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


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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[1])

**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;
3. 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*[2])

**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

Center for Biofilm Engineering, Montana State University - Interdisciplinary glossary, 1999; Available at: http://www.erc.montana.edu/Res-Lib99-SW/glossary/Gterms.html

Centers for Disease Control and Prevention - *Guidelines for Infection Control in Dental Health-Care Settings—2003.* Morbidity and Mortality Weekly Report; 52:RR-17. Available at: www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

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

Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee - *Guidelines for Environmental Infection Control in Health-Care Facilities*, Morbidity and Mortality Weekly Report, June 6, 2003 /52(RR10);1-42 Available at: 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[1, 3]. 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, air-water syringes and other devices used in patient care[4-6]. 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)[4].

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)[7-9] that can trigger and/or exacerbate asthma in dental patients and DHCPs[10]. 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*, non-tuberculous mycobacteria (NTM)[11-13] and *Legionella* species[14-16] have provided cause for concern[12, 13, 17]. Two cases of postoperative *Pseudomonas* infections in immunocompromised patients were the direct consequence of exposure to contaminated procedural water[18]. 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[19-22]. NTM are typically resistant to disinfectant residuals present in potable water and have been found in the effluent immediately after DUWL treatment[12]. *Mycobacterium abscessus*, isolated from DUWLs were found to be the source in separate outbreaks of pediatric post-operative infections in Georgia [23, 24] and California[25].

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[26]. 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[27].

Serological evidence of exposure to *Legionella* bacteria have been reported in dental health-care personnel[28-30]. 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[31].

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[32-35]. 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[36, 37.]

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*[2] 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[2] 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[23, 24]. 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[38-56].

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[7, 9, 10, 57, 58]. 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[59]. This phenomenon may be complicated by the presence of non-neutralized residual germicide in samples that may damage organisms and prevent their recovery[60].

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[61, 62] 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 action limit 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, three-way 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, **manufacturers** 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 anti-retraction 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.

## References


1. Donlan RM, Costerton JW. Biofilms: survival mechanisms of clinically relevant microorganisms. *Clin Microbiol Rev* 2002;15(2):167-93.
2. Centers for Disease Control and Prevention: Recommended infection control practices for dentistry, 1993. *MMWR* 1993;42(No. RR-8):1-12.
3. Costerton JW. Overview of microbial biofilms. *J Ind Microbiol* 1995;15(3):137-40.
4. Mills SE. The dental unit waterline controversy: defusing the myths, defining the solutions. *J Am Dent Assoc* 2000;131(10):1427-41.
5. Molinari JA. Dental unit water contamination. *Compend Contin Educ Dent* 1999;20(4):358-62.
6. Barbeau J.Tanguay R FR, et al. Multiparametric analysis of waterline contamination in dental units. *Appl Environ Microbiol* 1996;62(11):3954-9.
7. Huntington MK, Williams JF, Mackenzie CD. Endotoxin contamination in the dental surgery. *J Med Microbiol* 2007;56(Pt 9):1230-4.
8. Puttaiah R CR. Assessment of endotoxin levels in dental effluent water. *J Dent Res* 1998;77((AADR Abstracts )):262.
9. Szymanska J. Exposure to bacterial endotoxin during conservative dental treatment. *Ann Agric Environ Med* 2005;12(1):137-9.
10. Pankhurst CL, Coulter W, Philpott-Howard JN, et al. Evaluation of the potential risk of occupational asthma in dentists exposed to contaminated dental unit waterlines. *Prim Dent Care* 2005;12(2):53-9.
11. Barbeau J, Gauthier C, Payment P. Biofilms, infectious agents, and dental unit waterlines: a review. *Can J Microbiol* 1998;44(11):1019-28.
12. Porteous NB, Redding SW, Jorgensen JH. Isolation of non-tuberculosis mycobacteria in treated dental unit waterlines. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2004;98(1):40-4.
13. Schulze-Robbecke R FC, Fischeder R, et al. Dental units: an environmental study of sources of potentially pathogenic mycobacteria. *Tuber Lung Dis* 1995;76(4):318-23.
14. Challacombe SJ, Fernandes LL. Detecting *Legionella pneumophila* in water systems: a comparison of various dental units. *J Am Dent Assoc* 1995;126(5):603-8.
15. Oppenheim BA, Sefton AM, Gill ON, et al. Widespread *Legionella pneumophila* contamination of dental stations in a dental school without apparent human infection. *Epidemiol Infect* 1987;99(1):159-66.

16. Pankhurst CL. Risk assessment of dental unit waterline contamination. *Prim Dent Care* 2003;10(1):5-10.
17. Mills SE. Waterborne pathogens and dental waterlines. *Dent Clin North Am* 2003;47(3):545-57.
18. Martin M. The significance of the bacterial contamination of dental water systems. *Br Dent J* 1987;163:152-3.
19. Abdel-Nour M, Duncan C, Low DE, Guyard C. Biofilms: the stronghold of *Legionella pneumophila. Int J Mol Sci* 2013;14(11):21660-75.
20. Atlas RM, Williams JF, Huntington MK. *Legionella* contamination of dental-unit waters. *Appl Environ Microbiol* 1995;61(4):1208-13.
21. Mba Medie F, Ben Salah I, Henrissat B, Raoult D, Drancourt M. *Mycobacterium tuberculosis* complex mycobacteria as amoeba-resistant organisms. *PLoS One* 2011;6(6):e20499.
22. Vaerewijck MJ, Huys G, Palomino JC, Swings J, Portaels F. Mycobacteria in drinking water distribution systems: ecology and significance for human health. *FEMS Microbiol Rev* 2005;29(5):911-34.
23. Peralta G, Tobin-D'Angelo M, Parham A, et al. Notes from the Field: *Mycobacterium abscessus* Infections Among Patients of a Pediatric Dentistry Practice--Georgia, 2015. *MMWR Morb Mortal Wkly Rep* 2016;65(13):355-6.
24. Hatzenbuehler LA, Tobin-D'Angelo M, Drenzek C, et al. Pediatric Dental Clinic-Associated Outbreak of *Mycobacterium abscessus* Infection. *J Pediatric Infect Dis Soc* 2017;6(3):e116-e22.
25. Agency OCH. Dental Outbreak (Mycobacterium); 2017.
26. Ricci ML, Fontana S, Pinci F, et al. Pneumonia associated with a dental unit waterline. *Lancet* 2012;379(9816):684.
27. Schonning C, Jernberg C, Klingenberg D, et al. *Legionellosis* acquired through a dental unit: a case study. *J Hosp Infect* 2017;96(1):89-92.
28. Fotos PG, Westfall, HN, Snyder I S et al. Prevalence of *Legionella*-specific IgG and IgM antibody in a dental clinic population. *J Dent Res* 1985;64(12):1382-5.
29. Reinthaler FF, Mascher F, Stunzner D. Serological examinations for antibodies against *Legionella* species in dental personnel. *J Dent Res* 1988;67(6):942-3.
30. Pankhurst CL, Coulter W, Philpott-Howard JJ, et al. Prevalence of *legionella* waterline contamination and *Legionella pneumophila* antibodies in general dental practitioners in London and rural Northern Ireland. *Br Dent J* 2003;195(10):591-4; discussion 81.
31. Estrich CG, Gruninger SE, Lipman RD. Rates and predictors of exposure to *Legionella pneumophila* in the United States among dental practitioners: 2002 through 2012. *J Am Dent Assoc* 2017;148(3):164-71.
32. Sabria M, Yu VL. Hospital-acquired legionellosis: solutions for a preventable infection. *Lancet Infect Dis* 2002;2(6):368-73.
33. Sehulster L, Chinn RY. Guidelines for environmental infection control in health-care facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR Recomm Rep* 2003;52(RR-10):1-42.
34. Decker BK, Palmore TN. Hospital water and opportunities for infection prevention. *Curr Infect Dis Rep* 2014;16(10):432.
35. Kozicki ZA, Baiyasi-Kozicki SJ, Cwiek MA, Tymes N, Jr. Waterborne pathogen treatment of surgical water in U.S. hospitals: negative implications for vulnerable patient populations (elderly, immunosuppressed, and pediatric). *J Am Geriatr Soc* 2012;60(6):1178-9.
36. Kim AS, Chen H, Yuan R. EPS biofouling in membrane filtration: an analytic modeling study. *J Colloid Interface Sci* 2006;303(1):243-9.
37. Wright SJ, Semrau JD, Keeney DR. Microbial fouling of a reverse osmosis municipal water treatment system. *Water Environ Res* 2008;80(8):703-7.
38. Karpay RI, Plamondon TJ, Mills SE, Dove SB. Combining periodic and continuous sodium hypochlorite treatment to control biofilms in dental unit water systems. *J Am Dent Assoc* 1999;130(7):957-65.
39. Kim PJ, Cederberg RA, Puttaiah R. A pilot study of 2 methods for control of dental unit biofilms. *Quintessence Int* 2000;31(1):41-8.
40. Meiller TF, Kelley JI, Baqui AA, DePaola LG. Disinfection of dental unit waterlines with an oral antiseptic. *J Clin Dent* 2000;11(1):11-5.
41. Plamondon T, Mills, S. A practical approach to improving the quality of water used in routine dental treatments. *Gen Dent* 2000;48(6):682-88.
42. Lee TK, Waked EJ, Wolinsky LE, Mito RS, Danielson RE. Controlling biofilm and microbial contamination in dental unit waterlines. *J Calif Dent Assoc* 2001;29(9):679-84.
43. Meiller TF, Kelley JI, Baqui AA, DePaola LG. Laboratory evaluation of anti-biofilm agents for use in dental unit waterlines. *J Clin Dent* 2001;12(4):97-103.

44. Panagakos FS, Lassiter T, Kumar E. Dental unit waterlines: review and product evaluation. *J NJ Dent Assoc* 2001;72(2):20-5, 38.
45. Shepherd PA, Shojaei MA, Eleazer PD, Van Stewart A, Staat RH. Clearance of biofilms from dental unit waterlines through the use of hydroperoxide ion-phase transfer catalysts. *Quintessence Int* 2001;32(10):755-61.
46. Smith AJ, Bagg J, Hood J. Use of chlorine dioxide to disinfect dental unit waterlines. *J Hosp Infect* 2001;49(4):285-8.
47. Kettering JD, Munoz-Viveros CA, Stephens JA, Naylor WP, Zhang W. Reducing bacterial counts in dental unit waterlines: distilled water vs. antimicrobial agents. *J Calif Dent Assoc* 2002;30(10):735-41.
48. Larsen T, Fiehn NE. The effect of Sterilex Ultra for disinfection of dental unit waterlines. *Int Dent J* 2003;53(4):249-54.
49. Palenik CJ, Miller CH. The effect of distillation and line cleaning on the quality of water emitted from dental units. *Am J Dent* 2003;16(6):385-9.
50. Wirthlin MR, Marshall GW, Jr., Rowland RW. Formation and decontamination of biofilms in dental unit waterlines. *J Periodontol* 2003;74(11):1595-609.
51. Meiller TF, Kelley JI, Zhang M, DePaola LG. Efficacy of A-dec's ICX dental unit waterline treatment solution in the prevention and treatment of microbial contamination in dental units. *J Clin Dent* 2004;15(1):17-21.
52. Porteous NB, Cooley RL. Reduction of bacterial levels in dental unit waterlines. *Quintessence Int* 2004;35(8):630-4.
53. Bansal R, Puttaiah R, Harris R, Reddy A. Evaluation of two methods in controlling dental treatment water contamination. *J Contemp Dent* Pract 2011;12(2):73-83.
54. Lin SM, Svoboda KK, Giletto A, Seibert J, Puttaiah R. Effects of hydrogen peroxide on dental unit biofilms and treatment water contamination. *Eur J Dent* 2011;5(1):47-59.
55. Luo J, Porteous N, Sun Y. Rechargeable biofilm-controlling tubing materials for use in dental unit water lines. *ACS Appl Mater Interfaces* 2011;3(8):2895-903.
56. O'Donnell MJ, Boyle MA, Russell RJ, Coleman DC. Management of dental unit waterline biofilms in the 21st century. *Future Microbiol* 2011;6(10):1209-26.
57. Reed CE, Milton DK. Endotoxin-stimulated innate immunity: A contributing factor for asthma. *J Allergy Clin Immunol* 2001;108(2):157-66.
58. Rioufol C DC, Meunier G, Perraud M, Goullet D. Quantitative determination of endotoxins released by bacterial biofilms. *Hosp Infect* 1999 Nov;: 1999;43(3):203-9.
59. Deshmukh RA, Joshi K, Bhand S, Roy U. Recent developments in detection and enumeration of waterborne bacteria: a retrospective minireview. *Microbiologyopen* 2016;5(6):901-22.
60. Li J, Liu L, Yang D, et al. Culture-dependent enumeration methods failed to simultaneously detect disinfectant-injured and genetically modified *Escherichia coli* in drinking water. *Environ Sci Process Impacts* 2017;19(5):720-26.
61. Tickner J, Coffin M. What does the precautionary principle mean for evidence-based dentistry? J *Evid Based Dent Pract* 2006;6(1):6-15.
62. Vineis P. Scientific basis for the Precautionary Principle. *Toxicol Appl Pharmacol* 2005;207(2 Suppl):658-62.

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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.