cpsa
COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

Top 10 2025 MDR Deficiencies in Medical Clinics

IPAC Program Resource

Infection Prevention and Control (IPAC) Program
January 2026

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Background

CPSA collaborates with physicians and medical clinic staff to uphold patient safety and compliance with our Infection Prevention and Control (IPAC) Requirements and Reusable & Single-Use Medical Device Requirements in Alberta's medical clinics. Ensuring adherence to medical device reprocessing (MDR) requirements reduces infection risks and enhances patient safety. Clinics should prioritize regular training, proper documentation and compliance with the Manufacturer's Instructions for Use (MIFU).

Improving compliance & patient safety

In 2025, 158 medical clinics participated in and successfully completed MDR compliance reviews with CPSA's IPAC program. The assessment data collected revealed recurring deficiencies that can be corrected by clinics during regular compliance monitoring.

This resource is intended to assist physicians and medical clinic staff in reviewing and correcting the top 10 deficiencies that came directly from 2025 assessment data.

Questions? For assistance or more information, contact CPSA's IPAC Program at ipac@cpsa.ab.ca or 780-969-5004.

Top 10 2025 MDR deficiencies in medical clinics

Deficiency	Compliance measures	Compliance support
Quality management systems: MDR policies & procedures	Written policies and procedures must be in place that meet or exceed appropriate provincial and national standards and guide the clinic through all aspects of MDR.	• Developing Policies & Procedures Guidance • Obtain and review the medical device's MIFU. Ensure the clinic's reprocessing procedures reflect the MIFU.
Quality management systems: Single-use medical device policy	Written policy must be in place regarding single-use medical devices consistent with CPSA's Reusable & Single-Use Medical Device Requirements, Part A.	• Reusable & Single-Use Medical Device Requirements for Medical Clinics (Refer to Part A, Section 1)
Regular review of policies & procedures	Scheduled reviews must be conducted of all written MDR policies and procedures.	• Developing Policies & Procedures Guidance • Review policies and procedures frequently to ensure content is up to date. Date them with the review date. • CPSA recommends a 1-year review frequency or when there is a change in equipment or process.
Education & training: MDR staff training, education and documentation	Written policy must be in place outlining training requirements for staff who perform medical device reprocessing (MDR). Clinic must document and retain records of education, training, orientation and competency assessments for personnel who reprocess critical and semi-critical medical devices.	• MDR Staff Training Log Template • MDR Staff Competency Assessment Template
Operational & requalification testing of sterilizers	Annual testing and verification must be conducted and recorded after major sterilizer repairs, relocations or steam supply disruptions.	• Qualifying Sterilizers Guidance • Table-top steam sterilizer IQ, OQ & RQ Template
Installation qualification of sterilizers	Sterilization equipment must be installed and documented in accordance with the manufacturer's specifications. This requirement also applies when the equipment is moved to a different location within the clinic.	• Qualifying Sterilizers Guidance • Table-top steam sterilizer IQ, OQ & RQ Template
Daily biological indicator testing of sterilizers	A biological indicator (BI) test contained within a process challenge device (PCD) must be conducted daily for each sterilizer cycle used, ensuring effectiveness.	• Making Process Challenge Devices that Contain Biological Indicators • Video: Steps to create a biological indicator process challenge device (BI PCD)
MIFU documentation	MIFUs for medical devices, equipment and supplies must be readily accessible and regularly updated.	• Ensure all MIFUs are kept in a binder or electronically for MDR staff.

Documentation of sterility assurance	Detailed records must be maintained of device sterility assurance, including printouts, load control labels and test results.	• Sterilization Log Sheet • Sterilizer Maintenance Log • Endoscope Reprocessing Tracking Log
Record retention	Reprocessing records must be maintained in accordance with clinic policy and applicable legislation.	Records shall include, but not be limited to, the following: • Preventative maintenance of reusable medical devices and equipment • Results of installation, operational qualification and requalification • Routine testing of reprocessing equipment and products