Alberta Health Services

Infection Prevention and Control
Review of Medical Device Reprocessing For
Reusable Critical and Semicritical Medical Devices

Review Criteria and Supporting Standards

Background

This document was used to develop the three AHS IPC MDR Review Tools. It includes the review criteria for each item in all three review tools and provides recommendations on how to meet the corresponding standards. The review criteria in this document were developed from standards from Alberta Health, Accreditation Canada and the Canadian Standards Association.

The AHS IPC MDR Review Tools developed from this document are:

- Review Tool for Reprocessing General Medical Devices
- Review Tool for Reprocessing Surgical Textiles
- Review Tool for Reprocessing Flexible Endoscopes

These review tools are used review practices within departments reprocessing medical devices. They do not extend to activities outside of the departments.

Explanation of Content:

Each item is assigned a suggested responsibility which includes all groups that may be impacted by the item criteria. Each item is also assigned a category symbol corresponding to a timeline for correction as outlined below.

Category	Actions and Recommended Timelines for Correction
Red	Stop practice and correct **as soon as possible**.
Amber	Practice/Deficiency ideally corrected within 1-6 weeks. **If not completed within 6 weeks, identify action plan.**
Blue	Practice/Deficiency is of concern, however timeline for correction may be variable due to specific circumstances due to structural, financial or program impacts. **Action plan for deficiency required within 6 weeks.**

Note: The standards listed under the recommended corrective action for each item are under revision. They are being updated to be current with standards published prior to June 2013.

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Review Tool for Reprocessing General Medical Devices

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
Infection Prevention and Control (IPC)				
A 1.1	There is a documented policy or standard operating procedure (SOP) for hand hygiene.	Develop, update or obtain a written policy/SOP regarding hand hygiene practices. AHS Hand Hygiene Policy and Procedure: http://insite.albertahealthservices.ca/5154.asp AC[1], Clause: 5 CAN/CSA Z314.8-08, Clause: 4.2; 6.6.3, CAN/CSA Z314.0-13, Clause:6.6.2	▼	• Area Management • AHS Infection Prevention and Control
A 1.2	There is a documented policy or standard operating procedure (SOP) for personal protective equipment (PPE).	Develop, update or obtain a written policy/SOP indicating the requirement to wear PPE that should include: • selection of PPE for each reprocessing area. For example, PPE in decontamination work area includes: o gloves appropriate to the task o a protective gown or garment o full face shield, or high-filtration, fluid-impervious face mask and protective eyewear • prescription eye glasses are not acceptable for eye protection • maintenance of reusable PPE (e.g. daily cleaning, changing of soiled garments, etc.) • performing hand hygiene before putting on and after taking off PPE AC[1], Clause: 5.8 AH[2], Clause: 11.2.5 CAN/CSA Z314.8-08, Clause: 6.6.1.3; 6.7.1.2; 6.7.2.6 CAN/CSA Z314.3-09, Clause: 6.7.2 CSA Z314.0-13, Clause 7.7.2	▼	• Area Management • AHS Workplace Health and Safety
A 1.3	There is a documented policy or standard operating procedure (SOP) for staff Hepatitis B immunization.	Develop, update or obtain a written policy/SOP that offers Hepatitis B immunization. General information for AHS staff can be found at: http://insite.albertahealthservices.ca/8541.asp AH[2], Clause: 11.2.6 CSA Z314.0-13, Clause: 4.7.2(a), 6.1.3	▼	• Area Management • AHS Workplace Health and Safety
A 1.4	There is a documented policy or standard operating procedure (SOP) for environmental cleaning of the reprocessing area.	Develop, update or obtain a written policy/SOP indicating frequency and documentation of environmental cleaning that includes: • cleaning of floors, horizontal work surfaces and counters at least daily • cleaning of walls, ceilings, vents, light fixtures at least every 6 months AC[1], Clause: 3.7 CAN/CSA Z314.3-09, Clause: 7.5 CAN/CSA Z314.8-08, Clause: 7.4 CSA Z314.0-13, Clause 7.5.1	▼	• Area Management • AHS Environmental Services

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Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
A 1.5	There is a documented policy or standard operating procedure (SOP) for dress code for staff in the reprocessing area.	Develop, update or obtain a written policy/SOP for a dress code that includes: • wearing of clean attire • wearing a clean hair-cover • having clean, unpolished nails • wearing no artificial nails • wearing no loose, bulky or dangling jewelry • wearing clean, sturdy footwear AC[1], Clause: 5.7 CSA Z314.0-13, Clause:6.7.1.1; 6.7.1.2; 6.7.1.3; 6.7.1.4 CAN/CSA Z314.8-08, Clause: 6.7.1.1, AORN, Clause: 1b ORNAC, Section 2: Infection prevention and control, Clause: 5.3.10	▼	• Area Management
A 1.6	There is a documented policy or standard operating procedure (SOP) for prevention of staff exposure to blood and body fluids (e.g. splashes or sharps injuries).	Develop, update or obtain a written policy/SOP for the prevention of staff exposures to blood and body fluids (e.g. splashes or sharps injuries) that should include: • removing and disposing of single-use sharps at point of use • safe work practices such as never reaching blindly into instrument sets • handling glass or fragile objects with care AH[2], Clause:4.3,11.2.8, CAN/CSA Z314.8-08, Clause: 4.3.2(b); 6.6.1.2; 6.6.1.1; 6.6.1.2 CAN/CSA Z314.3-09, Clause: 4.3.2 CAN/CSA Z314.0-13, Clause6.6.1.2, 6.6.1.1,6.5.3,6.3.2	▼	• Area Management • AHS Workplace Health and Safety
A 1.7	There is a documented policy or standard operating procedure (SOP) for follow-up of staff exposure to blood and body fluids (e.g. splashes or sharps injuries).	Develop, update or obtain a written policy/SOP that describes procedures that are followed after staff exposures to blood and body fluids (e.g. splashes or sharps injuries) that should include: • immediate first aid • notification of supervisor • where to find instructions on follow-up AHS Policy for Occupational Exposure to Blood and Body Fluids http://www.albertahealthservices.ca/Policies/ahs-pol-occupational-exposure.pdf AH[2], Clause: 12.2 CAN/CSA Z314.8-.8, Clause: 6.6.1.1 CAN/CSA Z314.0-13 4, Clause 4.4.2(d)	▼	• Area Management • AHS Workplace Health and Safety

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Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
A 1.8	There is a documented policy or standard operating procedure (SOP) for management of health status of staff to prevent contamination of devices and to protect workers.	Develop, update or obtain a written policy/SOP for the management of staff health status that should include management of: • nonintact skin and skin injuries • dermatitis • staff who are symptomatic for communicable disease CAN/CSA Z314.8-08, Clause: 6.6.1.5 CAN/CSA 314.0-13, Clause 7.9.1 CAN/CSA 314.0-13, Clause 6.5.2	▼	• Area Management • AHS Workplace Health and Safety
A 1.9	There is a documented policy or standard operating procedure (SOP) for waste management including disposal of contaminated sharps and biomedical wastes.	Develop, update or obtain a written policy/SOP for the management of sharps and biomedical wastes disposal. This should include instructions on how staff disposes of sharps and biomedical wastes. AH[2], Clause: 4.1 CAN/CSA Z314.8-08, Clause: 6.6.2 CAN/CSA Z314.0-13, Clause 7.9.1 CAN/CSA 314.0-13, Clause 6.5.3	▼	• Area Management • AHS Workplace Health and Safety • AHS Infection Prevention and Control • AHS Environmental Waste Management
A 1.10	There is a documented policy or standard operating procedure (SOP) for prohibiting activities such as eating, drinking, storage of food, smoking, application of cosmetics or handling of contact lenses in work areas.	Develop, update or obtain a written policy/SOP that prohibits activities that put patients or staff in reprocessing areas at Category of exposure to communicable diseases. These activities include, but are not limited to: • eating • drinking • storage of food • smoking • application of cosmetics • handling of contact lenses AC[1], Clause: 5.6 CAN/CSA Z314.8-08, Clause: 6.6.1.3	▼	• Area Management • AHS Infection Prevention and Control

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Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
General				
A 1.11	There are documented policies or standard operating procedures (SOPs) for reprocessing (cleaning and sterilization) of reusable critical medical devices.	Develop, update or obtain a written policy/SOP that reusable critical medical devices must be cleaned and sterilized in accordance with manufacturer's written instructions prior to each use. Examples of critical devices include, but are not limited to: • surgical instruments • dental devices that penetrate soft tissue or bone (e.g. forceps, scalpels, bone chisels, scalers, burs) • dental handpieces • endoscopes that penetrate sterile tissue (e.g. arthroscopes, cystoscopes, laparoscopes) • endoscopic accessories that penetrate sterile tissue (e.g. reusable cytology brushes or biopsy devices) • reusable accessories that penetrate sterile tissue (e.g. biopsy forceps or other cutting devices) AC[1], Clause: 8.4,8.5, 8.6, 8.8, 8.10, 9.2, 9.4, AH[2], Clause 12.2 CAN/CSA Z314.8-08, Clause: 4.3.1; 4.4; 5.2.1; 5.2.2; 10.1.1; 10.2.2; 10.4.1; 10.4.3.1.1 CAN/CSA Z314.3-09, Clause: 4.3.1, 4.3.2, 4.4 CAN/CSA Z314.0-13, Clause 8.1.2,8.1.3, 8.2.1	▼	• Area Management • AHS Infection Prevention and Control
A 1.12	There is a documented policy or standard operating procedure (SOP) for reprocessing (cleaning and high level disinfection [HLD]) of reusable semicritical medical devices.	Develop, update or obtain a written policy/SOP stating that reusable semicritical medical devices must be cleaned and at least high level disinfected in accordance with manufacturer's written instructions prior to each use. Examples of semicritical devices include, but are not limited to: • respiratory/anesthetic circuit components • endocavity probes (e.g. endovaginal, transesophageal echocardiogram [TEE]) • dental devices that are not intended to penetrate oral soft tissue or bone but may come into contact with oral tissues (e.g. amalgam condensers, air-water syringes) • endoscopes and accessories contacting mucous membranes CAN/CSA Z314.8-08, Clause: 4.3; 4.4; 5.2.1; 5.3; 10.1.1; 10.4.2.1; 10.6.2; 10.6.3; 1; 13.1.1 CAN/CSA Z314.0-13, Clause 8.1.2,8.1.3,8.2.1	▼	• Area Management • AHS Infection Prevention and Control
A 1.13	There is a documented policy or standard operating procedure (SOP) for record and document retention.	Develop, update or obtain a written policy/SOP that describes the organization's, region's or site's document retention process. AHS Record Management Policy, http://www.albertahealthservices.ca/Policies/ahs-pol-records-management.pdf AC[1], Clause: 2.7, CAN/CSA Z314.3-09, Clause: 4.5.1(a) CAN/CSA Z314.8-08, Clause: 4.6.1	▼	• Area Management • AHS Administration

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Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
A 1.14	There is a documented policy or standard operating procedure (SOP) for evaluation and purchasing of reusable medical devices, reprocessing equipment and supplies/consumables.	Develop, update or obtain a written policy/SOP that applies to evaluation and purchasing of reusable medical devices, reprocessing equipment and supplies/consumables. This should include the requirement for: • manager/purchaser consults appropriate personnel prior to purchase. This includes, as applicable to the purchase: o Medical device reprocessing o Infection Prevention and Control o Workplace Health and Safety o End user department o Patient Services o Support Services (Environmental Services, Linen Services, etc.) o Biomedical Engineering or Facilities Maintenance and Engineering • review of validated manufacturer's written instructions • consideration of limiting purchase of reusable difficult to clean devices, where possible Examples of medical devices and consumables include, but are not limited to: • surgical instruments • endoscopes • reprocessing equipment (e.g. washer/disinfectors, sterilizers, etc.) • wrapping/packaging materials • sterilization indicators • process challenge devices (PCDs) • disinfectants • detergents, enzymatic cleaners, etc. AC[1], Clause: 7.1, AH[2], Clause: 3.1, 3.2, 3.3, 3.7 CAN/CSA Z314.8-08, Clause: 4.2; 4.4; 5.1; 5.2.1; 7.5.2 CAN/CSA Z314.3-09, Clause:8.2.2.2 CAN/CSA Z314.0-13, Clause: 4.2(g), 5.3.2, 5.3.3, 5.3.4	▼	• Area Management • AHS Contract Procurement and Supply Management
A 1.15	There is a documented policy or standard operating procedure (SOP) for contingency plans for emergency situations for sterilizer shutdown.	Develop, update or obtain a written policy/SOP (contingency plan) for emergency situations for sterilizer shutdown (e.g. backup sterilization arrangement with outside facility, surgery shutdown etc.). CAN/CSA Z314.3-09, Clause: 4.2(i); 4.3.2 (h) CAN/CSA Z314.0-13 4.3(h)	▼	• Area Management • AHS Administration • Facility Management

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Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
A 1.16	There is a documented policy or standard operating procedure (SOP) for contingency plans for emergency situations for automated equipment shutdowns.	Develop, update or obtain a written policy/SOP (contingency plan) for shutdown of automated equipment (e.g. manual cleaning). Examples of automated equipment are washer/disinfectors, ultrasonic cleaners, pasteurizers, automated endoscope reprocessors (AERs) etc. CAN/CSA Z314.3-09, Clause: 4.2(i); 4.3.2 (h) CAN/CSA Z314.0-13 4.3(h)	▼	• Area Management • AHS Administration • Facility Management
A 1.17	There is a documented policy or standard operating procedure (SOP) for contingency plans for emergency situations as a result of steam, water or other utility interruptions.	Develop, update or obtain a written policy/SOP (contingency plan) for steam, water or other utility interruptions. Examples of utility interruptions include heating, ventilation, air conditioning (HVAC) failure, boil water advisory, etc. AH[2], Clause:2.5 CAN/CSA Z314.3-09, Clause: 4.2(i); 4.3.2 CAN/CSA Z314.0-13 4.3(h)	▼	• Area Management • AHS Administration • Facility Management
A 1.18	There is a documented policy or standard operating procedure (SOP) for contingency plans for large scale inventory loss (e.g. situations involving excessive humidity in sterile storage areas).	Develop, update or obtain a written policy/SOP (contingency plan) for large scale inventory loss. CAN/CSA Z314.3-09, Clause: 4.2(i) CAN/CSA Z314.0-13 4.3(h)	▼	• Area Management • AHS Administration
A 1.19	There is a documented policy or standard operating procedure (SOP) for handling and management of loaned, shared or leased (e.g. clinician or vendor supplied) critical and semicritical medical devices.	Develop, update or obtain a written policy/SOP that applies to the transportation, receiving, handling and processing of loaned, shared or leased medical devices that should include: • receiving and following written manufacturer's reprocessing instructions • receiving devices in a timely manner to allow for reprocessing at the site prior to use AH[2], Clause: 12.2.4 CAN/CSA-Z314.22.	▼	• Area Management • AHS Administration
A 1.20	There is a documented policy or standard operating procedure (SOP) for transporting contaminated items to the reprocessing area.	Develop, update or obtain a written policy/SOP for contaminated devices/equipment transport to the reprocessing area. SOP should include: • removal of gross soil (e.g. blood clots, feces, etc.) at point of use • removal of disposable sharps at point of use • ensuring soil does not harden (e.g. cover instruments with a moist towel or use appropriate anti-drying product) • containing items in a protective, covered, leak-proof container • procedures to minimize contamination of environment and personnel • labeling or coding of containers to indicate contaminated contents AH[2], Clause: 4.1, 4.2,4.3,4,4 CAN/CSA Z3.14.8-08, Clause: 5.2; 9.3 13.4.1.1; 13.4.10.3 CAN/CSA Z314-3-09 11.4.1	▼	• Area Management • AHS Administration

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Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
A 1.21	There is a documented policy or standard operating procedure (SOP) for inspection, identification and disposal of damaged/defective devices.	Develop, update or obtain a written policy/SOP for inspection, identification and disposal of damaged equipment that includes labeling, repair, disposal, etc. CAN/CSA Z314.8-08, Clause: 4.3.2(e); 10.11.4; 10.11.5; 10.11.7; 10.11.8 CAN/CSA Z314.0-13 8.2.1.2	▼	• Area Management
Personnel				
A 1.22	There is a documented policy or standard operating procedure (SOP) for specifying management and staff responsibilities specific to medical device reprocessing (MDR).	Develop, update or obtain a written policy/SOP that specifies management and staff responsibilities specific to MDR. AC[1], Clause: 1.5, 1.4, 4.1 AH[2], Clause: 14.1; 14.4 CAN/CSA Z314.8-08, Clause: 4.2(a) CAN/CSA Z314.3-09, Clause: 4.2 CAN/CSA Z314.0-13, Clause: 4.5	▼	• Area Management
A 1.23	There is a documented policy or standard operating procedure (SOP) for specifying management and staff qualifications, education and training specific to medical device reprocessing (MDR).	Develop, update or obtain a written policy/SOP that specifies management and staff qualifications, education and training specific to MDR. AC[1], Clause: 2.2, 2.3, 2.4,2.5, 2.6 AH[2], Clause: 10 CAN/CSA Z314.0-013, Clause: 6.1.2, 6.2 CAN/CSA Z314.8-08, Clause: 4.2(b); 4.3.1; 4.5.1; 4.5.10; 6.2.1; 6.2.2; 6.3.1; 6.3.3; 6.4 CAN/CSA Z314.3-09, Clause: 4.2	▼	• Area Management
Cleaning				
A 1.24	There is a documented policy or standard operating procedure (SOP) for identification and handling of devices that are known to be difficult to clean.	Develop, update or obtain a written policy/SOP for identification and handling of devices that are known to be difficult to clean. This should include: • Identification of items that are difficult to clean or • Characteristics that make items difficult to clean (lumens, ridges, hinges, ribbing, grooves, etc.) • Procedures to clean these items that follow manufacturer's instructions. • Having device-specific reprocessing instructions available for staff Examples of difficult to clean devices are: • minimally invasive surgical instruments • biopsy forceps • reamers • devices with lumens, etc. AH[2], Clause: 5.6 CAN/CSA Z314.8-08, Clause: 4.3.2(d); 4.3.2(e); 10.4.2.1 CAN/CSA Z314.0-13, Clause: 8.2.1, D.2.4,4.4.2(g), 5.1.4	▼	• Area Management

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Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
A 1.25	There is a documented policy or standard operating procedure (SOP) for cleaning of medical devices, according to manufacturer's written instructions.	Develop, update or obtain a written policy/SOP for cleaning of medical devices according to the manufacturer's written instructions, including: • precleaning • disassembly (where applicable) • sorting and soaking • cleaning • rinsing • drying • lubrication • inspection of devices for cleanliness and functionality (e.g. wear, damage and mechanical defect) • reassembly AC[1], Clause: 4.0,4.5.4.6 AH[2], Clause: 1.3, .2.1, 3.1,3.3, 3.9 CAN/CSA Z314.8-08, Clause: 4.3.2(c); 10.1.1 CAN/CSA Z314.0-13, Clause:5.3,	▼	• Area Management
Sterilization				
A 1.26	There is a documented policy or standard operating procedure (SOP) for each method of sterilization utilized, according to manufacturer's written instructions.	Develop, update or obtain a written policy/SOP stating that each sterilization process utilized is in accordance with the manufacturer's written instructions. Develop, update or obtain SOP for each method of sterilization used in the area; examples include: • steam • ethylene oxide (ETO) • hydrogen peroxide gas plasma • liquid chemical (Steris System 1®) • other approved methods of sterilization AC[1], Clause: 4.3, 7, AH[2], Clause: 7.2 CAN/CSA Z314.0-13, Clause: 4.2,3.2(i),	▼	• Area Management
A 1.27	There is a documented policy or standard operating procedure (SOP) for packaging of reusable critical medical devices according to manufacturer's written instructions.	Develop, update or obtain a written policy/SOP for packaging of critical medical devices prior to sterilization that should include: • use of packaging appropriate to the sterilization method • inclusion of chemical indicators prior to sealing package • correct sealing and labeling practice AC[1], Clause: 8.11, CAN/CSA Z314.0-13, Clause: 4.4.2(k), 4.12, 8.5 CAN/CSA Z314.3-09, Clause: 5.3; 9	▼	• Area Management

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Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
A 1.28	There is a documented policy or standard operating procedure (SOP) for use of rigid sterilization container systems.	Develop, update or obtain a written policy/SOP for rigid sterilization container systems. SOP should include: • arrangement of devices within the container • placement of filter(s) • ensuring gaskets are intact and free of debris • properly latching lid • placement of tamper evident devices • labeling • decontamination of containers • storage CAN/CSA Z314.3-09, Clause: 9.5.3 CAN/CSA Z314.14-10	▼	• Area Management
A 1.29	There is a documented policy or standard operating procedure (SOP) for quarantine of implantable medical devices pending biological indicator (BI) results.	Develop, update or obtain a written policy/SOP for quarantine of sterilized packages containing implantable devices indicating the package should not be released until the BI result is obtained (i.e. is negative). AC[1], Clause: 8.14, AH[2], Clause: 7.3.5 CAN/CSA Z314.3-09, Clause: 4.3.2(f); 13.1.1	▼	• Area Management
A 1.30	There are documented policies or standard operating procedures (SOPs) for positive biological indicator (BI) or failed sterilization load.	Develop, update or obtain written policies/SOPs for positive BI or failed sterilization load that should include: • the person responsible to notify the manager or designate • notification of IPC personnel or designate • the process to recall and isolate all loads done since the last negative BI AC[1], Clause: 11.5,11.6,11.7 CAN/CSA Z314.0-13, Clause: 9.2 CAN/CSA Z314.3-09, Clause: 12.9; 12.10; 12.11	▼	• Area Management
A 1.31	There are documented policies or standard operating procedures (SOPs) for flash sterilization.	Develop, update or obtain a written policy/SOP stating flash sterilization should not be used for routinely scheduled procedures or to compensate for lack of inventory and is never performed on implantable devices. Develop, update or obtain a written policy/SOP for flash sterilization that includes the requirement for cleaning of devices prior to flash sterilization and outlines the steps to be taken for flash sterilization, including documentation requirements. AC[1], Clause: 1.3 AH[2], Clause: 7.1.3 CAN/CSA Z314.3-09, Clause: 13	▼	• Area Management • AHS Infection Prevention and Control

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
A 1.32	There is a documented policy or standard operating procedure (SOP) for use and maintenance of containers designed for flash sterilization according to manufacturer's written instructions.	Develop, update or obtain a written policy/SOP that include proper use and maintenance of containers used for flash sterilization (e.g. Flashpak®). CAN/CSA Z314.3-09, Clause: 4.4; 13.6.3; 13.6.4; 13.6.5	▼	• Area Management
High Level Disinfection (HLD)				
A 1.33	There is a documented policy or standard operating procedure (SOP) for chemical high level disinfection (HLD).	Develop, update or obtain a written policy/SOP for chemical HLD that includes: • cleaning and rinsing of devices prior to disinfection • use of appropriate product with a Health Canada Drug Identification Number (DIN) • manufacturer's written instructions • monitoring • documentation AC[1], Clause: 8.4,8.5 AH[2], Clause: 6.5 CAN/CSA Z314.0-13, Clause: 8.6.4 CAN/CSA Z314.8-08, Clause: 10.8	▼	• Area Management
A 1.34	There is a documented policy or standard operating procedure (SOP) for thermal high level disinfection (HLD) (e.g. pasteurizer or washer/disinfector with validated thermal disinfection cycle).	Develop, update or obtain a written policy/SOP for thermal HLD (e.g. pasteurizer or washer/disinfector with validated thermal disinfection cycle) that includes: • pre-cleaning and rinsing of devices prior to disinfection • manufacturer's written instructions • monitoring • documentation AH[2], Clause: 6.6 CAN/CSA Z314.8-08, Clause: 4.4; 4.5; 12	▼	• Area Management
Quality Monitoring				
A 1.35	There is a documented policy or standard operating procedure (SOP) for routine monitoring of automated cleaning/disinfection equipment used in reprocessing.	Develop, update or obtain a written policy/SOP that includes information on routine (e.g. every shift, daily, weekly, monthly, etc.) monitoring or testing of the equipment. Examples include: • daily testing of time and temperature for pasteurizers • testing ultrasonic cleaners at least weekly • testing of washer/disinfectors as per manufacturer's written instructions, or using indicator such as the Test Object Surgical Instrument (TOSI) test AC[1], Clause: 7.2 CAN/CSA Z314.8-08, Clause: 4.4; 4.5; 7.5.5; 7.5.6; 10.1; 10.4.3.1.5; 10.4.3.6; 10.4.3.8; 10.4.4.8	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
A 1.36	There is a documented policy or standard operating procedure (SOP) for sterility assurance monitoring.	Develop, update or obtain a written policy/SOP for sterility assurance monitoring that includes: • monitoring of each package that is sterilized with external and internal chemical indicators • testing the sterilizer with a biological indicator (BI) each day the sterilizer is in use and for each type of cycle used • including a BI in each load containing implantable devices • monitoring of mechanical indicators (e.g. time, temperature, pressure) • testing dynamic air removal sterilizers with a Bowie Dick test each day the sterilizer is in use AH[2], Clause: 7.2,7.3 CAN/CSA Z314.3-09, Clause: 10; 5.4; 9.5.5	▼	• Area Management
A 1.37	There is a documented policy or standard operating procedure (SOP) for routine monitoring of reusable chemical high level disinfectant minimum effective concentration (MEC) at least daily.	Develop, update or obtain a written policy/SOP for routine monitoring of reusable chemical high level disinfectant that includes: • frequency (e.g. minimum each day the disinfectant is used) • method of testing MEC • documentation AC[1], Clause: 8.8 AH[2], Clause: 6.5 CAN/CSA Z314.8-08, Clause: 4.5; 10 CAN/CSA Z314.0-13, Clause: 9	▼	• Area Management
A 1.38	There is a documented policy or standard operating procedure (SOP) for routine maintenance of automated equipment used in reprocessing.	Develop, update or obtain a written policy/SOP for routine maintenance of automated equipment used in reprocessing, including information on user provided maintenance such as routine (e.g. every shift, daily, weekly, and monthly, etc.) maintenance. Examples include: • cleaning or wiping external surfaces of automated equipment at regular intervals • maintaining water reservoir in table top steam sterilizers • routine bleach cycle of automated lumen cleaners AC[1], Clause: 7.2,7.3 AH[2], Clause: 6.6.2, 6.6.3,7.2, 8.3.2, CAN/CSA Z314.8-08, Clause: 5.2.3	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 1.0 Policies and Standard Operating Procedures (SOPs)**: There are documented policies or SOPs for:**				
A 1.39	There is a documented policy or standard operating procedure (SOP) for preventative maintenance (PM) of all automated equipment used in reprocessing.	Develop, update or obtain a written policy/SOP for PM of all automated equipment used in reprocessing. SOPs should include information on: • frequency of PM • who performs PM • documentation AC[1], Clause: 7.2 CAN/CSA Z314.3-09, Clause:14 CAN/CSA Z314.8-08, Clause: 4.4	▼	• Area Management • Facility Management
A 1.40	There is a documented policy or standard operating procedure (SOP) for receiving, investigating and follow-up of customer concerns.	Develop, update or obtain a written policy/SOP describing how users contact the MDR department with concerns, and how concerns are addressed and documented. AC[1], Clause: 12.7 CAN/CSA Z314.0-13, Clause: 4.20.2 CAN/CSA Z314.0-13, Clause: 4.4.2 (c) CAN/CSA Z314.3-09, Clause: 4.3.2(a)	▼	• Area Management
A 1.41	There is a documented policy or standard operating procedure (SOP) for periodic testing of water used for reprocessing of medical devices.	Develop, update or obtain a written policy/SOP for periodic testing, reporting and follow-up of the water supply to the MDR areas. Testing of potable (tap) water includes: • hardness • pH • iron content, etc. If treated water is used (e.g. reverse osmosis [RO] or de-ionized [DI]) manufacturer's written instructions for testing are followed. AH[2], Clause: 2.4.10 CAN/CSA Z314.0-13, Clause: 4.4.2 (i), 4.7.3,7.8 CAN/CSA Z314.3-09, Clause: 7.6.3.1 CAN/CSA Z314.8-08, Clause: 7.6.1; 7.6.2	▼	• Area Management • Facility Management
A 1.42	There is a documented policy or standard operating procedure (SOP) for evaluation and response to incidents of temperature and humidity extremes in the sterile storage areas.	Develop, update or obtain a written policy/SOP for evaluation and response to incidents of temperature and humidity extremes in the sterile storage areas. Temperature (18 – 23°C) and humidity (30 – 60%) should be measured and recorded daily. AC[1], Clause: 3.1 AH[2], Clause: 2.4.7 CAN/CSA Z314.0-13, Clause: 10.3.1.2 CAN/CSA Z314.3-09, Clause: 7.2.2 CAN/CSA Z314.15-10, Clause: 4.2.1(a); 6.2	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 2.0 Manufacturer's written instructions**: Manufacturer's written instructions are available for:**				
General				
A 2.1	Manufacturer's written instructions are available for reprocessing of medical devices being decontaminated, high level disinfected and/or sterilized in the area.	Obtain and file (electronically or on paper) manufacturer's written reprocessing instructions for each medical device reprocessed in the area. Detailed, validated instructions should include information on: • precleaning • disassembly (if required) • cleaning • rinsing • lubrication • inspection • reassembly • packaging • disinfection • sterilization AC[1], Clause: 4.0, 4.5, 4.6, 8.5, 8.10 AH[2], Clause: 3.3 CAN/CSA Z314.0-13, Clause: 4.2.3.2(f), 4.4.2,5. CAN/CSA Z314.8-08, Clause: 4.4; 5.2	▼	• Area Management
A 2.2	Manufacturer's written instructions are available for reusable cleaning accessories (e.g. brushes, sponges, etc).	Obtain and file (electronically or on paper) manufacturer's written instructions for reusable cleaning accessories. AH[2], Clause: 5.5 CAN/CSA Z314.8-08; 4.6.1 (d); 10.4.2.8	▼	• Area Management
A 2.3	Manufacturer's written instructions are available for using detergents and enzymatic cleaners.	Obtain and file (electronically or on paper) manufacturer's written instructions for detergents and enzymatic cleaners. Instructions include information on: • concentration • mixing/dilution • rinsing • shelf-life AC[1], Clause: 8.7, 8.8 CAN/CSA Z314.0-13, Clause:5.3.2(h), 7,8,2, CAN/CSA Z314.8-08, Clause: 5.2.1 (f); 5.2.3; 10.3.3; 10.4.2.4	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 2.0 Manufacturer's written instructions**: Manufacturer's written instructions are available for:**				
A 2.4	Manufacturer's written instructions are available for using device lubricants.	Obtain and file (electronically or on paper) manufacturer's written instructions for device lubricants. Instructions include information on: • compatibility with sterilant • dispensing/dilution • shelf-life • storage AC[1], Clause: 8.10 CAN/CSA Z314.3-09, Clause: 8.3 CAN/CSA Z314.8-08; 10.10	▼	• Area Management
A 2.5	Manufacturer's written instructions are available for using high level disinfectants.	Obtain and file (electronically or on paper) manufacturer's written instructions for all high level disinfectants used. Instructions include: • mixing (if required) • expiry after opening, mixing and pour-off (as applicable) • testing of minimum effective concentration (MEC) • contact time • temperature • rinsing • disposal • handling precautions, including personal protective equipment (PPE) (and ventilation if required) AH[2], Clause: 6.2,6.5 CAN/CSA Z314.8-08, Clause: 10.8	▼	• Area Management
A 2.6	Manufacturer's written instructions are available for biological indicators (BIs).	Obtain and file (electronically or on paper) manufacturer's written instructions for all BIs. CAN/CSA Z314.3-09, Clause: 12.9; 12.10; 12.11 CAN/CSA Z14161-06. DA.4, Clause: 12.2.3.1 CAN/CSA-Z14161-06	▼	• Area Management
A 2.7	Manufacturer's written instructions are available for chemical indicators.	Obtain and file (electronically or on paper) manufacturer's written instructions for all chemical indicators. CAN/CSA Z314.3-09, Clause: 9.5.5; 12.2.3. CAN/CSA-Z15882	▼	• Area Management
Installation, maintenance and operating instructions for all reprocessing equipment, including:				
A 2.8	There are installation, maintenance and operating instructions for all sterilizers.	Obtain and file (electronically or on paper) manufacturer's written instructions for each sterilizer. Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 5,8,7, 9,9.4, AH[2], Clause: 7.2,7.5, CAN/CSA Z314.3-09, Clause: 12.4.1; 14 CAN/CSA Z314.0-13, Clause:5.3	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 2.0 Manufacturer's written instructions**: Manufacturer's written instructions are available for:**				
A 2.9	There are installation, maintenance and operating instructions for all biological indicator (BI) monitoring equipment.	Obtain and file (electronically or on paper) manufacturer's written instructions for each BI incubator and reader. Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 7 AH[2], Clause: 7.2 CAN/CSA Z314.3-09, Clause: 12.1.1; 12.6.4.4. (d); 12.6.4.6 CAN/CSA Z314.0-13, Clause:5.3. CAN/CSA-Z14161-11	▼	• Area Management • Facility Management
A 2.10	There are installation, maintenance and operating instructions for all automatic washer/disinfectors.	Obtain and file (electronically or on paper) manufacturer's written instructions for each automatic washer/disinfector. Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 7 AH[2], Clause: 7.2 CAN/CSA Z314.8-08, Clause: 5.2; 7.5; 10.4.3.1.3	▼	• Area Management • Facility Management
A 2.11	There are installation, maintenance and operating instructions for all pasteurizers.	Obtain and file (electronically or on paper) manufacturer's written instructions for each pasteurizer. Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 7 AH[2], Clause: 7.2 CAN/CSA Z314.8-08, Clause: 5.2; 7.5; 12.6.2.2	▼	• Area Management • Facility Management
A 2.12	There are installation, maintenance and operating instructions for all drying cabinets.	Obtain and file (electronically or on paper) manufacturer's written instructions for each drying cabinet. Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 7 AH[2], Clause: 7.2 CAN/CSA Z314.8-08, Clause: 5.2; 7.5	▼	• Area Management • Facility Management
A 2.13	There are installation, maintenance and operating instructions for all automated endoscope reprocessors (AERs).	Obtain and file (electronically or on paper) manufacturer's written instructions for each AER. Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 7 AH[2], Clause: 7.2 CAN/CSA Z314.8-08, Clause: 5.2; 7.5	▼	• Area Management • Facility Management
A 2.14	There are installation, maintenance and operating instructions for all ultrasonic cleaners.	Obtain and file (electronically or on paper) manufacturer's written instructions for each ultrasonic cleaner. Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 7 AH[2], Clause: 7.2 CAN/CSA Z314.8-08, Clause: 5.2; 7.5; 10.4.4.1	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 2.0 Manufacturer's written instructions**: Manufacturer's written instructions are available for:**				
A 2.15	There are installation, maintenance and operating instructions for all automated lumen cleaners.	Obtain and file (electronically or on paper) manufacturer's written instructions for each automated lumen cleaner. Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 7 AH[2], Clause: 7.2 CAN/CSA Z314.8-08, Clause: 5.2; 7.5	▼	• Area Management • Facility Management
A 2.16	There are installation, maintenance and operating instructions for all transesophageal echocardiogram (TEE) probe reprocessing units.	Obtain and file (electronically or on paper) manufacturer's written instructions for each TEE probe reprocessing unit. Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 7 AH[2], Clause: 7.2 CAN/CSA Z314.8-08, Clause: 5.2; 7.5	▼	• Area Management • Facility Management
A 2.17	There are installation, maintenance and operating instructions for all high level disinfection (HLD) air handling systems (e.g. glutaraldehyde user station [GUS]).	Obtain and file (electronically or on paper) manufacturer's written instructions for each HLD air handling system (e.g. GUS). Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 7 AH[2], Clause: 7.2 CAN/CSA Z314.8-08, Clause: 5.2; 7.5	▼	• Area Management • Facility Management
A 2.18	There are installation, maintenance and operating instructions for all fume hoods.	Obtain and file (electronically or on paper) manufacturer's written instructions for each fume hood. Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 7 AH[2], Clause: 7.2 CAN/CSA Z314.8-08, Clause: 5.2; 7.5.5	▼	• Area Management • Facility Management
A 2.19	There are installation, maintenance and operating instructions for all instrument sterilization containers.	Obtain and file (electronically or on paper) manufacturer's written instructions for each instrument sterilization container or system (e.g. flashpack ®, rigid container systems, etc.). Instructions include information on installation, operation and maintenance. AC[1], Clause: 4.6, 7 AH[2], Clause: 7.2 CAN/CSA Z314.8-08, Clause: 5.2; 7.5.5	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:

Section A: Reprocessing Medical Devices – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
Cleaning				
A 3.1	Ultrasonic cleaning equipment is tested at least weekly to ensure functionality and results documented.	Ensure that weekly testing of ultrasonic cleaning equipment is performed and documented using test specified by manufacturer or foil test. AC[1], Clause: 4, 7 CAN/CSA Z314.8-08, Clause: 7.5.7; 10.4.4.8	▼	• Area Management
A 3.2	Automated cleaning equipment (i.e. washer/disinfector) is tested and results documented.	Ensure that testing and documentation of automated cleaning equipment is performed according to the manufacturer's written instructions or by another established method (e.g. TOSI test). AC[1], Clause: 4, 7 CAN/CSA Z314.8-08, Clause: 7.5.6; 7.5.7; 7.5.8	▼	• Area Management
Sterilization				
Operational qualification is done and results documented as follows:				
A 3.3	Operational qualification testing of steam and/or ethylene oxide (ETO) sterilizers by running three (3) consecutive cycles in the empty sterilizer using a process challenge device (PCD) (i.e. test pack) with biological indicators (BIs) is done and documented following installation and major repairs or significant modifications to the sterilizer.	Ensure operational qualification testing of steam and ETO sterilizers using PCDs is performed and documented following installation, major repairs or significant modifications. AC[1], Clause: 4, 7 AH[2], Clause: 7.2,7.5 CAN/CSA Z314.0-13, Clause:5.2.3, CAN/CSA Z314.3-09, Clause: 12.3 revised (Feb 2011), 12.4, 12.5	▼	• Area Management
A 3.4	Operational qualification testing of dynamic air removal sterilizers with three (3) consecutive air removal (Bowie Dick) tests in an empty sterilizer is done and documented following installation and major repairs or significant modifications to the sterilizer.	Ensure operational qualification testing using dynamic air removal (Bowie Dick) tests is done and documented following installation, major repairs or significant modifications to dynamic air removal sterilizers. AC[1], Clause: 4, 7 CAN/CSA Z314.3-09, Clause: 12.3 revised (Feb 2011)	▼	• Area Management
A 3.5	For sterilization methods other than steam or ethylene oxide (ETO), (e.g. Sterrad®, Steris System 1®) manufacturer's written instructions for operational qualification are followed. This is done and documented following installation and major repairs or significant modifications to the sterilizer.	Ensure that operational qualification testing for sterilization methods other than steam or ETO have been conducted according to manufacturer's written instructions following installation and major repairs or significant modifications to the sterilizer. AC[1], Clause: 4, 7 CAN/CSA Z314.3-09, Clause: 12.3 revised (Feb 2011), 12.4	▼	• Area Management
Performance qualification is done and results documented as follows:				

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
A 3.6	Performance qualification is done and documented to verify that packs/sets can be sterilized in the facility's sterilizer(s). This is done for each pack/set currently in use and when introducing: • new bundles containing surgical textiles • new, loaned or complex large or multi-level instrument sets • new packaging or wrapping systems • extended cycles as recommended by manufacturer	Ensure performance qualification is done and to verify that packs/sets can be sterilized in the facility's sterilizer(s). This is done for each pack/set currently in use and when introducing: • new bundles containing surgical textiles • new, loaned or complex large or multi-level instrument sets • new packaging or wrapping systems • extended cycles as recommended by manufacturer This includes placing biological and chemical indicators within packs/sets in location(s) presenting the greatest challenge to sterilization. Following sterilization, indicator results are reviewed to verify sterilization and documented prior to accepting the packs/sets for use. CAN/CSA Z314.3-09, Clause: 12.5	▼	• Area Management
Routine monitoring is done and results documented. Routine monitoring requires that:				
A 3.7	There is documentation that biological indicators (BIs) are appropriate for the method of sterilization.	Ensure that the BI used for each sterilization method is validated for use in that sterilizer. Examples of BIs are: • Steam: *Geobacillus stearothermophilus* • Ethylene oxide (ETO): *Bacillus atrophaeus* CAN/CSA Z314.3-09, Clause: 12.6.4.1; 12.6.4.4; 12.12.1 (ii)	▼	• Area Management
A 3.8	Biological indicators (BIs) contained within a process challenge device (PCD) are tested each day the sterilizer is in use and for each type of cycle that will be used during the day. Results are documented. For unwrapped or flash cycles, a BI must be run but does not need to be contained in a PCD.	Ensure that BIs contained within a PCD are tested each day the sterilizer is in use and for each type of cycle that will be used during the day. Results are documented. For unwrapped or flash cycles a BI must be run but does not need to be contained in a PCD. If a Flashpack is used for flash sterilization, the BI should be placed inside the container. Examples of cycles include dynamic air removal, gravity, extended cycles, etc. AC[1], Clause: 7.5,7.6 AH[2], Clause: 7.3.5 CAN/CSA Z314.3-09, Clause: 12.6.4 **Note:** For table top sterilizers refer to: CAN/CSA Z314.3-09, Clause: 12.4.2.3	▼	• Area Management
A 3.9	At a minimum, a control biological indicator (BI) from each shipping lot is incubated to verify the viability of the test spores and results are documented.	Ensure that a control BI from each shipping lot is incubated to verify the viability of the test spores and results are documented. Note: Control BIs are not subjected to the sterilization process. CAN/CSA Z14161-06. Annex DA, Clause: DA.9 (p. CSA/12)	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
A 3.10	Every load containing implantable devices is monitored with a biological indicator (BI) and packages containing implantable devices are quarantined until a negative BI result is obtained.	Ensure that every load containing implantable devices is monitored with a BI and packages containing implantable devices are quarantined until a negative BI result is obtained. AC[1], Clause: 8.4 AH[2], Clause: 7.3.5 CAN/CSA Z314.3-09, Clause: 12.6.4.2	▼	• Area Management
A 3.11	Time and temperature are verified and results documented for all biological indicator (BI) incubation or reading equipment. Verification is performed according to manufacturer's written instructions.	Ensure that time and temperature are verified, and results documented, for each BI incubator or reader used. Verification is performed as per manufacturer's written instructions. CAN/CSA Z14161-06. Annex DA, Clause: DA.12 (p. CSA/14)	▼	• Area Management
A 3.12	For dynamic air removal type sterilizers, an air removal test (Bowie Dick) is conducted each day the sterilizer is in use and results documented.	Ensure for dynamic air removal type sterilizers, an air removal (Bowie Dick) test is conducted each day the sterilizer is in use and results documented. CAN/CSA Z314.3-09, Clause: 12.6.3.3.1	▼	• Area Management
A 3.13	Sterilization practices are monitored on a regular basis and a method of follow-up is in place to remedy non-compliance.	Ensure that sterilization practices are monitored on a regular basis and a method of follow-up is in place to remedy non-compliance. Monitoring is documented. Examples of monitoring methods include manager's or designate's: • routine review of logs, printouts, etc.(e.g. initials or signature that record was reviewed) • supervision of practice including signoff by managers/ supervisors AC[1], Clause: 4,4.3,6, AH[2], Clause: 7.3. CAN/CSA Z314.3-09, Clause: 12.1.1	▼	• Area Management
A 3.14	A record is kept of each sterilization cycle including: • sterilizer identifier • load number • date and time of cycle • mechanical indicators of physical parameters (e.g. time, temp, etc.) • load contents • identification of person responsible for load release	Ensure a record is kept of each sterilization cycle. Documentation includes: • sterilizer identifier • load number • date and time of cycle • mechanical indicators of physical parameters (e.g. time, temp, etc.) • load contents • identification of person responsible for load release Mechanical indicators may be recorded in a log, printout, database or recording chart. AC[1], Clause: 6, AH[2], Clause: 7.3 CAN/CSA Z314.2-09, Clause: 12.6 CAN/CSA Z314.3-09, Clause: 9.5.7.2.1	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
A 3.15	A record is kept of each flash sterilization cycle including: • sterilizer number • load number • date and time of cycle • results of chemical and mechanical indicators of physical parameters (e.g. time, temp, etc.) • load contents • identification of person responsible for load release • patient name and ID number • surgeon's name • reason for flash sterilization	Ensure a record is kept of each flash sterilization cycle that includes: • sterilizer number • load number • date and time of cycle • results of chemical and mechanical indicators of physical parameters (e.g. time, temp, etc.) • load contents • identification of person responsible for load release • patient name and ID number • surgeon's name • reason for flash sterilization Mechanical indicators may be recorded in a log, printout, database or recording chart. AC[1], Clause: 6, AH[2], Clause: 7.3 CAN/CSA Z314.3-09, Clause: 13	▼	• Area Management
A 3.16	Record of all maintenance and interventions associated with a failed sterilization load or a positive biological indicator (BI).	Ensure there is documentation of all maintenance and interventions associated with a failed sterilization load or a positive BI. CAN/CSA Z314.3-09, Clause: 12.10; 13.10	▼	• Area Management
Chemical High Level Disinfection (HLD)				
A 3.17	High level disinfection (HLD) practices are monitored on a regular basis and a method of follow-up is in place to remedy non-compliance.	Ensure that HLD practices are monitored on a regular basis and a method of follow-up is in place to remedy non-compliance. Monitoring is documented. Examples of monitoring methods include manager's or designate's signature/initial indicating: • routine review of logs, printouts, etc. • supervision of practice CAN/CSA Z314.8-08, Clause: 10.8	▼	• Area Management
A 3.18	The chemical test strips used to check the minimum effective concentration (MEC) are specific to the type and concentration of disinfectant.	Ensure the chemical test strips used to check the MEC are specific to the type and concentration of the high level disinfectant. This information is documented. AH[2], Clause: 6.5 CAN/CSA Z314.8-08, Clause: 10.8	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
A 3.19	Minimum effective concentration (MEC) of high level disinfectant is tested at least daily when in use and results documented.	Ensure that the MEC of reusable high level disinfectant is tested at least daily when in use and results documented. Documentation should include: • the MEC test strip • name and concentration of the disinfectant • date of test • testing results If a method of testing concentration other than test strips is used (e.g. concentration testing during an automated cycle), concentration is documented and verified. Method of testing is validated by the manufacturer. AH[2], Clause: 6.5 CAN/CSA Z314.8-08, Clause: 10.8	▼	• Area Management
A 3.20	Quality control testing of MEC test strips is performed according to manufacturer's written instructions each time a new bottle is opened to verify efficacy of test strips. Results are documented.	Ensure that quality control testing is performed on MEC test strips according to manufacturer's written instructions each time a new bottle is opened to verify efficacy. Results are documented. AH[2], Clause: 6.5 CAN/CSA Z314.8-08, Clause: 10.8.3.8 PHAC, Clause: 5.3 d	▼	• Area Management
A 3.21	There is documentation when high level disinfectant is changed.	Ensure there is documentation when high level disinfectant is changed. Documentation includes: • name of high level disinfectant • date and time • individual changing the disinfectant CAN/CSA Z314.8-08, Clause: 10.8 PHAC, Clause, 2(f)(vii); 3(e)	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
A 3.22	Each high level disinfection (HLD) cycle or process is monitored by trained staff who document the process including: • identification of the devices being reprocessed • date and time • contact time with the chemical high level disinfectant • temperature (if applicable) • identification of person responsible for ensuring all requirements for reprocessing and releasing the devices are met When automated reprocessing equipment is used, documentation also includes: • automated reprocessing unit identification (e.g. make, model, serial number, etc.)	Ensure that each HLD cycle or process is monitored by trained staff who document the process including: • identification of the devices being reprocessed • date and time • contact time with the chemical high level disinfectant • temperature (if applicable) • identification of person responsible for ensuring all requirements for reprocessing and releasing the devices are met When automated reprocessing equipment is used, documentation also includes: • automated reprocessing unit identification (e.g. make, model, serial number, etc.) CAN/CSA Z314.8-08, Clause: 10.8	▼	• Area Management
A 3.23	For traceability of endoscope or endocavity probe to patient, documentation is maintained indicating: • date device used on the patient • the patient identification • the serial number or other identifier of the endoscope or endocavity probe	Ensure that documentation is maintained to ensure traceability of endoscope or endocavity probe to patient. Documentation should include: • date device used on the patient • the patient's identification • the serial number or other identifier of the endoscope or endocavity probe AH^2, Clause: 8.4.3 CAN/CSA Z314.8-08, Clause: 10.8; 13.9.3 PHAC, Clause: 5.3(g)	▼	• Area Management
Thermal High Level Disinfection (HLD) of Respiratory/Anesthesia Devices (including Pasteurization)				
A 3.24	Documentation for thermal HLD cycles of semicritical devices is maintained for each cycle and includes: • cycle parameters (e.g. time and temperature) • load contents • date and time • identification of individual verifying cycle parameters and releasing load	Ensure that documentation for thermal HLD cycles of semicritical devices is maintained and includes: • cycle parameters (e.g. time and temperature • load contents • date and time • identification of individual verifying cycle parameters and releasing load AH^2, Clause: 6.6.6 CAN/CSA Z314.8-08, Clause: 12	▼	• Area Management
A 3.25	Water temperature (minimum 71°C) within the pasteurizer is manually verified and recorded regularly.	Ensure that water temperature (minimum 71°C) within the pasteurizer is manually verified and recorded regularly. CAN/CSA Z314.8-08, Clause: 12.6.2	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
A 3.26	Cycle time (30 minutes) in pasteurizers is verified manually and recorded regularly.	Ensure that cycle time (30 minutes) in pasteurizers is verified manually and recorded regularly. CAN/CSA Z314.8-08, Clause: 12.6.2	▼	• Area Management
Environmental Cleaning				
A 3.27	Floors, horizontal working surfaces and counters are cleaned daily and documented.	Ensure environmental cleaning is documented, and that floors, horizontal working surfaces and counters are cleaned daily. AC[1], Clause: 3.7 CAN/CSA Z314.0-13, Clause: 7.5 CSA Z314.3-09, Clause: 7.5 CAN/CSA Z314.8-08, Clause: 7.4.1; 7.4.2	▼	• Area Management • AHS Environmental Services
A 3.28	Walls, ceilings, vents, light fixtures are cleaned at least every 6 months and documented.	Ensure environmental cleaning is documented, and that walls, ceilings, vents, light fixtures are cleaned at least every 6 months. AC[1], Clause: 3.7 CAN/CSA Z314.0-13, Clause: 7.5 CAN/CSA Z314.3-09, Clause: 7.5 CAN/CSA Z314.8-08, Clause: 7.4.1; 7.4.2	▼	• Area Management • AHS Environmental Services
Maintenance Records **There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for:**				
A 3.29	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all sterilizers.	Ensure all maintenance for each sterilizer is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.2,7.3 AH[2], Clause: 7.2 CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.3-09, Clause: 12.4.1; 14	▼	• Area Management • Facility Management
A 3.30	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all biological indicator (BI) monitoring equipment.	Ensure all maintenance for each BI incubator or reader is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.2,7.3 CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.3-09.12.6.4; 12.10	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
A 3.31	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all automatic washer/disinfectors.	Ensure all maintenance for each automatic washer/disinfector is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.2,7.3 CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.8-08, Clause: 7.5; 10.4.3.6; 10.4.3.7	▼	• Area Management • Facility Management
A 3.32	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all pasteurizers.	Ensure all maintenance for each pasteurizer is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.2,7.3 CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.8-08, Clause: 12.6.2; 12.9	▼	• Area Management • Facility Management
A 3.33	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all drying cabinets.	Ensure all maintenance for each drying cabinet is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.2,7.3 CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.8-08, Clause: 12.7; 12.9	▼	• Area Management • Facility Management
A 3.34	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all automated endoscope reprocessors (AERs).	Ensure all maintenance for each AER is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.2,7.3 AH[2], Clause: 8.3.2 CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.8-08, Clause: 13.4.8; 13.9.3	▼	• Area Management • Facility Management
A 3.35	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all ultrasonic cleaners.	Ensure all maintenance for each ultrasonic cleaner is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.2,7.3 CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.8-08, Clause: 7.5.7; 10.4.3.1.2; 10.4.4.1	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
A 3.36	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all automated lumen cleaners.	Ensure all maintenance for each automated lumen cleaner is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions AC[1], Clause: 7.2,7.3 CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.8-08, Clause: 7.5.7; 13.4.5	▼	• Area Management • Facility Management
A 3.37	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all transesophageal echocardiogram (TEE) probe reprocessing units.	Ensure all maintenance for each TEE probe reprocessing unit is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.2,7.3 CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.8-08, Clause: 13.4.5	▼	• Area Management • Facility Management
A 3.38	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all high level disinfection (HLD) air handling systems (e.g. glutaraldehyde user station [GUS]).	Ensure all maintenance for each HLD air handling system (e.g. GUS) is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.2,7.3 CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.8-08, Clause: 13.4.5	▼	• Area Management • Facility Management
A 3.39	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all fume hoods.	Ensure all maintenance for each fume hood is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.8-08, Clause: 13.4.5	▼	• Area Management • Facility Management
A 3.40	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all instrument sterilization containers.	Ensure all maintenance for each instrument sterilization container or system (e.g. flash pack®, rigid container systems, etc.) is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.2,7.3 CAN/CSA Z314.0-13, Clause: 7.11 CAN/CSA Z314.3-09, Clause: 9.4	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:

Section A: Reprocessing Medical Devices – Document Review **4.0 Education and Core Competency of Medical Device Reprocessing (MDR) Staff**				
Infection Prevention and Control (IPC) Education and Training				
There is documentation that all staff have received IPC training including the following topics: It should include each component listed in "Additional Information"				
A 4.1	Infection prevention and control (IPC) training is documented and includes basic microbiology.	Ensure IPC training includes information on requirements that support microbial growth and how microorganisms are spread and cause disease. AC[1], Clause: 2.7 CAN/CSA Z314.0-13, Clause: 6.3.2 CAN/CSA Z314.3-09, Clause: 6.3.3 CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control
A 4.2	Infection prevention and control (IPC) training is documented and includes Risks of contact with or exposure to infectious agents.	Ensure IPC training includes information on Risks of contact with or exposure to infectious agents, including information on "Chain of Infection" model. AC[1], Clause: 2.7 CAN/CSA Z314.0-13, Clause: 6.3.2 CAN/CSA Z314.3-09, Clause: 6.3.3 CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control
A 4.3	Infection prevention and control (IPC) training is documented and includes Category to patients exposed to inadequately reprocessed medical devices.	Ensure IPC training includes information on Risks to patients exposed to inadequately reprocessed medical devices (e.g. complications, infection, death, etc.). Information on Risks should include: • malfunctioning equipment • lack of knowledge • not following manufacturer's written instructions • inadequate storage and handling procedures AC[1], Clause: 2.7 CAN/CSA Z314.0-13, Clause: 6.3.2 CAN/CSA Z314.3-09, Clause: 6.3.3 CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control
A 4.4	Infection prevention and control (IPC) training is documented and includes personal hygiene including proper hand hygiene.	Ensure IPC training includes: • importance of clean skin, hair and clothing • when and how to use alcohol based hand rub (ABHR) • when to and how to wash hands with soap and water. • why hand washing sinks are dedicated for hand hygiene. AC[1], Clause: 2.7 CAN/CSA Z314.0-13, Clause: 6.3.2 CAN/CSA Z314.3-09, Clause: 6.3.3 CAN/CSA Z314.8-08, Clause: 6.3.3; 10.11.3	▼	• Area Management • AHS Infection Prevention and Control

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review **4.0 Education and Core Competency of Medical Device Reprocessing (MDR) Staff**				
A 4.5	Infection prevention and control (IPC) training is documented and includes use of personal protective equipment (PPE).	Ensure IPC training includes use and selection of PPE including correct sequence for putting on and removing PPE (including hand hygiene). AC[1], Clause: 2.7 CAN/CSA Z314.0-13, Clause: 6.3.2 CAN/CSA Z314.3-09, Clause: 6.3.3 CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control • AHS Workplace Health and Safety
A 4.6	Infection prevention and control (IPC) training is documented and includes IPC and work practices to prevent staff exposure to blood and body fluids.	Ensure IPC training includes information on IPC and work practices to prevent staff exposure to blood and body fluids. This includes prevention of needle stick injuries, mucous membrane exposures, etc. AC[1], Clause: 2.7 CAN/CSA Z314.0-13, Clause: 6.3.2 CAN/CSA Z314.3-09, Clause: 6.3.3 CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control • AHS Workplace Health and Safety
A 4.7	Infection prevention and control (IPC) training is documented and includes handling of sharps and waste management.	Ensure IPC training includes information on handling of sharps and waste management. AC[1], Clause: 2.7 CAN/CSA Z314.3-09, Clause: 6.3.3 CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control • AHS Workplace Health and Safety
A 4.8	Infection prevention and control (IPC) training is documented and includes procedures following staff exposure to blood and body fluids.	Ensure IPC training includes information on procedures for staff to follow if exposed to blood and body fluids. AC[1], Clause: 2.7 CAN/CSA Z314.0-13, Clause: 6.3.2 CAN/CSA Z314.3-09, Clause: 6.3.3 CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control • AHS Workplace Health and Safety
A 4.9	Infection prevention and control (IPC) training is documented and includes one-way work flow practices to prevent the contamination of clean items.	Ensure IPC training includes one-way work flow practices to prevent the contamination of clean items. AC[1], Clause: 2.7 CAN/CSA Z314.0-13, Clause: 6.3.2 CAN/CSA Z314.3-09, Clause: 6.3.3 CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control
Medical Device Reprocessing (MDR) Education and Training				
There is documentation on the frequency of training on fundamentals of MDR for manager(s) and staff responsible for reprocessing. Training is performed by competent personnel when:				

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section A: Reprocessing Medical Devices – Document Review **4.0 Education and Core Competency of Medical Device Reprocessing (MDR) Staff**				
A 4.10	There is documentation of training on fundamentals of MDR for manager(s) and staff responsible for reprocessing when staff are first employed.	Ensure the initial orientation of the manager and staff responsible for reprocessing includes education by competent personnel on basic reprocessing principles and how to reprocess instruments. All staff education and training is documented. AC[1], Clause: 2. 7 AH[2], Clause: 10 CAN/CSA Z314.3-09, Clause: 6.2; 6.3 CAN/CSA Z314.8-08, Clause: 13.9.1 CAN/CSA Z314.0-13, Clause: 6.3.2	▼	• Area Management
A 4.11	There is documentation of training on fundamentals of MDR for manager(s) and staff responsible for reprocessing when there is any authorized change in process.	Ensure authorized process changes are communicated to the manager and staff responsible for reprocessing. Education and training is provided. All staff education and training is documented. AC[1], Clause:, 27 10 AH[2], Clause: 3.3.4,10 CAN/CSA Z314.3-09, Clause: 6.3 CAN/CSA Z314.8-08, Clause: 13.9.1	▼	• Area Management
A 4.12	There is documentation of training on fundamentals of MDR for manager(s) and staff responsible for reprocessing when new equipment, devices, products and textiles are purchased.	Ensure manager and staff responsible for reprocessing receive education and training on all new equipment, devices and textiles, including information on reprocessing. All staff education and training is documented. AC[1], Clause: 2.7 AH[2], Clause: 10 CAN/CSA Z314.3-09, Clause: 6.3 CAN/CSA Z314.8-08, Clause: 13.9.1	▼	• Area Management
A 4.13	There is documentation of training on fundamentals of MDR for manager(s) and staff responsible for reprocessing when new processing equipment is purchased.	Ensure manager and staff responsible for reprocessing receives education and training on new reprocessing equipment. All staff education and training is documented. AC[1], Clause: 2. 7 AH[2], Clause: 10 CAN/CSA Z314.3-09, Clause: 6.2; 6.3 CAN/CSA Z314.3-09, Clause: 6.3 CAN/CSA Z314.8-08, Clause: 13.9.1	▼	• Area Management
Competency Testing				
A 4.14	Baseline and annual competency testing of staff members involved in reprocessing, high level disinfection (HLD) and sterilization is conducted and results are documented.	Ensure the manager and staff responsible for reprocessing can demonstrate reprocessing competencies initially and at specified intervals (at least annually). Competencies are documented. AC[1], Clause: 2.5, 2.5 AH[2], Clause: 10 CAN/CSA Z314.3-09, Clause: 6.3 CAN/CSA Z314.8-08, Clause: 13.9.1	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section B: Reprocessing Medical Devices – Single Use Medical Devices (SUMeds or SUDs)				
B 1.1	There is a documented policy stating that single use medical devices are not to be reprocessed in the facility.	Develop, update or obtain a written policy that states single use medical devices are not reprocessed. AHS Single use Medical Devices PS-07 http://insite.albertahealthservices.ca/Files/clp-single-use-medical-devices-policy.pdf AC[1], Clause: 8.1 AH Standards Single Use Medical Devices.	▼	• Area Management • AHS Administration
B 1.2	Single use medical devices are not reprocessed in the facility.	Ensure single use medical devices are not reprocessed. AHS Single use Medical Devices PS-07 http://insite.albertahealthservices.ca/Files/clp-single-use-medical-devices-policy.pdf AC[1], Clause: 8.1 AH Standards Single Use Medical Devices.	●	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **1.0 Area Design**				
C 1.1	There is a designated reprocessing area that is physically separate from areas where clean, disinfected or sterile items are stored or handled and where patient care is provided.	Ensure that there is a designated reprocessing area that is physically separated by walls or partitions from areas where clean and sterile items are stored or handled or where patient care is provided. AC[1], Clause: 3.3,3.4 AH[2], Clause: 2 CAN/CSA Z314.0-13, Clause: 7 CAN/CSA Z314.8-08, Clause: 7.1.1; 7.1.2	◆	• Area Management
C 1.2	Reprocessing work areas are separated by walls or partitions to control traffic and contain contaminants.	Ensure the reprocessing work areas (e.g. cleaning/decontamination area, clean work area, storage area) are separated by walls or partitions to control traffic and contain contaminants. AC[1], Clause: 3.3,3.4 AH[2], Clause: 2 CAN/CSA Z314.0-13, Clause: 7 CAN/CSA Z314.8-08, Clause: 7.1.2; 7.1.6 CAN/CSA Z314.3-09; 7.1.1; 7.1.2; 7.1.5	◆	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **1.0 Area Design**				
C 1.3	There are designated clean and soiled areas within the reprocessing work area.	Ensure there are designated clean and soiled areas within the reprocessing work area. AC[1], Clause: 3.3,3.4 AH[2], Clause: 2 CAN/CSA Z314.0-13, Clause: 7 CAN/CSA Z314.8-08, Clause: 7.1.6; 13.3.2	▼	• Area Management
C 1.4	There is a one-way work flow from dirty to clean to prevent cross-contamination.	Ensure the reprocessing space has one-way work flow from dirty to clean to prevent cross-contamination. AC[1], Clause: 3.3,3.4 AH[2], Clause: 2 CAN/CSA Z314.0-13, Clause: 7 CAN/CSA Z314.8-08, Clause: 7.1.2	▼	• Area Management
C 1.5	Eyewash stations are readily available and maintained in areas where staff handle chemicals or biological contaminants.	Ensure eyewash stations are readily available and maintained in areas where staff handle chemicals or biological contaminants. AC[1], Clause: 2.1 CAN/CSA Z314.8-08, Clause: 7.1.13 CAN/CSA 8000-11, Clause: 10.7.4.9(o)	▼	• Area Management
C 1.6	All walls, ceilings and work surfaces are intact and composed of non-porous, non-shedding material capable of withstanding frequent cleaning.	Ensure all walls, ceilings and work surfaces are intact and composed of non-porous, non-shedding material capable of withstanding frequent cleaning. AC[1], Clause: 3.6 AH[2], Clause: 2.4 CAN/CSA Z314.0-13, Clause: 7.2 CAN/CSA Z314.8-08, Clause: 7.1.8 CAN/CSA 8000-11, Clause: 10.7.4.8	◆	• Area Management
C 1.7	There are no exposed pipes or duct work.	Ensure there are no exposed pipes or duct work. AC[1], Clause: 3.6 CAN/CSA Z314.8-08, Clause: 7.1.8 CAN/CSA Z314.3-09, Clause: 7.1.8 CAN/CSA Z314.0-13, Clause: 7.2.9(b) CAN/CSA 8000-11, Clause: 10.7.4.8	◆	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **1.0 Area Design**				
C 1.8	There are dedicated hand hygiene stations at entrances/exits to the reprocessing area.	Ensure there are dedicated hand hygiene stations at entrances/exits to the reprocessing area. Hand hygiene stations include a sink with soap and an adjacent enclosed single-use towel dispenser or waterless alcohol-based hand rub dispenser. AC[1], Clause: 5.1 AH [2], Clause: 2.4 CAN/CSA Z314.3-09, Clause: 6.6.2 CAN/CSA Z314.8-08, Clause: 7.1.12	▼	• Area Management
C 1.9	Reprocessing work areas have doors that are kept closed.	Ensure reprocessing area has doors that are kept closed. AC[1], Clause: 3.4 CAN/CSA Z314.8-08, Clause: 7.1.7	▼	• Area Management
C 1.10	Signage is posted at all entry points indicating the area is restricted to authorized personnel only.	Ensure signage is posted at all entry points indicating the area is restricted to authorized personnel only. AC[1], Clause: 3.2 AH [2], Clause: 2.4.5 CAN/CSA Z314.0-13, Clause: 7.1.2,7.2.2,7.6 CAN/CSA Z314.8-08, Clause: 7.2.1	▼	• Area Management
C 1.11	Traffic in the reprocessing area is restricted to authorized personnel wearing appropriate attire.	Ensure traffic in the reprocessing area is restricted to authorized personnel wearing appropriate attire. AC[1], Clause: 3.2 CAN/CSA Z314.0-13, Clause: 6.7 CAN/CSA Z314.8-08, Clause: 7.2.1	▼	• Area Management
C 1.12	The flash sterilization area is located in a restricted area, adjacent to the area where the sterilized items will be used.	Ensure the flash sterilization area is located in a restricted area, adjacent to the area where the sterilized items will be used. The sterilizer should not be located in the patient care room or operating theater. CAN/CSA Z8000-11, Clause: 9.5.3.4.9, Table 9.5 10(iii), CAN/CSA Z314.3-09, Clause: 13.4	◆	• Area Management
C 1.13	Clean, high level disinfected or sterile medical devices are stored in a clean and secure area.	Ensure clean, high level disinfected or sterile storage areas are well-ventilated and protected from dust, moisture, insects, and temperature and humidity extremes. AC[1], Clause: 3.1,3.5, 10 AH[2], Clause: 9.2 CAN/CSA Z314.0-13, Clause: 7.4 CAN/CSA Z314.15-10, Clause: 6.3; 8.2.1; 8.6.2	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **1.0 Area Design**				
C 1.14	Functional work areas used for case cart assembly are separated from general storage/warehouse areas by walls or partitions.	Ensure functional work areas used for case cart assembly are separated from general storage/warehouse areas by walls or partitions. CAN/CSA Z8000-11, Clause: 10.7.3.1 CAN/CSA Z314.15-10, Clause: 10.1.1	◆	• Area Management
C 1.15	Portable fans are not used in the reprocessing area.	Ensure there are no portable fans used in the medial device reprocessing area(s). CAN/CSA Z314.8-08, Clause: 7.3.3	▼	• Area Management
C 1.16	The area is free of external shipping containers and corrugated cardboard.	Ensure the area is free of external shipping containers and corrugated cardboard. CAN/CSA Z314.0-13, Clause: 10.2.2 CAN/CSA Z314.3-09, Clause: 11.2.3	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **2.0 Decontamination/Cleaning of Reusable Medical Devices**				
C 2.1	Appropriate personal protective equipment (PPE) is worn when decontaminating/cleaning.	Ensure PPE (gown, gloves, mask and eye protection) is available and worn for cleaning/reprocessing activities. PPE includes: • gloves appropriate to the task • protective gown or garment • full face shield, or high-filtration, fluid-impervious face mask and protective eyewear Prescription eye glasses are not acceptable for eye protection. AC[1], Clause: 3.2,5.8,8.8 AH[2], Clause: 5.7.2, 11.2.5, CAN/CSA Z314.0-13, Clause: 6.6.1.2,6.6.1.3 CAN/CSA Z314.3-09, Clause: 6.7 CAN/CSA Z314.8-08, Clause: 6.7.1.1; 6.7.2.6; 8.1.3	▼	• Area Management
C 2.2	Staff perform hand hygiene prior to putting on and after removing personal protective equipment (PPE).	Ensure staff perform hand hygiene prior to putting on and after removing PPE. AC[1], Clause: 5.5 Health Canada. Hand Washing, Cleaning, Disinfection and Sterilization in Health Care. p.6. CAN/CSA Z314.0-13, Clause: 6.6.1.2 CAN/CSA Z314.8-08, Clause: 6.6.3; 6.7.2.4 CAN/CSA Z314.3-09; 6.6.3; 6.7.2.4	▼	• Area Management
C 2.3	Personal protective equipment (PPE) is removed and hands are cleaned when moving between contaminated and clean areas or tasks.	Ensure PPE is removed and hands are cleaned when moving between contaminated and clean areas or tasks. CAN/CSA Z314.8-08, Clause: 6.7.1.2	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **2.0 Decontamination/Cleaning of Reusable Medical Devices**				
C 2.4	Gross soil is removed from devices at point of use prior to transport for reprocessing.	Ensure that gross soil is removed from devices at point of use, prior to transport for reprocessing. AH [2], Clause: 5.2.1 CAN/CSA Z314.0-13, Clause: E4.2.41.1, CAN/CSA Z314.8-08, Clause: 8.2.2	▼	• Area Management
C 2.5	Contaminated devices are contained in labeled, leak-proof, covered containers during transport to the reprocessing area.	Ensure contaminated devices are contained in labeled, leak-proof, covered containers during transport to the reprocessing area. AH [2], Clause: 4.3.1, 4.1 CAN/CSA Z314.8-08, Clause: 9.1.2	▼	• Area Management
C 2.6	Transport containers are cleaned and disinfected between each use.	Ensure transport containers are cleaned and disinfected between each use. CAN/CSA Z314.8-08, Clause: 9.3.3	▼	• Area Management
C 2.7	If delay in reprocessing is anticipated, devices are treated with an approved process/product to prevent drying of soil.	Ensure devices are treated with an approved process/product to prevent hardening of bioburden if a delay in reprocessing is anticipated. AH [2], Clause: 4.2 CAN/CSA Z314.8-08, Clause: 8.2.2	▼	• Area Management
C 2.8	Cleaning is done in a distinctly separate area from where clean/disinfected/sterile devices are handled or stored.	Ensure that cleaning is done in a distinctly separate area from where clean/disinfected/sterile items are handled or stored. AC [1], Clause: 3.3,3.4, AH [2], Clause: 2 CAN/CSA Z314.8-08, Clause: 7	▼	• Area Management
C 2.9	Cleaning always precedes subsequent high level disinfection (HLD) or sterilization processes.	Ensure cleaning precedes HLD or sterilization processes. AC [1], Clause: 8.4,8.5,8.6 AH [2], Clause: 5.1,5.2 CAN/CSA Z314.0-13, Clause:8.6.1 CAN/CSA Z314.8-08, Clause: 10.4.1; 10.8.5.1.1	●	• Area Management
C 2.10	Devices are disassembled as per manufacturer's written instructions prior to cleaning.	Ensure devices are disassembled as per manufacturer's instruction prior to cleaning. AH[2], Clause: 5.1,5.2 CAN/CSA Z314.0-13, Clause:8.2.1 CAN/CSA Z314.8-08, Clause: 10.2.2	●	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **2.0 Decontamination/Cleaning of Reusable Medical Devices**				
C 2.11	Devices are cleaned using acceptable instrument detergents or enzymatic cleaning agents designed for cleaning medical devices.	Ensure devices are cleaned using acceptable instrument detergents or enzymatic cleaning agents designed for cleaning medical devices. Unacceptable cleaning agents include: • hand soap • dish soap • low-level disinfectants • surgical skin prep solutions • other products not labeled as appropriate for medical instrument cleaning AC [1], Clause: 8.1, AH[2], Clause: 5.7.1 CAN/CSA Z314.8-08, Clause: 10.4.2.4	▼	• Area Management
C 2.12	Detergents/enzymatic cleaners are compatible with metals/materials used in construction of devices to be cleaned.	Ensure detergents and enzymatic cleaners are compatible with the medical device being cleaned. AC [1], Clause: 8.8, CAN/CSA Z314.8-08, Clause: 10.4.2.4	▼	• Area Management
C 2.13	Detergent/enzymatic cleaning solutions are discarded after each use (i.e. sink or container is emptied following each use) and the sink or container is cleaned.	Ensure that detergents and enzymatic cleaners are discarded and that the sink or container is cleaned after each use. CAN/CSA Z314.8-08, Clause 7.4.2	▼	• Area Management
C 2.14	Detergents/enzymatic cleaners are prepared and used according to manufacturer's written instructions.	Ensure detergents/enzymatic cleaners are prepared and used according to manufacturer's written instructions. AC [1], Clause: 8.8, CAN/CSA Z314.8-08, Clause: 10.3.3; 10.4.2.4	▼	• Area Management
C 2.15	Containers for detergents or enzymatic cleaners are not topped up (i.e. new solution is never added to existing solution).	Ensure containers for detergents or enzymatic cleaners are not topped up. CAN/CSA Z314.8-08, Clause: 10.4.3.3.1	▼	• Area Management
C 2.16	Devices are thoroughly rinsed following cleaning.	Ensure devices are thoroughly rinsed following cleaning. AC [1], Clause: 8.4, AH[2], Clause: 5.2.2 CAN/CSA Z314.0-13, Clause:E.4.2.2.3.5 CAN/CSA Z314.8-08, Clause: 10.5	▼	• Area Management
C 2.17	Devices are dried after final rinsing with a lint-free cloth or mechanical method.	Ensure devices are dried after final rinsing with a lint-free cloth or mechanical method. AC [1], Clause: 8.10 AH[2], Clause: 5.2.3, 6.6.5 CAN/CSA Z314.8-08, Clause: 10.7	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **2.0 Decontamination/Cleaning of Reusable Medical Devices**				
C 2.18	Following cleaning, devices are visually inspected to ensure no visible soil or defects are present and are functioning as required.	Ensure devices are visually inspected to ensure no visible soil or defects are present and that they are functioning as required following cleaning. AC [1], Clause: 7.3,8.9 AH[2], Clause: 5.2, CAN/CSA Z314.0-13, Clause: 7.11.2.2, CAN/CSA Z314.8-08, Clause: 10.4.3.8; 10.4.2.7; 10.7	▼	• Area Management
C 2.19	Devices that do not pass inspection for cleanliness are re-cleaned.	Ensure devices that do not pass inspection for cleanliness are re-cleaned. CAN/CSA Z314.8-08, Clause: 12.8	●	• Area Management
C 2.20	Damaged devices are labeled and removed from service.	Ensure damaged devices are labeled and removed from service. CAN/CSA Z314.8-08, Clause: 10.11.8	▼	• Area Management
Manual Cleaning				
C 2.21	During manual cleaning, devices are completely submerged beneath the surface of the cleaning solution. For non-submersible devices, manufacturer's written instructions are followed.	Ensure devices are completely submerged beneath the surface of the cleaning solution during manual cleaning, or manufacturer's instructions are followed if device is non-submersible. CAN/CSA Z314.8-08, Clause: 10.4.2.5	▼	• Area Management
C 2.22	Unless otherwise indicated by manufacturer's instructions, devices with lumens are manually brushed, manually or mechanically flushed with a detergent solution, rinsed, and inspected.	Ensure that unless otherwise indicated by manufacturer's instructions, devices with lumens are cleaned by following these steps: manually brushing, manually or mechanically flushing with a detergent solution, rinsing, and inspecting. AH[2], Clause: 5.6, CAN/CSA Z314.8-08, Clause: 5.1.5, 10.4.2.1,10.4.2.6; 10.4.2.7, 10.5.2,12.5.2 CAN/CSA Z314.0-13, Clause: 5.1.4	●	• Area Management
C 2.23	Cleaning accessories (e.g. brushes, sponges, etc.) are handled appropriately following each use: • single use cleaning accessories are disposed of • reusable cleaning accessories are cleaned and high level disinfected or sterilized	Ensure single use cleaning accessories (e.g. brushes, sponges) are disposed of following each use and reusable cleaning accessories are cleaned and high level disinfected or sterilized following each use. AH[2], Clause: 5.5 CAN/CSA Z314.8-08, Clause:10.4.2.8		•
Automated Washer/Disinfectors				
C 2.24	Automated equipment is used in accordance with the manufacturer's written instructions.	Ensure the manufacturer's written instructions are readily available and followed by staff. AC [1], Clause:8.5 AH[2], Clause: 5.5 CAN/CSA Z314.8-08, Clause: 10.4.3.1.3; 10.4.3.5.2	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **2.0 Decontamination/Cleaning of Reusable Medical Devices**				
C 2.25	For thermal high level disinfection (HLD) cycles, cycle parameters are checked by staff prior to handling and releasing devices for additional processing. If cycle parameters are not achieved, devices are returned for re-cleaning.	Ensure that cycle parameters are checked by staff prior to handling and releasing devices for additional processing for thermal HLD cycles. If cycle parameters are not achieved, devices are returned for re-cleaning. AH[2], Clause: 5.5 CAN/CSA Z314.8-08, Clause: 10.4.3.8; 12.6.1.4 CAN/CSA Z314.0-13, Clause:8.3.3, E 4.2.2	▼	• Area Management
Ultrasonic Cleaning Equipment				
C 2.26	Prior to ultrasonic cleaning, gross soil is removed from devices.	Ensure that gross soil is removed from devices prior to ultrasonic cleaning. AH[2], Clause: 5.7.5 CAN/CSA Z314.0-13, Clause:E4.2.3 CAN/CSA Z314.8-08, Clause: 10.4.4.3 CAN/CSA Z314.3-09, Clause: 10.4.4.3	▼	• Area Management
C 2.27	Following ultrasonic cleaning, devices are thoroughly rinsed and inspected prior to sterilization or high level disinfection (HLD).	Ensure that devices are thoroughly rinsed and inspected following ultrasonic cleaning prior to sterilization or HLD. CAN/CSA Z314.8-08, Clause: 10.4.4.7 CAN/CSA Z314.3-09, Clause: 10.4.7	▼	• Area Management
C 2.28	Solution in ultrasonic cleaner is changed at least daily and when visibly soiled.	Ensure solution in ultrasonic cleaner is changed at least daily and when visibly soiled. CAN/CSA Z314.8-08, Clause: 10.4.4.8 CAN/CSA Z314.3-09, Clause: 10.4.4.8	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **3.0 Thermal High Level Disinfection (HLD) of Semicritical Devices (Pasteurization or Washer/Disinfector)**				
C 3.1	Prior to thermal high level disinfection (HLD), equipment is: • disassembled (as necessary) following manufacturer's written instructions • meticulously cleaned • rinsed	Ensure that devices are processed properly prior to thermal HLD; i.e. they are: • disassembled (as necessary) following manufacturer's written instructions • meticulously cleaned • rinsed AH[2], Clause: 6.6 CAN/CSA Z314.0-13, Clause:8.1.3 CAN/CSA Z314.8-08, Clause: 10.2.2; 12.4; 12.5.1; 12.5.2	●	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **3.0 Thermal High Level Disinfection (HLD) of Semicritical Devices (Pasteurization or Washer/Disinfector)**				
C 3.2	Manufacturer's written instructions for operation of the pasteurizer or washer/thermal disinfector are followed and available to the staff.	Ensure manufacturer's written instructions for installation, operation and ongoing maintenance of the pasteurizer or washer/thermal disinfector are readily accessible for staff and followed. Only automated washer/disinfectors with a validated thermal disinfection cycle can be used for thermal disinfection of semicritical devices. AH[2], Clause: 6.6 CAN/CSA Z314.8-08, Clause: 12.5.3; 12.6.3.2	▼	• Area Management
C 3.3	Documentation for thermal high level disinfection (HLD) cycles of semicritical devices is maintained for each cycle and includes: • cycle parameters (e.g. time and temperature) • load contents • date • identification of person verifying parameters and releasing load	Ensure documentation is completed for each load of semicritical items in the thermal disinfector. Documentation includes: • cycle parameters (e.g. time and temperature) • load contents • date • identification of person verifying parameters and releasing load AH[2], Clause: 6.6 CAN/CSA Z314.8-08, Clause: 12.6.4	▼	• Area Management
C 3.4	Following thermal high level disinfection (HLD), devices are handled in a manner that prevents contamination during transfer to the dedicated dryer.	Ensure that thermally disinfected devices are transported directly from the disinfector to a clean area for drying, assembly and packaging, using a method that prevents contamination (e.g. areas to be equipped with clean, dry tables covered with clean absorbent cloth for holding clean baskets after removal from pasteurizer or washer/disinfector and prior to being placed in drying cabinet). AH[2], Clause: 6.6 CAN/CSA Z314.3-09, Clause: 12.6.3.4	▼	• Area Management
C 3.5	Drying cabinet is HEPA-filtered and used exclusively for the drying of disinfected devices.	Ensure the drying cabinet is HEPA filtered and used exclusively for drying disinfected devices. AH[2], Clause: 6.6 CAN/CSA Z314.8-08, Clause: 12.7.1	◆	• Area Management
C 3.6	Following drying, devices are handled in a manner that prevents contamination.	Ensure devices are handled in a manner that prevents contamination after drying. AH[2], Clause: 6.6 CAN/CSA Z314.8-08, Clause: 12.6.2.5; 12.6.3.4; 12.7.2	▼	• Area Management
C 3.7	Following drying, devices are inspected for cleanliness, dryness and damage.	Ensure that devices are inspected for wear, cracks and soil after drying. There is a procedure for handling damaged devices and soiled devices are reprocessed. AH[2], Clause: 6.6 CAN/CSA Z314.8-08, Clause: 12.8	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **3.0 Thermal High Level Disinfection (HLD) of Semicritical Devices (Pasteurization or Washer/Disinfector)**				
C 3.8	For thermal high level disinfection, there is a process in place that clearly identifies a non-reprocessed device from one that has been reprocessed.	For thermal HLD, ensure there is a process in place that clearly identifies a non-reprocessed device from one that has been reprocessed to prevent the use of a non-reprocessed device on a patient. AH[2], Clause: 6.6, 8.4.1, CAN/CSA Z314.3-09, Clause:12.6.3.4.1, CSA Z314.0-13 F9(2)	●	• Area Management
Pasteurizer				
C 3.9	Water temperature (minimum 71°C) within the pasteurizer is manually verified and recorded regularly.	Ensure the water temperature within the pasteurizer is, at a minimum 71°C. This is manually verified and recorded regularly. CAN/CSA Z314.8-08, Clause: 12.6.2.3; 12.6.2.4	▼	• Area Management
C 3.10	Cycle time (30 minutes) is verified manually and recorded regularly.	Ensure that cycle time (30 minutes) in pasteurizers is verified manually and recorded regularly. CAN/CSA Z314.8-08, Clause: 12.6.2.3; 12.6.2.4	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **4.0 Chemical High Level Disinfection (HLD)**				
C 4.1	Semicritical devices are cleaned and at a minimum, high level disinfected.	Ensure all semicritical devices are cleaned and at a minimum, high level disinfected. AC [1], Clause:8.4 AH[2], Clause: 5.1 CAN/CSA Z314.8-08, Clause: 10.6.1; 10.8.2.5; 10.8.5.1.1	●	• Area Management
C 4.2	There are methods in place to contain or remove toxic vapors emitted by or from disinfecting agents.	Ensure there are methods in place to contain or remove toxic vapors emitted from disinfecting agents. AC [1], Clause:3.5 AH[2], Clause: 11.2.2 CAN/CSA Z314.3-09, Clause 7 CAN/CSA Z314.8-08, Clause: 10.8.2.6; 10.8.3.3	◆	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **4.0 Chemical High Level Disinfection (HLD)**				
C 4.3	Prior to chemical high level disinfection (HLD), devices are: • disassembled (as necessary) following manufacturer's written instructions • meticulously cleaned • rinsed • dried	Ensure devices are reprocessed correctly prior to chemical HLD; devices are: • disassembled (as necessary) following manufacturer's written instructions • meticulously cleaned • rinsed • dried AC [1], Clause:8.4 AH[2], Clause: 5 CAN/CSA Z314.8-08, Clause: 10.8.5.1.1,10.8.5.2	▼	• Area Management
C 4.4	High level disinfectant has a Health Canada Drug Identification Number (DIN).	Ensure high level disinfectant has a Health Canada Drug Identification Number (DIN). AH[2], Clause: 6.4 CAN/CSA Z314.8-08, Clause: 10.8.1.2 HC[17], Clause:3.4(c)p62	▼	• Area Management
C 4.5	High level disinfectants are used according to the manufacturer's written instructions, to ensure the following parameters are met: • time of exposure • temperature of disinfectant • minimum effective concentration (MEC)	Ensure high level disinfectants are used according to the manufacturer's written instructions including: • time of exposure • temperature of disinfectant • MEC AH[2], Clause: 6.5 CAN/CSA Z314.8-08, Clause: 10.8.2.2; 10.8.2.5; 10.8.5.3.1	▼	• Area Management
C 4.6	There is documentation when high level disinfectant is changed.	Ensure there is documentation when high level disinfectant is changed. Documentation should include: • name of high level disinfectant • date • individual changing the disinfectant CAN/CSA Z314.8-08, Clause: 13.9.3(c)	▼	• Area Management
C 4.7	Reusable containers or reservoirs for storing disinfectant and detergent/enzymatic are cleaned and dried before refilling.	Ensure that containers or reservoirs for storing disinfectant and detergent/enzymatic are cleaned and dried before refilling. Containers or reservoirs must never be topped up (i.e. never add new solution to the existing solution). Rationale: Mixing old and new solutions will decrease the effectiveness of the solution and promotes the growth of bacteria. CAN/CSA Z314.8-08, Clause: 10.8.3.4; 10.8.6.1	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **4.0 Chemical High Level Disinfection (HLD)**				
C 4.8	Containers of high level disinfectant that have been mixed or opened are labeled with the date of mixing or opening and the date the solution expires.	Ensure containers of high level disinfectant that have been mixed or opened are labeled with the date of mixing or opening and the date the solution expires. This is required on the bottle as well as any container or reservoir that the disinfectant is stored in. CAN/CSA Z314.8-08, Clause: 10.8.3.9	▼	• Area Management
C 4.9	Minimum effective concentration (MEC) of reusable high level disinfectant is tested at least daily when in use.	Ensure MEC of reusable high level disinfectant is tested at least daily when in use and results documented. If a method of testing concentration other than test strips is used (e.g. concentration testing during an automated cycle), concentration is documented and verified. Method of testing is validated by the manufacturer. AH[2], Clause: 6.5 CAN/CSA Z314.8-08, Clause: 10.8.3.8	●	• Area Management
C 4.10	The chemical test strips used to check the minimum effective concentration (MEC) are specific to the type and concentration of the high level disinfectant.	Ensure the chemical test strips used to check the MEC are specific to the type and concentration of the high level disinfectant. CAN/CSA Z314.8-08, Clause: 10.8.3.8	●	• Area Management
C 4.11	High level disinfectant solution that has reached the expiry date is discarded as recommended by the manufacturer even if the test strip passes.	Ensure that disinfectant solution is discarded when the expiry date is reached. Follow manufacturer's written instructions for disposal of the disinfectant. CAN/CSA Z314.8-08, Clause: 10.8.3.9	▼	• Area Management
C 4.12	Quality control testing of MEC test strips is performed according to manufacturer's written instructions each time a new bottle is opened to verify efficacy of test strips. Results are documented.	Ensure that quality control testing is performed on MEC test strips according to manufacturer's written instructions each time a new bottle is opened to verify their efficacy. Results are documented. CAN/CSA Z314.8-08, Clause: 10.8.3.8	▼	• Area Management
C 4.13	Test strip bottles are dated when opened.	Ensure test strip bottles are dated when opened. This is required by manufacturer's instructions.	▼	• Area Management
C 4.14	Test strips are not used past the expiry date.	Ensure test strips are not used past the expiry date. This includes the lot # expiry date and the open bottle expiry date. This is required by manufacturer's instructions.	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **4.0 Chemical High Level Disinfection (HLD)**				
C 4.15	Each high level disinfection (HLD) cycle is monitored by trained staff who document the process including: • identification of the devices being reprocessed • date • contact time with the chemical high level disinfectant • temperature (if applicable) • identification of person responsible for ensuring all requirements for reprocessing and releasing the devices are met When automated reprocessing equipment is used, documentation also includes: • automated reprocessing unit identification (e.g. make, model, serial number, etc.)	Ensure each HLD cycle is monitored by trained staff who document the process including: • identification of the devices being reprocessed • date • contact time with the chemical high level disinfectant • temperature (if applicable) • identification of person responsible for ensuring all requirements for reprocessing and releasing the devices are met When automated reprocessing equipment is used, documentation also includes: • automated reprocessing unit identification (e.g. make, model, serial number, etc.) AH[2], Clause: 6.6 CAN/CSA Z314.0-13, Clause:4.2.3.2(i) CAN/CSA Z314.8-08, Clause: 10.8.5.6	▼	• Area Management
C 4.16	The endoscope or endocavity probe can be traced back to the patient.	Ensure each endoscope or endocavity probe can be traced back to the patient. This may be achieved by having documentation of the identification number(s) of the device(s) used along with date of procedure(s), recorded on the patient's record or in a log entry. AH[2], Clause: 8.4.3	▼	• Area Management
C 4.17	If manual high level disinfection (HLD) is performed, the container is kept covered during use.	Ensure containers with chemical disinfectant are covered at all times including during use. CAN/CSA Z314.8-08, Clause: 10.8.3.7	▼	• Area Management
C 4.18	If manual high level disinfection (HLD) is performed, submersible components of devices are completely submerged and all internal channels/lumens are in contact with the disinfectant for the recommended contact time. Non-submersible components are cleaned and disinfected according to device manufacturer's written instructions.	Ensure that, during manual HLD is performed, submersible components of devices are completely submerged and all internal channels/lumens are in contact with the disinfectant for the recommended contact time. Ensure that non-submersible components are cleaned and disinfected according to device manufacturer's written instructions. HC[17], Clause 3.4(f) p.62 CAN/CSA Z314.8-08, Clause: 10.8.5.2	▼	• Area Management
C 4.19	Rinsing of medical devices following high level disinfection (HLD) is done with three (3) separate rinses, using sterile or submicron filtered water. Fresh rinse solution is used for each of the three (3) rinses.	Ensure rinsing of medical devices following HLD is done with three (3) separate rinses, using sterile or submicron filtered water. Fresh rinse solution is used for each of the three (3) rinses. CAN/CSA Z314.8-08, Clause: 10.8.5.4.1; 10.8.5.4.2	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **4.0 Chemical High Level Disinfection (HLD)**				
C 4.20	During rinsing, submersible components of devices are fully immersed and all lumens or channels are flushed during each rinse. Non-submersible components are rinsed according to device manufacturer's written instructions.	Ensure that submersible components of devices are fully immersed and all lumens or channels are flushed during each rinse. Ensure that Non-submersible components are rinsed according to device manufacturer's written instructions. CAN/CSA Z314.8-08, Clause: 10.8.5.4 HC[17], Clause: 3.4(k)	▼	• Area Management
C 4.21	Following rinsing, devices are dried using a clean, soft, lint free cloth.	Ensure devices are dried using a clean, soft, lint free cloth following rinsing. CAN/CSA Z314.8-08, Clause: 10.9	▼	• Area Management
C 4.22	For chemical high level disinfection (HLD), there is a process in place that clearly identifies a non-reprocessed device from one that has been reprocessed.	For chemical HLD, ensure there is a process in place that clearly identifies a non-reprocessed device from one that has been reprocessed to prevent the use of a non-reprocessed device on a patient AH[2] 8.4.1, CAN/CSA Z314.3-0912.6.3.4.1, CSA Z314.0-13 F9(2)	●	• Area Management
C 4.23	Following high level disinfection (HLD), dried devices are stored in a clean, dry, protected area until use.	Ensure that devices are dried and stored in a clean, dry, protected area following HLD. CAN/CSA Z314.8-08, Clause: 10.7.3; 10.9; 13.4.10	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **5.0 Assembly and Packaging**				
C 5.1	Staff adhere to dress code that includes: • wearing of clean attire • wearing a clean hair-cover • having clean, unpolished nails • wearing no artificial nails • wearing no loose, bulky or dangling jewelry • wearing clean, sturdy footwear	Ensure staff adhere to dress code that includes: • wearing of clean attire • wearing a clean hair-cover • having clean, unpolished nails • wearing no artificial nails • wearing no loose, bulky or dangling jewelry • wearing clean, sturdy footwear AC[1], Clause: 5.7 CAN/CSA Z314.0-13, Clause: 4.7.5 (a), 6.7.1.1 CAN/CSA Z314.8-08, Clause: 6.7.1.1 AORN. Recommended practices for hand hygiene in the perioperative setting, Clause: 1b ORNAC, Section 2: Infection prevention and control, Clause: 5.3.10	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **5.0 Assembly and Packaging**				
C 5.2	Critical devices are packaged according to the device manufacturer's written instructions.	Ensure devices are packaged according to the device manufacturer's written instructions. AC[1], Clause:8.11, CAN/CSA Z314.0-13, Clause :4.12(g) CAN/CSA Z314.3-09, Clause: 9.1.1	▼	• Area Management
C 5.3	Packaging is validated for the sterilization method, permits aseptic presentation and provides a barrier to contamination.	Ensure that packaging: • is validated for the sterilization method • permits aseptic presentation • provides a barrier to contamination AC[1], Clause:8.11, CAN/CSA Z310.1-10, Clause 10 CAN/CSA Z314.3-09, Clause: 9.1.4	▼	• Area Management
C 5.4	When woven or non-woven textiles are used as packaging materials, a square or envelope wrapping technique that covers the contents is used.	Ensure when woven or non-woven textiles are used as packaging materials, a square or envelope wrapping technique is used. Contents are entirely contained within the wrapper. CAN/CSA Z310.1-10, Clause 10.2.2.1 CAN/CSA Z314.3-09, Clause: 9.2	▼	• Area Management
C 5.5	Single use wrappers or packaging are not reused.	Ensure single use wrappers or packaging are not reused. CAN/CSA Z314.3-09, Clause: 9.2.3	●	• Area Management
C 5.6	Packages are closed with methods that have been validated by the manufacturer for use in sterilization.	Ensure packages are closed with methods that have been validated by the manufacturer for use in sterilization. CAN/CSA Z314.3-09, Clause: 9.5.2	▼	• Area Management
C 5.7	Banding material, if used, is validated for the sterilization method.	Ensure banding material is validated for the sterilization method. CAN/CSA Z314.3-09, Clause: 9.5.6.2.2	▼	• Area Management
C 5.8	Sterilization pouches are used for small, light weight items (e.g. one or two clamps)	Ensure sterilization pouches are used for small, light weight items (e.g. one or two clamps). CAN/CSA Z314.3-09, Clause: 9.5.2	▼	• Area Management
C 5.9	Sterilization pouches are sized to adequately contain the device (i.e. the device does not touch the pouch seams)	Ensure sterilization pouches are sized to adequately contain the device (i.e. the device does not touch the pouch seams). CAN/CSA Z314.3-09, Clause: 9.5.2	▼	• Area Management
C 5.10	If sterilization pouches are double pouched, the smaller pouch fits inside larger pouch without folding or touching outer pouch seams and paper surfaces are touching	Ensure that when sterilization pouches are double pouched, the smaller pouch fits inside larger pouch without folding or touching outer pouch seams and that paper surfaces are touching. CAN/CSA Z314.3-09, Clause: 9.5.2	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **5.0 Assembly and Packaging**				
C 5.11	Sterilization pouches have seals that are smooth and airtight (e.g. without folds, bubbles or wrinkles).	Ensure sterilization pouches have seals that are smooth and airtight (e.g. without folds, bubbles or wrinkles). CAN/CSA Z314.3-09, Clause: 9.5.2	▼	• Area Management
C 5.12	If sterilization pouches are heat sealed, they have one seal with a minimum width of 3mm or two rows of seals.	Ensure sterilization pouches that are heat sealed have one seal with a minimum width of 3mm or two rows of seals. CAN/CSA Z314.3-09, Clause: 9.5.2	▼	• Area Management
C 5.13	If sterilization pouches are labeled in writing, only a permanent, soft-tipped marker validated for this purpose is used and writing is on the plastic (not paper) side of the pouch.	Ensure that when labeling in writing on sterilization pouches, only a permanent, soft-tipped marker validated for this purpose is used and writing is on the plastic (not paper) side of the pouch. Rationale: Writing with pen will perforate the package. Ink used in non-validated marking pens can be toxic and can leach through the packaging and damage devices. CAN/CSA Z314.3-09, Clause: 9.5.7.1.2	▼	• Area Management
C 5.14	A chemical indicator is placed inside each package in the area where penetration of sterilant is of greatest concern.	Ensure a chemical indicator is included on the inside of each wrapped package in the location where penetration of sterilant is of greatest concern. CAN/CSA Z314.3-09, Clause: 9.5.5	▼	• Area Management
C 5.15	The exterior of each package has a chemical process indicator.	Ensure that a chemical process indicator (e.g. marking or tape) is used on the outside of each pack. CAN/CSA Z314.3-09, Clause: 9.5.5.1	▼	• Area Management
C 5.16	Rigid sterilization containers are assembled and checked to ensure: • placement of filter(s) • gaskets are intact and free of debris • properly latching lid • placement of tamper evident devices • load and contents labels are in place	Ensure rigid sterilization containers are assembled and checked to ensure: • placement of filter(s) • gaskets are intact and free of debris • properly latching lid • placement of tamper evident devices • load and contents labels are in place CAN/CSA Z314.3-09, Clause: 9.5.6.3	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **6.0 Sterilization**				
General Sterilization				
C 6.1	All devices are cleaned prior to sterilization.	Ensure that all devices are cleaned and dried prior to sterilization. This is done even if the device does not appear soiled or was in a package that was opened but the device was not used. CAN/CSA Z314.3-09, Clause: 8.2.2.1 CAN/CSA Z314.8-08, Clause: 10.4.1	●	• Area Management
C 6.2	Critical devices are sterilized by an approved sterilization process.	Ensure critical devices are sterilized by an approved sterilization process. Unacceptable methods include using: • boiling • glass bead sterilizers • microwaves • ultraviolet light AH[2], Clause: 9.1.1; 9.7	●	• Area Management
C 6.3	Endoscopes and accessories that pass through normally sterile tissues are cleaned and sterilized before each use.	Ensure endoscopes and accessories that pass through normally sterile tissues are subjected to cleaning and sterilization before each use. Examples of endoscopes that pass through sterile tissues are arthroscopes, cystoscopes, and laparoscopes. CAN/CSA Z314.8-08, Clause: 13.1.2	●	• Area Management
C 6.4	Sterilizer loading and operation instructions are available and followed by the staff.	Ensure sterilizer loading and operation instructions are available and followed by the staff. CAN/CSA Z314.3-09, Clause: 10.1.1	▼	• Area Management
C 6.5	Following each sterilization cycle the individual responsible for releasing the load: • Checks external chemical indicators and • Checks and signs off on mechanical indicators	Ensure that staff unloading sterilizer review mechanical and chemical indicators and sign off if all indicators pass. CAN/CSA Z314.3-09, Clause: 10.3.1	▼	• Area Management
C 6.6	Biological and chemical indicators are not used past their expiry date.	Ensure that all biological and chemical indicators are discarded when their expiry date is reached. CAN/CSA Z314.3-09, Clause: 12.6.4	▼	• Area Management
C 6.7	For sterilized devices, there is a process in place that clearly identifies a non-reprocessed package from one that has been sterilized.	For sterilized devices, ensure there is a process in place that clearly identifies a non-reprocessed instrument from one that has been reprocessed to prevent the use of a non-sterile item on a patient. AC[1], Clause: 11.2 AH[2] 8.4.1 CAN/CSA Z314.3-0912.6.3.4.1,	●	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **6.0 Sterilization**				
C 6.8	Biological indicators (BIs) are used for every load containing implantable items and packages containing implantable devices are not released until biological indicator (BI) results are negative.	Ensure BIs are used for every load containing implantable items and packages with implantable devices are quarantined until BI results are confirmed negative. CAN/CSA Z314.3-09, Clause: 12.6.4.2	▼	• Area Management
C 6.9	If the mechanical, biological or chemical indicators suggest inadequate processing the item(s) are not used.	Ensure items in a sterilization load are not used if the mechanical, biological or chemical indicators suggest inadequate processing. CAN/CSA Z314.3-09, Clause: 12.9.4; 12.9.5; 12.10	●	• Area Management
C 6.10	Packs or containers are clearly labeled indicating: • identification of package contents (e.g. package code and name) • identity of person assembling the package • sterilizer number • load number • sterilization date • "Product is not sterile if packaging is open, damaged or wet. Check before using" or equivalent wording.	Ensure packs or containers are clearly labeled indicating: • identification of package contents (e.g. package code and name) • identity of person assembling the package • sterilizer number • load number • sterilization date • "Product is not sterile if packaging is open, damaged or wet. Check before using" or equivalent wording. CAN/CSA Z314.3-09, Clause: 9.5.7.2	▼	• Area Management
C 6.11	During unloading, each package is inspected. Inspection includes checking external chemical indicators and ensuring dryness.	Ensure each package is inspected during unloading to verify that the external chemical process indicator is acceptable and that the packages are dry. CAN/CSA Z314.3-09, Clause: 10.3.7; 10.3.5	▼	• Area Management
C 6.12	Packages are removed from the sterilizer when dry and allowed to cool in a low traffic area prior to handling. Cooling time is monitored.	Ensure packages are removed from the sterilizer when dry and allowed to cool in a low traffic area prior to handling. Ensure cooling time is monitored; a minimum of 30 minutes is recommended. CAN/CSA Z314.3-09, Clause: 10.3	▼	• Area Management
Steris System 1®**: In addition to items C 4.1 – C 4.7 above**, **the following requirements must be met:**				
C 6.13	Endoscopes and reusable accessories are connected with the correct tray and attachment tubing and arranged in the Steris System 1® as per manufacturer's written instructions.	Ensure endoscopes and reusable accessories are connected with the correct tray and attachment tubing and arranged in the Steris System 1® tray as per the sterilizer manufacturer's written instructions. AH[2], Clause: 9.2 CAN/CSA Z314.8-08, Clause: 4.4	●	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **6.0 Sterilization**				
C 6.14	Critical devices processed in Steris System 1® are used immediately following processing and are not stored.	Ensure critical devices processed in Steris System 1® are used immediately following processing and are not stored. **Note:** Using Steris System 1® to sterilize critical items is equivalent to sterilization of unwrapped critical devices. CAN/CSA Z314.3-09, Clause: 13.8	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **7.0 Sterilization of Unwrapped Devices (Batch sterilization of semicritical medical devices)**				
C 7.1	Devices are cleaned before the unwrapped sterilization cycle.	Ensure all devices are cleaned before the unwrapped sterilization cycle. This must be done even if the device does not appear soiled or if the device is being reprocessed even if it was not used. CAN/CSA Z314.3-09, Clause: 8.2.2.1 CAN/CSA Z314.8-08, Clause: 10.4.1; 10.7.1	●	• Area Management
C 7.2	For unwrapped devices, sterilizer loading and operation instructions are available and followed by the staff.	Ensure sterilizer loading and operation instructions are available and followed by the staff for sterilization of all unwrapped devices. CAN/CSA Z314.3-09, Clause: 10.1.1	▼	• Area Management
C 7.3	Each sterilization cycle of unwrapped devices is monitored with mechanical and chemical indicators.	Ensure each sterilization cycle of unwrapped devices is monitored with mechanical and chemical indicators. CAN/CSA Z314.3-09, Clause: 12	▼	• Area Management
C 7.4	Following each sterilization cycle the individual responsible for releasing the load: • Checks chemical indicators and • Checks and signs off on mechanical indicators	Ensure that staff unloading sterilizer with unwrapped devices review mechanical and chemical indicators and sign off if all indicators pass. CAN/CSA Z314.3-09, Clause: 12	▼	• Area Management
C 7.5	If the mechanical or chemical indicators suggest inadequate processing, the items are not used.	Ensure that items are not used if the mechanical or chemical indicators suggest inadequate processing. CAN/CSA Z314.3-09, Clause: 12.9.4; 12.9.5; 12.10	●	• Area Management
C 7.6	Devices that are sterilized unwrapped are allowed to dry in the sterilizer and are left to cool before they are used.	Ensure devices are allowed to dry in the sterilizer and are left to cool before they are used. CAN/CSA Z314.3-09, Clause: 10.3	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **7.0 Sterilization of Unwrapped Devices (Batch sterilization of semicritical medical devices)**				
C 7.7	Critical devices that are sterilized unwrapped are used immediately and are not stored.	Ensure critical devices that are sterilized unwrapped are used immediately and are not stored. CAN/CSA Z314.3-09, Clause: 13.8	▼	• Area Management
C 7.8	For devices that are sterilized unwrapped, there is a process in place that clearly identifies a non-reprocessed device from one that has been reprocessed.	For devices that are sterilized unwrapped, ensure there is a process in place that clearly identifies a non-reprocessed device from one that has been reprocessed to prevent the use of a non-reprocessed item on a patient. AH[2] 8.4.1, CAN/CSA Z314.3-0912.6.3.4.1, CSA Z314.0-13 F9(2)	●	• Area Management
C 7.9	Semicritical devices (e.g. speculum) that are sterilized unwrapped are stored in a clean, dry, protected area until use.	Ensure semicritical devices (e.g. speculum) that are sterilized unwrapped are stored in a clean, dry, protected area until use. Storage in an exam-table drawer is not acceptable, as this is not a protected area. CAN/CSA Z314.15-10, Clause: 9.1.2	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **8.0 Flash Sterilization**				
C 8.1	All devices are cleaned prior to flash sterilization.	Ensure that items are cleaned and dried prior to flash sterilization. This is done even if the device does not appear soiled or was in a package that was opened but the device was not used. CAN/CSA Z314.3-09, Clause: 8.2.2.1	●	• Area Management
C 8.2	Flash sterilizer loading and operation instructions are available and followed by the staff.	Ensure flash sterilizer loading and operation instructions are available and followed by the staff. CAN/CSA Z314.3-09, Clause: 10.1.1	▼	• Area Management
C 8.3	Each flash sterilization cycle of is monitored with mechanical and chemical indicators.	Ensure each flash sterilization cycle is monitored with mechanical and chemical indicators. CAN/CSA Z314.3-09, Clause: 12	▼	• Area Management
C 8.4	Following each sterilization cycle the individual responsible for releasing the load: • Checks chemical indicators and • Checks and signs off on mechanical indicators	Ensure that staff unloading flash sterilizer review mechanical and chemical indicators and sign off if all indicators pass. CAN/CSA Z314.3-09, Clause: 12	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **8.0 Flash Sterilization**				
C 8.5	Flash sterilization is only used in emergency situations.	Ensure that flash sterilization is only used in emergency situations. Flash sterilization should not be used for routinely scheduled procedures or to compensate for lack of inventory. AH[2], Clause: 9.6 CAN/CSA Z314.3-09, Clause: 13.1.2; 13.1.3; 13.1.5	◆	• Area Management
C 8.6	Complete sets are not flash sterilized.	Ensure that complete sets are never flash sterilized. CAN/CSA Z314.3-09 ; 13.1.3	◆	• Area Management
C 8.7	Flash sterilization is never used for implantable equipment or devices.	Ensure implantable devices never undergo flash sterilization. CAN/CSA Z314.3-09 13.1.2	▼	• Area Management
C 8.8	Containers designed for flash sterilization are used and maintained according to manufacturer's written instructions.	Ensure containers designed for flash sterilization are used and maintained according to manufacturer's written instructions. CAN/CSA Z314.3-09, Clause: 13.1.6	▼	• Area Management
C 8.9	Documentation is completed for each flash sterilization cycle.	Ensure documentation is completed for each flash sterilization cycle and includes the following information: • sterilizer number • load number • date and time of cycle • results of chemical indicators • sterilizer mechanical indicators (e.g. time, temp, etc.) • load contents • identification of person responsible for verifying indicators and load release • patient name and ID number • surgeon's name • reason for flash sterilization **Note:** Mechanical indicators may be recorded in a log, printout, database or recording chart. CAN/CSA Z314.3-09, Clause: 13.1.7; 13.1.8	▼	• Area Management
C 8.10	Sterility of critical devices that are flash sterilized is maintained during removal from the sterilizer and transport to the point of use. Devices are used immediately and not stored.	Ensure sterility of critical devices that are flash sterilized is maintained during removal from the sterilizer and transport to the point of use. Devices are used immediately and not stored. CAN/CSA Z314.3-09, Clause: 13.1.4	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **9.0 Storage and Transport of Devices**				
C 9.1	There is a process for inventory management of sterile devices.	Ensure there is a process for inventory management of sterile devices. Examples include: • sterilization date • adequate spacing of packages • easy visibility and retrieval • visual inspection using "first in/first out" principle when stocking CAN/CSA Z314.3-09, Clause: 11.3.2	▼	• Area Management
C 9.2	The sterile storage area is dedicated to storage of clean and sterile supplies.	Ensure the sterile storage area is dedicated to storage of clean and sterile supplies. AH[2], Clause: 10.2 CAN/CSA Z314.15-10, Clause: 8.1	◆	• Area Management
C 9.3	Sterile storage areas are protected from dust, insects and vermin.	Ensure sterile storage areas are well-ventilated and protected from dust, insects and vermin. AH[2] , Clause: 10.2 CAN/CSA Z314.15-10, Clause: 7.1.1	▼	• Area Management
C 9.4	Sterile storage areas are monitored daily and documented for temperature and humidity extremes.	Ensure sterile storage areas are monitored daily and documented for temperature and humidity extremes. Temperature (18 – 23°C) and humidity (30 – 60%) should be measured and recorded daily. CAN/CSA Z314.3-09, Clause: 7.2.2 CAN/CSA Z314.15-10, Clause 6.2	▼	• Area Management
C 9.5	Shelving material is non-shedding with smooth surfaces and easily cleanable.	Ensure shelving material is non-shedding with smooth surfaces and is easily cleanable. CAN/CSA Z314.15-10, Clause: 8.3.1	▼	• Area Management
C 9.6	For open storage the bottom shelf is solid.	Ensure open storage units have a solid bottom shelf. CAN/CSA Z314.15-10, Clause: 8.3.3	▼	• Area Management
C 9.7	Sterile storage areas have doors that are closed and access is restricted to authorized personnel.	Ensure sterile storage areas doors are closed and access is restricted to authorized personnel. CAN/CSA Z314.15-10, Clause: 8.6.2	▼	• Area Management
C 9.8	Signage is posted indicating the sterile storage area is a restricted area.	Ensure signage is posted indicating the sterile storage area is a restricted area. CAN/CSA Z314.15-10, Clause: 8.6.2	▼	• Area Management
C 9.9	Case carts are cleaned and dried between each use and are in good repair.	Ensure case carts are cleaned and dried between each use and are in good repair. CAN/CSA Z314.8-08, Clause: 9.3.3 CAN/CSA Z314.3-09, Clause: 11.4.2 CAN/CSA Z314.15-10, Clause: 10.3	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section C: Reprocessing Medical Devices – Observational Tour **9.0 Storage and Transport of Devices**				
C 9.10	When a random package/set is inspected from the storage area, sterilized devices are visibly clean and identified as reprocessed.	Ensure appropriate corrective measures are implemented depending on the issue noted when a random package/set is inspected (e.g. cleanliness, dampness, perforation, no load control identifier, etc.). CAN/CSA Z314.15-10, Clause: 9.2.1	●	• Area Management
C 9.11	Clean and sterile devices are covered and transported separately (e.g. in separate carts or containers) from soiled devices or linens.	Ensure clean and sterile devices are covered and transported separately from soiled devices or linens. CAN/CSA Z314.8-08, Clause: 9.1.3; 9.3.1 CAN/CSA Z314.15-10, Clause: 10.4.1	▼	• Area Management
C 9.12	A container labeling system (e.g. colour coding or tagging) is in place to identify clean or contaminated contents of transport containers.	Ensure all transport containers have a labeling system (e.g. colour coding or tagging) to identify contents as clean or contaminated. CAN/CSA Z314.8-08, Clause: 9.3.2	◆	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Reference
Section C: Reprocessing Medical Devices – Observational Tour **10.0 Environmental Cleaning**				
C 10.1	Reprocessing equipment and environment appears clean and well maintained.	Ensure reprocessing equipment and environment is clean and well maintained. CAN/CSA Z314.8-08, Clause: 7.4.2; 7.5.7	◆	• Area Management
C 10.2	There is documentation that scheduled cleaning activities have been performed.	Ensure there is documentation that scheduled cleaning activities have been performed. CAN/CSA Z314.8-08, Clause: 7.4.2 CAN/CSA Z314.8-08, Clause: 7.4.1 Table 1 p. 23	▼	• Area Management
C 10.3	Vacuum cleaning equipment is equipped with HEPA filter.	Ensure the vacuum cleaning equipment is equipped with HEPA filter. CAN/CSA Z314.8-08, Clause: 7.4.3	▼	• Area Management
C 10.4	Cleaning equipment used in the decontamination area is not used in any other area.	Ensure cleaning equipment used in the decontamination area is not used in any other area. CAN/CSA Z314.8-08, Clause: 7.4.4	▼	• Area Management

Review Tool for Reprocessing Reusable Surgical Textiles

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section D – **Document Review** 1.0 Procedures**: There are written SOPs for reusable surgical textiles for:**				
D 1.1	There is a written policy or standard operating procedure (SOP) for reusable surgical textiles for evaluating, selecting and purchasing of reusable surgical textiles.	Develop, update or obtain a written policy/SOP for evaluating, selecting and purchasing of reusable surgical textiles that should include: • end user preference • anticipated usable lifespan • number of launderings • manufacturer's written instructions for laundering • manufacturer's validated instructions for sterilization CAN/CSA Z314.10.1-10, Clause: 4.2; 7.1	▼	• Area Management • AHS Laundry • AHS Contract Procurement and Supply Management
D 1.2	There is a written policy or standard operating procedure (SOP) for reusable surgical textiles for Inspection of newly purchased textiles for colour, finish, labels, markings and tags	Develop, update or obtain a written policy/SOP for inspection of newly purchased textiles for colour, finish, labels, markings and tags including inspection of the seam sealant on gortex gowns and drapes. CAN/CSA Z314.10.1-10, Clause: 7.1.9	▼	• Area Management • AHS Laundry
D 1.3	There is a written policy or standard operating procedure (SOP) for reusable surgical textiles for washing, conditioning and drying according to the manufacturer's written instructions.	Develop, update or obtain a written policy/SOP for laundering instructions for washing, conditioning and drying for each category of surgical textile. CAN/CSA Z314.10.2-10, Clause: 11.1	▼	• Area Management • AHS Laundry
D 1.4	There is a written policy or standard operating procedure (SOP) for reusable surgical textiles for tracking the number of times each surgical textile with barrier qualities is laundered.	Develop, update or obtain a written policy/SOP for tracking the number of times surgical textiles with barrier qualities are used. Tracking method (e.g. bar code, marking grid, or embedded chip) should record the age and number of uses. CAN/CSA Z314.10.1-10, Clause: 7.1.7	▼	• Area Management • AHS Laundry
D 1.5	There is a written policy or standard operating procedure (SOP) for reusable surgical textiles for inspection methods that follow manufacturer's written instructions.	Develop, update or obtain a written policy/SOP for inspection methods that follow manufacturer's written instructions. CAN/CSA Z314.10.1-10, Clause: 7.1.7 CAN/CSA Z314.10.2-10, Clause: 9.1.2	▼	• Area Management • AHS Laundry
D 1.6	There is a written policy or standard operating procedure (SOP) for reusable surgical textiles for visual inspection techniques using a light table or light bar.	Develop, update or obtain a written policy/SOP for visual inspection techniques using a light table or light bar. CAN/CSA Z314.10.2-10, Clause: 9.2.1	▼	• Area Management • AHS Laundry

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section D – **Document Review** 1.0 Procedures**: There are written SOPs for reusable surgical textiles for:**				
D 1.7	There is a written policy or standard operating procedure (SOP) for reusable surgical textiles for stain removal methods that follow manufacturer's written instructions.	Develop, update or obtain a written policy/SOP for stain removal methods that follow manufacturer's written instructions. This should include information on removing items from service if they have stains that cannot be removed, including but not limited to: • dark brown or rust colored stains that resemble blood. • tactile stains • raised residue (tape, plaster casting material, etc.) • scorched, burned or melted fabric CAN/CSA Z314.10.2-10, Clause: 9.2.2; Table 2, p.44; 9.1.2	▼	• Area Management • AHS Laundry
D 1.8	There is a written policy or standard operating procedure (SOP) for repairing damaged reusable surgical textiles including description of acceptable location, size and shape of patches.	Develop, update or obtain a written policy/SOP for repairing damaged textiles including description of acceptable location, size and shape of patches. CAN/CSA Z314.10.2-10, Clause: 9.2.3	▼	• Area Management • AHS Laundry
D 1.9	There is a written policy or standard operating procedure (SOP) for reusable surgical textiles for management of textiles that have failed the inspection process.	Develop, update or obtain a written policy/SOP for management of textiles that have failed the inspection process. CAN/CSA Z314.10.2-10, Clause: 9.1.2; 9.2.2.3	▼	• Area Management • AHS Laundry
D 1.10	There is a written policy or standard operating procedure (SOP) for reusable surgical textiles for performance qualification and documentation of results to verify that packs can be sterilized with the facility's equipment.	Develop, update or obtain a written policy/SOP for performance qualification of packs/sets that include reusable surgical textiles. This should include the requirement for documentation of testing of packs/sets within the facility's sterilizers to verify that packs/sets can be sterilized. This is achieved by placing biological and chemical indicators within packs/sets in location(s) presenting the greatest challenge to sterilization. Following sterilization, indicator results are reviewed to verify sterilization and documented prior to accepting the packs/sets for use. This is done for each pack/set currently in use and when introducing: • new bundles containing surgical textiles • new packaging or wrapping systems • extended cycles was recommended by the manufacturer CAN/CSA Z314.10.2-10, Clause: 7.1.2; 12.2.1.2 CAN/CSA Z314.3-09, Clause: 12.5.2	▼	• Area Management • AHS Laundry
D 1.11	There is a written policy or standard operating procedure (SOP) for reusable surgical textiles for packaging reusable surgical textiles for sterilization including correct placement of internal chemical indicators.	Develop, update or obtain a written policy/SOP for packaging of surgical textiles for sterilization including insertion of internal chemical indicators in the correct location. CAN/CSA Z314.3-09, Clause: 12.6.3.2.2	▼	• Area Management • AHS Laundry

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section D – **Document Review** 1.0 Procedures**: There are written SOPs for reusable surgical textiles for:**				
D 1.12	There is a written policy or standard operating procedure (SOP) for ensuring reusable surgical textiles are not ironed or pressed.	Develop, update or obtain a written policy/SOP for ensuring reusable surgical textiles are not ironed or pressed. CAN/CSA Z314.10.2-10, Clause: 11.3.4	▼	• Area Management • AHS Laundry
D 1.13	There is a written policy or standard operating procedure (SOP) for reusable surgical textiles with barrier properties for periodic testing of textile barrier integrity, as specified by the manufacturer's written instructions.	Develop, update or obtain a written policy/SOP for periodic testing of textile barrier integrity of textiles with barrier properties, as specified by the manufacturer's written instructions. CAN/CSA Z314.10.2-10, Clause: 9.1.2	▼	• Area Management • AHS Laundry

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section D **2.0 Single Use Medical Devices**				
D 2.1	There is a policy stating that single use surgical textiles (single use medical devices) are not to be reprocessed in the facility.	Develop, update or obtain a policy that single use surgical textiles (single use medical devices) are not to be reprocessed in the facility. AHS Single use Medical Devices PS-07 http://insite.albertahealthservices.ca/Files/clp-single-use-medical-devices-policy.pdf AC[1], Clause: 8.1 AH Standards Single Use Medical Devices.	▼	• Area Management • AHS Administration
D 2.2	Single use surgical textiles are not reprocessed.	Single use surgical textiles are not reprocessed. AHS Single use Medical Devices PS-07 http://insite.albertahealthservices.ca/Files/clp-single-use-medical-devices-policy.pdf AC[1], Clause: 8.1 AH Standards Single Use Medical Devices.	●	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section D – Observational Tour **3.0 General**				
D 3.1	The following activities for surgical textiles are performed in a separate, enclosed area that is dedicated to the activities: • inspection • repairing • handling • packaging	Ensure area for inspection, repairing, handling or packaging of clean surgical textiles is separate, enclosed and dedicated to this activity. CAN/CSA Z314.10.2-10, Clause: 7.1	◆	• Area Management
D 3.2	All walls, ceilings and work surfaces are intact and composed of non-porous, non-shedding material capable of withstanding frequent cleaning.	Ensure walls, ceilings and work surfaces are intact and composed of non-porous, non-shedding material capable of withstanding frequent cleaning. CAN/CSA Z314.10.2-10, Clause: 7.1.7; 7.1.8	◆	• Area Management
D 3.3	There are no exposed pipes or duct work.	Ensure there are no exposed pipes or duct work. CSA Z314.10.2-10;, Clause: 7.1.7	◆	• Area Management
D 3.4	Doors to all clean work areas are kept closed at all times.	Ensure doors to all clean work areas are kept closed at all times. CAN/CSA Z314.10.2-10, Clause: 7.1.6	▼	• Area Management
D 3.5	Signage is posted at all entry points indicating the area is restricted to authorized personnel only.	Ensure signage is posted at all entry points indicating the area is restricted to authorized personnel only. CAN/CSA Z314.10.2-10, Clause: 7.2.1	▼	• Area Management
D 3.6	There are dedicated hand hygiene stations at entrances/exits to the reprocessing area.	Ensure there are dedicated hand hygiene stations at entrances/exits to the reprocessing area. Hand hygiene stations include a sink with soap and an adjacent enclosed single-use towel dispenser or waterless alcohol-based hand rub dispenser. CAN/CSA Z314.10.2-10, Clause: 7.1.9; 7.2.2	▼	• Area Management
D 3.7	Personal protective equipment (PPE) is removed and hands are cleaned when moving between contaminated and clean areas or tasks.	Ensure PPE is removed and hands are cleaned when moving between contaminated and clean areas or tasks. CAN/CSA Z314.10.2-10, Clause: 6.5.4.1.6; 6.5.4.2.2	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
D 3.8	Personnel wear appropriate attire (e.g. hair-cover, clean attire, etc.) as per dress code when handling clean surgical textiles including: • inspecting • repairing • folding • packaging	Ensure personnel who inspect, repair, handle, fold and/or package clean surgical textiles wear appropriate attire including: • wearing of clean attire • wearing a clean hair-cover • having clean, unpolished nails • wearing no artificial nails • wearing no loose, bulky or dangling jewelry • wearing clean, sturdy footwear AC[1], Clause: 5.7 CAN/CSA Z314.8-08, Clause: 6.7.1.1 AORN, Clause: 1b ORNAC. Section 2: Infection prevention and control, Clause: 5.3.10	▼	• Area Management
D 3.9	Following laundering, textiles are handled in a manner that prevents contamination during transfer to the designated dryer.	Ensure textiles are handled in a manner that prevents contamination during transfer to the designated dryer. Clean textiles should not be dragged over the lip of the washer during removal. CAN/CSA Z314.10.2-10, Clause: 11.3.2; 13.2	▼	• Area Management
D 3.10	Traffic in the clean work area is restricted to authorized personnel.	Ensure traffic in the clean work area is restricted to authorized personnel. CAN/CSA Z314.10.2-10, Clause: 7.2	▼	• Area Management
D 3.11	Portable fans are not used in the reprocessing area.	Ensure there are no portable fans used in areas where clean surgical textiles are handled. CAN/CSA Z314.10.2-10, Clause: 7.3.3	▼	• Area Management
D 3.12	Reprocessing equipment and environment appears clean and well maintained.	Ensure reprocessing equipment and environment appears clean and well maintained. CAN/CSA Z314.10.2-10, Clause: 7.3; 7.5	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section D – Observational Tour **4.0 Textiles, Handling and Packaging**				
D 4.1	Wrappers have sufficient flexibility to maintain sealing, wrapping and unwrapping.	Ensure wrappers have sufficient flexibility to maintain sealing, wrapping and unwrapping. CAN/CSA Z314.10.1-10, Clause: 7.2.3	▼	• Area Management
D 4.2	Wrappers have sufficient strength to maintain the integrity and sterility of the package.	Ensure wrappers maintain the integrity and sterility of the package. CAN/CSA Z314.10.1-10, Clause: 10.2.1.4	▼	• Area Management
D 4.3	Wrappers are free of joining seams or cross stitching.	Ensure wrappers are free of joining seams or cross stitching. CAN/CSA Z314.10.1-10, Clause: 7.6.3	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section D – Observational Tour **4.0 Textiles, Handling and Packaging**				
D 4.4	Wrappers are coded to identify various types and sizes (e.g. colour or other marking).	Ensure wrappers are coded to identify various types and sizes (e.g. colour or other marking). CAN/CSA Z314.10.1-10, Clause: 7.6.4	▼	• Area Management
D 4.5	Surgical textiles are approved for the sterilization process according to the textile manufacturer's written instructions.	Ensure materials used for surgical textiles are approved for sterilization by the textile manufacturer. These textiles allow for sterilant penetration and exposure of the package contents to the sterilant. CAN/CSA Z314.10.1-10, Clause: 7.1.5; 7.1.6	▼	• Area Management
D 4.6	Textiles are finished (e.g. hemmed/salvaged), free of loose ends, loose threads and fraying.	Ensure textiles are hemmed, free of loose ends, loose threads and fraying. CAN/CSA Z314.10.1-10, Clause: 7.5.1.4	▼	• Area Management
D 4.7	Surgical gowns have a full overlap back with adequate closures.	Ensure surgical gowns have a full overlap back with adequate closures. CAN/CSA Z314.10.1-10, Clause: 7.5.2.1	▼	• Area Management
D 4.8	Surgical gowns are designed to facilitate the closed gloving technique.	Ensure cuff of gowns are snug, in good condition and sleeves are long enough to provide for full arm length coverage. CAN/CSA Z314.10.1-10, Clause: 7.5.2.1	▼	• Area Management
D 4.9	Surgical gowns have a front and sleeve that are either liquid resistant or liquid proof.	Ensure surgical gowns have a front and sleeve that are either liquid resistant or liquid proof. CAN/CSA Z314.10.1-10, Clause: 7.5.2.1; 7.5.2.2; Figure 1	▼	• Area Management
D 4.10	Gowns are folded so that the surgical team can easily put them on aseptically without touching the outer side with their bare hands.	Ensure gowns are folded so that the surgical team can easily put them on aseptically without touching the outer side with their bare hands. CAN/CSA Z314.10.2-10, Clause: 12.2.2; Annex C	▼	• Area Management
D 4.11	Huck towels are not used as wrappers or drapes.	Ensure huck towels are not used as wrappers or drapes. CAN/CSA Z314.10.1-10, Clause: 10.1.5	▼	• Area Management
D 4.12	Drapes are folded so that they can be easily identified, their initial orientation is clear and they can be aseptically applied.	Ensure drapes are folded so that they can be easily identified, their initial orientation is clear and they can be aseptically applied. CAN/CSA Z314.10.2-10, Clause: 12.2.3; 12.2.1.1	▼	• Area Management
D 4.13	Textiles are packaged according to the textile manufacturer's written instructions.	Ensure textiles are packaged according to the textile manufacturer's written instructions. CAN/CSA Z314.10.1-10, Clause: 9.1.3	▼	• Area Management
D 4.14	A chemical indicator is placed inside each package in the area where penetration of sterilant is of greatest concern.	Ensure a chemical indicator is included on the inside of each wrapped package in the location where penetration of sterilant is of greatest concern. CAN/CSA Z314.3-09, Clause: 9.5.5	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section D – Observational Tour **4.0 Textiles, Handling and Packaging**				
D 4.15	Packaging (e.g. wrapper) is validated for the sterilization method, permits aseptic presentation and provides a barrier to contamination.	Ensure packaging is validated for the sterilization method, permits aseptic presentation and provides a barrier to contamination. CAN/CSA Z314.10.1-10, Clause: 7.1.5; 7.1.6; 9.1.3	▼	• Area Management
D 4.16	Packages are closed with methods that have been validated by the manufacturer for use in sterilization. Banding material, if used, is validated for the sterilization method.	Ensure packages are closed with methods that have been validated by the manufacturer for use in sterilization. Pins, staples, string or rubber bands are not validated for sterilization. CAN/CSA Z314.10.1-10, Clause: 10.2.3.2; 10.2.3.5	▼	• Area Management
D 4.17	Bundle contents are arranged to allow effective sterilization, aseptic opening and items to be used in logical order.	Ensure bundle contents are arranged to allow effective sterilization, aseptic opening and items to be used in logical order. CAN/CSA Z314.10.2-10, Clause: 12.2; Annex C	▼	• Area Management
D 4.18	Bundles are wrapped using square or envelope wrapping technique that covers bundle contents.	Ensure bundles are wrapped using square or envelope wrapping technique. Bundle contents should be covered. CAN/CSA Z314.3-09, Clause: 9.1.1	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section D – Observational Tour **5.0 Inspection, Patching and Repairing**				
D 5.1	Each reusable surgical textile is visibly inspected on a light table or light bar before each use.	Ensure each reusable surgical textile is visibly inspected on a light table or light bar before each use. CAN/CSA Z314.10.2-10, Clause: 9.2.1.1	▼	• Area Management
D 5.2	Light tables or light bars are in good condition and provide strong light, with overhead light limited so that damage and defects can be seen.	Ensure light tables or light bars are in good condition and provide strong light, with overhead light limited so that damage and defects can be seen. CAN/CSA Z314.10.2-10, Clause: 9.2.1.3	▼	• Area Management
D 5.3	Periodic testing of textile barrier integrity (e.g. fluid repellency), as specified by the manufacturer, is performed and documented.	Ensure periodic testing of textile barrier integrity, as specified by the manufacturer, is performed and documented. CAN/CSA Z314.10.1-10, Clause: 9.1.2 CAN/CSA Z314.10.2-10, Clause: 9.1.3	▼	• Area Management
D 5.4	Barrier retreatment chemicals for textiles are applied as per the chemical's manufacturer's written instructions.	Ensure barrier retreatment chemicals for textiles are applied as per the chemical's manufacturer's written instructions. CAN/CSA Z314.10.2-10, Clause: 9.3.2	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section D – Observational Tour **5.0 Inspection, Patching and Repairing**				
D 5.5	Defective or damaged textiles are repaired, treated or removed from service.	Ensure defective or damaged textiles are repaired, treated or removed from service. CAN/CSA Z314.10.2-10, Clause: 9.1.2	▼	• Area Management
D 5.6	Heat sealers used for patch application are in good condition and used according to manufacturer's written instructions.	Ensure heat sealers used for patch application are in good condition and used according to manufacturer's written instructions. CAN/CSA Z314.10.2-10, Clause: 9.2.4.3	▼	• Area Management
D 5.7	Repairs of rips and tears of less than 2.5 cm (1 in) are made with round patches having a minimum diameter of 2.5 cm (1 in) and a maximum diameter of 5 cm (2 in) and are applied according to manufacturer's written instructions.	Ensure repairs of rips and tears of less than 2.5 cm (1 in) are made with round patches having a minimum diameter of 2.5 cm (1 in) and a maximum diameter of 5 cm (2 in). CAN/CSA Z314.10.2-10, Clause: 9.2.4.4	▼	• Area Management
D 5.8	Repairs of rips and tears greater than 2.5 cm are made with rectangular die-cut strips with rounded corners and are applied according to manufacturer's written instructions.	Ensure repairs of rips and tears greater than 2.5 cm are made with rectangular die-cut strips with rounded corners and are applied according to manufacturer's instructions. CAN/CSA Z314.10.2-10, Clause: 9.2.4	▼	• Area Management
D 5.9	Loose patches are removed and damaged areas re-patched according to the manufacturer's written instructions.	Ensure loose patches are removed and damaged areas re-patched according to the manufacturer's written instructions. CAN/CSA Z314.10.2-10, Clause: 9.2.4.5	▼	• Area Management
D 5.10	Patches are durable, heat sealable and made of fabric with the same performance characteristics as the textile being repaired.	Ensure patches are durable, heat sealable and made of fabric with the same performance characteristics as the textile being repaired. CAN/CSA Z314.10.2-10, Clause: 9.2.4.6	▼	• Area Management
D 5.11	Double ply textiles are patched on both sides.	Ensure double ply textiles are patched on both sides. CAN/CSA Z314.10.2-10, Clause: 9.2.4.8	▼	• Area Management
D 5.12	Single ply textiles are patched on one side.	Ensure single ply textiles are patched on one side. CAN/CSA Z314.10.2-10, Clause: 9.2.4.8	▼	• Area Management
D 5.13	For large holes, if a single sided patch shows through the hole, the other side is patched.	Ensure that if a single sided patch shows through large holes, the other side is patched. CAN/CSA Z314.10.2-10, Clause: 9.2.4.8	▼	• Area Management
D 5.14	Mending (stitching) of textiles is in non-critical zones only (e.g. gown ties).	Ensure mending (stitching) of textiles is in non-critical zones only (e.g. gown ties). Patches are not sewn onto the textile. CAN/CSA Z314.10.2-10, Clause: 9.2.5.2	▼	• Area Management

Review Tool for Reprocessing Flexible Endoscopes

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 1.0 Policies and Standard Operation Procedures (SOPs)**: There are documented policies or SOPs for:**				
Infection Prevention and Control (IPC)				
E 1.1	There is a documented policy or standard operating procedure (SOP) for hand hygiene.	Develop, update or obtain a written policy/SOP regarding hand hygiene practices. CAN/CSA Z314.8-08, Clause: 4.2; 6.6.3 AHS Hand Hygiene Policy PS-0: http://insite.albertahealthservices.ca/5154.asp AC[1], Clause: 5.5	▼	• Area Management • AHS Infection Prevention and Control
E 1.2	There is a documented policy or standard operating procedure (SOP) for personal protective equipment (PPE) for reprocessing of flexible endoscopes.	Develop, update or obtain a written policy/SOP indicating the requirement to wear PPE. SOP should include: • selection of PPE for each reprocessing area. For example, PPE in decontamination work area includes: o gloves appropriate to the task o a protective gown or garment o full face shield, or high-filtration, fluid-impervious face mask and protective eyewear • prescription eye glasses are not acceptable for eye protection • maintenance of reusable PPE (e.g. daily cleaning, changing of soiled garments, etc.) • performing hand hygiene before putting on and after taking off PPE AC[1], Clause: 5.8 AH[2], Clause: 13 CAN/CSA Z314.8-08, Clause: 6.6.1.3; 6.7.1.2; 6.7.2.6	▼	• Area Management • AHS Workplace Health and Safety
E 1.3	There is a documented policy or standard operating procedure (SOP) for Staff Hepatitis B immunization.	Develop, update or obtain a written policy/SOP that offers Hepatitis B immunization. AH[2], Clause: 13.1.7 CAN/CSA Z314.8-08, Clause: 6.5	▼	• Area Management • AHS Workplace Health and Safety
E 1.4	There is a documented policy or standard operating procedure (SOP) for environmental cleaning of the endoscopy reprocessing area.	Develop, update or obtain a written policy/SOP indicating frequency and documentation of environmental cleaning that includes: • cleaning of floors, horizontal work surfaces and counters at least daily • cleaning of walls, ceilings, vents, light fixtures at least every 6 months CAN/CSA Z314.8-08, Clause: 7.4	▼	• Area Management • AHS Environmental Services

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 1.0 Policies and Standard Operation Procedures (SOPs)**: There are documented policies or SOPs for:**				
E 1.5	There is a documented policy or standard operating procedure (SOP) for dress code for staff in the endoscopy reprocessing area.	Develop, update or obtain a written policy/SOP for dress code that includes: • wearing of clean attire • wearing a clean hair-cover • having clean, unpolished nails • wearing no artificial nails • wearing no loose, bulky or dangling jewelry • wearing clean, sturdy footwear AC[1], Clause: 5.7 CAN/CSA Z314.8-08, Clause: 6.7.1.1 AORN. Recommended practices for hand hygiene in the perioperative setting, Clause: 1b ORNAC. Section 2: Infection prevention and control, Clause: 5.3.10	▼	• Area Management
E 1.6	There is a documented policy or standard operating procedure (SOP) for prevention of staff exposure to blood and body fluids (e.g. splashes or sharps injuries).	Develop, update or obtain a written policy/SOP for the prevention of staff exposures to blood and body fluids (e.g. splashes or sharps injuries) that should include: • removing and disposing of single-use sharps at point of use • safe work practices such as never reaching blindly into instrument sets • handling glass or fragile objects with care AH[2], Clause: 13 CAN/CSA Z314.8-08, Clause: 4.3.2(b); 6.6.1.2; 6.6.1; 6.6.1.2 CAN/CSA Z314.3-09, Clause: 4.3.2	▼	• Area Management • AHS Workplace Health and Safety
E 1.7	There is a documented policy or standard operating procedure (SOP) for follow-up of staff exposure to blood and body fluids (e.g. splashes or sharps injuries).	Develop, update or obtain a written policy/SOP that describes procedures that are followed after staff exposures to blood and body fluids (e.g. splashes or sharps injuries) that should include: • immediate first aid • notification of supervisor • where to find instructions on follow-up AH[2], Clause: 13 CAN/CSA Z314.8-.8, Clause: 6.6.1.1	▼	• Area Management • AHS Workplace Health and Safety
E 1.8	There is a documented policy or standard operating procedure (SOP) for management of health status of staff to prevent contamination of devices and to protect workers.	Develop, update or obtain a written policy/SOP for the management of staff health status that should include management of: • nonintact skin and skin injuries • dermatitis • staff who are symptomatic for communicable disease AH[2], Clause: 13 CAN/CSA Z314.8-08, Clause: 6.6.1.5	▼	• Area Management • AHS Workplace Health and Safety

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 1.0 Policies and Standard Operation Procedures (SOPs)**: There are documented policies or SOPs for:**				
E 1.9	There is a documented policy or standard operating procedure (SOP) for waste management including disposal of contaminated sharps and biomedical wastes.	Develop, update or obtain a written policy/SOP for the management of sharps and biological wastes disposal that includes instructions on how staff disposes of sharps and biomedical wastes. AH[2], Clause: 13 CAN/CSA Z314.8-08, Clause: 6.6.2	▼	• Area Management • AHS Workplace Health and Safety • AHS Infection Prevention and Control • AHS Environmental Waste Management
E 1.10	There is a documented policy or standard operating procedure (SOP) for prohibiting activities such as eating, drinking, storage of food, smoking, application of cosmetics or handling of contact lenses in endoscopy reprocessing areas.	Develop, update or obtain a written policy/SOP that prohibits activities that put patients or staff in endoscopy reprocessing areas at Category of exposure to communicable diseases. These activities include, but are not limited to: • eating • drinking • storage of food • smoking • application of cosmetics • handling of contact lenses AH[2], Clause: 13 CAN/CSA Z314.8-.8, Clause: 6.6.1.8 AC1, Clause: 5.6	▼	• Area Management • AHS Infection Prevention and Control
General				
E 1.11	There is a documented policy or standard operating procedure (SOP) for reprocessing (cleaning and sterilization) of reusable critical medical devices.	Develop, update or obtain a written policy/SOP that reusable critical medical devices used for endoscopy must be cleaned and sterilized in accordance with manufacturer's written instructions prior to each use. Examples of critical devices (endoscopes and endoscopic accessories that penetrate sterile tissue) include, but are not limited to: • arthroscopes • cystoscopes • laparoscopes • reusable cytology brushes or biopsy devices AH[2], Clause 5.2; 6.0 CAN/CSA Z314.3-07, Clause: 8.2; 10.2 CAN/CSA Z314.8-08, Clause: 4.3.1; 4.4; 5.2.1; 5.2.2; 10.1.1; 10.2.2; 10.4.1; 10.4.3.1.1	▼	• Area Management • AHS Infection Prevention and Control
E 1.12	There is a documented policy or standard operating procedure (SOP) for reprocessing (cleaning and high level disinfection [HLD]) of reusable semicritical medical devices.	Develop, update or obtain a written policy/SOP stating that reusable semicritical medical devices used in endoscopy must be cleaned and at least high level disinfected in accordance to manufacturer's written instructions prior to each use. Examples of devices include endoscopes and accessories that contact mucous membranes. CAN/CSA Z314.8-08, Clause: 4.3; 4.4; 5.2.1; 5.3; 10.1.1; 10.4.2.1; 10.6.2; 10.6.3; 1; 13.1.1	▼	• Area Management • AHS Infection Prevention and Control

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 1.0 Policies and Standard Operation Procedures (SOPs)**: There are documented policies or SOPs for:**				
E 1.13	There is a documented policy or standard operating procedure (SOP) for record and document retention.	Develop, update or obtain a written policy/SOP that describes the organization's, region's or site's document retention process. AH[2], Clause: 14.7 CAN/CSA Z314.8-08, Clause: 4.6.1	▼	• Area Management • AHS Administration

E 1.14	There a documented policy or standard operating procedure (SOP) for evaluation and purchasing of reusable medical devices, reprocessing equipment and supplies/consumables to be used in endoscopy.	Develop, update or obtain a written policy that applies to evaluation and purchasing of reusable medical devices, reprocessing equipment and supplies/consumables that includes the requirement for:
		• manager/purchaser consults appropriate personnel prior to purchase. This includes, as applicable to the purchase:
		  • Medical device reprocessing
		  • Infection Prevention and Control
		  • Workplace Health and Safety
		  • End user department
		  • Patient Services
		  • Support Services (Environmental Services, Linen Services, etc.)
		  • Biomedical Engineering or Facilities Maintenance and Engineering
		
		• review of validated manufacturer's written instructions
		• ensuring compatibility of Automated Endoscopic Reprocessor (AER), high level disinfectant, detergent/enzymatic cleaner and endoscopes. For example:
		  o material compatibility
		  o availability of manifolds and connectors appropriate for model(s) of endoscopes in use
		
		Examples of medical devices and consumables include, but are not limited to:
		• endoscopes
		• reprocessing equipment (e.g. AERs, automated lumen cleaners, etc.)
		• high level disinfectants
		• detergents, enzymatic cleaners, etc.
		
		AH[2], Clause: 4; 5.2.2
		CAN/CSA Z314.8-08, Clause: 4.2; 4.4; 5.1; 5.2.1; 7.5.2
			▼	• Area Management
				• AHS Contract Procurement and Supply Management

E 1.15	There is a documented policy or standard operating procedure (SOP) for contingency plans for emergency situations for sterilizer shutdown.	Develop, update or obtain a written policy (contingency plan) for emergency situations for sterilizer shutdown (e.g. backup sterilization arrangement with another department, shut down of affected endoscopy procedures, etc.). CAN/CSA Z314.3-09, Clause: 4.2(i); 4.3.2 (h)	▼	• Area Management • AHS Administration • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 1.0 Policies and Standard Operation Procedures (SOPs)**: There are documented policies or SOPs for:**				
E 1.16	There is a documented policy or standard operating procedure (SOP) for contingency plans for emergency situations for automated equipment shutdowns.	Develop, update or obtain a policy/SOP (contingency plan) for shutdown of automated equipment (e.g. manual cleaning). Examples of automated equipment include automated endoscope reprocessors (AERs), ultrasonic cleaners, automated lumen cleaners, etc. CAN/CSA Z314.3-09, Clause: 4.2(i); 4.3.2 (h)	▼	• Area Management • AHS Administration • Facility Management
E 1.17	There is a documented policy or standard operating procedure (SOP) for contingency plans for emergency situations as a result of water or other utility interruptions.	Develop, update or obtain a written policy/SOP (contingency plan) for water or other utility interruptions. Examples of utility interruptions include heating, ventilation, air conditioning (HVAC) failure, boil water advisory, etc. AH^2, Clause: 3.4 CAN/CSA Z314.3-09, Clause: 4.2(i); 4.3.2 CAN/CSA Z314.8-08, Clause: 7.6.1	▼	• Area Management • AHS Administration • Facility Management
E 1.18	There is a documented policy or standard operating procedure (SOP) for handling and management of loaned, shared or leased (e.g. clinician or vendor supplied) critical and semicritical medical devices.	Develop, update or obtain a written policy/SOP for handling and management of loaned, shared or leased medical devices that includes: • receiving and following written manufacturer's reprocessing instructions • receiving devices in a timely manner to allow for reprocessing at the site prior to use AH^2, Clause: 14.2	▼	• Area Management • AHS Administration
E 1.19	There is a documented policy or standard operating procedure (SOP) for transporting contaminated items to the reprocessing area.	Develop, update or obtain a written policy/SOP for transporting contaminated items to the reprocessing area that includes: • point of use pre-cleaning • removal of disposable sharps at point of use • containing items in a protective, covered, leak-proof container • procedures to minimize contamination of environment and personnel • labeling or coding of containers to indicate contaminated contents AH^2, Clause: 11.0 CAN/CSA Z314.8-08, Clause: 13.4.1.1; 13.4.10.3	▼	• Area Management • AHS Administration
E 1.20	There is a documented policy or standard operating procedure (SOP) for shelf-life of semicritical flexible endoscopes.	Develop, update or obtain a written policy/SOP for shelf-life of semicritical flexible endoscopes (e.g. unused gastrointestinal endoscopes should be reprocessed after 7 days of storage). CAN/CSA Z314.8-08, Clause: 13.4.1.3; 13.4.10.3	▼	• Area Management
E 1.21	There is a documented policy or standard operating procedure (SOP) for inspection, identification and disposition of damaged/defective devices.	Develop, update or obtain a written policy/SOP for inspection, identification and disposal of damaged or defective devices that should include labeling, repair, disposal, etc. CAN/CSA Z314.8-08, Clause: 4.3.2(e); 10.11.4; 10.11.5; 10.11.7; 10.11.8	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 1.0 Policies and Standard Operation Procedures (SOPs)**: There are documented policies or SOPs for:**				
Personnel				
E 1.22	There is a documented policy or standard operating procedure (SOP) for specifying management and staff responsibilities specific to endoscope reprocessing.	Develop, update or obtain a written policy/SOP specifying management and staff responsibilities specific to endoscope reprocessing. AH[2], Clause: 14.1; 14.4 AC[3],Clause: 13.1 CAN/CSA Z314.8-08, Clause: 4.2(a)	▼	• Area Management
E 1.23	There is a documented policy or standard operating procedure (SOP) for specifying management and staff qualifications, education and training specific to endoscope reprocessing.	Develop, update or obtain a written policy/SOP that specifies management and staff qualifications, education and training specific to endoscope reprocessing. AH[2], Clause: 5.1; 5.2.4; 6.1; 12.0 AC[3],Clause: 13.1 CAN/CSA Z314.8-08, Clause: 4.2(b); 4.3.1; 4.5.10; 6.2.1; 6.2.2; 6.3.1; 6.3.3; 6.4	▼	• Area Management
Cleaning				
E 1.24	There is a documented policy or standard operating procedure (SOP) for cleaning of endoscopes, as per manufacturer's written instructions.	Develop, update or obtain a written policy/SOP for cleaning of endoscopes and accessories including: • point of use pre-cleaning • disassembly • leak testing • cleaning • rinsing • drying • inspection of devices for cleanliness and functionality (e.g. wear, damage and mechanical defect) AH[2], Clause: 8 CAN/CSA Z314.8-08, Clause: 13.4.1.1	▼	• Area Management
Sterilization				
E 1.25	There is a documented policy or standard operating procedure (SOP) for using Steris System 1®.	Develop, update or obtain a written policy/SOP for Steris System 1® for: • cleaning and rinsing of devices prior to sterilization • use of appropriate sterilant product that has a Health Canada Drug Identification Number (DIN) • manufacturer's written instructions • monitoring • documentation AH[2], Clause: 9.2	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 1.0 Policies and Standard Operation Procedures (SOPs)**: There are documented policies or SOPs for:**				
E 1.26	There is a documented policy or standard operating procedure (SOP) for positive biological indicator (BI) or failed sterilization cycle.	Develop, update or obtain a written policy/SOP for positive BI or failed sterilization load that should include: • the person responsible to notify the manager or designate • notification of IPC personnel or designate • the process to recall and isolate all endoscopes and accessories processed since the last negative BI AH[2], Clause: 9.3	▼	• Area Management
High Level Disinfection (HLD)				
E 1.27	There is a documented policy or standard operating procedure (SOP) for high level disinfection (HLD) of semicritical flexible endoscopes.	Develop, update or obtain a written policy/SOP for reprocessing of semicritical flexible endoscopes that includes: • point of use pre-cleaning, disassembly, manual cleaning and rinsing of endoscopes prior to disinfection • use of appropriate product with a Health Canada Drug Identification Number (DIN) • manufacturer's written instructions for disassembly, cleaning and disinfection • monitoring of disinfectant concentration (e.g. minimum effective concentration [MEC] testing) • documentation AH[2], Clause: 7 CAN/CSA Z314.8-08, Clause: 13.4.1.1	▼	• Area Management
Quality Monitoring				
E 1.28	There is a documented policy or standard operating procedure (SOP) for ensuring traceability of flexible endoscopes used on each patient.	Develop, update or obtain a written policy/SOP for traceability of flexible endoscopes used on each patient that should include the requirement for documentation of: • date endoscope was used • the patient's identification number • the serial number or other identifier of the endoscope(s) used in procedure(s) CAN/CSA Z314.8-08, Clause: 10.8; 13.9.1 (f); 13.9.3	▼	• Area Management
E 1.29	There is a documented policy or standard operating procedure (SOP) for routine monitoring of automated cleaning/disinfection equipment used in endoscope reprocessing.	Develop, update or obtain a written policy/SOP for monitoring of automated cleaning/disinfection equipment used in endoscope reprocessing that includes documentation of: • routine monitoring of AERs (e.g. verifying cycle time and temperature settings are appropriate to the load contents prior to starting, checking fluid levels at regular intervals [daily, every shift, etc.]) • testing of the equipment (e.g. testing ultrasonic cleaners at least weekly) CAN/CSA Z314.8-08, Clause: 4.4; 4.5; 7.5.5; 7.5.6; 10.1; 10.4.3.1.5; 10.4.3.6; 10.4.3.8; 10.4.4.8	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 1.0 Policies and Standard Operation Procedures (SOPs)**: There are documented policies or SOPs for:**				
E 1.30	There is a documented policy or standard operating procedure (SOP) for sterility assurance monitoring for Steris System 1®.	Develop, update or obtain a written policy/SOP for sterility assurance monitoring on the Steris System 1® that should include: • monitoring of each cycle with chemical indicators • testing the sterilizer with biological indicator (BI) each day the sterilizer is in use • monitoring of mechanical indicators printout • documentation AH[2], Clause: 9.3; 9.5	▼	• Area Management
E 1.31	There is a documented policy or standard operating procedure (SOP) for routine monitoring of reusable chemical high level disinfectant minimum effective concentration (MEC) at least daily.	Develop, update or obtain a written policy/SOP for routine monitoring of reusable chemical high level disinfectant that includes: • frequency (e.g. minimum each day the disinfectant is used) • method of testing MEC • documentation CAN/CSA Z314.8-08, Clause: 10.8.5.6; 13.4.1.1	▼	• Area Management
E 1.32	There is a documented policy or standard operating procedure (SOP) for routine maintenance of automated equipment used in endoscope reprocessing.	Develop, update or obtain a written policy/SOP for routine maintenance of automated equipment used in reprocessing (e.g. every shift, daily, weekly, monthly, etc.). Examples of routine maintenance includes: • cleaning or wiping external surfaces of automated equipment at regular intervals • routine bleach cycles of automated lumen cleaners CAN/CSA Z314.8-08, Clause: 5.2.3; 7.5.3 (e)	▼	• Area Management
E 1.33	There is a documented policy or standard operating procedure (SOP) for preventative maintenance (PM) of all automated equipment used in endoscope reprocessing.	Develop, update or obtain a written policy/SOP for PM of all automated equipment used in reprocessing that includes information on: • frequency of PM • responsible person • documentation of PM CAN/CSA Z314.8-08, Clause: 4.4; 7.5.3 (e)	▼	• Area Management • Facility Management
E 1.34	There is a documented policy or standard operating procedure (SOP) for receiving, investigating and follow-up of customer concerns related to endoscope reprocessing.	Develop, update or obtain a written policy/SOP describing how users contact the endoscope reprocessing department with concerns, and how concerns are addressed and documented. CAN/CSA Z314.3-09, Clause: 4.3.2(a)	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 1.0 Policies and Standard Operation Procedures (SOPs)**: There are documented policies or SOPs for:**				
E 1.35	There is a documented policy or standard operating procedure (SOP) for periodic testing of water used for reprocessing of flexible endoscopes.	Develop, update or obtain a written policy/SOP for periodic testing, reporting and follow-up of the water supply to the endoscopy areas. Testing of potable (tap) water includes: • hardness • pH • iron content, etc. If treated water is used (e.g. reverse osmosis [RO] or de-ionized [DI]) manufacturer's written instructions for testing are followed. AH[2], Clause: 3.3.8 CAN/CSA Z314.8-08, Clause: 7.6.1; 7.6.2	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 2.0 Manufacturer's written instructions**: Manufacturer's written instructions are available for:**				
General				
E 2.1	Manufacturer's written instructions are available for reprocessing of each endoscope type and model and accessories (including connection tubing kits) being reprocessed in the area.	Obtain and file (electronically or on paper) manufacturer's written instructions for each endoscope and its accessories. This includes the tubing connector kits for attaching the endoscope to AERs or chemical sterilizers, if used in the area. Detailed, validated instructions for endoscopes should include information on: • point of use pre-cleaning • disassembly • leak testing • cleaning, including lumen cleaning • rinsing • disinfection (including connection to AER or chemical sterilizer, if applicable) • rinsing post disinfection • drying • storage AH[2], Clause: 9.2 CAN/CSA Z314.8-08. 13.4.1.1	▼	• Area Management
E 2.2	Manufacturer's written instructions are available for using detergents and enzymatic cleaners.	Obtain and file (electronically or on paper) manufacturer's written instructions for detergents and enzymatic cleaners. Instructions include information on: • concentration • mixing/dilution • rinsing • shelf-life CAN/CSA Z314.8-08, Clause: 5.2.1 (f); 5.2.3; 10.3.3; 10.4.2.4	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 2.0 Manufacturer's written instructions**: Manufacturer's written instructions are available for:**				
E 2.3	Manufacturer's written instructions are available for using high level disinfectants.	Obtain and file (electronically or on paper) manufacturer's written instructions for all high level disinfectants used. Instructions include: • mixing (if required) • expiry after opening/mixing • testing of minimum effective concentration (MEC) • contact time • temperature • rinsing • disposal • handling precautions, including personal protective equipment (PPE) (and ventilation if required) CAN/CSA Z314.8-08, Clause: 10.8	▼	• Area Management
E 2.4	Manufacturer's written instructions are available for biological indicators (BIs).	Obtain and file (electronically or on paper) manufacturer's written instructions for all BIs. CAN/CSA Z14161-06. DA.4., Clause: 12.2.3.1	▼	• Area Management
E 2.5	Manufacturer's written instructions are available for chemical indicators.	Obtain and file (electronically or on paper) manufacturer's written instructions for all chemical indicators. AH[2], Clause: 9.2	▼	• Area Management
Installation, maintenance and operating instructions for all reprocessing equipment, including:				
E 2.6	Manufacturer's written instructions are available for sterilizers.	Obtain and file (electronically or on paper) manufacturer's written instructions for each sterilizer. Instructions include information on installation, operation and maintenance. AH[2], Clause: 9.2 AC[1], Clause: 7.4	▼	• Area Management • Facility Management
E 2.7	Manufacturer's written instructions are available for biological indicator (BI) monitoring equipment.	Obtain and file (electronically or on paper) manufacturer's written instructions for each BI incubator and reader. Instructions include information on installation, operation and maintenance. AC[1], Clause: 7.4 AH[2], Clause: 9.2	▼	• Area Management • Facility Management
E 2.8	Manufacturer's written instructions are available for automated endoscope reprocessors (AERs).	Obtain and file (electronically or on paper) manufacturer's written instructions for each AER. Instructions include information on installation, operation and maintenance. AH[2], Clause: 9.2 CAN/CSA Z314.8-08, Clause: 5.2; 7.5	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 2.0 Manufacturer's written instructions**: Manufacturer's written instructions are available for:**				
E 2.9	Manufacturer's written instructions are available for ultrasonic cleaners.	Obtain and file (electronically or on paper) manufacturer's written instructions for each ultrasonic cleaner. Instructions include information on installation, operation and maintenance. CAN/CSA Z314.8-08, Clause: 5.2; 7.5; 10.4.4.1	▼	• Area Management • Facility Management
E 2.10	Manufacturer's written instructions are available for automated lumen cleaners.	Obtain and file (electronically or on paper) manufacturer's written instructions for each automated lumen cleaner. Instructions include information on installation, operation and maintenance. CAN/CSA Z314.8-08, Clause: 5.2; 7.5	▼	• Area Management • Facility Management
E 2.11	Manufacturer's written instructions are available for fume hoods.	Obtain and file (electronically or on paper) manufacturer's written instructions for each fume hood. Instructions include information on installation, operation and maintenance. CAN/CSA Z314.8-08, Clause: 5.2; 7.5.5	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
E 3.1	Sterilization and high level disinfection (HLD) practices are monitored on a regular basis and a method of follow-up is in place to remedy non-compliance.	Ensure that sterilization and HLD practices are monitored on a regular basis and a method of follow-up is in place to remedy non-compliance. Monitoring is documented. Examples of monitoring methods include manager's or designate's signature/initials indicating: • routine review of logs, printouts etc. • supervision of practice AC[3],Clause: 13.1 CAN/CSA Z314.3-09, Clause: 12.1.1 CAN/CSA Z314.8-08, Clause: 10.8	▼	• Area Management
E 3.2	For traceability of endoscope to patient, documentation is maintained indicating: • date endoscope used on the patient • the patient identification • the serial number or other identifier of the endoscope(s) used in the procedure(s)	Ensure that documentation is maintained to ensure traceability of endoscope to patient. Documentation should include: • date endoscope used on the patient • the patient identification • the serial number or other identifier of the endoscope(s) used in the procedure(s) CAN/CSA Z314.8-08, Clause: 10.8; 13.9.1 (f); 13.9.3	▼	• Area Management
E 3.3	Record of all maintenance and interventions associated with a failed sterilization or high level disinfection (HLD) load or a positive biological indicator (BI).	Ensure there is documentation of all maintenance and interventions associated with a failed sterilization or HLD load or a positive BI. AH[2], Clause: 9 CAN/CSA Z314.3-09, Clause: 12.9; 12.10; 12.11	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
Cleaning				
E 3.4	Ultrasonic cleaning equipment is tested at least weekly to ensure functionality and results documented.	Ensure that weekly testing of ultrasonic cleaning equipment is performed and documented using test specified by manufacturer or foil test. CAN/CSA Z314.8-08, Clause: 7.5.7; 10.4.4.8	▼	• Area Management
Sterilization				
Operational qualification is done and documented as follows:				
E 3.5	Manufacturer's written instructions are followed for operational qualification following installation and major repairs or significant modifications to the sterilizer.	Ensure manufacturer's written instructions are followed for operational qualification of the Steris System 1®. Ensure operational qualification testing is done and documented following installation and major repairs or significant modifications to the sterilizer. AH[2], Clause: 9.5	▼	• Area Management
Routine monitoring is done and results documented. Routine monitoring requires that:				
E 3.6	Biological indicators (BIs) are appropriate for Steris System 1®.	Ensure that the BI used for the Steris System 1® is validated for use in that sterilizer, and information is documented. AH[2], Clause: 9.2	▼	• Area Management
E 3.7	Biological indicators (BIs) are tested each day the sterilizer is in use.	Ensure a BI is tested and results documented each day the sterilizer is in use. AH[2], Clause: 9.3.1	▼	• Area Management
E 3.8	At a minimum, a control biological indicator (BI) from each shipping lot is incubated to verify the viability of the test spores and results are documented.	Ensure that a control BI from each shipping lot is incubated to verify the viability of the test spores and results are documented. **Note:** Control BIs are not subjected to the sterilization process. CAN/CSA Z14161-06. Annex DA, Clause: DA.9 (p. CSA/12)	▼	• Area Management
E 3.9	Time and temperature are verified and results documented for all biological indicator (BI) incubation or reading equipment. Verification is performed according to manufacturer's written instructions.	Ensure that time and temperature are verified and results documented, for each BI incubator or reader used. Verification is performed as per manufacturer's instructions. CAN/CSA Z14161-06. Annex DA, Clause: DA.12 (p. CSA/14)	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
E 3.10	A record is kept of each sterilization cycle including: • sterilizer identifier • load number • date and time of cycle • mechanical indicators of physical parameters (time, temperature, etc.) • load contents (e.g. identification of endoscope) • identification of person responsible for load release	Ensure a record is kept of each sterilization cycle including: • sterilizer identifier • load number • date and time of cycle • mechanical indicators of physical parameters (e.g. time, temperature, etc.) • load contents (e.g. identification of endoscope) • identification of person responsible for load release Mechanical indicator may be recorded in a log, printout, database or recording chart. AH[2], Clause: 9.3.1	▼	• Area Management
Chemical High Level Disinfection (HLD)				
E 3.11	The chemical test strips used to check the minimum effective concentration (MEC) are specific to the type and concentration of the high level disinfectant.	Ensure the chemical test strips used to check the MEC are specific to the type and concentration of the high level disinfectant. This information is documented. CAN/CSA Z314.8-0, Clause: 10.8	▼	• Area Management
E 3.12	Minimum effective concentration (MEC) of reusable high level disinfectant is tested at least daily when in use and results documented.	Ensure that the MEC of reusable high level disinfectant is tested at least daily when in use and results documented. Documentation should include: • the MEC test strip • name and concentration of the disinfectant • date of test • testing results If a method of testing concentration other than test strips is used (e.g. concentration testing during an automated cycle), concentration is documented and verified. Method of testing is validated by the manufacturer. CAN/CSA Z314.8-08, Clause: 10.8	▼	• Area Management
E 3.13	Quality control testing of MEC test strips is performed according to manufacturer's written instructions each time a new bottle is opened to verify efficacy of test strips. Results are documented.	Ensure that quality control testing is performed on MEC test strips according to manufacturer's written instructions each time a new bottle is opened to verify efficacy. Results are documented. CAN/CSA Z314.8-08, Clause: 10.8.3.8	▼	• Area Management
E 3.14	There is documentation when high level disinfectant is changed.	Ensure there is documentation when high level disinfectant is changed. Documentation includes: • name of high level disinfectant • date • individual changing the disinfectant CAN/CSA Z314.8-08, Clause: 10.8	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
E 3.15	Each high level disinfection (HLD) cycle or process is monitored by trained staff who document the process including: • identification of the devices being reprocessed • date • contact time with the chemical high level disinfectant • temperature (if applicable) • identification of person responsible for ensuring all requirements for reprocessing and releasing the devices are met When an automated endoscope reprocessor (AER) is used, documentation also includes: • AER unit identification (e.g. make, model, serial number, etc.)	Ensure each HLD cycle or process is monitored by trained staff who document the process including: • identification of the devices being reprocessed • date • contact time with the chemical high level disinfectant • temperature (if applicable) • identification of person responsible for ensuring all requirements for reprocessing and releasing the devices are met When automated reprocessing equipment (e.g. AER) is used, documentation also includes: • automated reprocessing unit identification (e.g. make, model, serial number, etc.) CAN/CSA Z314.8-08, Clause: 10.8	▼	• Area Management
Environmental Cleaning				
E 3.16	Floors, horizontal working surfaces and counters are cleaned daily and documented.	Ensure environmental cleaning is documented, and that floors, horizontal working surfaces and counters are cleaned daily. CAN/CSA Z314.8-08; 7.4.1; 7.4.2	▼	• Area Management • AHS Environmental Services
E 3.17	Walls, ceilings, vents, light fixtures are cleaned at least every 6 months and documented.	Ensure environmental cleaning is documented, and that walls, ceilings, vents, light fixtures are cleaned at least every 6 months. CAN/CSA Z314.8-08; 7.4.1; 7.4.2	▼	• Area Management • AHS Environmental Services
Maintenance Records **There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for:**				
E 3.18	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all sterilizers.	Ensure all maintenance for each sterilizer is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.3 AH[2], Clause: 9.2; 9.5 AC[3],Clause: 13.14	▼	• Area Management • Facility Management
E 3.19	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all biological indicator (BI) monitoring equipment.	Ensure all maintenance for each BI incubator or reader is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[1], Clause: 7.3 AH[2], Clause: 9.2; 9.5 AC[3],Clause: 13.14	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review 3.0 Quality Monitoring**: Review documentation (e.g. records**, **logs**, **checklists**, **etc.) for the following processes:**				
E 3.20	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all automated endoscope reprocessors (AERs).	Ensure all maintenance for each AER is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. CAN/CSA Z314.8-08, Clause: 13.4.8; 13.9.3	▼	• Area Management • Facility Management
E 3.21	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all ultrasonic cleaners.	Ensure all maintenance for each ultrasonic cleaner is documented. This includes all routine maintenance, preventative maintenance and equipment repair and weekly testing of the ultrasonic cleaner (e.g. foil test). Frequency of routine and preventative maintenance follows manufacturer's written instructions. AC[3],Clause: 13.14 CAN/CSA Z314.8-08, Clause: 7.5.7; 10.4.3.1.2; 10.4.4.1	▼	• Area Management • Facility Management
E 3.22	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all automated lumen cleaners.	Ensure all maintenance for each automated lumen cleaner is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. CAN/CSA Z314.3-09.12.6.4; 12.10	▼	• Area Management • Facility Management
E 3.23	There are records of all maintenance (e.g. routine and preventative maintenance and equipment repair) for all fume hoods.	Ensure all maintenance for each fume hood is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions. CAN/CSA Z314.8-08, Clause: 13.4.5 AC[1], Clause: 7.0; 7.3	▼	• Area Management • Facility Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review **4.0 Education and Core Competency of Endoscopy Reprocessing Staff**				
Infection Prevention and Control (IPC) Education and Training				
There is documentation that all staff have received IPC training including the following topics: It should include each component listed in "Additional Information"				
E 4.1	Infection prevention and control (IPC) training is documented and includes basic microbiology.	Ensure IPC training includes information on requirements that support microbial growth and how microorganisms are spread and cause disease. CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control
E 4.2	Infection prevention and control (IPC) training is documented and includes Risks of contact with or exposure to infectious agents.	Ensure IPC training includes information on Risks of contact with or exposure to infectious agents including information on "Chain of Infection" model. CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review **4.0 Education and Core Competency of Endoscopy Reprocessing Staff**				
E 4.3	Infection prevention and control (IPC) training is documented and includes risks to patients exposed to inadequately reprocessed endoscopes.	Ensure IPC training includes information on risks to patients exposed to inadequately reprocessed endoscopes (e.g. complications, infection, death, etc.) and information relating to outbreaks of infection following endoscopy. Information on risks should include: • malfunctioning equipment • lack of knowledge • not following manufacturer's written instructions • inadequate storage and handling procedures CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control
E 4.4	Infection prevention and control (IPC) training is documented and includes personal hygiene including proper hand hygiene.	Ensure IPC training includes information on personal hygiene including proper hand hygiene including: • importance of clean skin, hair and clothing • when and how to use alcohol based hand rub (ABHR) • when to and how to wash hands with soap and water. • why hand washing sinks are dedicated for hand hygiene. CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control
E 4.5	Infection prevention and control (IPC) training is documented and includes use of personal protective equipment (PPE).	Ensure IPC training includes use and selection of PPE, including correct sequence for putting on and removing PPE (including hand hygiene). CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control • AHS Workplace Health and Safety
E 4.6	Infection prevention and control (IPC) training is documented and includes IPC and work practices to prevent staff exposure to blood and body fluids.	Ensure IPC training includes information on IPC and work practices to prevent staff exposure to blood and body fluids. This includes prevention of needle stick injuries, mucous membrane exposures, etc. CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control • AHS Workplace Health and Safety
E 4.7	Infection prevention and control (IPC) training is documented and includes handling of sharps and waste management.	Ensure IPC training includes information on handling of sharps and waste management. CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control • AHS Workplace Health and Safety

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review **4.0 Education and Core Competency of Endoscopy Reprocessing Staff**				
E 4.8	Infection prevention and control (IPC) training is documented and includes procedures following staff exposure to blood and body fluids.	Ensure IPC training includes information on procedures for staff to follow if exposed to blood or body fluids. CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control • AHS Workplace Health and Safety
E 4.9	Infection prevention and control (IPC) training is documented and includes one-way work flow practices to prevent the contamination of clean items.	Ensure IPC training includes information on one-way work flow practices to prevent the contamination of clean items. CAN/CSA Z314.8-08, Clause: 6.3.3	▼	• Area Management • AHS Infection Prevention and Control
Endoscope Reprocessing Personnel Education and Training				
E 4.10	Personnel responsible for and involved with endoscope reprocessing receive education and training on all aspects of endoscope reprocessing. Education and training is documented.	Ensure that personnel responsible for and involved with endoscope reprocessing receive education and training on all aspects of endoscope reprocessing. All education and training is documented. AC[3], Clause: 13.1 CAN/CSA Z314.8-08, Clause: 6.2.3; 6.3; 13.9.1	▼	• Area Management
There is documentation on the frequency of training on fundamentals of endoscope reprocessing for manager(s) and staff responsible for endoscope reprocessing. Training is performed by competent personnel when:				
E 4.11	There is documentation of training on fundamentals of MDR for manager(s) and staff responsible for reprocessing when staff are first employed.	Ensure the initial orientation of the manager and staff responsible for reprocessing of endoscopes includes education/training by competent personnel on basic reprocessing principles and how to reprocess instruments (including endoscopes and accessories). All staff education and training is documented. AH[2], Clause: 12.1 AC[3], Clause: 13.1 CAN/CSA Z314.8-08, Clause: 13.9.1	▼	• Area Management
E 4.12	There is documentation of training on fundamentals of MDR for manager(s) and staff responsible for reprocessing when there is any authorized change in process.	Ensure authorized process changes are communicated to the manager and staff responsible for reprocessing. Education and training is provided. All staff education and training is documented. AC[3], Clause: 13.1 CAN/CSA Z314.8-08, Clause: 13.9.1	▼	• Area Management
E 4.13	There is documentation of training on fundamentals of MDR for manager(s) and staff responsible for reprocessing when new endoscopes, accessory devices, or products are purchased.	Ensure manager and staff responsible for reprocessing receive education and training on all new equipment, devices and products, including information on reprocessing. All staff education and training is documented. AC[3], Clause: 13.1 CAN/CSA Z314.8-08, Clause: 13.9.1	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section E – Document Review **4.0 Education and Core Competency of Endoscopy Reprocessing Staff**				
E 4.14	There is documentation of training on fundamentals of MDR for manager(s) and staff responsible for reprocessing when new processing equipment is purchased.	Ensure manager and staff responsible for reprocessing receive education and training on new reprocessing equipment. All staff education and training is documented. AC[3], Clause: 13.1 CAN/CSA Z314.8-08, Clause: 13.9.1	▼	• Area Management
Competency Testing				
E 4.15	Baseline and annual competency testing of staff members involved in endoscope reprocessing is conducted and results are documented.	Ensure the manager and staff responsible for reprocessing can demonstrate reprocessing competencies initially and at specified intervals, (at least annually). Competencies are documented. AC[3], Clause: 13.1 CAN/CSA Z314.8-08, Clause: 13.9.1	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section F – Single Use Medical Devices (SUMeDs or SUDs)				
F 1.1	There is a documented policy stating that single use medical devices are not to be reprocessed in the facility.	Develop, update or obtain a written policy that states single use medical devices are not reprocessed. AHS Single use Medical Devices PS-07 http://insite.albertahealthservices.ca/Files/clp-single-use-medical-devices-policy.pdf AC[1], Clause: 8.1 AH Standards Single Use Medical Devices.	▼	• Area Management • AHS Administration
F 1.2	Single use medical devices are not reprocessed in the facility.	Ensure single use medical devices are not reprocessed. AHS Single use Medical Devices PS-07 http://insite.albertahealthservices.ca/Files/clp-single-use-medical-devices-policy.pdf AC[1], Clause: 8.1 AH Standards Single Use Medical Devices.	●	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **1.0 Area Design**				
G 1.1	There is a designated reprocessing area that is physically separate from areas where clean, disinfected or sterile items are stored or handled and where patient care is provided.	Ensure that there is a designated reprocessing area that is physically separated by walls or partitions from areas where clean and sterile items are stored or handled or where patient care is provided. AH[2], Clause: 3.3.2 AC3, Clause: 13.3 CAN/CSA Z314.8-08, Clause: 7.1.1; 7.1.2	◆	• Area Management
G 1.2	Endoscope reprocessing work areas are separated by walls or partitions to control traffic and contain contaminants.	Ensure endoscope reprocessing work areas (e.g. cleaning/decontamination area, high level disinfection (HLD) area, storage area) are separated by walls or partitions to control traffic and contain contaminants. AH[2], Clause: 3.3.2 CAN/CSA Z314.8-08, Clause: 7.1.2; 7.1.6 CAN/CSA Z314.3-09; 7.1.1; 7.1.2; 7.1.5	◆	• Area Management
G 1.3	There are designated clean and soiled areas within the endoscope reprocessing area.	Ensure there are designated clean and soiled areas within endoscope reprocessing work areas. AC3, Clause: 13.4 CAN/CSA Z314.8-08, Clause: 7.1.6; 13.3.2	▼	• Area Management
G 1.4	There is a one-way work flow from dirty to clean to prevent cross-contamination.	Ensure the endoscope reprocessing area has one-way work flow from dirty to clean to prevent cross-contamination. AH[2], Clause: 3.3.5 CAN/CSA Z314.8-08, Clause: 13.3.2	▼	• Area Management
G 1.5	There is a dedicated, protected, clean and well ventilated storage cabinet for endoscopes.	Ensure there is a dedicated, protected, clean and well ventilated storage cabinet for endoscopes. CAN/CSA Z314.8-08, Clause: 13.4.10.3; 13.4.10.4	◆	• Area Management
G 1.6	Eyewash stations are readily available where staff are exposed to chemical or biological agents.	Ensure eyewash stations are readily available in areas where staff handle chemical or biological agents. AH[2], Clause: 13.1.8 CAN/CSA Z314.8-08, Clause: 13.3.2	▼	• Area Management
G 1.7	Eyewash station is maintained as per manufacturer's written instructions.	Ensure the eyewash station is maintained as per manufacturer's written instructions. AH[2], Clause: 13.1.8 CAN/CSA Z314.8-08, Clause: 13.3.2	▼	• Area Management
G 1.8	All walls, ceilings and work surfaces are intact and composed of non-porous, non-shedding material capable of withstanding frequent cleaning.	Ensure all walls, ceilings and work surfaces are intact and composed of non-porous, non-shedding material capable of withstanding frequent cleaning. CAN/CSA Z314.8-08, Clause: 7.1.8	◆	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **1.0 Area Design**				
G 1.9	There are no exposed pipes or duct work.	Ensure there are no exposed pipes or duct work. CAN/CSA Z314.8-08, Clause: 7.1.8	◆	• Area Management • Facility Management
G 1.10	There are dedicated hand hygiene stations at entrances/exits to the reprocessing area.	Ensure there are dedicated hand hygiene stations at entrances/exits to the reprocessing area. Hand hygiene stations include a sink with soap and an adjacent enclosed single-use towel dispenser or waterless alcohol-based hand rub dispenser. CAN/CSA Z314.8-08, Clause: 7.1.12	▼	• Area Management
G 1.11	Endoscope reprocessing work areas have doors that are kept closed.	Ensure reprocessing area has doors that are kept closed. CAN/CSA Z314.8-08, Clause: 7.1.7	▼	• Area Management
G 1.12	Signage is posted at all entry points indicating the area is restricted to authorized personnel only.	Ensure signage is posted at all entry points indicating the area is restricted to authorized personnel only. CAN/CSA Z314.8-08, Clause: 7.2.1	▼	• Area Management
G 1.13	Traffic in the endoscope reprocessing area is restricted to authorized personnel wearing appropriate attire.	Ensure traffic in the reprocessing area is restricted to authorized personnel wearing appropriate attire. CAN/CSA Z314.8-08, Clause: 7.2.1	▼	• Area Management
G 1.14	Portable fans are not used in the endoscope reprocessing area.	Ensure there are no portable fans used in the reprocessing area. CAN/CSA Z314.8-08, Clause: 7.3.3	▼	• Area Management
G 1.15	The area is free of external shipping containers and corrugated cardboard.	Ensure the area is free of external shipping containers and corrugated cardboard. CAN/CSA Z314.3-09, Clause: 11.2.3	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **2.0 General Practices**				
G 2.1	Endoscopes and accessories that come in contact with mucous membranes are cleaned and receive at least high level disinfection (HLD) after each patient use.	Ensure endoscopes and accessories that come in contact with mucous membranes are cleaned and receive at least HLD after each patient use. CAN/CSA Z314.8-08, Clause: 13.1.1 CAN/CSA Z314.8-08, Clause: 10.6.1; 10.8.2.5; 10.8.5.1.1	●	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **2.0 General Practices**				
G 2.2	Reusable accessories (e.g. biopsy forceps or other cutting devices) that break the mucosal barrier are cleaned and then sterilized between each patient.	Ensure reusable accessories (e.g. biopsy forceps or other cutting devices) that break the mucosal barrier are cleaned and then sterilized between each patient. CAN/CSA Z314.8-08, Clause: 13.1.2		• Area Management
G 2.3	Staff performing endoscope reprocessing wear appropriate personal protective equipment (PPE).	Ensure PPE (gown, gloves, mask and eye protection) is available and worn for cleaning/reprocessing activities. PPE includes: • gloves appropriate to the task • protective gown or garment • full face shield, or high-filtration, fluid-impervious face mask and protective eyewear Prescription eye glasses are not acceptable for eye protection. AH[2], Clause: 11.3 CAN/CSA Z314.8-08, Clause: 6.7.1.1; 6.7.2.6; 8.1.3		• Area Management
G 2.4	The water bottle used to provide intra-procedural flush solution and its connecting tube are changed daily and sterilized or high level disinfected if reusable. If disposable, they are discarded daily.	Ensure the water bottle used to provide intra-procedural flush solution and its connecting tube are changed daily and sterilized or high level disinfected if reusable. If disposable, they are discarded daily. AH[2], Clause: 8.12 CAN/CSA Z314.8-08, Clause: 13.7.5		• Area Management
G 2.5	Reprocessing of flexible endoscopes is performed by personnel who are trained in reprocessing of flexible endoscopes.	Ensure reprocessing of flexible endoscopes is performed by personnel who are trained in reprocessing of flexible endoscopes. AC[3], Clause: 13.5CAN/CSA Z314.8-08, Clause: 13.2.1		• Area Management
G 2.6	There are written, detailed procedures for cleaning and handling of endoscopes available for staff.	Ensure there are written, detailed procedures for cleaning and handling of endoscopes available for staff. CAN/CSA Z314.8-08, Clause: 13.1.1; 13.4.1.1		• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **3.0 Cleaning of Flexible Endoscopes**				
G 3.1	Pre-cleaning of the endoscope is performed at point of use immediately following clinical procedure. Endoscope manufacturer's written instructions are followed.	Ensure pre-cleaning of the endoscope is performed at point of use immediately following clinical procedure. CAN/CSA Z314.8-08, Clause: 13.4.1.2; 13.4.1.3; 13.4.2		• Area Management
G 3.2	Personal protective equipment (PPE) is removed and hands are cleaned when moving between contaminated and clean areas or tasks.	Ensure PPE is removed and hands are cleaned when staff are moving between contaminated and clean areas or tasks. CAN/CSA Z314.8-08, Clause: 6.7.1.2		• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **3.0 Cleaning of Flexible Endoscopes**				
G 3.3	As soon as possible following use and pre-cleaning, meticulous manual cleaning is performed prior to high level disinfection (HLD) or sterilization.	Ensure that meticulous manual cleaning is performed as soon as possible following use and prior to HLD or sterilization. AC[3], Clause: 13.5; 13.7 CAN/CSA Z314.8-08, Clause: 13.4.5.1		• Area Management
G 3.4	Enzymatic or detergent solution is prepared and used according to manufacturer's written instructions.	Ensure enzymatic or detergent solution is prepared and used according to manufacturer's written instructions. AC[3], Clause: 13.7 CAN/CSA Z314.8-08, Clause: 13.4.5.2		• Area Management
G 3.5	Enzymatic or detergent solutions are discarded after each use and the sink or container is emptied and cleaned following cleaning of each endoscope.	Ensure enzymatic or detergent solutions are discarded after each use and the sink or container is emptied and cleaned following cleaning of each endoscope. AC[3], Clause: 13.7 CAN/CSA Z314.8-08, Clause 7.4.2 SGNA, Clause: E1		• Area Management
G 3.6	Accessories are disconnected and disassembled as per manufacturer's written instructions and completely immersed in the enzymatic detergent.	Ensure accessories are disconnected and disassembled as per manufacturer's written instructions. Devices are completely immersed in the enzymatic detergent. CAN/CSA Z314.8-08, Clause: 13.4.5.3		• Area Management
G 3.7	A leak test is performed prior to or during immersion of the endoscope following manufacturer's written instructions.	Ensure a leak test is performed prior to or during immersion of the endoscope following manufacturer's written instructions. CAN/CSA Z314.8-08, Clause: 13.4.4.1		• Area Management
G 3.8	The entire endoscope is completely immersed in the freshly prepared enzymatic or detergent solution.	Ensure the entire endoscope is completely immersed in the freshly prepared enzymatic or detergent solution. CAN/CSA Z314.8-08, Clause: 13.4.5.1; 13.4.5.2		• Area Management
G 3.9	The endoscope is entirely immersed during the entire cleaning process to prevent splashing or aerosolization.	Ensure endoscope is entirely immersed during the entire cleaning process to prevent splashing or aerosolization. CAN/CSA Z314.8-08, Clause: 13.4.5.4		• Area Management
G 3.10	The bending section of the endoscope is kept straight so brushing does not damage endoscope.	Ensure the bending section of the endoscope is kept straight so brushing does not damage the internal lumen of the endoscope. CAN/CSA Z314.8-08, Clause: 13.4.5.4		• Area Management
G 3.11	The exterior of the endoscope is cleaned with a soft brush or lint free cloth.	Ensure the exterior of the endoscope is cleaned with a soft brush or lint free cloth. CAN/CSA Z314.8-08, Clause: 13.4.5.3		• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **3.0 Cleaning of Flexible Endoscopes**				
G 3.12	All channels are cleaned as per manufacturer's written instructions until all visible debris is removed.	Ensure all channels are cleaned as per manufacturer's written instructions until all visible debris is removed. Example of a cleaning method is: • an appropriately sized channel cleaning brush is passed through a channel a minimum of three (3) times CAN/CSA Z314.8-08, Clause: 13.4.5.4	▼	• Area Management
G 3.13	Cleaning brush is washed in the enzymatic or detergent solution following each pass through the channel.	Ensure cleaning brush is washed in the enzymatic or detergent solution following each pass through the channel. CAN/CSA Z314.8-08, Clause: 13.4.5.4	▼	• Area Management
G 3.14	Suction valve housings and endoscope channel ports are washed with a cleaning brush until all debris is removed.	Ensure suction valve housings and endoscope channel ports are washed with a cleaning brush until all debris is removed. CAN/CSA Z314.8-08, Clause: 13.4.5.4	▼	• Area Management
G 3.15	Valves and removable parts are brushed and flushed until all visible debris is removed. Parts are inspected for cleanliness.	Ensure valves and removable parts are brushed and flushed until all visible debris is removed. Parts are inspected for cleanliness. CAN/CSA Z314.8-08, Clause: 13.4.5.3	▼	• Area Management
G 3.16	A syringe is attached to the correct channel adapter and enzymatic or detergent solution is injected into all channels of the endoscope at least three (3) times or equivalent cleaning is done by an approved automated system.	Ensure a syringe is attached to the correct channel adapter and enzymatic or detergent solution is injected into all channels of the endoscope at least three (3) times or equivalent cleaning is done by an approved automated system. Examples of an approved automated system are the Scope Buddy® or EndoFlush. **Note:** The syringe volume is as specified by the endoscope manufacturer. CAN/CSA Z314.8-08, Clause: 13.4.5.4; 13.4.5.6	▼	• Area Management
G 3.17	The accessories and endoscope, including all channels, are rinsed with clean tap water following cleaning. Channel rinses are performed using a syringe attached to the correct channel adapters or an approved automated system.	Ensure the accessories and endoscope, including all channels, are rinsed with clean tap water following cleaning. Channel rinses are performed using a syringe attached to the correct channel adapters or an approved automated system. Endoscope and accessories are thoroughly rinsed with tap water to remove all traces of enzymatic or detergent solution and debris. **Note:** The syringe volume is as specified by the endoscope manufacturer. AC^3, Clause: 13.8 CAN/CSA Z314.8-08, Clause: 13.4.6	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **3.0 Cleaning of Flexible Endoscopes**				
G 3.18	Channel rinses are followed by air purges using a syringe or an approved automated system.	Ensure that channel rinses are followed by air purges using a syringe or an approved automated system. **Note:** The syringe volume is as specified by the endoscope manufacturer. AC[3], Clause: 13.8 CAN/CSA Z314.8-08, Clause: 13.4.6	▼	• Area Management
G 3.19	Exterior of the endoscope and all removable parts are thoroughly dried using a clean lint-free cloth.	Ensure the exterior of the endoscope and all removable parts are thoroughly dried using a clean lint-free cloth. **Note:** If placing endoscope directly into AER with a washing function, drying is not required. AC[3], Clause: 13.8 CAN/CSA Z314.8-08, Clause: 13.4.6	▼	• Area Management
G 3.20	Cleaning accessories (e.g. brushes, sponges, etc.) are handled appropriately following each use: • single use cleaning accessories are disposed of • reusable cleaning accessories are cleaned and high level disinfected or sterilized	Ensure single use cleaning accessories (e.g. brushes, sponges, syringes) are disposed of following each use. Reusable cleaning accessories are cleaned and high level disinfected or sterilized following each use. CAN/CSA Z314.8-08, Clause: 13.4.5.4; 13.7.4	▼	• Area Management
Ultrasonic Cleaning Equipment				
G 3.21	Prior to ultrasonic cleaning, gross soil is removed from devices.	Ensure that gross soil is removed from devices prior to ultrasonic cleaning. CAN/CSA Z314.8-08, Clause: 10.4.4.3	▼	• Area Management
G 3.22	Following ultrasonic cleaning, devices are thoroughly rinsed and inspected prior to sterilization or high level disinfection (HLD).	Ensure that devices are thoroughly rinsed and inspected prior to sterilization or HLD following ultrasonic cleaning. CAN/CSA Z314.8-08, Clause: 10.4.4.7	▼	• Area Management
G 3.23	Solution in ultrasonic cleaner is changed at least daily and when visibly soiled.	Ensure solution in the ultrasonic cleaner is changed at least daily and when visibly soiled. CAN/CSA Z314.8-08, Clause: 10.4.4.8	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour 4.0 High Level Disinfection (HLD) of Flexible Endoscopes**: General Practices**				
G 4.1	There are methods in place to contain or remove toxic vapors emitted by or from disinfecting agents.	Ensure there are methods in place to contain or remove toxic vapors emitted by or from disinfecting agents. Methods may include: • using a fume hood • having a dedicated ventilation system • ensuring container for disinfectant remains closed at all times AC3, Clause: 13.4 CAN/CSA Z314.8-08, Clause: 10.8.2.6; 10.8.3.3 SGNA, Clause: H3	◆	• Area Management
G 4.2	Endoscopes are manually cleaned according to manufacturer's written instructions, prior to high level disinfection (HLD).	Ensure endoscopes are manually cleaned according to manufacturer's written instructions prior to HLD. AC^3, Clause: 13.7 CAN/CSA Z314.8-08, Clause: 13.4.5.1	●	• Area Management
G 4.3	Endoscope and high level disinfectant manufacturers' written instructions are followed and are available for staff.	Ensure the endoscope and high level disinfectant manufacturers' written instructions are followed and are available for staff. AC^3, Clause: 13.7 CAN/CSA Z314.8-08, Clause: 10.8.2.2; 10.8.3.1	▼	• Area Management
G 4.4	Chemical disinfectant has a Drug Identification Number (DIN) from Health Canada.	Ensure the chemical disinfectant has a (DIN) from Health Canada. CAN/CSA Z314.8-08, Clause: 10.8.1.2	▼	• Area Management
G 4.5	High level disinfectants are used correctly to achieve the manufacturer's recommended parameters including: • time of exposure • temperature of disinfectant • minimum effective concentration (MEC)	Ensure the high level disinfectants are used correctly to achieve the manufacturer's recommended parameters including: • time of exposure • temperature of disinfectant • MEC CAN/CSA Z314.8-08, Clause: 10.8.2.2; 10.8.2.5; 10.8.5.3.1	▼	• Area Management
G 4.6	Minimum effective concentration (MEC) of reusable high level disinfectant is tested daily when in use.	Ensure the MEC of reusable high level disinfectant is tested daily when in use and results are documented. If a method of testing concentration other than test strips is used (e.g. concentration testing during an automated cycle), concentration is documented and verified. Method of testing is validated by the manufacturer. CAN/CSA Z314.8-08, Clause: 10.8.3.8	●	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour 4.0 High Level Disinfection (HLD) of Flexible Endoscopes**: General Practices**				
G 4.7	Quality control testing of MEC test strips is performed according to manufacturer's written instructions each time a new bottle is opened to verify efficacy of test strips. Results are documented.	Ensure that quality control testing is performed on MEC test strips according to manufacturer's written instructions each time a new bottle is opened to verify efficacy. Document all results. CAN/CSA Z314.8-08, Clause: 10.8.3.8	▼	• Area Management
G 4.8	Test strip bottles are dated when opened.	Ensure test strip bottles are dated when opened. This is required by manufacturer's written instructions.	▼	• Area Management
G 4.9	Test strips are not used past the expiry date.	Ensure test strips are not used past the expiry date. This includes the lot # expiry date and the open bottle expiry date. This is required by manufacturer's written instructions.	▼	• Area Management
G 4.10	Reusable containers or reservoirs for storing disinfectant and enzymatic or detergent solution are cleaned and dried before refilling.	Ensure reusable containers or reservoirs for storing disinfectants, enzymatic or detergent solutions are cleaned and dried before refilling. CAN/CSA Z314.8-08, Clause: 10.8.3.4; 10.8.6.1	▼	• Area Management
G 4.11	Containers of high level disinfectant that have been mixed or opened are labeled with the date of mixing or opening and the date the solution expires.	Ensure containers of high level disinfectant that have been mixed or opened are labeled with the date of mixing or opening and the date the solution expires. **Note:** The expiry date for an opened/mixed bottle or poured-off portion of disinfectant may be different than the lot # expiry date printed or stamped on the bottle. CAN/CSA Z314.8-08, Clause: 10.8.3.9	▼	• Area Management
G 4.12	High level disinfectant solution that has reached the expiry date is discarded as recommended by the manufacturer even if the test strip passes.	Ensure high level disinfectant solution that has reached the expiry date is discarded as recommended by the manufacturer, even if the minimum effective concentration (MEC) test strip passes. CAN/CSA Z314.8-08, Clause: 10.8.3.9	▼	• Area Management
G 4.13	There is documentation when high level disinfectant is changed.	Ensure there is documentation when high level disinfectant is changed. Documentation includes: • name of high level disinfectant • date • identification of individual changing the disinfectant CAN/CSA Z314.8-08, Clause: 13.9.3(c)	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour 4.0 High Level Disinfection (HLD) of Flexible Endoscopes**: General Practices**				
G 4.14	Each high level disinfection (HLD) cycle is monitored by trained staff who document the process.	Ensure each HLD cycle or process is monitored by trained staff who document the process including: • identification of the devices being reprocessed • date • contact time with the chemical high level disinfectant • temperature (if applicable) • identification of person responsible for ensuring all requirements for reprocessing and releasing the devices are met When automated reprocessing equipment (e.g. AER) is used, documentation also includes: • automated reprocessing unit identification (e.g. make, model, serial number, etc.) AC[3], Clause: 13.12, 13.13 CAN/CSA Z314.8-08, Clause: 10.8.5.6	▼	• Area Management
G 4.15	The endoscope can be traced back to the patient.	Ensure that documentation for traceability of endoscope to patient is completed when an endoscope is used. Documentation includes: • date endoscope used on the patient • the patient identification • the serial number or other identifier of the endoscope(s) used in the procedure(s) CAN/CSA Z314.8-08, Clause: 10.8; 13.9.1 (f); 13.9.3	▼	• Area Management
G 4.16	After high level disinfection of flexible endoscopes, there is a process in place that clearly identifies a non-reprocessed endoscope or other device from one that has been reprocessed.	After high level disinfection of flexible endoscopes, ensure there is a process in place that clearly identifies a non-reprocessed endoscope or other device from one that has been reprocessed to prevent the use of a non-reprocessed device on a patient. PHAC , Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy 2011, 5.3(f)	●	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **5.0 Manual High Level Disinfection (HLD) of Flexible Endoscopes**				
G 5.1	Immediately following manual cleaning, the entire cleaned and dried endoscope, valves, cleaning brushes and removable parts are completely submerged in a basin of high level disinfectant.	Ensure that the endoscope, valves, cleaning brushes and removable parts are completely submerged in a basin of high level disinfectant immediately following manual cleaning. CAN/CSA Z314.8-08, Clause: 13.4.9.1	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **5.0 Manual High Level Disinfection (HLD) of Flexible Endoscopes**				
G 5.2	The endoscope is completely immersed in the high level disinfectant solution for the recommended contact time and temperature.	Ensure the endoscope is completely immersed in the high level disinfectant solution for the recommended contact time and temperature. CAN/CSA Z314.8-08, Clause: 13.4.9.1	▼	• Area Management
G 5.3	High level disinfectant is perfused into all channels of the endoscope using a syringe attached to the correct channel adapter or by an approved automated system.	Ensure the high level disinfectant is perfused into all channels of the endoscope using a syringe attached to the correct channel adapter or by an approved automated system. **Note:** The syringe volume is as specified by the endoscope manufacturer. CAN/CSA Z314.8-08, Clause: 13.4.9.1	▼	• Area Management
G 5.4	High level disinfection (HLD) container is covered at all times except when endoscopes are being placed in or removed from the container.	Ensure the HLD container is covered at all times except when endoscopes are being placed in or removed from the container. CAN/CSA Z314.8-08, Clause: 13.4.9.1	▼	• Area Management
G 5.5	Following recommended contact time with high level disinfectant, air is flushed through the endoscope channels using a syringe attached to the correct channel adapter or by an approved automated system.	Ensure that air is flushed through the endoscope's channels using a syringe attached to the correct channel adapter or by an approved automated system following the recommended contact time with the high level disinfectant. CAN/CSA Z314.8-08, Clause: 13.4.9.1	▼	• Area Management
G 5.6	Endoscope and accessories are immersed in fresh sterile or submicron filtered rinse water following air purge.	Ensure endoscope and accessories are immersed in fresh sterile or submicron filtered rinse water following the air purge. AC^3, Clause: 13.10 CAN/CSA Z314.8-08, Clause: 10.8.5.4	▼	• Area Management
G 5.7	Endoscopes, including all channels, are rinsed following high level disinfection (HLD) with three (3) separate rinses using sterile or submicron filtered water. Channel rinses are performed using a syringe attached to the correct channel adapters or an approved automated system.	Ensure endoscopes, including all channels, are rinsed following HLD with three (3) separate rinses using sterile or submicron filtered water. Channel rinses are performed using a syringe attached to the correct channel adapters or an approved automated system. **Note:** The syringe volume is as specified by the endoscope manufacturer. AC^3, Clause: 13.10 CAN/CSA Z314.8-08, Clause: 10.8.5.4	▼	• Area Management
G 5.8	Valves (including lumens) and removable parts of the endoscope are flushed with sterile or submicron filtered water.	Ensure valves and removable parts of the endoscope are flushed with sterile or submicron filtered water as per manufacturer's written instructions. CAN/CSA Z314.8-08, Clause: 10.8.5.4	▼	• Area Management
G 5.9	Rinsing of valves (including lumens) and removable parts is done with three (3) separate rinses using fresh rinse solution for each of the three (3) rinses.	Ensure valves (including lumens) and removable parts are rinsed with three (3) separate rinses, using fresh rinse solution for each rinse. CAN/CSA Z314.8-08, Clause: 10.8.5.4	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **5.0 Manual High Level Disinfection (HLD) of Flexible Endoscopes**				
G 5.10	Following rinsing, after high level disinfection (HLD), a channel air purge followed by a 70% alcohol flush and a final air purge is performed.	Ensure that after rinsing following HLD, the channel is air purged followed by a 70% alcohol flush and a final air purge. AH[2], Clause: 8.9 AC[3], Clause: 13.9 CAN/CSA Z314.8-08, Clause: 13.4.10.1	▼	• Area Management
G 5.11	Air purges are performed using medical grade air.	Ensure air purges are performed using medical grade air. AC[3], Clause: 13.9 CAN/CSA Z314.8-08, Clause: 13.4.10.1	▼	• Area Management
G 5.12	Endoscope is dried with a clean, lint-free cloth.	Ensure the endoscope is dried with a clean, lint-free cloth. SGNA, Clause: J5	▼	• Area Management
G 5.13	Following high level disinfection (HLD) endoscopes are handled in a manner to prevent contamination.	Ensure that endoscopes are handled in a manner to prevent contamination following manual HLD. Personnel wash their hands and put on a clean gown prior to handling disinfected endoscopes. CAN/CSA Z314.8-08, Clause: 10.11.3	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **6.0 Automated High Level Disinfection (HLD) of Flexible Endoscopes**				
G 6.1	Immediately following manual cleaning, the endoscope, valves, removable parts and reusable cleaning accessories are placed in the automated endoscope reprocessor (AER).	Ensure the cleaned endoscope, valves, brushes and removable parts are placed in the AER immediately following manual cleaning. CAN/CSA Z314.3-09, Clause: 13.4.8.1	▼	• Area Management
G 6.2	Automated Endoscope Reprocessor (AER) channel adaptors (attachments) are appropriate to the endoscope being reprocessed.	Ensure the AER channel adaptor attachments are appropriate to the scope being reprocessed. CAN/CSA Z314.3-09, Clause: 13.4.8.2	▼	• Area Management
G 6.3	Endoscope is attached to the automated endoscope reprocessor (AER) using the correct channel adaptors as per manufacturer's written instructions.	Ensure the endoscope adaptors are correctly attached to the AER and endoscope as per manufacturer's written instructions. AH[2], Clause: 8.9 CAN/CSA Z314.3-09, Clause: 13.4.8.2	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **6.0 Automated High Level Disinfection (HLD) of Flexible Endoscopes**				
G 6.4	Endoscope, accessories and removable parts (e.g. valves) are completely immersed in high level disinfectant in the Automated Endoscope Reprocessor (AER) for the recommended contact time and temperature.	Ensure the endoscope is completely immersed in high level disinfectant solution in the AER for the recommended time and temperature. CAN/CSA Z314.8-08, Clause: 13.4.8.3	▼	• Area Management
G 6.5	Endoscope is removed promptly after the final cycle has been completed.	Ensure the endoscope is removed promptly from the Automated Endoscope Reprocessor (AER) after the final cycle has completed. SGNA, Clause: J6 – Note.	▼	• Area Management
G 6.6	A channel air purge followed by a 70% alcohol flush and a final air purge is performed.	Ensure a channel air flush followed by a 70% alcohol and a forced-air purge is performed. If the Automated Endoscope Reprocessor (AER) does not have an alcohol rinse cycle, all three (3) steps must be performed manually. If the AER has an alcohol rinse cycle, only the final air purge must be performed following removal from the AER. AC[3], Clause: 13.9 AH[2], Clause: 8.9 CAN/CSA Z314.8-08, Clause: 13.4.10.1	▼	• Area Management
G 6.7	Endoscope is dried with a clean, lint-free cloth or mechanical method.	Ensure endoscope is dried with a clean, lint-free cloth or mechanical method. SGNA, Clause: J5	▼	• Area Management
G 6.8	Following automated high level disinfection (HLD) endoscopes are handled in a manner to prevent contamination.	Ensure that endoscopes are handled in a manner to prevent contamination following automated HLD. Personnel wash their hands and put on a clean gown prior to handling disinfected endoscopes. CAN/CSA Z314.8-08, Clause: 10.11.3	▼	• Area Management
G 6.9	Each reprocessing cycle is monitored by an automated printout or electronic log which includes: • load number • date of cycle • contact time with the high level disinfectant • temperature of high level disinfectant, if required • name of person responsible for verifying reprocessing parameters and releasing the endoscope	Ensure the automated printout or electronic log from the AER is monitored and signed off by staff releasing the load. Information includes: • load number • date of cycle • contact time with the high level disinfectant • temperature of high level disinfectant, if required • name of person responsible for verifying reprocessing parameters and releasing the endoscope CAN/CSA Z314.8-08, Clause: 13.9.3	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **7.0 Chemical Sterilization of Flexible Endoscopes (Steris System 1®)**				
G 7.1	All endoscopes are manually cleaned according to manufacturer's instructions prior to chemical sterilization.	Ensure endoscopes are cleaned according to manufacturer's written instructions prior to sterilization. AH[2], Clause: 9.1.1; 9.7 AC[3], Clause: 13.7 CAN/CSA Z314.3-09, Clause: 13.4.5.1	●	• Area Management
G 7.2	Endoscopes and reusable accessories are connected with the correct tray and attachment tubing and arranged in the Steris System 1® as per manufacturer's written instructions.	Ensure endoscope and reusable accessories are connected with the correct tray and attachment tubing and arranged in the Steris System 1® tray as per manufacturer's written instructions. AH[2], Clause: 9.2 CAN/CSA Z314.8-08, Clause: 13.4.8.2	●	• Area Management
G 7.3	Critical devices processed in Steris System 1® are used immediately following processing and are not stored.	Ensure critical devices processed in Steris System 1® are used immediately following processing and are not stored. **Note:** Using Steris System 1® to sterilize critical items is equivalent to sterilization of unwrapped critical devices. CAN/CSA Z314.3-09, Clause: 13.8 SGNA. p. 16	▼	• Area Management
G 7.4	Sterilizer loading and operation instructions are available and followed by the staff.	Ensure sterilizer loading and operation instructions are available and followed by the staff. AC[1], Clause: 9.2; 9.4 AH[2], Clause: 9.2	▼	• Area Management
G 7.5	Mechanical indicators are monitored and documented for each sterilization cycle.	Ensure mechanical indicators are monitored and documented for each sterilization cycle. AC[1], Clause: 9.5	▼	• Area Management
G 7.6	Mechanical indicators are reviewed by the individual responsible for releasing the load and signed after each sterilization cycle.	Ensure mechanical indicators are reviewed by the individual responsible for releasing the load and signed after each sterilization cycle. AC[1], Clause: 9.5	▼	• Area Management
G 7.7	A biological indicator (BI) is tested each day the sterilizer is in use and results documented.	Ensure a BI is tested each day the sterilizer is in use and results documented. AH[2], Clause: 9.3.1	▼	• Area Management
G 7.8	Biological indicators (BIs) are not used past their expiry date.	Ensure BIs are not used past their expiry date. As per manufacturer's instructions.	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **7.0 Chemical Sterilization of Flexible Endoscopes (Steris System 1®)**				
G 7.9	There is a record of each sterilization cycle that includes: • sterilizer identifier • load number • date and time of cycle • mechanical indicators of physical parameters (e.g. time, temp, etc.) • load contents • identification of person responsible for load release	Ensure a record is kept of each sterilization cycle that includes: • sterilizer identifier • load number • date and time of cycle • mechanical indicators of physical parameters (e.g. time, temp, etc.) • load contents • identification of person responsible for load release Mechanical indicators may be recorded in a log, printout, database or recording chart. AC[1], Clause: 6.1; 6.2 AH[2], Clause: 9.3.1 AC[3], Clause: 13.12;13.13	▼	• Area Management
G 7.10	After chemical sterilization of flexible endoscopes, there is a process in place that clearly identifies a non-reprocessed endoscope from one that has been reprocessed.	After chemical sterilization of flexible endoscopes, ensure there is a process in place that clearly identifies a non-reprocessed endoscope from one that has been reprocessed to prevent the use of non-reprocessed device on a patient. AC[1], Clause: 11.2 CAN/CSA Z314-8.08, Clause: 4.3.2(f)	●	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **8.0 Transport and Storage**				
G 8.1	Contaminated endoscopes are placed in a covered, leak-proof container that is labeled or coded to indicate contaminated contents for transport to the decontamination area.	Ensure contaminated endoscopes are placed in a covered, leak-proof container that is labeled or coded to indicate contaminated contents for transport to the decontamination area. CAN/CSA Z314.8-08, Clause: 13.4.3	▼	• Area Management
G 8.2	Transport containers are cleaned and disinfected between each use.	Ensure transport containers are cleaned and disinfected between each use. CAN/CSA Z314.8-08, Clause: 9.3.3	▼	• Area Management
G 8.3	Caps, valves and other detachable components are removed during storage.	Ensure caps, valves and other detachable components are removed during storage and reassembled before use. AC[3], Clause: 13.11 CAN/CSA Z314.3-09, Clause: 13.4.10.2	▼	• Area Management
G 8.4	Endoscopes are not stored or transported in the manufacturer's shipping cases.	Ensure that endoscopes are not stored or transported in the manufacturer's foam lined shipping case (suitcase). AC[3], Clause: 13.11 CAN/CSA Z314.8-08, Clause: 13.4.10.3	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **8.0 Transport and Storage**				
G 8.5	Endoscopes with lumens are hung vertically in well ventilated storage cabinets with nonporous, cleanable surfaces in a manner that protects them from contamination (e.g. tips do not touch the floor of the cabinet).	Ensure all flexible endoscopes are hung in a vertical position in a well-ventilated, protected, clean storage cabinet to facilitate drying. Tips of the endoscope do not touch the floor of the cabinet. AC[3], Clause: 13.11 CAN/CSA Z314.8-08, Clause: 13.4.10.3; 13.4.10.4	▼	• Area Management
G 8.6	Endoscopes are reprocessed when the established shelf-life is reached.	Ensure that endoscopes are reprocessed when their shelf-life is reached. Endoscopes for GI procedures should be reprocessed if storage exceeds 7 days. CAN/CSA Z314.8-08, Clause: 13.4.1.3; 13.4.10.3	▼	• Area Management
G 8.7	Endoscope storage cabinets are cleaned and disinfected at least weekly.	Ensure endoscope storage cabinets are cleaned and disinfected at least weekly. AH[2], Clause: 8.11 CAN/CSA Z314.8-08, Clause: 13.4.10.4	▼	• Area Management

Item #	Item Description	Recommended Corrective Actions	Category	Responsibility of:
Section G – Observational Tour **9.0 Environmental Cleaning**				
G 9.1	All reprocessing equipment and environment appears clean and well maintained.	Ensure all reprocessing equipment and environment appears clean and well maintained. CAN/CSA Z314.8-08, Clause: 7.4.2	◆	• Area Management
G 9.2	Vacuum cleaning equipment is equipped with HEPA filter.	Ensure vacuum cleaning equipment is equipped with HEPA filter. CAN/CSA Z314.8-08, Clause: 7.4.3	▼	• Area Management
G 9.3	The cleaning schedule is documented and posted.	Ensure the cleaning schedule is posted, and cleaning is documented when performed. CAN/CSA Z314.8-08, Clause: 7.4.1; Table 1	▼	• Area Management
G 9.4	Cleaning equipment used in the endoscopy decontamination area is not used in any other area.	Ensure cleaning equipment used in the endoscopy decontamination area is not used in any other area. CAN/CSA Z314.8-08, Clause: 7.4.4	▼	• Area Management

List of References Used for the, Clauses:

1. Accreditation Canada (AC), Qmentum Program. Reprocessing and sterilization of reusable medical devices. 2012.
2. Alberta Health (AH). Standards for Cleaning, Disinfection and sterilization of reusable medical devices for all health care facilities and settings, 2012.
3. Accreditation Canada (AC), Qmentum Program. Infection Prevention and Control. 2012.
4. Alberta Health (AH). Standards for Single Use Medical Devices, 2011.
5. Association of periOperative Registered Nurses (AORN). Perioperative standards and recommended practices. 2011 Edition. Denver: AORN; 2011.
6. Canadian Standards Association. CAN/CSA Z314.8-08. Decontamination of reusable medical devices. Toronto, ON: Canadian Standards Association; March 2008.
7. Canadian Standards Association. CAN/CSA Z314.3-09. Effective sterilization in health care facilities by the steam process. Toronto, ON: Canadian Standards Association; March 2009.
8. Canadian Standards Association. CAN/CSA Z314.2-09. Ethylene oxide sterilizers for health care facilities by ethylene oxide process. Toronto, ON: Canadian Standards Association; March 2009.
9. CSA Z314.0-13 Medical device reprocessing – General requirements
10. Canadian Standards Association. CAN/CSA Z314.10.1-10. Selection and use of gowns, drapes and wrappers in health care facilities. Toronto, ON: Canadian Standards Association; 2010.
11. Canadian Standards Association. CAN/CSA Z314.10.2-10. Laundering, maintenance, and preparation of multiple-use gowns, drapes, and wrappers in health care facilities. Toronto, ON: Canadian Standards Association; 2010.
12. Canadian Standards Association. CAN/CSA Z314.15-10. Warehousing, storage, and transportation of clean and sterile medical devices. Toronto, ON: Canadian Standards Association; 2003.
13. Canadian Standards Association. CAN/CSA Z314.14-10 Rigid Sterilization Containers Sterilization Toronto, ON: Canadian Standards Association; 2010
14. CAN/CSA-Z14161-11, Sterilization of health care products — Biological indicators — Guidance for selection, use, and interpretation of results
15. Health Canada. Hand Washing, Cleaning, Disinfection and Sterilization in Health Care. Canada Communicable Disease Report, December, 1998.
16. Health Canada, Infection Prevention and Control Guidelines for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy, PHAC 2010
17. Operating Room Nurses Association of Canada (ORNAC). Standards, guidelines and position statements for perioperative registered nursing practice. 9th edition. June 2009.
18. Public Health Agency of Canada. Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy. 2011
19. Society of Gastroenterology Nurses and Associates (SGNA). Guideline for use of high level disinfectants and sterilants for reprocessing flexible gastrointestinal endoscopes: 2007. http://www.sgna.org/Resources/standards.cfm