



Non-hospital Medical and Surgical
Facilities Accreditation Program

ACCREDITATION STANDARDS

Medical Device
Reprocessing

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Non-hospital Medical and Surgical Facilities Accreditation Program
College of Physicians and Surgeons of British Columbia
300-669 Howe Street
Vancouver BC V6C 0B4

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Introduction

The British Columbia Ministry of Health issued its first provincial policy on medical device reprocessing titled Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities in March 2007. These guidelines were adopted by the NHMSFAP Committee as the expected standards of practice for reprocessing of reusable medical devices in non-hospital facilities.

In December 2011, the Ministry of Health advised of updates to its provincial reprocessing policy and the NHMSFAP Committee adopted the Ministry of Health Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities, as the expected standards of practice for reprocessing of reusable medical devices in **all** non-hospital facilities. This aligns with the Ministry's Policy Communique¹ which requires that all reprocessing practices in health authority facilities and programs, as well as private or non-profit facilities and/or providers providing public health care services under contract to health authorities, comply with established standards for medical device reprocessing as stated by Health Canada, the Canadian Standards Association and BC's Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities.

This standard establishes the requirements for reprocessing of all critical and semi-critical medical devices used within nonhospital facilities as set by the BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011)² and is a transcription of the BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices.³

Medical device reprocessing

No.	Description	Reference	Risk	Change	Asmt.
MDR1.0	ASSESSMENT & PURCHASE OF MEDICAL DEVICES & REPROCESSING EQUIPMENT				
MDR1.1.1	<p>M There is a process in place to ensure that appropriate stakeholders are involved in decisions to trial or purchase all medical devices, consumables and reprocessing equipment (e.g. Medical Device Reprocessing Department (MDRD), Infection Prevention and Control (IPC), Biomedical Engineering).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1A Page 22-23. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.01a.</p>	1, 2, 3	M		P, F
MDR1.1.2	<p>M The process in place to ensure that appropriate stakeholders are involved in decisions to trial or purchase all medical devices, consumables and reprocessing equipment (e.g. Medical Device Reprocessing Department (MDRD), Infection Prevention and Control (IPC), Biomedical Engineering) is followed and is operational.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1A Page 22-23. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.01b.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR1.1.3	<p>M There is a process in place to ensure that for each device requiring reprocessing, device specific, validated, written reprocessing instructions are obtained from the manufacturer and are reviewed by the MDRD prior to trial or purchase.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1B Page 23-24. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.02a.</p>	1, 2, 3	M		P, F
MDR1.1.4	<p>M The process in place to ensure that for each device requiring reprocessing, device specific, validated, written reprocessing instructions are obtained from the manufacturer and are reviewed by the MDRD prior to trial or purchase is followed and is operational.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1B Page 23-24. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.02b.</p>	1, 2, 3	M		P, F
MDR1.1.5	<p>M There is a process in place to ensure that there are CURRENT validated, written instructions from the manufacturer regarding the safe and appropriate reprocessing of medical devices.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1B Page 23-24. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.03a.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR1.1.6	<p>M The process in place to ensure that there are CURRENT validated, written instructions from the manufacturer regarding the safe and appropriate reprocessing of medical devices is followed and is operational.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1B Page 23-24. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.03b.</p>	1, 2, 3	M		P, F
MDR1.1.7	<p>M There is a process in place to ensure all physician supplied or loaner medical devices used at any site are accompanied by validated manufacturer's instructions for reprocessing.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1C Page 24-25. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.04a.</p>	1, 2, 3	M		P, F
MDR1.1.8	<p>M The process in place to ensure all physician supplied or loaner medical devices used at any site are accompanied by validated manufacturer's instructions for reprocessing is followed and is operational.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1C Page 24-25. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.04b.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR1.1.9	<p>M There is a process in place to ensure that all physician supplied or loaner critical or semi-critical medical devices used at any site are reprocessed at the site prior to use unless facility policy states otherwise.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1C Page 24-25. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.05a.</p>	1, 2, 3	M		P, F
MDR1.1.10	<p>M The process in place to ensure that all physician supplied or loaner critical or semi-critical medical devices used at any site are reprocessed at the site prior to use unless facility policy states otherwise is followed and is operational.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1C Page 24-25. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.05b.</p>	1, 2, 3	M		P, F
MDR1.1.11	<p>M There is a process in place to ensure that all reprocessing equipment is installed, validated and performs in accordance with manufacturer’s specifications (installation, operation and performance qualifications).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1B Page 23-24. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.06a.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR1.1.12	<p>M The process in place to ensure that all reprocessing equipment is installed, validated and performs in accordance with manufacturer's specifications (installation, operation and performance qualifications) is followed and is operational.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1B Page 23-24. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 1.06b.</p>	1, 2, 3	M		P, F
MDR2.0	ENVIRONMENTAL REQUIREMENTS FOR THE REPROCESSING AREA				
MDR2.1.1	<p>M All reprocessing areas, including the decontamination area have restricted access.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 2A Page 26. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 2.01a.</p>	1, 2, 3	M		P, F
MDR2.1.2	<p>M All reprocessing areas, including the decontamination area Ensure one way workflow of staff and medical devices.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 2A Page 26. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 2.01b.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR2.1.3	<p>M All reprocessing areas, including the decontamination area Have adequate space for area tasks as well as equipment and supply storage.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 2A Page 26. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 2.01c.</p>	1, 2, 3	M		P, F
MDR2.1.4	<p>M All reprocessing areas, including the decontamination area Have surfaces that are easily cleaned and disinfected.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 2A Page 26. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 2.01d.</p>	1, 2, 3	M		P, F
MDR2.1.5	<p>M All reprocessing areas, including the decontamination area Have slip proof flooring that can withstand wet mopping and disinfecting.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 2A Page 26. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 2.01e.</p>	1, 2, 3	L		P, F
MDR2.1.6	<p>M All reprocessing areas, including the decontamination area Have easy access to hand hygiene facilities.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 2A Page 26. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 2.01f.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR2.1.7	<p>M In addition, the Decontamination area is distinctly separate from areas where clean/disinfected/sterile devices are handled or stored.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 2D Page 28. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 2.02.</p>	1, 2, 3	H		P, F
MDR2.1.8	<p>M Environmental cleaning includes written procedures and clearly defined responsibilities.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 2D Page 28. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 2.03.</p>	1, 2, 3	L		P, F
MDR2.1.9	<p>M Environmental cleaning procedures are protocols are followed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 2D Page 28. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 2.04.</p>	1, 2, 3	M		P, F
MDR3.0	POLICIES AND PROCEDURES				

No.	Description	Reference	Risk	Change	Asmt.
MDR3.1.1	<p>M There are current written policies and procedures for all aspects of reprocessing (e.g. medical devices, reprocessing equipment) based on current recognized standards and validated manufacturer’s instructions.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 3 Page 28-29. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 3.01.</p>	1, 2, 3	M		P, F
MDR3.1.2	<p>M There is a written procedure for the management of an adverse event e.g. incorrect reprocessing method used, high level disinfection failure.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12C Page 63. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 3.02.</p>	1, 2, 3	H		P, F
MDR3.1.3	<p>M Reprocessing policies and procedures are readily accessible for staff.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 3 Page 28; Section 7A Page 37. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 3.03.</p>	1, 2, 3	M		P, F
MDR3.1.4	<p>M Reprocessing policies and procedures are periodically reviewed (e.g. every 2 or 3 years) and updated when there is a change in practice.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 3 Page 28-29. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 3.04.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR4.0	EDUCATION AND TRAINING				
MDR4.1.1	<p>M In medical device reprocessing departments including satellite reprocessing areas MDR Managers directly accountable for reprocessing shall have demonstrated knowledge of reprocessing practices and infection prevention and control principles as they relate to medical device reprocessing in their area.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.01a.</p>	1, 2, 3	M		P, F
MDR4.1.2	<p>M In medical device reprocessing departments including satellite reprocessing areas reprocessing technicians who routinely perform medical device reprocessing activities shall, at a minimum, have successfully completed a recognized medical device reprocessing technician educational program.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.01b.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR4.1.3	<p>M In departments where medical device reprocessing is NOT the primary function any individual involved in any aspect of reprocessing shall obtain education, orientation and training specific to the function they perform/medical device to be reprocessed (e.g., medical imaging technologists, respiratory technicians and staff in endoscopy, dental, podiatry, residential care, and physician offices).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.02a.</p>	1, 2, 3	H		P, F
MDR4.1.4	<p>M In departments where medical device reprocessing is NOT the primary function the policies of the health care setting shall specify the requirements for, and frequency of, education and training as well as competency assessment for all personnel involved in the reprocessing of medical devices.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.02b.</p>	1, 2, 3	H		P, F
MDR4.1.5	<p>M In all reprocessing areas, a department policy specifies the requirements (including frequency) for staff education.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.03a.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR4.1.6	<p>M In all reprocessing areas, a department policy specifies the requirements (including frequency) for skills training and competency assessments.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.03b.</p>	1, 2, 3	M		P, F
MDR4.1.7	<p>M Once hired, the competencies of reprocessing staff are checked regularly as outlined in department policy.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.04.</p>	1, 2, 3	M		P, F
MDR4.1.8	<p>M All reprocessing staff receive orientation to the department’s policies, procedures and practices.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.05.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR4.1.9	<p>M All reprocessing staff receive ongoing education and/or training (i.e. “in-service”) when there is a change in reprocessing policies, procedures or practices.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.06a.</p>	1, 2, 3	M		P, F
MDR4.1.10	<p>M All reprocessing staff receive ongoing education and/or training (i.e. “in-service”) when there are changes in reprocessing equipment or consumables, e.g. chemical disinfectant</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.06b.</p>	1, 2, 3	M		P, F
MDR4.1.11	<p>M All reprocessing staff receive ongoing education and/or training (i.e. “in-service”) when there are changes in medical devices.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.06c.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR4.1.12	<p>M All reprocessing staff receive ongoing education and/or training (i.e. “in-service”) when there are gaps as identified by the competency assessments.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.06d.</p>	1, 2, 3	M		P, F
MDR4.1.13	<p>M Education, training and the results of competency assessments for each employee are documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 4 Page 29-30. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 4.07.</p>	1, 2, 3	M		P, F
MDR5.0	OCCUPATIONAL HEALTH AND SAFETY				
	Routine practices				
MDR5.1.1	<p>M Eating/drinking, storage of food, smoking, application of cosmetics or personal effects does not occur in the reprocessing area.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 5A Page 31. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 5.01.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR5.1.2	<p>M Jewellery and/or external body piercings are removed or securely covered prior to entering the work area</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 5A Page 31. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 5.02.</p>	1, 2, 3	M		P, F
MDR5.1.3	<p>M Hand hygiene stations are available.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 5A Page 31. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 5.03.</p>	1, 2, 3	H		P, F
MDR5.1.4	<p>M Staff have been trained in hand hygiene techniques.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 5A Page 31. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 5.04.</p>	1, 2, 3	H		P, F
MDR5.1.5	<p>M Staff perform hand hygiene at the appropriate times.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 5A Page 31. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 5.05.</p>	1, 2, 3	H		P, F
Safety					

No.	Description	Reference	Risk	Change	Asmt.
MDR5.1.6	<p>M Personal protective equipment (PPE), appropriate to the task, is worn when handling/cleaning/reprocessing contaminated devices (e.g. gloves, mask, protective eye wear and/or face shield and waterproof gown).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 5B Page 32. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 5.06.</p>	1, 2, 3	H		P, F
MDR5.1.7	<p>M Material Safety Data Sheet (MSDS) information is available for all chemicals in use and is readily accessible to staff.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 5 Page 30-31. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 5.07.</p>	1, 2, 3	M		P, F
MDR5.1.8	<p>M Spill kit(s) appropriate to the chemical(s) being used are readily accessible.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 2D Page 28. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 5.08.</p>	1, 2, 3	H		P, F
MDR5.1.9	<p>M Sharp objects are safely disposed of in puncture resistant containers.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 5C Page 32. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 5.09.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR6.0	CLEANING (DECONTAMINATION) OF REUSABLE MEDICAL DEVICES				
	General				
MDR6.1.1	<p>M Contaminated medical devices used within a facility are appropriately prepared at point of use (e.g. gross debris removed), placed in a leak proof container, and transported to the dedicated area.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6A and B Page 33-34. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.01.</p>	1, 2, 3	M		P, F
MDR6.1.2	<p>M There is a process in place that clearly distinguishes a non-reprocessed device from one that has been reprocessed to prevent use on a patient.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6B Page 35. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.02.</p>	1, 2, 3	H		P, F
	Detergents				
MDR6.1.3	<p>M Detergents (including enzymatics) are prepared and used according to the manufacturer’s instructions for use (e.g. concentration, temperature)</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6C and D Page 35-37. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.03.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR6.1.4	<p>M Detergents or enzymatic cleaners are compatible with the medical devices being cleaned.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6C and D Page 35-37. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.04.</p>	1, 2, 3	M		P, F
MDR6.1.5	<p>M Detergent or enzymatic cleaning solutions are discarded when visibly soiled and at least at the end of each shift.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6 Page 33; Section 6C Page 35. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.05.</p>	1, 2, 3	M		P, F
Cleaning					
MDR6.1.6	<p>M Cleaning always precedes high-level disinfection or sterilization processes.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6 Page 33; Section 6D Page 35-37. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.06.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR6.1.7	<p>M Cleaning is done immediately after use. If this is not possible the medical device is treated to prevent hardening of organic matter e.g. enzymatic pre-soak or spray, or watered moistened towel.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 33-37. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.07.</p>	1, 2, 3	M		P, F
MDR6.1.8	<p>M Devices are cleaned with an approved detergent solution unless otherwise recommended by the device manufacturer.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-37. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.08.</p>	1, 2, 3	L		P, F
MDR6.1.9	<p>M Friction is used when manually cleaning a device.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-36. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.09.</p>	1, 2, 3	M		P, F
MDR6.1.10	<p>M When manually cleaning, devices are completely immersed whenever possible.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-36. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.10.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR6.1.11	<p>M When being cleaned, devices are disassembled, sorted, and soaked to remove organic material (if necessary).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-36. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.11.</p>	1, 2, 3	H		P, F
Ultrasonic cleaner					
MDR6.1.12	<p>M Gross soil is removed prior to immersion in an ultrasonic cleaner.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-36. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.12a.</p>	1, 2, 3	M		P, F
MDR6.1.13	<p>M Following ultrasonic processing, the devices are rinsed per manufacturer’s instructions.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-36. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.12b.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR6.1.14	<p>M The ultrasonic cleaning solution is discarded at least daily and whenever visibly soiled</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-36. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.12c.</p>	1, 2, 3	M		P, F
Lubricant					
MDR6.1.15	<p>M Medical device lubricant, if used, is medical grade & is used according to manufacturer’s instructions for dispensing, shelf life, and storage.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-36. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.13.</p>	1, 2, 3	L		P, F
Rinsing					
MDR6.1.16	<p>M Devices are rinsed and excess water is removed after cleaning.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-36. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.14.</p>	1, 2, 3	H		P, F
Automatic washers					

No.	Description	Reference	Risk	Change	Asmt.
MDR6.1.17	<p>M Automatic washers are used in accordance with the manufacturer's recommendations.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-36. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.15.</p>	1, 2, 3	L		P, F
MDR6.1.18	<p>M Automated washing equipment has documented preventive maintenance as specified by the manufacturer.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-36. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.16.</p>	1, 2, 3	M		P, F
Cleaning accessories					
MDR6.1.19	<p>M Cleaning accessories (e.g. brushes, sponges) are disposable or thoroughly cleaned and disinfected/sterilized at least daily.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6D Page 35-36. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 6.17.</p>	1, 2, 3	M		P, F
MDR7.0	FACTORS AFFECTING PRODUCT SELECTION & EFFICACY OF LIQUID CHEMICALS FOR DISINFECTION OR MANUAL STERILIZATION				

No.	Description	Reference	Risk	Change	Asmt.
MDR7.1.1	<p>M There is a process in place to ensure that all products used in any/all reprocessing stages shall be approved by personnel knowledgeable in medical device reprocessing and infection prevention and control.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 3 Page 28-29. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 7.01a.</p>	1, 2, 3	M		P, F
MDR7.1.2	<p>M The process in place to ensure that all products used in any/all reprocessing stages shall be approved by personnel knowledgeable in medical device reprocessing and infection prevention and control is followed and operational.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 3 Page 28-29. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 7.01b.</p>	1, 2, 3	M		P, F
MDR8.0	<p>DISINFECTION OF REUSABLE MEDICAL DEVICES</p> <p>For automated high-level disinfection: see section 9 - reprocessing endoscopy devices</p>				
	<p>Manual high-level disinfection (HLD) - general</p>				
MDR8.1.1	<p>M Semi critical medical devices are high level disinfected (at a minimum).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8B Page 41. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.01.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.2	<p>M HLD has a Drug Identification Number (DIN) from Health Canada.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8B Page 41. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.02.</p>	1, 2, 3	H		P, F
MDR8.1.3	<p>M HLD is prepared according to the manufacturer’s instructions for use.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 41-42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.03.</p>	1, 2, 3	M		P, F
MDR8.1.4	<p>M Contamination is prevented when preparing disinfectants and detergents (e.g. containers, measuring devices, prep area).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 41-42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.04.</p>	1, 2, 3	L		P, F
MDR8.1.5	<p>M Minimum effective concentration (MEC) is checked at least each day that the solution is used with the appropriate chemical test strip.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.05.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.6	<p>M There is a quality control procedure for test strips (i.e. checked according to manufacturer's recommendations each time a new bottle is opened.)</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.06.</p>	1, 2, 3	M		P, F
MDR8.1.7	<p>M Test strips are used within their expiry dates i.e. shelf life and/or in-use life.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.07.</p>	1, 2, 3	M		P, F
MDR8.1.8	<p>M HLD is used within it's expiry dates i.e. shelf life and/or in-use life</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.08.</p>	1, 2, 3	M		P, F
MDR8.1.9	<p>M HLD solution is disposed of according to manufacturer's recommendations and local regulations.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.09.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.10	<p>M The soaking container is kept covered at all times . The only exceptions are; when placing or removing a device from the HLD or when the device is not completely immersible.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.10.</p>	1, 2, 3	M		P, F
MDR8.1.11	<p>M The soaking container is washed, rinsed and dried when the HLD is changed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.11.</p>	1, 2, 3	L		P, F
MDR8.1.12	<p>M Prior to disinfection, devices are cleaned in accordance with Section 6-- Cleaning</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6 Page 33-37; Section 8 Page 40. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.12.</p>	1, 2, 3	H		P, F
MDR8.1.13	<p>M Excess water is removed from the device prior to HLD.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8B Page 41. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.13.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.14	<p>M The device and accessories are completely immersed in HLD. Any lumens are filled with HLD.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 41-42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.14.</p>	1, 2, 3	H		P, F
MDR8.1.15	<p>M Contact with HLD (i.e. complete immersion in HLD) is maintained for the recommended time and temperature</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.15.</p>	1, 2, 3	H		P, F
MDR8.1.16	<p>M The device and accessories are rinsed with sterile water, bacteria free water or as specified by the device manufacturer’s instructions.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.16.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.17	<p>M Following rinsing, the device is thoroughly dried with a lint free cloth. Lumens are completely dried according to device manufacturer's instructions e.g. flushed with alcohol, flushed with air.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.17.</p>	1, 2, 3	M		P, F
MDR8.1.18	<p>M The rinse water is changed after each process.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 46. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.18.</p>	1, 2, 3	M		P, F
MDR8.1.19	<p>M There is a process in place that clearly distinguishes a non-reprocessed device from one that has been reprocessed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 2A Page 26; Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.19.</p>	1, 2, 3	H		P, F
HLD testing and documentation					

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.20	<p>M HLD solution documentation includes product name.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.20a.</p>	1, 2, 3	L		P, F
MDR8.1.21	<p>M HLD solution documentation includes lot number.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.20b.</p>	1, 2, 3	L		P, F
MDR8.1.22	<p>M HLD solution documentation includes expiry date.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.20c.</p>	1, 2, 3	L		P, F
MDR8.1.23	<p>M HLD solution documentation includes unopened, on the shelf.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.20d.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.24	<p>M HLD solution documentation includes in use.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.20e.</p>	1, 2, 3	M		F
MDR8.1.25	<p>M HLD solution documentation includes date of solution change.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.20f.</p>	1, 2, 3	M		P, F
MDR8.1.26	<p>M HLD solution documentation includes initials of staff doing preparation and documentation.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.20g.</p>	1, 2, 3	L		P, F
HLD test strip documentation					
MDR8.1.27	<p>M HLD test strip documentation includes name of test strip.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.21a.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.28	<p>M HLD test strip documentation includes lot number.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.21b.</p>	1, 2, 3	M		P, F
MDR8.1.29	<p>M HLD test strip documentation includes expiry date.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.21c.</p>	1, 2, 3	M		P, F
MDR8.1.30	<p>M HLD test strip documentation includes quality control test results (each time a new test strip bottle is opened).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.21d.</p>	1, 2, 3	M		P, F
MDR8.1.31	<p>M HLD test strip documentation includes routine test strip result: pass or fail.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.21e.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.32	<p>M HLD test strip documentation includes initials of staff doing the testing and documentation.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.21f.</p>	1, 2, 3	L		P, F
Medical device (being reprocessed) documentation					
MDR8.1.33	<p>M Medical device (being reprocessed) documentation includes medical device name or type.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.22a.</p>	1, 2, 3	M		P, F
MDR8.1.34	<p>M Medical device (being reprocessed) documentation includes unique identifier (if applicable) e.g. serial number.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.22b.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.35	<p>M Medical device (being reprocessed) documentation includes date and time of disinfection.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.22c.</p>	1, 2, 3	M		P, F
MDR8.1.36	<p>M Medical device (being reprocessed) documentation includes Contact time of the HLD.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.22d.</p>	1, 2, 3	M		P, F
MDR8.1.37	<p>M Medical device (being reprocessed) documentation includes temperature of the HLD (if applicable).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.22e.</p>	1, 2, 3	M		P, F
MDR8.1.38	<p>M Medical device (being reprocessed) documentation includes Results of leak test (if applicable).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9C Page 45-46; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.22f.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.39	<p>M Medical device (being reprocessed) documentation includes Initials of person doing the reprocessing</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.22g.</p>	1, 2, 3	L		P, F
Thermal disinfection (e.g. pasteurization)					
MDR8.1.40	<p>M Reprocessing equipment is used in accordance with manufacturer’s specifications.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.23.</p>	1, 2, 3	L		P, F
MDR8.1.41	<p>M Each thermal disinfection cycle is monitored for time and temperature. A printout records the results .(Min. 71 deg C for 30mins). It is signed & retained.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.24.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.42	<p>M Following the thermal disinfection cycle, devices are handled in a manner that prevents contamination i.e. hands must be CLEAN.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.25.</p>	1, 2, 3	M		P, F
MDR8.1.43	<p>M There is a drying cabinet that is used exclusively for the drying of thermally disinfected devices.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.26.</p>	1, 2, 3	L		P, F
MDR8.1.44	<p>M The drying cabinet for thermally disinfected devices is equipped with a HEPA filter.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.27.</p>	1, 2, 3	M		P, F
MDR8.1.45	<p>M HEPA filters are changed according to manufacturer's instructions for use.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.28.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR8.1.46	<p>M If devices are not dried in a drying cabinet, they are dried in a manner that prevents contamination and ensures all parts are completely dry.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 8.29.</p>	1, 2, 3	M		P, F
MDR9.0	REPROCESSING ENDOSCOPY DEVICES				
	General				
MDR9.1.1	<p>M Critical endoscopes, emergency bronchoscopes and GI accessories that break the mucosal barrier are sterilized.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9 Page 44. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.01.</p>	1, 2, 3	H		P, F
MDR9.1.2	<p>M Semi-critical endoscopes and accessories are high-level disinfected (at a minimum).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9 Page 44. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.02.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.3	<p>M The water bottle used to provide intra-procedural flush solution, and its connecting tube, should be high level disinfected or sterilized at least daily (according to device manufacturer's instructions).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9G Page 47-48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.03.</p>	1, 2, 3	H		P, F
MDR9.1.4	<p>M There are written, detailed procedures for cleaning, high-level disinfecting and handling of endoscopes.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.04.</p>	1, 2, 3	M		P, F
MDR9.1.5	<p>M Contamination is prevented when preparing disinfectants and detergents</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.05.</p>	1, 2, 3	L		P, F
Cleaning					

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.6	<p>M Pre-cleaning of the endoscope is performed at point of use, immediately following clinical procedure.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.06.</p>	1, 2, 3	H		P, F
MDR9.1.7	<p>M A leak test is performed prior to immersion according to the endoscope manufacturer's instructions for use.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45-46. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.07.</p>	1, 2, 3	M		P, F
MDR9.1.8	<p>M Enzymatic solution is prepared and used as per manufacturer's recommendations.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.05.</p>	1, 2, 3	L		P, F
MDR9.1.9	<p>M Enzymatic cleaning solutions are discarded after each scope is cleaned.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.09.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.10	<p>M Accessories (valves and removable parts) are disconnected, disassembled and completely immersed in the enzymatic detergent.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.10.</p>	1, 2, 3	M		P, F
MDR9.1.11	<p>M The valves and removable parts are brushed and flushed until all debris is removed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.11.</p>	1, 2, 3	H		P, F
MDR9.1.12	<p>M The entire endoscope is completely immersed in the freshly prepared enzymatic solution.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C and D Page 45-46. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.12.</p>	1, 2, 3	M		P, F
MDR9.1.13	<p>M Splashing and aerosolization is prevented during immersion and cleaning of the endoscope.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 46. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.13.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.14	<p>M The bending section is kept straight so brushing does not damage endoscope.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 46. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.14.</p>	1, 2, 3	L		P, F
MDR9.1.15	<p>M The exterior of the endoscope is cleaned with a soft brush or lint free cloth.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.15.</p>	1, 2, 3	H		P, F
MDR9.1.16	<p>M The biopsy/suction channel in the insertion tube is cleaned with the appropriate sized channel cleaning brush until all visible debris is removed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.16.</p>	1, 2, 3	H		P, F
MDR9.1.17	<p>M The brush is cleaned in the enzymatic solution each time it is passed through a channel.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.17.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.18	<p>M The air-water and suction biopsy cylinders as well as the instrument channel port are cleaned with appropriately sized channel/cylinder brushes until all debris is removed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.18.</p>	1, 2, 3	H		P, F
MDR9.1.19	<p>M Following device manufacturer's instructions, enzymatic solution is flushed through all channels of the endoscope.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C and D Page 45-46. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.19.</p>	1, 2, 3	M		P, F
MDR9.1.20	<p>M The endoscope is soaked in the enzymatic solution as per manufacturer's instructions.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9D Page 46. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.20.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.21	<p>M The scope and accessories are thoroughly rinsed with potable water. Excess water is removed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9D Page 46; Section 9G Page 47-48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.21.</p>	1, 2, 3	H		P, F
MDR9.1.22	<p>M Cleaning accessories (e.g. brushes, sponges) are disposable or thoroughly cleaned and high level disinfected/sterilized between uses.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C and D Page 45-46. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.22.</p>	1, 2, 3	M		P, F
Disinfectant					
MDR9.1.23	<p>M HLD has a Drug Identification Number (DIN) from Health Canada.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 41. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.23.</p>	1, 2, 3	H		P, F
MDR9.1.24	<p>M HLD is prepared according to the manufacturer’s instructions for use.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 41-42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.24.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.25	<p>M Minimum effective concentration (MEC) is checked at least each day that the solution is used with appropriate chemical test strip.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.25.</p>	1, 2, 3	H		P, F
MDR9.1.26	<p>M There is a quality control procedure for test strips (i.e. checked according to manufacturer's recommendations each time a new bottle is opened.)</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.26.</p>	1, 2, 3	L		P, F
MDR9.1.27	<p>M Test strips are used within their expiry dates i.e. shelf life and/or in-use life.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.27.</p>	1, 2, 3	M		P, F
MDR9.1.28	<p>M HLD is used within its expiry dates i.e. shelf life and/or in-use life.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.28.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.29	<p>M HLD solution is disposed of according to manufacturer's recommendations and local regulations.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.29.</p>	1, 2, 3	M		P, F
Automatic endoscope reprocessor (AER)					
MDR9.1.30	<p>M AER is operated according to manufacturer's instructions for use.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9E Page 46-47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.30.</p>	1, 2, 3	H		P, F
MDR9.1.31	<p>M Endoscope and components are validated for reprocessing the AER</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9E Page 46-47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.31.</p>	1, 2, 3	H		P, F
MDR9.1.32	<p>M Elevator channels of duodenoscope (ERCP) scopes are processed according to AER and endoscope manufacturer's instructions.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9E Page 46-47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.32.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.33	<p>M The device and accessories are positioned in the AER so that they will be completely immersed in HLD.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9E Page 46-47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.33.</p>	1, 2, 3	H		P, F
MDR9.1.34	<p>M All channels of the endoscope are attached to the AER using manufacturer's specified connectors and adapters</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9E Page 46-47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.34.</p>	1, 2, 3	H		P, F
MDR9.1.35	<p>M The AER parameters are set according to the HLD's instructions for use.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9E Page 46-47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.35.</p>	1, 2, 3	H		P, F
MDR9.1.36	<p>M On cycle completion, the printout is checked and signed to verify correct parameters were achieved.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9E Page 46-47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.36.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.37	<p>M The endoscope is removed promptly after the final cycle has been completed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9E Page 46-47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.37.</p>	1, 2, 3	L		P, F
Drying and storage					
MDR9.1.38	<p>M Following automatic reprocessing, the device is thoroughly dried with a lint free cloth. Lumens are completely dried according to device manufacturer's instructions e.g. flushed with air, 70% alcohol and then air.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8c Page 42; Section 9F Page 47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.38.</p>	1, 2, 3	H		P, F
MDR9.1.39	<p>M There is a process in place that clearly distinguishes a non-reprocessed instrument from one that has been reprocessed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9F Page 47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.39.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.40	<p>M Endoscopes are hung in a vertical position in a well-ventilated, protected, clean area to facilitate drying.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9F Page 47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.40.</p>	1, 2, 3	H		P, F
MDR9.1.41	<p>M Endoscopes and components are stored in a manner that protects them from contamination (e.g. They do not touch the floor of the cabinet).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9F Page 47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.41.</p>	1, 2, 3	M		P, F
MDR9.1.42	<p>M Except for emergency scopes, caps, valves and other components are detached for storage.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9F Page 47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.42.</p>	1, 2, 3	M		P, F
MDR9.1.43	<p>M Endoscope storage cabinets are cleaned at least weekly. Cleaning is documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9F Page 47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.43.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.44	<p>M All semi-critical endoscopes , including bronchoscopes, are reprocessed if stored for longer than 7 days.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9F Page 47. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.44.</p>	1, 2, 3	M		P, F
Documentation of endoscope reprocessing AER detergent and HLD solution					
MDR9.1.45	<p>M Documentation of AER detergent and HLD solution includes product names.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.45a.</p>	1, 2, 3	L		P, F
MDR9.1.46	<p>M Documentation of AER detergent and HLD solution includes lot numbers.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.45b.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.47	<p>M Documentation of AER detergent and HLD solution includes expiry dates.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.45c.</p>	1, 2, 3	M		P, F
MDR9.1.48	<p>M Documentation of AER detergent and HLD solution includes dates of solution changes.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.45d.</p>	1, 2, 3	M		P, F
MDR9.1.49	<p>M Documentation of AER detergent and HLD solution includes initials of staff doing preparation and documentation.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.45e.</p>	1, 2, 3	L		P, F
Documentation of endoscope reprocessing HLD test strip					
MDR9.1.50	<p>M HLD test strip documentation includes Name</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.46a.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.51	<p>M HLD test strip documentation includes Lot number.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.46b.</p>	1, 2, 3	L		P, F
MDR9.1.52	<p>M HLD test strip documentation includes Expiry date.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.46c.</p>	1, 2, 3	L		P, F
MDR9.1.53	<p>M HLD test strip documentation includes Quality control test results (each time a new bottle is opened).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.46d.</p>	1, 2, 3	L		P, F
MDR9.1.54	<p>M HLD test strip documentation includes Routine test strip result: Pass or Fail.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.46e.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.55	<p>M HLD test strip documentation includes Initials of staff doing the testing and documentation.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8C Page 43. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.46f.</p>	1, 2, 3	L		P, F
Documentation of the medical device (being reprocessed)					
MDR9.1.56	<p>M Documentation of medical device (being reprocessed) includes patient unique ID (e.g. record number).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.47a.</p>	1, 2, 3	M		P, F
MDR9.1.57	<p>M Documentation of medical device (being reprocessed) includes medical Device name or type.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.47b.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.58	<p>M Documentation of medical device (being reprocessed) includes serial number or other unique identifier.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.47c.</p>	1, 2, 3	M		P, F
MDR9.1.59	<p>M Documentation of medical device (being reprocessed) includes date and time of disinfection.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.47d.</p>	1, 2, 3	M		P, F
MDR9.1.60	<p>M Documentation of medical device (being reprocessed) includes contact time of the HLD (printout).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.47e.</p>	1, 2, 3	M		P, F
MDR9.1.61	<p>M Documentation of medical device (being reprocessed) includes temperature of the HLD (printout).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.47f.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR9.1.62	<p>M Documentation of medical device (being reprocessed) includes results of leak test.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45-46; Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.47g.</p>	1, 2, 3	M		P, F
MDR9.1.63	<p>M Documentation of medical device (being reprocessed) includes initials of person doing the reprocessing.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.47h.</p>	1, 2, 3	M		P, F
MDR9.1.64	<p>M Documentation of medical device (being reprocessed) includes protocol to link reprocessed scope to patient.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 9.47i.</p>	1, 2, 3	H		P, F
MDR10.0	STERILIZATION OF REUSABLE MEDICAL DEVICES				

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.1	<p>M Installation, validation and performance records are documented and maintained according to health authority policy for documents</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12 Page 62-64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.01.</p>	1, 2, 3	L		P, F
MDR10.1.2	<p>M Critical devices are sterilized by an approved sterilization process. (Unacceptable sterilization methods include boiling, glass bead sterilizers, microwaves and ultraviolet light.)</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10A Page 49-50. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.02.</p>	1, 2, 3	H		P, F
MDR10.1.3	<p>M Endoscopes and accessories (e.g., arthroscopes, cystoscopes, laparoscopes) that pass through normally sterile tissues are cleaned and sterilized before each use.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10A Page 49-50. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.03.</p>	1, 2, 3	H		P, F
General					

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.4	<p>M There is a system in place that clearly distinguishes a non-processed item from one that has been processed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10A Page 49-50; Section 10D Page 55. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.04.</p>	1, 2, 3	H		P, F
MDR10.1.5	<p>M Devices being sterilized are validated for the steam process and the cycle selected</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10A and 10B Page 49-50. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.05.</p>	1, 2, 3	M		P, F
MDR10.1.6	<p>M Consumables in use e.g. Biological Indicator (BI), Chemical Indicator (CI) strips and tape are appropriate for the sterilization method to be used.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10A and 10B Page 49-50. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.06.</p>	1, 2, 3	M		P, F
MDR10.1.7	<p>M Consumables in use e.g. BIs, CI strips and tape are used before the expiry date</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10A and 10B Page 49-50. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.07.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
Preparation and packaging					
MDR10.1.8	<p>M Devices are prepared in a manner that facilitates sterilization and aseptic presentation e.g. disassembled, stop-cocks opened, standard wrapping methods, appropriate sized packaging materials</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.08.</p>	1, 2, 3	H		P, F
MDR10.1.9	<p>M An internal chemical indicator is placed inside each package.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 50; Section 10D Page 55; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.09.</p>	1, 2, 3	M		P, F
MDR10.1.10	<p>M Packaging materials are validated and approved.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.10.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.11	<p>M Total weight of an instrument set (including container) to be steam sterilized does not exceed 10 Kg.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.11.</p>	1, 2, 3	M		P, F
MDR10.1.12	<p>M Total weight of a wrapped basin set to be steam sterilized does not exceed 3 Kg.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.12.</p>	1, 2, 3	M		P, F
MDR10.1.13	<p>M Sterilized items are labelled with a load/cycle number, sterilizer number, and the date of sterilization.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.13.</p>	1, 2, 3	H		P, F
MDR10.1.14	<p>M External process indicator is on the outside of each package</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10D Page 55; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.14.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
Loading, unloading and cooling					
MDR10.1.15	<p>M Package items are loaded in a manner that facilitates sterilization e.g. not overcrowded, away from chamber walls, peel pouches on edge.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.15.</p>	1, 2, 3	H		P, F
MDR10.1.16	<p>M Correct cycle (including parameters (i.e. time and temperature) is used for each load.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 52. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.16.</p>	1, 2, 3	H		P, F
MDR10.1.17	<p>M Printout is reviewed and initialled for critical elements on cycle completion i.e. exposure time, exposure temperature, and cycle number matches lot control label.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 52. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.17.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.18	<p>M Load is examined for visible signs of moisture and/or compromised packaging.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 52. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.18.</p>	1, 2, 3	M		P, F
MDR10.1.19	<p>M Load cools to room temperature before items are handled.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 52. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.19.</p>	1, 2, 3	M		P, F
MDR10.1.20	<p>M Cooling area is traffic free and without strong air currents (warm or cool).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 52. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.20.</p>	1, 2, 3	M		P, F
Monitoring and documentation - general					
MDR10.1.21	<p>M The contents of each load are documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.21.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.22	<p>M The results of all monitoring tests are documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 52. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.22.</p>	1, 2, 3	M		P, F
Monitoring and documentation - physical monitors					
MDR10.1.23	<p>M The printout is reviewed and initialed for critical elements on cycle completion (e.g. time, temperature).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 52; Section 10D Page 54; Section 10E Page 57; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.23.</p>	1, 2, 3	H		P, F
MDR10.1.24	<p>M Cycle number on printout matches lot control label</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.24.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.25	<p>M A leak test is performed according to the sterilizer manufacturer's instructions for use.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45-46; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.25.</p>	1, 2, 3	M		P, F
Monitoring and documentation - chemical indicators					
MDR10.1.26	<p>M Bowie Dick air removal test (high-vacuum sterilizers only) is done daily.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.26.</p>	1, 2, 3	H		P, F
MDR10.1.27	<p>M The external process indicator is on the outside of each wrapped package is checked when package is unloaded.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 57-58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.27.</p>	1, 2, 3	M		P, F
Monitoring and documentation - biological indicators					

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.28	<p>M Biological indicator test is run each day (at a minimum) that the sterilizer is used.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.28.</p>	1, 2, 3	H		P, F
MDR10.1.29	<p>M Each type of cycle to be used is monitored with a biological indicator. e.g., high vac, gravity, extended cycles.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.29.</p>	1, 2, 3	M		P, F
MDR10.1.30	<p>M Biological indicators are used for every load containing implantable medical devices.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.30.</p>	1, 2, 3	M		P, F
MDR10.1.31	<p>M If biological indicator is positive, loads are recalled and the positive test is investigated according to facility's policy.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.31</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.32	<p>M A "Control" test is run according to the Biological Indicator's manufacture's instruction for use e.g. lot number of control matched test BI.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12 Page 62-64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.32.</p>	1, 2, 3	L		P, F
B - IMMEDIATE USE (FLASH) STERILIZATION					
General					
MDR10.1.33	<p>M Flash sterilization is only used in emergency situations.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.33.</p>	1, 2, 3	M		P, F
MDR10.1.34	<p>M There is a system in place that clearly distinguishes a non-processed item from one that has been processed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10A Page 49-50; Section 10D Page 55. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.34.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.35	<p>M Implantable devices are not flash sterilized. (If implantable devices are flash sterilized for any reason, answer NO)</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.35.</p>	1, 2, 3	M		P, F
MDR10.1.36	<p>M Complete sets are not flash sterilized.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.36.</p>	1, 2, 3	M		P, F
MDR10.1.37	<p>M If flash sterilization is done, all criteria from Sections 6 (Cleaning) and 10-1 (Steam Sterilization) except packaging, are met.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.37.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.38	<p>M Flash sterilization incidents are reported in patient safety learning system (PSLS).</p> <p>Guidance: Flash sterilization incidents are reported and investigated as part of the organization’s risk management framework. BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.38.</p>	1, 2, 3	L		P, F
Monitoring and documentation					
MDR10.1.39	<p>M Each flash sterilization cycle is documented with the sterilizer ID.</p> <p>Guidance: Flash sterilization incidents are reported and investigated as part of the organization’s risk management framework. BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.39a.</p>	1, 2, 3	L		P, F
MDR10.1.40	<p>M Each flash sterilization cycle is documented with the device(s) flash sterilized.</p> <p>Guidance: Flash sterilization incidents are reported and investigated as part of the organization’s risk management framework. BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.39b.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.41	<p>M Each flash sterilization cycle is documented with the verified and initialed sterilizer printout.</p> <p>Guidance: Flash sterilization incidents are reported and investigated as part of the organization’s risk management framework. BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.39c.</p>	1, 2, 3	M		P, F
MDR10.1.42	<p>M Each flash sterilization cycle is documented with the results of CI and BI (if applicable, i.e. with implant).</p> <p>Guidance: Flash sterilization incidents are reported and investigated as part of the organization’s risk management framework. BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 51-58; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.39d.</p>	1, 2, 3	M		P, F
MDR10.1.43	<p>M Each flash sterilization cycle is documented with the note in the patient’s chart describing the device(s) and reason for flash sterilizing.</p> <p>Guidance: Flash sterilization incidents are reported and investigated as part of the organization’s risk management framework. BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.39e.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.44	<p>M Each flash sterilization cycle is documented with the load documentation (above) and is verified and initialed by the individual responsible for releasing the flashed items.</p> <p>Guidance: Flash sterilization incidents are reported and investigated as part of the organization's risk management framework. BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.39f.</p>	1, 2, 3	H		P, F
MDR10.1.45	<p>M Each flash sterilization cycle is documented with the chemical and biological indicators used to monitor the cycle are appropriate for flash sterilization.</p> <p>Guidance: Flash sterilization incidents are reported and investigated as part of the organization's risk management framework. BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.39g.</p>	1, 2, 3	M		P, F
Physical monitors					
MDR10.1.46	<p>M The physical parameters (i.e. exposure time and temperature) of each cycle are monitored and results are recorded.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 53; Section 10E Page 57-58; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.40.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.47	<p>M A leak test is performed according to the sterilizer manufacturer's instructions for use. (Applicable to pre-vac sterilizers).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45-46. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.41.</p>	1, 2, 3	M		P, F
Chemical Indicators					
MDR10.1.48	<p>M Bowie Dick air removal test (pre-vacuum sterilizers only) is done daily and documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.42.</p>	1, 2, 3	M		P, F
MDR10.1.49	<p>M An internal chemical indicator is placed inside each tray holding device(s) being sterilized</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 50; Section 10D Page 55; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.43.</p>	1, 2, 3	M		P, F
Biological Indicators					

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.50	<p>M Biologic indicator test is run each day (at a minimum) that the sterilizer is used.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.44.</p>	1, 2, 3	H		P, F
MDR10.1.51	<p>M Each type of cycle to be used is monitored with a biological indicator. e.g., high vac, gravity, extended cycles,</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.45.</p>	1, 2, 3	M		P, F
MDR10.1.52	<p>M Biological indicators are used for every load containing implantable items.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.46.</p>	1, 2, 3	M		P, F
MDR10.1.53	<p>M If biological indicator is positive, the positive test is investigated according to facility's recall procedure.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12 Page 62-64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.47.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.54	<p>M A "Control" test is run according to the Biological Indicator's manufacture's instruction for use e.g. lot number of control matched test BI</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.48.</p>	1, 2, 3	L		P, F
Tabletop sterilizers					
MDR10.1.55	<p>M All steam sterilization criteria apply. See sections 6 and 10A.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6 Page 33-37; Section 10A Page 49. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.49.</p>	1, 2, 3	H		P, F
C - CHEMICAL (LOW TEMPERATURE) STERILIZATION METHODS - STERIS SYSTEM 1 (SS1)					
General					
MDR10.1.56	<p>M Devices are cleaned and dried in accordance with Section 6-Cleaning</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6 Page 33-37. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.50.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.57	<p>M Device has been validated for reprocessing in Steris system 1.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10C Page 54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.51.</p>	1, 2, 3	M		P, F
MDR10.1.58	<p>M Critical devices that are sterilized are used immediately.</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.52.</p>	1, 2, 3	H		P, F
MDR10.1.59	<p>M Semi-critical devices are completely dried prior to storage.</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.53.</p>	1, 2, 3	M		P, F
MDR10.1.60	<p>M The Steris System 1 channel attachments (quick connects) and holding trays are appropriate for the scope being reprocessed.</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.54.</p>	1, 2, 3	H		P, F
MDR10.1.61	<p>M The channel quick-connects are attached to the Steris System 1 as per Steris instructions.</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.55.</p>	1, 2, 3	H		P, F
MDR10.1.62	<p>M A diagnostic cycle is performed as the first cycle of each day that the sterilizer is used. Results are documented and initialed.</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.56.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.63	<p>M Chemical and biological indicators are appropriate for Steris System 1.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.57.</p>	1, 2, 3	M		P, F
MDR10.1.64	<p>M Chemical indicators are used with each cycle except the diagnostic cycle.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.58.</p>	1, 2, 3	M		P, F
MDR10.1.65	<p>M A biological indicator test is performed in accordance with manufacturer's instructions.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.59.</p>	1, 2, 3	H		P, F
MDR10.1.66	<p>M There is a system in place that clearly distinguishes a non-processed item from one that has been processed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10A Page 49-50; Section 10D Page 55. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.60.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.67	<p>M After each cycle the peracetic acid cup is checked to ensure that it is completely empty.</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.61.</p>	1, 2, 3	H		P, F
MDR10.1.68	<p>M Partially used and/or outdated sterilant is disposed of according to manufacturer's instructions.</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.62.</p>	1, 2, 3	M		P, F
Monitoring and documentation					
MDR10.1.69	<p>M Sterilant monitoring and documentation includes sterilant lot number.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.63a.</p>	1, 2, 3	L		P, F
MDR10.1.70	<p>M Sterilant monitoring and documentation includes expiry Date.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.63b.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.71	<p>M Sterilant monitoring and documentation includes initials of staff verifying cycle parameters.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.63c.</p>	1, 2, 3	L		P, F
MDR10.1.72	<p>M Chemical indicator monitoring and documentation includes Lot number.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.64a.</p>	1, 2, 3	L		P, F
MDR10.1.73	<p>M Chemical indicator monitoring and documentation includes Expiry date.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.64b.</p>	1, 2, 3	L		P, F
MDR10.1.74	<p>M Chemical indicator monitoring and documentation includes CI test result: Pass or Fail.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.64c.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.75	<p>M Chemical indicator monitoring and documentation includes initials of staff doing the testing and documenting.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.64d.</p>	1, 2, 3	L		P, F
MDR10.1.76	<p>M Biological indicator monitoring includes lot number.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.65a.</p>	1, 2, 3	L		P, F
MDR10.1.77	<p>M Biological indicator monitoring includes expiry date.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.65b.</p>	1, 2, 3	L		P, F
MDR10.1.78	<p>M A "Control" test is run according to the Biological Indicator's manufacture's instruction for use e.g. lot number of control matched test BI.</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.65c.</p>	1, 2, 3	L		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.79	<p>M Biological indicator monitoring includes BI test result: Pass or Fail.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.65d.</p>	1, 2, 3	M		P, F
MDR10.1.80	<p>M Biological indicator monitoring includes initials of staff doing the testing and documenting.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.65e.</p>	1, 2, 3	L		P, F
MDR10.1.81	<p>M Monitoring of the medical device being reprocessed includes patient unique ID (e.g. record number).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.66a.</p>	1, 2, 3	M		P, F
MDR10.1.82	<p>M Monitoring of the medical device being reprocessed includes medical Device name or type.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.66b.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.83	<p>M Monitoring of the medical device being reprocessed includes serial number or other unique identifier.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.66c.</p>	1, 2, 3	M		P, F
MDR10.1.84	<p>M Monitoring of the medical device being reprocessed includes date and time of reprocessing.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.66d.</p>	1, 2, 3	M		P, F
MDR10.1.85	<p>M Monitoring of the medical device being reprocessed includes contact time of the sterilant (printout).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.66e.</p>	1, 2, 3	M		P, F
MDR10.1.86	<p>M Monitoring of the medical device being reprocessed includes temperature of the sterilant (printout).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.66f.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.87	<p>M Monitoring of the medical device being reprocessed includes concentration of the sterilant (printout).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10C Page 53-54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.66g.</p>	1, 2, 3	M		P, F
MDR10.1.88	<p>M Monitoring of the medical device being reprocessed includes results of leak test.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9C Page 45-46. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.66h.</p>	1, 2, 3	M		P, F
MDR10.1.89	<p>M Monitoring of the medical device being reprocessed includes initials of person doing the reprocessing.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.66i.</p>	1, 2, 3	L		P, F
MDR10.1.90	<p>M Monitoring of the medical device being reprocessed includes protocol to link reprocessed scope to patient.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12 Page 62-64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.66j.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.91	<p>M Log is kept of biological indicator test results and any interventions associated with positive test results.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10C Page 53-54; Section 12A Page 63-64; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.67.</p>	1, 2, 3	M		F
D - STERRAD					
General					
MDR10.1.92	<p>M There is a system in place that clearly distinguishes a non-processed item from one that has been processed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10A Page 49-50; Section 10D Page 55. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.68.</p>	1, 2, 3	H		P, F
MDR10.1.93	<p>M Devices being sterilized are validated for Sterrad sterilization and the cycle selected.</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.69.</p>	1, 2, 3	M		P, F
MDR10.1.94	<p>M Correct cycle (including parameters) is selected e.g. Long cycle for flexible endoscopes</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.70.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.95	<p>M Consumables in use (e.g. BIs, CIs, Sterilant, tape) are not expired</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 50. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.71.</p>	1, 2, 3	M		P, F
MDR10.1.96	<p>M The vapourizer plate is changed every 30 days or 145 cycles. The change is documented.</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.72.</p>	1, 2, 3	L		P, F
Preparation and Packaging					
MDR10.1.97	<p>M Devices are cleaned in accordance with Section 6--Cleaning and/or Section 9--Endoscopes.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6 Page 33-37; Section 9 Page 44-48. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.73.</p>	1, 2, 3	H		P, F
MDR10.1.98	<p>M Devices are prepared in a manner that facilitates sterilization and aseptic presentation e.g. disassembled, stop-cocks opened, standard wrapping methods, appropriate sized packaging materials.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6 Page 35; Section 10B Page 51. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.74.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.99	<p>M Internal chemical indicator is placed inside each package.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 50; Section 10D Page 55; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.75.</p>	1, 2, 3	M		P, F
MDR10.1.100	<p>M Boosters are used when required, and are applied correctly.</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.76.</p>	1, 2, 3	H		P, F
MDR10.1.101	<p>M Packaging materials and consumables are validated and approved for Sterrad sterilization.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.77.</p>	1, 2, 3	M		P, F
MDR10.1.102	<p>M External chemical indicator is on the outside of each package.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.78.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.103	<p>M Sterilized items are labelled with a load/cycle number, sterilizer number and the date of sterilization.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.79.</p>	1, 2, 3	M		P, F
Loading and unloading					
MDR10.1.104	<p>M Package items are loaded in a manner that facilitates sterilization e.g. Trays are flat, not overcrowded, away from chamber walls, peel pouches on edge, paper to plastic.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51-52; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.80.</p>	1, 2, 3	H		P, F
MDR10.1.105	<p>M Correct cycle (Long or Short) is used for each load.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51-52. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.81.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.106	<p>M Load is examined for visible signs of moisture and/or compromised packaging.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 52. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.82.</p>	1, 2, 3	M		P, F
MDR10.1.107	<p>M External chemical indicator results are verified.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.83.</p>	1, 2, 3	M		P, F
Monitoring and documentation - general					
MDR10.1.108	<p>M The contents of each load are documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.84.</p>	1, 2, 3	M		P, F
MDR10.1.109	<p>M The results of all monitoring tests are documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.85.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.110	<p>M Chemical and biological indicators (including tape) are appropriate for Sterrad.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.86.</p>	1, 2, 3	M		P, F
Monitoring and documentation - physical monitors					
MDR10.1.111	<p>M The printout is reviewed and initialed for critical elements on cycle completion i.e. Correct cycle , 2 repetitions of injection, diffusion, plasma, and the words "Cycle Complete" at the bottom of the printout.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10B Page 52; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.87.</p>	1, 2, 3	H		P, F
MDR10.1.112	<p>M Cycle number on printout matches lot control label.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10B Page 52; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.88.</p>	1, 2, 3	H		P, F
Monitoring and documentation - chemical indicators					

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.113	<p>M The external process indicator on the outside of each wrapped package is checked for colour change when package is unloaded.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10B Page 52; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.89.</p>	1, 2, 3	M		P, F
Monitoring and documentation - biological indicators					
MDR10.1.114	<p>M Biologic indicator test are run each day (at a minimum) that the sterilizer is used.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.90.</p>	1, 2, 3	H		P, F
MDR10.1.115	<p>M Biological indicators are used for every load containing implantable items.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.91.</p>	1, 2, 3	H		P, F
MDR10.1.116	<p>M Results of the BI test are documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.92.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.117	<p>M If biological indicator is positive, loads are recalled and the positive test is investigated according to facility's policy</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12 Page 62-64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.93.</p>	1, 2, 3	H		P, F
MDR10.1.118	<p>M A "Control" test is run according to the Biological Indicator's manufacture's instruction for use e.g. lot number of control matched test BI</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.94.</p>	1, 2, 3	L		P, F
E - ETHYLENE OXIDE (ETO)					
General					
MDR10.1.119	<p>M Devices being sterilized are validated for ethylene oxide sterilization.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10C Page 54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.95.</p>	1, 2, 3	M		P, F
MDR10.1.120	<p>M Consumables in use (e.g. BIs, CIs, Sterilant, tape) are not expired</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10C Page 54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.96.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.121	<p>M Ventilation, monitoring and ETO discharge comply with Occupational Health and Safety (OH&S) and Environment Canada guidelines.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10C Page 54. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.97.</p>	1, 2, 3	H		P, F
MDR10.1.122	<p>M There is a system in place that clearly distinguishes a non-processed item from one that has been processed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10A Page 49-50; Section 10D Page 55. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.98.</p>	1, 2, 3	H		P, F
Preparation and packaging					
MDR10.1.123	<p>M Devices are cleaned and dried in accordance with Section 6--Cleaning</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6 Page 33-37. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.99.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.124	<p>M Devices are prepared in a manner that facilitates sterilization and aseptic presentation e.g. disassembled, stop-cocks opened</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 6 Page 33-37. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.100.</p>	1, 2, 3	H		P, F
MDR10.1.125	<p>M Internal chemical indicator is placed inside each package</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 50; Section 10D Page 55; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.101.</p>	1, 2, 3	M		P, F
MDR10.1.126	<p>M Packaging materials and consumables are validated and approved for use.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.102.</p>	1, 2, 3	M		P, F
MDR10.1.127	<p>M External chemical indicator is on the outside of each package</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.103.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.128	<p>M Sterilized items are labelled with a load/cycle number, sterilizer number, and the date of sterilization.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.104.</p>	1, 2, 3	M		P, F
Loading and unloading					
MDR10.1.129	<p>M Package items are loaded in a manner that facilitates sterilization e.g. not overcrowded, away from chamber walls, peel pouches on edge</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51-52; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.105.</p>	1, 2, 3	H		P, F
MDR10.1.130	<p>M Correct cycle (if applicable) is selected.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51-52. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.106.</p>	1, 2, 3	H		P, F
MDR10.1.131	<p>M Load is examined for compromised packaging.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 52. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.107.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.132	<p>M External chemical indicator results are verified.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.108.</p>	1, 2, 3	M		P, F
Monitoring and documentation - general					
MDR10.1.133	<p>M The contents of each load are documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.109.</p>	1, 2, 3	M		P, F
MDR10.1.134	<p>M The results of all monitoring tests are documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.110.</p>	1, 2, 3	M		P, F
MDR10.1.135	<p>M Chemical and biological indicators are appropriate for ETO.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10B Page 51; Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.111.</p>	1, 2, 3	M		P, F
Monitoring and documentation - physical monitors					

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.136	<p>M The printout is reviewed and initialed for critical elements on cycle completion (e.g. time, temperature and/or pressure).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10B Page 52; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.112.</p>	1, 2, 3	H		P, F
MDR10.1.137	<p>M Cycle number on printout matches lot control label</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10B Page 52; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.113.</p>	1, 2, 3	M		P, F
Monitoring and documentation - chemical indicators					
MDR10.1.138	<p>M The external process indicator is on the outside of each wrapped package is checked when package is unloaded.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 9H Page 48; Section 10B Page 52; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.114.</p>	1, 2, 3	M		P, F
Monitoring and documentation - biological indicators					

No.	Description	Reference	Risk	Change	Asmt.
MDR10.1.139	<p>M Biologic indicator test are run in each load.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.115.</p>	1, 2, 3	M		P, F
MDR10.1.140	<p>M Results of the BI test are documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 10E Page 58; Section 12A Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.116.</p>	1, 2, 3	M		P, F
MDR10.1.141	<p>M If biological indicator is positive, loads are recalled and the positive test is investigated according to facility's policy.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12 Page 62-64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.117.</p>	1, 2, 3	H		P, F
MDR10.1.142	<p>M A "Control" test is run according to the Biological Indicator's manufacture's instruction for use e.g. lot number of control matched test BI</p> <p>Guidance: BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 10.118.</p>	1, 2, 3	L		P, F
MDR11.0	STORAGE AND USE OF REPROCESSED MEDICAL DEVICES				

No.	Description	Reference	Risk	Change	Asmt.
MDR11.1.1	<p>M Sterile storage is located in a limited access area. If access cannot be controlled, the sterile storage area is enclosed e.g. cupboard, cabinet, closed cart.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 11A Page 61. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 11.01.</p>	1, 2, 3	M		P, F
MDR11.1.2	<p>M Temperature and humidity are maintained and monitored (18-23 deg C and 30-60% relative humidity).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 11A Page 61. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 11.02.</p>	1, 2, 3	M		P, F
MDR11.1.3	<p>M Sterile packages are stored at least 25cm above the floor, 46 cms away from the ceiling and 5 cms away from any exterior wall.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 11A Page 61. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 11.03.</p>	1, 2, 3	M		P, F
MDR11.1.4	<p>M The top and bottom shelves of storage carts are solid.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 11A Page 61. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 11.04.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR11.1.5	<p>M All reprocessing areas are free of external shipping containers and corrugated boxes.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 11A Page 61. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 11.05.</p>	1, 2, 3	M		P, F
MDR11.1.6	<p>M Packages are dated with a date of sterilization, for in-house processed packages.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 11 Page 61; Section 11A Page 61. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 11.06.</p>	1, 2, 3	L		P, F
MDR11.1.7	<p>M Sterile packages are stored on a first in first out basis (FIFO)</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 11A Page 61. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 11.07.</p>	1, 2, 3	L		P, F
MDR11.1.8	<p>M Packages are routinely checked when taken from the shelf for holes, tears etc.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 11A Page 61. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 11.08.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR11.1.9	<p>M Rigid containers are checked for filters, locks, etc.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 11B Page 61. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 11.09.</p>	1, 2, 3	M		P, F
MDR11.1.10	<p>M There is a cleaning procedure in-place for cleaning carts and containers that store sterile supplies</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 11 Page 61. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 11.10.</p>	1, 2, 3	L		P, F
MDR12.0	QUALITY ASSURANCE				
MDR12.1.1	<p>M The reprocessing department or area has a quality assurance plan in place which is reviewed and revised annually.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12 Page 62-64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.01.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR12.1.2	<p>M The quality assurance plan includes management's roles and responsibilities.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.02a.</p>	1, 2, 3	L		P, F
MDR12.1.3	<p>M The quality assurance plan includes resources.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.02b.</p>	1, 2, 3	L		P, F
MDR12.1.4	<p>M The quality assurance plan includes staff training, education and competency assessments.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.02c.</p>	1, 2, 3	M		P, F
MDR12.1.5	<p>M The quality assurance plan includes internal compliance and reporting systems including adverse events/incident reports.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.02d.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR12.1.6	<p>M The quality assurance plan includes standards and best practices.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.02e.</p>	1, 2, 3	M		P, F
MDR12.1.7	<p>M The quality assurance plan includes reprocessing cycle management including policies and standard operating procedures, testing/monitoring results, equipment maintenance.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.02f.</p>	1, 2, 3	M		P, F
MDR12.1.8	<p>M The quality assurance plan includes current manufacturer’s instructions for use for reprocessing equipment and for the medical devices being reprocessed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.02g.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR12.1.9	<p>M The quality assurance plan includes OH&S including Material Safety Data Sheets (MSDS).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.02h.</p>	1, 2, 3	M		P, F
MDR12.1.10	<p>M The quality assurance plan includes a protocol in place to address any reprocessing failure, e.g. recall following failed sterilization.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12C and D Page 63-64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.02i.</p>	1, 2, 3	H		P, F
MDR12.1.11	<p>M When a random package is inspected, the device is visibly clean and assembled in accordance with best practice guidelines.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 62-63. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.03.</p>	1, 2, 3	M		P, F
MDR12.1.12	<p>M Reprocessing equipment is used in accordance with manufacturer's specifications.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 63. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.04.</p>	1, 2, 3	M		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR12.1.13	<p>M Reprocessing equipment has documented calibrations as specified by the manufacturer.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 63. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.05.</p>	1, 2, 3	M		P, F
MDR12.1.14	<p>M Maintenance associated with reprocessing equipment malfunction is documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12B Page 62-63. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.06.</p>	1, 2, 3	L		P, F
MDR12.1.15	<p>M There is a process in place to address any indicator failure e.g. printout, chemical indicator or biological indicator.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12A and C and D Page 62-64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.07.</p>	1, 2, 3	H		P, F
MDR12.1.16	<p>M A positive biological indicator is addressed immediately and actions are documented.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12 Page 62-64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.08.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR12.1.17	<p>M All interventions associated with a positive biological indicator are documented,</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12 Page 62-64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.09.</p>	1, 2, 3	M		P, F
MDR12.1.18	<p>M If any indicator suggests inadequate processing of devices, these devices are reprocessed.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12 Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.10.</p>	1, 2, 3	H		P, F
MDR12.1.19	<p>M All records are retained according to Corporate Administrative Directives and or quality management system requirements.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 12 Page 62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 12.11.</p>	1, 2, 3	L		P, F
MDR13.0	SINGLE USE MEDICAL DEVICES				

No.	Description	Reference	Risk	Change	Asmt.
MDR13.1.1	<p>M Single use critical and semi-critical medical devices are considered disposable and discarded at point of use (except when reprocessed by an approved third party reprocessor).</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 13 Page 64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 13.01.</p>	1, 2, 3	M		P, F
MDR13.1.2	<p>M Devices that cannot be cleaned safely or effectively are not reused e.g. burrs.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 13 Page 64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 13.02.</p>	1, 2, 3	H		P, F
MDR14.0	RESIDENTIAL, HOME/COMMUNITY CARE, PUBLIC HEALTH SETTINGS				
MDR14.1.1	<p>M 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.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 13B Page 65. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 14.01.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR14.1.2	<p>M In the home setting, reusable semi-critical devices for use on the same patient (e.g., tracheotomy 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.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 13B Page 65. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 14.02.</p>	1, 2, 3	H		P, F
MDR15.0	DENTAL CLINICS (PROVIDING SERVICES TO A HEALTH-CARE FACILITY)				
MDR15.1.1	<p>M Medical device reprocessing in a dental clinic complies with Sections 1 to 11 (excluding section 7) of this document.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 1-6 Page 22-37; Section 8-11 Page 40-62. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 15.01.</p>	1, 2, 3	H		P, F
MDR15.1.2	<p>M 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.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 13 Page 64. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 15.02.</p>	1, 2, 3	H		P, F

No.	Description	Reference	Risk	Change	Asmt.
MDR15.1.3	<p>M 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.</p> <p>Guidance: BC Ministry of Health Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (December 2011), Section 8B and C Page 41-42. BC Ministry of Health Audit Checklist For Reprocessing Critical and Semi-Critical Medical Devices, 15.03.</p>	1, 2, 3	H		P, F

References

1. British Columbia Ministry of Health. Updated Provincial Reprocessing Policy. Victoria (BC): Ministry of Health; 2011 Dec. Year of Publication. 4p.
2. Best practice guidelines for cleaning, disinfection and sterilization of critical and semi-critical medical devices in BC health authorities [Internet]. Victoria (BC): British Columbia Ministry of Health; 2007 Mar [revised 2011 Dec; cited 2025 Aug 21]. 136p.
3. Audit checklist for reprocessing critical and semi-critical medical devices. Victoria (BC): British Columbia Ministry of Health; 2011. 21p.

Revision history

Date	Revisions
September 11, 2025	<ul style="list-style-type: none"> NHMSFAP Medical Device Reprocessing standard approved (version 1.0) <p><i>Transcription of the Ministry of Health Audit Checklist for Reprocessing Critical and Semi-Critical Medical Devices which reflects the Ministry of Health Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices, December 2011.</i></p>
April 1, 2026	<ul style="list-style-type: none"> Transcribed to new template (no content changes) (version 1.1)