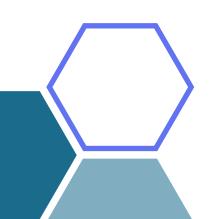


# Infection Prevention and Control (IPAC) **Guidelines**





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# Introduction

Oral health care workers (OHCW) have an obligation to their clients to establish and maintain practice environments that have organizational structures, policies and resources in place that are consistent with legal, professional and ethical responsibilities that promote safety, respect, and support for all persons within the practice setting. An OHCW meets this practice standard by:

- ensuring that all legislative requirements are met
- ensuring written policies and protocols are in place for the practice environment, such as workplace health and safety, infection prevention and control, managing hazardous wastes, and respecting human rights
- maintaining facilities, equipment, supplies and technology sufficient to provide a full scope of practice safely and effectively
- securing and maintaining appropriate service schedules and service records
- ensuring that current scientifically accepted infection prevention and control practices are in place.

# **Professional and Regulatory Considerations**

These guidelines contain infection prevention and control (IPAC) best practice recommendations which must be followed by all dental hygienists practising in Ontario while providing client care.

The CDHO's infection prevention and control guidelines are consistent with guidance documents from Public Health Ontario (PHO), the Public Health Agency of Canada (PHAC), the Provincial Infectious Disease Advisory Committee (PIDAC) and the Canadian Standards Association (CSA).

This document will be used by the College of Dental Hygienists of Ontario and/or may be used by others in determining whether appropriate standards of practice and professional responsibilities have been implemented and maintained.

The CDHO recognizes that this aspect of practice is constantly evolving, therefore, this document presents best practices at the time of publication and will be amended as new information becomes available.

# **Written Policies and Procedures**

According to PIDAC, CSA and PHAC, all oral health care workers are required to establish and document **practice-specific** written policies and procedures that are based on current recognized standards and best practices. A policy and procedure manual for up-to-date IPAC protocols must be followed by all OHCWs, reviewed at least annually or more frequently as new information becomes available, and must address the following:

- requirements for education and training of all OHCWs, including a process for continual improvement, and documentation of quality improvement IPAC goals
- immunization and vaccination status of OHCWs
- routine practices such as
  - hand hygiene
  - o risk assessment
  - o appropriate selection of personal protective equipment
- all aspects of the reprocessing of dental hygiene instruments/devices including
  - the employment of single-use items when dental equipment/devices can<u>not</u> be cleaned and reprocessed according to the recommended standards
  - the removal of faulty instruments/devices until repaired or replaced
  - the documentation of maintenance and repair of all cleaning and sterilization equipment kept for 10 years as indicated in the CDHO Records Regulation
  - quality monitoring and documentation of the reprocessing procedure including biological indicator tests, chemical indicator tests, and physical parameters. (All test results must be logged, evaluated after each cycle, signed by the person responsible, and kept for 10 years as per the CDHO Records Regulation.)
  - information to be recorded on instrument packages which must include a sterilizer number, load number and date of sterilization, load contents, and person who assembled the package
  - a recall of improperly reprocessed equipment that includes notification of the appropriate authorities, assessment of client risk, and determining if additional notification of client, other facilities, and/or regulatory bodies (e.g. public health unit, regulatory college) is required
  - a documented auditing process of competency of OHCWs involved in reprocessing and IPAC procedures, including corrective measures if needed
  - o a regular schedule for environmental cleaning of the reprocessing area that includes clearly defined responsibilities
- managing hazardous waste (biohazardous, mercury, lead, sharps)

- water and water use within the dental setting
  - for maintaining dental unit waterline quality
  - during a Boil-Water Advisory (Safe Drinking Water Act, 2002, Ontario Regulation 169/03 regulatory standards for drinking water)
- suction and suction line maintenance
- procedure for immediate containment, cleaning and disinfection of spills of blood and body fluids
- facilities maintenance (environmental cleaning, even if contracted out), such as
  - o a detailed schedule of cleaning of each area of the clinic
  - sufficient equipment, supplies and technology for all areas requiring environmental cleaning
  - o the maintenance of appropriate service schedules and service records.

# Occupational Health and Safety Requirements and Workplace Hazardous Information System (WHMIS)

In Ontario, employers have the responsibility to meet the requirements of the <u>Occupational Health and Safety Act (OHSA)</u> which includes the Ontario Regulation 860: <u>Workplace Hazardous Materials</u> <u>Information System (WHMIS)</u>. Employers and employees must comply with provincial legislation and use any equipment, protective devices or clothing required.

According to OHSA, it is a requirement that written policies and procedures are established to protect health care workers in their workplace. The policies and procedures must include the following:

- a specified health and safety representative or committee to audit the health and safety program within the practice
- a written workplace violence and harassment policy
- a clear expectation that OHCWs do not come to work when ill with symptoms of infection
- training for all new employees, new equipment, and/or new job procedures
- workplace inspections and hazard analysis
- investigations of any accidents that may occur in the workplace, including the management of needle stick injuries with specific post-exposure protocols
  - knowing the immunization status of OHCWs is important information for the physician to have in the event of an injury
- the prohibition of eating/drinking, storage of food, smoking, application of cosmetics and handling of contact lenses in non-designated areas
- a health and safety budget
- a formal means of communication to promptly address the concerns of workers
- material-handling practices and procedures (see Workplace Hazardous Materials Information System)
- emergency procedures, including medical emergencies
- first-aid and rescue procedures
- fire prevention and emergency procedures/evacuation plan.

### CDHO Infection Prevention and Control (IPAC) Guidelines

WHMIS is Canada's national communication standard that deals with hazardous materials in the workplace. According to WHMIS, any workplace that uses materials classified as controlled products is required to:

- use cautionary labelling on hazardous materials
  - label must display the product identifier, safe handling precautions, and reference to the safety data sheets (SDS)
- maintain the most current SDS for all hazardous substances, which must be renewed every three years
- provide worker education programs on how to use, handle, store and dispose of hazardous material.

A useful resource, Workplace Hazardous Materials Information System (WHMIS): A Guide to the Legislation is available at the Ontario Ministry of Labour website:

https://www.ontario.ca/document/workplace-hazardous-materials-information-system-guide-legislation

# **Human Rights**

The Ontario Human Rights Code (the Code) provides for equal rights and opportunities, and freedom from discrimination. The Code prohibits discrimination based on any of the following:

- Race
- Colour
- Creed
- Gender identity
- Marital status

- Ancestry
- Ethnic origin
- Sex
- Gender expression
- Family status

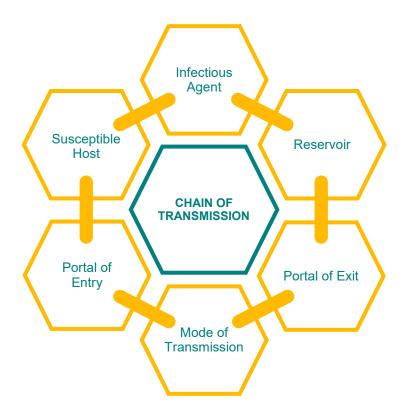
- Place of origin
- Citizenship
- Sexual orientation
- Age
- Disability

The Code recognizes persons living with certain illnesses as disabled. As such, OHCWs must <u>not</u> discriminate against such clients. This includes using additional and/or unnecessary infection control practices or other measures that are <u>not</u> used for other clients. Modifications to routine practices may be required based on the risks associated with certain procedures, provided that they are used for all clients undergoing the same procedures.

# **Transmission of Microorganisms**

There are six elements in the chain of infection. All six need to be present in order for infection to spread. Absence of any one of these elements will break the chain.

- **Infectious Agent** the pathogen that causes the disease (bacteria, fungi, parasites, viruses, prions)
- Reservoir where the pathogen lives (people, water, food)
- Portal of Exit the way the infectious agents leave the reservoir (blood, secretions, excretions, skin)
- Mode of Transmission the way the infectious agents are transferred (direct or indirect contact, droplet, airborne)
- Portal of Entry the way the infectious agents enter the host (mucous membrane, respiratory, skin, gastrointestinal tract)
- Susceptible Host any person at risk



It is critical that OHCWs understand the modes of transmission for infection to occur in order to protect their clients, their colleagues and themselves. Visiting an oral health care setting presents the risk of exposure to pathogenic microorganisms.

### CDHO Infection Prevention and Control (IPAC) Guidelines

Understanding the modes of transmission is important in the development of appropriate IPAC principles. The three main modes of transmission of microorganisms in an oral health care setting are:

- Direct transmission (from hands)
- Indirect transmission (from object such as a dental scaler)
- Droplet transmission (from coughing or sneezing)

# **Oral Health Care Provider and Client Safety**

### **Routine Practices**

The Public Health Agency of Canada uses the term "routine practices" to describe basic standards of infection prevention and control that are required for safe client care.

Routine practices are based on the assumption that all clients are potentially infectious, even when symptoms are <u>not</u> clinically evident. The same safe standards of practice must routinely apply to everyone when dealing with blood, body fluids and secretions (e.g. saliva), mucous membranes and non-intact skin, in order to break the chain of transmission.

There are five principles that are essential in routine practices:

- Risk assessment
- 2. Hand hygiene
- 3. Use of personal protective equipment
- Environmental controls
- 5. Administrative controls

### Risk Assessment

The first step for an effective use of routine practices is the performance of an at point risk assessment by the OHCW, relevant to the task at hand. A point-of-care risk assessment is applied before and at every interaction with the client, including:

- When booking and/or confirming of appointments (if appropriate, e.g., same day or next day appointment). A good opportunity to screen clients in advance for illness is when confirming dental hygiene appointments.
- Upon arrival in the reception area. All clients must be prescreened for any symptoms of communicable disease or acute respiratory infections such as influenza, fever, cough, vomiting, diarrhea, or cold and must be rescheduled in order to prevent the spread of microorganisms. An appropriate sign to alert clients to report the above symptoms must be displayed prominently in the reception area.
- In the dental hygiene operatory. OHCWs must screen the client to determine whether the client
  has a communicable disease and to assess the risk of exposure to blood, body fluids,
  secretions, excretions and non-intact skin and thus identify the strategies that will decrease
  exposure risk throughout the dental hygiene appointment.

For more information on specific conditions which may require rescheduling of clients, please refer to the CDHO Knowledge Network <a href="http://www.cdho.org/my-cdho/practice-advice/the-knowledge-network">http://www.cdho.org/my-cdho/practice-advice/the-knowledge-network</a>



OHCWs should check regularly with their local Public Health Unit for any diseases which may require pre-screening.

## Hand Hygiene

The term "hand hygiene" encompasses washing hands with soap and water or the use of alcohol-based hand rubs (ABHR). Hand washing with soap and water is required to remove visible soil, and remove/kill transient microorganisms from the hands. ABHR is the preferred method of hand hygiene if hands are <u>not</u> visibly soiled. A hand care program supports hand hygiene and includes actions taken to maintain healthy hands and fingernails. Maintaining good skin integrity is important in a thorough hand hygiene routine as intact skin is the first line of defense to protect one's self from infection.

For a quick reference please refer to the <u>4 Moments of Hand Hygiene</u> by Public Health Ontario.

### Hand hygiene must be performed:

### **BEFORE:**

- initial contact with a client
- making contact with items in client environment
- entry into the treatment room, even if the client has <u>not</u> been touched
- putting on personal protective equipment
- eating or drinking.

### **AFTER:**

- care involving contact with blood, body fluids, and secretions of a client, even if gloves are worn
- removing personal protective equipment
- moving between extra oral and intra oral procedures
- contact with a client or items in their immediate surroundings
- hands are visibly soiled
- personal bodily functions.

## Alcohol-Based Hand Rub vs Soap and Water

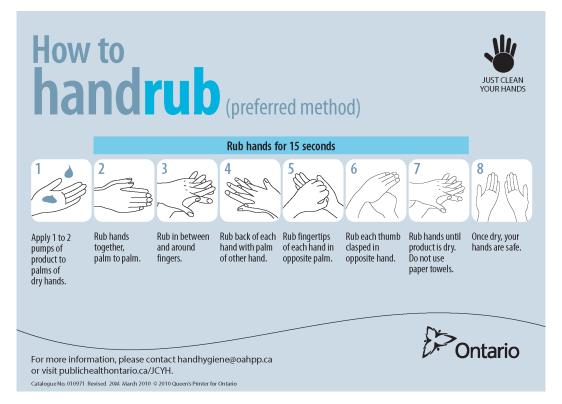
Alcohol-based hand rub (ABHR):	Hand washing with soap and running water:
<ul> <li>preferred use when hands are not visibly soiled</li> <li>must contain 70%–90% alcohol</li> <li>takes less time than hand washing</li> <li>more effective than hand washing with soap and water when hands are not visibly soiled</li> <li>requires mechanical rubbing action to kill transient bacteria</li> <li>less drying to hands than soap and water</li> <li>kills the intended microorganisms.</li> </ul>	<ul> <li>preferred when hands are visibly soiled because alcohol is inhibited by organic matter</li> <li>requires mechanical action of washing, rinsing and drying, which removes most transient bacteria</li> <li>lifts and washes away microorganisms</li> <li>must not include bar soaps.</li> </ul>

<sup>\*\*\*</sup> Best evidence suggests that antimicrobial soap is equivalent to ABHR in terms of microorganism reduction but is harsher on the hands and more time-consuming to use.

Alcohol-based hand rub and liquid soap must be dispensed in disposable containers and must <u>not</u> be "topped up".

A good hand hygiene routine should include a moisturizer that is compatible with gloves and the product being used to clean your hands.

### **Effective Hand Hygiene Techniques**





[Source: Just Clean Your Hands]

### **Barriers to Effective Hand Hygiene**

Consider the following barriers when performing effective hand hygiene:

- **Condition of the hands:** the presence of dermatitis, cracks, cuts or abrasions can trap bacteria and compromise hand hygiene.
- **Barrier creams** are absorbed by the skin and may actually be harmful as they trap agents beneath them.
- **Nails** should be short enough (i.e. <u>not</u> more than 2 mm beyond fingertip) to allow thorough cleaning underneath and <u>not</u> cause glove tears.
- Acrylic nails harbour more microorganisms and are more difficult to clean than natural
  nails. Artificial nails and nail enhancements (i.e. Shellac) are also associated with poor hand
  hygiene practices and result in more tears to gloves.
- Studies have shown that **chipped nail polish** or **nail polish worn longer than four days** can harbour microorganisms that are <u>not</u> removed by hand washing.
- **Gel polish** has been shown to damage nails, resulting in nail weakness, brittleness and thinning, putting nails at increased risk for breaking. **Nail art** (adding decorative paint effects to nails) has been shown to be associated with outbreaks of infection.
- Accessories such as rings and watches are highly discouraged as they have the
  potential to harbour microorganisms. If worn, rings must be limited to a single smooth band
  without projections or mounted stones and watches should be covered by a glove or sleeve.
- **Long sleeves** or **jewelry** should <u>not</u> interfere with, or become wet when performing hand hygiene. If watches and other wrist jewelry are present, remove or push up above the wrist before performing hand hygiene.<sup>ii</sup>



Artificial nails and nail enhancements are <u>not</u> to be worn by those having direct contact with a client/patient.

### Personal Protective Equipment (PPE)

#### **General Considerations**

Personal Protective Equipment (PPE) is worn to protect the OHCW and clients from exposure to potentially infectious material. PPE serves as a barrier to protect from exposure to splashing, spraying or spatter of blood, saliva or other body fluids, and from introducing microorganisms into deeper tissues by traumatic injuries. The selection of PPE must be based on a thorough risk assessment and the potential for transmission of infectious agents. PPE includes gloves, gowns and/or lab coats and facial protection (i.e. protective glasses, masks, face shields) as well as any techniques or equipment (e.g. high-volume suction) used to protect against diseases spread by droplets, spatter and sprays. PPE not only protects the OHCW but also protects the clients against any cross-contamination from previous clients.

PPE should be removed prior to leaving the operatory. Single-use barriers, such as gloves and masks, must be discarded immediately after use.

### **Protective Covering**

Whenever spatter or spray is anticipated during dental hygiene procedures, the use of a water-resistant gown is required. Clinical and laboratory coats or jackets are <u>not</u> a substitute for gowns where a gown is indicated.

- Regular clinical attire (e.g. uniforms, scrubs) is <u>not</u> intended to function as protection against a
  hazard where spatter or spray is anticipated. If clinical attire becomes inadvertently
  contaminated it must be changed.
- Clinical attire must <u>NOT</u> be worn outside of the office or worn home.
- A gown must be worn if it is anticipated that arms and/or clothing will be in contact with blood, body fluids, secretions or excretions.
- Disposable gowns must be removed and discarded immediately after use and prior to leaving treatment and/or reprocessing room.
- Reusable gowns must be laundered between patients/clients.
- Gowns must be long-sleeved and cuffed and provide full frontal coverage from neck to mid-thigh
  or below.
- Footwear worn in the client treatment and reprocessing areas, needs to have enclosed toes and heels and be easily cleaned.
- Hair must be secured and worn away from the face or properly covered with hair or a beard covering. If hair coverings are worn, they must be changed at least daily or more frequently if soiled.
- Staff involved in reprocessing must confine all hair including facial and body hair.
- Staff must never share PPE.

Contaminated PPE must never come in contact with clean surfaces; for example, a contaminated gown must be removed and discarded prior to removing sterilized items from the sterilizer.



Clients' clothing should be protected against spatter and debris with plastic-lined single-use bibs. Bib chains/holders require cleaning and low-level disinfection between clients or may be purchased in a single-use form.

### **Masks**

Surgical masks that cover the nose and mouth must be worn during dental procedures to protect the respiratory mucosa from coming in contact with droplets and spatter. Masks also form the basis of protection for diseases spread by the droplet route (e.g. influenza). Masks lose efficiency over time and must be changed when they become contaminated (wet, visibly soiled and/or according to manufacturer's directions) and between clients.

#### Masks are:

- to be worn by OHCWs when performing aseptic or invasive procedures
- to be securely covering the nose and mouth and substantial enough to prevent droplet penetration
- to be put on immediately before the procedure for which it is required
- to be removed and discarded immediately after the intended use
- not to be re-used (must be changed after each client or more frequently as needed)
- not to be touched while being worn
- not to be hung around the neck or under chin
- not to be folded or stored in a pocket.

### **Protective Eyewear**

Protective eyewear for the client and the OHCW shields the eyes from spatter and debris that may be created by the use of certain instruments (e.g. handpieces, ultrasonic instruments, air/water syringe) as well as protection from sharps or foreign objects.

#### Protective eyewear:

- must always be worn throughout the appointment to shield the eyes and the conjunctival mucosa from spatter and debris generated during dental procedures
- should be comfortable, fit securely, and not interfere with vision
- is to be put on immediately before the procedure for which it is required
- is to be removed immediately after the intended use

 re-usable protective eyewear including loupes, must be cleaned and disinfected after use or according to manufacturer's instructions for use (MIFU), between clients, and once they become visibly contaminated.



Prescription eyeglasses for oral health care workers are <u>not</u> considered appropriate eye protection as they do <u>not</u> provide protection against splashes around the top and sides of the glasses.

### **Gloves**

Gloves are worn to protect the hands of the OHCW from contamination. The following should be considered when using gloves as a PPE:

- selection of gloves should be appropriate to the task
- do <u>not</u> replace the need for hand hygiene
- appropriate hand hygiene protocols must be followed before donning and after removing
- must be worn when contact with mucous membranes, non-intact skin, or body fluids is anticipated
- must be put on immediately before the activity for which they are being used
- must be removed and discarded immediately after the activity for which they were used
- must not be worn outside any room or area where they are required for personal protection
- must <u>not</u> be washed and reused as soaps and alcohols can compromise the surface of the glove, leading to micro-perforations and loss of integrity
- must be changed between care for each client or more frequently as necessary
- if using lotion, check with the manufacturer's recommendations regarding the compatibility of lotions with gloves; for example, petroleum-based lotions may weaken the glove material resulting in increased permeability.

# PUTTING ON PERSONAL PROTECTIVE EQUIPMENT

PERFORM
HAND HYGIENE



PUT ON GOWN



PUT ON MASK OR N95 RESPIRATOR



PUT ON EYE PROTECTION



5 PUT ON GLOVES





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# REMOVING PERSONAL PROTECTIVE EQUIPMENT

REMOVE GLOVES



**P** REMOVE GOWN



PERFORM HAND HYGIENE



REMOVE EYE PROTECTION



FEMOVE MASK OR N95 RESPIRATOR



6 PERFORM HAND HYGIENE





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### Latex Allergy/Sensitivity

Many common dental products such as gloves, rubber dams and prophylaxis cups may contain latex and pose a severe risk for clients with latex allergies/sensitivities. Consider the following:

- As part of the medical history-taking process, questions should be asked relating to possible latex allergy/sensitivity.
- Treat in an environment where contact with latex proteins, either directly or airborne, is kept as low as reasonably achievable.
- Remove all latex-containing materials or devices from the operatory.
- Always check labels of dental products for latex content.

The use of latex gloves is <u>not</u> recommended. Allergic reactions have been reported with the use of latex gloves, and consideration must be given to this when purchasing gloves. If the OHCW or the client has a latex allergy, latex-free gloves must be used.

### **Environmental Controls**

### **Handling of Sharps and Exposure Prevention**

Sharps are devices that are capable of causing a cut or puncture wound. Sharps should be kept out of the reach of clients and safely collected in a clearly labelled puncture-resistant container at point of use and/or must be transported to the reprocessing area in a leak-proof covered container (i.e. plastic tray with a secured hard plastic cover) or cassette.

Exposures to blood-borne pathogens can occur via percutaneous injuries, non-intact skin, or through the eyes, mouth and nose. Injury prevention strategies include:

- maintaining good skin condition; intact skin is the first line of defense as a barrier to disease transmission
- using occlusive dressings to protect non-intact skin; work duties may need to be adjusted to accommodate any large skin lesions
- ensuring needles are capped prior to use and immediately recapped using a one-handed scoop method or commercial recapping device
- removing disposable sharps from the tray and disposing inside an appropriate sharps container immediately after use
- transporting sharps by using a puncture-resistant secured container when disposal at point of use is <u>not</u> possible
- removing burs from handpieces immediately after use
- wearing heavy-duty utility gloves and appropriate PPE when cleaning instruments.



In Ontario, all health care settings shall use safety-engineered needles, according to the Needle Safety Regulation (O. Reg. 474/07). The regulation is available at: http://www.ontario.ca/laws/regulation/070474

### **Exposure Management**

Pathogens that are blood borne such as Hepatitis B (HBV), Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV) can be transmitted to OHCWs through the exposure to blood, saliva and other body fluids via a puncture/laceration or by splashing onto non-intact skin or mucosa of the eyes, nose or mouth. An exposure management protocol must be included in the IPAC manual and must include the following:

- First aid procedures for the management of exposure to blood-borne pathogens
- Treatment by the appropriate health care professional (personal physician or emergency department). This may include counselling, post-exposure screening, baseline and follow-up serology and/or post-exposure prophylaxis
- Documentation of the incident
  - Include the name and vaccination status of persons exposed
  - Record the date and time of the incident and what the OHCW was doing, including the dental hygiene procedure being performed
  - o Identify what preventive measures were being implemented at the time of exposure (i.e. use of utility gloves while handling sharp instruments)
  - Document name (case number) and health status of source person if known, including any known blood-borne diseases (e.g. Hepatitis B, Hepatitis C or HIV indicated on their medical history).



All oral health care workers should be aware of the exposure management protocol and should review it periodically.

### **Administrative Controls**

### **Education and Training**

OHCWs receive education in IPAC in their professional programs. It is their responsibility to ensure that current scientifically accepted infection control practices are in place and followed. In addition to their formal training, OHCWs, including those who own their own clinic, need to ensure:

- formal IPAC education and training appropriate to their position and responsibilities is provided upon hire, at least annually, and whenever new equipment or processes are introduced
- regular continuing education is required and should be supported, as well as encouraged
- those assigned to reprocess dental equipment/devices/instruments receive device-specific reprocessing instructions from the manufacturer and seek clarification or education as required
- there are regular documented internal audits to assess the competency of staff involved in IPAC procedures
- IPAC Manuals are reviewed by all staff members and updated at least annually.

### **Immunization**

Immunizations are an important component to infection prevention and control. They minimize the OHCWs potential risk for contracting an infectious disease from a client and from transferring an infectious disease to clients and other staff.

All OHCWs should be aware of their personal immunization status and ensure their vaccines are up to date. It is highly recommended that health care professionals be immunized against:

- Hepatitis B (HBV)
- Rubella
- Diphtheria
- Polio

- Measles
- Varicella
- Pertussis

- Mumps
- Influenza
- Tetanus

Refer to the <u>Canadian Immunization Guide</u> for a complete list of recommended immunizations for health care workers.

### **Illness and Work Restrictions**

Hand hygiene is the single most important measure in protecting clients and clinicians from the transmission of microorganisms. However, even with the best of efforts, a clinician may fall victim to microorganisms and become ill.

When should an OHCW not work on clients?

- If they have acute conjunctivitis
- If they have severe respiratory illness with fever
- If they have <u>influenza</u> or a common cold
- If they have acute viral gastroenteritis with vomiting and diarrhea
- If they have non-intact skin lesions, they may need to adjust their work duties until any skin lesions have been resolved
- If an OHCW is immunocompromised, they are at an increased risk of becoming infected, therefore, when possible, considerations for work duties and exposure risk should be taken into account.

### **Additional Precautions**

In some cases, routine practices may <u>not</u> be sufficient for clients who are infected or colonized with certain microorganisms. The term "additional precautions" refers to measures that are taken in addition to routine practices to break the chain of transmission of such microorganisms.

- This is especially relevant for OHCWs treating clients in health care institutions, such as a long-term care home.
- Clients with weakened immune systems and chronic illnesses are more susceptible to methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococcus (VRE), or respiratory tract viruses like influenza.
- Clients who may be suspected of having infections transmitted by respiratory droplets must be rescheduled until the period of communicability is over.
- In emergency situations, persons who are known or suspected of having infections that can be transmitted by respiratory droplets should be offered a mask and hand hygiene upon arrival, and ideally, should maintain a distance of two metres from others in the office.
- The use of dental hygiene instruments such as ultrasonic scalers, handpieces, air polishers and the air/water syringes may create sprays, droplets or spatter. Every effort should be made to reduce the spread by using a high-volume suction or a rubber dam. Using these items will also reduce the possibility of your client ingesting or inhaling contaminated material and/or debris.



According to the Ministry of Health and Long-Term Care document Occupational Health and Safety and Infection Prevention and Control in Health Care Settings, during a pandemic influenza warning, a N95 respirator is required for OHCWs.

# Reprocessing

In order to prevent transmission of microorganisms, all reusable dental equipment and instruments being used on clients must be cleaned, disinfected and/or sterilized according to the current standards and guidelines from the Provincial Infectious Diseases Advisory Committee (PIDAC), Canadian Standards Association (CSA), and Public Health Agency of Canada (PHAC).

#### General considerations include:

- Manufacturers must supply information for all dental equipment/instruments and decontamination equipment.
- Facilities must maintain manufacturers' instructions in a format that allows for easy access by staff carrying out the reprocessing activities.
- Equipment that is used to clean, disinfect or sterilize must meet standards established by Health Canada and provincial best practices.
- Designated staff assigned to reprocessing must be trained to a level required for the volume and complexity of the equipment to be reprocessed.
- There must be a written protocol to deal with staff exposures that occur during reprocessing (chemical exposures, heat exposure, and sharps exposure).

# **Classification of Client Care Equipment**

All dental equipment/instruments used in client care are categorized as critical, semi-critical, and non-critical. The classifications of these equipment/instruments determine the minimal type of reprocessing required and the potential risk of infection associated with their use.

Category	Use	Minimum level of reprocessing	Examples
Critical	Enters sterile body site or vascular system	Cleaned and sterilized	Periodontal scalers, ultrasonic scaler tips and surgical instruments
Semi-critical	Comes in contact with mucous membranes or non-intact skin	Cleaned and sterilized  If items are heat sensitive, then they need to be replaced by single- use items	Handpieces including motors and impression trays
Noncritical	Comes in contact with only intact skin and <u>not</u> mucous membranes	Clean and low-level disinfection	Stethoscope, blood pressure cuff, shade guide, bib chain/holder

Newly purchased, non-sterile critical and semi-critical dental/medical equipment/devices must be inspected and reprocessed prior to use, according to their intended use as per manufacturer's recommendations.

## Single-Use Items/Devices

Single-use items are intended for one-time use only and are to be discarded after each client. Single-use instruments/items include:

- such items as syringes, needles, prophylaxis cups and brushes, saliva ejectors, gloves, and bibs
- some prophylaxis angles, high-volume suction tips and air/water syringe tips
- certain orthodontic brackets.

Single-use devices are usually <u>not</u> heat-tolerant and can<u>not</u> be reliably cleaned or disinfected. Therefore, they must be disposed of appropriately after use.

Single-use items will be labelled with icons similar to the following:





# **Reprocessing Area**

The reprocessing area is where all instruments, devices and equipment are cleaned, disinfected, dried, packaged, sterilized and prepared for reuse. The physical space used for reprocessing instruments must have the following:

- a clearly segregated area away from direct client care and from where clean, disinfected or sterile items are handled and/or stored
- a one-way work flow from dirty to clean to prevent cross-contamination that include separate areas for cleaning, rinsing/drying, packaging, and sterilization/cooling
- a sink sufficient in size and depth for cleaning client care equipment and instruments
- a dedicated handwashing sink or 70%–90% alcohol-based hand sanitizers available for use if a sink is <u>not</u> available
- surfaces (walls, cabinets) capable of being cleaned and disinfected
- a sufficient cleanable, non-porous counter space to handle the volume of work
- slip-proof flooring that can withstand wet mopping
- the ability to control the environment (e.g. temperature, ventilation, humidity)
- readily available PPE (gloves, gowns, mask, and/or eye protection) for staff
- a plumbed or self-contained eyewash station within a 10-second walk (16 to 17 metres [55 feet])
   of the reprocessing area that has a flushing capacity of 15–20 minutes
- a puncture-resistant sharps container.



Any instruments or sharps that are transported to the reprocessing area must be transported in a leak-proof, puncture-resistant and sealed container (e.g. plastic tray with hard plastic cover) or cassette.

## **Cleaning Reusable Dental Instruments/Devices**

Cleaning is the removal of gross debris, organic and inorganic matter including blood and saliva. The following criteria must be incorporated into cleaning routines:

- Instruments must be pre-cleaned of gross debris immediately after use at chair side to ensure that organic material will <u>not</u> dry on them.
- If cleaning can<u>not</u> be performed immediately, instruments must be kept moist and placed in a puncture-resistant holding container and soaked with a detergent or an enzymatic cleaner to prevent drying of organic material. If an instrument is <u>not</u> cleaned, remaining organic and inorganic matter may prevent effective disinfection and sterilization.
- All instruments and devices must be cleaned according to manufacturers' direction. This may include disassembly of removable parts and opening of hinges.

## **Manual Cleaning**

- Cleaning is achieved by manually scrubbing the instruments with a surfactant, detergent, or an enzymatic cleaner and must be done while immersed in water to minimize splashing.
- The brush used for scrubbing instruments must be inspected frequently and rinsed throughout the day.
- All brushes must be disposed or sterilized at the end of each day.
- Instruments must be rinsed after cleaning to remove any disinfectant, or surfactant residue.
- Instruments must be dried with a lint-free cloth or designated automatic dryer.
- Instruments must be visually inspected to ensure all organic and inorganic materials have been removed and integrity of the instruments has not been altered.



To prevent injury when handling contaminated and sharp instruments, the following precautions should be taken:

- Using puncture-resistant utility gloves
- Not reaching into trays or containers that are holding sharp instruments that cannot be seen (for example, soap-filled sinks)
- Using a long-handled brush if manually scrubbing instruments
- Wearing a mask, protective-eyewear, and gown to protect from sprays, splashes and spatter.

### Ultrasonic Cleaner

- Equipment must be tested for efficacy at least weekly and preventive maintenance should be performed according to the MIFUs.
- Basket must not be overloaded and lid must remain on especially when in use.
- Instruments must be rinsed after cleaning to remove any disinfectant, or surfactant residue.
- Instruments must be dried with a lint-free cloth or designated automatic dryer.
- Instruments must be visually inspected to ensure all organic and inorganic materials have been removed and integrity of the instrument has <u>not</u> been altered.
- Detergent or enzymatic cleaning solutions must be discarded at the end of each day, or more frequently, if they become soiled or cloudy and as per the MIFU.
- A log of all testing and maintenance procedures must be maintained.

### Washer-Disinfectors

Washer-disinfectors are computer-controlled units used for cleaning, disinfecting, and drying solid and hollow surgical and dental equipment.

- Manufacturer's instructions must be followed for the operation, maintenance and testing of the washer-disinfector to ensure that it works properly.
- The cleaning and disinfecting process must be monitored regularly according to the manufacturer's instructions and fully documented.
- Instruments must <u>not</u> be stacked or overloaded in the washer-disinfectors and devices must be disassembled if required.
- Instruments must be dried with a lint-free cloth if required.
- Instruments must be visually inspected to ensure all organic and inorganic materials have been removed and integrity of the instrument has not been altered.

### **Disinfection**

### Low to Intermediate Level

- Appropriate Personal Protective Equipment (PPE) should be worn during disinfection.
- An appropriate disinfectant must be selected that:
  - has a Drug Identification Number (DIN) from Health Canada
  - has efficacy for the intended use
  - o is compatible with the material to be disinfected (as per MIFUs)
  - o is safe for use, with minimal toxic and irritating effects to/for staff.

 Manufacturer's recommendations regarding the stability and integrity of material when selecting products for disinfection must be followed (e.g. amount, dilution, contact time, safe use and disposal).

## High Level (Cold Soak)

The use of high-level disinfectant (HLD) is highly discouraged because of its toxic vapours, special ventilation requirements, and its inability to destroy some microorganisms.

# **Preparing and Packaging of Reusable Dental Instruments/Devices**

All cleaned instruments must be prepared and packaged in a manner that will maintain sterility until use. Preparing and packaging must include the following:

- Instruments requiring sterilization must be packed and/or wrapped according to MIFUs.
- Instruments must be prepared for packaging in a manner that will allow adequate air flow and steam penetration (e.g. avoid over filling packages).
- Hinged instruments must be packaged and processed open and unlocked.
- Disassembled instruments/devices must remain disassembled until use.
- Suitable packaging materials could include peel pouches of plastic/paper, and woven or nonwoven sterilization wrap that is compatible with the sterilization process being used.
- Each package must be labelled before sterilization with:
  - Date processed
  - Sterilizer used
  - Cycle or load number
  - Initials of the OHCW who packaged the instruments.
- Labels must be placed on the transparent side of a plastic/paper pouch or directly on the closure tape of wrapped packages, taking care not to block the breathable area of the package.
- Permanent soft-tipped markers that have been validated for the sterilizer should be used ensuring they do not puncture or damage the packaging.
- The inside contents of the package need to be labelled if instruments are <u>not</u> visible (e.g. in a wrapped cassette).
- All packages must include both external and internal chemical indicators.



Please see Monitoring – Determining the Effectiveness of the Steam Sterilization Process section for requirements for physical, chemical and biological indicators on page 36.





If quarantine pending BI results is <u>not</u> possible, evaluation of a Type 5 or 6 chemical indicator and the specific cycle physical parameters may be used to justify the release of routine loads. There are contingency plans (i.e. recall policy and procedure) in the event of reprocessing failures.

### Sterilization of Reusable Dental Instruments/Devices

Sterilization is the killing of disease-producing microorganisms, including spores. All critical and semicritical instruments/devices must be sterilized before use on clients.

When sterilizing, ensure that:

- written policies and procedures are in place for the sterilization of instruments following the MIFUs.
- MIFUs have been validated, meaning that the instruments/devices will be effectively sterilized when written manufacturer's instructions for sterilization are followed.
- validated MIFUs shall be followed when sterilizing reusable instruments/devices. In the absence
  of validation, evidence-based IPAC standards and guidelines should be incorporated into the
  sterilization process.
- the MIFUs for the installation, operation, cleaning and preventive maintenance of the sterilizing equipment are followed.
- staff involved are trained to operate sterilizers, including ongoing audits and documentation of training.
- all sterilizers are tested for performance using physical, chemical and biological monitors and indicators.
- loading of packaged items into the sterilizer must follow both the MIFUs of the sterilizer and the individual instruments/items being sterilized.
- temperature at which items are sterilized must follow both the MIFUs of the sterilizer and the individual instruments/items being sterilized.
- all sterilized instruments/items must be fully dried in the sterilizer chambers prior to unloading.
- when unloading items from the sterilizer, heat-resistant mitts must be used and laundered at least weekly.
- a record is kept of all maintenance and repairs performed on all equipment used to sterilize instruments.
- a log is kept of all procedures and results used to confirm proper functioning of all sterilizers (physical, chemical and biological indicators).

### Steam Sterilization

The most common method of sterilization in a dental hygiene setting is through the use of dynamic air removal sterilizers. Pre-vacuum table-top sterilizers are recommended, however, steam flush pressure-pulse sterilizers are also acceptable for clinical office settings. All sterilization equipment used must have a Health Canada medical device licence. The cycles available on the sterilizer must be compatible with the cycles required to sterilize your instruments as per the MIFUs.

## Unacceptable Methods of Sterilization

The following methods are NOT acceptable methods of sterilization.

- Dishwasher (including those with sanitizing cycles)
- Ultraviolet irradiation
- Chemiclave sterilizers

- Boiling
- Glass bead sterilizers
- Microwave ovens

## Flash Sterilization

Flash sterilization, also known as immediate-use steam sterilization (IUSS), is a modification of conventional steam sterilization in which an unwrapped item is placed in an open tray or is placed in a specially designed, covered, rigid container to allow for rapid penetration of steam. Flash sterilization should only be used in urgent emergency situations where the instrument will be used immediately and no other options are available. Client scheduling and/or lack of instruments do <u>not</u> qualify as reasons to use flash sterilization.

The following must be considered regarding the use of flash sterilization:

- A log is kept of all particulars when this method is used (i.e. client name, procedure and instrument used).
- Instruments must be clean and dry prior to sterilization.
- Every cycle must be monitored using the appropriate indicators.
- Care is taken to prevent contamination of instruments prior to use.

A log must be kept of immediate-use steam sterilization including contents of the load and confirming all physical parameters were met. Equipment/devices sterilized in this manner must be noted in the patient's chart along with the rationale.

# **Monitoring**

## **Determining the Effectiveness of the Steam Sterilization Process**

Monitoring of the sterilizer must be done routinely and involves the evaluation of physical, chemical and biological parameters.

**Physical** – Physical indicators are the gauges or displays on the sterilizer for cycle time, temperature and pressure. Newer sterilizers have the capability to print results and/or record digitally. Physical indicators must be checked and recorded for each load. Readings that indicate the required time, temperature and pressure have been reached do <u>not</u> ensure sterilization was successful and for this reason chemical and biological testing must also be used. However, unacceptable readings must be investigated.

**Chemical** – Chemical indicators (CI) (internal and external) use sensitive chemicals to access physical conditions such as time, temperature and presence of steam. Chemical indicators must be used on the inside and outside of each package to show that it has undergone a sterilization cycle. The colour change alone is <u>not</u> enough to prove that sterilization has been achieved.

- External indicators are intended to indicate that the unit has been directly exposed to steam for a minimum amount of time and is used to distinguish between a processed and unprocessed package. Each package must have an externally visible Type 1 indicator.
- Internal indicators are intended to respond to one or more chemical or physical change. An
  internal CI must be placed in each package that is undergoing sterilization in the area least
  accessible to steam penetration. At minimum an internal Type 4 indicator must be used in each
  package.

#### **Classes of Chemical Indicators**

Туре	Description	Common Uses
Type 1: Process Indicators	Used to differentiate processed from non-processed items	Responds to one or more critical process variables
		Usually applied to the outside of packages
		E.g. Peel back pouches usually have a chemical indicator manufactured on the paper side of the package and chemical indicator tape is also available
Type 2: Specific Test Indicator	Indicator is used in specific tests or procedures to evaluate sterilizer performance	To be used with dynamic air removal (pre- vacuum) sterilizer and must be performed each day the sterilizer is used
	Its purpose is to evaluate proper air removal from the sterilizer	E.g. Bowie-Dick Test

<b>Type 3:</b> Single Variable Indicator	Reacts to a single critical process variable (i.e. temperature or time)	Exposure control monitoring in a specific location Rarely used in dental settings
Type 4: Multi-Variable Indicator	Indicator reacts to two or more critical variable in the sterilization cycle  The manufacturer specifies the conditions under which the parameters are met	May be used for process control  E.g. Indicator strips are manufactured inside on the paper side of the peel back pouches
Type 5: Integrating Indicator	Responds to all critical variables in the sterilization process (i.e. time, temperature, presence of steam)	Used as an internal CI process control Responds to all critical variables in the same way that a BI responds May be used as an additional monitoring tool to release loads that do not contain implants E.g. Indicator strips
Type 6: Emulating Indicator	Indicator reacts to all critical variables (time, temperature and presence of steam) for a specified sterilization cycle (i.e. 10 min, 18 min, 40 min)	Used as an internal CI process control  A different Type 6 emulating indicator is required for each sterilization cycle time and temperature used  May be used as an additional monitoring tool to release loads that do not contain implants

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices. 3<sup>rd</sup> ed. Toronto, ON: Queen's Printer for Ontario; May 2013.

**Biological** – Biological indicators (BI), also known as spore tests, use viable microorganisms (e.g. spore-laden strips or vials) to test sterilizer efficacy. Spore tests are the most accepted means for monitoring sterilization because spores are the most difficult microorganisms to kill. When choosing a BI spore test, the microorganism used to test must be compatible with the sterilization process being used. For example, *Geobacillus stearothermophilus* is the best microorganism to use to test efficacy of steam sterilization. A passed BI indicates that live spores have been killed, and therefore, indicates that all other microorganisms have also been killed. BI testing must be done each day a sterilizer is used and with each type of cycle. Best practice is <u>not</u> to release items of the processed load until the results of the BI test are available.

## Process Challenge Devices (PCD)

A process challenge device is "a test device intended to provide a challenge to the sterilization process that is equal to or greater than the challenge posed by the most difficult item routinely processed." (1, 2) A PCD is used to confirm that a sterilizer has effectively sterilized ALL items processed in that cycle. One example of a PCD is a set of instruments with a BI spore test and a Type 5 indicator strip inserted inside the package. This package is then placed in a routine load with other instrument pouches or wrapped cassette to challenge and test the sterilization process. If these two tests show that all spores have been killed in the BI test, all critical variables have met or exceeded the performance requirements according to the Type 5 indicator results, and that all physical parameters (time,

temperature and pressure) have been verified, you can be confident that the sterilization process has been effective and that the sterilizer is working properly. It is important to note that a PCD must only be used for the sterilizer type and sterilization cycle for which it is intended (2).

The three types of PCDs most commonly encountered in a dental hygiene practice are:

- 1. Air removal/Bowie-Dick PCD test pack
- 2. A biological indicator PCD test pack
- 3. A chemical indicator PCD test pack

## Air Removal/Bowie-Dick PCD Test Pack

If using pre-vacuum sterilizer, a Bowie-Dick PCD test pack (Type 2 CI) must be performed in an empty sterilizer at the beginning of each day it is used. The MIFUs of both the sterilizer and PCD will indicate where the test pack should be placed in the sterilizer. It is critical to confirm the type of sterilizer being used as this test is <u>only</u> required for pre-vacuum sterilizers.

An air removal/Bowie-Dick PCD test pack can be purchased commercially and is used to assess if air has been properly evacuated and whether any air leaks are present. Once the cycle containing the test pack has passed, record the results and dispose of the test pack.



For all sterilizers, follow the manufacturer's instructions for relevant sterilization monitoring tests.

## Biological Indicator PCD Test Pack

A BI PCD test pack is used for daily monitoring of sterilizers and is placed in the chamber with a full load of items to be sterilized. This must be completed once a day at the same time for each type of cycle (i.e. wrapped, plastics, handpieces, etc.)

A BI PCD test pack can be either prepared commercially or in office. To prepare your own, consider all packages routinely sterilized and choose the one that is most challenging to sterilize. For example this could be considered a package that has the most instruments. The package must be assembled as indicated by the MIFU, with a BI spore test and a Type 5 CI strip added in the area of the package where steam would have most difficulty penetrating. The package must be sealed and labelled "PCD". A BI PCD test pack must be placed in the area of the load that will be coolest during the cycle. To determine the coolest areas, the MIFUs must be followed.

Upon cycle completion, the BI is to be removed from the PCD test pack, prepared and incubated for the recommended time as indicated by the MIFU. A control BI, from the same lot as the test indicator <u>not</u> processed through the sterilizer, must be prepared and incubated with the test BI; effective sterilization is indicated when the control BI yields positive results for bacterial growth while the sterilized BI yields negative results.

The Type 5 CI must also be checked. If the results indicate a pass and all physical parameters have been met (time, temperature, pressure), the instruments may be released for use. Once the PCD test pack has been opened, it is no longer sterile, and therefore, all items within the PCD test pack must be repackaged with new indicators and re-sterilized. Although instruments can be released based on the results of the chemical indicator (Type 5), best practice is to quarantine the load until results of the BI are available.

A log must be kept documenting the date and time of sterilization, sterilizer number, sterilizer cycle, and location of the PCD within the cycle. Once the results are available and documented, the BI may be disposed of according to the MIFU. The results of all sterilization monitoring tests must be recorded and retained for 10 years as per the CDHO Records Regulation.

## Biological Indicator PCD Failure

In the event a BI PCD yields positive results for bacterial growth (a failed test), the OHCW should follow the steps below to ensure the client's safety:

- 1. Inform the supervisor/owner of the practice.
  - The supervisor/owner will want to know the time and date of failure, sterilizer and load/ cycle number in question, CI results, results of physical monitoring, BI results, and any other information that may be useful in determining the problem.
- 2. Investigate the problem.
  - Review cycle parameters (physical and CI) since the last negative BI (successful test)
    result Discuss the possibility of errors such as overloading, failing to provide acceptable
    package separation, and using incorrect and/or excessive packaging material with all
    equipment operators.
- 3. Temporarily take sterilizer out of service and quarantine all instruments back to previous negative BI (successful test).
- 4. Retest the sterilizer with a second BI PCD test.
  - While waiting for the test results, the sterilizer should remain out of service.
- 5. If the repeat BI PCD test is negative for growth (successful test) and chemical and physical indicators demonstrate adequate processing, the sterilizer may be put back into service.
  - All items from the failed load must be resterilized.
- 6. If the repeat BI PCD test is positive for growth (failed test) and all sterilization procedures have been performed accurately, the sterilizer must remain out of service and be inspected and repaired. Prior to returning the sterilizer to service, it must be qualified with three BI PCD tests in three consecutive empty chamber cycles. All three tests must yield negative results.
  - Initiate recall protocol, which means all items from suspect loads dating back to the last negative BI must be recalled, to the extent possible, and reprocessed.

- 7. Follow the recall protocol for client notification as per policy, including consulting with your local public health unit for risk assessment and to determine if client notification is necessary.
- 8. Keep a recall log of all maintenance associated with a positive BI PCD test.

## Chemical Indicator PCD Test Pack

A CI PCD test pack measures two or more variables for the area in the sterilizer in which it is placed. If the sterilizer has a printer/USB, and instruments are <u>not</u> quarantined, a CI PCD test pack containing a Type 5 CI must be placed in every subsequent load after the BI PCD test pack load. The remainder of the packages in the load need to have a Type 1 CI on the outside and a Type 4 CI on the inside.

If the sterilizer does <u>not</u> have a printer/USB, plan to replace it with one that does. In the meantime, all the physical parameters (time, temperature, pressure) need to be evaluated and documented manually, and a Type 5 CI must be used in every package.

The easiest way to assemble a chemical indicator test pack in office is to choose the instrument pack that is most challenging to sterilize (i.e. the package with the most instruments) and insert a CI strip (Type 5) in the area of the package where steam would have the most difficulty penetrating. The package should be sealed and labelled as a "PCD". The CI PCD test pack should be placed in the area of the load that will be coolest during the cycle. To determine the coolest areas, the MIFUs must be followed.

Once the load containing a CI PCD test pack has been sterilized, the Type 5 CI within the PCD should be evaluated for a successful pass and all physical parameters should have been met (time, temperature, pressure). Once confirmed, the instruments may be released for use. As soon as the CI PCD test pack has been opened, it is no longer sterile and therefore all items within the CI PCD test pack must be repackaged with new indicators and re-sterilized.



If Instruments are quarantined and the sterilizer has a recording device (i.e. USB/printer), every package must have an external Type 1 CI and an internal Type 4 CI.

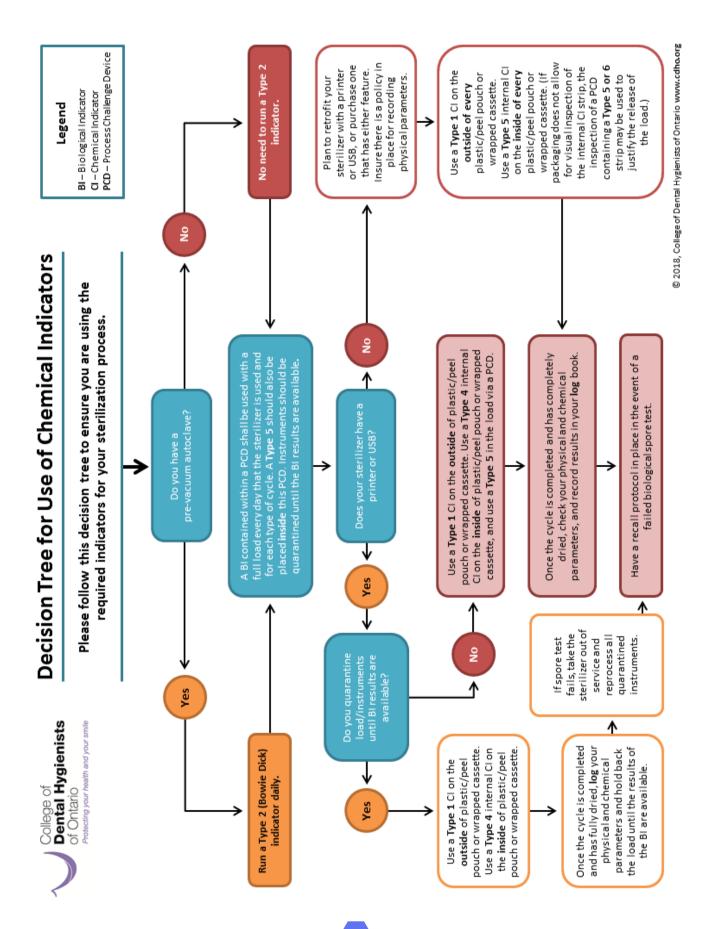
## CI, CI PCD and/or Physical Parameters Failures

- 1. Inform the supervisor/owner of the practice.
  - The supervisor/owner will want to know the time and date of failure, sterilizer and load/ cycle number in question, CI results, results of physical monitoring, BI results if available and any other information that may be useful in determining the problem.
- 2. The sterilizer should be temporarily taken out of service.
- 3. The cause of the failure should be investigated.
- 4. If the failure is confined to one load and can be immediately corrected, simply correct the problem and reprocess the load.

- If a failed CI is found in one package, the contents of the package must be reprocessed before use.
- o If a failed CI is found in multiple packages, or if any physical parameters are <u>not</u> met, the entire load must be reprocessed.
- 5. If the failure can<u>not</u> be immediately corrected, recall and reprocess all items back to the last successful load (both CI and physical parameters met).
- 6. If a major repair is done, requalify the sterilizer (see section below for qualifying and requalifying sterilizers).
- 7. Keep a log of all maintenance associated with any failed tests.



Do <u>not</u> use any reprocessed instrument if there are any doubts about the sterility of instruments.



## **Logging the Sterilization Process**

A log book must be maintained for each load sterilized. This is a key component of the recall protocol as it allows for identification of clients who may have been exposed to non-sterile instruments or equipment.

The log book needs to include:

- 1. Date
- 2. Load number
- 3. Time cycle started
- 4. Cycle parameters (total time of cycle, pressure and temperature reached)
- 5. Load contents
- 6. Internal and external chemical indicator results (pass or fail)
- 7. Biological and chemical indicator results via BI and CI PCDs (pass or fail)

## **Documenting a Recall Incident**

A recall log must be kept of all failed tests outlining the procedures for the recall of improperly reprocessed items. The following should be included:

- 1. Circumstances (i.e. failed tests) that prompted a recall order
- 2. A list of medical devices, sterilizers, loads included in the recall
- A list of supervisors, owners or public health units that were notified of the recall
- 4. A list of items that were ordered for recall but <u>not</u> collected (i.e. those that were already used on clients)
- 5. The corrective actions taken to resolve the issue and procedures implemented to prevent re-occurrence
- 6. The client notification procedures

## **Qualifying and Requalifying Your Sterilizer**

Sterilizers must be rigorously qualified on installation and requalified following disruptions to their normal activity. They must be installed according to the manufacturer's instructions by a qualified technician and must pass three consecutive cycles with the appropriate Bowie-Dick (if required), and three BI PCDs placed in three additional empty loads. Finally, the sterilizer must be qualified with at least **one full** BI PCD test load, before the sterilizer can be put into routine service. A sterilizer must <u>not</u> be approved for use if any indicator(s) yield a failed test on any of the tests conducted for the purposes of **qualifying** or **requalifying** the sterilizer.



Sterilizers must be monitored with a test load and be fully **requalified** annually and under the following circumstances:

- 1. The purchase and installation of a new sterilizer or loaner sterilizer
- 2. After construction or other environmental changes in the area
- 3. The relocation of a sterilizer
- 4. After the sterilizer is repaired or modified
- 5. After unexplained sterility failure.

## Storage of Reprocessed Dental Instruments / Single-Use Devices

All items must be carefully handled and stored to avoid contamination through small, often undetected holes:

- in a clean, dry, moisture- and dust-free area (e.g. closed shelves or containers)
- away from high areas of traffic
- not under sinks as this may cause contamination.

If the integrity of the package has been maintained during storage, the sterilized items remain sterile. A plastic jacket may greatly extend the shelf life of the package and should be used on muslin- or crepewrapped packs. The expiry dates that some manufacturers put on their packaging products must also be followed. Prior to use, sterile packages/bags must be checked to ensure that the sterility has <u>not</u> been compromised by:

- visually inspecting for discoloration, dampness, dust, soil, and tears
- validating CI results
- checking for defects in the instruments.

Extremes of temperature and humidity must be avoided. Instruments/devices must always be stored at a temperature of 18°C to 23°C and humidity level of 30% to 60%.



It is a standard of practice for dental hygienists to ensure that current scientifically accepted IPAC guidelines are in place and followed. Other team members may be involved in the reprocessing, but ultimately, the dental hygienist as the end user is responsible for verifying whether the equipment used on his/her client is sterilized and treatment is provided in a clean and safe environment.

# **Environmental Cleaning**

Dental hygiene services should only be provided in environments that are able to support safe, quality care. When evaluating the environment, OHCWs should consider ways in which to minimize the transfer of microorganisms from soiled hands, soiled instruments or soiled environmental surfaces. When choosing finishes and furnishings for the clinical practice setting, seamless, non-porous and easy to clean items should be considered.

There are two categories of environmental cleaning for clinical office settings:

- Public contact surfaces (low-touch surfaces)
- Clinical contact surfaces (high-touch surfaces)

## **Public Contact Surfaces**

Generally, there is minimal risk of microorganism transmission in these areas as they typically do <u>not</u> come into contact with blood and saliva. Some examples of public contact surfaces include the reception area (e.g. chairs, toys, countertops, etc.), consultation rooms and business office. To minimize the risk to clients and staff, any soiled clothing (lab coats/gowns worn during treatment) and PPE must be removed after leaving treatment rooms and before entering public spaces. These areas should be cleaned daily, or more frequently, if soiled. Floors should be HEPA-filter vacuumed and/or wet mopped daily. Mop heads and buckets must be cleaned thoroughly between uses and allowed to dry completely. Mops used in clinical contact areas should <u>not</u> be used in public contact areas. Carpeted areas and upholstered furnishings are discouraged, however, if used, must be cleaned on a regular schedule.

In the event public contact surfaces become soiled with blood or body fluids (i.e. a client vomits in the reception area), using appropriate PPE, the surfaces must be cleaned first, and then disinfected for the appropriate contact time according to the product's MIFUs.

## **Clinical Contact Surfaces**

Carpeted areas, upholstered and wood furnishings are <u>not</u> acceptable in treatment rooms or instrument reprocessing areas as they are difficult to clean and disinfect. Clinical contact surfaces are very likely to be contaminated with blood and body fluids through direct spray, spatter, contaminated instruments, or from the clinician's gloved hands.

High-contact surfaces include:

- Dental chair/switches
- Chairside computer keyboards, monitors and mouse
- Intraoral cameras
- Sink and faucet handles
- Telephones (if in operatory) and pens

- Overhead light handle and switches
- Radiography equipment
- Drawer and door handles
- Countertops

Clinical contact surfaces include those high-touch surfaces that are in the immediate area of client treatment and must be cleaned of gross debris and then disinfected with a low-level disinfectant between every client and at the end of each work day. Treatment areas must be free of clutter and unnecessary supplies and equipment on counter tops in order to minimize contamination with spatter, droplets or sprays and facilitate effective disinfection. Appropriate PPE must be worn while disinfecting surfaces to prevent occupational exposure to infectious microorganisms and chemicals.

## **Barriers**

Barriers should be used on high-touch surfaces that are difficult to clean and disinfect. Suitable barriers should be moisture-proof such as plastic bags or plastic sheets.

Consideration should be given to using barriers on:

- exposure button on radiography equipment
- switches of low- and high-volume suctions
- buttons of air/water syringe
- computer keyboards, mouse and monitor screen
- headrest
- overhead light handle and switches
- radiography equipment and digital sensors
- intraoral cameras

Barriers must be changed between clients using appropriate PPE. Areas covered by barriers should be disinfected and allowed to dry completely prior to placing a new barrier as these areas may become contaminated during treatment.



Any surfaces that come into contact with blood and saliva must be readily cleaned first, and then disinfected.

## **Waste Management**

Waste must be separated into biomedical waste (hazardous waste) and general office waste then disposed of in an appropriate manner to prevent the transmission of possible infections from contaminated waste.

## **Biomedical Waste**

Biomedical waste requires special storage, handling and disposal according to Ontario provincial and municipal regulations.

Biomedical waste must be:

- stored in colour-coded containers that are marked with the universal biohazard symbol
- released to an approved biomedical waste carrier for disposal.

## Blood-soaked materials (release liquid or semi-liquid blood if compressed)

- Blood-soaked materials must be placed in a YELLOW liner bag labelled with the universal biohazard symbol.
- If blood-soaked materials are to remain on site for more than four days, they
  must be stored in a refrigerated storage area marked "Biomedical Waste
  Storage Area" displaying the universal biohazard symbol.



- Blood-soaked materials must be released to an approved biomedical waste carrier for disposal
- If gauze, cotton rolls, and examination gloves do <u>not</u> release liquid or semi-liquid when compressed, they are considered general office waste.
- For more information refer to <u>Best Management Practices for Disposal of Biomedical/</u>
  <u>Pathological Waste in Ontario</u>

Sharps (needles, syringes with needles, scalpel blades, clinical glass, scalers and cavitron tips, etching tips, etc.)

- **Sharps** must be disposed of in a YELLOW puncture-resistant, leak-proof container specifically designed for their management and labelled with the universal biohazard symbol
  - Containers must <u>not</u> be filled beyond their designated capacity
  - Must only be released to an approved biomedical waste carrier for disposal.

## **General Office Waste**

General office waste includes items that are no more infectious than residential waste and therefore require only careful containment and removal.

- Plastic bags to line garbage containers should be removed and tied when ¾ full and replaced with a new bag (do <u>not</u> overfill).
- Use waterproof containers with tight-fitting lids for storage until disposal.

Environment Canada provides a reliable resource on best practice options which are clinically effective and environmentally sound in the management and disposal of dental waste materials.

Flowcharts are available and provide all members of the dental community with an easy access to best practice options for the management/disposal of heavy metals, biomedical/pathological and chemical wastes with minimum impact on the environment.

## **Disposal of Teeth**

Teeth can be disposed of as general office waste if they do <u>not</u> contain amalgam restoration. If teeth contain amalgam restorations they should be discarded according to the guidelines for mercury-containing waste.

## Mercury-Containing Waste Protocol

Best practices for the disposal of dental amalgam and mercury wastes in Ontario are subject to provincial regulations and municipal bylaws. For more information refer to <a href="Best Management Practice">Best Management Practice</a> Flowchart.

# **Special Considerations**

## **Dental Unit Waterlines**

Dental unit waterlines (DUW) are made of narrow-bore plastic tubing that carries water to handpieces, air/water syringes, ultrasonic scalers and prophy jets. They can become heavily colonized with waterborne microorganisms, including bacteria, fungi, and protozoa by forming a biofilm on the interior surface of the waterline. However, DUW are generally <u>not</u> considered to be conducive environments for the colonization of bacteria commonly found in the oral cavity.

Generally, high numbers of these opportunistic microorganisms are <u>not</u> dangerous to the general population, unless the client or OHCW is an immunocompromised susceptible host. Examples of immunocompromised susceptible hosts include OHCW or clients with HIV, persons undergoing oncology treatment or organ transplantation procedures, those with cystic fibrosis, or those with chronic bronchitis.

The potential risk of infection from DUW microorganisms can be effectively reduced to counts similar to those in potable water standards by following regular waterline maintenance procedures.

For offices using city water supplies:

- Waterline heaters must <u>not</u> be used, as the heat can foster the growth of microorganisms.
- All waterlines must be purged at the beginning of each workday by flushing them thoroughly
  with water for a minimum of 2 minutes. Handpieces, air/water syringe tips and ultrasonic tips
  must be removed prior to purging the waterlines.
- Handpieces using water coolant are run for a minimum of 20 seconds after each client. The handpiece is then removed for reprocessing.

For offices using closed or other special water delivery systems:

- The MIFUs must be followed for required maintenance.
- OHCW should be careful <u>not</u> to touch the tubing with fingers or soiled gloved hands when changing the water coolant bottle, as this can easily contaminate the entire system.



Manufacturer's instructions regarding testing, maintenance and preventative maintenance of lines, anti-retraction valves and other accessories must be followed.

## **Devices with Lumens**

During the sterilization process, a sterilizing agent has more difficulty penetrating dental devices with a hollow centre or lumen, than it does penetrating one with a solid centre, such as a dental mirror. Air can become trapped in the lumen and can hinder the efficacy of the sterilizing agent's contact with the internal surface of the instrument. To safeguard against putting patients/clients at risk, the following process must be followed for cleaning of dental devices that have lumens where applicable.

- Cleaned with a brush as per the MIFU.
- Manually or mechanically flushed with a detergent solution.
- Final rinse with commercially prepared sterile, pyrogen-free water.
- Checked for obstructions and leakage.
- Dried with compressed air that has been filtered and dried.



For devices that have small lumens, such as air/water syringes that cannot be properly cleaned as stated above, single-use devices shall be used.

## **Dental Handpieces and Other Devices**

There are many different devices used in the dental office that contact mucous membranes and are attached to the air and/or waterlines of the dental unit, including:

- high- and low-speed handpieces including motors
- ultrasonic and sonic instruments
- prophylaxis angles / prophy jets
- air/water syringe tips

Dental handpieces including motors and devices can draw back oral fluids into their internal compartments, which can then be introduced into the oral cavity of another client during use.

- Flush out any potential client material that might have entered the turbine or air and waterlines by activating the device to discharge air and water for a minimum of 20 seconds after each use.
- Handpieces must be disassembled prior to sterilization.
- Dental handpieces and other intraoral devices that are attached to air or waterlines must be cleaned, lubricated and sterilized after each client use according to the MIFUs.
- If components are permanently attached to dental unit waterlines (e.g. electric handpiece
  motors, handles for ultrasonic devices, and attachments for saliva ejectors, high-volume suction
  and air/water syringes), they must be covered with barriers that are changed after each client
  use. The item must then be cleaned and disinfected with a low-level disinfectant before the next
  client is brought into the treatment room.

## **Boil-Water Advisory**

When a boil-water advisory (BWA) is issued, it indicates that water is unsafe to drink or use in any dental treatment including hand hygiene and reprocessing. Consult with your local Public Health Unit for information on advisories in your area.

## Saliva Ejectors and Suction Lines

Closing lips and making a seal around a low-volume saliva ejector can create a partial vacuum, therefore creating backflow. This backflow can result in microorganisms from the suction lines entering the client's mouth. Therefore, OHCWs should be careful <u>not</u> to allow clients to close their mouths over the saliva ejector tip. Specially designed saliva ejectors exist that do <u>not</u> allow a negative pressure to form around the tip. Additionally, to minimize debris and microorganisms from the suction lines:

- Purge between clients by aspirating water and/or an appropriate cleaning solution with air to produce turbulent flow in the lines.
- Flush with an enzymatic cleaner or appropriate cleaning solution at least once per week or as per MIFUs.

## Radiography Equipment

When handling radiographs and radiographic equipment, special considerations should be taken to prevent cross-contamination from blood or saliva.

## Film

- After a radiograph is exposed, the film packet should be cleaned of gross debris, and saliva.
- Film packet should be disinfected with an appropriate low-level disinfectant and dried before opening to develop the film.
- Alternatively, if a barrier pouch is used over the film, it should be removed and disposed of. The
  film should be dropped onto a clean surface while being careful to avoid contamination of the
  inner film packet. Gloves should then be removed, hand hygiene performed, and clean gloves
  used while developing film. These steps will help to prevent contamination of the developing
  equipment.
- When inserting hands into a developer with sleeves, care should be taken <u>not</u> to contaminate the sleeves by only inserting cleaned, disinfected films and clean gloved hands.
- In the event the sleeves become contaminated, they should be removed, washed with soap and water, dried and replaced.

## Digital Radiography

Digital radiography is gaining popularity and special precautions need to be considered.

- Digital radiography sensors should be protected with barriers as they come into contact with mucous membranes.
- After barrier removal, sensors should be cleaned of gross debris and saliva, and disinfected with a low-level disinfectant or as per manufacturer's instructions.
- If keyboards are used in conjunction with the digital radiography equipment, a barrier should be placed to avoid contaminating the keyboard/mouse.
- Once procedure is completed, barriers must be removed after each client, equipment disinfected, and new barriers placed.

## **Intraoral Cameras**

Intraoral cameras come in many models.

- Barriers should be used on the portion that goes intra-orally and on any surfaces that can become contaminated.
- After use, barriers must be removed, cleaned of gross debris and saliva, and wiped with a lowlevel disinfectant or as per MIFUs.

## Lasers

Depending on the use of the laser, special precautions should be taken.

- Proper ventilation to accommodate for odours, tissue debris and laser plume
- Appropriate suction units with in-line filters suitable to capture debris being removed
- MIFUs followed for cleaning and disinfection/sterilization.

## **Sharpening Stones**

Sharpening stones must be sterilized according to validated MIFUs. Instruments must be cleaned and sterilized following sharpening and prior to being used on a client. If the sharpening stone is <u>not</u> a registered medical device with Health Canada then sharpening must <u>not</u> be conducted chairside.

## Injectable Medications, Vials and Solutions

- Single-dose injectable medications are prepared at the time of use, used once on a single client and discarded immediately.
- Rubber stoppers (diaphragm/septum) on vials are scrubbed with a 70% alcohol prep pad prior to entry into the vial in preparation for administration. Stopper is allowed to dry before inserting a new needle into the vial.
- Unopened vials and other products are discarded upon expiration and according to the manufacturer's instructions.

## **Dental Laboratory**

Proper IPAC protocols are necessary when handling impressions, prostheses, and appliances in order to prevent the exposure of potential pathogens to clients, the office environment and OHCWs. Good communication within clinical dental/dental hygiene offices and outside providers (i.e. dental laboratory) is important to ensure that appropriate IPAC protocols are in place and being followed. This will minimize the risk to clients while preserving the integrity or quality of materials used.

Although they pose the least risk of transmission of infection due to lack on contact with clients, cleaning, disinfection and maintenance of non-critical dental laboratory equipment such as trimmers, articulators, spatulas, bowls, case pans and buffer wheels must be followed as per MIFUs.

## Sending Items to a Commercial Lab

All items sent to a commercial laboratory should be considered contaminated and as a possible source of infectious agents. Contaminated items must be properly decontaminated, packaged and labelled before sending them out to the lab.

For example, alginate impressions that have come into contact with the client's oral cavity must be cleaned of gross debris and saliva, secured in a plastic leak-proof bag, and sprayed with a low-level disinfectant.

## Receiving Items from a Commercial Lab

- All items received must be properly disinfected prior to dispensing or placing in a client's mouth.
- Reusable plastic containers must be properly disinfected/sterilized according to MIFUs.

## Sending Items Out for Repair and/or Maintenance

Ensure contaminated items are properly decontaminated, packaged and labelled before sending out to limit the risk of transmission.

- Clean, package, and decontaminate (if possible sterilize) instruments before sending for repair or maintenance.
- Once cleaned, place items in a new sealed plastic bag; label to indicate "cleaned"; and then place in a clean, puncture-resistant container for transport.
- Do <u>not</u> reuse single-use shipping materials (e.g. plastic bags).



Dental/dental hygiene practices and commercial dental laboratories should collaborate on an agreed-upon protocol regarding appropriate cleaning and disinfection procedures for all items being received and sent out.

## Resources

- MDRAO. Medical Device Reprocessing Manual. 4<sup>th</sup> ed. Scarborough: Brown Brook Company; cJune 2017.
- CSA Group. SPE 1112-14: User handbook for medical device reprocessing in community health care settings. Toronto, ON: CSA Group; 2014.
- Ontario Agency for Health Protection and Promotion (Public Health Ontario). Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices. 3<sup>rd</sup> ed. Toronto, ON: Queen's Printer for Ontario; May 2013.
- Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Heath Care Settings, 2013 Provincial Infectious Diseases Advisory Committee, Ontario Ministry of Health and Long-Term Care <a href="https://www.publichealthontario.ca/-/media/documents/bp-cleaning-disinfection-sterilization-hcs.pdf?la=en">https://www.publichealthontario.ca/-/media/documents/bp-cleaning-disinfection-sterilization-hcs.pdf?la=en</a>
- Best Practices for Environmental Cleaning for Prevention and Control of Infections in All Health Care Settings, 2018 Provincial Infectious Diseases Advisory Committee, Ontario Ministry of Health and Long-Term Care
  - https://www.publichealthontario.ca/-/media/documents/bp-environmental-cleaning.pdf?la=en
- Best Practices for Hand Hygiene in All Heath Care Settings, 2014 Provincial Infectious Diseases Advisory Committee, Ontario Ministry of Health and Long-Term Care <a href="https://www.publichealthontario.ca/-/media/documents/bp-hand-hygiene.pdf?la=en">https://www.publichealthontario.ca/-/media/documents/bp-hand-hygiene.pdf?la=en</a>
- Canadian Medical Device Reprocessing (CAN/CSA-Z314-18), 2018 Canadian Standards Association <a href="https://store.csagroup.org/ccrz">https://store.csagroup.org/ccrz</a> ProductDetails? <a href="https://store.csagroup.org/ccrz">viewState=DetailView&cartID=&sku=2704392&isCSRFlow=true&portalUser=&store=&cclcl=en\_US</a>
- Infection Prevention and Control (IPAC) Checklist for Dental Practice Core Elements, 2019 Public Health Ontario
  - https://www.publichealthontario.ca/-/media/documents/checklist-ipac-dental-core.pdf?la=en
- Infection Prevention and Control (IPAC) Checklist for Dental Practice: Reprocessing of Dental/Medical Equipment/Devices, 2019 Public Health Ontario <a href="https://www.publichealthontario.ca/-/media/documents/checklist-ipac-dental-reprocessing.pdf?la=en">https://www.publichealthontario.ca/-/media/documents/checklist-ipac-dental-reprocessing.pdf?la=en</a>
- Guideline C-4: The Management of Biomedical Waste in Ontario, 2016 Ontario Ministry of the Environment <a href="https://www.ontario.ca/page/c-4-management-biomedical-waste-ontario">https://www.ontario.ca/page/c-4-management-biomedical-waste-ontario</a>
- Infection Prevention and Control for Clinical Office Practice, 2015 Provincial Infectious Diseases Advisory Committee, Ontario Ministry of Health and Long-Term Care <a href="https://www.publichealthontario.ca/-/media/documents/bp-clinical-office-practice.pdf?la=en">https://www.publichealthontario.ca/-/media/documents/bp-clinical-office-practice.pdf?la=en</a>
- Routine Practices and Additional Precautions in All Heath Care Settings, 2012 Provincial Infectious Diseases Advisory Committee, Ontario Ministry of Health and Long-Term Care <a href="https://www.publichealthontario.ca/-/media/documents/bp-rpap-healthcare-settings.pdf?la=en">https://www.publichealthontario.ca/-/media/documents/bp-rpap-healthcare-settings.pdf?la=en</a>

### CDHO Infection Prevention and Control (IPAC) Guidelines

Standard of Practice: Infection Prevention and Control Standards and Risk Management for Dentistry, 2010 Alberta Dental Association and College <a href="https://www.dentalhealthalberta.ca/wp-content/uploads/2019/03/Standard-of-Practice-Infection-Prevention-and-Control.pdf">https://www.dentalhealthalberta.ca/wp-content/uploads/2019/03/Standard-of-Practice-Infection-Prevention-and-Control.pdf</a>

Workplace Hazardous Materials Information System (WHMIS): A Guide to the Legislation, 2017 Ontario Ministry of Labour <a href="https://www.ontario.ca/document/workplace-hazardous-materials-information-system-guide-legislation">https://www.ontario.ca/document/workplace-hazardous-materials-information-system-guide-legislation</a>

Infection Prevention and Control Guidelines, 2012 College of Dental Hygienists of British Columbia. <a href="http://www.cdhbc.com/Documents/Infection-Prevention.aspx">http://www.cdhbc.com/Documents/Infection-Prevention.aspx</a>

https://www.publichealthontario.ca/-/media/documents/bp-hand-hygiene.pdf?la=en

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# **Glossary**

## **Additional precautions**

Additional precautions are based on the mode of transmission for the pathogen in question. They are always in addition to Routine Practices. Additional precautions are intended to be used with patients/ clients who have been or are suspected of being infected or colonized by highly-transmissible pathogenic agents, or are deemed to be a high epidemiological risk, in order to prevent transmission in the workplace.

### Alcohol-Based Hand Rub (ABHR)

An alcohol-containing product designed for application to the hands to reduce the number of viable microorganisms on the hands; in health care settings products should contain 70% to 90% alcohol.

#### **Bacteria**

Bacteria are single celled, living organisms.

#### **Barrier**

An obstacle or obstruction that resists the penetration of microorganisms.

## **Biological Indicator (BI)**

A test system containing viable microorganisms providing a defined resistance to a specified sterilization process. Biological indicators are made up of small plastic vials containing two elements: living, non-pathogenic spores resistant to sterilizing agents, and a culture medium to encourage growth after sterilization.

### **Biomedical waste**

Contaminated, infectious waste from a clinical setting that requires treatment prior to disposal in landfill. Biomedical waste includes human anatomical waste, human liquid blood and blood products, items contaminated with blood or blood products that would release liquid or semi-liquid blood if compressed, body fluids visibly contaminated with blood, body fluids removed in the course of surgery, sharps, and broken glass which has come into contact with blood or body fluid.

#### **Chemical Indicator (CI)**

A system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process. Chemical indicators are placed both on the external surfaces and internal packages to be processed.

### Cleaning

The removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use.

#### **Critical devices**

Devices that enter sterile tissues, including the vascular system.

#### **CSA**

Canadian Standards Association

#### **Decontamination**

The process of cleaning, followed by the inactivation of pathogenic microorganisms, in order to render an object safe for handling.

### **Detergent**

A synthetic cleansing agent that can emulsify oil and suspend soil.

#### Disinfectant

A chemical agent that kills most disease-producing microorganisms, but <u>not</u> necessarily resistant bacterial spores.

#### Disinfection

A process that kills the majority of pathogenic microorganisms, but <u>not</u> necessarily the resistant bacteria spores.

### **Droplets**

Particles (greater than or equal to 5 µm) projected over a short distance (less than 1 m) when a person speaks, coughs, sneezes.

## **Drug Identification Number (DIN) registration**

A computer-generated eight-digit number assigned by Health Canada to a drug product prior to being marketed in Canada.

### Dynamic air removal

The evacuation of air from the sterilization chamber and the load by mechanical means (pressure or vacuum) at the beginning of the sterilization cycle.

### **Enzymatic detergent**

A formulated pre-cleaning agent that contains enzymes that break down proteins such as blood, body fluids, secretions and excretions from surfaces and equipment. Most enzymatic detergents also contain a surfactant and are used to loosen and dissolve organic substances prior to cleaning.

### **Exposure time**

The time for which the sterilizer chamber is maintained within the specified range for temperature, sterilant concentration, pressure, and relative humidity.

### Flash sterilization (Immediate-Use Sterilization)

A special steam sterilization process designed and used for the emergency sterilization of surgical goods when routine sterilization cannot be done.

## Guidelines

A set of general principles and elements that help with the choice of process and approach.

#### **Immunization**

The process by which an individual's immune system becomes fortified against an agent. Immunization is done through various techniques, most commonly vaccination.

## Infectious agent

A microorganism, parasite, or other type of biological agent likely to cause infection in its host. It has the ability to damage human health in various ways, from simple reactions to serious medical conditions, even death. Also known as "pathogenic agent".

### Lapse

A lapse occurs when there is a deviation from infection prevention and control best practices resulting in possible infectious disease transmission to clients/patients, or staff through exposure to blood, body fluids, secretions, excretions, mucous membranes, non-intact skin or soiled items.

## Manufacturer's instructions for Use (MIFU)

The written directions provided by the manufacturer or distributor of a product that contain the necessary information for the safe and effective use of the product.

## Medical Device (MD)

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 human beings for the purpose of (a) diagnosis, prevention, monitoring, treatment, or alleviation of disease; (b) diagnosis, monitoring, treatment, and alleviation of, or compensation for, an injury or handicap; (c) investigation, replacement, or modification of the anatomy or of a physiological process; and (d) control of conception.

### **Microorganisms**

Living organisms of microscopic size. Note: the term is generally used to refer to bacteria, fungi, viruses, and bacterial spores.

#### Non-critical

A medical device which either touches only intact skin but <u>not</u> mucous membranes, or does <u>not</u> directly touch the client/patient.

### Occlusive dressing

An air- and water-tight trauma medical dressing that provides a total seal to block out pathogens prevent further trauma and promote optimal healing conditions.

### One-way workflow

The practice of ensuring that reprocessing work flows in one direction, from the dirtiest to cleanest. Note: one-way workflow ensures that each level of reprocessing, including cleaning, disinfection, and sterilization, incrementally reduces the microbial load on medical devices being reprocessed. One-way workflow prevents contamination that would occur if items processed to a higher level came into contact with a lower level processed medical device or processing areas.

### **Packaging**

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

### **Personal Protective Equipment (PPE)**

Specialized clothing or equipment worn by an employee for protection against hazards.

## **Physical indicators**

The sterilizer's physical performance indicators (e.g. time, temperature, pressure) presented in the form of pressure gauges, recording printouts, graphs or other integrated accessories.

#### Point of care

The place where three elements occur together: the client/patient, the health care provider and care or treatment involving client/patient contact.

## **Process Challenge Device (PCD)**

An item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process. Note: PCD is a global term that encompasses a range of test devices intended to provide a challenge to the sterilization process that is equal to or greater than the challenge posed by the most difficult item routinely processed. For the purposes of this standard, a PCD will usually be one of the following: (a) a BI test pack (which also contains a chemical indicator); (b) a BI test tray (which also contains a chemical indicator); or (c) a CI test pack (which contains a Type 5 integrating indicator or an enzyme-only indicator).

#### **Provincial Infectious Diseases Advisory Committee (PIDAC)**

A standing source of expert advice on infectious diseases in Ontario. PIDAC has created best practice documents, reports and recommendations on matters related to communicable diseases, immunization, infection prevention and control and surveillance.

### Recall order

An order given to retrieve goods that have been incorrectly processed. Incorrect processing is most often indicated by a failed monitor or test (e.g. a failed biological indicator in a sterilization cycle).

#### Recall procedure

A written procedure that outlines the steps to be taken when a recall is required.

#### Reprocessing

The steps performed to prepare reusable medical equipment for use (cleaning, disinfection and sterilization).

#### Reusable device

A device that has been designed by the manufacturer, through the selection of materials and/or components, to be reused.

#### Risk assessment

Identification of the situations or activities that may cause a risk to the client/patient or staff.

#### **Routine practices**

Routine practices refer to infection prevention and control practices used at all times when reprocessing medical devices to prevent and control the transmission of infection.

#### Safety Data Sheet (SDS)

A document that contains information and instructions on hazardous materials present in the workplace.

### Semi-critical

Instruments that come into contact with a mucous membrane or non-intact (broken) skin.

### **Sharps**

Pointed, sharp or cutting devices.

### Single-use/disposable device

A device designated by the manufacturer for single-use only.

### **Spaulding classification**

The Spaulding classification determines the level of reprocessing required for specific groups of medical devices (critical, semi-critical and non-critical). It is based on the risk of infection that a reprocessed device will pose to a client/patient using that type of device.

#### Steam sterilizer

A sterilizing apparatus that uses saturated steam under pressure as the sterilant.

#### Sterilization

A validated process used to render a product free from viable microorganisms.

### **Tabletop steam sterilizer**

A steam sterilizer that has a chamber volume of <u>not</u> more than 42.5 L (1.5 ft3) and that generates its own steam when distilled or deionized water is added by the user.

#### Ultrasonic cleaner

A machine that cleans medical devices by the cavitation produced by ultrasound waves.

#### Washer-disinfector

A machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical, and veterinary practices.

### **Workplace Hazardous Materials Information System (WHMIS)**

Health Canada's Workplace Hazardous Materials Information System.