported taking this back and noted this feedback seems to be substantial and needs to be vetted, but it delays the process. She noted when the Board hears that regulations take years and years, this is an example of why. She reiterated it was important for stakeholders to do their homework ahead of time.

Tara Welch asked Ms. Schieldge for more information on the process if the working group determines additional changes are necessary. Ms. Schieldge responded that if this gets referred back, the working group would reconvene. She noted a new working group member will need to be appointed, due to the loss of Ms. Pacheco. Ms. Welch noted the Council Chair can appoint the new working group member. Ms. Schieldge added that the working group would need another Board expert on infection control, as Council Member Miyasaki is now the only working group member. Ms. Schieldge commented that it helps to have two Board experts as the DHBC has two, and it seemed to work well previously. Ms. Schieldge stated that once the individual is appointed, the proposal will go back to the working group. The working group would go

through the recommendations and comments made at this meeting. When the working group makes a recommendation on what they think are good changes, if any, then the proposal would be sent to the DHBC's working group. They would look at it, tell Board staff if they agree or want to make changes, and the proposal would go back and forth until there is some kind of a consensus. Then the proposal would come back to either one of the boards, depending on which is going to be meeting first or consider having a joint board meeting of the two boards. If the DHBC reviews the proposal first, then the proposal would return to the Council for review prior to referral to the Dental Board.

Ms. Welch asked whether stakeholders can submit their written comments, so the working group has actual text to review. Ms. Schieldge responded that would be helpful to the working group, but that they are not required to do so.

Council Member Olague volunteered to partner with Council Member Miyasaki and the DHBC to get this across the finish line.

Chair Epps-Robbins called for the vote on the motion. Ms. Taran took a roll call vote on the motion.

Ayes: Epps-Robbins, Fowler, Gerlach, Larin, Miyasaki, Olague, Smith.

Nays: None.

Abstentions: None. Absent: None. Recusals: None.

The motion passed.

Council Member Miyasaki voiced that many of these concerns could be easily addressed and reminded everyone that all this information is evidence based on state and federal guidelines, so the working group will have to refer to those guidelines. For instance, Council Member Miyasaki would personally prefer taking out the hand scrubbing provision, but her opinion is not evidence based and she could not enforce her own guidelines. She agreed the dental unit water line monitoring should be included in the regulatory proposal.

Council Member Larin agreed to removal of the areas that say "immediately;" that is not feasible in dental offices. Regarding the motor hand piece part, she conveyed that is also very important to clarify and recommended changing the language on that.

Vice Chair Fowler agreed with Council Members Larin and Miyasaki and added that the utility gloves for the setup issue is something that should be addressed.

<u>Agenda Item 9: Update, Discussion, and Possible Recommendation to the Board on</u> Proposed Legislation

Agenda Item 9.a.: Legislation of Interest

Mr. Nelson provided the report, which is available in the meeting materials.

Mr. Nelson reported that there is currently no legislation of interest as of January 10, 2025 and added that he anticipates having a much larger analysis at the May Board meeting.

Chair Epps-Robbins requested public comment on this item. There were no public comments made on this item.

Agenda Item 9.b.: Discussion and Possible Recommendation on Legislative Proposal to Amend Business and Professions Code (BPC) Sections 1725, 1750, and 1753.52 and Repeal BPC Sections 1754.5 and 1755 Regarding Dental Assisting Courses Dr. Montez introduced this item.

Dr. Montez expressed that back in November, Board staff explained to the Council and the Board that there were provisions within the Board's Sunset bill [Senate Bill (SB) 1453 (Ashby, Ch. 483, Stats. 2024)] regarding the infection control course, primarily that the Board was unable to implement. It was explained that Sunset bill was rather large, and as Board staff started moving into implementation, Board staff realized there were details of grave concern that prevented the Board from implementing this piece. After working with the working groups and stakeholders and trying to reach a compromise on how to address the concerns, Board staff realized there were deficiencies and discrepancies that could not be resolved. Therefore, Board staff was going to recommend and has to the Council and the Board to repeal these sections and essentially correct the issues through the regulatory process. However, in recent weeks the Board has received quite a bit of feedback from stakeholders about frustrations with a delay of implementing this portion of the Sunset bill. Dr. Montez voiced that a legislative proposal was drafted for additional consideration with the item that was originally in the meeting materials. She emphasized the legislative proposal was something that Board staff had attempted to do but pulled back as it was very challenging to get consensus. Due to the concerns, Board staff put something together and tried to articulate the true intent of SB 1453, which had to do primarily with the interest in having a virtual option of the eight-hour infection control coupled with the public safety, and that is requiring unlicensed dental assistants to take a course prior to working with patients. She expressed that was the two pieces that were very important that was captured in the Sunset bill. Where it became difficult to implement was that there is no detail about the laboratory instruction. Dr. Montez emphasized the importance of collaboration and working together and realizing the need to look at this from the perspective of consumer safety.

Mr. Nelson provided the report, which is available in the meeting materials.

Ms. Welch noted that in the legislative proposal the Council Members received prior to the meeting, instead of repealing BPC section 1754.5, the radiation safety course, the new proposal would also add a Board approval process and laboratory and clinical

provisions that are currently in the regulations, move those into the statute, and provide student protection for electronic course delivery with the intent to ultimately repeal the radiation safety course regulations, CCR, title 16, sections 1014 and 1014.1, if possible. Ms. Welch advised the intent to clean up the regulations. Since there is a new radiation safety course statute, the idea is to move the regulations into the statute so it is clearer what are the radiation safety course requirements.

Ms. Welch added that this infection control course, in particular, is the one that Board staff have been trying to get resolved as soon as possible, as that statute [BPC section 1755] is already in effect. She noted the Board's implementation problems and need to address consumer safety through having more dental professionals available. Therefore, if the infection control courses can be made available to dental assistants so they can start to provide services to consumers; that is one of the balancing tests here. Instead of trying to repeal what the Legislature added last year in the Board sunset bill, Board staff is trying to tweak these so they are more palatable for Board staff in terms of implementation. She added a Board process to approve or deny applications was needed in case there is noncompliance. She stated clarification was needed on what laboratory instruction is, especially when the laboratory instruction in regulation requires oversight, such as supervision and in person participation, whereas the new statute contemplates electronic delivery of both didactic and laboratory instruction. Ms. Welch conveyed that Board staff is also focusing the statute on dental assistants. From what was heard in stakeholder meetings on these issues in December, the real concern is getting dental assistant course access, not necessarily changing how individuals applying for RDA licensure access infection control courses. Right now, the statute establishes a different pathway for some RDA license applicants, who would have to take this statutory electronic infection control course, while other RDA license applicants, who go through a standard educational program or the Dental Assisting National Board (DANB) pathway, are not accommodated in this new statute. Ms. Welch stated Board staff is trying to understand why there needs to be a different infection control course for RDA license applicants depending upon the pathway the individual chooses to seek for their license. The focus in conversation was on unlicensed dental assistants and getting them working as soon as possible. She voiced that the amendments distributed yesterday refocus that statute on unlicensed dental assistants and provide some additional grandfathering clauses so that dental assistants who have been working for many years and took the eight-hour infection control course under regulation would not have to immediately turn around and take this new eight-hour course where there is six hours of didactic instruction and two hours of laboratory instruction. She stated [the intent in the new proposal] is to be helpful and make sure dental assistants do not have to take multiple courses on the same issue.

Council Member Fowler conveyed that she saw [in the new proposal] the addition of the eight-hour course, with the six-hour didactic, the two-hour laboratory using a series of video training tools, ultimately removing the hands-on component with that option. She added that there is benefit to having hands-on in that infection control course and raised concern about that option. Council Member Fowler noted the new proposal states the

"course director shall possess a valid, active, and current license issue by the DHBC" and expressed that this eliminates the possibility of a dentist becoming director and limits the possible amount of infection control courses just down to maybe a hygienist being a director.

Ms. Welch responded that through the Sunset bill process last year, there was a lot of conversation about whether or not in-person instruction is necessary for infection control. She conveyed that the Legislature voted to not require it in BPC section 1755 for these two purposes, one being unlicensed dental assistants and the other being RDA licensure pathway. She added that for unlicensed dental assistants, the existing statute does not require in-person instruction and recognized that there is a public safety component to that, but from conversations with legislative staff, the Legislature has already approved that. Ms. Welch noted there is concern about no in-person instruction on infection control. Coming out of COVID-19, there is an understanding how important infection control is, especially for dental health providers. She asked whether RDA license applicants should, any pathway to that licensure and the additional duties that they are allowed to do under the statute, be allowed any pathway to take an infection control course electronically. Because of the expanded duties that RDAs perform and subsequently RDAEFs, she asked whether there should be more public protection by requiring in-person clinical instruction for all RDA license pathways. Regarding the dentist provision, Ms. Welch noted that is not currently in the regulations; the infection control course [in regulation] requires the course directors to have a Board RDA license or a DHBC license.

Council Member Fowler expressed that would be fine, it could be continued to be written that way. Right now, it is just stated as the director has to have a license from the DHBC and does not mention anything else in that. Ms. Welch responded that this language is intended to mirror what is in the regulations. Council Member Fowler asked whether it should be added that the director can have a license from the Board. Ms. Welch responded that it is in regulation right now.

Council Member Miyasaki noted that on page 11 of the new materials, it says the course director shall possess a valid, active, and current license issued by the Board or the DHBC.

(M/S/C) (Miyasaki/Smith) to approve the recommendation for submission to the Board the legislative proposal to amend BPC sections 1725, 1753.52, 1754.5, and 1755 regarding dental assisting courses.

Council Member Olague requested clarification on the motion and whether it proposed [amendments to BPC section 1750] to change the requirement to complete the infection control course within 30 to 60 days. Ms. Welch stated the motion is for the new legislative proposal that does not make any changes to BPC section 1750. That section was proposed to be amended in the first legislative proposal [in the meeting materials] that also would have repealed BPC section 1755 for infection control. If BPC section

1755 was repealed, so the Board can move quickly with stakeholders and buy time to have conversations about the appropriate levels of instruction and flesh out what should be required for electronic delivery of some of the instruction, Board staff heard there was a need to do something about the immediate requirement for dental assistants to take the infection control course in BPC section 1750. Since the new proposal amends BPC section 1755 and not repeal it, there seemed to be no need to amend BPC section 1750.

Chair Epps-Robbins requested public comment before the Council acted on the motion. The Council received public comment.

Ms. Zokaie, representing CDA, thanked the Board for their collaboration and emphasizing this significant challenge. She voiced that over the past 60 days, CDA has received numerous complaints from dental members about challenges regarding the timing of the eight-hour infection control course to be before blood and saliva. This has been 10% of their member interactions, surpassing other topics by 23%. She indicated that this unintended consequence to hiring and confusion about the course timing can be addressed through this swift legislative action, giving the Board the clarity it needs to approve the virtual course option it supported in last year's Sunset in this proposal, and by providing a cushion for employers to ensure the course is completed soon after the hire by giving employers up to 90 days to have their dental assistants complete the course. This would be an amendment to BPC section 1750, subdivision (c). These changes will allow providers to get online courses Board approved, addresses the new barriers to practice hiring, and allows unlicensed dental assistants to take the course early on, but at a time where they have enough context from on-the-job experience to understand the material. While CDA is very pleased to see that the Board is taking this collaborative approach with stakeholders and the legislator on this issue, they anticipate there to be no changes to the law, even with urgency language, effective until summer. She asked whether, in the interim, the Board can provide guidance to dentist employers when they are unable to get their new unlicensed dental assistants enrolled in a course in a timely manner and whether it recommends documenting these challenges when an unlicensed dental assistant begins work in the office and the eight-hour infection control course cannot be practically completed within the new time frame to avoid any workforce stoppages. Ms. Zokaie voiced that CDA hopes the Board considers this proposed amendment to BPC section 1750, subdivision (c), and explore the questions on documentation of the challenges without a currently online Board-approved course that addresses the full scope of the course.

Dr. Whitcher spoke in support of Ms. Zokaie's comments.

Ms. Randolph, representing the Dental Assisting Alliance, voiced that she is confused about the grandfathering in issue, if that is grandfathering in somebody who has already taken the four and four, eight-hour infection control not having to do a six and two. She asked whether that includes grandfathering in the providers that are approved for a four and four, or if they would have to reapply to be approved for the six and two, or are they

grandfathered in to be able to change their course from the approved four and four to a six and two. She noted the way she read the proposal, it still causes a problem having no approved eight-hour infection control providers as no one is approved for a six and two. Speaking as herself, Ms. Randolph expressed that she agrees with the comments that [Board] counsel made about the RDA having two different pathways for the infection control. If [an RDA license applicant is] on-the-job trained, they would not have to do a lab, whereas somebody graduating from a Board-approved RDA program does a lab session. She believes the compromise in the new proposal that an RDA would have to take the eight-hour infection control with a lab component in order to qualify for the RDA [license] clears up that problem, so that there is not two different pathways. If a virtual only option is approved, the Dental Assisting Alliance strongly opposes the 60-day option for getting it done. She stated the course can be completed in one day; if a person is hired on Monday, they can do the course on Tuesday, and start working on Wednesday.

Ms. Becker, representing the Alliance, concurred and agreed with Ms. Randolph's statements.

Dr. Kushner, speaking as an individual, voiced that he supports amending BPC section 1755 and the motion that is on the floor presented.

Ms. Canham, registered provider of the eight-hour infection control course, concurred with the recommendation to grandfather providers in to expedite the process of the six and two process for delivery of the eight-hour infection control course. She disclosed that she has been certified in dental infection prevention and control fully online and noted that it is possible to provide public safety and expedite course delivery to unlicensed dental assistants through an online process.

Council Member Miyasaki clarified that the portion in BPC section 1750 that says the employer of a dental assistant shall be responsible for ensuring the dental assistant has successfully completed a Board-approved eight-hour course in infection control will stay as prior to performing any basic dental procedures involving potential exposure to blood, saliva, or potentially infectious material.

Ms. Welch stated she did not believe the Board could automatically grandfather in currently Board-approved infection control courses and give them Board approval for this new eight-hour and six-hour didactic/two-hour lab under their prior approval. She believed the course providers who wanted to do that would need to submit additional documentation of compliance with the new requirements proposed in BPC section 1755. If they were already Board approved to offer the eight-hour infection control course under a program or the infection control course regulation, they would also, if they want to continue to have Board approval for the BPC section 1755 electronic course, have to submit an application showing compliance with those requirements, as they are somewhat different than the regulatory infection control course requirements. These infection control courses, with only didactic and laboratory instruction, would all

be offered reportedly through electronic means. Ms. Welch indicated the currently approved providers would need to submit an application to get approval to offer these new courses.

Council Member Miyasaki asked that if a provider is teaching a course that is 32 hours and 20 hours are lecture and the rest is lab, would they still have to resubmit a new application.

Tina Vallery responded that all of the Board's current infection control course providers are approved under CCR, title 16, section 1070.6, and with this new statute and the new requirements, all providers would have to apply under this new pathway as this would be applicable to unlicensed dental assistants, so there would be two separate courses. She added that if the eight-hour course is offered under CCR, title 16, section 1070.6, the course provider could still apply and teach both, but it would require a separate application.

Council Member Miyasaki noted on the public comment concerning a person in a rural area and being required to immediately take the course would be a hardship. She referred back to her comments on page 22 of the meeting materials about the retention rates of dental assisting. She believed this could be a workforce issue; if more dental assistants are retained, then there would not be a need to have more coming into the workforce as often. She noted this may be something that could be addressed by the stakeholders because that way, there would not be a need for more new courses, with the burden on Board staff to approve those new courses. She noted the retention rate for dental assisting is much lower than the rates for dental hygienists and dentists.

Chair Epps-Robbins called for the vote on the motion. Ms. Taran took a roll call vote on the motion.

Ayes: Epps-Robbins, Fowler, Gerlach, Larin, Miyasaki, Olague, Smith.

Nays: None.

Abstentions: None. Absent: None. Recusals: None.

The motion passed.

Agenda Item 10: Adjournment

Chair Epps-Robbins adjourned the meeting at 10:26 a.m.



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### MEMORANDUM

DATE	April 21, 2025
то	Members of the Dental Assisting Council
FROM	Mirela Taran, Administrative Analyst Dental Board of California
SUBJECT	Agenda Item 4.: Assistant Executive Officer Report

#### **Background**

Christy Bell will provide an update on Board activities.

### **Action Requested**

No action required.



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### MEMORANDUM

DATE	April 7, 2025
то	Members of the Dental Assisting Council
FROM	Rikki Parks, Dental Assisting Program Manager Dental Board of California
SUBJECT	Agenda Item 5.: Update on Dental Assisting Examination Statistics

#### **Background**

The following table provides the examination statistics for candidates who attempted dental assisting examinations in fiscal years (FY) 2021–22, 2022–23, 2023–24, and 2024–25 through March 31, 2025.

	License Type	RDA	OA	DSA		RDAEF	
		Written	Written	Written	Clinical	Practical	Written
	Total 1st Time Candidates Tested	1,773	156	3	N/A	N/A	120
	1st Time Candidates Pass	1,466	137	3	N/A	N/A	104
	1st Time Candidates Pass %	83%	88%	100%	N/A	N/A	87%
	1st Time Candidates Fail	307	19	0	N/A	N/A	16
	1st Time Candidates Fail %	17%	12%	N/A	N/A	N/A	13%
	Total Repeat Candidates Tested	601	64	2	N/A	N/A	45
FY	Repeat Candidates Pass	263	36	1	N/A	N/A	22
2024/25	Repeat Candidates Pass %	44%	56%	50%	N/A	N/A	49%
2024/23	Repeat Candidates Fail	338	28	1	N/A	N/A	23
	Repeat Candidates Fail %	56%	44%	50%	N/A	N/A	51%
	Total Candidates Tested	2,374	220	5	N/A	N/A	165
	Total Candidates Passed	1,729	173	4	N/A	N/A	126
	Total Candidates Pass %	73%	79%	80%	N/A	N/A	76%
	Total Candidates Failed	645	47	1	N/A	N/A	39
	Total Candidates Failed %	27%	21%	20%	N/A	N/A	24%
	Total 1st Time Candidates Tested	2,466	171	8	N/A	N/A	213
	1st Time Candidates Pass	1,973	123	7	N/A	N/A	176
	1st Time Candidates Pass %	80%	72%	87.5%	N/A	N/A	83%
FY	1st Time Candidates Fail	493	48	1	N/A	N/A	37
2023/24	1st Time Candidates Fail %	20%	28%	12.5%	N/A	N/A	17%
	Total Repeat Candidates Tested	1,065	150	1	N/A	N/A	107
	Repeat Candidates Pass	504	47	1	N/A	N/A	46
	Repeat Candidates Pass %	47%	31%	100%	N/A	N/A	43%

Agenda Item 5.: Update on Dental Assisting Examination Statistics Dental Assisting Council Meeting May 14, 2025

	Repeat Candidates Fail	561	103	0	N/A	N/A	61
	Repeat Candidates Fail %	53%	69%	0	N/A	N/A	57%
	Total Candidates Tested	3,531	321	9	N/A	N/A	320
	Total Candidates Passed	2,477	170	8	N/A	N/A	222
	Total Candidates Pass %	70%	53%	89%	N/A	N/A	69%
	Total Candidates Failed	1,054	151	1	N/A	N/A	98
	Total Candidates Failed %	30%	47%	11%	N/A	N/A	31%
	Total 1st Time Candidates Tested	2,107	255	8	N/A	N/A	194
	1st Time Candidates Pass	1,644	189	7	N/A	N/A	155
	1st Time Candidates Pass %	78%	74%	88%	N/A	N/A	80%
	1st Time Candidates Fail	463	66	1	N/A	N/A	39
	1st Time Candidates Fail %	22%	26%	12%	N/A	N/A	20%
	Total Repeat Candidates Tested	814	100	3	N/A	N/A	130
FY	Repeat Candidates Pass	361	54	3	N/A	N/A	52
2022/23	Repeat Candidates Pass %	44%	54%	100%	N/A	N/A	40%
2022/23	Repeat Candidates Fail	453	46	0	N/A	N/A	78
	Repeat Candidates Fail %	56%	46%	N/A	N/A	N/A	60%
	Total Candidates Tested	2,921	355	11	N/A	N/A	324
	Total Candidates Passed	2,005	243	10	N/A	N/A	207
	Total Candidates Pass %	69%	68%	91%	N/A	N/A	64%
	Total Candidates Failed	916	112	1	N/A	N/A	117
	Total Candidates Fail %	31%	32%	9%	N/A	N/A	36%
	Total 1st Time Candidates Tested	1,556	137	5	54	58	160
	1st Time Candidates Pass	1,077	102	4	37	46	111
	1st Time Candidates Pass %	69%	74%	80%	69%	79%	69%
	1st Time Candidates Fail	479	35	1	17	12	49
	1st Time Candidates Fail %	31%	26%	20%	31%	21%	31%
	Total Repeat Candidates Tested	1,001	130	1	14	19	108
FY	Repeat Candidates Pass	411	66	1	9	12	43
2021/22	Repeat Candidates Pass %	41%	51%	100%	64%	63%	40%
LVL 1/LL	Repeat Candidates Fail	590	64	N/A	5	7	65
	Repeat Candidates Fail %	59%	49%	N/A	36%	37%	60%
	Total Candidates Tested	2,557	267	6	68	77	268
	Total Candidates Passed	1,488	168	5	46	58	154
	Total Candidates Pass %	58%	63%	80%	68%	75%	57%
	Total Candidates Failed	1,069	99	1	22	19	114
	Total Candidates Fail %	42%	37%	20%	32%	25%	43%

The Office of Professional Examination Services (OPES) monitors the passing rates for the dental assistant examinations. OPES works with subject matter experts (i.e., actively practicing licensees who are in good standing) to build a bank of quality questions that adhere to professional guidelines and technical standards for use on occupational licensing examinations.

### **Action Requested**

Informational only. No action required.

Agenda Item 5.: Update on Dental Assisting Examination Statistics Dental Assisting Council Meeting May 14, 2025



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# MEMORANDUM

DATE	April 11, 2025
то	Members of the Dental Assisting Council
FROM	Rikki Parks, Dental Assisting Program Manager Dental Board of California
SUBJECT	Agenda Item 6.: Update on Dental Assisting Licensing Statistics

### **Dental Assistant License Application Statistics**

The following tables provide monthly dental assistant license application statistics for fiscal years 2021–2022, 2022–2023, 2023–2024, and 2024–2025.

		De	ental As	sistant	Applic	ations (	1010) R	eceived	by Mon	th			
	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Totals
RDA 21-22	212	220	246	256	176	174	172	159	222	199	278	331	2,645
RDA 22-23	265	213	138	184	156	100	187	155	190	272	281	183	2,324
RDA 23-24	329	277	224	251	190	165	118	203	200	171	291	246	2,665
RDA 24-25	189	238	213	220	144	158	185	142	163				1,162
RDAEF 21-22	4	7	27	14	21	13	9	9	5	42	10	29	190
RDAEF 22-23	4	14	11	24	10	8	4	10	20	29	31	40	205
RDAEF 23-24	16	15	4	25	1	5	23	16	24	37	10	25	201
RDAEF 24-25	24	8	12	20	24	0	13	8	19				128
OA 21-22	14	24	26	25	30	28	18	14	25	26	22	20	272
OA 22-23	16	28	23	16	18	8	27	19	19	25	17	13	229
OA 23-24	19	21	19	13	26	29	12	18	27	23	24	17	248
OA 24-25	20	21	24	26	14	16	30	20	28				199
DSA 21-22	0	0	1	5	0	2	0	1	2	6	1	0	18
DSA 22-23	0	4	3	8	0	1	0	0	1	3	1	0	21
DSA 23-24	1	1	0	4	0	0	1	0	0	1	2	1	11
DSA 24-25	1	0	0	1	1	0	0	0	0				3
		De	ental As	sistant	Applica	ations (	1010) Ap	proved	by Mor	nth			
	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Totals
RDA 21-22	225	273	225	209	176	108	71	118	114	139	118	121	1,897
RDA 22-23	129	271	846	378	480	338	180	140	286	252	247	284	3,831
RDA 23-24	171	332	232	407	152	203	130	251	270	210	227	326	2,911
RDA 24-25	179	296	281	340	169	177	217	154	161				1,974

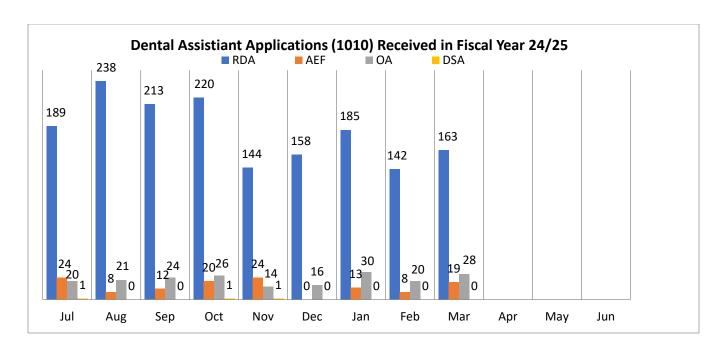
Agenda Item 6.: Update on Dental Assisting Licensing Statistics Dental Assisting Council Meeting

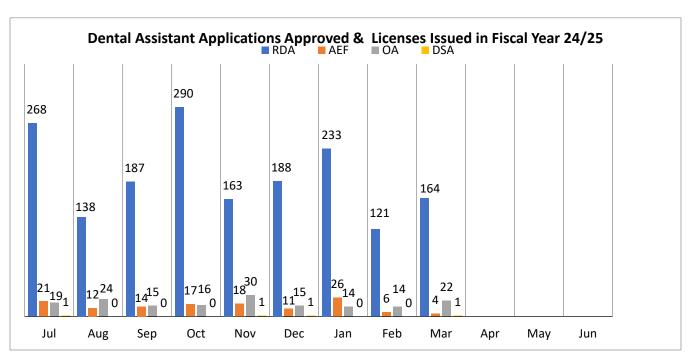
	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Totals
RDAEF 21-22	18	1	4	22	25	12	3	11	9	7	24	35	171
RDAEF 22-23	25	20	0	21	18	10	17	4	32	26	20	33	226
RDAEF 23-24	12	18	6	33	8	3	8	22	12	33	26	16	197
RDAEF 24-25	15	20	10	18	14	16	12	3	3	+			111
OA 21-22	20	18	13	6	23	12	10	10	7	13	11	14	157
OA 22-23	22	22	36	56	26	19	20	15	35	23	19	13	306
OA 23-24	3	8	12	29	12	23	17	18	27	17	24	23	213
OA 24-25	15	18	19	41	13	9	20	16	22				173
DSA 21-22	2	0	0	0	0	0	0	1	2	0	1	0	6
DSA 22-23	2	1	0	2	1	4	1	2	0	0	1	3	17
DSA 23-24	0	0	1	4	1	1	0	0	0	0	0	1	8
DSA 24-25	0	0	1	0	1	1	0	0	0				3
		De	ntal As	sistant	Applica	tions (1	1010) AI	bandone	d by M	onth			
	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Totals
RDA 21-22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
RDA 22-23	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
RDA 23-24	49	221	2	4	204	19	0	10	36	7	41	9	602
RDA 24-25	16	9	31	39	15	6	20	0	44				180
RDAEF 21-22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
RDAEF 22-23	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
RDAEF 23-24	8	0	0	0	0	2	0	3	0	0	1	0	14
RDAEF 24-25	0	0	1	1	0	0	0	0	0	1	1		2
OA 21-22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OA 22-23	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OA 23-24	27	0	0	0	20	2	0	2	4	1	2	1	59
OA 24-25	1	1	2	1	0	1	2	0	0				8
DSA 21-22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
DSA 22-23	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
DSA 23-24	3	0	0	0	0	9	0	0	0	0	0	0	12
DSA 24-25	0	0	0	1	1	0	0	0	0	1		I	2
	Denta	al Assis	tant Ap	plication	ns (102	20) App	roved a	nd Licer	nses Iss	ued by	Month		
	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Totals
RDA 21-22	244	151	126	149	155	181	79	97	99	97	121	100	1,599
RDA 22-23	115	126	117	248	221	222	153	165	221	136	166	159	2,049
RDA 23-24	215	173	259	281	209	196	219	186	139	188	207	231	2,503
RDA 24-25	268	138	187	290	163	188	233	121	164				1,752
RDAEF 21-22	0	46	1	1	0	0	262	0	2	6	7	4	329
RDAEF 22-23	39	20	19	8	14	24	11	8	25	21	18	30	237
RDAEF 23-24	15	14	25	27	18	12	8	6	19	20	34	22	220
RDAEF 24-25	24	8	12	17	18	11	26	6	4			ı	129

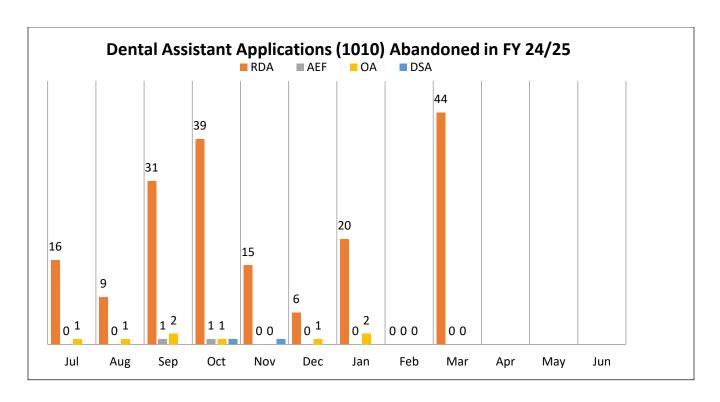
D	ental A	ssistan	t Applic	ations	(1020) A	Approve	ed and	License	s Issue	d by Mo	onth – C	ont'd	
	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Totals
OA 21-22	10	17	2	0	32	19	22	13	15	17	11	11	169
OA 22-23	18	20	12	30	28	34	19	16	24	21	20	25	267
OA 23-24	15	8	6	4	26	12	17	11	18	16	17	19	169
OA 24-25	19	24	15	16	30	15	14	14	22				169
DSA 21-22	0	0	0	0	0	2	0	0	0	2	0	1	5
DSA 22-23	0	1	1	0	0	2	0	2	0	0	1	3	10
DSA 23-24	1	0	0	1	0	2	1	2	2	0	0	0	9
DSA 24-25	1	0	0	0	1	1	0	0	1				4
			Dental	Assista	ant App	lication	s (1020	) Denie	d by Mo	nth		I .	
	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Totals
RDA 21-22	1	0	0	0	0	1	0	0	0	0	4	0	6
RDA 22-23	2	1	0	0	0	2	0	2	0	0	5	2	14
RDA 23-24	0	1	3	3	0	1	2	2	0	1	0	0	13
RDA 24-25	1	0	0	0	1	0	4	0	0				6
RDAEF 21-22	0	0	0	0	0	0	0	0	0	0	0	0	0
RDAEF 22-23	0	0	0	0	0	0	0	0	0	0	0	0	0
RDAEF 23-24	0	0	0	0	0	0	0	0	0	0	0	0	0
RDAEF 24-25	0	0	0	0	0	0	0	0	0				0
OA 21-22	0	0	0	0	0	0	0	0	0	0	0	0	0
OA 22-23	0	0	0	0	0	0	0	0	0	0	0	0	0
OA 23-24	0	0	0	0	1	0	0	0	0	0	0	0	1
OA 24-25	0	0	0	0	0	0	0	0	0				0
DSA 21-22	0	0	0	0	0	0	0	0	0	0	0	0	0
DSA 22-23	0	0	0	0	0	0	0	0	0	0	0	0	0
DSA 23-24	0	0	0	0	0	0	0	0	0	0	0	0	0
DSA 24-25	0	0	0	0	0	0	0	0	0				0
		D	ental As	ssistant	Applic	ations	(1020)	bando	ned by I	Month		I .	
	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Totals
RDA 21-22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
RDA 22-23	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
RDA 23-24	676	70	20	60	81	36	28	30	31	36	21	15	1,104
RDA 24-25	38	21	91	68	37	34	32	38	11				370
RDAEF 21-22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
RDAEF 22-23	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
RDAEF 23-24	6	0	0	0	0	0	0	0	0	0	1	3	10
RDAEF 24-25	1	0	1	0	0	0	0	1	0				3
OA 21-22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OA 22-23	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OA 23-24	15	8	4	1	3	2	4	2	1	1	0	0	41
OA 24-25	4	0	3	5	4	3	3	3	1				26

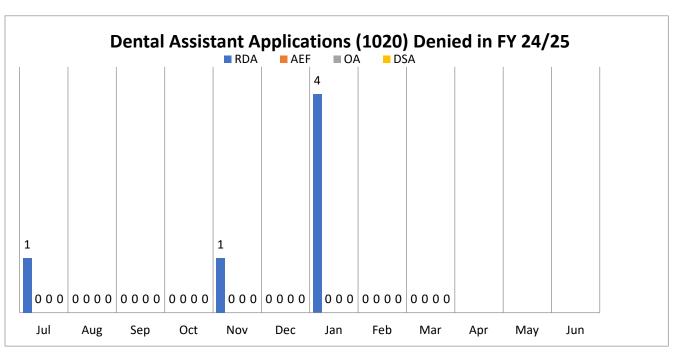
	Dental Assistant Applications (1020) Abandoned by Month – Cont'd												
	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Totals
DSA 21-22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
DSA 22-23	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
DSA 23-24	0	0	0	0	0	0	0	0	0	1	0	0	1
DSA 24-25	0	0	0	0	0	0	0	0	0		1	1	0

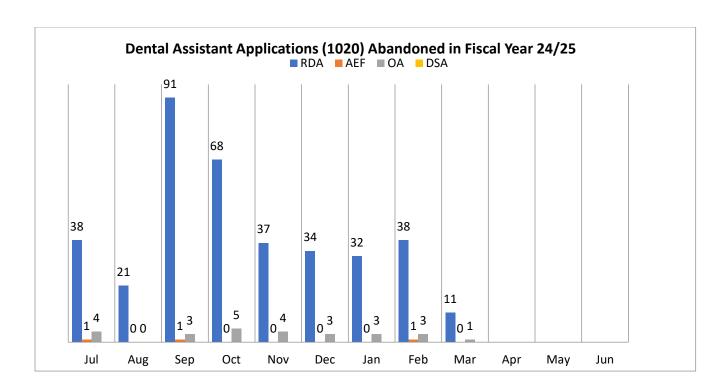
	Application Definitions							
Received	Application received in paper format or electronically through BreEZe system.							
Approved	Application for eligibility of licensure processed with required documentation and examination eligibility issued.							
License Issued	Final application including examination results approved and license issued.							
Abandoned (1010)	n applicant who fails to complete application requirements within one year after be stified by the Board of deficiencies.							
Abandoned (1020)	Pursuant to CCR, title 16, section 1004, an application is considered abandoned if:							
	<ol> <li>The applicant fails to submit the application, examination, or reexamination fee within 180 days after notification by the Board that such fee is due and unpaid.</li> </ol>							
	<ol> <li>The applicant fails to take the licensing examination within two years after the date their application was received by the Board.</li> </ol>							
	3) [A]fter failing the examination, [the applicant] fails to take a reexamination within two years after the date the applicant was notified of such failure.							
Denied	The Board denies an application on the grounds that the applicant has been convicted of a crime or has been subject to formal discipline; in accordance with Business and Professions Code, Division 1.5, Chapter 2, Denial of Licenses.							

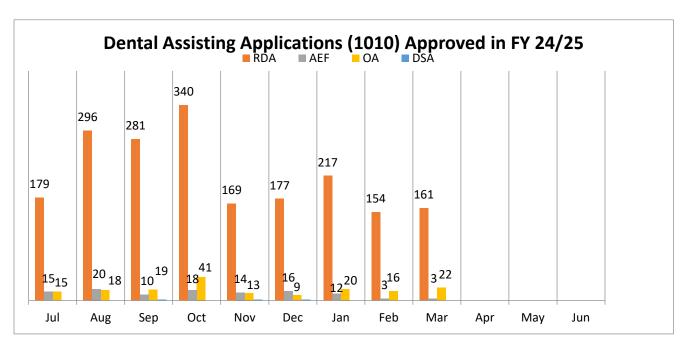












### **Dental Assistant License Status Statistics**

The following table provides dental assistant license and permit status statistics for fiscal years 2021–22, 2022–23, 2023–24, and 2024–25. Cancelled licenses indicates number of licenses/permits cancelled to date.

License Type	License Status	FY 2021–22	FY 2022–23	FY 2023–24	FY 2024–25
	Active	28,902	28,437	28,711	29,055
Registered Dental	Inactive	3,991	3,790	3,611	3,491
Assistant	Delinquent	12,992	13,543	13,696	13,666
	Cancelled	51,512	53,712	55,903	57,481
License Type	License Status	FY 2021–22	FY 2022–23	FY 2023–24	FY 2024–25
	Active	1,756	1,950	2,082	2,189
Registered Dental	Inactive	75	77	78	83
Assistant in Extended Functions	Delinquent	298	305	352	337
1 dilotions	Cancelled	420	462	494	527
License Type	License Status	FY 2021–22	FY 2022–23	FY 2023–24	FY 2024–25
	Active	1,407	1,602	1,678	1,801
Outh a double Assistant	Inactive	44	46	50	50
Orthodontic Assistant	Delinquent	286	333	399	408
	Cancelled	27	51	78	111
License Type	License Status	FY 2021–22	FY 2022–23	FY 2023–24	FY 2024–25
	Active	38	45	52	56
Dental Sedation	Active Inactive	38	45 4	52 4	56 3
Dental Sedation Assistant					

License Status De	efinitions
Active	An individual who has an active status and has completed all renewal requirements.
Inactive	An individual who has an inactive status and has paid the renewal fees, but who cannot perform the duties of the license unless the license is re-activated. Continuing education units are not required for inactive license renewal.
Delinquent	An individual who does not comply with renewal requirements. This status remains until renewal requirements are met.
Cancelled	An individual who fails to comply with renewal requirements by a set deadline.

The following table provides statistics on population, current and active Registered Dental Assistant (RDA) licenses by county, and population per RDA license by county for fiscal years 2021–22, 2022–23, 2023–24, and 2024–2025. These statistics represent the licensee's address of record and not necessarily the licensee's workplace address.

County	RDA 22-23	Pop. 22-23	Pop. per RDA 22-23	DDS 22-23	RDA to DDS Ratio 22-23	RDA 23-24	Pop. 23-24	Pop. per RDA 23-24	DDS 23-24	RDA to DDS Ratio 23-24	RDA 24-25	Pop. 24-25	Pop. per RDA 24-25	DDS 24-25	RDA to DDS Ratio 24-25
Alameda	1,221	1,651,979	1,352	1,485	0:1	1,106	1,636,194	1,479	1,472	0:1	1,127	1,641,869	1,456	1,468	0:1
Alpine	0	1,200	0	0	0	0	1,184	0	0	0	0	1,179	0	0	0
Amador	78	40,297	516	21	2:1	52	39,837	766	23	2:1	56	39,611	707	25	2:1
Butte	291	201,608	692	124	2:1	271	205,592	758	118	2:1	268	205,928	768	112	2:1
Calaveras	69	45,049	652	21	2:1	59	44,890	760	21	2:1	58	44,842	773	16	3:1
Colusa	28	21,807	778	6	4:1	28	21,771	777	4	4:1	27	21,743	805	3	9:1
Contra Costa	1320	1,156,555	876	1,103	1:1	1222	1,147,653	939	1,092	1:1	1,221	1,146,626	939	1,096	1:1
Del Norte	30	27,218	907	11	2:1	28	26,599	949	11	2:1	29	26,345	908	13	2:1
El Dorado	257	190,465	741	152	1:1	202	189,006	935	148	1:1	192	188,583	982	145	1:1
Fresno	962	1,011,273	1,051	620	1:1	891	1,011,499	1,135	625	1:1	887	1,017,431	1,147	634	1:1
Glenn	46	28,750	625	7	7:1	50	28,636	572	7	7:1	47	28,736	611	8	5:1
Humboldt	162	135,168	834	63	2:1	161	134,047	832	66	2:1	165	133,100	806	66	2:1
Imperial	102	179,329	1,758	39	2:1	90	179,476	1,994	40	2:1	91	182,881	2,009	40	2:1
Inyo	8	18,978	2,372	5	1:1	7	18,896	2,699	7	1:1	7	18,856	2,693	7	1:1
Kern	734	909,813	1,239	341	1:1	624	907,476	1,454	350	1:1	659	910,300	1,381	350	1:1
Kings	157	152,023	968	61	2:1	155	151,018	974	58	2:1	160	152,627	953	56	2:1
Lake	112	67,407	601	39	1:1	84	66,800	795	37	1:1	85	67,001	788	41	2:1
Lassen	40	30,274	756	22	1:1	35	28,275	807	18	1:1	33	28,197	854	18	1:1
Los Angeles	5099	9,861,224	1,933	8,416	0:1	4505	9,761,210	2,166	8,464	0:1	4,522	9,824,091	2,172	8,470	0:1
Madera	144	157,396	1,093	44	3:1	155	158,148	1,020	47	3:1	147	159,328	1,083	54	2:1
Marin	183	257,135	1,405	290	0:1	172	252,959	1,470	279	0:1	170	252,844	1,487	271	0:1
Mariposa	11	17,045	1,549	7	1:1	9	16,935	1,881	6	1:1	8	16,966	2,120	6	1:1
Mendocino	112	89,999	803	49	1:1	94	89,164	948	45	1:1	93	89,476	962	49	1:1

Agenda Item 6.: Update on Dental Assisting Licensing Statistics Dental Assisting Council Meeting May 14, 2025

County	RDA 22-23	Pop. 22-23	Pop. per RDA 22-23	DDS 22-23	RDA to DDS Ratio 22-23	RDA 23-24	Pop. 23-24	Pop. per RDA 23-24	DDS 23-24	RDA to DDS Ratio 23-24	RDA 24-25	Pop. 24-25	Pop. per RDA 24-25	DDS 24-25	RDA to DDS Ratio 24-25
Merced	264	284,338	1,077	92	2:1	233	285,337	1,224	98	2:1	251	287,303	1,144	96	2:1
Modoc	3	8,690	2,896	3	0:1	3	8,527	2,842	5	0:1	4	8,484	2,121	5	0:1
Mono	5	13,379	2,675	5	1:1	5	13,156	2,631	5	1:1	5	12,861	2,572	3	1:1
Monterey	436	433,716	994	248	1:1	370	430,368	1,163	244	1:1	366	437,614	1,195	250	1:1
Napa	141	136,179	965	110	1:1	130	134,637	1,035	106	1:1	129	135,029	1,046	101	1:1
Nevada	100	101,242	1,012	72	1:1	84	100,720	1,199	69	1:1	84	100,177	1,192	66	1:1
Orange	1814	3,162,245	1,743	4,073	0:1	1632	3,137,164	1,922	4,183	0:1	1627	3,150,835	1,936	4,212	0:1
Placer	534	409,025	765	472	0:1	469	410,305	874	482	0:1	462	412,844	893	488	0:1
Plumas	18	18,942	1,052	13	1:1	14	18,996	1,356	13	1:1	14	18,841	1,345	12	1:1
Riverside	2171	2,435,525	1,121	1,142	1:1	2019	2,439,234	1,208	1,163	1:1	2,005	2,442,378	1,218	1,180	1:1
Sacramento	1887	1,576,618	835	1,176	1:1	1590	1,572,453	988	1,207	1:1	1585	1,578,938	996	1,213	1:1
San Benito	118	65,479	554	23	4:1	98	65,666	670	26	4:1	101	65,853	652	27	3:1
San Bernardino	1688	2,187,665	1,296	1,398	1:1	1530	2,182,056	1,426	1,403	1:1	1562	2,181,433	1,396	1,435	1:1
San Diego	2808	3,287,306	1,170	2,820	0:1	2537	3,269,755	1,288	2,853	0:1	2541	3,291,101	1,295	2,852	0:1
San Francisco	452	842,754	1,864	1,151	0:1	424	831,703	1,961	1,127	0:1	419	843,071	2,012	1,122	0:1
San Joaquin	873	784,298	898	376	1:1	793	786,145	991	393	1:1	803	791,408	985	391	2:1
San Luis Obispo	248	280,721	1,131	210	1:1	207	278,348	1,344	217	1:1	203	278,469	1,371	213	1:1
San Mateo	572	744,662	1,301	843	0:1	533	737,644	1,383	829	0:1	537	741,565	1,380	840	0:1
Santa Barbara	399	445,164	1,115	307	1:1	355	440,557	1,241	312	1:1	354	443,623	1,253	309	1:1
Santa Clara	1662	1,894,783	1,140	2,289	0:1	1517	1,886,079	1,243	2,283	0:1	1,503	1,903,198	1,266	2,274	0:1
Santa Cruz	225	266,564	1,184	168	1:1	196	262,051	1,336	171	1:1	191	262,572	1,374	169	1:1
Shasta	203	180,531	889	100	1:1	164	179,436	1,094	109	1:1	161	179,195	1,113	110	1:1
Sierra	2	3,229	1,614	0	0:1	2	3,193	1,596	0	0:1	1	3,171	3,171	0	0:1
Siskiyou	28	43,830	1,565	23	1:1	21	43,548	2,073	23	1:1	19	43,409	2,284	22	1:1
Solano	623	447,241	717	279	2:1	562	443,749	789	277	2:1	568	446,426	785	279	2:1
Sonoma	675	482,404	714	382	1:1	607	478,174	787	374	1:1	616	478,152	776	379	1:1

Agenda Item 6.: Update on Dental Assisting Licensing Statistics Dental Assisting Council Meeting May 14, 2025

County	RDA 22-23	Pop. 22-23	Pop. per RDA 22-23	DDS 22-23	RDA to DDS Ratio 22-23	RDA 23-24	Pop. 23-24	Pop. per RDA 23-24	DDS 23-24	RDA to DDS Ratio 23-24	RDA 24-25	Pop. 24-25	Pop. per RDA 24-25	DDS 24-25	RDA to DDS Ratio 24-25
Stanislaus	665	549,466	826	274	2:1	577	545,939	946	277	2:1	558	548,744	983	283	2:1
Sutter	143	99,145	693	51	2:1	120	98,952	824	49	2:1	119	100,110	841	52	2:1
Tehama	95	65,052	684	31	2:1	75	64,271	856	28	2:1	83	64,308	774	29	2:1
Trinity	5	16,023	3,204	3	1:1	5	15,939	3,187	2	1:1	7	15,915	2,273	2	3:1
Tulare	491	475,014	967	217	2:1	474	475,064	1,002	218	2:1	485	478,918	987	225	2:1
Tuolumne	81	55,291	682	47	1:1	77	54,590	708	45	1:1	79	54,407	688	43	1:1
Ventura	590	833,652	1,412	627	0:1	512	825,653	1,612	634	0:1	530	823,863	1,554	628	0:1
Yolo	210	221,165	1,053	122	1:1	187	220,880	1,181	125	1:1	187	221,666	1,185	120	1:1
Yuba	104	82,275	791	7	13:1	97	82,677	852	10	13:1	94	83,721	890	11	8:1
TOTAL	31,499	39,185,605	66,100	32,080	N/A	28,219	38,940,231	72,942	32,298	N/A	28,305	39,128,162	73,350	32,389	0:1

<sup>\*</sup>Population data obtained from Department of Finance, Demographic Research Unit. \*\*Ratios are rounded to the nearest whole number.

Counties with the Highest Population per RDA:	Sierra County (1:3,171)		Alpine County (No RDAs)	
	Inyo County (1:2,693)	Counties with the Lowest	Glenn County (1:611)	
	Mono County (1:2,572)	Population per RDA:	San Benito County (1:652)	
	Siskiyou County (1:2,284)		Tuolumne County (1:688)	
	Los Angeles County (1:2,273)		Amador County (1:707)	

### **Action Requested**

Informational only. No action required.

Agenda Item 6.: Update on Dental Assisting Licensing Statistics Dental Assisting Council Meeting May 14, 2025







# MEMORANDUM

DATE	April 22, 2025
то	Members of the Dental Assisting Council
FROM	Victor Libet, Manager of License and Program Compliance Unit Dental Board of California (Board)
SUBJECT	Agenda Item 7.: Update and Discussion on Registered Dental Assistant and Registered Dental Assistant in Extended Functions Educational Programs and Courses Application Approvals and Re-Evaluations

The following table provides dental assisting (DA) educational programs and courses application statistics for fiscal years 2021–22, 2022–23, 2023–24 and 2024–2025 through March 31, 2025.

RDA and RDAEF Educational P	rogram and	Course Applic	ations Appr	oved
Program/Course	2021–22	2022–23	2023–24	2024–25
RDA Program	1	0	0	1
RDAEF Program	0	0	0	1
RDAEF-ITR	0	0	0	0
Radiation Safety	9	11	5	5
Coronal Polishing	9	9	3	4
Pit & Fissure Sealant	9	5	3	1
Ultrasonic Scaling	7	0	2	0
Infection Control	11	4	4	5
DSA Permit	13	3	0	1
OA Permit	9	19	6	4
Total Applications Approved	68	51	23	22
RDA and RDAEF Educational F	Program and	Course Appli	cations Den	ied
Program/Course	2021–22	2022–23	2023–24	2024–25
RDA Program	1	0	1	1
RDAEF Program	0	0	1	0
RDAEF-ITR	0	0	0	0
Radiation Safety	3	0	7	7
Coronal Polishing	0	0	4	7
Pit & Fissure Sealant	1	0	0	9
Ultrasonic Scaling	1	0	1	3

Agenda Item 7.: Update and Discussion on Registered Dental Assistant and Registered Dental Assistant in Extended Functions Educational Programs and Courses Application Approvals and Re-Evaluations

Dental Assisting Council Meeting

Infection Control	3	1	16	7
DSA Permit	1	1	1	1
OA Permit	0	0	2	7
Total Applications Denied	10	2	33	42
RDA and RDAEF Educational P	rogram and (	Course Applic	ations Defi	cient
Program/Course	2021-22	2022-23	2023-24	2024-25
RDA Program	0	0	1	0
RDAEF Program	0	0	0	0
RDAEF-ITR	0	0	0	0
Radiation Safety	0	0	2	1
Coronal Polishing	0	0	3	1
Pit & Fissure Sealant	0	0	2	0
Ultrasonic Scaling	0	0	1	0
Infection Control	0	0	3	2
DSA Permit	1	0	0	0
OA Permit	1	1	2	0
Total Applications Deficient	2	1	14	4
RDA and RDAEF Educational P	rogram and (	Course Applic	ations Pen	ding
Program/Course	2021-22	2022-23	2023-24	2024-25
RDA Program	0	0	0	2
RDAEF Program	0	1	0	1
RDAEF-ITR	0	0	0	0
Radiation Safety	6	0	6	9
Coronal Polishing	4	0	3	8
Pit & Fissure Sealant	2	0	3	9
Ultrasonic Scaling	0	0	1	1
Infection Control	3	0	4	8
DSA Permit	0	0	0	0
OA Permit	6	0	3	3
Total Applications Pending	21	1	20	41

	Application Definitions
Approved	Application for Board approval of educational program/course processed with required documentation, and approval number issued.
Denied	The Board denies an application on the grounds that the application lacks documentation that the educational program/course complies with the requirements of the California Code of Regulations.
Deficient	Application for Board approval of educational program/course processed with submitted documentation, and additional documentation requested from applicant. For completed fiscal years, this is a snapshot of the number of deficient applications on June 30. For the current fiscal year, this is a snapshot of the number of deficient applications on March 31, 2025. Status changes weekly.

Agenda Item 7.: Update and Discussion on Registered Dental Assistant and Registered Dental Assistant in Extended Functions Educational Programs and Courses Application Approvals and Re-Evaluations

Dental Assisting Council Meeting

Pending	Board staff and/or contracted subject matter expert is reviewing an application for Board approval of an educational program/course with
	submitted documentation.

The following table provides the number of Registered Dental Assistant (RDA) and RDA in Extended Functions (RDAEF) program site visits conducted in fiscal years 2021–22, 2022–23, 2023–24, and 2024–25 through March 31, 2025.

	RDA and RDAEF Educational Program Site Visits											
	RDA P	rograms	RDAEF P	rograms	Grand Total							
	Provisional	Full	Provisional	Full								
2021–22	1	0	0	0	1							
2022–23	0	0	0	0	0							
2023–24	1	0	0	0	1							
2024–25	1	2	1	0	4							

The following table provides approved programs and courses by name and type of program for fiscal year 2024–25, through March 31, 2025.

Programs and Cours	es by Nam	e and	Тур	e App	rove	d in	Q1–Q	3 202	24–25	5	
Provider	Approval Date	RDA	RDAEF	RDAEF ITR	RS	CP	PF	SN	<u></u>	DSA	OA
Triumph University	7/1/24					X					
Triumph University	7/1/24				Х						
OceanPointe Dental Assisting Academy - La Crescenta	7/16/24								Х		
West Coast Grins	7/26/24										X
Triumph University	7/29/24						X				
Aviara Academy	7/29/24				Х						
Chaffey Community College	7/29/24				Х						
OceanPointe Dental Assisting Academy - La Crescenta	10/9/24				х						
OceanPointe Dental Assisting Academy - Merced	10/21/24				х						
OceanPointe Dental Assisting Academy - Merced	10/21/24								X		
North West College - Anaheim	10/24/24					X					
North West College - West Covina	10/24/24					Х					
Sheila T. Luwiharto DDS, MS, PC	11/19/24					X					
Rolling Hills Dental Clinic	12/10/24										Х
Capital Pediatric Dentistry	12/19/24									Х	
Citrus College	12/31/24										Х

Agenda Item 7.: Update and Discussion on Registered Dental Assistant and Registered Dental Assistant in Extended Functions Educational Programs and Courses Application Approvals and Re-Evaluations

Dental Assisting Council Meeting

Central California Dental Academy	1/3/2025		X								
Rockstar Family Dental	1/21/2025								Х		
Lincoln Dental Academy	3/3/2025								Х		
Buena Park Dental Assisting	3/5/2025								Х		
California Dental Institute	3/7/2025										Х
San Manuel Gateway College – Loma Linda University Health	3/24/2025	Х									
PROGRAM/COURSE TOTALS		1	1	0	5	4	1	0	5	1	4
TOTAL APPROVALS = 22											

The following table provides the total number of approved DA educational programs and courses in active status as of March 31, 2025.

То	tal Approv	ved DA E	ducation	Table nal Progr	_	d Courses	s in Acti	ve Status	S
RDA Program	RDAEF Program	RDAEF-ITR	Radiation Safety	Coronal Polishing	Pit & Fissure Sealant	Ultrasonic Scaling	Infection Control	DSA Permit	OA Permit
81	11	3	194	133	104	46	173	34	205

### **Background on Re-Evaluations**

DA educational programs and courses are subject to re-evaluation and inspection by the Board to review and investigate compliance with the requirements of the Dental Practice Act and California Code of Regulations (CCR), title 16, sections 1005, 1014, 1014.1, and 1070 et seg. The Board may withdraw approval at any time that it determines that a program or course is out of compliance.

The Board is mandated to re-evaluate DA educational programs and courses every seven years. In fiscal year 2024-2025, the Board reinitiated mandated, standard reevaluations (SRE). The Board prioritized Pit and Fissure Sealant Courses for reevaluation. In addition, the Board is conducting re-evaluations based on complaints (CRE). Complaints may be received from external sources, such as students or faculty, or they may be initiated internally by Board management.

Programs and courses receive a Notice of Re-Evaluation and are asked to submit a Re-Evaluation Application to the Board documenting compliance with regulatory requirements and to pay the applicable fee. The Re-Evaluation Application is the same application used to apply for first-time Board approval. Once the Re-Evaluation Application has been received by the Board, it is reviewed by one of the Board's Subject Matter Experts (SMEs). Once the review is completed, the program or course is notified of the continuance of their approval or of any deficiencies. If deficiencies were identified, the program or course receives a Notice of Deficiencies and is asked to provide a

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deficiency response.

The following table provides DA educational programs and courses re-evaluation statistics for fiscal year 2024–2025 through March 31, 2025.

**Note on Withdrawals**. The table shows that approval was withdrawn from 10 Pit and Fissure Sealant Courses. The most common reason for withdrawal of approval of a Pit and Fissure Sealant course was that the course failed to respond timely to the Board's Notice of Re-Evaluation. Courses whose approval is withdrawn may reapply for Board approval by submitting a new application and paying applicable fees.

RDA and RD	RDA and RDAEF Educational Program and Course Re-Evaluations Q1-3 of FY2024–25							
Program/Course	SRE	CRE	Approval Continued	Reported Closed	Approval Withdrawn	App Deficient	App Pending	Awaiting Initial Response
RDA	0	3	0	0	2	1	0	0
RDAEF	0	2	0	0	0	0	0	2
RDAEF-ITR	0	0	0	0	0	0	0	0
RS	1	5	0	0	0	0	4	2
СР	1	5	0	0	0	0	2	4
PF	43	1	3	6	10	2	19	4
US	0	1	0	0	0	0	0	1
IC	2	2	0	0	0	1	2	1
DSA	0	1	0	0	0	0	0	1
OA	0	2	0	0	0	0	1	1
Totals	47	22	3	6	12	4	28	16

	Re-Evaluation Definitions				
SRE	Standard Re-Evaluation – Initiated based on CCR 1070 (a)(2) which requires the Board to re-evaluate educational programs and courses approximately every seven years.				
CRE	Complaint Re-Evaluation – Initiated in response to a complaint received. A complaint can be generated by an external source or by Board staff.				
Approval Continued	The program or course successfully demonstrated compliance with applicable regulations during the re-evaluation process. A Notice of Continuance was issued to the re-evaluated program or course.				
Reported Closed	The Board received notification of closure from a program or course in response to a Notice of Re-Evaluation.				

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Approval Withdrawn	The program or course was found to be out of compliance with the applicable regulations or did not respond within the required timeframes set by the Board and a Notice of Withdrawal of Approval was issued to the program or course. The program or course is notified to cease operation.
Deficient	The program or course was issued a Notice of Deficiency indicating the areas in which their application was missing information or was not in compliance with applicable regulations. Programs and courses are given 30 days to respond. This number is a snapshot of deficient applications on March 31, 2025. Status changes weekly.
Pending	The program or course application package is pending action by Board staff or SME's. This can be either the review of program or course submissions or the drafting of letters related to those submissions. This number is a snapshot of pending applications on March 31, 2025. Status changes weekly.
Awaiting Response	The Board has issued a Notice of Re-Evaluation to a Board-approved program or course and are awaiting the response from the program or course.

Action Requested Informational only. No action required.



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### MEMORANDUM

DATE	April 29, 2025
то	Members of the Dental Assisting Council
FROM	Working Group Jeri Fowler, RDAEF, OA Cara Miyasaki, RDA, RDHEF, MS
SUBJECT	Agenda Item 8.: Update, Discussion, and Possible Recommendation to the Board on Legislative Proposal to Add Business and Professions Code (BPC) Section 1778 Relating to Board Approval of Dental Assistant Educational Programs and Courses

### Introduction

The Dental Board of California (Board) staff have identified inefficiencies in the regulations for approving, inspecting, and evaluating Registered Dental Assistant (RDA) and Registered Dental Assistant in Extended Functions (RDAEF) educational programs and courses. Further, recent trends suggest a decline of licensed dental auxiliaries, which impacts consumer access to dental care. Board staff seek the Dental Assisting Council (Council) review of dental auxiliary education requirements to determine if legislative or regulatory amendments may improve dental auxiliary licensure, education, and/or licensure portability, and Board program/course approval. This memorandum discusses issues regarding continued Board approval of dental assistant educational programs and courses and a potential legislative solution to resolve the issues identified herein.

### **Background**

At the August 2022 Council meeting, the Council moved to create a two-member working group, consisting of Council Member Pacheco and a second Council Member, who was selected and announced later, to review issues regarding dental assistant certification and education requirements in other states, and review the applicable statutes and regulations regarding Board approval of the RDA and RDAEF programs and courses for potential amendments. (August 25, 2022 Council Meeting Minutes, Agenda Item 7.)

### License Requirements in Other States

At the Council's November 2022 meeting, the Working Group, consisting of Council Members Cara Miyasaki and Joanne Pacheco, provided an update on their research of

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these issues. (November 17, 2022 Council Meeting Minutes, Agenda Item 7.) To determine if other states require dental assistant certification and licensure and/or educational requirements, eight questions were developed by the Working Group and sent to all dental boards in the United States inquiring whether the state boards certify or license dental assistants and/or require educational requirements. The Working Group received some responses back from approximately 17 states and was still waiting for more responses. Before the next Council meeting in February 2023, the data would be aggregated, and the report would be presented at that meeting.

### CODA Approval of Educational Programs and License Reciprocity

At the November 2022 Council Meeting, Council Member Jeri Fowler noted her research on dental assistant certification and licensure and/or educational requirements in other states and noticed there were a substantial number of other states that required Commission on Dental Accreditation (CODA) approval of educational programs. She believed one of the reasons there are not that many CODA-approved dental assistant programs were due to the high cost to obtain CODA approval. She hoped the Council would work with the Dental Assisting National Board (DANB) to get reciprocity.

Council Member Miyasaki noted there tended to be license reciprocity between states using CODA-approved program education, but having a CODA-approved program was pricey. She raised concern that in California, having all dental assistant educational programs be CODA approved would wipe out many programs, such as ones that are taught in high schools. She stated that as there were many different types of dental assistant programs in California, it would not be possible for all dental assistant programs to be CODA-approved, and there was a nice balance of having CODA-approved programs and ones that were not approved that met the Board requirements for RDA licensure.

Council Member Fowler noted there were possibly 23 states that participate in license reciprocity, and 35 states had expanded function dental assistants. However, in some states, their idea of expanded function was coronal polishing and sealants, and 22 states had restorative functions in their allowable duties.

At the Council's February 2023 meeting, the Working Group presented the results of their national dental board survey and Board staff's additional research of common practices or requirements for dental assisting licensure across the states. (February 9, 2023 Council Meeting Materials, Agenda Item 9.) The Working Group noted that the Dental Practice Act limits how individuals can become qualified for examination and licensure in California and current graduates of California dental assistant programs would not be eligible for DANB Certified Dental Assistant (CDA) certification because they must graduate from a CODA-approved program or meet the work experience pathway requirements. For California to be consistent with DANB and for the applicant to have transportability between other states, the educational program for RDA licensure would need to be a CODA-approved program. If the Board were to accept

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CODA-approved educational programs, statutory and regulatory changes would be required, including courses completed as part of the CODA-approved educational program, such as Radiation Safety, Pit and Fissure Sealants, Coronal Polishing, and Infection Control.

# <u>Proposed Amendments to Board Approval of Dental Assistant Educational Programs</u> and Courses Regulations

Also at the Council's February 2023 meeting, the Working Group had several observations, including that there are multiple course approvals containing the same content for a course that has already been approved but it is only submitted due to the course being taught at a different clinical site. This multiplies the amount of work needed for the approval process and the amount of work by Board staff.

The Working Group proposed that once a course has been Board approved, it would be approved regardless of the clinical site the course is or will be taught at, and this would allow the courses, such as infection control, coronal polishing, and pit and fissure sealants, to be taught at the actual clinical site where the student or candidate was working. (February 9, 2023 Council Meeting Minutes, Agenda Item 9.) This would help ensure the student is familiar with the equipment, materials, and supplies that are available at their office. Equipment materials and supplies could be supplemented by the provider if anything was missing or needed. The Working Group proposed changing the language for a provider of a dental assistant continuing education course requiring lab, clinical, free clinical, and/or clerical requirements to omit the need to apply for a course that was already approved simply because the course was taught at a different location. This would minimize the number of applications received by Board staff. Since such changes would require regulatory amendments, the Working Group could bring forward a regulatory proposal to make those changes.

The Council requested an estimate on the number of programs applying for Board approval of multiple locations and inquired on the impact of submitting multiple applications for multiple locations. The Council also was made aware of the California Dental Association's (CDA) legislative proposal (Assembly Bill (AB) 481 (Wendy Carrillo, 2023)) to create a pathway, including DANB certification, for dental assistants from states outside of California to apply for licensure. CDA representatives noted that if AB 481 went into effect, it likely would impact the Board's RDA and RDAEF educational program and course approval regulations. Although AB 481 died in the Assembly Appropriations Committee, the most of the provisions of that bill were made effective in the Board's Sunset bill, Senate bill (SB) 1453 (Ashby, Chapter 483, Statutes of 2024).

## <u>Data on Applications for Board Approval of Dental Assistant Educational Programs/Courses</u>

At the May 2023 Council meeting, Board staff presented data on dental assistant educational programs/courses application approvals and site visits and noted that due to the COVID-19 pandemic, there were no site visits conducted in 2022. (May 18, 2023)

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Council Meeting Materials, Agenda Item 7.) At that time, Board staff was preparing to streamline internal processes and preparing to conduct site visits. In addition, Council Members Pacheco and Miyasaki volunteered to research on what other accrediting bodies require to perform program site visits. (May 18, 2023 Council Meeting Minutes, Agenda Item 7.) Board staff continued to provide updated data on dental assistant educational programs/courses application approvals at the next several meetings.

At the November 2024 Council meeting, Board staff provided an overview of educational program and course re-evaluations and noted that Board staff began the preliminary stages of the re-evaluation process by sending a request for information to 173 approved Pit & Fissure course providers who obtained Board approval prior to 2023. (November 7, 2024 Council Meeting Materials, Agenda Item 7.a.)

### Statutory Issues

In addition, following passage of the Board's Sunset bill, SB 1453, Board staff began reviewing the new infection control course requirements for Board approval in Business and Professions Code (BPC) section 1755 and identified several clarification and implementation problems, which were presented to the Board at its November 2024 meeting. (November 7-8, 2024 Meeting Materials, Agenda Item 27.e.) The Board referred the issues to the Council for review and recommendation by a Council Working Group. (November 7-8, 2024 Board Meeting Minutes, Agenda Item 27.e.)

In December 2024, the Infection Control Working Group, Council Members Pacheco and Miyasaki, who were simultaneously working on amendments to California Code of Regulations (CCR), title 16, 1005, Minimum Standards for Infection Control, began their review of the new statutory infection control course for solutions to the infection control statute and additional radiation safety statute issues identified by Board staff. The Infection Control Working Group, down to one member, Council Member Miyasaki following the terming out of Council Member Pacheco on January 1, 2025, presented the Working Group legislative proposal to amend BPC sections 1725, 1753.52, 1754.5, and 1755 at the Council's February 2025 meeting. (February 6, 2025 Meeting Materials and Supplement, Agenda Item 9.b.) The Board approved the legislative proposal at its February 6-7, 2025 meeting.

### **Update**

During the Working Group review of the infection control and radiation safety course statutes, concern was raised by Board staff and Board Counsel regarding the Board's ability to continue reviewing and approving dental assistant educational programs and courses. Board Counsel proposed changing the dental assistant educational program and course review and approval process to an accreditation process through a state or national accrediting body that regularly reviews educational programs. As the Board is a licensing and oversight body, the Board struggles to perform regular reviews of education requirements and advancements. Indeed, the Board's last substantive review

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of the educational program and course requirements regulations, CCR, title 16, sections 1070 through 1071, was completed in July 2011, with the revised regulations going into effect on November 11, 2011.

Notably, in the 15 years since the last revisions to these regulation, significant advancements have been made in the electronic delivery of education. Further, the Board has struggled to review initial and renewal applications and perform site visits to ensure the educational program or course meets the minimum regulatory requirements. As such, it would appear important to relieve the Board and its staff from performing educational program and course applications review and site visits, but the task must be placed with an appropriate oversight entity, such as an existing entity that accredits educational programs or courses. These issues were presented to Council Member Miyasaki, who raised concerns with the ability of dental assisting course providers to obtain or afford accreditation and the resulting decrease in access by dental assistants and license and permit applicants to access these courses.

### <u>Data on Re-Evaluations of Board-Approved Dental Assistant Educational Programs and</u> Courses

As shown under Agenda Item 7 for this meeting, during Fiscal Year 2024-2025, the Board has been conducting re-evaluations of dental assistant educational programs and courses. The re-evaluations have identified major compliance issues justifying withdrawal of Board approval of the programs and courses. The most common issues are as follows.

- Board-approved RDA Programs Compliance Issues. During re-evaluations of RDA educational programs, Board staff have identified the following compliance issues:
  - Failure to provide minimum required number of 265 hours of clinical instruction in extramural dental facilities per CCR, title 16, section 1070.2, subsection (d)(5).
  - b. Failure of program director to maintain accurate and complete individual student records per CCR, title 16, section 1070, subsection (b)(1).
  - c. For modular or open-entry programs, lack of documentation that students receive basic instruction in infection control and basic chairside skills prior to other program content and activities involving patients per CCR, title 16, section 1070.2, subsection (d)(8)(A).
- Issues with Board-approved Stand-alone Courses. During re-evaluations of stand-alone dental assistant courses, Board staff have identified the following compliance issues:
  - a. Failure to identify the location where students are receiving clinical instruction to ensure compliance with CCR, title 16, sections 1070, subsection (f), and 1070.3, subsection (c)(2)(C).

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- b. Failure to demonstrate that clinical instruction is planned and supervised per CCR, title 16, section 1070, subsection (j).
- c. Failure to provide written contracts of affiliation with each extramural dental facility used for clinical instruction per CCR, title 16, section 1070, subsection (j)(4).
- d. Lack of documentation of compliance with required instructor-student ratios per CCR, title 16, section 1070.1.
- e. No data provided on number of students enrolled or simultaneously engaged in instruction to ensure compliance with CCR, title 16, sections 1070, subsection (f)(1), 1070.1, and as applicable, sections 1014.1, subsections (f) and (g), 1070.3, subsection (f), 1070.4, subsection (f), and 1070.5, subsection (f).
- f. Infection control protocols required in CCR, title 16, section 1070, subsection (g), that are provided to students and faculty are incomplete and/or missing protocols required by CCR, title 16, section 1005, subsection (b).
- 3. Issue with both RDA Programs and stand-alone courses:
  - a. Lack of documentation that students are provided with specific performance objectives and standards of performance for laboratory and clinical experiences per CCR, title 16, section 1070, subsection (i), and as applicable, sections 1014.1, subsection (e), 1070.3, subsection (g), 1070.4, subsection (g), and 1070.5, subsection (g). Some performance evaluation forms indicate merely "done" or "not done" rather than provide evaluations with specific standards.

Notably, as discussed under Agenda Item 7, between Fiscal Years 2021-2022 and 2024-2025, the Board only conducted six educational program site visits, four of which were performed in the last Fiscal Year. Yet, there are currently 92 Board approved educational programs that must be re-evaluated every seven years (CCR, tit. 16, § 1070, subs. (a)(2)). Further, out of 43 pit and fissure course standard re-evaluations conducted in the past year, only three courses have been issued continued Board approval. Six of those courses were reported closed, 10 courses had Board approval withdrawn, and 19 course re-evaluation course applications are pending.

### Board Staffing and Costs

With so many dental assistant educational programs and stand-alone courses that must be monitored and re-evaluated, and Board staff's inability to re-evaluate all the programs and courses on a regular basis, it appears Board oversight of dental assistant education is insufficient and inadequate, raising significant concerns of appropriate student education and licensee practice on patients.

Board staff also note the Assembly Appropriations Committee analysis of AB 873 (Alanis, 2025) indicated the \$300 application fees proposed to be charged for Board review of the new interim therapeutic restoration and radiographic decisionmaking

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(BPC, § 1753.52), radiation safety (BPC, § 1754.5), and infection control (BPC, § 1755) courses appears insufficient to cover staff costs. The proposed \$300 application fee is based on the existing course application fees set in regulation (CCR, tit. 16, § 1022), which has not been updated since those fees were initially set, effective on August 24, 2017. Accordingly, the Board likely will need to perform a desk audit to determine whether the educational program and course application fees should be increased to cover staff costs.

### Research on Alternatives to Board Approval

To resolve the issues raised above, Board staff researched whether Board approval of dental assistant educational programs and courses could be moved to education accrediting or approval entities. Board staff reached out to various education oversight entities to understand their accreditation/approval process and applicability to dental assistant educational programs and courses.

Specifically, Board staff inquired whether each entity accredits or approves programs or courses for dental assisting, and if so, whether the entity used the Board's regulations to determine dental assistant program compliance for accreditation. Board staff also requested information on average, how long accreditation or approval takes from program submission of the accreditation application to approval. Board staff received the following responses:

- American Dental Association Commission on Dental Accreditation (CODA), Allied Dental Education Programs:
  - CODA accredits programs and courses for dental assisting.
     CODA does not use Board regulations to determine dental assistant education program compliance. CODA accredits dental assistant education programs utilizing the Commission's Accreditation Standards for Dental Assisting Education Programs (available online at <a href="https://coda.ada.org/standards">https://coda.ada.org/standards</a>), which are national in scope and represent the minimum requirements for accreditation; it is expected that institutions that voluntarily seek CODA accreditation will recognize the ethical obligation of complying with the spirit as well as the letter of these standards.
  - CODA accreditation process: Programs seeking accreditation must submit an
    application that addresses the Criteria for Consideration of an Application for
    Accreditation and the CODA Standards. Provided that the application is in
    order, the first opportunity for the Commission to consider the program is
    generally 12 to 18 months following the Commission's formal
    acknowledgment of receipt of the application, initiation of the review process,
    and following an initial site visit.

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- 2. Bureau for Private Postsecondary Education (BPPE):
  - BPPE does not accredit dental assistant educational programs. BPPE grants approval to both unaccredited and accredited dental assistant programs to operate in California. BPPE noted that "accredited" means accreditation by an accrediting body recognized by the U.S. Department of Education (e.g., CODA). Dental assistant courses are exempt from BPPE approval if they do not offer a degree and charge students less than \$2,500 in total fees per Education Code section 94874, subdivision (f).
  - For dental assistant programs that are accredited, BPPE verifies accreditation details, such as the institution's name, locations, ownership structure, and approved programs (CCR, tit. 5, § 71390). For unaccredited dental assistant programs that do not lead to licensure and are not approved by the Board, BPPE relies on its own regulations and minimum operating standards when granting approval. (See, CCR, tit. 5, §§71110-71340.) Among other things, BPPE reviews:
    - The program's primary administrative location and the physical address of each branch or satellite.
    - The type of business organization of the program or school.
    - o The ownership structure of the program or school.
    - Student enrollment, fee payment, and financial aid policies, practices, and disclosures.
    - Advertising materials, public statements about the program, and a copy of the institution's catalog.
    - Degrees and educational programs offered.
    - Admissions requirements.
    - Financial resources and statements.
    - Faculty number and qualifications.
    - Facilities and equipment, including leases and rental agreements.
    - Copy of diploma or certificate of completion.
  - In approving unaccredited RDA programs that lead to licensure, BPPE relies on Board approval to ensure programmatic compliance. BPPE will not approve an unaccredited RDA program to operate unless it has been approved by the Board per CCR, title 5, section 71220, subsection (f). The Board sets specific requirements for RDA educational programs under BPC section 1614 and CCR, title 16, sections 1070, 1070.1, and 1070.2, including:
    - A minimum of 800 hours of instruction.
    - Adequate provision for the supervision and operation of the program.
    - Faculty qualifications and instructor-student ratios.
    - Facilities and equipment requirements.

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- Required areas of instruction in dental assistant and RDA duties, as well as specific duties related to infection control, radiation safety, coronal polishing, and pit and fissure sealants.
- BPPE's approval process for an unaccredited DA program typically takes
  three to six months for a complete application, but delays can extend this to
  six to 12 months if issues arise. However, exact timelines vary on a case-bycase basis. Institutions must submit a comprehensive application, which can
  range from 200 to 500 pages, including a recent audited financial statement,
  a \$5,000 non-refundable fee, and documentation of program approvals (e.g.,
  Board approval for RDA programs).
- 3. Western Association of Schools and Colleges, Senior College and University Commission (WSCUC):
  - Institutional accreditation involves a comprehensive review of all institutional functions. Institutional accrediting organizations, like WSCUC, accredit the institution rather than individual programs, although new programs are reviewed through the substantive change process.
  - Program review is a required element in the WSCUC accreditation process.
    While accreditation attests to the institution's capacity and effectiveness, it is
    not possible for WSCUC to review and evaluate every degree program in the
    course of an accreditation review. Instead, WSCUC expects institutions to
    have processes that assure program currency, quality and effectiveness.
    When implemented effectively and followed up deliberately, program review is
    a powerful means of engaging faculty in evaluating and improving programs
    in the organization.
  - The WSCUC internal review process for an academic program or institution typically takes one to 36 months from the start of self-study to final accreditation decision. Timelines vary based on institutional complexity and application completeness.
- 4. Accrediting Commission for Community and Junior Colleges (ACCJC)
  - ACCJC is an institutional accreditor recognized by the US Department of Education and Council for Higher Education Accreditation (CHEA). The accreditation process ensures that an institution is meeting its mission and delivering high-quality academic and learning support programs. The accreditation processes for the institutions are inclusive of the academic programs offered by the institution, regardless of location or modality.

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- ACCJC does not use the Board's regulations as it does not have separate program specific accreditation standards. ACCJC uses <u>Standards of</u> <u>Accreditation</u> and the federal requirements and recognition criteria set forth by the Department of Education under 34 CFR Part 602.
- Institutions must seek ACCJC approval when they make substantive changes to their academic offerings, such as the addition of a new program or a change in modality to deliver the program. In those instances, the institution would complete a substantive change application and provide information to demonstrate that the new program (or other changes) is in alignment with the institution's mission, is appropriately resourced, demonstrates expected rigor and academic quality, and supports attainment of equitable student outcomes. ACCJC reviews and makes decisions on substantive changes typically within a month of receiving an application (the committee meets on a schedule four to five times each semester).

### **Working Group Discussion**

In March 2025, Council Member Fowler joined Council Member Miyasaki on the Working Group. On March 28, 2025, Council Member Fowler, met with Board staff and Board Counsel to discuss the ability of the Board's continued review and approval of dental assistant educational programs and courses and the legislative proposal to add BPC section 1778 to move oversight of dental assistant education to accrediting bodies. On April 3, 2025, Council Members Fowler and Miyasaki met to discuss the legislative proposal and the submission of it as an agenda item for the May 14, 2025 Council meeting.

### **Legislative Proposal to Add BPC Section 1788**

Every course required to be completed for dental assisting practice must be Board approved as established in the relevant statutes. Further, various pathways to dental assisting licensure require the dental assistant education to be completed through a Board-approved educational program.

To address the inability of the Board to continue reviewing and visiting dental assistant educational programs and courses, Board staff and Board Counsel presented a proposal to the Working Group for their consideration. The Working Group reiterated the prior concerns with the high cost of obtaining accreditation and resulting decline of dental assistant and license and permit applicant access to such courses. As such, the Working Group does not recommend requiring the stand-alone dental assisting courses to be accredited.

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However, the Working Group noted that dental assistant educational programs likely are both accredited and Board approved, resulting in duplicate applications and fees to the accrediting body and the Board. As such, Board staff drafted a legislative proposal to change Board approval of educational programs to accept accreditation from specified entities and reduce barriers to the educational programs in offering courses to dental assisting students. Further, allowing DANB certificates to satisfy course requirements would increase license reciprocity and reduce dental assisting license barriers.

Board staff propose to add BPC section 1778 that would define, for purposes of the dental assisting statutes, the term "board approved" to mean accreditation by at least one of the following:

- (1) CODA;
- (2) BPPE;
- (3) Accrediting Commission for Senior Colleges and Universities, Western Association of Schools and Colleges; or
- (4) Accrediting Commission for Community and Junior Colleges, Western Association of Schools and Colleges.

In addition, Board staff propose to add statutory provisions to authorize successful completion of DANB examinations in radiation safety, infection control, pit and fissure sealants, and coronal polishing to satisfy completion of a Board-approved course in those areas. To ensure that license and permit applicants would not immediately have to retake courses offered through educational programs that, going forward, would have to be accredited by one of the above-listed entities, the legislative proposal would provide that Board-approved educational programs and courses successfully completed prior to January 1, 2029 would qualify as completion of the required course, subject to the statutory requirements for completion of the program or course (i.e., BPC, §§ 1750.2, 1750.4, and 1752.1 contain timeframes within which the courses must be completed prior to application). In addition, to assure implementation of the new statute, the legislative proposal would include a delayed effective date of January 1, 2029.

Board staff note that the accrediting bodies may use the dental assistant course requirements set forth in the Board's regulations, so the regulations are not proposed to be repealed.

### **Action Requested**

The Working Group asks the Council to discuss the legislative proposal, including the strengths and weaknesses, and consider stakeholder input and any viable alternatives to resolve the issues raised herein. If the Council determines the legislative proposal would resolve the concerns presented, the Council may wish to recommend to the Board for submission to the California State Legislature the legislative proposal to add

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BPC section 1778 relating to Board approval of dental assistant educational programs and courses.

Attachment: Legislative Proposal to Add Business and Professions Code Section 1778 Relating to Board Approval of Dental Assistant Educational Programs and Courses

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### LEGISLATIVE PROPOSAL TO ADD BUSINESS AND PROFESSIONS CODE SECTION 1778 RELATING TO BOARD APPROVAL OF DENTAL ASSISTANT EDUCATIONAL PROGRAMS AND COURSES

Proposed amendments are indicated in <u>underline</u> for new text and <del>strikethrough</del> for deleted text.

Add Section 1778 to Article 7 of Chapter 4 of Division 2 of the Business and Professions Code as follows:

### **1778.** Beginning on January 1, 2029, for purposes of this Article:

- (a) An educational program that is board approved shall mean a program offered by a dental assisting educational program that is accredited by at least one of the following:
  - (1) American Dental Association Commission on Dental Accreditation (CODA).
  - (2) Bureau for Private Postsecondary Education.
  - (3) Accrediting Commission for Senior Colleges and Universities, Western Association of Schools and Colleges.
  - (4) Accrediting Commission for Community and Junior Colleges, Western Association of Schools and Colleges.
- (b) Successful completion of a radiation health and safety examination administered by the Dental Assisting National Board (DANB) shall qualify as completion of a board-approved course in radiation safety.
- (c) Successful completion of an infection control examination administered by the DANB shall qualify as completion of a board-approved course in infection control.
- (d) Successful completion of a general chairside assisting examination administered by the DANB shall qualify as completion of board-approved courses in pit and fissure sealants and coronal polishing.
- (e) Board-approved educational programs and courses successfully completed prior to January 1, 2029, shall qualify as completion of board-approved educational programs and courses for purposes of applying for a dental assisting license or permit, subject to the statutory requirements for completion of such program or course prior to receipt by the Board of the dental assisting license or permit application.



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### MEMORANDUM

DATE	April 16, 2025
то	Members of the Dental Assisting Council
FROM	Brant Nelson, Legislative and Regulatory Specialist Dental Board of California
SUBJECT	<b>Agenda Item 9.:</b> Update, Discussion, and Possible Recommendation to the Board on Legislation

AB 873 (Alanis, 2025) Dentistry: dental assistants: infection control course.

Introduced: February 19, 2025

Amended in Assembly April 9, 2025 Last Amended: Assembly Appropriations Committee Location:

Re-referred to Assembly Appropriations Committee Status:

Summary: This California Dental Association (CDA) sponsored bill removes the requirement that an unlicensed dental assistant complete an 8-hour infection control course approved by the Dental Board of California (Board) prior to providing specified services, instead allowing DAs to provide the services but requiring those who have been in continuous employment for 90 days or more to take the infection control course within a year of the date of employment, and deletes other provisions related to the infection control course.

As amended on April 9, 2025, Assembly Bill (AB) 873 would revise Business and Professions Code (BPC) section 1750 to change the deadline for a dental assistant to successfully complete a Board-approved eight-hour course in infection control. The current requirement to successfully complete the infection control course prior to performing any basic supportive dental procedures involving potential exposure to blood, saliva, or other potentially infectious materials became effective on January 1, 2025, pursuant to the Board's sunset review bill [Senate Bill (SB) 1453 (Ashby, Ch. 483, Stats. 2024)]. The Board discussed these proposed amendments submitted by CDA, but the Board has no position on these amendments.

Board staff note that the April 9, 2025, amendments to AB 873 incorporate all the Board's requested amendments to BPC section 1755 to better clarify the requirements for Board approval of an infection control course for unlicensed dental assistants. While the bill's sponsor, CDA, agreed to most of those amendments, CDA raised concern

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regarding limiting the use of an electronic infection control course with no in-person clinical instruction to only unlicensed dental assistants (prop. BPC, § 1755, subd. (g)).

The Board sought to add new BPC section 1755, subdivision (g), to limit the use of the electronic infection control courses solely to unlicensed dental assistants, so that all registered dental assistant (RDA) license, orthodontic assistant, and dental sedation permit applicants would continue to take the eight-hour infection control course offered by an education program or infection control course provider under regulation.

Currently, BPC section 1755 creates a disparity in the infection control course requirement for RDA applicants – subdivision (a) provides that an unlicensed dental assistant not enrolled in a Board-approved program or alternative dental assisting program (two of the five pathways for RDA licensure) have to take the new infection control course with six hours of didactic instruction and two hours of laboratory instruction (no in-person supervised clinical instruction).

The Board has received comment from dental assisting stakeholders that clinical instruction on infection control is extremely important for public safety; such instruction on the use of personal protective equipment (PPE) and instrument cleaning, disinfection, and sterilization cannot be effectively taught through electronic means. Since RDAs perform many more dental procedures involving infectious materials, many of which are not directly supervised, than unlicensed dental assistants, the Board believes RDAs and other dental assisting permitholders should receive effective clinical instruction on infection control. The original issue communicated to the Board was the need to improve access by unlicensed dental assistants to infection control courses; the April 9, 2025 amendments would accomplish this by allowing three different infection control courses, including the new electronic course, while maintaining consumer protection by requiring RDA license and dental assisting permit applicants to receive clinical instruction.

The Board had communicated to the Assembly Business and Professions Committee staff that BPC section 1755, subdivision (g), in the Board's requested amendments was a concern for CDA, and the Board requested the Committee to resolve the issue, which it did by voting the bill out of Committee with this amendment, discussed in the Committee analysis. The Board considers this issue resolved; however, the Board understands CDA may attempt to have this provision stricken as the bill moves through the process. At this time, the Board could not support the bill if BPC section 1755, subdivision (g), is stricken.

The Board approved several other legislative proposals at its November 2024 and February 2025 meetings to better clarify other SB 1453 implementation issues. Board staff have been in continued discussions with stakeholders on these issues, and CDA has expressed willingness to incorporate additional amendments to the bill, including:

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- Amending BPC sections 1628 and 1633 regarding Dentist Licensure Requirements
- Amending BPC section 1635.5 regarding Licensure by Credential Pathway Requirements
- Amending BPC section 1638.1 regarding Elective Facial Cosmetic Surgery (EFCS) Permits
- Amending BPC sections 1753.52 and 1754.5 regarding Dental Assisting Courses

**Board Impact**: Board staff would need to implement evaluation and approval of the infection control course providers. Board staff anticipate that this would involve one new staff position at the Associate Governmental Program Analyst (AGPA) level and include two addition subject matter expert contracts to review infection control courses offered by providers.

**Recommended Board Position:** The Board is taking a SUPPORT IF AMENDED position on AB 873.

### **Action Requested:**

The Council is asked to discuss, if needed, and consider the update provided.

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### MEMORANDUM

DATE	April 28, 2025
то	Members of the Dental Assisting Council
FROM	Dental Board of California
SUBJECT	<b>Agenda Item 10.:</b> Discussion and Possible Recommendation to the Board on Legislative Proposal to Amend BPC, Division 2, Chapter 4, Article 7 Title Regarding Dental Auxiliaries

This item is being tabled until the August 2025 Dental Assisting Council and Board meetings.



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### MEMORANDUM

DATE	April 28, 2025
то	Members of the Dental Assisting Council
FROM	Tina Vallery, Division Chief License and Program Compliance and Dental Assisting Dental Board of California
SUBJECT	Agenda Item 11.: Discussion and Possible Recommendation to the Board on Legislative Proposal to Amend BPC Sections 1753 and 1753.5 Regarding Authorized Duties and Procedures of Registered Dental Assistants in Extended Functions

This memorandum discusses concerns and a legislative proposal to resolve those concerns regarding the allowable duties of registered dental assistants in extended functions (RDAEFs) licensed on or after January 1, 2010 (Business and Professions Code (BPC), § 1753.5), and the licensing requirements for RDAEFs who were licensed prior to January 1, 2010 (BPC, § 1753).

### **Background**

Assembly Bill (AB) 2637 (Eng, Chapter 499, Statutes of 2008), among other things, repealed, revised, and recast RDAEF license education and examination requirements. Under that bill, RDAEFs licensed on or after January 1, 2010, were authorized to perform the following duties (BPC, § 1753.5, subd. (b)):

- (1) Conduct preliminary evaluation of the patient's oral health, including, but not limited to, charting, intraoral and extra-oral evaluation of soft tissue, classifying occlusion, and myofunctional evaluation.
- (2) Perform oral health assessments in school-based, community health project settings under the direction of a dentist, registered dental hygienist, or registered dental hygienist in alternative practice.
- (3) Cord retraction of gingiva for impression procedures.
- (4) Size and fit endodontic master points and accessory points.
- (5) Cement endodontic master points and accessory points.
- (6) Take final impressions for permanent indirect restorations.
- (7) Take final impressions for tooth-borne removable prosthesis.
- (8) Polish and contour existing amalgam restorations.
- (9) Place, contour, finish, and adjust all direct restorations.

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- (10) Adjust and cement permanent indirect restorations.
- (11) Other procedures authorized by regulations adopted by the board.

However, RDAEFs licensed prior to January 1, 2010, were limited to performing only registered dental assistant (RDA) duties and specified RDAEF duties, until the licensee completed a Board-approved course in and examination of the following additional procedures specified in BPC section 1753.5, subdivision (b), paragraphs (1), (2), (5), and (7) through (11):

- (1) Conduct preliminary evaluation of the patient's oral health, including, but not limited to, charting, intraoral and extra-oral evaluation of soft tissue, classifying occlusion, and myofunctional evaluation.
- (2) Perform oral health assessments in school-based, community health project settings under the direction of a dentist, registered dental hygienist, or registered dental hygienist in alternative practice.
- (5) Cement endodontic master points and accessory points.
- (7) Take final impressions for tooth-borne removable prosthesis.
- (8) Polish and contour existing amalgam restorations.
- (9) Place, contour, finish, and adjust all direct restorations.
- (10) Adjust and cement permanent indirect restorations.
- (11) Other procedures authorized by regulations adopted by the board. (BPC, §§ 1753, 1753.4.)

As of January 1, 2022, SB 607 (Min, Chapter 367, Statutes of 2021) eliminated the clinical and practical examination requirement for RDAEFs and required those who were licensed on or after January 1, 2010, to take and pass a written examination. Those licensed prior to January 1, 2010, who completed a board-approved educational course in the additional procedures specified in paragraphs (1), (2), (5), (7) to (11) of Section 1753.5 were not required to take an examination.

### **Discussion**

As of January 1, 2025, SB 1453 (Ashby, Chapter 483, Statutes of 2024) further revised the duties that can be performed by RDAEFs under BPC section 1753.5. Two of the major changes, were the removal of "polish and contour existing amalgam restorations" (prior RDAEF duty under BPC, §1753.5, subd. (b), para. (8)), and the addition of "perform post, core, and build-up procedures in conjunction with direct and indirect restorations" (new subd. (b), para. (6)). BPC section 1753.5, subdivision (b), now states:

(b) A registered dental assistant in extended functions licensed on or after January 1, 2010, is authorized to perform the following additional procedures under direct supervision and pursuant to the order, control, and full professional responsibility of a licensed dentist:

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- (1) Perform oral health assessments, including intraoral and extraoral soft tissue evaluations to identify oral lesions, classifying occlusion, performing myofunctional evaluations, and oral cancer screenings as authorized by the supervising dentist.
- (2) Perform oral health assessments in school-based, community health project settings under the direction of a dentist, registered dental hygienist, or registered dental hygienist in alternative practice.
- (3) Gingival retraction for impression and restorative procedures.
- (4) Size and fit endodontic master points and accessory points.
- (5) Cement endodontic master points and accessory points.
- (6) Perform post, core, and build-up procedures in conjunction with direct and indirect restorations.
- (7) Take final impression for permanent indirect restorations.
- (8) Take final impressions for tooth-borne removeable prosthesis.
- (9) Place, contour, finish, and adjust all direct restorations.
- (10) Adjust and adhere all permanent indirect restorations.
- (11) Other procedures authorized by regulations adopted by the board.

Board staff believe "polish and contour existing amalgam restorations" under prior BPC section 1753.5, subdivision (b)(8), may have been erroneously omitted in the amendment process of SB 1453. Board staff note this is a specialized duty that requires specific training. As such, Board staff believe the RDAEF duty to "polish and contour existing amalgam restorations" should be reinserted on the list of allowable duties for RDAEFs licensed on and after January 1, 2010. Attachment 1 hereto is a legislative proposal to amend BPC section 1753.5 to add "polish and contour existing amalgam restorations" back into this section.

In addition, it appears the list of duties set forth in BPC section 1753 that may only be performed by RDAEFs licensed prior to January 1, 2010, after completion of a Board-approved course in those duties, was not updated to reflect the new RDAEF duties added and renumbered in the amendments to BPC section 1753.5 made by SB 1453. As such, Board staff recommend BPC section 1753, subdivision (a)(3)(B), be amended to require an RDAEF licensee licensed prior to January 1, 2010, to successfully complete a Board-approved course in the following updated RDAEF duties listed under BPC section 1753.5, subdivision (b), as proposed to be amended, to perform those duties:

 Perform oral health assessments, including intraoral and extraoral soft tissue evaluations to identify oral lesions, classifying occlusion, performing myofunctional evaluations, and oral cancer screenings as authorized by the supervising dentist (BPC, § 1753.5, subd. (b), para. (1)).

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- Perform oral health assessments in school-based, community health project settings under the direction of a dentist, registered dental hygienist, or registered dental hygienist in alternative practice (BPC, § 1753.5, subd. (b), para. (2)).
- Cement endodontic master points and accessory points (BPC, § 1753.5, subd. (b), para. (5)).
- Perform post, core, and build-up procedures in conjunction with direct and indirect restorations (BPC, § 1753.5, subd. (b), para. (6) – new duty added by SB 1453).
- Take final impressions for tooth-borne removeable prosthesis (BPC, § 1753.5, subd. (b), para. (8)).
- Place, contour, finish, and adjust all direct restorations (BPC, § 1753.5, subd. (b), para. (9)).
- Polish and contour existing amalgam restorations (BPC, § 1753.5, subd. (b), new para. (10) old para. (8)).
- Adjust and adhere all permanent indirect restorations (BPC, § 1753.5, subd. (b), renumbered para. (11)).
- Other procedures authorized by regulations adopted by the board (BPC, § 1753.5, subd. (b), renumbered para. (12)).

### **Action Requested**

The Council is asked to consider the proposed legislative amendments. If the Council agrees with the recommendation to amend the RDAEF duties and education requirements discussed above, the Council is asked to make one of the following motions.

Option 1 (support the proposed recommendation): Move to recommend to the Board the legislative proposal in **Attachment 1** for submission to the California State Legislature to amend Business and Professions Code sections 1753 and 1753.5 regarding RDAEF duties and education requirements.

Option 2 (support the proposed recommendation as revised during this meeting): Move to recommend to the Board the legislative proposal in **Attachment 1**, as revised during this meeting, for submission to the California State Legislature to amend Business and Professions Code sections 1753 and 1753.5.

Option 3 (no action): If the Council does not wish to act on the recommendation, no motion is needed.

#### Attachment

 Legislative Proposal to Amend Business and Professions Code Sections 1753 and 1753.5 Regarding Authorized Duties and Procedures of Registered Dental Assistants in Extended Functions

Agenda Item 11.: Discussion and Possible Recommendation to the Board on Legislative Proposal to Amend BPC Sections 1753 and 1753.5 Regarding Authorized Duties and Procedures of Registered Dental Assistants in Extended Functions Dental Assisting Council Meeting

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### LEGISLATIVE PROPOSAL TO AMEND BUSINESS AND PROFESSIONS CODE SECTIONS 1753 AND 1753.5 REGARDING AUTHORIZED DUTIES AND PROCEDURES OF REGISTERED DENTAL ASSISTANTS IN EXTENDED FUNCTIONS

Proposed amendments are indicated in <u>underline</u> for new text and <del>strikethrough</del> for deleted text.

Amend Section 1753 of Article 7 of Chapter 4 of Division 2 of the Business and Professions Code as follows:

- **1753.** (a) On and after January 1, 2010, the board may license as a registered dental assistant in extended functions a person who files a completed application, pays the applicable fee, and submits written evidence, satisfactory to the board, of all of the following eligibility requirements:
  - (1) Current, active, and valid licensure as a registered dental assistant.
  - (2) A full set of fingerprints for purposes of conducting a criminal history check.
  - (3) Successful completion of either of the following:
    - (A) An extended functions postsecondary program approved by the board in all of the procedures specified in Section 1753.5.
    - (B) An extended functions postsecondary program approved by the board to teach the duties that registered dental assistants in extended functions were allowed to perform pursuant to board regulations prior to January 1, 2010, and a course approved by the board in the procedures specified in paragraphs (1), (2), (5), (6), and (78) to (4112), inclusive, of subdivision (b) of Section 1753.5.
  - (4) Current certification in basic life support issued by American Red Cross, American Heart Association, American Safety and Health Institute, American Dental Association's Continuing Education Provider Recognition Program, or Academy of General Dentistry's Program Approval for Continuing Education.
  - (5) Successful completion of a board-approved pit and fissure sealant course.
  - (6) Passage of a written examination administered by the board. The board shall designate whether the written examination shall be administered by the board.
- (b) A registered dental assistant in extended functions with permits in either orthodontic assisting or dental sedation assisting shall be referred to as an "RDAEF with orthodontic assistant permit," or "RDAEF with dental sedation assistant permit," as applicable. These terms shall be used for reference purposes only and do not create additional categories of licensure.

- (c) Completion of the continuing education requirements established by the board pursuant to Section 1645 by a registered dental assistant in extended functions who also holds a permit as an orthodontic assistant or dental sedation assistant shall fulfill the continuing education requirement for such permit or permits.
- (d) The licensee shall be responsible for complying with all applicable licensure renewal requirements, including continuing education pursuant to Section 1645.

Amend Section 1753.5 of Article 7 of Chapter 4 of Division 2 of the Business and Professions Code as follows:

- **1753.5.** (a) A registered dental assistant in extended functions licensed on or after January 1, 2010, is authorized to perform all duties and procedures that a registered dental assistant is authorized to perform as specified in and limited by Section 1752.4, and the duties in this section.
- (b) A registered dental assistant in extended functions licensed on or after January 1, 2010, is authorized to perform the following additional procedures under direct supervision and pursuant to the order, control, and full professional responsibility of a licensed dentist:
  - (1) Perform oral health assessments, including intraoral and extraoral soft tissue evaluations to identify oral lesions, classifying occlusion, performing myofunctional evaluations, and oral cancer screenings as authorized by the supervising dentist.
  - (2) Perform oral health assessments in school-based, community health project settings under the direction of a dentist, registered dental hygienist, or registered dental hygienist in alternative practice.
  - (3) Gingival retraction for impression and restorative procedures.
  - (4) Size and fit endodontic master points and accessory points.
  - (5) Cement endodontic master points and accessory points.
  - (6) Perform post, core, and build-up procedures in conjunction with direct and indirect restorations.
  - (7) Take final impression for permanent indirect restorations.
  - (8) Take final impressions for tooth-borne removeable prosthesis.
  - (9) Place, contour, finish, and adjust all direct restorations.
  - (10) Polish and contour existing amalgam restorations.
  - (10)(11) Adjust and adhere all permanent indirect restorations.

(11)(12) Other procedures authorized by regulations adopted by the board.

(c) A registered dental assistant in extended functions licensed on or after January 1, 2010, may perform a duty specified in this section using contemporary techniques and materials designed for use in the performance of that duty under the direct supervision and pursuant to the order, control, and full professional responsibility of a licensed dentist if the registered dental assistant in extended functions has completed the appropriate education and training, and whose skill, knowledge, and education in the use of such contemporary technique or material has been determined clinically competent by the supervising licensed dentist.



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### MEMORANDUM

DATE	April 16, 2025
ТО	Members of the Dental Assisting Council
FROM	Brant Nelson, Legislative and Regulatory Specialist Dental Board of California
SUBJECT	Agenda Item 12.a: Status Update on Pending Regulations

### **Background**

This memo addresses rulemaking packages that have moved forward in the rulemaking process since the last Dental of California Board (Board) meeting. Rulemaking packages that require Board action will be presented as separate agenda items or will be presented at a future Board meeting.

Rulemaking to Amend California Code of Regulations (CCR), Title 16, Sections 1021, 1028, 1028.4, 1028.5, 1030, and 1035, and Repeal Sections 1032, 1032.1, 1032.2, 1032.3, 1032.4, 1032.5, 1032.6, 1032.7, 1032.8, 1032.9, 1032.10, 1033.1, 1034, and 1036.01 Regarding Applications for Dentist Licensure and Fees

### **Summary of Proposed Changes:**

A summary of the proposed changes can be found within the <u>February 6-7, 2025 Board meeting materials</u>.

### **Update:**

The proposed text was approved by the Board at its February 6-7, 2025 Board meeting. Since that time, Board staff have drafted an initial rulemaking package, which includes the proposed text, and Initial Statement of Reasons (ISOR) explaining the regulation's purpose and impact. This package is now undergoing internal review by the DCA regulatory counsel and budget staff as a standard part of the regulatory process.

### **Action Requested**

This item is informational only. No action is requested.



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## MEMORANDUM

DATE	April 28, 2025
то	Members of the Dental Assisting Council
FROM	Brant Nelson, Legislative and Regulatory Specialist Dental Board of California
SUBJECT	Agenda Item 12.b.: Discussion and Possible Action to Recommend Initiation of a Rulemaking to Amend California Code of Regulations (CCR), Title 16, Section 1005 Regarding Minimum Standards for Infection Control

### **Background**

Business and Professions Code (BPC) section 1680, subdivision (ad), requires the Dental Board of California (Board) to review infection control guidelines (Guidelines), if necessary, on an annual basis. Proposed changes to the Guidelines must be reviewed by the Dental Hygiene Board of California (DHBC) by law. Section 1680, subdivision (ad), requires the DHBC to submit any recommended changes to the Guidelines to the Board for review "to establish a consensus." The Board has adopted its Guidelines at CCR, title 16, section 1005, which were last revised in 2011. Beginning on April 15, 2024, DBC and DHBC working groups met to discuss possible updates to the Guidelines and further develop specific recommendations for discussion and possible action at future Dental Assisting Council (Council), DHBC, and Board meetings.

To begin the process of establishing a "consensus" on the Guidelines, the Board's and DHBC's working groups' original final draft at **Attachment 1** was brought to the DHBC's Legislation and Regulatory Committee on November 15, 2024, for review and action, and thereafter brought to the DHBC at its November 16, 2024 Board meeting. However, at these DHBC meetings, the California Dental Association (CDA) raised concerns about two issues in the proposed regulatory amendments. After the DHBC's meetings, Board staff, in consultation with the Board's and DHBC's working groups, revised the text.

The revised text was presented at the Council's February 6, 2025 meeting (Agenda Item 8.b. found here: February 6, 2025 Meeting Materials). However, at the meeting, stakeholders provided public comments about additional concerns with the proposed text. In response to those concerns, the Council voted to take back public comment and any discussion that the Council had to the working groups and have this proposal come

Agenda Item 12.b.: Discussion and Possible Action to Recommend Initiation of a Rulemaking to Amend California Code of Regulations (CCR), Title 16, Section 1005 Regarding Minimum Standards for Infection Control

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back to a future Council meeting for consideration. Commenters who provided comments on the proposed text at either the Board or Council meetings on February 6 and 7, 2025, were asked to provide their comments in writing to the Board's Regulatory Specialist to facilitate review by the Board's and DHBC's respective working groups. These comments were submitted as provided in **Attachments 3 through 6** ("public comments").

### **Update**

Following the Board and Council meetings in February, Board staff requested input from the Board's and DHBC's working groups, which are comprised of subject matter experts, on the public comments received and advice on any possible further revisions. **Attachment** 2 reflects the working groups' revisions to the regulatory text to resolve the public concerns. In addition, Board staff have provided in **Attachment 7** explanations for changes made and the rationales for accepting or rejecting prior public comments submitted at the February 6 and 7, 2025, Council and Board meetings and/or in writing, and any additional recommendations for revisions to the Guidelines from the working groups.

Considering the recommendations from both the Board's and DHBC's working groups, Board staff recommends that the Council consider approval of the text as set forth in **Attachment 2**.

### **Action Requested**

The Council members should review the proposed regulatory text and consider whether they would support the staff's recommendation to adopt **Attachment 2** or if there are suggested changes to the proposed text. After review, Board staff requests that the Council consider one of the following motions:

**Option 1** (if the Council agrees with the staff recommendation and has no changes):

Move to recommend to the Board the proposed regulatory text in **Attachment 2** for approval and recommend that Board staff submit **Attachment 2** to the Dental Hygiene Board of California for their review and reconsideration of their prior action on this item, and to obtain a consensus with this Board on the Guidelines. Upon receiving notice that the Dental Hygiene Board of California has approved **Attachment 2** and thereby reached consensus with the Board, submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency for review. If no adverse comments are received, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any non-substantive changes to the text and the package, and set the matter for a hearing if requested. If after the 45-day public comment period, no adverse comments are received, and no public hearing is requested, authorize the

Agenda Item 12.b.: Discussion and Possible Action to Recommend Initiation of a Rulemaking to Amend California Code of Regulations (CCR), Title 16, Section 1005 Regarding Minimum Standards for Infection Control Dental Assisting Council Meeting

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Executive Officer to take all steps necessary to complete the rulemaking, and adopt the proposed regulations as noticed for CCR, title 16, section 1005.

**Option 2** (The Council has suggested changes for the proposed regulatory text in **Attachment 2**.)

Move to recommend to the Board approval of the proposed regulatory text in **Attachment 2** with the following changes (describe the proposed changes to the proposed text here) and recommend that Board staff provide Attachment 2 as revised to the Dental Hygiene Board of California for their review and reconsideration of their prior action on this item, and to obtain a consensus with the Board on the Guidelines. Upon receiving notice that the Dental Hygiene Board of California has approved **Attachment 2** and thereby reached consensus with this Board, submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency for review. If no adverse comments are received, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any non-substantive changes to the text and the package, and set the matter for a hearing if requested. If after the 45-day public comment period, no adverse comments are received, and no public hearing is requested, authorize the Executive Officer to take all steps necessary to complete the rulemaking, and adopt the proposed regulations as noticed for CCR, title 16, section 1005.

### Attachments:

- 1. Proposed Regulatory Text to Amend CCR, Title 16, Section 1005 Approved by DHBC and dated 11/5/24
- 2. Proposed Regulatory Text to Amend CCR, Title 16, Section 1005, dated 5/14/25
- 3. Letter from the California Dental Assisting Alliance, dated February 7, 2025
- 4. Email from Leslie Canham, dated February 11, 2025, with seven attachments (eighth attachment C.V./BIO not provided, and CE provider advertising redacted from email)
- 5. Email from Amy Condrin, dated March 1, 2025, with attachment from CDC's Morbidity and Mortality Weekly Report entitled "Guidelines for Infection Control in Dental Health-Care Settings 2003," dated December 19, 2003
- 6. Email from Amy Condrin, dated March 2, 2025
- 7. 16 CCR 1005 Summary of Stakeholder Comments with the Board's Working Group's Responses and Other Recommendations

Agenda Item 12.b.: Discussion and Possible Action to Recommend Initiation of a Rulemaking to Amend California Code of Regulations (CCR), Title 16, Section 1005 Regarding Minimum Standards for Infection Control

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## DENTAL BOARD OF CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

### PROPOSED REGULATORY LANGUAGE

Proposed amendments to the regulatory language are shown in single <u>underline</u> for new text and single <u>strikethrough</u> for deleted text. Where the Board proposes to renumber existing paragraphs to a new paragraph within this section, the Board has <u>struck through</u> the existing number of the paragraph and <u>underlined</u> the new proposed paragraph number to show the proposed re-ordering of paragraphs within this section.

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

- § 1005. Minimum Standards for Infection Control.
- (a) Definitions of terms used in this section:
  - (1) "Standard precautions" are a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, infection prevention protocols and procedures established for use in any setting in which dental healthcare is delivered. These include: hand hygiene protocols and hand care, use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure, use of personal protective equipment, procedures for patient care items, and safe handling of sharps, safe handling and disposal of contaminated medical waste, respiratory hygiene or cough etiquette, and use of disinfectant agents in accordance with this section. Standard precautions shall be used for care of all patients regardless of their diagnoses or personal infectious status. The procedure performed or the health history of the patient.
  - (4) "Instrument/device classifications" are categories used to identify patient care items ("items") as critical, semi-critical, or non-critical depending on the potential risk for infection associated with their intended use and their required level of sterilization or disinfection for safe practice, as follows:
    - (2)(A) "Critical items" confer a high risk for infection if they are contaminated with any microorganism. carry the highest risk of transmitting infection. These include all instruments, devices, and other items used to penetrate soft tissue or bone, such as surgical instruments, periodontal instruments, hygiene scalers, and burs.
    - (3) (B) "Semi-critical items" are instruments, devices, and other items that are not used to penetrate soft tissue or bone, but contact oral mucous membranes, non-

- intact skin or other potentially infectious materials (OPIM). come into contact with oral tissue, blood, or OPIM without penetration, such as those items used for intraoral examination, and dental procedures including dental mouth mirrors, amalgam condensers, reusable dental impression trays, and orthodontic pliers with plastic parts.
- (4) (C) "Non-critical items" are instruments, devices, equipment, and surfaces ("clinical contact surfaces") that come in contact with soil (e.g., organic and inorganic material), debris, blood, OPIM and intact skin, but not oral mucous membranes, and are utilized extraorally or are indirectly contaminated with debris, blood, or OPIM during clinical procedures, such as dental X-ray machines, assistant cart attachments, dental material delivery systems, patient safety eyewear, plastic dental syringes, and countertops.
- (5) "Disinfect" or "Disinfection" means the use of a chemical solution to reduce or lower the number of microorganisms on inanimate objects using a Cal/EPA-registered product.
- (6) "Disinfection classifications" are categories used to determine the effectiveness of a disinfectant agent to inactivate mycobacterium during surface disinfection procedures and are as follows:
  - (5) (A) "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) (B) "Intermediate-level disinfection" kills mycobacterium tuberculosis var bovis indicating that many human pathogens are also killed. This process does not necessarily kill spores.
  - (7) (C) "High-level disinfection" kills some, but not necessarily all bacterial spores. This process kills mycobacterium tuberculosis var bovis, bacteria, fungi, and viruses. inactivates all vegetative bacteria, mycobacteria, viruses, fungi, and some bacterial spores.
- (7) "Cal/EPA-registered" means a product registered by the U.S. Environmental Protection Agency (EPA) and the California Environmental Protection Agency (Cal EPA) that has demonstrated bactericidal, fungicidal, and virucidal activity. The product used shall include a label from the manufacturer that indicates the level of disinfection (low, intermediate, or high) and both the EPA registration number and the California Department of Pesticide Regulation (Cal DPR) registration number.

- (8) "Germicide" is a chemical agent that can be used to disinfect items and surfaces based on the level of contamination.
- (9)(8) "Sterilization" is a validated process used to render a product free of all forms of viable microorganisms. mechanical process used to eliminate all forms of microbial life using acceptable methods of sterilization set forth in this section with a device approved by the U.S. Food and Drug Administration (FDA) for sterilization.
- (10)(9) "Cleaning" is the removal of visible soil (e.g., organic and inorganic material), debris, blood, and OPIM from objects and surfaces and shall be accomplished manually or mechanically using water with detergents or enzymatic products-prior to the use of a sterilization device or disinfectant for surface disinfection, using one of the following applicable methods:
  - (A) Cleaning of clinical contact surfaces and non-critical items means hand scrubbing using water and a detergent, or a surface disinfectant, either of which is registered with Cal/EPA as a disinfectant to clean surfaces or items according to manufacturer's instructions.
  - (B) Cleaning of semi-critical or critical items means hand scrubbing with a long-handled brush or using an FDA-approved mechanical device to remove visible soil from contaminated items using detergents or enzymatic products. Acceptable mechanical cleaning devices shall include ultrasonic cleaners using enzymatic products or detergents that require manual drying, or devices manufactured specifically for washing and mechanical drying of dental instruments, cassettes, and devices prior to preparing for sterilization. All mechanical cleaning devices shall be used in accordance with the manufacturer's instructions for the device or item type and quantity being cleaned.
- (11)(2) "Personal Protective Equipment" (PPE) is specialized clothing or equipment worn or used for protection against a hazard. PPE items may include, but are not limited to, gloves, masks, respiratory devices, protective eyewear, and protective attire which are intended to prevent exposure to blood, body fluids, OPIMother potentially infectious materials, and chemicals used for infection control. General work attire such as uniforms, scrubs, pants, and shirts, are not considered to be PPE.
- (12)(3) "Other Potentially Infectious Materials" (OPIM) means any one of the following:
  - (A) Human body fluids such as saliva in dental procedures and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.

- (B) Any unfixed tissue or organ (other than intact skin) from a human (living or dead).
- (C) Any of the following, if known or reasonably likely to contain or be infected with human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV):
  - 1. Cell, tissue, or organ cultures from humans or experimental animals;
  - 2. Blood, organs, or other tissues from experimental animals; or
  - 3. Culture medium or other solutions.
- (13)(10) "Dental Healthcare Personnel" (DHCP), are all paid and non-paid personnel in the dental healthcare setting treatment facility who might be occupationally exposed to infectious materials, including body substances blood, OPIM, 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).
- (11) "Contaminated medical waste" shall include "medical waste" as defined in Section 117690 of the Health and Safety Code occurring in the dental healthcare setting and shall not include those applicable items set forth in Section 117700 of the Health and Safety Code.
- (b) All DHCP shall comply with <u>all applicable</u> infection control <u>standard</u> precautions and enforce the following <u>applicable</u> minimum <u>standard</u> precautions <u>in the treatment facility</u> to protect patients and DHCP and to minimize the transmission of pathogens in health care settings as mandated by the California Division of Occupational Safety and Health (Cal/OSHA).
  - (1) Standard precautions shall be practiced used in the care of all patients.
  - (2) A written-protocol shall be developed, maintained, and periodically updated for proper instrument processing, operatory cleanliness, and management of injuries. The protocol shall be made available to all DHCP at the dental office. infection control plan detailing the protocols and procedures that shall be developed, maintained, and periodically updated for all standard precautions in accordance with the requirements of this section. The written infection control plan shall be made readily available to all DHCP at the treatment facility and reviewed and updated at least annually by the DHCP employer or employer-designated representative

<u>responsible for infection control compliance, and as needed to maintain compliance</u> with this section.

- (3) A copy of this regulation shall be conspicuously posted in each dental office. treatment facility and included in the written infection control plan described in paragraph (2).
- (4) Personal Protective Equipment: (PPE):
  - (4)(A) All DHCP shall wear <u>single-use</u>, <u>disposable</u> surgical facemasks in combination with either chin length plastic face shields or protective eyewear <u>during patient treatment or</u> whenever there is potential for aerosol spray, splashing, or spattering of the following: droplet nuclei, blood, chemical or <u>germicidaldisinfectant</u> agents, or OPIM. For the purposes of this section, <u>"protective eyewear" includes safety glasses with top and side shields bearing evidence of compliance with American National Standard for Occupational and Education Personal Eye and Face Protection Devices ANSI/ISEA Z87.1-2020 (the "Z87" marking).</u>
  - (B) A new, single-use, disposable surgical facemask shall be used for each patient at the beginning of their treatment session. Surgical facemask replacement shall occur at any point during a procedure where the mask becomes moist or soiled. Chemical-resistant utility gloves and appropriate, task specific PPE shall be worn when handling hazardous chemicals. After each patient treatment, surgical facemasks shall be changed and disposed when leaving laboratories or areas of patient care activities.
  - (C) Chin-length face shields and face visors are acceptable replacements for protective eyewear when worn in combination with a surgical facemask. Face shields and face visors shall not be used as a replacement for a surgical facemask. After each patient treatment, face shields and protective eyewear shall be cleaned, disinfected, or disposed when leaving laboratories or areas of patient care activities.
  - (D) Chemical and puncture-resistant utility gloves and chemical-resistant PPE shall be worn when handling hazardous chemicals and shall be worn in accordance with paragraph (6).
  - (E) Reusable protective eyewear, face shields and visors shall be washed with soap and water, or if visibly soiled, cleaned and disinfected between patients.
  - (5)(F) Protective attire shall be worn for disinfection, sterilization, and housekeeping procedures involving the use of germicides disinfectants or when handling contaminated items. All DHCP shall wear reusable or disposable

protective attire <u>during patient treatment, or</u> whenever there is a potential for aerosol spray, splashing, or spattering of blood, OPIM, or chemicals and <u>germicidal disinfectant</u> agents. Protective attire <u>mustshall</u> be changed daily, or <u>between patientsimmediately</u> if they should become moist or visibly soiled. All PPE used during patient care shall be removed when leaving laboratories or areas of patient care activities. Reusable gowns shall be laundered in accordance with Cal/OSHA Bloodborne Pathogens Standards (Title 8, Cal. Code Regs., section 5193).

#### (5) Hand Hygiene: Protocols and Hand Care:

- (6)(A) All DHCP shall thoroughly wash their hands with soap and water (covering all surfaces of hands and fingers) for no less than 20 seconds 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, with an alcohol concentration between 60-95%, may be used as an alternative to soap and water. An alcohol-based hand rub shall be used according to the manufacturer's instructions. Hands shall be thoroughly dried completely dry before donning gloves in order to prevent promotion of bacterial microbial growth and washed again immediately after glove removal.
- (B) A DHCP shall refrain from providing direct patient care <u>and from handling</u> <u>patient care equipment</u> if hand conditions <u>such as the presence of lesions, rash, or weeping dermatitis</u> are present that may render DHCP or patients more susceptible to opportunistic infection or exposure.
- (7) All DHCP who have exudative lesions or weeping dermatitis of the hand shall refrain from all direct patient care and from handling patient care equipment until the condition resolves.

#### (6) Gloves:

- (8)(A) Medical examination gloves shall be worn by DHCP whenever there is contact with mucous membranes, blood, OPIM, and during all pre-clinical, clinical, post-clinical, and laboratory procedures. Medical examination gloves are disposable, synthetic single-use only items. Gloves shall be replaced when torn or punctured, upon completion of dental treatment, and before leaving laboratories or areas of patient care activities.
- (B) Chemical and puncture-resistant utility gloves shall be available at the point of use and worn by DHCP for clinical care break-down (setting up or breaking down a treatment room), cleaning, and disinfectant procedures. Chemical and

<u>puncture-resistant utility gloves shall be cleaned and sterilized in accordance with</u> the manufacturer's instructions after each use.

- (C) When processing contaminated sharp instruments, needles, and devices, DHCP shall wear heavy-dutychemical and puncture-resistant utility gloves-to prevent puncture wounds. Utility gloves shall be cleaned and sterilized in accordance with the manufacturer's instructions after each use.
- (D) Gloves mustshall be discarded under any of the following circumstances:
  - (i) when torn or punctured;
  - (ii) upon completion of <u>dental</u> treatment <u>when using medical examination</u> <u>gloves;</u>, and,
  - (iii) before leaving laboratories or areas of patient care activities when using medical examination gloves.
- (E) All DHCP shall perform hand hygiene <u>protocols and hand care</u> procedures <u>specified in paragraph (5)</u> before donning gloves and after removing and discarding <u>medical examination gloves</u>. <u>Medical examination Ggloves shall not be washed before or after use, or reused</u>.
- (7) Needle and Sharps Safety:
  - (9)(A) 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.
  - (B) 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.
- (8) Sterilization and Disinfection:
  - (10)(A) All germicides must products used to clean or disinfect items or surfaces shall be used in accordance with intended use and label instructions.
  - (11)(B) Standard precautions for disinfection and sterilization shall be performed in the following order:
    - (i) first, use appropriate hand hygiene protocols and hand care in accordance with paragraph (5);

- (ii) second, Ccleaning must precede items or surfaces prior to any disinfection or sterilization process; and,
- (iii) third, use the disinfection or sterilization standards required by this section. Products used to clean items or surfaces prior to disinfection procedures shall be used according to all label instructions. Disinfection procedures shall include use of a Cal/EPA-registered product with an applicable disinfection classification in accordance with paragraph (6) of subsection (a) to disinfect items.
- (12)(C) Critical instruments, items, and devices shall be discarded or precleaned, packaged or wrapped, and sterilized immediately after each use. Methods of sterilization shall include steam under pressure (autoclaving), chemical vapor, and dry heat. If a critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection and packaged or wrapped upon completion of the disinfection process. These instruments, items, and devices, shall remain sealed and stored in a manner so as to prevent contamination, and shall be labeled with the date of sterilization and the specific sterilizer used if more than one sterilizer is utilized in the treatment facility. If stored, sterilized packaging is compromised (e.g., wet, torn, or punctured), the instruments shall be recleaned, packaged in new wrap, and sterilized again before use.
- (13)(D) Semi-critical instruments, items, and devices shall be pre-cleaned, packaged or wrapped, and sterilized immediately after each use. Methods of sterilization include steam under pressure (autoclaving), chemical vapor and dry heat. If a semi-critical item is heat sensitive, it shall, at minimum, be processed with high level disinfection and packaged or wrapped upon completion of the disinfection process. These packages or containers shall remain sealed and shall be stored in a manner so as to prevent contamination, and shall be labeled with the date of sterilization and the specific sterilizer used if more than one sterilizer is utilized in the treatment facility. If stored, sterilized packaging is compromised (e.g., wet, torn, or punctured), the instruments shall be recleaned, packaged in new wrap, and sterilized again before use.
- (14)(E) Non-critical surfaces and patient care items shall be cleaned and disinfected after every use with a California Environmental Protection Agency (Cal/EPA)-registered hospital disinfectant (low-level disinfectant) spray or wipe labeled effective against HBV and HIV. When the item is visibly contaminated with blood or OPIM, a Cal/EPA-registered hospital intermediate-level disinfectant with a tuberculocidal claim shall be used.

- (15)(F) All high-speed dental hand pieces, low-speed hand pieces, rotary components, and dental unit attachments such as reusable air/water syringe tips and ultrasonic scaler tips, shall be packaged, labeled, and heat-sterilized in a manner consistent with the same sterilization practices as a semi-critical item.
- (16)(G) Single use <u>critical</u>, <u>semi-critical</u>, and <u>non-critical</u> disposable items such as <u>scalpel blades</u>, prophylaxis angles, prophylaxis cups and brushes, tips for high-speed evacuators, saliva ejectors, air/water syringe tips, and gloves shall be used for one patient only and discarded.
- (17)(H) Proper functioning of the sterilization cycle of all sterilization devices shall be verified at least weekly through the use of a biological indicator (such as a spore test) with results confirmed by either authorized DHCP or an independent laboratory. Test results shall be documented and maintained for 12 months.
- (I)(i) A chemical indicator shall be used inside every sterilization package to verify that the sterilizing agent has penetrated the package and reached the instruments inside. If the internal chemical indicator is not visible from the outside of the package, an external chemical indicator shall also be used.
  - (ii) The chemical indicator shall be inspected immediately when removing packages from the sterilizer; if the chemical indicator did not register that the sterilizing agent has penetrated the package, the instruments shall be repackaged and sterilized again.

#### (9) Irrigation:

- (18)(A) Sterile coolants/irrigants shall be used for surgical procedures involving soft tissue or bone.
- (B) When performing procedures on exposed dental pulp, water or other irrigation solutions shall be sterile or contain disinfecting or antibacterial properties.
- (C) Sterile coolants/irrigants mustshall be delivered using a sterile delivery system.

#### (10) Treatment Facilities:

(19)(A) If non-critical items or <u>clinical contact</u> surfaces likely to be contaminated <u>are-or</u> manufactured in a manner preventing cleaning and disinfection, they shall be <u>protected physically covered</u> with disposable impervious barriers <u>approved by the FDA and designed by the manufacturer for that purpose</u>. Disposable barriers shall be changed when visibly soiled or damaged and between patients.

- (20)(B) 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 germicidedisinfectant after each patient. The low-level disinfectants used shall be labeled effective against HBV and HIV. Use an intermediate-level disinfectant if visibly contaminated with blood. Use disinfectants in accordance with the manufacturer's instructions.
- (C) 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 DHCP shall follow all material safety data sheet (MSDS) handling and storage instructions.
- (21)(D) 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, or other devices. The dental unit lines and devices shall be flushed between each patient and after the final patient of the day for a minimum of twenty (20) seconds.
- (22)(E) Contaminated solid waste shall be disposed of according to applicable local, state, and federal environmental standards.

#### (11) Lab Areas:

- (23)(A) Splash shields and equipment guards shall be used on dental laboratory lathes. Fresh pumice and a sterilized or new, disposable rag-wheel shall be used for each patient. Devices
- (B) Laboratory equipment, including handpieces, polishing (rag) wheels, grinding wheels, and laboratory burs, used to polish, trim, or adjust contaminated appliances and intraoral prosthetic devices shall be cleaned, disinfected or sterilized, properly packaged or wrapped, and heat-sterilized in a manner consistent with the same sterilization practices as a semi-critical item as specified in subparagraph (D) of paragraph (8), or if a single-use item, disposed of in accordance with subparagraph (G) of paragraph (8).
- (C) Laboratory equipment shall be stored in a manner consistent with the same storage practices as a semi-critical item as specified in subparagraph (D) of paragraph (8).

- (24)(D) All intraoral items such as impressions, bite registrations, <u>and</u> prosthetic and orthodontic appliances shall be cleaned and disinfected with an <u>Cal/EPA-registered</u> intermediate-level disinfectant before <u>and after</u> 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.
- (12) Respiratory Hygiene/Cough Etiquette: Measures shall be implemented to contain respiratory secretions and to prevent droplet and fomites transmission of respiratory pathogens, especially during seasonal outbreaks of viral respiratory infections such as influenza, RSV, adenovirus, parainfluenza virus, or SARS-CoV-2 (COVID-19) virus, as follows.
  - (A) Prominently posting at least one sign at every point of entrance and reception or registration desk of the treatment facility, accessible to public view, in which case the signs shall be in at least 12-point type font. The signs shall contain instructions to patients who cough or sneeze at the treatment facility to do at least all of the following: (i) cover their mouths or noses when coughing or sneezing; (ii) use and dispose of tissues in waste receptables; and, (iii) wash hands with soap and water or use alcohol hand rub after coughing or sneezing.
  - (B) Provide tissues and no-touch receptacles (e.g. foot-pedal operated lid or open plastic-lined waste basket) for disposal of tissues.
  - (C) Have soap, warm running water, and paper towels, or alcohol hand rub available for use in or immediately adjacent to waiting areas.
  - (D) Offer masks to coughing or sneezing patients or other persons when they enter the treatment facility.
  - (E) Provide distance between patients who cough or sneeze in common waiting areas. If available, facilities shall place these patients in a separate area while waiting for care.
- (c) DHCP who are employers of other DHCP shall provide those personnel with a training program on the minimum standards required by this section and the infection control plan specified in paragraph (2) of subsection (b). Such training program shall be provided at no cost to the DHCP and during working hours in accordance with all of the following.
  - (1) The training program shall be provided as follows:
    - (A) Prior to assignment to tasks where OPIM exposure may take place; and,
    - (B) Within one year of the date of the DHCP's previous training thereafter.

- (2) DHCP employers shall provide additional training prior to or by the effective date of any change to the minimum standards in this section or to the written infection control plan specified in paragraph (2) of subsection (b). The additional training may be limited to addressing the changes in the standards required by this section or the written infection control plan.
- (c) The Dental Board of California and Dental Hygiene Committee of California shall review this regulation annually and establish a consensus.

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

<sup>&</sup>lt;sup>4</sup> Cal/EPA contacts: WEBSITE <u>www.cdpr.ca.gov</u> or Main Information Center (916) 324-0419.

### DENTAL BOARD OF CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

#### PROPOSED REGULATORY LANGUAGE

Proposed amendments to the regulatory language are shown in single <u>underline</u> for new text and single <u>strikethrough</u> for deleted text.

Where the Board proposes to re-number existing paragraphs to a new paragraph within this section, the Board has struck through the existing number of the paragraph and underlined the new proposed paragraph number to show the proposed re-ordering of paragraphs within this section.

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

- § 1005. Minimum Standards for Infection Control.
- (a) Definitions of terms used in this section:
  - (1) "Standard precautions" are a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, infection prevention protocols and procedures established for use in any setting in which dental healthcare is delivered. These include: hand hygiene protocols and hand care, use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure, use of personal protective equipment, procedures for patient care items, and safe handling of sharps—, safe handling and disposal of contaminated medical waste, respiratory hygiene or cough etiquette, and use of disinfectant agents in accordance with this section. Standard precautions shall be used for care of all patients regardless of their diagnoses or personal infectious status—the procedure performed or the health history of the patient.
  - (4) "Instrument/device classifications" are categories used to identify patient care items ("items") as critical, semi-critical, or non-critical depending on the potential risk for infection associated with their intended use and their required level of sterilization or disinfection for safe practice, as follows:
    - (2)(A) "Critical items" confer a high risk for infection if they are contaminated with any microorganism. carry the highest risk of transmitting infection. These include all instruments, devices, and other items used to penetrate soft tissue or bone. such as surgical instruments, periodontal instruments, hygiene scalers, and burs.

- (3) (B) "Semi-critical items" are instruments, devices, and other items that are not used to penetrate soft tissue or bone, but contact oral mucous membranes, non-intact skin or other potentially infectious materials (OPIM). come into contact with oral tissue, blood, or OPIM without penetration, such as those items used for intraoral examination, and dental procedures including dental mouth mirrors, amalgam condensers, reusable dental impression trays, and orthodontic pliers with plastic parts.
- (4) (C) "Non-critical items" are instruments, devices, equipment, and surfaces ("clinical contact surfaces") that come in contact with soil (e.g., organic and inorganic material), debris, blood, OPIM and intact skin, but not oral mucous membranes, and are utilized extraorally or are indirectly contaminated with debris, blood, or OPIM during clinical procedures, such as dental X-ray machines, assistant cart attachments, dental material delivery systems, patient safety eyewear, plastic dental syringes, and countertops.
- (5) "Disinfect" or "disinfection" means the use of a chemical solution to reduce or lower the number of microorganisms on inanimate objects using a Cal/EPA-registered product.
- (6) "Disinfection classifications" are categories used to determine the effectiveness of a disinfectant agent to inactivate mycobacterium during surface disinfection procedures and are as follows:
  - (5) (A) "Low-level disinfection" is the least effective disinfection process. It killsinactivates some bacteria, some viruses, and fungi, but does not killinactivate bacterial spores or mycobacterium tuberculosis var bovis, a laboratory test organism used to classify the strength of disinfectant chemicals.
  - (6) (B) "Intermediate-level disinfection" killsinactivates mycobacterium tuberculosis var bovis indicating that many human pathogens are also killedinactivated. This process does not necessarily killinactivate spores.
  - (7) (C) "High-level disinfection" kills some, but not necessarily all bacterial spores. This process kills mycobacterium tuberculosis var bovis, bacteria, fungi, and viruses. inactivates all vegetative bacteria, mycobacterium, viruses, fungi, and some bacterial spores.
- (7) "Cal/EPA-registered" means a product registered by the U.S. Environmental Protection Agency (EPA) and the California Department of Pesticide Regulation for sale and use in California as a pesticide.

- (8) "Germicide" is a chemical agent that can be used to disinfect items and surfaces based on the level of contamination.
- (9)(8) "Sterilization" is a validated process used to render a product free of all forms of viable microorganisms. eliminate all forms of microbial life using acceptable methods of sterilization set forth in this section.
- (10)(9) "Cleaning" is the removal of visible soil (e.g., organic and inorganic material), debris, blood, and OPIM from objects and surfaces and shall be accomplished manually or mechanically using water with detergents or enzymatic products-prior to the use of a sterilization device or disinfectant for surface disinfection, using one of the following applicable methods:
  - (A) Cleaning of clinical contact surfaces and non-critical items means scrubbing using water and a detergent, or a surface disinfectant, either of which is registered with Cal/EPA as a disinfectant to clean surfaces or items according to manufacturer's instructions.
  - (B) Cleaning of semi-critical or critical items means scrubbing with a long-handled brush or using an FDA-approved mechanical device to remove visible soil from contaminated items using detergents or enzymatic products. Acceptable mechanical cleaning devices shall include ultrasonic cleaners using enzymatic products or detergents that require manual drying, or devices manufactured specifically for washing and mechanical drying of dental instruments, cassettes, and devices prior to preparing for sterilization. All mechanical cleaning devices shall be used in accordance with the manufacturer's instructions for the device or item type and quantity being cleaned.
- (11)(2) "Personal Protective Equipment" (PPE) is specialized clothing or equipment worn or used for protection against a hazard. PPE items may include, but are not limited to, gloves, masks, respiratory devices, protective eyewear, and protective attire which are intended to prevent exposure to blood, body fluids, OPIMother potentially infectious materials, and chemicals used for infection control. General work attire such as uniforms, scrubs, pants, and shirts, are not considered to be PPE.
- (12)(3) "Other Potentially Infectious Materials" (OPIM) means any one of the following:
  - (A) Human body fluids such as saliva in dental procedures and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.

- (B) Any unfixed tissue or organ (other than intact skin) from a human (living or dead).
- (C) Any of the following, if known or reasonably likely to contain or be infected with human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV):
  - 1. Cell, tissue, or organ cultures from humans or experimental animals;
  - 2. Blood, organs, or other tissues from experimental animals; or
  - 3. Culture medium or other solutions.
- (13)(10) "Dental Healthcare Personnel" (DHCP), are all paid and non-paid personnel in the dental healthcare setting treatment facility who might be occupationally exposed to infectious materials, including body substances blood and OPIM, 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).
- (11) "Contaminated medical waste" shall include "medical waste" as defined in Section 117690 of the Health and Safety Code occurring in the dental healthcare setting and shall not include those applicable items set forth in Section 117700 of the Health and Safety Code.
- (b) All DHCP shall comply with <u>all applicable</u> infection control <u>standard</u> precautions and enforce the following <u>applicable</u> minimum <u>standard</u> precautions <u>in the treatment facility</u> to protect patients and DHCP and to minimize the transmission of pathogens in health care settings as mandated by the California Division of Occupational Safety and Health (Cal/OSHA).
  - (1) Standard precautions shall be practiced used in the care of all patients.
  - (2) A written-protocol shall be developed, maintained, and periodically updated for proper instrument processing, operatory cleanliness, and management of injuries. The protocol shall be made available to all DHCP at the dental office. infection control plan detailing the protocols and procedures that shall be developed, maintained, and periodically updated for all standard precautions in accordance with the requirements of this section. The written infection control plan shall be made readily available to all DHCP at the treatment facility and reviewed and updated at least annually by the DHCP employer or employer-designated representative

<u>responsible for infection control compliance, and as needed to maintain compliance</u> with this section.

- (3) A copy of this regulation shall be conspicuously posted in each dental office. treatment facility and included in the written infection control plan described in paragraph (2).
- (4) Personal Protective Equipment: (PPE):
  - (4)(A) All DHCP shall wear single-use, disposable surgical facemasks in combination with either chin length plastic face shields or protective eyewear during patient treatment or whenever there is potential for aerosol spray, splashing, or spattering of the following: droplet nuclei, blood, chemical or germicidal disinfectant agents, or OPIM. For purposes of this section, "protective eyewear" includes safety glasses with side shields bearing evidence of compliance with American National Standard for Occupational and Education Personal Eye and Face Protection Devices ANSI/ISEA Z87.1-2020 (the "Z87" marking).
  - (B) A new, single-use, disposable surgical facemask shall be used for each patient at the beginning of their treatment session. Surgical facemask replacement shall occur at any point during a procedure where the mask becomes moist or soiled. Chemical-resistant utility gloves and appropriate, task specific PPE shall be worn when handling hazardous chemicals. After each patient treatment, surgical facemasks shall be changed and disposed when leaving laboratories or areas of patient care activities.
  - (C) Chin-length face shields and face visors are acceptable replacements for protective eyewear when worn in combination with a surgical facemask. Face shields and face visors shall not be used as a replacement for a surgical facemask. After each patient treatment, face shields and protective eyewear shall be cleaned, disinfected, or disposed when leaving laboratories or areas of patient care activities.
  - (D) Chemical and puncture-resistant utility gloves and chemical-resistant PPE shall be worn when handling hazardous chemicals and shall be worn in accordance with paragraph (6).
  - (E) Reusable protective eyewear, face shields, and visors shall be washed with soap and water, or if visibly soiled, cleaned and disinfected between patients.
  - (5)(F) Protective attire shall be worn for disinfection, sterilization, and housekeeping procedures involving the use of germicides disinfectants or when handling contaminated items. All DHCP shall wear reusable or disposable

protective attire <u>during patient treatment</u>, <u>or</u> whenever there is a potential for aerosol spray, splashing, or spattering of blood, OPIM, or chemicals and <u>germicidal disinfectant</u> agents. Protective attire <u>mustshall</u> be changed daily or between patients. <u>Protective attire shall be changed immediately</u> if they <u>attire should</u> becomes <u>moist or visibly</u> soiled <u>with blood or OPIM</u>. All PPE used during patient care shall be removed when leaving laboratories or areas of patient care activities. Reusable gowns shall be laundered in accordance with Cal/OSHA Bloodborne Pathogens Standards (Title 8, Cal. Code Regs., section 5193).

#### (5) Hand Hygiene: Protocols and Hand Care:

- (6)(A) All DHCP shall thoroughly wash their hands with soap and water (covering all surfaces of hands and fingers) for no less than 20 seconds 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, with an alcohol concentration between 60-95%, may be used as an alternative to soap and water. An alcohol-based hand rub shall be used according to the manufacturer's instructions. Hands shall be thoroughly dried completely dry before donning gloves in order to prevent promotion of bacterial microbial growth and washed again immediately after glove removal.
- (B) A DHCP shall refrain from providing direct patient care <u>and from handling</u> <u>patient care equipment</u> if hand conditions <u>such as the presence of lesions, rash, or weeping dermatitis</u> are present that may render DHCP or patients more susceptible to opportunistic infection or exposure.
- (7) All DHCP who have exudative lesions or weeping dermatitis of the hand shall refrain from all direct patient care and from handling patient care equipment until the condition resolves.

#### (6) Gloves:

- (8)(A) Medical examination gloves shall be worn by DHCP whenever there is contact with mucous membranes, blood, OPIM, and during all pre-clinical, clinical, post-clinical, and laboratory procedures. Medical examination gloves are disposable, synthetic single-use only items. Gloves shall be replaced when torn or punctured, upon completion of dental treatment, and before leaving laboratories or areas of patient care activities.
- (B) Chemical and puncture-resistant utility gloves shall be available at the point of use and worn by DHCP for cleaning, sterilization, and disinfectant procedures. Chemical and puncture-resistant utility gloves shall be cleaned and disinfected or

- sterilized in accordance with the manufacturer's instructions. Disposable utility gloves shall be disposed of after each use.
- (C) When processing contaminated sharp instruments, needles, and devices, DHCP shall wear heavy-dutychemical and puncture-resistant utility gloves to prevent puncture wounds. Utility gloves shall be cleaned and sterilized in accordance with the manufacturer's instructions after each use.
- (D) Gloves mustshall be discarded under any of the following circumstances:
  - (i) when torn or punctured;
  - (ii) upon completion of <u>dental</u> treatment <u>when using medical examination</u> <u>gloves;</u>, and,
  - (iii) before leaving laboratories or areas of patient care activities when using medical examination gloves.
- (E) All DHCP shall perform hand hygiene <u>protocols and hand care</u> procedures <u>specified in paragraph (5)</u> before donning gloves and after removing and discarding <u>medical examination gloves</u>. <u>Medical examination Ggloves shall not be washed before or after use, or reused</u>.
- (7) Needle and Sharps Safety:
  - (9)(A) 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.
  - (B) 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.
- (8) Sterilization and Disinfection:
  - (10)(A) All germicides must products used to clean or disinfect items or surfaces shall be used in accordance with intended use and label instructions.
  - (11)(B) Standard precautions for disinfection and sterilization shall be performed in the following order:
    - (i) first, use appropriate hand hygiene protocols and hand care in accordance with paragraph (5);

- (ii) second, Ccleaning must precede items or surfaces prior to any disinfection or sterilization process; and,
- (iii) third, use the disinfection or sterilization standards required by this section. Products used to clean items or surfaces prior to disinfection procedures shall be used according to all label instructions—Disinfection procedures shall include use of a Cal/EPA-registered product with an applicable disinfection classification in accordance with paragraph (6) of subsection (a) to disinfect items.
- (12)(C) Critical instruments, items, and devices shall be discarded or precleaned, packaged or wrapped, and sterilized after each use. Methods of sterilization shall include steam under pressure (autoclaving), chemical vapor, and dry heat. If a critical item is heat-sensitive, it shall, at minimum, be processed with high-level disinfection and packaged or wrapped upon completion of the disinfection process. These instruments, items, and devices, shall remain sealed and stored in a manner so as to prevent contamination, and shall be labeled with the date of sterilization and the specific sterilizer used if more than one sterilizer is utilized in the treatment facility. If stored, sterilized packaging is compromised (e.g., wet, torn, or punctured), the instruments shall be recleaned, packaged in new wrap, and sterilized again before use.
- (13)(D) Semi-critical instruments, items, and devices shall be pre-cleaned, packaged or wrapped, and sterilized after each use. Methods of sterilization include steam under pressure (autoclaving), chemical vapor and dry heat. If a semi-critical item is heat sensitive, it shall, at minimum, be processed with high-level disinfection and packaged or wrapped upon completion of the disinfection process. These packages or containers shall remain sealed and shall be stored in a manner so as to prevent contamination, and shall be labeled with the date of sterilization and the specific sterilizer used if more than one sterilizer is utilized in the treatment facility. If stored, sterilized packaging is compromised (e.g., wet, torn, or punctured), the instruments shall be recleaned, packaged in new wrap, and sterilized again before use.
- (14)(E) Non-critical surfaces and patient care items shall be cleaned and disinfected <u>after every use</u> with a California Environmental Protection Agency (Cal/EPA)-registered hospital disinfectant (low-level disinfectant) <u>spray or wipe labeled effective against HBV and HIV</u>. When the item is visibly contaminated with blood or OPIM, a Cal/EPA-registered hospital intermediate-level disinfectant with a tuberculocidal claim shall be used.
- (15)(F) All high-speed dental hand pieces, low-speed hand pieces, rotary components, including the motor, and dental unit attachments such as reusable

air/water syringe tips and ultrasonic scaler tips, shall be packaged, labeled, and heat-sterilized in a manner consistent with the same sterilization practices as a semi-critical item.

- (16)(G) Single use <u>critical</u>, <u>semi-critical</u>, <u>and non-critical</u> disposable items such as <u>scalpel blades</u>, prophylaxis angles, prophylaxis cups and brushes, tips for high-speed evacuators, saliva ejectors, air/water syringe tips, and gloves shall be used for one patient only and discarded.
- (17)(H) Proper functioning of the sterilization cycle of all sterilization devices shall be verified at least weekly through the use of a biological indicator (such as a spore test) with results confirmed by either authorized DHCP or an independent laboratory. Test results shall be documented and maintained for 12 months.
- (I)(i) A chemical indicator shall be used inside every sterilization package to verify that the sterilizing agent has penetrated the package and reached the instruments inside. If the internal chemical indicator is not visible from the outside of the package, an external chemical indicator shall also be used.
  - (ii) The chemical indicator shall be inspected immediately when removing packages from the sterilizer; if the chemical indicator did not register that the sterilizing agent has penetrated the package, the instruments shall be repackaged and sterilized again.

#### (9) Irrigation:

- (18)(A) Sterile coolants/irrigants shall be used for surgical procedures involving soft tissue or bone.
- (B) When performing procedures on exposed dental pulp, water or other irrigation solutions shall be sterile or contain disinfecting or antibacterial properties.
- (C) Sterile coolants/irrigants mustshall be delivered using a sterile delivery system.

#### (10) Treatment Facilities:

(19)(A) If non-critical items or clinical contact surfaces likely to be contaminated are or manufactured in a manner preventing cleaning and disinfection, they shall be protected physically covered with disposable impervious barriers approved by the FDA and designed by the manufacturer for that purpose. Disposable barriers shall be changed when visibly soiled or damaged and between patients.

- (20)(B) 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 germicidedisinfectant after each patient. The low-level disinfectants used shall be labeled effective against HBV and HIV. Use an intermediate-level disinfectant if visibly contaminated with blood. Use disinfectants in accordance with the manufacturer's instructions.
- (C) 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 DHCP shall follow all material safety data sheet (MSDS) handling and storage instructions.
- (21)(D) 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, or other devices. The dental unit lines and devices shall be flushed between after each patient for a minimum of twenty (20) seconds. Dental unit water lines shall be monitored or tested routinely in accordance with manufacturer's instructions.
- (22)(E) Contaminated solid waste shall be disposed of according to applicable local, state, and federal environmental standards.

#### (11) Lab Areas:

- (23)(A) Splash shields and equipment guards shall be used on dental laboratory lathes. Fresh pumice and a sterilized or new, disposable rag-wheel shall be used for each patient. Devices
- (B) Laboratory equipment, including handpieces, polishing (rag) wheels, grinding wheels, and laboratory burs, used to polish, trim, or adjust contaminated appliances and intraoral-prosthetic devices shall be cleaned, disinfected-or sterilized, properly packaged or wrapped, and heat-sterilized in a manner consistent with the same sterilization practices as a semi-critical item as specified in subparagraph (D) of paragraph (8), or if a single-use item, disposed of in accordance with subparagraph (G) of paragraph (8).
- (C) Laboratory equipment shall be stored in a manner consistent with the same storage practices as a semi-critical item as specified in subparagraph (D) of paragraph (8).

- (24)(D) All intraoral items such as impressions, bite registrations, <u>and prosthetic</u> and orthodontic appliances shall be cleaned and disinfected with an <u>Cal/EPA-registered</u> intermediate-level disinfectant before <u>and after manipulation</u> 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.
- (12) Respiratory Hygiene/Cough Etiquette: Measures shall be implemented to contain respiratory secretions and to prevent droplet and fomites transmission of respiratory pathogens, especially during seasonal outbreaks of viral respiratory infections such as influenza, RSV, adenovirus, parainfluenza virus, or SARS-CoV-2 (COVID-19) virus, as follows.
  - (A) Prominently posting at least one sign at every point of entrance and reception or registration desk of the treatment facility, accessible to public view, in which case the signs shall be in at least 12-point type font. The signs shall contain instructions to patients who cough or sneeze at the treatment facility to do at least all of the following: (i) cover their mouths or noses when coughing or sneezing; (ii) use and dispose of tissues in waste receptables; and, (iii) wash hands with soap and water or use alcohol-based hand rub after coughing or sneezing.
  - (B) Provide tissues and no-touch receptacles (e.g. foot-pedal operated lid or open plastic-lined waste basket) for disposal of tissues.
  - (C) Have soap, warm running water, and paper towels, or alcohol-based hand rub available for use in or immediately adjacent to waiting areas.
  - (D) Offer masks to coughing or sneezing patients or other persons when they enter the treatment facility.
  - (E) Provide distance between patients who cough or sneeze in common waiting areas. If available, facilities shall place these patients in a separate area while waiting for care.
- (c) DHCP who are employers of other DHCP shall provide those personnel with a training program on the minimum standards required by this section and the infection control plan specified in paragraph (2) of subsection (b). Such training program shall be provided at no cost to the personnel and during working hours in accordance with all of the following.
  - (1) The training program shall be provided as follows:
    - (A) Prior to assignment to tasks where OPIM exposure may take place; and,

- (B) Within one year of the date of the DHCP's previous training thereafter.
- (2) DHCP employers shall provide additional training prior to or by the effective date of any change to the minimum standards in this section or to the written infection control plan specified in paragraph (2) of subsection (b). The additional training may be limited to addressing the changes in the standards required by this section or the written infection control plan.
- (c) The Dental Board of California and Dental Hygiene Committee of California shall review this regulation annually and establish a consensus.

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

<sup>&</sup>lt;sup>1</sup>-Cal/EPA contacts: WEBSITE <u>www.cdpr.ca.gov</u> or Main Information Center (916) 324-0419.

#### ATTACHMENT 3

February 7, 2025



Dental Board of California 2005 Evergreen Street #1550 Sacramento, CA 95815

RE: Dental Assisting Alliance comments on Section 1005 – Minimum Standards of Infection Control

To Whom it May Concern:

At the February 6 <sup>th</sup> Dental Assisting Council meeting, we provided testimony regarding issues we see that need to be addressed on the following items within the proposed new 1005 regulations:

(a)(8 ) – definition of "sterilization: it says a "mechanical process" of elimination of all forms of life ... <u>Issue</u>: This eliminates the use of "cold sterile" with the word "mechanical" – is the intent to eliminate the use of cold sterile as an option?

(a)(9)(A) and (B) – mentions hand scrubbing first, which seems to indicate that hand scrubbing is the first acceptable method of removing debris.

Issue: Hand sc rubbing should be a last resort when other methods of cleaning are not effective. Aren't mechanical devices for debris remova I recommended by OSHA for the safety of the ADHP?

**(b)(4)(F)** – "Protective attire shall be changed daily, or <u>immediately</u> if they should become moist or v isibly soiled."

<u>Issue</u>: This would indicate that when doing a coronal polish, for example, we have to change the attire as soon as we see some prophy paste specks on our gown . . . if we

Issue: utility gloves are absolutely **NOT** the protocol for setting up a treatment room!

We need to set up with clean hands – not with gloves and especially not with utility gloves which are meant to be used for PROCESSING INSTRUMENTS and HANDLING CHEMICALS.

6)(B) – "utility gloves shall be cleaned and		sterilized	in
accordance with the manufacturer's instructions	after each use	,,	

#### MEETING MATERIALS Page 92 of 147

#### **ATTACHMENT 3**

Issue 1: The requirement to sterilize utility gloves after each use is exceedingly unrealistic.

It is hard enough to get offices to even use the utility gloves, but to require them to sterilize

them is just not going to happen.

Routine disinfection of the utility gloves is more realistic.

<u>Issue 2</u>: The verbiage here seems to indicate that disposable utility gloves are unacceptable since "utility gloves must be sterilized."

PROPOSED CHANGE: "utility gloves shall be cleaned and routinely disinfected and discarded if compromised in any way. Disposable utility gloves shall be disposed of after each use."

**(b)(8)(c)** – states that critical instruments . . . shall be . . . "sterilized **immediately** after each use."

Issue: This is unrealistic in the average dental office. ADHPs are often not able to process the instruments and get them sterilizing immediately; especially with the shortage of ADHPs. In addition, this does not allow for when the sterilizers are all full and running . . . the instruments are not going to be able to be sterilized immediately.

<u>PROPOSED CHANGE</u>: T hough we understand that ambiguity is tough to enforce in regulation, better wording would be "critical instruments . . . shall be . . . . processed and placed into packets or wrappers and "sterilized as soon as possible after each use."

(b)(8)(F) – This section has been an issue historically as it doesn't address whether or not the "motor" of a slowspeed handpiece must be sterilized after each use.

<u>Issue</u>: This is a VERY common issue in offices where there is confusion as to whether or not the motor is part of the handpiece that needs to be sterilized.

PROPOSED CHANGE: Add a statement specifically addressing whether or not the motor is considered part of the handpiece that needs to be sterilized — or specifically state that when the motor is deattachable from the nosecone, the motor does (or does not) need to be sterilized. Suggestion: "'Handpieces shall be processed and sterilized after each use including the motor and all component parts"

(b)(10)(D) – This section is on waterline maintenance.

<u>Issue 1</u>: The state of California has a law which requires the use of disinfectants in the water to control biofilm. The DBC regulations should reiterate and/or expand on that law. For example, the DBC could add a requirement for monthly water testing which would help to support the process for keeping the biofilm levels below 500 CFU.

#### **ATTACHMENT 3**

Sincerely,

The Dental Assisting Alliance

From: Leslie Canham & Associates, LLC

To: <a href="mailto:cara-Miyasaki; Montez">Cara Miyasaki; Montez</a>, <a href="mailto:Tracy@DCA">Tracy@DCA</a>; <a href="mailto:Nelson">Nelson</a>, <a href="mailto:Brant@DCA">Brant@DCA</a>; <a href="mailto:Bell">Bell</a>, <a href="mailto:Christy@DCA">Christy@DCA</a></a>

Subject: RE: Input Requested

**Date:** Tuesday, February 11, 2025 12:15:25 AM

Attachments: <u>image001.png</u> <u>image003.png</u>

Leslie Canham CV BIO- 2024.pdf

2025-02-10 23 33 01-Topics - Dental Unit Waterlines (DUWL) .pnc

<u>2025-02-10 23 36 23-Topics - Dental Unit Waterlines (DUWL) .png</u> <u>2025-02-10 23 37 29-RR5217 Dental Front.pmd.png</u>

2025-02-10 23 38 03-RR5217 Dental Front.pmd.png

2025-02-10 23 43 15-Notice-of-Intent-to-Adopt-Rule-150-8-.05 (002).pdf - Adobe Acrobat Pro.png 5075-dental-unit-water-quality-organization-for-safety-asepsis-and-prevention-white-paper-and-

recommendations-2018 (2).pdf

DUWL One Page Guide Infection Control.pdf

#### This Message Is From an Untrusted Sender

Warning: This email originated from outside of the organization! Do not click links, open attachments, or reply, unless you recognize the sender's email.

Report Suspicious

#### Cara,

Thank you for bringing my name and contact information to the members of DCA.

#### Dr. Montez, Brant, and Christy,

I would very much like to participate in the IC working group and contribute my expertise, knowledge, and experience in providing reliable resources concerning Dental Infection Control to the working group to update the § 1005. Minimum Standards for Infection Control. I previously participated with the Calif Dental Assistants Association workgroup for the 2011 Infection Control "draft" language and helped to form a consensus with the Dental Hygiene "Committee".

I have over 53 years of experience in dentistry, have been a Registered Dental Assistant for 48 years, and hold a Certified Dental Assistant certification. I'm also Certified in Dental Infection Prevention and Control. For the last 25 years, I have been a CA Dental Board Registered CE provider (including Infection Control and Calif Dental Practice Act) and a provider of the 8 hour Infection Control course since 2009. I'm Authorized by the Federal government as an OSHA outreach trainer and I have experience writing questions for the Dental Assisting National Board (DANB) Infection Control exam required for applicants to become Certified Dental Assistants.

In 2017, Dr. Jayanth Kumar, the state's Dental Director brought my name forward to the Orange County Public Health Agency, where Chief Eric G. Handler asked me to investigate the 2016 Nontuberculous Mycobacterium outbreak at the Children's Dental Group. My investigative report was submitted to Dr. Handler and forwarded to CDC's Division of Oral Health. Since my investigation, I have provided Expert Witness testimony in numerous depositions in the 200 lawsuits that have been filed as a result of this outbreak.

I believe I can help the IC working group form draft regulations in a quick and efficient manner that have validated scientific evidence, are consistent with CDC Guidelines for Dental Healthcare settings, ADA recommendations and CAL/OSHA regulations on bloodborne pathogen/hazard communication standards. I also have collected a library of resources and references that support my recommendations on Dental Infection Control.

I understand that DCA does not want to go back to the drawing board with more delays. I believe that my experience, expertise, and my long time relationship with the California Dental Association will expedite the review process and help move the revised draft language forward.

I attached my CV to this email for your review. And per Cara's email last week, For the DUWL – Cara asked me to provide information on how I recommend monitoring of DUWL (screen shots) and provide the CDC/OSHA or other agency where I found the information. Please see the 2<sup>nd</sup> and 3<sup>rd</sup> attachments which are screenshots of DUWL referenced and resources on the ADS (formerly OSAP) website. The 4<sup>th</sup> and 5<sup>th</sup> attachments are from the 2003 CDC Guidelines for Infection Control,

Also in addition to Washington state's requirements for Dental Unit Water testing, on 2-7-25, Georgia passed new water quality rules, (6<sup>th</sup> attachment and see the link below):

https://www.gadental.org/latest-news/2025/02/07/board-of-dentistry-adopts-new-dental-unit-water-quality-rule

The  $7^{th}$  attachment is the DENTAL UNIT WATER QUALITY: ORGANIZATION FOR SAFETY,

ASEPSIS AND PREVENTION WHITE PAPER AND RECOMMENDATIONS—2018 which has the current recommendations on Dental Unit Water testing and frequency.

The last attachment is a PDF on ADA's recommendation for DUWL

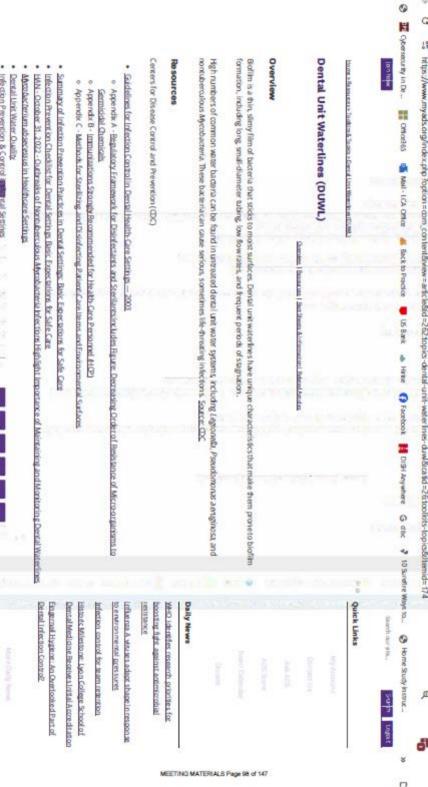
Disclaimer: I do not currently have a financial interest in any dental unit water testing companies.

Respectfully,

Leslie Canham, CDA, RDA, CDIPC, CSP	

From: Cara Miyasaki <miyasakicara@fhda.edu> Sent: Monday, February 10, 2025 4:54 PM

To: Montez, Tracy@DCA <Tracy.Montez@dca.ca.gov>; Nelson, Brant@DCA









lopics - Dental Unit Waterlines X

Cybersecurity in De...

**Education & Training** Membership

- Dental Unit Water Quality: Organization for Safety, Asepsis and Prevention White Paper and Recommendations 2018
- ADS Recommendations to Clinicians
- Message to My Patients
- Ouestions to Help Guide Selection of Dental Waterline Devices and Chemical Treatment Options
- Checklist for Dental Unit Water Quality Improvement
- Troubleshooting Dental Water Quality Problems
- Glossary of Terminology

Food and Drug Administration (FDA)

Dental Unit Waterlines

American Dental Association (ADA)

Dental Unit Waterlines

#### **Fact Sheets & Information**

Association for Dental Safety (ADS), formerly known as the Organization for Safety, Asepsis and Prevention (OSAP)

Dental Unit Waterline Fact Sheet

#### **Related Articles**

- Woman Dies After Contracting Legion naires' Disease From Dentist's Office
- Notes from the Field: Mycobacterium abscessus Infections Among Patients of a Pediatric Dentistry Practice Georgia, 2015
- Invasive Mycobacterium abscessus Outbreak at a Pediatric Dental Clinic MEETING MATERIALS Page 99 of 147

#### **Strategies To Improve Dental Unit Water Quality**

In 1993, CDC recommended that dental waterlines be flushed at the beginning of the clinic day to reduce the microbial load (2). However, studies have demonstrated this practice does not affect biofilm in the waterlines or reliably improve the quality of water used during dental treatment (315,338,343). Because the recommended value of ≤500 CFU/ mL cannot be achieved by using this method, other strategies should be employed. Dental unit water that remains untreated or unfiltered is unlikely to meet drinking water standards (303-309). Commercial devices and procedures designed to improve

the quality of water used in dental treatment are available (316); methods demonstrated to be effective include self-contained water systems combined with chemical treatment, in-line microfilters, and combinations of these treatments. Simply using source water containing ≤500 CFU/mL of bacteria (e.g., tap, distilled, or sterile water) in a self-contained water system will not eliminate bacterial contamination in treatment water if biofilms in the water system are not controlled. Removal or inactivation of dental waterline biofilms requires use of chemical germicides.

# Maintenance and Monitoring of Dental Unit Water DHCP should be trained regarding water quality, biofilm

previously validated protocol.

formation, water treatment methods, and appropriate maintenance protocols for water delivery systems. Water treatment and monitoring products require strict adherence to maintenance protocols, and noncompliance with treatment regimens has been associated with persistence of microbial contamination in treated systems (345). Clinical monitoring of water quality can ensure that procedures are correctly performed and

Dentists should consult with the manufacturer of their dental unit or water delivery system to determine the best method for maintaining acceptable water quality (i.e., ≤500 CFU/mL) and the recommended frequency of monitoring. Monitoring of den-

that devices are working in accordance with the manufacturer's

the recommended frequency of monitoring. Monitoring of dental water quality can be performed by using commercial self-contained test kits or commercial water-testing laboratories. Because methods used to treat dental water systems target the entire biofilm, no rationale exists for routine testing for such specific organishter and MANTERIAL PROPERTIES (244).

## SYNOPSIS OF PROPOSED ADOPTIONS OF THE GEORGIA BOARD OF DENTISTRY RULE 150-8-.05 DENTAL UNIT WATER QUALITY.

**Purpose:** To require and set standards for the testing of dental unit water lines in the

practice of dentistry in Georgia, and to require remedial action in the

event dental unit water lines fail testing.

Main Features: This rule requires routine testing of dental unit water lines, establishes

standards and procedures for said testing, provides criteria for a failed test

and remedial action, and requires maintenance of a record of such testing.

## DIFFERENCES OF PROPOSED ADOPTIONS OF THE GEORGIA BOARD OF DENTISTRY RULE 150-8-.05 DENTAL UNIT WATER QUALITY.

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

A copy of the draft rule approved by the Board is attached hereto.

## DENTAL UNIT WATER QUALITY: ORGANIZATION FOR SAFETY, ASEPSIS AND PREVENTION WHITE PAPER AND RECOMMENDATIONS-2018

#### **Statement Editors\*:**

Shannon E. Mills, DDS, Concord, NH

Nuala Porteous, BDS, MPH, University of Texas Health, School of Dentistry, San Antonio, TX (Retired)

Jeff Zawada, PhD, Director, Technical Research, A-dec, Inc., Newberg OR and Chair, Subcommittee 6 - Dental Equipment, ANSI/ADA Standards Committee for Dental Products

This white paper and recommendations replaces the Organization for Safety, Asepsis and Prevention (OSAP) Dental Unit Waterline Position Paper originally published in January 1997 and revised in 2000.

Purpose: This OSAP white paper is intended to:

- Provide guidance for the manufacturers of dental units, dental water treatment devices and chemical agents to meet or exceed Centers for Disease Control and Prevention (CDC) recommendations for dental water quality, current US and international voluntary consensus standards and regulatory and/or registration requirements of the US Food and Drug Administration (FDA) and state and federal Environmental Protection Agencies (EPA).
- Provide recommendations for dental health care personnel (DHCP) on managing dental procedural water quality to meet or exceed current CDC recommendations to ensure the health and safety of patients and DHCPs.
- Provide recommendations regarding the adoption of voluntary consensus standards related to dental procedural water quality.

**Applicability:** The recommendations contained in this white paper apply to the design and use of devices and products that deliver water used for dental procedures or are marketed to improve, maintain or monitor the microbiological quality of dental procedural water used in patient treatment including:

- Dental units and accessories including handpieces and air-water syringes.
- Portable dental equipment.

- Ultrasonic scalers.
- Surgical handpieces.
- · Dental lasers.
- Dental water treatment devices, such as slow release cartridges, water conditioning devices, antimicrobial tubing and reservoirs.
- Chemical germicides and cleaners.
- In-office test kits and third-party testing and monitoring services.

**Exclusions:** This document is not intended to serve as a manual or provide exclusive guidance for the control of waterline contamination in clinical settings. Dentists should contact the manufacturer of their dental equipment or water treatment products for specific guidance and instructions on methods to improve and maintain the quality of dental procedure water.

OSAP concurs with applicable recommendations on the general management of water used in health-care settings contained in the 2003 CDC Guidelines for *Environmental Infection Control in Health-Care Facilities* but does not provide specific guidance in this document on:

- The design, monitoring and remediation of water contamination in premise plumbing.
- The quality of water delivered by publicly owned water treatment works.
- Dental vacuum systems and amalgam separators.

#### **DEFINITIONS**

**510(k)** - A premarket submission made to the US Food and Drug Administration to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to Pre-Market Approval (PMA).

**Biofilm** - An assemblage of microbial cells that is irreversibly associated (not removed by gentle rinsing) with a surface and enclosed in a matrix of primarily polysaccharide material. (After Donlan, RM, 2002<sup>1</sup>)

**Dental equipment** - Furniture, machines, apparatus and accessories made for use in the practice of dentistry and/or its associated procedures. (Adapted from ISO 1942:2009, definition 2.68)

**Dental unit** - Combination of interconnected dental equipment and dental instruments constituting a functional assembly for use in the provision of dental treatment. (Source: ISO 1942:2009, definition 2.86)

**Device (Medical)** - An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- 1. recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;
- 2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or;
- intended to affect the structure or any function of the body of man or other animals, and which
  does not achieve its primary intended purposes through chemical action within or on the body of
  man or other animals and which is not dependent upon being metabolized for the achievement
  of its primary intended purposes. (Source: US FDA, Food, Drug and Cosmetics Act Section
  201(h))

**Heterotrophic plate count (HPC)** - Formerly known as the standard plate count. A culture method for estimating the number of live heterotrophic bacteria in water. (Source: US Environmental Protection Agency. *Fed. Regist.* 54(124): 27486–27541.)

**Oral Surgical Procedures** - The incision, excision, or reflection of tissue that exposes the normally sterile areas of the oral cavity. Examples include biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth (e.g., removal of erupted or nonerupted tooth requiring elevation of mucoperiosteal flap, removal of bone or section of tooth, and suturing if needed). (Source: Centers for Disease Control and Prevention *Guidelines for Infection Control in Dental Health-Care Settings - 2003*<sup>2</sup>)

**Procedural water** - Water for use in the oral cavity. Also known as dental unit water or dental treatment water. (Adapted from ISO 7494-2: 2015 *Dentistry - Dental Units*)

**Sterile water for irrigation** - Sterile, hypotonic, nonpyrogenic water prepared by distillation that contains no antimicrobial or bacteriostatic agents or added buffers. The pH is 5.7 (5.0-7.0). (Source: United States Pharmacopeia, USP 29: 2265)

**Sterile Saline** - A 0.9% solution of sodium chloride utilized for a variety of clinical indications such as sterile irrigation of body cavities, tissues or wounds that also serves as a diluent or vehicle for drugs used for irrigation or other pharmaceutical preparations. (Source: United States Pharmacopeia – USP 29-NF24:1976)

#### **ABBREVIATIONS**

ADA - American Dental Association

ANSI - American National Standards Institute

AWWA - American Water Works Association

CDC - Centers for Disease Control and Prevention

CFU/mL - Colony forming units per milliliter

DFU - Directions for use (see also IFU)

DHCP - Dental health-care personnel

**DUWL** - Dental unit waterline

EPA - US Environmental Protection Agency

FDA - US Food and Drug Administration

HAI - Healthcare-associated infections

HPC - Heterotrophic plate count

IC - Infection control (or infection prevention and control)

IFU - Instructions for Use (See also DFU)

ISO - International Organization for Standardization

LPS - Lipopolysaccharide

MCL - Maximum contaminant level

NTM - Non-tuberculous mycobacteria

OSHA - US or State Occupational Safety and Health Administration

SOP - Standard operating procedure

Sterile - Free from all living microorganisms; usually described as a 1 in 1 million chance that a microorganism will survive the sterilization process

USP - United States Pharmacopeia

UVGI - Ultraviolet germicidal irradiation

#### APPLICABLE GUIDELINES STANDARDS AND REGULATIONS

American Dental Association. Oral Health Topics: Dental unit waterlines, April 2016. Available at: http://www.ada.org/en/member-center/oral-health-topics/dental-unit-waterlines

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Centers for Disease Control and Prevention - Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care – 2016, Available at:

www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-care.pdf

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https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm

International Organization for Standardization - ISO 16954:2015 Dentistry — *Test Methods for Dental Unit Waterline Biofilm Treatment,* International Organization for Standards, Geneva, Switzerland. July 2015. Available at: https://www.iso.org/standard/58009.html

Occupational Safety and Health Administration. 15A, 1999. Available at: http://www.oshaslc.gov/dts/osta/otm/otm\_toc.html

- U.S. Environmental Protection Agency; *National Primary Drinking Water Regulations*. Available at: https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations
- U.S. Environmental Protection Agency, *Frequently Asked Questions on the Dental Office Category Rule*. Available at: https://www.epa.gov/sites/production/files/2017-12/documents/dental-office-category\_frequent-questions\_nov-2017.pdf
- U.S. Food and Drug Administration, *Dental Unit Waterlines*. Available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm610545.htm
- U.S. Food and Drug Administration, Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff Guidance for Industry and Food and Drug Administration Staff. Available at: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf

#### BACKGROUND

**Biofilm and Human Health:** Microbial biofilms can be found virtually anywhere there is moisture and a solid surface for bacterial attachment<sup>1, 3</sup>. Consisting primarily of naturally occurring, slime-producing bacteria and fungi, biofilms in dental units form on the luminal walls of the small-bore plastic tubing that delivers water for cooling and irrigation to the dental handpieces, sonic and ultrasonic scalers, airwater syringes and other devices used in patient care<sup>4-6</sup>. The narrow diameter of dental unit waterlines (DUWL) increases the surface area available for biofilm growth relative to the volume of water in the lines, leading to levels of microbial contamination in effluent water that may exceed 1,000,000 colony-forming units per milliliter (CFU/mL)<sup>4</sup>.

Although bacteria of possible human origin have been reported in the literature, most of the organisms recovered from DUWLs occur naturally in aquatic environments. Water from dental units colonized with gram negative heterotrophic biofilms can have high levels of lipopolysaccharide (LPS also known as endotoxin)<sup>7-9</sup> that can trigger and/or exacerbate asthma in dental patients and DHCPs<sup>10</sup>. LPS can also cause skin rashes, gastrointestinal reactions and may result in delayed wound healing.

The presence of opportunistic human pathogens in DUWLs, such as *Pseudomonas aeruginosa*, nontuberculous mycobacteria (NTM)<sup>11-13</sup> and *Legionella* species<sup>14-16</sup> have provided cause for concern<sup>12, 13, 17</sup>. Two cases of postoperative *Pseudomonas* infections in immunocompromised patients were the direct consequence of exposure to contaminated procedural water<sup>18</sup>. Biofilms can be important replication sites for NTM and *Legionella* species as they can survive and replicate in free-living amoebae and protozoa found in biofilms<sup>19-22</sup>. NTM are typically resistant to disinfectant residuals present in potable water and have been found in the effluent immediately after DUWL treatment<sup>12</sup>. *Mycobacterium abscessus*, isolated from DUWLs were found to be the source in separate outbreaks of pediatric postoperative infections in Georgia <sup>23, 24</sup> and California<sup>25</sup>.

A fatal case of *Legionella pneumonia* in an elderly woman in Italy was reported in 2014. Investigators traced the origin of the *Legionella* species to DUWLs where the patient had received recent treatment<sup>26</sup>. In 2017, a case report from Sweden described a fatal case of Legionellosis in elderly immunocompromised man who received dental treatment in a hospital dental clinic. In this case, analysis of clinical specimens and isolates from the dental unit cup-filler used for oral rinsing strongly suggested that they were of common origin<sup>27</sup>.

Serological evidence of exposure to *Legionella* bacteria have been reported in dental health-care personnel<sup>28-30</sup>. A post-hoc review of screening for serologic markers of *Legionella* exposure in dentists conducted as part of the American Dental Association (ADA) dentist health screening program however, found that dentists appeared to be no more likely to exhibit evidence of exposure than the general population<sup>31</sup>.

Several investigations studying the quality of water in hospitals have established that potable, non-sterile water contains naturally occurring bacteria (some of which are opportunistic pathogens). Typically, only rare infections have occurred in healthy persons from ingestion or contact. However, there is an increased risk of infection for exposed immune compromised patients. Health care-associated infections have been linked to contaminated potable water, tap water, and other hospital water systems, especially among patients who are immune compromised or severely ill<sup>32-35</sup>. Distillers and reverse osmosis devices can remove contaminants including microorganisms from water, but membranes, tubing and holding tanks connected to them can also become colonized with biofilm<sup>36, 37</sup>.

There are currently no case reports of infections, nor is there a scientific basis for determining a threshold limit of risk associated with the use of water for non-surgical dental procedures that meets current CDC recommendations for water used in dental treatment. The use of water with high levels of bacterial contamination for dental therapeutic procedures however, is inconsistent with recognized standards of infection control and can potentially undermine public confidence in the dental profession. For these reasons, OSAP urges all stakeholders to strive to achieve the lowest possible levels of microbial contamination achievable within the limitations of current technology.

**CDC Recommendations for Dental Water Quality:** The Centers for Disease Control and Prevention *Guidelines for Infection Control in Dental Health-Care Settings—2003*<sup>2</sup> include specific recommendations on the use of coolant and irrigating solutions in dentistry and on the control of microbial contamination in water used for dental treatment:

- Use water that meets the CDC recommended limit for dental procedural water (i.e., <500 CFU/mL of heterotrophic water bacteria) for routine dental treatment.
- Consult with the dental unit manufacturer for appropriate methods and equipment to maintain the recommended quality of dental water.
- Follow recommendations for monitoring water quality provided by the manufacturer of the unit or waterline treatment product.
- Discharge water and air for a minimum of 20–30 seconds after each patient, from any device connected to the dental water system that enters the patient's mouth (e.g., handpieces, ultrasonic scalers, and air/water syringes).
- Consult with the dental unit manufacturer on the need for periodic maintenance of anti-retraction mechanisms.

The CDC recommended limit is derived from recommendations for HPC bacterial counts under the U.S. EPA's Surface Water Treatment Rule for systems using surface water or groundwater under the direct influence of surface water.

According to the EPA, heterotrophic plate count (HPC) and related methods such as those described above do not provide a measure of health effects. They are analytic methods used to measure the variety of bacteria that are common in water and demonstrates how well maintained the water system is.

EPA does not have a Maximum Contaminant Level (MCL) for HPC and cannot specify a scientifically rational level (other than zero) at which no adverse health effects occur because HPC analysis measures both pathogenic and harmless (innocuous) bacteria. Drinking water with any level of HPC might contain numerous, few, or no pathogens.

EPA considers the health benefits of complying with a bacteria concentration near zero versus some higher level (e.g., 500/mL) as unquantifiable and probably negligible. Additionally, high concentrations of disinfectant would be needed to achieve a near-zero level and could result in excessive levels of disinfection byproducts (which carry their own health risks) in finished drinking water.

The CDC recommended 500 CFU/mL limit for heterotrophic mesophilic water bacteria in water used for non-surgical dental procedures is an engineering standard that does not represent a threshold limit for the avoidance of adverse health outcomes. OSAP concurs with CDC that this limit provides a useful goal for manufacturers of devices, or germicides intended to improve the quality of dental treatment water.

**CDC Guidelines for "Boil Water" Advisories:** The 2003 dental guideline<sup>2</sup> also addresses "boil water" advisories by advising dentists not to deliver water from the public water system through the dental operative unit, ultrasonic scaler, or other dental equipment that uses the public water system until the advisory is lifted. Engineering solutions that isolate dental devices from municipal water provide an additional margin of safety when municipal water supplies are unsafe.

The CDC Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care. 2016, Mobile App and Checklist: The CDC issued an online publication and mobile app in 2016 that provides an infection control checklist, which includes a DUWL section that can be used as published or modified for use by dental facilities to assist with IC compliance.

**Progress in Dental Water Quality Management Since 2000:** Since the OSAP position papers of 1997 and 2000, there has been significant progress in developing reliable and economical engineering methods to mitigate the formation of biofilm in dental unit waterlines. There are now numerous FDA-cleared and/or EPA-registered products available for use by the profession. When as directed, these agents and devices enable dentists to provide procedural water of acceptable quality with minimal impact on dental equipment or materials. Products currently marketed to control, eliminate or prevent biofilm formation in dental equipment include:

- EPA-registered chemical germicides or antimicrobial surface treatments.
- Non-EPA-registered waterline cleaners without germicidal claims.
- Independent water reservoirs that isolate dental units from municipal water systems that can be used with intermittent or continuously present cleaners or germicides.
- Automated germicide metering or slow release devices which may also include filtration technology that can be used with independent reservoirs or municipal water connections.
- Sterile water delivery systems, which employ either sterile, disposable or heat sterilized reusable components that are independent of the dental unit water supply.
- Distillers, reverse osmosis and microfiltration devices that can remove microorganisms from procedural water, but which do not effectively limit the growth of biofilm in DUWL or reservoirs without addition of germicidal agents or other anti-biofilm treatment.

Methods for the clinical monitoring of water quality and compliance with treatment protocols include:

- In office test kits for drinking water quality using various media.
- Mail-in or local water laboratory testing services.

### **Monitoring Water Quality in Clinical Settings:**

Recent water related outbreaks have heightened awareness of the risks posed by contaminated dental procedural water and have reinforced the importance of monitoring procedural water quality<sup>23, 24</sup>. CDC Guidelines provide general recommendations for monitoring of dental procedural water but do not provide IFU for monitoring by DHCPs using manufacturer validated methods. Monitoring procedural water quality and inspection of dental procedural water systems provides an important margin of safety for DHCPs and patients by confirming that dental equipment and/or water treatment products are achieving water quality objectives. Regular monitoring and inspection can also identify problems with water quality management including but not limited to:

- Staff non-compliance with directions for use.
- Dental unit or device design variables such as dead legs that compromise water quality management.
- Units with excessive biofilm growth that may be refractory to treatment.
- Incompatibility of water treatment products or devices with dental units or other devices.
- Contaminated source water.

While recent reports of outbreaks of NTM and a report of a fatal Legionellosis death in dental settings have raised concerns about current monitoring recommendations, OSAP concurs with current CDC guidelines that do not recommend routine microbiological testing for potential pathogens such as *Legionella* species, *Pseudomonas aeruginosa*, NTM or other waterborne pathogen in health-care settings. Testing as directed by local or state health authorities for specific pathogens in procedural water, should only be performed to investigate the source of infection(s) caused by a water-associated opportunistic pathogen. A negative test for a difficult-to-culture potential pathogen such as *Legionella* may give false reassurance of the safety of dental treatment water.

In the United States, manufacturers of dental units and other equipment have not consistently provided specific recommendations for the control and monitoring of microbial contamination in procedural water. For example, most units presently on the market come with independent water reservoirs as a default option, but the choice of approaches to ensuring water quality including monitoring procedural water quality may be left up to the purchaser.

Similarly, the manufacturers of germicides, cleaners, water conditioning systems, antimicrobial tubing, slow release cartridges and other products, do not always provide specific recommendations on monitoring procedural water quality.

Successful management of water quality is subject to many variables including dental unit design characteristics, efficacy and compatibility of germicidal or cleaning products, input water quality, and

staff compliance. This inherent complexity can lead to treatment failure even with products that have shown excellent results in laboratory or controlled clinical settings.

While FDA and EPA requirements for labeling of products and directions for use clearly apply to products marketed to manage procedural water, consensus appears lacking among product manufacturers on the appropriate methods and frequency of monitoring necessary to ensure the safety of patients and health-care practitioners.

To address these concerns, OSAP recommends that monitoring be performed periodically regardless of the product or protocol used to manage dental procedural water quality, even when manufacturer directions for monitoring are absent or unclear.

OSAP believes that providing minimum baseline guidance for monitoring methods, frequency and for troubleshooting problems with water quality management will assist DHCPs in achieving compliance and guide manufacturers in the development of more effective directions for use.

**Voluntary Consensus Standards:** Voluntary consensus standards are developed within an international framework that sets regional national, regional and global technical standards for products and services. The American Dental Association (ADA) is recognized by the American National Standards Institute (ANSI) as the US representative to International Organization for Standardization (ISO) Technical Committee 106 – Dentistry (TC 106). Regulatory agencies including the US Food and Drug Administration and the US Environmental Protection Agency use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical.

ISO 16954:2015(ANSI/ADA Standard 167) -- Test methods for dental unit waterline biofilm treatment -- establishes laboratory test methods for evaluating the effectiveness of treatment methods intended to prevent or inhibit the formation of biofilm or to remove biofilm present in dental unit procedural water delivery systems under laboratory conditions.

It does not apply to devices intended to deliver sterile procedural water or sterile solution. It also does not apply to lines, tubing, or hoses that deliver compressed air within the dental unit.

The standard does not establish specific upper limits for bacterial contamination or describe test methods to be used in clinical situations. It also does not establish test methods for evaluating any deleterious side effects potentially caused by treatment methods.

The test methods provided in ISO 16954:2015 can be used to test other dental equipment that delivers non-sterile water to the oral cavity.

With modification, the test methods described in ISO 16954:2015 should also be applicable for evaluating the effectiveness of devices and germicides that are sold separately from dental delivery systems.

**Off-label use of chemical germicides and cleaners:** OSAP does not recommend off-label use of germicides or cleaning agent that do not have regulatory approval or registration for the control of biofilm in dental equipment.

**Areas for Further Research and Development:** Much progress has been made over the last four decades in understanding the nature of biofilm and its role in human disease. In dentistry we have seen the development of procedures and marketing of technology to improve the quality of water used for clinical dental procedures<sup>38-56</sup>.

Recent case reports of multiple infections with non-tuberculous Mycobacteria in two pediatric dental practices and a fatal case of Legionellosis linked to dental treatment reinforce the need for research to understand how such cases occur and how they can be prevented.

A limited number of studies have suggested that chronic exposure among dental health-care workers to contaminated dental procedural water in the form of aerosols and droplets containing bacteria and bacterial byproducts including lipopolysaccharide may lead to exacerbation of asthma and onset of other respiratory conditions<sup>7, 9, 10, 57, 58</sup>. Additional investigations may help determine the frequency and consequences of chronic occupational exposure to waterborne contaminants and lead to more effective ways to protect health-care workers.

Continued efforts to conduct research and develop technologies for controlling or eliminating biofilm in dental units and other devices can lead to more safe, effective, and less costly methods for managing dental procedural water quality in dentistry. These efforts should be combined with efforts by manufacturers of dental units and other devices to develop engineering solutions that simplify and where possible, automate water management practices using products that are safe, compatible with dental materials, and that minimize environmental impact.

Monitoring and testing methods currently in use rely on culture recovery methods that use growth media to recover and count viable bacteria. Although they are based on currently accepted standard methods for examination of water, both point-of-use test kits and outsourced laboratory culture methods may undercount bacterial numbers to varying degrees<sup>59</sup>. This phenomenon may be complicated by the presence of non-neutralized residual germicide in samples that may damage organisms and prevent their recovery<sup>60</sup>.

Researchers and services that provide dental procedural water testing, should investigate the adoption

of other approaches including non-culture methods that can provide more accurate counts even in the presence of residual germicide.

**Application of the Precautionary Principle:** The precautionary principle<sup>61, 62</sup> is a strategy for decision-making when extensive scientific knowledge relating to potential health risks are lacking but there is plausible risk of harm to patients or health-care workers if the risk is not remediated. In this situation, reasonable measures to avoid threats that are serious and plausible based on anecdotal evidence or extrapolation may be warranted.

OSAP's position is that the presence of high numbers of potentially pathogenic microorganisms in procedural water used for dental treatment is inconsistent with best health-care practices and warrants the application of the precautionary principle to create guidance for improving and maintaining the quality of water used in dentistry even where direct scientific evidence of harm may be lacking. The following recommendations and statements are intended to provide guidance to all stakeholders to help ensure a safe and healthy dental treatment environment.

# OSAP RECOMMENDATIONS FOR MANAGEMENT AND MONITORING OF WATER USED IN DENTAL TREATMENT:

- 1. General Statements Regarding the Use of Coolant and Irrigating Solutions in Dentistry
  - 1.1. OSAP concurs with the recommendation in the CDC *Guidelines for Infection Control in Dental Health-Care Settings—2003* that water used for non-surgical dental procedures should, at a minimum, meet nationally recognized microbiological standards for drinking water according to standard test methods from the American Water Works Association (AWWA) at no more than 500 CFU/mL of heterotrophic, mesophilic water bacteria.
  - 1.2. OSAP supports this limit as a useful goal for manufacturers of devices or germicides intended to improve the quality of dental treatment water, as well as for dental practitioners, but recommends that manufacturers and practitioners should strive to **reduce levels of bacterial contamination to the lowest levels achievable** as measured using standard microbiological methods including new technologies as they become available.
  - 1.3. Boil Water Advisories: OSAP concurs with CDC recommendations for the management of water for dental treatment during and after boil water advisories by public health authorities, but further advises that methods for managing dental water quality that isolate dental units from municipal water systems may provide an additional margin of safety.
- 2. Recommendations for Dental Health-Care Personnel

- 2.1. General Recommendations: OSAP recommends that dental practices implement current CDC recommendations for microbial quality in dental procedural water to ensure a safe and healthy environment for patients and staff. To accomplish this, OSAP recommends that DHCP:
  - Make a reasonable effort to stay informed about current recommendations on the use of water for dental treatment and on the control of microbial biofilm contamination in DUWLs.
  - Review instructions for use from the dental unit or device manufacturer for controlling contamination in the waterlines and maintaining the quality of dental procedural water.
  - Obtain and review information on the safety, effectiveness and compatibility with dental equipment when selecting germicidal products and devices for controlling biofilm colonization in dental water systems.
  - Flush waterlines for 20-30 seconds at the beginning and end of day and between patients to remove patient material potentially retracted during treatment (refer to Section 2.2 for specific flushing recommendations).
  - Use only sterile solutions for coolant and irrigation supplied by a sterile device for surgical procedures that involve the incision, excision, or reflection of tissue that exposes initially sterile areas of the oral cavity (refer to Section 2.3 for specific recommendations on solutions for surgical procedures).
  - Monitor and document dental unit water quality regularly according to the directions for use provided for the dental device, germicidal product or biofilm prevention device (refer to Section 2.4 for specific monitoring recommendations).
  - Develop and implement Standard Operating Procedures (SOP) for maintaining, monitoring and documenting dental procedural water quality that are consistent with the recommendations presented here and manufacturer IFUs for the equipment, devices, germicides and monitoring methods used in the clinic as part of the clinic's overall Infection Control Plan (refer to Section 2.5 for specific SOP recommendations).
  - Educate all members of the dental team on the importance of managing dental water quality and provide training in compliance with SOPs to ensure a safe, infection free environment for patients and DHCPs.

- 2.2. Discharging Dental Water and Air Lines between Patients: OSAP agrees with CDC recommendations to discharge water and air for a minimum of 20-30 seconds after each patient from any device connected to the dental water system that enters the patient's mouth but does not recommend flushing between patients as a sole means to improve dental procedural water quality.
- 2.3. Indications for Use of Sterile Irrigating Solutions: OSAP concurs with the 2003 recommendation of the CDC that only sterile solutions be used for procedures that involve the incision, excision, or reflection of tissue that exposes the normally sterile areas of the oral cavity. Examples include biopsy, periodontal surgery, apical endodontic surgery, implant surgery, and surgical extractions of teeth (e.g., removal of erupted or nonerupted tooth requiring elevation of mucoperiosteal flap, removal of bone or section of tooth, and suturing if needed). The following statements expand on this guideline:
  - OSAP recommends that sterile irrigating solutions used in surgical dental procedures conform to standards for sterile water for irrigation or sterile saline solution from the United States Pharmacopeia (USP).
  - **Non-surgical tooth extractions:** Use of sterile irrigation should also be considered for all dental extractions other than exfoliating deciduous teeth.
  - **Gingival procedures:** The decision to use sterile irrigation for gingival procedures such as prophylaxis, non-surgical periodontal therapy (scaling and root planing) and periodontal maintenance is a matter of clinical judgment based on the extent of exposure of vascular system and the patient's risk for infection due to compromised immune status (e.g., immunosuppressive therapies, cancer chemotherapy, neutropenia).
  - Non-surgical endodontic procedures: Procedural water that meets CDC recommendations for microbial quality may be used when creating access to the pulp chamber for either pediatric or adult endodontic procedures. Irrigation during manipulation, amputation and/or debridement of pulpal tissues should employ either sterile water, sterile saline solutions and/or antimicrobials such as diluted sodium hypochlorite. The pulp chamber should be thoroughly irrigated with a sterile and/or antimicrobial solution prior to interim or final closure.

(Refer to Section 3.44 for information on design characteristics of sterile water delivery systems.)

- 2.4. Clinical Monitoring: Dental procedural water monitoring is intended to identify failures in clinical water management practices and can also provide a positive-reinforcement feedback loop for the dental staff.
  - Action limits: The CDC recommendation that water used for non-surgical dental treatment not exceed 500 colony forming units per milliliter using standard test methods should serve as an <u>action limit</u> for water management interventions as directed by the device manufacturer.
  - Monitoring methods: Dental procedural water monitoring can be accomplished using water-testing laboratory services or in-office, chairside kits. The method used for dental treatment water monitoring should correlate to the extent possible with assessment methods based on AWWA standard methods.
  - Laboratory testing: When using a laboratory testing service, users should request
    that water be tested using the most current version of the spread plate R2A agar
    method (9215C) or membrane filtration method (9215D) from Standard Methods for
    the Evaluation of Water and Wastewater published by the American Water Works
    Association (AWWA) or the most current equivalent method.
    - Users should follow laboratory instructions for aseptic collection, germicide neutralization and shipping/transport of samples.
    - Samples may be collected from individual lines or by combining samples from all water bearing lines on an individual dental unit.
    - Tests should be conducted for longer incubation times at lower recommended temperature to allow growth of slow-growing water bacteria.
  - In-office test kits: When using in-office test kits, select a product designed to test drinking water that correlates with AWWA Method 9215 or heterotrophic plate count (HPC) methods.
    - Collect samples aseptically according to the manufacturer's instructions and incubate as directed at room temperature.
    - Neutralize residual germicide according to manufacturer IFU and use longer recommended incubation times to allow for growth of slower growing water bacteria.

- Laboratory versus in-office monitoring: All culture based counting methods will underestimate the numbers of microorganisms in water samples.
  - Laboratory testing using standard agar plate test methods can provide more accurate counts than in-office test kits and provide better baseline measures and provide an external validation of in-office monitoring program.
  - In-office test kits used on a more frequent basis however, may help ensure staff compliance with biofilm mitigation protocols and provide early warning of problems with biofilm control.
- Testing for specific organisms: Test for specific pathogens in procedural water only
  to investigate the source of infection(s) caused by a water-associated opportunistic
  pathogen as directed by local or state health authorities.
- Frequency recommendations for monitoring, inspection, maintenance and replacement of dental units and water treatment products:
  - Review information from the manufacturer of the equipment or device providing dental procedural water for patients and from the manufacturer of the device or germicide for controlling dental procedural water quality for recommendations for frequency for monitoring dental procedural water quality, as well as inspection and maintenance of devices.
  - When there are no manufacturer directions available for dental units (e.g., older equipment), OSAP recommends that periodic monitoring and inspection should be performed according to directions for use provided by the treatment product manufacturer or at least monthly on each dental unit or device.
  - OSAP recommends that periodic monitoring and inspection should be performed at least monthly on each dental unit or device following installation of treatment devices or initiation of new protocols.
  - If monitoring results indicate that water quality is acceptable for two consecutive monthly cycles, the frequency of testing may be reduced, but should not be less than every three months.
  - When a dental unit exceeds the action limit for an initial or periodic test, the unit should be treated according to manufacturer IFU, and re-tested immediately after treatment.
- Other indications for monitoring: In addition to scheduled periodic monitoring, all

dental devices that provide procedural water for patient treatment should be tested for bacterial contamination in the following circumstances:

- Following installation of new equipment such as water reservoirs or procedural water treatment devices.
- Following initiation of new procedural water treatment protocols using chemical germicides or cleaners.
- After extended periods of disuse or lack of maintenance.
- Following changes to manufacturer IFU or clinic protocols.
- · Following maintenance or repair of dental units or devices.
- 2.5. Standard Operating Procedures (SOPs) for maintaining and monitoring dental procedural water quality: SOPs are an important measure for assuring the current processes established by the clinic for maintaining and monitoring dental procedural water quality are consistently followed. SOPs are useful for training new staff as well as for reference by all involved in infection control in the clinic. SOPs should be updated when process changes occur. SOP updates and training should be provided for clinic staff as needed.
  - SOPs for maintaining dental procedural water quality should follow the manufacturer's IFUs for cleaning and disinfecting the dental unit and provide:
    - Input water specifications (e.g. sterile, bottled drinking water, distilled water),
    - Instructions for inspecting and maintaining devices for preparation of procedural water such as distillers, deionizers, reverse osmosis systems and other purification systems (if used),
    - Instructions and schedule for periodic and/or continuous application of germicidal agents (if used),
    - Instructions and schedule for replacement of water treatment devices, and other manufacturer recommended maintenance (if used), and
    - Precautions regarding disposal of germicidal agents and potential interactions with amalgam in amalgam separators.
  - SOPs for monitoring and documenting dental procedural water quality should be based on manufacturer IFUs and standard methods for microbiological analysis of water including:
    - Type and frequency of monitoring (e.g. in-office chairside test kits or external

laboratory services)

- Instructions for all steps to be performed within the clinic including:
  - Sample collection including labeling to specify source (unit, handpiece, threeway syringe etc.) and date/time collected.
  - Germicide neutralization if indicated
  - Storage and shipping including need for refrigeration if applicable
  - In-office test kit procedure if applicable
- Action limits and recommended interventions when test results exceed recommended levels
- Instructions for documenting monitoring results including:
  - Source, date and time of sample collection
  - · Identity of person performing monitoring
  - · Date and method of analysis
  - Test results
  - Remediation efforts for failed tests and follow-up test results including removal and return to service of units where indicated
  - · Where documentation of monitoring results is to be maintained

### 3. Recommendations for Manufacturers

- 3.1. General recommendations: Manufacturers of dental units, other devices that provide irrigation and/or coolant solutions for dental procedures as well as products for controlling or improving dental procedural water quality must meet applicable Federal and state regulatory requirements (refer to Section 4 for further information on regulatory requirements). OSAP recommends the following to dental product manufacturers:
  - Manufacturers of dental units and other devices which deliver dental procedural
    water should develop a scientifically validated procedure for maintaining the water
    delivery system, verifying that the device can provide water that meets or exceeds
    current CDC recommendations for the microbial quality of dental procedural water
    when used as directed.

- Manufacturers of products intended to control or improve dental procedural
  water quality should develop a scientifically validated procedure for the use of
  their product with dental units and other devices which deliver dental procedural
  water, verifying that their product is capable of meeting or exceeding current CDC
  recommendations for the microbial quality of dental procedural water when used as
  directed.
- Manufacturers of products intended to control or improve dental procedural
  water quality should provide users with instructions for collection of germicide free
  samples or neutralization of germicide residual to obtain the most accurate bacterial
  counts using plate count methods. If neutralization is not possible, other enumeration
  methods such as microfiltration and staining may be necessary to obtain reliable
  results.
- All manufacturers should provide complete and easily understood instructions for the validated procedures associated with their product to meet or exceed current CDC recommendations for the microbial quality of water used in dentistry.
- Where applicable, <u>manufacturers</u> should verify the effectiveness of products and associated procedures using standard test methods such as those described in ISO 16954:2015 (ANSI/ADA 167).
- Manufacturers of dental units and other devices which deliver dental procedural
  water should provide comprehensive and easily understood guidance for periodic
  inspection, maintenance, replacement and trouble-shooting of dental units and
  devices intended to control or improve dental procedural water quality.
- All manufacturers should continuously improve the design and performance of dental devices and waterline treatment products to provide cost effective methods for controlling the quality of dental procedural water delivered by dental units and other devices (refer to Sections 3.2 and 3.3 for further information on design considerations for dental units and sterile water delivery systems).

### 3.2. Design Considerations for Dental Units:

Waterline length and dead legs: OSAP encourages designers of dental equipment
to minimize the amount of surface area for biofilm formation by using the shortest
practical pathway from the water source to handpieces and irrigating devices, limiting
the surface area available in control blocks and avoiding "dead legs" where biofilm
can proliferate and continuously re-contaminate the water delivery system.

- Unused waterlines: IFUs should include recommendations to block or disconnect
  waterlines that are connected to devices not currently in use such as low-speed
  handpieces, air-water syringes, and ultrasonic scaler ports to avoid creating "dead
  legs" that are inaccessible to antimicrobial agents and that will harbor biofilm and
  continuously re-contaminate the water system.
- Low temperature water heaters: OSAP discourages the use of low-temperature
  water-heating systems designed to maintain dental treatment water at, or near body
  temperature due to the potential to increase the quantity of biofilm, create a more
  hospitable environment for growth of pathogens such as Legionella species and
  stimulate the expression of virulence factors such as heat tolerance in opportunistic
  water bacteria.
- Anti-retraction valves: OSAP encourages manufacturers to design dental water systems that are passively non-retracting without the use of anti-retraction valves that require periodic replacement or maintenance. Manufacturers who install antiretraction devices must provide instructions for maintenance or replacement frequency in their IFUs.
- 3.3. Safety and efficacy of germicidal agents and treatment devices used with dental equipment not supplied by the manufacturer: OSAP recommends that manufacturers that do not offer factory installed devices or methods for water quality management specifically recommend and provide IFUs for methods to ensure acceptable water quality that they have determined to be safe and effective when used with their procedural water delivery systems.
- 3.4. **Considerations for Sterile Water Delivery Systems**: Devices that provide surgical irrigation in the oral cavity must use sterile tubing and reservoirs for solutions that enter the surgical site.
  - All components including handpieces must be single-use disposable or compatible with heat sterilization methods used in outpatient dental settings.
  - Manufacturers should validate the efficacy of recommended re-processing and sterilization procedures. Examples include oral surgery and implant handpieces, sonic and ultrasonic scalers used during periodontal surgery, and surgical irrigation devices such as bulb syringes.

### 4. Regulatory Requirements and Recommendation - US Food and Drug Administration

- 4.1. Instructions for use must comply with relevant FDA, Environmental Protection Agency, and state and local regulations applicable to the disinfection and maintenance of the dental unit waterlines.
- 4.2. FDA encourages manufacturers to follow recommended practices, including the FDA Guidance *Document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"* issued on March 17, 2015. Specifically, as outlined in this guidance FDA expects that:
  - Reprocessing methods for dental unit waterlines should be validated, and validations should be completed prior to submission of a 510(k).
  - Reprocessing instructions should reflect the validated methods. Consistent with our current practice for dental unit waterlines, submission of reprocessing validation data should be provided in your 510(k).
- 4.3. FDA recommends that the reprocessing instructions for devices be updated to contain comprehensive reprocessing instructions based on validation and recommends that manufacturers:
  - Review current reprocessing instructions to identify if Instructions are comprehensive according to Section VI – "FDA's Six Criteria for Reprocessing Instructions" of the FDA Guidance.
  - Conduct an assessment to evaluate if additional validation testing is necessary to provide up-to-date comprehensive reprocessing instructions.
  - Ensure that customers are notified promptly of any available updated Instructions for Use.
  - Consult the FDA Guidance, "Deciding When to Submit a 510(k) for a Change to an Existing Device" to determine if a new 510(k) submission may be necessary for any labeling or design changes.
  - Submit reprocessing validation test reports in future dental operative unit 510(k)s and describe how reprocessing was considered in the design of the device (e.g., water source, materials, connectors).
  - Contact the FDA with any questions related to new validation and labeling instructions for dental unit waterlines.
- 4.4. FDA recommends submission of reprocessing validation protocols via the Pre-Submis-

sion process prior to conducting testing as described in the FDA Guidance document "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" issued on September 29, 2017.

- **5. Regulatory Requirements State or Federal Environmental Protection Agencies:**Products with germicidal claims must conform to applicable state and Federal requirements under the Federal Fungicide Insecticide and Rodenticide Act (FIFRA) for registration of germicidal agents including directions for use and disposal.
  - 5.1. EPA best management practice (BMP) specified in 441.30(b)(2) of the "Effluent Limitations Guidelines and Standards for the Dental Category" prohibits the use of oxidizing cleaners that solubilize mercury from dental amalgam in the wastewater lines in a dental facility.
  - 5.2. EPA has clarified in *Frequently Asked Questions on the Dental Office Category Rule* that this prohibition does not apply to dental unit water line cleaning products when those products are used in water supply lines to ensure the safety of the water that dentists place in their patient's mouth due to the de minimus quantities that will be indirectly discharged through a wastewater line in a dental facility.
  - 5.3. Dental vacuum lines connected to amalgam separators should not be used to dispose of oxidizing waterline products when performing shock treatment of procedural waterline systems or for bulk disposal of used or outdated waterline treatment products.
  - 5.4. Oxidizing waterline cleaners may be discarded in municipal sewer systems as permitted by local ordinances and regulations governing disposal of germicidal or cleaning agents.

### 6. Voluntary Consensus Standards Related to Dental Water Quality

6.1. OSAP supports the adoption of ISO 16954:2015 - Dentistry -- Test methods for dental unit waterline biofilm treatment as an American National Standard (ANSI/ADA 167) by the American Dental Association and the American National Standards Institute and recommends that the U.S. Food and Drug Administration (FDA) recognize ISO 16954:2015 and ANSI/ADA Standard 167 as standard test methods in reviewing clearance-to-market submissions for dental waterline treatment products. OSAP also recommends that Federal and state environmental protection agencies recognize ISO 16954:2015 and ANSI/ADA Standard 167 as standard test methods in reviewing submissions for the registration of chemical agents and germicides with claims for prevention, inhibition or removal of dental waterline biofilm.

- 6.2. OSAP supports a proposal by the ANSI/ADA Standards Committee on Dental Products (SCDP) to develop an additional standard based on ISO 16954:2015 and ANSI/ADA Standard 167 to simplify and generalize the test method by specifying a model water delivery system.
- 6.3. When approved as ADA and American National Standards, OSAP recommends that these standard test methods be considered for adoption by state and Federal environmental protection agencies for registration of germicides intended for the control and prevention of biofilm formation in dental equipment.
- 7. Conclusions: All members of the dental profession and dental industry have an obligation to ensure the health and safety of dental patients and staff. OSAP encourages all stakeholders to take immediate measures to conform with current recommendations for water quality and to continuously strive to develop new approaches to ensure the quality of water used in dental practices.

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### **OSAP Organizational information**

OSAP is a group of dentists, auxiliary staff, allied health professionals, government representatives, industry members, academicians, and researchers devoted to advancing the art and science of dental infection control and practice safety. A clearinghouse of information on dental asepsis and safety issues, OSAP works to educate the dental community through its publications, annual conference, and website (www.osap.org). For additional information on the organization and the efforts of its educational foundation, contact OSAP at 800-298-6727.

### **DENTAL UNIT WATERLINE** INFECTION CONTROL

A GUIDE TO DENTAL WATER INFECTION CONTROL FROM:

ADA

.::HuFriedyGroup



Every practice should have a designated infection control coordinator



Water used in dental units should have less than 500 CFU/mL

### Every practice should have a policy & procedure manual for maintaining dental unit waterlines.

### Where should they come from?

CDC, state, and local guidance



Dental waterline treatment products



Dental unit manufacturer instructions



Secondhand knowledge



### What should be included?

Frequency of dental waterlines testing



Remediation protocol following failed testing (results >500 CFU/ml)



What to do in the event of a water boil advisory



Special circumstance protocol (boil-water, extended office closure)



### WHICH LINES SHOULD BE REGULARLY TESTED?



High-speed handpiece(s) lines



Air/water syringe(s) lines



Ultrasonic scaler(s) lines



**Unused waterlines** 



\*If these dental unit waterlines have been shocked and a contamination problem persists, source water or reservoirs should be tested

### WHEN SHOULD DENTAL UNIT **WATERLINES BE FLUSHED?**

According to manufacturers' instructions....... 20-30 seconds after each patient...... 2 minutes at the end of each day..... After the final patient of the day......

Additionally, waterlines should be emptied and dried overnight to remove as much water as possible.

### WHAT TO DOCUMENT WHEN TESTING DENTAL UNIT WATERLINES

Test date..... Location (i.e., chair/operatory #)..... Water source..... Test results..... Waterline maintenance/shock product name... Waterline maintenance/shock product lot #..... Pooling details\* (if samples pooled)..... Name of team member sampling.....

\*Pooling: Sampling from multiple waterlines that is then combined for testing

From: Amy Condrin

To: Nelson, Brant@DCA

Subject: Re: Urgent: Dental Board of California Contact to Submit Feedback on Proposed Infection Control Language

**Date:** Saturday, March 1, 2025 8:14:26 PM

Attachments: image001.png

CDC Dental IC Recs-2003 - Appendix A.pdf

### This Message Is From an Untrusted Sender

Warning: This email originated from outside of the organization! Do not click links, open attachments, or reply, unless you recognize the sender's email.

Report Suspicious

#### Hi Brant,

Hope you are having a nice weekend so far. Here is some feedback on the proposed amendments to the DBC's Infection Control Regulation, to be considered by the Infection Control Reg Working Group/Committee as the amendments are being drafted. As I mentioned in a previous email, since this is not the official 45-day comment period comments, I am emailing this feedback informally, but I feel as necessary.

OSHA Review, Inc., the company for which I work, is a DBC-registered CE provider for the last 30+ years. I have worked there as senior consultant for over 21 years. OSHA Review, Inc. also sells a disinfectant (low-level according to the CDC) that is registered with EPA for US distribution and Cal/EPA for distribution in California.

My feedback regarding the proposed rules concerns Section 1005(a)(7):

"Cal/EPA-registered" means a product registered by the U.S. Environmental Protection Agency (EPA) and the California Environmental Protection Agency (Cal EPA) that has demonstrated bactericidal, fungicidal, and virucidal activity. The product used shall include a label from the manufacturer that indicates the level of disinfection (low, intermediate, or high) and both the EPA registration number and the California Department of Pesticide Regulation (Cal DPR) registration number.

The concerns with proposed Section 1005(a)(7) are the following:

- 1. Disinfectants' labels approved/registered by EPA and then DPR (if sold in CA) are not required to be labeled with the terms "low, intermediate, or high". Therefore, the rule is mandating something that is not a legal requirement, and the disinfectants may or may not have these terms on their labels since they are not required, only optional. I am attaching the CDC's *Guidelines for Infection Control in Dental Health-Care Settings 2003 Appendix A: Regulatory Framework for Disinfectants and Sterilants*. Please refer to the yellow-highlighted sections in the attached document, which describe clearly how EPA regulates disinfectants.
- 2. Disinfectants' labels do not have two separate Federal EPA and CA DPR (Cal/EPA) registration numbers. They only have one the registration number provided by Federal EPA.
- 3. As a point of information, EPA (and/or Cal/EPA) does not regulate high-level disinfectants. FDA is responsible for regulating both chemical sterilants and high-level disinfectants for use on medical devices, while EPA regulates CDC-defined low- and intermediate-level disinfectants for environmental surfaces (although EPA does not refer to them as low-level or intermediate-level). Again, please refer to the attached document (green highlights).

Thank you again for getting back to me and for forwarding this feedback to the IC Reg Working Group/Committee members for their information and consideration. Please feel free to contact me with

any questions or concerns about the information in this email.

Best regards, Amy

Amy Knepshield Condrin, MPH Senior Consultant OSHA Review, Inc. 11306 Sunco Drive, Ste 7 Rancho Cordova, CA 95742 800-555-6248 x3030 916-362-7891 - Fax



### **Morbidity and Mortality Weekly Report**

**Recommendations and Reports** 

**December 19, 2003 / Vol. 52 / No. RR-17** 

# Guidelines for Infection Control in Dental Health-Care Settings — 2003





**INSIDE: Continuing Education Examination** 

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

### **Appendix A**

### **Regulatory Framework for Disinfectants and Sterilants**

When using the guidance provided in this report regarding use of liquid chemical disinfectants and sterilants, dental health-care personnel (DHCP) should be aware of federal laws and regulations that govern the sale, distribution, and use of these products. In particular, DHCPs should know what requirements pertain to them when such products are used. Finally, DHCP should understand the relative roles of the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA) and CDC.

The choice of specific cleaning or disinfecting agents is largely a matter of judgment, guided by product label claims and instructions and government regulations. A single liquid chemical germicide might not satisfy all disinfection requirements in a given dental practice or facility. Realistic use of liquid chemical germicides depends on consideration of multiple factors, including the degree of microbial killing required; the nature and composition of the surface, item, or device to be treated; and the cost, safety, and ease of use of the available agents. Selecting one appropriate product with a higher degree of potency to cover all situations might be more convenient.

In the United States, liquid chemical germicides (disinfectants) are regulated by EPA and FDA (A-1-A-3). In healthcare settings, EPA regulates disinfectants that are used on environmental surfaces (housekeeping and clinical contact surfaces), and FDA regulates liquid chemical sterilants/ high-level disinfectants (e.g., glutaraldehyde, hydrogen peroxide, and peracetic acid) used on critical and semicritical patientcare devices. Disinfectants intended for use on clinical contact surfaces (e.g., light handles, radiographic-ray heads, or drawer knobs) or housekeeping surfaces (e.g., floors, walls, or sinks) are regulated in interstate commerce by the Antimicrobials Division, Office of Pesticide Programs, EPA, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947, as amended in 1996 (A-4). Under FIFRA, any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, including microorganisms but excluding those in or on living man or animals, must be registered before sale or distribution. To obtain a registration, a manufacturer must submit specific data regarding the safety and the effectiveness of each product.

EPA requires manufacturers to test formulations by using accepted methods for microbicidal activity, stability, and toxicity to animals and humans. Manufacturers submit these data to EPA with proposed labeling. If EPA concludes a product

may be used without causing unreasonable adverse effects, the product and its labeling are given an EPA registration number, and the manufacturer may then sell and distribute the product in the United States. FIFRA requires users of products to follow the labeling directions on each product explicitly. The following statement appears on all EPA-registered product labels under the Directions for Use heading: "It is a violation of federal law to use this product inconsistent with its labeling." This means that DHCP must follow the safety precautions and use directions on the labeling of each registered product. Not following the specified dilution, contact time, method of application, or any other condition of use is considered misuse of the product.

FDA, under the authority of the 1976 Medical Devices Amendment to the Food, Drug, and Cosmetic Act, regulates chemical germicides if they are advertised and marketed for use on specific medical devices (e.g., dental unit waterline or flexible endoscope). A liquid chemical germicide marketed for use on a specific device is considered, for regulatory purposes, a medical device itself when used to disinfect that specific medical device. Also, this FDA regulatory authority over a particular instrument or device dictates that the manufacturer is obligated to provide the user with adequate instructions for the safe and effective use of that device. These instructions must include methods to clean and disinfect or sterilize the item if it is to be marketed as a reusable medical device.

OSHA develops workplace standards to help ensure safe and healthful working conditions in places of employment. OSHA is authorized under Pub. L. 95-251, and as amended, to enforce these workplace standards. In 1991, OSHA published Occupational Exposure to Bloodborne Pathogens; final rule [29 CFR Part 1910.1030] (*A-5*). This standard is designed to help prevent occupational exposures to blood or other potentially infectious substances. Under this standard, OSHA has interpreted that, to decontaminate contaminated work surfaces, either an EPA-registered hospital tuberculocidal disinfectant or an EPA-registered hospital disinfectant labeled as effective against human immunodeficiency virus (HIV) and hepatitis B virus (HBV) is appropriate. Hospital disinfectants with such HIV and HBV claims can be used, provided surfaces are not contaminated with agents or concentration of agents for which higher level (i.e., intermediate-level) disinfection is recommended. In addition, as with all disinfectants, effectiveness is governed by strict adherence to the label instructions for intended use of the product.

CDC is not a regulatory agency and does not test, evaluate, or otherwise recommend specific brand-name products of chemical germicides. This report is intended to provide overall guidance for providers to select general classifications of products based on certain infection-control principles. In this report, CDC provides guidance to practitioners regarding appropriate application of EPA- and FDA-registered liquid chemical disinfectants and sterilants in dental health-care settings.

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One point of clarification is the difference in how EPA and FDA classify disinfectants. FDA adopted the same basic terminology and classification scheme as CDC to categorize medical devices (i.e., critical, semicritical, and noncritical) and to define antimicrobial potency for processing surfaces (i.e., sterilization, and high-, intermediate- and low-level disinfection) (A-6). EPA registers environmental surface disinfectants based on the manufacturer's microbiological activity claims when registering its disinfectant. This difference has led to confusion on the part of users because the EPA does not use the terms intermediate- and low-level disinfectants as used in CDC guidelines.

CDC designates any EPA-registered hospital disinfectant without a tuberculocidal claim as a low-level disinfectant and any EPA-registered hospital disinfectant with a tuberculocidal claim as an intermediate-level disinfectant. To understand this comparison, one needs to know how EPA registers disinfectants. First, to be labeled as an EPA hospital disinfectant, the product must pass Association of Official Analytical Chemists (AOAC) effectiveness tests against three target organisms: Salmonella choleraesuis for effectiveness against gram-negative bacteria; Staphylococcus aureus for effectiveness against grampositive bacteria; and Pseudomonas aeruginosa for effectiveness

against a primarily nosocomial pathogen. Substantiated label claims of effectiveness of a disinfectant against specific microorganisms other than the test microorganisms are permitted, but not required, provided that the test microorganisms are likely to be present in or on the recommended use areas and surfaces. Therefore, manufacturers might also test specifically against organisms of known concern in health-care practices (e.g., HIV, HBV, hepatitis C virus [HCV], and herpes) although it is considered likely that any product satisfying AOAC tests for hospital disinfectant designation will also be effective against these relatively fragile organisms when the product is used as directed by the manufacturer.

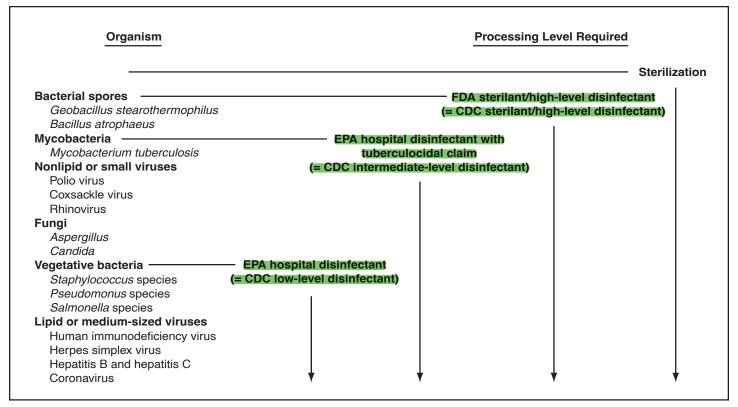
Potency against Mycobacterium tuberculosis has been recognized as a substantial benchmark. However, the tuberculocidal claim is used only as a benchmark to measure germicidal potency. Tuberculosis is not transmitted via environmental surfaces but rather by the airborne route. Accordingly, use of such products on environmental surfaces plays no role in preventing the spread of tuberculosis. However, because mycobacteria have among the highest intrinsic levels of resistance among the vegetative bacteria, viruses, and fungi, any germicide with a tuberculocidal claim on the label is considered capable of inactivating a broad spectrum of pathogens, including such less-resistant organisms as bloodborne pathogens (e.g., HBV, HCV, and HIV). It is this broad-spectrum capability, rather than the product's specific potency against mycobacteria, that is the basis for protocols and regulations dictating use of tuberculocidal chemicals for surface disinfection.

EPA also lists disinfectant products according to their labeled use against these organisms of interest as follows:

- List B. Tuberculocide products effective against Mycobacterium species.
- List C. Products effective against human HIV-1 virus.
- List D. Products effective against human HIV-1 virus and HBV
- List E. Products effective against Mycobacterium species, human HIV-1 virus, and HBV.
- List F. Products effective against HCV.

Microorganisms vary in their resistance to disinfection and sterilization, enabling CDC's designation of disinfectants as high-, intermediate-, and low-level, when compared with EPA's designated organism spectrum (Figure). However, exceptions to this general guide exist, and manufacturer's label claims and instructions should always be followed.

FIGURE. Decreasing order of resistance of microorganisms to germicidal chemicals



**Source:** Adapted from Bond WW, Ott BJ, Franke K, McCracken JE. Effective use of liquid chemical germicides on medical devices; instrument design problems. In: Block SS, ed. Disinfection, sterilization and preservation. 4<sup>th</sup> ed. Philadelphia, PA: Lea & Gebiger, 1991:1100.

### References

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- A-6. Spaulding EH. Role of chemical disinfection in preventing nosocomial infections. In: Proceedings of the International Conference on Nosocomial Infections, 1970. Brachman PS, Eickhoff TC, eds. Chicago, IL: American Hospital Association, 1971:247–54.

 From:
 Amy Condrin

 To:
 Nelson, Brant@DCA

Subject: Re: Urgent: Dental Board of California Contact to Submit Feedback on Proposed Infection Control Language

**Date:** Sunday, March 2, 2025 6:21:52 AM

Attachments: <u>image001.png</u>

### This Message Is From an Untrusted Sender

Warning: This email originated from outside of the organization! Do not click links, open attachments, or reply, unless you recognize the sender's email.

Report Suspicious

### Hi again,

I wanted to add another point of information to item #2:

2. Disinfectants' labels do not have two separate Federal EPA and CA DPR (Cal/EPA) registration numbers. They only have one – the registration number provided by Federal EPA.

A point of information about this... Similar to checking on which dental unit waterline cleaners (considered antimicrobial pesticides by Federal EPA and Cal/EPA) are registered for use by CDPR in California, the easiest way to tell that a surface disinfectant has been registered with CDPR is by going to their website (cdpr.ca.gov) and using their search tool that links to CDPR's pesticide database. Also, surface disinfectants must be registered by Federal EPA first, before obtaining approval for use in CA by CDPR.

That's it! Thanks!
:)
Amy

Amy Knepshield Condrin, MPH Senior Consultant OSHA Review, Inc. 11306 Sunco Drive, Ste 7 Rancho Cordova, CA 95742 800-555-6248 x3030 916-362-7891 - Fax



### **Morbidity and Mortality Weekly Report**

**Recommendations and Reports** 

**December 19, 2003 / Vol. 52 / No. RR-17** 

# Guidelines for Infection Control in Dental Health-Care Settings — 2003





**INSIDE: Continuing Education Examination** 

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

### **Appendix A**

### **Regulatory Framework for Disinfectants and Sterilants**

When using the guidance provided in this report regarding use of liquid chemical disinfectants and sterilants, dental health-care personnel (DHCP) should be aware of federal laws and regulations that govern the sale, distribution, and use of these products. In particular, DHCPs should know what requirements pertain to them when such products are used. Finally, DHCP should understand the relative roles of the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA) and CDC.

The choice of specific cleaning or disinfecting agents is largely a matter of judgment, guided by product label claims and instructions and government regulations. A single liquid chemical germicide might not satisfy all disinfection requirements in a given dental practice or facility. Realistic use of liquid chemical germicides depends on consideration of multiple factors, including the degree of microbial killing required; the nature and composition of the surface, item, or device to be treated; and the cost, safety, and ease of use of the available agents. Selecting one appropriate product with a higher degree of potency to cover all situations might be more convenient.

In the United States, liquid chemical germicides (disinfectants) are regulated by EPA and FDA (A-1-A-3). In healthcare settings, EPA regulates disinfectants that are used on environmental surfaces (housekeeping and clinical contact surfaces), and FDA regulates liquid chemical sterilants/ high-level disinfectants (e.g., glutaraldehyde, hydrogen peroxide, and peracetic acid) used on critical and semicritical patientcare devices. Disinfectants intended for use on clinical contact surfaces (e.g., light handles, radiographic-ray heads, or drawer knobs) or housekeeping surfaces (e.g., floors, walls, or sinks) are regulated in interstate commerce by the Antimicrobials Division, Office of Pesticide Programs, EPA, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947, as amended in 1996 (A-4). Under FIFRA, any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, including microorganisms but excluding those in or on living man or animals, must be registered before sale or distribution. To obtain a registration, a manufacturer must submit specific data regarding the safety and the effectiveness of each product.

EPA requires manufacturers to test formulations by using accepted methods for microbicidal activity, stability, and toxicity to animals and humans. Manufacturers submit these data to EPA with proposed labeling. If EPA concludes a product

may be used without causing unreasonable adverse effects, the product and its labeling are given an EPA registration number, and the manufacturer may then sell and distribute the product in the United States. FIFRA requires users of products to follow the labeling directions on each product explicitly. The following statement appears on all EPA-registered product labels under the Directions for Use heading: "It is a violation of federal law to use this product inconsistent with its labeling." This means that DHCP must follow the safety precautions and use directions on the labeling of each registered product. Not following the specified dilution, contact time, method of application, or any other condition of use is considered misuse of the product.

FDA, under the authority of the 1976 Medical Devices Amendment to the Food, Drug, and Cosmetic Act, regulates chemical germicides if they are advertised and marketed for use on specific medical devices (e.g., dental unit waterline or flexible endoscope). A liquid chemical germicide marketed for use on a specific device is considered, for regulatory purposes, a medical device itself when used to disinfect that specific medical device. Also, this FDA regulatory authority over a particular instrument or device dictates that the manufacturer is obligated to provide the user with adequate instructions for the safe and effective use of that device. These instructions must include methods to clean and disinfect or sterilize the item if it is to be marketed as a reusable medical device.

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against a primarily nosocomial pathogen. Substantiated label claims of effectiveness of a disinfectant against specific microorganisms other than the test microorganisms are permitted, but not required, provided that the test microorganisms are likely to be present in or on the recommended use areas and surfaces. Therefore, manufacturers might also test specifically against organisms of known concern in health-care practices (e.g., HIV, HBV, hepatitis C virus [HCV], and herpes) although it is considered likely that any product satisfying AOAC tests for hospital disinfectant designation will also be effective against these relatively fragile organisms when the product is used as directed by the manufacturer.

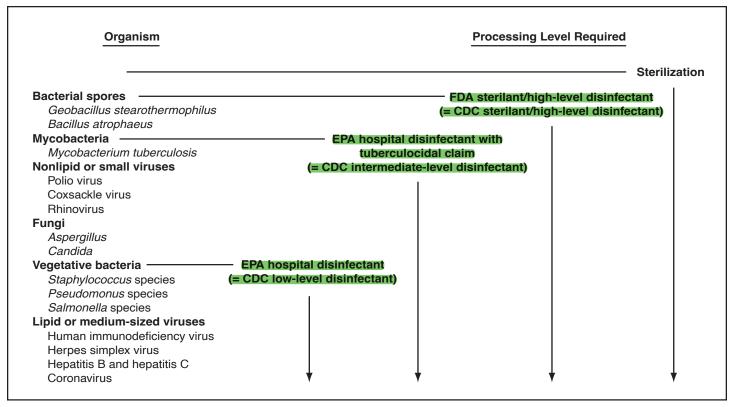
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EPA also lists disinfectant products according to their labeled use against these organisms of interest as follows:

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- **List F**. Products effective against HCV.

Microorganisms vary in their resistance to disinfection and sterilization, enabling CDC's designation of disinfectants as high-, intermediate-, and low-level, when compared with EPA's designated organism spectrum (Figure). However, exceptions to this general guide exist, and manufacturer's label claims and instructions should always be followed.

FIGURE. Decreasing order of resistance of microorganisms to germicidal chemicals



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### 16 CCR 1005 Summary of Stakeholder Comments with the Board's Working Group's Responses and Other Recommendations

### Comments from the Dental Assisting Alliance (Alliance) (Summary of Letter in Attachment 3):

1. Comment: On top of page 3, (a)(8) – definition of "sterilization: it says a "mechanical process" of elimination of all forms of lif e. The Alliance is concerned that this eliminates the use of "cold sterile" with the word "mechanical" – is the intent to eliminate the use of cold sterile as an option?

Response: Cold sterilization using "high level disinfection" would still be an option for heat -sensitive items in lieu of using a mechanical device since the current proposal would retain the following standards for sterilizing critical and non -critical instruments in subsections (b)(8)(C) and (D), which reads, in pertinent part:

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.

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.

However, to avoid an apparent conflict between the above
-referenced sections and the definition for Sterilization, the Infection
Control Working Group (Working Group) revised the definition of "Sterilization"
to remove references to "mechanical process" and instead
proposes to retain the existing text referencing a "validated process". The revised
definition would read as follows:

(9)(8) "Sterilization" is	a validated prod	cess used to	render a product free of
all	forms of viable	microorganisms.	<u>eliminate</u>
all forms of microbial li	fe using a	acceptable methods	of sterilization set forth in
this section.			

2. **Comment:** Hand scrubbing on page 3, (a)(9)(A) and (B) – being mentioned first is a problem for the Alliance as it seems to be an acceptable alternative to using the ultrasonic. The Alliance recommends putting hand scrubbing last and states that hand scrubbing should be a last resort when other methods of cleaning are not effective.

Response: The Board's Infection Control Working Group, in consultation with the DHBC's working group ("Working Group"), believes that manual cleaning prior to the use of a sterilization device or disinfectant for surface disinfection is an important additional level of infection control for consumer protection. However, the Working Group agrees that it does not necessarily mean that it be done by "hand" and therefore has proposed to eliminate the reference to "hand" scrubbing and instead proposes to simply require "scrubbing" for subsections (a)(9)(A) and (B).

3. **Comment:** Top of page 6, (b)(4)(F), where it "says protective attire shall be changed daily, or immediately if they become soiled" ... The Alliance says there might be a question on the use of the word "immediately" where you'd have to stop the procedure if your gown is "visibly soiled" "as soon as we see some prophy paste specks on our gown which would be problematic." The Alliance states that this needs to be clarified for better interpretation of intent.

**Response:** Changes were made to address these concerns and ensure greater worker protections in accordance with the Working Group's understanding of the dental community's current minimum standards for infection control, which would require changing attire immediately when attire becomes soiled with blood or OPIM during a patient procedure. The Working Group revised (b)(4)(F) to state, ". . . Protective attire shall be changed immediately if they attire should becomes moist or visibly—soiled with blood or OPIM."

4. **Comment:** Bottom of page 6, (b)(6)(B), where it says "chemical and puncture resistant utility gloves shall be available at the point of use" ... for "clinical breakdown" ... The Alliance is concerned this implies that setting up or breaking down a treatment room requires gloves. Alliance says this is not the protocol for setting up a treatment room and that clean hands, not gloves are needed. Utility gloves are meant to be used for "PROCESSING INSTRUMENTS and HANDLING CHEMICALS."

Response: The Working Group agreed with these comments and has revised (b)(6)(B) by removing the language concerning clinical care breakdown (setting up or breaking down a treatment room).

5. **Comment:** Bottom of page 6, (b)(6)(B), sterilizing utility gloves after each use is overkill. The Alliance suggests the word "sterilize" should be changed to "disinfect".

Routine disinfection of the utility gloves is more realistic according to the Alliance.

The Alliance proposes that the Board use the language, "utility gloves

shall be compromised in any way. of after each use."

cleaned and routinely disinfected and discarded if Disposable utility gloves shall be disposed

Response: It is the understanding of the Working Group that depending on the type of glove used, the manufacturer may require disinfection or sterilization. The Working Group agreed that, to the extent that an office uses disposable utility gloves, they should be disposed of after each use. As a result, the Working Group revised (b)(6)(B) to state, " . . . Chemical and puncture -resistant utility gloves shall be cleaned and disinfected or sterilized in accordance with the manufacturer's instructions. Disposable utility gloves shall be disposed of after each use."

6. **Comment:** On page 8, (b)(8)(C), use of the word "immediately" in connection with sterilization of instruments. The Alliance says that a lot of times dental offices cannot immediately sterilize instruments and instruments will sit in a preclean/presoak (maybe an hour or so before sterilization). The Alliance feels sterilizing "immediately" is unrealistic. The Alliance states that ADHPs are often not able to process the instruments and get them sterilizing immediately; especially with the shortage of ADHPs. The Alliance feels better wording would be "critical instruments . . . shall be . . . processed and placed into packets or wrappers and sterilized as soon as possible after each use."

Response: The Working Group agrees with the comments and revised (b)(8)( C) by removing the word "immediately" in connection with sterilization of critical instruments, so that it would read:

Critical instruments, items, and devices shall be discarded or pre-cleaned, packaged or wrapped, and sterilized after each use.

A similar change was made to remove the reference to "immediately" when referring to semi-critical instruments in subsection (b)(8)(D). To avoid ambiguity, the Working Group did not add "as soon as possible" to the proposed changes noted above.

7. **Comment:** Bottom of page 8, (b)(8)(F), language about having to sterilize all slowspeed hand pieces. The Alliance would like more clarification added to the existing standard. There is a question of if disinfecting should include the motor (or "quick connector") in addition to the nose cone. The Alliance said it would be great to have some clarification added as to if the motor

needs to be sterilized. The Alliance suggests adding a statement specifically addressing whether the motor is considered part of the handpiece that needs to be sterilized. Alternatively, the Alliance recommends that the Board specify that when the motor is detachable from the nosecone, the motor does (or does not) need to be sterilized. The Alliance proposes the Board use the following language, "Handpieces shall be processed and sterilized after each use including the motor and all component parts ."

Response: The Working Group believe that the existing text referring to "rotary components" would necessarily include the motor since it is in fact a rotary component of a hand piece. However, since commenters state that whether the motor should be sterilized has been "an issue historically," the Working Group revised (b)(8)(F) to state, "All high -speed dental hand pieces, low -speed hand pieces, rotary components \_\_including the motor, and dental unit attachments such as reusable air/water syringe tips and ultrasonic scaler tips, shall be packaged, labeled, and heat -sterilized in a manner consistent with the same sterilization

labeled, and heat -sterilized in a manner consistent with the same sterilization practices as a semi-critical item."

- 8. **Comment**: On page 10, (b)(10)(D), dental unit waterlines.
  - Disinfectants The Alliance says California has a law which requires the use
     of disinfectants in the water to
     control biofilm. The DBC regulations should reiterate and/or expand on that law.
     For example, the DBC could add a requirement for monthly water testing
     which would help to support the process for keeping the biofilm levels below 500
     CFU.
  - The Alliance asserts that the addition of the requirement to flush the waterlines "after the final patient of the day" is unnecessary and in contradiction to the purpose of flushing the lines.
  - Flushing Flushing provides the freshest water for the patient, removing the free-floating biofilm so that the patient doesn't get the "stagnant" water, with a higher concentration of biofilm sprayed in their mouth. Flushing the waterlines after the last patient of the day, when the water is going to sit for 12-hours and will be flushed for 2 -minutes at the beginning of the next day, is illogical and unnecessary.

Response: After review of the CDC 's Guidelines on Best Practices for Dental Unit

Water Quality | Dental Infection Prevention and Control, the Working Groups revised (b)(10)(D) to remove language that would require flushing water lines after the last

patient of the day and add the following: "Dental unit water lines shall be monitored or tested routinely in accordance with manufacturer's instructions."

### Comments from Leslie Canham, CDA, RDA:

Comment: At the Board's and Council's meetings in February 2025, Ms. Canham testified that she is concerned that there is no recommendation or requirement for dental unit waterline testing on page 10 of the Board's proposed regulations. Ms. Canham says that monitoring waterlines is essential and recommended by the CDC Best practices

. Ms. Canham stated studies show that without monitoring we don't know if we have colonization of bacteria in the waterlines

. Waterborne bacteria in dental plumbing systems have caused children to be hospitalized for infection with nontuberculous Mycobacteria.

Ms. Canham emailed Board staff with additional reference material as provided in

Ms. Canham emailed Board staff with additional reference material as provided in Attachment 4 to the meeting materials.

**Response:** In response to these and other concerns raised by commenters about water—line testing standards, the Infection Control Working Group revised (b)(10)(D) to state, "Dental unit water lines shall be monitored or tested routinely in accordance with manufacturer's instructions." This is the direction that the CDC has provided in the Guidelines noted above for dental unit water quality.

### Comments from Amy Condrin, MPH (Summary of emailed comments in Attachments 5 and 6):

**Comment:** My feedback regarding the proposed rules concerns Section 1005(a)(7):

"Cal/EPA-registered" means a product registered by the U.S. Environmental Protection Agency (EPA) and the California Environmental Protection Agency (Cal EPA) that has demonstrated bactericidal, fungicidal, and virucidal activity. The product used shall include a label from the manufacturer that indicates the level of disinfection (low, intermediate, or high) and both the EPA registration number and the California Department of Pesticide Regulation (Cal DPR) registration number.

The concerns with proposed Section 1005(a)(7) are the following:

Disinfectants' labels approved/registered by EPA and then DPR (if sold in CA) are not required to be labeled with the terms "low, intermediate, or high". Therefore, the rule is mandating something that is not a legal requirement, and the disinfectants may or may not have these terms on their labels since they are not required, only optional. I am attaching the CDC's Guidelines for Infection Control in Dental Health-Care Settings – 2003 Appendix A: Regulatory Framework for Disinfectants and Sterilants.

- Please refer to the yellow-highlighted sections in the attached document, which describe clearly how EPA regulates disinfectants.
- Disinfectants' labels do not have two separate Federal EPA and CA DPR (Cal/EPA) registration numbers. They only have one the registration number provided by Federal EPA. Disinfectants' labels do not have two separate Federal EPA and CA DPR (Cal/EPA) registration numbers. They only have one the registration number provided by Federal EPA.
- 3. A point of information about this... Similar to checking on which dental unit waterline cleaners (considered antimicrobial pesticides by Federal EPA and Cal/EPA) are registered for use by CDPR in California, the easiest way to tell that a surface disinfectant has been registered with CDPR is by going to their website (cdpr.ca.gov) and using their search tool that links to CDPR's pesticide database. Also, surface disinfectants must be registered by Federal EPA first, before obtaining approval for use in CA by CDPR.
- 4. As a point of information, EPA (and/or Cal/EPA) does not regulate high-level disinfectants. FDA is responsible for regulating both chemical sterilants and high level disinfectants for use on medical devices, while EPA regulates CDC-defined low- and intermediate-level disinfectants for environmental surfaces (although EPA does not refer to them as low-level or intermediate-level). Again, please refer to the attached document (green highlights).

Response: Upon review, the Working Group agrees with the concerns raised and , on page 2, has revised (a)(7) to state, "Cal/EPA - registered" means a product registered by the U.S.

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for sale and use in California as a pesticide." To avoid confusion about the meaning of Cal/EPA registered, references to the type of disinfectant classification and registration numbers in the prior proposal were deleted since these items can be confirmed independently by staff when investigating compliance with these regulations.

### Additional Changes Recommended by the DHBC's and Board's Working Groups:

On page 2, replacing the word "kills" in (a)(6)(A) and (a)(6)(B) with "inactivates" wherever listed in these subparagraphs. This ensures more accurate and consistent use of terminology throughout the proposal and avoids confusion since the introductory paragraph refers to "inactivates", and not "kills".