IPAC Checklist for Clinical Office Practice: Endoscopy

This checklist was reformatted for College of Physicians and Surgeons of Ontario (CPSO) to include additional space under *Notes and Recommendations* section. To see the original checklist, please visit Public Health Ontario website.

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IPAC CHECKLIST FOR CLINICAL OFFICE PRACTICE

Endoscopy

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 Endoscopy in Clinical Office Practice based on content from the Provincial Infectious Disease Advisory Committee's (PIDAC's) 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., 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.

Types of endoscopes

For the purpose of this checklist, two types of endoscopes will be considered:

- **Critical Endoscope:** Endoscopes used in the examination of critical spaces, such as joints and sterile cavities. Many of these endoscopes are rigid with no lumen. Examples of critical endoscopes are arthroscopes, bronchoscopes and laparoscopes. Critical endoscopes are to be sterilized prior to use (PIDAC CDS, pg 43).
- **Semicritical Endoscope:** Fibreoptic or video endoscopes used in the examination of the hollow viscera. These endoscopes generally invade only semicritical spaces, although some of their components might enter tissues or other critical spaces. Examples of semicritical endoscopes are laryngoscopes, nasopharyngeal endoscopes, transesophageal probes, colonoscopes, gastroscopes, duodenoscopes, sigmoidoscopes and enteroscopes. Semicritical endoscopes require a minimum of high-level disinfection prior to use.

> Opinions differ regarding the reprocessing requirements for flexible bronchoscopes and cystoscopes. Since they are entering a sterile cavity, it is preferred that bronchoscopes and cystoscopes be sterilized; however, if the cystoscope or bronchoscope is not compatible with sterilization, high-level disinfection is the minimum requirement.

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. Policies and Procedures

1	Policies and Procedures	LR	R	C	NC	NA NR
1.1	The purchase of endoscopes that cannot be cleaned and reprocessed according to recommended standards is prohibited; there is a written policy to support this. ➢ **Resource:** Refer to the section on Purchasing and Assessing Medical Equipment/Devices and/or Products for Disinfection or Sterilization Processes		IE	☐	☐	☐
1.2	There are written, detailed device-specific procedures for the handling (including disassembly and reassembly), cleaning, and disinfection/ sterilization of each type of endoscope and accessories that follow the manufacturer's instructions for use (MIFU). ➢ **Resource:** Refer to the section on Reprocessing Endoscopy Equipment/Devices Additional ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		IE	☐	☐	☐

1	Policies and Procedures	LR	R	C	NC	NA NR
1.3	There are written procedures and MIFU for the use of automated endoscope reprocessors (AERs), sterilizers, or other equipment used in reprocessing. ➢ **Resource:** Refer to CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		IE	☐	☐	☐

Notes and Recommendations:

2. Education

2	Education	LR	R	C	NC	NA NR
2.1	Staff assigned to reprocess endoscopes receive device-specific reprocessing instructions to ensure proper cleaning and high-level disinfection or sterilization; education includes theoretical and practical components. ➢ **Resource:** For 2.1 & 2.2, refer to the section on Reprocessing Endoscopy Equipment/Devices ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		M	☐	☐	☐
2.2	Competency testing of personnel reprocessing endoscopes is performed at least annually and documented.		M	☐	☐	☐
2.3	Staff involved in reprocessing are trained in the correct use, wearing, limitations, and indications for PPE. ➢ **Resource**: Refer to the section on Occupational Health and Safety for Reprocessing: Personal Protective Equipment (PPE).		M	☐	☐	☐

Notes and Recommendations:

3. Personal Protective Equipment

3	Personal Protective Equipment (PPE)	LR	R	C	NC	NA NR
3.1	PPE, such as gown, gloves, mask, and eye protection, is available. ➢ **Resource:** For 3.1 and 3.2, refer to the section on Occupational Health and Safety for Reprocessing: Personal Protective Equipment (PPE). ➢ **Additional Resource:** Occupational Health and Safety Act, RSO 1990, c O.1, s.25.	LR	M	☐	☐	☐
3.2	PPE (gloves, gown, mask, eye protection) is worn during a procedure and during reprocessing activities (e.g., endoscope cleaning) that are likely to result in splashes or sprays of blood or other body fluids. ➢ **Resource:** Occupational Health and Safety Act, RSO 1990, c O.1, s.28.	LR	M	☐	☐	☐

Notes and Recommendations:

4. Safe Medication Administration

4	Safe Medication Administration	LR	R	C	NC	NA NR
4.1	There are facilities for hand hygiene in the medication room/area. These include either a dedicated hand hygiene sink and/or alcohol based hand rub (ABHR). ➢ **Resources:** For 4.1 to 4.10, refer to PIDAC Infection Prevention and Control for Clinical Office Practice (April 2015). See sections on Medications, Vaccines and Skin Antisepsis, and Appendix H: Checklist for Safe Medication Practices.		M	☐	☐	☐
4.2	There is a dedicated medication refrigerator as needed (e.g., vaccine).		M	☐	☐	☐
4.3	Single-dose injectable medications are preferred and prepared at the time of use, used once on a single patient and discarded immediately.		H	☐	☐	☐

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

4	Safe Medication Administration	LR	R	C	NC	NA NR
4.4	Unopened vials and other products are discarded according to the manufacturer's expiration dates.		M	☐	☐	☐
4.5	If a multidose vial is used, it is to be used for a single patient/client whenever possible and labelled with the patient's/client's name.		M	☐	☐	☐
4.6	The multidose vial is labelled with the date it was first used and discarded according to the MIFU or within 28 days, whichever is shorter.		M	☐	☐	☐
4.7	All needles are single-use only.		H	☐	☐	☐
4.8	All syringes are single-use only.		H	☐	☐	☐
4.9	Once medication is drawn up, the needle is immediately withdrawn from the vial; a needle is never left in a vial to be attached to a new syringe.		H	☐	☐	☐
4.10	Multidose vials are discarded immediately if sterility is compromised or questioned.		H	☐	☐	☐

Notes and Recommendations:

5. Environmental Cleaning

5	Environmental Cleaning	LR	R	C	NC	NA NR
5.1	The treatment area and endoscopy suite are cleaned between patients, after each case and at least twice per day. ➢ **Resource:** Refer to PIDAC Best Practices for Environmental Cleaning for Infection Prevention and Control (April 2018). See Appendix 21.		M	☐	☐	☐

5	Environmental Cleaning	LR	R	C	NC	NA NR
5.2	Laundry is handled with minimum agitation to avoid contamination of the air, surfaces, and persons. ➢ **Resource:** For 5.2 and 5.3, refer to: PIDAC Infection Prevention and Control for Clinical Office Practice (April 2015). See section on (Laundry and Bedding)		IE	☐	☐	☐
5.3	The setting considers the MIFU of the washer and dryer, the materials to be laundered, and the detergent used when laundering.		IE	☐	☐	☐

Notes and Recommendations:

6. Physical Space

6	Physical Space	LR	R	C	NC	NA NR
6.1	There is a one-way work flow from dirty to clean with adequate separation to minimize risk of cross-contamination. ➢ **Resource:** For 6.1 – 6.6, refer to the section on Reprocessing Endoscopy Equipment/Devices: Physical Space ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐
6.2	There is adequate space for the storage and holding of soiled materials that is separate from other activities and controlled to prohibit public contact.		M	☐	☐	☐
6.3	Processing/decontamination room(s) is/are provided with utility sink(s) appropriate to the size and type of endoscope used, the volume of work and method of decontamination used.		M	☐	☐	☐

6	Physical Space	LR	R	C	NC	NA NR
6.4	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.		M	☐	☐	☐
6.5	Dedicated hand washing sinks, preferably hands-free, and/or ABHR are conveniently located in or near all reprocessing and preparation areas and at all entrances to and exits from the reprocessing area.		M	☐	☐	☐
6.6	The reprocessing area has engineering controls to ensure good air quality, specifically: • air-exchange equipment (e.g., ventilation system, exhaust hoods) is in place to minimize the exposure of all persons to potentially toxic vapours; • documented, regular maintenance of the air-exchange equipment; and • chemical products are maintained in closed, covered, labelled containers at all times.		M	☐	☐	☐

Notes and Recommendations:

7. Point-of-Care Cleaning

7	Point-of-Care Cleaning (immediately following completion of the endoscopy procedure)	LR	R	C	NC	NA NR
7.1	Chemical products containing a disinfectant are licensed for use in Canada. ➢ **Resource:** Refer to the section on Methods Of Disinfection For Semicritical Medical Equipment/Devices		H	☐	☐	☐

7	Point-of-Care Cleaning (immediately following completion of the endoscopy procedure)	LR	R	C	NC	NA NR
7.2	All endoscope channels are flushed with enzymatic detergent or water, according to the MIFU. ➢ **Resource:** For 7.2 – 7.6 refer to the section on Reprocessing Endoscopy Equipment/Devices: Cleaning Procedures		H	☐	☐	☐
7.3	The exterior is wiped with a soft lint-free cloth or endoscope sponge.		H	☐	☐	☐
7.4	The endoscope and accessories should be kept moist during transport and until manual cleaning occurs. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		M	☐	☐	☐
7.5	The endoscope and accessories are placed in a covered, leak proof container and transported to the designated decontamination area.		H	☐	☐	☐
7.6	Transportation to decontamination area should be completed and full manual or AER cleaning started within one hour of bedside pre-cleaning. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐

Notes and Recommendations:

8. Cleaning of Endoscopes in Reprocessing Area

8	Cleaning of Endoscopes in Reprocessing Area	LR	R	C	NC	NA NR
8.1	The MIFU for cleaning and cleaning products are followed. ➢ **Resource:** For 8.1 to 8.16, refer to the section on Reprocessing Endoscopy Equipment/Devices		H	☐	☐	☐
8.2	A leak test is performed after each use, prior to cleaning, according to the MIFU.		H	☐	☐	☐

8	Cleaning of Endoscopes in Reprocessing Area	LR	R	C	NC	NA NR
8.3	There is a policy and procedure that ensures that an endoscope that fails the dry leak test does not undergo the immersion leak test and is sent for repair.		IE	☐	☐	☐
8.4	All immersible endoscope components are soaked and manually cleaned with water and a recommended cleaning agent prior to automated or further manual disinfection or sterilization.		H	☐	☐	☐
8.5	Endoscope components (e.g., air/water and suction valves) are disconnected and disassembled as far as possible and completely immersed in enzymatic cleaner.		H	☐	☐	☐
8.6	All channels and lumens of the endoscope are flushed and brushed (where appropriate) while submerged to remove debris and minimize aerosols.		H	☐	☐	☐
8.7	The endoscope and all components are thoroughly rinsed with clean, fresh tap water prior to disinfection/sterilization and excess rinse water is removed from the channels by purging with forced air.		M	☐	☐	☐
8.8	Damaged endoscopes/accessories are identified and immediately removed from service.		H	☐	☐	☐
8.9	Enzymatic cleaner is discarded after each use and sink is cleaned		M	☐	☐	☐
8.10	Brushes, cloths, syringes, and other cleaning devices used for cleaning lumens are of a correct size, and inspected for cleanliness and good repair before use. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		M	☐	☐	☐
8.11	After each use, cleaning devices are discarded (e.g., single-use, damaged) or cleaned, high-level disinfected or sterilized, dried, and inspected before reuse. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		M	☐	☐	☐
8.12	Reusable semicritical endoscopic accessories are cleaned (e.g., in an ultrasonic washer), then receive high-level disinfection (HLD) according to MIFU.		H	☐	☐	☐
8.13	Reusable critical endoscopic accessories (e.g., biopsy forceps, cytology brushes, papillatomes) are cleaned, then sterilized according to MIFU.		H	☐	☐	☐
8.14	The water bottle, cap, and its connecting tube used for cleaning the endoscope lens and irrigation during the procedure are sterilized according to MIFU.		H	☐	☐	☐

8	Cleaning of Endoscopes in Reprocessing Area	LR	R	C	NC	NA NR
8.15	The water bottle is filled with sterile water.		H	☐	☐	☐
8.16	Fully cleaned and rinsed endoscopes do not sit longer than 30 min. prior to proceeding to the HLD process. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		M	☐	☐	☐

Notes and Recommendations:

9. High Level Disinfection (HLD)

9	High Level Disinfection (HLD)	LR	R	C	NC	NA NR
9.1	Semicritical endoscopes receive, at a minimum, high-level disinfection. ➢ **Resource**: For 9.1 to 9.9, refer to the section on Methods of Disinfection for Semicritical Medical Equipment/Devices: Liquid Chemical Disinfection.		H	☐	☐	☐
9.2	Disinfectant/chemical sterilant is compatible with the endoscope.		M	☐	☐	☐

9	High Level Disinfection (HLD)	LR	R	C	NC	NA NR
9.3	Minimum effective concentration (MEC) testing is performed before each medical device is processed for manual high-level disinfection; MEC testing is performed in each cycle for automated high-level disinfection. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐
9.4	High-level disinfectant test strip bottles are dated when opened and discarded as per the MIFU.		M	☐	☐	☐
9.5	When high-level disinfectants are opened, the container is dated and the disinfectant is not used past the expiry date or date indicated by MIFU.		M	☐	☐	☐
9.6	The MIFU are followed regarding the disinfectant's ambient temperature and duration of contact. ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		M	☐	☐	☐
9.7	If manual disinfection is performed, the disinfectant container is kept covered during use and washed, rinsed, and dried when the solution is changed.		M	☐	☐	☐
9.8	The endoscope/endoscope components are completely immersed in the disinfectant/chemical sterilant and all channels are perfused. ➢ **Additional Resource:** For items 9.8 to 9.9, refer to the section on Reprocessing Endoscopy Equipment/Devices		H	☐	☐	☐
9.9	Following high level disinfection, the endoscope is rinsed and the channels are flushed with filtered or sterile water; sterile water is preferred. Tap water followed by a 70-90% alcohol rinse may be acceptable depending on the intended use of the device.		H	☐	☐	☐

Notes and Recommendations:

10. Automated Endoscope Reprocessors (AER)

10	Automated Endoscope Reprocessors (AER)	LR	R	C	NC	NA NR
10.1	The sterilizer/AER is licensed in Canada; the unit appears on Health Canada's listing of active medical device. ➢ **Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐
10.2	The AER is compatible with all endoscopes to be reprocessed in the AER. ➢ **Resource:** For 10.2 to 10.7, refer to the section on Reprocessing Endoscopy Equipment/Devices-Automated Endoscope Reprocessor (AER)		H	☐	☐	☐
10.3	There is a process to routinely review alerts and advisories for reports of AER deficiencies.		IE	☐	☐	☐
10.4	AER process indicators are monitored for each run and results are recorded in a logbook that includes identification of endoscopic equipment processed (see Record-Keeping).		H	☐	☐	☐
10.5	Once started, the AER is not opened or stopped for any reason; if a cycle is stopped, the entire process is repeated.		H	☐	☐	☐
10.6	There is a documented preventive maintenance program for the AER(s).		M	☐	☐	☐
10.7	If an AER with a drying cycle is used, verification of a rinse with 70% isopropyl alcohol and forced air drying is done as required.		H	☐	☐	☐

Notes and Recommendations:

11. Drying and Storage of Endoscopes

11	Drying and Storage of Endoscopes	LR	R	C	NC	NA NR
11.1	During the final drying of semicritical endoscopes: • all channels are initially flushed with medical or filtered air; • all channels are then flushed with 70% isopropyl alcohol to aid in the drying process; and • the channels receive a second flush with medical or filtered air or are placed to dry in in a HEPA-filtered drying cabinet. ➢ **Resource:** For items 11.1 to 11.9, refer to the section on Reprocessing Endoscopy Equipment/Devices ➢ **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐
11.2	Reprocessing date is identified for each endoscope.		M	☐	☐	☐
11.3	Caps, valves, and other detachable components are removed during storage and reassembled just before use.		M	☐	☐	☐
11.4	Detachable components are stored close to the endoscope in a manner that minimizes contamination.		M	☐	☐	☐
11.5	After cleaning and disinfection/sterilization, endoscopes are stored by hanging vertically in a dedicated, closed, ventilated cabinet that has a sealed door outside of the reprocessing area, procedure room, hallway, or high traffic area.		M	☐	☐	☐
11.6	Endoscopes are prevented from coiling or touching the floor or bottom of the cabinet while hanging.		H	☐	☐	☐
11.7	Endoscope storage cabinets are constructed of non-porous, cleanable material.		M	☐	☐	☐
11.8	Endoscope storage cabinets are cleaned and disinfected (LLD) at least weekly.		M	☐	☐	☐
11.9	Colonoscopes are reprocessed if not used within seven days.		M	☐	☐	☐

Notes and Recommendations:

12. Endoscope Transport

12	Endoscope Transport	LR	R	C	NC	NA NR
12.1	Immediately following the completion of the endoscopic procedure, endoscopes are transported in a lidded, leak proof container that protects the endoscope from damage. ➢ **Resource:** Refer to the section on Reprocessing Endoscopy Equipment/Devices		M	☐	☐	☐
12.2	Transport containers used to carry contaminated endoscopes are cleaned and disinfected after each use. ➢ **Resource**: Refer to the section on Transportation and Handling of Contaminated Medical Equipment/Devices		M	☐	☐	☐
12.3	There is a system in place to differentiate transport containers used for clean and contaminated endoscopes (e.g., colour-coding). ➢ **Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		M	☐	☐	☐

Notes and Recommendations:

13. Record Keeping

13	Record Keeping	LR	R	C	NC	NA NR
13.1	For each procedure, the following are documented: patient's name and record number, date and time of the procedure, type of procedure, name of endoscopist, serial number, or other identifier of both the endoscope and the AER to facilitate contact tracing, as required. ➢ **Resource:** Refer to section on Reprocessing Endoscopy Equipment/Devices		M	☐	☐	☐

13	Record Keeping	LR	R	C	NC	NA NR
13.2	A record is kept of each sterilizer/HLD cycle, including: • the load control label which includes the sterilizer/AER number, load number and date of HLD; • recording chart or printout of the physical parameters of the sterilization/HLD cycle; • load contents; and • person responsible for the sterilization/ HLD cycle. ➢ **Resource:** For 13.2 to 13.8, refer to CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐
13.3	The following is recorded for AERs: • date of any maintenance performed; • fault codes recorded and corrective actions taken; • filter changes; • cycle printouts; and • resetting or verification of correct cycle parameters following repair or maintenance.		H	☐	☐	☐
13.4	A written log of high-level disinfectant concentration monitoring is maintained. **Additional Resource:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018).		H	☐	☐	☐
13.5	The following is recorded for endoscopes: • endoscope inventory; and • repair and maintenance history.		M	☐	☐	☐
13.6	A log is kept of chemical indicator monitoring results.		H	☐	☐	☐
13.7	A log is kept of all maintenance and interventions associated with a positive chemical indicator.		H	☐	☐	☐
13.8	Records are retained according to the policy of the health care facility.		IE	☐	☐	☐

Notes and Recommendations:

14. Occupational Health and Safety

14	Occupational Health and Safety	LR	R	C	NC	NA NR
14.1	Setting reviews all policies and procedures for reprocessing medical equipment/devices to verify that worker safety measures and procedures to eliminate or minimize the risk of exposure are followed and are in compliance. ➢ **Resource:** Refer to the section on Occupational Health and Safety for Reprocessing Additional resource. ➢ **Additional Resources:** CAN/CSA – Z314-18 Canadian medical device reprocessing (2018). ➢ Occupational Health and Safety Act, R.S.O. 1990, c.0.1	**LR**	**IE**	☐	☐	☐
14.2	There is a policy or procedure in place to prevent the transmission of blood-borne pathogens (i.e. hepatitis B, hepatitis C and HIV) that includes an immunization policy for hepatitis B vaccination and a record of documented immunity to hepatitis B by serology. ➢ **Resource:** Refer to PIDAC Infection Prevention and Control for Clinical Office Practice (April 2015). See section on Administrative Control ➢ **Additional Resource:** Blood- borne Diseases Surveillance Protocol for Ontario Hospitals developed by the OHA/OMA in collaboration with the MOHLTC.		**IE**	☐	☐	☐
14.3	An eyewash fountain is provided when there is the potential for injury to the eye due to contact with a biological or chemical substance. ➢ **Additional Resource:** Refer to Canadian Centre for Occupational Health and Safety	**LR**	**IE**	☐	☐	☐
14.4	There is a plumbed or self-contained eyewash station within a 10-second walk (16 to 17 metres [55 feet]) of the reprocessing area. ➢ **Resource:** Refer to the Appendix C: Recommendations for Physical Space for Reprocessing.		**IE**	☐	☐	☐
14.5	There is a policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics or lip balm, and handling contact lenses in the reprocessing area.		**IE**	☐	☐	☐

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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Disclaimer

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Ontario
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