cpsa
COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

Top 10 2024 MDR Deficiencies in Medical Clinics

IPAC Program Resource

Infection Prevention and Control (IPAC) Program
April 2025

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Improving compliance & patient safety

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) standards reduces infection risks and enhances patient safety. Clinics should prioritize regular training, proper documentation and compliance with the Manufacturer's Instructions for Use (MIFU).

In 2024, 223 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 2024 assessment data.

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

Top 10 2024 MDR deficiencies in medical clinics

Deficiency	Compliance measures	Compliance support
Critical Steps in Reprocessing	All critical steps in the reprocessing of reusable medical devices must follow equipment and device Manufacturer's Instructions for Use (MIFU).	• Obtain and review the medical device's MIFU. • Ensure the clinic's reprocessing procedures reflect the MIFU.
Education & Training	Clinic must document MDR personnel education and training in medical device reprocessing to ensure safe practices.	• MDR Staff Training Log Template • MDR Staff Competency Assessment Template
Single-Use Medical Device Policy	Clinics must have a written policy regarding the use of single-use medical devices, in alignment with CPSA standards.	• Reusable & Single-Use Medical Device Requirements for Medical Clinics (Refer to Part A, Section 1)
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 and RQ Template
Regular Review of Policies & SOPs	Clinics must conduct scheduled reviews of all written MDR policies and procedures.	• 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.
MIFU Documentation	MIFUs for medical devices, equipment, and supplies must be readily accessible and regularly updated.	• Ensure all MIFU's are kept in a binder or electronically for MDR staff.
Reprocessing Training & Competency Testing	The clinic shall ensure all personnel involved in the reprocessing of critical and semi-critical medical devices are appropriately educated and trained for the reprocessing duties/tasks that they perform.	• MDR Staff Training Log Template • MDR Staff Competency Assessment 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.	• Place a BI in a PCD for daily testing when sterilizer is in use. • Making Process Challenge Devices that Contain Biological Indicators
Installation Qualification of Sterilizers	Sterilization equipment installation must be documented and performed according to manufacturer specifications.	• Qualifying Sterilizers Guidance • Table-top steam sterilizer IQ, OQ and RQ Template
Documentation of Sterility Assurance	Clinics must maintain detailed records of device sterility assurance, including printouts, load control labels, and test results.	• Sterilization Log Template • Sterilizer Maintenance Log Template • Endoscope Reprocessing Tracking Log Template