

# ***INFECTION CONTROL AND ENVIRONMENT OF CARE IN DENTAL HEALTH-CARE SETTINGS***

**Federal Bureau of Prisons  
Clinical Guidance**

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## ACRONYMS

<b>BI</b>	Biological indicators
<b>ADA</b>	American Dental Association
<b>BOP</b>	Federal Bureau of Prisons
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CJD</b>	Creutzfeldt-Jakob Disease
<b>DHCP</b>	Dental health-care personnel
<b>EPA</b>	Environmental Protection Agency
<b>ESCA</b>	Environmental and Safety Compliance Administrator
<b>FDA</b>	Food and Drug Administration
<b>IFU</b>	Instructions for use (from the manufacturer)
<b>OSHA</b>	Occupational Safety and Health Administration
<b>OPIM</b>	Other potential infectious materials
<b>PPE</b>	Personal protective equipment
<b>PSP</b>	Phosphor storage plate
<b>SDS</b>	Safety Data Sheet

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## 1. PURPOSE

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The professional and community standards for dental infection control are derived from the Centers for Disease Control and Prevention (CDC) guidance, U.S. Food and Drug Administration (FDA) regulations, and Occupational Safety and Health Administration (OSHA) standards.

- **The purpose of this Clinical Guidance is to provide recommendations to all clinic sites to assist dental providers in meeting governmental guidelines, regulations, and standards.**
- This guidance consolidates and complements governmental standards and guidance into a brief, practical, “working” format, with emphasis on reusable dental instrument processing.
- This guidance does not supersede governmental guidance, regulations, and standards, including the following:
  - ▶ CDC Guidelines for Infection Control in Dental Health Care Settings
  - ▶ CDC Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care
  - ▶ OSHA Bloodborne Pathogens and Needlestick Prevention Standards
  - ▶ FDA Guidelines for Dental Handpiece Sterilization
  - ▶ FDA Guidance for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
  - ▶ BOP Program Statement Employee Health Care (PS6701.series)
  - ▶ BOP Dental Program Statement (PS6400.series)
  - ▶ Instructions for Use (IFU) provided by manufacturers

The recommendations in this guidance are based on the applicable BOP policies and current governmental guidelines, regulations, standards. This guidance should not be used for non-dental equipment or instrumentation. Sterilization of non-dental equipment and instrumentation should follow the manufacturer’s IFU.

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## 2. EDUCATING AND PROTECTING DENTAL HEALTH-CARE PERSONNEL

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To ensure competency and safety of staff and patients, training of dental health-care personnel (DHCP) takes place upon hire, annually, and when new tasks are introduced.

**At a minimum, the training should include:**

- A description of exposure risk for DHCP
- Review of preventive measures
- Management of occupation-related illness and injuries
- Review of work restrictions for the prevention of exposure or infection

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### 3. PREVENTING TRANSMISSION OF BLOODBORNE PATHOGENS

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- ➔ *DHCP are at risk for exposure to and transmission of infectious organisms/materials. To mitigate transmission risk, employees should be familiar with the Immunization Program for medical/dental staff, as referenced in the BOP Program Statement Employee Health Care, (PS6701.series).*

**Prevention is the key to minimizing the exposure risk.** Prevention can be achieved by implementing **STANDARD PRECAUTIONS**. Standard Precautions are the minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where health care is delivered. These practices are designed to protect DHCP and to prevent DHCP from spreading infections among patients.

**The following STANDARD PRECAUTIONS in the dental care setting are discussed below:**

[A. Hand hygiene](#)

[B. Personal protective equipment \(PPE\)](#)

[C. Respiratory hygiene/cough etiquette](#)

[D. Sharps safety](#)

[E. Safe injection practices](#)

[F. Sterilization and disinfection of patient-care items](#)

[G. Clean and disinfected environmental surfaces](#)

[H. Dental unit waterlines, biofilm, and water quality](#)

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#### A. HAND HYGIENE

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The preferred method for hand hygiene depends on the type of procedure, the degree of contamination, and the desired persistence of antimicrobial action on the skin. Hands should be washed before and after glove donning and doffing.

- With the exception of surgical procedures, handwashing and hand antisepsis are achieved by using soap (either plain or antimicrobial) and water. If the hands are not visibly soiled, an alcohol-based hand rub is adequate.
- Prior to surgical procedures, use an antimicrobial soap and water. After drying hands, apply an alcohol-based surgical hand scrub product. Hands should be dry before gloves are donned. Factors that can influence the effectiveness of surgical hand antisepsis include: the specific antiseptic agent used, duration and technique of scrubbing (reference the IFU for the antiseptic agent), and techniques used for drying and gloving.
- Fingernails should be short enough to allow DHCP to thoroughly clean underneath them and prevent glove tears. If nail polish is used, it should not be chipped.

## **B. PERSONAL PROTECTIVE EQUIPMENT (PPE)**

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### **SURGICAL MASKS**

- A surgical mask that covers both the nose and mouth is to be worn. Masks should be changed between patients, and during patient treatment if the mask becomes soiled.

### **PROTECTIVE EYEWEAR AND FACE SHIELDS**

- Protective eyewear is defined by the BOP Dental Program as having solid-side shields or a face shield. DHCP who wear prescription glasses should utilize the face shield as protective eyewear.
- Inmates receiving treatment are to be provided protective eyewear.
- Reusable PPE (e.g., clinician or patient protective eyewear and face shields) should be cleaned with soap and water, when visibly soiled, and disinfected between patients according to the IFU.

### **PROTECTIVE CLOTHING**

- Standard Precautions require the sleeves of the protective gown to be long enough to protect the forearms. The sleeves of the gown should overlap the edge of the protective glove.
- The quality and gauge of the gown should be impervious to liquids.
- DHCP should change protective clothing when it becomes visibly soiled.
- All protective clothing should be removed before leaving the patient care area.

### **GLOVES AND GLOVING**

- Medical gloves should be used for only one patient and then discarded.
- Care should be taken not to cross-contaminate items in one's vicinity once gloves are donned.
- Hand hygiene should be performed immediately before donning and immediately after doffing gloves.
- Sterile surgeon gloves should be used when performing oral surgical procedures that involve normally sterile tissue that support the oral cavity (e.g., bone or subcutaneous tissue).
- Non-latex (nitrile or vinyl) gloves should also be made available for DHCP with a latex allergy and when working with patients who have a documented latex allergy or who declare a latex allergy.
- DHCP and patients with declared latex allergies should not have contact with other latex products (e.g., latex rubber dams), and all latex-containing products should be removed from the vicinity of the treatment area.
- PPE, including puncture-resistant gloves, should be worn at all times by DHCP during instrument processing.
- Non-medical grade vinyl gloves (like those used in Food Service) are inappropriate for dental procedures and should not be used in a dental setting.

## **LOTIONS**

- Petroleum-based lotion formulation can weaken latex gloves and increase permeability.
- DHCP should obtain information from lotion manufacturers regarding interaction between lotions, gloves, dental materials, and antimicrobial products.

## **C. RESPIRATORY HYGIENE/COUGH ETIQUETTE**

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Respiratory hygiene/cough etiquette infection prevention measures are designed to limit the transmission of respiratory pathogens spread by droplet or airborne routes. Patients exhibiting signs of illness (cough, congestion, runny nose, or increased production of respiratory secretions) should be rescheduled in the case of non-emergent dental treatment.

### **The following measures can reinforce respiratory etiquette:**

- Posting signs at dental setting entrances that advise patients to cover their mouths/noses when coughing or sneezing, to use and dispose of tissues, and to perform hand hygiene after hands have been in contact with respiratory secretions.
- Providing tissues and no-touch receptacles for disposal of contaminated tissues.
- Providing hand hygiene resources such as alcohol-based hand rub.
- Educating DHCP on the importance of infection prevention measures when examining and caring for patients who have signs and symptoms of a respiratory infection.
- DHCP refraining from direct patient care when possibly suffering from a transient respiratory illness themselves, so as to reduce risk of infecting patients.

## **D. SHARPS SAFETY**

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Most percutaneous injuries among DHCP involve needlesticks and cuts with burs or other sharp instruments. Most exposures in dentistry are preventable through engineering and work-practice controls. Of the two methods, engineering controls will be the primary method of reducing exposures to bloodborne pathogens from sharp object injuries.

### **Examples of engineering controls include:**

- Self-sheathing anesthetic needles
- Needle recapping devices
- Safety scalpels
- Puncture-resistant utility gloves for use when cleaning instruments
- Appropriate containers for transporting instruments from the treatment area to the instrument reprocessing area



**When engineering controls are not available or appropriate, work-practice controls should be used. Work-practice controls are behavior-based and include measures such as the following:**

- One-handed scoop technique for recapping needles
  - Not bending/breaking needles before disposing of them
  - Not passing a syringe with an unsheathed needle by hand to another person
  - Removing burs from the handpiece prior to disassembling the handpiece
  - Not using fingers for tissue retraction during suturing or administration of anesthesia
- ➔ *All used sharps will be discarded into appropriate puncture-resistant sharps containers located close to the area where they are used.*

## **E. SAFE INJECTION PRACTICES**

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- Local anesthetic cartridges do not require disinfection of the cartridge plunger. (An oral local anesthetic cartridge is not considered a “medication vial” and thus does not require this disinfection procedure.)
  - When preparing an anesthetic syringe, use an *aseptic* technique (see glossary in [Appendix 1](#)) in a clean area (disinfected operatory).
  - Dental needles and anesthetic cartridges are to be used for one patient only, and the dental aspirating syringe is to be reprocessed according to its respective IFU.
- ➔ *For more information on managing exposures, refer to PS 6130 Management of Staff Exposures to Bloodborne Pathogens.*

## **F. STERILIZATION AND DISINFECTION OF PATIENT-CARE ITEMS**

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- ➔ *This section addresses the sterilization and disinfection of dental patient-care items, and is not guidance for the sterilization and disinfection of medical patient-care items.*

### **LEVELS OF STERILIZATION/DISINFECTION**

There are three levels of sterilization/disinfection for dental patient-care items, depending on the intended use of the items:

1. **HIGH** (chemical sterilant)
  2. **INTERMEDIATE** (EPA-registered, hospital disinfectant with a tuberculocidal claim)
  3. **LOW** (EPA-registered, hospital disinfectant with no label claim regarding tuberculocidal activity)
- ➔ *Follow the product manufacturer’s instructions regarding concentrations and disinfectant contact time.*
- ➔ ***High-level disinfectants (for example, Ortho-Phthalaldehyde) should NOT be utilized** due to (1) required exhaust ventilators, (2) required continuous gas monitors, (3) required DHCP respirators, and (4) required OSHA Hazcom Standard training. Specifically, it is important to recognize that the intra-oral radiograph-sensor holders do have an established autoclave IFU and their respective high-level disinfectant alternative should NOT be utilized.*

### SPAULDING CLASSIFICATION SYSTEM

Patient-care items are categorized by the Spaulding Classification System as **CRITICAL**, **SEMI-CRITICAL**, and **NON-CRITICAL**. The IFU will determine classification of each instrument or device. See **Table 1** below for characteristics and examples of each category.

**TABLE 1: SPAULDING CLASSIFICATION SYSTEM OF DENTAL PATIENT-CARE ITEMS**

Classification	Characteristics	Examples
<b>CRITICAL</b>	<ul style="list-style-type: none"> <li>• Penetrate soft tissue/ bone.</li> <li>• Pose greatest risk of transmitting infections.</li> <li>• <b>Heat sterilization required.</b></li> </ul>	<ul style="list-style-type: none"> <li>• Rongeur</li> <li>• Bone file</li> <li>• Periosteal elevator</li> <li>• Root tip elevators</li> <li>• Tissue forceps</li> <li>• Periodontal scalers</li> <li>• Handpiece tissue retractors</li> </ul>
<b>SEMI-CRITICAL</b>	<ul style="list-style-type: none"> <li>• Come into contact with non-intact skin/mucous membranes.</li> <li>• Lower risk of infection transmission relative to CRITICAL patient-care items.</li> <li>• <b>Heat sterilization required for heat-tolerant instruments.</b></li> </ul>	<ul style="list-style-type: none"> <li>• Bite blocks/props</li> <li>• Digital radiography sensors</li> <li>• Retractors</li> <li>• Prophylactic latches</li> <li>• Amalgam carrier</li> <li>• Dental handpieces, e.g., high-speed, low-speed, including the motor (refer to IFU)</li> <li>• Radiograph positioning devices</li> </ul>
<b>NON-CRITICAL</b>	<ul style="list-style-type: none"> <li>• Contacts only intact skin.</li> <li>• Lowest risk of infection transmission.</li> <li>• <b>In the majority of cases, cleaning is adequate.</b> If visibly soiled, cleaning (physical removal of potentially infectious material) followed by disinfection with an EPA-registered, hospital-grade intermediate-level disinfectant (with a tuberculocidal claim) is adequate.</li> <li>• <b>Use of disposable items and barriers is recommended when possible.</b></li> </ul>	<ul style="list-style-type: none"> <li>• Blood pressure cuff</li> <li>• Stethoscope</li> <li>• Patient education mirror</li> <li>• Typodont</li> <li>• Computer keyboard</li> <li>• Apex locator unit</li> <li>• Apex locator wire (outside of the patient's mouth)</li> </ul>

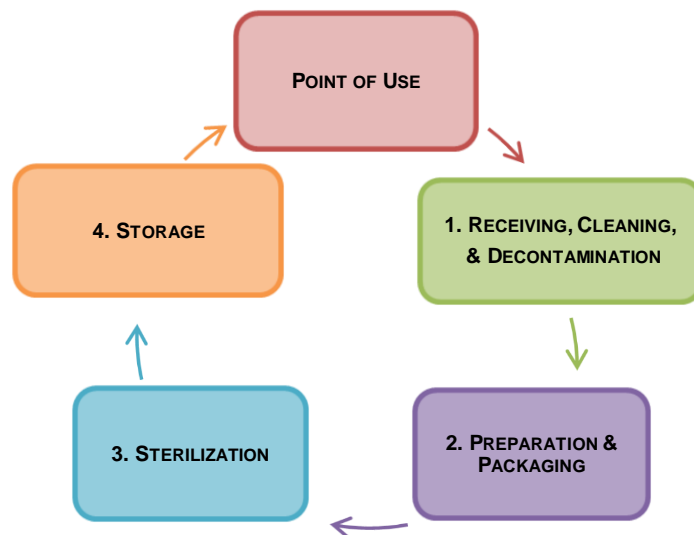
### TRANSPORTATION OF CRITICAL AND SEMI-CRITICAL PATIENT-CARE ITEMS

- Handling and transportation of contaminated dental instruments by DHCP increases the risk of percutaneous injuries, exposure to intact skin, and mucous membranes.
- It is recommended that contaminated patient-care items be placed in an appropriate, covered, puncture-resistant container at the point-of-use before being transported to the instrument processing area.
  - ➔ *Locked containers are recommended in the BOP, as it may prevent unintended injuries if instruments are dropped.*

## INSTRUMENT PROCESSING AREA

- Instrument processing areas should ideally have storage, partitions, or enough spatial separation so as to promote proper instrument flow, while containing contaminants during instrument processing.
- **Designate an instrument processing area.** Divide the area physically, or at least spatially, into four distinct sections (one for each phase of instrument processing), labeling each one:
  1. **Receiving, cleaning, and decontamination**
  2. **Preparation and packaging**
  3. **Sterilization**
  4. **Storage**
- **The goal for instrument processing is uni-directional flow, as shown below in Figure 1:**

FIGURE 1: FOUR PHASES OF INSTRUMENT PROCESSING



The four sections of the Instrument Processing Area are discussed below. Each section is numbered and color-coded to match the flow chart above.

➔ During Phases 1–3, instruments should be handled as though they are contaminated. During Phases 1 and 2, PPE (including puncture-resistant gloves) should be worn at all times by DHCP.

### 1. Receiving, Cleaning, and Decontamination Section

- ▶ Items that do not have an IFU for reprocessing are classified as single-use only and discarded appropriately (for example, burs and endodontic files). See *CFR, Title 21, Part 801, Adequate Instructions, and FDA 510 (k) Program*.

- ▶ **Cleaning precedes disinfection/sterilization and should remove all debris, as well as organic and inorganic contamination:**
  - Instruments that are not to be cleaned immediately should be placed in a puncture-resistant container with an approved detergent, detergent/disinfectant, or enzymatic cleaner.
  - Although instruments can be scrubbed by hand, the use of an automated processor such as a FDA-cleared ultrasonic cleaner or automated instrument washer is preferred. This approach is recognized as the most effective means of debris removal and has shown to increase productivity and improve cleaning effectiveness.

Manufacturer's recommendations for the selected ultrasonic enzymatic solution should be followed, including ensuring the optimal temperature range for the solution, the dilution ratio, and processing time. Preference should be given to cleaners/solutions that have documented efficacy at room temperature.

Ultrasonic enzymatic solutions may have special disposal requirements. Consultation with the local Environmental and Safety Compliance Administrator (ESCA) is recommended.
  - After cleaning, instruments should be rinsed with water to remove chemical or detergent residue.
  - Allow sufficient time for the instruments to dry prior to packaging. Wet instruments may compromise the integrity of the packaging material and interfere with sterilization.

## 2. Preparation and Packaging

- ➔ *All reusable patient-care items will remain packaged or wrapped during sterilization and storage. "Flash" or "unwrapped" autoclave cycles should not be used in the BOP Dental Program.*
- ▶ Hinged instruments should be processed open and unlocked.
- ▶ Instruments that can be disassembled should be packaged disassembled as indicated by the IFU.
- ▶ When packages have both incorporated external and internal indicators, additional indicators are not necessary.
- ▶ Wrapped cassette systems require both an internal and external chemical process indicator. Refer to the IFU regarding use and placement of chemical process indicators.
- ▶ All packages to be sterilized should be labeled with: (1) date of sterilization; (2) load number, if provided by printer; (3) expiration date once processed through autoclave, as determined from the IFU; and (4) the assigned autoclave number, if multiple autoclaves are used in the facility. Labeling may be accomplished by using a separate piece of chemical process indicator tape (autoclave tape) or a label gun appropriate for this purpose.

## 3. Sterilization

- ➔ *BOP Dental Programs should strive to attain an FDA-cleared gravity displacement autoclave that includes a recording system of cycle parameters (e.g., attached printer, approved USB capacity).*
- ▶ The sterilization section of the patient-care items processing area should have adequate space for loading, unloading, and cool down/drying. Manufacturer and local building code specifications determine placement and room ventilation requirements.

- ▶ The sterilization times, temperatures, and other operating parameters recommended by the manufacturer of the equipment used and the items processed, as well as the IFU for containers, wraps, and chemical/biological indicators, should always be followed.
- ▶ Instruments possessing a lumen (e.g., handpieces) require a higher level of physical parameters, and special attention should be given to the IFU.
- ▶ Because equipment will vary in specification, it is important to locate and follow each instrument's IFU.
- ▶ Items to be sterilized should be arranged so as to permit free circulation of the sterilizing agent, and the IFU for loading the sterilizer should be followed.
  - ➔ *Improper loading of the autoclave is the most prevalent cause of biological indicator failure (positive biological indicator result).*
- ▶ Review the autoclave's IFU to determine if peel pouches need to be autoclaved in an "edge" fashion, utilizing a pouch rack.
- ▶ Instrument packs should be allowed to dry and cool inside the autoclave chamber.
- ▶ Packs should not be touched until they are cool and dry.

### **Sterilization Monitoring**

The autoclave should be monitored by **mechanical**, **chemical**, and **biological** means.

➔ *Mechanical and chemical monitor readings do not ensure sterilization, but incorrect readings can be the first indication of a problem with the autoclave cycle.*

- ▶ **Mechanical indicators:** Mechanical techniques for monitoring the sterilization cycle include visually assessing the cycle time, temperature, and pressure by observing the autoclaves gauges and documenting the observations. Many contemporary autoclaves have some type of recording device and provide a printout.
- ▶ **Chemical indicators:** Multi-parameter chemical indicators such as Class 5 Integrators are designed to react to at least two of the physical parameters and can provide a more reliable indication that sterilization conditions have been achieved.

Although not recommended by the 2003 CDC Guidelines, the BOP Dental programs should place a single Class 5 Integrator within each load (per the indicator's IFU) and document the results in the chemical monitoring log.

- ▶ **Biological indicators (BI):**

➔ *Of the three means of monitoring the cycle parameters, biological monitoring is the most accepted method for monitoring the sterilization process because it directly assesses the cycle's ability to have destroyed highly resistant microorganisms.*

- Biological indicators should be used at least weekly. Periods where there are no dental services provided (leave, annual refresher training, etc.) are noted in the log. The IFU determines the placement of the BI in the autoclave/load.
- Clinics should utilize an in-office system with an incubation period of 24 hours or less. If multiple autoclaves are used in the same facility, follow the IFU for differentiating one BI in the incubator from another.
- Mail-in indicator services should not be used in the BOP.

- ▶ Logs for weekly BI, autoclave printouts, and chemical indicators (internal/external chemical indicators on pouches and Class 5 Integrators) should be retained for five years or longer as required by respective State/Local regulations.
- ▶ Routine maintenance for sterilization equipment should be performed according to the IFUs and documented by written maintenance records.

#### **Protocol for Positive BI Tests**

Upon a positive BI test result, the Chief Dental Officer, or the Acting Chief Dental Officer, should notify the appropriate BOP personnel (Infectious Disease Coordinator and Improving Organizational Performance program manager).

**The following positive BI contingency protocol should be included in the dental institutional supplement:**

**1) The steps listed below should be followed in the case of a positive spore test:**

- a) Remove the sterilizer from service and review sterilization procedures (e.g., work practices and use of mechanical and chemical indicators) to determine whether an operator error could be responsible.
- b) Retest the sterilizer by using biological, mechanical, and chemical indicators after correcting any identified procedural problems.
- c) If the repeat spore test is negative, and mechanical and chemical indicators are within normal limits, put the sterilizer back in service.

**2) If the repeat spore test is positive, the steps listed below should be followed:**

- a) Do not use the sterilizer until it has been inspected or repaired, or the exact reason for the positive test has been determined.
- b) Recall, to the extent possible, and reprocess all items processed since the last negative spore test.
- c) Before placing the sterilizer back in service, rechallenge the sterilizer with biological indicator tests in three consecutive empty chamber sterilization cycles after the cause of the sterilizer failure has been determined and corrected.

#### **4. Storage of Sterilized Patient-Care Items**

- ▶ All sterilization pouches and wrapped instruments should be dry prior to handling and placing in a designated enclosed storage area.
- ▶ Wrapped instruments and peel pouches have expiration dates, from the date of being processed through the autoclave, as established by the IFU.
- ▶ Prior to use, each packet should be inspected carefully. Instruments should not be used if chemical indicators indicate inadequate processing (e.g., the chemical indicator has not changed color) or if the package integrity has been compromised. If either applies, the instruments should be reprocessed.

## **G. CLEAN AND DISINFECTED ENVIRONMENTAL SURFACES**

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**ENVIRONMENTAL SURFACES** refers to surfaces and equipment in the operatory that are not in direct contact with the patient, but which could become contaminated due to splatter or hand contact.

➔ *PPE should be worn during cleaning/disinfection of environmental surfaces.*

### **TWO LEVELS OF DISINFECTION FOR ENVIRONMENTAL SURFACES**

- 1) **INTERMEDIATE LEVEL:** EPA-registered, hospital disinfectant with a tuberculocidal claim.
  - ➔ *It is recommended that intermediate-level disinfection be used in clinic settings, especially if the surface is contaminated with blood or other infectious material (OPIM).*
- 2) **LOW LEVEL:** EPA-registered, hospital disinfectant with an HIV/HBV claim.

### **TWO TYPES OF ENVIRONMENTAL SURFACES**

- 1) **CLINICAL CONTACT SURFACES:** Surfaces immediately surrounding the treatment area.
  - ▶ When possible, barrier coverings should be used. If used, they should be replaced after each patient.
  - ▶ Covered surfaces should be disinfected/cleaned after the barrier covering is removed, using EPA-registered, hospital-grade, low- or intermediate-level disinfectant. Be sure to verify the necessary contact time, as contained in the IFU.
  - ▶ Intermediate-level disinfectant should be used if the surface is visibly contaminated with blood or OPIM.
- 2) **HOUSEKEEPING SURFACES:** Walls, floors, and sinks surrounding the treatment area.
  - ▶ Water/detergent combination or EPA-registered, hospital-grade disinfectant/detergent should be used to clean these surfaces depending on the nature of the surface and the type/degree of contamination.
  - ▶ Mops and cloths should be cleaned and allowed to dry after each use. The use of disposable cleaning items is encouraged.
  - ▶ Cleaning methods should try to minimize the use of cleaning methods that involve mist/aerosols/dust dispersion.
  - ▶ Refer to the IFU for the appropriate contact time for cleaning solutions.

### **BLOOD SPILLS**

- Should be cleaned as soon as possible, as directed by OSHA requirements.
- PPE should be worn by the person performing this task.
- Cleanup should begin by wiping off visible organic material with disposable absorbent towels, which should be discarded in a leak-proof, appropriately labeled container.
- Non-porous surfaces should be cleaned and then decontaminated with intermediate-level EPA-registered hospital-grade disinfectant or EPA-registered sodium hypochlorite.

**NON-REGULATED AND REGULATED MEDICAL WASTE**

➔ See **TABLE 2** below for some examples of both types of waste.

- The majority of soiled items in dental offices is **NON-REGULATED MEDICAL WASTE** and can be disposed of with ordinary waste.
- Infectious waste that carries a substantial risk of causing infection during handling and disposal is considered **REGULATED MEDICAL WASTE**.
  - ▶ A single leak-resistant biohazard bag is usually adequate for containment of non-sharp regulated waste.
  - ▶ Puncture-resistant, one-way latch containers with a biohazard label, located at the point of use, are used as containment for all sharps. Do not overfill containers as per the IFU.
  - ▶ Dispose of all regulated medical waste in compliance with Federal, State, and Local regulations.

**TABLE 2: SOME EXAMPLES OF NON-REGULATED AND REGULATED MEDICAL WASTE**

Non-Regulated Waste	Regulated Waste
<ul style="list-style-type: none"> <li>• Mask not saturated with OPIM</li> <li>• Gowns not saturated in OPIM</li> <li>• Patient napkins not saturated in OPIM</li> <li>• Gloves not saturated in OPIM</li> <li>• Disinfectant wipes not saturated in OPIM</li> </ul>	<ul style="list-style-type: none"> <li>• Soiled mask saturated in OPIM</li> <li>• Soiled gowns saturated in OPIM</li> <li>• Soiled patient napkins in OPIM</li> <li>• Gloves saturated in OPIM</li> <li>• Teeth not containing amalgam restorations</li> </ul>

**H. DENTAL UNIT WATERLINES, BIOFILM, AND WATER QUALITY**

**STRATEGIES TO IMPROVE DENTAL UNIT WATER QUALITY FOR NONSURGICAL USE**

To address dental unit waterline contamination, the CDC has adopted the EPA standard for safe drinking water as the standard for nonsurgical dental procedures. The number of bacteria in water used as a coolant/irrigant for nonsurgical dental procedures must be less than or equal to 500 colony-forming units per milliliter ( $\leq 500$  CFU/ml). All strategies to combat dental waterline biofilm should be put into place, and equipment should be operated according to the IFU.

- Replace aging dental delivery units that use direct municipal or well-water sources with self-contained (independent) water systems.
- Until replacement, use in-line microfilters for delivery units that utilize direct municipal or well water sources.
- Recognize that removal or inactivation of dental waterline biofilm requires use of chemical germicides (for self-contained water delivery systems), as recommended by the IFU.
- Replace standard tubing with treated tubing (tubing impregnated with silver ions); for direct municipal/well water units, retrofit with tubing that can be autoclaved.
- The frequency of dental unit waterline quality monitoring should be determined by the IFU for the delivery unit or the monitoring system/kit, whichever is more robust.
- Older dental delivery units may not have the engineering mechanisms (one-way valves) to prevent the retraction of patient oral fluids back into the tubing. The manufacturer of the



specific dental delivery unit used should be contacted to determine if anti-retraction mechanisms are present and, if they are, ensure that they are in working order.

- ➔ *The CDC recommends that DHCP 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).*

### **WATER QUALITY FOR SURGICAL DENTAL PROCEDURES**

Whereas in-line coolant water of  $\leq 500$  CFU/ml is adequate for nonsurgical procedures, it is inadequate for coolant/irrigation of surgical procedures. Sterile cooling solutions should be used for all surgical procedures that compromise tissues that are normally sterile (e.g., bone or subcutaneous tissue). Delivery devices such as 60 ml individually-packaged, single-use, disposable, and sterile bulb syringes are ideal and cost effective for delivering sterile irrigation. These bulb syringes can be easily stored in an automated medication delivery unit.

### **BOIL-WATER ADVISORIES**

During a boil-water advisory, water is not delivered to patients through dental units that use a municipal or well water supply as its source. Patients should rinse with bottled or distilled water until the boil-water advisory has been cancelled. Independent water-source delivery units are to use bottled water (distilled or otherwise) as the source of water with appropriate manufacturer's germicide. For hand hygiene, products that do not require water (alcohol-based hand rubs) should be used. Once the advisory has been lifted, all incoming waterlines from the municipal/well water system inside the dental clinic (faucets, waterlines, and dental equipment) should be flushed for 5 minutes. After the incoming municipal/well water system lines are flushed, the dental units should be disinfected according manufacturer's recommendations.

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## **4. SPECIAL CONSIDERATIONS**

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### **DENTAL HANDPIECES AND OTHER DEVICES ATTACHED TO AIR AND WATER LINES**

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For any device connected to the air/water system that enters the patient's mouth (e.g., low-speed handpieces, high-speed handpieces, prophylaxis angles, and ultrasonic scalers), DHCP will:

- Discharge air/water for a minimum of 20–30 seconds after each patient.
- Ensure effectiveness and longevity of handpieces by following their IFU for cleaning, lubrication, and sterilization.
- Heat-sterilize between patients all dental handpieces and associated attachments, including low-speed motors and reusable prophylaxis angles. High-level or surface disinfection is not appropriate.
- Note that use of barriers does not replace the requirements for reprocessing of dental devices per their IFU.

Components of the dental operatory that are permanently attached to the unit and do not enter the patient's oral cavity (e.g., air evacuators and air/water devices) should be:

- Wiped down after each use with a germicidal disposable wipe that contains an EPA-registered hospital-grade disinfectant, per the IFU.
- Covered with FDA-cleared impervious barriers that are changed after each patient.

## **SALIVA EJECTORS**

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Studies have reported that backflow in low-volume suction lines can occur, and microorganisms present in the lines are retracted into the patient's mouth, when a seal around the saliva ejector is created.

### **Recommendations to prevent cross-contamination include:**

- Patients should be instructed to keep their mouths open and not to close their lips around the tip.
- The high-volume evacuation metal ejector system is to be cleaned or autoclaved between patients in accordance with the IFU. Cleaning is done by evacuating a detergent or water-based detergent-disinfectant through the system in accordance with the IFU.
- The IFU determines when traps are to be replaced.
  - ➔ *DHCPs should wear PPE when cleaning or replacing these traps to avoid contact via splashing or direct contact with patient materials in the lines.*

## **DENTAL RADIOLOGY**

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- Appropriate barriers should be utilized to protect the x-ray cone and activation button.
- Panoramic bite blocks should be covered by appropriate barriers or reprocessed per their IFU.
- Patient-treatment gloves should be worn when taking radiographs and handling contaminated sensors or packets.
- If splattering of blood or other body fluids is likely, utilize proper PPE (see [personal protective equipment](#) above).
- FDA-cleared protective barriers should be used for digital sensors or phosphor storage plates (PSP).
- Refer to the IFUs for sensors and PSPs for cleaning and disinfection protocols between patients.
- All sensor/PSP holders should be sterilized between patients, following the appropriate IFUs.
- Sensors currently used in the BOP cannot be heat-sterilized; therefore, digital radiography sensors should be protected by an FDA-cleared barrier during use and then cleaned and disinfected with an EPA-registered hospital-grade, intermediate-level disinfectant (tuberculocidal claim) between patients. Always refer to the manufacturer's IFU.

## **SINGLE-USE OR DISPOSABLE DEVICES**

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- These items are designed to be used on one patient and then discarded (not reprocessed).
- The BOP Dental Program recommends the use of disposable devices that include, but are not limited to, the following: burs, endodontic files, high-volume evacuators, saliva ejectors, and irrigation syringes. Items that do not have instructions for use for reprocessing should be determined to be single-use only and discarded appropriately (*CFR, Title 21, Part 801 Adequate Instructions and FDA 510 (k) Program*).
  - ➔ *All items must have an IFU from the manufacturer indicating that the device can be reprocessed (sterilized); otherwise, they are considered to be single-use devices.*
- Single-use patient-care items are usually not heat-resistant, and therefore cannot be reliably processed.
- Single-use devices for oral surgical procedures that are not packaged as sterile or have an IFU to achieve sterility should be sterilized prior to the time of use.

## **HANDLING OF BIOPSY SPECIMENS**

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- A sturdy, leak-proof container with a secure lid is provided for each specimen. Please contact the laboratory for mailing instructions.
- Avoid contaminating the outside of the container with any of the materials from the biopsy.
- Ensure that each container has a label with the biohazard symbol during storage, transport, shipment, and disposal.

## **HANDLING OF EXTRACTED TEETH**

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- OSHA considers extracted teeth to be potentially infectious material that should be disposed in regulated medical waste containers.
  - ➔ [Appendix 2](#) provides guidance for Native Americans requesting their extracted teeth.
- Extracted teeth containing amalgam restorations should not be placed into regulated medical waste containers that use incineration for final disposal.
  - ▶ Commercial metal-recycling companies may accept extracted teeth with metal restorations, including amalgam. State and local regulations should be consulted regarding the disposal of amalgam. Please consult with the ESCA regarding local requirements. Additional information about amalgam waste may be found at the ADA and EPA websites.
  - ▶ Refer to *Program Statement 6400.03* for proper disposition of intraoral precious metal.

## **DENTAL LABORATORY PROCEDURES**

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- Metal impression trays and other heat-tolerant prosthodontic patient-care items will be cleaned and heat-sterilized. Disposable impression trays should be used when clinically acceptable.

- Clean and disinfect impressions as soon as possible after removal from patient's mouth.
- Dental items should be thoroughly cleaned, disinfected with an EPA-registered, hospital-grade, intermediate-level disinfectant (tuberculocidal claim), and thoroughly rinsed before being sent out to an off-site dental lab.
- When a laboratory case is sent off-site, DHCP should provide written information on the lab prescription about the type of disinfectant used and the exposure time.
- All returned laboratory cases should be disinfected by the DHCP before placement (interim procedures or final delivery).

## **LASER/ELECTROSURGERY PLUMES OR SURGICAL SMOKE**

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- Use Standard Precautions such as the use of a high-filtration N-95 surgical mask, central room suction units with inline filters to collect particulate matter, and dedicated mechanical smoke exhaust evacuation systems.

## ***M. TUBERCULOSIS***

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- Patients infected with *M. tuberculosis* (TB) occasionally seek urgent dental treatment. Only patients with an active TB (non-latent) infection may be contagious and present a risk of transmission to DHCP.
- If urgent dental care is provided for a patient with communicable active TB disease, the care should be provided in a facility that provides airborne infection isolation (negative-pressure isolation room).
  - ▶ Standard surgical face masks do not protect against TB transmission, and DHCP should use respiratory protection such as a fit-tested, disposable N-95 respirator.
  - ▶ If patient care cannot be provided locally, consideration should be given to an offsite provider with the appropriate facilities.

## **CREUTZFELDT-JAKOB DISEASE (CJD) AND OTHER PRION DISEASES**

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**Precautions for patients with prion diseases include the following:**

- Using single-use, disposable items and equipment whenever possible.
- Keeping used instruments moist until cleaned and decontaminated.
- Cleaning instruments thoroughly and then steam-autoclave.

## **CHEMICAL DISPOSAL**

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- **For all chemicals utilized within this document, the IFU and respective safety data sheet (SDS) should be adhered to regarding use and proper environmental disposal.**
- **All chemicals should be reviewed with the local ESCA—prior to purchase—to ensure that they meet local regulations.**

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## 5. INFECTION CONTROL PROGRAM EVALUATION

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A systematic evaluation of a dental unit's infection control program is required to ensure compliance with the standard of care set forth by the *2003/2016 CDC Guidelines/Summary*. Evaluation of a dental unit's program should include standard elements that are reviewed by an auditing agency.

- ➔ *The CDC 2016 Summary provides an infection prevention checklist and should be referenced for evaluation and training purposes. See Sections I and II (pp. 21–27), available at: <http://www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-care.pdf>*

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## 6. REFERENCES

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<http://www.fda.gov/downloads/MedicalDevices/.../UCM079092.pdf>

U.S. Food and Drug Administration. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff. March 17, 2015. Available at:  
<https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf>

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## 7. INFECTION CONTROL INTERNET RESOURCE WEBSITES

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**American Dental Association (ADA):**

<http://www.ada.org>

**Centers for Disease Control and Prevention (CDC) –  
Infection Prevention & Control Guidelines & Recommendations:**

<http://www.cdc.gov/oralhealth/infectioncontrol/guidelines/>

**Environmental Protection Agency (EPA):**

<http://www.epa.gov>

**Occupational Safety and Health Administration (OSHA) –  
Dentistry and Bloodborne Pathogens:**

<http://www.osha.gov/SLTC/dentistry/index.html>

<http://www.osha.gov/SLTC/bloodbornepathogens/index.html>

**Organization for Safety and Asepsis Procedures (OSAP):**

<http://www.osap.org>



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## APPENDIX 1. GLOSSARY

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**ALCOHOL-BASED HAND RUB:** An alcohol-containing preparation designed for reducing the number of viable microorganisms on the hands.

**ANTIMICROBIAL SOAP:** A detergent containing an antiseptic agent.

**ANTISEPTIC:** A germicide used on skin or living tissue for the purpose of inhibiting or destroying microorganisms.

**ASEPTIC TECHNIQUE:** A technique that prevents or reduces the spread of microorganisms from one site to another, such as from patient to DHCP, from patient to operatory surfaces, or from one operatory surface to another.

**BIOBURDEN:** Microbiological load (i.e., number of viable organisms in or on an object or surface) or organic material on a surface or object before decontamination, or sterilization. Also known as **bioload** or **microbial load**.

**CLASS 5 INTEGRATING CHEMICAL INDICATOR (INTEGRATOR):** Integrating indicators are designed to react to all critical variables. The stated values are generated to be equivalent to, or exceed the performance requirements of Biological Indicators in saturated steam.

**COLONY-FORMING UNIT (CFU):** The minimum number (i.e., tens of millions) of separable cells on the surface of or in semisolid agar medium that give rise to a visible colony of progeny. CFUs can consist of pairs, chains, clusters, or as single cells and are often expressed as colony-forming units per milliliter (CFUs/mL).

**DECONTAMINATION:** Use of physical or chemical means to remove, inactivate, or destroy pathogens on a surface or item so that they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

**DENTAL HEALTH-CARE PERSONNEL (DHCP):** Refers to all paid and unpaid 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 include 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). This broad definition of personnel is to include all staff, contractors, and inmate dental assistants in the certification program.

**DENTAL TREATMENT WATER:** Nonsterile water used during dental treatment, including irrigation of nonsurgical operative sites and cooling of high-speed rotary and ultrasonic instruments.

**DISINFECTANT:** A chemical agent used on inanimate objects (e.g., floors, walls, or sinks) to destroy virtually all recognized pathogenic microorganisms, but not necessarily all microbial forms (e.g., bacterial endospores). The U.S. Environmental Protection Agency (EPA) groups disinfectants on the basis of whether the product label claims limited, general, or hospital disinfectant capabilities.

**DISINFECTION:** Destruction of pathogenic and other kinds of microorganisms by physical or chemical means. Disinfection is less lethal than sterilization, because it destroys the majority of recognized pathogenic microorganisms, but not necessarily all microbial forms (e.g., bacterial spores). Disinfection does not ensure the degree of safety associated with sterilization processes.

**ENDOTOXIN:** The lipopolysaccharide of gram-negative bacteria, the toxic character of which resides in the lipid protein. Endotoxins can produce pyrogenic reactions in persons exposed to their bacterial component.

**FDA-APPROVED:** Approved medical devices are those devices for which FDA has approved a premarket approval (PMA) application prior to marketing. This approval process is generally reserved for high-risk medical devices and involves a more rigorous premarket review than the 510(k) pathway.

**FDA-CLEARED:** These medical devices are ones that FDA has determined to be substantially equivalent to another legally marketed device. A premarket notification, referred to as a 510(k), must be submitted to FDA for clearance. A 510(k) is most often submitted by the medical device manufacturer.

**GERMICIDE:** An agent that destroys microorganisms, especially pathogenic organisms. Terms with the same suffix (e.g., virucide, fungicide, bactericide, tuberculocide, and sporicide) indicate agents that destroy the specific microorganism identified by the prefix. Germicides can be used to inactivate microorganisms in or on living tissue (i.e., antiseptics) or on environmental surfaces (i.e., disinfectants).

**HAND HYGIENE:** General term that applies to handwashing, antiseptic handwash, antiseptic hand rub, or surgical hand antisepsis.

**HAND ANTISEPSIS:** Refers to either antiseptic handwash or antiseptic hand rub.

**HIGH-LEVEL DISINFECTION:** Disinfection process that inactivates vegetative bacteria, mycobacteria, fungi, and viruses but not necessarily high numbers of bacterial spores. FDA further defines a high-level disinfectant as a sterilant used for a shorter contact time.

**HOSPITAL DISINFECTANT:** Germicide registered by EPA for use on inanimate objects in hospitals, clinics, dental offices, and other medical-related facilities. Efficacy is demonstrated against *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.

**IATROGENIC:** Induced inadvertently by health care personnel, medical (including dental) treatment, or diagnostic procedures; used particularly in reference to an infectious disease or other complication of treatment.

**IFU:** For the purposes of this CG, IFU implies a manufacturer's adequate directions for use (notably a manufacturer's reprocessing instructions for reusable dental devices) that have been validated by the FDA's labeling criteria. IFU also implies any manufacturer's recommendations or instructions not specific to reprocessing instructions for reusable dental devices. **Other terms used that are synonymous with IFU include, but are not limited to: (1) adequate directions for use, (2) manufacturer's instructions or recommendations, (3) manufacturer's reprocessing instructions, and (4) manufacturer validated instructions.**

**IMMUNIZATION:** Process by which a person becomes immune, or protected against a disease. Vaccination is defined as the process of administering a killed or weakened infectious organism or a toxoid; however, vaccination does not always result in immunity.

**IMPLANTABLE DEVICE:** Device placed into a surgically or naturally formed cavity of the human body and intended to remain there for  $\geq 30$  days.

**INDEPENDENT WATER RESERVOIR:** Container used to hold water or other solutions and supply it to handpieces and air and water syringes attached to a dental unit. The independent reservoir, which isolates the unit from the public water system, can be provided as original equipment or as a retrofitted device.

**INTERMEDIATE-LEVEL DISINFECTION:** Disinfection process that inactivates vegetative bacteria, the majority of fungi, mycobacteria, and the majority of viruses (particularly enveloped viruses), but not bacterial spores.

**INTERMEDIATE-LEVEL DISINFECTANT:** Liquid chemical germicide registered with EPA as a hospital disinfectant and with a label claim of potency as tuberculocidal.

**LATEX:** Milky white fluid extracted from the rubber tree *Hevea brasiliensis* that contains the rubber material cis-1,4 polyisoprene.

**LOW-LEVEL DISINFECTION:** Process that inactivates the majority of vegetative bacteria, certain fungi, and certain viruses, but cannot be relied on to inactivate resistant microorganisms (e.g., mycobacteria or bacterial spores).

**LOW-LEVEL DISINFECTANT:** Liquid chemical germicide registered with EPA as a hospital disinfectant. OSHA requires low-level hospital disinfectants also to have a label claim for potency against HIV and HBV if used for disinfecting clinical contact surfaces.

**MICROFILTER:** Membrane filter used to trap microorganisms suspended in water. Filters are usually installed on dental unit waterlines as a retrofit device. Microfiltration commonly occurs at a filter pore size of 0.03–10  $\mu\text{m}$ . Sediment filters commonly found in dental unit water regulators have pore sizes of 20–90  $\mu\text{m}$  and do not function as microbiological filters.

**OCCUPATIONAL EXPOSURE:** Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or OPIM (see below) that can result from the performance of an employee's duties.

**OPIM:** Other potentially infectious materials. OPIM is an OSHA term that refers to **(1)** body fluids including semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures; any body fluid visibly contaminated with blood; and all body fluids in situations where differentiating between body fluids is difficult or impossible; **(2)** any unfixed tissue or organ (other than intact skin) from a human (living or dead); and **(3)** HIV-containing cell or tissue cultures, organ cultures; HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

**PARENTERAL:** Means of piercing mucous membranes or skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

**PRION:** Protein particle lacking nucleic acid that has been implicated as the cause of certain neurodegenerative diseases (e.g., scrapie, CJD, and bovine spongiform encephalopathy [BSE]).

**RETRACTION:** Entry of oral fluids and microorganisms into waterlines through negative water pressure.

**STANDARD PRECAUTION:** The minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where health care is delivered.

**STERILE:** Free from all living microorganisms; usually described as a probability (e.g., the probability of a surviving microorganism being 1 in 1 million).

**STERILIZATION:** Use of a physical or chemical procedure to destroy all microorganisms including substantial numbers of resistant bacterial spores.

**SURFACTANTS:** Surface-active agents that reduce surface tension and help cleaning by loosening, emulsifying, and holding soil in suspension, to be more readily rinsed away.

**SURGICAL HAND ANTISEPSIS:** Antiseptic handwash or antiseptic hand rub performed preoperatively by surgical personnel to eliminate transient and reduce resident hand flora. Antiseptic detergent preparations often have persistent antimicrobial activity.

**ULTRASONIC CLEANER:** Device that removes debris by a process called cavitation, in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces.

**VACCINE:** Product that induces immunity, therefore protecting the body from the disease. Vaccines are administered through needle injections, by mouth, and by aerosol.

**WASHER-DISINFECTOR:** Automatic unit that cleans and thermally disinfects instruments, by using a high-temperature cycle rather than a chemical bath.

**WICKING:** Absorption of a liquid by capillary action along a thread or through the material (e.g., penetration of liquids through undetected holes in a glove).

## APPENDIX 2. DISPOSAL OF NATIVE AMERICAN TEETH



U.S. Department of Justice  
Federal Bureau of Prisons

Washington, D.C. 20534

November 28, 2012

MEMORANDUM FOR ALL DENTAL STAFF

FROM: CAPT Nick Makrides, Chief Dentist  
Health Services Division

SUBJECT: Disposal of Native American Teeth

Extracted teeth are considered infectious and disposed as regulated medical waste. Occasionally, Native American inmates may request permission to ceremonially dispose their extracted teeth. After consultation with the Chaplaincy Services Branch, we suggest the following procedures for fulfillment of this sincerely held religious belief.

1. Dental staff refer inmate's request to ceremonially dispose of the tooth to the Chaplain's office.
2. The Chaplain(s) contact the inmate's family to verify that they agree to receive the shipped tooth.
3. The inmate is advised of the shipping charges, for which he/she is responsible.
4. While wearing personal protective equipment, the Dental staff thoroughly rinses the tooth to remove all traces of blood and surface disinfected with an EPA-registered hospital disinfectant with intermediate-level activity.
5. The Dental Staff follows the American Dental Association Guidelines for handling extracted teeth  
[http://www.ada.org/sections/professionalResources/pdfs/cdc\\_handling\\_extracted.pdf](http://www.ada.org/sections/professionalResources/pdfs/cdc_handling_extracted.pdf).
6. Dental staff then follows established procedures for inmate shipments through R&D after packaging in a leak-proof bag (i.e., ZipLoc).

Should you have any questions regarding this instruction please contact your Regional Chief Dentist.

cc: Michael R. Smith, Chief, Chaplaincy Services