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IPAC CHECKLIST FOR CHIROPODY AND PODIATRY

Reprocessing of Medical Equipment/Devices

When to use this checklist?

This infection prevention and control (IPAC) checklist:

- helps guide public health units (PHUs) and regulatory colleges in conducting inspections/assessments/investigations related to infection prevention and control (IPAC) practices.
- supports chiropody and podiatry practices in examining, evaluating (e.g., self-assessment) and comparing their current IPAC practices using provincial recommendations.
- does not replace legislative requirements.

Public Health Ontario (PHO) has developed this checklist in collaboration with the College of Chiropodists of Ontario. Its content is based on the Provincial Infectious Disease Advisory Committee's (PIDAC's) Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices (May 2013).

For more information about this IPAC Checklist, please contact ipac@oahpp.ca.

Legend

Legislated Requirement (LR): Must be compliant with the relevant Act or regulation (e.g., *Occupational Health and Safety Act*).

High Risk (H): Immediate health hazard exists. Correct the specific high risk activity/activities immediately. The act or failure to act immediately may lead to the transmission of infection or risk of illness or injury.

Medium Risk (M): Correct the medium risk activity/activities. Timelines for compliance or agreement on alternate process to be determined during the inspection.

Inform and Educate (IE): Provide information on best practices and mandatory legislated practice requirements (where applicable). Just-in-time education may be provided.

> These categorizations represent the minimum risk level. Based on judgment and circumstance, public health units or any others using the IPAC Checklist may increase the risk category.

Contents

LR: Legislated Requirement **R**: Risk **C:** Compliant **NC:** Not Compliant **NA/NR:** Not Applicable/Not Reviewed

Setting Name:

Setting Address:

☐ **Assessment** ☐ **Inspection** **Date:** **Time:**

Name(s) and Designation of Inspector/Investigator/Assessor:

Setting Contact Name(s) and Phone Number(s):

1. Record Keeping

1	Record Keeping	LR	R	C	NC	NA NR
1.1	A log of test results during sterilization is maintained and reviewed. Information to be recorded includes: • Load control label (sterilizer number, load number and date of sterilization) • Chart/printout of physical parameters of the sterilization cycle • Load contents • Person responsible for the sterilization cycle • CI monitoring results • BI monitoring results ➢ **Resources:** Refer to the sections on Sterilization of Reusable Medical Equipment/Devices. ➢ **Additional Resources:** Refer to CAN/CSA – Z314-18 Canadian medical device reprocessing (2018). ➢ PHO logs: Sterilization monitoring log for tabletop steam sterilizers.		H	☐	☐	☐

1	Record Keeping	LR	R	C	NC	NA NR
1.2	Other logs are maintained, as per MIFU: • Ultrasonic cleaner • Washer/disinfector ➢ **Resources:** Refer to the sections on Policies and Procedures and Methods of Disinfection for Semi-Critical Medical Equipment/Devices Mechanical Cleaning.		M	☐	☐	☐

Notes and Recommendations:

2. Personal Protective Equipment

2	Personal Protective Equipment (PPE)	LR	R	C	NC	NA NR
2.1	PPE is available and readily accessible in appropriate sizes. ➢ **Resource:** For items 2.1 and 2.2, refer to the section on Personal Protective Equipment. ➢ **Additional Resource:** *Occupational Health and Safety Act*, RSO 1990, c O.1, s.25, Reg. 851 s.	LR	M	☐	☐	☐
2.2	PPE (gloves, gown, mask, eye protection) is selected based on a risk assessment and worn for procedures (e.g., instrument cleaning) that are likely to result in splashes or sprays of blood or other body fluids. ➢ **Additional Resource:** *Occupational Health and Safety Act*, RSO 1990, c O.1, s.28, Reg. 851.	LR	M	☐	☐	☐

Notes and Recommendations:

3. Physical Space

3	**Physical Space**	**LR**	**R**	**C**	**NC**	**NA NR**
3.1	There is a designated reprocessing area that is separated into distinct areas for: • Receiving, cleaning and decontamination • Preparation and packaging • Sterilization • Storage ➢ **Resource:** Refer to the section on Environmental Requirements for Reprocessing Areas. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**M**	☐	☐	☐
3.2	There is a one-way work flow from dirty to clean to prevent cross-contamination. ➢ **Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**H**	☐	☐	☐
3.3	There is a sink sufficient in size and depth for cleaning medical equipment/devices in the designated reprocessing area. ➢ **Resource:** Refer to Appendix C: Space Recommendations. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**M**	☐	☐	☐
3.4	There are sufficient flat, cut-resistant, seamless and non-porous work surfaces that can be cleaned, disinfected and dried to handle the volume of work. ➢ **Resource:** Refer to Appendix C: Space Recommendations. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**M**	☐	☐	☐
3.5	Dedicated hand washing sinks and/or alcohol-based hand rub dispensers are conveniently located in or near all reprocessing and preparation areas. ➢ **Resource:** Refer to the section on Environmental Requirements for Reprocessing Area, Physical Space.		**M**	☐	☐	☐
3.6	There is a puncture-resistant sharps container at point-of-use. ➢ **Resource:** Refer to the section on Transportation and Handling of Contaminated Medical Equipment/ Devices.		**M**	☐	☐	☐

3	**Physical Space**	**LR**	**R**	**C**	**NC**	**NA NR**
3.7	There is a regular schedule for environmental cleaning in the designated reprocessing area that includes a written policy and procedure and clearly defined responsibilities. ➢ **Resource:** Refer to the section on Environmental Cleaning in Sterile Processing Departments. ➢ **Additional Resource**: CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**M**	☐	☐	☐

Notes and Recommendations:

4. Single Use Medical Equipment/Devices

4	**Single Use Medical Equipment/Devices**	**LR**	**R**	**C**	**NC**	**NA NR**
4.1	Critical and semi-critical medical equipment/devices labelled as single-use are not reprocessed and/or reused. ➢ **Resource:** Refer to the section on Single-Use Medical Equipment/Devices.		**H**	☐	☐	☐

Notes and Recommendations:

5. Cleaning of Semi-critical and Critical Medical Equipment/Devices

5	**Cleaning of Semi-critical and Critical Medical Equipment/Devices**	**LR**	**R**	**C**	**NC**	**NA NR**
5.1	Newly purchased, non-sterile critical and semi-critical medical equipment/devices are inspected and reprocessed prior to use, according to their intended use, as per MIFU. ➢ **Resource:** Refer to PIDAC Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings, May 2013. See section on Purchasing and Assessing Medical Equipment/Devices and/or Products for Disinfection or Sterilization Processes.		**H**	☐	☐	☐
5.2	Contaminated medical equipment/devices are kept separate from clean medical equipment/devices. ➢ **Resource:** For items 5.2 to 5.14, refer to the section on Disassembly, Inspection and Cleaning of Reusable Medical Equipment/Devices.		**H**	☐	☐	☐
5.3	Immediately after use, the medical equipment/devices are pre-cleaned (e.g., wiped, gross soil removed manually) at the point of use before transport for further manual or mechanical cleaning. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**M**	☐	☐	☐
5.4	If cleaning cannot be done immediately, the medical equipment/devices are kept moist in a transport container by using a product specifically intended for this use and in accordance with the MIFU.		**M**	☐	☐	☐
5.5	All medical equipment/devices consisting of multiple components (e.g., Beaver blade handles) are disassembled according to the MIFU and/or opened for cleaning and sterilization. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**H**	☐	☐	☐
5.6	Medical equipment/devices are cleaned manually, using friction, with a detergent or an enzymatic solution. Alternatively, mechanical cleaning is done with a washer/disinfector or ultrasonic cleaner. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**H**	☐	☐	☐

5	**Cleaning of Semi-critical and Critical Medical Equipment/Devices**	**LR**	**R**	**C**	**NC**	**NA NR**
5.7	Cleaning equipment (e.g., brush) is cleaned, disinfected, dried and stored after each use or else discarded.		**M**	☐	☐	☐
5.8	Ultrasonic cleaners, if used, are tested for sonification performance at least weekly or preferably each day it is used, using a commercial method or foil test in accordance with MIFU. ➢ **Additional Resource**: CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**M**	☐	☐	☐
5.9	The ultrasonic cleaning solution is changed, as per ultrasonic cleaner and/or solution MIFU or more frequently when visibly soiled (e.g., with every cycle). ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**M**	☐	☐	☐
5.10	Medical equipment/devices are completely immersed in the ultrasonic cleaning solution.		**H**	☐	☐	☐
5.11	Washer/disinfectors are tested for cleaning efficacy using commercially available indicators or test kits in accordance with MIFU; daily and weekly maintenance is carried out, as per MIFU. ➢ **Additional Resource**: CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**M**	☐	☐	☐
5.12	Ultrasonic cleaners and washer/disinfectors receive documented preventative maintenance, as per MIFU.		**IE**	☐	☐	☐
5.13	Medical equipment/devices are thoroughly rinsed with water after cleaning to remove residues.		**M**	☐	☐	☐
5.14	Medical equipment/devices are dried prior to sterilization (e.g., using lint-free cloth). ➢ **Additional Resource**: CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**M**	☐	☐	☐

Notes and Recommendations:

6. Sterilization

6	Sterilization	LR	R	C	NC	NA NR
6.1	Critical and semi-critical medical equipment/devices are either disposable or sterilized using an approved sterilization process. ➢ **Resources:** For items 6.1 to 6.20, refer to the section on Sterilization of Reusable Medical Equipment/Devices. ➢ CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐
6.2	The MIFU are followed for installation, operation and preventative maintenance of sterilizing equipment.		M	☐	☐	☐
6.3	Qualification or re-qualification of sterilizers is done, as per MIFU.		M	☐	☐	☐
6.4	Medical equipment/devices are packaged according to the MIFU for both the packaging and the medical equipment/devices.		M	☐	☐	☐
6.5	Medical equipment/devices are packaged for sterilization in such a way that the steam can move around and through the item(s) and contact all surfaces.		H	☐	☐	☐
6.6	Medical equipment/devices are disassembled for sterilization, unless otherwise stated in the MIFU.		H	☐	☐	☐
6.7	Medical equipment/devices are in the unlocked and open position for sterilization.		H	☐	☐	☐
6.8	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 the medical equipment/devices are not visible, package contents are labelled.		M	☐	☐	☐
6.9	CIs are placed appropriately in (internal – minimum Type 4) and on (external – Type 1) each package, if not built into the pouch/package.		H	☐	☐	☐
6.10	Packaged medical equipment/devices are placed in the sterilizer, according to sterilizer's MIFU.		H	☐	☐	☐
6.11	Medical equipment/devices are sterilized in accordance with the MIFU (e.g., recommended cycle parameters).		H	☐	☐	☐

6	Sterilization	LR	R	C	NC	NA NR
6.12	Sterilizer mechanical display, print out or USB is checked, verified and signed for each cycle by the person sterilizing the medical equipment/devices. If the sterilizer does not have a printer, there is a plan to replace it; in the meantime, time and temperature are recorded at intervals during each cycle and a Type 5 CI is placed in each package.		H	☐	☐	☐
6.13	Sterilizer is tested with a BI in a process challenge device (PCD) each day the sterilizer is used and with each type of cycle used that day.		H	☐	☐	☐
6.14	A control BI from the same lot number as the test BI and unexposed to sterilant is incubated according to the MIFU each day that routine BIs are incubated.		M	☐	☐	☐
6.15	A BI in a PCD is included in every load containing implantable devices and devices are not released until the result of the BI is available.		H	☐	☐	☐
6.16	Medical equipment/devices are only released when the BI results are available; if quarantine pending BI results is not possible, evaluation of a Type 5 or 6 CI in a PCD and the specific cycle physical parameters are used to justify the release of routine loads.		M	☐	☐	☐
6.17	There are contingency plans (i.e., recall policy and procedure) in the event of reprocessing failures.		IE	☐	☐	☐
6.18	If a dynamic air removal-type (i.e., pre-vacuum) sterilizer is used, an air-detection PCD (e.g., Bowie-Dick test pack) is done every day the sterilizer is used in an empty chamber.		H	☐	☐	☐
6.19	Processed packages are allowed to dry inside the sterilizer chamber before removing and handling.		M	☐	☐	☐
6.20	Processed packages that are unsealed, damaged, wet, visibly soiled or have been dropped on the floor are considered contaminated and are reprocessed through the full reprocessing cycle.		M	☐	☐	☐
6.21	Sterilized medical equipment/devices are not used until the CIs are checked. ➢ **Resource:** Refer to the section on Routine Monitoring of Sterilizers.		H	☐	☐	☐

6	Sterilization	LR	R	C	NC	NA NR
6.22	If a failed CI is found, the contents of the package are reprocessed again before use. ➢ **Resource:** Refer to the section on Continued Monitoring and System Failures. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐

Notes and Recommendations:

7. Transportation

7	Transportation	LR	R	C	NC	NA NR
7.1	When footcare is done off-site, pre-clean the medical equipment/device(s) at the point of use before transport for further manual or automated cleaning. Pre-cleaning can be accomplished by manual removal of gross soil, soaking or application of a gel, foam or moist towel to ensure material does not dry on the medical equipment/device(s). ➢ **Resource:** for items 7.1 to 7.5, refer to CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		M	☐	☐	☐

7	Transportation	LR	R	C	NC	NA NR
7.2	Containers used to transport footcare equipment/device(s) used off-site are labeled to indicate they contain contaminated medical equipment/device(s).		M	☐	☐	☐
7.3	Containers used for the transport of contaminated medical equipment/device(s) are sturdy, leak-proof and capable of being sealed or covered to prevent the risk of disease transmission.		M	☐	☐	☐
7.4	Single-use containers are disposed of in accordance with MIFU after each use. Reusable containers are of a design that allows for effective decontamination and are decontaminated after each use.		M	☐	☐	☐
7.5	There is no cross-contamination between clean/sterile and contaminated medical equipment/device(s) during transport (e.g., two bags properly labeled).		M	☐	☐	☐

Notes and Recommendations:

8. Storage

8	Storage	LR	R	C	NC	NA NR
8.1	Sterile critical medical equipment/devices are stored in their sterile packaging until time of use. ➢ **Resource:** For items 8.1 & 8.2, refer to the section on Storage and Use of Reprocessed Medical Equipment/Devices.		H	☐	☐	☐
8.2	Packaged, sterilized critical medical equipment/devices are stored securely in a manner that keeps them clean, dry and prevents contamination (e.g., not under a sink, kept away from potential splashing).		H	☐	☐	☐

8	Storage	LR	R	C	NC	NA NR
8.3	Medical equipment/devices that have been reprocessed are differentiated from equipment/devices that have not been reprocessed (e.g., colour coding). ➢ **Resource:** Refer to the section on Transportation and Handling of Contaminated Medical Equipment/Devices. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐

Notes and Recommendations:

9. Education and Training

9	Education and Training	LR	R	C	NC	NA NR
9.1	The level of education, training and certification of staff is based on the volume and complexity of the reprocessing activity, as determined by an organizational risk assessment. ➢ **Resource:** For items 9.1 to 9.4, refer to the section on Education and Training. ➢ **Additional Resource:** Recommendations for Education, Training and Certification for Reprocessing in Clinical Office Settings.		IE	☐	☐	☐
9.2	Staff assigned to reprocess medical equipment/devices receive device-specific reprocessing instructions from the device manufacturer to ensure proper cleaning and sterilization.		M	☐	☐	☐
9.3	There is a policy that specifies the requirements for, and frequency of, education and training at regular intervals (e.g., orientation and continuing education), as well as competency assessment for all personnel involved in the reprocessing of medical equipment/devices.		IE	☐	☐	☐

9	Education and Training	LR	R	C	NC	NA NR
9.4	Continuing education programs for reprocessing are provided at regular intervals, as needed so that personnel can review and update their knowledge and skills. Records of training and continuing education are maintained. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		IE	☐	☐	☐
9.5	In settings where surgical procedures are done and where reprocessing is performed on site, there is a designated individual(s) responsible for reprocessing, with training to the level that is required for the volume and complexity of the equipment to be reprocessed. ➢ **Resource:** Refer to PIDAC – Infection Prevention and Control for Clinical Office Practice, June 2013. See section on Requirements for Staff Training.		M	☐	☐	☐

Notes and Recommendations:

10. Policies and Procedures

10	Policies and Procedures	LR	R	C	NC	NA NR
10.1	There is a written policy and procedure that indicates if medical equipment/devices (e.g., nail nippers, burs, curettes, scalpel handles) cannot be reprocessed according to the manufacturer's instructions for use (MIFU), they are not to be purchased or they are designated as single-use. ➢ **Resource:** For items 10.1 and 10.2, refer to the section on Purchasing and Assessing Medical Equipment/Devices and/or Products for Disinfection or Sterilization Processes.		IE	☐	☐	☐

10	Policies and Procedures	LR	R	C	NC	NA NR
10.2	There are written policies and procedures for all aspects of reprocessing that are based on current recognized standards/recommendations/MIFU and these are reviewed regularly and/or as new information becomes available. ➢ **Resource:** For 10.2 and 10.3, refer to CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**IE**	☐	☐	☐
10.3	There is a written policy and procedure that addresses the safe handling and transportation of contaminated medical equipment/instruments from the procedure area/other location (e.g., satellite office, patient's home) to the reprocessing area that are based on MIFU.		**IE**	☐	☐	☐
10.4	There is a policy and procedure for the recall of improperly reprocessed equipment that includes notification of the owner(s)/operator(s), assessment of patient risk and potential notification of patients, other facilities and/or regulatory body/bodies. ➢ **Resource:** Refer to the section on Recalls. ➢ **Additional Resource:** Roles and Responsibilities in Community Health Care Settings During Potential Infection Prevention and Control Lapse Investigations; Information for Public Health Units and Stakeholders.		**IE**	☐	☐	☐
10.5	There is a policy and procedure that requires scheduled preventative maintenance of cleaning and sterilization equipment with written documentation that this has occurred. ➢ **Resource:** Refer to the section on Policies and Procedures.		**IE**	☐	☐	☐
10.6	There is a policy and procedure for quality monitoring and documentation of the reprocessing process (e.g., biological indicators (BI), chemical indicators (CI)). ➢ **Resource:** Refer to the section on Policies and Procedures.		**IE**	☐	☐	☐
10.7	There is a policy and procedure regarding single-use medical equipment/devices. ➢ **Resource:** Refer to the section on Single-Use Medical Equipment/Devices.		**IE**	☐	☐	☐

10	Policies and Procedures	LR	R	C	NC	NA NR
10.8	There is a policy and procedure outlining the process for removing from use faulty medical equipment/devices (e.g., rusty or corroded hinged instruments, loose handles) until repaired or replaced. ➢ **Resource:** Refer to the section on Policies and Procedures. ➢ **Additional Resource:** Refer to CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**IE**	☐	☐	☐

Notes and Recommendations:

11. Other Considerations

11	Other Considerations	LR	R	C	NC	NA NR
11.1	There is a process for receiving and disseminating medical equipment/devices alerts and recalls originating from the manufacturer(s) or government agencies and there is a process in place to ensure recall has occurred within the practice. ➢ **Resource:** Refer to the section on Continued Monitoring and System Failures. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018). ➢ Government of Canada Recalls and Safety Alerts.		**M**	☐	☐	☐

Notes and Recommendations:

Please Print and Sign

Owner/Operator (Print Name):

Signature: **Date:**

Inspector/Assessor/Investigator Signature:

Additional Inspector/Assessor/Investigator Signature(s):

Additional Notes

Citation

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