

Dear Kim Huynh,

Thank you for participating in the Residential Care Audit last week.

Please take the following action as soon as possible, and submit your updated report by **10th February 2009**

Please:

1. Open the Excel file sent to you after the audit (attached).
2. Open that file, and note in Column D those audit questions that had a "No" response (that is you were found to be non-compliant on that item)
3. Beside the comment field (the auditors' comments, if any), enter in column H YOUR comments on your plan and timeline to achieve compliance, or the impediments to achieving compliance (e.g. "work is ongoing to improve procedure documents, will be in place by June, 2009", or "cannot implement without \$50,000 capital, request has been submitted")
4. In column I, indicate the anticipated cost of achieving compliance, and indicate whether that would be capital or operating. (e.g. \$80,000 / year operating). You may need to engage colleagues in estimating costs, for example Facilities Planning to assist in estimating renovation costs.
5. Save and submit your updated excel file to [reprocessing@vch.ca](mailto:reprocessing@vch.ca) by **10th February 2009**
6. Maintain pursuit of compliance on each "No" item; discuss them with your supervisor, and as you achieve compliance, change the relevant "No" to "Yes" on the spreadsheet, and email the updated sheet to [reprocessing@vch.ca](mailto:reprocessing@vch.ca) , indicating in the email body the updated item (e.g. "4.b.7 is now resolved") You may also wish to highlight the updated row in the spreadsheet with a different colour, which would be ideal.

Should you have any questions on this request, please contact me, at [reprocessing@vch.ca](mailto:reprocessing@vch.ca), in the Reprocessing Practices Improvement Project, or by phone at 604-875-4111 local 66514.

Thank you

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Thank You

HSDA:	Vancouver Community
Sector:	Residential Care
Facility/Grouping:	Lakeview Care Centre
Program:	Contract
Date:	22/01/2009
Auditor 1:	Rita Steeple
Auditor 2:	Vicky Dabbs
Participants:	Kim Huynh

### AUDIT CHECKLIST FOR REPROCESSING CRITICAL AND SEMICRITICAL MEDICAL DEVICES

1. SINGLE-USE ITEMS		YES	NO	N/A	INHERENT RISK	COMMENTS
1.1	Single-use medical devices are not being reprocessed (except by an approved third party reprocessor)		NO		High	
TOTAL		0	1	0		
SCORE		0/1				
Percentage of Compliance		0				

2. REUSABLE ITEMS		YES	NO	N/A	INHERENT RISK	COMMENTS
2.1	All critical and semi-critical reusable medical devices are reprocessed between patients.		NO		High	
TOTAL		0	1	0		
SCORE		0/1				
Percentage of Compliance		0				

3. INDICATIONS FOR STERILIZATION, OR HIGH-LEVEL DISINFECTION		YES	NO	N/A	INHERENT RISK	COMMENTS
3.1	Critical medical devices are sterilized before each patient use, ie: that puncture the skin or mucous membranes, enter the vascular system or a sterile cavity; devices through which a sterile fluid flows; or contacts a sterile area.		NO		High	
3.2	Semi critical medical devices receive as a minimum chemical or thermal high level disinfection ie: that touch mucous membranes or intact skin (e.g., gastrointestinal endoscopes, endotracheal tubes, anaesthesia breathing circuits, and respiratory therapy equipment) or non intact skin.		NO		High	
TOTAL		0	2	0		
SCORE		0/2				
Percentage of Compliance		0				

4. GENERAL		YES	NO	N/A	INHERENT RISK	COMMENTS
4.1	Appropriate personal protective equipment (PPE) is worn when handling/cleaning/reprocessing contaminated devices (e.g. gloves, mask, protective eye wear and/or face shield and water-proof gown).		NO		High	
4.2	Hand hygiene stations are available.		NO		High	
4.3	Staff have been trained in hand hygiene techniques.	YES			High	
4.4	Staff perform hand hygiene at the appropriate times.	YES			High	
4.5	Solied equipment is reprocessed.		NO		High	

4.6	There is a designated reprocessing area that is separated into distinct areas that ensure one-way work flow.		NO			High
4.7	Where reprocessing is not being done at the point of use, medical devices are sent to a designated reprocessing area.			N/A		High
4.8	Contaminated medical devices transported within a facility are appropriately prepared and transported (e.g. gross debris removed), placed in a covered container, in a manner that minimizes contamination of the environment and personnel.			N/A		High
4.9	Contaminated devices transported between facilities are labeled and transported appropriately.			N/A		High
4.10	There are current written policies and procedures for all aspects of reprocessing based on current recognized standards and validated manufacturer's instructions.		NO			Med
4.11	Reprocessing policies and procedures are readily accessible for staff.		NO			Med
4.12	Reprocessing policies and procedures are periodically reviewed and updated when necessary.		NO			Med
4.13	There are current written validated instructions from the manufacturer regarding the safe and appropriate reprocessing of the medical device.		NO			High
4.14	There is a process in place that clearly identifies a non-reprocessed instrument from one that has been reprocessed to prevent use on a patient.		NO			High
4.15	There is a written procedure established for the recall of improperly reprocessed medical devices.		NO			High
4.16	There is a procedure for handling damaged equipment.	YES				Low
4.17	All physician supplied or loaner medical devices used at any site are accompanied by validated manufacturer's instructions for reprocessing.			N/A		High
4.18	All physician supplied or loaner critical or semi-critical medical devices used at any site are reprocessed at the site prior to use.			N/A		High
4.19	The reprocessing area is free of external shipping containers (e.g. corrugated cardboard boxes).		NO			Low
4.20	There is a quality assurance program in place for all reprocessing activities.		NO			High
4.21	Housekeeping procedures and protocols are followed.		NO			Low
4.22	Cleaning accessories (e.g. brushes, sponges) are disposable or thoroughly cleaned and disinfected/sterilized at least daily.		NO			High
	TOTAL SCORE	3	14	5		
	Percentage of Compliance	3/17		17.64705882		

4.a. GENERAL - DETERGENTS		YES	NO	N/A	INHERENT RISK
4.a.1	Detergents are prepared according to the manufacturer's recommended use-dilution.	YES			High
4.a.2	There is a process to determine when detergents must be changed.	YES			High
4.a.3	Detergents must be discarded as recommended by the manufacturer.	YES			High
	TOTAL SCORE	3	0	0	
	Percentage of Compliance	3/3			

COMMENTS

Percentage of Compliance	100
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4.b. GENERAL – MEDICAL DEVICES AND EQUIPMENT – (use APPENDIX		YES	NO	N/A	INHERENT RISK	COMMENTS
4.b.1	Policies and procedures for reprocessing are written and readily accessible for staff. These are reviewed periodically and compatible with current published reprocessing standards and guidelines. Reprocessing equipment is installed, validated and performs in accordance with manufacturer's specifications (Installation, operation and performance qualifications).		NO	N/A	High	
4.b.2	Reprocessing equipment is used in accordance with manufacturer's specifications.			N/A	High	
4.b.3	There are current written procedures (such as operator's manuals) for the operation of reprocessing equipment.			N/A	High	
4.b.4	Reprocessing equipment has documented preventative maintenance as specified by the manufacturer.			N/A	High	
4.b.5	Reprocessing equipment has documented calibrations as specified by the manufacturer.			N/A	High	
4.b.6	Maintenance associated with reprocessing equipment malfunction is documented.			N/A	High	
4.b.7	Staff have documented training of the reprocessing equipment they operate.			N/A	High	
4.b.8	Staff have documented training of the reprocessing equipment they operate.			N/A	High	
	<b>TOTAL</b>	0	1	7		
	<b>SCORE</b>	0/1		0		
	Percentage of Compliance					

5. CLEANING		YES	NO	N/A	INHERENT RISK	COMMENTS
5.1	Cleaning is done in a distinctly separate area from where clean/disinfected/sterile devices are handled or stored.	YES			High	
5.2	Medical devices are cleaned using appropriate detergents or enzymatic cleaners.		NO		Low	
5.3	Detergents and enzymatic cleaners are used according to manufacturers' written instructions.		NO		High	
5.4	Detergents or enzymatic cleaners are compatible with metals/materials used in the medical device.		NO		High	
5.5	Detergent or enzymatic cleaning solutions are discarded at least daily and when visibly soiled.		NO		High	
5.6	There is a written procedure for cleaning medical devices including disassembly, sorting and soaking, physical removal of organic material, rinsing, drying, physical inspection and wrapping.		NO		High	
5.7	Cleaning is done immediately after use. If this is not possible the medical device is treated to prevent hardening of organic matter.	YES			Med	
5.8	Cleaning always precedes high-level disinfection or sterilization processes.			N/A	High	
5.9	Cleaning is done manually, using friction, or approved mechanical washer.	YES			High	
5.10	Prior to ultrasonic cleaning gross soil is removed and solution is discarded at least daily & when visibly soiled. Rinse if appropriate.			N/A	Med	

5.11	Automatic washers are used in accordance with the manufacturer's recommendations.			N/A	High	
5.12	Automated washing equipment has documented preventive maintenance as specified by the manufacturer.			N/A	High	
5.13	Medical device lubricant, if used, must be medical grade & be used according to manufacturer's instructions for dispensing, shelf life, and storage.			N/A	High	
5.14	Devices are rinsed and appropriately dried after cleaning.	YES			High	
5.15	Devices must be visibly clean or are they are returned to the decontamination area for re-cleaning.	YES			High	
<b>TOTAL</b>		5	5	5		
<b>SCORE</b>		5/10		50		
<b>Percentage of Compliance</b>						

<b>6. CHEMICAL HIGH-LEVEL DISINFECTION (HLD) (E.G. ENDOCAVITY PRO)</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>INHERENT RISK</b>	<b>COMMENTS</b>
6.1	Semi-critical devices are subjected to high-level disinfection (at a minimum) according to manufacturer's recommendations.			N/A	High	
6.2	Disinfectant has a Drug Identification Number (DIN) from Health Canada.			N/A	High	
6.3	Current manufacturers' instructions are available for the preparation of HLDs.			N/A	High	
6.4	HLDs are prepared correctly to achieve the manufacturer's recommended use-dilution.			N/A	High	
6.5	Contamination is prevented when preparing disinfectants and detergents (e.g. contaminated containers, measuring devices, prep area).			N/A	High	
6.6	Reusable HLD concentration is checked daily at a minimum, with appropriate chemical test strip.			N/A	High	
6.7	There is a quality control procedure for test strips (i.e. checked according to manufacturer's recommendations each time a new bottle is opened to verify they are accurate).			N/A	High	
6.8	Test strips are used within the listed expiry date.			N/A	High	
6.9	Reusable HLD concentration is checked daily at a minimum with appropriate chemical test strip and discarded/changed if the concentration is less than the minimum effective concentration (MEC).			N/A	High	
6.10	HLD solution is discarded as recommended by the manufacturer.			N/A	High	
6.11	The soaking container is kept covered during use.			N/A	Med	
6.12	The soaking container is washed, rinsed and dried when the solution is changed.			N/A	Med	
6.13	Devices are thoroughly cleaned and rinsed prior to HLD.			N/A	High	
6.14	Excess water is removed from the device prior to HLD.			N/A	High	
6.15	The device and accessories are completely immersed in the HLD solution for the recommended time and temperature.			N/A	High	
6.16	The HLD solution is flushed through any lumens to remove air and to ensure all lumens are perfused with HLD.			N/A	High	
6.17	Following HLD, air is flushed through the lumens.			N/A	High	
6.18	The device and accessories are rinsed with sterile water, bacteria free water or as specified by the device manufacturer's instructions.			N/A	High	

6.19	The rinse water is changed after each process unless otherwise specified by the HLD manufacturer.			N/A	High	
6.20	The device is dried with a clean, lint-free cloth.			N/A	High	
6.21	HLD practices are monitored on a regular basis and a quality improvement process is in place.			N/A	High	
6.22	There is a process in place that clearly identifies a non-reprocessed instrument from one that has been reprocessed to prevent use on a patient.			N/A	High	
TOTAL		0	0	22		
SCORE		0/0				
Percentage of Compliance						

6.a. CHEMICAL HIGH-LEVEL DISINFECTION (HLD) - DOCUMENTATION		YES	NO	N/A	INHERENT RISK	COMMENTS
6.a.1	HLD Preparation: Product name			N/A	High	
6.a.2	DIN number			N/A	High	
6.a.3	Lot number			N/A	High	
6.a.4	Expiry Date			N/A	High	
6.a.5	Date of solution change			N/A	High	
6.a.6	Initials of staff doing preparation and documentation			N/A	High	
HLD Quality Control:						
6.a.7	Test Strip name			N/A	High	
6.a.8	Test Strip lot number			N/A	High	
6.a.9	Test Strip Expiry date			N/A	High	
6.a.10	Test strip result Pass or Fail			N/A	High	
6.a.11	Initials of staff doing the QC testing			N/A	High	
Reprocessing of Medical Device:						
6.a.12	Medical Device name or type			N/A	High	
6.a.13	Serial number (if applicable).			N/A	High	
6.a.14	Date of disinfection.			N/A	High	
6.a.15	Method of HLD (e.g. automated, manual).			N/A	High	
6.a.16	Contact time of the HLD (printout if available).			N/A	High	
6.a.17	Temperature of the HLD (printout if available)			N/A	High	
6.a.18	Results of leak test.			N/A	High	
6.a.19	Initials of person doing the reprocessing.			N/A	High	
TOTAL		0	0	19		
SCORE		0/0				
Percentage of Compliance						

7. PASTEURIZATION		YES	NO	N/A	INHERENT RISK	COMMENTS
7.1	Devices are thoroughly cleaned and rinsed prior to pasteurization.			N/A	High	
	The process is monitored with temperature gauges and timing mechanisms for each load with a paper printout (min. 71 C for 30mins) & retained.			N/A	High	
7.2	Following the pasteurization cycle, devices are handled in a manner that prevents contamination.			N/A	High	
7.3	There is a drying cabinet that is used exclusively for the drying of disinfected devices.			N/A	Med	
7.4	The drying cabinet for pasteurized devices is equipped with a HEPA filter.			N/A	Low	

TOTAL	0	0	5	
SCORE	0/0			
Percentage of Compliance				

8. STERILIZATION - (EXCLUDES STERIS SYSTEM 1 SEE SECTION 8.B)		YES	NO	N/A	INFERRNT RISK	COMMENTS
8.1	Critical devices are sterilized by an approved sterilization process. (Unacceptable sterilization methods include boiling, glass bead sterilizers, microwaves and ultraviolet light.)			N/A	High	
8.2	Endoscopes and accessories (e.g., arthroscopes, cystoscopes, laparoscopes) that pass through normally sterile tissues are subjected to a cleaning and sterilization process before each use.			N/A	High	
8.3	Devices to be sterilized are appropriately packaged.			N/A	High	
8.4	Sterilized items are labeled with a load/cycle number, sterilizer number, and the date of sterilization.			N/A	High	
8.5	The contents of each load are documented.			N/A	High	
8.6	There is a system in place that clearly identifies a non-processed load from one that has been processed.			N/A	High	
8.7	Bowie Dick air removal test (high-vacuum sterilizers only) done daily and documented.			N/A	High	
8.8	The physical parameters of each cycle are monitored. The parameters are recorded electronically or on a printout (i.e. time, temperature, pressure)			N/A	High	
8.9	Sterilizer physical parameters are verified by the individual responsible for releasing the load and verification is documented (e.g. printout is initialed).			N/A	High	
8.10	An external process indicator is on the outside of each wrapped package.			N/A	High	
8.11	An internal chemical indicator, appropriate for the sterilization technology being used, is placed inside each package.			N/A	Med	
8.12	Sterilizers are monitored with appropriate biologic indicator each day the sterilizer is used.			N/A	High	
8.13	In a steam sterilizer, each type of cycle to be used is monitored with a biological indicator e.g., high vac, gravity, extended cycles,			N/A	High	
8.14	Biological indicators are used for every load containing implantable items.			N/A	High	
8.15	Biological indicator results are documented.			N/A	High	
8.16	If biological indicator is positive, loads are recalled and the positive test is investigated according to facility's recall procedure.			N/A	High	
8.17	All interventions associated with a positive biological indicator are documented.			N/A	High	
8.18	If any indicator suggests inadequate processing of devices, these devices are reprocessed.			N/A	High	
8.19	There is a process in place to address any indicator failure e.g. printout, chemical indicator or biological indicator.			N/A	High	
8.20	All records are retained according to Corporate Administrative Directives and or quality management system requirements.			N/A	Low	
8.21	Sterile storage areas are well-ventilated and protected from contamination (e.g. dust, moisture, insects, and temperature and humidity extremes).			N/A	High	

8.22	When a random package is inspected sterilized instruments are visibly clean.			N/A	High	
	<b>TOTAL</b>	0	0	22		
	<b>SCORE</b>	0/0				
	Percentage of Compliance					

8.a. FLASH STERILIZATION		YES	NO	N/A	INHERENT RISK	COMMENTS
8.a.1	If flash sterilization is done, all criteria from section 8 are met.			N/A	High	
8.a.2	Flash sterilization is only used in emergency situations and complete sets are not flash sterilized.			N/A	High	
8.a.3	If flash sterilization is done, devices are cleaned according to all criteria in section 5.			N/A	High	
8.a.4	Flash sterilization is never used for implantable devices. (If implantable devices are flash sterilized for any reason, answer 'no') <b>Documentation related to flash sterilization includes:</b>			N/A	High	
8.a.5	a) Flash sterilizer used.			N/A	High	
8.a.6	b) Contents:			N/A	High	
8.a.7	c) Physical Parameters.			N/A	High	
8.a.8	Flash sterilized devices are noted in the patient's chart along with reason for flashing.			N/A	High	
	<b>TOTAL</b>	0	0	8		
	<b>SCORE</b>	0/0				
	Percentage of Compliance					

8.b. STERIS SYSTEM 1 STERILIZATION		YES	NO	N/A	INHERENT RISK	COMMENTS
8.b.1	Critical and semi-critical devices are cleaned before sterilization.			N/A	High	
8.b.2	Critical devices that are sterilized are used immediately.			N/A	High	
8.b.3	Semi-critical devices that are not used immediately are completely dried prior to storage.			N/A	High	
8.b.4	A diagnostic cycle is performed and documented each day the sterilizer is used.			N/A	High	
8.b.5	Identified problems are addressed immediately and actions are documented.			N/A	High	
8.b.6	Printout is checked after each cycle for time, temperature and use-dilution.			N/A	High	
8.b.7	Chemical indicators are used with each cycle run except the diagnostic cycle.			N/A	High	
8.b.8	A biological indicator test is performed in accordance with manufacturer's instructions and documented.			N/A	High	
8.b.9	A positive biological indicator is addressed immediately and actions are documented.			N/A	High	
8.b.10	Log is kept of biological indicator test results and any interventions associated with positive test results.			N/A	High	
8.b.11	If any indicator suggests inadequate processing of devices, these devices are reprocessed.			N/A	High	
8.b.12	After each cycle the peracetic acid cup is checked to ensure that it is completely empty.			N/A	High	
8.b.13	There is a system in place that clearly identifies a non-processed load from one that has been processed to prevent use of a non-sterile item.			N/A	High	

The Stens System 1 channel attachments (quick connects) are appropriate to the scope being reprocessed.			N/A	High	
The channel quick-connects are attached to the Stens System 1 as per Stens instructions.			N/A	High	
The content of each load is documented.			N/A	High	
There are written policies and procedures for the sterilization process.			N/A	High	
<b>TOTAL</b>	0	0	17		
<b>SCORE</b>	0/0				
Percentage of Compliance					

<b>MANAGING AND REPROCESSING INSTRUCTIONS</b>		YES	NO	N/A	INHERENT RISK	COMMENTS
Managers of SPD and IPC are involved in purchase decision for all medical devices requiring reprocessing.	YES				High	decisions made at head office.
Explicit written reprocessing instructions are obtained from the manufacturer and reviewed prior to purchase for each device to be reprocessed.	YES				High	
<b>TOTAL</b>	2	0	0			
<b>SCORE</b>	2/2					
Percentage of Compliance				100		

<b>ACTION AND TRAINING OF REPROCESSING PERSONNEL</b>		YES	NO	N/A	INHERENT RISK	COMMENTS
A department policy specifies the requirements (including frequency) for:						
a) staff education:				N/A	Med	
b) skills training and competency assessments:				N/A	Med	
All reprocessing staff, including first line managers, have completed a recognized qualification/certification program that includes both reprocessing theory and clinical skills training.				N/A	High	
Once hired, the competencies of reprocessing staff are checked regularly as outlined in department policy.				N/A	Med	
All reprocessing staff receive orientation to the department's policies, procedures and practices			NO		Med	
All reprocessing staff receive ongoing education and/or training (i.e. "in-service") at the following points in time:						
a) Change in reprocessing procedures or practices:		NO	NO		INHERENT RISK	
b) Changes in reprocessing equipment:		YES	NO		Med	
c) Changes in medical devices:		YES			Med	
d) Gaps as identified by the competency assessments.		YES			Med	
Education, training and the results of competency assessments for each employee are documented.		YES			Med	
<b>TOTAL</b>	3	3	4			
<b>SCORE</b>	3/6					
Percentage of Compliance				50		

<b>CARE SETTING</b>		YES	NO	N/A	INHERENT RISK	COMMENTS
Critical or semi critical medical devices are disposable whenever possible and discarded at point of use. If they are not disposable, then gross soil is removed and the medical device sent to a hospital Sterile Processing Department for reprocessing.			NO		High	

11.2	In the home setting, reusable semi-critical devices for use on the same patient (e.g., tracheostomy tubes) are cleaned then disinfected by immersion in a 1:2 dilution of 6% household bleach for 3 minutes, or 70% isopropyl alcohol for 5 minutes, or 3% hydrogen peroxide for 30 minutes.	0	1	1	N/A	Med	
<b>TOTAL</b>		0/1		0			
<b>SCORE</b>							
<b>Percentage of Compliance</b>							

<b>12. DENTAL CLINICS</b>		<b>YES</b>		<b>NO</b>		<b>N/A</b>		<b>INHERENT RISK</b>		<b>COMMENTS</b>	
12.1	Medical device reprocessing in a dental clinic complies with Sections 1 to 11 (excluding section 7) of this document.					N/A		High			
12.2	Dental instruments that penetrate soft tissue or bone (e.g., forceps, scalpels, bone chisels, scalers, and burs) and hand pieces are classified as critical and are sterilized between each patient or discarded.					N/A		High			
12.3	Dental instruments that are not intended to penetrate oral soft tissue or bone (e.g., amalgam condensers, air-water syringes) but may come into contact with oral tissues are classified as semi-critical and are minimally high level disinfected between each patient.					N/A		High			
<b>TOTAL</b>		0	0	0	3						
<b>SCORE</b>		0/0									
<b>Percentage of Compliance</b>											

<b>13. HIGH-LEVEL DISINFECTION (HLD) OF FLEXIBLE ENDOSCOPES (GI SC)</b>		<b>YES</b>		<b>NO</b>		<b>N/A</b>		<b>INHERENT RISK</b>		<b>COMMENTS</b>	
13.1	Endoscopes are subjected to HLD (at a minimum) according to manufacturer's recommendations.					N/A		High			
13.2	There are written, detailed procedures for cleaning, high-level disinfecting and handling of endoscopes.					N/A		High			
13.3	Reusable accessories (e.g., biopsy forceps or other cutting instruments) that break the mucosal barrier are cleaned and then sterilized between each patient.					N/A		High			
13.4	Disinfectant has a Drug Identification Number (DIN) from Health Canada.					N/A		High			
13.5	HLDs are prepared correctly to achieve the manufacturer's recommended use/dilution.					N/A		High			
13.6	Sources of contamination are prevented when preparing HLDs (e.g. contaminated containers, measuring devices, prep area).					N/A		High			
13.7	Reusable HLD concentration is checked daily at a minimum with appropriate chemical test strip and discarded/changed if the concentration is less than the minimum effective concentration (MEC).					N/A		High			
13.8	HLD solution is discarded as recommended by the manufacturer.					N/A		High			
13.9	There is a quality control procedure for test strips (i.e. checked according to manufacturer's recommendations each time a new bottle is opened to verify they are accurate).					N/A		High			
13.10	Test strips are used within the listed expiry date.					N/A		High			
13.11	The water bottle used to provide intra procedural flush solution, and its connecting tube, should be sterilized or receive high-level disinfection at least daily.					N/A		High			

13.12	There is a process in place that clearly identifies a non-reprocessed instrument from one that has been reprocessed to prevent use on a patient.			N/A	High	
13.13	HLD practices are monitored on a regular basis and a quality improvement process is in place.			N/A	High	
	TOTAL	0	0	13		
	SCORE	0/0				
	Percentage of Compliance					

13.a. HIGH-LEVEL DISINFECTION (HLD) OF FLEXIBLE ENDOSCOPES - CI		YES	NO	N/A	INHERENT RISK	COMMENTS
13.a.1	Pre-cleaning of the endoscope is performed at point of use, immediately following clinical procedure.			N/A	High	
13.a.2	Endoscopes are cleaned prior to HLD.			N/A	High	
13.a.3	Enzymatic solution is prepared and used as per manufacturer's recommendations.			N/A	High	
13.a.4	Enzymatic cleaning solutions are discarded after each scope.			N/A	High	
13.a.5	Accessories are disconnected and disassembled and completely immersed in the enzymatic detergent.			N/A	High	
13.a.6	A leak test is performed prior to, and/or during immersion of the endoscope.			N/A	High	
13.a.7	The entire endoscope is completely immersed in the freshly prepared enzymatic solution.			N/A	High	
13.a.8	Splashing and aerosolization is prevented during immersion and cleaning of the endoscope.			N/A	High	
13.a.9	The bending section is kept straight so brushing does not damage endoscope.			N/A	High	
13.a.10	The exterior of the endoscope is cleaned with a soft brush or lint free cloth.			N/A	High	
13.a.11	The biopsy/suction channel in the insertion tube is cleaned with the appropriate sized channel cleaning brush until all visible debris is removed (min 3 times).			N/A	High	
13.a.12	The brush is cleaned in the enzymatic solution each time it is passed through the channel.			N/A	High	
13.a.13	The suction valve housing and instrument channel port are cleaned with appropriately sized channel brush until all debris is removed.			N/A	High	
13.a.14	Following device manufacturer's instructions, enzymatic solution is injected into all channels of the endoscope.			N/A	High	
13.a.15	The endoscope is soaked in the enzymatic solution as per manufacturer's instruction to ensure proper contact time for the enzymatic cleaner.			N/A	High	
13.a.16	The scope and accessories are thoroughly rinsed with tap water to remove all traces of enzymatic detergent and debris.			N/A	High	
13.a.17	The valves and removable parts are brushed and flushed until all debris is removed.			N/A	High	
13.a.18	Final rinses prior to disinfection are performed in clear tap water followed by air purges using a syringe or an approved automated system.			N/A	High	
13.a.19	The exterior of the endoscope and all removable parts are thoroughly dried using a clean lint free cloth.			N/A	High	

13.a.20	Cleaning accessories (e.g. brushes, sponges) are disposable or thoroughly cleaned and high level disinfected/sterilized between uses.				N/A	High	
	TOTAL	0	0	20			
	SCORE	0/0					
	Percentage of Compliance						

<b>13.b. HIGH-LEVEL DISINFECTION (HLD) OF FLEXIBLE ENDOSCOPES - M</b>		YES	NO	N/A	INHERENT RISK	COMMENTS
13.b.1	The soaking container is kept covered during use.			N/A	Med	
13.b.2	The soaking container is washed, rinsed and dried when the solution is changed.			N/A	Med	
13.b.3	Reusable HLD concentration is checked daily at a minimum with appropriate chemical test strip and discarded/changed if the concentration is less than the minimum effective concentration (MEC).			N/A	High	
13.b.4	HLD solution is discarded as recommended by the manufacturer.			N/A	Med	
13.b.5	Excess water is removed from the endoscope prior to HLD.			N/A	High	
13.b.6	The HLD solution is flushed through all channels to purge air from each channel and to ensure all channels are perfused with HLD.			N/A	High	
13.b.7	The endoscope and parts are completely immersed in the HLD solution for the recommended time and temperature.			N/A	High	
13.b.8	Following HLD, air is flushed through the endoscope channels.			N/A	Low	
13.b.9	The endoscope and parts (e.g. valves and buttons) are rinsed with sterile water, bacteria free water or as specified by the device manufacturer's instructions.			N/A	High	
13.b.10	The rinse water is changed after each process unless otherwise specified by the HLD manufacturer.			N/A	High	
13.b.11	The endoscope is dried with a clean, lint-free cloth.			N/A	High	
13.b.12	There is a process in place that clearly identifies a non-reprocessed instrument from one that has been reprocessed to prevent use on a patient.			N/A	High	
13.b.13	Disinfection practices are monitored on a regular basis and a quality improvement process is in place.			N/A	High	
13.b.14	All channels are flush with air followed by a 70% alcohol and an air purge.			N/A	High	
13.b.15	The endoscope is dried with a clean, lint-free cloth.			N/A	High	
	TOTAL	0	0	15		
	SCORE	0/0				
	Percentage of Compliance					

<b>13.c. HIGH-LEVEL DISINFECTION OF FLEXIBLE ENDOSCOPES -AUTOMA</b>		YES	NO	N/A	INHERENT RISK	COMMENTS
13.c.1	Reusable HLD concentration is checked daily (at a minimum) with appropriate chemical test strip and discarded/changed if the concentration is less than the minimum effective concentration (MEC).			N/A	High	
13.c.2	Immediately following manual cleaning the dried endoscope, valves, cleaning brush and removable parts are placed in the Automated Endoscope Reprocessor (AER) following manufacturer's instructions for loading.			N/A	High	

13.c.3	The AER channel attachments are appropriate to the scope being reprocessed.			N/A	High	
13.c.4	The endoscope connectors/adapters are correctly attached to the AER.			N/A	High	
13.c.5	The AER is operated so that the HLD completely contacts the endoscope for the recommended time and temperature as per AER manufacturer's instructions for use.			N/A	High	
13.c.6	The endoscope is removed promptly after the final cycle has been completed.			N/A	High	
13.c.7	All channels are flushed with air followed by 70% alcohol and an air purge.			N/A	High	
<b>TOTAL</b>		0	0	7		
<b>SCORE</b>		0/0				
Percentage of Compliance						

<b>13.d. HIGH-LEVEL DISINFECTION OF FLEXIBLE ENDOSCOPES -STORAGE</b>						
		YES	NO	N/A	INHERENT RISK	COMMENTS
13.d.1	Endoscopes are hung in a vertical position in a well-ventilated, protected, clean area to facilitate drying.			N/A	High	
13.d.2	Endoscopes and components are stored in a manner that protects them from contamination (i.e. do not touch the floor of the cabinet). Except for emergency scopes, caps, valves and other components are detached for storage.			N/A	High	
13.d.3	Endoscope storage cabinets are cleaned at least weekly.			N/A	High	
13.d.4	There are written procedures for shelf-life of stored endoscopes (e.g., colonoscopes have a shelf - life of 7 days, if stored dry).			N/A	Low	
13.d.5	<b>TOTAL</b>	0	0	5		
<b>SCORE</b>		0/0				
Percentage of Compliance						

<b>13.g. HIGH-LEVEL DISINFECTION OF FLEXIBLE ENDOSCOPES -DOCUME</b>						
		YES	NO	N/A	INHERENT RISK	COMMENTS
<b>HLD Preparation:</b>						
13.e.1	Product name			N/A	High	
13.e.2	DIN number			N/A	High	
13.e.3	Lot number			N/A	High	
13.e.4	Expiry Date			N/A	High	
13.e.5	Date of solution change			N/A	High	
13.e.6	Initials of staff doing preparation and documentation			N/A	High	
<b>HLD Quality Control:</b>						
13.e.7	Test Strip name			N/A	High	
13.e.8	Test Strip lot number			N/A	High	
13.e.9	Test Strip Expiry date			N/A	High	
13.e.10	Test strip result: Pass or Fail			N/A	High	
13.e.11	Initials of staff doing the QC testing			N/A	High	
<b>Reprocessing of Medical Device:</b>						
13.g.12	Medical Device name or type			N/A	High	
13.g.13	Serial number (if applicable)			N/A	High	
13.g.14	Date of disinfection			N/A	High	
13.g.15	Method of HLD (e.g. automated, manual)			N/A	High	
13.g.16	Contact time of the HLD (printout if available)			N/A	High	
13.g.17	Temperature of the HLD (printout if available)			N/A	High	

13.e.18	Results of leak test			N/A	High
13.e.19	Initials of person doing the reprocessing			N/A	High
	Traceability of Scope: (documented by clinical staff)				
13.e.20	Patient name			N/A	High
13.e.21	Patient record number			N/A	High
13.e.22	Date			N/A	High
13.e.23	Time			N/A	High
13.e.24	Type of procedure			N/A	High
13.e.25	Endoscopist			N/A	High
13.e.26	Serial number of scope			N/A	High
13.e.27	Initials of staff completing documentation			N/A	High
	TOTAL	0	0	27	
	SCORE	0/0			
	Percentage of Compliance				

	SUMMARY		
	YES	NO	N/A
OVERALL TOTAL	16	28	205
SCORE		16/44	
OVERALL PERCENTAGE OF COMPLIANCE		36.36363636	