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Medical Device Reprocessing of Reusable Critical and Semi-critical Medical Devices:

Review Criteria and Supporting Standards

Alberta Health Services
Infection Prevention & Control

Medical Device Reprocessing of Reusable Critical and Semi-critical Medical Devices: Review Criteria and Supporting Standard

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POLICIES AND PROCEDURES
Provincial Policies and Procedures

There are current written provincial policies and procedures for all steps of reprocessing (e.g, medical devices, reprocessing equipment) based on current recognized standards and validated manufacturer's instructions.

Additional Information
If the site is using the provincial set of policies and procedures, all items in the *Site-Specific Policies and Procedures* sub-section are marked N/A.

If the site is using site-specific policies, mark this as N/A and complete *Site-Specific Policies and Procedures* sub-section.

Recommended Corrective Actions
Use provincial set of policies, complete customization of applicable policies for site-specific information.

Reference
AH, Clauses: 6.4, 11.1.1, 11.2
CSA Z314-18: Clause 5

POLICIES AND PROCEDURES
Provincial Policies and Procedures

Site-specific customization of provincial policies and procedures is completed.

Additional Information
The following policies from the provincial set require customization:

- Quarantine of implantable medical devices pending biological indicator
- Positive biological indicator or failed sterilization load
- Routine Monitoring of automated cleaning/disinfection equipment used in reprocessing.
- Steam sterilizers-daily routine biological monitoring
- Routine and preventive maintenance of automated equipment used in reprocessing

The provincial AHS policy on Creutzfeldt-Jakob disease requires a site-specific policy: “All sites will develop, and adhere to, approved procedures for the quarantine and decontamination of instruments and equipment used for High-Risk Patients”.

AHS Prion Disease (Creutzfeldt-Jacob Disease) Precautions for the Surgical Patient (Adult or Child) Policy
https://extranet.ahsnet.ca/teams/policydocuments/1/clp-creutzfeldt-jacob-disease-ps-03-policy.pdf#search=cjd%20policy

Recommended Corrective Actions
Ensure all the customizable policies contain information specific to the site.

Reference
AH, Clauses: 11.1.1, 11.9
CSA Z314-18: Clause 5

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.1 Hand Hygiene

Additional Information
There is a documented policy or standard operating procedure for hand hygiene that includes when and how hand hygiene must be performed.

Hand hygiene must be performed:

- before beginning work (e.g, before clean procedures or donning personal protective equipment),
- before breaks (e.g, after handling patient care items or a risk of blood or body fluid exposure) and
- upon completion of their work duties (e.g, after handling patient care items or a risk of blood or body fluid exposure).

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure regarding hand hygiene practices.

AHS Hand Hygiene Policy
https://extranet.ahsnet.ca/teams/policydocuments/1/clp-hand-hygiene-ps-02-policy.pdf
AHS Hand Hygiene Procedure
https://extranet.ahsnet.ca/teams/policydocuments/1/clp-hand-hygiene-ps-02-01-procedure.pdf

Reference
AC, Clause: 8
AH, Clause: 11.4.2
CSA Z314-18: 6.7.1.2(b)
Health Canada. Hand Washing, Cleaning, Disinfection and Sterilization in Health Care.
Canada Communicable Disease Report, December, 1998.

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.2 Personal Protective Equipment (PPE)

Additional Information
There is a documented policy or standard operating procedure for personal protective equipment (PPE) that indicates the requirement to wear PPE when working in the decontamination area and PPE that is to be worn.

Must include details on:

- Selection of PPE for each reprocessing area. For example, PPE in decontamination work area includes:
    - gloves appropriate to the task
    - a protective gown or garment
    - full face shield, or high-filtration, fluid-impervious face mask and protective eyewear

      Note: Prescription eye glasses are not appropriate 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

  Note: Remove torn gloves immediately, follow with hand hygiene and don a new pair of gloves.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure indicating the requirement to wear PPE that should include:

- Selection of PPE for each reprocessing area. For example, PPE in decontamination work area includes:
    - gloves appropriate to the task
    - a protective gown or garment
    - full face shield, or high-filtration, fluid-impervious face mask and protective eyewear

      Note: 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

Reference
AC, Clause: 8.5, 8.8
AH, Clause: 11.4.1
CSA Z314-18: 6.7.1.2(e), 6.7.2.2
Health Canada. Hand Washing, Cleaning, Disinfection and Sterilization in Health Care. Canada Communicable Disease Report, December, 1998.
ORNAC, Section 2: Infection prevention and control, clause 2.9, 2.11 & 2.12.10

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.3 Staff Hepatitis B immunization and other applicable immunizations.

Additional Information
There is a documented policy or standard operating procedure for staff Hepatitis B immunization and other applicable immunizations. All staff are offered Hepatitis B immunization and other applicable immunizations.

Note: This does not have to be specific to MDR.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure that offers Hepatitis B immunization and other applicable immunizations.

Workplace Health and Safety Communicable Disease Assessment

Reference
AH, Clause: 11.4.1
CSA Z314-18: 6.3, 6.7.1.1
ORNAC, Section 2: Infection prevention and control, clause 2.2.3, 4.10.15

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.4 Environmental cleaning of the reprocessing area.

Additional Information
There is a documented policy or standard operating procedure for environmental cleaning of the reprocessing area, including sterile storage.

Must indicate frequency and requirement for documentation:

- cleaning of walls, ceilings, vents, light fixtures at least every six months
- cleaning of floors, horizontal work surfaces and counters at least daily

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure indicating frequency and documentation of environmental cleaning that includes:

- cleaning of walls, ceilings, vents, light fixtures at least every six months
- cleaning of floors, horizontal work surfaces and counters at least daily

Reference
AC, Clause: 3.7
AH, Clause 2.3.4, 11.4.2
CSA Z314-18:-18: 6.7.1.2(g), 10.2.1, 10.5 Table 10.2

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.5 Dress code for staff in the reprocessing area.

Additional Information
There is a documented policy or standard operating procedure for dress code for staff in the reprocessing area.

Dress code includes the following:

- clean attire
- clean hair-cover
- clean, unpolished nails
- no artificial nails
- no jewelry
- clean, sturdy footwear

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for a dress code that includes:

- clean attire
- clean hair-cover
- clean, unpolished nails
- no artificial nails
- no jewelry
- clean, sturdy footwear

Reference
AC, Clause: 8.7
AH, Clause: 11.4.1
CSA Z314-18: 6.3, 6.7.2.1
ORNAC, Section 2: Infection prevention and control, Clause: 2.9

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.6 Prevention of staff exposure to blood and body fluids (e.g, splashes or sharps injuries).

Additional Information
There is a documented policy or standard operating procedure for prevention of staff exposure to blood and body fluids (e.g, splashes or sharps injuries).

Includes:

- removing and disposing of single-use sharps, at point of use
- safe work practices (e.g, never reaching blindly into instrument sets)
- handling glass or fragile objects with care
- wearing personal protective equipment appropriate to the task

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure 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 (e.g, never reaching blindly into instrument sets)
- handling glass or fragile objects with care
- wearing personal protective equipment appropriate to the task

AHS Policy for Occupational Exposure to Blood and Body Fluids
https://extranet.ahsnet.ca/teams/policydocuments/1/clp-ahs-pol-occupational-exposure.pdf

Reference
AH, Clause: 11.4.1
CSA Z314-18: 6.7.3, 11.2.3,
ORNAC, Section 4: Risk Management and Occupational Health and Safety, clause 4.12

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.7 Follow-up of staff exposure to blood and body fluids (e.g, splashes or sharps injuries).

Additional Information
There is a documented policy or standard operating procedure for follow-up of staff exposure to blood and body fluids (e.g, splashes or sharps injuries).

Includes:

- immediate first aid
- notification of supervisor
- where to find instructions on follow-up

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure that describes procedures that are followed after staff exposures to blood and body fluids (e.g, splashes or sharps injuries) that includes:

- immediate first aid
- notification of supervisor
- where to find instructions on follow-up

AHS Occupational Exposure to Blood and Body Fluids Policy
https://extranet.ahsnet.ca/teams/policydocuments/1/clp-ahs-pol-occupational-exposure.pdf

Reference
AH, Clause: 11.4.1
CSA Z314-18: 6.7.1, 6.7.2, 6.7.4
ORNAC, Section 4: Risk Management and Occupational Health and Safety, clause 4.12

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.8 Management of health status of staff to prevent contamination of devices and to protect workers.

Additional Information
There is a documented policy or standard operating procedure for management of health status of staff to prevent contamination of devices and to protect workers.

Addresses the following issues:

- Symptomatic for communicable disease (acute gastrointestinal, respiratory infections, and exudative skin lesions).

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for the management of staff health status that should include management of:

Staff who are symptomatic for communicable disease (acute gastrointestinal, respiratory infections, and exudative skin lesions).

Reference
AH, Clause: 11.4.1
CSA 314-18: 6.7.1.1 (b) (v, vii), 6.7.1.3

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.9 Waste management including disposal of contaminated sharps and biomedical wastes.

Additional Information
There is a documented policy or standard operating procedure for waste management including disposal of contaminated sharps and biomedical wastes.

Must include instructions on how staff dispose of sharps and biomedical waste.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for the management of sharps and biomedical wastes disposal. This must include instructions on how staff disposes of sharps and biomedical wastes.

Reference
AHS Biomedical Waste Procedure
https://extranet.ahsnet.ca/teams/policydocuments/1/clp-prov-esm-biomedical-waste-procedure-esm-01-01.pdf
AH, Clauses: 5.1.1, 11.4.2
CSA Z314-18: 4.2, 6.6.2, 6.7.1, 6.7.4

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.10 Prohibiting activities such as eating, drinking, storing food, smoking, and applying cosmetics or handling of contact lenses in work areas.

Additional Information
There is a documented policy or standard operating procedure for prohibiting activities such as eating, drinking, storing food, smoking, applying cosmetics or handling of contact lenses in work areas.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure that prohibits activities that put patients or staff in reprocessing areas at risk of exposure to communicable diseases. These activities include, but are not limited to:

- eating
- drinking
- storing food
- applying cosmetics
- handling of contact lenses

Reference
AC, Clause: 8.6

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.11 Reprocessing (cleaning and sterilization) of reusable critical medical devices.

Additional Information
There are documented policies or standard operating procedures for reprocessing (cleaning and sterilization) of reusable critical medical devices, including a statement that:

- Newly purchased devices shall be reprocessed before initial use, unless packaged and sterilized by the manufacturer.
- Devices that come from an opened or compromised package shall be reprocessed prior to use.

Indicates that reusable critical medical devices must be cleaned and sterilized in accordance with manufacturer's written instructions before each use.

Note to Reviewer: examples of critical devices include, but are not limited to:

- *surgical instruments*
- *dental devices that penetrate soft tissue or bone (e.g, bone chisels, forceps, scalpels, scalers, burs)*
- *hand pieces, including dental*
- *endoscopes that penetrate sterile tissue (e.g, arthroscopes, cystoscopes, laparoscopes)*
- *reusable accessories (endoscopic or other) that penetrate sterile tissue (e.g, cytology brushes, biopsy forceps, cutting devices)*
- *multi-client reusable foot care devices*

All areas that *use* critical devices *must* have this policy or standard operating procedure.

This item is N/A if the area is *neither:*

- using critical devices
- reprocessing critical devices

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure that reusable critical medical devices must be cleaned and sterilized in accordance with manufacturer's written instructions before each use.

Examples of critical devices include, but are not limited to:

- surgical instruments
- dental devices that penetrate soft tissue or bone (e.g, bone chisels, forceps, scalpels, scalers, burs)
- hand pieces, including dental
- endoscopes that penetrate sterile tissue (e.g, arthroscopes, cystoscopes, laparoscopes)
- reusable accessories (endoscopic or other) that penetrate sterile tissue (e.g, cytology brushes, biopsy forceps, cutting devices)
- multi-client reusable foot care devices

Reference
AC, Clause: 9.0 and 10.0
AH, Clauses: 4.2; 4.3, 8.1, 11.2.1.1
CSA Z314-18: 4.1, 7.1; 8.1.6; 17.5.3.1

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.12 Reprocessing (cleaning and high-level disinfection) of reusable semi-critical medical devices.

Additional Information
There is a documented policy or standard operating procedure for reprocessing (cleaning and high-level disinfection) of reusable semi-critical medical devices. Indicates that reusable semi-critical medical devices must be cleaned and at a minimum high-level disinfected in accordance with manufacturer's written instructions before each use.

Examples of semi-critical devices include, but are not limited to:

- respiratory devices
- anaesthetic circuit components
- endovaginal, transesophageal echocardiogram (TEE) probes
- 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)
- diagnostic lenses in Ophthalmology Clinic areas

All areas who *use* semi-critical devices *must* have this policy or standard operating procedure.

This item is N/A if the area is *neither:*

- using semi-critical devices
- reprocessing semi-critical devices

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure stating that reusable semi-critical medical devices must be cleaned and at least high-level disinfected in accordance with manufacturer's written instructions before each use.

Examples of semi-critical devices include, but are not limited to:

- respiratory devices
- anesthetic circuit components
- endovaginal, transesophageal echocardiogram (TEE) probes
- 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)
- diagnostic lenses in Ophthalmology Clinic areas

Reference
AH, Clause: 7.1, 11.2.1.1
CSA Z314-18: 4.1, 7.1

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.13 Record and document retention.

Additional Information
There is a documented policy or standard operating procedure for record and document retention. The organizational, regional or site policy or standard operating procedure applies. Indicate in "Observed Deficiency" the time frame for record and document retention.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure that describes the organization's, region's or site's document retention process.

AHS Record Management Policy
https://extranet.ahsnet.ca/teams/policydocuments/1/clp-ahs-pol-records-management.pdf

AHS Records Retention Schedule (1133-01)
http://www.albertahealthservices.ca/assets/info/hp/him/if-hp-him-records-retention-schedule.pdf

Reference
AC, Clause: 13.3
AH, Clause 11.6
CSA Z314-18: 5.7.1

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.14 Evaluation and purchasing of reusable medical devices, reprocessing equipment, and supplies or consumables.

Additional Information
There is a documented policy or standard operating procedure for evaluation and purchasing of reusable medical devices, reprocessing equipment, and supplies or consumables.

Should include:

- Manager/purchaser consults appropriate personnel before purchase. This includes, as applicable to the purchase: MDR, Infection Prevention and Control, Workplace Health and Safety, End user department, Patient Services, Support Services (Environmental Services, Linen Services, etc.) and Biomedical Engineering or Facilities Maintenance and Engineering.
- Review of validated manufacturer's written instructions. They must match the processes in the MDR area and have the following components:
    - reprocessing before initial use, unless packaged and sterilized by the manufacturer
    - manufacturer's instructions for use for the methods used
    - disassembly (if required)
    - cleaning (ensure method used is compatible with the manufacturer's instructions for use)
    - inspection
    - reassembly
    - disinfection (ensure method used is compatible with the manufacturer's instructions)
    - sterilization (ensure method used is compatible with the manufacturer's instructions)
    - reposable components, number of reprocessing cycles, and tracking method (if indicated)
    - list of single-use components
- consideration of limiting purchase of reusable difficult to clean devices, where possible

Examples are: surgical instruments, non-sterile critical and semi-critical medical devices (e.g, dental burrs), endoscopes, reprocessing equipment (e.g, washer/disinfectors, sterilizers, etc.), wrapping/packaging materials, sterilization indicators and process challenge devices, disinfectants, detergents /enzymatic cleaners.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure that applies to evaluation and purchasing of reusable medical devices, reprocessing equipment, and supplies or consumables. This should include the requirement for:

- Manager/purchaser consults appropriate personnel before purchase. This includes, as applicable to the purchase: MDR, 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
- consideration of limiting purchase of reusable difficult to clean devices, where possible

Reference
AC, Clause: 4.2, 7.1
AH, Clauses: 3.1, 3.6
CSA Z314-18: 7.1; 7.2; 8
CSA Z17664: 3.1

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.15 Contingency plans for emergency situations for sterilizer shutdown.

Additional Information
There is a documented policy or standard operating procedure for contingency plans for emergency situations for sterilizer shutdown.

Must include information on:

- who is notified,
- how to get the problem fixed,
- measures taken in the interim such as
    - cancelling affected procedures,
    - transferring reprocessing to another department,
    - preparing devices for transport, etc.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure (contingency plan) for emergency situations for sterilizer shutdown (e.g, backup sterilization arrangement with outside facility, surgery shutdown, etc.).

Reference
AC, Clause: 7.5
AH, Clause 11.4.6
CSA Z314-18: 18.1.1
CSA Z314.23-16, Clause: 13.2

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.16 Contingency plans for emergency situations for automated equipment shutdowns.

Additional Information
There is a documented policy or standard operating procedure for contingency plans for emergency situations for automated equipment shutdowns.

Must include information on:

- who is notified,
- how to get the problem fixed, and
- measures taken in the interim such as
    - cancelling affected procedures,
    - transferring reprocessing to another department,
    - preparing devices for transport, etc.

Examples of automated equipment include washer or disinfector, ultrasonic cleaners, pasteurizer, GUS, DI probe reprocessing units, etc.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure (contingency plan) for shutdown of automated equipment (e.g, manual cleaning).

Examples of automated equipment are: washer/disinfectors, ultrasonic cleaners, pasteurizers, automated endoscope reprocessors (AER), etc.

Reference
AH, Clause 11.4.6
CSA Z314-18: 18.1.1

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.17 Contingency plans for emergency situations as a result of steam, water or other utility interruptions.

Additional Information
There is a documented policy or standard operating procedure for contingency plans for emergency situations as a result of steam, water or other utility interruptions.

Must include information on:

- who is notified,
- how to get the problem fixed,
- measures taken in the interim such as
    - cancelling affected procedures,
    - transferring reprocessing to another department,
    - preparing devices for transport, etc.

Examples of utility interruptions include heating, ventilation, air conditioning (HVAC) failure, boil water advisory, etc.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure (contingency plan) for steam, water or other utility interruptions.

Examples of utility interruptions include heating, ventilation, air conditioning (HVAC) failure, boil water advisory, etc.

Reference
AC, Clause: 7.5
AH, Clause 11.4.6
CSA Z314-18: 18.1.1

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.18 Contingency plans for large scale inventory loss (e.g, situations involving excessive humidity in sterile storage areas).

Additional Information
There is a documented policy or standard operating procedure for contingency plans for large scale inventory loss (e.g, situations involving excessive humidity in sterile storage areas).

Must include information on:

- who is notified,
- how to get the problem fixed,
- measures taken in the interim such as
    - cancelling affected procedures,
    - transferring reprocessing to another department,
    - preparing devices for transport, etc.

Examples of large scale inventory loss include:

- sterile storage conditions resulting in condensation in packs (extremes of temperature or humidity),
- discarding of devices due to Creutzfeldt-Jakob disease cases,
- flooding, fire or other natural disaster and
- other source of contamination to majority of devices.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure (contingency plan) for large scale inventory loss.

Reference
AH, Clause 11.4.6
CSA Z314-18: Table A.1, 4.2.1

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.19 Handling and management of loaned, shared or leased (e.g, clinician or vendor supplied) critical and semi-critical medical devices.

Additional Information
There is a documented policy or standard operating procedure for handling and management of loaned, shared or leased (e.g, clinician or vendor supplied) critical and semi-critical medical devices.

Includes:

- Receiving and following written manufacturer's reprocessing instructions
- Receiving devices in a timely manner to allow for reprocessing at the site before use
- Inspection of received devices

If an area does not routinely accept loaned, shared or leased devices, they must have a policy or standard operating procedure that states this.

Note: devices that travel with physicians or other clinicians are clinician supplied devices and are applicable to this item. Vendor supplied devices for trials or evaluations are also applicable to this item

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure 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 before use

AHS Management of Loaned and Reusable Medical Devices Policy
https://extranet.ahsnet.ca/teams/policydocuments/1/clp-management-loaned-reusable-medical-devices-policy-ps-91.pdf

Reference
AC, Clause: 7.3
AH, Clause: 11.2.1.8, 11.6.3
CSA-Z314-18: 9

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.20 Transporting contaminated items to the reprocessing area.

Additional Information
There is a documented policy or standard operating procedure for transporting contaminated items to the reprocessing area.

Must:

- removing of gross soil (e.g, blood clots, feces, etc.) at point of use
- removing 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
- labelling or coding of transport containers to indicate contaminated contents

Note: Labelling must be cleanable. Manufacturer's labels or stickers should be removed before first use.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for contaminated devices/equipment transport to the reprocessing area.

Standard operating procedure must include:

- removing of gross soil (e.g, blood clots, feces, etc.) at point of use
- removing 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

Reference
AH, Clause: 5.2, 5.3
CSA Z314-18: 11.2, 11.37

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.21 Inspection, identification and disposal of damaged/defective devices.

Additional Information
There is a documented policy or standard operating procedure for inspection, identification, and disposal of damaged or defective devices that includes labelling, repair, disposal, etc. Inspection of returned repaired items also occurs.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for inspection, identification and disposal of damaged equipment that includes labeling, repair, disposal, etc.

Reference
AH, Clauses: 4.2, 4.4
CSA Z314-18: 5.7.6.2, 14.3.3

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.22 Specifying management and staff responsibilities specific to MDR, including endoscope reprocessing.

Additional Information
There is a documented policy or standard operating procedure for specifying management and staff responsibilities specific to MDR.

Must indicate who is responsible for various functions within the area, for all steps of reprocessing, including endoscopes.

- Management
- Staff

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure that specifies management and staff responsibilities specific to MDR.

Reference
AC, Clause: 2.4; 5.0; 7.1
AH, Clauses: 10.1; 11.5.2
CSA Z314-18: 6.4, 6.5

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.23 Specifying management and staff qualifications, education and training specific to MDR, including endoscope reprocessing.

Additional Information
There is a documented policy or standard operating procedure for specifying management and staff qualifications, education and training specific to MDR.

Indicates education, certification and training qualifications of staff involved in MDR, for all steps of reprocessing, including endoscopes.

Policy states

- Personnel in a developmental role and are not yet certified must be directly supervised by an individual who is certified in one of the recognized certification programs.
- Personnel who have not been fully trained and/or competency tested shall not reprocess critical and semi-critical medical devices unless under the direct supervision of fully trained and/or competency tested personnel.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure that specifies management and staff qualifications, education and training specific to MDR.

Reference
AC, Clause: 5.0; 7.1
AH, Clause: 10.1
CSA Z314-18: 6.2; 6.4, 6.5, 6.6

POLICIES AND PROCEDURES
SITE-SPECIFIC POLICIES AND PROCEDURES

A1.24 Identification and handling of devices that are known to be difficult to clean.

Additional Information
There is a documented policy or standard operating procedure for identification and handling of devices that are known to be difficult to clean.

Includes:

- 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 them that follow manufacturer's instructions
- having device specific reprocessing procedures available for staff

Note: Difficult to clean devices should be manually cleaned unless automated methods have been proven to be more effective.

Examples of difficult to clean devices are:

- minimally invasive surgical instruments (laparoscopes, etc.)
- biopsy forceps
- reamers
- devices with lumens, etc.

Recommended Corrective Actions
Develop, update or obtain a written policy for identification and handling of devices that are known to be difficult to clean. This must 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 (laparoscopes, etc.)
- biopsy forceps
- reamers
- devices with lumens, etc.

Reference
AH, Clause: 11.2.1.2
CSA Z314-18: 11.6.5.2.3, 8.1.5, 8.2.3

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.25 Cleaning of medical devices, including endoscopes, according to manufacturer's written instructions.

Additional Information
There is a documented policy or standard operating procedure for cleaning of medical devices, according to manufacturer's written instructions.

The policy contains a statement that medical devices shall be cleaned using an automated process whenever possible.

Steps include:

- pre-cleaning
- disassembly (where applicable)
- sorting and soaking
- cleaning
- physical removal of soil
- rinsing
- drying
- lubricating
- inspecting of devices for cleanliness and functionality (e.g, wear, damage and mechanical defect)
- reassembly, if required by manufacturer's instructions for use

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for cleaning of medical devices according to the manufacturer's written instructions, including:

- pre-cleaning
- 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, if required by manufacturer's instructions for use, in a clean and dry area

Reference
AC, Clause: 7.0; 9.0
AH, Clauses: 6.4, 6.9, 6.12, 11.2.1.1, 11.2.1.2
CSA Z314-18: 11

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.26 Each method of sterilization used, according to manufacturer's written instructions.

Additional Information
There is a documented policy or standard operating procedure for each method of sterilization used, according to manufacturer's written instructions. Policy or standard operating procedure for each method of sterilization used in the area. This may include:

- steam
- ethylene oxide (ETO)
- hydrogen peroxide gas plasma
- liquid chemical (Steris System 1®)
- other approved methods of sterilization (as indicated on page one)

This may be one general standard operating procedure for all methods that indicates that manufacturer's instructions for use are followed.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure stating that each sterilization process used is in accordance with the manufacturer's written instructions.

Develop, update or obtain a policy or standard operating procedure 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 (as indicated on page one)

Reference
AC, Clause: 10.0
AH, Clauses: 8.4.1, 8.4.2
CSA Z314-18: 16.1

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.27 Packaging of reusable critical medical devices according to manufacturer's written instructions.

Additional Information
There is a documented policy or standard operating procedure for packaging of reusable critical medical devices according to manufacturer's written instructions.

Must include:

- use of packaging appropriate to the sterilization method
- inclusion of chemical indicators before sealing package
- correct sealing and labelling practice

Chemical integrators (Type 5) and emulators (Type 6) are types of chemical indicators. If a package is released based on monitored physical parameters and internal chemical indicator results, the internal chemical indicator shall be Type 5 or Type 6.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for packaging of critical medical devices before sterilization that includes:

- use of packaging appropriate to the sterilization method
- inclusion of chemical indicators before sealing package
- correct sealing and labeling practice

Reference
AH, Clause 8.13, 8.22, 11.2.1.1, 11.4.4
CSA Z314-18: 15.1.1, 15.1.2, 15.5.1, 15.5.2, 15.6, 15.8.3.4

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.28 Use of rigid sterilization container systems.

Additional Information
There is a documented policy or standard operating procedure for use of rigid sterilization container systems.

Includes details on:

- 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
- labelling
- decontamination of containers
- storage

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for rigid sterilization container systems. Standard operating procedure includes:

- 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

Reference
AH, Clause 8.13, 11.2.1.1
CSA Z314-18: 15.9

POLICIES AND PROCEDURES
Site-specific Policies and Procedures

A1.29 Quarantine of implantable medical devices pending biological indicator results.

Additional Information
There is a documented policy or standard operating procedure for quarantine of implantable medical devices pending biological indicator results.

Policy includes:

- Early release of implants shall not be used to compensate for inventory shortages or scheduling problems.
- Early release of implants shall only be done in situations where there is an urgent, unplanned need (e.g., trauma-related devices) and if an implant must be released before the biological indicator test results are available, the following shall apply:
    - Evaluation of a Type 5 or Type 6 chemical indicator in the biological indicator PCD, the specific cycle physical parameters, and any visible chemical indicators shall be assessed and the results documented.
    - Information identifying the implant and the client it was used on shall be documented.
    - A report shall be prepared, reviewed, and maintained according to the organization's risk management policy and shall contain the:
        - client's identifier;
        - implant identification number;
        - surgeon's name;
        - time and date of the procedure;
        - results of any physical or chemical indicators used in the sterilization process; and
        - results of the biological indicator once they are known.
    - For steam sterilization, if a Type 5 or 6 chemical indicator is also used to monitor an implant load, the results shall be interpreted before a load is released.

If a package is released based on monitored physical parameters and internal chemical indicator results, the internal chemical indicator shall be Type 5 or Type 6.

Note: Type 5 and Type 6 internal chemical indicators measure all critical parameters for steam sterilization and provide additional quality assurance for monitoring medical devices. Other types of internal chemical indicators might not be designed to measure all critical parameters, so deviations in critical variables might go undetected.

Recommended Corrective Actions
Packages containing implantable devices are not released until the biological indicator result is obtained (e.g, is negative).

Reference
AC, Clause: 9.15
AH, Clauses: 8.19.5. 8.22
CSA Z314-18: 16.6.6, 16.6.11.1

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.30 Positive biological indicator or failed sterilization load.

Additional Information
There are documented policies or standard operating procedures for positive biological indicator or failed sterilization load.

Must 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 biological indicator

Possible sterilization failures may include:

- wet load
- failed mechanical parameters
- failed chemical indicators
- equipment failure
- human error

Recommended Corrective Actions
Develop, update or obtain written policies or standard operating procedure for positive biological indicator or failed sterilization load that includes:

- the person responsible to notify the manager or designate,
- notification of IPC personnel or designate and
- the process to recall and isolate all loads done since the last negative biological indicator.

Reference
AC, Clause: 14.4; 14.5; 14.6, 14.7
AH, Clauses: 8.25, 11.2.1.5, 11.2.1.7
CSA Z314-18: 5.7.7.1, 16.6.12, 16.6.13

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.31 Immediate use steam sterilization (IUSS)

Additional Information
There are documented policies or standard operating procedures for immediate use steam sterilization (IUSS).

Must:

- include the requirement for cleaning of device before immediate use steam sterilization
- outline the steps to be taken for immediate use steam sterilization
- include documentation requirements for immediate use steam sterilization

Documentation for immediate use steam sterilization includes:

- sterilizer identifier
- load number
- date and time of cycle
- results of chemical indicators and mechanical indicators of physical parameters (e.g, time, temp, etc.)
- load contents
- identification of person responsible for indicators and load release
- patient name and ID number
- surgeon's name
- reason for immediate use steam sterilization

Immediate use steam sterilization must not be used for routinely scheduled procedures or to compensate for lack of inventory, and is never performed for implantable devices.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure stating immediate use steam sterilization (IUSS) must 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 or standard operating procedure for immediate use steam sterilization (IUSS) that includes the requirement for cleaning of devices before IUSS and outlines the steps to be taken for IUSS, including documentation requirements.

Reference
AC, Clause: 7.4
AH, Clause: 8.26-28
CSA Z314-18: 16.7

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.32 Use and maintenance of containers designed for immediate use steam sterilization according to manufacturer's written instructions.

Additional Information
There is a documented policy or standard operating procedure for use and maintenance of containers designed for immediate use steam sterilization according to manufacturer's written instructions.

Includes proper use and maintenance of containers (e.g, Flashpak®).

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure that include proper use and maintenance of containers used for immediate use steam sterilization (e.g, Flashpak®).

Reference
AH, Clause: 11.2.1.1
CSA Z314-18: 16.7.5.2

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.33 Chemical high-level disinfection of semi-critical medical devices, including endoscopes.

Additional Information
There is a documented policy or standard operating procedure for chemical high-level disinfection.

Includes:

- cleaning and rinsing of devices (including endoscopes) before disinfection
- using appropriate product with a Health Canada Medical Device License, Class II
- manufacturer's written instructions, including current Safety Data Sheet (SDS)
- monitoring (including a statement that high-level disinfectant is not used beyond any expiry date or a failed minimum effective concentration test)
- documentation

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for chemical high-level disinfection that includes:

- cleaning and rinsing of devices (including endoscopes) before disinfection
- using appropriate product with a Health Canada Medical Device License, Class II
- manufacturer's written instructions, including current Safety Data Sheet (SDS)
- monitoring
- documentation

Reference
AH, Clauses: 7.1-4, 7.7.4, 11.2.1.1
CSA Z314-18: 11.7.2

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.34 Thermal high-level disinfection (e.g, pasteurizer or washer/disinfector with validated thermal disinfection cycle).

Additional Information
There is a documented policy or standard operating procedure for thermal high-level disinfection (e.g, washer/disinfector with validated thermal disinfection cycle).

Should include:

- cleaning and rinsing of devices before disinfection
- manufacturer's written instructions
- monitoring
- documentation

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for thermal high-level disinfection (e.g, washer/disinfector with validated thermal disinfection cycle) that includes:

- cleaning and rinsing of devices before disinfection
- manufacturer's written instructions
- monitoring
- documentation

Reference
AH, Clauses: 7.14-20, 11.2.1.1
CSA Z314-18: 11.8.1, 11.8.2, 11.8.3, 11.8.4

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.35 Routine monitoring of automated cleaning or disinfecting equipment used in reprocessing (e.g, lumen cleaners, ultrasonic cleaners, washer or disinfectors, pasteurizers, AER, BI incubators, sterilizers).

Additional Information
There is a documented policy or standard operating procedure for routine monitoring of automated cleaning/disinfection equipment used in reprocessing. Includes information on routine (e.g, every shift, daily, weekly, monthly, etc.) monitoring or testing of the equipment.

Examples include:

- testing ultrasonic cleaners at least weekly
- testing of washer/disinfectors daily
- testing of washer/disinfector as per manufacturer's written instructions, or using indicator such as the Test Object Surgical Instrument (TOSI)

- testing routine monitoring of AER (e.g, verifying cycle time and temperature settings are appropriate to the load contents before starting, checking fluid levels at regular intervals [daily, every shift, etc.])

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure that includes information on routine (e.g, every shift, daily, weekly, monthly, etc.) monitoring or testing of the equipment.

Examples include:

- testing ultrasonic cleaners at least weekly
- testing of washer/disinfectors daily
- testing of washer/disinfector as per manufacturer's written instructions, or using indicator such as the Test Object Surgical Instrument (TOSI)

- testing routine monitoring of AER (e.g, verifying cycle time and temperature settings are appropriate to the load contents before starting, checking fluid levels at regular intervals [daily, every shift, etc.])

Reference
AH, Clauses: 6.8-9. 11.2.1.4
CSA Z314-18: 11.6.5.3.4, 11.6.6.6

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.36 Sterility assurance monitoring.

Additional Information
There is a documented policy or standard operating procedure for sterility assurance monitoring.

Includes:

- monitoring of each package that is sterilized with chemical indicators:
- external
- internal
- testing the sterilizer with biological indicator each day the sterilizer is in use and for each type of cycle used
- including a biological indicator 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
- instructions on performance qualification and requalification for device sets used in the facility and documentation of results.

Examples of cycle types include dynamic air removal (prevac), gravity, extended cycles, standard cycles, etc.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure 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 each day the sterilizer is in use and for each type of cycle used
- including a biological indicator 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
- instructions on performance qualification and requalification for device sets used in the facility and documentation of results.

Reference
AH, Clause: 8.10; 8.19, 8.21
CSA Z314-18: 16.5.4.1; 16.6

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.37 Routine monitoring of reusable chemical high-level disinfectant minimum effective concentration at least daily.

Additional Information
There is a documented policy or standard operating procedure for routine monitoring of reusable chemical high-level disinfectant minimum effective concentration at least daily.

Minimum effective concentration testing of **reusable** chemical high-level disinfectant should include:

- frequency (minimum each day the disinfectant is used)
- method of testing
- documentation requirement

This is N/A for single-shot disinfectant from an individual container or large container source (Trophon, Innova, some Medivators, etc.)

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for routine monitoring of reusable chemical high-level disinfectant that includes:

- frequency (e.g, minimum each day the disinfectant is used)
- method of testing minimum effective concentration
- documentation requirement

Reference
AC, Clause: 9.7
AH, Clause: 7.7
CSA Z314-18: 11.7.2.4.2

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.38 Routine maintenance of automated equipment used in reprocessing (e.g, lumen cleaners, ultrasonic cleaners, washer or disinfectors, pasteurizers, air handling systems, AER, probe reprocessors, BI incubators, sterilizers).

Additional Information
There is a documented policy or standard operating procedure for routine maintenance of automated equipment used in reprocessing.

Includes information on:

- what routine (user provided) maintenance is required on each piece of equipment (e.g, cleaning, water level checks, descaling, etc.)
- frequency of routine maintenance (e.g, every shift, daily, weekly monthly, etc.)
- who performs routine maintenance
- documentation of routine maintenance

This applies to all automated equipment including, but not limited to: Steam Sterilizer(s), HP Gas Plasma Sterilizer(s), ETO Sterilizer(s), Steris System 1, Steam BI Incubator, HP Gas Plasma BI Incubator, ETO BI Incubator, Steris System 1 BI Incubator, Washer Disinfectors, Pasteurizer, Ultrasonic cleaner, Air handling Systems (e.g, GUS), Automated Lumen Cleaners, DI probe reprocessing unit, Fume Hoods, and Automated Endoscope Reprocessors (AER).

Routine maintenance may include:

- cleaning or wiping external surfaces of automated equipment at regular intervals
- maintaining water reservoir in table top steam sterilizers
- regular bleaching cycles of lumen cleaners
- regular inspection of filters, gaskets, etc.
- descaling of sterilizer chamber
- inspection of chamber drain

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure 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

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.2.1.4
CSA Z314-18: 18

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.39 Preventive maintenance of all automated equipment used in reprocessing (e.g, lumen cleaners, ultrasonic cleaners, washer or disinfectors, pasteurizers, air handling systems, AER, probe reprocessors, BI incubators, sterilizers).

Additional Information
There is a documented policy or standard operating procedure for preventive maintenance of all automated equipment used in reprocessing.

Includes information on:

- frequency of preventive maintenance
- who performs preventive maintenance
- documentation of preventive maintenance and any testing required

Note: preventive maintenance is usually done annually or every six months.

This applies to all automated equipment, including:

- Steam Sterilizer(s)
- HP Gas Plasma Sterilizer(s)
- ETO Sterilizer(s)
- Steris System 1
- Steam BI Incubator
- HP Gas Plasma BI Incubator
- ETO BI Incubator
- Trophon
- Washer Disinfectors
- Pasteurizer
- Ultrasonic cleaner
- Air handling System
- Automated Lumen Cleaners
- Fume Hoods
- Automated Endoscope Reprocessors (AER)

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for preventative maintenance of all automated equipment used in reprocessing that includes information on:

- frequency of preventive maintenance
- who performs preventive maintenance
- documentation of preventive maintenance and any testing required

Reference
AC, Clause: 4.5; 4.6
AH, Clauses: 11.6.1, 11.2.1.4
CSA Z314-18: 5.7.6.2

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.40 Receiving, investigating and follow-up of customer concerns.

Additional Information
There is a documented policy or standard operating procedure for receiving, investigating and follow-up of customer concerns.

This would include:

- methods that users of medical devices contact reprocessing department with concerns
- how concerns are addressed
- how concerns are documented

Customers include:

- end-user (OR, DI, Clinics, Units, etc.)
- patients

Customer concerns may include:

- reports by end user of:
  - dirty instrument
  - wet packs
- chemical indicator failure, etc.
- reports of patient injury such as: chemical burns

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure describing how users contact the MDR department with concerns, and how concerns are addressed and documented.

Reference
AC, Clause: 15.2; 15.3
CSA Z314-18: 5.2.3

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.41 Periodic testing of water used for reprocessing of medical devices.

Additional Information
There is a documented policy or standard operating procedure for periodic testing of water used for reprocessing of medical devices. This is required for all areas using ultrasonic cleaners, automated washer disinfectors or steam sterilizers. The policy or standard operating procedure emphasizes the importance of making sure the water source meets the equipment manufacturer's specifications for water and steam quality.

Testing of water **may** include:
- microorganisms
- endotoxins for:
    - RO
    - distilled
- total organic carbon
- pH for:
    - potable
    - softened
- hardness
- resistivity for:
    - deionized
    - RO
    - distillation
- chloride content
- iron content
- copper content
- manganese content
- colour and turbidity

Policy indicates:
- type of water used
- frequency of testing
- who performs testing

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure 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.

Reference
AH, Clause: 2.2.8
CSA Z314-18: Annex G

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

A1.42 Evaluation and response to incidents of temperature and humidity extremes in the sterile storage areas.

Additional Information
There is a documented policy or standard operating procedure for evaluation and response to incidents of temperature and humidity extremes in the sterile storage areas.

Policy or standard operating procedure includes:

- Evaluation
  - measured and recorded daily

- Response to extremes. Acceptable ranges are:
  - Temperature: 18 – 23°C
  - Humidity: 30 – 60%

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for evaluation and response to incidents of temperature and humidity extremes in the sterile storage areas. Temperature (18 – 23°C) and humidity (30 – 60%) is measured and recorded daily.

Reference
AC, Clause: 3.5
AH, Clause: 11.4.3, 11.4.6
CSA Z314-18: Annex Q

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

E1.20 Shelf-life of semi-critical flexible endoscopes.

Additional Information
There is a documented policy or standard operating procedure for shelf-life of semi-critical flexible endoscopes. Unused channeled flexible endoscopes should be reprocessed (cleaning plus high-level disinfection or unwrapped sterilization) before use after seven days storage.

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for shelf-life of semi-critical flexible endoscopes.

- unused gastrointestinal endoscopes shall be fully reprocessed after seven days of storage
- unused bronchoscopes, if sterilization is not possible, shall be reprocessed before patient-use if stored seven days or more since last being reprocessed

Reference
AH, Clause: 11.2.1.2
CSA Z314.8-14, Clause: 11.1.2; 11.7.12.5; 11.8.1; Table 2 (p. 52)
SGNA Storage p. 25, para 5, para 6 item e

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

E1.24 Cleaning of endoscopes, as per manufacturer's written instructions.

Additional Information
There is a documented policy or standard operating procedure for cleaning and storage of endoscopes, as per manufacturer's written instructions (high-level disinfection steps are addressed in another policy).

Steps include:

- point of use pre-cleaning
- disassembly
- leak testing
- cleaning
- sorting and soaking
- physical removal of soil
- rinsing
- drying
- inspection of devices for cleanliness and functionality (e.g, wear, damage and mechanical defect)
- seven day shelf-life and cabinet components

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure 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)
- seven day shelf-life and cabinet components

Reference
AC, Clause: 7.0; 7.6; 7.7; 9.0, 9.2; 9.3; 9.4; 9.5; 9.7; 9.8; 9.9; 11.0; 11.4; 11.5; 11.6; 11.7
AH, Clause: 11.2.1.2
CSA Z314.8-14, Clause: 11.1.2; 11.1.3; 11.7.1.2
CSA Z314.0-13, Clause: 4.4.2; 5.3; 8.1.7; 8.2.1
SGNA, p.13-26

POLICIES AND PROCEDURES
Site-Specific Policies and Procedures

E1.28 Ensuring traceability of flexible endoscopes and endocavity probes used on each patient.

Additional Information
There is a documented policy or standard operating procedure for ensuring traceability of flexible endoscopes and endocavity probes used on each patient.

Includes keeping documentation of:

- date endoscope/probe was used
- patient identification
- the serial number or other identifier of the endoscope/probe used in procedure

Recommended Corrective Actions
Develop, update or obtain a written policy or standard operating procedure for traceability of flexible endoscopes used on each patient that includes the requirement for documentation of:

- date endoscope/probe was used
- patient identification
- the serial number or other identifier of the endoscope/probe used in procedure

Reference
AC, Clause: 11.9
AH, Clause: 11.6.4
CSA 314-18: 12.4.2 (endoscopes) and 13.3.2 (U/S Probes)
SGNA, (Quality Assurance para 1-3)

POLICIES AND PROCEDURES
General Policies and Procedures

Reprocessing policies and procedures are readily accessible for staff.

Additional Information
The site demonstrates easy access to this set of policies and procedures.

Recommended Corrective Actions
Ensure easy access to this set of policies and procedures.

Reference
AH, Clause: 11.7
CSA Z314-18: Clause 5

POLICIES AND PROCEDURES
General Policies and Procedures

Reprocessing policies and procedures are periodically reviewed, according to organizational requirements, and updated earlier when there is a change in practice.

Additional Information
These policies and procedures are considered Practice Documents by AHS Policy Development, and as such, are reviewed and updated periodically according to organizational/department processes.

Recommended Corrective Actions
Ensure policies and procedures are dated and reviewed periodically according to organizational/department processes.

Reference
AH, Clause 11.5
CSA Z314-18: Clause 5

POLICIES AND PROCEDURES
Manufacturer's Instructions for Use

Manufacturer's written instructions are available for reprocessing of medical devices (including endoscopes) being decontaminated, high-level disinfected or sterilized in the area.

Additional Information
Check manufacturer's instructions for two types of endoscopes (if used).

Note: CSA reinforces that the manufacturer's instruction for use for some endoscope parts (e.g, caps, valves) require ultrasonic cleaning and sterilization (rather than high-level disinfection).

Check manufacturer's instructions for two general medical devices such as:

- respiratory masks (CPAP, LMA, etc.) - watch for reposability, single-use parts
- lumened device
- devices processed by different methods (steam, Sterrad, high-level disinfection, etc.)

Detailed instructions must match the processes in the area and have the following components:

- validated manufacturer's instructions for use for the methods used
- disassembly (if required)
- cleaning (ensure method used is compatible with the validated manufacturer's instructions for use)
- inspection
- reassembly
- disinfection (ensure method used is compatible with the validated manufacturer's instructions for use)
- sterilization (ensure method used is compatible with the validated manufacturer's instructions for use)
- reposable components
    - number of reprocessing cycles
    - tracking method (if indicated)
- single-use components

Manufacturer's instructions include, if applicable, a statement that:
- newly purchased devices shall be reprocessed before initial use (unless they come packaged and sterilized by the manufacturer).
- devices that come from an opened or compromised package shall be reprocessed prior to use.

Recommended Corrective Actions
Obtain and file (electronically or on paper) validated manufacturer's written instructions.

Reference
AC, Clause: 7.6; 7.7; 7.10; 9.0
AH, Clauses: 4.2, 4.3, 6.4, 7.1, 8.4, 11.2.1.6, 11.4.4, 11.7
CSA Z314-18: 7.1

EDUCATION AND TRAINING
Qualifications

Managers directly accountable for reprocessing shall have proven knowledge of reprocessing practices and infection prevention and control principles as they relate to MDR in their area.

Additional Information
Documentation should indicate education and training of management involved in MDR, for all steps of reprocessing, including endoscopes (formal training in MDR and human resources, educational seminars, in services, and training in Workplace Health and Safety and IPC).

Recommended Corrective Actions
Document all management training components.

Reference
AH, Section 10
CSA Z314-18: 6.4

EDUCATION AND TRAINING
Qualifications

Personnel employed as MDR technicians shall be certified (CSA or IAHCSMM) and maintain certification, having successfully completed a recognized medical device reprocessing technician educational program.

Additional Information
Check that current certification is available.

Recommended Corrective Actions
Ensure current certification of all MDR staff is maintained and available.

Reference
AH, Clause 10.1.1.1

EDUCATION AND TRAINING
Qualifications

In departments where MDR is NOT the primary function, any person involved in any aspect of reprocessing shall obtain education, orientation and training specific to the function they perform or medical device to be reprocessed (e.g, medical imaging technologists, respiratory/cardiac lab technicians, service workers).

Additional Information and Recommended Corrective Actions

Infection prevention and control (IPC) training is documented with the following via Centralized MDR and Decentralized MDR videos available on MyLearningLink:

- Basic microbiology, including conditions that support microbial growth, how microorganisms are spread and cause disease.
- Risks of contact with or exposure to infectious agents, including chain of infection model.
- Risks to patients (e.g, infection, complications, death) from exposure to inadequately reprocessed medical devices due to:
    - malfunctioning equipment
    - lack of knowledge
    - not following manufacturer's written instructions
    - inadequate storage and handling procedures
- Personal hygiene and hand hygiene including:
    - importance of clean skin, hair and clothing
    - when and how to use alcohol-based hand rub
    - when to and how to wash hands with soap and water
    - why handwashing sinks are dedicated for hand hygiene
- Use of personal protective equipment (PPE), including donning, doffing, and hand hygiene
- IPC and work practices to prevent staff exposure to blood and body fluids and includes prevention of :
    - needle stick injuries
    - mucous membrane exposures, etc.
- Safe work practices such as:
    - handling of glass and fragile items with care
    - not blindly sticking hands into instrument sets
    - wearing appropriate PPE, etc.
- Handling of sharps and waste management, including:
    - appropriate use of PPE
    - use of sharps disposal containers at point of use
    - discarding gross debris (feces, blood clots, etc.) at point of use, etc.
- Procedures following staff exposure to blood and body fluids
- One-way workflow practices to prevent the contamination of clean items

Reference
AC, Clause: 5.0
AH, Clause: 10.1.2, 10.1.2.1, 10.1.2.2
CSA Z314-18: 6.6

EDUCATION AND TRAINING
Training Documentation

Staff are first employed (orientation checklist).

Additional Information
Check that orientation documentation is available.

Recommended Corrective Actions
Ensure the initial orientation of staff responsible for reprocessing includes education by competent personnel on basic reprocessing principles and how to reprocess instruments, including endoscopes. Document all staff education and training.

Reference
AH, Clauses: 10.1.3, 10.1.3.1
CSA Z314-18: Clause 6.6

EDUCATION AND TRAINING
Training Documentation

Baseline and annual competency testing of staff members are completed.

Additional Information
Check that competency testing documentation is available.

Recommended Corrective Actions
Ensure the manager and staff responsible for reprocessing can demonstrate reprocessing competencies initially and at specified intervals (at least annually). Document competency testing.

Reference
AH, Clauses: 10.1.3, 10.1.3.1
CSA Z314-18: Clause 6.6

EDUCATION AND TRAINING
Training Documentation

There is an authorized change in process (policies, procedures, practices).

Additional Information
Check that in service/educational session documentation is available.

Recommended Corrective Actions
Ensure authorized process changes are communicated to the manager and staff responsible for reprocessing. Provide education and training. Document all staff education and training.

Reference
AH, Clauses: 10.1.3, 10.1.3.1
CSA Z314-18: Clause 6.6

EDUCATION AND TRAINING
Training Documentation

New or updated equipment, devices, products, and textiles are purchased.

Additional Information
Check that in-service/educational session documentation is available.

Recommended Corrective Actions
Ensure manager and staff responsible for reprocessing receive education and training on all new equipment, devices, and textiles, including information on reprocessing. Document all staff education and training.

Reference
AH, Clauses: 10.1.3, 10.1.3.1
CSA Z314-18: Clause 6.6

EDUCATION AND TRAINING
Training Documentation

MDR practices are regularly monitored and any training associated with gaps is documented.

Additional Information
This includes managers or designates conducting:

- routine review of logs, printouts, etc.
- supervision of practice

Review documentation for manager's or designates signature/initials on items reviewed.

Ask what is done for practice improvement to address gaps, and request documentation.

Recommended Corrective Actions
Ensure that reprocessing practices are monitored on a regular basis and a method of follow-up is in place to remedy non-compliance.

Document monitoring; examples of monitoring methods include managers or designates signature/initials indicating:

- routine review of logs, printouts, etc.
- supervision of practice

Document all measures to address knowledge gaps.

Reference
AC, Clause: 2.4
AH, Clauses: 10.1.3, 10.1.3.1
CSA Z314-18, 5.3.6, 5.7.1

WORKPLACE HEALTH AND SAFETY - IPC CONSIDERATIONS
Workplace Health and Safety - IPC Considerations

Eating, drinking, storing food, smoking, or applying cosmetics or personal effects does not occur in the reprocessing area.

Additional Information

Recommended Corrective Actions
Ensure that there is no eating, drinking, storing food, smoking, or applying cosmetics or personal effects occurring in the reprocessing area.

Reference
AC, Clause: 8.6
AH, Clause: 2.2.5

WORKPLACE HEALTH AND SAFETY - IPC CONSIDERATIONS
Workplace Health and Safety - IPC Considerations

Staff adhere to dress code that includes:

- **clean attire**
- **clean hair-cover**
- **clean, unpolished nails**
- **no artificial nails**
- **no jewelry**
- **clean, sturdy footwear**

Additional Information
Hair cover must be changed between dirty and clean tasks.

Recommended Corrective Actions
Ensure staff adhere to a dress code that includes:

- clean attire
- clean hair-cover
- clean, unpolished nails
- no artificial nails
- no jewelry
- clean, sturdy footwear

Reference
CSA Z314-18: 6.7.2

WORKPLACE HEALTH AND SAFETY - IPC CONSIDERATIONS
Workplace Health and Safety - IPC Considerations

Hand hygiene stations are available.

Additional Information
Hand hygiene stations include a sink with a soap dispenser and an adjacent enclosed, single-use towel dispenser or waterless alcohol-based hand rub dispenser.

Check each entrance/exit and ensure that hand hygiene stations are available.

Clean areas must have either alcohol-based hand rub dispensers or a hand hygiene sink.

Recommended Corrective Actions
Ensure there are dedicated alcohol-based hand rub dispensers in all areas.

Ensure there is a hand hygiene sink at entrance/exit to decontamination area.

Hand hygiene stations include a sink with soap and an adjacent enclosed single-use towel dispenser or waterless alcohol-based hand rub dispenser.

Reference
AH, Clauses: 2.2.3, 2.2.3.1
CSA Z314-18: 10.2.3.1

WORKPLACE HEALTH AND SAFETY - IPC CONSIDERATIONS
Workplace Health and Safety - IPC Considerations

Hand hygiene sink is available on entrance or exit to decontamination.

Additional Information
Decontamination areas must have a **dedicated hand hygiene sink** with associated soap dispenser, paper towel dispenser and waste receptacle.

Entrance or exit sink location must be within one metre of the door, on either side, ensuring no contact with the decontamination room environment.

Recommended Corrective Actions
Collaborate with Capital Management to have a hand hygiene sink installed at the decontamination room entrance/exit.

Reference
AH, Clause 2.2.3
CSA Z314-18: 10.2.3.1

WORKPLACE HEALTH AND SAFETY - IPC CONSIDERATIONS
Workplace Health and Safety - IPC Considerations

Staff perform hand hygiene at the appropriate times.

Additional Information
Hand hygiene must be performed:

- before beginning work (e.g, before clean procedures or donning personal protective equipment (PPE))
- before breaks (e.g, after handling patient care items or a risk of blood or body fluid exposure)
- upon completion of their work duties (e.g, after handling patient care items or a risk of blood or body fluid exposure)
- before putting on and after removing personal protective equipment (PPE)

Recommended Corrective Actions
Ensure staff perform hand hygiene at appropriate times:

- before beginning work (e.g, before clean procedures or donning personal protective equipment (PPE))
- before breaks (e.g, after handling patient care items or a risk of blood or body fluid exposure)
- upon completion of their work duties (e.g, after handling patient care items or a risk of blood or body fluid exposure)
- before putting on and after removing personal protective equipment (PPE)

Reference
AC, Clause: 8.5
AH, Clause: 11.4.2
CSA Z314-18: 6.7.1.2(b); 6.7.2.2.1
Health Canada. Hand Washing, Cleaning, Disinfection and Sterilization in Health Care, pp. 6-7.

WORKPLACE HEALTH AND SAFETY - IPC CONSIDERATIONS
Workplace Health and Safety - IPC Considerations

Personal protective equipment (PPE), appropriate to the task, is worn when handling or reprocessing contaminated devices (e.g, gloves, mask, protective eye wear or face shield and waterproof gown).

Additional Information

- Observe for PPE donning and doffing, with hand hygiene practices.
- PPE is worn as per hazard assessment and SDS.
- Reusable PPE shall be cleaned at least daily.

Note: Prescription eye glasses are not acceptable for eye protection.

Recommended Corrective Actions

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

Note: Prescription eye glasses are not acceptable for eye protection

Reusable PPE shall be cleaned at least daily.

Reference

AC, Clause: 8.5
AH, Clause: 11.4.2
CSA Z314-18: 6.7.2.2

WORKPLACE HEALTH AND SAFETY - IPC CONSIDERATIONS
Workplace Health and Safety - IPC Considerations

Eyewash stations are readily available where staff are exposed to chemical or biological agents.

Additional Information
These are in decontamination, high-level disinfection and chemical sterilization areas.

Recommended Corrective Actions
Ensure eyewash stations are readily available in areas where staff handle chemicals or biological contaminants, such as decontamination, and high-level disinfection and sterilization areas.

Reference
CSA Z314-18: 10.2.2.1
CSA Z8000-18: 10.7.4.8(p)

WORKPLACE HEALTH AND SAFETY - IPC CONSIDERATIONS
Workplace Health and Safety - IPC Considerations

Eyewash stations are maintained as per manufacturer's written instructions.

Additional Information
Ensure that disposable eyewash bottles are not expired.
Find out how plumbed-in eyewashes are flushed and verify procedure with manufacturer's instructions.

Recommended Corrective Actions
Ensure eyewash stations are maintained in areas where staff handle chemicals or biological contaminants and document maintenance activities for plumbed-in eyewash stations.

Reference
CSA Z314-18: 10.2.2.1
CSA Z8000-18: 10.7.4.8(p)

WORKPLACE HEALTH AND SAFETY - IPC CONSIDERATIONS
Workplace Health and Safety - IPC Considerations

There are methods in place to contain or remove toxic vapours emitted by or from disinfecting agents.

Additional Information
Methods may include:

- fume hood
- dedicated ventilation system
- keeping the reservoir for disinfectant closed at all times

Recommended Corrective Actions
Ensure there are methods in place to contain or remove toxic vapours emitted from disinfecting agents.

Reference
AC, Clause: 3.7
CSA Z314-18: 6.7.4.1.2; 10.2.4.2.1; 10.2.4.2.2; 12.4.11.1b; 13.3.12.1 (U/S Probes)

MDR AREA DESIGN
MDR Area Design

There is a designated reprocessing area that is physically separate from areas where patient care is provided.

Additional Information
Physical separation means there is a physical barrier between the MDR area and areas where patient care is provided.

Recommended Corrective Actions
Ensure that there is a designated reprocessing area that is physically separated by walls or partitions from areas where patient care is provided.

Reference
AC, Clause: 3.2; 3.3; 3.4
AH, Clauses: 2.1, 2.2.7, 2.3.3
CSA Z314-18: 10.1

MDR AREA DESIGN
MDR Area Design

Reprocessing work areas are separated by walls or partitions to control traffic and contain contaminants.

Additional Information
Physical separation means there is a physical barrier between the decontamination area and the clean area.

Recommended Corrective Actions
Ensure the reprocessing work areas (e.g, cleaning and decontamination area) are separated by walls or partitions to control traffic and contain contaminants.

Reference
AC, Clause: 3.2; 3.3; 3.4
AH, Clause: 2.2.1, 2.2.5
CSA Z314-18: 10.1

MDR AREA DESIGN
MDR Area Design

There are designated clean and soiled areas within the reprocessing work area.

Additional Information
Check to see that areas are separated spatially, with signage, walls or partitions.

Recommended Corrective Actions
Ensure areas are separated spatially, with signage, walls or partitions.

Reference
AC, Clause: 3.2; 3.3; 3.4
AH, Clause: 2.2.1
CSA Z314-18: 10.1

MDR AREA DESIGN
MDR Area Design

Area has restricted access (signage) for authorized personnel wearing appropriate attire.

Additional Information
Check that signage is posted at all entry points indicating the area is restricted to authorized personnel only.

Recommended Corrective Actions
Ensure signage is posted at all entry points indicating the area is restricted to authorized personnel only.

Reference
AC, Clause: 3.3
AH, Clause: 2.2.5
CSA Z314-18: 10.2.1.1.1

MDR AREA DESIGN
MDR Area Design

One-way workflow occurs from dirty to clean to prevent cross-contamination.

Additional Information
One-way workflow is the practice of performing duties from dirty to clean.

Recommended Corrective Actions
Ensure the reprocessing space has one-way workflow from dirty to clean to prevent cross-contamination.

Reference
AC, Clause: 3.1, 3.2; 3.3; 3.4
AH, Clause: 2.2.6
CSA Z314-18: 10.1

MDR AREA DESIGN
MDR Area Design

Surfaces (walls, ceilings and work surfaces) are composed of non-porous, non-shedding material that can withstand frequent cleaning.

Additional Information
For both decontamination and clean areas, inspect walls and ceilings and work surfaces to ensure they are clean, intact and non-porous.

Examples of porous surfaces are:

- acoustic ceiling tiles
- unfinished or worn surfaces
- damaged walls (gouges, chipped paint, etc.)

Recommended Corrective Actions
Ensure all walls, ceilings and work surfaces are intact and composed of non-porous, non-shedding material capable of withstanding frequent cleaning.

Reference
AC, Clause: 3.6
AH, Clause: 2.2.4
CSA Z314-18: 10.2.1.4, 10.2.1.5

MDR AREA DESIGN
MDR Area Design

There are no exposed pipes or duct work above work surfaces (i.e. inaccessible to frequent cleaning).

Additional Information
Exposed pipes above work surfaces must be enclosed to facilitate cleaning. Above work surfaces refers to pipes or fixtures that are inaccessible to frequent cleaning or those that cannot be cleaned given the surface of pipe or fixture.

Recommended Corrective Actions
Cover pipes or fixtures above work surfaces that are inaccessible to frequent cleaning or cannot be cleaned.

Reference
AHS MDR Exposed Pipes Policy
AC, Clause: 3.6
CSA Z314.0-13, Clause: 7.2.9(b); 7.2.10.3
CSA Z8000-11, Clause: 10.7.4.8.3(b); 10.7.4.8.4(e)

MDR AREA DESIGN
MDR Area Design

Flooring can withstand frequent cleaning.

Additional Information
For both decontamination and clean areas, inspect flooring to ensure it is clean, intact and non-porous.

Recommended Corrective Actions
Ensure floors are clean, intact and non-porous and capable of withstanding frequent cleaning.

Reference
AH, Clauses: 2.2.4
CSA Z314-18: 10.2.1.2

MDR AREA DESIGN
MDR Area Design

Reprocessing work areas have doors that are kept closed.

Additional Information
Mark as deficient if there are no doors or if they are open.

Recommended Corrective Actions
Ensure reprocessing area has doors that are kept closed.

Reference
AC, Clause: 3.4
AH, Clause: 2.2.5
CSA Z314-18: 10.2.1.3

MDR AREA DESIGN
MDR Area Design

Clean, high-level disinfected or sterile medical devices are stored in a clean and secure area.

Additional Information
There is no storage of clean, disinfected, or sterile devices in decontamination areas. Storage areas may be in a dedicated area on the clean side of MDR.

Recommended Corrective Actions
Ensure clean, high-level disinfected or sterile devices are not stored in decontamination areas.

Reference
AH, Clauses: 2.3, 9.1
CSA Z314-18: 10.2.5.1

MDR AREA DESIGN
MDR Area Design

Functional work areas used for case cart assembly are separated from general storage or warehouse areas by walls or partitions.

Additional Information

Recommended Corrective Actions
Ensure functional work areas used for case cart assembly are separated from general storage/warehouse areas by walls or partitions.

Reference
CSA Z314-18: 10.2.6.1.2
CSA Z8000-18: 10.7.3.1.1; 10.7.3.1.2

MDR AREA DESIGN
MDR Area Design

Portable fans are not used in the reprocessing area.

Additional Information
Indicate where fan is located.

Recommended Corrective Actions
Ensure there are no portable fans used in the MDR area(s).

Reference
CSA Z314-18: 17.3.3.3.4

MDR AREA DESIGN
MDR Area Design

The area is free of external shipping containers.

Additional Information
External shipping containers are external corrugated cardboard boxes or any container bearing a shipping label. Indicate location of any items found.

Inner boxes may be used for storage of single-use medical devices and supplies, but shall be discarded after empty, not be topped up.

Recommended Corrective Actions
Ensure the area is free of external shipping containers (e.g, external corrugated cardboard boxes or any container bearing a shipping label).

Inner boxes may be used for storage of single-use medical devices and supplies, but shall be discarded after empty, not be topped up.

Reference
CSA Z314-18: 10.2.5.9; 10.2.5.14; 17.2.2

ENVIRONMENTAL CLEANING
Environmental Cleaning

Reprocessing equipment and environment appears clean and well maintained.

Additional Information
None.

Recommended Corrective Actions
Ensure reprocessing equipment and environment is clean and well maintained.

Reference
AH, Clause: 2.3.4
CSA Z314-18: 10.5.2; 10.5.5

ENVIRONMENTAL CLEANING
Environmental Cleaning

There is documentation that scheduled cleaning activities have been performed.

Additional Information
For all spaces in the MDR, including sterile storage:

- Floors, horizontal working surfaces and counters are cleaned daily and documented.
- Walls, ceilings, vents, light fixtures are cleaned at least every six months and documented

Recommended Corrective Actions
For all spaces in the MDR, including sterile storage, ensure:

- Floors, horizontal working surfaces and counters are cleaned daily and documented.
- Walls, ceilings, vents, light fixtures are cleaned at least every six months and documented.

Reference
AH, Clause 2.3.4
CSA Z314-18: 10.2.5.12; 10.5.5

ENVIRONMENTAL CLEANING
Environmental Cleaning

Vacuum cleaning equipment is equipped with HEPA filter.

Additional Information
If vacuum is not used, indicate N/A.
If a central vacuum system that does not vent into the room is used, indicate N/A.

Recommended Corrective Actions
Ensure the vacuum cleaning equipment is equipped with HEPA filter.

Reference
CSA Z314-18: 10.5.3

ENVIRONMENTAL CLEANING
Environmental Cleaning

Cleaning equipment used in the decontamination area is not used in any other area.

Additional Information
Mop handles and buckets must be dedicated to the decontamination area.

The cleaning attachments of automated floor cleaning machines shall be designated for a specific area (e.g., reprocessing, clean/sterile area, within the MDRD) and should not be used in other areas. If automated floor cleaning machines are used in other areas, special care shall be taken to ensure that they are clean before and after use in the MDRD (from Z314-18, 10.5.4).

Recommended Corrective Actions
Ensure cleaning equipment used in the decontamination area is not used in any other area.

Reference
CSA Z314-18: 10.5.4

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
General

Gross soil is removed from devices at point of use before transport for reprocessing.

Additional Information
Observe or ask staff if devices arrive free of gross soil (e.g, blood clots, feces, etc.)

Recommended Corrective Actions
Ensure that gross soil is removed from devices at point of use, before transport for reprocessing.

Reference
AH, Clauses: 5.1, 5.1.2
CSA Z314-18: 11.2.1
ORNAC: 2.5.26

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
General

Contaminated medical devices used within a facility are placed in a labelled, covered, leak-proof container, and transported to the reprocessing area.

Additional Information
Labelling must be cleanable (not paper).

Determine transport route to assess whether it avoids high traffic and patient care areas, and areas designated for clean or sterile storage of medical devices and supplies.

Recommended Corrective Actions
Ensure contaminated devices are contained in labeled, leak-proof, covered containers during transport to the reprocessing area.

Reference
AH, Clauses: 5.2, 5.3, 5.3.1
CSA Z314-18: 11.3.1.3; 11.3.2.2; 11.3.2.3

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
General

Transport containers are cleaned and disinfected between each use.

Additional Information
None.

Recommended Corrective Actions
Ensure transport containers are cleaned and disinfected between each use.

Reference
CSA Z314-18: 11.3.1.3

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Detergents

Detergents (including enzymatics), intended for medical devices, are prepared and used according to the manufacturer's instructions for use (e.g, concentration, temperature, and contact time).

Additional Information
Instructions should include:

- mixing/dilution
- rinsing
- shelf-life/expiry date(s)

Instructions are often on the bottle; if the product is decanted a copy of the instructions or package insert must be kept.

Recommended Corrective Actions
Obtain and file (electronically or on paper) manufacturer's written instructions.

Reference
AC: Clause: 9.7
AH, Clauses 6.4; 6.6
CSA Z314-18: 11.1.3; 11.6.3

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Detergents

Detergents or enzymatic cleaners are compatible with the medical devices being cleaned.

Additional Information
Check Device manufacturer's instructions for use if any question arises with an unfamiliar product.

Unacceptable cleaning agents include:

- hand soap or dish soap
- low-level disinfectant wipes (e.g, Cavi wipes, Sani cloths, OxiVir, etc.)
- surgical skin prep solutions (e.g, chlorhexidine gluconate, providone-iodine)
- other products not labelled as appropriate for medical instrument cleaning

Some devices require other procedures for cleaning according to manufacturer's instructions for use. For example, many ophthalmology devices require lumens only to be flushed with sterile water instead of brushing and flushing.

Recommended Corrective Actions
Ensure detergents and enzymatic cleaners are compatible with the medical device being cleaned.

Reference
AC, Clause: 9.7
AH, Clauses 6.4; 6.6
CSA Z314-18: 11.6.3.1.1

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Detergents

Detergent or enzymatic cleaning solutions are discarded when visibly soiled, after each endoscope, or batch of respiratory equipment and at the end of each shift, and sink cleaned.

Additional Information
Sinks used for decontamination of instruments or devices shall be **cleaned** whenever the solution is changed. At the end of each day, all sinks shall be **emptied, cleaned, and disinfected.**

After each scope or batch of respiratory equipment has been cleaned, sinks shall be **cleaned and disinfected**.

Recommended Corrective Actions
Ensure that detergents and enzymatic cleaners are discarded and that the sink or container is cleaned after each use.

Reference
CSA Z314-18: 10.5.2; 11.8.3

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Detergents

Containers for detergents or enzymatic cleaners are not topped up (i.e. new solution is never added to existing solution).

Additional Information
None.

Recommended Corrective Actions
Ensure containers for detergents or enzymatic cleaners are not topped up.

Reference
CSA Z314-18: 11.6.3.2.1

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Cleaning

Cleaning, including disassembly and lumen cleaning, always precedes high-level disinfection or sterilization processes.*

Additional Information
This item combines several individual items from the tools from previous cycles. Make sure to check that appropriate disassembly and lumen cleaning is done.

Some devices require other procedures for cleaning according to manufacturer's instructions for use. For example, many ophthalmology devices require lumens only to be flushed with sterile water instead of brushing and flushing.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AC, Clause: 9.2; 9.5; 9.7; 9.8
AH, Clauses: 6.2, 6.3
CSA Z314-18: 4.1; 11.6.1.1

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Cleaning

If delay in reprocessing is anticipated, devices are treated with an approved process or product to prevent drying of soil.

Additional Information
Approved methods:

- keeping devices moist in a transport container by adding a towel moistened with water (**not saline**)
- using a foam, spray, or gel product specifically intended for this use

Recommended Corrective Actions
Ensure devices are treated with an approved process or product to prevent hardening of bioburden if a delay in reprocessing is anticipated.

Reference
AH, Clause: 5.1.2
CSA Z314-18: 11.2.1; 11.3.2.1

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Cleaning

When manually cleaning, devices are completely immersed whenever possible.

Additional Information
Two adjacent sinks, large enough to immerse all submersible medical devices.

Non-submersible components must follow manufacturer's instructions.

Recommended Corrective Actions
Have at least two adjacent sinks, large enough to immerse all submersible medical devices for cleaning and rinsing.

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.

Reference
AH, Clauses: 2.2.2, 6.7
CSA Z314.8-18: 11.6.4.2; 11.6.4.3

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Cleaning

Medical device lubricant, if used, is medical grade and is used according to manufacturer's instructions for dispensing, shelf-life, and storage.

Additional Information
Instructions include:

- compatibility with sterilant
- dispensing
- dilution
- shelf-life
- storage

Instructions are often on the bottle; if the product is decanted a copy of the instructions or package insert must be kept.

Recommended Corrective Actions
Obtain and file (electronically or on paper) manufacturer's written instructions.

Reference
AC, Clause: 9
CSA Z314-18: 7

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Cleaning

Devices are rinsed and excess water is removed after cleaning.

Additional Information
Water quality for rinsing (potable, RO, DI) is determined by the medical device or automated cleaner manufacturer's instructions for use.

Recommended Corrective Actions
Ensure devices are thoroughly rinsed following cleaning.

Reference
AC, Clause: 9.8
AH, Clause: 6.10
CSA Z314-18: 11.6.4.2d

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Cleaning

Devices are visually inspected following cleaning to ensure no visible soil or defects are present and are functioning as required.

Additional Information
Devices that have been cleaned should be:

- clean
- functional

Ask staff if they can adequately perform visual inspection (sufficient lighting or other factors).

Recommended Corrective Actions
Ensure devices are visually inspected to ensure no visible soil or defects are present and that they are functioning as required following cleaning.

Reference
AC, Clause: 9.9
AH, Clauses: 2.2.7, 6.13.1
CSA Z314-18: 10.2.2.3.1; 11.4.2
CSA Z8000-18: 7.6.4.4
CSA Z317.5-17: 4.5.2

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Cleaning

Devices that do not pass inspection for cleanliness are re-cleaned.*

Additional Information
None.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause 6.13
CSA Z314-18: 11.4.2; 14.3.2.1

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
CLEANING

Damaged devices are labelled and removed from service.

Additional Information
None.

Recommended Corrective Actions
Ensure damaged devices are labelled and removed from service.

Reference
AH, Clause 6.13.2
CSA Z314-18: 14.3.3

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Ultrasonic Cleaning

Gross soil is removed before immersion in ultrasonic cleaner.

Additional Information
None.

Recommended Corrective Actions
Ensure that gross soil is removed from devices before ultrasonic cleaning.

Reference
CSA Z314-18: 11.6.6.2

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Ultrasonic Cleaning

Following ultrasonic cleaning, the devices are rinsed per manufacturer's instructions for use.

Additional Information
Rinsing not required if the device is placed directly into a washer-disinfector with a pre-rinse step.

Recommended Corrective Actions
Ensure that devices are thoroughly rinsed and inspected following ultrasonic cleaning before sterilization or high-level disinfection.

Reference
AH, Clause: 6.10
CSA Z314-18: 11.6.7.1

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Ultrasonic Cleaning

The ultrasonic solution is discarded at least daily and whenever visibly soiled.

Additional Information
New solution in an ultrasonic must be degassed before use, following the ultrasonic manufacturer's instructions.

Recommended Corrective Actions
Ensure solution in ultrasonic cleaner is changed at least daily and when visibly soiled.

Reference
AH, Clause 6.8.3
CSA Z314-18: 11.6.6.5

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Ultrasonic Cleaning

Ultrasonic cleaning equipment is used according to manufacturer's recommendations.

Additional Information
Manufacturer indicates devices or materials validated for ultrasonic cleaning. Instructions should include:

- installation (check specifications for required water quality)
- operating instructions
- daily, routine, and preventive maintenance, and repairs
- weekly sonication testing (e.g, foil test, SonoCheck)

Recommended Corrective Actions
Obtain and file (electronically or on paper) manufacturer's written instructions.

Reference
AC, Clause: 4.0; 7.7
AH, Clause: 6.8
CSA Z314-18: 7; 16.8.3.2; 18.6; and Annex G

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Ultrasonic Cleaning

Ultrasonic equipment is monitored weekly (e.g, SonoCheck, foil test) and documented.

Additional Information
Check log or documentation that weekly testing is performed using test specified by manufacturer or foil test.

Some Washer-disinfectors have a sonification capacity, check manufacturer's instructions for use.

Recommended Corrective Actions
Ensure that weekly testing of ultrasonic cleaning equipment is performed and documented using test specified by manufacturer or foil test.

Reference
AH, Clause 6.8.2
CSA Z314-18: 11.6.6.6

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Washer-Disinfector

Washer-Disinfectors are used according to manufacturer's recommendations.

Additional Information
Manufacturer indicates devices or materials validated for cleaning and, if applicable, validated thermal disinfection cycles. Include checking for appropriate detergents, racks and manifold systems for the medical devices being reprocessed.

Instructions include:

- installation (check specifications for required water quality)
- operating instructions
- daily, routine, and preventive maintenance, and repairs
- daily testing (e.g, TOSI testing)

Recommended Corrective Actions
Obtain and file (electronically or on paper) manufacturer's written instructions.

Reference
AC, Clause: 4.0, 7.7
AH, Clause: 6.10
CSA Z314.8-18: 7; 16.8.3.2; 18.6; and Annex G

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Washer-Disinfector

Washer-Disinfectors are monitored daily (e.g, TOSI test) and documented.

Additional Information
Check log or documentation that **daily** testing is performed, according to the manufacturer's written instructions or by another established method (e.g, TOSI test).

Recommended Corrective Actions
Ensure that daily 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).

Reference
AH, Clause: 6.8.1
CSA Z314-18: 11.6.5.3.5

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Accessories

Cleaning accessories (e.g, brushes, sponges) are disposable or thoroughly cleaned, and disinfected or sterilized according to manufacturer's instructions.

Additional Information
Check manufacturer’s instructions for use for reprocessing instructions for reusable accessories.

Inspect accessories for damage and indicate a deficiency if any damage is present.

Indicate a deficiency if single-use accessories are reused.

Recommended Corrective Actions
Ensure single-use cleaning accessories (e.g, brushes, sponges) are disposed of following each use and reusable cleaning accessories are reprocessed, according to manufacturer’s instructions.

Reference
AH, Clauses: 4.4-6
CSA Z314-18: 11.6.4.4; 12.7.1.6

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Accessories

Reusable cleaning accessories are thoroughly cleaned and disinfected or sterilized according to manufacturer's instructions after each endoscope or batch of respiratory equipment.

Additional Information
Reusable and disposable accessories used for respiratory equipment or endoscopes must be reprocessed or discarded after each load/scope.

Inspect accessories for damage and indicate a deficiency if any damage is present.

Recommended Corrective Actions
Ensure single-use cleaning accessories (e.g, brushes, sponges) are disposed of following each use and reusable cleaning accessories are reprocessed following each respiratory load or endoscope.

Reference
AH, Clause: 4.5
CSA Z314-18: 11.6.4.4

CLEANING/DECONTAMINATION OF MEDICAL DEVICES AND ENDOSCOPES
Cleaning

Devices are dried after final rinsing with a lint-free cloth or mechanical method, before high-level disinfection or sterilization.

Additional Information
Examples of drying cloths that are **not** lint-free include:

- terry towel
- paper towel

Examples of **lint-free** drying cloths include:

- huck towels
- disposable lint-free cloths

Mechanical methods include instrument-grade air.

Recommended Corrective Actions
Ensure devices are dried after final rinsing with a lint-free cloth or mechanical method.

Reference
AC, Clause: 9.9; 11.6
AH, Clause: 6.11.1
CSA Z314-18: 11.6.8

THERMAL HIGH-LEVEL DISINFECTION
Manufacturer's Instructions for Use

Reprocessing equipment (pasteurizers and washer-disinfectors) is used according to manufacturer's specifications.

Additional Information
Manufacturer indicates devices or materials validated for cleaning and, if applicable, validated thermal disinfection cycles. Include checking for appropriate detergents, racks and manifold systems for the medical devices being reprocessed.

Instructions should include:

- installation (check specifications for required water quality)
- daily, routine, and preventive maintenance, and repairs
- operating instructions
- cleaning indicators for washer-disinfectors (e.g, TOSI) done daily and documented

Recommended Corrective Actions
Obtain and file (electronically or on paper) manufacturer's written instructions.

Reference
AC, Clause: 4.0, 7.7
AH, Clauses: 7.14, 7.17, 7.18, 7.19.1
CSA Z314-18: 7; 16.8.3.2; 18.6; and Annex G

THERMAL HIGH-LEVEL DISINFECTION
Pasteurization

Water temperature (minimum 71°C) and cycle time (30 minutes) within the pasteurizer is manually verified and recorded for each cycle.

Additional Information
None.

Recommended Corrective Actions
Ensure the water temperature within the pasteurizer is, at a minimum 71°C and cycle time is 30 minutes. Manually verify and document for each cycle.

Reference
AH, Clause 7.19
CSA Z314-18: 11.8.4.2

THERMAL HIGH-LEVEL DISINFECTION
General

Following thermal high-level disinfection, devices are handled in a manner that prevents contamination during transfer to the dedicated dryer.

Additional Information
Staff remove personal protective equipment and wash hands before handling disinfected devices.

Recommended Corrective Actions
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 before being placed in drying cabinet).

Reference
AH, Clause: 7.20
CSA Z314-18: 11.8.4.1.5

THERMAL HIGH-LEVEL DISINFECTION
General

There is a HEPA-filtered drying cabinet that is used exclusively for the drying of thermally disinfected devices.

Additional Information
None.

Recommended Corrective Actions
Ensure the drying cabinet is HEPA filtered and used exclusively for drying disinfected devices.

Reference
AH, Clause: 7.20.1
CSA Z314-18: 11.8.4.1.8; 11.8.4.2.5; 11.8.5

THERMAL HIGH-LEVEL DISINFECTION
General

HEPA filters are changed according to manufacturer's instructions for use.

Additional Information
None.

Recommended Corrective Actions
Ensure the HEPA filter for the drying cabinet is changed according to manufacturer’s instructions.

Reference
AH, Clause: 7.20.1
CSA Z314-18: 11.8.4.1.8; 11.8.4.2.5; 11.8.5

THERMAL HIGH-LEVEL DISINFECTION
General

Following drying, devices are handled in a manner that prevents contamination.

Additional Information
None.

Recommended Corrective Actions
Ensure devices are handled in a manner that prevents contamination after drying.

Reference
AH, Clause: 7.20
CSA Z314-18: 11.8.4.1.5

THERMAL HIGH-LEVEL DISINFECTION
General

For thermal high-level disinfection, there is a process in place that clearly identifies a non-reprocessed device from one that has been reprocessed.*

Additional Information
This is done to prevent use of a non-reprocessed device on a patient.

Examples include:

- labelling reprocessed devices with reprocessing date and reprocessing expiry date (if applicable)
- tracking of the device identifier at each step documenting the date and time that it has been received for cleaning, cleaned, received for disinfection, disinfected, etc.

- placing unwrapped, semi-critical devices in clean bags or containers labelled with reprocessing date and expiry date (if applicable)

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 4.1.1
CSA Z314-18: 13.3.1.1 & 13.3.14 (U/S Probes); 12.4.1.1 (endoscopes)

THERMAL HIGH-LEVEL DISINFECTION
Documentation

Documentation includes identification of the devices being reprocessed.

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each load of items receiving thermal high-level disinfection.

Reference
AH, Clause: 11.6
CSA Z314-18: 5.0; 11.8.4.2.4; 11.8.4.3; 11.8.4.1.9

THERMAL HIGH-LEVEL DISINFECTION
Documentation

Documentation includes date and time of disinfection.

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each load of items receiving thermal high-level disinfection.

Reference
AH, Clause: 11.6
CSA Z314-18: 5.0; 11.8.4.2.4; 11.8.4.3; 11.8.4.1.9

THERMAL HIGH-LEVEL DISINFECTION
Documentation

Documentation includes contact time and temperature.

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each load of items receiving thermal high-level disinfection.

Reference
AH, Clauses: 7.15, 11.6
CSA Z314-18: 5.0; 11.8.4.2.4; 11.8.4.3; 11.8.4.1.9

THERMAL HIGH-LEVEL DISINFECTION
Documentation

Documentation includes reprocessing unit identification (e.g, make, model, serial number, etc.).

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each load of items receiving thermal high-level disinfection.

Reference
AH, Clause: 11.6
CSA Z314-18: 5.0; 11.8.4.2.4; 11.8.4.3; 11.8.4.1.9

THERMAL HIGH-LEVEL DISINFECTION
Documentation

Documentation includes identification of person responsible for ensuring all requirements for reprocessing and releasing the devices are met.

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each load of items receiving thermal high-level disinfection.

Reference
AH, Clause: 11.6
CSA Z314-18: 5.0; 11.8.4.2.4; 11.8.4.3; 11.8.4.1.9

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
GENERAL

Semi-critical medical devices are high-level disinfected (at a minimum).*

Additional Information
None.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 7.6
CSA Z314-18: 4.1; 11.6.1.1

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

High-level disinfectant has a Class II medical device license from Health Canada.

Additional Information
DIN has been replaced by medical device license number from Health Canada.

Check label for device license.

Recommended Corrective Actions
Ensure high-level disinfectant has a medical device license number from Health Canada.

Reference
AH, Clause: 7.2
CSA Z314-18: 11.7.2.1.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

High-level disinfectant is prepared and used according to the manufacturer's instructions for use.

Additional Information
Instructions include:

- shelf-life
- mixing (if required)
- expiry after opening/mixing
- expiry after decanting (if applicable)
- testing of minimum effective concentration
- contact time
- temperature
- rinsing
- disposal
- handling precautions

Instructions are often on the bottle; if the product decanted a copy of the instructions or package insert must be kept.

Some of the above steps may be not applicable (e.g, Sonex HL for the Trophon).

Recommended Corrective Actions
Obtain and file (electronically or on paper) manufacturer's written instructions.

Reference
AH, Clauses: 7.1, 7.7
CSA Z314-18: 7

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

High-level disinfectant is not used past the shelf-life expiry date or the open bottle expiry date.

Additional Information
The expiry date for an opened or mixed bottle or a portion that is poured-off into another container may be different than the lot number expiry date.

There are three important dates:

- Shelf-life expiry is for unopened, stored high-level disinfectant. The expiry is printed on the label by the manufacturer.
- Open bottle expiry is after the high-level disinfectant bottle has been opened, but contains high-level disinfectant that has not been used. Look for a handwritten date of opening/mixing on the bottle.
- In use expiry refers to high-level disinfectant that has been poured into a soaking container ready for a medical device. Look for a handwritten date on the container.

Recommended Corrective Actions
Ensure containers of high-level disinfectant that have been mixed or opened are labelled 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.

Reference
AH, Clause: 7.3
CSA Z314-18: 11.7.2.3.3; 11.7.2.3.5

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

The chemical test strips used to check the minimum effective concentration are specific to the type and concentration of the high-level disinfectant.*

Additional Information
Review manufacturer's written instructions for test strips to determine they are appropriate.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clauses: 7.7, 7.7.2
CSA Z314-18: 11.7.2.4.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

Test strips are dated when opened.

Additional Information
Dating includes the opening date and open bottle expiry date (if applicable).

Recommended Corrective Actions
Ensure test strip bottles are dated when opened. This is required by manufacturer's instructions.

Reference
AH, Clause: 7.7.3
CSA Z314-18: 11.7.2.5.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

Test strips are not used past the shelf-life expiry date or the open bottle expiry date.

Additional Information
None.

Recommended Corrective Actions
Ensure test strips are not used past the expiry date. This includes the lot number expiry date and the open bottle expiry date. This is required by manufacturer's instructions.

Reference
AH, Clause: 7.7.3
CSA Z314-18: 11.7.2.5.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

The minimum effective concentration of reusable high-level disinfectant is tested at least daily when in use.*

Additional Information
If concentration is tested in another manner (e.g, during AER cycle), concentration is documented and verified. Method of testing is validated by the manufacturer.

Frequency may be more often than daily if indicated by manufacturer.

If a method of testing concentration other than test strips is used that is validated by the manufacturer (e.g, concentration testing during an automated cycle, as in the Trophon), verify and document results.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 7.7.1
CSA Z314-18: 11.7.2.3.5

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

The soaking container is kept covered at all times, except when placing or removing a device or when the device is not completely immersible.

Additional Information
Watch for containers with lids that do not close when devices are being disinfected. If this is observed, mark as a deficiency.

Recommended Corrective Actions
Ensure containers with chemical disinfectant are covered at all times including during use.

Reference
AH, Clause: 7.4.3
CSA Z314-18: 11.7.2.3.5

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

The soaking container is washed, rinsed and dried when the high-level disinfectant is changed.

Additional Information
Reservoirs include those in AER and manual disinfection systems.

Recommended Corrective Actions
Ensure that containers or reservoirs for storing disinfectant and detergent/enzymatic are cleaned and dried before refilling. Never add new solution to the existing solution in a container.

Reference
AH, Clause: 7.4.2
CSA Z314-18: 11.7.2.3.3

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

Submersible components of devices are completely submerged and all internal channels or lumens are in contact with the disinfectant for the recommended contact time. (For reviews of only endoscope reprocessing, use Section 9, mark this item N/A.)

Additional Information
None.

Recommended Corrective Actions
Ensure that, during manual high-level disinfection, submersible components of devices are completely submerged and all internal channels/lumens are in complete contact with the disinfectant, and all air bubbles removed for the recommended contact time.

Ensure that non-submersible components are cleaned and disinfected according to device manufacturer's written instructions.

Reference
AH, Clause: 7.8
CSA Z314-18: 11.7.2.5.1

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

Rinsing of medical devices using sterile or submicron filtered water following high-level disinfection is done with three separate rinses, unless otherwise specified by the high-level disinfectant manufacturer. Fresh rinse solution is used for each rinse. (For reviews of only endoscope reprocessing, use Section 9, mark this item N/A.)

Additional Information
None.

Recommended Corrective Actions
Ensure rinsing of medical devices following high-level disinfection 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.

Reference
AH, Clause: 7.11
CSA Z314-18: 11.7.2.6

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

During rinsing, submersible components of devices are fully immersed and all lumens or channels are flushed during each rinse. (For reviews of only endoscope reprocessing, use Section 9, mark this item N/A.)

Additional Information
Non-submersible components must follow manufacturer's instructions.

Recommended Corrective Actions
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.

Reference
CSA Z314-18: 7.1

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

Following rinsing, the device is thoroughly dried with a lint-free cloth. Lumens are completely dried according to device manufacturer's instructions e.g, flushed with alcohol, flushed with air. (For reviews of only endoscope reprocessing, use Section 9, mark this item N/A.)

Additional Information
Examples of cloths that are **not** lint-free include:

- terry towel
- paper towel

Examples of **lint-free** cloths include:

- huck towels
- disposable lint-free cloths

Recommended Corrective Actions
Ensure devices are dried using a clean, soft, lint-free cloth following rinsing.

Reference
AH, Clause: 7.12
CSA Z314-18: 11.8.5; 13.3.13

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
General

There is a process in place that clearly identifies a non-reprocessed device from one that has been reprocessed. (For reviews of only endoscope reprocessing, use Section 9, mark this item N/A.)*

Additional Information
None.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 4.1.1
CSA Z314-18: 13.3.1.1; 13.3.14; 12.4.1.1

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Solution Documentation

Solution documentation includes product name.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clauses: 7.4.1, 7.13.1, 11.6
CSA Z314-18, 11.7.2.5.2(a)

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Solution Documentation

Solution documentation includes lot number.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clauses: 7.4.1, 7.13.1, 11.6
CSA Z314-18, 11.7.2.5.2(a)

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Solution Documentation

Solution documentation includes expiry date.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clauses: 7.4.1, 7.13.1, 11.6
CSA Z314-18, 11.7.2.5.2(a)

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Solution Documentation

Solution documentation includes in use expiry date.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clauses: 7.4.1, 7.13.1, 11.6
CSA Z314-18, 11.7.2.5.2(a)

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Solution Documentation

Solution documentation includes date of solution change.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clauses: 7.13.1, 11.6
CSA Z314-18, 11.7.2.5.2(a)

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Solution Documentation

Solution documentation includes initials of staff doing preparation and documentation.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clauses: 7.13.1, 11.6
CSA Z314-18, 11.7.2.5.2(a)

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Test Strip Documentation

Test strip documentation includes name of test strip.

Additional Information
None.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clauses: 7.13.2, 11.6
CSA Z314-18, 11.7.2.4.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Test Strip Documentation

Test strip documentation includes lot number.

Additional Information
None.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clauses: 7.13.2, 11.6
CSA Z314-18, 11.7.2.4.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Test Strip Documentation

Test strip documentation includes expiry date.

Additional Information
None.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clauses: 7.13.2, 11.6
CSA Z314-18, 11.7.2.4.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Test Strip Documentation

Test strip documentation includes quality control test results (each time new test strip bottle is opened).

Additional Information
May be done through the high-level disinfection manufacturer website.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clauses: 7.7.2, 7.13.2, 11.6
CSA Z314-18, 11.7.2.4.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Test Strip Documentation

Test strip documentation includes daily minimum effective concentration test strip result: Pass or Fail.

Additional Information
None.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clauses: 7.13.3, 11.6
CSA Z314-18, 11.7.2.4.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Test Strip Documentation

Test strip documentation includes other chemical or process indicators, if applicable (e.g, Trophon)

Additional Information
None.

Recommended Corrective Actions
Ensure documentation of other applicable chemical or process indicators.

Reference
AC, Clause: 9.7
AH, Clauses: 7.13.2, 11.6
CSA Z314-18, 11.7.2.4.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Test Strip Documentation

Test strip documentation includes initials of staff doing the testing and documentation.

Additional Information
None.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clauses: 7.13.2, 11.6
CSA Z314-18, 11.7.2.4.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Device Documentation

Device documentation includes identification of the devices being reprocessed.

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each item (or load) receiving chemical high-level disinfection.

Reference
AH, Clauses: 7.10, 7.13.6, 11.6
CSA Z314-18, 11.7.2.5.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Device Documentation

Device documentation includes patient identification, with date used, and serial number of probe (some or all these components of traceability may be done in another department).

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each item (or load) receiving chemical high-level disinfection.

Reference
AH, Clauses: 7.10, 7.13.6, 11.6, 11.6.4
CSA Z314-18, 11.7.2.5.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Device Documentation

Device documentation includes date and time of disinfection.

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each item (or load) receiving chemical high-level disinfection.

Reference
AH, Clauses: 7.10, 11.6
CSA Z314-18, 11.7.2.5.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Device Documentation

Device documentation includes contact time (exposure) of the high-level disinfectant.

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each item (or load) receiving chemical high-level disinfection.

Reference
AH, Clauses: 7.8.2, 7.10, 7.13.4, 11.6, 11.6.4
CSA Z314-18, 11.7.2.5.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Device Documentation

Device documentation includes temperature of the high-level disinfectant (if applicable).

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each item (or load) receiving chemical high-level disinfection.

Reference
AH, Clauses: 7.8.2, 7.10, 7.13.4, 11.6
CSA Z314-18, 11.7.2.5.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Device Documentation

Device documentation includes automated reprocessing unit identification (e.g, make, model, serial number, etc.).

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each item (or load) receiving chemical high-level disinfection.

Reference
AH, Clauses: 7.10, 11.6
CSA Z314-18, 11.7.2.5.2

CHEMICAL HIGH-LEVEL DISINFECTION (including ENDOSCOPES)
Device Documentation

Device documentation includes identification of person responsible for ensuring all requirements for reprocessing and releasing the devices are met.

Additional Information
None.

Recommended Corrective Actions
Ensure documentation is completed for each item (or load) receiving chemical high-level disinfection.

Reference
AH, Clauses: 7.10, 11.6
CSA Z314-18, 11.7.2.5.2

REPROCESSING ENDOSCOPY DEVICES
General

The water bottle used to provide intra-procedural flush solution, and its connecting tube, should be sterilized at least daily (according to device manufacturer's instructions). If disposable, they are discarded daily.

Additional Information
For procedures other than ERCP, the water bottle, cap, and connecting tubing shall be removed and replaced with sterile supplies at the following times:

- at the beginning of each day, at minimum
- before any procedure that invades sterile tissue
- if the bottle becomes contaminated (i.e. has visible turbidity)

For ERCP, all components are replaced before each procedure.

Recommended Corrective Actions
Ensure the water bottle used to provide intra-procedural flush solution and its connecting tube are changed at least daily (before each procedure for ERCP) and sterilized if reusable. If disposable, they are discarded daily.

Reference
CSA Z314-18 12.7.2.1; 12.7.2.2

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

Pre-cleaning of the endoscope is performed at point of use, immediately following clinical procedure.

Additional Information
If unable to observe, ask if pre-cleaning of endoscopes is done at the point of use.

Recommended Corrective Actions
Ensure pre-cleaning of the endoscope is performed at point of use immediately following clinical procedure.

Reference
AH, Clause: 5.1
CSA Z314-18: 12.4.1.2

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

A leak test is performed before immersion according to the endoscope manufacturer's instructions for use.

Additional Information
May be a dry or wet leak test or both.

Recommended Corrective Actions
Ensure a leak test is performed before or during immersion of the endoscope following manufacturer's written instructions.

Reference
CSA Z314-18: 12.4.6

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

Accessories (valves and removable parts) are disconnected, disassembled and completely immersed in the enzymatic detergent.

Additional Information
Some accessories require sonification and sterilization, check manufacturer's instructions for use.

Recommended Corrective Actions
Ensure accessories are disconnected and disassembled as per manufacturer's written instructions. Devices are completely immersed in the enzymatic detergent.

Reference
AH, Clause: 6.2
CSA Z314-18: 12.4.8

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

The valves and removable parts are brushed and flushed until all debris is removed.

Additional Information
None.

Recommended Corrective Actions
Ensure valves and removable parts are brushed and flushed until all visible debris is removed. Parts are inspected for cleanliness.

Reference
CSA Z314-18: 12.4.7.2.2

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

The entire endoscope is completely immersed in the freshly prepared enzymatic solution.

Additional Information
None.

Recommended Corrective Actions
Ensure endoscope is entirely immersed during the entire cleaning process to prevent splashing or aerosolization.

Reference
CSA Z314-18: 12.4.7.2.1

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

The bending section is kept straight so brushing does not damage endoscope.

Additional Information
None.

Recommended Corrective Actions
Ensure the bending section of the endoscope is kept straight so brushing does not damage the internal lumen of the endoscope.

Reference
CSA Z314-18: 12.4.7.2.3

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

The exterior of the endoscope is cleaned with a soft brush or lint-free cloth.

Additional Information
None.

Recommended Corrective Actions
Ensure the exterior of the endoscope is cleaned with a soft brush or lint-free cloth.

Reference
CSA Z314-18: 12.4.7.2.2

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

All ports, channels and lumens are cleaned with appropriately sized brushes until all debris is removed.

Additional Information

To assure effective cleaning of gastrointestinal endoscope channels, it is important to note there are two channels that are accessed from the same valve/port, one that extends to the suction connector at the light source and the other to the distal tip. (The steps below are specific to one brand of endoscopes and are provided as an example.)

To access the channel extending to the distal tip (i.e. instrument/suction channel):

- Hold the tip of the channel cleaning brush at a 45^0 angle as it enters the suction port and advance the brush until it emerges from the distal tip of the endoscope.
- Clean the tip and withdraw the brush from the endoscope, then clean the tip again.
- Repeat these steps until the no debris is visible.

To access the channel extending to the suction connector at the light source:

- Insert the channel cleaning brush into the centre of the suction port and advance it until it emerges from the suction connector.
- Clean the tip and withdraw the brush from the endoscope, then clean the tip again.
- Repeat these steps until the no *debris is visible.*

It is also very important to clean all channel openings with a channel opening brush and flush all channels with detergent solution, followed by rinsing.

Example of a cleaning method: an appropriately sized channel cleaning brush is passed through a channel a minimum of three (3) times, or according to brush manufacturer's instructions for use, or until visibly clean.

Check manufacturer's instructions for use as some do not require brushing of ports.

Check ERCP scope manufacturer's instructions for use for specific cleaning requirements (e.g, elevator).

Recommended Corrective Actions

Ensure all ports and channels/lumens are cleaned as per manufacturer's written instructions until all visible debris is removed.

Reference

CSA Z314-18: 12.4.7.2.3

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

The brush is cleaned in the enzymatic solution each time it is passed through a channel.

Additional Information
None.

Recommended Corrective Actions
Ensure cleaning brush is washed in the enzymatic or detergent solution following each pass through the channel.

Reference
CSA Z314-18: 12.4.7.2.3

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

Following device manufacturer's instructions, enzymatic solution is flushed and/or suctioned through all channels of the endoscope (either manually using a syringe or using an automated flushing and/or suction system).

Additional Information
The syringe volume is as specified by the endoscope manufacturer.

All channels should be flushed as indicated in the endoscope manufacturer's instructions, including the biopsy port/channel.

Recommended Corrective Actions
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 times or equivalent cleaning is done by an approved automated system (e.g, Scope Buddy or EndoFlush).

Reference
CSA Z 314-18:12.4.7

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

During rinsing, endoscopes are fully immersed.

Additional Information
None.

Recommended Corrective Actions
Ensure endoscope is entirely immersed during the rinsing to prevent splashing or aerosolization.

Reference
CSA Z314-18: 12.4.8

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

The accessories and endoscopes, 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.

Additional Information
The syringe volume is as specified by the endoscope manufacturer.

All channels should be rinsed as indicated in the endoscope manufacturer's instructions, including the biopsy port/channel. A general rule is that three times the volume of the lumen is rinsed (e.g, a colonoscope would require 300 mL).

Recommended Corrective Actions
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 (e.g, Scope Buddy or EndoFlush).

Reference
CSA Z314-18: 12.4.8

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

Channel rinses are followed by air purges using a syringe or an approved automated system.

Additional Information
The syringe volume is as specified by the endoscope manufacturer.

Recommended Corrective Actions
Ensure that channel rinses are followed by air purges using a syringe or an approved automated system.

Reference
CSA Z314-18: 12.4.8

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

The outside of the endoscope is dried and inspected for cleanliness and integrity.

Additional Information
If placing endoscope directly into AER with a washing function, drying is not required.

Recommended Corrective Actions
Ensure the exterior of the endoscope and all removable parts are thoroughly dried using a clean lint-free cloth and inspected for integrity.

Reference
CSA Z314-18: 12.4.8; 12.4.10

REPROCESSING ENDOSCOPY DEVICES
Cleaning Specific to Endoscopes

Cleaning accessories (e.g, brushes, sponges) are disposable or thoroughly cleaned and high-level disinfected or sterilized between uses.

Additional Information
Syringes are single-use, so are discarded after each endoscope.

Recommended Corrective Actions
Ensure single-use cleaning accessories (e.g, brushes, sponges, syringes, etc.) are disposed of following each use. Reusable cleaning accessories are cleaned and high-level disinfected or sterilized following each use.

Reference
AH, Clauses: 4.6, 4.7
CSA Z314-18 12.4.7.2.3

REPROCESSING ENDOSCOPY DEVICES
Automatic Endoscope Reprocessor (AER)

AER is operated according to manufacturer's instructions for use.

Additional Information
Check manufacturer’s instructions for use for:

- installation (check specifications for required water quality)
- daily (e.g, fluid levels, surface cleaning), routine, and preventive maintenance, and repairs
- operating instructions (e.g, testing)

Recommended Corrective Actions
Obtain and file (electronically or on paper) manufacturer’s written instructions.

Reference
CSA Z314-18: 7; 16.8.3.2; 18.6; and Annex G

REPROCESSING ENDOSCOPY DEVICES
Automatic Endoscope Reprocessor (AER)

Endoscope and components are validated for reprocessing in the AER.

Additional Information
Check manufacturer's instructions for use for validation information.

Recommended Corrective Actions
Ensure that endoscopes and their components are validated for reprocessing in the AER.

Reference
AC, Clause: 7.6; 7.7; 7.10; 9.0
CSA Z314-18: 7.1

REPROCESSING ENDOSCOPY DEVICES
Automatic Endoscope Reprocessor (AER)

Elevator channels of duodenoscopes are processed according to AER and endoscope manufacturer's instructions.

Additional Information
Ask if updated instructions are in use.
There was an E&P Advisory about this.

Recommended Corrective Actions
Ensure updated instructions are followed for reprocessing.

Reference
AC, Clause: 7.6; 7.7; 7.10; 9.0
CSA Z314-18: 7.1

REPROCESSING ENDOSCOPY DEVICES
Automatic Endoscope Reprocessor (AER)

The device and accessories are positioned in the AER so that they will be completely immersed in high-level disinfectant.

Additional Information
None.

Recommended Corrective Actions
Ensure the cleaned endoscope, valves, brushes and removable parts are placed in the AER so they are completely immersed.

Reference
CSA Z314-18: Table 12.1

REPROCESSING ENDOSCOPY DEVICES
Automatic Endoscope Reprocessor (AER)

All channels of the endoscope are attached to the AER using manufacturer's specified connectors and adapters.*

Additional Information
None.

Recommended Corrective Actions
Ensure the AER channel adaptor attachments are appropriate to the scope being reprocessed.

Reference
CSA Z314-18: 12.4.12.4

REPROCESSING ENDOSCOPY DEVICES
Automatic Endoscope Reprocessor (AER)

On cycle completion, the printout is checked and signed to verify correct parameters were achieved.

Additional Information
Documentation may be paper or electronic.

Recommended Corrective Actions
Ensure the automated printout or electronic log from the AER is monitored and signed off by staff releasing the load.

Reference
AH, Clause: 7.9
CSA Z314-18: 12.9.2.1

REPROCESSING ENDOSCOPY DEVICES
Automatic Endoscope Reprocessor (AER)

The endoscope is removed promptly after the final cycle has been completed.

Additional Information
None.

Recommended Corrective Actions
Ensure the endoscope is removed promptly from the Automated Endoscope Reprocessor (AER) after the final cycle has completed.

Reference
CSA Z314-18: 12.4.3; Table 12.1

REPROCESSING ENDOSCOPY DEVICES
Automatic Endoscope Reprocessor (AER)

A channel air purge followed by a 70% alcohol flush and a final air purge is performed.

Additional Information
Some AER have an alcohol rinse cycle. If so, only the final air purge must be performed following removal from the AER.

Some AER include a drying cycle.

Alcohol flush is not necessary between cases if endoscope is used immediately.

Recommended Corrective Actions
Ensure all steps are followed, either manually or by the AER.

Reference
CSA Z314-18: Table 12.1; 12.4.13

REPROCESSING ENDOSCOPY DEVICES
Automatic Endoscope Reprocessor (AER)

The device is thoroughly dried with a lint-free cloth or mechanical method.

Additional Information
Examples of cloths that are not lint-free include:

- terry towel
- paper towel

Examples of lint-free cloths include:

- huck towels
- disposable lint-free cloths

Mechanical methods include instrument-grade air.

Recommended Corrective Actions
Ensure endoscope is dried with a clean, lint-free cloth or mechanical method.

Reference
CSA Z314-18: Table 12.1

REPROCESSING ENDOSCOPY DEVICES
Automatic Endoscope Reprocessor (AER)

There is a process in place that clearly identifies a non-reprocessed device from one that has been reprocessed.*

Additional Information
Examples of identification as reprocessed includes:

- labelling reprocessed devices with a label, tag, foam boot or other visual identifier. Adding the reprocessing date and expiry date helps to easily track the outdated scopes
- sign off of the endoscope serial number or identifier at every step of the process documenting the date and time that it has been received for cleaning, cleaned, received for disinfection, disinfected, etc.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 4.1.1
CSA Z314-18: 12.4.1.1

REPROCESSING ENDOSCOPY DEVICES
Solution Documentation

Solution documentation includes product name.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clause: 11.6
CSA Z314-18, 11.7.2.5.2(a)

REPROCESSING ENDOSCOPY DEVICES
Solution Documentation

Solution documentation includes lot number.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clause: 11.6
CSA Z314-18, 11.7.2.5.2(a)

REPROCESSING ENDOSCOPY DEVICES
Solution Documentation

Solution documentation includes expiry date.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clause: 11.6
CSA Z314-18, 11.7.2.5.2(a)

REPROCESSING ENDOSCOPY DEVICES
Solution Documentation

Solution documentation includes in use expiry date.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clause: 11.6
CSA Z314-18, 11.7.2.5.2(a)

REPROCESSING ENDOSCOPY DEVICES
Solution Documentation

Solution documentation includes date of solution change.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clause: 11.6
CSA Z314-18, 11.7.2.5.2(a)

REPROCESSING ENDOSCOPY DEVICES
Solution Documentation

Solution documentation includes initials of staff doing preparation and documentation.

Additional Information
None.

Recommended Corrective Actions
Ensure this is documented when high-level disinfectant is changed.

Reference
AH, Clause: 11.6
CSA Z314-18, 11.7.2.5.2(a)

REPROCESSING ENDOSCOPY DEVICES
Test Strip Documentation

Test strip documentation includes name of test strip.

Additional Information
None.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clause: 11.6
CSA Z314-18, 11.7.2.4.2

REPROCESSING ENDOSCOPY DEVICES
Test Strip Documentation

Test strip documentation includes lot number.

Additional Information
None.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clause: 11.6
CSA Z314-18, 11.7.2.4.2

REPROCESSING ENDOSCOPY DEVICES
Test Strip Documentation

Test strip documentation includes expiry date.

Additional Information
None.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clause: 11.6
CSA Z314-18, 11.7.2.4.2

REPROCESSING ENDOSCOPY DEVICES
Test Strip Documentation

Test strip documentation includes quality control test results (each time new test strip bottle is opened).

Additional Information
May be done through the high-level disinfection manufacturer website.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clause: 11.6
CSA Z314-18, 11.7.2.4.2

REPROCESSING ENDOSCOPY DEVICES
Test Strip Documentation

Test strip documentation includes daily minimum effective concentration test strip result: Pass or Fail.

Additional Information
Documentation may be paper or electronic.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clause: 11.6
CSA Z314-18, 11.7.2.4.2

REPROCESSING ENDOSCOPY DEVICES
Test Strip Documentation

Test strip documentation includes initials of staff doing the testing and documentation.

Additional Information
None.

Recommended Corrective Actions
Ensure this is included in documentation when high-level disinfectant is tested for minimum effective concentration.

Reference
AC, Clause: 9.7
AH, Clause: 11.6
CSA Z314-18, 11.7.2.4.2

REPROCESSING ENDOSCOPY DEVICES
Device Documentation

Device documentation includes identification of the devices being reprocessed.

Additional Information
Documentation may be paper or electronic.

Recommended Corrective Actions
Ensure documentation is completed for each endoscope being reprocessed.

Reference
AH, Clause: 11.6
CSA Z314-18, 12.9.2

REPROCESSING ENDOSCOPY DEVICES
Device Documentation

Device documentation includes patient identification, with date used, and serial number of probe (some or all these components of traceability may be done in another department).

Additional Information
Documentation may be paper or electronic.

Recommended Corrective Actions
Ensure documentation is completed for each endoscope being reprocessed.

Reference
AH, Clause: 11.6.4
CSA Z314-18, 12.9.2

REPROCESSING ENDOSCOPY DEVICES
Device Documentation

Device documentation includes date and time of disinfection.

Additional Information
Documentation may be paper or electronic.

Recommended Corrective Actions
Ensure documentation is completed for each endoscope being reprocessed.

Reference
AH, Clause: 11.6
CSA Z314-18, 12.9.2

REPROCESSING ENDOSCOPY DEVICES
Device Documentation

Device documentation includes contact time (exposure) of the high-level disinfectant.

Additional Information
Documentation may be paper or electronic.

Recommended Corrective Actions
Ensure documentation is completed for each endoscope being reprocessed.

Reference
AH, Clauses: 7.9, 11.6
CSA Z314-18, 12.9.2

REPROCESSING ENDOSCOPY DEVICES
Device Documentation

Device documentation includes temperature of the high-level disinfectant (if applicable).

Additional Information
Documentation may be paper or electronic.

Recommended Corrective Actions
Ensure documentation is completed for each endoscope being reprocessed.

Reference
AH, Clauses: 7.9, 11.6
CSA Z314-18, 12.9.2

REPROCESSING ENDOSCOPY DEVICES
Device Documentation

Device documentation includes automated reprocessing unit identification (e.g, make, model, serial number, etc.).

Additional Information
Documentation may be paper or electronic.

Recommended Corrective Actions
Ensure documentation is completed for each endoscope being reprocessed.

Reference
AH, Clause: 11.6
CSA Z314-18, 12.9.2

REPROCESSING ENDOSCOPY DEVICES
Device Documentation

Device documentation includes identification of person responsible for ensuring all requirements for reprocessing and releasing the devices are met.

Additional Information
Documentation may be paper or electronic.

Recommended Corrective Actions
Ensure documentation is completed for each endoscope being reprocessed.

Reference
AH, Clause: 11.6
CSA Z314-18, 12.9.2

REPROCESSING ENDOSCOPY DEVICES
Device Documentation

Device documentation includes results of leak test.

Additional Information
Documentation may be paper or electronic.

Recommended Corrective Actions
Ensure documentation is completed for each endoscope being reprocessed.

Reference
AH, Clause: 11.6
CSA Z314-18, 12.9.2

STERILIZATION OF REUSABLE MEDICAL DEVICES
Manufacturer's Instructions for Use

Sterilizer loading and operating instructions are available and followed by the staff.

Additional Information
Are available for each sterilizer in use (Steam, SS1, Low Temp, ETO).

- install (check specifications for required water and steam quality, as applicable)
- preventative maintenance
- routine maintenance
- operating instructions

Recommended Corrective Actions
Obtain and file (electronically or on paper) manufacturer's written instructions.

Reference
AH, Clause 8.4.2
CSA Z314-18: 7; 16.8.3.2; 18.6; and Annex G

STERILIZATION OF REUSABLE MEDICAL DEVICES
General

Critical devices are sterilized by an approved sterilization process. (Unacceptable sterilization methods include boiling, glass bead sterilizers, microwaves and ultraviolet light.)*

Additional Information
Ensure critical devices are being sterilized.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 8.1

STERILIZATION OF REUSABLE MEDICAL DEVICES
General

Endoscopes and accessories (e.g., arthroscopes, cystoscopes, laparoscopes, reusable endoscopic accessories) that pass through normally sterile tissues are cleaned and sterilized before each use.*

Additional Information
Critical scopes examples include:

- arthroscopes
- cystoscopes
- laparoscopes

Endoscopic accessories include:

- biopsy forceps
- brushes
- other cutting devices

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Spaulding Table, p. 7 and Clause: 8.1and Clause: 8.1
CSA Z314-18: 16.1.2.1

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging

Devices are prepared in a manner that facilitates sterilization and aseptic presentation (e.g, disassembled, stop-cocks opened, standard wrapping methods, appropriate sized packaging materials validated for sterilization).

Additional Information
None.

Recommended Corrective Actions
Ensure that packaging:

- is validated for the sterilization method
- permits aseptic presentation
- provides a barrier to contamination

Reference
AC, Clause: 9.11; 9.12
AH, Clauses: 8.13, 11.4.4
CSA Z314-18: 14.5.1; 15.4.2

STERILIZATION OF REUSABLE MEDICAL DEVICES
Manufacturer's Instructions for Use

Critical devices are packaged according to the device manufacturer's written instructions.

Additional Information
Instructions may include that devices are opened, disassembled, etc.

Watch for items without manufacturer's instructions for reprocessing; these may include:

- gauze (most don't have instructions)
- sponges
- tensor bandages
- items packed with critical devices:
    - terry towel
    - flannel

Double pouching is not allowed unless validated by the manufacturer.

Recommended Corrective Actions
Ensure devices are packaged according to the device manufacturer's written instructions.

Reference
AC, Clause: 9.11; 9.12
AH, Clauses: 8.13, 11.4.4
CSA Z314-18: 15.2.3

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging

When woven or non-woven textiles are used as packaging materials, a square or envelope wrapping technique that covers the contents is used.

Additional Information
Disposable wrappers are a non-woven textile.

Recommended Corrective Actions
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. Envelope wrapping technique is given as an example.

Reference
CSA Z314-18: 15.8.3.3

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging

Packages are closed with methods that have been validated by the manufacturer for use in sterilization.

Additional Information
Methods may include:

- tape that has been validated for sterilization
- tamper evident devices, etc.

Pins, staples, string or rubber bands are not used to close bundles.

Recommended Corrective Actions
Ensure packages are closed with methods that have been validated by the manufacturer for use in sterilization.

Reference
AH, Clauses: 8.13, 11.4.4
CSA Z314-18: 15.7.1d; 15.8.3.4c

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging

Banding material, if used, is validated for the sterilization method.

Additional Information
None.

Recommended Corrective Actions
Ensure banding material is validated for the sterilization method.

Reference
AH, Clause 8.13
CSA Z314-18: 15.8.3.4c

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging - Sterilization Pouches

Sterilization pouches are used for small, lightweight items (e.g, one or two clamps).

Additional Information
None.

Recommended Corrective Actions
Ensure sterilization pouches are used for small, lightweight items (e.g, one or two clamps).

Reference
AH, Clause 8.13
CSA Z314-18: 15.7.1a

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging - Sterilization Pouches

Sterilization pouches are sized to adequately contain the device (i.e. the device does not touch the pouch seams).

Additional Information
None.

Recommended Corrective Actions
Ensure sterilization pouches are sized to adequately contain the device (i.e. the device does not touch the pouch seams).

Reference
AH, Clause 8.13
CSA Z314-18: 15.7.1a

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging - Sterilization Pouches

Sterilization pouches, if double pouched, the smaller pouch fits inside larger pouch without folding or touching outer pouch seams and paper surfaces are touching.

Additional Information
None.

Recommended Corrective Actions
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.

Reference
CSA Z314-18: 15.7.1c

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging - Sterilization Pouches

Sterilization pouches have seals that are smooth and airtight (e.g, without folds, bubbles or wrinkles).

Additional Information
None.

Recommended Corrective Actions
Ensure sterilization pouches have seals that are smooth and airtight (e.g, without folds, bubbles or wrinkles).

Reference
AH, Clause: 11.4.4
CSA Z314-18: 15.7.1d&e

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging - Sterilization Pouches

Sterilization pouches if heat sealed, have one seal with a minimum width of three millimeters or two rows of seals.

Additional Information
None.

Recommended Corrective Actions
Ensure sterilization pouches that are heat sealed have one seal with a minimum width of three millimeters or two rows of seals.

Reference
CSA Z314-18: 15.7.5.2

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging - Sterilization Pouches

Sterilization pouches if labelled 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.

Additional Information
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.

Note: Black Sharpie #13601 and #13801 pens are validated for this purpose.

Pre-printed paper labels must be validated for sterilization.

Recommended Corrective Actions
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.

Reference
AH, Clause: 8.14.1, 8.14.2
CSA Z314-18: 15.6.2a, g

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging

Rigid sterilization containers are assembled, according to manufacturer's instructions, 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**

Additional Information
Some tamper evident devices have a chemical process indicator on them.

Recommended Corrective Actions
Ensure rigid sterilization containers are assembled appropriately.

Reference
AH, Clause: 8.13
CSA Z314-18: 15.9.1; 15.9.4.3.1

STERILIZATION OF REUSABLE MEDICAL DEVICES
Preparation and Packaging

Packs or containers are clearly labelled 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**

Additional Information
Labelling (included printed labels) must be validated for sterilization.

For wrapped packages, writing is on the closure tape, not directly on the wrappers.

This item is N/A to immediate use steam sterilization and unwrapped sterilization.

Recommended Corrective Actions
Ensure packs or containers are clearly labeled.

Reference
AH, Clauses: 8.14.1, 8.14.3
CSA Z314-18: 15.6.2; 15.6.3.1; 15.6.3.2

STERILIZATION OF REUSABLE MEDICAL DEVICES
General

If the mechanical, biological or chemical indicators suggest inadequate processing the item(s) are not used.*

Additional Information
Ask staff what action is taken if biological, mechanical or chemical indicators do not pass.

Answer must include that items are reprocessed. For sterilization failure, loads are recalled and investigated according to their standard operating procedure.

Chemical integrators and emulators are types of chemical indicators.

This item is N/A to unwrapped sterilization.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 8.25
CSA Z314-18: 16.2.5.2; 16.6.13

STEAM STERILIZATION
General

Consumables in use (e.g, biological indicator and chemical indicator strips and tape) are used before the expiry date.

Additional Information
Check the expiry date of all types of biological and chemical indicators.

Recommended Corrective Actions
Ensure that all biological and chemical indicators are discarded when their expiry date is reached.

Reference
AH, Clause 8.19.1
CSA Z314-18: 16.6.2.4

STEAM STERILIZATION
General

There is a process in place that clearly identifies a non-reprocessed package from one that has been sterilized.*

Additional Information
Observe that steam sterilized items have an external chemical indicator that distinguishes sterilized from non-sterilized packages.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AC, Clause: 10.8
AH, Clause: 4.1.1, 8.19.2
CSA Z314-18: 16.6.5

STEAM STERILIZATION
Loading and Unloading

Packaged items are loaded in a manner that facilitates sterilization (e.g, Not overcrowded, away from chamber walls, peel pouches on edge).

Additional Information
None.

Recommended Corrective Actions
Ensure package items are loaded in a manner that facilitates sterilization.

Reference
AH, Clauses: 8.15, 11.4.4
CSA Z314-18: 16.2

STEAM STERILIZATION
Loading and Unloading

During unloading, each package is inspected. Inspection includes checking external chemical indicators and ensuring dryness.

Additional Information
Observe staff unloading. If unable to view unloading, ask what steps are taken when unloading the sterilizer.

Recommended Corrective Actions
Ensure each package is inspected during unloading to verify that the external chemical process indicator is acceptable and that the packages are dry.

Reference
AC, Clause: 10.6
AH, Clauses: 8.18, 8.19.2, 8.21
CSA Z314-18: 16.2.5.2

STEAM STERILIZATION
Loading and Unloading

Packages are removed from the sterilizer when dry and allowed to cool in a low traffic area before handling. Cooling time is monitored.

Additional Information
Packages are “cool” when they have reached room temperature. This usually takes at least 30 minutes to occur.

Packages must not be touched before they are cool as microorganisms from the hands will wick into warm packages and contaminate them.

Touching packages is not an appropriate method to monitor cooling time.

Recommended Corrective Actions
Ensure packages are removed from the sterilizer when dry and allowed to cool in a low traffic area before handling. Ensure cooling time is monitored according to sterilizer and medical device manufacturer’s instructions.

Reference
AH, Clause: 8.16
CSA Z314-18: 16.2.5.6

STEAM STERILIZATION
Load Documentation

Load documentation includes sterilizer identifier.

Additional Information
Sterilizer identifier may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

STEAM STERILIZATION
Load Documentation

Load documentation includes load number.

Additional Information
Sterilizer load number may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

STEAM STERILIZATION
Load Documentation

Load documentation includes date and time of cycle.

Additional Information
Date and time may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

STEAM STERILIZATION
Load Documentation

Load documentation includes mechanical indicators of physical parameters (e.g, time, temperature, pressure).

Additional Information
Mechanical indicators may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 8.20, 11.6
CSA Z314-18: 16.6.10

STEAM STERILIZATION
Load Documentation

Load documentation includes load contents.

Additional Information
Includes type of items and quantity of each type.

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

STEAM STERILIZATION
Load Documentation

Load documentation includes identification of person responsible for load release.

Additional Information
Sign-off may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

STEAM STERILIZATION
Quality Assurance Monitoring

Consumables in use (e.g, biological indicator and chemical indicator strips and tape) are appropriate for the sterilization method to be used.

Additional Information
None.

Recommended Corrective Actions
Ensure that the consumables used for steam sterilization method is validated for use in that sterilizer.

Reference
AH, Clause: 8.19
CSA Z314-18: 16.6.4; 16.6.8

STEAM STERILIZATION
Quality Assurance Monitoring

An internal chemical indicator is placed inside each package.

Additional Information
Watch for incorrect location (e.g, on the top of the pack) or position (e.g, extender handle inside and indicator outside). Correct location is an area of the pack least susceptible to sterilization. Multi-level packs require a chemical indicator at each level.

Chemical integrators and emulators are types of chemical indicators.

Recommended Corrective Actions
Ensure a chemical indicator is included on the inside of each wrapped package in the location where penetration of sterilant is of greatest concern.

Reference
AC, Clause: 9.14
AH, Clauses: 8.19, 8.19.2, 8.19.2.1
CSA Z314-18: 16.6.6

STEAM STERILIZATION
Quality Assurance Monitoring

The printout is reviewed and initialed for critical elements on cycle completion (e.g, exposure time, temperature, and pressure).

Additional Information
None.

Recommended Corrective Actions
Ensure that staff unloading sterilizer review mechanical and chemical indicators and sign off if all indicators pass.

Reference
AH, Clauses: 8.20, 8.21
CSA Z314-18: 16.6.3

STEAM STERILIZATION
Quality Assurance Monitoring

Bowie Dick/DART air removal test (pre-vacuum sterilizers only) is done daily and documented.

Additional Information
Dynamic air removal sterilizers include prevac sterilizers.

Recommended Corrective Actions
Ensure an air removal test (e.g, Bowie Dick) is conducted each day the sterilizer is in use and results documented.

Reference
AH, Clause: 8.19.3
CSA Z314-18: 16.6.7.1

STEAM STERILIZATION
Quality Assurance Monitoring

A biological indicator, contained within a process challenge device, is run each day (at a minimum) the sterilizer is used and is documented.

Additional Information
Should be done for each cycle used (pre-vacuum and gravity).

Recommended Corrective Actions
Ensure that biological indicator contained within a process challenge device 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.

Reference
AC, Clause: 4.7; 10.4
AH, Clause: 8.19.4
CSA Z314-18: 16.6.8

STEAM STERILIZATION
Quality Assurance Monitoring

Biological indicators are used for every load containing implantable medical devices and packages containing implantable devices are quarantined until a negative biological indicator result is obtained.

Additional Information
If early release occurs (due to urgent, unplanned need), a report must be generated stating:

- patient's name
- surgeon's name
- date and time
- results of the physical and chemical monitors used in the sterilization process, plus the results of the biological indicator once known

If all of these are present in the early release report and the reason for early release is valid (e.g, urgent unplanned need), from a quality assurance function, answer yes.

A copy of report is stored in the reprocessing area.

If a package is released based on monitored physical parameters and internal chemical indicator results, the internal chemical indicator shall be Type 5 or Type 6.

Note: Type 5 and Type 6 internal chemical indicators measure all critical parameters for steam sterilization and provide additional quality assurance for monitoring medical devices. Other types of internal chemical indicators might not be designed to measure all critical parameters, so deviations in critical variables might go undetected.

Recommended Corrective Actions
Ensure that every load containing implantable devices is monitored with a biological indicator and packages containing implantable devices are quarantined until a negative biological indicator result is obtained.

Reference
AC, Clause: 9.15
AH, Clauses: 8.19.5, 8.22
CSA Z314-18: 16.6.6; 16.6.8.2; 16.6.11.1

STEAM STERILIZATION
Quality Assurance Monitoring

At a minimum, a control biological indicator from each shipping lot is incubated to verify the viability of the test spores and results are documented.

Additional Information
Note: control biological indicators are not subjected to the sterilization process.

Recommended Corrective Actions
Ensure that a control biological indicator from each shipping lot is incubated to verify the viability of the test spores and results are documented.

Reference
CSA Z14-18: 16.6.8

STEAM STERILIZATION
Quality Assurance Monitoring

Time and temperature are verified and results documented for all biological indicator incubation or reading equipment. Verification is performed according to manufacturer's written instructions.

Additional Information
Review documentation of biological indicator incubator or reader routine monitoring.

Note: The 3M Attest Auto-reader Model 290 or newer is an exception to this item and is not applicable.

Recommended Corrective Actions
Ensure that time and temperature are verified, and results documented, for each biological indicator incubator or reader used. Verification is performed as per manufacturer's written instructions.

Reference
AH, Clause: 8.21
CSA Z314-18: 7, 16.6.8

IMMEDIATE USE STEAM STERILIZATION (IUSS)
General

The immediate use steam sterilization area is located in a restricted area, adjacent to the area where the sterilized items will be used.

Additional Information
The sterilizer should not be located in the patient care room or operating theatre.

Recommended Corrective Actions
Ensure the immediate use steam 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, operating theater, near any potential source of contamination, or adjacent to sterile storage.

Reference
CSA Z8000-18: Clause: 9.3.4.1.9; 9.9.3.4.5, Table 9.2 (9); Table 9.5 (7)
CSA Z314-18: 16.7.2.1; 16.7.2.2

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Preparation and Packaging

Containers designed for immediate use steam sterilization are used and maintained according to manufacturer's written instructions.

Additional Information
A Flashpak® and One Tray are examples of this type of container. Instructions for use/should be readily available to staff.

Recommended Corrective Actions
Ensure containers designed for immediate use steam sterilization are used and maintained according to manufacturer's written instructions.

Reference
CSA Z314-18: 16.7.4.2c

IMMEDIATE USE STEAM STERILIZATION (IUSS)
General

Immediate use steam sterilization is only used in emergency situations.

Additional Information
Immediate use steam sterilization must not be used for routinely scheduled procedures or to compensate for lack of inventory. Observe if possible. If not possible, ask staff when they would perform immediate use steam sterilization.

Recommended Corrective Actions
Ensure that immediate use steam sterilization is only used in emergency situations.

Reference
AH, Clause: 8.27
CSA Z314-18: 16.7.1.3

IMMEDIATE USE STEAM STERILIZATION (IUSS)

General

Implantable devices are not sterilized by immediate use steam sterilization.

Additional Information

Other than for unavoidable, emergency situations (urgent, unplanned need, with no other options available, or the medical device can only be sterilized with an immediate-use cycle), IUSS shall not be used to sterilize:

- implants or
- organic materials (e.g., cranial bone flaps).

Recommended Corrective Actions

Ensure implantable devices never undergo immediate use steam sterilization.

Reference

AH, Clause: 8.27
CSA Z314-18: 16.7.1.4

IMMEDIATE USE STEAM STERILIZATION (IUSS)
General

Complete sets are not sterilized by immediate use steam sterilization.

Additional Information
Observe if possible. If not possible, ask staff if they immediate use steam sterilize complete sets of instruments.

Recommended Corrective Actions
Ensure that complete sets are never immediate use steam sterilized.

Reference
CSA Z314-18: 16.7.1.4

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Loading and Unloading

Sterility of critical devices is maintained during removal from the sterilizer and transport to the point of use. Devices are used immediately.

Additional Information
Observe if possible. If not, ask staff to explain how devices are removed and transported from the sterilizer to point of use.

Recommended Corrective Actions
Ensure sterility of critical devices that are immediate use steam sterilized is maintained during removal from the sterilizer and transport to the point of use. Devices are used immediately and not stored.

Reference
AH, Clause: 8.28, 11.4.4
CSA Z314-18: 16.7.5.3; 16.7.6

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Load Documentation

Load documentation includes sterilizer identifier.

Additional Information
Sterilizer identifier may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Load Documentation

Load documentation includes date and time of cycle.

Additional Information
Date and time may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Load Documentation

Load documentation includes device sterilized.

Additional Information
Includes identification of item being reprocessed.

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Load Documentation

Load documentation includes mechanical indicators of physical parameters (e.g, time, temperature, pressure).

Additional Information
Mechanical indicators may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clauses: 8.21, 11.6
CSA Z314-18: 16.6.10

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Load Documentation

Load documentation includes results of chemical indicator and biological indicator.

Additional Information
Results may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clauses: 8.21; 11.6
CSA Z314-18: 16.6.10

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Load Documentation

Load documentation includes reason for immediate use steam sterilization.

Additional Information
Rationale for IUSS may be recorded in a log, printout, database or recording

chart. Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Load Documentation

Load documentation includes patient identification.

Additional Information
Patient information may be recorded in a log, printout, database or recording chart.

This information may be retrieved from the patient chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Load Documentation

Load documentation includes name of surgeon.

Additional Information
Surgeon name may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Load Documentation

Load documentation includes identification of person responsible for indicators and load release.

Additional Information
Sign-off may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Quality Assurance Monitoring

Consumables in use (e.g, biological indicator and chemical indicator strips) are appropriate for IUSS.

Additional Information
None.

Recommended Corrective Actions
Ensure that the consumables used for IUSS is validated for use in that sterilizer.

Reference
AH, Clause: 8.19
CSA Z314-18: 16.6.4; 16.6.8

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Quality Assurance Monitoring

An internal chemical indicator is placed inside each tray holding device(s) being sterilized.

Additional Information
Watch for incorrect location (e.g, on the top of the pack) or position (e.g, extender handle inside and indicator outside). Correct location is an area of the pack least susceptible to sterilization. Multi-level packs require a chemical indicator at each level.

Recommended Corrective Actions
Ensure each immediate use steam sterilization cycle is monitored with mechanical and chemical indicators.

Reference
AH, Clause: 8.19
CSA Z314-18: 15.5.2.2; 16.7.3.1

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Quality Assurance Monitoring

The printout is reviewed and initialed for critical elements on cycle completion (e.g, exposure time, temperature, and pressure).

Additional Information
If unable to observe, ask staff what the protocol requires for verifying the load.

Recommended Corrective Actions
Ensure that staff unloading immediate use steam sterilizer review mechanical and chemical indicators and sign off if all indicators pass.

Reference
AH, Clauses: 8.20, 11.6
CSA Z314-18: 16.6.3.1

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Quality Assurance Monitoring

Bowie Dick/DART air removal test (pre-vacuum sterilizers only) is done daily and documented.

Additional Information
Dynamic air removal sterilizers include prevac sterilizers.

Recommended Corrective Actions
Ensure an air removal test (e.g, Bowie Dick) is conducted each day the sterilizer is in use and results documented.

Reference
AH, Clauses: 8.19.3, 11.6
CSA Z314-18: 16.6.7.1

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Quality Assurance Monitoring

Biological indicator test is run each day (at a minimum) that the sterilizer is used and is documented.

Additional Information
None.

Recommended Corrective Actions
Ensure that a biological indicator test is run each day the sterilizer is in use. Results are documented.

Reference
AC, Clause: 4.7; 10.4
AH, Clauses: 11.6, 8.19.4
CSA Z314-18: 16.6.8

IMMEDIATE USE STEAM STERILIZATION (IUSS)
Quality Assurance Monitoring

At a minimum, a control biological indicator from each shipping lot is incubated to verify the viability of the test spores and results are documented.

Additional Information
*Note: control biological indicators are **not** subjected to the sterilization process.*

Recommended Corrective Actions
Ensure that a control biological indicator from each shipping lot is incubated to verify the viability of the test spores and results are documented.

Reference
CSA Z14-18: 16.6.8

UNWRAPPED STEAM STERILIZATION
Quality Assurance Monitoring

An internal chemical indicator is placed with the unwrapped devices being sterilized.

Additional Information
Watch for incorrect location (e.g, on the top of the devices) or position (e.g, extender handle inside and indicator outside). Correct location is in an area least susceptible to sterilization.

Recommended Corrective Actions
Ensure each unwrapped steam sterilization cycle is monitored with a chemical indicator.

Reference
AH, Clause: 8.19
CSA Z314-18: 15.5.2.2; 16.7.3.1

UNWRAPPED STEAM STERILIZATION
Quality Assurance Monitoring

The printout is reviewed and initialed for critical elements on cycle completion (e.g, exposure time, temperature, and pressure).

Additional Information
None.

Recommended Corrective Actions
Ensure that staff unloading sterilizer with unwrapped devices review mechanical and chemical indicators and sign off if all indicators pass.

Reference
AH, Clause: 11.6
CSA Z314-18: 16.2.5.4

UNWRAPPED STEAM STERILIZATION
General

Devices that are sterilized unwrapped are allowed to dry in the sterilizer and are left to cool before they are used.

Additional Information
None.

Recommended Corrective Actions
Ensure devices are allowed to dry in the sterilizer and are left to cool before they are used.

Reference
AH, Clause: 8.16
CSA Z314-18: 16.2.4.2.2

UNWRAPPED STEAM STERILIZATION
General

Semi-critical devices (e.g, speculum) that are sterilized unwrapped are stored in a clean, dry, protected area until use.

Additional Information
None.

Recommended Corrective Actions
Ensure semi-critical 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.

Reference
CSA Z314-18: 17.5.1.3

UNWRAPPED STEAM STERILIZATION
General

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.*

Additional Information
This is done to prevent use of a non-reprocessed device on a patient.

Examples include:

- labelling reprocessed devices with reprocessing date and reprocessing expiry date (if applicable)
- tracking of the device identifier at each step documenting the date and time that it has been: received for cleaning, cleaned, received for disinfection, disinfected, etc.
- placing unwrapped, semi-critical devices in clean bags or containers labelled with reprocessing date and expiry date (if applicable)

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 4.1.1
CSA Z314-18: 13.3.1.1; 13.3.14; 12.4.1.1

CHEMICAL STERILIZATION METHODS (Steris System 1)
Manufacturer's Instructions for Use

Medical devices reprocessed in the SS1 have been validated.

Additional Information
Check manufacturer's instructions for use for validation information.

Recommended Corrective Actions
Ensure that medical devices validated for reprocessing in the Steris System 1.

Reference
AC, Clause: 7.6; 7.7; 7.10; 9.0
AH, Clause: 8.4.2
CSA Z314-18: 7.1

CHEMICAL STERILIZATION METHODS (Steris System 1)
General

Critical devices that are sterilized in the SS1 are used immediately.

Additional Information
None.

Recommended Corrective Actions
Ensure critical devices processed in Steris System 1 are used immediately following processing and are not stored.

Reference
CSA Z314-18: 16.2.4.4.3; 16.2.4.4.4

CHEMICAL STERILIZATION METHODS (Steris System 1)
General

Semi-critical devices are completely dried before storage.

Additional Information
Examples of cloths that are not lint-free include:

- terry towel
- paper towel

Examples of lint-free cloths include:

- huck towels
- disposable lint-free cloths

Recommended Corrective Actions
Ensure devices are dried using a clean, soft, lint-free cloth following rinsing.

Reference
CSA Z314-18: 11.8.5; 13.3.13

CHEMICAL STERILIZATION METHODS (Steris System 1)
Manufacturer's Instructions for Use

Devices are connected to the correct tray and attachment tubing and arranged in the SS1, according to manufacturer's instructions.*

Additional Information
Tray and attachment must be validated for use with the specific devices.

Ensure devices, including endoscopes, 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.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 8.4.2
CSA Z314-18: 16.2.4.3.2

CHEMICAL STERILIZATION METHODS (Steris System 1)
Quality Assurance Monitoring

A diagnostic cycle is performed as the first cycle of each day that the sterilizer is used. Results are documented and initialed.

Additional Information
None.

Recommended Corrective Actions
Ensure a diagnostic test is performed as the first cycle of each day the sterilizer is in use.

Reference
AH, Clause: 8.19.4.2
CSA Z314-18:16.5.1

CHEMICAL STERILIZATION METHODS (Steris System 1)
General

Consumables in use (e.g, biological indicator, chemical indicator strips and sterilant) are appropriate for the sterilization method to be used.

Additional Information
For the sterilant, DIN has been replaced by medical device license number from Health Canada. Check label for device license.

Recommended Corrective Actions
Ensure that the biological indicator, chemical indicator strips and sterilant used for Steris System 1 are validated for use in the sterilizer.

Reference
AH, Clauses: 8.11, 8.19
CSA Z314-18: 16.2.4.3.1; 16.6.4; 16.6.8

CHEMICAL STERILIZATION METHODS (Steris System 1)
Quality Assurance Monitoring

A biological indicator is tested each day the sterilizer is in use and results documented.

Additional Information
None.

Recommended Corrective Actions
Ensure a biological indicator is tested each day the sterilizer is in use. Results are documented.

Reference
AC, Clause: 4.7; 10.4
AH, Clause: 8.19.4
CSA Z314-18: 16.6.8

CHEMICAL STERILIZATION METHODS (Steris System 1)
Quality Assurance Monitoring

Consumables in use (e.g, biological indicator, chemical indicator strips, and sterilant) are used before the expiry date.

Additional Information
Check the expiry date of all types of biological indicators, chemical indicators and sterilant.

Recommended Corrective Actions
Ensure that all biological indicator, chemical indicator and sterilant are discarded when their expiry date is reached.

Reference
AH, Clause 8.19.1
CSA Z314-18: 16.6.2.4

CHEMICAL STERILIZATION METHODS (Steris System 1)
Quality Assurance Monitoring

Mechanical indicators are reviewed by the individual responsible for releasing the load and signed after each sterilization cycle.

Additional Information
If unable to observe, ask staff what the protocol requires for verifying the load.

Recommended Corrective Actions
Ensure that staff unloading Steris System 1 review mechanical indicators and sign off if all indicators pass.

Reference
CSA Z314-18: 16.6.3.1

CHEMICAL STERILIZATION METHODS (Steris System 1)
General

There is a process in place that clearly identifies a non-reprocessed device from one that has been sterilized.*

Additional Information
This is done to prevent use of a non-reprocessed device on a patient.

Examples include:

- labelling reprocessed devices with reprocessing date and reprocessing expiry date (if applicable)
- tracking of the device identifier at each step documenting the date and time that it has been: received for cleaning, cleaned, received for disinfection, disinfected, etc.
- placing unwrapped, semi-critical devices in clean bags or containers labelled with reprocessing date and expiry date (if applicable)

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 4.1.1
CSA Z314-18: 13.3.1.1; 13.3.14; 12.4.1.1

CHEMICAL STERILIZATION METHODS (Steris System 1)
Load Documentation

Load documentation includes sterilizer identifier.

Additional Information
Sterilizer identifier may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

CHEMICAL STERILIZATION METHODS (Steris System 1)
Load Documentation

Load documentation includes load number.

Additional Information
Sterilizer load number may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

CHEMICAL STERILIZATION METHODS (Steris System 1)
Load Documentation

Load documentation includes date and time of cycle.

Additional Information
Date and time may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

CHEMICAL STERILIZATION METHODS (Steris System 1)
Load Documentation

Load documentation includes sterilant lot number and expiry date.

Additional Information
Sterilant lot number and expiry date may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

CHEMICAL STERILIZATION METHODS (Steris System 1)
Load Documentation

Load documentation includes mechanical indicators of physical parameters (time, temperature, etc.).

Additional Information
Mechanical indicators may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clauses: 8.24, 11.6
CSA Z314-18: 16.6.10

CHEMICAL STERILIZATION METHODS (Steris System 1)
Load Documentation

Load documentation includes chemical indicator test result.

Additional Information
Results may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

CHEMICAL STERILIZATION METHODS (Steris System 1)
Load Documentation

Load documentation includes biological indicator test result.

Additional Information

Check with manufacturer's instructions for cycles to test.

Results may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clauses: 8.19.4.2, 11.6
CSA Z314-18: 16.6.8.1; 16.6.10

CHEMICAL STERILIZATION METHODS (Steris System 1)
Load Documentation

Load documentation includes contact time of the sterilant (printout).

Additional Information
Contact time may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clauses: 8.20, 11.6
CSA Z314-18: 16.6.10

CHEMICAL STERILIZATION METHODS (Steris System 1)
Load Documentation

Load documentation includes temperature of the sterilant (printout).

Additional Information
Temperature may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clauses: 8.20, 11.6
CSA Z314-18: 16.6.10

CHEMICAL STERILIZATION METHODS (Steris System 1)
Load Documentation

Load documentation includes identification of person responsible for load release.

Additional Information
Sign-off may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

CHEMICAL STERILIZATION METHODS (Steris System 1)
Quality Assurance Monitoring

At a minimum, a control biological indicator from each shipping lot is incubated to verify the viability of the test spores and results are documented.

Additional Information
Control biological indicators are **NOT** subjected to the sterilization process.

Recommended Corrective Actions
Ensure that a control biological indicator from each shipping lot is incubated to verify the viability of the test spores and results are documented.

Reference
CSA Z14-18: 16.6.8

CHEMICAL STERILIZATION METHODS (Steris System 1)
Device Documentation

Device documentation includes identification of the devices being reprocessed.

Additional Information
Load contents may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

CHEMICAL STERILIZATION METHODS (Steris System 1)
Device Documentation

Device documentation includes patient identification, with date used, and serial number of probe (some or all these components of traceability may be done in another department).

Additional Information
Patient information may be recorded in a log, printout, database or recording chart.

This information may be retrieved from the patient chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each item being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6.4
CSA Z314-18: 16.6.10

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Manufacturer's Instructions for Use

Medical devices being reprocessed in a low temperature sterilizer are validated.

Additional Information
Check manufacturer's instructions for use for validation information.

Recommended Corrective Actions
Ensure that medical devices validated for reprocessing in a low temperature sterilizer.

Reference
AC, Clause: 7.6; 7.7; 7.10; 9.0
AH, Clause: 8.4.2
CSA Z314-18: 7.1

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
General

Consumables in use (e.g, biological indicator, chemical indicator strips, sterilant and tape) are appropriate for the sterilization method to be used.

Additional Information
For the sterilant, DIN has been replaced by medical device license number from Health Canada. Check label for device license.

Recommended Corrective Actions
Ensure that the biological indicator, chemical indictor, sterilant and tape used in low temperature sterilization are validated for use in the sterilizer.

Reference
AH, Clause: 8.11, 8.19
CSA Z314-18: 16.2.4.3.1; 16.6.4; 16.6.8

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
General

Consumables in use (e.g, biological indicator, chemical indicator strips, sterilant and tape) are used before the expiry date.

Additional Information
Check the expiry date of all types of biological indicators and chemical indicators, plus the tape and sterilant.

Recommended Corrective Actions
Ensure that all biological and chemical indicators, sterilant and tape are discarded when their expiry date is reached.

Reference
AH, Clause 8.19.1
CSA Z314-18: 16.6.2.4

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
General

There is a process in place that clearly identifies a non-reprocessed package from one that has been sterilized.*

Additional Information
This is done to prevent use of a non-reprocessed device on a patient.

Examples include:

- labelling reprocessed devices with reprocessing date and reprocessing expiry date (if applicable)
- tracking of the device identifier at each step documenting the date and time that it has been: received for cleaning, cleaned, received for disinfection, disinfected, etc.
- placing unwrapped, semi-critical devices in clean bags or containers labelled with reprocessing date and expiry date (if applicable)

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 4.1.1
CSA Z314-18: 13.3.1.1; 13.3.14; 12.4.1.1

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Loading and Unloading

Packaged items are loaded in a manner that facilitates sterilization (e.g, Trays are flat, not overcrowded, away from chamber walls, peel pouches on edge, paper to plastic).

Additional Information
None.

Recommended Corrective Actions
Ensure package items are loaded in a manner that facilitates sterilization.

Reference
AH, Clause: 8.15
CSA Z314-18: 16.2

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Loading and Unloading

Correct cycle is used for each load.

Additional Information
None.

Recommended Corrective Actions
Ensure correct cycle is used for each load.

Reference
CSA Z314-18: 16.2.4

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Loading and Unloading

During unloading, each package is inspected. Inspection includes checking external chemical indicators and ensuring dryness.

Additional Information
Observe staff unloading. If unable to view unloading, ask what steps are taken when unloading the sterilizer.

Recommended Corrective Actions
Ensure each package is inspected during unloading to verify that the external chemical process indicator is acceptable and that the packages are dry.

Reference
AC, Clause: 10.6
AH, Clauses: 8.18, 8.19.2, 8.21
CSA Z314-18: 16.2.5.2

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Load Documentation

Load documentation includes sterilizer identifier.

Additional Information
Sterilizer identifier may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Load Documentation

Load documentation includes load number.

Additional Information
Sterilizer load number may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Load Documentation

Load documentation includes date and time of cycle.

Additional Information
Date and time may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Load Documentation

Load documentation includes mechanical indicators of physical parameters (e.g, time, temperature, pressure).

Additional Information
Mechanical indicators may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clauses: 8.24, 11.6
CSA Z314-18: 16.6.10

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Load Documentation

Load documentation includes load contents.

Additional Information
Load contents may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Load Documentation

Load documentation includes identification of person responsible for load release.

Additional Information
Sign-off may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Quality Assurance Monitoring

An internal chemical indicator is placed inside each package.

Additional Information
Watch for incorrect location (e.g, on the top of the pack) or position (e.g, extender handle inside and indicator outside). Correct location is an area of the pack least susceptible to sterilization. Multi-level packs require a chemical indicator at each level.

Recommended Corrective Actions
Ensure each low temperature sterilization cycle is monitored with a chemical indicator.

Reference
AH, Clause: 8.19.2.1
CSA Z314-18: 15.5.2.2; 16.7.3.1

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Quality Assurance Monitoring

The printout is reviewed and initialed for critical elements on cycle completion.

Additional Information
If unable to observe, ask staff what the protocol requires for verifying the load.

Recommended Corrective Actions
Ensure that staff unloading review mechanical indicators and sign off if all indicators pass.

Reference
AH, Clause: 8.21
CSA Z314-18: 16.6.3.1

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Quality Assurance Monitoring

Biological indicator test is run each day (at a minimum) that the sterilizer is used and is documented.

Additional Information
Check with manufacturer's instructions for cycles to test.

Recommended Corrective Actions
Ensure that a biological indicator test is run each day the sterilizer is in use. Results are documented.

Reference
AC, Clause: 4.7; 10.4
AH, Clauses: 8.19.4, 8.19.4.2
CSA Z314-18: 16.6.8

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Quality Assurance Monitoring

Each type of cycle to be used is monitored with a biological indicator.

Additional Information
Should be done for each cycle used.

Recommended Corrective Actions
Ensure that biological indicators contained within a process challenge device 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.

Reference
AC, Clause: 4.7; 10.4
AH, Clause: 8.19.4
CSA Z314-18: 16.6.8

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Quality Assurance Monitoring

Biological indicators are used for every load containing implantable medical devices.

Additional Information
If early release occurs (due to urgent, unplanned need), a report must be generated stating:

- patient's name
- surgeon's name
- date and time
- results of the physical and chemical monitors used in the sterilization process, plus the results of the BI, once known

If all of these are present in the early release report and the reason for early release is valid (e.g, urgent unplanned need), from a quality assurance function, answer yes.

A copy of report is stored in the reprocessing area.

If a package is released based on monitored physical parameters and internal chemical indicator results, the internal chemical indicator shall be Type 5 or Type 6.

Note: Type 5 and Type 6 internal chemical indicators measure all critical parameters for steam sterilization and provide additional quality assurance for monitoring medical devices. Other types of internal chemical indicators might not be designed to measure all critical parameters, so deviations in critical variables might go undetected.

Recommended Corrective Actions
Ensure that every load containing implantable devices is monitored with a biological indicator and packages containing implantable devices are quarantined until a negative biological indicator result is obtained.

Reference
AC, Clause: 9.15
AH, Clauses: 8.19.5, 8.22
CSA Z314-18: 16.6.8.2; 16.6.11.1

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Quality Assurance Monitoring

At a minimum, a control biological indicator from each shipping lot is incubated to verify the viability of the test spores and results are documented.

Additional Information
Control biological indicators are **NOT** subjected to the sterilization process.

Recommended Corrective Actions
Ensure that a control biological indicator from each shipping lot is incubated to verify the viability of the test spores and results are documented.

Reference
CSA Z14-18: 16.6.8

LOW TEMPERATURE STERILIZATION (Sterrad, V-Pro)
Quality Assurance Monitoring

Time and temperature are verified and results documented for all biological indicator incubation or reading equipment. Verification is performed according to manufacturer's written instructions.

Additional Information
Review documentation of biological indicator incubator or reader routine monitoring.

Recommended Corrective Actions
Ensure that time and temperature are verified, and results documented, for each biological indicator incubator or reader used. Verification is performed as per manufacturer's written instructions.

Reference
AH, Clause: 8.21
CSA Z14161-11
CSA Z314-18: 7, 16.6.8

ETHYLENE OXIDE (ETO)
Manufacturer's Instructions for Use

Devices being sterilized are validated for ethylene oxide sterilization.

Additional Information
Check manufacturer's instructions for use for validation information.

Recommended Corrective Actions
Ensure that medical devices validated for reprocessing by ethylene oxide sterilization.

Reference
AC, Clause: 7.6; 7.7; 7.10; 9.0
AH, Clause: 8.4.2
CSA Z314-18: 7.1

ETHYLENE OXIDE (ETO)
General

Consumables in use (e.g, biological indicator, chemical indicator strips, sterilant and tape) are appropriate for the sterilization method to be used.

Additional Information
For the sterilant, DIN has been replaced by medical device license number from Health Canada. Check label for device license.

Recommended Corrective Actions
Ensure that the biological indicator and chemical indicator used for ethylene oxide are validated for use in the sterilizer.

Reference
AH, Clause: 8.19
CSA Z314-18: 16.2.4.3.1; 16.6.4; 16.6.8

ETHYLENE OXIDE (ETO)
General

Consumables in use (e.g, biological indicator, chemical indicator strip, sterilant and tape) are not expired.

Additional Information
None.

Additional Information
Check the expiry date of all types of biological indicators and chemical indicators.

Recommended Corrective Actions
Ensure that all biological and chemical indicators are discarded when their expiry date is reached.

Reference
AH, Clause 8.19.1
CSA Z314-18: 16.6.2.4

ETHYLENE OXIDE (ETO)
General

There is a process in place that clearly identifies a non-reprocessed package from one that has been sterilized.*

Additional Information
This is done to prevent use of a non-reprocessed device on a patient.

Examples include:

- labelling reprocessed devices with reprocessing date and reprocessing expiry date (if applicable)
- tracking of the device identifier at each step documenting the date and time that it has been: received for cleaning, cleaned, received for disinfection, disinfected, etc.
- placing unwrapped, semi-critical devices in clean bags or containers labelled with reprocessing date and expiry date (if applicable)

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 4.1.1
CSA Z314-18: 13.3.1.1; 13.3.14; 12.4.1.1

ETHYLENE OXIDE (ETO)
Loading and Unloading

Packaged items are loaded in a manner that facilitates sterilization (e.g, not overcrowded, away from chamber walls, peel pouches on edge).

Additional Information
None.

Recommended Corrective Actions
Ensure package items are loaded in a manner that facilitates sterilization.

Reference
AH, Clause: 8.15
CSA Z314-18: 16.2

ETHYLENE OXIDE (ETO)
Loading and Unloading

Correct cycle (if applicable) is selected.

Additional Information
None.

Recommended Corrective Actions
Ensure correct cycle is used for each load.

Reference
CSA Z314-18: 16.2.4

ETHYLENE OXIDE (ETO)
Loading and Unloading

During unloading, each package is inspected. Inspection includes checking external chemical indicators and package integrity.

Additional Information
Observe staff unloading. If unable to view unloading, ask what steps are taken when unloading the sterilizer.

Recommended Corrective Actions
Ensure each package is inspected during unloading to verify that the external chemical process indicator is acceptable and that the packages are dry.

Reference
AC, Clause: 10.6
AH, Clauses: 8.18, 8.19.2, 8.21
CSA Z314-18: 16.2.5.2

ETHYLENE OXIDE (ETO)
Load Documentation

Load documentation includes sterilizer identifier.

Additional Information
Sterilizer identifier may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

ETHYLENE OXIDE (ETO)
Load Documentation

Load documentation includes load number.

Additional Information
Sterilizer load number may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

ETHYLENE OXIDE (ETO)
Load Documentation

Load documentation includes date and time of cycle.

Additional Information
Date and time may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

ETHYLENE OXIDE (ETO)
Load Documentation

Load documentation includes mechanical indicators of physical parameters (e.g, time, temperature, pressure).

Additional Information
Mechanical indicators may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clauses: 8.24, 11.6
CSA Z314-18: 16.6.10

ETHYLENE OXIDE (ETO)
Load Documentation

Load documentation includes load contents.

Additional Information
Load contents may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

ETHYLENE OXIDE (ETO)
Load Documentation

Load documentation includes identification of person responsible for load release.

Additional Information
Sign-off may be recorded in a log, printout, database or recording chart.

Information can be:

- manually recorded
- downloaded and printed or
- checked on the electronic database and signed off electronically after each cycle

Recommended Corrective Actions
Ensure documentation is completed for each load being reprocessed.

Reference
AC, Clause: 13
AH, Clause: 11.6
CSA Z314-18: 16.6.10

ETHYLENE OXIDE (ETO)
Quality Assurance Monitoring

Internal chemical indicator is placed inside each package.

Additional Information
Watch for incorrect location (e.g, on the top of the pack) or position (e.g, extender handle inside and indicator outside). Correct location is an area of the pack least susceptible to sterilization. Multi-level packs require a chemical indicator at each level.

Recommended Corrective Actions
Ensure each ethylene oxide sterilization cycle is monitored with a chemical indicator.

Reference
AH, Clause: 8.19.2
CSA Z314-18: 15.5.2.2; 16.7.3.1

ETHYLENE OXIDE (ETO)
Quality Assurance Monitoring

The printout is reviewed and initialed for critical elements on cycle completion.

Additional Information
If unable to observe, ask staff what the protocol requires for verifying the load.

Recommended Corrective Actions
Ensure that staff unloading review mechanical indicators and sign off if all indicators pass.

Reference
AH, Clause: 8.21
CSA Z314-18: 16.6.3.1

ETHYLENE OXIDE (ETO)
Quality Assurance Monitoring

Biological indicator test is run each day the sterilizer is used and results documented.

Additional Information
None.

Recommended Corrective Actions
Ensure that a biological indicator test is run each day the sterilizer is in use. Results are documented.

Reference
AC, Clause: 4.7; 10.4
AH, Clause: 8.19.4, 8.19.4.2
CSA Z314-18: 16.6.8

ETHYLENE OXIDE (ETO)
Quality Assurance Monitoring

Each type of cycle to be used is monitored with a biological indicator.

Additional Information
Must done for each cycle used.

Recommended Corrective Actions
Ensure that biological indicators contained within a process challenge device 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.

Reference
AC, Clause: 4.7; 10.4
AH, Clause: 8.19.4
CSA Z314-18: 16.6.8

ETHYLENE OXIDE (ETO)
Quality Assurance Monitoring

Biological indicators are used for every load containing implantable medical devices.

Additional Information
If early release occurs (due to urgent, unplanned need), a report must be generated stating:

- patient's name
- surgeon's name
- date and time
- results of the physical and chemical monitors used in the sterilization process, plus the results of the BI, once known

If all of these are present in the early release report and the reason for early release is valid (e.g, urgent unplanned need), from a quality assurance function, answer yes.

A copy of report is stored in the reprocessing area.

If a package is released based on monitored physical parameters and internal chemical indicator results, the internal chemical indicator shall be Type 5 or Type 6.

Note: Type 5 and Type 6 internal chemical indicators measure all critical parameters for steam sterilization and provide additional quality assurance for monitoring medical devices. Other types of internal chemical indicators might not be designed to measure all critical parameters, so deviations in critical variables might go undetected.

Recommended Corrective Actions
Ensure that every load containing implantable devices is monitored with a biological indicator and packages containing implantable devices are quarantined until a negative biological indicator result is obtained.

Reference
AC, Clause: 9.15
AH, Clauses: 8.19.5, 8.22
CSA Z314-18: 16.6.8.2; 16.6.11.1

ETHYLENE OXIDE (ETO)
Quality Assurance Monitoring

At a minimum, a control biological indicator from each shipping lot is incubated to verify the viability of the test spores and results are documented.

Additional Information
Control biological indicators are **NOT** subjected to the sterilization process.

Recommended Corrective Actions
Ensure that a control biological indicator from each shipping lot is incubated to verify the viability of the test spores and results are documented.

Reference
CSA Z14-18: 16.6.8

ETHYLENE OXIDE (ETO)
Quality Assurance Monitoring

Time and temperature are verified and results documented for all biological indicator incubation or reading equipment. Verification is performed according to manufacturer's written instructions.

Additional Information
Review documentation of biological indicator incubator or reader routine monitoring.

Recommended Corrective Actions
Ensure that time and temperature are verified, and results documented, for each biological indicator incubator or reader used. Verification is performed as per manufacturer's written instructions.

Reference
AH, Clause: 8.21
CSA Z14161-11
CSA Z314-18: 7, 16.6.8

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

The sterile storage area is well-lit and dedicated to storage of clean and sterile supplies.

Additional Information
Look for inappropriate items stored in this area, such as shipping containers, soiled items, housekeeping equipment.

Make sure there is sufficient lighting to allow easy reading of labels and to determine the condition of packaging, ask staff if they have any concerns about sufficient lighting.

Recommended Corrective Actions
Ensure the sterile storage area is dedicated only to the storage of clean and sterile supplies.

Reference
AH, Clauses: 2.3.1, 9.1c, 11.4.3
CSA Z314-18: 10.2.5.1

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

Sterile storage areas have doors that are closed and access is restricted to authorized personnel.

Additional Information
May be within the clean side of MDR.

Recommended Corrective Actions
Ensure sterile storage areas doors are closed and access is restricted to authorized personnel.

Reference
CSA Z314-18: 10.2.5.9; 17.3.2.2.1

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

Signage is posted indicating the sterile storage area is a restricted area.

Additional Information
Sterile storage may be within the clean side of MDR.

Recommended Corrective Actions
Ensure signage is posted indicating the sterile storage area is a restricted area.

Reference
CSA Z314-18: 10.2.5.9

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

Sterile storage areas are protected from dust, insects and vermin.

Additional Information
None.

Recommended Corrective Actions
Ensure sterile storage areas are protected from dust, insects and vermin.

Reference
AH, Clauses: 2.3.4, 9.1b, 11.4.3
CSA Z314-18: 10.2.5.1

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

Sterile storage areas are monitored daily and documented for temperature and humidity extremes.

Additional Information
Check temperature and humidity:

- Temperature: 18°C – 23°C and
- Humidity: 30% – 60%.

Recommended Corrective Actions
Ensure sterile storage areas are monitored daily and documented for temperature and humidity extremes. Measure and document temperature (18 – 23°C) and humidity (30 – 60%) daily.

Reference
AH, Clauses: 9.1b, 11.4.3
CSA Z314-18: 10.2.5.1

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

Shelving material is non-shedding with smooth surfaces and easily cleanable.

Additional Information
Shelving construction shall be:

- non-porous on all surfaces
- non-shedding and easily cleanable
- free of burrs and sharp or rough edges

Recommended Corrective Actions
Ensure shelving material is non-porous on all surfaces, non-shedding and easily cleanable, and free of burrs and sharp or rough edges.

Reference
AH, Clause: 9.1e
CSA Z314-18: 10.2.5.6

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

The top and bottom shelves of storage carts are solid.

Additional Information
None.

Recommended Corrective Actions
Ensure open storage units have a solid top and bottom shelf.

Reference
AH, Clause: 9.1e
CSA Z314-18: 10.2.5.6

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

Sterile packages are stored at least 25 cm above the floor, 46 cm away from the ceiling and 5 cm away from any exterior wall.

Additional Information
Imperial dimensions:

- Ten inches above the floor on a solid cleanable surface,
- Eighteen inches from the ceiling and
- Two inches from outside walls.

Recommended Corrective Actions
Ensure sterile packages are stored at least 25 cm (10 inches) above the floor, 46 cm (18 inches) away from the ceiling and 5 cm (two inches) away from any exterior wall.

Reference
AH, Clause: 9.1e
CSA 314-18: 10.2.5.7

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

Packages are adequately spaced.

Additional Information
For rigid sterilization containers, check that container manufacturer's instructions for use allows for stacking.

Recommended Corrective Actions
Ensure packages are adequately spaced.

Reference
AH, Clauses: 2.3.2, 9.1c
CSA Z314-18: 17.3.2.2.2

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

Sterile packages are stored on a first in first out basis (FIFO).

Additional Information
Ask MDRT how they operationalize the FIFO principle.

Recommended Corrective Actions
Use “first in/first out” principle when stocking and retrieving devices.

Reference
AH, Clause: 9.1a)
CSA Z314-18: 17.1.2

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

Case carts are cleaned and dried between each use and are in good repair.

Additional Information
None.

Recommended Corrective Actions
Ensure case carts are cleaned and dried between each use and are in good repair.

Reference
CSA Z314-18: 10.2.6.2.2

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

Clean and sterile devices are covered and transported separately (e.g, in separate carts or containers) from soiled devices or linens.

Additional Information
None.

Recommended Corrective Actions
Ensure clean and sterile devices are covered and transported separately from soiled devices or linens.

Reference
AH, Clauses: 5.2.1, 9.1d
CSA Z314-18: 17.6.1.1

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

A container labeling system (e.g, colour coding or tagging) is in place to identify clean or contaminated contents of transport containers.

Additional Information
Labeling must be cleanable (not paper).

Recommended Corrective Actions
Ensure all transport containers have a labeling system (e.g, colour coding or tagging) to identify contents as clean or contaminated.

Reference
AH, Clauses: 5.2.2, 9.1d, 11.4.3
CSA Z314-18: 11.3.1.3

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

Following high-level disinfection, dried devices are stored in a clean, dry, protected area until use.

Additional Information
None.

Recommended Corrective Actions
Ensure that devices are stored in a clean, dry, protected area following high-level disinfection.

Reference
AH, Clause: 9.1
CSA Z314-18: 17.5.1.3

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
Storage Cabinets

Endocavity probes (e.g, endovaginal DI probes, TEE probes) are stored in a dedicated, closed, ventilated cabinet.

Additional Information
None.

Recommended Corrective Actions
Ensure there is a dedicated, protected, clean and well ventilated storage cabinet for probes.

Reference
AH, Clause: 11.4.3
CSA Z314-18: 13.3.14

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
Storage Cabinets

Endoscopes with lumens are hung vertically in ventilated (HEPA filtration) storage cabinets with non-porous, cleanable surfaces in a manner that protects them from contamination (e.g, tips do not touch the floor of the cabinet).

Additional Information
Air channel purge cabinets don't require vertical hanging of endoscopes, check manufacturer's instructions for use to confirm.

Recommended Corrective Actions
Ensure there is a dedicated, protected, clean and well ventilated storage cabinet for endoscopes.

Reference
AC: 11.8
AH, Clause: 11.4.3
CSA Z314-18: 12.5.1; 12.5.2.1; 12.5.2.2

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
Storage Cabinets

Caps, valves and other detachable components are removed during storage.

Additional Information
None.

Recommended Corrective Actions
Ensure caps, valves and other detachable components are removed during storage and reassembled before use.

Reference
AC, Clause: 11.8
AH, Clause: 11.4.3
CSA Z314-18: 12.5.3

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
Storage Cabinets

Endoscope and endocavity probe storage cabinets are cleaned at least weekly. Cleaning is documented.

Additional Information
None.

Recommended Corrective Actions
Ensure endoscope storage cabinets are cleaned at least weekly and documented.

Reference
AH, Clause: 11.4.3
CSA Z314-18: 12.5.2.2

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

All semi-critical endoscopes, including bronchoscopes, are reprocessed if stored for longer than seven days.

Additional Information
None.

Recommended Corrective Actions
Ensure that endoscopes are reprocessed when their shelf-life is reached. Endoscopes for GI procedures should be reprocessed if storage exceeds seven days. Bronchoscopes that are high-level disinfected and not sterilized, should be reprocessed if storage exceeds seven days.

Reference
AH, Clause: 11.4.3
CSA Z314-18: 12.5.4

STORAGE AND USE OF REPROCESSED MEDICAL DEVICES
General

When a random package or set is inspected from the storage area, sterilized devices are visibly clean and identified as reprocessed.*

Additional Information
Random packages include wrapped, pouches, and linen bundles (check as Surgical Textiles review tool no longer done).

If visible soil (e.g, blood) or a wet package is observed or items are not identified as sterile (external indicators), indicate “No”.

If there is anything observed wrong, other than that above, go back to the item in the tool and ensure the item for that issue is a “No”. For example:

- chemical indicator not in correct location: Question 232
- items without manufacturer’s instructions for sterilization: Question 207
- textiles that do not have manufacturer’s instructions for sterilization: Question 209

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AH, Clause: 11.4.3
CSA Z314-18: 17.5.2.1; 17.5.2.2

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Installation and Qualification Documentation

All sterilizers are installed, validated and performs according to manufacturer's specifications (installation and operational qualification) and results documented.

Additional Information
Check for installation qualification only on sterilizers installed after Cycle 3 (2016/17).

This item includes Steris System 1.

Review documents that show tests have been conducted following installation and major repair. Results of the tests should be included with the documentation.

Operational Qualification needs to be done at least annually, and after:

- major repairs, including:
    - replacing controls
    - replacing plumbing
    - major rebuilding
    - installation of new major component
- sterilizer relocation
- construction in the sterilizer area
- environmental changes in the area (changes to HVAC, etc.)
- unexplained sterility failure
    - changes in steam supply or delivery

For table top sterilizers that are sent out for maintenance or repairs, *Operational Qualification* needs to be done each time a sterilizer is received (re-installed).

Check manufacturer's instructions for use for equipment-specific installation and operational qualification requirements. For example, for steam sterilizers, qualification requires running three consecutive cycles in an empty chamber using process challenge devices with biological indicators and, if dynamic air removal sterilizers are used, they also require testing with three consecutive air removal tests (e.g., Bowie-Dick) in an otherwise empty sterilizer. For example, for table-top steam sterilizers, testing will take place in a fully loaded chamber.

Recommended Corrective Actions
Ensure operational qualification testing of sterilizers is performed and documented following installation, major repairs or significant modifications.

Reference
AC, Clause: 4.4
AH, Clauses: 8.5, 8.6, 8.7, 8.8, 8.9, 11.2.1.3
CSA Z314-18: 16.5.2; 16.5.3; 16.8.3.3; 7

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Performance Qualification Documentation

Performance qualification is done and documented to verify that packs or sets (including loaners) can be sterilized in the facility's sterilizer(s).

Additional Information
This is achieved by placing biological and chemical indicators within packs or sets in location(s) presenting the greatest challenge to sterilization.

Following sterilization, indicator results are reviewed to verify sterilization and documented before accepting the packs or sets for use.

Review documented performance qualification results.

Recommended Corrective Actions
Ensure performance qualification is done and to verify that packs or sets can be sterilized in the facility's sterilizer(s). This is done for each pack or set, or "product family", as determined by the MDR department, 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
- new processes (e.g, extended cycles as recommended by manufacturer)

This includes placing biological and chemical indicators within packs or sets in location(s) presenting the greatest challenge to sterilization. Following sterilization, indicator results are reviewed to verify sterilization and documented before accepting the packs or sets for use.

Reference
AH, Clause: 8.10, 11.2.1.3
CSA Z314-18: 7; 16.5.4

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Record of all maintenance and interventions associated with a failed sterilization load or a positive biological indicator.

Additional Information
Review documentation from a follow-up of a failed sterilization load or positive biological indicator.

Recommended Corrective Actions
Ensure there is documentation of all maintenance and interventions associated with a failed sterilization load or a positive biological indicator.

Reference
AC, Clause: 14
AH, Clause: 8.25
CSA Z314-18, 5.7.7.1, 5.7.7.2, Figure 5.1, 18.1.3

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation for Sterilizer Type

Maintenance and repair documentation is available for steam sterilizers.

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for each sterilizer is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation for Sterilizer Type

Maintenance and repair documentation is available for Immediate Use Steam Sterilization.

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for each sterilizer is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation for Sterilizer Type

Maintenance and repair documentation is available for chemical sterilization methods (Steris System 1).

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for each sterilizer is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation for Sterilizer Type

Maintenance and repair documentation is available for low temperature (V-Pro).

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for each sterilizer is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation for Sterilizer Type

Maintenance and repair documentation is available for low temperature (Sterrad).

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for each sterilizer is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation for Sterilizer Type

Maintenance and repair documentation is available for Ethylene Oxide.

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for each sterilizer is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Maintenance and repair documentation is available for biological indicator monitoring equipment.

Additional Information
Check documentation for routine (daily or weekly) and preventative maintenance and equipment repair.

Some biological indicator incubators may be N/A if the manufacturer does not recommend any maintenance or repair.

Recommended Corrective Actions
Ensure all maintenance is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Maintenance and repair documentation is available for automatic washer or disinfectors.

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Check manufacturer's instructions for use for requirements around checking the accuracy of the recording device on the equipment, using an independent calibration device, and check records that this has been done.

Recommended Corrective Actions
Ensure all maintenance for this equipment is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clauses: 7.15.1, 11.6.1
CSA Z314-18: 11.8.4.1.7; 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Maintenance and repair documentation is available for pasteurizers.

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Check manufacturer's instructions for use for requirements around checking the accuracy of the recording device on the equipment, using an independent calibration device, and check records that this has been done.

Recommended Corrective Actions
Ensure all maintenance for this equipment is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clauses: 7.15.1, 11.6.1
CSA Z314-18: 11.8.4.1.7; 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Maintenance and repair documentation is available for drying cabinets.

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for this equipment is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Maintenance and repair documentation is available for Automated Endoscope Reprocessors (AER).

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for this equipment is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Maintenance and repair documentation is available for ultrasonic cleaners.

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for this equipment is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Maintenance and repair documentation is available for automated lumen cleaners.

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for this equipment is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1; 12.4.12.2.2

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Maintenance and repair documentation is available for probe reprocessing units (e.g, Trophon, TD100).

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for this equipment is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Maintenance and repair documentation is available for high-level disinfection air handling systems (e.g, GUS, AirClean System)

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for this equipment is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Maintenance and repair documentation is available for fume hoods.

Additional Information
Maintenance includes routine maintenance (done by MDRD and Facilities Maintenance and Engineering) as well as preventive maintenance and repairs.

In some sites, routine and preventive maintenance and repairs are done by contracted service technicians. Check these reports.

Recommended Corrective Actions
Ensure all maintenance for this equipment is documented. This includes all routine maintenance (done by MDR and Facilities Maintenance and Engineering), preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

INSTALLATION, QUALIFICATION, MAINTENANCE AND REPAIR DOCUMENTATION
Maintenance and Repair Documentation

Maintenance and repair documentation is available for instrument sterilization containers.

Additional Information
Examples include Flashpak®, rigid container systems, etc.

Check documentation for routine (daily/weekly inspection, checking gaskets, changing filter, etc.) and preventative maintenance and equipment repair.

Inspection performed when the container is set up may be documented by initialing the container during assembly if the standard operating procedure outlines this as the process.

Recommended Corrective Actions
Ensure all maintenance is documented. This includes all routine maintenance, preventative maintenance and equipment repair. Frequency of routine and preventative maintenance follows manufacturer's written instructions.

Reference
AC, Clause: 4.5; 4.6
AH, Clause: 11.6.1
CSA Z314-18: 18.1

SINGLE-USE MEDICAL DEVICES
Provincial Policies and Procedures

There is a documented policy stating that single-use medical devices are not to be reprocessed in the facility.

Additional Information
There is an AHS policy/procedure available on Insite.

Recommended Corrective Actions
Develop, update or obtain a written policy that states single-use medical devices are not reprocessed.

AHS Critical and Semi-critical Single-use Medical Devices Policy
https://extranet.ahsnet.ca/teams/policydocuments/1/clp-single-use-medical-devices-ps-07-policy.pdf

Reference
AC, Clause: 7.2
AH, Clauses: 1, 11.3

SINGLE-USE MEDICAL DEVICES
General

Single-use medical devices are not reprocessed in the facility.*

Additional Information
Reviewers to note if any single-use medical devices are observed being reprocessed during the observational tour

Ask the staff:

- if they ever get single-use medical devices in the area,
- how they identify single-use medical devices, and
- what they do with single-use medical devices.

Recommended Corrective Actions
Confirm that corrective actions implemented at the time deficiency was identified on review day remain in place.

Reference
AC, Clause: 7.2
AH, Clauses: 1, 11.1.2