Public Health Ontario | Santé publique Ontario

2nd Revision: July 2019

IPAC CHECKLIST FOR CLINICAL OFFICE PRACTICE

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 clinical office 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 for Reprocessing of Medical Equipment/Devices in Clinical Office Practice based on content from the Provincial Infectious Disease Advisory Committee's (PIDAC) Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices.

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., *the 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:

☐ **Self-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; and • BI monitoring results. ➢ **Resources:** Refer to the sections on: Sterilization of Reusable Medical Equipment/Devices and Appendix E: Sample Program Audit Tool for Endoscope Reprocessing. ➢ **Additional Resources:** 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	A log is kept of medical equipment/devices that receive high level disinfection (HLD) which includes: • date/time of HLD; • length of contact time with HLD; and • person performing HLD. ➢ **Resource:** Refer to the section on Disinfection of Reusable Medical Equipment/Devices – High-Level Disinfection(HLD).		H	☐	☐	☐
1.3	Other logs are maintained, as per MIFU: • Ultrasonic cleaner; and • Washer/ disinfector. ➢ **Resources:** Refer to the sections on: Policies and Procedures and Methods of Disinfection for Semicritical Medical Equipment/Devices Mechanical Cleaning.		M	☐	☐	☐

Section 1 - 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:** *The Occupational Health and Safety Act*, RSO 1990, c O.1, s.25, Reg. 851 s.	LR	M	☐	☐	☐

2	Personal Protective Equipment (PPE)	LR	R	C	NC	NA NR
2.2	PPE (gloves, gown, 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. ➢ **Additional Resource:** *The Occupational Health and Safety Act*, RSO 1990, c O.1, s.28, Reg. 851.	LR	M	☐	☐	☐

Section 2 - 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/HLD; and • 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	Physical Space	LR	R	C	NC	NA NR
3.3	There is a sink sufficient in size and depth for cleaning medical equipment/devices in the 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 Appendix C: Recommendations for Physical Space for Reprocessing.		**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**	☐	☐	☐
3.7	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**	☐	☐	☐

Section 3 - 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 semicritical 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	☐	☐	☐

Section 4 - Notes and Recommendations:

5. Cleaning of Semicritical and Critical Medical Equipment/Devices

5	Cleaning of Semicritical and Critical Medical Equipment/Devices	LR	R	C	NC	NA NR
5.1	Newly purchased, non-sterile critical and semicritical 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 5.2 to 5.15, refer to the section on Disassembly, Inspection and Cleaning of Reusable Medical Equipment/Devices.		H	☐	☐	☐

5	Cleaning of Semicritical and Critical Medical Equipment/Devices	LR	R	C	NC	NA NR
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 are disassembled according to the MIFU and/or opened for cleaning and HLD/sterilization. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐
5.6	Medical equipment/devices that have lumens: • Are cleaned with a brush, according to the MIFU; • Are manually or mechanically flushed with a detergent solution; • Receive a final rinse using commercially prepared sterile, pyrogen-free water; • Are checked for obstructions and leakage; and • Are dried with compressed air that has been filtered and dried. ➢ **Additional Resource:** Refer to the section on Factors Affecting the Efficacy of the Reprocessing Procedure.		H	☐	☐	☐
5.7	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	☐	☐	☐
5.8	Cleaning equipment (e.g., brush) is cleaned, disinfected, dried and stored after each use or else discarded.		M	☐	☐	☐
5.9	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	☐	☐	☐
5.10	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	☐	☐	☐
5.11	Medical equipment/devices are completely immersed in the ultrasonic cleaning solution.		H	☐	☐	☐

5	Cleaning of Semicritical and Critical Medical Equipment/Devices	LR	R	C	NC	NA NR
5.12	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**	☐	☐	☐
5.13	Ultrasonic cleaners and washer/disinfectors receive documented preventative maintenance, as per MIFU.		**IE**	☐	☐	☐
5.14	Medical equipment/devices are thoroughly rinsed with water after cleaning to remove residues.		**M**	☐	☐	☐
5.15	Medical equipment/devices are dried prior to HLD or sterilization (e.g., air-dry, using lint-free cloth). ➢ **Additional Resource**: CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**M**	☐	☐	☐

Section 5 - Notes and Recommendations:

6. Chemical Products Used for Disinfection and Sterilization

6	Chemical Products Used for Disinfection and Sterilization	LR	R	C	NC	NA NR
6.1	Chemical products used for disinfection/sterilization are: • licensed for use in Canada; • prepared and used, according to MIFU, for dilution, temperature, water hardness, use, shelf life and storage conditions; • labelled with expiry date; • stored in a manner that reduces risk of contamination; and • compatible with medical equipment/devices being reprocessed, according to MIFU. ➢ **Resource**: For items 6.1 to 6.5, refer to the section on Methods Of Disinfection For Semicritical Medical Equipment/Devices – Liquid Chemical Disinfection.		H	☐	☐	☐
6.2	Disinfectants are not used past expiry date.		M	☐	☐	☐
6.3	HLD test strips specific to the product are checked for accuracy when each test strip bottle is opened, as per MIFU.		M	☐	☐	☐
6.4	Minimum effective concentration (MEC) testing of the HLD solution is performed using test strips before each medical device is processed for manual HLD; MEC testing is performed in each cycle for automated HLD. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐
6.5	Disinfectant test strip bottles are dated when opened and discarded when expired.		M	☐	☐	☐

Section 6 - Notes and Recommendations:

7. High-Level Disinfection

7	High-level Disinfection (HLD)	LR	R	C	NC	NA NR
7.1	Semicritical medical equipment/devices receive at a minimum HLD (sterilization is preferred), as per equipment/device MIFU and disinfectant MIFU for time, temperature and concentration. ➢ Resource: **For items 7.1 to 7.4, refer to the section on Disinfection of Reusable Medical Equipment/Devices – High-Level Disinfection(HLD)**.		H	☐	☐	☐
7.2	Medical equipment/devices are totally submerged in HLD, as per MIFU.		H	☐	☐	☐
7.3	Medical equipment/devices are thoroughly rinsed with sterile, filtered or tap water depending on the intended use of the medical equipment/devices and dried if not being used immediately.		M	☐	☐	☐
7.4	➢ The disinfectant container is washed, rinsed, and dried when the solution is changed.		M	☐	☐	☐

Section 7 - Notes and Recommendations:

8. Sterilization

8	Sterilization	LR	R	C	NC	NA NR
8.1	Critical (and preferably semicritical) medical equipment/devices are either disposable or sterilized using an approved sterilization process. ➢ **Resources:** For items 8.1 to 8.20, refer to the section on Sterilization of Reusable Medical Equipment/Devices and ➢ CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐
8.2	The MIFU are followed for installation, operation, and preventative maintenance of sterilizing equipment.		M	☐	☐	☐

8	Sterilization	LR	R	C	NC	NA NR
8.3	Qualification or re-qualification of sterilizers is done, as per MIFU.		M	☐	☐	☐
8.4	Medical equipment/devices are packaged according to the MIFU for both the packaging and the medical equipment/devices.		M	☐	☐	☐
8.5	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	☐	☐	☐
8.6	Medical equipment/devices are disassembled for sterilization, unless otherwise stated in the MIFU.		H	☐	☐	☐
8.7	Medical equipment/devices are in the unlocked and open position for sterilization.		H	☐	☐	☐
8.8	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	☐	☐	☐
8.9	CIs are placed appropriately in (internal – minimum Type 4) and on (external – Type 1) each package, if not built into the pouch/package.		H	☐	☐	☐
8.10	Packaged medical equipment/devices are placed in the sterilizer, according to sterilizer's MIFU.		H	☐	☐	☐
8.11	Medical equipment/devices are sterilized in accordance with the MIFU (e.g., recommended cycle parameters).		H	☐	☐	☐
8.12	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	☐	☐	☐
8.13	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	☐	☐	☐
8.14	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	☐	☐	☐
8.15	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	☐	☐	☐
8.16	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	☐	☐	☐
8.17	There are contingency plans (i.e., recall policy and procedure) in the event of reprocessing failures.		IE	☐	☐	☐

8	Sterilization	LR	R	C	NC	NA NR
8.18	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	☐	☐	☐
8.19	Processed packages are allowed to dry inside the sterilizer chamber before removing and handling.		M	☐	☐	☐
8.20	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	☐	☐	☐
8.21	Sterilized medical equipment/devices are not used until the CIs are checked. ➢ **Resource:** Refer to the section on Routine Monitoring of Sterilizers.		H	☐	☐	☐
8.22	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	☐	☐	☐
8.23	Sterilizer MIFU are followed for performance qualifications for lumen sterilization that include written instructions and limitations, such as load configuration and weights, length of lumens, materials (e.g., stainless steel, cellulose), barrier systems, and conditions that could cause a cycle cancellation. ➢ **Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐

Section 8 - Notes and Recommendations:

9. Storage

9	Storage	LR	R	C	NC	NA NR
9.1	Sterile critical medical equipment/devices are stored in their sterile packaging until time of use. ➢ **Resource:** For items 9.1 & 9.2, refer to the section on Storage and Use of Reprocessed Medical Equipment/Devices.		H	☐	☐	☐
9.2	Packaged, sterilized critical medical equipment/devices are stored securely in a manner that keeps them clean, dry, and prevents contamination (e.g., not under sink, away from potential splashing).		H	☐	☐	☐
9.3	Medical equipment/devices which have been reprocessed are differentiated from equipment/devices which 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	☐	☐	☐

Section 9 - Notes and Recommendations:

10. Education and Training

10	Education and Training	LR	R	C	NC	NA NR
10.1	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 10.1 to 10.4, refer to the section on Education and Training. ➢ **Additional Resource:** Recommendations for Education, Training and Certification for Reprocessing in Clinical Office Settings.		IE	☐	☐	☐

10	Education and Training	LR	R	C	NC	NA NR
10.2	Staff assigned to reprocess medical equipment/devices receive device-specific reprocessing instructions from the device manufacturer to ensure proper cleaning and HLD or sterilization.		**M**	☐	☐	☐
10.3	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**	☐	☐	☐
10.4	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**	☐	☐	☐
10.5	In settings where surgical procedures are done (including IHF, OHP) 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**	☐	☐	☐

Section 10 - Notes and Recommendations:

11. Policies and Procedures

11	Policies and Procedures	LR	R	C	NC	NA NR
11.1	There is a written policy and procedure that says if medical equipment/devices 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 11.1 and 11.2, refer to the section on Purchasing and Assessing Medical Equipment/Devices and/or Products for Disinfection or Sterilization Processes.		**IE**	☐	☐	☐
11.2	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:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		**IE**	☐	☐	☐
11.3	There is a policy and procedure for the recall of improperly reprocessed equipment that includes notification of the principle physician(s)/owner(s)/operator, 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**	☐	☐	☐
11.4	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**	☐	☐	☐
11.5	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**	☐	☐	☐
11.6	There is a policy and procedure regarding single-use medical equipment/devices. ➢ **Resource:** Refer to the section on Single-Use Medical Equipment/Devices.		**IE**	☐	☐	☐

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

Section 11 - Notes and Recommendations:

12. Other Considerations

12	Other Considerations	LR	R	C	NC	NA NR
12.1	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 Resources:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018). ➢ Government of Canada Recalls and Safety Alerts.		M	☐	☐	☐

Section 12 - Notes and Recommendations:

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

Please print and sign:

Owner/Operator (print name):

Signature: **Date:**

Inspector/Assessor/Investigator Signature:

Additional Inspector/Assessor/Investigator Signature(s):

Additional Notes:

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Public Health Ontario

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