Medical Device Reprocessing Assessment Preparation Checklist

Your medical clinic has been selected for an upcoming Medical Device Reprocessing (MDR) assessment. What do you need to do next?

Use this checklist to help prepare for the assessment by ensuring required processes and documentation are in place.

Review key resources

- ☐ Review CPSA's Reusable and Single-Use Medical Device Requirements for Medical Clinics guidance.
- ☐ Review CPSA's offsite reprocessing resources, if applicable.
- ☐ Review the resources available on CPSA's MDR webpage.
- ☐ Review CPSA's Top 10 MDR Deficiencies in Medical Clinics resource.
- ☐ Complete CPSA's MDR self-assessment tool to identify and address gaps before the assessment.

Address common areas of non-compliance

- ☐ Ensure your clinic has current written MDR policies and procedures available.
- ☐ Ensure current manufacturer instructions for use (MIFU) documentation is readily accessible to reprocessing staff.
- ☐ Conduct staff training (Excel) (PDF) and competency assessments (Excel) (PDF), and maintain training and assessment records.
- ☐ Conduct sterilizer installation qualification, operational qualification/requalification and maintain records.

- [ ] Conduct daily biological indicator testing and maintain records.
- [ ] Retain sterilization logs (Excel) (PDF) and maintenance records (Excel) (PDF).
- [ ] Retain MDR records in accordance with clinic policy and applicable legislation.

Prepare for the day of the assessment

- [ ] Ensure the Medical Lead/Director or designate is available during the assessment.
- [ ] Ensure at least one MDR staff member is available to discuss procedures, policies and daily practices.
- [ ] Gather and make accessible all relevant documents (e.g., MDR policies and procedures, sterilization and maintenance logs and training records).
- [ ] Notify all physicians at the clinic about the assessment.
- [ ] Ensure any outstanding *Request for Information and/or Clinic Tasks* have been completed through the clinic dashboard, if applicable.

Complete follow-up after the assessment

- [ ] Review the Medical Device Reprocessing Action Plan (MAP) report when received.
- [ ] Submit responses to corrective actions through the Medical Clinic Registry dashboard within 28 days.
- [ ] Contact CPSA's Infection Prevention & Control (IPAC) Program if clarification or additional time is needed.
- [ ] Complete the assessment evaluation survey.

QUESTIONS? Contact ipac@cpsa.ab.ca.