### Appendix 3

### Dental Board of California Infection Control Regulations

California Code of Regulations Title 16 Section 1005

Amended August 2011

### DENTAL BOARD OF CALIFORNIA INFECTION CONTROL REGULATIONS

### California Code of Regulations Title 16 §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, in any setting in which healthcare is delivered. These include hand hygiene, use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure, and safe handling of sharps. Standard precautions shall be used for care of all patients regardless of their diagnoses or personal infectious status.
  - (2) "Critical items" confer a high risk for infection if they are contaminated with any microorganism. These include all instruments, devices, and other items used to penetrate soft tissue or bone
  - (3) "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).
  - (4) "Non-critical items" are instruments, devices, equipment, and surfaces that come in contact with soil, debris, saliva, blood, OPIM and intact skin, but not oral mucous membranes.
  - (5) "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) "Intermediate-level disinfection" kills mycobacterium tuberculosis var bovis indicating that many human pathogens are also killed. This process does not necessarily kill spores.
  - (7) "High-level disinfection" kills some, but not necessarily all bacterial spores. This process kills mycobacterium tuberculosis var bovis, bacteria, fungi, and viruses.
  - (8) "Germicide" is a chemical agent that can be used to disinfect items and surfaces based on the level of contamination.
  - (9) "Sterilization" is a validated process used to render a product free of all forms of viable microorganisms.
  - (10) "Cleaning" is the removal of visible soil (e.g., organic and inorganic material) debris and OPIM from objects and surfaces and shall be accomplished manually or mechanically using water with detergents or enzymatic products.
  - (11) "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, and OPIM, and chemicals used for infection control. General work attire such as uniforms, scrubs, pants and shirts, are not considered to be PPE.
  - (12) "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 HIV, HBV, or 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) "Dental Healthcare Personnel" (DHCP) are all paid and non-paid personnel in the dental health-care setting who might be occupationally exposed to infectious materials, including body substances 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).
- (b) All DHCP shall comply with infection control precautions and enforce the following minimum precautions to minimize the transmission of pathogens in health care settings mandated by the California Division of Occupational Safety and Health (Cal/OSHA).
  - (1) Standard precautions shall be practiced 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.
  - (3) A copy of this regulation shall be conspicuously posted in each dental office.

### **Personal Protective Equipment:**

- (4) All DHCP shall wear surgical facemasks in combination with either chin length plastic face shields or protective eyewear whenever there is potential for aerosol spray, splashing or spattering of the following: droplet nuclei, blood, chemical or germicidal agents or OPIM. Chemical-resistant utility gloves and appropriate, task specific PPE shall be worn when handling hazardous chemicals. After each patient treatment, masks shall be changed and disposed. After each patient treatment, face shields and protective eyewear shall be cleaned, disinfected, or disposed.
- (5) Protective attire shall be worn for disinfection, sterilization, and housekeeping procedures involving the use of germicides or handling contaminated items. All DHCP shall wear reusable or disposable protective attire whenever there is a potential for aerosol spray, splashing or spattering of blood, OPIM, or chemicals and germicidal agents. Protective attire must be changed daily or between patients 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).

### Hand Hygiene:

(6) All DHCP shall thoroughly wash their hands with soap and water 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 may be used as an alternative to soap and water. Hands shall be thoroughly dried before donning gloves in order to prevent promotion of bacterial growth and washed again immediately after glove removal. A DHCP shall refrain from providing direct patient care if hand conditions 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.

### Gloves:

(8) Medical exam gloves shall be worn whenever there is contact with mucous membranes, blood, OPIM, and during all pre-clinical, clinical, post-clinical, and laboratory procedures. When processing contaminated sharp instruments, needles and devices, DHCP shall wear heavy-duty utility gloves to prevent puncture wounds. Gloves must be discarded when torn or punctured, upon completion of treatment, and before leaving laboratories or areas of patient care activities. All DHCP shall perform hand hygiene procedures before donning gloves and after removing and discarding gloves. Gloves shall not be washed before or after use.

### **Needle and Sharps Safety:**

(9) 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. 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.

### **Sterilization and Disinfection:**

- (10) All germicides must be used in accordance with intended use and label instructions.
- (11) Cleaning must precede any disinfection or sterilization process. Products used to clean items or surfaces prior to disinfection procedures shall be used according to all label instructions.
- (12) Critical instruments, items and devices shall be discarded or pre-cleaned, 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 a 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 facility.
- (13) 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 facility.

- (14) Non-critical surfaces and patient care items shall be cleaned and disinfected with a California Environmental Protection Agency (Cal/EPA)-registered hospital disinfectant (low-level disinfectant) 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) 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) Single use disposable items such as 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) 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). Test results shall be documented and maintained for 12 months.

### **Irrigation:**

(18) Sterile coolants/irrigants shall be used for surgical procedures involving soft tissue or bone. Sterile coolants/irrigants must be delivered using a sterile delivery system.

### **Facilities:**

- (19) If non-critical items or surfaces likely to be contaminated are manufactured in a manner preventing cleaning and disinfection, they shall be protected with disposable impervious barriers. Disposable barriers shall be changed when visibly soiled or damaged and between patients.
- 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 germicide after each patient. The low-level disinfectants used shall be labeled effective against HBV and HIV. Use disinfectants in accordance with the manufacturer's instructions. 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) 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 for a minimum of twenty (20) seconds.
- (22) Contaminated solid waste shall be disposed of according to applicable local, state, and federal environmental standards.

### Lab Areas:

(23) Splash shields and equipment guards shall be used on dental laboratory lathes. Fresh pumice and a sterilized or new rag-wheel shall be used for each patient. Devices used to polish, trim, or adjust contaminated intraoral devices shall be disinfected or sterilized, properly packaged or wrapped and labeled with the date and the specific sterilizer used if

- more than one sterilizer is utilized in the facility. If packaging is compromised, the instruments shall be recleaned, packaged in a new wrap, and sterilized again. Sterilized items will be stored in a manner so as to prevent contamination.
- (24) All intraoral items such as impressions, bite registrations, prosthetic and orthodontic appliances shall be cleaned and disinfected with an intermediate-level disinfectant before manipulation in the laboratory and before placement in the patient's mouth. Such items shall be thoroughly rinsed prior to placement in the patient's mouth.
- (c) The Dental Board of California and the Dental Hygiene Committee of Caifornia 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.

### HISTORY:

- 1. New section filed 6-29-94; operative 7-29-94 (Register 94, No. 26).
- 2. Repealer and new section filed 7-8-96; operative 8-7-96 (Register 96, No. 28).
- 3. Repealer of subsection (a)(5) and subsection renumbering, amendment of subsections (b)(7), (b)(10), (b)(18)-(19) and (b)(23) and repealer of subsection (c) and subsection relettering filed 10-23-97; operative 11-22-97 (Register 97, No. 43).
- 4. Change without regulatory effect amending subsection (b)(4) filed 12-7-98 pursuant to section 100, title 1, California Code of Regulations (Register 98, No. 50).
- 5. Amendment of subsections (b)(11), (b)(13) and (b)(15) filed 6-30-99; operative 7-30-99 (Register 99, No. 27).
- 6. Amendment filed 3-1-2005; operative 3-31-2005 (Register 2005, No. 9). 9.
- 7. Amendment operative 8-20-2011

### Dental Board of California Infection Control Requirements Eve Cuny, MS University of the Pacific Arthur A. Dugoni School of Dentistry

### Minimum Standards for Infection Control

- Title 16 CCR
  - Section 1005
- Latest revision effective August 20, 2011
- Must be posted in the office/clinic

### Minimum Standards for Infection Control

- Applies to all dental healthcare personnel (DHCP)
  - "...DHCP includes dentists, dental hygienists, dental assistants, dental laboratory technicians, 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)."

### Infection Control Program

- Standard Precautions
- Written protocol developed, maintained and periodically updated
  - Instrument processing
  - Operatory cleanliness
  - Management of injuries
- Protocol must be available to all DHCP at the dental office

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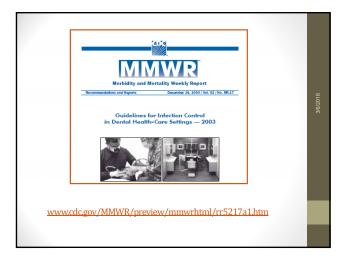
### **Standard Precautions**

- Blood and all body fluids, excretions, secretions except sweat considered potentially infectious
- The same infection control procedure for all patients every time
- Includes hand hygiene, PPE, handling of sharps, sterilization and disinfection



### **Transmission-based Precautions**

- For infectious diseases not preventable with Standard Precautions
- Primarily applies to hospital settings
- Droplet precautions:
  - respiratory illnesses (influenza, adenovirus)
  - · use facemask even for exams
  - place facemask on patient when they will be in close proximity to other patients.
- Airborne precautions
  - For airborne pathogens such as tuberculosis, chicken pox and measles
  - Patients should be treated under isolation precautions
  - Delay treatment or refer to appropriate facility

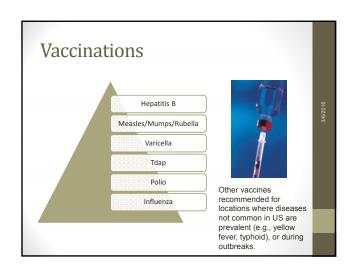


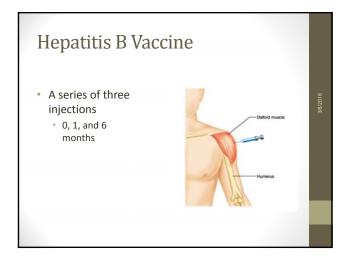
### Are 2003 guidelines still relevant?

- Systematic review of literature undertaken by CDC
- No significant new findings in dental infection control research
- Review of reported clusters of bloodborne disease transmission in dental settings (Data from state health depts.)
  - Three incidents of Hepatitis (B and C) transmission to patients and/or DHCP since 2003, compared to multiple clusters prior to 1990.
    - Patient-to-patient HBV transmission
    - Patient-to-patient HCV transmission
    - 3 patients and 2 volunteers HBV acquired at a large temporary dental clinic (community event)
- It appears that as long as recommended standard precautions are followed they are effective in protecting DHCP and patients

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# Infection Control Practices Vaccinations Personal Protective Equipment Hand Hygiene Sharps Safety Sterilization Disinfection Dental Laboratory





# Post-immunization • HbsAb Anti-body Test • >10 mili – International Units • Consider a booster, repeating the series, or checking for past infection if no antibodies are detected

### HCP not tested post-vaccination

- Since vaccine-induced anti-HBs wanes over time, testing HCP for anti-HBs years after vaccination might not distinguish vaccine nonresponders from responders.
- Pre-employment or pre-matriculation Anti-HBs testing.
  - Additional doses of HBV vaccine for responders <10 mIU/mL who will have exposure to blood, body fluids or sharps

CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. *Recommendations and Reports*. December 20, 2013 / 62(RR10):1-19

### **Booster Injections**

- · CDC does not recommend boosters
  - Immune memory remains intact
    - Even if antibodies fall below detectible levels
  - Only applies to individuals that had post-vaccine testing indicating immune response to the vaccine

### Measles, mumps, rubella

- $^{\circ}\,$  Childhood vaccination given at ages 12 15 months and 4 6 years.
- College students with no evidence of immunity should get two doses of MMR, separated by at least 28 days
- Adults who do not have evidence of immunity should receive at least one dose of MMR

### Varicella vaccine

- Protects against chickenpox
- Two doses for unprotected children, adolescents and adults
- 98% effective; those who do still get infected have a milder disease

### Tdap vaccine

- Tetanus, diphtheria, acellular pertussis
- One dose at age 11 or 12 as a booster to the DTP or DTaP given as an infant
- Adults who have not received the vaccine should get it as soon as possible

### Polio vaccine

- Given at ages 2 months, 4 months, 6-18 months, and a booster at 4-6 years
- Oral polio is not used in the US, but is still used in many parts of the world
- People who received oral polio vaccine do not need to be revaccinated.

### Influenza

- Recommended for everyone age 6 months and older
- Nasal spray vaccine may be given to people ages 2 49

### Bloodborne Diseases Modes of Transmission

- Direct contact with blood and body fluids
- Indirect contact with contaminated instruments or surfaces
- Contact of mucosa of the eyes, nose or mouth with droplets or spatter





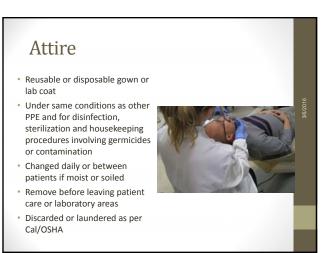




### Personal Protective Equipment (PPE)

- Worn whenever there is a potential for:
  - Aerosol spray
- Splashing or spattering of:
  - Droplet nuclei
  - Blood
  - Chemical or germicidal agents
  - OPIM





### **Contaminated Laundry**

- "Laundry which has been soiled with blood or other potentially infectious materials or may contain sharps."
  - Cal/OSHA Bloodborne Pathogens Rule

### Cal/OSHA Laundry Requirement

- The employer shall clean, launder, and dispose of personal protective equipment at no cost to the employee
- Placed in containers that are labeled or color-coded
- Transported in containers that are labeled or colorcoded
- May be done onsite (by trained employees) or by a professional service (ensure the use of Standard Precautions)

### Exam Gloves

- For contact with mucous membranes, blood, OPIM
- During pre-clinical, clinical, post-clinical and laboratory procedures



### **Exam Gloves**

 Remove and discard gloves that are torn, cut or punctured



 Do not wash gloves before or after use



### Heavy-duty utility Gloves

- Chemical-resistant utility gloves
  - handling hazardous chemicals (in addition to appropriate, task-specific PPE)
  - processing contaminated sharp instruments, needles and devices.



### Hand Hygiene – Soap and Water

- At the start and end of each workday
- If contaminated or visibly soiled
- Before placing and after removing gloves (unless using hand sanitizer)



### Alcohol-based Hand Sanitizers

- Alternative to soap and water
- For hands free of debris
- Good antimicrobial
- · Not a cleaning agent



### Patient Care Restrictions

- Refrain from direct patient care and handling patient care equipment if:
  - Weeping dermatitis
- Exudative lesions
- Hand condition making DHCP or patient more susceptible to opportunistic infection or exposure

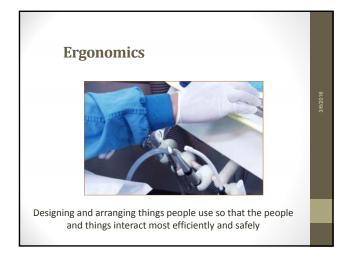


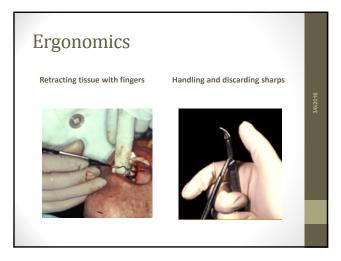


















### Post-exposure Management

- Prompt reporting of injuries
- Interview of patient
- Testing of patient and exposed worker
- · Referral for medical counseling
- Written report documenting details of incident, including whether or not a safety device was involved

### Postexposure Management for HIV

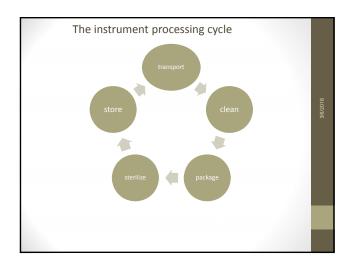
- Collect source patient information
  - Types of medications if patient is HIV-positive
- · Testing of exposed worker
  - Baseline, 4-6 weeks, 12 weeks, 6 months
- Risk assessment by qualified healthcare professional
- Post-exposure prophylaxis, if indicated by assessment

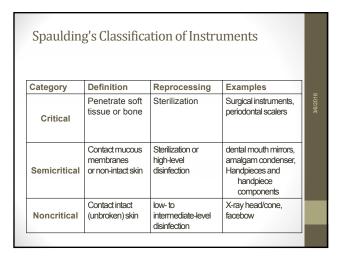
### Postexposure Management HBV

- Vaccinated responders
- No PEP
- Unvaccinated person
  - HBIG
  - Begin vaccine series
- · Vaccinated nonresponder
  - HBIG x2 (or more, if recommended by healthcare provider)

# Postexposure Management for HCV IG, antivirals not recommended for prophylaxis Follow-up after needlesticks, sharps, or mucosal exposures to HCV-positive blood Test source for anti-HCV Stest worker if source anti-HCV positive Anti-HCV and ALT at baseline and 4-6 months later For earlier diagnosis, HCV RNA at 4-6 weeks Confirm all anti-HCV results with RIBA Refer infected worker to specialist for medical evaluation and management

# INSTRUMENT PROCESSING Transporting, cleaning, sterilizing and storing





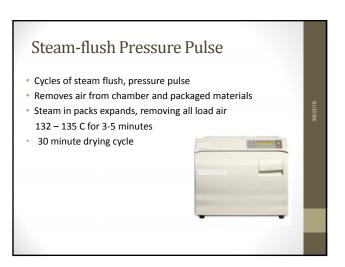
### Sterilization of Instruments

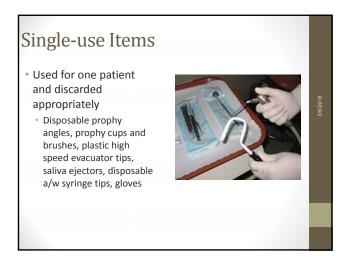
- · Critical and semicritical instruments
  - Cleaned
  - Heat sterilize
  - High level disinfect or sterilize using chemical germicides only if item cannot be heat sterilized
  - Discard if disposable
- Heat sterilize all high-speed handpieces, low-speed handpieces, rotary components and all other attachments (e.g.: reusable air/water syringe tips, ultrasonic scaler tips, etc.)

### **Heat-Based Sterilization**

- · Steam under pressure (autoclaving)
  - · Gravity displacement
- Dynamic air removal
  - · Steam-flush pressure pulse
  - prevacuum
- Dry heat
  - Static air (convection, oven-type)
- Forced air (rapid heat transfer)
- Unsaturated chemical vapor
  - · Proprietary formula of alcohol/formaldehyde

### • Steam is admitted through a control valve • Steam forms stratified layer across the top of chamber • Steam mass displaces air via drain vent • Best for unwrapped or lightly wrapped materials • 121 C for 30 minutes • 30 minute drying cycle



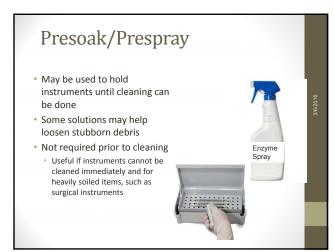










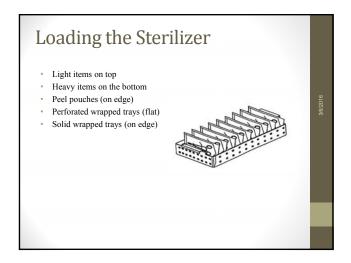


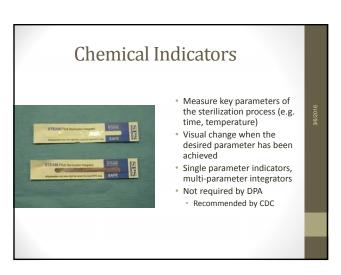


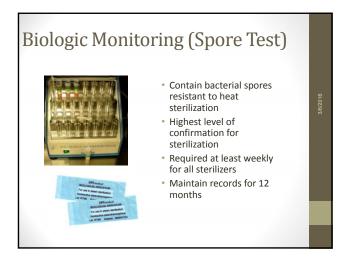




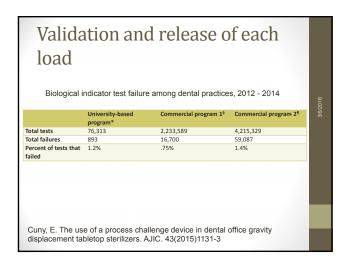


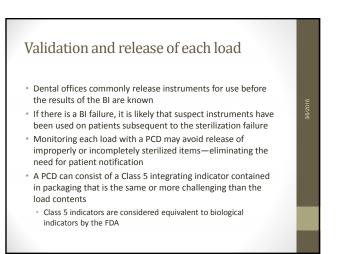












### Use of a Class 5 Indicator

- Place Class 5 integrating indicator in the geometric center of a wrapped cassette or tray, or the center of a pouch of instruments.
- The test pack should be placed in the center of a load
- Upon removal of the load, check the indicator before releasing the load
- The use of a Class 5 does not eliminate the need for weekly spore testing

### Liquid Chemical Sterilant/Disinfectants



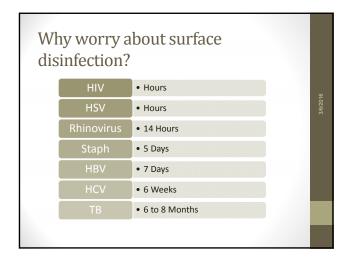
- "If a semi-critical item is heat sensitive, it shall, at minimum, be processed with high level disinfection and packaged or wrapped upon completion of the disinfection process." California Dental Practice Act
- Heat tolerant or disposable alternative available for most items

### Use of High Level Disinfectants

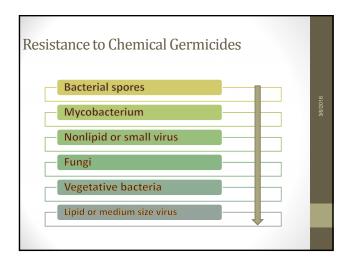
- Ventilation
- OSHA recommendations
- Disposal
  - May be hazardous waste
- Risks
- Associated with skin irritation
- Asthma potential



## Clinical Surface Disinfection Clinical contact surfaces Housekeeping surfaces

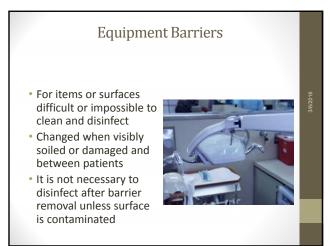
















### Limitations of Surface Disinfectants

- Must ensure surfaces remain wet for indicated contact time
- · Dilution may affect efficacy
- Contact with some materials may decrease efficacy
- Subject to ineffectiveness due to user error
- May cause chemical sensitization—PPE is important



