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COLLEGE OF PHYSICIANS
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Competency Assessment Template for Medical Device Reprocessing (MDR) Staff in Medical Clinics

IPAC Program Template

Infection Prevention and Control (IPAC) Program

Last updated November 2024

Purpose

Competency assessments ensure that clinic staff responsible for reusable medical device reprocessing (MDR) are knowledgeable and adhere to all manufacturers' instructions for use (MIFU) and clinic protocols. MDR competency is essential to maintaining safe patient care.

The assessments also verify that the evaluator, who is knowledgeable and responsible for MDR oversight, has regularly confirmed staff compliance with competency criteria.

Competency assessments should be conducted:

- Annually,
- Following training and orientation and
- When new equipment, products or changes in MDR procedures are introduced.

These evaluations support consistent adherence to best practices and uphold patient safety.

Evaluator instructions

1. Assess your employee's understanding of each criterion by using the appropriate assessment method (e.g., direct observation, verbal confirmation).
2. Rate each criterion as either "Competent" or "Needs Improvement."
3. Use the comments section to note specific actions for improvement opportunities (e.g., additional training) for each criterion rated as "Needs Improvement."
4. For any improvement actions needed, record the completion date once the action has been completed.

Note: This is a template, and clinics should adjust the template to include clinic specifics (e.g. criteria specific for reprocessing flexible endoscopes, references to specific products and equipment, including their manufacturer's instructions for use).

For assistance or more information, please contact the CPSA IPAC Program at ipac@cpsa.ab.ca or 780-969-5001.

Employee Competency Assessment

Clinic name: _____

Employee name: _____

Evaluator name: _____

Date: _____

Competency assessment components

Competency criteria	Performance standard	Assessment method	Ratings: ✓ = Competent ✕ = Needs improvement	Comments	Improvement opportunity completion (DATE)
1. Understanding manufacturer's instructions for use (MIFU)					
Understands all steps in the MIFU	Staff demonstrates knowledge of each step required in the MIFU, including disassembly, cleaning, inspecting, drying, assembly, packaging and sterilization.	Verbal Q&A, documentation review			
Recognizes critical warnings and precautions in MIFU	Staff can identify and explain critical warnings, precautions and limitations provided in the MIFU.	Verbal Q&A			

Competency criteria	Performance standard	Assessment method	Ratings: ✓ = Competent ✕ = Needs improvement	Comments	Improvement opportunity completion (DATE)
2. Soiled transportation and cleaning of medical devices					
Staff dons/doffs personal protective equipment	Staff dons/doffs required personal protective equipment as per clinic procedures.	Observation			
Performs point-of-use cleaning	Staff performs point-of-use cleaning of soiled medical devices as per clinic procedures	Observation			
Correctly transports soiled reusable medical devices	Staff transports soiled reusable medical devices as per the clinic's procedures.	Observation			
Prepares cleaning solution according to MIFU	Staff prepares cleaning solution following the specific MIFU guidelines, including concentration and temperature.	Observation			
Performs cleaning procedure as per MIFU	Staff demonstrates correct cleaning procedures, including brushing, rinsing, and wiping as outlined in the MIFU of the devices, products and solutions.	Observation			
Correctly handles and disposes of cleaning materials	Staff safely handles and disposes of cleaning materials or reprocesses reusable cleaning accessories as per the MIFU.	Observation			

Competency criteria	Performance standard	Assessment method	Ratings: ✓ = Competent ✕ = Needs improvement	Comments	Improvement opportunity completion (DATE)
Drying of medical devices	Staff demonstrates correct procedure for drying of medical devices. Staff uses low-linting wipe to ensure all surfaces are completely dry.	Observation			
3. Medical device inspection and function testing					
Conducts visual inspection of devices	Staff performs thorough inspection for visible damage, debris, or wear following cleaning. Staff can explain next steps if debris or damage is discovered as per the clinic procedures.	Observation			
Performs function testing as per MIFU	Staff completes functional testing of medical device to ensure it is in working condition.	Observation			
4. Sterilization process					
Prepares devices for sterilization	Staff packages or wraps devices according to medical device and packaging material MIFU and clinic procedures.	Observation			

Competency criteria	Performance standard	Assessment method	Ratings: ✓ = Competent ✕ = Needs improvement	Comments	Improvement opportunity completion (DATE)
Loads sterilizer correctly	Staff arranges devices in sterilizer to ensure effective sterilization, following sterilizer MIFU loading instructions.	Observation			
Selects sterilization cycle	Staff selects appropriate sterilization cycle as per the device/product MIFU.	Observation			
Prepares biological indicator process challenge devices (BI PCD)	Staff prepares BI PCDs as outlined in the clinic procedures.	Observation			
Monitors and documents sterilization cycle	Staff verifies cycle parameters and documents results accurately, including BI.	Documentation review, verbal, Q&A			
Unloads sterilizer	Staff inspects packages and indicators as per clinic procedures.	Observation			
5. Sterile transportation and storage					
Transports reprocessed devices	Staff transports reprocessed medical devices as per clinic procedures.	Observation			

Competency criteria	Performance standard	Assessment method	Ratings: ✓ = Competent ✕ = Needs improvement	Comments	Improvement opportunity completion (DATE)
Stores devices	Staff places devices in appropriate storage location as per clinic procedures (e.g. no crushing).	Observation			
6. Steam sterilizer maintenance and cleaning					
Daily maintenance and cleaning	Staff performs daily cleaning and maintenance as outlined in the steam sterilizer MIFU.	Observation			
Weekly maintenance and cleaning	Staff performs weekly cleaning and maintenance as outlined in the steam sterilizer MIFU.	Observation			
Monthly maintenance and cleaning	Staff performs monthly cleaning and maintenance as outlined in the steam sterilizer MIFU.	Observation			
Documents cleaning and maintenance	Staff documents the completion of daily, weekly and monthly cleaning and maintenance as per clinic procedures.	Documentation review			

Competency criteria	Performance standard	Assessment method	Ratings: ✓ = Competent × = Needs improvement	Comments	Improvement opportunity completion (DATE)
7. Qualification of table-top sterilizers					
Installation Qualification (IQ)	Staff explains how to perform installation qualification of steam sterilizers and when to perform IQ. Staff explains the documentation process. Explanation aligns with CPSA requirements.	Verbal, Q&A			
Operational Qualification (OQ)	Staff explains how to perform operational qualification of steam sterilizers and when to perform OQ. Staff explains the documentation process. Explanation aligns with CPSA requirements.	Verbal, Q&A			
Requalification	Staff explains how to perform requalification of steam sterilizers and frequency. Staff explains the documentation process. Explanation aligns with CPSA requirements.	Verbal, Q&A			

Employee acknowledgment

I acknowledge that this assessment was conducted to evaluate my competency in medical device reprocessing as per the clinic's procedures, policies and applicable MIFU and CPSA requirements. I understand that my performance is essential for maintaining quality and safety in our reprocessing practices.

Employee signature: _____ Date: _____

Evaluator signature: _____ Date: _____

Note: Competency assessments should be completed annually, after training and orientation and upon introduction of new equipment, products or changes in the medical device reprocessing procedures. Retain records of competency as evidence of completion.