



In CONTROL Fact Sheet **NUMBER 22**

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Recommendations vs. Regulations **Who Does What in Infection Control?**

Overview

Regulations are made by groups (e.g., governmental agencies, licensing boards) who have the authority for enforcement. In contrast, recommendations are made by individuals or groups who have no authority for enforcement.

Regulatory Agencies

Occupational Safety and Health Administration (OSHA) www.osha.gov

The Occupational Safety and Health Administration's (OSHA) mission is to assure the safety and health of America's workers by setting and enforcing standards; providing training, outreach, and education; establishing partnerships; and encouraging continual improvement in workplace safety and health. It is important to understand that OSHA's sole intent is to protect the worker, not the patient. OSHA began to develop its standard for protection against occupational exposure to bloodborne pathogens in 1986 and published the final rule in 1991— *Bloodborne Pathogens Standard* (29 CFR Part 1910. Occupational Exposure to Bloodborne Pathogens; Final Rule). In 2001, OSHA amended the 1991 *Bloodborne Pathogens Standard* (29 CFR Part 1910. Occupational Exposure to Bloodborne Pathogens, Needlestick and Other Sharps Injuries; Final Rule; effective 18 April 2001) adding new requirements for employers specifically providing more detail on using engineering controls, such as safer medical devices to reduce or eliminate worker exposure. OSHA requires a copy of this document be available in every dental office and clinic.



Food and Drug Administration (FDA) www.fda.gov



The Food and Drug Administration is part of the U.S. Department of Health and Human Services. The purpose of the FDA is to assure the safety and effectiveness of drugs and medical devices by requiring "good manufacturing practices". The FDA also reviews labeling of the devices to ensure that manufacturers' claims can be supported. Relative to infection control, the Center for Devices and Radiological Health (CDRH) within the FDA regulates the manufacturing and labeling of medical devices (e.g., sterilizers, biologic and chemical indicators, ultrasonic cleaners and cleaning solutions, liquid sterilants, gloves, masks, surgical gowns, protective eyewear, handpieces, dental instruments, dental chairs, dental unit lights) and antimicrobial handwashing agents and mouth rinses. All medical devices to be sold in the U.S. must first be cleared by the FDA. To do so, the manufacturer must submit a 510K application (premarket notification) describing the device and the manufacturing facilities. The manufacturer must also present results of studies conducted to support any claims of effectiveness and safety made for the device. The FDA does not control the actual use of the medical device, but indicates that any use contrary to instructions on the device transfers any liability for problems that develop from the manufacturer to the user.

The Food and Drug Administration is part of the U.S. Department of Health and Human Services. The purpose of

Environmental Protection Agency (EPA) www.epa.gov



medical waste after it leaves the dental office. The Office of Pesticide Programs requires manufacturers to submit information on the safety and effectiveness of disinfectants to the EPA for review to ensure that safety and the antimicrobial claims stated for the products are supported with scientific evidence. If the claims meet the criteria, the disinfectant product receives an EPA registration number that must appear on the product label.

The Environmental Protection Agency has two main divisions that directly impact infection control. The Office of Solid Waste is involved in regulating

State and Local Regulations

It's also important to be aware that state and local agencies may have special dental infection control regulations. Usually, the special requirements are in the areas of medical waste management, instrument sterilization, and sterilizer spore testing. Also, 26 states have their own Division of Occupational Safety and Health Administration in their Departments of Labor. These states have standards that are at least as stringent as the federal OSHA standards.

Recommending Agencies

Centers for Disease Control and Prevention (CDC) www.cdc.gov



The Centers for Disease Control and Prevention is the most important recommending agency with respect to infection control. Most dental infection control procedures practiced today are based on the CDC dental infection-control recommendations. The most recent set of recommendations for dentistry was in December 2003: *Guidelines for Infection Control in Dental Health-Care Settings—2003*. CDC does not have the authority to make laws but many of the local, state, and federal agencies use the CDC

recommendations to formulate laws. Other CDC centers and agencies impacting infection control practices include:

- National Center for Infectious Disease, including the Division of Healthcare Quality Promotion (DHQP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC)
- National Institute for Occupational Safety and Health (NIOSH)
- National Center for HIV, STD and TB Prevention
- Epidemiology Program Office

American Dental Association (ADA) www.ada.org



The American Dental Association makes infection control recommendations through its Councils on Scientific Affairs and Dental Practice and has published several updates over the years. The most recent recommendations were published in August 1996. In March 2004 the ADA decided not to publish a separate set of dental infection-control guidelines and encouraged all dental health-care personnel to follow appropriate infection-control procedures as described in the 2003 CDC guidelines.

Association for Advancement of Medical Instrumentation (AAMI) www.aami.org



The Association for the Advancement of Medical Instrumentation is a voluntary organization composed of manufacturers, distributors, researchers, regulators, and users of medical equipment. One part of this organization is devoted to developing sterilization standards, including information on how to properly use sterilizers and related equipment.

Miscellaneous Recommending Agencies

The Association for Professionals in Infection Control and Epidemiology (APIC) is a multidisciplinary voluntary international organization. Its purpose is to influence, support and improve the quality of healthcare through the practice and management of infection control and the application of epidemiology in all health settings. The Organization for Safety, Asepsis & Prevention Procedures (OSAP) is a non-profit organization composed of dental practitioners; allied health-care workers; and industry representatives with a collective mission to promote infection control and related science-based health and safety policies and practices.

Additional Resources

Miller CH, Palenik CJ. Infection control rationale and regulations. In: Miller CH, Palenik CJ, eds. *Infection Control and Management of Hazardous Materials for the Dental Team*, 4th ed. St. Louis: Mosby, 2009:83–104.