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CHECKLIST

Reprocessing in Dental Practice Settings

This checklist was developed as a tool to assist public health units and stakeholders in conducting inspections related to infection prevention and control lapse investigations. Unless otherwise indicated, the resource used was the Provincial Infectious Disease Advisory Committee's (PIDAC's) Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices (May 2013). Specific sections are cited for where the information may be found within the document.

The checklist was developed in collaboration with Royal College of Dental Surgeons of Ontario, The College of Dental Hygienists of Ontario and Ontario Ministry of Health and Long-Term Care. For more information about this resource, please contact ipac@oahpp.ca.

Clinic Name: _____

Clinic Address: _____

Date of Inspection: _____ Inspection Type: _____

Name of Inspector: _____

Clinic Contacts (name and phone numbers):_____

- **Legislated Requirement (Leg):** Must be compliant with the relevant Act or regulation (e.g., *Occupational Health and Safety Act*).
- **High Risk (High):** Immediate health hazard exists. Stop practice and correct immediately. The act or failure to act immediately may lead to the transmission of infection or risk of illness or injury. Practices that cannot be corrected immediately must be stopped until the health hazard is observed to have been eliminated. An Order may be warranted/ issued.
- **Medium Risk (Med):** Practices must be corrected. Timelines for compliance or agreement on alternate process to be determined during inspection.
- **Inform and Educate (I/E):** Provide information on best practices and mandatory legislated practice requirements. This may also include just-in-time education.

NOTE: These categorizations represent the minimum risk level. Based on good judgement and circumstance, public health units may increase the risk category.

Leg Req: Legislated Requirement **C:** Compliant **NC:** Not Compliant **N/A:** Not Applicable

TABLE 1. POLICIES AND PROCEDURES

1	Policies and Procedures	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
1.1	There is a written policy that says if dental/medical equipment/devices cannot be cleaned and reprocessed according to the recommended standards, they are not purchased or they are designated as single-use.		I/E	☐	☐	☐	For items 1.1 and 1.2, refer to the section on Purchasing and Assessing Medical Equipment/Devices and/or Products for Disinfection or Sterilization Processes. Additional resource: Royal College of Dental Surgeons of Ontario (RCDSO). Guidelines Infection Prevention and Control in the Dental Office, 2010.	
1.2	There are written policies and procedures for all aspects of reprocessing that are based on current recognized standards/ recommendations and these are reviewed regularly and/or as new information becomes available.		I/E	☐	☐	☐	Refer to: Canadian Standards Association. (CSA) Z314.0-13 Medical Device Reprocessing - General requirements, 2013.	

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1	Policies and Procedures	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
1.3	There is a policy and procedure for the recall of improperly reprocessed equipment that includes notification of the principle dentist or dental hygienist, assessment of patient risk and determining if additional notification of patients, other facilities and/or regulatory bodies (e.g., public health unit, regulatory college), is required.		**I/E**	☐	☐	☐	Refer to the section on Recalls. For key roles and responsibilities and contact information for all those who may be involved in investigation of a potential IPAC lapse in community health setting, please refer to the Minstry of Health and Long-term Care (MOHLTC): "Roles and Responsibilities in Community Health Care Settings During Potential Infection Prevention and Control Lapse Investigations; Information for Public Health Units and Stakeholders."	
1.4	There is a policy that requires scheduled preventative maintenance of cleaning and sterilization equipment, with written documentation that this has occurred.		**I/E**	☐	☐	☐		

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1	Policies and Procedures	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
1.5	There is a policy and procedure for quality monitoring and documentation of the reprocessing process (e.g., biological indicators, chemical indicators).		I/E	☐	☐	☐		
1.6	The health care setting has written policies regarding single-use dental/medical equipment/devices.		I/E	☐	☐	☐	Refer to the section on Single-Use Medical Equipment/Devices.	
1.7	There is a policy outlining the process for removing faulty dental/medical equipment/devices/ instruments until repaired or replaced.		I/E	☐	☐	☐		

TABLE 2. EDUCATION AND TRAINING

2	Education and Training	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
2.1	Staff (dentists, dental hygienists, certified dental assistants) assigned to reprocess dental/medical equipment/devices/ instruments have completed formal education and training in reprocessing as part		High	☐	☐	☐	For items 2.1 to 2.3, refer to the section on Education and Training. Additional resource: RCDSO. Guidelines Infection Prevention and Control in the Dental Office, 2010.	

2	Education and Training	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
	of their entry to practice education. Education should include theoretical and practical components.							
2.2	Staff assigned to reprocess dental/medical equipment/devices/ instruments receive device-specific reprocessing instructions from the device manufacturer's representative to ensure proper cleaning and high-level disinfection or sterilization. In addition, staff responsible for reprocessing reusable dental/medical instruments and devices are trained upon hire, at least annually and whenever new equipment or processes are introduced.		**High**	☐	☐	☐	Note: On purchase of simple items (e.g., explorer, scaler, forceps), staff review the manufacturer's reprocessing instructions (MIFUs) and seek clarification as required. For more complex instruments (e.g., handpiece, laser parts), education is provided from the device manufacturer's representative, based on manufacturer's reprocessing instructions.	
2.3	There are ongoing audits with documentation of competency of staff involved in reprocessing medical devices.		**Med**	☐	☐	☐	Competency requirements include ongoing education and training.	

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TABLE 3. SINGLE USE ITEMS

3	Single Use Items	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
3.1	Single-use items including needles are not reprocessed. Some items, such as prophylaxis angles, high-volume suction tips and air/water syringe tips are commonly available in single-use forms or reusable forms.		**High**	☐	☐	☐	Critical and semi-critical dental/medical equipment/devices labelled as single-use are not reprocessed and reused unless the reprocessing is done by a licensed reprocessor. Refer to the section on Single-Use Medical Equipment/Devices. Additional resource: RCDSO. Guidelines Infection Prevention and Control in the Dental Office, 2010.	

TABLE 4. PHYSICAL SPACE

4	Physical Space	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
4.1	Dental/medical equipment/devices/ instruments are cleaned in a designated area that is physically separate from direct care areas and from where clean, disinfected or sterile items are handled or stored.		**Med**	☐	☐	☐	The reprocessing work area is physically separated from clean areas by walls or if not possible, partitions or other barriers may be used. Walls or partitions should be cleaned regularly and be constructed of materials that can withstand	

4	Physical Space	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
							cleaning and disinfection. Refer to Environmental Requirements for Reprocessing Areas. If physical barriers are not feasible (e.g., family practice office), IPAC principles related to separation of clean and dirty are followed (also see 4.2).	
4.2	There is a one-way work flow from dirty to clean to prevent cross-contamination.		**High**	☐	☐	☐	For items 4.2 to 4.4, refer to the section on Reprocessing Endoscopy Equipment/Devices: Physical Space. Additional resource: RCDSO Guidelines for Infection Prevention and Control in the Dental Office, 2010.	
4.3	There is a sink sufficient in size and depth for cleaning dental/medical equipment/devices/ instruments in the reprocessing area.		**Med**	☐	☐	☐		
4.4	There is sufficient cleanable, non-porous counter space to handle the volume of work.		**Med**	☐	☐	☐		

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4	Physical Space	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
4.5	There is a dedicated hand hygiene sink and/or ABHR in the reprocessing area.		**Med**	☐	☐	☐	Do not use a hand washing sink for equipment cleaning. Refer to Appendix C: Recommendations for Physical Space for Reprocessing.	
4.6	There is a puncture-resistant sharps container at point-of-use AND/OR sharps are transported to the reprocessing area in a covered container (e.g., plastic tray with hard plastic cover) or cassette.	**Leg.**	**High**	☐	☐	☐	Refer to the section on Transportation and Handling of Contaminated Medical Equipment/ Devices. Additional resources: Occupational Health and Safety Act [O. Reg. 67/93]. For information on safety needles in the dental practice setting, please see RCDSO Dispatch article "Changes to Needle Safety Regulation Come into Effect July 1, 2010."	
4.7	There is a plumbed or self-contained eyewash station within a 10-second walk (16 to 17 metres [55 feet]) of the reprocessing area.	**Leg.**	**High**	☐	☐	☐	Refer to Appendix C: Recommendations for Physical Space for Reprocessing. Additional resources: Canadian Centre for Occupational Health and Safety. Ontario Occupational Health and Safety Act, R.R.O. 1990, Reg. 851, s.124.	

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4	Physical Space	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
4.8	There is a regular schedule for environmental cleaning in the reprocessing area that includes written procedures and clearly defined responsibilities.		**High**	☐	☐	☐	Refer to the section on Environmental Cleaning in Sterile Processing Departments. Additonal resource: CSA. Z314.0-13 Medical Device Reprocessing – General Requirements, 2013.	

TABLE 5. PERSONAL PROTECTIVE EQUIPMENT

5	Personal Protective Equipment (PPE)	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
5.1	PPE is available and readily accessible in appropriate sizes at point of care.	**Leg.**	**High**	☐	☐	☐	For items 5.1 and 5.2, refer to the section on Personal Protective Equipment.	
5.2	PPE (gloves, gowns, mask, eye protection) is worn for procedures (e.g., instrument cleaning) that are likely to result in splashes or sprays of blood or other body fluids.		**High**	☐	☐	☐		

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TABLE 6. CLEANING OF SEMI-CRITICAL AND CRITICAL DENTAL/MEDICAL EQUIPMENT/DEVICES

6	Cleaning of Semi-critical and Critical Dental/medical Equipment/Devices	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
6.1	Contaminated dental/medical equipment/devices are kept separate from clean items.		**High**	☐	☐	☐	For 6.1 to 6.10, refer to the section on Disassembly, Inspection and Cleaning of Reusable Medical Equipment/Devices.	
6.2	Gross soil (e.g., blood, sputum) is removed immediately, in the reprocessing area, to prevent organic matter from drying on the dental/medical equipment/devices.		**High**	☐	☐	☐		
6.3	If cleaning cannot be done immediately, the dental/medical equipment/device is kept moist in a transport container by using a product specifically intended for this use and in accordance with the products MIFUs.		**Med**	☐	☐	☐		
6.4	Dental/medical equipment/devices are cleaned manually with an enzymatic solution. Alternatively, mechanical cleaning can be done with a washer/disinfector or ultrasonic washer.		**Med**	☐	☐	☐		

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6	Cleaning of Semi-critical and Critical Dental/medical Equipment/Devices	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
6.5	The brush is inspected frequently and changed when dirty; sterilize or dispose of at the end of the day.		**Med**	☐	☐	☐	When using brushes for cleaning several instruments organic matter can accumulate on the brush.	
6.6	Reusable cleaning items (e.g., brushes) are discarded if worn or damaged.		**Med**	☐	☐	☐		
6.7	Ultrasonic washers and or washer/ disinfectors, if used, are tested for efficacy at least weekly or according to manufacturer's recommendations.		**High**	☐	☐	☐	Additional resource: CSA. Z314.8-14 Decontamination of Reusable Medical Devices, 2014.	
6.8	Ultrasonic washers and washer/ disinfectors receive documented preventative maintenance.		**I/E**	☐	☐	☐	If weekly performance testing parameters are being met; advise regarding importance of regular preventative maintenance.	
6.9	Dental/medical equipment/devices are dried prior to sterilization (e.g., with lint-free cloth).		**Med**	☐	☐	☐		
6.10	Detergent or enzymatic cleaning solution is discarded as per the MIFU.		**Med**	☐	☐	☐		

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TABLE 7. STERILIZATION

7	Sterilization	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
7.1	Critical instruments/ items are either disposable or sterilized using an approved sterilization process.		**High**	☐	☐	☐	For items 7.1 to 7.9, refer to the section on Sterilization of Reusable Medical Equipment/Devices.	
7.2	Items are packaged according to the manufacturer recommendations for both the packaging and the instruments.		**High**	☐	☐	☐	Additional resource: RCDSO Guidelines Infection Prevention and Control in the Dental Office.	
7.3	Each package is labelled with date processed, sterilizer used, cycle or load number and the health care provider's initials in a manner that does not puncture or dampen the package. If instruments are not visible, (e.g., in a wrapped cassette) package contents should be labelled.		**High**	☐	☐	☐		
7.4	Chemical indicators (CI) are placed appropriately in and/or on each package, if not part of the pouch/pack wrap. See Notes.		**High**	☐	☐	☐	Internal CI – Class 4 as a minimum External CI – Class 1	

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7	Sterilization	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
7.5	Items are placed in the sterilizer according to sterilizer's MIFUs.		**High**	☐	☐	☐		
7.6	Sterilizer mechanical display, printout or USB is checked, verified and signed for each cycle by the person sterilizing the instruments.		**High**	☐	☐	☐		
7.7	Sterilizer is tested with a biological indicator (BI) each day the sterilizer is used.		**High**	☐	☐	☐		
7.8	Items in the processed load should not be released until the results of the BI test are available; if quarantine pending BI results is not possible, evaluation of a Class 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.		**High**	☐	☐	☐	Refer to the section on Policies and Procedures. At a minimum, a Class 4 CI with verification of specific cycle physical parameters are checked, verified and documented. Inform and educate as necessary.	

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7	Sterilization	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
7.9	If dynamic air removal-type (i.e., pre-vacuum) sterilizer is used, an air-detection PCD (e.g., Bowie-Dick test pack) is used.		**High**	☐	☐	☐	For gravity and pressure-pulsed sterilizers follow the MIFUs.	
7.10	Records are kept to document that all sterilization parameters have been met (e.g., BIs, CIs, time/temperature/ pressure readings).		**High**	☐	☐	☐	A device is not used if any of the monitoring parameters suggest inadequate processing.	
7.11	Sterilized items are not used until the CI(s) are checked.		**High**	☐	☐	☐	Refer to the section on Routine Monitoring of Sterilizers.	
7.12	Instrument packs are allowed to dry inside the sterilizer chamber before removing and handling.		**High**	☐	☐	☐	Refer to RCDSO Guidelines Infection Prevention and Control in the Dental Office, 2010.	
7.13	If a failed chemical indicator is found, the contents of the package are reprocessed before use.		**High**	☐	☐	☐	Refer to the section on Continued Monitoring and System Failures. Additonal resource: CSA. Z314.3-14 Effective sterilization in health care settings by the steam process, 2014.	
7.14	Sterile packages are inspected for integrity. Contents of compromised		**High**	☐	☐	☐		

Leg Req: Legislated Requirement **C:** Compliant **NC:** Not Compliant **N/A:** Not Applicable

7	Sterilization	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
	packages cannot be used until the items have been reprocessed again.							

TABLE 8. STORAGE

8	Storage	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
8.1	Sterile items are stored in their sterile packaging until time of use.		High	☐	☐	☐	Refer to the section on Storage and Use of Reprocessed Medical Equipment/Devices.	
8.2	Packaged, sterilized instruments are stored securely in a manner that keeps them clean, dry and prevents contamination.		High	☐	☐	☐	Event-related sterility Refer to the section on Storage and Use of Reprocessed Medical Equipment/Devices.	
8.3	Dental/medical equipment/devices which have been reprocessed can be differentiated from equipment/devices which have not been reprocessed (e.g., colour coding).		High	☐	☐	☐	Refer to the section on Transportation and Handling of Contaminated Medical Equipment/Devices. Additional resource: CSA. Z314.8-14 Decontamination of Reusable Medical Devices, 2014.	

Leg Req: Legislated Requirement **C:** Compliant **NC:** Not Compliant **N/A:** Not Applicable

TABLE 9. OTHER CONSIDERATIONS

9	Other Considerations	Leg. Req.	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
9.1	There is a process for receiving and disseminating dental/medical equipment/device alerts and recalls originating from manufacturers or government agencies.		**Med**	☐	☐	☐	Refer to the section on Continued Monitoring and System Failures. Additional resource: CSA. Z314.0-13 Medical Device Reprocessing – General Requirements, 2013.	

TABLE 10. RECORD KEEPING

10	Record Keeping	Leg. Req	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
10.1	A written log of test results is maintained.		**High**	☐	☐	☐	A log is kept of chemical indicator monitoring results. Information to be recorded: load control label (sterilizer number, load number and date of sterilization); recording chart/printout of physical parameters of the sterilization cycle; load contents; person responsible for the sterilization cycle. Refer to the following sections on: Sterilization of Reusable Medical Equipment/Devices	

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10	Record Keeping	Leg. Req	Risk	C	NC	N/A	Notes/Resources	Inspection Notes (to be completed by individuals conducting visits/inspection)
							AND Appendix E: Sample Program Audit Tool for Endoscope Reprocessing. Additional resource: CSA. Z314.0-13 Medical Device Reprocessing – General Requirements, 2013. IPAC Canada Endoscopy audit tool, 9.10 and 9.11, pg. 14.	

Please print and sign:

Owner/Operator (print name): _____

Signature: _____ Date:_____

Signatures as appropriate: _____ Date: _____

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