CPSA Medical Device Reprocessing Standards: Summary of major changes

CPSA's updated Medical Device Reprocessing (MDR) standards come into effect January 1, 2022. We encourage physicians and medical clinic staff to review the updated standards now to see what they may need to address by January 1, 2022.

This summary of significant changes will help you prepare for the coming changes to ensure your medical clinic meets minimum MDR standards.

Our MDR standards align with Alberta Health's Reusable & Single-Use Medical Devices standards (2019). Some wording has been amended to better reflect the language used by medical clinic teams.

Questions? Please contact CPSA's IPAC team at ipac@cpsa.ab.ca.

MAJOR CHANGES TO MDR STANDARDS

Key change	Standard	Description	What you need to know
Printer or Electronic Recording Requirements for Sterilizers	Part B Section 8.13	Cycle documentation through the use of either a printer or electronic data recorder is now considered essential quality assurance for sterilization.	Immediately check your sterilizer to ensure that it has either a printer or electronic data recorder. CPSA is giving clinics extra time to adapt or replace any sterilizers that do not meet this requirement. Sterilizers without this capability must be adapted or replaced by January 1, 2023. Prior to January 1, 2023, if a clinic is using a sterilizer that does not come equipped with a printer, personnel shall check the sterilizer's displays and manually record the sterilization time and temperature at intervals during each cycle and use a Type 5 chemical indicator in each package.

Key change	Standard	Description	What you need to know
Quality Management System (Enhancements to Policy and Procedures)	Part C	More specificity has been added to the requirements for clinic policies, procedures and documentation. MDR policies and procedures will now require regularly documented and scheduled review. **A summary of Quality Management System requirements is provided below.**	Clinics are already required to develop and maintain MDR policies and procedures. Additional documentation will now be required effective January 1, 2022. Clinic personnel should immediately review their existing MDR policy and procedure manuals to determine what documentation might be missing. CPSA is working to develop MDR policy and procedure templates for clinics to help them meet this objective.
Additional detail around steps of disinfection and sterilization	Part B Sections 4-9	Additional standards have been added that clarify minimum necessary steps to achieve disinfection and sterilization. This includes new documentation requirements.	Most new standards reflect what should already be existing practice. Detailed expectations are now more explicitly stated. These new requirements come into force on January 1, 2022. Clinic personnel should review the steps as set out in the new Standards and review against existing reprocessing procedures. Any necessary enhancements to these processes, included staff training, should be documented and implemented by January 1, 2022.
Procuring Medical Devices	Part B Section 3	Clinics will be required to ensure in advance that all medical devices they trial or purchase have a medical device licence. Reprocessing personnel will also be required to review device and equipment manufacturer information in advance of trial or purchase to ensure that recommended reprocessing instructions are achievable in their specific clinic setting.	This measure signals that medical devices not registered by Health Canada must not be used on patients. Licensed devices are validated for both safe use and reprocessing. GOC – Medical Devices Active License Listing (MDALL) These new standards help clinics start processes on the right path, promote involvement of expert staff in decision making and reflect longstanding best practice in most clinics.
Storage of clean, disinfected and sterilized equipment and devices	Part B Section 9 Part D Section 15	Specificity has been added around requirements for the storage of medical devices.	New standards reflect what should be existing practice, but allow for compliance to be more easily audited. Clinic personnel should review these requirements to ensure compliance by January 1, 2022.

Key change	Standard	Description	What you need to know
Medical Device Reprocessing and Flexible Endoscope Standards are now combined	Part D	Two existing CPSA standards are being combined into one. The new standards are entitled "Medical Device Reprocessing in Unaccredited Settings for Reusable Semi-critical and Critical Medical Devices".	Effective January 1, 2022, CPSA will no longer have separate Standards for medical device reprocessing and endoscope reprocessing. These are now being combined into one standard. Part D of the new standards is only applicable for clinics that use and reprocessed flexible endoscopes.
Thermal Disinfection / Pasteurization	Part B Sections 7.14-7.22 Part C Section 11.2.1	Standards have been added for those clinics that reprocess devices via thermal disinfection or pasteurization.	Very few clinics reprocess using thermal disinfection / pasteurization. However, these changes offer clarity to clinics who perform this type of reprocessing now, or in the future. Standards reflect longstanding minimum requirements set out by the Canadian Standards Association.

QUALITY MANAGEMENT SYSTEMS

Summary of enhanced requirements/changes for MDR policies, procedures and documentation, including tracking logs.

Outgoing MDR standards		2022 MDR Standards	
M.1.1.1	Storage of dirty	Part C/11.2.1	Pre-cleaning and transport
M.1.1.2	Transport of dirty		
M.1.1.3	Disassembly	Part C/11.2.1	Sorting, disassembly, soaking
M.1.1.4	Sorting and soaking		
M.1.1.5	Physical removal of soil	Part C/11.2.1	Manual or automated cleaning
M.1.1.6	Rinsing	Part C/11.2.1	Rinsing
M.1.1.7	Drying	Part C/11.2.1	Drying

Outgoing MDR standards		2022 MDR Standards	
M.1.1.8	Physical Inspection	Part C/11.2.1	Inspection
M.1.1.9	Wrapping of sterile	Part C/11.2.1	Packaging and labeling
M.1.1.10	HLD	Part C/11.2.1	Chemical high level disinfection (HLD) if applicable
M.1.1.11	Sterilization	Part C/11.2.1	Sterilization
M.1.1.12	Storage of Sterile	Part C/11.2.1	Storage
M.1.1.13	Use, cleaning and disposal of PPE	Part C/11.2.5	The required occupational health and safety activities, including use of appropriate personal protective equipment (PPE) when performing MDR and when using single-use medical devices.
M.1.1.14	Use and cleaning of cleaning accessories	Part B/4.4	Cleaning accessories
M.1.1.15	Recall process for cycle/failed chemical indicator and failed BI	Part C/11.2.3	Recall Procedures
M.1.2	There is written information from the manufacturer on the safe and appropriate processing of all medical equipment included in the procedures.	Part C/11.6	The MIFU for medical devices, equipment, and supplies shall be received and maintained in printed form (e.g., in binders, manuals, or monographs) or in electronic format and be readily accessible to those needing access and shall be updated as required.
M.4.2	All sterilization procedures follow the manufacturer's instructions for installation, operation, and preventative maintenance of sterilization equipment.	Part C/11.5.1	Preventative maintenance of devices and equipment
M.4.2.1	Independent biomedical or technician services perform regularly scheduled inspection and verification that the sterilizer is working properly.	Part C/11.5.2	Results of installation, operational qualification and requalification, and routine testing of reprocessing equipment and products.

Outgoing MDR standards		2022 MDR Standards	
M.1.7	There is a documented training process for staff performing reprocessing.	Part C/11.2.2	Education and Training

SUMMARY OF NEW STANDARDS FOR QUALITY MANAGEMENT SYSTEMS

New standards: quality management systems/documentation	
Part C/11.1	The clinic shall have clear accountability and lines of responsibility for all aspects of medical device reprocessing (MDR), wherever MDR takes place in the clinic, and the appropriate use of single-use medical devices.
Part C/11.2.1	Manual and/or automated cleaning.
Part C/11.2.1	Sterility assurance, including physical, chemical and biological.
Part C/11.2.1	Thermal disinfection/pasteurization.
Part C/11.2.4	Specific, detailed procedures for medical devices that present unique and complex challenges for reprocessing, such as flexible endoscopes, based on manufacturer's instructions for use (MIFU).
Part C/11.3	The clinic shall have written policy regarding single-use medical devices that is consistent with Part A of these standards.
Part C/11.5.1	Preventative maintenance of reusable medical devices and equipment.
Part C/11.5.2	Results of installation, operational qualification and requalification, and routine testing of reprocessing equipment and products.
Part C/11.6	The MIFU for medical devices, equipment, and supplies shall be received and maintained in printed form or in electronic format and be readily accessible to those needing access and shall be updated as required.