College of Dental Surgeons of Alberta

Standard of Practice: Infection Prevention and Control Standards and Risk Management for Dentistry

January 2023

The Alberta Dental Association and College is now operating under the name College of Dental Surgeons of Alberta. This name will become official when Alberta's *Health Professions Act* is amended.

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Introduction

Since January 1, 2011, the College of Dental Surgeons of Alberta (CDSA) has required that Infection Prevention and Control (IPC) Standards must be fully implemented in all dental offices. The principles and procedures in this document, *Standard of Practice, Infection Prevention and Control Standards and Risk Management for Dentistry* must be followed by dentists in Alberta. Failure to do so may constitute unprofessional conduct under the *Health Professions Act* (HPA) and may result in disciplinary action by the CDSA.

The goals of this Standard of Practice are to:

- control and prevent the transmission of microorganisms to patients, personnel, the public, and the environment;
- minimize the risk of harm to patients and personnel;
- promote the safe use of single-use medical devices; and
- support health profession regulatory colleges, health care professionals, and other personnel who use or reprocess medical devices.

The standards set out in this document were developed using the Alberta Health, Government of Alberta *Reusable & Single-Use Medical Devices Standards*, and the *CSA Z314-18 Canadian Medical Device Reprocessing* standards prepared by the Canadian Standards Association (CSA). These Standards are consistent with recommendations and guidelines from Alberta Health, Alberta Health Services (AHS), Health Canada, the Public Health Agency of Canada (PHAC), and the Spaulding Classification System.

This standard applies to all clinical, laboratory and medical device reprocessing area settings.

All sterilizers used in dental clinics must come equipped with either a printer or an electronic data recorder that records cycle parameters. Sterilizers without this capability must be adapted or replaced by January 1, 2023.

Numerous terms in this Standard of Practice are defined in the Definitions (see page 26). Readers are advised to consult the definitions when reviewing this Standard.

1.0 Written Policies and Procedures

1.1 The dental office or clinic must have written IPC policies and procedures. These policies and procedures must include but are not limited to:

1.1.1 The reporting structure of individuals who have authorization, responsibility, and accountability to develop, approve, monitor, and maintain all IPC and risk management policies and procedures;

1.1.2 A hand hygiene policy and procedure must be developed by each dental office/clinic that includes the following:

- Indications for hand hygiene;
- Selection of hand hygiene agent;
- Management of soap containers and Alcohol-Based Hand Rub (ABHR);
- Hand lotion use;
- Use of ABHRs; and
- Hand hygiene monitoring and compliance audits.

1.1.3 The selection, acquisition, transportation, receiving, handling, processing, and disposal of new, loaned, shared, and leased dental instruments and devices;

1.1.4 Manufacturer's Instructions for Use (MIFU) regarding maintenance and reprocessing;

1.1.5 Sterilization processes following IPC principles as set out in the CDSA Standards; and

1.1.6 The protection and safety of personnel in accordance with the Alberta *Occupational Health and Safety Act* (OHS).

1.2 The dentist must ensure that the Dental Health Care Personnel (DHCP) employed by the dentist are aware and comply with the documentation required for IPC and OHS purposes.

1.3 The dental clinic owner and dentists working in each facility must review all policies annually to ensure policies are kept up-to-date with all current CDSA Standards of Practice.

1.3.1 IPC training and continuing education must be in accordance with the CDSA Standards of Practice.

2.0 Patient Evaluation

2.1 It is the dentist's responsibility to assess/perform a medical history for every patient. This must include a point-of-care risk assessment with each patient interaction for all patients at all times to determine which, if any, IPC measures beyond routine practice need to be used.

2.2 Dentists must be vigilant with respect to the signs, symptoms and epidemiology of various communicable diseases when presented, including blood-borne pathogens, Methicillin Resistant Staphylococcus aureus (MRSA), Pseudomembranous colitis (*Clostridium difficile* infection), Severe acute respiratory syndrome (SARS-CoV-1) and COVID-19 (SARS-CoV-2) and other influenza-like illnesses, Tuberculosis (patients with active TB should have their treatment delayed, if at all possible, until they are no longer infectious, or they should be referred to a more controlled environment for treatment) and Vancomycin Resistant Enterococcus (VRE).

Additional (transmission-based) Precautions:
Additional (transmission-based) precautions are taken while ensuring routine practices are maintained in the following situations.

2.2.1 Airborne Precautions must be used in addition to Routine Practices for patients with influenza-like illnesses or tuberculosis.

2.2.2 Contact Precautions (including gowns for example) must be used in addition to Routine Practices for patients with known or suspected MRSA, Clostridium difficile or VRE colonization or infection.

2.3 Dental offices must have a respiratory protection plan in place, which takes into consideration the chemical, biological, or environmental hazard determined in a point-of-care risk assessment performed prior to each clinical, laboratory, or reprocessing task.

3.0 Hand Hygiene

3.1 Proper hand hygiene must be performed by the dentist and all DHCP:

3.1.1 Before and after contact with any patient, their body substances or items contaminated by them and after handling soiled equipment.

3.1.2 Before and after performing invasive procedures.

3.1.3 Before preparing, handling, serving, or eating food.

3.1.4 After assisting patients with personal care (providing oral hygiene or oral hygiene instruction).

3.1.5 Before putting on (Donning) and after taking off (Doffing) gloves and any personal protective equipment (PPE).

3.1.6 After performing personal functions (e.g., using the toilet, blowing nose).

3.1.7 When hands come into contact with secretions, excretions, blood or bodily fluids.

3.1.8 Before handling clean supplies and setting up.

3.2 The hands of the DHCP must be washed using appropriate soap, water, and disposable towel combination at the beginning of the workday, after eating, after using the washroom or whenever the hands become contaminated with blood, saliva, or other bodily fluid, or have been in contact with contaminated instruments or devices. Although a separate sink for hand hygiene is desirable, sinks that have been used by patients to expectorate in or sinks that have been used to decontaminate instruments must be cleaned, disinfected, and identified before being used by DHCP for hand washing.

3.3 The hands of the DHCP must undergo antisepsis, using either appropriate soap, water, disposable towel combination or an appropriate ABHR containing 60-90% alcohol with products that have a Health Canada Drug Identification Number (DIN) or Natural Product Number (NPN) prior to beginning patient treatment before donning gloves, between patients after removing gloves or whenever gloves are changed during a patient visit. ABHRs are to be used only if the hands are not visibly soiled.

3.4 Soap and ABHR dispensers must be used (including pump assemblies), if not single-use, must be cleaned and dried prior to refilling. A cartridge system that cannot be topped up is preferred.

3.5 DHCP must not wear hand jewellery, other than smooth metal band rings, when performing hand hygiene or during clinical treatment. All hand jewellery must be removed when invasive dental procedures are performed.

3.6 DHCP must not wear artificial nails, nail enhancements or long nails. Fingernails shall be kept short (less than 3-4mm). The nail shall not show past the end of the finger.

3.6.1 DHCP must not have chipped nail polish on their fingers. Only nail polish that is fresh and free of all cracks or chips is acceptable.

3.7 DHCP must not use a standing basin of water to rinse hands.

3.8 DHCP must use disposable hand towels to dry hands after hand hygiene.

3.9 DHCP must not use non-alcohol based waterless antiseptic agents for hand hygiene.

4.0 Personal Protective Equipment (PPE)

4.1 DHCP must wear new single-use exam gloves for patient care, whenever the hands might be contaminated with blood, saliva, or other bodily fluid, or will be in contact with contaminated instruments or devices.

4.1.1 DHCP must wear sterile gloves whenever invasive surgical procedures are performed. This includes:

- Whenever intentional gingival, mucosal, or dermal flaps are raised; and
- Whenever the cutting or sectioning of bone is anticipated; and whenever a simple procedure becomes a surgical procedure (e.g., a tooth breaking that then requires surgical extraction).

4.1.2 DHCP must wear chemical resistant, puncture proof utility gloves when reprocessing instruments. Selection and use of PPE, including gloves, must provide proper

protection and be appropriate to the task considering necessary dexterity for cleaning.

4.2 DHCP must wear a surgical mask that covers the nose and mouth during dental procedures whenever splashes, sprays or spatter of blood, saliva, other body fluids, or water contaminated with blood, saliva or other body fluids may be produced. The mask must be changed whenever it becomes contaminated or wet or according to MIFU.

4.3 DHCP must wear protective eyewear (e.g., safety glasses, safety googles or face shields as determined by a point-of-care risk assessment) during dental procedures whenever splashes, sprays or spatter of blood, saliva, other body fluids, or water contaminated with blood, saliva or other body fluids may be produced.

4.4 All PPE must be removed prior to leaving the patient care area.

4.5 All PPE (utility gloves, gowns, protective eyewear, and masks) must be worn by DHCP during instrument decontamination and removed when completed.

4.6 A face shield does not replace a mask.

5.0 Laundering for Onsite Linens and Reusable PPE

5.1 Laundry in a dental office may include gowns/lab coats, uniforms/scrubs, contaminated textiles, and fabrics often contain high numbers of microorganisms from body substances, including blood other body tissues and fluids. Laundry services for dental offices are provided either onsite or by off-site commercial laundries. To minimize transmission of infectious disease while handling linen, general good hygiene measures and consistent use of appropriate personal protective equipment is recommended. When laundry services are possible onsite, utilize the following guidelines.

At home laundry of contaminated PPE must not be performed.

If using an off-site laundry service, there must be written documentation that the service meets or exceeds with the requirements of this section.

Handling of Soiled Linens

5.1.1 Appropriate PPE (e.g., gloves and long sleeve gowns) shall be worn while sorting soiled laundry or linens when there is a risk of clothing being contaminated by blood and bodily fluids.

5.1.2 Remove PPE including gloves once soiled laundry has been placed in the laundry bag/covered hamper.

- Handle soiled laundry with minimum agitation before placing it in a laundry bag at point-of-care to avoid contamination of environmental surfaces and people.

5.1.3 Perform hand hygiene following taking off PPE.

- Gloves are not needed to transport the laundry bag/ covered hamper to the soiled laundry room.

Washing Soiled Linen

5.1.4 Wash and dry linen according to routine standards and laundering practices of the dental office.

5.1.5 Avoid overloading the machine.

5.1.6 Follow detergent instructions for load size and load soiling.

5.1.7 Follow manufacturer written instructions regarding amount of detergent and water

temperature.

- Use complete wash, rinse, and dry cycles.
- Hot-water laundry cycles, wash with detergent or disinfectant in water at 70°C (160°F) for at least 25 minutes.
- If low-temperature (i.e., < 70°C; < 160°F) laundry cycles are used, choose a chemical that is suitable for low-temperature washing when used at the proper concentration.
- A disinfectant can be used to enhance the overall disinfection of the laundry process when there is heavy soiling. Use as per MIFU.

5.1.8 Run empty washer with 1 chlorine disinfectant tablet (equivalent to 1 cup of chlorine bleach) and water between loads ONLY after heavily soiled loads of linen or if patient is on Additional Precautions.

- Chlorine bleach tablets must be stored securely and used in a manner that follows the product's posted safety data sheet.

5.1.9 After loading the washer with soiled linen, clean and disinfect all high touch surfaces of the washer (washer surfaces, knobs, door pulls, buttons/switches etc.) to avoid re-soiling when it is unloaded. All washers and dryers must be left empty at the end of the operating day.

5.1.10 Wash hands with soap and water after handling soiled linen.

5.1.11 Follow manufacturer recommendations for the maintenance and cleaning of the washing machine and dryer. Keep a log these activities.

Handling and Storing Clean Linen

5.1.12 Dry linen promptly. Laundered items shall be taken out of the washer as soon as feasible to reduce the risk of contaminating the washer and formation of biofilm.

5.1.13 Perform hand hygiene before removing clean linen from the washing machine.

5.1.14 Fold linen on a clean surface with clean hands.

5.1.15 Store clean linen in a clean dry place such as a dedicated clean linen storage room or clean linen shelf/cart (constructed from plastic, stainless steel or suitable non-porous) material that is cleanable.

5.1.16 Avoid storing linen in patient care rooms. Unused linen left after patient discharge is considered contaminated. Any linen that enters a patient room shall only exit that room in a soiled linen laundry bag.

6.0 Purchasing and Assessing Dental Instruments and Devices and Products for Disinfection or Sterilization Processes

The decision to purchase a reusable medical device requires many considerations including the capacity of the organization's MDR resources to safely reprocess the medical device for re-use.

6.1 Dentists must ensure that all instruments, medical devices and chemical products are licensed by Government of Canada's *Medical Devices Regulations* and are used within these licensing parameters. Dental suction units are considered to be medical devices and as such must have a license issued by Health Canada Medical Devices Bureau in accordance with the Medical Devices Regulations, Section 36. Reusable dental instruments and devices that cannot be reprocessed according to the manufacturer's instructions and

CDSA standards must not be used.

6.1.1 The dentist shall not purchase or trial a reusable medical device that does not have a valid medical device licence.

6.2 Instrument manufacturers are required to identify at least one method of sterilization in their instructions for use. Both pre-vacuum and steam flush pressure pulse (SFPP) are recognized as standard dynamic air removal cycles. However, many instrument manufacturers recommend processing with a standard pre-vacuum cycle in their instructions for use and end users may be uncertain if the SFPP cycle can be substituted.

6.2.1 Since both pre-vacuum and SFPP cycles are considered of the dynamic air removal type, if an instrument manufacturer's instructions for use state that a pre-vacuum cycle with sterilize time of 4 minutes 270F° (132°C) or 3 minutes 275°F (135°C) shall be used for processing, the SFPP cycle with a sterilize time of 4 or 3 minutes, respectively, may be substituted.

6.3 DHCP must comply with *Occupational Health and Safety Act* (OHS) requirements.

6.4 The dental clinic must have available from the manufacturer of all reusable dental devices:

6.4.1 Information about the design of the dental device; manuals/direction for use;

6.4.2 Dental device-specific recommendations for cleaning and reprocessing of device;

6.4.3 Personnel training materials on the use, cleaning, and the correct reprocessing of all dental devices; and

6.4.4 Recommendations for monitoring the procedures required for reprocessing of the device.

6.5 Newly purchased non-sterile critical and semi-critical dental instruments and devices must be inspected and processed according to MIFU prior to use. Examples would include, but not be limited to burs, endodontic files, implant parts, etc.

6.6 Surgical instruments that are used on low risk neurological tissue (e.g., dental pulp tissue) from patients at high risk for Creutzfeldt-Jakob Disease (CJD) must be disposed of, or decontaminated in accordance with Health Canada and the Public Health Agency of Canada's *Infection Control Guidelines: Classic Creutzfeldt-Jakob Disease in Canada - Quick Reference Guide*

6.7 Non-critical medical devices intended for use between patients shall be purchased with validated MIFU for reprocessing when available, and when not available, a standard operating procedure (SOP) shall be developed in consultation with IPC and MDR personnel.

Note: *Dentists may need to go outside their organization to find the appropriate IPC and MDR expertise to develop reprocessing SOP for non-critical medical devices.*

6.8 Prior to purchasing or trialing a reusable critical or semi-critical medical device, the dentist shall confirm that there is written confirmation that the MIFU for reprocessing have been validated according to Health Canada's requirements.

6.8.1 The dentist shall not purchase or trial a reusable critical or semi-critical medical device if there is no written confirmation that the MIFU for reprocessing have been validated.

6.9 Prior to purchasing or trialing a reusable critical or semi-critical medical device, personnel accountable for MDR shall review the written, validated MIFU to determine:

6.9.1 That the recommended reprocessing procedures are specific to the dental or medical device and the instructions are clear, complete, adequate, and in accordance with the level of reprocessing required for the dental or medical device's

intended use.

6.9.2 That there are instructions for disassembly, cleaning, type of sterilization or level of disinfection required, cycle parameters, and maintenance.

6.9.3 If there is a limit to the number of times the dental or medical device can be reprocessed (i.e., if the dental device is a reposable device) or if reprocessing will contribute to degradation of the dental or medical device; and

6.9.4 That the recommended reprocessing procedures can be achieved, given the dentist's reprocessing resources.

6.10 In the event that the MIFU does not contain the information required in 6.9.1, 6.9.2, and 6.9.3, the dentist shall contact the manufacturer for clarification or additional information.

Note: Dental offices that are not able to obtain the relevant information should report this to Health Canada at:

a) mdpr-dimm@hc-sc.gc.ca; or

b) https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-medical-device-problem-reporting-form-industry-adverse-reaction-reporting.html

6.11 Before purchasing reprocessing equipment, the dentist shall:

6.11.1 Obtain technical and safety data, specifications, and other information specific to the equipment for required utilities and connections (e.g., electrical, steam, water, plumbing, air supply, and ventilation); and

6.11.2 Ensure the minimum service space requirements set out by the manufacturer can be met.

7.0 Selection of Products and Processes for Reprocessing

7.1 All reusable dental instruments and devices must have written device-specific manufacturer's cleaning, decontamination, disinfection, wrapping and sterilization instructions.

7.1.1 The processes and products used for reprocessing must be compatible with each other and the device.

7.1.2 The reprocessing processes and products used in the reprocessing of a dental instrument or device must be determined by the intended use of the device in accordance with the Spaulding Classification.

7.1.3 If disassembly or reassembly is required, responsible DHCP must ensure that MIFU used includes detailed instructions and diagrams.

7.2 The dentist is ultimately responsible for the selection of products and processes for reprocessing. The delegation of this responsibility must only be to an individual whose competency in the area of instrument reprocessing has been demonstrated to the dentist.

7.2.1 Staff training must be provided on disassembly, reassembly and reprocessing before the dental instrument or device is placed into use.

8.0 Environmental and Structural Requirements for a Medical Device Reprocessing (MDR) Area

8.1 The MDR area shall be a designated area, separate from clinical care areas, and activity in the area shall be restricted to the reprocessing of reusable dental or medical devices.

8.2 The reprocessing space must:

8.2.1 Have adequate space for the cleaning process and storage of necessary equipment and supplies;

8.2.2 Have physically or spatially separate decontamination areas from areas where clean, disinfected, or sterile dental instruments and devices are handled or stored;

8.2.3 Have easy access to hand hygiene facilities;

8.2.4 Have surfaces that can be easily cleaned;

8.2.4.1 All work surfaces and surrounding area shall be intact, cut-resistant, and seamless, and shall be composed of non-porous, non-shedding material capable of withstanding frequent cleaning.

8.2.5 Have one-way movement of instruments through the reprocessing process, from dirty to sterile;

8.2.5.1 In existing facilities where physical separation (i.e., with walls or partitions) of reprocessing areas is not possible, spatial separation and a one-way workflow pattern must be established to limit cross-contamination.

8.2.6 Have air changes, temperature, and humidity appropriate to the process and product being used as set out by MIFU;

8.2.7 Have adequate lighting for the tasks being performed in all work locations;

8.2.8 New construction, office renovation or relocation must consider environmental, structural and ventilation considerations, including a separate room for reprocessing with one-way instrument and personnel flow; and

8.2.9 In existing facilities or settings where two adjacent sinks dedicated for equipment cleaning and rinsing are not possible have a dedicated basin for rinsing equipment.

Note: *In any new construction, future renovation, or relocation of the MDR area should comply with this Standard. (Have at least two adjacent sinks, large enough to immerse the largest piece of equipment, to clean and rinse soiled items). Notwithstanding 8.2.9, in facilities or settings where two adjacent sinks dedicated for equipment cleaning and rinsing are not possible, a dedicated basin for rinsing equipment.*

8.3 The dental clinic must use a water supply which is tested for and free of contaminants, such as a monitored municipal water supply.

8.3.1 Sterile water or sterile saline must be used for irrigation during surgery where there are open vascular sites or whenever bone is cut.

8.4 Forward venting handpieces are NOT to be used for surgical or invasive procedures. It is important to understand and recognize issues like air embolisms that may occur.

8.5 The dental clinic must have written contingency plans for loss of potable water, boil water advisories and other situations where the water supply becomes compromised.

8.6 DHCP must not touch non-barrier protected environmental surfaces (e.g., doorknobs, cupboards, pens, computer keyboard or mouse, clipboards, etc.) with contaminated gloves during or after patient treatment.

8.7 The dental office premises must be kept neat, clean, and free of exposed waste material.

9.0 Pre-Cleaning, Transportation and Handling of Contaminated Dental Instruments

and Devices

9.1 Disposable sharps must be removed and disposed of in an approved sharps container at the point of use, or immediately following transportation to the reprocessing area. Sharps containers must be labeled and disposed of according to local municipal regulations.

9.2 DHCP must be aware of the handling and proper disposal of biomedical waste and hazardous materials from a clinical office or clinic. The *Guide for Best Practice Management of Dental Office Waste* document has detailed instruction on best practice management in dental wastes.

9.2.1 Gauze which is heavily saturated with blood (i.e., dripping) or removed tissue must be disposed of in properly identified biohazardous containers and transported for final disposal according to local municipal regulations.

9.3 Personnel shall pre-clean used reusable dental or medical devices immediately after use and prior to transportation and further manual or automated cleaning.

9.3.1 At the point of use, single-use sharps shall be removed from reusable dental or medical devices and disposed of in a puncture-resistant sharps container.

9.3.2 Organic matter shall not be allowed to dry on reusable dental or medical devices. Reusable dental or medical devices shall be kept moist by using foam, spray, or gel specifically intended for this use, or by using a towel moistened with water, and in accordance with the MIFU.

9.4 All personnel who handle contaminated dental instruments and devices must handle those devices in a manner which reduces the risk of:

9.4.1 Exposure and/or injury to self, other personnel, and patients; and

9.4.2 Contamination of environmental surfaces.

9.5 From the point of use, contaminated critical and semi-critical dental instruments and devices must be taken directly to the area designated for handling contaminated devices and if required, initial disassembly completed.

9.6 Contaminated items shall be transported in covered, fully enclosed, leak-proof containers or closed carts that are designed to prevent the spill of liquids, protect reusable dental or medical devices from damage, and allow for effective decontamination after each use.

9.6.1 Sterile or clean reusable dental or medical devices and soiled reusable dental or medical devices shall be transported in a manner that prevents cross-contamination (i.e., in separate containers and carts).

9.7 Contaminated dental instruments and devices which have not been reprocessed must be clearly identified as not reprocessed by use of a labeling system such as colour coding or tagging.

9.8 Intra-operative sharpening of hand and dental hygiene instruments using a sterile stone is permitted with the following conditions:

9.8.1 Stones are sterilized according to validated MIFU written instructions; and

9.8.2 After sharpening, instruments must be wiped.

10.0 Preparation and Cleaning Reusable Dental Instruments and Devices

10.1 Reusable dental instruments and devices must be cleaned of all debris, including dental materials and bioburden before disinfection or sterilization.

10.2 The cleaning process must include sorting and disassembly (if required), cleaning, manual cleaning, automated cleaning, rinsing, and drying, reassembly, and inspection.

Sorting and Disassembly

10.3 All contaminated medical devices shall be inspected and sorted before reprocessing to ensure that the appropriate cleaning agents and procedures are applied to the correct devices.

10.4 All medical devices consisting of multiple components (e.g., minimally invasive surgical medical devices) shall be disassembled in accordance with the MIFU.

Cleaning

10.5 Each medical device shall be thoroughly cleaned prior to disinfection or sterilization.

10.6 Cleaning methods shall be consistent with the medical device's MIFU and appropriate for the type of medical device and the amount of soil to be removed.

10.7 While cleaning may be done by either a manual or automated process, critical and semi-critical medical devices shall be cleaned using an automated process whenever possible.

Manual Cleaning

10.8 If manual cleaning is required, the dental or medical device's MIFU for reprocessing shall be followed, including any specifications for detergent type, water type, or water temperature and cleaning methods.

10.9 Immersible dental or medical devices shall be completely submerged during cleaning to prevent the generation of aerosols and non- dental or medical devices shall be cleaned according to the MIFU.

Automated Cleaning

10.10 Automated washers and ultrasonic cleaners used for cleaning shall be used in accordance with the MIFU.

10.10.1 The performance of the automated cleaning system (e.g., automated washers) shall be tested according to specific MIFU each day that it is in use, using commercially available indicators or test kits. The results of the test shall be documented in a logbook.

10.10.2 Ultrasonic cleaners shall be tested for sonication performance (e.g., commercial methods or the foil test) weekly. The results of the weekly test results shall be documented in a logbook.

10.10.3 The ultrasonic detergent solution shall be changed at least daily or more frequently when visibly soiled or if the ultrasonic cleaner or solution MIFU specifies more frequent changes (e.g., with every cycle).

10.11 The dental or medical device's MIFU shall be followed to ensure dental or medical devices are compatible with the automated washer's process conditions (e.g., moisture, temperature, chemicals, water quality, and pressure).

Rinsing and Drying

10.12 Chemical residues and loosened soil shall be completely rinsed from the dental or medical device prior to disinfection or sterilization. Rinsing may be included as a final step in an automated cleaning process. If not, the dental or medical device shall be rinsed manually.

10.13 Reusable dental or medical devices shall be dried prior to disinfection or sterilization, as directed by the MIFU.

10.13.1 Unless dried using an automated process, the exterior surfaces of dental or medical devices shall be manually dried with a clean, lint-free, or low-lint soft-

absorbent towel.

Note: Drying of non-critical devices may be done by air-drying, or in accordance with the MIFU.

Reassembly

10.14 Decontaminated dental or medical devices shall be reassembled according to the MIFU. Reassembly shall take place in a clean and dry area.

- Corrosion reduction and/or lubrication shall be applied if required by the MIFU.

Inspection

10.15 Dental or Medical devices shall be visually inspected for cleanliness, damage, integrity, and functionality prior to disinfection, sterilization, or subsequent use.

10.15.1 Cleaned dental or medical devices that are visibly soiled shall be cleaned again.

10.15.2 Dental or medical devices that are damaged or in poor working condition shall be removed from service, labelled, and segregated from usable dental or medical devices. Such dental or medical devices shall either be repaired or disposed of in accordance with the documented SOPs.

10.16 In contrast to critical and semi-critical items, most non-critical reusable items may be decontaminated where they are used and do not need to be transported to a central MDR area. Low-level disinfectant (LLD) must be used as per MIFU for cleaning then disinfecting non-critical patient care items.

10.17 Reusable dental instruments must be cleaned with an instrument detergent or enzymatic product that is utilized according to MIFU and is discarded after each use.

10.18 Automated cleaning equipment (e.g., ultrasonic cleaners, instrument washers) must be operated and maintained according to MIFU and this must be documented.

10.19 Cleaning accessories (e.g., long-handled brushes) must be disposable or thoroughly cleaned and high-level disinfected or sterilized between uses.

10.19.1 Cleaning accessories shall be inspected before use to ensure they are not damaged. Damaged cleaning accessories shall not be used.

10.19.2 Reusable cleaning accessories shall be reprocessed after use in accordance with the MIFU, inspected for damage, and stored in a clean, dry place.

10.19.3 Single-use cleaning accessories shall be discarded following use.

10.20 Reusable dental or medical devices that come from an opened or compromised package shall be reprocessed prior to use.

11.0 Disinfection of Reusable Dental Instruments and Devices

11.1 Heat sensitive semi-critical dental instruments or devices must be disinfected as per MIFU using high-level disinfection or a pasteurization process.

11.1.1 X-Ray film packets are a single-use item and must be disinfected with a LLD prior to developing to avoid contamination of the radiograph processor. Digital X-Ray sensors must be barrier protected and, if contaminated, disinfected between patient use.

11.2 Disinfection of reusable dental or medical devices shall take place in accordance with the MIFU of the device and shall also follow the MIFU for the disinfection process, equipment, and products.

11.3 Only chemical disinfectants that have a Health Canada drug identification number (DIN) or a medical device licence (MDL) issued by Health Canada, shall be used in dental offices for the disinfection of reusable dental or medical devices.

11.4 A liquid chemical disinfectant shall not be used beyond its:

a) expiry date; and
b) in-use shelf life.

11.5 Reusable liquid chemical disinfectant solutions shall:

11.5.1 Be clearly identified and include the expiry date;

11.5.2 Be stored in containers that are cleaned, disinfected, and dried prior to changing the solution; and

11.5.3 Be kept covered with a tight-fitting lid, except when introducing or removing a dental or medical device to or from the solution.

Non-Critical Devices

Note: In most cases, non-critical reusable dental or medical devices can be disinfected at the point of use.

11.6 Non-critical reusable dental or medical devices shall be disinfected between patient use using an intermediate-level disinfectant (ILD) or LLD.

11.6.1 ILD or LLD wipes shall be moist enough to thoroughly wet the surface for the indicated contact time and a new wipe shall be used if the area to be disinfected cannot be completely wetted with a single wipe.

Semi-Critical Medical Devices

11.7 If a reusable semi-critical device cannot be sterilized, then it shall, at a minimum, be high level disinfected between patient use.

Liquid Chemical High Level Disinfection

11.8 The minimum effective concentration (MEC) of a reusable HLD shall be tested and recorded, according to the MIFU of the disinfectant.

11.8.1 MEC testing shall be performed at the beginning of each day that the solution is used for manual HLD (or more frequently if specified in the MIFU of the HLD) and in each cycle for automated HLD.

11.8.2 Quality assurance testing of test strips used to test MEC shall be followed in accordance with test strip MIFU.

11.8.3 Test strips used to test MEC shall not be used beyond the test strip's expiry date or the manufacturer's in-use shelf life.

11.8.4 An HLD shall not be used beyond a failed MEC test.

11.9 When performing manual disinfection of a semi-critical medical device:

11.9.1 All parts of the dental or medical device shall be in complete contact with the HLD, and all air bubbles shall be removed; and

11.9.2 The contact time and temperature shall be measured from the point at which the semi-critical dental or medical device achieves complete contact with the HLD and there are no trapped air bubbles.

11.10 Automated disinfection systems shall provide a record that critical cycle parameters (e.g., disinfectant temperature, concentration, contact time) have been met.

11.11 Following chemical HLD, each semi-critical dental or medical device shall be thoroughly rinsed with sterile or bacteria-free water (e.g., achieved by submicron filtration).

11.11.1 If rinsing is done manually, it shall include at least three separate rinses unless otherwise specified by the HLD manufacturer.

11.12 After HLD and rinsing, the semi-critical dental or medical device shall be dried in accordance with the MIFU.

11.13 At a minimum, the DHCP shall document and maintain records on:

11.13.1 HLD solution (including product name, lot number, expiry date, in-use shelf life, date of solution change, and initials of staff preparing the solution and documenting the process);

11.13.2 HLD test strips (including name of test strip, lot number, expiry date, in-use shelf life, quality control test results for each time a new test strip bottle is opened, and the initials of staff doing the testing and documentation);

11.13.3 Results of MEC testing;

11.13.4 Contact time and temperature during HLD;

11.13.5 Cycle parameters; and

11.13.6 Dental or medical device name or type documentation.

11.14 Devices not easily disinfected, and not routinely used in dentistry, such as endoscopes, must be cleaned and disinfected/sterilized according to the MIFU.

12.0 Sterilization of Reusable Dental Instruments and Devices

12.1 A reusable critical dental or medical device shall be sterilized between each patient use.

12.2 Semi-critical dental or medical devices that are compatible with heat and moisture shall be steam sterilized between each patient use.

12.3 Sterilization of reusable dental or medical devices shall take place in accordance with:

12.3.1 The MIFU of the device; and

12.3.2 The MIFU for the sterilization process, equipment, and products.

12.4 The following processes must not be used for sterilization of dental instruments or devices:

12.4.1 Boiling;

12.4.2 Ultraviolet light;

12.4.3 Glass bead sterilization;

12.4.4 Ovens designed for food preparation; or

12.4.5 Microwave ovens.

Qualification and Requalification of Sterilization Equipment

12.5 Installation qualification of sterilization equipment (including large chamber and tabletop steam sterilizers) shall be performed and documented according to the MIFU.

12.6 Operational qualification of sterilization equipment (including large chamber and tabletop steam sterilizers) shall be performed at installation.

12.7 Operational requalification shall take place at least annually and following a major sterilizer repair, sterilizer relocation, an unexplained sterility failure, and, for steam sterilizers, following any disruption to steam supply or change to steam pressures and documented according to MIFU.

12.8 Operational qualification and requalification testing shall include a verification of each cycle used by the dental office, according to the MIFU for testing.

12.9 Operational qualification and requalification testing shall be conducted by:

12.9.1 Running three consecutive cycles in an empty chamber using Process Challenge Device (PCD) with biological indicators. For table-top steam sterilizers, testing will take place in a fully loaded chamber.

12.9.2 Additionally, in dynamic air removal sterilizers that use pre-vacuum cycles, ensuring that the sterilizer:

a) Meets the requirements of an air removal test and leak-rate test; and

b) Is tested with three consecutive air removal tests (e.g., Bowie-Dick/Dart) in an otherwise empty sterilizer.

12.9.3 The above shall be documented.

12.10 Performance qualification shall be performed to ensure setting-specific packages and loads can be sterilized with the equipment and processes used in the dental office.

12.10.1 Performance qualification shall use products (e.g., instrument sets) and sterilizer loads used by the dental office. The products and loads shall:

a) Be assembled according to the sterilizer MIFU; and

b) Adhere to any limitations of validated dental or medical devices, materials, and weights.

12.10.2 In addition, performance qualification shall be performed when there are new materials, processes, or conditions that could affect sterilization.

Packages and Labels

12.11 Packaging of reusable dental or medical devices for sterilization shall take place in accordance with the MIFU of the device, the sterilization equipment, and the sterilization packaging manufacturer, and when packaging is required, it shall be done using a validated sterile barrier system (e.g., pouches, wrappers, or rigid sterilization container systems).

12.12 Packages shall be labelled with sterilizer load identification information, including the sterilizer number, the load number in that sterilizer, and the sterilization date.

12.12.1 Labelling systems shall be validated for the sterilization process.

12.12.2 For pouches, a label shall be placed on the transparent portion of the packaging.

12.12.3 For wrapped packages, writing shall be on the closure tape, not directly on the wrappers.

Loading and Unloading

12.13 Packages shall be placed in the sterilizer chamber (following sterilizer MIFU) in a manner that facilitates air removal, sterilizing agent penetration, sterilant evacuation, and, in the case of steam sterilization.

12.13.1 Wrapped items shall not contact the interior walls of the sterilizer chamber, as contact can damage the wrapper.

12.13.2 Pouches and wrapped packages shall not be stacked or compressed.

12.13.3 Between packages there shall be adequate space to ensure effective sterilizing agent penetration, evacuation, and drying.

12.14 Sterile pouches and packages shall be cooled to room temperature before handling.

12.15 During unloading, pouches and packages shall be inspected for:

a) Package integrity;
b) Dryness;
c) Presence of a label;
d) The correct change in an external chemical indicator;
e) An intact seal, if used; and
f) Evidence of potential contamination.

If a pouch or package does not meet the inspection criteria, the contents shall not be used.

Mechanical Monitoring

All sterilizers used in dental clinics must come equipped with either a printer or an electronic data recorder that records cycle parameters. Sterilizers without this capability must be adapted or replaced by January 1, 2023.

Mechanical or electronic failure alarms for time, temperature, and pressure must be in place, and their correct functioning recorded for each cycle; integrated printouts or data retrieval devices recording these parameters.

12.16 All sterilization processes must follow the MIFU for installation, operation, preventative maintenance, and quality assurance monitoring of the equipment and must be documented.

12.17 The sterilization process must be tested, monitored, documented, and audited for all sterilizers; the following must be completed to ensure that effective sterilization has been achieved:

Chemical Indicator

12.18 Both internal and external chemical indicators shall be included with each package prepared for sterilization. Each instrument pack or cassette must have an external Type 1 process indicator applied to, or visible from, the exterior of the package, and an internal chemical indicator. Type 5 or Type 6 chemical indicator must be used inside the material and/or instrument package.

Air Removal Test

12.19 For dynamic air removal-type sterilizers (pre-vacuum cycles), an air removal test shall be performed every day the sterilizer is used (i.e., Bowie-Dick/Dart).

Biologic Indicators

12.20 A biological indicator contained within a PCD shall be used to test the sterilizer for each type of cycle used (e.g., dynamic air removal, gravity, and steam flush pressure pulse) and at the shortest exposure time, within a full load. This test shall be done at least daily when the sterilizer is in use.

Note: A PCD should present a challenge to the process that is equal to or greater than the challenge posed by the most difficult item that is routinely sterilized. A biological test pack is an example of a PCD. A PCD can be commercially manufactured or prepared in-house following the PCD MIFU.

An in-house PCD can be made with a cassette or bag that includes metal instruments, a BI and a Type 5 CI.

12.20.1 If a steam sterilizer will be used for multiple types of cycles, each type of cycle used shall be tested daily.

12.21 Implantable Devices

12.21.1 Every load containing implantable devices shall be monitored using a biological indicator PCD.

12.21.2 A biologic indicator must be used with each load of surgical instruments if implantable devices (for example, dental implants, bone grafting screws, temporary anchorage devices, bone plates, etc.) are being placed. These instrument packs and implantable devices or materials must not be used until the results of the biologic indicator test are known, and must be tracked for date, load and sterilizer used, and this information must be recorded in the patient's record at the time of placement.

12.21.3 Implantable devices shall be quarantined until the results of the biological indicator test are available.

12.21.4 Early release of implantable devices shall not be used to compensate for inventory shortages or scheduling problems.

12.21.5 Early release of implantable devices shall only be done in situations where there is an urgent, unplanned need (e.g., trauma-related devices) and if an implantable device must be released before the biological indicator test results are available, the following apply:

- Evaluation of a Type 5 or Type 6 chemical indicator in the biological indicator PCD, the specific cycle physical parameters, and any visible chemical indicators shall be assessed, and the results documented in the patient's record at the time of placement.

12.22 Documentation of sterility assurance shall include a printout or electronic cycle parameter record, a load control label, a load contents record, and associated chemical or biological indicator test results for each cycle.

12.23 In the event of a failed indicator test or any other issue noted upon inspection, the dentist shall have processes in place to recall and reprocess the affected dental or medical devices.

Immediate-Use Steam Sterilization

12.24 Immediate-use steam sterilization (IUSS) shall be used only for situations where there is an urgent, unplanned need, with no other options available, or the dental or medical device can only be sterilized with an immediate-use cycle.

12.24.1 Further to 12.24, IUSS shall not be used for reasons of convenience, to save time, to compensate for inventory shortages, or to address scheduling problems.

Note: *Practical measures that should be taken by the dentist to avoid the need for IUSS include:*

a) Maintaining adequate inventories of dental or medical devices; and

b) Coordinating dental or medical device reprocessing with surgical schedules so that properly reprocessed devices are available when needed.

12.25 Other than for the unavoidable, emergency situations described in 12.24, IUSS shall not be used to sterilize implantable devices.

12.26 Dental or medical devices that have been sterilized using IUSS shall be used immediately and shall not be stored.

Note: *It is important that critical dental or medical devices are maintained as sterile until point of use. Prior to and upon opening a package containing a critical dental or medical device at the point of use, the user should inspect the integrity of the*

packaging (including reviewing the results of the internal and external chemical indicators) and the reprocessed dental or medical device itself, to ensure no obvious contamination or damage exists.

12.27 In the event of a failure in the sterilization process (failure of the sterilizer, failure of chemical indicators or the failure of the biological indicator) there must be a process in place to investigate the cause of the event, document actions taken, and recall sterilization loads if necessary.

12.28 All loaned or shared dental instruments and devices received by the office/facility must be reprocessed according to MIFU by the receiving office/facility on site prior to patient use.

13.0 Storage and Use of Reprocessed Dental Instruments and Devices

13.1 Packages containing the sterile dental instruments or devices must be clearly labeled with the sterilizer number, load number of that sterilizer and sterilization date that they were reprocessed.

13.2 Sterile dental instruments or devices must be maintained as sterile until the point of use. If the integrity of the package or container has been compromised (e.g., wet, torn, visibly soiled) the contents must not be used, and the devices must be reprocessed.

13.3 Areas where clean, disinfected, and sterile dental or medical devices are stored shall:

13.3.1 Be dedicated to the storage of clean, disinfected, and sterile items;

13.3.2 Be designed to have adequate space to prevent crushing or damage to packaging;

13.3.3 Have sufficient lighting to allow easy reading of labels and to determine the condition of packaging; and

13.3.4 Be cleaned following an established schedule.

13.4 Reprocessed critical and semi-critical dental or medical devices shall be protected from contamination by:

a) Rotating stock via first-in, first-out; and

a) Ensuring they are not stored on the floor or a window sill, under sinks or near water sources, or in the same area as hazardous materials.

13.5 Reprocessed dental instruments or devices must be inspected for integrity upon opening the instrument or device pack or cassette at the point of use. The results of the internal chemical indicator must be validated prior to the use of the dental instruments or devices.

14.0 Education and Training

14.1 The dentist shall ensure all personnel involved in the reprocessing of critical and semi-critical dental devices are appropriately educated and trained for the reprocessing duties/tasks that they perform.

14.2 The dentist shall document and maintain records of education, training, orientation, and competency assessments of personnel who reprocess critical and semi-critical dental devices.

15.0 Environmental Infection Prevention and Control Practices

15.1 All finishes in the clinical, laboratory and reprocessing setting must be cleanable and intact (i.e., chair covers, flooring, counter tops, and dental unit).

15.2 All clinical contact surfaces must be cleaned and disinfected between patients.

15.3 If surfaces covers are used:

15.3.1 They must cover the entire surface including the edges;

15.3.2 They must be moisture impervious;

15.3.3 They must be applied with clean hands (hands that have recently had hand hygiene performed on them) or clean gloves; and

15.3.4 They must be removed and discarded, using single-use protective gloves, between patients. Following their removal, all surfaces must be inspected for evidence of contamination and cleaned and disinfected if contaminated.

15.4 If surface covers are not used:

15.4.1 All surfaces must be cleaned and disinfected between each patient; and

15.4.2 A hospital–grade LLD that is labeled, stored, prepared, and applied according to MIFU must be used to clean and disinfect clinical contact surfaces.

15.5 Components of dental devices that are permanently attached to the dental unit water lines (i.e., electric handpiece motors, handles for ultrasonic devices attachments for saliva ejectors, high-speed air evacuators, etc.) must be disinfected after each use.

15.6 Radiographic equipment (e.g., tube heads and control panel) must be cleaned and disinfected between patients.

16.0 Dental Unit Waterlines

16.1 All waterlines must be purged at the beginning of each workday by flushing the lines thoroughly with water for a minimum of two minutes.

16.2 Waterlines must be purged for a minimum of twenty seconds after patient care.

16.3 MIFU of the dental units and dental equipment must be followed for daily and weekly maintenance whenever closed water systems or other special water delivery systems are utilized.

16.4 Suction lines must be aspirated with water or disinfectant solution (that is compatible with the evacuation system according to MIFU) between patients to reduce likelihood of infectious material backflow.

16.5 Suction lines must be cleaned once a week with an enzymatic cleaner (that is compatible with the evacuation system according to MIFU).

17.0 Single-Use Instruments and Devices

17.1 Single-use dental instruments or devices that are labeled by the manufacturer as single-use must not be reused on any other patient. Single-use dental devices must only be used on an individual patient for a single procedure and then must be discarded.

17.1.1 Any item marked with the symbol below is considered single-use, and would include, but is not limited to syringe needles, disposable syringes, prophylaxis cups and brushes, implant parts, temporary anchorage devices, bone grafting materials and some orthodontic brackets and wires.

17.1.2 Packaged bone grafting materials are single-use, and must only be used on a single patient, on a single day and then must be discarded.

17.1.3 Single-use dental devices are single-use, and must only be used on a single patient, on a single day and then must be discarded.

17.1.4 A single-use dental or medical device shall not be used beyond the expiry date specified by the manufacturer.

17.1.5 A sterile critical single-use dental or medical device shall be maintained as sterile until point of use.

17.1.6 Opened but unused single-use dental or medical devices must be discarded, unless the manufacturer provides validated MIFU for reprocessing (e.g., dental implant/screws).

17.1.7 Prior to using a single-use dental device that was purchased in a non-sterile state, that single-use dental device shall be inspected and processed according to the validated MIFU (e.g., dental burs, endodontic files, and dental implant/screws).

17.2 Dentists administering medications using multi-use vials (such as for intravenous sedation) must use a new single-use disposable needle and a new single-use disposable syringe for each entry into a multi-dose vial and follow proper aseptic technique when administering the medication.

17.2.1 Multi-dose vials must be dated upon opening and discarded prior to the expiry date listed on the label.

17.2.2 Multi-dose vials have a manufacturer recommended discard date of 28 days after opening, refer to product specific MIFU.

17.2.3 The vial septum must be cleaned with a new disinfectant swab prior to each entry.

17.2.4 A new needle and a new syringe must be used for each entry into a vial.

17.2.5 Drugs must never be delivered to more than one patient, or IV system attached to the patient from a common syringe or IV bag.

17.2.6 Multi dose vials must be inspected prior to use and discarded if they appear to be contaminated.

18.0 Occupational Health and Safety Requirements

18.1 The dental clinic must comply with the Alberta *Occupational Health and Safety Act, Regulation and Code*.

18.1.1 A written hazard assessment must be completed to identify physical, biological, chemical and radiation risks in the dental clinic, according to *Alberta Safe Workplaces Employment and Immigration Standards*.

18.1.2 The reprocessing area must be limited to reprocessing activities only and all other activities are prohibited, including eating or drinking, storage of food, smoking, application of cosmetics, or handling of contact lenses.

18.1.3 Air handling systems must be adequate to protect personnel from toxic vapours.

18.1.4 Chemicals must be stored according to MIFU, and SDS documentation must be available, as required by the Government of Canada's *Workplace Hazardous Material Information System* (WHMIS).

18.1.5 DHCP handling contaminated dental instruments or devices must wear PPE.

18.1.6 All DHCP must comply with immunizations required in a clinical dental setting.

18.1.6.1 All clinical DHCP and reprocessing personnel must be assessed regarding their immunity to Hepatitis B and, if not adequately protected, provided Hepatitis B immunization, if required.

18.1.7 A first aid plan, equipment and services must be in place.

18.1.7.1 All Alberta dental offices must have a working Automated External Defibrillator (AED) on their premise. Must be serviced according to the MIFU.

18.1.8 All DHCP must be aware of the signs of possible latex adverse reactions and have a plan in place to deal with such reactions.

18.1.9 The dental clinic must have written policies regarding Work Practice Controls to prevent exposure to blood and body fluids, exposure to chemicals, and injuries from sharp objects.

18.1.10 The dental clinic must have written policy protocol for sharps, syringes and safety engineered syringes (SES).

18.1.11 Policies and procedures must be in place for immediate response to worker exposure to chemicals.

18.1.12 Policies and procedures must be in place for immediate response and post-exposure management of workers exposed to blood and body fluids.

18.1.13 An eye-wash station or commercial eye-wash bottle with proper eyepieces must be available and immediately accessible.

18.1.14 Policies and procedures must be in place for immediate response to worker exposure to sharp objects.

18.1.15 The dental clinic must ensure that ventilation is in place to remove toxic vapours generated by, or emitted from, cleaning or disinfecting agents.

19.0 Ethical Responsibilities

19.1 DHCP must not refuse oral health care to individuals based solely on the patient's seropositivity status to any blood-borne pathogen (including Human Immunodeficiency Virus [HIV], Hepatitis B Virus [HBV] and Hepatitis C Virus [HCV]).

19.2 If a dentist has a blood borne infection (HBV, HCV and/or HIV), the dentist must immediately inform the CDSA.

19.3 If a dentist knows of or has reason to suspect the existence of a nuisance or a threat that is or may be injurious or dangerous to the public heath, the dentist has a legal obligation to immediately notify the Medical Officer of Health of the appropriate regional health region by the fastest means possible, according to the *Health Professions Act* (HPA). Contact information can be obtained from Alberta Health and Alberta Health Services (AHS).

19.4 These Standards must be followed by dentists in Alberta. Failure to do so may constitute unprofessional conduct under the *Health Professions Act* (HPA) and may result in disciplinary action by the CSDA.

20.0 Quality Management

20.1 The dentist shall have clear accountability and lines of responsibility for:

20.1.1 All aspects of MDR, wherever MDR takes place in the dental office; and

20.1.2 The appropriate use of single-use dental and medical devices.

20.2 The dentist shall have written policies and SOPs in place that meet or exceed appropriate provincial and national standards and guide the dentist through all aspects of MDR.

20.2.1 All steps in the reprocessing of reusable dental or medical devices, based on MIFU;

20.2.2 The installation, operational, and performance qualification and requalification requirements of reprocessing equipment and products, based on MIFU;

20.2.3 Regular inspection and preventative maintenance requirements for reusable medical devices and equipment, based on MIFU;

20.2.4 Actions to be taken following a failed sterility indicator or unexplained parameter change, based on MIFU;

20.2.5 Management of limited use (reposable) devices, if used, based on MIFU;

20.2.6 Recall procedures; and

20.2.7 Management of loaned, reusable dental or medical devices, if applicable.

20.3 The dentist shall have a written policy regarding single-use dental and medical devices that is consistent with section 17 of these standards.

20.3.1 The dentist shall make sure that its policies related to single-use dental or medical devices are available to all users and shall provide awareness training as required.

20.4 The dentist shall have policies and/or SOPs in place that include but are not limited to:

20.4.1 The required occupational health and safety activities, including use of appropriate personal protective equipment when performing MDR and when using single-use dental or medical devices;

20.4.2 IPC routine practices;

20.4.3 The storage (including environmental conditions and requirements related to identification and labelling), transportation, and distribution of single-use and reusable devices and products;

20.4.4 The practices and procedures required to maintain the sterility of packages and sterile dental or medical devices, over time and until point of use, based on MIFU; and

20.4.5 Contingency plans for emergency situations that include but are not limited to:

a) Loss of staff;

b) Loss of or decrease in supply chain or inventory;

c) Loss of utilities including potable water;

d) Loss of reprocessing equipment;

e) Loss of or damage to sterile storage and/or laundry areas; and

f) Spills of hazardous substances.

20.5 The dentist shall conduct a regularly scheduled review of all written policies and SOPs.

20.5.1 The dentist shall review, and revise policies and SOPs related to improvements or corrective actions as required (e.g., following a review of an accident, error, or event related to the function); and

20.5.2 The development and subsequent review and update of policies and SOPs shall be performed by an individual experienced in medical device reprocessing who has the authority to make the necessary changes to ensure conformance with current or new requirements and/or changes in practice.

Documentation

20.6 Dentists shall retain records of reprocessing according to the health care facility or setting's policy and applicable legislation or as long as medico-legally prudent. These records shall include, but not be limited to, the following:

20.6.1 Preventative maintenance of reusable dental or medical devices and equipment;

20.6.2 Results of installation, operational, performance qualification and requalification, and routine testing of reprocessing equipment and products; and

20.6.3 Management and handling of loaned, shared, and leased dental or medical devices.

20.7 The MIFU for dental or medical devices, equipment, and supplies shall be received and maintained in printed form (e.g., in binders, manuals, or monographs) or in electronic format and be readily accessible to those needing access and shall be updated as required.

20.8 If reprocessing of reusable dental or medical devices is being performed by an external or internal subcontractor, the subcontractor shall comply with these Standards.

20.9 Dentists that provide services involving contact with high-risk tissues from patients suspected or known to have Creutzfeldt-Jakob Disease or prion-related disease shall develop policies to manage dental or medical devices in accordance with Government of Canada, Health Canada and the Public Health Agency of Canada's *Infection Control Guidelines: Classic Creutzfeldt-Jakob Disease in Canada – Quick Reference Guide*.

20.10 The dentist shall review and monitor personnel compliance with these standards in accordance with its written policy on monitoring and reporting, and results of such monitoring shall be documented.

Definitions

Accountability: a state of being accountable, answerable, or liable. Regarding IPC Standards, the dentist is accountable to the Alberta Dental Association and College.

Additional Precautions: practices used to prevent transmission of infectious agents that are spread by direct or indirect contact with the client or client's environment that are necessary in addition to Routine Practices for certain pathogens or clinical presentations. These precautions are based on the method of transmission of the infectious agent, and include Contact Precautions, Droplet Precautions, and Airborne Precautions.

Aerosol: particles of respirable size (<10 μm) generated by both humans and environmental sources that can remain viable and airborne for extended periods in the indoor environment; commonly generated in dentistry during use of handpieces, ultrasonic scalers, and air/water syringes.

Airborne Transmission: a means of spreading infection in which airborne droplet nuclei (< 5 microns) are inhaled by the susceptible host.

Alcohol-Based Hand Rub (ABHR): a liquid, gel of foam formulation of alcohol (e.g., ethanol, isopropanol) which is used to reduce the number of microorganisms on hands in clinical situations when the hands are not visibly soiled. ABHRs contain emollients to reduce skin irritation and are less time-consuming to use than washing with soap and water.

Anaphylaxis (immediate anaphylactic hypersensitivity): a severe and sometimes fatal Type 1 reaction in a susceptible person after a second exposure to a specific antigen (e.g., food, pollen, proteins in latex gloves, or penicillin) after previous sensitization. Anaphylaxis is characterized commonly by respiratory symptoms, itching, hives, and rarely by shock and death (anaphylactic shock).

Antiseptic: a germicide that is used on skin or living tissue for the purpose of inhibiting or destroying microorganisms. Examples include alcohols, chlorhexidine, chlorine, hexachlorophene, iodine, chloroxylenol (PCMX), quaternary ammonium compounds and triclosan.

Aseptic Technique: specific practices aimed at preventing the introduction of or reducing the number of microorganisms in an area of the body or preventing the spread of microorganisms in the dental office or clinic. Aseptic technique is also designed to prevent exposure of workers to blood, body fluids, tissue and other potentially infectious materials or surfaces during health care procedures. Aseptic techniques would include but are not limited to removing or killing microorganisms on hands and objects, using only sterile instruments in order to reduce patients' risk of exposure to microorganisms that cannot be removed. Both medical and surgical aseptic techniques (defined below) are employed in dental settings, depending on a number of factors and the resultant degree of sterility required for proper IPC.

Automated Instrument Washer: an automatic unit specifically designed to clean and thermally disinfect medical or dental devices and instruments. The unit uses a high-temperature cycle rather than a chemical bath.

Bead Sterilizer (endodontic dry heat sterilizer): a device that used small glass beads (1.2–1.5 mm diameter) and high temperature (217–232°C) for brief exposures (e.g., 45 seconds) to inactivate microorganisms. The term is a misnomer because these devices are not cleared as sterilizers by CSA or Health Canada.

Bioburden: the microbiological load (e.g., number of viable organisms in or on the object or surface) or organic material on a surface or object prior to decontamination, or sterilization, also known as "bioload" or "microbial load."

Biological Indicator (BI): a test system containing viable bacterial spores providing a defined resistance to a specified sterilization process.

Biological Monitoring: a monitoring process used to validate and audit sterilization process. Biological monitoring uses Biological Indicators.

Biomedical Waste: waste in health care facilities is divided into three categories: general, biological, and pathological. In Canada, biomedical waste does not include domestic waste. Legislation requires that biomedical waste be handled and disposed of in such a way as to avoid transmission of potential infections. The most obvious biomedical wastes in dental offices or clinics are disposable single-use sharps and gauze soaked with blood. Non-anatomical waste, such as liquid blood or body fluid drainage (e.g., IV tubing filled with blood) must also be disposed of as biological waste. Anatomical waste such as body parts (not including teeth) are classified as pathological waste and must be disposed of according to the regulations for handling pathological waste. All other waste such as general office waste, used gloves or non-sharp medical equipment, may be disposed of in regular waste and requires no special handling other than containment during disposal and removal.

Canadian Standards Association (CSA): a not-for-profit, non-statutory, voluntary membership association, engaged in standards development and certification activities. CSA standards reflect a national consensus of producers and users – including manufacturers, consumers, retailers, unions and professional organizations, and government agencies.

Chemical Indicator (CI): a test system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to the process.

Chemical Sterilant: chemicals used for the purpose of destroying all forms of microbial life including bacterial spores. High-Level Disinfectants (HLD) can be chemical sterilants but require different contact times.

Clean Hands: hands that have had appropriate hand hygiene.

Cleaning: the removal of contamination from an item to render it visually free of soil and quantified as below specified levels of the substance to be measured.

Clostridium difficile (C. difficile or "C. diff"): a bacterium that can cause symptoms (can also be asymptomatic and colonized) ranging from diarrhoea to life-threatening inflammation of the colon (Pseudomembraneous colitis). Illness from C. difficile most commonly affects older adults in hospitals or in long-term care facilities and typically occurs after use of antibiotic medications.

Competent: in relation to a person, means adequately qualified, suitably trained, and with sufficient experience to safely perform work without supervision or with only a minimal degree of supervision.

Contact Precautions: a type of Additional Precautions used in addition to Routine Practices to prevent transmission of infectious agents that are spread by direct or indirect contact with an infectious person or an infectious person's environment. Contact Precautions also apply where the presence of uncontained wound drainage, fecal incontinence or other discharges from the body suggest an increased potential transmission risk of pathogens by this route.

Contaminated: affected by the presence of a harmful substance on workers or at the work site in a quantity sufficient to pose a risk to health. As used in health care, the term generally refers to the presence of microorganisms on inanimate or animate objects that could be capable of producing disease or infection that could be transported on body surfaces such as hands, or in substances (e.g., food, water, milk).

Creutzfeldt-Jakob Disease (CJD): a degenerative neurological disorder of humans thought to be transmitted by abnormal isoforms of neural proteins called prions. CJD is one of a group of related diseases known as transmissible spongiform encephalopathies (TSEs).

Critical: part of the Spaulding Classification. Critical medical or dental devices or instruments are introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. These devices or instruments may be single-use disposable or may be designed to be reprocessed by sterilization. Examples of critical medical or dental devices include, but are not limited to, needles, syringes, scalpels and invasive/surgical instruments, all implantable devices, biopsy forceps and dental handpieces. These items create a substantial risk of acquiring infection if the item is contaminated with microorganisms at the time of use.

Critical Medical Device: a medical device that enters sterile tissues, including the vascular system.

Decontamination/Decontaminated: the process of cleaning, by use of physical and/or chemical means, to remove, inactivate, or destroy pathogenic micro-organism, in order to render an object safe for handling.

Dental Offices: any clinic, dental clinic, place, practice, office, health service, institution, including research and teaching settings, where a dentist provides dental services to patients.

Dental Health Care Personnel (DHCP): the variety of paid and unpaid personnel in the dental health-care setting who might be exposed to infectious materials, including body substances (blood, saliva, etc.) and contaminated supplies, equipment, environmental surfaces, water, or air. DHCP includes dentists, dental hygienists, dental assistants, dental laboratory technicians (in-office and commercial), nurses, students and trainees, contractual personnel, as well as other personnel that may not be directly involved in patient care but may be potentially exposed to infectious agents (e.g., administrative, clerical, housekeeping, maintenance, or volunteer personnel).

Dentist: a person who is a regulated member of the Alberta Dental Association and College. Under the Health Professions Act, all dentists are responsible for meeting the CDSA IPC Standards as a practitioner in their practice, as a dental facility owner in their office or mobile practice, as a dental operator in a Dental Surgical Facility, and as an employer when Dental Owner/operator of the. Dentists are health practitioners under the Health Professions Act.

Detergents: compounds that possess a cleaning action and have hydrophilic and lipophilic parts. Although products used for hand washing or antiseptic hand wash in a health-care setting represent various types of detergents, the term "soap" is commonly used to refer to such detergents in this context.

Direct Contact Transmission: physical transfer of microorganisms between an infected or colonized person and a susceptible host.

Disinfectant: chemical(s) used for disinfection, including high-level disinfectant (HLD), intermediate-level disinfectant (ILD), and low-level disinfectant (LLD).

Disinfection/Disinfect/Disinfected: the process to inactivate viable micro-organisms to a level previously specified as being appropriate for a defined purpose. (See definitions for high-level disinfection, intermediate-level disinfection, and low-level disinfection).

Drug Identification Number (DIN): a drug identification number (DIN) is an eight (8) digit numerical code assigned to each drug product marketed under the *Food and Drugs Act* and *Regulations*. A DIN identifies the following product characteristics: manufacturer, brand name, medicinal ingredients(s); strength of medicinal ingredient(s), pharmaceutical form, and route of administration.

Hand Hygiene: hand washing, hand antisepsis or other actions taken to maintain healthy hands and fingernails.

Hand Washing: a process for the removal of visible soil/organic material and transient microorganisms from the hands by washing with soap (plain or antiseptic) and water.

Hazard: a situation, condition or thing that may be dangerous to the safety or health of workers.

Hazard Assessment: an employer must assess a work site and identify existing and potential hazards before work begins at the work site. An employer must prepare a report of the results of a hazard assessment and the methods used to control or eliminate the hazards identified. An employer must ensure that the date on which the hazard assessment is prepared or revised is recorded on it. An employer must ensure that the hazard assessment is repeated at reasonably practical intervals when a new work process is introduced or when a work process changes.

Health Care Facility or Setting: a facility or setting in which a client receives health services including, but not limited to, the following: hospitals; ambulatory care clinics; urgent care services; non-hospital surgical facilities; mobile treatment centres; public health clinics; hospices; addiction and mental health clinics and facilities; private clinics delivering health services in community settings; settings where dental and dental hygiene services are provided; diagnostic imaging centres; laboratories; supportive living facilities (including but not limited to designated-supportive living); long-term care facilities (nursing homes and auxiliary hospitals); educational institutions; correctional centres; and private dwellings, when health services are provided in the client's home or another private dwelling such as a home-based business.

Hepatitis B Immune Globulin (HBIg): a product available for prophylaxis against hepatitis B virus infection. HBIg is prepared from plasma containing high titres of anti-HBs and provides short-term protection (3–6 months).

High Efficiency Particulate Air (HEPA) Filter: an air filter with an efficiency of 99.97% in the removal of airborne particles 0.3μm or larger in diameter.

High-Level Disinfectant (HLD): a chemical agent capable of killing bacterial spores when used in sufficient concentration under suitable conditions. Common high-level disinfectant solutions include glutaraldehydes, glutaraldehydes with phenols, high-concentration hydrogen peroxide, and hydrogen peroxide with peracetic acid.

High-Level Disinfection: a process capable of killing vegetative bacteria, mycobacteria (including *Mycobacterium tuberculosis*), fungi, and lipid and nonlipid viruses, as well as some, but not necessarily high numbers of, bacterial spores.

Immediate Use Steam Sterilization (IUSS): *a steam sterilization process designed and used for the sterilization of surgical devices when routine sterilization processes cannot be used.*

Immunity: protection against a disease using a person's immune system. Immunity is indicated by the presence of antibodies in the blood and can usually be determined with a laboratory test.

Immunization: the process by which a person becomes immune, or protected, against a disease either actively by vaccine or passively via administration of immune globulin. This term is often used interchangeably with vaccination or inoculation. However, the term "vaccination" is defined as the injection of a killed or weakened infectious organism in order to prevent the disease. Thus, vaccination, by inoculation with a vaccine, does not always result in immunity.

Implantable Device: a device or material that is placed into a surgically or naturally formed cavity of the human body that is intended to remain there for a period of 30 days or more.

In-use Shelf Life: The term "shelf life" of a drug slightly differs from a drug's "expiration date." The shelf life generally relates to a drug's quality over a specified period of time (i.e., once opened or diluted), whereas the expiration date relates to both quality and safety of a medication at a specific point in time. (i.e., the absolute date beyond which an unopened product must not be used).

Infection Prevention and Control (IPC): the discipline concerned with preventing health care associated infection.

Intermediate-Level Disinfectant (ILD): a liquid chemical germicide with a MDL from Health Canada, with a label claim of potency as a tuberculocidal.

Intermediate-Level Disinfection: a process capable of killing vegetative bacteria, mycobacteria (including *Mycobacterium tuberculosis*), fungi, and lipid and nonlipid viruses.

Installation Qualification/Installation: the process of obtaining and documenting evidence that equipment has been provided and installed according to its specification.

Latex: a milky white fluid extracted from the rubber tree Hevea brasiliensis that contains the rubber material cis-1, 4 polyisoprene.

Low-Level Disinfectant (LLD): a liquid chemical germicide with a MDL from Health Canada, which has a label claim for potency against HIV and HBV if used for disinfecting clinical contact surfaces.

Low-Level Disinfection: a process capable of killing most vegetative bacteria and some fungi, as well as enveloped (lipid) viruses (e.g., influenza, hepatitis B and C, and HIV). Low level disinfection does not kill mycobacteria, non-enveloped viruses, or bacterial spores.

Manufacturer: a person (partnership, firm or association) who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person and with the respect to the medical device, is a responsible for the following: designing; manufacturing; assembling; processing labelling; packaging; refurbishing; modifying; assigning the medical device an intended purpose; or depending upon the class of the medical device, providing validated MIFU for reprocessing; whether those tasks are performed by that person or on their behalf. A manufacturer may also be a person or department who develops or modifies a medical device for use within the organization (but not for resale).

Manufacturer's Instruction for Use (MIFU): the validated, written directions provided by the manufacturer or distributor of a medical device or product, that contains the necessary information for the safe and effective use of the medical device or product.

Note: The term MIFU may also be used to refer to written instructions for use developed internally or by a commercial reprocessor, that have been validated by an approved laboratory.

Medical Device: any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for a human being for any of the following purpose of: diagnosis, prevention, monitoring, treatment, surgery or alleviation of disease; diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap; investigation, replacement or modification of the anatomy, or of a physiologic process; or control of conception, and that does not achieve its principal intended purpose in or on the human body by pharmacological, immunological, or metabolic means, but that can be assisted in its function by such means.

Notes:

1. *For the purpose of clarity and in alignment with the definitions of (medical) devices in the federal Food and Drugs Act and the Medical Devices Regulations, dental devices are considered medical devices.*
2. *For the purposes of these Standards, foot care devices are considered medical devices.*
3. *Under the Medical Devices Regulations, Health Canada licenses high-level disinfectants and sterilants used in the reprocessing of medical devices as medical devices. However, in the context of these Standards, the term "medical device" does not include high-level disinfectants and sterilants.*

Medical Device License (MDL): a license issued to a manufacturer by Health Canada, for a specific medical device.

Medical Device Reprocessing (MDR) Area: an area where the reprocessing of reusable critical and semi-critical dental or medical devices occurs. This includes centralized MDR departments, or any

area where reprocessing of reusable critical and semi-critical dental or medical devices takes place.

Methicillin Resistant Staphylococcus Aureus (MRSA): Staphylococcus aureus is a bacterium that may commonly live on the skin or in the noses of healthy people. MRSA is the term for Staphylococcus aureus that have become resistant to semi-synthetic penicillins, such as cloxacillin and methicillin. Clinically, MRSA infections generally start as small red bumps that resemble pimples, boils or spider bites. These can quickly turn into deep, painful abscesses that require surgical draining. Sometimes the bacteria remain confined to the skin, but they can also penetrate into the body, causing potentially life-threatening infections in bones, joints, surgical wounds, the bloodstream, heart valves and lungs.

Minimum Effective Concentration (MEC): the lowest concentration of a liquid chemical sterilant or disinfectant that achieves the claimed microbial activity.

Monitor: to observe, record, or detect an operation or condition with instruments or devices that have no effect upon the operation or condition. For IPC purposes, it also means to oversee, supervise or regulate (as does the CDSA). It also means to watch closely for purposes of control or surveillance.

Natural Product Number (NPN): a Health Canada NPN is assigned after Health Canada finishes assessing the product to ensure safety, efficacy, and quality. This 8-digit identifier number must appear on the principal panel of the NHP label. It indicates that Health Canada has reviewed and approved the health product for sale in the Canadian market.

Non-Critical Medical Device: a medical device, which either touches only intact skin but not mucous membranes or does not touch the client.

Occupational Health and Safety (OHS): a cross-disciplinary field that is concerned with protecting the physical, psychological, and social health and safety of people at work, preventing worker injury and illness, and considers both the worker and the work environment.

One-Way Workflow: the practice of ensuring that reprocessing workflows in one direction from the dirtiest to the cleanest.

Operational Qualification (OQ): the process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

Organization: an entity responsible for the management of a health care facility or setting.

Packaging: (verb) – a step in the sterilization process in which a medical device is enclosed in materials or a container designed to allow the penetration and removal of the sterilant during sterilization; and protect the medical device from contamination and other damage following sterilization and until the time of use.

Pasteurization: is a process that kills the pathogenic bacteria by heating to a certain temperature for a set period of time.

Performance Qualification (PQ): the process of obtaining and documenting evidence that the equipment, as installed and operated according to operational procedures, consistently performs according to predetermined criteria, and thereby yields product meeting its specification.

Personal Protective Equipment (PPE): equipment or clothing worn by a person for protection from health or safety hazards associated with conditions at a work site.

Policy: a document outlining an organization's plan or course of action.

Point-of-Care Risk Assessment: is a systematic process of reviewing work activities, evaluating the possible hazards/risks and implementing suitable control measures to eliminate, reduce or minimize the possible hazards/risks.

Potable (drinking) Water: water suitable for drinking, according to applicable public health standards.

Process Challenge Device (PCD): an item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process. A PCD should present a challenge to the process that is equal to or greater than the challenge posed by the most difficult item that is routinely sterilized. A biological test pack is an example of a PCD. A PCD can be commercially manufactured or prepared in-house following the PCD MIFU. An in-house PCD can be made with a cassette or bag that includes metal instruments, a BI and a Type 5 CI.

Prion: a protein particle that lacks nucleic acid and has been implicated as the cause of various neurodegenerative diseases (e.g., Creutzfeldt-Jakob disease, bovine spongiform encephalopathy, etc.). It is a pathogenic form of a neural protein that is both less soluble and more resistant to enzyme degradation than the normal form.

Pseudomembraneous colitis: a severe infection from C. difficile (see Clostridium difficile).

Reposable Medical Device: a medical device designated for a specific and limited number of uses by the manufacturer.

Reprocessing/Reprocess/Reprocessed: the cleaning, disinfection, and/or sterilization of a potentially contaminated dental instrument or device so that it is safe and effective for use on a patient.

Reusable Medical Device: a device that has been designed by the manufacturer, through the selection of materials and/or components, to be reprocessed and reused.

Routine Practices: the approach to infection control used to minimize or prevent exposure to microorganisms in health care facilities and settings, i.e., blood and body fluid, secretions, and excretions from all clients. Examples of routine practices include hand hygiene, point-of-care risk assessment, use of personal protective equipment, environmental cleaning, and waste and sharps handling.

Safety Data Sheet (SDS): a document that contains specified, required information about a hazardous product, including information related to the hazards associated with any use, handling or storage of the hazardous product in a workplace.

Semi-Critical Medical Device: a medical device that comes into contact with mucous membranes or non-intact skin but does not penetrate them.

Sharps: needles, knives, scalpels, blades, scissors, and other items that can cut or puncture a person, that may also be contaminated with a biohazardous material.

Single-Use/Disposable Medical Device: critical and semi-critical medical devices labelled by their manufacturers to be used only once. The manufacturer may use terms, including but not limited to the following, to designate a device for single-use only: disposable; consumable; not for re-use or do not re-use; discard after single-use; do not use twice; or by a symbol such as:

Spatter: visible drops of liquid or body fluid that are expelled forcibly into the air and settle out quickly, as distinguished from particles of an aerosol, which remain airborne indefinitely.

Spaulding Classification: a system for sterilization or disinfection of inanimate objects and surfaces based on the degree of risk involved in their use. The three categories are critical, semi-critical, or non-critical. The system also established three levels of germicidal activity for disinfection (high, intermediate and low).

Standard Operating Procedure (SOP): a thorough, step-by-step documentation of a procedure.

Note: The objectives of an SOP are to:

a) *define the system of information and control;*
b) *minimize the risk of misinterpretation and error inherent in oral or casually written communication;*
c) *provide unambiguous procedures to be followed and the order in which they should be performed; and*
d) *provide confirmation that process parameters have been achieved.*

Sterilant: a liquid chemical germicide or high-level disinfectant that destroys all forms of microbiological life, including high numbers of resistant bacterial spores.

Sterile/Sterility: the state of being free from all living microorganisms. In practice, sterility is usually described as a probability function, (e.g., the probability of a surviving microorganism being 1 in 1,000,000).

Sterile Water: water that is sterilized and is free from viable micro-organisms. (Distilled water is not necessarily sterile or pyrogen-free).

Sterilization/Sterilize/Sterilized: the validated process used to render a product free from viable microorganisms.

Substantive: a products ability to shift microbial baseline levels on the hands progressively downwards when the product is used repeatedly over time. This property results from product adherence to the stratum corneum layer of the skin, inhibiting microbial recolonization.

Surfactants: surface-active agents that reduce surface tension. Surfactants help cleaning by loosening, emulsifying, and holding soil or bioburden in suspension, which can then be more readily rinsed away.

Transmissible Spongiform Encephalopathies (TSEs): a group of rapidly progressive, invariably fatal, degenerative neurological disorders affecting both humans and animals that are caused by infection with prions (see Creutzfeldt-Jakob disease and prion).

Transmission: the transfer of microorganisms from source to host in the infection chain. Transmission of infection during the provision of health care requires three elements: a source of infecting microorganisms in sufficient quantities and sufficient virulence to cause infection, a susceptible host, and a means of transmission for the microorganism.

Ultrasonic Cleaner: a device that uses waves of acoustic energy (a process known as "cavitation") to loosen and break up debris on instruments.

Validation/Validated: a confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Notes:

1. *The objective evidence needed for validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.*
2. *The term "validated" is used to designate the corresponding status.*
3. *The use conditions for validation can be real or simulated.*

Ventilation: the process of supplying and removing air by natural or mechanical means to and from any space; such air may be conditioned.

Workplace Hazardous Materials Information System (WHMIS): Canada's national hazard communication standard. The key elements of the system are cautionary labeling of containers of WHMIS "controlled products", the provision of Safety Data Sheet (SDS), (formerly referred to as Material Safety Data Sheet [MSDS]) and worker education and training programs. WHMIS requirements place an onus on employers to ensure that controlled products used, stored, handled

or disposed of in the workplace are properly labeled, SDS are made available to workers, and workers receive education and training to ensure the safe storage, handling and use of controlled products in the workplace.

Work Practice Controls: practices or behaviours incorporated into the everyday work routine that reduce the likelihood of exposure by altering the manner in which a task is performed in order to reduce the likelihood of injury (e.g., identifying contaminated sharps prior to clean up, not recapping needles by a two-handed technique, not passing contaminated sharps during four-handed dentistry, etc.

Charts
Spaulding Classification and Managing Contaminated Surfaces

Patient Care Items – Modified Spaulding Classification

Spaulding's description	Type of contact	Risk of infection	Reprocessing level required	Management	Examples
Critical	Penetrates soft tissue or bone	High	Sterilization	Items that are not single- use disposable must be sterilized and stored wrapped until point of use. Single-use disposable items must not be re-processed.	Air/water syringe tips Anaesthetic syringes Endodontic instruments, including files (hand and rotary), reamers, and broaches Handpieces Instrument trays Metal Matrix Bands Mouth mirrors (when used during a procedure where tissue is cut or manipulated) Orthodontic Bands Periodontal instruments including ultrasonic tips Polishing cups, points and mandrels Restorative / operative instruments Rotary burs and diamonds Rubber dam clamps Scalers Stainless Steel Crowns Surgical instruments Surgical suction tips
Semi-Critical	Touches intact mucous membrane or non-intact skin	Moderate	High-level Disinfection (HLD)	Items that are not single-use disposable, must be sterilized, may be stored unwrapped in a clean, dry, covered area and handled with clean hands or forceps. Single-use disposable items must not be re-processed. Heat-sensitive items must receive high-level disinfection between patient use.	Articulating ribbon holder Cotton rolls Crown removing instruments Impression trays Lab burs Mouth mirrors (when used for examination only) Mixing spatula Nasal hoods Orthodontic pliers Rubber dam frame Rubber dam and rubber dam clamp forceps Suction tips other than for surgery Wedges
Non-Critical	Contacts intact skin only	Low	Intermediate- or Low-level Disinfection (LLD)	Items must be disinfected between uses.	Blood pressure cuffs Curing lights Face bows Intra-oral camera and radiograph sensors Laboratory knives and spatulas Rubber dam punch Shade guides

Environmental Surfaces

Category	Description	Management	Examples
Clinical Contact Surfaces	Direct contact with DHCP hands, patient-care items or patient skin	Protect with barriers, or clean then tuberculocidal low-level disinfection if contaminated.	Dental chairs Dental units and countertops Doorknobs Drawer and cupboard handles Light handles Radiograph equipment
Housekeeping Surfaces	Inadvertent contact with DHCP hands, patient-care items or dental appliances	Periodic cleaning, or clean and low-level disinfection if blood/saliva spills, splashes or otherwise contaminated.	Floors Sinks Walls

Note: The examples given are for illustration only and these lists are not to be considered exhaustive. Semi-critical instruments or devices that have been exposed to blood or have the potential to be exposed to blood must be treated as critical. DHCPs must use professional judgment for every instrument, device, and surface for their specific practices to ensure that the Standards are being met.

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(Links assessed October 21, 2022)

402-7609 109 ST NW
Edmonton, AB T6G 1C3

Phone: 780-432-1012
Fax: 780-433-4864
Email: reception@cdsab.ca
www.cdsab.ca