Review of Decontamination Practices within the Winnipeg Health Region

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Executive Summary

The Winnipeg Regional Health Authority undertook a quality assurance project to ensure that the critical elements and methods of cleaning and decontamination of medical devices are compliant with recognized Standards and Best Practices. While a comprehensive practice audit and gap analysis of cleaning and disinfection practices for medical devices demonstrated a high degree of compliance with standards, it also identified some activities that require improvement. When deficits were identified, the manager or staff initiated remedial action to rectify the issue. If the deficit required longer-term mitigation, management immediately mobilized resources to address the issue.

While most phases of cleaning and decontamination complied with standards, some sites achieved higher compliance than others. At most sites compliance with standards was observed with instrument handling in the operating room, immediate handling of the case cart on arrival in decontamination, sorting and disassembly, management of rigid sterilization container systems, cleaning, rinsing, inspection, and use and maintenance of equipment.

Where compliance with an expected practice is not specifically mentioned in this report, compliance is confirmed.

Project Background and Scope

The efficacy of any sterilization process depends on a consistent system for lowering and limiting bioburden before sterilization. The thorough cleaning of a reusable medical device is essential in order to remove soil, including organic matter (blood, protein, feces, mucus, and tissue) and other material, prior to submitting the device to a sterilization or disinfection process. Failure to remove organic matter and residue prior to sterilization or disinfection can impair the efficacy of these processes. Such matter retained on devices not only furnishes a medium for the growth of micro-organisms, but can also physically protect micro-
organisms from the sterilization or disinfection process or render chemical disinfectants inactive. Extension of the sterilization or disinfection process will not necessarily remove the microbial load. (CSA Z314.8-08)

The Winnipeg Regional Health Authority (WRHA) directed an external review of processes related to cleaning and decontamination at WRHA sites to determine if practices are compliant with CSA Standards and identify areas for improvement. Compliance with Standards is necessary for accreditation and risk management. The review included central reprocessing areas and reprocessing areas adjacent to operating rooms. The review included the instrument inspection process prior to sterilization. The review encompassed care of the instruments during the surgical procedure, the immediate post procedure care of instruments in the operating room (OR) and the final quality assurance check which also occurs in the OR while setting up for the surgical procedure.

Reprocessing areas reviewed included:

- Health Sciences Centre (HSC) – Adult and Children’s Medical Device Reprocessing (MDR), Women’s Hospital – OR;
- St. Boniface General Hospital – Central Processing Department (CPD) & – OR;
- Concordia Hospital – MDR;
- Victoria General Hospital – MDR;
- Seven Oaks General Hospital – MDR;
- Grace General Hospital – MDR & - OR;
- Misericordia Health Centre – MDR & OR; and
- Pan Am Clinic.

Medical device reprocessing departments are being re-named to medical device reprocessing (MDR) as the term describes the function of the department. Previous names include Central Processing Department (CPD), Central Sterile
Department (CSD) and others. The change started with the Winnipeg Regional Health Authority and has been embraced by CSA and reprocessing departments across Canada.

**Methodology**

Management should be commended for organizing the review process and facilitating access to key areas and personnel. The regional educator and site managers accompanied the auditor during site visits, facilitating quick responses to questions, and immediate feedback. Staff at all sites was willing to respond to questions and assist with the review. Managers and staff were responsive to suggestions and impressive in their enthusiasm to accept change. The participation of all involved was greatly appreciated.

The review occurred from Monday, February 7 to Friday, February 11, and Monday, February 14, 2011. A second visit was made on Friday, February 18 to Misericordia Health Centre and Health Sciences Centre’s Women’s Hospital.

The review commenced at each site with observation of the immediate handling of contaminated devices at the point of use. Surgical procedures in the OR were observed at all sites.

Circulating and scrub nurses were observed at set-up prior to the surgical procedure to see what steps were taken to assure the sterility of medical devices to be used during the procedure.

The activities of the scrub nurses were observed intraoperatively in order to determine that practices regarding segregation and removal of gross soiling of used instruments, and management of the medical devices were being followed.

Staff in the operating rooms, including surgeons and anaesthesiologists, was interviewed about their experiences in this area.
Following surgery, the cart with the used instruments was followed to the reprocessing area to determine the process and length of time for transportation of the soiled medical devices to the reprocessing department.

Equipment and work flow in the cleaning and decontamination area were then observed. Staff in the decontamination area were observed and interviewed to assess work practices and knowledge. Maintenance staff was consulted regarding equipment maintenance and functioning.

The audit tool (attached) is based on CSA Standards and Health Canada/PHAC/PIDAC recommendations. The audit included assessment of policies, procedures, practices and quality systems, decontamination areas and equipment and accessories, supplies required for patient and staff safety, transportation, staff qualifications, education and training and waste management.

The audit tool was adapted from one currently used provincially in British Columbia, which was adapted from the audit tool used in Alberta, based on what was initially developed at Sunnybrook Hospital in Toronto. British Columbia’s Ministry of Health mandated implementation of the audit tool in 2007 and 2008 to determine/confirm compliance with established standards for reprocessing of medical devices.

The Decontamination Skill Competency Checklist was developed by and adapted from Providence Health, Vancouver. The Checklist facilitated the practice and knowledge review.

A gap analysis was completed for each site examining compliance issues, to identify both strengths and areas in need of improvement in order to meet CSA standards. A verbal report was provided to managers throughout the audit and at the conclusion of the review at each site.
GENERAL FINDINGS:

The reviewer was positively received at every site with managers available to accompany and guide the reviewer, respond to questions, and implement immediate change where possible. The review determined compliance with most of the elements that were expected. Where deficiencies were identified, mitigation was implemented immediately if possible. If the practice deficit required a broader strategy to achieve compliance, action was commenced by the department manager and regional manager. All sites exhibited an openness and willingness to change and improve practice where indicated.

Personnel qualification and training is consistent with current standards. Personnel are required to have passed a recognized reprocessing course prior to being hired. Most reprocessing managers have completed an approved program and ongoing education. There were a few exceptions at some sites where the reprocessing manager and staff had not completed a recognized reprocessing program.

Orientation and in-service education was well organized in most sites, less structured in others. Documentation of ongoing education and scheduled competency assessment varies among the sites.

Mechanical washers were used, loaded, cleaned, tested and maintained according to requirements. The auditor consulted with facilities maintenance staff and the washer-disinfector manufacturers to confirm maintenance and documentation. The manufacturers confirmed that staff operates the equipment appropriately and that facility maintenance provides competent service on the equipment when necessary. A representative of a washer-disinfector manufacturer suggested that facilities should monitor the temperature achieved in washer-disinfector cycles.

Perioperative nurses consistently inspected the sterile items for appropriate packaging, intact seals, package integrity, external and internal sterility indicators, visually inspected instruments and sterile sets for flaws, visible soil, or missing instruments, and knew the appropriate corrective action to take. OR staff follows
protocol when they find a soiled instrument or a set without indicator. The OR nurses without exception all said that if a soiled instrument was found that the entire set is considered contaminated and needs to be replaced.

The perioperative nurses handled surgical instruments appropriately, and rinsed off gross soil and blood as soon as safely possible during surgery. At most sites, the perioperative nurses demonstrated appropriate management of sterile supplies and management of the used instruments at the end of the surgical procedure. At some sites, the point-of-use cleaning and removal of blood and organic matter was not as thorough and timely as possible.

Scrub nurses wore surgical masks appropriately, in the presence of open sterile supplies and when patients were present. Circulating nurses, surgeons, and anesthesthetists were not as consistent with appropriate wearing of surgical masks. Hair was frequently observed outside of hair covering.

A visitor, a company representative, was observed in the operating room at one site teaching the ophthalmologist and nurses how to use new equipment. The visitor had not followed hand hygiene protocol and did not maintain distance of one foot from the sterile field.

Flash (immediate use) sterilization is used regularly at some sites. OR staff was not aware that cleaning steps are shortened when flash is requested. There is a narrow margin of safety with flash sterilization and thus requires strict adherence to required parameters and protocols.

Some sites have duplicate staffing, equipment, and resources for reprocessing in the OR area as well as the main MDR department. Significant deficits in practice were found in the reprocessing areas in which managers and staff lacked the same qualifications, training and knowledge as their counterparts in the main reprocessing departments. Supervisors with dual (or more) managerial responsibilities usually were not prepared through education, training, and experience in reprocessing. Older equipment was found more frequently in sites supporting two reprocessing areas. Policies, procedures and manufacturer’s
instructions for reprocessing were not current and available to staff in auxiliary reprocessing areas.

In most sites, transportation of contaminated medical devices was done in covered, fully enclosed containers. Some sites did not comply with requirements for transportation of soiled devices.

At most sites the MDR manager was not involved in the evaluation and purchase of a medical device.

Written policies and procedures were outdated and not readily available to reprocessing staff at many sites. Staff in some reprocessing departments could not locate any manufacturer’s instructions for reprocessing medical devices being reprocessed there.

Inspection occurred at several phases of the reprocessing process. In the operating room the scrub nurse rinsed and cleaned soiled instruments. On arrival in the decontamination area, staff inspected the devices for organic matter and other material such as cement. Staff used a brush if visible soil was observed. Staff inspected devices when removed from ultrasonic cleaner prior to placing in washer-disinfector. If visible soil was observed, the device was scrubbed with a brush or a polish, depending on what the soil was. On the clean side, staff inspected the devices on removal from the washer-disinfector.

Soaking, use of enzymatic detergents, and manual cleaning was inconsistent among the sites and staff, and was not based on the device manufacturer’s instructions at some sites. All instruments were soaked at some sites. At other sites no instruments were soaked. Rather, the instrument was rinsed under running water. At some sites the instruments were placed in basins rather than sinks. Most sites were observed manually scrubbing difficult-to-clean instruments.

Use of the ultrasonic cleaner was inconsistent among the sites and staff. Some sites put all instruments in the ultrasonic cleaner. Other sites rarely used the ultrasonic cleaner. Detergent injection was automatic in most ultrasonic cleaners. When used, staff operated the ultrasonic cleaner according to recommendations. Cycle times varied among sites.
One-way workflow was observed in many sites. The physical limitations of some sites prevented a one-way workflow. One-way workflow prevents contamination that would occur if items processed to a higher level come into contact with a lower-level-processed medical device. In some decontamination areas the tray of instruments removed from a completed ultrasonic cleaning cycle are placed adjacent to the tray intended for the next ultrasonic cleaning cycle.

The design of the decontamination area in some sites facilitated effective cleaning and decontamination and met the requirements of CSA Z 314.8: 7. In other sites safe practice is compromised by lack of space, one-way workflow, traffic control, physical separation from clean area, equipment, degree of mechanization, hand hygiene facilities, areas for storage, donning and removing personal protective equipment (PPE), environmental controls, and waste management.

In some sites staff practices were observed that placed the staff and environment at risk of exposure to body substances, e.g., scrub nurse and OR aide disposing of blood and body fluids.

Hand hygiene facilities were not available in some decontamination areas. When brought to the attention of the manager an alcohol based hand rub was placed in the decontamination area. Personnel in decontamination did not consistently wash their hands according to standards. In one site staff moved frequently from decontamination to clean areas without washing their hands. In one site staff from the clean area went to decontamination to wash their hands. On occasion the sink used for hand washing was also used for soaking contaminated medical devices.

In the decontamination area at some sites, protective attire was either not worn at all or was hung on a hook for reuse in decontamination.

Environmental cleaning was inconsistent – most staff clean work surfaces minimally at end of shift, some staff do not clean their work area at end of shift as they think that housekeeping staff clean work surfaces. Chemical agents used for environmental cleaning included hospital grade germicide, alcohol, vinegar, hydrogen peroxide.
In some sites outdated chemical agents, and agents no longer being used, were found on shelves in the decontamination area. Appropriate environmental cleaning includes de-cluttering to facilitate a clean environment.
Site Reports

Results of the audit at all sites are reflected in the findings and recommendations listed in the next section of the report.

Compliance with the elements in the audit tool and competency checklist was met unless noted in the following reports specific to each site. Thus, the shorter the site report, the higher the compliance with standards.

The auditor would like to thank all managers and staff for their cooperation and willingness to respond to questions and to demonstrate practices. The auditor appreciates the dedication shown by all managers and staff. The positive response to suggestions and findings demonstrates the commitment to providing quality care of which the Winnipeg Regional Health Authority can be proud.
Health Sciences Centre – Adult OR, Adult and Children’s MDR

OBSERVATIONS

HSC exhibited many examples of Best Practices, including housekeeping protocols, management of cleaning accessories, the timeliness with which contaminated instruments are received and cleaned in decontamination, inspection of instruments in decontamination. Policies and procedures were current. Manufacturer’s written instructions were used to develop the cleaning and decontamination protocols. HSC is highly automated, for example, the OR has the Neptune system (so no liquids go to MDR).

A rather unique strength of HSC reprocessing department is the involvement of biomedical engineering that inspect and refurbish the reprocessing equipment.

Staff and managers are well trained and eager to demonstrate practices.

In compliance with ORNAC, OR scrub nurses use a damp sponge for wiping medical devices.

The site has a well-organized system of communication and transportation that enables OR staff to bring the case cart quickly to elevator to be sent to MDR. The decontamination team knows when to expect case cart and so are ready and waiting to start cleaning immediately upon arrival of carts. Staff is instantly aware when the elevator arrives with a case cart as an alarm automatically goes off to alert them.

There are dedicated elevators at HSC for both clean and sterile supplies and dirty equipment.

The cart washer is cleaned daily including filters on bottom to remove gross debris.

The ultrasonic cleaner is cleaned daily and tested weekly.

Decontamination staff was observed inspecting the soiled instruments to determine whether they needed to undergo a manual cleaning, be soaked in
enzymatic detergent and/or be brushed. They then initiated the appropriate next steps.

**RECOMMENDATIONS:**

- That protocols for manual cleaning and use of the ultrasonic cleaner be further standardized, based on manufacturer’s instructions.
- That reprocessing staff from other WRHA reprocessing departments benefit from working and observing in HSC MDR as part of their orientation and ongoing education.

**Health Sciences Centre – Women’s**

**OBSERVATIONS:**

HSC’s Women’s Hospital is now fifty years old and so was not designed or built to meet current MDR standards. Currently, used medical devices are cleaned in Women’s Hospital, which does not have the same staff expertise or equipment of the Hospital’s Central Medical Device Reprocess department (although all staff there has taken the appropriate Red River course).

Some areas in need of improvement:

- Equipment is old and outdated, or lacking, e.g., there is no forced air system for flushing lumens;
- The manner of disposing of body fluids is out of date and poses a potential risk to staff safety;
- Staff are working within a small space that compromises one way work flow making it difficult to clearly identify a soiled device from a clean device; and
- An old Getinge 6606 in decontamination is being used as a hopper for blood and body fluids from suction bottles.
- Used equipment is currently transported uncovered to the reprocessing area.
HSC management is aware of these issues and already working to address them. The manager has begun the process to purchase covered carts to transport contaminated devices. In the case of the Getinge 6606 they are considering decommissioning the machine and using a solidifier for fluid management.

Essentially, the main challenge currently facing HSC Women’s is the adoption and initiation of new procedures to improve medical device reprocessing prior to the completion of the new state-of-the-art facility.

RECOMMENDATIONS:

- That used (i.e. contaminated) medical devices be transported from Women’s Hospital to HSC MDR in covered carts via the tunnel system;
- That all equipment should be serviced, tested, and maintained according to the manufacturer’s manual.
- That management should review whether the most appropriate equipment is being used for each procedure; and
- That staff should be reminded on an ongoing basis about appropriate hand hygiene.

Management has already committed to addressing these issues, in particular to transferring the reprocessing of used equipment to HSC central MDR as soon as possible.
OBSERVATIONS (OR Reprocessing Area):

MDR staff was inconsistent in their method of cleaning and decontaminating medical devices and did not follow the manufacturer’s written instructions.

Flash sterilizing – a procedure that once was common practice, but now is recognized as being outdated and should only be used as an emergency practice - is being used inappropriately on a large number of medical devices.

Staff in the OR reprocessing area lacks sufficient training, supervision and appropriate equipment.

Staff was inconsistent in performing hand hygiene. The lack of a dedicated sink for hand washing as well as the lack of a dispenser for alcohol-based hand rub in the decontamination room undoubtedly contributes to this issue.

Personal protective equipment (PPE) was not always worn by reprocessing staff, putting them at risk from splashes and aerosols during procedures.

Some equipment (the ultrasonic cleaner as an example) is old, outdated and does not meet the facility’s needs. In addition, manufacturer’s operating and maintenance manuals were not available to reference.

When technicians in the OR reprocessing area package instruments to be sterilized in the central MDR, the packages are frequently received in the central MDR in incorrect packages with incorrect indicators.

There was a visible lack of appropriate housekeeping in the OR reprocessing area. Gross dust was clearly visible on a shelf and containers of chemical agents.

RECOMMENDATIONS:

- That Central MDR immediately assume responsibility for the reprocessing area in the OR department.
• That hand hygiene, PPE and hair covering protocols for both the OR and the
OR decontamination area immediately be reinforced and supervised on an
ongoing basis.
• That appropriate protocols for the cleaning and decontamination of
medical devices immediately be developed based on manufacturer’s
written instructions.
• That cleaning accessories, e.g., brushes, be cleaned, disinfected, and
discarded according to CSA standards.

**Misericordia Central MDR**

**OBSERVATIONS:**

The central MDR functions at a high level in spite of having inadequate space and
equipment. The decontamination area lacks dedicated hand hygiene facilities,
environmental controls, reprocessing equipment, etc. Counter space for sorting
and inspecting is limited.

All staff including the manager in the central MDR has taken an approved
reprocessing course and has ongoing education.

There is a dedicated dumb waiter for the delivery of clean and sterile devices.

However, soiled medical devices are transported on an elevator used for other
purposes. And while the devices transported from OR are sent in closed carts,
those transported from Urgent Care are uncovered.

There is also an issue with the packaging and storage of infrequently used
supplies, specifically how to protect sterile equipment that may not be used for
an extended period from moisture, dust or other damage.

**RECOMMENDATIONS:**

• Undertake a review of rarely used sets and trays. Replace with disposable
deVICES/SETS where available. Develop a strategy to ensure that devices are
available and work when needed.
• Sterilized items that may not be used for a long period of time be protected with a medical grade plastic cover or that some be replaced with single use devices.

• That the Misericordia redevelopment plan take into consideration the space and equipment issues raised in this report including: capital investment in reprocessing so that MDR can assume the work of the OR reprocessing area.
  ➢ The expansion of the central MDR to accommodate the required reprocessing to accommodate the number of procedures being performed, including infrastructure, space, work-flow, equipment;
  ➢ The need for new updated equipment (appropriate sinks ultrasonic cleaners, washer disinfectors, cart washers, medical gas, covered carts to transport contaminated devices to MDR, drying cabinets);
  ➢ The need for an improved water supply system (quality, pressure, volume of flow), including demineralised water for effective sterilization; and
  ➢ The urgent need for a pressurized air supply;

• The redevelopment plan should also include capital investment in the reprocessing area in the OR if it continues to be used for reprocessing. Hand hygiene, PPE and reprocessing equipment needs to be available. Traffic should not be going through an OR between decontamination and sterilizers.

All stakeholders should be involved in resolving issues, including OR, MDR, IP&C, facilities management.
Concordia Hospital

OBSERVATIONS:

In the OR the instruments received minimal treatment at point of use. OR scrub nurse wiped soiled instruments with a dry sponge, rinsed with a small amount of water, used foam on soiled instruments for last case of day.

The nurses stated that the MDR requested that OR nurses segregate used medical devices from open but unused devices.

In the MDR used medical devices were cleaned under running water, they were not immersed in a sink in water and detergent.

Staff was sometimes observed roughly handling delicate expensive equipment.

RECOMMENDATIONS:

- That carts containing used (contaminated) equipment be brought to the MDR and cleaned in a more timely manner;
- That policies and procedure be reviewed and updated as appropriate to adhere to CSA standards;
- That protocols for hand hygiene, PPE etc., be reviewed and reinforced on an ongoing basis with staff;
- That the appropriate steps for cleaning medical devices and accessories (brushes etc.) be reviewed and reinforced with staff on an ongoing basis;
- That staff be reminded to handle equipment gently; and
- That equipment such as the ultrasonic cleaner be serviced and maintained according to manufacturer’s instructions.
Seven Oaks General Hospital

OBSERVATIONS:

OR staff reported finding soiled instruments in the past month. In those instances, staff acted appropriately, returning the entire set to MDR for replacement.

The process to get contaminated equipment from the OR to the MDR post-surgery is too slow and cumbersome, taking more than an hour rather than minutes. Because orthopaedic surgeries are performed at this site, used instruments are frequently very soiled and so need to be cleaned in a timely manner in order to prevent foreign matter (bone fragments, dried blood) from hardening, making it much more difficult to reprocess the equipment.

Staff did not always wear the appropriate PPE, putting them at risk from splashing during the disposal of liquid waste and potentially contaminating sterile equipment.

Staff members were observed transporting both sterile and soiled equipment in elevators used for other purposes, including public transportation.

Proper hand hygiene procedures were not always observed.

Manufacturer’s written instructions were not always readily available and were not always followed.

RECOMMENDATIONS:

- That the process to get soiled instruments to MDR post-surgery be streamlined. Currently, there are too many middle men and too many stages;
- That the new streamlined process ensures that neither soiled equipment or containers full of fluid destined for disposal be left unattended;
• That the process for disposal of bodily fluids be reviewed to minimize the potential for staff injury and to ensure staff are wearing the appropriate PPE;
• That all staff be reminded of the appropriate protocols for the proper use of PPE, and that it be reinforced on an ongoing basis;
• That OR staff be reminded of the protocol to manage instruments destined for reprocessing as per ORNAC, CSA standards and the manufacturer’s instructions;
• That medical equipment – both sterile and soiled – not be transported in an elevator that is also used by members of the public;
• That the use of flash sterilization be reviewed to ensure procedures are based on a documented quality process that measures objective performance criteria;
• That the use of flash sterilization for any medical device be reviewed to assess the rationale for use and compliance with CSA Standard Z314.3;
• That all members of Operating Room team receive upgraded training regarding flash sterilization: the indicators for it and the appropriate policies and procedures to apply when using it;
• That OR personnel be reminded of the appropriate aseptic practices to follow when sterile sets are open including the appropriate wearing of masks;
• That access to hand hygiene facilities (including dispensers for alcohol-based rub) be improved;
• That OR and MDR staff be reminded of appropriate hand hygiene protocol and that the protocol continue to be reinforced on an ongoing basis;
• That the cleaning of accessories be standardized and upgraded in order to meet CSA standards;
• That the use of detergent be standardized and upgraded in order to meet CSA standards (automatic dispensers would assist in addressing this issue);
• That the sink used for manual cleaning be repaired;
• That the appropriate use of the ultrasonic cleaner be reviewed with staff to ensure that devices that can be cleaned in the ultrasonic cleaner are put through the ultrasonic cycle, as per the manufacturer’s instructions;
• That the cleaning and disinfection of power tools be reviewed to ensure compliance with CSA standards;
• That staff be educated about the appropriate protocols for cleaning difficult-to-clean medical devices (based on manufacturer’s instructions) and that written copies of the protocols be available to staff for review;
• That copies of all manufacturer’s manuals (devices, equipment, agents) be available to staff for review;
• That the MDR manager be involved in the decision-making process for medical devices;
• That regular in-service education and competency checks are instituted for reprocessing staff and that they are appropriately documented;
• That the cleaning, testing and maintenance of equipment (for example washer-disinfector and ultrasonic cleaner) be regularly scheduled and documented according to the reprocessing equipment manufacturer’s instructions.
Grace Hospital

OBSERVATIONS:

Grace Hospital MDR is well managed. Many examples of Best Practices were observed.

The OR educator assists the MDR manager with policy & procedure maintenance and teaching.

Inservice education is regular and documented. IP&C is involved in staff education, for example, teaching PPE protocols.

Manufacturer’s instructions are available to staff in manager’s office and in the decontamination area.

Automatic pump for enzymatic detergent assures correct dilution in sink for manual cleaning in MDR.

Grace Hospital has some physician-supplied and loaner medical devices.

The site is progressing towards merging the OR reprocessing and MDR departments.

RECOMMENDATIONS:

- That policies and procedures be developed regarding the use and reprocessing of physician-supplied and loaner medical devices based on the device manufacturer’s written, validated instructions for reprocessing;
- That appropriate training / education is provided to ensure that cleaning accessories (brushes etc.) are properly cleaned, disinfected and discarded;
- That steps are taken to ensure standards for lubrication are met (CSA Z314.3:8.3); and
- That ward staff be reminded of the proper protocols for sending contaminated medical devices and equipment to MDR (for example, no
sharps or body fluids), and that the protocols be reinforced on an ongoing basis.
Victoria Hospital

OBSERVATIONS:

MDR and IPC are occasionally involved with purchase decisions.

The MDR manager is encouraging staff to further their education by taking the CSA certification exam.

The staff is well trained, following most practices according to standards.

RECOMMENDATIONS:

- That MDR and IPC staff be involved in all purchasing decisions regarding medical devices that require reprocessing;
- That staff be reminded on an ongoing basis of the importance of following proper hand hygiene; and
- That the old Castle ultrasonic cleaner receives more maintenance than it currently receives, as per the manufacturer’s instructions.
Pan Am Clinic

OBSERVATIONS:

The cleaning of devices is done in timely manner. Staff in decontamination knows when to expect case carts carrying contaminated devices. The decontamination area is in close proximity to the procedure rooms.

The facility has in place a procedure for handling damaged equipment – maintenance takes care of returning damaged devices to manufacturer.

The MDR manager is involved in purchase decisions and obtains written reprocessing instructions.

The Pan Am Clinic has two decontamination areas, neither of which meets the requirements of CSA Standard 314.8: 7 Work areas and equipment. The West end decontamination area is more compromised than the other. The West end decontamination area has no one way work flow, no window for passing devices through to clean area. Staff in decontamination has to wash up and remove gloves and gown to bring cleaned medical devices to prep and pack.

A hopper in each decontamination area is used to empty blood and body fluids from suction bottles. Staff then collapse the suction containers prior to disposal. Hoppers pose a risk of aerosolization and cross-contamination.

In both decontamination areas, staff use basins rather than sinks for manual cleaning. The basins are too small for soaking and immersion. The basins are also inappropriately used for cleaning scopes.

There were too many instruments placed in too many layers on the tray for the washer- disinfector. Correct spacing allows water and cleaning agents to be exposed to the devices.

The use of detergent is inconsistent between areas and frequently not done in accordance with the manufacturer’s instructions.
An OR nurse reported that on the previous day she had found 3 sterile sets without an internal indicator. She returned the sets to MDR to be reprocessed again. The sets had staff initials on the external indicator, facilitating follow-up and teaching.

**RECOMMENDATIONS:**

- That Pan Am Clinic work with the Health Region to develop a long-term plan to address the physical challenges of the reprocessing areas which would include consolidation of reprocessing to one area to optimize staff, equipment, all resources (For description of design of work area for decontamination refer to CSA Z314.8 and the Infection Prevention and Control section of this report, page 35) ;
- That the clinic review the equipment needs for the decontamination areas (an additional ultrasonic cleaner is on order; there is no cart washer);
- That the clinic implement a fluid management system for blood and body fluids generated during surgical procedures;
- That the clinic review the accessibility of hand hygiene stations including alcohol-based hand rub;
- That staff be reminded on an ongoing basis about the importance of following hand hygiene protocols;
- That the clinic investigates the feasibility of installing an eye-wash station inside the decontamination area;
- That staff be educated about spill kits, made aware of their availability and appropriate use;
- That the issue of staff using basins rather than sinks in the decontamination areas be addressed;
- That staff review manufacturer’s instructions for the correct number and configuration of instruments on the tray for washer-disinfection;
- That a protocol for the proper cleaning and decontamination of devices be developed, taught and supervised on an ongoing basis;
- That OR staff be reminded that contaminated medical devices must be covered when being transported to the decontamination area;
• That staff be reminded of all policies and procedures for reprocessing and that written versions of these policies and procedures be readily available for review;
• That an updated version of all appropriate and applicable CSA standards be readily accessible to staff;
• That the appropriate use of flash sterilization be reviewed with staff to ensure it is only used in compliance with CSA Z314.3;
• That a policy be developed and implemented regarding the use and reprocessing of physician-supplied or loaner equipment;
• That an automated detergent preparation system be put in place to minimize the risk of human error;
• That environmental cleaning between cases and at the end of a shift be standardized in order to ensure appropriate CSA standards are being met;
• That the clinic ensure that the reprocessing manager and staff have completed the appropriate qualification / certification program (that includes both reprocessing theory and clinical skills training as required by CSA standards and Accreditation Canada);
• That the clinic ensures the necessary documentation of training and competency checks is in place; and
• That the decontamination area be reconfigured to address Infection Prevention & Control issues.
OBSERVATIONS:

In the OR, the scrub nurse separates sharps and lumens and places in kidney basins, immerses visibly soiled instruments in water, brushes organic matter from instruments as much as possible, and uses foam when indicated.

Instruments are transported from OR to decontamination covered.

Visual inspection is good in the decontamination area. The auditor observed inspection being done before, during and after cleaning.

The OR Manager is starting to do staff competency checks.

In the OR Reprocessing area, most medical devices are not manually cleaned but are put directly in mechanical washer-disinfector or ultrasonic cleaner.

When manual cleaning is done, the proper protocols (immersion, brushing and appropriate layering) are generally not followed.

Work flow in decontamination is a challenge, for example, the tray from ultrasonic cleaner is placed where instruments are sitting prior to manual clean.

In the sub-basement reprocessing area of the hospital, there are infrastructure and equipment challenges, for example, both washer-disinfectors were not working at the time of the audit. Medical devices were transported from sub basement MDR to OR MDR uncovered to be put in washer-disinfector.

RECOMMENDATIONS:

- That MDR be consolidated to one area / department in order to decrease duplication of equipment and resources and to mitigate gaps to compliance with standards;
- That St. Boniface ensure staff meet CSA Standards and Accreditation Canada requirements for reprocessing managers and staff to have
completed a recognized qualification/certification program that includes both reprocessing theory and clinical skills training.

- That orientation, ongoing education and competency assessments for all reprocessing staff should be scheduled and documented.
- That reprocessing and IP&C staff be involved in purchase decisions for medical devices requiring reprocessing;
- That upon purchase of equipment and medical devices requiring reprocessing, written manufacturer’s instructions for reprocessing be obtained and made available to staff on an ongoing basis;
- That staff be reminded on an ongoing basis of the need for careful inspection of devices following manual cleaning;
- The appropriate protocols for the use and maintenance of the ultrasonic cleaner should be reviewed with staff on an ongoing basis to ensure CSA standards are met and manufacturer’s instructions followed, e.g., devices must be manually cleaned prior to being placed in ultrasonic cleaner and rinsed following;
- That the management of cleaning accessories be standardized to ensure reusable brushes and other items are cleaned, decontaminated, dried, stored and discarded appropriately;
- That staff be reminded on an ongoing basis of the importance of following PPE protocol;
- That management review work flow processes to identify areas of possible improvement;
- That staff be reminded of the importance of discarding unneeded or out-of-date chemical agents;
- That staff receive ongoing education and training re WHMIS;
- That the environmental cleaning processes are reviewed with staff to ensure that the appropriate steps are being followed;
- That the washer-disinfectors in the sub-basement be repaired or replaced;
- That staff be reminded that contaminated devices are to be covered and contained for transportation to MDR. Garbage, soiled linen, bio waste, all
soiled devices should not go in same elevator as clean equipment and sterile supplies.
Regional Recommendations

The adoption and implementation of the site-specific recommendations in this report will ensure decontamination practices within the Winnipeg Health Region meet both CSA and AC standards. The opportunity to further strengthen the process exists through the standardization of policies and practices throughout the region. To that end, the following regional recommendations are included for your consideration. Many of the following recommendations are applicable to each facility for implementation.

Recommendations

**Immediate recommendation (commenced)** Engage upper management in resolution of identified issues, i.e., infrastructure challenges, consolidating MDR functions, decreasing duplication, standardizing reprocessing equipment.

**Long term recommendation (commenced)** Consider consolidating surgical and reprocessing services to minimize duplication. Prior to investing in infrastructure and capital projects, strategize on how to decrease the duplication of reprocessing services. Having fewer reprocessing areas would optimize personnel performance, work areas, equipment and compliance with requirements in CSA Standards.

Quality system

**Long term recommendation** Implement a standardized quality assurance system to ensure ongoing safety and quality of reprocessing activities. Refer to CSA Z314.8: 4.5 Quality System. The quality assurance program should include:

- Clear roles and accountabilities for management of reprocessing activities;
- Appropriate staffing and resources to ensure reprocessing standards are met;
- Ongoing staff training, education and competency assessments
- Internal compliance audit and reporting function; and
- Process to identify and implement changes to standards as they evolve, so that compliance with standards is maintained over time.
Include interdisciplinary team, OR, MDR, infection prevention and control (IP&C), facilities planning and management, document management, etc. to assist with maintenance of quality system.

The infrastructure and environment of the reprocessing departments should be included in the quality assurance system. Assessment to ensure compliance with the CSA Z314 and Z317 series should be conducted at all sites, including initial evaluation and regular monitoring. Monitoring should include air temperature, pressure, relative humidity, power, steam, water supply and quality (sterile, demineralised, distilled, reverse-osmosis, pyrogen-free), water pressure, volume of water flow, pipelines serving reprocessing departments, and waste management to ensure that criteria is met.

**Immediate recommendation** Review flash (immediate use) sterilization, if used, to decrease use of flash sterilization and ensure that process is followed according to the requirements of CSA Z314.3: 13 Flash sterilization. If used, procedures for flash sterilization should be based on a documented quality process that measures objective performance criteria. There should be a planned, systemic, and ongoing process for verifying compliance with procedures. Cleaning and decontamination of medical devices being prepared for immediate use sterilization must be meticulous and thorough as there is a narrow margin of safety with immediate use sterilization. Management of immediate use sterilization includes educating surgeons and OR staff re flash sterilization indications, policies and procedures.

**Evaluation and purchase of reusable medical devices, chemical agents, and reprocessing equipment**

**Immediate recommendation** Involve MDR and IP&C prior to purchase of medical devices, chemical agents and reprocessing equipment. Ensure that all medical devices/equipment meet established quality reprocessing parameters. Ensure that prior to purchase all medical devices are accompanied by the manufacturer’s written, validated instructions for reprocessing and that the facility has the equipment and infrastructure required for reprocessing the device.
Short term recommendation  Ensure that reprocessing equipment meets CSA Standards, e.g., Z314.8, 15883 - Parts 1 and 2.

Policies, procedures, and manufacturer’s instructions

Long term recommendation  Ensure that policies and procedures are updated, current, and based on recognized Standards and manufacturer’s written, validated instructions. Refer to CSA-ISO 17664. It is recommended that a review and revision of policies and procedure manuals, and instrument assembly manuals, occur in all sites. Regional management is leading the development of regional policies such as recall and management of loaner devices. Each site should dedicate staff to updating policy and procedure manuals, and details for instrument reprocessing.

Long term recommendation  Manufacturers must provide medical device-specific instructions for disassembly, cleaning, disinfection, assembly, and sterilizing where appropriate. The policies and procedures, and reprocessing practice must follow the manufacturer’s instructions and Standards. The medical device may be labelled with specific methods of cleaning and sterilization that have been validated by the manufacturer. The manufacturer’s written instructions should be kept on file and periodically reviewed for any updates. If there are no specific instructions on the labelling, then the manufacturer should be contacted directly to provide a documented method. The template at the end of the report was developed and approved by CSA and MEDEC to provide a consistent list of instructions that manufacturers should provide to purchasers. Canadian health care facilities have been able to obtain medical device manufacturer’s instructions by purchasing an online subscription to One Source. It can be found at this link: http://www.onesourcedocs.com/about_us.html

Another resource for developing and implementing policies and procedures for reprocessing difficult-to-clean medical devices is the link in Resources to the Health Canada Scientific Advisory Panel on Reprocessing of Medical Devices. It includes detailed, current instructions for health care facilities written by front-line MDR and IP&C managers.
**Long term recommendation**  Review policies and procedures at least annually. Ensure input by infection prevention and control into reprocessing policies and procedures.

**Short term recommendation**  Ensure that policies and procedures, Standards, and manufacturer’s written, validated instructions for reprocessing medical devices are placed in a central location and readily accessible to staff to facilitate reprocessing and maintenance of devices and staff training and education. Comprehensive manuals, including detailed instrument instructions and diagrams, are essential in order to expect staff accountability and to develop a quality assurance program.

**Long term recommendation**  Process audits to monitor compliance with policies and procedures should be performed on a scheduled basis, with appropriate follow-up addressing problems.

**Reprocessing personnel qualifications and training**

**Short term recommendation**  The CSA Standards and Accreditation Canada requirement is that all reprocessing staff, including managers, have completed a recognized qualification/certification program that includes both reprocessing theory and clinical skills training. Patient safety and legal concerns have acknowledged the complexity of medical device reprocessing, necessitating implementation of quality assurance systems that require qualified, competent managers and staff.

**Short term recommendation**  Centralize MDR activities as much as possible. Consolidate reprocessing activities so that the reprocessing process is conducted and managed by staff that has completed a recognized reprocessing program. This is consistent with findings reported in British Columbia that demonstrated that qualified reprocessing personnel practiced according to standards to a much higher level than staff that had not completed a recognized reprocessing program and whose primary responsibilities and training were other than reprocessing. WRHA is consolidating MDR functions as the duplication of resources had already been identified. This review identified practice and risk issues with reprocessing
being done and supervised by staff not qualified and trained in reprocessing medical devices.

**Orientation, training, continuing education, supervision**

**Long term recommendation** Standardize education for MDR staff, qualifications for hiring (must have completed a recognized course in reprocessing prior to hiring), orientation, in-service education, competency assessments, certification, documentation. In-service education should include PPE, hand hygiene (HH), principles of work flow to minimize cross-contamination, manual cleaning, management of cleaning accessories, manufacturer’s written, validated instructions for reprocessing medical devices, disassembly and assembly of devices, procedures for cleaning complex and difficult-to-clean instruments, tray configuration and assembly, operator’s instructions for reprocessing equipment, WHMIS, reading and following instructions on labels of chemical agents, end of shift cleaning of sinks and counters, etc. In-service education should occur when there is a change in reprocessing procedures, equipment and medical devices. Gaps identified from competency assessments provide input for education sessions. Education participation should be documented. Management should strongly encourage reprocessing staff to take the CSA certification exam when practice requirements are met.

Reprocessing staff and managers from other sites in the WRHA would benefit from practical rotations in the HSC MDR.

**Short term recommendation** Ensure adequate supervision of reprocessing process and activities, including the front-line manager having completed a recognized reprocessing course. A culture of learning will encourage managers and staff to seek additional education which will reinforce Best Practices.

Suggest sharing regular education sessions as regional project, different staff (MDR, OR, IP&C) can prepare teaching sessions and teach the prepared presentation in all sites, e.g., Sharon Cizik at Concordia has developed a template. Sharing teaching will help develop expertise and leadership skills.
Short term recommendation  Staff education regarding safe handling of sharps should be done throughout the facilities. MDRs reported that sharps are occasionally inappropriately found with equipment received from departments other than ORs, e.g., emergency departments and clinical units. This can endanger MDR staff as well as staff in other departments such as laundry.

Infection prevention and control practices

The physical space frequently assigned to MDR limits and compromises adherence to recognized standards of practice. The process of decontamination generates microbial and particulate contamination. For patient and staff safety the decontamination area must be large enough to provide for one way work flow, physical separation from clean areas, adequate space for equipment, carts and trays, hand hygiene facilities, area for donning and doffing personal protective equipment (PPE), storage of cleaning supplies, eye-wash station, environmental controls, and waste management.

Dedicated hand hygiene facilities should be available for staff working with contaminated and clean medical devices. Refer to CSA Z 314.8: 6.6.3. Minimally ensure that wall mounted dispensers for alcohol based hand rub are available in the decontamination area.

Long term recommendation  Teach and supervise attire and PPE in decontamination areas. Refer to CSA Z314.8: 6.7.

Long term recommendation  Improve the functional work area for effective and safe decontamination practices, e.g., sinks must be deep enough to allow immersion of devices so that aerosols are not generated during cleaning. Refer to CSA Z314.8: 7.

Short term recommendation  Standardize management of fluids, i.e., blood and body fluids from operative procedures to minimize risk. Refer to CSA Z 314.8:6.6. Develop protocols to prevent exposure of staff to blood and body fluids. This starts at point of use, i.e., OR. At end of case, staff in the OR is not wearing PPE that will protect them from splashes of body fluids. Appropriate management of the body fluids in the OR was observed in some sites, e.g., suction the blood and
body fluids so that pouring into a bucket, etc. is not necessary. At one site in decontamination, staff exposure to splashing occurred when flushing a lumen, due to improper equipment and PPE.

**Short term recommendation** Standardize management of suction containers, e.g., solidification agents. To minimize risk to staff, teach staff not to collapse the containers.

**Immediate recommendation** An assessment of occupational risks should be undertaken. Frequently staff was not aware of WHMIS and appropriate use of chemical agents. Staff practices may increase risk to exposure to blood and body fluids, whether by lack of PPE or splashing and aerosolization. Lack of attention to proper body mechanics can put staff at risk when handling heavy instruments. Eye wash stations should be available and maintained according to occupational health and safety requirements.

**Long term recommendation** Assess environmental air changes, exhaust, pressure, temperature and humidity in decontamination areas and ensure that standards are met. Refer to CSA Z 317.2.

**Long term recommendation** Standardize environmental cleaning – use CSA, ORNAC, PIDAC, Health Canada/Public Health Agency of Canada for protocols. Refer to CSA Z314.8: 7.4 Decontamination area cleaning. MDR, IP&C and housekeeping need to develop protocols and monitor cleanliness to ensure that roles and responsibilities are identified, staff de-clutter to facilitate cleaning, and clarify procedures for chemical agents to use on environmental surfaces as needed and at end of each shift.

**Immediate recommendation (commenced at time of audit)** Discard chemical agents no longer being used or past expiry date.

**Handling of contaminated devices at point of use**

**Long term recommendation** Standardize the pre-operative OR checklist to include checking the sterility indicators during set-up. Some sites (e.g., Concordia)
have this but not in the same row/format as the rest of the surgical check (can be missed if not in same checklist).

**Short term recommendation** Standardize management of medical devices intraoperatively, i.e. removing visible organic soil from instruments in OR. Sites differed re rinsing, soaking, wiping off organic matter with dry versus wet gauze.

**Long term recommendation** Develop standardized protocols for segregation of medical devices at point of use. Most sites removed visible soil and replaced the instruments to keep sets together. Some sites separated the devices with visible soil, e.g., in a basin. Guidance in CSA standards includes: Delicate devices shall be segregated to prevent damage to the devices. Refer to CSA Z 314.8: 8.2. Additional guidance regarding sorting and disassembly is found in CSA Z314.8: 10.2. The indicators for sorting are similar procedures or the same cleaning agents, or to keep medical devices that belong to a set together. Most sites kept devices that belong to a set together. The recommendation is to follow the above standards for separation rather than those with visible soil.

**Immediate recommendation** Facilitate delivery of the used medical devices to the MDR as quick as possible at the end of the surgical case to prevent drying of organic matter on devices. This requires that the OR nurses and aides are supported in placing a priority on expediting delivery of the case cart to MDR. Additional resource(s) may be required to accomplish this and the theatre cleaning changeover.

**Long term recommendation** Follow requirements for transport of contaminated devices. Refer to CSA Z 314.8: 9 and Z 314.15. Devices must be covered and contained when transported from the OR to reprocessing area.

**Long term recommendation** Provide regular in-service education and monitoring of appropriate use of PPE and hair covering in operating room. Include visitors in education and monitoring of apparel and behaviour in OR. Enforce compliance with policy of visitors in OR.

**Decontamination**
Guidance for soaking is found in CSA Z314.8: 10.3. Immersible devices with heavy or difficult-to-remove soil should be soaked before cleaning. Soaking prevents soil drying on the device and softens residue to make devices easier to clean.

**Long term recommendation**  Develop standardized policies and protocols for cleaning and decontamination of grossly soiled devices (e.g., orthopaedic) and complex and difficult-to-clean instruments, including intraoperative management.

**Long term recommendation**  Develop and teach protocols for manual inspection and cleaning of medical devices. Guidance for cleaning is found in CSA Z314.8: 10.4. Cleaning may be done manually or mechanically, according to device manufacturer’s instructions. The device manufacturer’s cleaning instructions shall be followed, including specifications for detergent type, dilution, water temperature, soak time, and cleaning methods. Difficult-to-clean devices shall be manually cleaned unless a mechanical process provides equal or better results. Heavily soiled devices should be manually cleaned prior to mechanical cleaning, unless the washer can process such devices without pre-cleaning.

**Immediate recommendation**  Devices shall be cleaned with a detergent solution. Immersible devices shall be completely submerged during cleaning. Practice change is required in several sites that are rinsing instruments under running water with no detergent, scrubbing instruments under running water, or using basins that are too small to immerse the instruments. Rinsing blood from devices with cool water is an approved method of removing blood. However, the pre-cleaning procedures should be standardized.

**Immediate recommendation**  Medical devices should be mechanically cleaned whenever possible, in accordance with manufacturer’s instructions.

**Immediate recommendation (action commenced after audit)**  Automate detergent preparation and dilution if possible to prevent human error in assuring that the solution concentration complies with manufacturer’s recommendations. The manufacturer of the enzymatic detergent installs automatic dispensing systems complimentary. Some sites are not following the detergent label instructions for dilution and use. One site was pre-mixing the enzymatic
detergent. Another was using Sunlight dishwashing soap to soak instruments. The rationale given was that too much enzymatic detergent was being used.

**Immediate recommendation** Brushes and cleaning accessories shall be inspected and cleaned and decontaminated according to CSA Standard. At a couple of sites handling of brushes was not according to Standard.

**Immediate recommendation** Devices with lumens shall be cleaned and rinsed according to device manufacturer’s instructions and CSA Z314.8: 10.4. CSA Z314.3 requires that lumens of tubing, suction devices, and needles be moistened with pyrogen-free water immediately prior to steam sterilization. Decontamination areas must have the appropriate equipment and space for cleaning and rinsing lumens according to standards.

**Long term recommendation** Develop specific protocols for soaking and manual cleaning, and use of the ultrasonic cleaner based on the device manufacturer’s written, validated instructions, the degree and type of soil on the device, structure of the device (e.g., lumens, articulations).

**Immediate recommendation** Use of ultrasonic cleaners should be standardized and based on standards and the device manufacturer’s written, validated reprocessing instructions. Each site should test their ultrasonic cleaners to ensure that the set cycle time meets cleaning parameters. According to CSA Z314.8:10.4.4, ultrasonic cleaners are designed to remove soil from joints, crevices, lumens, and other areas of devices that are difficult to clean by other methods. Gross soil must be removed from the device before ultrasonic cleaning, as heavy soiling interferes with the ultrasonic cavitation process.

For guidance on how to reprocess difficult-to-clean medical devices, refer to the Health Canada SAP link for the report from the Canadian front-line MDR and IP&C managers who developed a unique list of problem devices and detailed instructions for their reprocessing.

Upon completion of pre-soaking and ultrasonic cleaning, all devices shall be rinsed thoroughly prior to further decontamination.
Refer to CSA Z 314.8: 10.5 Rinsing to ensure that standards are being followed for rinsing and water quality. Distilled water is not necessarily sterile or pyrogen-free.

Use of detergents, disinfectants and chemical additives shall be compliant with CSA Z314.8: 10.4.3. Some sites require practice change, particularly sites in which the detergent is manually dispensed rather than by an automated detergent injection or dispensing system. Sites should ensure that the detergents and other agents being used are recommended by the medical device and reprocessing equipment manufacturer.

Visual inspection was conscientiously done at each site, before, during and after cleaning, following removal from washer-disinfector, and prior to use in the OR. For effective inspection, staff needs good lights and magnification. Inspection in prep and pack following removal from the washer-disinfector is especially important due to lack of consistency of manual wash and ultrasonic cleaner.

**Long term recommendation** Assess lighting in decontamination and clean areas to facilitate inspection of medical devices for soiling. Refer to CSA Z 317.5 Task lighting (e.g., magnifying light) would facilitate inspection in some decontamination areas.

**Protection of clean and sterile supplies**

Refer to CSA Z 314.15-10 *Warehousing, storage, and transportation of clean and sterile medical devices*.

With transfer of services from a hospital, or where an emergency department does not require the same equipment as previously, the question arose of how to protect sterile medical devices that may not be used for an extended period, from events that may compromise sterility, e.g., moisture, dust, vermin, damage. The shelf life of a sterile package is event-related. As long as the package has not been compromised or questionable, the package is considered sterile.

**Long term recommendation** Sterilized items that are seldom used can be protected from dust with a medical grade plastic cover. Careful review of turnover rates and actual need will help to prevent excess storage of a large number
of instrument sets in dust covers. An inventory of procedure trays and devices not being used can generate sharing among sites.

**Immediate recommendation** Remove all external packing containers, e.g., corrugated boxes, from reprocessing areas and clean and sterile supply areas. Refer to CSA Z314.3: 11 Storage.

**Implementation Guidelines**

Involve all stakeholders in resolving issues and developing the action plan and timeframe.

Continue dissemination of resources such as the CSA Standards purchased for region. The manager at each site is responsible for discarding outdated CSA standards.

Implement the recall policy developed for the region. Continue to develop policies applicable regionally, e.g., shared and loaned medical devices.

The sites can share methods of implementing policies and procedures, e.g., tagging devices for repair.

An additional review that the auditor suggests from previous experience is reprocessing areas and practices in labour and delivery.

**Use approved resources to develop protocols:**

HC link to Scientific Advisory Panel report, recommendations and list of difficult to clean medical devices with instructions for health care facilities:


Health Canada Guidance Document *Information to be provided by the manufacturer for the processing of sterilizable medical devices*

CSA Z 17664 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices

CSA/MEDEC template

CSA Standards for Sterilization of Medical Devices (Z314 series and CSA/ISO Standards)

CSA Z 15883-1-09 Washer-disinfectors – Part 1: General requirements, terms & definitions and tests

CSA Z 15883-2-09 Washer-disinfectors – Part 2: Washer-disinfectors – Part 2: Requirements & tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

CSA Z 11138-1-09 Sterilization of health care products – Biological indicators

CSA Z 317.2 Special requirements for heating, ventilation, and air conditioning (HVAC) systems in health care facilities

CSA Z 317.5 Illumination systems in health care facilities

CSA Z 317.1 Special requirements for plumbing installations in health care facilities

Health Canada/Public Health Agency of Canada Infection Control Guidelines


ORNAC (2009) Recommended standards, guidelines, and position statements for perioperative registered nursing practice.

American Association for the Advancement of Medical Instrumentation. AAMI ST79:2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

AAMI. TIR 34:2007 Water for the reprocessing of medical devices

CDC guideline for prevention of surgical site infections, 1999.

Provincial Infectious Disease Advisory Committee (PIDAC) Best Practices for Cleaning, Disinfection and Sterilization in all Health Care Settings. 2010.


HSC Adult Operating Room Perioperative Nursing Orientation Manual

Summary of Benefits

Improved patient and staff safety

Identification of practices requiring improvement

Risk stratification and management identified

Reinforcement of Best Practices
Identification of need for broader evaluation of needs such as infrastructure, facilities maintenance, etc.
### MEDICAL DEVICE MANUFACTURER'S VALIDATED INSTRUCTIONS
**FOR REPROCESSING OF REUSABLE MEDICAL DEVICES**
(according to CSA/ISO 17664)

Version 1.1 January 2010

Note: Manufacturers should indicate which of these processes/steps are recommended and not recommended. Attach a copy of the validated, detailed reprocessing instructions where applicable. This template is a checklist and should be made available to users in addition to, or in conjunction with the detailed instructions for use/reprocessing instructions.

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<table>
<thead>
<tr>
<th>Process Name:</th>
<th>Contact (Name, Tel.,# email):</th>
</tr>
</thead>
</table>

#### PROCESS

<table>
<thead>
<tr>
<th>PROCESS</th>
<th>Process Stage:</th>
<th>RECOMMENDED</th>
<th>NOT RECOMMENDED</th>
<th>Specific Info needed from Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preparation at point of use</strong></td>
<td>Soaked or not after use?</td>
<td>Specify type of detergent to use for soak (e.g. alkaline, acidic, neutral pH, enzymatic or enzymatic foam) vs water</td>
<td>Specify maximum soak time and volume of rinse solution</td>
<td></td>
</tr>
<tr>
<td><strong>DECONTAMINATION</strong></td>
<td>PREPARATION</td>
<td>DISASSEMBLY</td>
<td>Device specific disassembly instructions with pictures</td>
<td></td>
</tr>
<tr>
<td>CLEANING</td>
<td>MANUAL</td>
<td>(includes rinsing)</td>
<td>Specify any special cleaning brushes/tools needed</td>
<td></td>
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<tr>
<td><strong>AUTOMATED (Machine)</strong></td>
<td></td>
<td></td>
<td>Specify water quality needed and minimum volume for rinsing</td>
<td></td>
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<tr>
<td><strong>ULTRASONIC</strong></td>
<td></td>
<td></td>
<td>Specify if cleaning solution to be used and if so specify type (e.g. low sudsing)</td>
<td></td>
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<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
<td>Recommend tests that healthcare facility could use to ensure proper cleaning has been achieved</td>
<td></td>
</tr>
<tr>
<td><strong>DISINFECTION</strong></td>
<td>LIQUID CHEMICAL</td>
<td></td>
<td>Specify intended use of the device and minimum level of disinfection required. Please indicate below:</td>
<td></td>
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<tr>
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<td>___Low level disinfection ___High level disinfection ___Sterilization</td>
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<td></td>
<td>Automated or Manual</td>
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<td>Specify compatible Liquid Chemicals that can be used</td>
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<td>Specify validated exposure time to Liquid Chemical</td>
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<td></td>
<td>Specify water quality for rinse and minimum volume for rinsing</td>
<td></td>
</tr>
<tr>
<td><strong>DISINFECTION</strong></td>
<td>THERMAL</td>
<td></td>
<td>Specify maximum thermal conditions that medical device can tolerate (e.g. time and temperature)</td>
<td></td>
</tr>
<tr>
<td><strong>DRYING</strong></td>
<td>REASSEMBLY</td>
<td></td>
<td>Specify condition of air gun, max pressure, manual, heat, etc</td>
<td></td>
</tr>
<tr>
<td><strong>PREP and PACK</strong></td>
<td>MAINTENANCE</td>
<td></td>
<td>Specify any medical device requirements for ensuring functionality e.g. sharpening, lubrication, testing function, etc</td>
<td></td>
</tr>
<tr>
<td><strong>STERILIZATION</strong></td>
<td>Dynamic Air Removal</td>
<td></td>
<td>Specify condition of air gun, max pressure, manual, heat, etc</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>CAN/ISO 11140-3</strong> Bowie-Dick Test (Prevac)</td>
<td></td>
<td>Ensure that commonly used North American Healthcare cycles are considered (See CAN/ISO 17665-2* Annex B)</td>
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<tr>
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<td></td>
<td>If medical device requires exposure times longer than the commonly available North American Healthcare cycles recommended by CAN/ISO 17665, harmonize to 132 - 135oC for 10 or 20 mins</td>
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<tr>
<td></td>
<td><strong>GRAVITY DISPLACEMENT</strong></td>
<td></td>
<td>Ensure that commonly used North American Healthcare cycles are considered (See CAN/ISO 17665-2* Annex B)</td>
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<tr>
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<td></td>
<td>If medical device requires exposure times longer than the commonly available North American Healthcare cycles recommended by CAN/ISO 17665, harmonize to 121oC for 40 or 60 mins</td>
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<td></td>
<td><strong>ETO</strong></td>
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<td>Specify aeration conditions (including time) that has been validated for instrument</td>
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<tr>
<td></td>
<td><strong>OTHER APPROVED STERILIZATION</strong></td>
<td></td>
<td>Specify sterilization process including cycle and conditions that instrument is validated for</td>
<td></td>
</tr>
</tbody>
</table>

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