Biofilm contamination in dental unit waterlines is well described and explored throughout the dental literature. Fortunately, there have been numerous treatment devices and solutions to emerge over the past decade and a half. The Centers for Disease Control and Prevention (CDC) recommends dental offices take advantage of the availability of control measures in their Infection Control Guidelines for Dental Health-Care Settings—2003. The guidelines state that practitioners should, “use water that meets EPA regulatory standards for drinking water (i.e., <500 CFU/mL of heterotrophic water bacteria) for routine dental treatment output water”. This is not possible to achieve in a dental unit system without using some treatment method of the device, the water, or both. Some states may regulate the quality of output water for surgical and/or routine dental procedures. The dentist and other licensed dental healthcare providers are responsible for meeting all regulations and standards in the delivery of patient care.

**Product regulations**

A separate regulatory issue worth exploring is that of the devices and treatment solutions themselves. In general, the Food and Drug Administration (FDA) clears devices for use and the Environmental Protection Agency (EPA) registers products that make a germicidal claim.

**FDA**

The FDA regulates the manufacturing process and the claims that a company may make in connection with the marketing of a medical device. Anything that connects to medical equipment or comes into direct contact with the patient usually falls under the FDA’s jurisdiction. There are some exceptions to this and the line between a dental device and a nonregulated product is not always simple to define.

Title 21, Chapter I, Subchapter H, part 872 of the Code of Federal Regulations addresses dental operative units and accessories. Manufacturers may expedite their FDA clearance by establishing that their product is “substantially equivalent” to products already on the market. It may be difficult to determine independently if a device is FDA-cleared because the agency does not allow the manufacturer to use their clearance status in marketing materials or on the product label. The FDA does have a searchable database where one may look up the status of a product’s clearance to market. This information is on the web at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm.

Some of the devices intended for control of biofilm will also require EPA registration as a pesticide. The EPA usually requires registration if a product makes any...

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**Learning Objectives**

After reading this article, the reader should be able to:

- understand the difference between FDA and EPA regulations as they relate to dental waterline treatment devices and products.
- be able to identify registration and clearance of products for dental waterline treatment.
- understand how to evaluate waterline treatment products during the selection process.
Beyond Biofilms
continued from front cover

claims of biofilm removal, decontamination, or other microbial control.

EPA

The EPA issue is a little more complex. Companies must register products that make an antimicrobial, decontamination or biofilm control claim through Federal EPA, and all fifty states have EPA agencies that may also require state-specific registration. Without federal and/or state EPA registration, companies may be in violation of federal and state laws if they make certain claims about the efficacy of their products. EPA also registers other product claims such as odor reduction and cleaning, so it is possible for a product’s EPA registration to be for something other than biofilm disinfection or removal.

As with hospital disinfectants, products with claims regarding the decontamination of waterlines must receive and display on the product label an EPA registration number (identified on the container as “EPA Reg. No.”). This EPA registration number indicates that the manufacturer has provided data to the EPA to verify the efficacy and safety claims of their product. The company is restricted in their labeling and marketing literature to making only EPA-registered statements.

A product EPA registration number is not the same as the facility EPA identification number (identified on the container as “EPA Establishment No.”). The facility identification is unrelated to product safety and registration issues. Products that actually produce a germicidal agent from raw materials may not require registration with the EPA. Any germicide that does not have EPA registration also does not have EPA verification of claims.

In recent months, the California EPA’s Department of Pesticide Regulation (DPR) has subjected dental waterline products to scrutiny. The California DPR became aware that many companies were selling dental waterline products within the state that made a claim of killing organisms, removing biofilm, or having a chemical composition consistent with biocides without a California EPA registration number. As a result, the DPR sent notices to manufacturers and distributors of these products informing them that they were in violation of state requirements. The EPA levied fines against some companies for selling unregistered products. California DPR is currently in the process of reviewing and registering products, and so far is not pursuing enforcement activity at the dental office level. Dental offices should still consider asking manufacturers and distributors to provide information regarding the status of that product’s registration in their state when purchasing devices and products. A person using a product in a manner not consistent with the EPA labeling may be subject to administrative fines or criminal action under federal or state law.

— OSAP

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Compliance Corner

FDA
"Section 510(k) of the Food, Drug and Cosmetic Act requires those device manufacturers who must register to notify FDA, at least 90 days in advance, of their intent to market a medical device. This is known as Premarket Notification - also called PMN or '510(k)'. It allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories. Thus, 'new' devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified. Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected." Information on Releasable 510(k)’s. Retrieved July 15, 2006. http://www.fda.gov/cdrh/510khome.html

EPA
The EPA regulates disinfectants and other antimicrobials under its pesticide rules.
"EPA and the states (usually the State Department of Agriculture) register or license pesticides for use in the United States. EPA receives its authority to register pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). States are authorized to regulate pesticides under FIFRA and under state pesticide laws. States may place more restrictive requirements on pesticides than EPA. Pesticides must be registered both by EPA and the state before distribution.” Pesticides: Regulating Pesticides. Retrieved July 15, 2006. http://www.epa.gov/pesticides/regulating/index.htm

Glossary

Biofilm: a community of microorganisms attached to a solid surface. A biofilm community can include bacteria, fungi, yeasts, protozoa, and other microorganisms.

CFU/mL: colony forming units per milliliter. A measurement of bacterial colonies in a sample.

EPA registration: the review and registration of pesticides by the Environmental Protection Agency that are determined not to pose an, "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." [FIFRA Section 2(bb)]

Germicide: an agent that destroys microorganisms, especially pathogenic organisms. Other terms with the suffix "-cide" (e.g., virucide, fungicide, bactericide, tuberculocide, sporicide) indicate an agent that destroys the microorganism identified by the prefix.

Heterotrophic bacteria: bacteria often found in water which require minimal nutrition for growth.

Hospital disinfectant: a germicide that is registered by EPA for use on inanimate objects in hospitals, clinics, dental offices, or any other medical-related facility. Efficacy is demonstrated against Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa.

Pesticide: substances intended to repel, kill, or control any species designated a "pest" including weeds, insects, rodents, fungi, bacteria, or other organisms.
Checklist for Dental Unit Water Quality Improvement

Understanding the regulatory framework for devices and products intended to improve water quality is part of the product selection process. A comprehensive approach to improved water quality also includes proper selection, use, maintenance, and monitoring of all equipment, devices, and products. Use this checklist to help ensure the quality of dental water.

The basics
- Contact the dental unit manufacturer to request recommendations for treatment and maintenance
- Select products that are intended for dental waterline treatment rather than household products or disinfectants
- Use clean (tap or distilled) source water
- Routinely clean independent water bottle according to manufacturer’s instructions
- Provide training to all personnel in how to properly replenish, treat, test or otherwise manage the bottled water systems

Treating waterlines
Always follow the manufacturer’s instructions for the use of chemical products or devices to treat waterlines. Several best practices will help you ensure good results:
- Always wash hands before handling water bottle to prevent inadvertent contamination from hands
- Change microfilter cartridges according to the manufacturer’s stated time interval
- Do not use products for continuous use as coolant water to handpieces or other dental patient care devices unless specifically indicated on the product label or insert
- Use shock treatment initially and as indicated by the waterline treatment product manufacturer
- If the manufacturer does not indicate a time interval for shock treatment, periodically monitor water quality to determine if additional treatment is necessary

Testing waterlines
There is no universal rule for testing waterlines. The frequency depends on the type of treatment and the history of the office regarding levels of contamination despite the use of treatment methods. Best practices for testing include:
- Test water immediately before scheduled treatment
- Wash hands before collecting sample
- Take care to not contaminate inside of water collection bottle
- Do not place water collection bottle top face-down on counter
- Test water immediately or refrigerate and prepare for transport to testing facility
- When performing tests in-house ensure the use of proper sampling media, incubation times, and temperatures. The scientific literature suggests that in-office testing results are less reliable than those performed in a qualified water testing laboratory.
- Neutralize chemicals in tap water that will interfere with sample growth (sodium thiosulfate is one type, check with test kit instructions)
- Maintain a record of sampling results for the same period of time that you keep spore test results
- Use sampling results to establish reasonable schedule for future sampling (i.e., if monthly testing for a year results in no waterlines exceeding 500 CFU/mL, consider testing every other month or quarterly)

OSAP

Ask OSAP

Q: We are using a dental waterline treatment that goes in the bottle attached to our units. How do I know that it actually makes the water meet the 500 CFU/mL goal in the CDC guidelines?

A: The only way to ensure that the product is producing the desired effect is to monitor the water quality. There are a number of reasons that water quality may remain poor in spite of the use of a product intended to treat dental waterlines. These can include failure of the product, failure to provide initial "shock" treatment if required, improper use of the product, or contamination of the water bottle. There are several companies that offer water-testing kits, including some university dental schools. It is important to follow the instructions carefully for water quality testing. For suggested frequency of water quality testing, consult the manufacturer of either your dental equipment or the water treatment product.

Do you have an inquiry about infection control, occupational health, or practice safety? Ask OSAP. Send your questions to office@OSAP.org
Questions to Help Guide Selection of Dental Waterline Devices and Chemical Treatment Options

With the variety of dental units and water treatment options available to dental practices, it is sometimes difficult to determine which device or method is best for a practice. These questions, when asked of the manufacturer or distributor, can help personnel gather information critical to the purchasing decision.

**Device Selection Questions**
1. Do dental units in the office have a system to provide water that meets the quality recommendations in the CDC guidelines (500 CFU/mL)?
2. What type of system is it, and how does it work?
   - Independent reservoir
   - Water filtration/conditioning system
   - Intermittent chemical treatment
   - Continuous chemical treatment
   - Automated or passive device including antimicrobial tubing or reservoirs
3. Do you have written instructions on how to maintain the dental water system?
4. Do you recommend a specific water treatment agent or device for use with this unit?
5. Do you have written recommendations for monitoring water quality?
6. Can you provide test data or published studies that show that this unit can provide water that meets current CDC recommendations?
7. If the water treatment device is manufacturer provided, can you give an estimate of the annual cost of operation for the system?

**Treatment Product Questions**
1. Can this chemical agent or device help me ensure that water from dental unit will meet the current CDC guidelines?
2. What type of product is it, and how does it work?
   - Germicidal chemical agent for intermittent (shock) treatment
   - Germicidal chemical agent for continuous (maintenance) treatment
   - Non-germicidal cleaner (removes biofilm)
   - Passive slow release cartridge system
   - Automated chemical treatment device
   - Antimicrobial tubing or reservoirs
   - Micropore filter
   - Other non-chemical system
3. On what types of units has this product been tested?
4. Do any dental unit manufacturers recommend this product for use on their equipment?
5. Will this product damage any materials commonly used in dental units (metals, plastics)?
6. Is the product, toxic, caustic or sensitizing to humans? What testing has been performed to verify this? Can you provide me with a Material Safety Data Sheet (MSDS)?
7. What is the initial purchase price of this product and how much will it cost to use it per dental unit per year?
8. How frequently and how long will it take to perform scheduled treatment or maintenance procedures with this product?
9. How frequently will I need to monitor to ensure that the product is working correctly?
10. Do you have any test data or published studies that support the safety and effectiveness of this product for maintaining dental unit water quality?
11. For devices: Has the FDA provided a 510(k) clearance or Pre-Market Approval for this device? [Note: Some products may be considered "exempt" by the FDA]
12. For chemical agents: Is this product a chemical germicide? If so, is it registered by the Environmental Protection Agency and state environmental regulatory agencies if required? [Note: Some chemicals marketed before 2000 may also have an FDA 510(k)]
To help practices stay on track, OSAP provides this calendar listing typical schedules for periodic maintenance, record-keeping, and infection control activities. This schedule is intended only to serve as a guide. Proper practices, procedures, and maintenance schedules can vary according to the kinds of products used, the practice type, and patient volume. Always follow the device or equipment manufacturer’s instructions for maintenance and infection control.

**AUGUST 2006**

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For each question, pick the best answer.

1. The CDC recommends water quality meet the EPA standards for drinking water, which is:
   a. 200 CFU/mL  b. 300 CFU/mL  c. 500 CFU/mL  d. 700 CFU/mL

2. Devices that connect to medical equipment or come into direct contact with the patient fall under which regulatory agency?
   a. EPA  b. FDA  c. OSHA  d. CDC

3. Manufacturers may expedite their FDA clearance by showing:
   a. substantial equivalency  b. EPA registration  c. germicidal activity  d. pesticide activity

4. Products that make claims of biofilm removal, decontamination, or other microbial control fall under which regulatory agency?
   a. EPA  b. FDA  c. OSHA  d. CDC

5. Companies whose products are not EPA-registered, yet make germicidal claims may be in violation of _______________ laws.
   a. state  b. federal  c. state and federal  d. international

6. Which agency may levy civil or criminal penalties against a person for using a product in a manner inconsistent with the product label?
   a. EPA  b. FDA  c. OSHA  d. CDC

7. A community of microorganisms attached to a solid surface is called a:
   a. CFU/mL  b. biofilm  c. DUWL  d. infectious organism

8. Under which Federal Act does the EPA receive its authority to register products?
   a. OSH  b. RCRA  c. FEMA  d. FIFRA

9. The source water for routine dental procedures should be:
   a. sterile  b. clean  c. filtered  d. deionized

10. Standard Operating Procedures (SOPs) should be reviewed and updated:
    a. routinely  b. never  c. when new employees are hired  d. every other year

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MAIL TO: OSAP CE • P.O. Box 6297 • Annapolis, MD 21401 • USA • FAX TO: 410.571.0028
While dental offices must have an office safety manual, some may not have a key management tool that can really increase safety and compliance: Standard Operating Procedures (SOPs). SOPs are procedure and activity-specific lists of directions for accomplishing tasks.

One way to help develop the office’s safety and health SOPs is to discuss the tasks done by various individuals during an office staff meeting. Make a list of the tasks that you would want to teach a new hire or temporary employee, then determine who should be responsible for developing an SOP in each identified area. For instance, the dental assistant is probably the best person to develop an SOP on instrument sterilization and personal protective attire. The dentist or office manager may be the best person to address exposure incident follow-up.

SOPs should be brief and to the point. A list of instructions without rationale is easier to implement than a detailed protocol that gives all the background and reasoning for each procedure. Of course, it is important to base all SOPs on sound rationale and all applicable regulations and guidelines. OSHA regulations and CDC guidelines are a good basis for the information from which to build your SOPs.

Finally, make SOPs a part of your routine review. Just as you must annually review your OSHA-required Exposure Control Plan, SOPs need to reflect changes in procedures that result from new information, changes in the regulations or changes in procedures and equipment in the office.

SOP example:

- **What is to be done.** Biologic Monitoring
- **Who is responsible.** Jane Doe
- **How to do it.** Step by step directions from the monitoring service or in-house program.
- **Specific products or devices.** Name the specific spore strips and where they are located.
- **When to do the procedure or task.** Weekly or more often if..........
- **Where to document completion of the SOP.** Complete the biological monitoring record located: ______________.