

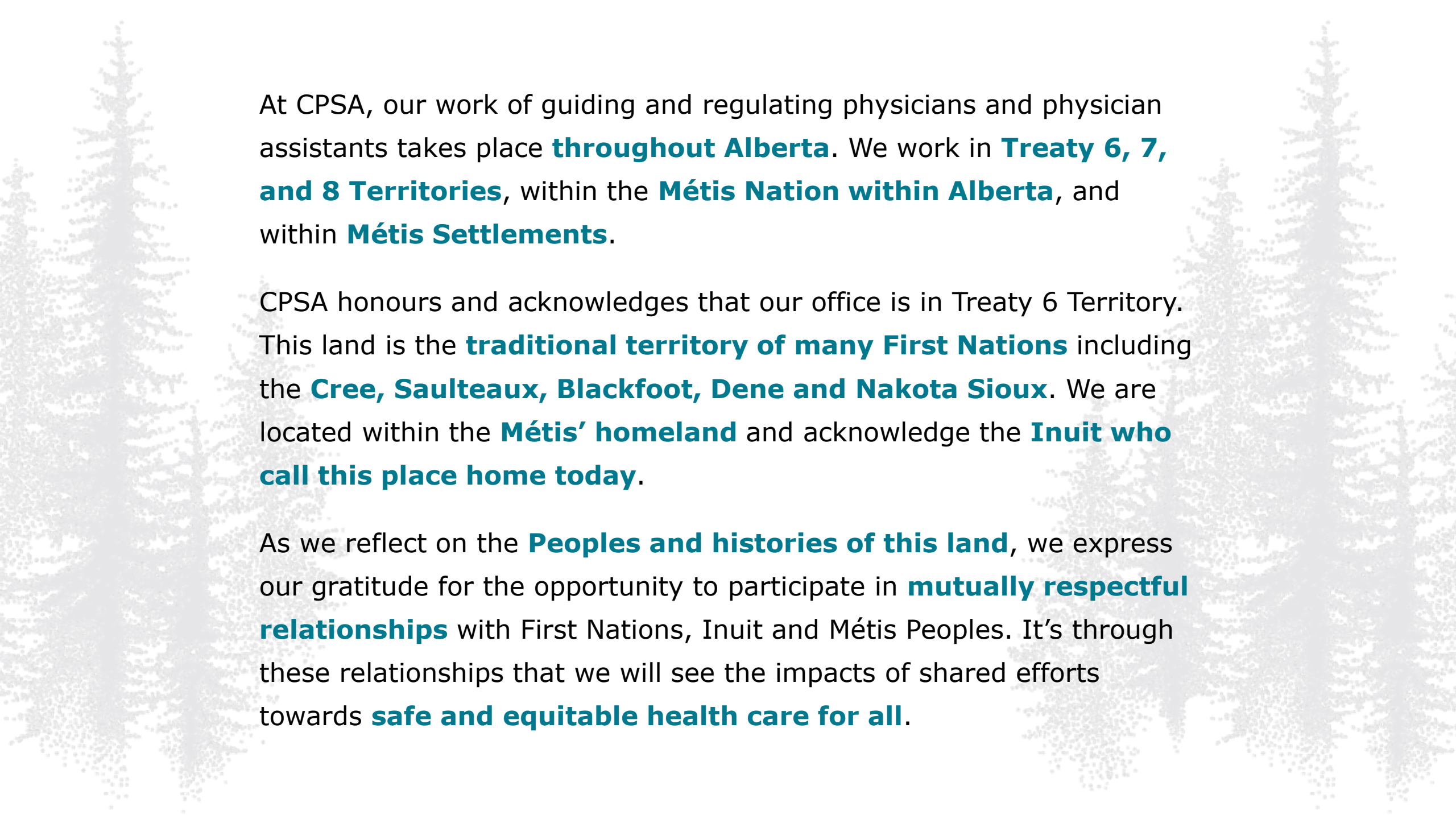
Medical Clinic Registry Lunch & Learn Session

Preparing for success

How to plan for an MDR assessment

September 17, 2026





At CPSA, our work of guiding and regulating physicians and physician assistants takes place **throughout Alberta**. We work in **Treaty 6, 7, and 8 Territories**, within the **Métis Nation within Alberta**, and within **Métis Settlements**.

CPSA honours and acknowledges that our office is in Treaty 6 Territory. This land is the **traditional territory of many First Nations** including the **Cree, Saulteaux, Blackfoot, Dene and Nakota Sioux**. We are located within the **Métis' homeland** and acknowledge the **Inuit who call this place home today**.

As we reflect on the **Peoples and histories of this land**, we express our gratitude for the opportunity to participate in **mutually respectful relationships** with First Nations, Inuit and Métis Peoples. It's through these relationships that we will see the impacts of shared efforts towards **safe and equitable health care for all**.

Today's agenda

- IPAC Information Questionnaire (IQ)
- Pre-assessment
- Assessment
- Post-assessment
- Q&A

Note: Today's session will be recorded and share with registered clinics that request a recording via the survey at the end of the presentation.

What is an MDR assessment?

- A medical device reprocessing (MDR) assessment is a tool CPSA uses to determine whether the [Reusable and Single-Use Medical Device Requirements for Medical Clinics](#) have been met.
- The MDR assessment covers:
 - Single-use medical devices
 - Reprocessing of reusable medical devices, from pre-cleaning to storage
 - Quality management systems
 - Flexible endoscope reprocessing



Why does CPSA conduct MDR assessments?

- **Albertans expect medical clinics to provide care in a safe environment.**
- CPSA's medical device requirements help clinics protect patients and staff.
- The requirements set the minimum expectations for MDR in medical clinics that perform procedures using reusable medical devices.

Infection Prevention and Control (IPAC) Information Questionnaire (IQ)

IPAC IQ

- Responses provided in the IPAC IQ help determine if your clinic meets the criteria for an onsite MDR assessment.
- IPAC IQ sections includes information about:
 - Medical Lead and Personnel
 - Infection Prevention and Control
 - Clinic Discipline/Practice Areas
 - Reusable and Single-Use Medical Devices
- Clinics may be asked to provide copies of IPAC policies and procedures, reusable and single use medical device policies and procedures, device and equipment manufacturer information, and if applicable, photos of clinic areas related to single-use and/or reusable medical devices and reprocessing.

Clinic IPAC Information Questionnaire

Based on the information in your Medical Clinic Registry profile, CPSA has determined that your clinic meets the criteria for an onsite Infection Prevention and Control (IPAC) compliance review.

Please complete this survey to provide accurate, up-to-date information about your IPAC practices and Medical Device Reprocessing (MDR) processes. The onsite review will assess your clinic's practices against CPSA's [IPAC Requirements](#) and if applicable, [Reusable and Single-Use Medical Device Requirements](#) for Medical Clinics. Your responses will help CPSA understand your clinic's current level of compliance and identify where additional guidance or resources may be helpful.

Your participation helps CPSA ensure clinics across Alberta have the tools and knowledge required to maintain safe, effective, and consistent standards of care.

If you have any questions or difficulties with this form, please contact us at ipac@cpsa.ab.ca or 780-969-5001.

CPSA Clinic ID **Clinic/Facility Name**

Address/Location

Medical Leads & Personnel Contact Information



Infection Prevention and Control Requirements



Clinic Discipline/Practice Areas



Reusable and Single-Use Medical Device (SUD) Requirements



Conclusion and Next Steps



Save Draft

Submit

Cancel

Pre-Assessment

Assessment scheduling timeline

- The clinic receives an email advising that it has been identified for an upcoming MDR assessment.
- The assessor contacts the clinic to book the assessment.
 - If a Clinic Manager is listed in the clinic profile, they will be contacted first.
- The clinic receives an email confirming the assessment date and time.
 - If the assessment needs to be rescheduled more than 24 hours before the scheduled date and time, contact the IPAC Program by email or phone.
 - If the assessment needs to be rescheduled within 24 hours of the scheduled date and time, call the IPAC Program (contact details found at the end of the presentation).
 - Assessments should ideally be rescheduled within two weeks of the original date.
- The clinic receives an email reminder seven days before the scheduled assessment. The assessor will also call to confirm.

We ask that you...

- Respond promptly to the assessor during scheduling.
- Provide as much notice as possible if assessment needs to be rescheduled.
- Review CPSA's [Reusable and Single-Use Medical Device Requirements for Medical Clinics](#) before the assessment.
- Review the resources available on CPSA's [MDR webpage](#).

Top 10 MDR deficiencies in medical clinics

Deficiency/Requirement	Compliance measures	Compliance support
Quality management systems: MDR policies & procedures 11.2	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 11.3	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 11.4	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 10 & 11.2.2	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 qualification & requalification testing of sterilizers 8.4	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

Top 10 MDR deficiencies in medical clinics

Deficiency / Requirement	Compliance measures	Compliance support
Installation qualification of sterilizers 8.3	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 8.10.4	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 11.6	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 8.14	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 11.5	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

Please ensure...

- At least one staff member involved in MDR (preferably the lead) will be available to discuss procedures, policies, and daily practices.
- The Medical Lead/Director or a designated representative will be available during the assessment (this is not a requirement).
- Relevant documents (e.g., MDR policies and procedures, cleaning, sterilization, maintenance logs, and training records) will be readily accessible.
- All physicians at the clinic are aware of the scheduled CPSA visit.



Assessment

Assessment overview



- The assessment guides and supports clinic staff in meeting MDR requirements.
- CPSA works with clinics as a partner in patient and staff safety.
- The assessment may take up to two hours.
- The assessor will complete a walkthrough of the procedure/exam room, MDR area, and relevant documentation.

During the assessment

- The assessor may take photos to document observations.
- The assessor will ask questions about MDR processes, policies, and daily practices.
- Feedback will be provided onsite and in the assessment report.
- Immediate action may be required if a risk to patient or staff safety is identified.



Post-Assessment

After the assessment

- The MDR Action Plan (MAP) report will be emailed as a PDF within 14 days.
 - The corrective actions from the MAP will also be available in your clinic profile.
- You have 28 days from date of receipt to respond to the deficiencies.
 - This must be done through your clinic registry dashboard.
 - If more time is needed, contact the IPAC Program to discuss.
- If you are unsure what information to provide, contact the IPAC Program.
- If a response is incomplete or does not address the deficiency, the assessor may return it with a note explaining what is missing or incorrect.
- Once the IPAC Program approves all corrective actions, you will receive your MDR Certificate of Compliance.
- You will also receive a request to complete an assessment evaluation survey.

Follow-up assessment

- A follow-up assessment may be scheduled before the MDR Certificate of Compliance is issued if direct observation of the corrected deficiencies is needed.
- The follow-up assessment follows the same process as the initial assessment.
- It may be completed by the same assessor or a different assessor.
- The post-assessment steps are the same as those following the initial assessment.



Questions?

Thank you for joining us today

Find IPAC and MDR resources at
cpsa.ca/ipac

Phone: 780-969-5001 or 780-969-5004

Email: ipac@cpsa.ab.ca